



"A CLEAR AND VISIBLE SHORT CASE"

/ STRONG SELL OPINION /

Align Technology, Inc | Nasdaq: ALGN



SPRUCE POINT
CAPITAL MANAGEMENT

INVESTMENT RESEARCH REPORT

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Spruce Point's Success Shorting Product Companies Ahead Of The Street





Spruce Point has a successful track record of identifying inflection points in consumer and medical product companies well ahead of sell-side analysts and other investors.

				
Report	Nasdaq: MGPI 1/12/17	TSX: TOS 8/23/17	Nasdaq: CSTE Aug 2015 / Oct 2015	Nasdaq: IRBT Nov 2018 , Mar 2019
Market Cap	\$784 million	C\$250 million	\$1.7 billion	\$2.0 billion
Company Promotion	Producer of ingredients and alcohol beverages hires new management and promotes reprioritization of “higher-margin” premium alcohol beverages (e.g. bourbon and whiskey)	Maker of low-temperature sterilization systems for microbial contaminant removal repeatedly promoting potential for broad commercialization of new product versions	Leading quartz countertop maker capable of producing sustainable 43% and 26% gross and EBITDA margins. The Company claimed it needed to construct a U.S. manufacturing facility	Premium robot vacuum protected against cheap, low-end competition
Our Criticism	Customer Diageo (8% LTM sales) was close to completing KY distillery of its own. Proliferation of US distilleries saturates market. Key ingredient patent, customer contracts set to expire in '17. History of operational disasters (explosions, etc.). Effectively out of cash, relying heavily on credit facility for liquidity. Restatements of related-party transactions did not reconcile. Regulators expanded audit investigation into MGP.	Poorly promoted single-product Canadian healthcare company with limited product value. Disclosure issues obfuscate actual end market sales, and overstatement of total addressable market. Over-promotion of a partnership with Getinge that would be destined to fail. Terrible insider alignment with mgmt. owning 1% of shares. 80%+ downside when Getinge deal fails.	Our intense fundamental and forensic due diligence uncovered evidence of slowing U.S. growth, and margin pressure being covered-up. We also expressed grave concerns about the Company's strategy to build a U.S. manufacturing facility and believed its capex costs seemed overstated, which would allow capitalization of costs on the balance sheet and potentially overstate earnings	Increasingly high-end competitors taking share in robot vacuum space and pressuring ASPs. History of failures in non-vacuum products suggests inability to grow mop sales or successfully launch lawnmower. Rising DSIs suggest financial strain. Distributor acquisitions obscure underlying sales declines
Successful Outcome	Whiskey growth story ends as premium alcohol bubble falters. Long-term guidance recently slashed. CFO with ties to accounting-challenged KHC resigns . Stock falls from high of ~\$95 per share to ~\$25 per share.	On Jan 25, 2018, TSO3 discloses amendments to the Getinge partnership, validating Spruce Point's criticisms (source). Multiple brokers downgrade shares from >C\$5.00 to C\$2.00. Share price made a low of C\$0.48 in Oct 2018, down 81%.	Two CEO/CEO's and two CFO/CFO's of Caesarstone have subsequently resigned. The Company has reported numerous manufacturing problems in both its new U.S. production and Israeli facilities. Gross margins contracted to 25%. The share price has fallen >70% from our initiation price	Disappointing sales growth due to slower-than-projected robotic mop sales. Gross margins continue to decline due to increasing competition at both the low and high end of the market. FY outlook lowered. Long-time CFO Alison Dean announces transition plan in Feb 2020

Align Technology: Another S&P 500 Company; Spruce Point's Unparalleled Success Shorting S&P 500 Companies



Quote From
Ben Axler

"Being an S&P 500 company is a validation of absolutely nothing, and can be a wasteland of corporate mediocrity. The bigger the Company, the worse the research is from sell-side analysts. Buyer beware!"

				
Index	S&P 500	S&P 500	S&P 500	S&P 500
Report	NYSE: CHD 9/5/19	NYSE: AME 11/14/14	NYSE: MTD 7/24/19	NYSE: AOS 5/16/19
Market Cap	\$22.7 billion	\$12.3 billion	\$21.8 billion	\$6.1 billion
Company Promotion	Best of breed roll-up acquiror of personal care and consumer products with the core Arm & Hammer brand providing a stable backbone to diversify into other products	Best of breed roll-up in the test and measurement equipment space with world class EBITDA margins and an ability to never miss Wall St estimates through any economic cycle	Best of breed weights, test and measurement equipment company with superior margins and an ability to never miss Wall St. EPS targets	Leading maker of water heaters and treatment products, boilers, and air purifiers. Fast and sustainable growth in China, allowing for corporate gross margins in excess of industry peers
Our Criticism	New management is more aggressive, using financial and accounting tactics to inflate the share price. The recent acquisition of FLAWLESS hair care was expensive and will disappoint investors. Governance lapses have allowed management to reap unjust bonuses based on non-cash gains. Shares at \$80 trade 8% above analyst targets	AMETEK isn't creating any value by delivering zero organic growth and that its financial statements showed signs of strain with aggressive accounting. We believed its premium valuation multiple could not be sustained as the quality of its acquisitions deteriorated	Excessive cost capitalization from a 12 year "Blue Ocean" ERP implementation. Unusual corporate structure that omits product level margin discussion. Closeness of mgmt with PwC its auditor. Financial strains being signaled and anomalies in China. Extreme valuation with price 14% over avg analyst price target	China capital expenditure anomalies, notably consistent mis-forecasting. Capex issues often linked to gross margin inflation. Excessive spending on a protracted ERP implementation also often linked to accounting and financial issues
Successful Outcome	Within the first quarter after our report, CHD reported disappointing Q3 sales results, cut its full year revenue guidance, and issued Q4 earnings at \$0.54, well below the \$0.62 expected. Management blamed higher sales and marketing expenses on FLAWLESS. CHD's new 10-K added risk factors around financial controls and its Chief Accounting Officer is " retiring "	By early 2016, AMETEK began guiding down sales and earnings expectations for multiple quarters. Its CEO and CFO abruptly retired. Its share price fell nearly 20% from our initial report date	Q2 2019 missed sales estimates by the widest margin in years, and initial 2020 guidance issued in Q3 2019 , missed estimates with lower sales and earnings growth. Management failed to address any of the issues identified by Spruce Point. The share price corrected by 22%	AOS admitted an undisclosed material supply chain partner following a report by firm J Capital. In Q2 2018 , AOS substantially revised guidance, showing weakness in China with sales projected down 16-17%. AOS fired its head of China after an investigation

We've Seen This Story Before: Align Mirrors Other Successful Spruce Point Shorts

We believe that Align shares many features and themes of other successful Spruce Point shorts. In particular, we believe that Align, much like iRobot, is an industry incumbent whose investors mistakenly believe can continue its pace of growth with little threat of serious competition. Spruce Point, however, finds evidence of new competitors which are poised to upend industry economics – NOT just SmileDirectClub and other direct-to-consumer players, but other players which, to our knowledge, have never before been taken into consideration by investors.

		
Perceived High-End Industry Incumbent With History Of Limited Competition	✓	✓
Unique New Evidence Of Little-Known Low-Priced Competitors	✓	✓
Investors Put Misguided Faith In Strength Of Legacy Player's Brand	✓	✓
Investors Put Misguided Faith In Legacy Player's R&D Head Start, IP and Patent Protection	✓	✓
Investors Mistakenly Believe That Company Can Grow Into New Markets / Product Lines	✓	✓
Key Employees Leave To Join Or Found New Competitors	✓	✓
Company Pivots To M&A To Support Sales As Competitive Headwinds Slow Pace Of Growth	✓	✓
Accelerated Buyback And Insider Selling Ahead Of Competitive Onslaught	✓	✓

Which Product Looks More Complex To You?





Executive Summary

Short ALGN: Spruce Point Sees 40%-55% Downside To \$80-\$115 Per Share

By now, investors in Align Technology, Inc. (“ALGN” or “the Company”) are used to hearing that competitors are, for the first time, beginning to penetrate the clear aligner space. The bullish consensus: dental equipment competitors can coexist with Align, but cannot yet compete toe-to-toe with the 20-year incumbent.

The reality: the economics of clear aligners are on the precipice of a radical shift – and it has little to do with SmileDirectClub or other direct-to-consumer players. Once considered high-value-added “dental tech,” FDA-approved aligners of similar quality to Invisalign – Align’s clear aligner product – are now being printed at scale by commodity 3D printing labs, which price their aligners at less than half the cost of Align’s. Meanwhile, patent expirations have ushered in under-the-radar developments in aligner design software which are removing the final barriers to the widespread adoption of 3D printers by orthodontists – many of whom are infuriated with Align’s aggressive tactics, and who are actively exploring their options in a market which, for the first time, offers numerous (cheaper) alternatives to Align. On-the-ground diligence reveals that large dental players are already slashing aligner prices in response to these shifts, in some cases to as low as a third the price of Invisalign. We believe that it is only a matter of time – perhaps accelerated by industry cost pressures brought on by the pandemic – until Align is forced to follow suit.

Third-Party Labs Turning Aligners Into Commodities: For close to 20 years, Align operated as the lone major player in the clear aligner space, with other large dental equipment suppliers only recently entering the industry. Over just the past two years, however, patent expirations and developments in 3D printing have enabled dozens of third-party printing labs to begin to produce FDA-approved aligners of their own, threatening to transform the clear aligner from “high-tech” dental equipment into a low-value-added, easy-to-source commodity. What’s more, the former developer and provider of Align’s own polymer has developed a new plastic which can be used by third-party labs to produce aligners of comparable quality to Invisalign. Spruce Point has obtained term sheets from one such third-party lab which reveal that dental practitioners can save over 50% per case on average by sourcing from it rather than Align, and that a typical practice – depending on its volume – could increase its cash flow by close to 10% simply by switching from Align. We find evidence that large orthodontic organizations are considering switching from Align to third-party labs, and that other major dental players are already slashing prices to as low as 33% of Align’s in response to this competition. We believe that Align will inevitably be forced to follow suit – or else lose significant case volume – as third-party labs grow increasingly mainstream.

Under-The-Radar Improvements In Workflow Technology Make In-House 3D Printing A Threat: Until now, Align bulls have generally considered in-house 3D printing an inconvenient alternative to Align, as in-house printing forces orthodontists to bring entirely new workflows into their offices. Through a proprietary survey of high-volume orthodontists, together with conversations with industry experts, we find that interest towards in-house printing is in fact extremely high among doctors, who are attracted to the potential efficiencies and cost savings. We find that broader adoption of in-house printing has been constrained NOT by limited demand, but by the relatively limited supply of quality technological infrastructure to support this workflow – in particular, high-quality CAD/CAM aligner design software. However, with Align’s patents on this technology recently having expired, major innovations are coming to this space as we speak. Notably, uLab Technologies – a company founded by former Align executives and employees who were themselves behind the most successful attempt to compete with Align during the 2000s – is in the process of rolling out CAD/CAM software which experts believe to represent a step change over existing solutions. The full-scale launch is expected to occur this spring. With the final barriers to widespread in-house printing adoption set to fall in the near term, we expect interest in 3D printing – which offers even greater cost savings than third-party labs – to expand dramatically.

Emergent Competition Already Putting Pressure On Align: Though still relatively novel, Spruce Point observes that these competitive forces are already beginning to pressure industry pricing and threaten Align’s case volume. Our diligence reveals that a large dental service organization (DSO) representing up to 12% of Align’s US aligner volume is actively exploring opportunities to source aligners from third-party labs. Meanwhile, we are told that 3M is offering orthodontists lab fees as low as \$500-\$600 per case – less than one third the price of a comprehensive Invisalign case. We believe that this is just the beginning of a longer-term trend.

Short ALGN: Spruce Point Sees 40%-55% Downside To \$80-\$115 Per Share

Widespread Dissatisfaction With Align Could Accelerate Customer Losses: Align bulls are quick to argue that the Company's brand and practitioner network protect it from new competition. We find that orthodontists are, almost universally, anywhere from dissatisfied to infuriated with Align, which continues to raise prices aggressively on orthodontic practices even as costs fall across the rest of the space, and which has threatened orthodontists' control over the teeth alignment industry by selling to dentists and backing direct-to-consumer players. With competitive options proliferating across the space for the first time in ~20 years, Spruce Point observes that even Align's highest-volume orthodontists are actively pursuing alternatives – and doubly so as they pause normal operations in response to the COVID-19 pandemic, which has given them a unique opportunity to explore cost-saving measures.

Growth Into The Purported TAM Will Be More Difficult Than Expected: Management claims that Align captures just 1.5M of over 8M annual worldwide malocclusion cases which Invisalign can be used to treat, and that there are more than 300M additional candidates who would benefit from more minor treatments with clear aligners. However, we estimate that Align is already close to 80% penetrated among US orthodontists, making further growth into the domestic orthodontic channel difficult – particularly as increasing competition induces churn and causes utilization to fall. Meanwhile, cheaper competitors and DTC players like SmileDirectClub will make it difficult for Align to capture meaningful share of lower-complexity cases without reducing prices materially.

Management Reducing Transparency While Showing Little Confidence In The Business: After reducing disclosures which would have made it easier for investors to see the impact of competitive pressures on Company results, management expanded a number of risk factors in its most recent 10-K in ways that suggest that more aggressive competition is on the way. At the same time – just as sales growth decelerates and margins compress – insiders are selling their holdings of ALGN shares in size, while simultaneously increasing the Company buyback by 4x. With the Company experiencing declining growth as it is pinched by a more crowded competitive landscape, pivoting to M&A to support future growth, and buying back shares just as insiders sell out, Spruce Point feels that Align exhibits many of the classic characteristics of a business under pressure.

COVID-19 Pandemic Poses Unique Short-Term Risk, While Competitive Threats Could Inhibit Rebound: Shares in ALGN have largely traded in-line with the market as investors bet on when restrictions on normal economic activity will be lifted. However, with clear aligner therapy – an elective, cosmetic treatment – falling among the least critical of medical procedures, Align bears outsized risk to the potential lingering effects of the disease, which may not only depress discretionary spending for an extended period, but also prevent orthodontic offices from reopening entirely for up to a number of months, and discourage patients from entering what may be a high-risk, aerosol-laden environment thereafter. Meanwhile, our diligence indicates that orthodontists are using their time off to evaluate their practices' cost structures and identify areas of potential cost savings – a trend which could result in accelerated switching away from Invisalign as the competitive landscape becomes increasingly crowded with low-priced providers. We estimate that case volume could fall by anywhere from 30% to 90% worldwide YoY in Q2, with the lingering effects continuing to drive declines of 20-30% for the rest of the year. We believe that near-term earnings revisions in the face of the ongoing crisis will serve as catalysts for downward moves in the stock, as revisions have before.

Not A Post-Pandemic Bounce Back Candidate, Even As Shares Trade Down: As ALGN shares trade lower with the market as the pandemic grows increasingly drawn-out, bulls with faith in the long-term growth story likely see the stock as a strong “buy low” opportunity. Spruce Point strongly disagrees: not only does Align bear outsized risk to the continued prevalence of COVID-19 beyond 2020, but the proliferation of competitors and alternative aligner printing technologies will, in our opinion, prevent the Company from bouncing back with the same force as the rest of the dental/orthodontic space. Spruce Point sees 40%-55% downside in ALGN to \$80-\$115 per share on disappointing case volume growth in FY21 and ongoing ASP pressure amidst an expanded competitive landscape. ALGN's ~24x FY21 earnings multiple could also compress as investors increasingly understand the competitive forces facing the Company going forward, bringing the potential for even greater downside to ALGN shares.

Align Showing The Typical Signs Of A Company Under Pressure

Key Signs of Increased Pressures

Increased Presence At Align

Product Commoditization Leading To...



Decelerating Sales Growth



Declining Gross Margins



Eliminating Disclosures Reduces Transparency Into Performance



Expanded Risk Factors



Accelerated Insider Selling



Ramped Up Buyback



Pivoting to M&A to Support Future Growth



Spruce Point believes that the writing is on the wall: Align is increasingly facing powerful competitive pressure and is reaching to keep the growth story alive, all while insiders exit the stock.

Not A Long-Term Buy Amidst COVID Selling: A New Competitive Landscape Will Exist On The Other Side

Spruce Point believes that very recent and underappreciated developments in the clear aligner landscape undermine most of the key tenets of the bull case for Align. Investors must begin to adapt their understanding of the space to new and rapidly-evolving competitive realities.

Theme	Bulls Believe...	Spruce Point Findings And Conclusions
Competition And Pricing	<ul style="list-style-type: none"> The only material competitors in the space are other large dental equipment providers, none of which has made significant headway in the space Align has a 20+ year head-start on clear aligner technology, and produces aligners which are both superior to competing products and applicable in a wider range of treatments Align's limited competition and technological advantages support a stable pricing environment Orthodontists are comfortable with Invisalign and do not yet see competing products as sufficient substitutes 	<ul style="list-style-type: none"> Third-party 3D printing labs are obtaining FDA approval to print clear aligners at a rapid pace, and, as a whole, quickly achieving sufficient scale to compete Third-party labs now have access to high-quality aligner materials developed by Align's own former plastics provider. Industry experts report that these aligners are of comparable quality to Align's. Third-party labs offer aligners which, on an all-in cost basis, are 50-65% cheaper to the orthodontist than Invisalign. Other large dental equipment players are slashing prices to similar levels in response. Large buying groups – including one representing up to 12% of Align's orthodontic Americas case volume – are actively exploring lower-cost alternatives to Invisalign
In-House 3D Printing	<ul style="list-style-type: none"> Orthodontists and dentists are not interested in taking the hassle of 3D printing in-house 3D printing technology cannot produce aligners of comparable quality to Invisalign Align has a massive head-start in Aligner design software technology 	<ul style="list-style-type: none"> Interest towards in-house 3D printing is extremely high among orthodontists: over 50% of high-volume orthodontists surveyed by Spruce Point either have or are actively considering in-house 3D printers, which produce aligners at an all-in cost (to the doctor) 75% below Invisalign Orthodontists can use the same high-quality material now used by third-party labs to print their own clear aligners Recent developments in CAD/CAM aligner design software by highly-experienced industry veterans are making in-house 3D printing extremely user-friendly
Addressable Market	<ul style="list-style-type: none"> Align has penetrated just ~12% of the global malocclusion market Align has a long runway for growth by opening the teeth alignment market to 300M unpenetrated potential treatment candidates with less complex treatment needs 	<ul style="list-style-type: none"> Align is near a saturation point in its US orthodontist base. Competition is becoming fierce among the lower-complexity market as competition enters both the doctor-directed and direct-to-consumer spaces. Align will likely have to dramatically reduce prices to be suited to this market
Doctor Loyalty	<ul style="list-style-type: none"> Doctors want to remain Align customers to benefit from volume-based discounts and to receive leads from Align's practitioner network 	<ul style="list-style-type: none"> Orthodontists are infuriated with Align for continuing to increase prices even as other costs across the orthodontic industry fall, and for opening up alignment treatments to dentists and the direct-to-consumer channel
COVID-19 Risk	<ul style="list-style-type: none"> Align performance will suffer through the pandemic, but practices will inevitably return to normal and experience pent-up demand for Invisalign 	<ul style="list-style-type: none"> Teeth-straightening treatment is not just elective, but cosmetic and discretionary, and will be among the last medical treatments to return as the pandemic subsides – particularly if unemployment remains elevated, and if concerns over aerosols discourage orthodontist visits Orthodontists are using their time off from normal business as an opportunity to review cost-cutting opportunities, putting Align at risk for accelerated competitive losses

FDA Approvals For Clear Aligner Production Are Accelerating Rapidly

More informed investors may have been aware of the presence of third-party 3D printing labs in the clear aligner space in prior years. Until now, however, they have been only very minor players, as only one or two new producers were granted FDA 510(k) approvals for printing clear aligners in most years prior to 2018. However, since 2018, 33 new producers have been approved by the FDA to print clear aligners – more than those cleared in all years leading up to 2018 combined – and we are currently on pace to see more than 18 new approvals through the rest of 2020.

510(k) Premarket Notification

● FDA Home ● Medical Devices ● Databases

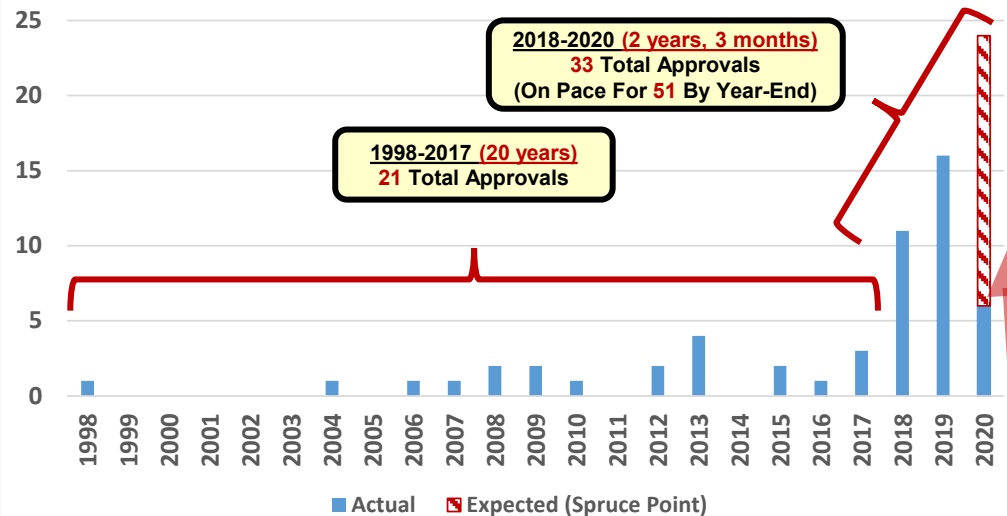
1 to 55 of 55 Results
Product Code: nxc Decision Date To: 03/23/2020

Product Code: nxc
("Aligner, Sequential")

Device Name	Applicant	510(K) Number	Decision Date
Clearform Aligners	Motor City Lab Works	K191838	03/20/2020
Neolab Clear Aligners	New England Ortho Lab, Inc.	K192338	03/12/2020
3d Predict	3D Smile USA, Inc.	K200214	02/24/2020
Ulab Systems Dental Aligner Kit	ULab Systems, Inc.	K192596	02/11/2020
Argen Clear Aligner, Argen Clear Aligner Premium	Argen Corporation	K192846	02/10/2020
Unismile Clear Aligner System	Vitang Technology, LLC	K191837	01/29/2020
Clear Aligner	Royal Dental Lab	K192767	01/08/2020
Clear Aligners	CDB Corporation	K191823	12/20/2019
DenMat Orthodontic Aligners	DenMat Holdings, LLC	K192470	12/20/2019
Krystal Clear Aligners	Shatkin F.I.R.S.T. LLC	K182388	12/19/2019
Sunclear Aligner System	Sun Dental Laboratories, LLC	K190394	12/16/2019
Vivid Aligners	Orthodont Laboratory, Inc.	K190003	11/06/2019
Smilealign Orthodontic Aligner System	3D Global Biotech Inc.	K191774	09/30/2019
3m Clarity Aligners	3M Company	K192119	09/05/2019
Osw Aligner System	OSW Manufacturing, LLC	K191990	08/23/2019
Dynaflex	Dynaflex	K190583	08/27/2019
Biolineer	Five Star Orthodontic Lab & Supply	K182658	06/19/2019
Argen Clear Aligner	Argen Corporation	K183229	06/07/2019
Magic Clear Aligners	Voodoo Manufacturing, Inc.	K190948	05/09/2019
Orthodontic Appliance	Shandong Huge Dental Material Corporation	K181747	04/18/2019

Source

FDA 510(k) Approvals for Clear Aligner Production



"You can setup a clear aligner FDA approved lab in less than a year. Your capital equipment costs between buying three [high-volume] 3D printers and thermoforming machines can be less than \$100K to get started. If you add in labor, your total costs in your first year will be less than \$200K."

- Senior Employee, Major Dental Equipment Supplier

"We are at the point where we can switch to another clear aligner vendor and we would not have even entertained that two years ago... There are over 100 aligner companies coming out of Asia. Two to three years from now, I don't see how Invisalign will see the same amount of cases that they had in the past."

- Dentist, DSO

On pace for ~18 more approvals for remainder of 2020

To the extent that investors are at all aware of the presence of third-party 3D printing labs in the clear aligner space, they have likely been conditioned to treat them as extremely minor players with limited scale and/or limited credibility among doctors.

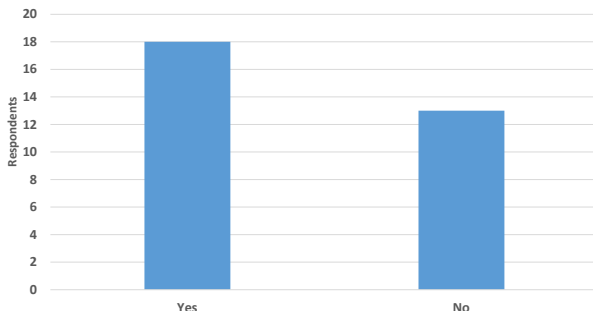
Spruce Point believes that, with so many now obtaining FDA approvals, third-party labs are, as a whole, quickly achieving the scale and credibility necessary to pose a serious threat to established clear aligner producers.

Doctors Reveal That Pricing Pressure Is Already Coming To The Space

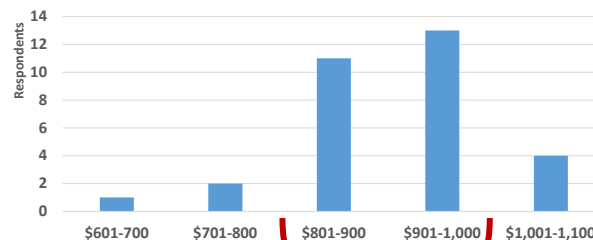
Dentists and orthodontists across the US tell us that the influx of competition is already beginning to weigh on industry pricing. Through a proprietary survey of high-volume orthodontists and conversations with a variety of dental professionals, we have learned that 3M is acting aggressively to win new business for its Clarity aligners by offering steep discounts. Of the 31 high-volume orthodontists included in our survey – a far different population than the more diverse groups covered most sell-side surveys, but one much more critical to the business – close to 60% have had an in-office visit from 3M to discuss Clarity aligners. Our conversations reveal that 3M is offering lab fees as low as \$500-600 per case, far below Align’s average lab fee – even among high-volume orthodontists receiving heavy discounts. Our survey also reveals that most orthodontists would consider Align alternatives if offered lab fees between \$800-1,000, a threshold which 3M already appears to have surpassed.

Spruce Point Proprietary Survey (31 Align-Using Orthodontists, Minimum Platinum Tier)

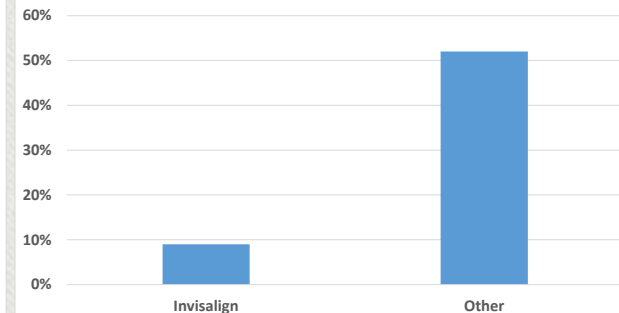
Has Clarity (3M) been in your offices to discuss their clear aligner products and pricing?



At approximately what price level of lab fees would you (or did you) consider switching a majority of your Invisalign case volume to other clear aligner providers or alternative third-party workflow solutions, assuming clinical outcomes were similar?



Survey Results: 2019-2020E Expected Case Growth, Align vs. Competitors (Aggregate)



“3M is offering me cases at a \$500 lab fee compared to my Invisalign Lab fee of \$1,000. If I can start doing more cases with 3M and it will save me money, why not just switch? 3M software is excellent. It is very easy to use. They brought a lot of people over from Invisalign. It’s getting to the point where it will be as good as Invisalign.”

- Orthodontist, Diamond Plus Align Tier

“3M came to me and said that we can do all of your cases for \$600... I expect my Invisalign volumes to be down going forward”

- Orthodontist, Diamond Plus Align Tier

“We are going to see major price compression with lab fees in the next one to two years.”

- Senior Employee, Major Dental Equipment Supplier

Spruce Point believes that it is only a matter of time before Align is forced to slash its own lab fees to maintain its existing orthodontist base, or else risk losing significant case volume.



Not Just Hypothetical: Major DSOs Considering 3D Printing Centers, Both In-Sourced And Outsourced

Spruce Point emphasizes that, while 3D printing centers are relatively new to the clear aligner space, the threat which they pose is not merely hypothetical: high-volume buying groups are actively considering switching to them from Invisalign. Our diligence reveals that, just as third-party labs have become a realistic option for aligner sourcing among independent dentists & orthodontists, larger dental service organizations (DSOs) are exploring the possibility of setting up their own 3D printing labs to support their practices, as well as to support new revenue streams. In particular, we find that one DSO representing up to 12% of Align's orthodontic case starts in the Americas is actively exploring 3D printing center opportunities. Given the low cost of setting up an FDA-compliant printing lab – less than \$200K, per industry experts – these organizations, which can represent thousands of practices, would have little trouble establishing organization-wide printing centers, which could generate significant savings across a large number of practices. Industry experts confirm that DSO migration represents a major risk to Align's case volumes.

Easy For DSOs To Set-Up Printing Labs...

"You can setup a clear aligner FDA approved lab in less than a year. Your capital equipment costs between buying three [high-volume] 3D printers and thermoforming machines can be less than \$100K to get started. If you add in labor, your total costs in your first year will be less than \$200K."

- Senior Employee, Major Dental Equipment Supplier

...And Large DSOs Are Actively Considering The Option

"There is a 50% chance that we move away from Invisalign when our contract comes up in 2020 and for me to say that is a big deal. It's a really big deal. I personally have not been happy with the service for the last year and half."

- Dentist, Top 10 DSO

"Invisalign case volume at DSOs is the biggest risk in the dentist channel. One big one that launches in house aligners and it is going to be a huge loss. If you have 1,000 practices in your DSO, each dentist could easily be doing 50 Invisalign cases a year, so with just one DSO, you could have 50,000 annual cases at risk."

- Dentist, Top 10 DSO

Spruce Point Diligence: Large DSO Actively Exploring 3D Printing Center Opportunities

"Our group has a committee looking to get a relationship with one of these [third-party labs] as our own print farm. They seem keen on one or two affiliated with carbon printers."

- Orthodontist, Large DSO

Large DSO: Materiality to Align Case Volume	
(A) DSO Group Orthodontists (Est.)	~300
(B) Invisalign Cases per DSO Group Orthodontist, Annual (Est.)	~200
(C) DSO Group Invisalign Cases, Annual (Est.) ((A) x (B))	~60,000
(D) Total Invisalign Case Starts, Annual – Orthodontists (Americas) (Est.)	520,000
DSO Group Share of Invisalign Orthodontist Cases (Americas) (Est.) ((C) / (D))	~11.5%

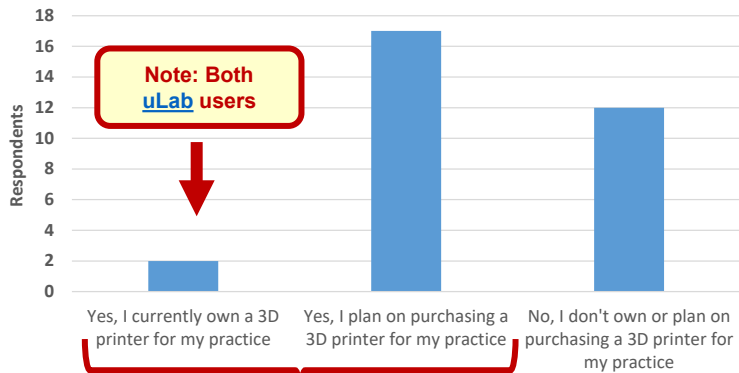
Could 11.5% of Align's orthodontic case starts in the Americas be at risk to the loss of a single DSO customer?



Align Bulls Are Mistaken About Orthodontist Attitudes Towards 3D Printing

Most Align bulls all but take for granted the notion that orthodontists and dentists view in-house 3D printing as an inevitable nuisance. They acknowledge recent innovation and price declines within the in-house 3D printing space, but are convinced that many orthodontists simply do not want to deal with the logistics of in-house printing. Our survey and conversations with high-volume orthodontists suggest otherwise. Spruce Point finds that, while just 6% of surveyed orthodontists currently own a 3D printer, over 50% plan on purchasing a 3D printer in the future – even with prevailing software not quite yet up to par with third-party CAD/CAM aligner design software. In particular, when asked what in particular would most likely convince them to allocate aligner cases to channels other than Align, the most popular answers given were the major selling points of in-house 3D printing: greater case control and more efficient case execution.

Do you own or plan to own a 3D printer specifically to fabricate your own clear aligners?



Over 60% of respondents plan to use an in-house 3D printer to print clear aligners (or do already)

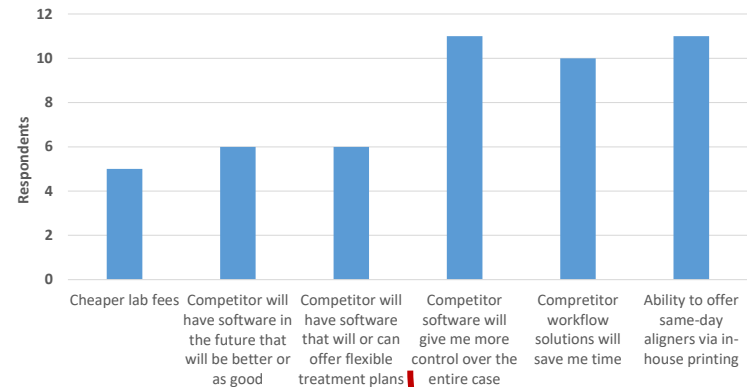
*"I know that when you are a new doctor, you get the worst Invisalign technicians out of Costa Rica that are designing your case. **Sometimes, you are going back and forth with the technician as many as eight times before the case is right.**"*

- Dental Consultant

*"I now have the capability of providing same day treatment with clear aligners which I could not do with Invisalign. I would have to wait at least two weeks. With my own 3D printer, I can have aligners the same day and I can also alter an aligner case on the same day. **This really helps my practice be more efficient throughout the patient's treatment.**"*

- Orthodontist

Which of the following are reasons that your peak clear aligner cases would not be allocated to Invisalign? Select all that apply.



Biggest drivers behind desire to seek Align alternatives match major selling points of in-house 3D printing

*"The difference between braces and Invisalign is if there is a change needed mid case. With Invisalign, I may need to wait 2-4 weeks to get a new aligners to continue the case. With braces, I can make the change immediately. **With 3D printing in your office, you have an aligner the same day which will make case management simpler.**"*

- Orthodontist, Diamond Plus Align Tier

As in-house 3D printing grows increasingly mainstream, Spruce Point believes that the major selling points of in-house 3D printing will drive significant demand for this option.

New Software Overcomes Many Of The Shortcomings Of In-House 3D Printing

Spruce Point believes that the recent emergence of uLab Systems – a relatively little-known developer of aligner CAD/CAM software – represents a major step towards making in-house 3D printing a practical option for a broad range of doctors. Much as Zendura's newest aligner material was created by Align's original plastics supplier, uLab was created by former Align technology and sales executives with close knowledge of the aligner software market, and a strong understanding of where current 3D printing software is coming up short. These same individuals launched a similar competitive bid against Align in the early 2000s in the form of OrthoClear – a bid so threatening that, when they settled their litigation with Align by having Align buy them out in Sep 2006, Align's share price immediately more than doubled.

Driven by Former Align Execs

Name	Align Role	OrthoClear Role
Charlie Wen	CTO	Founder
Joe Breeland	VP, Sales	VP, Sales
Rick Geracitano	Sales	Sales

5,000+ Doctors Trained In Just ~1 Year

OrthoClear is the technology leader in the clear removable aligner orthodontics market. OrthoClear offers the most advanced method of straightening teeth on the market today. Founded in January 2005, OrthoClear has become the fastest growing company in orthodontic history. OrthoClear has over 1300 employees, has trained over 5000 doctors in the use of its products, and in June received over 3000 new orders for its OrthoClear System. For more information, go to <http://www.orthoclear.com>

[Source](#)

Stock Immediately Responds To Settlement



uLab executives have a history of winning over doctors rapidly, and appear to be repeating their past success with uLab

Driven by Former Align/OrthoClear Execs

Name	Align Role	uLab role
Charlie Wen	CTO	Founder and CTO
Amir Abolfathi	Officer, EVP of R&D	Founder
Joe Breeland	VP, Sales	CCO
Rick Geracitano	Sales	Sales

"What we created 22 years ago [at Align Technologies took] control from the orthodontists and clinicians to do the treatment planning because a lot of things were unknown back then.... We didn't have the computational power that is available to us today. We didn't have intraoral scanning, the 3D printing was not in a state it is in today... The system that was designed in such a way that it was a centralized model that was highly controlled by the manufacturer. And like anything else, as businesses grow and scale, their legacy issue is that they keep the same architecture. About 4 years ago, we looked at the state of the technology and no one [was] breaking the mold and coming up with new ideas of how to do clear aligners differently and that is how uLab was born."

- Amir Abolfathi – uLab Systems, Co-Founder

NOW:
uLab

With Align's software patents now having largely expired, uLab represents the first new user-friendly CAD/CAM software offering in years.

Third-Party Labs And In-House 3D Printing Offer Overwhelming Cost Savings On Case-By-Case Basis

Spruce Point observes that the cost savings made possible by sourcing from third-party labs or printing aligners in-house are overwhelming. In particular, printing aligners in-house allows dentists and orthodontists to save over 75% versus Align on a per-case basis. This on top of the fact that in-house printing gives the orthodontist greater control over the case, allows him to complete the treatment with substantially fewer patient visits, and can be faster and easier than designing an aligner remotely with an outsourced technician (10 minutes vs. 30 minutes when done with the right software, per our conversations with doctors).

Clear Aligner Case Economics Example: Comprehensive Case with 44 Aligners (Covering Both Arches)

	Third-Party Lab		In-House 3D Print
	\$15/Aligner	\$10/Aligner	\$10/Aligner
(A) Aligner Price	\$15	\$10	\$10
(B) Aligners per Case	44	44	44
(C) Total Aligner Price per Case ((A) x (B))	\$660	\$440	\$440
(D) Impression Scan Price	\$20	\$20	-
(E) Arch Scans per Case	2	2	2
(F) Total Scan Price per Case ((D) x (E))	\$40	\$40	-
(G) Treatment Planning per Case	\$149	\$149	-
(H) Fee per Order	\$25	\$25	-
(I) Total Case Price to Orthodontist / Dentist ((C) + (F) + (G) + (H))	\$874	\$654	\$440
All-In Price per Aligner, Align ((I) / (44 Aligners))	\$19.86	\$14.86	\$10.00
(J) Invisalign System (Comprehensive Case) – List Price per Case	\$1,879	\$1,879	\$1,879
All-In Price per Aligner, Align ((J) / (44 Aligners))	\$42.70	\$42.70	\$42.70
Discount to Invisalign	53%	65%	77%

"My material costs per aligner are about \$5 to \$6 and when I factor in labor, I am printing aligners for approximately \$10. As my staff gets more efficient, the cost will go lower. 3D printers are getting faster and cheaper as well, so a new investment there will eventually lower the cost as well."

- Orthodontist



Third-Party Printing Labs And In-House 3D Printing Offer Substantial Cost Savings

Spruce Point finds that, for large-volume orthodontists, printing in-house could produce over 50% *more* savings over Align compared to sourcing from third-party labs, and would allow most orthodontists even of lesser tiers to save over 60% compared to Align fees themselves. We estimate that the option to switch to in-house printing presents the average Diamond Plus Align customer with a \$400K per year cost savings opportunity. We believe that, as in-house 3D printing grows increasingly mainstream with improvements in printer and software technology, printing in-house could well become a no-brainer option for a large share of the orthodontist population. Align would inevitably be forced to cut prices dramatically or otherwise suffer serious case volume losses among its highest-volume customers.

Align v. Third-Party Lab v. In-House Printing: Cost-per-Case

	Comprehensive Case (@ 44 Aligners ¹)	Non-Comprehensive Case (@ 40 Aligners ¹)
Invisalign System – List Price	\$1,879	\$1,699
Third-Party Lab - \$10 per Aligner	\$654	\$614
Discount to Invisalign	\$1,225	\$1,058
In-House Print - \$10 per Aligner	\$440	\$400
Discount to Invisalign	\$1,439	\$1,299

Additional In-House Printing Expenses

	Total Cost	Included In Total Annual Cost Below?
3D Printer	Varies (as low as <\$4k)	No: Negligible Over Time
Thermoformer	Varies (as low as ~\$3k)	No: Negligible Over Time
Software License (Annual Fee, uLab)	\$14,400	Yes

Align vs. Third-Party Lab vs. In-House Printing: Total Annual Cost Comparison

Invisalign Tier	Avg. Annual Cases	Case Mix (Est.) ²		(A) Tier Discount	Total Invisalign Fees		Third-Party Lab: \$10/Aligner		In-House Printing: \$10/Aligner	
		Comprehens. Cases	Non-Comp. Cases		(B) Pre-Discount (Cases x Price)	(C) Discounted ((B) x (1-(A)))	(D) Total Lab Fees (Cases x Price)	Savings v. Align ((C) - (D))	(E) Total Fees (Ca x Pr + License)	Savings v. Align ((C) - (E))
Gold Plus	99	74	25	18%	\$181,521	\$148,847	\$63,746	\$85,101	\$56,960	\$91,887
Platinum	164	123	41	28%	\$300,766	\$216,559	\$105,616	\$110,943	\$84,920	\$131,639
Plat. Plus	239	179	60	34%	\$438,281	\$289,265	\$153,906	\$135,359	\$117,160	\$172,105
Diamond	339	254	85	38%	\$621,681	\$385,442	\$218,306	\$167,136	\$160,160	\$225,282
Diam. Plus	600	450	150	40%	\$1,100,400	\$660,240	\$386,400	\$273,840	\$272,400	\$387,840

1. Spruce Point diligence

2. Assumes 75 / 25 case mix between comprehensive and non-comprehensive cases, based on Spruce Point diligence

Case Study: Cost Savings From Align Alternatives A Material Benefit To Orthodontist Profitability

Our diligence into the cost structure of orthodontic offices allows us to evaluate the potential impact of Align alternatives on their bottom lines. Our findings: current Align customers could increase their cash flows by close to 10% by instead sourcing their aligners from a third-party lab, or by over 12% by printing aligners in-house. We believe that the magnitude of this potential cost savings will be too great for many orthodontic offices to ignore – something which the current pandemic-driven pause in business will allow (and encourage) them to evaluate.

Cost Savings: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
Align Discount Tier	Platinum	Platinum Plus	Diamond Plus
(D) Align Discount	28%	34%	40%
(E) Case Expense, Wires & Brackets ²	\$600	\$600	\$600
(F) COGS, Wires & Brackets ((A) x (E))	\$168,000	\$216,000	\$240,000
(G) Avg. Case Expense, Aligners (ALGN) ³	\$1,834	\$1,834	\$1,834
(H) Pre-Discount COGS, Aligners ((B) x (G))	\$220,080	\$440,160	\$733,600
(I) ALGN Discount ((H) x (1 - (D)))	(61,622)	(149,654)	(293,440)
(J) COGS, Aligners (ALGN) ((H) + (I))	\$158,458	\$290,506	\$440,160
(K) Avg. Case Expense, Aligners (3 rd Party Lab) ⁴	\$859	\$644	\$644
(L) COGS, Aligners (3 rd Party Lab) ((B) x (K))	\$103,080	\$154,560	\$257,600
Cost Savings vs. ALGN (3rd Party Lab) ((J) - (L))	\$55,378	\$135,946	\$182,560
(M) Case Expense, Aligners (In-House Print) ⁵	\$550	\$490	\$466
(N) COGS, Aligners (In-House Print) ((B) x (M))	\$66,000	\$117,600	\$186,600
Cost Savings vs. ALGN (In-House Print) ((J) - (N))	\$92,458	\$172,906	\$253,760

Cash Flow Benefit: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
(D) Case Fee, Wires & Brackets ²	\$5,500	\$5,500	\$5,500
(E) Case Fee, Clear Aligners ²	\$5,700	\$5,700	\$5,700
Revenue, Wires & Brackets ((A) x (D))	\$1,540,000	\$1,980,000	\$2,200,000
Revenue, Clear Aligners ((B) x (E))	684,000	1,368,000	2,280,000
Revenue, Total	\$2,224,000	\$3,348,000	\$4,480,000
COGS: Wires and Brackets	(168,000)	(216,000)	(240,000)
COGS: Clear Aligners (ALGN)	(158,458)	(290,506)	(440,160)
Gross Profit (ALGN)	\$1,897,542	\$2,841,494	\$3,799,840
Staff Expense (25% Sales) ²	(556,000)	(837,000)	(1,120,000)
Rent (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Other Overhead (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Net Cash Flow Before Taxes (ALGN)	\$918,982	\$1,435,334	\$2,007,840
Cost Savings (3rd Party vs. ALGN)	\$55,378	\$135,946	\$182,560
Savings As a % of Pre-Tax Cash Flow	6.0%	9.5%	9.1%
Cost Savings (In-House vs. ALGN)	\$92,458	\$172,906	\$253,760
Savings As a % of Pre-Tax Cash Flow	10.1%	12.0%	12.6%

1. Case mix representative of typical mix at relevant practice size based on Spruce Point diligence
2. Average based on Spruce Point diligence
3. Assumes 75 / 25 comprehensive / non-comprehensive mix
4. Includes \$10 / aligner fee (\$15 for 120 aligner practice) and all other fees. Assumes 75 / 25 comprehensive / non-comprehensive mix.
5. Includes \$10 / aligner fee and \$14,400 annual software license fee

TAM-Driven Argument For Future Case Growth Undermined By Emerging Threats

Prior to the COVID-19 pandemic, the sell side anticipated top-line growth of approximately 20% in FY20 and beyond for Align, on long-term case growth of 20-30% per year. However, with the North American orthodontist channel increasingly saturated for Align, and with overwhelming competition coming to the dental, orthodontic, and all international channels, we believe that total case growth could revert to a run-rate level of just over 10% in the near-to-medium term. With Align likely to experience powerful pricing pressure from the onset of new competition at the same time, run-rate revenue growth could collapse to mid-single-digit levels – a tremendous drop-off from consensus estimates of ~20% long-term annual growth.

		2012	2013	2014	2015	2016	2017	2018	2019	7-Year CAGR	Future Run-Rate (Spruce Point)	
Orthodontists, North America (Est.)	Doctors	5,665	6,040	6,392	6,749	7,060	7,275	7,607	7,991	5%	0%	Orthodontist saturation limits case growth Spread of alternatives introduces churn
	Utilization	24.2	26.4	27.7	31.8	36.6	46.6	56.7	65.0	15%	0%	
	Cases (000s)	137.1	159.5	177.1	214.6	258.4	339.0	431.3	519.4	21%	0%	
Dentists, N. Amer., & All S. Amer. (Est.)	Doctors	19,285	21,290	23,498	24,961	27,005	30,955	34,393	39,139	11%	8%	Proliferation of low-cost alternatives introduces churn
	Utilization	7.2	7.2	6.9	7.4	7.6	8.0	8.6	8.6	2%	0%	
	Cases (000s)	139.7	154.3	161.5	183.8	205.4	247.2	296.8	336.1	13%	8%	
International (Est.)	Doctors	5,420	10,800	13,450	16,460	20,415	26,175	36,040	48,650	37%	20%	Proliferation of alternatives introduces churn
	Utilization	16.0	10.0	10.4	11.2	12.0	13.2	13.9	13.8	-2%	0%	
	Cases (000s)	86.8	10.5	139.5	184.8	244.7	344.8	500.0	669.8	34%	20%	
Total (Est.)	Doctors	30,370	38,130	43,340	48,170	54,480	64,405	78,040	95,780	18%	13%	
	Utilization	12.0	11.1	11.0	12.1	13.0	14.5	15.7	15.9	4%	0%	
	Cases (000s)	363.6	422.2	478.0	583.2	708.5	931.0	1,228.1	1,525.4	23%	11%	

Estimates derived from management disclosures. Figures not disclosed directly by management are Spruce Point estimates.

Medium-to-Long Term Growth Trajectory
Consensus vs. Spruce Point

	Sell-Side	Spruce Point
Case Volume Growth, Annual	20%	11%
ASP Growth, Annual	-1%	-5%
Total Revenue Growth, Annual	19%	6%

Spruce Point View
The sell side does not yet appreciate the consequences of emerging competitive threats

How Bad Could The Coming Quarter Be?

While it is no secret that Q2 will be a historically bad quarter for many companies and sectors, Spruce Point believes that investors are not fully prepared for the likely near-term impact of the pandemic on Align. As of today, the most conservative of orthodontists and dentists anticipate closures through the end of April. Many more plan to be closed through the middle or end of May at earliest. Even then, we anticipate that new cases will be extremely sparse immediately upon their return for at least several weeks. This suggests that Q2 FY20 EPS could be down by close to 50% YoY in an optimistic scenario in which dental practitioners return to work in mid-May – an aggressive timetable at this point.

(\$, Millions, except percentages)	Q2 FY19	Q2 FY20E			
		Early May Return	Mid-May Return	Late May Return	Late June Return
April Revenue Growth, YoY	-	-90.0%	-90.0%	-90.0%	-90.0%
May Revenue Growth, YoY	-	0.0%	-50.0%	-90.0%	-90.0%
June Revenue Growth, YoY	-	0.0%	0.0%	-50.0%	-90.0%
Q2 Revenue Growth, YoY	22.5%	-30.0%	-46.7%	-76.7%	-90.0%
Revenue	\$600.7	\$420.5	\$320.4	\$140.2	\$60.1
COGS	(167.1)	(126.2)	(96.1)	(42.1)	(18.0)
Gross Profit	\$433.6	\$294.3	\$224.3	\$98.1	\$42.1
Gross Margin %	72.2%	70.0%	70.0%	70.0%	70.0%
SG&A	(246.8)	(246.8)	(246.8)	(246.8)	(246.8)
YoY Growth, %	16.3%	-	-	-	-
R&D	(38.9)	(38.9)	(38.9)	(38.9)	(38.9)
YoY Growth, %	26.1%	-	-	-	-
EBIT	\$148.0	\$8.7	(\$61.4)	(\$187.5)	(\$243.6)
Operating Margin %	24.6%	2.1%	-19.2%	-133.8%	-405.5%
Interest Inc. (Exp.) & Other	13.8	-	-	-	-
Taxes	(41.8)	(2.0)	13.8	42.2	54.8
Tax Rate	25.8%	22.5%	22.5%	22.5%	22.5%
Net Income (Non-GAAP)	\$120.0	\$6.8	(\$47.6)	(\$145.3)	(\$188.8)
Diluted Shares Outstanding	80.6	79.1	79.1	79.1	79.1
EPS (Adj.)	\$1.49	\$0.09	(\$0.60)	(\$1.84)	(\$2.39)
Growth, YoY	14.3%	-94.3%	-140.4%	-223.4%	-260.3%

'Game over. That's it.' How the coronavirus impacted dentistry in Memphis

[Source](#)

But, the executive order meant a sharp downturn in patient numbers across the state. Since then, some practices have shut down completely.

"It's just been a very, very trying week," Fagala told *MBJ* on March 27. "The way a practice runs, especially an orthodontist practice like mine ... you may go from seeing 70-90 patients a day, and then you're able to see three. And, it's a huge change."

Some gross margin compression with lower capacity utilization

Assume no change in cost structure for purposes of analysis

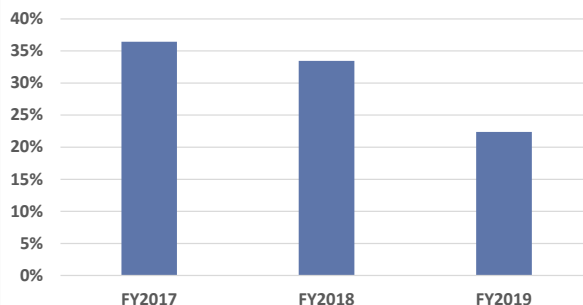
Spruce Point believes that investors are not fully prepared for the likely magnitude of the impact of the pandemic on Invisalign performance, for at least the coming quarter (and likely more to follow)

Management Trimming Exposure As Competition Mounts And Results Falter

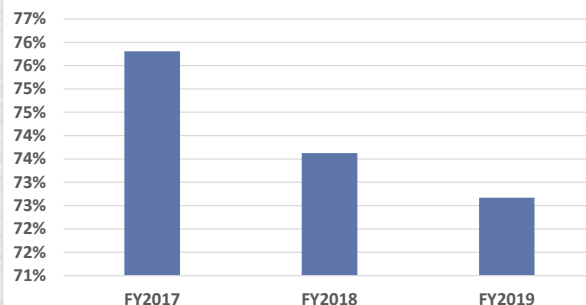
Spruce Point observes that, just as Align's performance has begun to deteriorate with the emergence of new competition, insiders have steadily and consistently trimmed their exposure to the stock. Today, insiders own just over 1% of outstanding shares. Meanwhile, the Company has expanded its buyback from just under \$100M in FY14 to \$400M in FY19. Spruce Point frequently sees insider selling paired with accelerated buybacks among companies under increasing strain. We worry that this is a signal that Align's insiders are heading for the exits ahead of renewed pressures with an explosion of new competitors.

Company Performance Deteriorating...

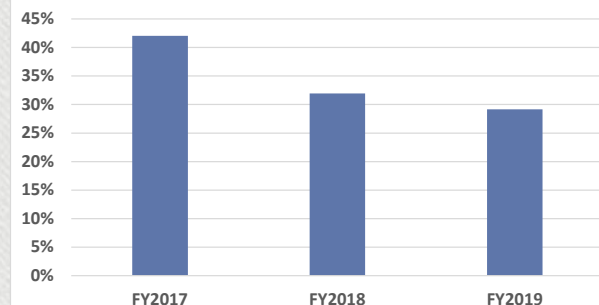
Sales Growth, YoY



Gross Margin

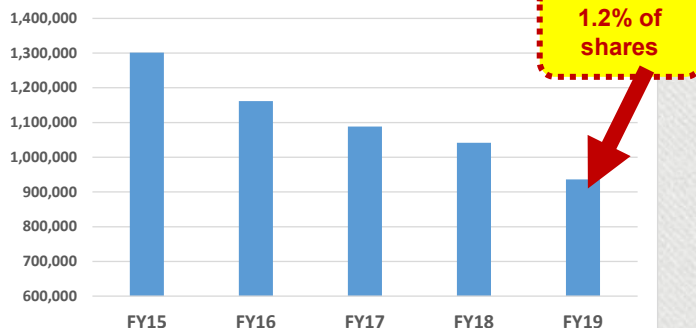


EBIT Growth (Non-GAAP), YoY



...And Insiders Exiting The Stock (While Buying On Shareholders' Behalf)

ALGN: Shares Held By Insiders



ALGN: Annual Share Buybacks



Capitalization And Valuation

With most sell-side estimates having been adjusted only conservatively in the face of tremendous uncertainty for Align amidst the current pandemic, Spruce Point believes that near-term earnings adjustments are highly likely, and could serve as a catalyst for a material downward move in the stock – [just as they have before](#). Meanwhile, just as it begins to face stronger growth headwinds amidst an increasingly congested competitive landscape, the Company spent close to \$420M – half its available cash – on a software acquisition intended to increase sell-through to the dentist channel. Spruce Point believes that, not only could near-term uncertainty elicit earnings revisions which pressure the stock, but longer-term competitive challenges will prevent the Company from rebounding as bulls expect.

(\$ in millions, except per share figures)

		<u>Street Valuation</u>	FY19E	FY20E	FY21E
Stock Price	\$184.41	EV / EBITDA	22.8x	23.9x	16.6x
Diluted Shares	79.1	Price / EPS	34.2x	32.0x	23.6x
Market Capitalization	\$14,586.8	Price / FCF	40.7x	67.9x	27.0x
Debt	\$0.0	<u>Growth and Margins</u>			
Minority Interest	\$0.0	Sales Growth	22.1%	6.9%	25.0%
Operating Leases	\$43.5	Adj. EBITDA Margin	25.9%	23.1%	26.6%
Less: Cash	\$449.9				
Net Debt (Cash)⁽¹⁾	(\$406.5)	<u>Credit Metrics</u>			
Total Enterprise Value	\$14,180.4	Net Debt / EBITDA	-0.7x	-0.7x	-0.5x

Source: Bloomberg

1. Pro-forma for acquisition of exocad Global Holdings GmbH



Clear Aligners: A Brief Background

A Brief History Of Clear Aligners

While single-piece tooth positioners have existed in some form since 1945, it was only in the late 1990s and early 2000s that clear aligners emerged as a practical alternative to bracket-and-wire systems for teeth realignment. In 1997, Align's founders – Stanford graduate students at the time – developed a system by which oral impressions could be replicated in computer imaging software, which could then be used to 3D-print sets of aligners designed specifically for an individual patient's teeth. Throughout a course of treatment ranging from 6 to 18 months, an orthodontist or dentist applies to the patient's teeth a number of aligners designed to accomplish specific "movements." Each set of aligners is swapped out for another at various stages of the treatment process until each "movement" is complete. Clear aligner treatment plans can include the use of traditional wire braces to address more complex cases or to shorten the duration of the treatment.

Aligners are worn 22 hours per day and removed only for eating and brushing. Each stage of treatment consists of a series of up to 6 aligners to be used for a period of 2 weeks each. There may be as many as 4 stages of treatment. Staging allows for IPR coordinating and scheduling, and tracking and monitoring progress. Treatment time can take 6-18 months.

ALIGNER SERIES



STAGED TREATMENT

	STAGE 1	STAGE 2	STAGE 3
Crowding	Up to 1.5mm	Up to 2.5mm	Up to 5.0mm
Spacing	Up to 1.5mm	Up to 2.5mm	Up to 5.0mm
Tipping	Minor	Moderate	Severe
Rotation	Minor	Moderate	Severe
Midline Misalignment	Minor	Up to 2.5mm	Up to 3mm
Anterior Misalignment	Minor	Moderate	Severe
Torquing	--	--	Minor

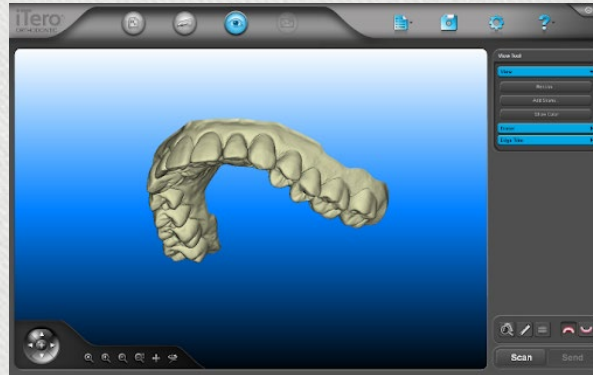
The Clear Aligner Process

Today, the Invisalign process begins with an “intraoral scan” of the patient’s teeth. Using Invisalign’s proprietary iTero intraoral scanner (or another scanner if desired, though only outside the US), the orthodontist or dentist generates a 3D digital image of the patient’s teeth, which can then be used to develop a customized treatment plan via Invisalign’s ClinCheck software. The doctor submits the image to a technician in Invisalign’s design headquarters in San Jose, Costa Rica, who then consults with the doctor to develop and finalize the treatment plan through ClinCheck. Once finalized, the plan is sent to Invisalign’s manufacturing plant, where the aligners are printed and ultimately shipped to the doctor.

1. Scan Patient’s Mouth



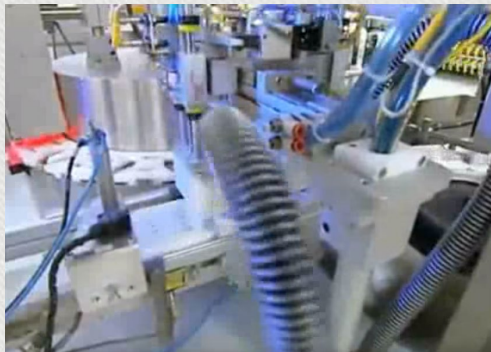
2. Establish Treatment Plan And Design Aligners In Consultation With Align Technician (Costa Rica)



3. Treatment Plan Finalized in Costa Rica



4. Aligner Design Sent To Mexican Production Facility For Manufacture



5. Aligners Delivered to Dentist (2-3 Weeks After Initial Patient Scan)



Competition Finally Enters After 20 Years Of Align Dominance

For years, Align was effectively the lone major player in the clear aligner space, protected by an IP portfolio which it enforced vigorously in court. However, the Company's key patents finally began to expire in 2017, creating an opening for dental tech competitors to enter the market. The influx of competition in the clear aligner space has dramatically transformed the market landscape since 2010. Even those with limited knowledge of the clear aligner industry will likely be familiar with the emergence of the SmileDirectClub, a provider of "do-it-yourself" aligners sold directly to the consumer ("DTC") rather than through dentists or orthodontists. Bulls have arrived at the consensus that DTC aligners cannot address the more serious cases of malocclusion which Align is used to treat, and, as such, do not pose an immediate threat to Align. Spruce Point does not necessarily disagree. Rather, we observe newly-emerging competitive dynamics which pose a threat to the economics and competitive rationality of Align's core "doctor-directed" channel, among both "comprehensive" and "non-comprehensive" cases.

The Evolving Clear Aligner Competitive Landscape

	Obtaining Oral Models		Clear Aligner Design Software And Printing Providers	Pure-Play Clear Aligner Design Software Providers	Pure-Play Clear Aligner Printing Providers
	Intra-Oral Scanners	Other			
2010	-	Polyvinyl Silicon (PVS) Impressions	Invisalign	-	-
Today	iTero (Align)	Polyvinyl Silicon (PVS) Impressions	Invisalign	3Shape Clear Aligner Studio	FDA-Approved Third-Party 3D Printing Labs
	Dentsply Sirona / Cerec	-	ClearCorrect	Archform	In-House 3D Printing
	Planscan	-	SureSmile	FullContour	-
	3M	-	Clarity	iROK Digital Dentistry Studio	-
	3Shape Trios	-	SLX	uLab Systems	-
	Carestream	-	-	(Others)	-
	Candor	-	-	-	-

Some of these changes to the competitive landscape will be familiar to Align investors. Others will not. Spruce Point believes, however, that, taken as a whole, these developments will (and are beginning to) drive seismic shifts in the economics of the clear aligner space, which was until recently occupied by just one major player.



New Competition Reshaping Economics Of Clear Aligners

Third-Party Labs Blow Open Doors To The Competitive Landscape

Most commentary on the evolving aligner landscape among the investment community has tended to focus on established players in the dental industry – 3M, Dentsply Sirona, Straumann, Henry Schein, and Envista in particular (in addition to SmileDirectClub). This commentary, however, ignores another major source of competition which has begun to make inroads among orthodontists and dentists: third-party 3D printing labs.

Outsourced 3D printing centers which print a wide variety of products for other clients are increasingly beginning to offer their services to dentists and orthodontists for the manufacture of custom clear aligners, designed by outsourced dental technicians in consultation with the doctor. This has opened a new avenue for disruptive upstarts to offer FDA-approved clear aligners in what is perceived to be a space occupied by just a handful of established dental players.

Clear Aligner Production Landscape: Through Mid-2010s



Clear Aligner Production Landscape: Perceived Current State



Clear Aligner Production Landscape: Actual Current State



INVESTOR PERCEPTION: Clear aligners as specialized medical equipment which can be produced by only a small number of established dental device players.

REALITY: Medical-grade clear aligners are plastic commodities that can be printed by any 3D printing lab which bothers to obtain FDA approval.

Third-Party Labs New To The Space, But Ramping Quickly, And Proactively Marketing To Doctors

Align bulls may be inclined not to take third-party 3D printing labs seriously as a potential Invisalign competitor. Spruce Point would strongly advise that investors not underestimate this emerging threat. Not only are these labs capable of producing aligners of [comparable quality to Invisalign](#), but they are rapidly expanding capacity and, per our conversations with dental professionals, aggressively reaching out to orthodontists and dentists. Align investors should not be taken off-guard by the novelty of outsourced 3D printing in the clear aligner space: our diligence reveals that third-party labs are quickly gaining traction.

Third-Party 3D Printing Labs Quickly Ramping Up Aligner Printing Capacity

VOODOO MANUFACTURING LAUNCHES CLEAR ALIGNER SERVICE AND EXPANDS BROOKLYN FACTORY

ARLENE LO - SEPTEMBER 16TH 2019 - 3:56PM

To meet the demands of the fast-growing teledentistry and clear aligner market in the U.S., Voodoo is expanding its factory in Brooklyn with a new wing of Formlabs 3D printers and an automated post-processing line.

Later this month, Voodoo will be starting production with Smilelove, 3Shape, FullContour, and ZenduraDental have been named as Voodoo's premier technical, digital design and material partners respectively.

"Long delivery times for aligners have consistently been a hurdle," said Spencer Grider, Founder of Smilelove. "But thanks to our partnership with Voodoo, we'll be able to cut the times down from 2-5 weeks, to just 2-5 days."

Other than delivering the product in one third the time, Smilelove's custom-fit aligners are sold at a price tag 75% less than braces or Invisalign. Smilelove believes that its clear aligners provide a discreet, accessible and easy teeth-straightening

[Source](#)

[General 3D printing lab](#) now capable of printing clear aligners

Developing entirely new wing dedicated to clear aligner printing

Much faster turn-around time

[Low cost](#) allows for cheaper aligner price to end-user

Third-Party 3D Printing Labs Quickly Gaining Traction After Coming To Market [Only Recently](#)

"Our [buying] group has a committee looking to get a relationship with one of these as our own print farm."

- Orthodontist, Platinum Align Tier

"We are at the point where we can switch to another clear aligner vender and we would not have even entertained that two years ago... There are over 100 aligner companies coming out of Asia. Two to three years from now, I don't see how Invisalign will see the same amount of cases that they had in the past."

- Dentist, DSO

"The need for Invisalign is diminishing. Dental laboratories are going to have the software and printing capabilities to compete with Invisalign. The production costs will not be as cheap as Invisalign [per aligner], but the lab will not need the same margin as Align because they won't have to cover advertising costs. This is going to cause significant pricing pressure in the industry. Today, we have a few big competitors. As soon as labs get involved, there will be different pricing."

- Former C-Level Executive, Major Dental Equipment Company

Spruce Point believes that the aggressive entry of third-party 3D printing labs into the clear aligner space could quickly render the aligner a low-value-added commodity in short order.

FDA Approvals For Clear Aligner Production Are Accelerating Rapidly

More informed investors may have been aware of the presence of third-party 3D printing labs in the clear aligner space in prior years. Until now, however, they have been only very minor players, as only one or two new producers were granted FDA 510(k) approvals for printing clear aligners in most years prior to 2018. However, since 2018, 33 new producers have been approved by the FDA to print clear aligners – more than those cleared in all years leading up to 2018 combined – and we are currently on pace to see more than 18 new approvals through the rest of 2020.

510(k) Premarket Notification

● FDA Home ● Medical Devices ● Databases

1 to 55 of 55 Results
Product Code: nxc Decision Date To: 03/23/2020

Product Code: nxc
("Aligner, Sequential")

Device Name	Applicant	510(K) Number	Decision Date
Clearform Aligners	Motor City Lab Works	K191838	03/20/2020
Neolab Clear Aligners	New England Ortho Lab, Inc.	K192338	03/12/2020
3d Predict	3D Smile USA, Inc.	K200214	02/24/2020
Ulab Systems Dental Aligner Kit	ULab Systems, Inc.	K192596	02/11/2020
Argen Clear Aligner, Argen Clear Aligner Premium	Argen Corporation	K192846	02/10/2020
Unismile Clear Aligner System	Vitang Technology, LLC	K191837	01/29/2020
Clear Aligner	Royal Dental Lab	K192767	01/08/2020
Clear Aligners	CDB Corporation	K191823	12/20/2019
DenMat Orthodontic Aligners	DenMat Holdings, LLC	K192470	12/20/2019
Krystal Clear Aligners	Shatkin F.I.R.S.T. LLC	K182388	12/19/2019
Sunclear Aligner System	Sun Dental Laboratories, LLC	K190394	12/16/2019
Vivid Aligners	Orthodont Laboratory, Inc.	K190003	11/06/2019
Smilealign Orthodontic Aligner System	3D Global Biotech Inc.	K191774	09/30/2019
3m Clarity Aligners	3M Company	K192119	09/05/2019
Osw Aligner System	OSW Manufacturing, LLC	K191990	08/23/2019
Dynaflex	DynaFlex	K190583	08/27/2019
Biolineer	Five Star Orthodontic Lab & Supply	K182658	06/19/2019
Argen Clear Aligner	Argen Corporation	K183229	06/07/2019
Magic Clear Aligners	Voodoo Manufacturing, Inc.	K190948	05/09/2019
Orthodontic Appliance	Shandong Huge Dental Material Corporation	K181747	04/18/2019

Source

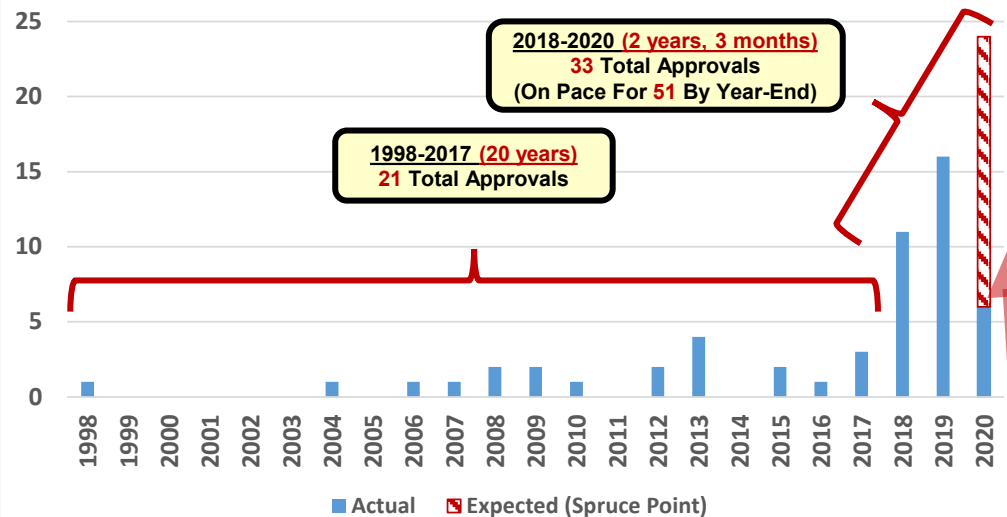
"You can setup a clear aligner FDA approved lab in less than a year. Your capital equipment costs between buying three [high-volume] 3D printers and thermoforming machines can be less than \$100K to get started. If you add in labor, your total costs in your first year will be less than \$200K."

- Senior Employee, Major Dental Equipment Supplier

"We are at the point where we can switch to another clear aligner vendor and we would not have even entertained that two years ago... There are over 100 aligner companies coming out of Asia. Two to three years from now, I don't see how Invisalign will see the same amount of cases that they had in the past."

- Dentist, DSO

FDA 510(k) Approvals for Clear Aligner Production



On pace for ~18 more approvals for remainder of 2020

To the extent that investors are at all aware of the presence of third-party 3D printing labs in the clear aligner space, they have likely been conditioned to treat them as extremely minor players with limited scale and/or limited credibility among doctors.

Spruce Point believes that, with so many now obtaining FDA approvals, third-party labs are, as a whole, quickly achieving the scale and credibility necessary to pose a serious threat to established clear aligner producers.

Outsourced Design Services Also Embracing Third-Party 3D Printing Labs

Similar disruption is occurring across the clear aligner value chain in ways that are supporting innovative competition in the manufacturing process. In particular, the space has seen the emergence of numerous dedicated aligner design services, which work with orthodontists and dentists to develop treatment plans and to design a patient's aligners accordingly – a similar role played by Align's treatment planning headquarters in Costa Rica. These increasingly high-quality third-party design services allow doctors to design aligners to be printed by third-party printing labs just as they would design aligners to be printed by Align itself. FullContour, one such third-party design service, has alone seen its base of aligner manufacturer partners grow by 50% since June 2018. Spruce Point believes that the growth and improving quality of these services will support the continued penetration of third-party 3D printing labs into the clear aligner space.

SEND TO THESE
MANUFACTURERS



[Source](#)

FullContour: Supported 3D Printing Labs Up 50% Since June 2018

Supported Manufacturers (Jun 2018)		Supported Manufacturers (Present)		
Argon	Talladium Milling	Argon	Talladium Milling	Voodoo Clear Aligners
Core3dcentres	Tru Abutment	Core3dcentres	Tru Abutment	Tusk Dentures
BioHorizons	Primotec	BioHorizons	Primotec	Desert Rose Biomedical
Straumann	Streamline Dental	Straumann	Streamline Dental	Complete Milling Lab
Nobel Biocare	Precision Fit Dental	Nobel Biocare	Precision Fit Dental	Cosmetic Dentistry Lab
Alien Milling Tech.	Scanbiz	Alien Milling Tech.	Scanbiz	Cadmus Dental
Zimmer Biomet	Digital Dental	Zimmer Biomet	Digital Dental	Dura-Metrics, Inc.
Custom Milling Center	Durban Dental Labs	Custom Milling Center	Durban Dental Labs	Ashford Orthodontics
3DRPD	TheLabsLab	3DRPD	TheLabsLab	Old World Labs
Strategy Milling	AU Dental	Strategy Milling	AU Dental	Sculpt
Axis Dental Milling	Laguna Dental Arts	Axis Dental Milling	Laguna Dental Arts	CAMcube
Fusion Digital Solutions	Zahntechnik	Fusion Digital Solutions	Zahntechnik	Arizona 3D Dental Lab

[Archived Source](#) (images may not render, but visible in source code)

[Source](#)

New as of last 18 months

By supporting not only large, recognizable players like Straumann and Zimmer Biomet, but also third-party 3D printing labs like Voodoo Manufacturing, third-party aligner design services are lowering the barrier to entry in the aligner manufacturing space, and making low-cost aligner manufacturers more accessible to a wider range of dentists and orthodontists.

Has The Materials Gap Closed?

Align management touts its proprietary SmartTrack material as superior to all other plastics available to other clear aligner producers (and users of in-house 3D printers). New developments, however, appear to have closed any outstanding gaps between SmartTrack and the rest of the field. In particular, Bay Materials – the same polymer product development laboratory which supplied Align’s own clear aligner plastics through the early 2010s – recently announced the release of Zendura FLX, its newest clear aligner material. Our conversations with industry experts reveal that this material achieves a multi-layer structure similar to that of SmartTrack, giving it analogous flexibility and crack resistance while allowing for a similar level of comfort. Spruce Point believes that further developments by materials producers – particularly one as experienced in aligner plastics development as Align’s own former supplier – will only continue to close any gaps between SmartTrack and other aligner plastics.

ALGN: Stephens Investor Conference (Nov 13, 2019)

“So the question is on product differentiation between us and maybe some of the other traditional orthodontic clear aligner companies. It starts with, one, we’ve been able to -- over 22 years being able to understand how to move teeth in a predictable, reliable way. Some of that’s product we’ve been able to put down. We have over 800 patents that are around how to move teeth from a software standpoint, from just the mechanics of moving teeth with attachments and gingiva cut and other parts of the -- even the material, SmartTrack material, which is a multi-layer material that moves teeth on a predictable, reliable way. So there’s a lot of technology that’s gone in that certainly differentiates products.”

- John Morici – CFO, Align Technology

Align’s Former Plastics Supplier Now Producing Comparable Aligner Material

May 15, 2019 02:00 AM

Silicon Valley firm touts new clear orthodontic material

[Source](#)

Founded in Silicon Valley in 1999, the company says it has a new thermoformable material, branded Zendura FLX, that is appealing to mass manufacturers, orthodontists, orthodontic labs and consumers in the fast-growing, multi-billion-dollar industry known as clear aligner therapy.

In its early days, Bay Materials developed and supplied the first-generation material used to produce Invisalign-brand aligners, which pioneered invisible and removable orthodontics for teeth straightening. The most well-known product, Invisalign, made by Align Technology, now uses its own patented material.

“We first developed transparent, high-strength thermoformable polyurethanes to replace previously used polyester materials,” Bay Materials founder and CEO Ray Stewart said in an email. “Those materials helped spark the clear aligner revolution. As the market has grown there is increasing demand for advanced materials requiring a challenging combination of mechanical, optical and biocompatibility properties.”

Twenty years after opening, Bay Materials says it has met a new performance standard for clear aligner materials with Zendura FLX, which was designed to maximize tooth-moving force while reducing the initial pressure on patient’s teeth. The material comes in three-layer sheets with the inner shell designed to grip teeth, an outer shell that acts as a tough barrier, and a central elastomeric layer to apply gentle yet consistent pressure to move teeth predictably.

To meet demand for the plastic sheets, Bay Materials says it doubled production volume in 2018 for Zendura FLX and another product called Zendura A, which is used primarily for post-treatment retainers that keep newly straightened teeth in position.

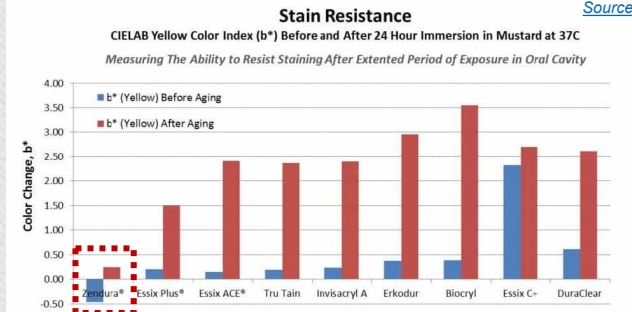
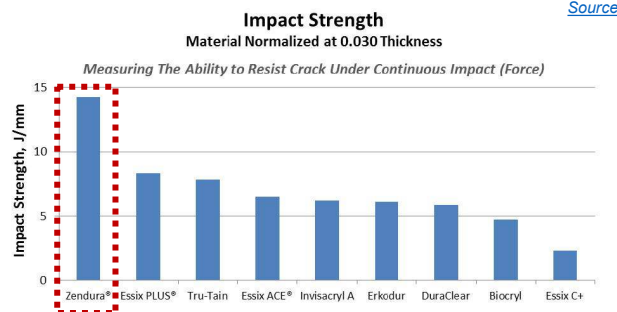
“As we expanded our product line 300 percent over the last 12 months and added new customers, we ran into a wall space-wise and are now completing our facility expansion,” Stewart said.

In the next 12 months, the business will need to more than double production again for the two materials. The original space will continue to be heavily

New Zendura Polymer Superior To Existing Third-Party Clear Aligner Plastics (And To Align’s SmartTrack?)

“SmartTrack and Zendura FLX are both 3 layer plastics with patents. They have different methods of using 3 layers. I think Zendura FLX is better, but they are not that different in practice.”

- Orthodontic Consultant, Aligner Materials Expert



Spruce Point believes that the ongoing proliferation of third-party 3D printing labs in the clear aligner space will only incentivize further R&D directed at clear aligner development: whereas Align was, until recently, the only major player in the clear aligner space, materials producers now face a broad and rapidly-growing number of potential customers for clear aligner plastics.

Last-Ditch Effort To Pitch Its Material As A Competitive Advantage?

Spruce Point observes that, just as competitors make inroads towards creating clear aligner plastics of comparable quality to Align's, the Company is now – for the first time – listing its SmartTrack Aligner material as a “key competitive factor” in its 10-K. We see this as a last-ditch effort to reinforce management's argument that its material is truly differentiated and unlike any other material offered by other clear aligner providers. Our diligence reveals that [this is no longer the case](#). Indeed, the fact that management cites its material as a key competitive factor just as other providers are developing aligner materials of comparable quality suggests to us that Align's competitive advantage is quickly eroding.

ALGN: 2018 10-K

Key competitive factors include:

- effectiveness of treatment;
- price;
- software features;
- aesthetic appeal of the treatment method;
- customer support;
- customer online interface;
- brand awareness;
- innovation;
- distribution network;
- comfort associated with the treatment method;
- oral hygiene;
- ease of use; and
- dental professionals' chair time.

ALGN: 2019 10-K

Key competitive factors include:

- **Our SmartTrack aligner materials;**
- effectiveness of treatment;
- price;
- software features;
- aesthetic appeal of the treatment method;
- customer support;
- customer online interface;
- brand awareness;
- innovation;
- distribution network;
- comfort associated with the treatment method;
- oral hygiene;
- ease of use; and
- dental professionals' chair time.

Why is management suddenly listing its SmartTrack material as its #1 key competitive factor after not even disclosing it as a competitive factor *at all* in the past?

Individual Labs Do Not Need Massive Scale To Put Pricing Pressure On Align Collectively

Do third-party labs have sufficient scale to compete with Align, a global clear aligner producer? Spruce Point believes that they are well on their way: while many of these labs are, individually, relatively smaller in scale, their rapid proliferation could make them a powerful force in the industry on a collective basis in the near future. Importantly, our diligence reveals that clear aligner printing labs are neither difficult nor expensive to start up: a lab of modest scale could cost as little as \$100K in up-front spending. While such a lab would have relatively limited capacity individually, the rapid spread of clear aligner producers across the US – encouraged by exceedingly low startup costs – is quickly expanding the scale of third-party labs. The dramatically lower prices offered by these labs versus Align will only intensify industry-wide pricing pressure into the future.

"You can setup a clear aligner FDA approved lab in less than a year. Your capital equipment costs between buying three [high-volume] 3D printers and thermoforming machines can be less than \$100K to get started. If you add in labor, your total costs in your first year will be less than \$200K."

- Senior Employee, Major Dental Equipment Supplier

"Our group has a committee looking to get a relationship with one of these [third-party labs] as our own print farm. They seem keen on one or two affiliated with carbon printers."

- Orthodontist

Low up-front cost to start up moderate-volume third-party lab, and higher-volume carbon-based printing labs are proliferating as well

ALGN: Legacy Manufacturing

ALGN FY19
1.5M Cases Worldwide

Third-Party Labs: Proliferation Of Manufacturers With Minute Startup Costs

As of early October, Voodoo's manufacturing capacity was around 20,000 aligners per month, said Friefeld, adding that the goal is to be making 50,000 to 80,000 monthly by the end of 2019. [Source](#)

FDA-Approved Third-Party Labs – Annual Case Capacity Estimate

(A) Aligner Capacity per Month	80,000
(B) Aligners per Case, Average (Est.)	30
(C) Case Capacity per Month ((A) x (B))	2,667
(D) Case Capacity per Year ((C) x 12)	32,000
(E) FDA-Approved 3 rd Party Aligner Printing Labs, End 2020 (Est)	~50
Aggregate Third-Party Lab Capacity, Annual Cases ((D) x (E))	1,600,000

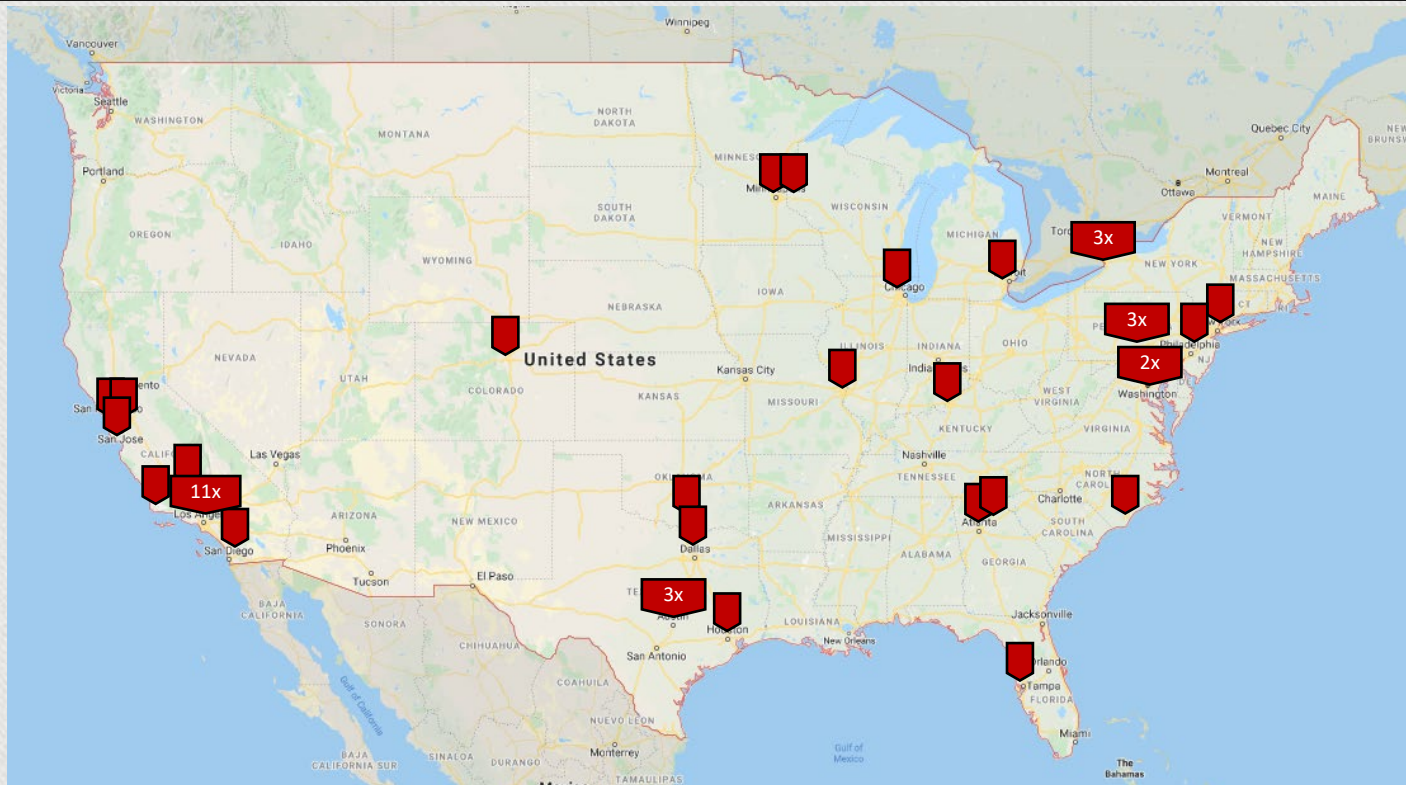
Third-party labs can ramp production quickly, and have a clear path to developing enough scale to match ALGN production

While Align has relative scale in manufacturing, it has not been pressured to leverage its scale to match competitors' prices until now, as it was effectively the only major player in the clear aligner space until the mid-2010s. The expansion of third-party labs, we believe, will help to force Align to adjust its prices downwards.



Clear Aligner Production Proliferating Rapidly

Spruce Point observes that domestic, FDA-approved clear aligner producers are distributed widely across the country. This suggests that, though some third-party 3D printing sites may individually be relatively smaller in scale than Align (for now), most US orthodontists and dentists are in close proximity to at least one clear aligner producer with sufficient capacity to service a more regionalized market. Local third-party labs need not necessarily match Align's global scale in order to pose a serious competitive threat as a whole: they can collectively achieve meaningful scale by serving only smaller regions individually. With start-up costs so low for a third-party lab with modest capacity, it may not be long before low-cost clear aligner producers blanket the country.



While clear aligner producers can ship anywhere, their increasingly broad distribution across the US highlights the fact that, collectively, individual labs are quickly growing capacity and achieving national scale. Even individual orthodontists with in-house printers are offering capacity at the margin.



Source Materials Allow Spruce Point To Conduct Comprehensive Cost Comparison

Through our rigorous diligence process, we have obtained Align's Pricing Terms and Conditions sheet for US practitioners, in addition to the details of Align's volume-based discount program ("Advantage"). Taken together, these documents reveal the price charged by Align to its dental practitioner base for each Invisalign treatment program. We have also obtained the Terms and Conditions for Voodoo Clear Aligners, a third-party 3D printing lab FDA-approved to print aligners. These source documents allow us to conduct a comprehensive head-to-head analysis comparing the cost of Invisalign against the cost of aligners printed by a typical third-party lab.

Align Technology: Pricing Terms and Conditions (USA)

Align Technology Pricing Terms and Conditions ("Terms") for USA

Effective as of January 1, 2020

Product and price for EACH patient treatment (each a "Treatment")	Number of Aligners per arch	Additional Aligners	Treatment Expiration Date	Replacement Aligners	All Materials Required (Plus completed Informed Patient Consent Form) (together "AMR")	All Materials Required for Additional Aligners/Refinement ("AMR" for these Products)
Invisalign System - Comprehensive US\$1,879	Varies per treatment	Reasonable number of Additional Aligners are included in the treatment price for 5 years after the shipment date of the initial set of aligners. No Additional Aligners can be purchased after the Treatment Expiration Date.	5 years after the shipment date of the initial set of aligners	US\$10 each; not to exceed more than US\$500 per replacement aligner order. Additional shipping charges apply.	Complete online prescription form Online photos Upper and lower impressions or intra-oral scans Optional X-rays	Complete online prescription form New photos New upper and lower impressions or intra-oral scans optional for Additional Aligners (recommended if last aligner does not fit)
Invisalign System - Moderate Dual Arch: US\$1,699 Single Arch: US\$1,275	Up to 20	1 set of Additional Aligners orders are included in the treatment price for 2 years after the shipment date of the initial set of aligners. A fee of \$130 will apply for each additional set of Additional Aligners purchased before the Treatment Expiration Date. No Additional Aligners can be purchased after	3 years after the shipment date of the initial set of aligners	US\$10 each; not to exceed more than US\$500 per replacement aligner order. Additional shipping charges apply.	Complete online prescription form Online photos Upper and lower impressions or intra-oral scans Optional X-rays	Complete online prescription form New photos New upper and lower impressions or intra-oral scans optional for Additional Aligners (recommended if last aligner does not fit)

CNTR-000048 Rev K USA | Align Pricing Terms & Conditions | January 1, 2020

Voodoo Clear Aligners: Basic Terms and Conditions



BASIC TERMS AND CONDITIONS

Contact Info:

- Hours of Support: Monday to Friday, 10:00 am to 6:00 pm EST
- Contact Email: aligner.support@voodoomfg.com
- Contact number (text or call): (646) 854-4571

Product Details:

- Pricing:
 - Impression scanning: \$20/arch
 - Treatment planning: \$149/case
 - Aligners: \$15 per aligner/retainer/template + \$25 fee per order (covers support, packaging, and UPS Ground shipping within the U.S.)¹
- Standard semi-scalloped trimline
- Materials:
 - Aligners made with Zendura FLX 0.76mm
 - Retainers made with Essix Ace 0.040"
 - Templates made with Essix A+ .020"
- Every aligner is laser marked with step number, arch and unique identification code
- Individual aligner-pairs are bagged and labeled with patient name, prescribing doctor name, and all FDA required markings
- Aligners are FDA compliant and covered by our 510K (K190948)

With third-party 3D printing labs only just now entering the clear aligner industry in size, Spruce Point believes that this head-to-head comparison is similar to the kind of cost comparisons which will increasingly be conducted by orthodontists and dentists as third-party labs enter the mainstream.

Accordingly, we believe that this represents a cutting-edge analysis which details the pricing pressure soon to beset the industry.

Medical Equipment Or Commodity?

Third-Party Labs Upending Industry Economics

Spruce Point finds that the proliferation of third-party 3D printing labs capable of producing high-quality clear aligners is already beginning to reshape the economics of the aligner space. For a typical comprehensive clear aligner case consisting of a series of 44 total aligners covering both arches, doctors would pay over 50% less than Align's list price by instead sourcing from Voodoo. Industry experts inform us that Voodoo and other third-party labs can offer prices as low as \$10 or less per aligner, suggesting that doctor savings could be even more significant.

Voodoo Clear Aligners Term Sheet



BASIC TERMS AND CONDITIONS

Contact Info:

- Hours of Support: Monday to Friday, 10:00 am to 6:00 pm EST
- Contact Email: aligner.support@voodoomfg.com
- Contact number (text or call): (646) 854-4571

Product Details:

- Pricing:
 - Impression scanning: \$20/arch
 - Treatment planning: \$149/case
 - Aligners: \$15 per aligner/retainer/template + \$25 fee per order (covers support, packaging, and UPS Ground shipping within the U.S.)¹
- Standard semi-scalloped trimline
- Materials:
 - Aligners made with Zendura FLX 0.76mm
 - Retainers made with Essix Ace 0.040"
 - Templates made with Essix A+ .020"
- Every aligner is laser marked with step number, arch and unique identification code
- Individual aligner-pairs are bagged and labeled with patient name, prescribing doctor name, and all FDA required markings
- Aligners are FDA compliant and covered by our 510K (K190948)

50%+ discount despite comparable high-quality material

Clear Aligner Case Economics Example: Comprehensive Case with 44 Aligners (Covering Both Arches)

	\$15/Aligner	\$10/Aligner
(A) Aligner Price	\$15	\$10
(B) Aligners per Case	44	44
(C) Total Aligner Price per Case ((A) x (B))	\$660	\$440
(D) Impression Scan Price	\$20	\$20
(E) Arch Scans per Case	2	2
(F) Total Scan Price per Case ((D) x (E))	\$40	\$40
(G) Treatment Planning per Case	\$149	\$149
(H) Fee per Order	\$25	\$25
(I) Total Case Price to Orthodontist / Dentist ((C) + (F) + (G) + (H))	\$874	\$654
All-In Price per Aligner, Third-Party Printing ((I) / (44 Aligners))	\$19.86	\$14.86
(J) Invisalign System (Comprehensive Case) – List Price per Case	\$1,879	\$1,879
All-In Price per Aligner, Align ((J) / (44 Aligners))	\$42.70	\$42.70
Third-Part Lab Discount to Invisalign (Representative)	53%	65%

Until now, the price paid by the doctor for clear aligners has been dictated by dental device and equipment companies – Align in particular. However, with third-party 3D printing labs now inundating the space, dentists and orthodontists will increasingly be presented with opportunities to purchase aligners at prices set by producers of 3D printed commodities, which clear aligners themselves are now inevitably becoming.

Clear aligners are well on their way to becoming plastic commodities from a manufacturing perspective, not difficult-to-produce medical equipment.

Sourcing From Third-Party 3D Printing Labs Results In Substantial Cost Savings

Spruce Point finds that sourcing clear aligners from a third-party 3D printing lab rather than from Align results in significant cost savings for effectively all dentists and orthodontists, even after accounting for Align's volume-based discounts. With third-party labs [becoming increasingly accessible](#) to doctors while offering [similar-quality aligners](#), we believe that this represents the beginning of a seismic shift in the economics of the clear aligner industry – a space which, for nearly 20 years, featured almost no real competition. We believe that the proliferation of FDA-approved third-party labs will inevitably put pressure on more traditional dental equipment providers – Align included – to slash aligner prices.

Align vs. Third-Party Lab: Cost-per-Case Comparison

	Comprehensive Case (@ 44 Aligners ¹)	Non-Comprehensive Case (@ 40 Aligners ¹)
Invisalign System – List Price	\$1,879	\$1,699
Third-Party Lab - \$15 per Aligner	\$874	\$814
Discount to Invisalign	\$1,005	\$885
Third-Party Lab - \$10 per Aligner	\$654	\$614
Discount to Invisalign	\$1,225	\$1,085

Align Advantage Program: Tier-Based Discounts

The Advantage Program consists of eight (8) membership Tiers:

	BRONZE	SILVER	GOLD	GOLD+	PLATINUM	PLATINUM+	DIAMOND TOP 1%	DIAMOND+ TOP 1%
Membership Tier	Bronze	Silver	Gold	Gold Plus	Platinum	Platinum Plus	Diamond	Diamond Plus
Qualifying Points	0	5,000	24,000	35,000	65,000	100,000	140,000	200,000
Discount	0 %	0 %	8 %	18 %	28 %	34 %	38 %	40 %

Advantage Program members are granted tier status by earning the minimum number of required program points for a given tier within a semi-annual Program Period.

Align vs. Third-Party Lab: Total Annual Cost Comparison

Invisalign Tier	Avg. Annual Cases	Case Mix (Est.) ²		(A) Tier Discount	Total Invisalign Fees		Third-Party Lab: \$15/Aligner		Third-Party Lab: \$10/Aligner	
		Comprehens. Cases	Non-Comp. Cases		(B) Pre-Discount (Cases x Price)	(C) Discounted ((B) x (1-(A)))	(D) Total Lab Fees (Cases x Price)	Savings v. Align ((C) - (D))	(E) Total Lab Fees (Cases x Price)	Savings v. Align ((C) - (E))
Bronze	5	4	1	0%	\$9,215	\$9,215	\$4,310	\$4,905	\$3,230	\$5,985
Silver	28	21	7	0%	\$51,352	\$51,352	\$24,052	\$27,300	\$18,032	\$33,320
Gold	58	44	14	8%	\$106,462	\$97,945	\$49,852	\$48,093	\$37,372	\$60,573
Gold Plus	99	74	25	18%	\$181,521	\$148,847	\$85,026	\$63,821	\$63,746	\$85,101
Platinum	164	123	41	28%	\$300,766	\$216,559	\$140,876	\$75,683	\$105,616	\$110,943
Plat. Plus	239	179	60	34%	\$438,281	\$289,265	\$205,286	\$83,979	\$153,906	\$135,359
Diamond	339	254	85	38%	\$621,681	\$385,442	\$291,186	\$94,256	\$218,306	\$167,136
Diam. Plus	600	450	150	40%	\$1,100,400	\$660,240	\$515,400	\$144,840	\$386,400	\$273,840

1. Spruce Point diligence

2. Assumes 75 / 25 case mix between comprehensive and non-comprehensive cases, based on Spruce Point diligence

Case Study: Cost Savings From Align Alternatives A Material Benefit To Orthodontist Profitability

Our diligence into the cost structure of orthodontic offices allows us to evaluate the potential impact of Align alternatives on their bottom lines. Our findings: current Align customers could increase their cash flows by close to 10% by instead sourcing their aligners from a third-party lab. We believe that the magnitude of this potential cost savings will be too great for many orthodontic offices to ignore – something which the current pandemic-driven pause in business will allow (and encourage) them to evaluate.

Cost Savings: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
Align Discount Tier	Platinum	Platinum Plus	Diamond Plus
(D) Align Discount	28%	34%	40%
(E) Case Expense, Wires & Brackets ²	\$600	\$600	\$600
(F) COGS, Wires & Brackets ((A) x (E))	\$168,000	\$216,000	\$240,000
(G) Avg. Case Expense, Aligners (ALGN) ³	\$1,834	\$1,834	\$1,834
(H) Pre-Discount COGS, Aligners ((B) x (G))	\$220,080	\$440,160	\$733,600
(I) ALGN Discount ((H) x (1 - (D)))	(61,622)	(149,654)	(293,440)
(J) COGS, Aligners (ALGN) ((H) + (I))	\$158,458	\$290,506	\$440,160
(K) Avg. Case Expense, Aligners (3 rd Party) ⁴	\$859	\$644	\$644
(L) COGS, Aligners (3 rd Party Lab) ((B) x (K))	\$103,080	\$154,560	\$257,600
Savings vs. ALGN (3 rd Party Lab) ((J) - (L))	\$55,378	\$135,946	\$182,560

Cash Flow Benefit: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
(D) Case Fee, Wires & Brackets ²	\$5,500	\$5,500	\$5,500
(E) Case Fee, Clear Aligners ²	\$5,700	\$5,700	\$5,700
Revenue, Wires & Brackets ((A) x (D))	\$1,540,000	\$1,980,000	\$2,200,000
Revenue, Clear Aligners ((B) x (E))	684,000	1,368,000	2,280,000
Revenue, Total	\$2,224,000	\$3,348,000	\$4,480,000
COGS: Wires and Brackets	(168,000)	(216,000)	(240,000)
COGS: Clear Aligners (ALGN)	(158,458)	(290,506)	(440,160)
Gross Profit (ALGN)	\$1,897,542	\$2,841,494	\$3,799,840
Staff Expense (25% Sales) ²	(556,000)	(837,000)	(1,120,000)
Rent (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Other Overhead (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Net Cash Flow Before Taxes (ALGN)	\$918,982	\$1,435,334	\$2,007,840
Cost Savings (3 rd Party vs. ALGN)	\$55,378	\$135,946	\$182,560
Savings As a % of Pre-Tax Cash Flow	6.0%	9.5%	9.1%

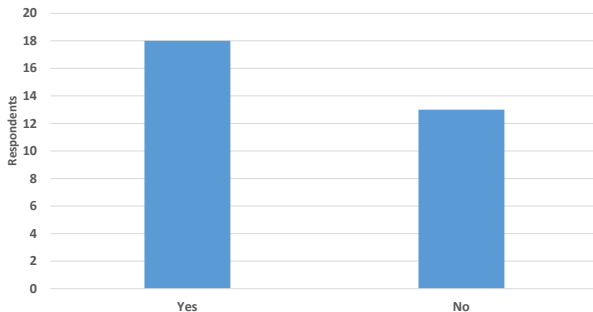
1. Case mix representative of typical mix at relevant practice size based on Spruce Point diligence
2. Average based on Spruce Point diligence
3. Assumes 75 / 25 comprehensive / non-comprehensive mix
4. Includes \$10 / aligner fee (\$15 for 120 aligner practice) and all other fees. Assumes 75 / 25 comprehensive / non-comprehensive mix.

Doctors Reveal That Pricing Pressure Is Already Coming To The Space

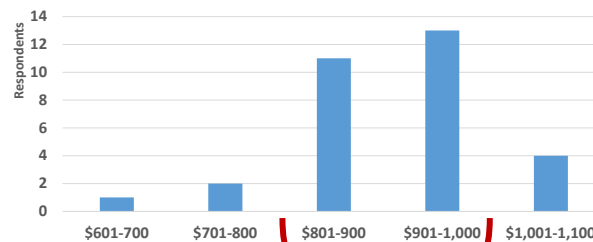
Dentists and orthodontists across the US tell us that the influx of competition is already beginning to weigh on industry pricing. Through a proprietary survey of high-volume orthodontists and conversations with a variety of dental professionals, we have learned that 3M is acting aggressively to win new business for its Clarity aligners by offering steep discounts. Of the 31 high-volume orthodontists included in our survey – a far different population than the more diverse groups covered most sell-side surveys, but one much more critical to the business – close to 60% have had an in-office visit from 3M to discuss Clarity aligners. Our conversations reveal that 3M is offering lab fees as low as \$500-600 per case, far below Align’s average lab fee – even among high-volume orthodontists receiving heavy discounts. Our survey also reveals that most orthodontists would consider Align alternatives if offered lab fees between \$800-1,000, a threshold which 3M already appears to have surpassed.

Spruce Point Proprietary Survey (31 Align-Using Orthodontists, Minimum Platinum Tier)

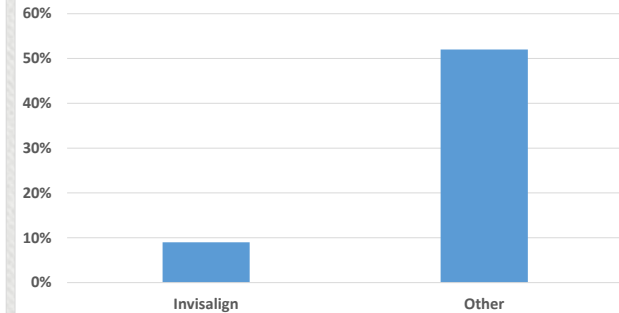
Has Clarity (3M) been in your offices to discuss their clear aligner products and pricing?



At approximately what price level of lab fees would you (or did you) consider switching a majority of your Invisalign case volume to other clear aligner providers or alternative third-party workflow solutions, assuming clinical outcomes were similar?



Survey Results: 2019-2020E Expected Case Growth, Align vs. Competitors (Aggregate)



“3M is offering me cases at a \$500 lab fee compared to my Invisalign Lab fee of \$1,000. If I can start doing more cases with 3M and it will save me money, why not just switch? 3M software is excellent. It is very easy to use. They brought a lot of people over from Invisalign. It’s getting to the point where it will be as good as Invisalign.”

- Orthodontist, Diamond Plus Align Tier

“3M came to me and said that we can do all of your cases for \$600... I expect my Invisalign volumes to be down going forward”

- Orthodontist, Diamond Plus Align Tier

“We are going to see major price compression with lab fees in the next one to two years.”

- Senior Employee, Major Dental Equipment Supplier

Spruce Point believes that it is only a matter of time before Align is forced to slash its own lab fees to maintain its existing orthodontist base, or else risk losing significant case volume.



Not Just Hypothetical: Major DSOs Considering 3D Printing Centers, Both In-Sourced And Outsourced

Spruce Point emphasizes that, while 3D printing centers are relatively new to the clear aligner space, the threat which they pose is not merely hypothetical: high-volume buying groups are actively considering switching to them from Invisalign. Our diligence reveals that, just as third-party labs have become a realistic option for aligner sourcing among independent dentists & orthodontists, larger dental service organizations (DSOs) are exploring the possibility of setting up their own 3D printing labs to support their practices, as well as to support new revenue streams. In particular, we find that one DSO representing up to 12% of Align's orthodontic case starts in the Americas is actively exploring 3D printing center opportunities. Given the low cost of setting up an FDA-compliant printing lab – less than \$200K, per industry experts – these organizations, which can represent thousands of practices, would have little trouble establishing organization-wide printing centers, which could generate significant savings across a large number of practices. Industry experts confirm that DSO migration represents a major risk to Align's case volumes.

Easy For DSOs To Set-Up Printing Labs...

"You can setup a clear aligner FDA approved lab in less than a year. Your capital equipment costs between buying three [high-volume] 3D printers and thermoforming machines can be less than \$100K to get started. If you add in labor, your total costs in your first year will be less than \$200K."

- Senior Employee, Major Dental Equipment Supplier

...And Large DSOs Are Actively Considering The Option

"There is a 50% chance that we move away from Invisalign when our contract comes up in 2020 and for me to say that is a big deal. It's a really big deal. I personally have not been happy with the service for the last year and half."

- Dentist, Top 10 DSO

"Invisalign case volume at DSOs is the biggest risk in the dentist channel. One big one that launches in house aligners and it is going to be a huge loss. If you have 1,000 practices in your DSO, each dentist could easily be doing 50 Invisalign cases a year, so with just one DSO, you could have 50,000 annual cases at risk."

- Dentist, Top 10 DSO

Spruce Point Diligence: Large DSO Actively Exploring 3D Printing Center Opportunities

"Our group has a committee looking to get a relationship with one of these [third-party labs] as our own print farm. They seem keen on one or two affiliated with carbon printers."

- Orthodontist, Large DSO

Large DSO: Materiality to Align Case Volume	
(A) DSO Group Orthodontists (Est.)	~300
(B) Invisalign Cases per DSO Group Orthodontist, Annual (Est.)	~200
(C) DSO Group Invisalign Cases, Annual (Est.) ((A) x (B))	~60,000
(D) Total Invisalign Case Starts, Annual – Orthodontists (Americas) (Est.)	520,000
DSO Group Share of Invisalign Orthodontist Cases (Americas) (Est.) ((C) / (D))	~11.5%

Could 11.5% of Align's orthodontic case starts in the Americas be at risk to the loss of a single DSO customer?



Barriers To In-House 3D Printing Collapsing

New Developments Poised To Make In-House 3D Printing A More Practical And Competitive Option

Until recently, orthodontists and dentists looking to print clear aligners in-house have had very few software options from which to choose. With Align having maintained such tight control of the clear aligner value chain for most of the last 20 years, and with in-house 3D printing still a relatively novel development, relatively little has been invested in third-party CAD/CAM software to support in-house clear aligner design. Importantly, Align also maintained a suite of patents over its CAD/CAM clear aligner software which began to expire only in 2017. Accordingly, 3Shape – a platform which gets mixed reviews, per our conversations with orthodontists – has been perhaps the only practical CAD/CAM software option for users of in-house 3D printers.

Benefits To In-House 3D Printing

Benefit	Explanation
Reduce Turn-Around Time	<ul style="list-style-type: none"> Waiting period between patient scan and aligner delivery slashed from several weeks to several minutes or hours Allows orthodontist/dentist to complete cases in less time and with fewer patient visits
Cost Savings	<ul style="list-style-type: none"> Removing “middle-man” technician and outsourced printing services reduces overall cost of aligner cases
Case Control	<ul style="list-style-type: none"> Gives orthodontist/dentist greater control over aligner design and case planning rather than outsourcing to less-knowledgeable technician Allows orthodontist/dentist to redesign aligners mid-case as necessary and print immediately rather than wait 2-3 weeks for delivery

So Why Isn't In-House 3D Printing More Widespread?

Reason	Explanation	Barrier Overcome?
Limited Software Options	<ul style="list-style-type: none"> Align patents prevented competitors from developing comprehensive, high-quality aligner design software 	<ul style="list-style-type: none"> YES <ul style="list-style-type: none"> Most key software patents expired in 2017 uLab Systems preparing large-scale roll-out of new aligner design software
Available Aligner Materials Not Of Comparable Quality	<ul style="list-style-type: none"> Align SmartTrack aligner polymer considered superior to most alternatives 	<ul style="list-style-type: none"> YES <ul style="list-style-type: none"> Bay Materials – Align’s former plastics provider – has developed a comparable aligner material which is available for use with in-house printers
Complicates Workflow	<ul style="list-style-type: none"> Orthodontist/dentist must design aligners independently rather than outsource to third-party technician 	<ul style="list-style-type: none"> YES <ul style="list-style-type: none"> New uLab software allows for aligner design in as little as 10 minutes (vs. 30 minute consultation with outsourced technician)

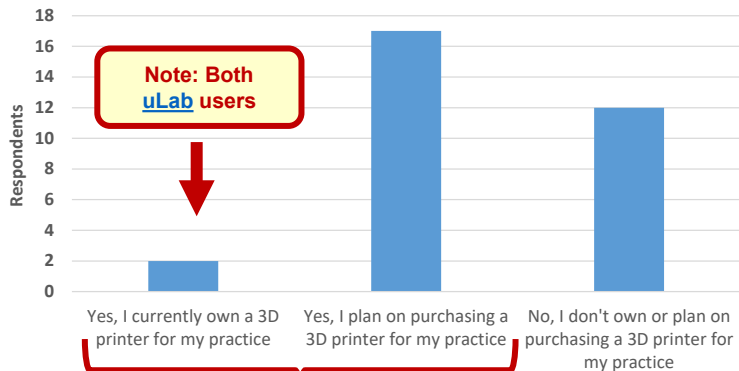
Align bulls generally do not consider in-house 3D printing a serious threat to the Company. However, Spruce Point finds that historical limitations to in-house 3D printing have little to do with doctor preference, brand loyalty, or cost savings limitations, as is believed by most Align bulls. Spruce Point finds, rather, that they are largely the product of technological barriers which are now beginning to collapse with recent industry innovation.



Align Bulls Are Mistaken About Orthodontist Attitudes Towards 3D Printing

Most Align bulls all but take for granted the notion that orthodontists and dentists view in-house 3D printing as an inevitable nuisance. They acknowledge recent innovation and price declines within the in-house 3D printing space, but are convinced that many orthodontists simply do not want to deal with the logistics of in-house printing. Our survey and conversations with high-volume orthodontists suggest otherwise. Spruce Point finds that, while just 6% of surveyed orthodontists currently own a 3D printer, over 50% plan on purchasing a 3D printer in the future – even with prevailing software not quite yet up to par with third-party CAD/CAM aligner design software. In particular, when asked what in particular would most likely convince them to allocate aligner cases to channels other than Align, the most popular answers given were the major selling points of in-house 3D printing: greater case control and more efficient case execution.

Do you own or plan to own a 3D printer specifically to fabricate your own clear aligners?



Over 60% of respondents plan to use an in-house 3D printer to print clear aligners (or do already)

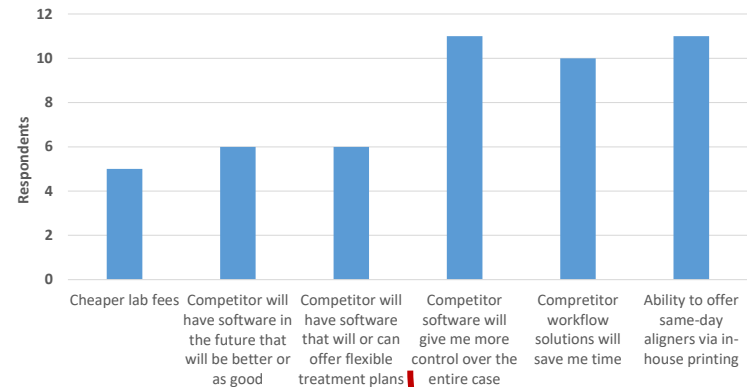
*"I know that when you are a new doctor, you get the worst Invisalign technicians out of Costa Rica that are designing your case. **Sometimes, you are going back and forth with the technician as many as eight times before the case is right.**"*

- Dental Consultant

*"I now have the capability of providing same day treatment with clear aligners which I could not do with Invisalign. I would have to wait at least two weeks. With my own 3D printer, I can have aligners the same day and I can also alter an aligner case on the same day. **This really helps my practice be more efficient throughout the patient's treatment.**"*

- Orthodontist

Which of the following are reasons that your peak clear aligner cases would not be allocated to Invisalign? Select all that apply.



Biggest drivers behind desire to seek Align alternatives match major selling points of in-house 3D printing

*"The difference between braces and Invisalign is if there is a change needed mid case. With Invisalign, I may need to wait 2-4 weeks to get a new aligners to continue the case. With braces, I can make the change immediately. **With 3D printing in your office, you have an aligner the same day which will make case management simpler.**"*

- Orthodontist, Diamond Plus Align Tier

As in-house 3D printing grows increasingly mainstream, Spruce Point believes that the major selling points of in-house 3D printing will drive significant demand for this option.



The Bottleneck To In-House 3D Printing Has Not Been Demand, But Workflow Infrastructure

Bulls are not wrong to think that, until now, in-house 3D printing has been relatively inconvenient in some respects. It would be inappropriate, however, to conclude from this that interest in 3D printing is low. Spruce Point finds just the opposite – that interest towards in-house 3D printing is extremely high, but that limitations to existing software options have tempered demand. With [new players now developing innovative, high-quality 3D printing software](#) following the expiration of Align's software patents, Spruce Point believes that orthodontists are now in a position to explore the possibility of shifting a portion of their aligner cases from Align to in-house 3D printing, if only as an exploratory measure. This could lead to an accelerated shift to 3D printing not long thereafter as orthodontists grow increasingly comfortable with in-house 3D printing workflows.

ALGN: William Blair Growth Stock Conference (Jun 14, 2018)

"As the patents end will your competitive advantage be maintained by technology, scale or how do you see that maintaining your competitive advantage?"

- Analyst

"Yes, remember, we -- you could arguably say we had 10 to 15 key patents burn off at the last -- last part of last year and I call those CAD/CAM patents which means you could design something on a computer screen and then 3D print it and that's what choked most companies from getting into the marketplace because you really couldn't scale."

- Joseph Hogan – CEO, Align Technology

IP protections around Align's CAD/CAM aligner design software were what prevented wider-scale competition in the in-house 3D printing market...

Orthodontist Color Regarding In-House 3D Printing And Supporting Software

"In the future, we are going to see a change where a company is going to develop software that is so easy to use where I will pay a monthly fee and then I will be able to print the aligners in my office. We are not that far away from that. It is coming."

- Orthodontist, Diamond Plus Align Tier

"Better software and alternative workflows are what will take over Invisalign."

- Orthodontist

"In the future, the best software will rule as 3D printing becomes more mainstream."

- Orthodontist, Diamond Plus Align Tier

"uLab has a huge waitlist to use [the software]."

- Dental Consultant

...and interest in 3D printing remains high just as [new players develop novel software platforms](#)

With one of the major bottlenecks preventing more widespread in-house 3D printing demand now gone with the expiration of key Align patents and the [development of new software](#), Spruce Point believes that the [cost savings](#) and workflow efficiency offered by in-house printing will trigger a new wave of demand for 3D printers among orthodontists, posing a significant threat to Align's case volumes.

Expired Patents Open The Door For Innovation Which Will Break The Barrier To In-House 3D Printing

With many of Align's key CAD/CAM software patents having rolled off from 2018-20, Spruce Point observes that new, innovative companies are beginning to disrupt what has been one of the major barriers to widespread 3D printer adoption among orthodontists. With demand for in-house 3D printing options high among orthodontists, and with Align's CEO having effectively admitted that third-party CAD/CAM software limitations were one of the major choke points to more intense competition in the space, we expect the proliferation of new software options to catalyze more intense clear aligner competition in the form of 3D printing infrastructure.

(54) COMPUTER USER INTERFACE FOR ORTHODONTIC USE

(10) Patent No.: **US 6,664,986 B1**
(45) Date of Patent: **Dec. 16, 2003**

US6664986B1

United States

[Download PDF](#) [Find Prior Art](#) [Similar](#)

Inventor: [Avi Kopelman, Baruch Nissenbaum](#)

Current Assignee: [Align Technology Inc](#)

Worldwide applications

1997 - [IL](#) 1998 - [AT](#) [WO](#) [EP](#) [JP](#) [DE](#) [US](#) [AU](#)

Application US09/424,167 events

1997-05-20 • Priority to IL120867

1997-05-20 • Priority to IL12086797A

1998-05-19 • Application filed by Cadent Ltd

1998-05-19 • Priority to PCT/IL1998/000222

2000-05-30 • Assigned to CADENT LTD. ©

2003-12-16 • Application granted

2003-12-16 • Publication of US6664986B1

2008-12-03 • Assigned to ORIX VENTURE FINANCE LLC ©

2014-12-11 • Assigned to ALIGN TECHNOLOGY, INC. ©

2018-05-19 • Anticipated expiration

2020-03-28 • Application status is Expired - Lifetime [Source](#)

(54) METHOD FOR OBTAINING A DENTAL OCCLUSION MAP

(10) Patent No.: **US 6,334,853 B1**
(45) Date of Patent: **Jan. 1, 2002**

US6334853B1

United States

[Download PDF](#) [Find Prior Art](#) [Similar](#)

Inventor: [Avi Kopelman, Baruch Nissenbaum](#)

Current Assignee: [Align Technology Inc](#)

Worldwide applications

1997 - [IL](#) 1998 - [AU](#) [US](#) [DE](#) [WO](#) [JP](#) [AT](#) [EP](#)

Application US09/424,195 events

1997-05-22 • Priority to IL120892

1997-05-22 • Priority to IL12089297A

1998-05-14 • Application filed by Cadent Ltd

1998-05-14 • Priority to PCT/IL1998/000219

2000-06-12 • Assigned to CADENT LTD. ©

2002-01-01 • Application granted

2002-01-01 • Publication of US6334853B1

2008-12-03 • Assigned to ORIX VENTURE FINANCE LLC ©

2014-12-11 • Assigned to ALIGN TECHNOLOGY, INC. ©

2017-11-14 • US case filed in Delaware District Court ©

2017-11-14 • USITC case 3274 filed (Terminated) ©

2017-12-19 • US case filed in International Trade Commission ©

2018-05-14 • Anticipated expiration

2018-11-12 • PTAB case IPR2019-00153 filed (Pending - Instituted) ©

2020-03-28 • Application status is Expired - Lifetime [Source](#)

(54) METHOD AND SYSTEM FOR ACQUIRING THREE-DIMENSIONAL TEETH IMAGE VERFAHREN UND SYSTEM ZUR DREIDIMENSIONALEN BILDERFASSUNG VON ZÄHNEN PROCÉDE ET SYSTÈME D'ACQUISITION D'IMAGE TRIDIMENSIONNELLE DE LA DENTURE

(11) **EP 0 840 574 B1**

EP0840574B1

European Patent Office

[Download PDF](#) [Find Prior Art](#) [Similar](#)

Other languages: [German](#), [French](#)

Inventor: [Avi Kopelman, Eldad Taub](#)

Current Assignee: [Cadent Ltd](#)

Worldwide applications

1996 - [JP](#) [AU](#) [DE](#) [US](#) [WO](#) [AT](#) [DE](#) [EP](#)

Application EP96921061A events

1995-07-21 • Priority to IL11469195

1995-07-21 • Priority to IL11469195A

1996-05-31 • Priority to IL11852396A

1996-05-31 • Priority to IL11852396

1996-07-04 • Application filed by Cadent Ltd

1996-07-04 • Priority to PCT/IL1996/000036

1998-05-13 • Publication of EP0840574A1

2003-02-19 • Application granted

2003-02-19 • Publication of EP0840574B1

2016-07-04 • Anticipated expiration

2020-03-28 • Application status is Expired - Lifetime [Source](#)

(54) DENTAL IMAGE PROCESSING METHOD AND SYSTEM VERFAHREN UND VORRICHTUNG ZUR VERARBEITUNG VON DENTALBILDERN PROCÉDE ET SYSTÈME DE TRAITEMENT D'IMAGE DENTAIRE

(11) **EP 1 124 487 B1**

EP1124487B1

European Patent Office

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Other languages: [German](#), [French](#)

Inventor: [Avi Kopelman, Eldad Taub](#)

Current Assignee: [Cadent Ltd](#)

Worldwide applications

1998 - [IL](#) 1999 - [DE](#) [AT](#) [WO](#) [EP](#) [AU](#) [JP](#) 2001 - [US](#)

Application EP19990952782 events

1998-11-01 • Priority to IL12683898

1998-11-01 • Priority to IL12683898A

1999-11-01 • Application filed by Cadent Ltd

1999-11-01 • Priority to PCT/IL1999/000577

2001-08-22 • Publication of EP1124487A1

2007-05-23 • Application granted

2007-05-23 • Publication of EP1124487B1

2019-11-01 • Anticipated expiration

2020-03-28 • Application status is Expired - Lifetime [Source](#)

"Yes, remember, we -- you could arguably say we had 10 to 15 key patents burn off at the last -- last part of last year and I call those CAD/CAM patents which means you could design something on a computer screen and then 3D print it and that's what choked most companies from getting into the marketplace because you really couldn't scale."

- Joseph Hogan – CEO, Align Technology

New Software Overcomes Many Of The Shortcomings Of In-House 3D Printing

Spruce Point believes that the recent emergence of uLab Systems – a relatively little-known developer of aligner CAD/CAM software – represents a major step towards making in-house 3D printing a practical option for a broad range of doctors. Much as Zendura's newest aligner material was created by Align's original plastics supplier, uLab was created by former Align technology and sales executives with close knowledge of the aligner software market, and a strong understanding of where current 3D printing software is coming up short. These same individuals launched a similar competitive bid against Align in the early 2000s in the form of OrthoClear – a bid so threatening that, when they settled their litigation with Align by having Align buy them out in Sep 2006, Align's share price immediately more than doubled.

Driven by Former Align Execs

Name	Align Role	OrthoClear Role
Charlie Wen	CTO	Founder
Joe Breeland	VP, Sales	VP, Sales
Rick Geracitano	Sales	Sales

5,000+ Doctors Trained In Just ~1 Year

OrthoClear is the technology leader in the clear removable aligner orthodontics market. OrthoClear offers the most advanced method of straightening teeth on the market today. Founded in January 2005, OrthoClear has become the fastest growing company in orthodontic history. OrthoClear has over 1300 employees, has trained over 5000 doctors in the use of its products, and in June received over 3000 new orders for its OrthoClear System. For more information, go to <http://www.orthoclear.com>

[Source](#)

THEN:
OrthoClear

Stock Immediately Responds To Settlement



uLab executives have a history of winning over doctors rapidly, and appear to be repeating their past success with uLab

Driven by Former Align/OrthoClear Execs

Name	Align Role	uLab role
Charlie Wen	CTO	Founder and CTO
Amir Abolfathi	Officer, EVP of R&D	Founder
Joe Breeland	VP, Sales	CCO
Rick Geracitano	Sales	Sales

NOW:
uLab

"What we created 22 years ago [at Align Technologies took] control from the orthodontists and clinicians to do the treatment planning because a lot of things were unknown back then.... We didn't have the computational power that is available to us today. We didn't have intraoral scanning, the 3D printing was not in a state it is in today... The system that was designed in such a way that it was a centralized model that was highly controlled by the manufacturer. And like anything else, as businesses grow and scale, their legacy issue is that they keep the same architecture. About 4 years ago, we looked at the state of the technology and no one [was] breaking the mold and coming up with new ideas of how to do clear aligners differently and that is how uLab was born."

- Amir Abolfathi – uLab Systems, Co-Founder

With Align's software patents now having largely expired, uLab represents the first new user-friendly CAD/CAM software offering in years.

Industry sources confirm that CAD/CAM software limitations have been among the most significant barriers to broader in-house 3D printer adoption – and that developments by uLab are helping to reduce these barriers.

The Technological Revolution in Implants and Aligners: How 3-D Printing and Planning Software Are Impacting Care

Category: [Digital Dentistry](#) Created: [Saturday, 01 February 2020 00:00](#) Written by Drs. Brady Frank, Kevin Ison, Pete Stover, and Trent Anderson [Print](#) [Email](#)

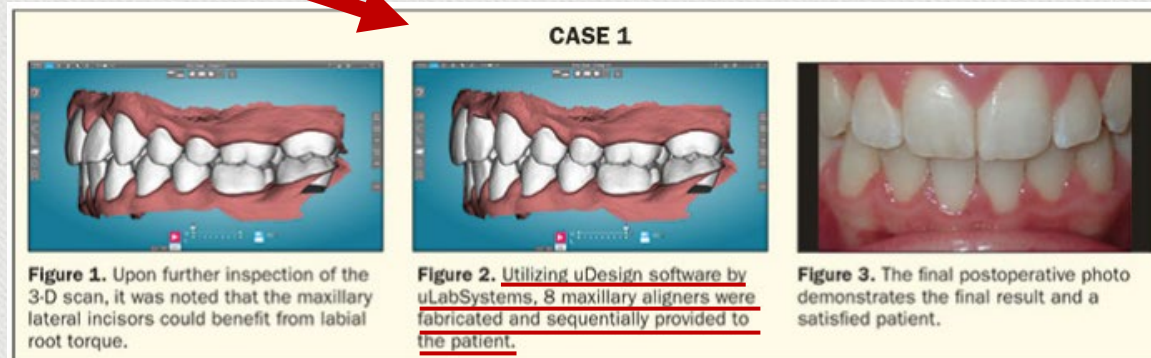
In-House 3-D Printing of Implant Guides and Aligner Models

Only a few years ago, it was not thought feasible for a clinician to efficiently and cost effectively print surgical implant guides and models for in-house aligner therapy. Clinicians who adopted in-house 3-D printing protocols early have positioned themselves to benefit the most from dentistry's next big revolution. These clinicians are now producing guides and sets of aligners at a fraction of the retail cost of such appliances and have outsourced the majority of the workload to staff, creating very scalable growth. And, for clinicians yet to adopt these new technologies, there is still good news. Only recently have the printers and software for aligner therapy become efficient, user-friendly, and accurate enough to warrant the investment. At present, the minor investment to get into 3-D printing as a private practitioner creates multi-fold ROI possibilities. In fact, a recent article² described in great detail how a college student used software to plan his own case and 3-D printed 12 models, procured clear aligner material from eBay, and successfully treated his own case. While this enterprising student had no dental training or experience and, as a result, put himself at great risk, the example still serves to demonstrate the relative simplicity of this technology, and, indirectly, it highlights the dawn of the 3-D printing revolution that can be beneficial for both doctor and patient when implemented professionally and with proper training.

Source: [Dentistry Today](#)

**Industry Blog (Feb 2020)
Highlights Aligner Design
Software As A (Falling) Barrier
To Broader In-House 3D Printer
Adoption**

**Blog Highlights uLab's uDesign
Software As Next Stage In
Aligner Design Software
Development**





uLab Making Quick Inroads Among Doctors And Venture Capital

Just as did OrthoClear ~15 years ago, uLab is making quick inroads among orthodontists. It already has 250 doctors trained on its system and 65,000 annual cases since early 2019 – all accomplished with just three salesmen – and orthodontists with whom we spoke indicate that the waitlist for the software is long ahead of its planned full-scale launch in May 2020. Dental professionals confirm that the platform represents a material improvement over legacy 3D printing software, and that it supports treatments which legacy platforms could not – “combo cases” in particular, which involve the patient wearing traditional braces instead of clear aligners at various points throughout the treatment. Between its quick uptake among doctors and demonstrated ability to attract institutional capital, uLab appears to represent a meaningful step forward in a clear aligner software space which has seen relatively little development through much of the 2010s.

uLab Attracting Institutional Capital

March 26, 2019 | 5:12 pm

uLab Systems Secures \$6M in Series C Financing Led by Light Bridge Ventures

Silicon Valley, CA – uLab Systems, developer of the software platform that enables chairside aligner treatment planning, has completed a \$6M Series C financing round which was led by Light Bridge Ventures. [Source](#)

uLab Systems Secures \$18M in Series D Financing Led by Park West

January 27, 2020 11:00 AM Eastern Standard Time

REDWOOD CITY, Calif. – (BUSINESS WIRE) – uLab Systems, the creator of the state-of-the-art aligner planning software, has completed an \$18M Series D financing round led by Park West Asset Management and supported by minority investors including Ortho Studio Express. [Source](#)

uLab Attracting Strong Doctor Interest On Only A Limited Launch

uLab Systems, the creator of the state-of-the-art uDesign aligner planning software, has released Version 5.5 of their software. Charlie Wen, President and Chief Technology Officer of uLab states, “The uLab uDesign 5.5 release offers a whole new level of control and simplicity for our users. We are committed to continuous innovation to provide our doctors with the best tools possible.”

uLab Systems has completed a limited launch of the software with over 250 U.S. orthodontists and is planning for a significant launch at the American Association of Orthodontists’ annual meeting in May of this year. The current users of the software have been impressed with the simplicity and control that uLab has to offer. With uLab, doctors are able to complete an aligner treatment plan in as little as 10 minutes. uLab users have consistently reported that they are able to increase aligner usage in their offices by offering unique treatment options such as hybrid, combination or finishing aligners to their patients. In a survey of existing uLab users, 100% of orthodontists would recommend uLab to a friend or colleague – a clear vote of confidence. [Source](#)

“The uLab software is advancing very rapidly. They are developing attachments that will allow an orthodontist to do the most comprehensive cases by just using clear aligners.”

- Dental Consultant

“With uLab, I can now do combo cases. Wires and brackets are often much more efficient for certain necessary movements. When I am doing combo cases, I am completing them much faster. I would guess that I am completing cases 6 months faster.”

- Orthodontist

“uLab has a huge waitlist to use [the software].”

- Dental Consultant

With the aligner printing software space finally attracting innovators which are addressing historical shortcomings among in-house 3D printing software, Spruce Point believes that one of the major bottlenecks prohibiting more widespread in-house aligner printing is set to collapse.

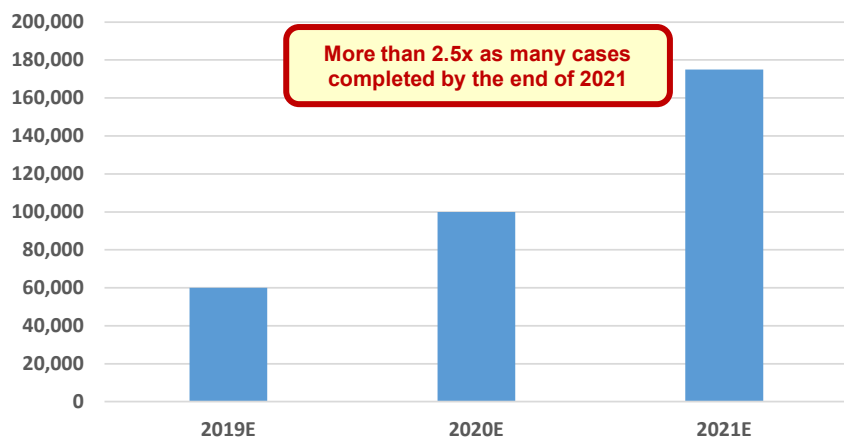
We believe that enlarged interest with in-house 3D printing among doctors will quickly follow from uLab’s impending broad-scale launch.

Rapid Uptake A Sign Of Things To Come?

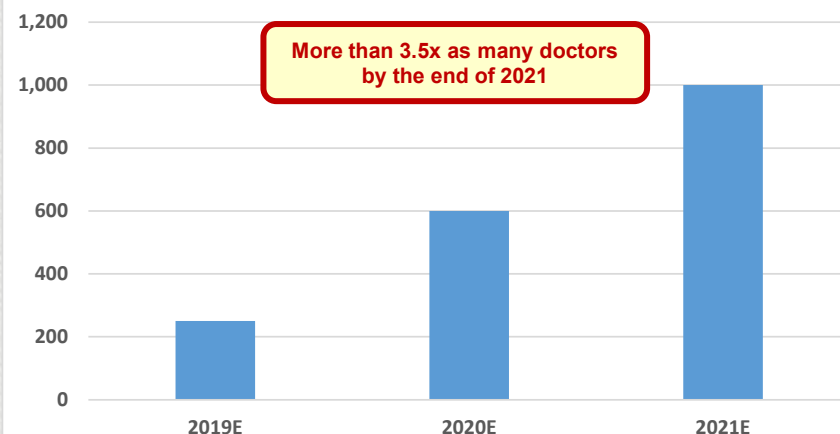
Importantly, we observe that uptake of uLab's software has been swift even during its limited launch period – again, despite the fact that it had just three sales representatives through early 2020. Again, since early Jan 2019, orthodontists have already conducted 65,000 cases using uLab software, and the Company is expected to have 600 dental practitioners on its platform by the end of 2020. Given the pace of uLab's uptake and our conversations with industry experts, we anticipate that uLab could have as many as 1,000 doctors on its platform by the end of 2021, and could reach an annual case count of 175,000.

Date	Jan 23, 2019	Mar 29, 2019	Sep 3, 2019	Oct 25, 2019	Feb 3, 2020	Feb 18, 2020	Mar 9, 2020	2020E
Cases (Cumulative)	6,000	13,000	25,000	-	60,000	-	65,000	-
Dental Practitioners	-	-	-	225	-	250	-	600
Sales Representatives	-	-	-	-	3	-	-	11
Source	Press Release	Press Release	Press Release	YouTube Video	Spruce Point Expert Call	Press Release	Press Release	YouTube Video , Spruce Point Expert Call

Cases Performed Using uLabs Systems, Annual



Doctors Using uLab Systems



uLab also plans to support clear aligner design for third-party labs in addition to in-house 3D printing. We anticipate that such software improvements could also encourage greater interest in third-party labs among current Align customers.

In-House 3D Printing Offers Overwhelming Cost Savings On Case-By-Case Basis

Spruce Point observes that the cost savings made possible by printing aligners in-house are overwhelming, even when compared against third-party 3D printing labs. Printing aligners in-house allows dentists and orthodontists to save over 75% versus Align on a per-case basis. This on top of the fact that in-house printing gives the orthodontist greater control over the case, allows him/her to complete the treatment with substantially fewer patient visits, and can be faster and easier than designing an aligner remotely with an outsourced technician (10 minutes vs. 30 minutes when done with the right software, per our conversations with doctors).

Clear Aligner Case Economics Example: Comprehensive Case with 44 Aligners (Covering Both Arches)

	Third-Party Lab		In-House 3D Print
	\$15/Aligner	\$10/Aligner	\$10/Aligner
(A) Aligner Price	\$15	\$10	\$10
(B) Aligners per Case	44	44	44
(C) Total Aligner Price per Case ((A) x (B))	\$660	\$440	\$440
(D) Impression Scan Price	\$20	\$20	-
(E) Arch Scans per Case	2	2	2
(F) Total Scan Price per Case ((D) x (E))	\$40	\$40	-
(G) Treatment Planning per Case	\$149	\$149	-
(H) Fee per Order	\$25	\$25	-
(I) Total Case Price to Orthodontist / Dentist ((C) + (F) + (G) + (H))	\$874	\$654	\$440
All-In Price per Aligner, Align ((I) / (44 Aligners))	\$19.86	\$14.86	\$10.00
(J) Invisalign System (Comprehensive Case) – List Price per Case	\$1,879	\$1,879	\$1,879
All-In Price per Aligner, Align ((J) / (44 Aligners))	\$42.70	\$42.70	\$42.70
Discount to Invisalign	53%	65%	77%

"My material costs per aligner are about \$5 to \$6 and when I factor in labor, I am printing aligners for approximately \$10. As my staff gets more efficient, the cost will go lower. 3D printers are getting faster and cheaper as well, so a new investment there will eventually lower the cost as well."

- Orthodontist

In-House 3D Printing Offers Substantial Cost Savings

Spruce Point finds that, for large-volume orthodontists, printing in-house could produce over 50% *more* savings over Align compared to sourcing from third-party labs, and would allow most orthodontists even of lesser tiers to save over 60% compared to Align fees themselves. We estimate that the option to switch to in-house printing presents the average Diamond Plus Align customer with a \$400K per year cost savings opportunity. We believe that, as in-house 3D printing grows increasingly mainstream with improvements in printer and software technology, printing in-house could well become a no-brainer option for a large share of the orthodontist population. Align would inevitably be forced to cut prices dramatically or otherwise suffer serious case volume losses among its highest-volume customers.

Align v. Third-Party Lab v. In-House Printing: Cost-per-Case

	Comprehensive Case (@ 44 Aligners ¹)	Non-Comprehensive Case (@ 40 Aligners ¹)
Invisalign System – List Price	\$1,879	\$1,699
Third-Party Lab - \$10 per Aligner	\$654	\$614
Discount to Invisalign	\$1,225	\$1,058
In-House Print - \$10 per Aligner	\$440	\$400
Discount to Invisalign	\$1,439	\$1,299

Additional In-House Printing Expenses

	Total Cost	Included In Total Annual Cost Below?
3D Printer	Varies (as low as <\$4k)	No: Negligible Over Time
Thermoformer	Varies (as low as ~\$3k)	No: Negligible Over Time
Software License (Annual Fee, uLab)	\$14,400	Yes

Align vs. Third-Party Lab vs. In-House Printing: Total Annual Cost Comparison

Invisalign Tier	Avg. Annual Cases	Case Mix (Est.) ²		(A) Tier Discount	Total Invisalign Fees		Third-Party Lab: \$10/Aligner		In-House Printing: \$10/Aligner	
		Comprehens. Cases	Non-Comp. Cases		(B) Pre-Discount (Cases x Price)	(C) Discounted ((B) x (1-(A)))	(D) Total Lab Fees (Cases x Price)	Savings v. Align ((C) - (D))	(E) Total Fees (Ca x Pr + License)	Savings v. Align ((C) - (E))
Gold Plus	99	74	25	18%	\$181,521	\$148,847	\$63,746	\$85,101	\$56,960	\$91,887
Platinum	164	123	41	28%	\$300,766	\$216,559	\$105,616	\$110,943	\$84,920	\$131,639
Plat. Plus	239	179	60	34%	\$438,281	\$289,265	\$153,906	\$135,359	\$117,160	\$172,105
Diamond	339	254	85	38%	\$621,681	\$385,442	\$218,306	\$167,136	\$160,160	\$225,282
Diam. Plus	600	450	150	40%	\$1,100,400	\$660,240	\$386,400	\$273,840	\$272,400	\$387,840

1. Spruce Point diligence

2. Assumes 75 / 25 case mix between comprehensive and non-comprehensive cases, based on Spruce Point diligence

Case Study: Cost Savings From Align Alternatives A Material Benefit To Orthodontist Profitability

By once again analyzing the cost structure of orthodontic offices, we find that in-house 3D printing offers even greater savings than do third-party labs: current Align customers could increase their cash flows by over 12% by printing aligners in-house. Again, we believe that the magnitude of this potential cost savings will be too great for many orthodontic offices to ignore – something which [the current pandemic-driven pause in business will allow \(and encourage\) them to evaluate.](#)

Cost Savings: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
Align Discount Tier	Platinum	Platinum Plus	Diamond Plus
(D) Align Discount	28%	34%	40%
(E) Case Expense, Wires & Brackets ²	\$600	\$600	\$600
(F) COGS, Wires & Brackets ((A) x (E))	\$168,000	\$216,000	\$240,000
(G) Avg. Case Expense, Aligners (ALGN) ³	\$1,834	\$1,834	\$1,834
(H) Pre-Discount COGS, Aligners ((B) x (G))	\$220,080	\$440,160	\$733,600
(I) ALGN Discount ((H) x (1 - (D)))	(61,622)	(149,654)	(293,440)
(J) COGS, Aligners (ALGN) ((H) + (I))	\$158,458	\$290,506	\$440,160
(K) Avg. Case Expense, Aligners (3 rd Party Lab) ⁴	\$859	\$644	\$644
(L) COGS, Aligners (3 rd Party Lab) ((B) x (K))	\$103,080	\$154,560	\$257,600
Cost Savings vs. ALGN (3rd Party Lab) ((J) - (L))	\$55,378	\$135,946	\$182,560
(M) Case Expense, Aligners (In-House Print) ⁵	\$550	\$490	\$466
(N) COGS, Aligners (In-House Print) ((B) x (M))	\$66,000	\$117,600	\$186,600
Cost Savings vs. ALGN (In-House Print) ((J) - (N))	\$92,458	\$172,906	\$253,760

Cash Flow Benefit: Align vs. Third Party Lab vs. In-House 3D Printing

Orthodontist Practice Volume	Medium	High	Very High
(A) Case Starts: Wires & Brackets ¹	280	360	400
(B) Case Starts: Clear Aligners ¹	120	240	400
(C) Total Case Starts ((A) + (B))	400	600	800
(D) Case Fee, Wires & Brackets ²	\$5,500	\$5,500	\$5,500
(E) Case Fee, Clear Aligners ²	\$5,700	\$5,700	\$5,700
Revenue, Wires & Brackets ((A) x (D))	\$1,540,000	\$1,980,000	\$2,200,000
Revenue, Clear Aligners ((B) x (E))	684,000	1,368,000	2,280,000
Revenue, Total	\$2,224,000	\$3,348,000	\$4,480,000
COGS: Wires and Brackets	(168,000)	(216,000)	(240,000)
COGS: Clear Aligners (ALGN)	(158,458)	(290,506)	(440,160)
Gross Profit (ALGN)	\$1,897,542	\$2,841,494	\$3,799,840
Staff Expense (25% Sales) ²	(556,000)	(837,000)	(1,120,000)
Rent (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Other Overhead (7.5-10% Sales) ²	(211,280)	(284,580)	(336,000)
Net Cash Flow Before Taxes (ALGN)	\$918,982	\$1,435,334	\$2,007,840
Cost Savings (3rd Party vs. ALGN)	\$55,378	\$135,946	\$182,560
Savings As a % of Pre-Tax Cash Flow	6.0%	9.5%	9.1%
Cost Savings (In-House vs. ALGN)	\$92,458	\$172,906	\$253,760
Savings As a % of Pre-Tax Cash Flow	10.1%	12.0%	12.6%

1. Case mix representative of typical mix at relevant practice size based on Spruce Point diligence
2. Average based on Spruce Point diligence
3. Assumes 75 / 25 comprehensive / non-comprehensive mix
4. Includes \$10 / aligner fee (\$15 for 120 aligner practice) and [all other fees](#). Assumes 75 / 25 comprehensive / non-comprehensive mix.
5. Includes \$10 / aligner fee and \$14,400 annual software license fee

In-House 3D Printing Creating Revenue Opportunities?

Spruce Point finds that a number of clear aligner printing early-adopters among orthodontists and dentists have managed to turn their in-house 3D printers into sources of revenue by offering to print clear aligners for other local practices. Opportunities to generate revenue through in-house 3D printing would only make the economic benefits of switching from Invisalign to in-house printers even more overwhelming. Furthermore, that individual dentists could effectively serve as third-party printing labs for other local practices reinforces the threat posed by third-party 3D printing to Align: the barriers to entry in third-party printing appear so low that individual practices could explore the opportunity, if only on a local scale.

Use the DDSO Model to Secure Your Retirement

Case Studies

Seth Wasson, DMD, is a dentist in Brentwood, Missouri, who has been utilizing DDSO concepts for about a year. Last month, he added a second location funded by another dentist using private lending resources that didn't require any personal guarantee such as traditional bank financing. He also has plans for additional growth.

"I am opening a 3-D printing center for aligner cases to provide retail aligner lab revenue as another stream of income. I am opening an aligner institute to educate other dentists, recruit dentists to my group, and add new business to the 3-D printing center," Wasson said.

[Source](#)

DDSO strategies: Converting active/earned dental income to passive income

Ever since the major push of DSOs in the 1990s, there has been a steady trend related to the "centralization of the fragmented market" of dentistry.

Author — Brady Frank, DDS

Nov 1st, 2019

[Source](#)

Mini DDSO case studies from three dentists

Kevin Ison, DDS

One of the most misunderstood DDSO concepts is that it is not necessary to have multiple locations to benefit from DDSO concepts. In my DDSO I have incorporated a 3-D printing center to save on aligner costs (as low as \$52 per aligner case), and I've added retail revenue from serving other dental practices. My DDSO has created

Opening User-Friendly Software To Multiple Workflows Only Creates More Alternatives To Align

Spruce Point finds that, in Feb 2020, uLab received FDA approval to print its *own* clear aligners. This helps to confirm other sources which suggested to us that uLab is on the verge of opening its own outsourced 3D printing lab. We believe that this development represents yet another step towards the general easing of clear aligner sourcing: orthodontists and dentists will be able to use uLab's well-regarded software to design aligners to be printed in-house or by a third-party lab. As more and more third-party labs, printers, and aligner design software options are introduced to the market, doctors will have a wide variety of ways to organize their respective workflows in whichever manner is easiest and most user-friendly for them. This will only encourage greater doctor migration away from Align.

uLab: FDA 510(k) Premarket Notification Approval For Clear Aligner System

Device Classification Name [Aligner, Sequential](#)
 510(K) Number K192596
 Device Name ULab Systems Dental Aligner Kit
 Applicant ULab Systems, Inc.
 6 Lagoon Drive, Suite 180
 Redwood City, CA 94065
 Applicant Contact Charlie Wen
 Correspondent Sylvia Erickson Consulting
 157 Ruby Avenue
 San Carlos, CA 94070
 Correspondent Contact Sylvia Erickson
 Regulation Number [872.5470](#)
 Classification Product Code [NXC](#)
 Date Received 09/20/2019
 Decision Date 02/11/2020
 Decision Substantially Equivalent (SESE)
 Regulation Medical Specialty Dental
 510k Review Panel Dental
 Summary [Summary](#)
 Type Traditional
 Reviewed By Third Party No
 Combination Product No

[Source](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.
Indications for Use		
510(k) Number (if known) K192596		
Device Name uLab Systems Dental Aligner		
Indications for Use (Describe) The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of <u>malocclusions by way of continuous gentle forces.</u>		

[Source](#)

"In the next few months, uLab is also going to offer their own lab to print aligners. So you can use uLab software to design a case and print in your office or send it out to them."

- Orthodontist

As low-cost workflow options grow increasingly diverse and easier-to-use, we expect more and more Align doctors to explore alternatives to Invisalign.



Align's Purported Moat Is Overblown And Eroding

Bulls Have An Unrealistically Rosy View Of Orthodontists' Relationship With Align

It's common for Align bulls to reference the Company's dentist/orthodontist base as an important protection against the expanding competitive landscape. This, combined with a twenty-year head start on clear aligner IP and strong retail brand recognition, supposedly give Align a powerful moat against both direct-to-consumer and doctor-directed players. As discussed, Spruce Point finds that Align's IP advantage is quickly eroding with the introduction of new third-party plastics and software. Importantly, we also find that the strength of its practitioner network is, in our opinion, vastly overstated: across nearly every call that we conducted with high-volume orthodontists, we found practitioner attitudes to be chilly at best, and more commonly openly disdainful.

Competitive Advantage	Investor Perception	Spruce Point Findings
Brand Recognition	<ul style="list-style-type: none"> Customers shop for Invisalign in particular – not just clear aligners more generally – and seek out dental practitioners who offer Align Products 	<ul style="list-style-type: none"> Patients generally do not shop for Invisalign in particular, and, even then, will trust their practitioners if they suggest a different provider
Practitioner Network	<ul style="list-style-type: none"> Offering Invisalign allows a dentist/orthodontist to remain on Align's practitioner directory, which can generate leads 	<ul style="list-style-type: none"> Most individuals will seek advice from their own dentist or orthodontist about clear aligners rather than seek out an entirely new practitioner for the sole purpose of inquiring about Invisalign
Practitioner Loyalty	<ul style="list-style-type: none"> Dentists and orthodontists appreciate Align as a lead-generating brand, and are incentivized to sell as much Invisalign as possible to achieve Align's volume-based discounts 	<ul style="list-style-type: none"> Dentists and orthodontists generally see Align as an unfriendly business partner and are actively looking for alternatives

Orthodontists And Dentists Pinched In The Pocket Book By Align

Dental practitioners with whom we spoke told us that Align is an outlier in the orthodontics industry today: while costs for dental equipment are coming down almost across the board, Align continues to raise prices on its orthodontists and dentists. This has angered many of Align's clients – high-volume offices included – and has motivated many of them to more actively seek out alternatives. Spruce Point believes that this trend may accelerate as the space continues to be inundated by new, lower-cost competitors, which will likely put downward pressure on the price to the end customer and squeeze orthodontist margins. Several orthodontists report that this is already happening.

Orthodontists Upset By Align Price Hikes...

"The cost of orthodontics is coming down across the board. The demand for orthodontic treatment is growing but the suppliers is growing exponentially, so costs again are going to come down. So we are going to see an absolute decrease in the cost of treatment. This is the problem with Invisalign, they keep raising their fees every year. This is opposite of the rest of the market. I am getting squeezed by Invisalign, I am charging less for it and they keep raising their prices..."

- Orthodontist, Diamond Plus Align Tier

"Align has been so arrogant over the last three to five years. They raise prices every summer and have done it every summer. If they don't adjust their prices, they are going to see major market share erosion."

- Senior Employee, Major Dental Equipment Supplier

...And Do Not Feel That Align Generates Leads For Them

"I don't think the customer really cares which clear aligner treatment they are getting."

- Dentist, DSO

"From a patient perspective, they are relatively impartial to the brand of clear aligner. If the doctor recommends Clarity or ClearCorrect, the patient is not going to care."

- Dentist, DSO

...so why remain a user of Align?

Despite the recent influx of competition in the space, Align appears to continue to behave as a monopolistic player in the doctor-directed clear aligner market. Spruce Point believes that industry pushback – given more leverage by the recent proliferation of new competitive alternatives – will inevitably force Align to stop forcing price increases on its customers, lest it lose significant case volume.

Less Of A Partner, More Of A Sales Organization

Many dentists and orthodontists report a high level of dissatisfaction with Align's business practices. Notably, Align recently announced that, for US dental practitioners, third-party intra-oral scanners would no longer be compatible with Align's software, forcing them to purchase its own proprietary iTero scanners in order to continue to offer Invisalign.

"I bought 3 Trios wireless scanners.... **I am very angry with Align that they will fight a legal battle over the backs of their customers.** I have invested more than \$150K in Trios scanners and then **from one day to the next they may say to me, 'I am sorry, you can not use your scanner to submit cases that way.'**"

- Orthodontist (Ex-US)

"**I hate Invisalign. I think they are the worst company in the world to deal with.** I philosophically hate what Invisalign has turned my practice into.... I am sick and tired of Invisalign taking my information and using it against me. You don't see 3M or Ormco doing that... **Invisalign is not a company that I am partnered with.** They are not going to help me. **It is simply a product that I am going to buy and eventually I will move to a competitor. I have no loyalty to Invisalign.... It is just a matter of time that I move as much of my case volume as possible away from Invisalign.**"

- Orthodontist, Diamond Plus Align Tier

"**There is a 50% chance that we move away from Invisalign when our contract comes up in 2020** and for me to say that is a big deal. It's a really big deal. **I personally have not been happy with the service for the last year and half.**"

- Dentist, Top 10 DSO

"**Clear aligners cases will go up in my practice, but Invisalign will not.... Invisalign is the evil empire.**"

- Orthodontist, Diamond Plus Align Tier

"**It would be the best thing to come out of this [pandemic]. Invisalign getting f*cked.**"

- Orthodontist, Platinum Tier



Sacrificing Customer Relationships In Pursuit Of Growth?

Most Align bulls do not see SmileDirectClub and other DTC aligner providers as a direct threat to Align, as Invisalign is generally used to treat more complex cases for which DTC aligners would not be appropriate. Dentists and orthodontists are nonetheless unhappy about the fact that potential patients can now seek out teeth-straightening devices without having to go through them. The fact that, until recently, Align was a major investor in – and supplier of – SmileDirectClub angered many of the dentists and orthodontists with whom we spoke. Similarly, many orthodontists are upset that Align has made its teeth-alignment treatments available to the dentist channel: what was historically a source of referrals for teeth alignments is now a source of competition. Again, bulls see this move as primarily “market-expanding” – e.g. as providing teeth alignment options to a population which would have never consulted an orthodontist about braces in the first place – but orthodontists nonetheless feel slighted by Align for its decision to open up its services more broadly.

Jul 28, 2016

ALIGN TECHNOLOGY TO SUPPLY NON-INVISALIGN CLEAR ALIGNERS TO SMILEDIRECTCLUB IN NORTH AMERICA

SAN JOSE, CA – (Marketwired) -- 07/28/16 -- Align Technology, Inc.(NASDAQ: ALGN) today announced a supply agreement with SmileDirectClub to manufacture non-Invisalign clear aligners for SmileDirectClub's doctor-directed, at-home program for affordable, cosmetic teeth straightening. SmileDirectClub aligners will include up to 20 stages without attachments or interproximal reduction (IPR), and will be manufactured by Align per SmileDirectClub's specifications for minor tooth movement. The Invisalign brand and system of clear aligners will continue to be available exclusively for in office treatment with Invisalign-trained orthodontists and general dentists.

 [Align Technology to Supply Non-Invisalign Clear Aligners to SmileDirectClub in North America](#)

Starting October 2016, Align will become SmileDirectClub's exclusive third-party supplier for its minor tooth movement aligner program. Specifically, Align will provide a case setup through SmileDirectClub's SMILECHECK viewer portal, and, upon review and approval by a participating licensed orthodontist or general dentist in SmileDirectClub's network, Align will manufacture clear aligners and ship them directly to SmileDirectClub.

"This doctor-directed, at-home model follows the trend towards other convenient and more affordable at-home solutions for procedures including contact lenses, hearing aids, and diabetes care," said Joe Hogan, Align Technology president and CEO. "At-home teeth straightening is only possible with clear aligners, and as the leader in clear aligners, we believe we must participate and help shape this new model."

"Invisalign has diluted the orthodontic industry. They took away our exclusivity. The damage is done now.... We just don't trust Invisalign.... It is just a matter of time that I move as much of my case volume as possible away from Invisalign."

- Orthodontist, Diamond Plus Align Tier

"I expect my Invisalign volumes to be down going forward. Direct to Consumer offerings are taking business away from us."

- Orthodontist, Diamond Plus Align Tier

"If I had to guess 30% to 40% of SDC cases are cases that would have gone to Invisalign if the DTC option was not available."

- Dentist, DSO

Changing Risk Factors Reveal Acknowledgment of Competitive Threats?

Recent changes to Align's risk factor on competition suggest that management views the recent influx of new competitors as a material threat to the business. Spruce Point believes that its decision to expand this risk factor may reveal that Align already sees pricing pressure and customer losses as orthodontists begin to push back against Align. We strongly believe that pushback will only grow more intense as orthodontists become increasingly aware of and comfortable with the current alternatives to Align.

ALGN: 2018 10-K

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors and other companies that may introduce new technologies in the future.

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including well-established regional competitors in certain foreign markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Due in part to the expiration of certain key patents owned by us beginning in 2017, we are facing increased competition in the clear aligner market as a result of the entry of new, large companies into certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents started to expire in 2018 and will likely result in increased competition in some of the markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we also face competition from companies that now offer clear aligners directly to the consumer and do not require the consumer to see a doctor before or during orthodontic treatment. Unlike these direct to consumer competitors, we are committed to a doctor in the core of everything we do, and Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patient's dentition before treatment can begin. In addition, we may also face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, and reduce dental professionals' efforts and commitment to expand their use of our products, any of which could have a material adverse effect on our net revenues, volume growth, net income and stock price. We cannot assure that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

ALGN: 2019 10-K

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors and other companies that may introduce new technologies in the future.

The dental industry is in a period of immense and rapid transformation involving products, technologies, distribution channels and business models, much of which is based on digital transformation involving information technology, data, artificial intelligence, scanning, 3D printing, software and algorithms. While our clear aligner and iTero scanners facilitate this transition, there remains significant uncertainty concerning the technologies that will achieve market acceptance and, if adopted, whether and when they may become obsolete as new offerings become available.

Currently, our clear aligner products compete directly against traditional metal brackets and wires and increasingly against clear aligner products manufactured and distributed by new market entrants as well as traditional manufacturers of wires and brackets, both within and outside the U.S., and from traditional medical device companies, laboratories, startups and, in some cases, from doctors themselves. Although the number and type of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including new and well-established regional competitors in certain foreign markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Due in part to the expiration of certain of our key patents beginning in 2017, we have faced increased competition in the clear aligner market. These competitors include existing larger companies in certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us, direct-to-consumer ("DTC") companies that provide clear aligners using a remote teledentistry model that requires little or no in-office care from trained and licensed physicians, and doctors themselves who can manufacture custom aligners in their offices using modern 3D printing technology. In addition, corresponding foreign patents began expiring in 2018 which has resulted in increased competition in markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market.

The manipulation and movement of teeth and bone is a delicate process with potentially painful and debilitating results if not appropriately performed and monitored. Accordingly, we remain committed to delivering our solutions primarily through trained and skilled doctors. Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patient's dentition before beginning treatment. However, with the advent of DTC providers accompanied by significant advertising

campaigns, there has been some shifting away from traditional practices that may impact our primary selling channels. We also believe doctors are sampling alternative products and/or taking advantage of wires and brackets bundles that essentially give clear aligners away for free or at reduced prices. In addition, we may also face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors or one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any new technologies, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins and profitability, loss of market share, and result in the reduction of dental professionals' efforts and commitment to use our products, any of which could materially adversely affect our net revenues, volume growth, net income and stock price. We cannot assure that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

Management Not Transparent About Exposure To Competitive Threats

Spruce Point believes that Company disclosures are contributing to a broad misunderstanding of the share of Align cases for which other players can effectively compete. Management disclosures implying that its mix of comprehensive to non-comprehensive cases is ~75 / 25 suggest that a large share of its case load is complex in nature, including advanced cases such as mandibular advancement and treatments for anterior intrusion which competitors cannot yet address. However, our conversations with industry experts reveal that, at most, just 50% of Align's comprehensive cases are aligner / wire "combo cases" that cannot be addressed by competitors, implying that just ~35% of Align cases can be conducted only by Align. The remaining ~65% "more typical" cases are exposed to competition among players capable of providing similar or precisely the same treatments. uLab's ability to support such combo cases, which are planned to begin with wire braces before switching to clear aligners, will only reduce the share of cases which be addressed only by Align

(\$, Millions, except percentages and multiples)	FY19	FY19 Mix
(A) Comprehensive Cases (Spruce Point Analysis)	1,163	76.4%
(B) Non-Comprehensive Cases, Ex-SDC (Spruce Point Analysis)	361	23.6%
(C) Total Cases, Ex-SDC ((A) + (B))	1,524	100%
(D) Comprehensive Cases Accessible To Competitors, % (Est.)	50%	N/A
(E) Comprehensive Cases Accessible To Competitors (Est.) ((A) x (D))	582	38.2%
(F) Non-Comprehensive Cases, Ex-SDC (B)	361	23.6%
(G) Total Cases Accessible To Competitors ((E) + (F))	942	61.8%
Total Cases Protected From Competition ((C) - (G))	582	38.2%

Align's implied comprehensive case mix overstates the share of its cases which cannot be addressed by competitors

Bulls frequently argue that Align's multi-year IP head start protects it from competition from newer players. Spruce Point finds that the vast majority of Align's cases can be addressed by competing products and, as such, are exposed to competition.

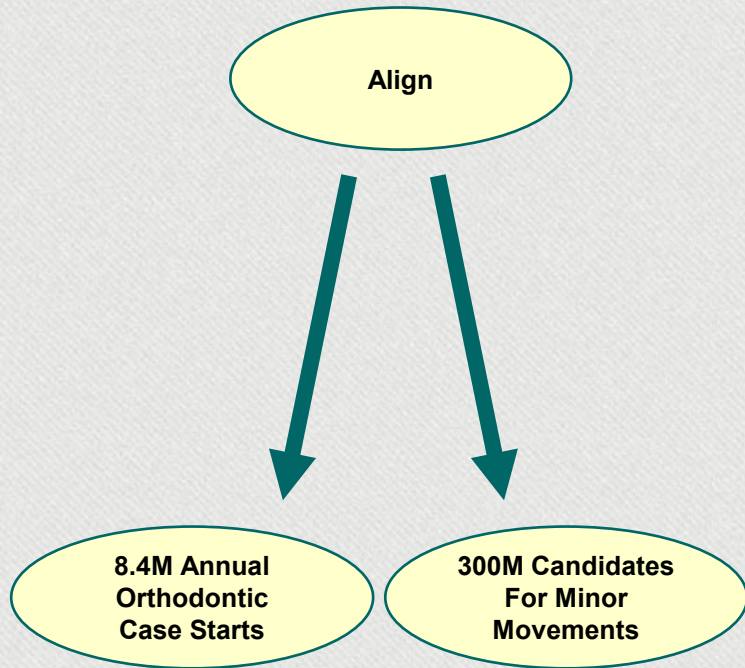


Recalibrating The Addressable Market

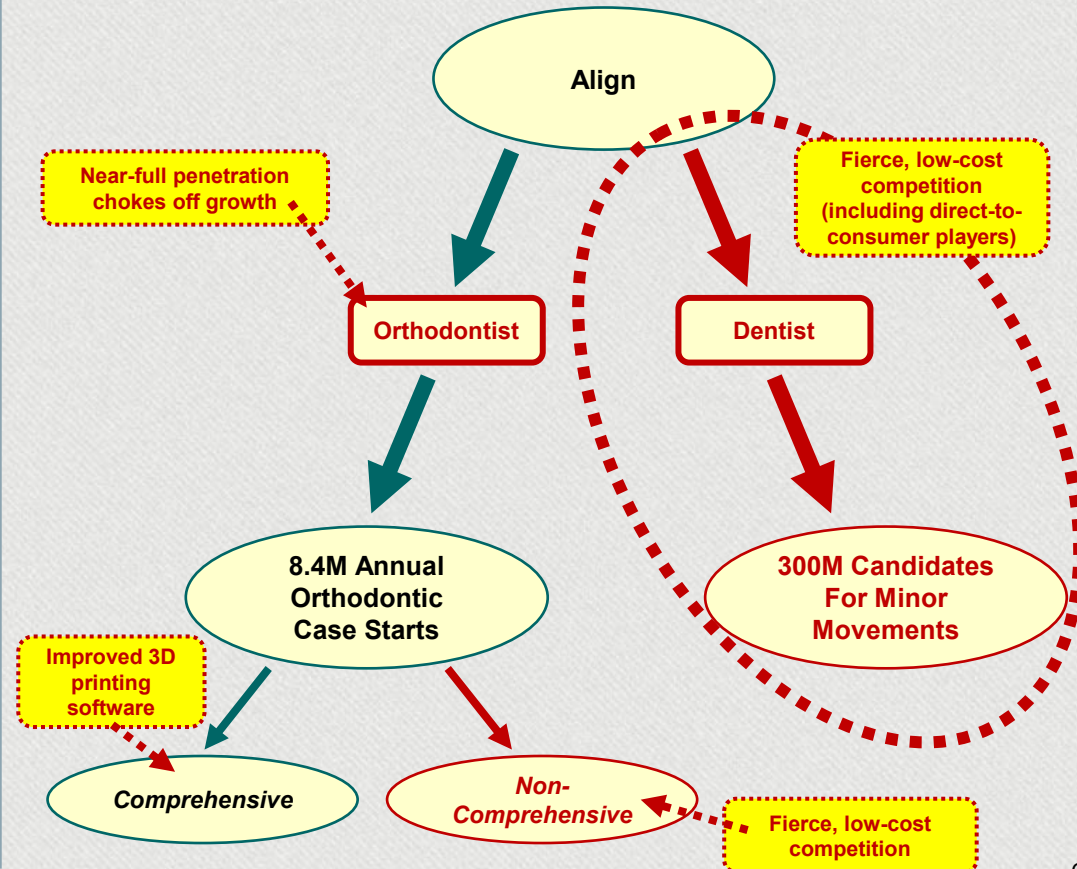
The Growth Runway Is Not As Smooth As The Bulls Think

Align bulls have grown accustomed to being warned about the threat of new competitors since the major dental equipment suppliers began to enter the aligner space in the mid-2010s. Those who have remained in the stock throughout have generally done so on their faith in the magnitude of the clear aligner TAM: management cites that, between aligners and wire braces, 12M teeth alignment cases are initiated each year worldwide – 8.4M of which Invisalign can address – of which Align captures just 1.5M as of FY19. Meanwhile, management claims that another 300M globally are candidates for more minor alignment treatments from dentists. Spruce Point, however, believes that bulls have far too naïve a view of Align's market opportunity, and that they overlook material barriers which will make it difficult for the Company to expand into both sub-markets.

Global Aligner Market: Bull Perspective



Global Aligner Market: Spruce Point Perspective



Uncomplicated Cases A Prime Target For Low-Cost Competition

Management claims that, as clear aligners grow increasingly mainstream, individuals who wouldn't have otherwise been candidates for dental alignment procedures – put off by the aesthetics of traditional wire braces – may begin to migrate to clear aligners. However, this market is also ripe for low-cost competitors – particularly DTC players such as SmileDirectClub, which allow teeth alignment candidates to obtain treatment without having to make frequent visits to the dentist/orthodontist, and, indeed, without having to consult a dental professional at all. It is also a prime target for other, lower-cost clear aligner providers among the large dental equipment suppliers, as well as third-party printing labs which offer aligners at a fraction of the cost of Invisalign.

ALGN: Robert W. Baird Global Healthcare Conference (Sep 4, 2019)

"We're really going to try to continue to grow our market. 75% of our market is comprehensive.... That really mostly addresses that 12 million TAM that we talked about, but **25% of our portfolio is non-comprehensive. That's growing very fast, in part because it's going after these 300 million consumers.**"

- John Morici – CFO, Align Technology

"Yes. And over the last year or two, one thing we've worried about/thought about with your business is, SmileDirect does create demand.... Again, **the 25-year-old maybe doesn't even think to go into the dentist's office. They just want to do it online**.... But one thing we've worried about is that 40-year-old parent goes into the office and the doctor says, "Oh yes, I can do that, \$6,000, write me a check and we're done," versus \$1,895 or whatever SmileDirect is. So **are you seeing your doctors understand that they need to reprice, reset their pricing policies or how they charge patients?** Because it seems like to me orthodontics, GP's doing orthodontics, has been one of the wild, wild west out there where they can charge anything they damn well want because it's a cash paid business. Now **they finally have a regulator there. They have a governor there that's going to say 'No, no, no, market's going to tell you that you're really only valued at \$2,000 or something.'** Are the dentists getting that message? **Are they starting to maybe not price match but at least become more price competitive?**"

- Jeffrey Johnson – Analyst, Robert W. Baird

"**Yes. Many doctors are realizing that those patients or potential patients are coming in and price shopping.** They have an idea that maybe it should cost them \$2,000, you're right for if it's an easier movement, don't need a lot of aligners to be able to move their teeth in the right way, **maybe they shouldn't be charging \$5,000 or \$6,000. And I think those doctors who kind of get that, get that the market is shifting in front of them, will charge something that if you're sub \$3,000, ideally \$2,500, then the comparison between some of the others is less....**"

- John Morici – CFO, Align Technology

A Crowded Non-Comprehensive Landscape

Doctor-Directed	Direct-to-Consumer (DTC)
3M	SmileDirectClub
Dentsply Sirona	Orthly
Straumann	Candid Co.
Henry Schein	Smilelove
Envista	SnapCorrect
Third-Party Labs	Third-Party Labs
Etc.	Etc.

Historical Pricing

Treatment	Consumer Price (Avg.)
Invisalign / Comprehensive	\$5,500
DTC / Non-Comprehensive	\$2,000

As end-user prices compress, can Align really continue to charge doctors the same price?

To the extent that Align is able to penetrate the non-comprehensive market and/or expand its addressable patient base, Spruce Point believes that it will experience dramatic price compression.

Orthodontic Channel Growth In Americas Choked Off By Saturation Among US Orthodontists

Align bulls claim that, despite the growing congestion in the dental and DTC channels, Align remains the leader in the orthodontic channel (particularly among comprehensive cases) due to its 20-year head-start on clear aligner technology. We have disputed Align's purported technological advantages at other points throughout this report. However, even then, the one channel in which it *may* be able to resist aggressive competition and pricing pressure offers a far more limited window for growth. Based on management's claims regarding the expansion of its doctor base, orthodontic utilization rates, and orthodontic case growth, Spruce Point estimates that Align currently serves ~8,000 North American orthodontists, leaving little room for further growth among the total market of ~10,500 orthodontists in North America. Meanwhile, the proliferation of alternative aligner providers could result in losses among its orthodontist base while pressuring orthodontist utilization.

North America Growth Opportunity: Orthodontist Penetration vs. Dentist Penetration (Spruce Point Estimates)

		2012	2013	2014	2015	2016	2017	2018	2019
Orthodontists, North America (Estimate)	Cases (000s)	137.1	159.5	177.1	214.6	258.4	339.0	431.3	519.4
	Utilization	24.2	26.4	27.7	31.8	36.6	46.6	56.7	65.0
	Doctors	5,665	6,040	6,392	6,749	7,060	7,275	7,607	7,991
	Penetration	53.9%	57.5%	60.9%	64.2%	67.2%	69.3%	72.4%	76.1%
Dentists, North America, and All South America ¹ (Estimate)	Cases (000s)	139.7	154.3	161.5	183.8	205.4	247.2	296.8	336.1
	Utilization	7.2	7.2	6.9	7.4	7.6	8.0	8.6	8.6
	Doctors	19,285	21,290	23,498	24,961	27,005	30,955	34,393	39,139
	Penetration	9.6%	10.6%	11.7%	12.5%	13.5%	15.5%	17.2%	19.6%

Reaching a
saturation
point?

Estimates derived from management disclosures. Figures not disclosed directly by management are Spruce Point estimates.

With some orthodontists perhaps not interested in offering clear aligner treatment (at least in high volume), how much runway really remains in the North American orthodontic channel? Spruce Point believes that Align's saturation of this channel could slow the pace of case volume growth, while more aggressive competition threatens to increase orthodontist churn and pressure utilization.

Changing Disclosures Obfuscate Growth Headwinds

Spruce Point observes that changes in management disclosures have obscured a number of the aforementioned barriers to Align's continued growth into its purported addressable market. After FY13, management stopped disclosing its North American doctor breakout between orthodontists and dentists, making it more difficult for investors to observe Align's increasing saturation of this channel through the ensuing years. Further, it stopped disclosing its case breakout by product level, obscuring its gradual shift towards lower-complexity cases as dentists represent an increasingly large share of the Company's case mix. We also note that, in FY18, management redefined its "North America" segment to "Americas," and recategorized its South American markets into this segment, improving growth in this key category by an estimated 2%.

Changing Disclosures Obfuscate Growth Headwinds

	2012	2013	2014	2015	2016	2017	2018	2019
Orthodontists, North America	5,665	6,040	?	?	?	?	?	?
Dentists, North America	19,285	21,290	?	?	?	?	?	?
Total Doctors, North America	24,950	27,330	29,890	31,710	34,065	36,415	?	?

Change in disclosure obfuscates increasing saturation of orthodontist channel

Invisalign Full Cases (000s)	235.0	262.4	?	?	?	?	?	?
Invisalign Express/Lite Cases (000s)	58.7	79.0	?	?	?	?	?	?
Invisalign Teen Cases (000s)	48.3	59.6	?	?	?	?	?	?
Invisalign Assist Cases (000s)	21.5	21.4	?	?	?	?	?	?
Invisalign Cases, Total (000s)	363.5	422.3	478.0	583.2	708.5	931.0	1,228.1	1,525.4

Change in disclosure obfuscates growing importance of low-complexity (and lower-ticket) cases

TAM-Driven Argument For Future Case Growth Undermined By Emerging Threats

Prior to the COVID-19 pandemic, the sell side anticipated top-line growth of approximately 20% in FY20 and beyond for Align, on long-term case growth of 20-30% per year. However, with the North American orthodontist channel increasingly saturated for Align, and with overwhelming competition coming to the dental, orthodontic, and all international channels, we believe that total case growth could revert to a run-rate level of just over 10% in the near-to-medium term. With Align likely to experience powerful pricing pressure from the onset of new competition at the same time, run-rate revenue growth could collapse to mid-single-digit levels – a tremendous drop-off from consensus estimates of ~20% long-term annual growth.

		2012	2013	2014	2015	2016	2017	2018	2019	7-Year CAGR	Future Run-Rate (Spruce Point)	
Orthodontists, North America (Est.)	Doctors	5,665	6,040	6,392	6,749	7,060	7,275	7,607	7,991	5%	0%	Orthodontist saturation limits case growth Spread of alternatives introduces churn
	Utilization	24.2	26.4	27.7	31.8	36.6	46.6	56.7	65.0	15%	0%	
	Cases (000s)	137.1	159.5	177.1	214.6	258.4	339.0	431.3	519.4	21%	0%	
Dentists, N. Amer., & All S. Amer. (Est.)	Doctors	19,285	21,290	23,498	24,961	27,005	30,955	34,393	39,139	11%	8%	Proliferation of low-cost alternatives introduces churn
	Utilization	7.2	7.2	6.9	7.4	7.6	8.0	8.6	8.6	2%	0%	
	Cases (000s)	139.7	154.3	161.5	183.8	205.4	247.2	296.8	336.1	13%	8%	
International (Est.)	Doctors	5,420	10,800	13,450	16,460	20,415	26,175	36,040	48,650	37%	20%	Proliferation of alternatives introduces churn
	Utilization	16.0	10.0	10.4	11.2	12.0	13.2	13.9	13.8	-2%	0%	
	Cases (000s)	86.8	10.5	139.5	184.8	244.7	344.8	500.0	669.8	34%	20%	
Total (Est.)	Doctors	30,370	38,130	43,340	48,170	54,480	64,405	78,040	95,780	18%	13%	11%
	Utilization	12.0	11.1	11.0	12.1	13.0	14.5	15.7	15.9	4%	0%	
	Cases (000s)	363.6	422.2	478.0	583.2	708.5	931.0	1,228.1	1,525.4	23%	11%	

Estimates derived from management disclosures. Figures not disclosed directly by management are Spruce Point estimates.

Medium-to-Long Term Growth Trajectory
Consensus vs. Spruce Point

	Sell-Side	Spruce Point
Case Volume Growth, Annual	20%	11%
ASP Growth, Annual	-1%	-5%
Total Revenue Growth, Annual	19%	6%

Spruce Point View
The sell side does not yet appreciate the consequences of emerging competitive threats



Pandemic Poses Unprecedented And Underappreciated Risk To The Business

Dental Practices Shut Down In Response To Pandemic – But Risks Could Linger On

Orthodontic and dental offices have been effectively shut down across the US and abroad as the world continues to cope with the COVID-19 pandemic. ALGN shares have effectively traded in-line with the market as investors continue to bet on when the world begins to return to normal. However, Spruce Point believes that – while, to date, most offices have announced closures only through April or May – Align is put at particular risk by the ongoing pandemic, and that investors have not yet properly taken the associated near-to-medium term risks into account.

Close X

Message to Our Patients

Dear families, we will be closed until April 6th due to the Covid-19 health emergency. We have tried to call and email all scheduled patients. If we have somehow missed you, please call us to reschedule. If you are a new patient, we ask that you wait until after April 6th. Of course, if you have an emergency don't hesitate to call the emergency number on our voicemail. We are looking forward to getting back soon. Stay safe! Dr. S and staff.

CAMBRIDGE  ORTHODONTICS

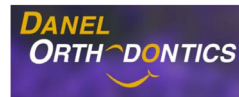
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Coronavirus (Covid-19) Update:

Danel Orthodontics is planning to be closed the week of March 23-27 per the recommendations of the ADA (American Dental Association). All patients scheduled will be rescheduled no earlier than April 20th (due to the possibility of an extended closure). If you have an appointment during this time, we will be reaching out to you to reschedule your appointments.

We want to thank you for your understanding and do know that we are in this together. Our main concerns are the health of our patients, families, staff and our community. We look forward to seeing you all soon!



Close X

Close X

Message from Kazley Orthodontics:

"COVID-19 Update: The health and safety of our community is our main priority. We are taking all necessary precautions to keep ourselves and our patients safe, as defined by the guidelines set forth by the CDC. As a result, Kazley Orthodontics will be closed from Wednesday, March 18th, 2020 to Tuesday, April 14th, 2020."

Close X

Welcome to Hawaii Orthodontist

ATTENTION

To Our Hawaii Orthodontist Patients and Families

Since the start of the COVID-19 pandemic, we have tried to balance, as best as we can, the benefits of remaining open to continue serving our patients, and their families. At this point, we believe that the duty to everyone's long-term health outweighs the benefits of remaining open.

To minimize exposure and protect the health and safety of our patients and team members, the Hawaii Dental Association, along with the guidance of the Centers for Disease Control and Prevention (CDC), the American Dental Association (ADA) and the American Association of Orthodontists (AAO), have advised for dental offices to suspend all elective and regular dental treatment.

Therefore, effective Tuesday, March 17, 2020, our offices will be temporarily closed until at least **April 4, 2020** in accordance with the guidelines we have been given. If your next appointment falls within this time frame, your appointment has been cancelled. Someone will be contacting you to reschedule your appointment as soon as we are able to resume regular business hours.

COVID-19: Status of Clinical Operations

Clinics Closed for Elective Care March 16–April 10, 2020

As many of you know, Governor Baker declared a state of emergency in Massachusetts in order to further prepare for the outbreak of COVID-19, and the World Health Organization declared a pandemic. We are balancing our clinical, educational and research missions with the health and safety measures of our community, including you our patients.

We have decided to close our clinics for all treatment, EXCEPT emergency care from March 16–April 10, 2020. If you have a dental emergency during this time period, please call: 617-636-6998.

We understand the interruption caused by this closure but hope that you understand this decision is being made in the best interest of our community and to help stop the spread of any infection that might cause a burden on our medical colleagues and on our hospitals.

We will be posting messages to this webpage about the status of our clinics.

We will call you back to reschedule once a firm date for re-opening is established.

Please do also check back for updates.

For Coronavirus updates and guidance from the Tufts University School of Dental Medicine Dean's Office, please visit: <https://dentalfaculty.tufts.edu/coronavirus-updates/>.

For Tufts University Office of Emergency Department communications and additional resources, please visit: go.tufts.edu/coronavirus.

COVID-19 Update

As of March 18, 2020, all dental offices in the state of Louisiana are closed to routine appointments until April 16, 2020, due to the COVID-19 virus. We can and will be available to treat any true orthodontic emergencies however; if you are in pain and need help we are here for you! During these times we are limiting the team members and office hours on a daily basis, but if you are in need of assistance or have any questions please call the office at 337-988-2025 and we will respond to you as soon as possible. We apologize for any inconvenience this may cause and we appreciate your patience at this time. Thank you!



When Will “The Most Elective Of Procedures” Return?

Paralleling the broader medical community, dental oversight and regulatory boards have issued recommendations that dental practices postpone all elective procedures for the foreseeable future, with most states barring them outright for the foreseeable future. As one dental practitioner said to us, “there is nothing more elective than orthodontics” – particularly a procedure which, in most cases, is cosmetic. While public sentiment continues to swing back and forth on when restrictions on public activity may be lifted, Spruce Point believes that cosmetic orthodontics may be among the last businesses to “return to normal” following the current crisis – particularly if the disease continues to linger into the future, in which case medical equipment may continue to be reserved for emergency purposes.

American Dental Association And Other Industry Boards Recommends Indefinite Postponement of Elective Procedures...

ADA recommending dentists postpone elective procedures

March 16, 2020

Most dental procedures stopped until April 10, ADPH says

Posted Mar 18, 2020

OHIO (WJW) — In response to the coronavirus outbreak and requests from Gov. Mike DeWine, the State Dental Board is asking practicing dentists to reschedule any elective procedures, including cleanings.

Any cosmetic or aesthetic procedures, such as veneers, teeth bleaching, or cosmetic bonding

- All routine hygiene appointments
- Any cosmetic or aesthetic procedures, such as veneers, teeth bleaching, or cosmetic bonding
- Any orthodontic procedures not including those that relieve pain and infection or restore oral function or are trauma-related

...And State Governments Are Banning Elective Dental Procedures Outright And Indefinitely

Texas Gov. Greg Abbott orders dentists to postpone elective procedures for one month

The move is a reversal, as last week, the State Board of Dental Examiners told dentists to ‘use their professional judgment’ on whether to keep providing routine care.

Iowa orders additional retail closures, halts elective and nonessential surgeries and dental procedures

Ian Richardson, Des Moines Register Published 1:56 p.m. CT March 26, 2020 | Updated 6:59 p.m. CT March 26, 2020

TENNESSEE SAYS ELECTIVE MEDICAL & DENTAL PROCEDURES MUST WAIT

MARCH 23, 2020

“There is nothing more elective than orthodontics.”

- Dental Practitioner

...especially a cosmetic treatment like clear aligners!

We are already closing in on some of the first proposed return dates in early/mid-April with no end in sight as to the public health crisis. That the initial return dates were so unreasonably optimistic only highlights the industry’s uncertainty as to when it might be able to return to business as usual. Spruce Point believes that investors should expect projected return dates to continue to be delayed for the foreseeable future.

Dental And Orthodontic Offices Could Be A Major Health Hazard In The COVID-19 Era

Regardless of when local and national governments begin to lift restrictions, [experts agree that we may continue to see new cases of COVID-19 for a year or more](#). Even if the disease were to become less virulent over time, Spruce Point anticipates that [consumers could be reluctant to undergo dental procedures for an extended period of time](#) – particularly elective cosmetic procedures. Dental tools can create aerosols within a patient's mouth which spray mucous and saliva into the surrounding environment, exposing anyone in the immediate vicinity to the potential for infection by an unknowingly-contagious dental patient. We believe that lingering stigma around entering such environments could slow dental office activity for months into the future, given that [the disease itself is not expected to disappear until later this year at the absolute earliest](#).

Dental And Orthodontic Offices May Represent A Health Hazard For An Extended Period...

"We have really good ways to prescreen patients: by taking their temperature, asking them questions regarding travel in the last two weeks, asking how they're feeling and if they have flu-like symptoms," said Dr. Fotinos Panagakos, vice dean of administration and research at West Virginia University School of Dentistry in Morgantown.

"But they may still answer 'no' to all of those questions, and their temperature may be normal, but they may still be infected though they're not showing symptoms yet," he said in a university news release.

Patients' coughs and sneezes aren't the only ways dentists can be exposed to the coronavirus.

"In dentistry, many of the procedures that we do require using a handpiece to drill a tooth, or an ultrasonic scaler to clean the teeth," Panagakos said. "The water used can form an aerosol. If you aerosolize something, it's going to end up in the air. You can just imagine what that means if a patient is carrying the virus."

Covaney & Covaney, DDS, which has an office in Newport News, is closing.

"We know that the Coronavirus (COVID-19) is spread through aerosol droplets, and unfortunately those are inherent to the practice of dentistry!" the office wrote on Facebook.

...And When Will Dental And Orthodontic Offices Get Access To Standard Protective Equipment Again For Basic Protections?

Where is all the PPE?

KEN BUDD, SPECIAL TO AAMCNEWS

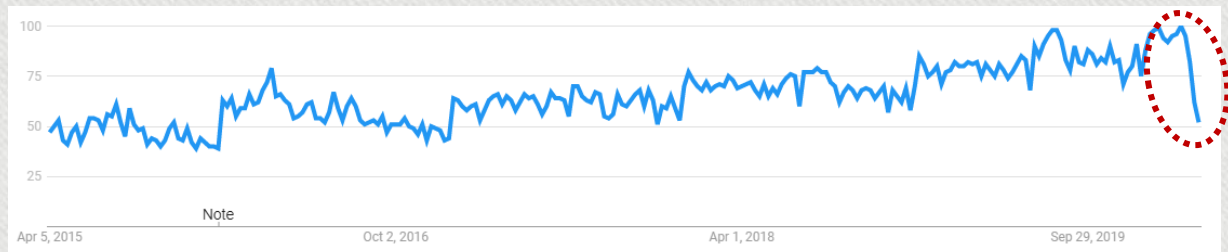
MARCH 27, 2020

SHARE: [f](#) [t](#) [in](#) [e](#)

"Every clinical institution and leader that I'm talking to is saying PPE, PPE, PPE," says Janis Orlowski, MD, a practicing nephrologist and the AAMC's chief health care officer. "That is the number one issue for our health institutions at this time." On a March 20 phone call, one clinical leader told Orlowski that her hospital was already down to a one-day supply of PPE despite their efforts to conserve. Orlowski has also spoken with hospital leaders about potentially obtaining PPE from dental offices and surgi-centers that have closed. "It's getting five boxes here, 10 boxes there, that kind of thing — it's a serious shortage," she says.

"We're not putting on hazmats suits if we're doing a filling. But, we want to keep our aerosols that we're breathing, and we have patients breathing in our face," Dr. Rodriguez says. " So, there is a certain amount of protection we need."

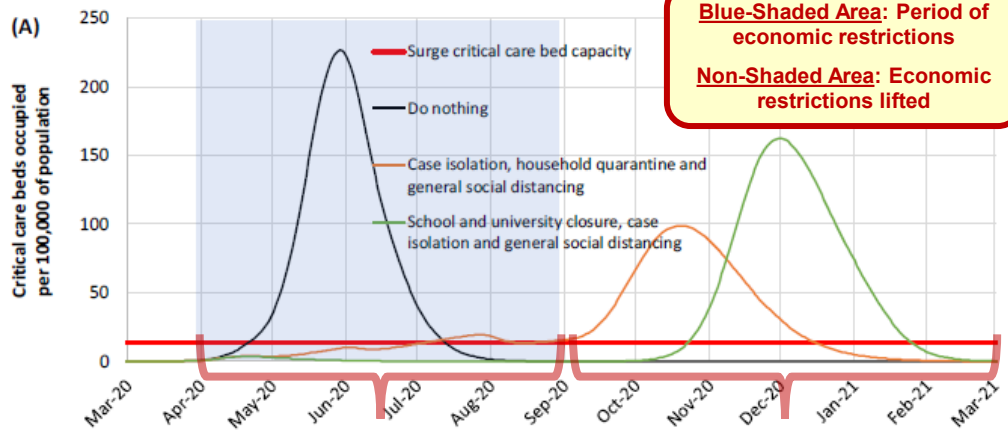
Google Trends Search Volume Analysis: "Invisalign"



If The Disease Persists In Any Scale, When Will People Feel Comfortable Returning To The Dentist?

Of late, ALGN shares have traded up on broader market optimism that the economy could begin to return to normal sooner than expected. However, investors should bear in mind that not all industries will return on the same schedule – and orthodontics and dentistry could be among the most significant laggards. Over the coming months, consumers may gradually grow more comfortable returning to retail stores and other public places, but will they be comfortable returning to a setting in which aerosols are spraying mucous in the open air? Spruce Point believes that, for as long as new cases of COVID-19 continue to arise – which could last well beyond the first signs of a broader return to normalcy – there could be a powerful stigma against returning to dental and orthodontic offices, particularly for elective and cosmetic procedures. Unfortunately, some of the most credible studies on the likely trajectory of the pandemic – including the [Imperial College London \(ICL\) study](#) which most western nations are using to inform their action plans – predict that the disease could continue to linger for at least another 18 months at least.

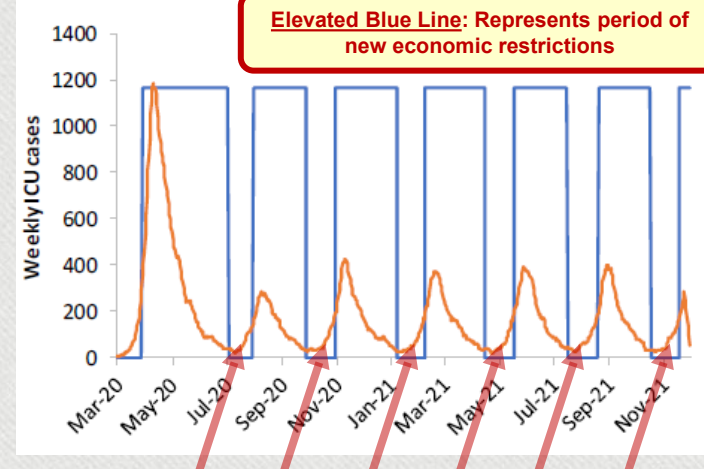
ICL Case Study: As soon as restrictions on human interaction and economic activity are lifted, cases of coronavirus are likely to reaccelerate



Economic restrictions limit case counts for as long as they remain in place...

...but any lifting of those restrictions would allow case counts to reaccelerate

ICL Case Study: We will see waves of rising case counts as restrictions are intermittently relaxed / reintroduced



Case counts will reaccelerate as governments relax economic restrictions, potentially forcing them to implement them once again

If the disease itself does not dissipate for another 18 months – regardless of when retail, transportation, and other sectors begin to return to normal – will people really be willing to return to the orthodontist for an elective procedure?

Prime Opportunity For Dental Practitioners To Review Expenses

The current uncertainty surrounding the dental industry notwithstanding, the current pause in business presents dental practitioners with a unique opportunity to review their expenses and evaluate cost-saving alternatives – particularly amidst an environment in which dentists are likely to see very limited revenue for a period of time. Several dentists and orthodontists have told us that they are using their time off to do just this. Align may be at particular risk of losing younger orthodontists with newer practices, many of whom carry significant loans – both student and business – and who, per our conversations, are likely the most comfortable switching to newer software and 3D printing technologies. Accordingly, we believe that the current crisis – however short-term in nature – could have lasting longer-term consequences for Align by accelerating the shift to competing aligner alternatives.

“The whole industry is being encouraged during this time to re-examine their expenditures and work flow efficiencies.”

- Dentist

“I talk to between 5-15 dentists a day, and they are greatly reducing their Invisalign numbers. For those dentists that are not yet switching, they are thinking about it.”

- Dental Consultant

“The biggest risk to Invisalign is the core base of users are looking for alternatives. There are study clubs in my area that are called ‘Invisalign alternative study clubs,’ meaning you have a roomful of 30-40 of the heaviest hitter orthodontists in [region redacted] come together every 2-3 months to sit there and talk about other companies other than Invisalign that you can use.

- Orthodontist, Diamond Plus Align Tier

“The orthodontists coming out of school are more in debt than ever in the history of the profession. They are very tech savvy. If they know that they can save money, they will.”

- Senior Employee, Major Dental Equipment Supplier

“The younger to midcareer guys, a lot of them are switching away from Invisalign.”

- Dentist, DSO

Now could be a convenient time for them to think through these alternatives more seriously...

With new, low-cost competitors having only recently entered the clear aligner space, and with in-house 3D printing becoming increasingly economical, we believe that the current pause in business presents a uniquely ominous threat to Align. Not only could case volumes be slashed to near-zero in the near term, but long-time orthodontic customers may be given an opportunity to evaluate a newly-evolved competitive landscape with whose offerings they have yet to fully understand – and they may be forced to opt for an alternative out of necessity.



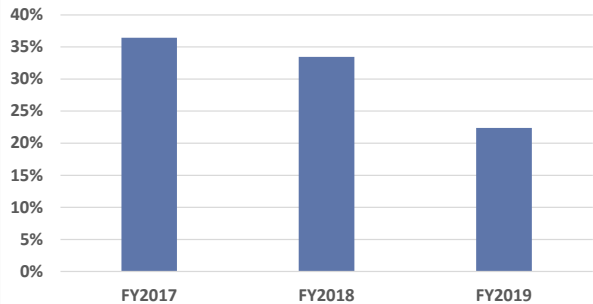
Short-Term Risks And Longer-Term Pressures Make ALGN Shares Unattractive At Current Levels

Management Trimming Exposure As Competition Mounts And Results Falter

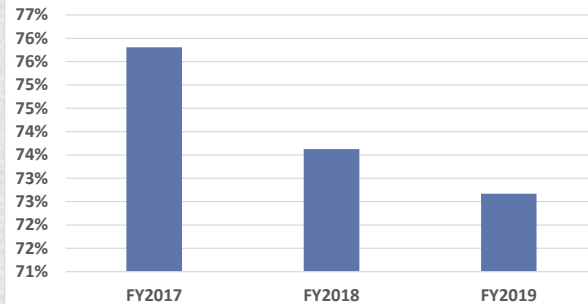
Spruce Point observes that, just as Align's performance has begun to deteriorate with the emergence of new competition, insiders have steadily and consistently trimmed their exposure to the stock. Today, insiders own just over 1% of outstanding shares. Meanwhile, the Company has expanded its buyback from just under \$100M in FY14 to \$400M in FY19. Spruce Point frequently sees insider selling paired with accelerated buybacks among companies under increasing strain. We worry that this is a signal that Align's insiders are heading for the exits ahead of renewed pressures with an explosion of new competitors.

Company Performance Deteriorating...

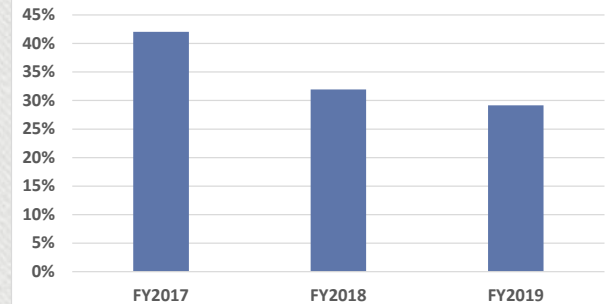
Sales Growth, YoY



Gross Margin

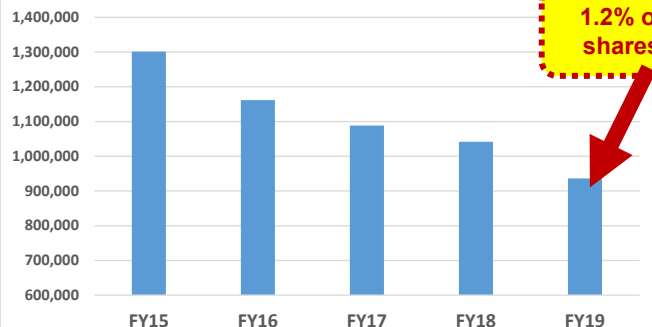


EBIT Growth (Non-GAAP), YoY



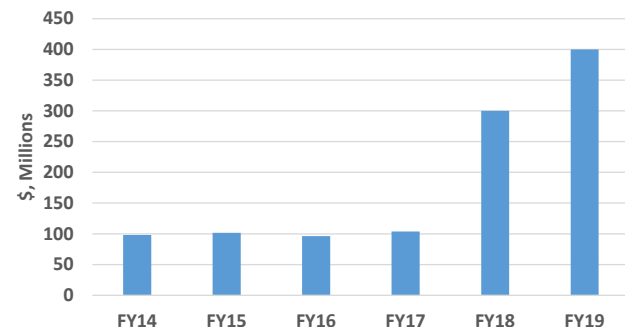
...And Insiders Exiting The Stock (While Buying On Shareholders' Behalf)

ALGN: Shares Held By Insiders



1.2% of shares

ALGN: Annual Share Buybacks



Ill-Timed Acquisition Raises Concerns Regarding Remaining Growth Runway

On March 4, Align spent €376 (\$419) – half of its available cash – to purchase exocad Global Holdings, GmbH, a producer of dental CAD/CAM software. Spruce Point finds it curious that a business such as Align – which, given its early communication to investors about the impact of coronavirus in China, was well-aware of the threat that COVID-19 could pose to sales in a given geography – would decide to make such a significant non-earnings accretive acquisition at 24x TTM sales just as it enters a period of extreme uncertainty and risk to forward performance. Management claimed that the goal of the acquisition was to sell more clear aligners by integrating Align more closely with GP dentists, but experts with whom we spoke are skeptical that it will gain traction.

Management Deceptive About exocad Performance?

2.2.1 Earnings situation

Income statement (01/01/2018 - 12/31/2018)	Fiscal year (kEUR)	Previous year (kEUR)
Sales	19,380	17,662
Other targeted income	230	176
Cost of materials	-2,803	-2,118
Personnel expenses	-3,767	-2,569
Depreciation	-282	-233
Other operating expenses	-3,359	-3,192
EBIT	9,399	9,726

Source: Bundesanzeiger

10% YoY Growth

"If you're not familiar with exocad, they're a 10-year-old innovative software company based in Darmstadt, Germany, growing approximately 20% annually."

- Joseph Hogan – Align Technology, CEO

Why was management not transparent about exocad's sales growth trajectory?

exocad Justification: Align Management vs. Independent Orthodontist

"The overall trend that we're really addressing here, Steve, is a whole idea of digital dentistry and how dentists are really reaching out, whether they reach out to their lab partners, whether they reach out to customers or whatever, they're looking for that digital platform that we're talking about. And that digital platform, it has to be broad and wide when you're -- we're a basic GP.... this is all about how in the future we sell more clear aligners and how we sell more clear aligners through these specific channels. And we think that this deal really helps us to facilitate that in the future."

- Joseph Hogan – Align Technology, CEO

"Trying to make it smoother to integrate Invisalign with dentists restorative treatment. And get more involved with the restorative nuts and bolts. It's a risky play I think with all the other restorative platforms with scanning and milling."

- Orthodontist

Spruce Point is concerned that management is overspending on M&A in order to support growth as competition from both doctor-directed and DTC players makes it harder for Align to grow into the remaining dental channel TAM.

Playing Games With EPS Just As Competitive Forces Accelerate

In FY19, management added stock-based compensation back to its Non-GAAP Net Income figure for the first time. Spruce Point estimates that this added \$0.86 to FY19 Non-GAAP EPS, boosting management's reported EPS figure by a significant 16.7%. We find it concerning that management would choose to take this new, large add back to EPS just as the clear aligner competitive landscape grows increasingly crowded.

Stock-Based Compensation Add-Back Benefit to Non-GAAP EPS

(\$, Thousands, except share data)	FY19
(A) Net Income, GAAP	\$442,776
(B) Stock-Based Compensation	88,184
(C) Impairments and Other (Gains) Charges	22,990
(D) Litigation Settlement Gain ¹	(51,000)
(E) Tax Impact	(24,635)
(F) Non-GAAP Net Income	\$478,315
(G) Tax-Effectuated Non-GAAP Add-Backs ¹ ((C) + (D))	\$111,174
(H) Implied Tax Rate on Non-GAAP Add-Backs $-(E) / (G)$	22.2%
(I) Tax Effect on Stock-Based Compensation $((B) \times (H))$	\$19,541
(J) After-Tax Stock Based Compensation Benefit $((B) - (I))$	\$68,643
(K) Diluted Shares Outstanding	80.1
(L) After-Tax Stock Based Compensation Benefit to EPS $((J) / 1,000) / (K)$	\$0.86
(M) Non-GAAP EPS	\$5.97
(N) Non-GAAP EPS Ex-SBC Benefit $((M) - (L))$	\$5.11
SBC Benefit to Non-GAAP EPS, % $((L) / (M))$	16.7%

Spruce Point does not believe that this significant Non-GAAP add back is justified, and finds it concerning that management would choose to include it in Non-GAAP EPS just as it begins to face an increasingly threatening competitive landscape

How Bad Could The Coming Quarter Be?

While it is no secret that Q2 will be a historically bad quarter for many companies and sectors, Spruce Point believes that investors are not fully prepared for the likely near-term impact of the pandemic on Align. Many official practice notices indicate discuss closures only through the end of April, but our diligence – confirmed by a call with Invisalign sales – reveals that most plan to remain closed through late May / early June. Even then, we anticipate that new cases will be sparse immediately upon their return for at least several weeks. This suggests that Q2 FY20 EPS could be down significantly even in an optimistic scenario in which dental practitioners return in mid-May – an aggressive timetable at this point.

(\$, Millions, except percentages)	Q2 FY19	Q2 FY20E			
		Early May Return	Mid-May Return	Late May Return	Late June Return
April Revenue Growth, YoY	-	-90.0%	-90.0%	-90.0%	-90.0%
May Revenue Growth, YoY	-	0.0%	-50.0%	-90.0%	-90.0%
June Revenue Growth, YoY	-	0.0%	0.0%	-50.0%	-90.0%
Q2 Revenue Growth, YoY	22.5%	-30.0%	-46.7%	-76.7%	-90.0%
Revenue	\$600.7	\$420.5	\$320.4	\$140.2	\$60.1
COGS	(167.1)	(126.2)	(96.1)	(42.1)	(18.0)
Gross Profit	\$433.6	\$294.3	\$224.3	\$98.1	\$42.1
Gross Margin %	72.2%	70.0%	70.0%	70.0%	70.0%
SG&A	(246.8)	(246.8)	(246.8)	(246.8)	(246.8)
YoY Growth, %	16.3%	-	-	-	-
R&D	(38.9)	(38.9)	(38.9)	(38.9)	(38.9)
YoY Growth, %	26.1%	-	-	-	-
EBIT	\$148.0	\$8.7	(\$61.4)	(\$187.5)	(\$243.6)
Operating Margin %	24.6%	2.1%	-19.2%	-133.8%	-405.5%
Interest Inc. (Exp.) & Other	13.8	-	-	-	-
Taxes	(41.8)	(2.0)	13.8	42.2	54.8
Tax Rate	25.8%	22.5%	22.5%	22.5%	22.5%
Net Income (Non-GAAP)	\$120.0	\$6.8	(\$47.6)	(\$145.3)	(\$188.8)
Diluted Shares Outstanding	80.6	79.1	79.1	79.1	79.1
EPS (Adj.)	\$1.49	\$0.09	(\$0.60)	(\$1.84)	(\$2.39)
Growth, YoY	14.3%	-94.3%	-140.4%	-223.4%	-260.3%

'Game over. That's it.' How the coronavirus impacted dentistry in Memphis

[Source](#)

But, the executive order meant a sharp downturn in patient numbers across the state. Since then, some practices have shut down completely.

"It's just been a very, very trying week," Fagala told *MBJ* on March 27. "The way a practice runs, especially an orthodontist practice like mine ... you may go from seeing 70-90 patients a day, and then you're able to see three. And, it's a huge change."

Some gross margin compression with lower capacity utilization

Assume no change in cost structure for purposes of analysis

Spruce Point believes that investors are not fully prepared for the likely magnitude of the impact of the pandemic on Invisalign performance, for at least the coming quarter (and likely more to follow)

Volumes Could Be Down Substantially Due To The Impact Of The Pandemic

To date, sell-side estimates have generally been revised only very conservatively in response to the ongoing pandemic, and there remains a great deal of uncertainty about the near-term future for Align. Spruce Point believes that, with elective procedures delayed for the indefinite future, and given the potential stigma that may surround dental offices over the coming months, Align could see US and international cases decline by anywhere between 20-60% year-over-year in Q2 and remain down between 20-30% for the remainder of the year.

Bull

(\$, Millions, except percentages)	Q1 FY20E	Q2 FY20E	Q3 FY20E	Q4 FY20E	FY20E
Americas Volume Growth	10.0%	-40.0%	-20.0%	10.0%	-9.9%
International Volume Growth	5.0%	-15.0%	-20.0%	10.0%	-4.9%
Clear Aligner Revenue	\$500.7	\$361.9	\$409.7	\$593.6	\$1,865.9
Scanner Growth	8.0%	-60.0%	-30.0%	0.0%	-21.9%
Scanner Revenue	\$86.1	\$41.6	\$63.8	\$106.2	\$297.7
Total Revenue	\$586.9	\$403.4	\$473.5	\$699.8	\$2,163.6
Growth, YoY	6.9%	-32.8%	-22.0%	-7.7%	-10.1%

Base

Americas Volume Growth	10.0%	-50.0%	-25.0%	5.0%	-15.0%
International Volume Growth	5.0%	-25.0%	-25.0%	5.0%	-10.0%
Clear Aligner Revenue	\$500.7	\$314.8	\$385.7	\$567.8	\$1,768.9
Scanner Growth	8.0%	-60.0%	-30.0%	0.0%	-21.9%
Scanner Revenue	\$86.1	\$41.6	\$63.8	\$106.2	\$297.7
Total Revenue	\$586.9	\$356.4	\$449.4	\$674.0	\$2,066.7
Growth, YoY	6.9%	-40.7%	-26.0%	-3.7%	-14.1%

Bear

Americas Volume Growth	10.0%	-60.0%	-30.0%	0.0%	-20.0%
International Volume Growth	5.0%	-60.0%	-30.0%	0.0%	-21.4%
Clear Aligner Revenue	\$500.7	\$213.2	\$361.6	\$541.9	\$1,617.5
Scanner Growth	8.0%	-60.0%	-30.0%	0.0%	-21.9%
Scanner Revenue	\$86.1	\$41.6	\$63.8	\$106.2	\$297.7
Total Revenue	\$586.9	\$254.8	\$425.4	\$648.1	\$1,915.2
Growth, YoY	6.9%	-57.6%	-30.0%	0.2%	-20.4%

In light of the prevailing restrictions on non-emergency dental activity and expert predictions which indicate that the coronavirus may linger for months into the future, Spruce Point believes that it is not outlandish to believe that, not only could US volumes collapse to near-zero in Q2, but that volumes may remain heavily depressed through the remainder of the year.

An elective, discretionary, cosmetic procedure is unlikely to experience a rapid recovery as the economic consequences of the pandemic grow.

...and earnings revisions will likely affect the stock



Not A Bounce-Back Candidate: Spruce Point Sees 40%-55% Downside To \$80-\$115 Per Share

As ALGN shares trade lower with the market as the pandemic grows increasingly drawn-out, bulls with faith in the long-term growth story likely see the stock as a strong “buy low” opportunity. Spruce Point strongly disagrees: not only does Align bear outsized risk to the continued prevalence of COVID-19 beyond 2020, but the proliferation of competitors and alternative aligner printing technologies will, in our opinion, prevent the Company from bouncing back with the same force as the rest of the dental/orthodontic space.

ALGN: FY21 Revenue Build

(\$, Millions, except cases)	Bull (FY21E)	Base (FY21E)	Bear (FY21E)
Americas Case Growth	25.0%	22.5%	10.0%
Americas Cases	909.6	891.4	800.4
Americas ASP	\$1,159	\$1,159	\$1,159
Americas Revenue	\$1,054.3	\$1,033.2	\$927.8
International Case Growth	25.0%	22.5%	10.0%
International Cases	753.2	738.2	662.9
International ASP	\$1,276	\$1,276	\$1,276
International Revenue	\$960.8	\$941.6	\$845.5
Non-Case Revenue	125.0	125.0	125.0
Total Revenue	\$2,467.6	\$2,427.3	\$2,225.8
Growth	19.4%	17.5%	7.7%

Further pressure on ASPs and multiple compression due to a slowed growth trajectory could bring even further downside to the stock

ALGN: Valuation

(\$, Millions, except shares)	Consensus (FY21E)	Bull (FY21E)	Base (FY21E)	Bear (FY21E)
Revenue	\$3,210.6	\$2,467.6	\$2,427.3	\$2,225.8
Growth	25.0%	19.4%	17.5%	7.7%
COGS	(\$884.7)	(\$740.3)	(\$728.2)	(\$667.7)
Gross Profit	\$2,325.9	\$1,727.3	\$1,699.1	\$1,558.0
Gross Margin %	72.4%	70.0%	70.0%	70.0%
SG&A	N/A	(\$1,073.4)	(\$1,055.9)	(\$968.2)
% of Sales	N/A	43.5%	43.5%	43.5%
R&D	N/A	(\$175.0)	(\$175.0)	(\$175.0)
% of Sales	N/A	7.1%	7.2%	7.9%
EBIT	\$717.0	\$478.9	\$468.2	\$414.8
Operating Margin %	22.3%	19.4%	19.3%	18.6%
Interest Income (Expense)	N/A	(\$5.2)	(\$5.2)	(\$5.2)
Taxes	N/A	(\$108.9)	(\$106.5)	(\$94.5)
Tax Rate	N/A	22.5%	22.5%	22.5%
Net Income (Non-GAAP)	\$596.5	\$375.2	\$366.9	\$325.5
Diluted Shares Outstanding	76.3	79.1	79.1	79.1
EPS (Adj.)	\$7.82	\$4.74	\$4.64	\$4.12
P/E Multiple	23.6x	24.0x	22.0x	20.0x
Target Price	\$184.41	\$113.84	\$102.05	\$82.31
Upside/Downside	-	-38%	-45%	-55%

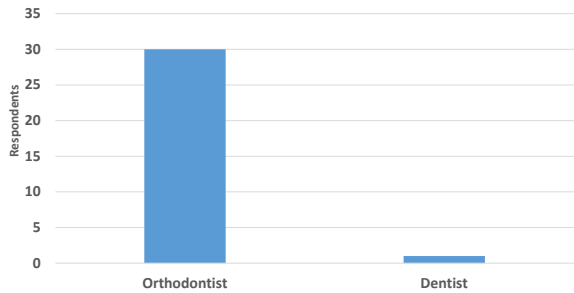


Appendix: Survey Methodology

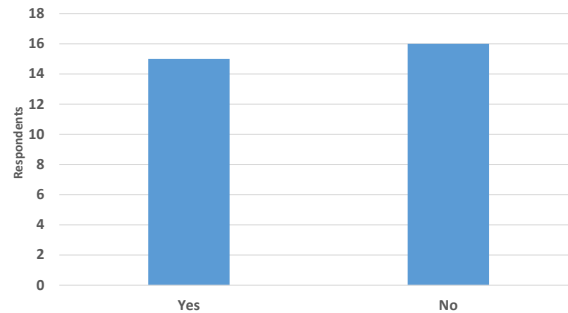
Survey Methodology: Focus On High-Volume Users Allows Us To Capture Trends Among Align's Largest, Most Important Customers

As part of our diligence, Spruce Point surveyed 31 dental practitioners who use administer Invisalign clear aligners in their practices. Importantly – and unlike most sell-side surveys – our survey targeted only high-volume users, with no participant administering fewer than 100 case starts in 2019 (participant average of 182), or qualifying for anything lower than Align's Diamond-tier discount. We believe that, by surveying only high-volume users, our analysis captures the behavior and sentiment of dental practitioners whose buying patterns will be most material to Align's performance going forward. We also believe that the behavior and sentiment shown in their responses reflects the early impact of emerging competitive threats, which are likely to emerge first among higher-volume users.

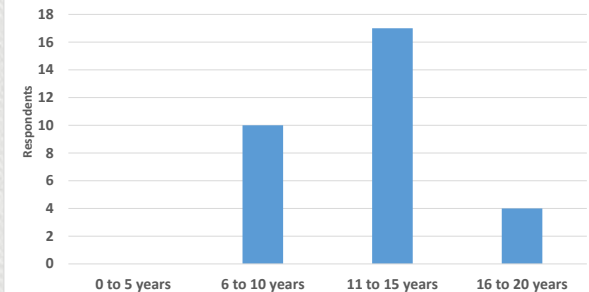
Are you a dentist, orthodontist, or other type of dental / oral doctor?



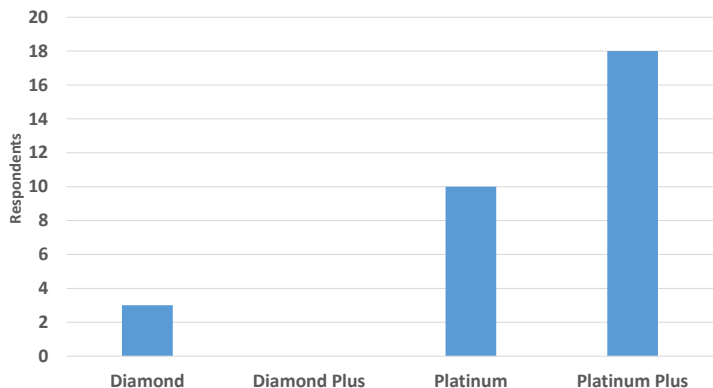
Does your practice offer competing Invisalign clear aligners?



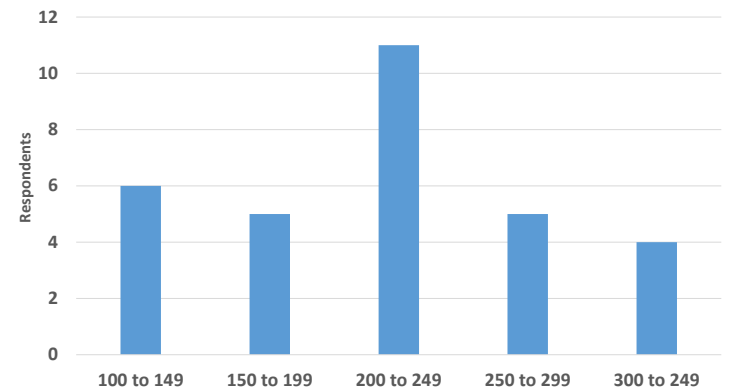
How long have you been in the dental profession (post-residency)?



What is your current Tier Status with Invisalign?



How many clear aligner case starts did you begin in 2019?

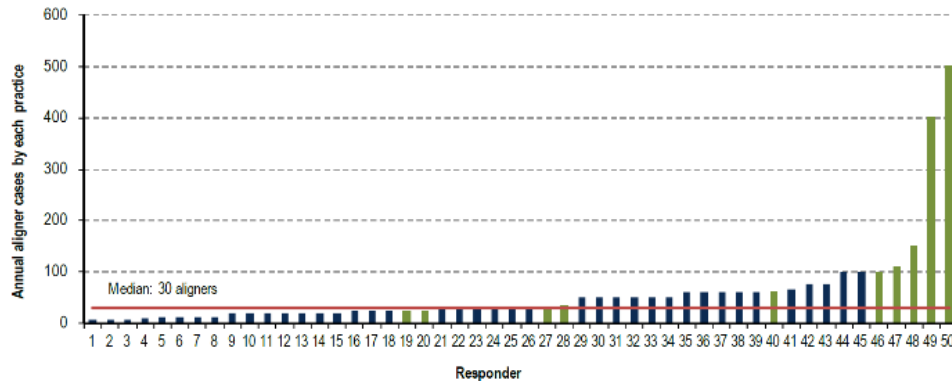


Survey Methodology: Focus On High-Volume Users Allows Us To Capture Trends Among Align's Largest, Most Important Customers

As part of our diligence, Spruce Point surveyed 31 dental practitioners who use administer Invisalign clear aligners in their practices. Importantly – and unlike most sell-side surveys – our survey targeted only high-volume users, with no participant administering fewer than 100 case starts in 2019 (participant average of 220), or qualifying for anything lower than Align's Diamond-tier discount. We believe that, by surveying only high-volume users, our analysis captures the behavior and sentiment of dental practitioners whose buying patterns will be most material to Align's performance going forward. We also believe that the behavior and sentiment shown in their responses reflects the early impact of emerging competitive threats, which are likely to emerge first among higher-volume users.

Bank of America: Survey Respondent Case Volume Distribution

Chart 1: How many clear aligner cases/placements does your practice complete annually, on average?



Spruce Point: Survey Respondent Case Volume Distribution

Spruce Point Survey: Annual Aligner Cases By Surveyed Practitioner

