

Value Analysis Brief

Cervical-One™ Kit

Single-use, surgery-ready ACDF Kit



Cervical-One™ Kit

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Who is ECA Medical?

One Instrument, One Patient at a Time™

Since 1979, the company has designed and delivered over 40 million single-use instruments and sterile-packed procedural kits to our medical device and implant customers.

ECA Medical is advancing a legacy of trusted surgical solutions. We are the world's leading manufacturer of single-use torque-limiting instruments and are innovating in surgery-ready procedural kits.

At ECA Medical, medical device manufacturers, hospitals, surgery centers, surgeons and patients alike rely on ECA's precision single-use instruments and sterile-packed kits in the operating room each day to safely secure critical implant devices used in Cardiac Rhythm Management, Neuromodulation, Orthopaedic, Spine, Trauma, Extremity, and Cranio-Maxillofacial procedures.



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Why ECA Medical?

Every 15 seconds an ECA Medical Instrument is used to secure a medical device implant - **One Patient at a Time™**

#1

MedTech Torque
Limiter Worldwide

39

Years Serving Medical
Device Leaders

40M+

Torque Limiters
Distributed Worldwide

2M+

Single Use Instruments
Distributed Per Year

25k+

Surgery-Ready
Orthopaedic Kits Distributed

82

Registered and
Granted Patents



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Inefficiencies of reusables

Reusable instrumentation has traditionally been the gold standard for hospitals. In a recent study of a regional medical center and their use of reusable instrumentation, they identified that there were three main drivers of inefficiencies when using reusables:



Lost productivity

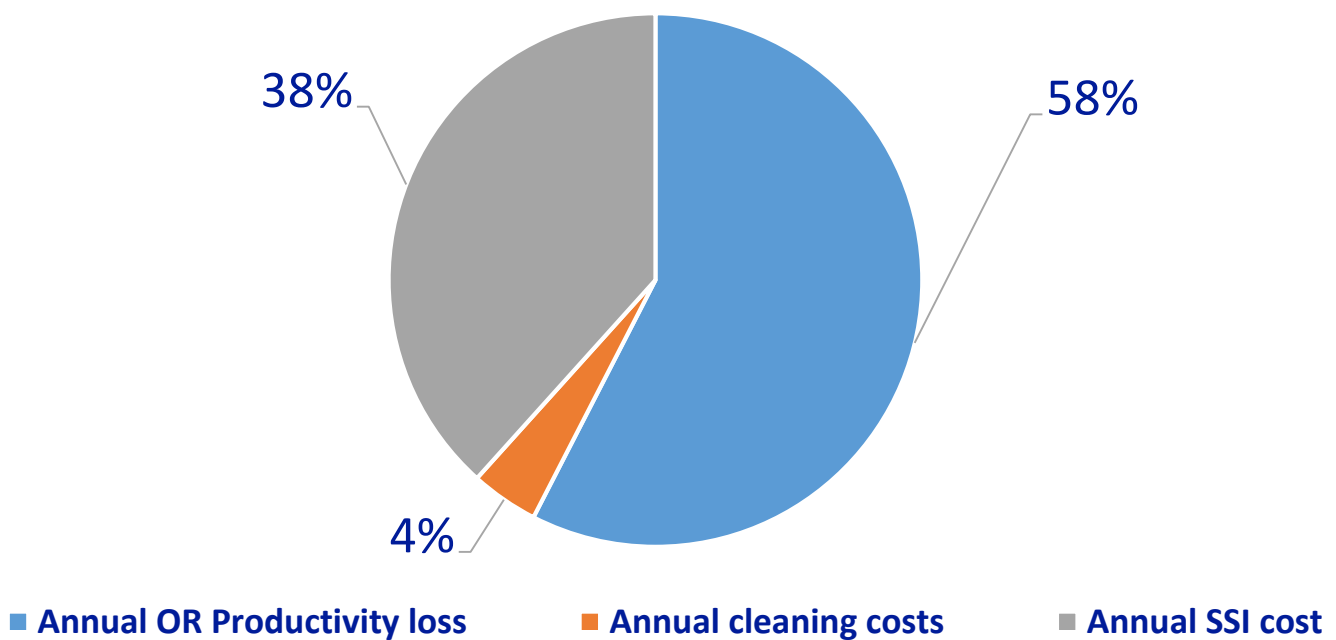


Surgical site infection



Sterilization costs

Percent (%) Cost Impact Using Reusable Instruments



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Lost productivity costs



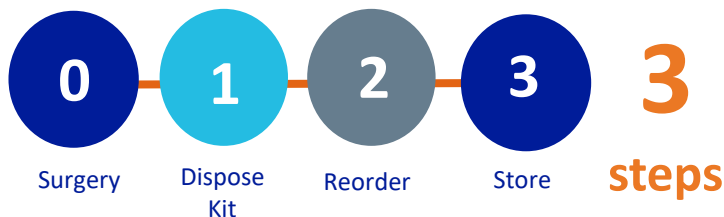
Lost productivity

In a single-blind interview of ASC owners¹, all respondents rated “time efficiencies to perform more cases” as the most important reason to using single-use procedure kits. In figure 1. reprocessing adds 5.5 hours to instrumentation preparation time for surgery and adds human error with the 8 steps required. These times are exacerbated when instrumentation issues occur (dirty, missing or damaged). For simple, high volume procedures, this inefficiency can be eliminated.

REUSABLE



SINGLE-USE



1. Data on file – internal use only

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Surgical site infection costs

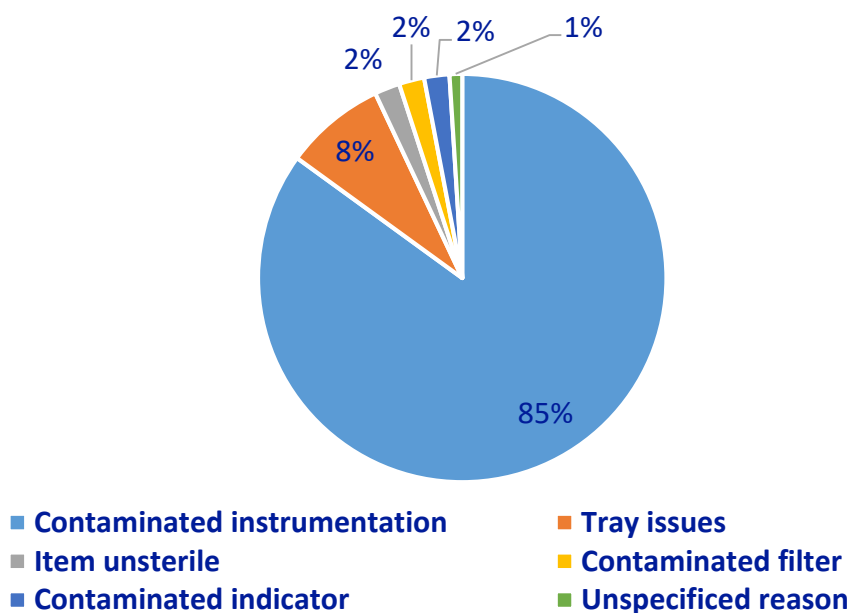


Surgical site infection

In a recent study of a regional medical center and their use of reusable instrumentation, they identified that contaminated instrumentation (debris (>60%) and holes in the wrap) were 85% of the defects reported, which may have led to potential delays in surgery due to re-sterilization and surgical site infection¹.

To mitigate issues as such, Litrico et al reported in a prospective randomized bi-centric study of single-use instrumentation in posterior lumbar fusion, that using this kind of device (single-use) decreased incidence of surgical site infection².

Percent (%) Impact Reported Instrument Defects



1. "Surgical Site Infection (SSI) Event." *Procedure-Associated Module SSI*, Jan. 2018, p. 1., www.cdc.gov/nhsn/PDFs/pscManual/9pscSSICurrent.pdf.
2. Single-use instrumentation in posterior lumbar fusion could decrease incidence of surgical site infection: a prospective bi-centric study. [Litrico S¹](#), [Recanati G²](#), [Gennari A³](#), [Maillot C²](#), [Saffarini M³](#), [Le Huec JC⁴](#).

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Sterilization costs



Sterilization costs

There are many costs associated with sterilization, and costs often differ from state and facility. The process below in Figure 1, illustrates the complexity and redundancy of the sterilization process (a 5.5 hour process from collection to storage). With 2.5 hours allocated to manual labor and with the addition of fixed costs of chemicals and utilization of sterilization units collected from sterilization department managers, the costs amass to over \$20,000 annually per reusable instrument tray. These costs are exacerbated when instruments are found dirty, missing or damaged, see Figure 2, which shows the added delays associated.

REUSABLE



Figure 1

REUSABLE

Process of Missing or Damaged Instrumentation



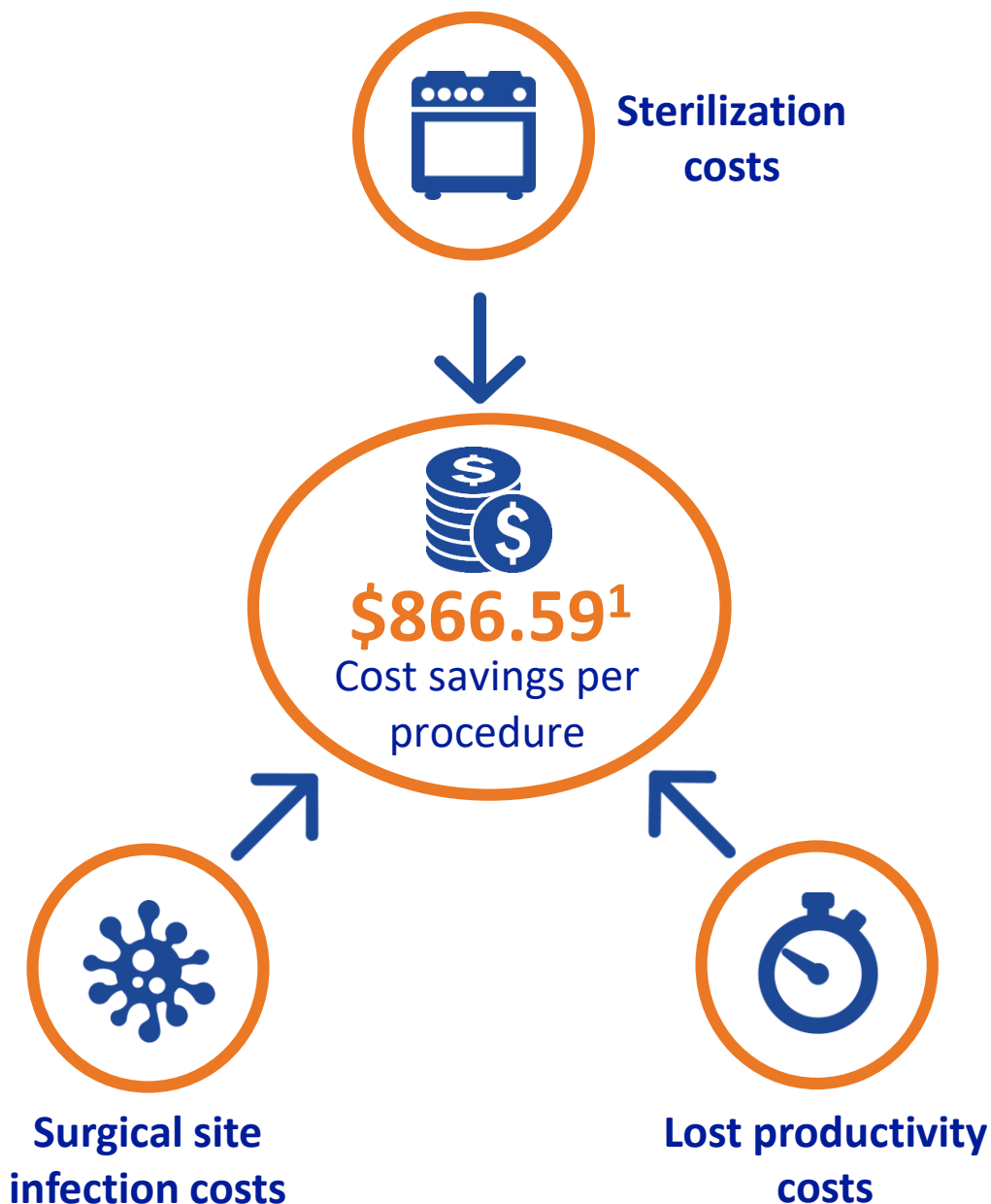
Figure 2



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Delivering cost savings

Shifting from reusable to single-use procedural kits can save facilities up to \$866.59 per case due to eliminating annual OR productivity losses (58%), mitigating annual surgical site infection costs (38%) and reducing sterilization (4%).



1. Data on file – internal use.

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The solution

The first All-In-One ACDF Kit



Faster OR turnover
than reusable



97% faster than
sterilizing reusable



Perform more cases



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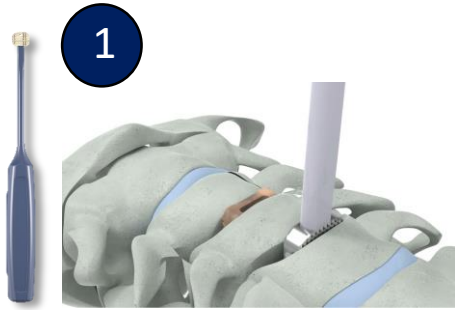
Tray layout card



	Item Number	Description	Set Qty
1	C1-1000B	Rasp	1
2	C1-1056B	Sizer (5-6)	1
3	C1-1001B	Inserter	1
4	C1-1002B	Tamp	1
5	C1-1003B	Drill Guide and Sleeve	1
6	C1-1004B	Drill Bit	1
7	C1-1005B	Template	1
8	C1-1006B	Screwdriver 2.5mm Hex	1

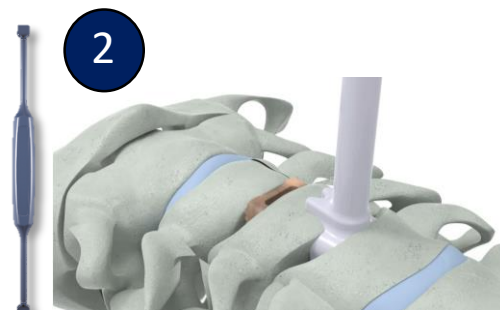
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Summarized surgical steps



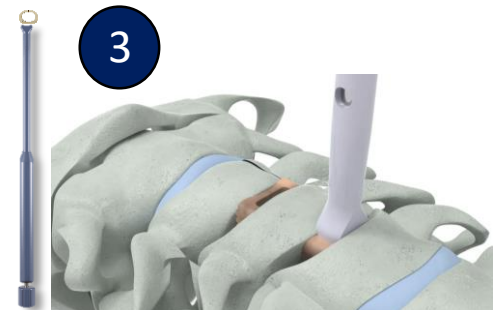
1

1. Prepare vertebral endplates via the use of a combination of curettes, rasps, osteotomies, disc shavers, or rongeurs to remove disc material and cartilage.



2

2. Insert the trials into the disc space to determine the size of the desired implant, starting with the smallest footprint and height of the trial, and progressing to larger and taller sizes as needed.



3

3. Attach interbody spacer onto inserter, turn the top spindle clockwise until engaged. Insert the interbody spacer.



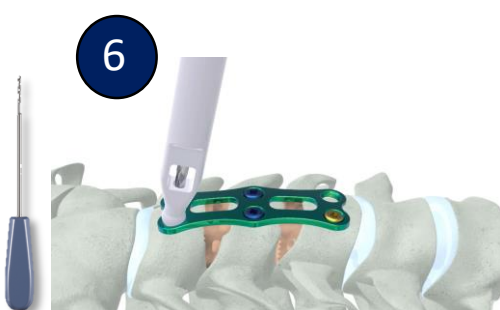
4

4. Freehand technique uses a tamp-style inserter to insert the implant.



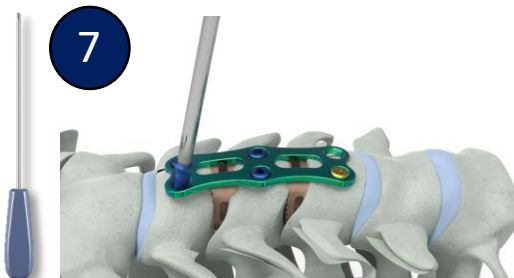
5

5. Use the hex driver to template the plate. Plate template can be broken to size required.



6

6. Use drill bit with drill guide and sleeve.



7

7. Drive screws in.

	Description
1	Rasp and prepare end plates
2	Cage sizing
3	Cage insertion
4	Tamp cage
5	Plate templating
6	Drilling
7	Insert screws and final tightening

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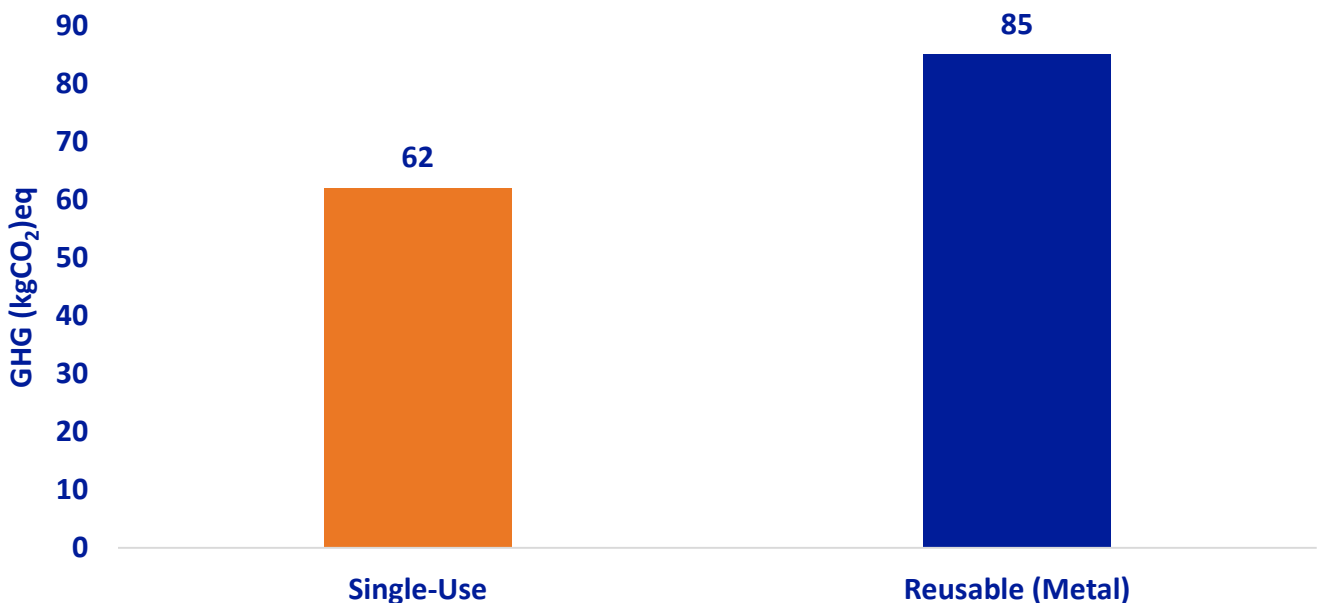
Environmentally responsible

Single-use did not create a larger carbon footprint

ECA Medical has chosen to partner with innovative organizations to source polymer materials that have gone through rigorous tests to determine whether materials used generate a larger carbon footprint.

A lifecycle analysis was performed, as per ISO 14011 guidelines, whereby review of entire continuum from material acquisition, production, sterilization, distribution and end-of-life showed that single-use instruments did not create a significantly larger carbon footprint than their reusable counterparts in any of the study's scenarios.¹

Overall US Carbon Footprint for Single-Use vs. Reusable



1. Data on file – internal use only.

Notes



This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. ECA does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate a ECA Medical product. A surgeon must always refer to the package insert, product label and / or instructions for use before using any ECA Medical product. Products may not be available in all markets because product availability is subject to the regulatory and / or medical practices in individual markets. Please contact your ECA Medical representative if you have questions about the availability of ECA Medical products in your area. ECA Medicals owns, use or have applied for the following trademarks or service marks: Cervical-One, ECA Medical. All other trademarks are trademarks of their respective owners or holders.



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