Reusable surgical instruments

DSI Tools for implantation procedure

INSTRUCTIONS FOR USE

DESCRIPTION

DSI Dental Implant system consists of endosseous dental implants with corresponding abutments, healing abutments, cover and fixing screws, other prosthetic parts and surgical instruments.
Tools related to the implantation procedure there are reusable devices that intended for surgical use, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out for the placement of the different types of the DSI Dental Implants.
Tools related to the implantation procedure can only be used in sterile packaging.
These devices are designed and labeled for multiple uses and are reprocessed by thorough cleaning followed by high-level disinfection or sterilization between patients. They are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals.
Tools related to the implantation procedure are made from Stainless steel (SS316) or Titanium Alloy (Ti 6Al-4V ELI) and supplied in non-sterile packaging.

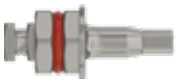
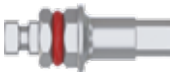
TOOLS RELATED TO THE IMPLANTATION PROCEDURE THERE ARE:

Implant drivers – intended for manual insertion of the implant to the cavity prepared in the mouth.
Implant driver bender – intended to make a bending of the neck of Dental implant, if required and applicable.
Manual drivers – intended for screwing the components to the DSI Dental Implants and related dental superstructures.
Handles:
a) handle for the connection with ratchet driver inserts intended for manual manipulation while preparing the implant bed, or for manual implant insertion. Very useful for manipulations in the maxilla and for jne-piece implants.
b) handle with AO connection intended for manual implant insertion.

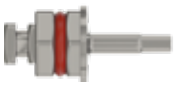
BASIC INFORMATION

Implant drivers placement – tools with internal or external platforms for use with DSI Dental Implants, for manual implant insertion.

Product	L (mm)	Type	Ref:
	7.0	⬡ 2.42	RDK24070

	10.0	⬡ 2.42	RDK24100
	15.0	⬡ 2.42	RDK24150
	10.0	⬡ 2.25	RDKC-NP10
	15.0	⬡ 2.25	RDKC-NP15
	10.0	⬡ 2.65	RDKC-RP10
	15.0	⬡ 2.65	RDKC-RP15
	18.0	Short Driver	RDOP
	50.0	Long Driver	RDOPL
	6.0	Short Driver	RDMC06
	10.0	Long Driver	RDMC10
	10.0	for MCB Bend	RDMCB
	23.0	Driver for Root-Shape Implant	OPD

Ratchet Driver Prosthetic – tools are used to turn the attachment or abutment screws that secure different components to implant fixtures. Universal (for all orthopedic elements) ending 1.25mm.

Product	L (mm)	Type	Ref:
	7.0	⬡ 1.25	RDK125070
	10.0	⬡ 1.25	RDK125100
	15.0	⬡ 1.25	RDK125150

Manual Prosthetic Driver – It is a hand screwdriver with a tip holder function. Universal (for all orthopedic elements) end 1.25 mm.

Product	L (mm)	Type	Ref:
	7.0	⬡ 1.25	HDK125070

	10.0	⬡ 1.25	HDK125100
	15.0	⬡ 1.25	HDK125150
	25.0	⬡ 1.25	HDK125250

Product	H (mm)	Type	Ref:
	60.0	⬡ 1.25	XL125600

Surgical handle driver –
1. It is used in the process of implantation, for manual insertion of the implant.
2. Used as an extension when working with hex keys that are inserted into the tip.

Product	L (mm)	Type	Ref:
	142.0	⬡ 2.42	HD
	143.0	⬡ 6.35	RHD

INTENDED PURPOSE/ INTENDED FUNCTION
Tools related to the implantation procedure are intended for surgical use, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out for the placement of the different types of the DSI Dental Implants. Tools related to the implantation procedure have no stand-alone intended use, because the different variants of the Reusable surgical instruments are assigned to an implant type.

CONTRAINDICATIONS
Tools related to the implantation procedure are only used for placement of a DSI Dental Implant so all contraindications that prohibit the use of a dental implant prohibit the use of Tools related to the implantation procedure as well. The contraindications of the Tools related to the implantation procedure are always connected to that of the dental implants.
Patients who are contraindicated for treatment with DSI Dental implants.
Allergy or hypersensitive to materials from which the Tools related to the implantation procedure are made:
Stainless steel (SS316).

Patient population
Tools related to the implantation procedure are used for the placement of a DSI Dental Implant, so all requirements to the patient population and selection criteria are always connected to that of the dental implants.
The patient population and selection criteria are always connected to that of the dental implants.

Intended part of the body or type of tissue applied to interacted with
The upper and lower jaws in all types of bone tissue.

Intended users
For use only by dental professionals within the dental clinic.

Summary of clinical benefit
As a clinical benefit of the Dental Implant treatment, patients can expect to have their missing / lost tooth or teeth to be

replaced. Dental Implant treatment may lead to restored masticatory function, bite force, enabled natural speech, enhanced comfort, restored aesthetics. Dental Implant treatment may also prevent bone loss, prevent facial sagging, and keep adjacent teeth stable and leave them intact.

STERILITY

Tools related to the implantation procedure are multiple use medical devices, can only be used in sterile conditions and intended to be resterilized.
Tools related to the implantation procedure are supplied in non-sterile conditions. Can be used only in dental clinics during implantation surgery.

CLEANING, DISINFECTION, AND STERILIZATION

Tools related to the implantation procedure are determined as multiple use devices. Before and after usage they must be cleaned, disinfected and sterilized properly.
Tools related to the implantation procedure are supplied in non-sterile conditions. For initial use and for all next uses Tools related to the implantation procedure must be cleaned, disinfected and sterilized prior to use.
For cleaning can be used both methods: manual and automated cleaning.
If possible, automated method should be used for cleaning and disinfection. A manual method should be used only if an automated method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath.
Perform pretreatment both in manual and in automated cleaning!
The products can be sterilized in the autoclave at 132°C in one standard sterilization cycle with a dwell time of 3 minutes to achieve a SAL of 10^{-6}.
For cleaning, disinfection and sterilization requirements of “Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from DSI Dental Implant System” must be followed.

STORAGE

Prior to the first use of the device, products should be stored in its original packaging at room temperature in dust free and humidity free conditions and not exposed to direct sunlight.
Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity and recontamination).
After sterilization, the products need to be stored in sterilization wrapping in a dry and dust free place and not exposed to direct sunlight. Follow the expiration date marked in the sterilization label.

OPERATING PRINCIPLES

Before surgery:
Tools related to the implantation procedure should be selected individually taking the anatomy and spatial circumstances into account and what implant diameter, implant type, position and number of implants.
Before implant treatments various tests should be done: Blood test, Mouth examination, X-ray examination, CT examination.

At surgery:
All instruments and toollings used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

After surgery:
Tools related to the implantation procedure must be reprocessed (cleaned, disinfected, inspected and sterilized) immediately.
For cleaning, disinfection and sterilization requirements of “Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System DSI must be followed.

RESIDUAL RISKS

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.
Inappropriate use of the products leads to badly executed work and increased risk.

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.
Mechanical failure could occur in case of torque force violated, the device is used in unintended way or with not DSI system instruments.
DSI Ltd. medical devices do not have risks of fire or explosion during normal use and in single fault condition and its intended use does not include use in association with flammable or explosive substances or substances which could cause combustion.

Swallowed or aspirated small devices by patients.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).
Inappropriate cleaning, disinfection and sterilization procedures of reusable instruments can lead to whole implantation failure. Effective decontamination is essential in reducing the potential risk of cross-contamination. Also, risk of infection develops from improperly processed devices which allow for accumulation of microbial biofilms.
Risk of injury related with sharpness of instruments can not be reduced as it represents intended use of instrument and it is clinician responsibility to be attentive, use forceps and protectors for sharp points.
Occurrence of temporary discomfort after the invasive treatment such as typical side effects are common.
Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the treatment.

SIDE EFFECTS, COMPLICATIONS WITH REUSABLE SURGICAL INSTRUMENTS

Tools related to the implantation procedure are only used if dental implant placed, so all side effects and complications that appear during the use of a dental implant can appear in the use of Tools related to the implantation procedure as well.
Complications may occur if DSI Tools related to the implantation procedure are used for non-DSI implants and superstructures treatment.
Temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.
More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, dysesthesia, loss of maxillary / mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of jaw, bone, aesthetic problems, nerve damage, exfoliation, hyperplasia.

MEDICAL EMERGENCIES IN DENTAL PRACTICE

Medical emergencies can occur in the dental practice. The emergencies that potentially could happen during the general dental treatment are listed in below:
• Bleeding, Adrenal crisis, Anaphylaxis asthma, Cardiac emergencies, Epileptic seizures, Hypoglycaemia, Red flag sepsis, Stroke, Syncope, Allergy.
Members of the dental team have a duty of care to ensure they provide an effective and safe service to their patients. A patient could collapse on any premises at any time, whether they have received treatment or not. It is therefore essential that all registrants must be trained in dealing with medical emergencies, including resuscitation, and possess up to date evidence of capability.
Planning ahead, there should be at least two people available within the working environment to deal with medical emergencies when treatment is scheduled to take place (in exceptional circumstances, the second person could be a receptionist or a person accompanying the patient.
Thus, this instruction does not contain the description of sighs, symptoms and management of medical emergency situations. Please, follow the recommendations to have trained members of the team and publicly available poster of the General Dental Council related to the Medical emergencies in dental practise.

REQUIREMENTS FOR SPECIFIC TRAINING AND FACILITIES FOR USERS

For use only by dental professionals within the dental clinic. Recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. DSI Ltd. offers a wide range of different courses. For more information, please visit www.dsisrael.com

INSTRUCTIONS IN THE EVENT OF THE PACKAGING IS DAMAGED

If the primary package has been damaged or unintentionally opened before use DO NOT USE IT and contact the local representative of DSI for exchange via web page: www.dsisrael.com

COMPATIBILITY INFORMATION

Tools related to the implantation procedure are compatible with DSI Dental implants and Related superstructures due to their technical characteristics.
For detailed information about DSI Dental Implants and related to them system components compatibility see Compatibility book.
For tools used for implant placement see Placement protocols. For Related Dental superstructures fixation see Prosthetic protocols.

WARNINGS

Tools related to the implantation procedure are only compatible to use with DSI Dental Implants and Related Dental superstructures.
These products must be used in sterile conditions.
Inadequate planning may compromise the performance of the implant resulting in system failure, such as loss or fracture of the implant.
Be aware in cases of patients that show signs of allergy or hypersensitivity to chemical components of the material: surgical stainless steel.
Do not use the product if the packaging is broken.
Before each procedure, make sure the pieces are properly seated. Ensure that the parts are not swallowed or aspirated by the patient.
Make sure you have all the necessary instruments for the surgery according to surgical planning.
Before each procedure, check the conditions of the DSI instruments, always respecting their product life.
Replace the instruments if there is damage, markings deleted, sharpening jeopardized, deformation and wear.
Avoid any contact of the instruments with foreign substances prior to their use. Do not touch the working part of the instruments.
Do not use damaged or blunt instruments for implantation.
Tools related to the implantation procedure consisting of several parts or components must be disassembled prior reprocessing. The information of assembling and disassembling of the instruments is provided in the Assemble and disassemble of the products.
Do not bend instruments.
Do not exceed recommended torque limitations with instruments, as it might cause bone necrosis or system components fracture.
Always use the work sequence recommended for DSI products. The use of prosthetic components and/or instruments of other manufacturers does not ensure the perfect function of the DSI Implant System and exempts any product warranty.
It is the professional's responsibility to use the DSI products according to the instructions for use, and to determine whether it suits the individual situation of each patient.
Tools related to the implantation procedure can not be used during any radiographic examinations (e.g. MRI and others).
Users of the Tools related to implantation procedure should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the working edges to break off.

CAUTIONS / PRECAUTIONS

It is recommended that DSI Dental implants are used only with dedicated surgical instruments and prosthetic components, as violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment results.
It is strongly recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. For more information, please visit www.dsisrael.com

Products should not be used if are visible these defects:

- Corrosion, rusting;
- Pitting, discoloration;
- Cutting surfaces become blunt, are damaged, increased susceptibility to corrosion;
- Destruction of the material surface, removal of oxide layer increased susceptibility to corrosion;
- Damage of the instruments, especially of cutting surfaces increased susceptibility to corrosion.

Causes of defects:

- Unsuitable and/or incorrectly used cleaning agents and disinfectants, saline solution, iodine tinctures, unsuitable water;
- Cleaning with steel wool, steel brushes;
- Contact between instruments of different metallic materials;

- Overloading the instruments;
- Mutual contact of the instruments;
- Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer;
- Insufficient drying of the instruments.

DSI does not define the maximum number of uses appropriate for reusable devices. The useful life of these devices depends on a number of factors including the methods and duration of each use and the handling between uses.

Product lifetime will be preserved and extended if:

- Use each instrument only for its intended purpose.
- Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.
- Thoroughly clean off incrustations with soft brushes only. Disassemble instruments, clean cavities especially well.
- Never disinfect, clean (also ultrasound) or sterilize instruments made of different materials together.
- Only use cleaning agents and disinfectants intended for the material and follow the instructions for use of the manufacturers.
- Rinse disinfectants and cleaning agents very thoroughly with water.
- Never leave or store instruments moist or wet.

The user must at all times avoid touching the instruments and parts without protection (protective sterile gloves and gowns should be worn).
During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.
Instruments that are bent and/or do not run true should be discarded forthwith. The general waste management procedures for dental offices see in Biohazardous Implant-related Waste Disposal Instruction for the Dental Offices.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

Tools related to the implantation procedure can not be used during any radiographic examinations and MRI scanning.

MATERIALS

Titanium Alloy Ti 6Al-4V ELI:

Chemical components	Composition % (mass/mass)
Carbon, max	0.08
Aluminium	5.5-6.50
Nitrogen, max	0.05
Oxygen, max	0.13
Vanadium	3.5-4.5
Iron, max	0.25
Hydrogen, max	0.013
Other, total (max)	0.40
Titanium	balance

Stainless steel SS 316 L:

Chemical components	Composition % (mass/mass)
Carbon	0.023
Silicon	0.64
Manganese	1.76
Chromium	16.84
Molybdenum	2.03
Nickel	10.03

DISPOSAL

Disposed Reusable surgical instruments should be handled as potentially contaminated products unless conclusive evidence exists to the contrary. Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account. The general waste management procedures for dental offices see in Biohazardous Implant-related Waste Disposal Instruction for the Dental Offices.
According to the Warranty and return policy, disposed DSI Ltd. medical devices under specified conditions which are failed, fractured or damaged, after removal, together with the accompanying documents, can be returned to DSI Ltd. under a

feedback procedure. Potentially biologically contaminated product for DSI Ltd. determined as returned product that was in use.
All other products, which were in use, but not returned to DSI Ltd. must be handled in line with waste regulations of the country in which they were used.
Used devices under Warranty and return policy, returned to a DSI Ltd. should have been cleaned and decontaminated by the user before shipment and labeled as such.

Please note
Some products may not be available in all markets. Please contact your local DSI Ltd. representative to review the product range available.

EXPLANATION OF PICTOGRAMS

Catalogue number	
Batch Code	
Quantity	
Use by date	
Medical Device	
Consult instructions for use	
Caution	
Do not re-use	
Symbol for “Use by Prescription only”	
Temperature	
Non-sterile product	
Magnetic resonance conditional	
Regulatory compliance	
Manufacturer	

MANUFACTURER INFORMATION

Dental Solutions Israel Ltd.
59 haAvoda str. Light Industrial Zone
Ashdod, 7706300 Israel
Tel: +(972) 8-931-7235.
Cell: +(1) 972-200-3265
e-mail: info@dsisrael.com
www.dsisrael.com