Reusable surgical instruments

DSI Instruments

INSTRUCTIONS FOR USE

DESCRIPTION

DSI Dental Implant system consists of endosseous dental implants with corresponding abutments, healing abutments, covering and fixing screws, other prosthetic parts, and surgical instruments.
Reusable surgical instruments are devices that 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 sterilization have been carried out for the placement of the different types of the DSI Dental Implants.
Reusable surgical instruments 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.
Reusable surgical instruments are made from Stainless steel (SS316) or Titanium Alloy (Ti 6Al-4V ELI) and supplied in non-sterile packaging.

REUSABLE SURGICAL INSTRUMENTS THERE ARE

The **Parallel Pin** is a metal tool for manual use in preparing the site for implant placement. The guide pins are made of Stainless Steel (SS316) and are supplied under non-sterile conditions.

Product	Type	H (mm)	Ref:
Short Parallel Pin		**10.0**	**SPP100**
Long Parallel Pin		**16.0**	**SPP160**

Implant depth gauge – surgical instrument for intra-oral checkings during implant treatment procedure. Gauges are made from Stainless steel and supplied in non-sterile conditions.

Product	Type	Ref:
Gauge Depth probe measuring Tool		**DPKOP**

Manual Ring For Ratchet Driver Insert – Used as a hand crank to turn torque wrenches directly without the aid of other tools.

Product	L (mm)	Type	Ref:
	11.0	Hex 6.35	HW

Universal key for "Loc-in"– Used to install and remove famale inserts of the Loc-in system from a metal cap.

Product	Type	Ref:
	Universal Insertion & Extraction Tool	DFL

Adapters for latch grip motor maount.

Product	H (mm)	Type	Ref:
	15.4	Turning handle	TH-01
	22.0	Wrench Condenser	RCCON

Manual tissue punch.

Product	L (mm)	H (mm)	Ref:
	12.0	26.0	TPD

INDICATIONS

Reusable surgical instruments 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. Reusable surgical instruments have no stand-alone intended use, because the different variants of the Reusable surgical instruments are assigned to an implant type.

CONTRAINDICATIONS

Reusable surgical instruments 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 Reusable surgical instruments as well. The contraindications of the Reusable surgical instruments 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 Reusable surgical Instruments are made:
Stainless steel (SS316) or Titanium Alloy (Ti 6Al-4V ELI).

Patient population

Reusable surgical instruments 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 dental implants.
Intended part of the body or type of tissue applied to interact 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 teeth or teeth to be replaced. Dental Implant treatment may lead to restored masticatory function, bite force, enabled natural speech, enhanced comfort, and restored aesthetics. Dental Implant treatment may also prevent bone loss, prevent facial sagging, keep adjacent teeth stable and leave them intact.

STERILITY

Reusable surgical instruments are multiple-use medical devices, that can only be used in sterile conditions, and are intended to be resterilized. Reusable surgical instruments are supplied in non-sterile conditions. Can be used only in dental clinics during implantation surgery.

CLEANING, DISINFECTION, AND STERILIZATION

Reusable surgical instruments are determined as multiple-use devices. Before and after usage they must be cleaned, disinfected, and sterilized properly.
Reusable surgical instruments are supplied in non-sterile conditions. For initial use and for all next uses Reusable surgical instruments must be cleaned, disinfected, and sterilized prior to use.
Cleaning can be used in both methods: manual and automated cleaning.
If possible, an 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 automated cleaning! A cleaning procedure shall be used which is valid within the 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 must be followed the requirements of “Instruction for cleaning, disinfection and sterilization of non-sterile and reusable medical devices from Dental Implant System DSI”.

STORAGE

Prior to the first use of the device, products should be stored in their 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 on the sterilization label.

OPERATING PRINCIPLES

Before surgery:
Reusable surgical instruments 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, and CT examination.

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

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

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 surgeons, restorative dentists,s and dental laboratory technicians is essential for successful implant treatment.
Mechanical failure could occur in case of torque force is violated, the device is used in an unintended way, or with no DSI system instruments.
DSI medical devices do not have risks of fire or explosion during normal use and in single fault conditions and their intended use does not include use in association with flammable or explosive substances or substances that could cause combustion.

Swallowed or aspirated small devices by patients.

Because of the small size of the devices, care must be taken so that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent the 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, the risk of infection develops from improperly processed devices which allow for the accumulation of microbial biofilms.
The risk of injury related to the sharpness of instruments can not be reduced as it represents the intended use of the instrument and it is the clinician's responsibility to be attentive, and use forceps and protectors for sharp points.
Occurrences 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 is assured during the whole implant surgery and if proper maintenance, medication, and oral hygiene are taken upon after the treatment.

SIDE EFFECTS, COMPLICATIONS WITH REUSABLE SURGICAL INSTRUMENTS

Reusable surgical instruments are only used if a dental implant is placed, so all side effects and complications that appear during the use of a dental implant can appear in the use of Reusable surgical instruments as well.
Complications may occur if DSI Reusable surgical instruments 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, unfavorably affected adjacent teeth, fracture of the jaw, bone, aesthetic problems, nerve damage, exfoliation, hyperplasia.

MEDICAL EMERGENCIES IN DENTAL PRACTICE

Medical emergencies can occur in dental practice. The emergencies that potentially could happen during the general dental treatment are listed 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 signs, symptoms, and management of medical emergency situations. Please, follow the recommendations to have trained members of the team and publicly available posters of the General Dental Council related to Medical emergencies in dental practice.

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 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

Reusable surgical instruments are compatible with DSI Dental implants due to their technical characteristics.

RESTRICTIONS TO COMBINATIONS

All that is not mentioned in the Compatibility book is restricted to use in combination with the devices.

WARNINGS

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 or Titanium Alloy.
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 surgical instruments, always respecting their useful 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.
Always use the DSI product sequence. 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.
Reusable surgical instruments can not be used during any radiographic examinations (e.g. MRI and others).

CAUTIONS / PRECAUTIONS

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeons, restorative dentists, and dental laboratory technicians is essential for successful implant treatment.
It is recommended that DSI Dental implants are used only with dedicated surgical instruments and prosthetic components, as a 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. DSI offers a wide range of different courses. 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, and increased susceptibility to corrosion;
- Destruction of the material surface, removal of oxide layer increased susceptibility to corrosion;
- Damage to the instruments, especially to 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, and 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, and 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 by 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.

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 of 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 of 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. A potentially biologically contaminated product for DSI Ltd. was determined as a 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

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