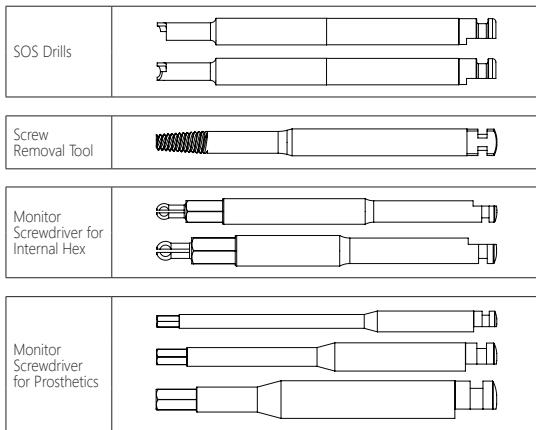


Instructions For Use for Screwdrivers/Extractors

Description:



The Screwdriver for Implants and Screws is a Medical Device related to dental implantology. It is a mechanical torque-limiting tool. It is used to screw in implants into the jawbone. It is also used to secure abutment screws, healing caps or cover screws in dental implants.

The Screwdrivers are made from Stainless steel.

Intended Purpose, Indications for use:

- The Screwdrivers are non-reusable devices that are intended for surgical use. The Screwdriver is intended for driving in and retracting a hexagonal screw used to fasten abutments to dental root form implants fixed into patient's jawbone in the clinic or to fasten abutments to plaster cast model in dental laboratory.
- Abutments & Suprastructures Monitor Screwdriver intended for screwing the components to the Dental Implants and related dental superstructures.
 - Implant Monitor Screwdriver intended for insertion of the implant to the implantation cavity.
 - Monitor Removal Screw Tool with left-hand thread intended for the removal of screws with a damaged hexagonal socket.
 - SOS Drill intended for Removal of stuck locking head screws.

Directions for Use

Examination:

- Prior to use, visually inspect the instrument for damage: deformation, breakage, corrosion.
- Dispose the damaged instrument.

Cleaning:

- Rinse the components under running water to remove residue.
- Rinse in ultrasonic bath with an anticorrosive cleaning agent for 15 minutes.
- Thoroughly rinse from cleaning and disinfecting agents under running water.
- Dry with hot compressed air, use absorbent paper tissue.

Disinfection and Sterilization:

- Disinfect with alcohol.
- Sterilize in autoclave - for 15 minutes at 135°C.

Storage:

- Before the first use store in their original packaging at room temperature in dry, dust-free area.
- Keep away from chemicals, do not expose to direct sunlight.

Summary of Clinical Benefit:

All Surcam screwdrivers are used for placement of Dental Implants, therefore all clinical benefit typical to implantation are equally applicable to the related screwdrivers.

Residual risk:

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may fail.

Treatment by means of implants may lead to loss of bone, and biological and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeons, restorative dentists, and dental laboratory technicians is essential for successful implant treatment.

Side effects:

Monitor Screwdrivers are only used upon dental implant placement: all side effects and complications that appear during the use of a dental implant appear with the use of Monitor Screwdrivers. Possible undesirable side effects associated with dental implants include: Bleeding, short-term swelling and bruising of the gums and face, local pain, infection, injuries to the nerve, jaw fractur. Allergic reaction to materials, Stainless Steel.

Contraindications:

Tools related to the implantation procedure are only used for placement of 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.

Patient population:

Tools related to the implantation procedure are used for the placement of Dental Implants, so all requirements to the patient population criteria are always associated to that of the dental implants.

Sterilization:

Individual parts should be placed in an autoclave or dry heat pouch. When sterilizing parts within a set, parts should be placed in appropriate locations and the set should be wrapped in sterilization wrap. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-6 sterile assurance level (SAL): autoclave time 15 minutes for minimum of 132°C.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed above. Verify the calibration of your unit to ensure that recommended temperatures are not being exceeded. Chemclave sterilization is NOT recommended for any Surcam instruments. **Do not re-sterilize.**

Warnings:

Do not re-sterilize. Do not re-use. Repeated use can lead to serious problems of infection.

Surcam tools used in the implantation procedure are only compatible with Surcam implants and superstructures.

These instrument must be used in sterile conditions.

Do not use the product if the packaging is broken.

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 use. Do not touch the working part of the instruments. Before each procedure, check the instrument condition. Do not use damaged or blunt instrument for implantation. Do not bend.

Do not exceed recommended torque limitations, as it might cause bone necrosis or system components fracture.

It is the professional's responsibility to use the Surcam products according to the instructions for use and to determine whether it suits the individual situation of each patient.

Users of the Tools related to the 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.

Risk Reduction and Control:

Hazard	Possible Cause	Risk Reduction and Control
Integrity failure	Inferior materials	Strong stainless steel used
Contamination	Failure to clean or sterilize properly	Clean per IFU; sterilization in autoclave
User manual data deficiency - inadequate usage	Lack of significant information, human error	PMS analysis - User manual correction

Lack of adequate training of practitioners is a major risk factor for the success of the implant procedure.


















Limited Warranty:

In case of failure, Surcam undertakes to replace the instrument, free of charge, Subject to the following conditions: A written notice of such failure is submitted to Surcam, not later than within 6 months of first sign indicating such failure, accompanied by a follow-up report in the form issued by Surcam.

Basic UDI-DI:

Families	Basic UDI-DI
Monitor Screwdriver	729012048MonitorScrew1MZ
SOS Drill	729012048SOSDrill1EX

Symbolic Information:

	Catalog Number
	Batch Code
	Manufacturer
	Date of Manufacture
	Non sterile
	Do not re-use, Single use
	Keep away from sunlight
	Keep dry
	Do not re-sterilize
	Notified Body
	Authorized EU Representative
	Consult accompanying documents
	Do not use if package is opened or damaged
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Medical device
	Importer
	Information website for patients

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