msdi

Accessories and Tools Instructions for Use

Devices description

MSDI sleeves are products with cylindrical shape used by technicians to place over the chosen abutment and adjust it to be the base of the future restoration (e.g. when the layers of ceramic will be applied over). Sleeves are made of plastic and titanium.

MSDI Ti-Bases provide a connection for customized digital restorations. The Ti-Base is cemented to the prosthetic ensuring suitable connection to the implant/multi-unit.

MSDI Silicone caps are used to cover the ball attachment abutment. They inserted into metal cap in the overdenture to ensure good friction.

MSDI Lock metal housing provides advanced anchoring for implant-retained overdentures.

MSDI Silicon rings are used to get impressions in the preparation of crowns, bridges, onlays and inlays. In some cases, it's used for an impression in the process of preparation for complete dentures.

MSDI Castable abutments are prefabricated components, with or without a prefabricated cylinder, used to make a custom abutment for a cement-retained or screw-retained prosthesis.

MSDI Abutment screws are devices used to secure the abutment to the implant. This fastener is threaded and is typically tightened until it reaches its final seating position.

MSDI Transfer open trays are tool used for demonstrate the position of dental implant in relation to existing teeth and soft tissue contours and used in open tray technique specifically indicated when the implants are not sufficiently parallel to allow an impression to be withdrawn from multiple impression copings.

MSDI Transfer closed trays are tool used for demonstrate the position of dental implant in relation to existing teeth and soft tissue contours and used in closed tray impression technique utilized when the implants are sufficiently parallel to each other.

Transfer click is used with a closed trays when taking measurements with impression material.

MSDI Snap on transfer closed tray is a type of transfer used for closed tray technique for impression taking.

MSDI Snap on cap are used for open tray technique for impression taking.

MSDI They play an essential role in successfully designing and fabricating accurately fitting implant-supported restorations.

MSDI Analogs are made of stainless steel and exist in two sizes: standard and wide.

Analogs are device that are embedded in the operative model and are used during fabrication of the laboratory prosthetics to duplicate the shape and position of the implant/abutment platform.

The analogs have substantially the same height and dimensions as conventional implants and abutments.

MSDI tools (drivers, ratchets, wrenches, holders, screwdrivers, probes, depth guides) are made of surgical stainless steel and undergo thermal treatment.

This process strengthens the steel and protects from wear. The tools are unique as they grip the screws and prevent them from falling into the patient's mouth.

Intended purpose

MSDI accessories and tools are manually powered and are intended for use for the sole placement of MSDI dental implant systems and aid in the placement or removal of dental implants and abutments, prepare the site for placement of dental implants, aid in the fitting of dental implants and aid in the fabrication of dental prosthetics.

Indication(s)

MSDI Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Contraindication(s)

Pre-operative patient evaluation is necessary to determine any factors that may put the patient at risk or factors that may affect healing capabilities. Treatment is contraindicated where the patient has a preexisting allergy to the used parts. Accessories and tools that are used with non-MSDI products is contraindicated.

Warnings

- All accessories and tools are provided cleaned and non-sterile and are intended

to be sterilized prior to use. The devices bear a "non-sterile" marking on the label.
- The accessories are single use devices.
- The tools are reusable devices. Re-use of tools may cause cross-contamination and infection if not sterilized before use.
- Reusable tools must be replaced when damaged or dull.

Intended patient group and the medical conditions to be treated

Partially or fully edentulous patients.

Sterilization Instructions:

Important note: A sterilization pouch suitable for steam sterilization should be used. We recommend you to use of a FDA-cleared pouch for the intended sterilization cycle. (e.g.: WIPAK, self-sealing sterilization pouch that was used by MSDI in the steam sterilization study).
Prior to use, tools are to be sterilized, by steam sterilization as follows:

For Pre-vacuum process:
1. Place the tool in the sterilization pouch.
2. Applyafractionatedpre-vacuumprocess– 3 pre-vacuum phases with at least 60 mill bar
3. Heat up to a minimum sterilization temperature of 132C / 270F
4. Minimum Holding time: 4 min
5. Drying time: 30 min

For gravity process:
1. Place the tool in the pouch.
2. Apply a fractionated with at least 60 mill bar
3. Heat up to a minimum sterilization temperature of 132 C/270 F
4. Minimum Holding time: 15 min
5. Drying time: 30 min

Cleaning and Disinfection Instruction:
1. Remove tissue residuals by immersing the used instrument in cold water (<40°C/104 F). do not use fixation agents or hot water (>40°C/104 F) as this could influence your subsequent cleaning results. Instruments should be kept in a wet environment until the next step indicated below is initiated.
2. Scrub the outer, and if applicable, inner side of the instruments with a suitable soft bristled nylon brush until all visible soil is removed.
3. Rinse the outer, and if applicable inner, side of the instrument with tap water to remove all cleaning solution.

Automated Cleaning and Drying
1. Place the instruments on an instrument rack and load the instrument rack in the washer for 2 minutes pre-clean with cold water and empty.
2. Dry the outer side of the instrument through drying cycle of washer. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Disposal:

Used devices are considered biohazard and need to be discarded as biohazard waste, according to applicable local laws and regulations or institutional protocol

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Explanation of Symbols

LOT	Lot number		Keep dry
REF	Catalogue reference		Keep away from sunlight
	Manufacturer	MD	Medical Devices
	Date of manufacture	UDI	Unique Device Identifier
	Do not re-use		Caution, consult accompanying documents
NON STERILE	Non-sterile product	CE	CE Mark

EC REP Authorized representative in the European Community

℞ Only CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or dentist

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