msdi

Reusable Tools Instructions for Use

Device description and intended use:

1. Analogs

MSDI Analogs are made of stainless steel and exist in two sizes: standard and wide.
An analog is a device that is embedded in the operative model and is used during fabrication of the laboratory prosthetics to duplicate the shape and position of the implant/abutment platform.
The analog has substantially the same height and dimensions as a conventional implant and abutment.
Analogs are considered as non-invasive devices, and classified as class I devices, according to rule 1.

2. Transfers

MSDI transfers are made of stainless steel and available for closed and open tray.
They are used by the prosthetist in order to create the dental prosthesis.
Non- engaging Impression Transfer: transfer with a flat platform for impression - taking from non-parallel implants.
Clip impression transfer with no affixing screw. Suitable for closed tray method with higher precision.
Transfers are considered as invasive devices intended for transient use, and therefore are classified as class I devices, according to rule 5.

3. Implantology tools

MSDI tools 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.
Drivers are considered as invasive devices intended for transient use with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device. Therefore, they are Class I medical devices, according to rule 5.

Indications for use:

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.
It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
MSDI surgical instruments are used for the sole placement of MSDI dental implant systems.
Surgical dental implant accessories are manually powered devices intended to aid in the placement of 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.

Contraindication:

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. Instruments that are used with none MSDI products is contraindicated.

Warnings:

- All the following products are delivered non-sterile, drivers, analogs, transfers, parallel pins, ratchets, and motor mounts. The devices delivered non-sterile have a "non-sterile" marking on label.
- The following products are provided cleaned and non-sterile and are intended to be sterilized prior to use.
- All the following products are reusable tools: drivers, analogs, transfers, parallel pins, ratchets, and motor mounts.
- Re-use of tools may cause cross-contamination and infection if not sterilized before use.

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 132 C/270 F
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.

Explanation of Symbols:

	Caution, consult accompanying documents
LOT	Lot number
REF	Catalogue reference
	Manufacturer
	Date of manufacturer
	Caution
	Do not re-use
NON STERILE	Non-sterile product
EC REP	Authorized representative in the European Community
Rx Only	CAUTION: U.S. Federal law restricts this advice to sale by or on the order of a physician or dentist

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