



Cleaning & Sterilization of Surgical & Prosthetic Instruments and Reusable Drills Instructions

INSTRUCTIONS FOR USE

Note: Care and maintenance of reusable instruments are crucial for a successful treatment and are essential for the outcome of the total treatment.

Sterile Components

The devices delivered sterile have a "Sterile" marking on the label. Opened packages of components that have never entered the oral cavity of a patient may be cleaned and sterilized / autoclaved again following the procedures stated below.

NON STERILE

1. Abutments and Plastic Copings:

The following products are delivered none sterile: Abutments, Overdenture, Drivers, Analogs, Transfers, Retrieval Screws, Parallel Pin, Drill Extension, Transfer Screw and Plastic Handle.

Non-Sterile Components & Instruments:

The devices delivered non-sterile have a "non-sterile" marking on the label. Opened packages of components that have never entered the oral cavity of a patient may be cleaned and sterilized/autoclaved again following

the procedures stated below.

For components & instruments made of the following material, titanium, stainless steel, nylon, gold alloy and plastic delivered non-sterile. It is recommended to sterilize the components & instruments prior to placing in oral cavity. For sterilization use steam sterilization for 30 minutes at 134°C/274°F. If modification has been made to the components & instruments clean prior to sterilization.

1. Adin Dental Implant System Surgery Kit (Plastic):
Surgical Kit Includes instruments to perform implant surgery for:

- 1.1 Standard Internal Hex Connection Implants; Touareg™, Touareg™-S, Touareg™-OS, and Swell™.
- 1.2 Conical Hex Connection; Touareg CloseFit™.
- 1.3 One™-One Piece Implant.

The Surgical Kit includes all drivers for restorative procedures and are delivered non-sterile. For sterilization use steam sterilization for 30 minutes at 120°C/248°F.

2. Instruments & Surgical Tools and Drills:

Drills

All drills for our implant systems; Touareg CloseFit™, Touareg™, Touareg™ S, Touareg™ OS, Swell™ and One™ are delivered unsterile and must be sterilized before use.

2.1 Pre-Cleaning of Instruments:

- 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.

2.2 Automated Cleaning & Drying:

1. Place the instruments on an instrument rack and load the instrument rack in the washer for a 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.

2.3 Functional Testing & Maintenance:

1. Visual inspection for cleanliness should be preformed with magnifying glasses.
2. If necessary perform reprocessing process again until the instruments are visibly clean.

2.4 Packaging:

Place instruments in sterilization packets.

2.5 Sterilization:

1. Sterilize the instruments by applying a fractionated pre-vacuum process (according to ISO13060 / ISO17665) under consideration of the respective country requirements.






Note: Parameters for the pre-vacuum cycle:
3 pre-vacuum phases with at least 60 mill bar.

2. Heat up to a minimum sterilization temperature of 132°C - 134°C / 269.6°F - 273.2°F; maximum temperature 135°C / 274°F.
3. Minimum Holding time: 4 min.
4. Drying time: minimum 20 min.

2.6 Storage:

Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C / 41°F – 104°F.

Explanation of Pictograms:

 Batch number	 Manufacturer
 Catalogue number	 Attention
 Non-sterile product	

 0473 is the Notified Body number for Intertek

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