Instructions for use

EN

Dental Implant, Instruments
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URIS OMNI System Instruments are manually powered devices intended to aid the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid the fitting of endosseous dental implants or abutments, aid the fabrication dental prosthetics, and used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drills, screwdrivers, torque wrenches, implant placement and removal tools, laboratory pieces used for fabrication of dental prosthetics.

General Principles of Surgical Tool Management

1. Because all surgical tools are provided in a non-sterile condition, they must be cleansed and sterilized before use.
   Caution - Incorrect cleansing and sterilizing processes cause corrosion and damage to the tools and if used directly, can cavse second infection.
2. The recommended number of use of a drill is 20~30 times based on the bone status, and must be replaced if the blade has been damaged or transformed.
   Caution - If a damaged drill is used, heat necrosis may occur
3. When managing the surgical tool, one must wear a mask and a glove to prevent infection.

Before sterilization

1. To prevent contaminants such as blood, tissue cell or bone residue from attaching to the surface of the instruments, the instruments must be immersed in an antiseptic solution immediately after use.
2. When using antiseptic solution, to prevent corrosion or bronzing, follow the directions given by the manufacturer for the antiseptic concentration and the duration of the instrument immersion in the antiseptic.
   Check Concentration : Completely liquify the concentrate before placing the instruments in the antiseptic solution.
   Immersion Duration : The instruments must not be immersed more than a day.
3. The instruments must be fully immersed in the antiseptic solution.
4. To decrease in sterilizing power and to prevent corrosion, the antiseptic solution must be replaced every day.

Before rinse
To prevent protein from clotting in 45°C, the instruments must be rinsed in running cold water.

Caution
Cleanse the instruments right after preliminary rinse

Sterilization

1. Must only use antiseptic solution that is FDA and CE approved, and follow the manufacturer's directions.
2. When cleansing metal instruments, corrosion free antiseptic solution and cleansing product use is recommended.
3. For safety, always wear personal protection gear such as gloves, glasses, and masks.
4. The user is responsible for the sterilization and management of the instrument.
5. Restriction and limitation of the instrument reuse:
   - With repetition of cleansing, the life expectancy of all instruments will decrease. If the instruments show corrosion, transformation or discoloring of the marking area, they have exceeded the safety criteria that is required for use.
   - Product with a disposable mark cannot be reused.
   - Tungsten carbide burs, plastic composition and NiTi instruments can be damaged with hydrogen peroxide and aluminum material instruments can be damaged by caustic soda solution.
   - Do not use acid solution (pH < 6) and alkaline solution (pH > 8).

Caution

After use, if the contaminants such as residual bone or blood stain are not completely removed, it may lead to corrosion; therefore, all separable instruments must all be disassembled beforethe cleansing process.

Cleanse / Dry

1. Contaminants must be completely removed using a soft brush.
   Do not use a wire brush or stainless material brush, and do not put too much pressure.
2. Immerse the products in the antiseptic solution of their characteristics and clean with an ultrasonic cleaner. However, do not cleanse different materials together. Also, when immersing the instruments in the ultrasonic cleaner, make sure that the instruments do not touch each other.
3. Make sure that debris is not visible.
   - Products that are fractured or transformed must be discarded.
   - One should follow the recommendations for the level of concentration or the length of time provided by the manufacturer.
   - The antiseptic solution must not include aldehyde, di- or tri-ethanolamines components to control the corrosion.
4. After cleaning, the products must be rinsed with distilled water or deionized water for at least a minute. If the antiseptic solution contains corrosion inhibitor, rinsing before placing in the sterilizer is recommended.
5. To prevent corrosion or water stain on the instruments, completely dry with a dryer or filtered compressed air
6. To prevent corrosion, decrease in sterilizing power, and contamination, antiseptic must be supplemented every day.

Caution

If the instruments are not properly rinsed, residue is left behind, or not properly dried, the sterilization process might discolor or corrode the instruments, and therefore the whole process
must be repeated.

Caution

Corrosion may start if debris such as blood stain or bone residue is not completely removed. They must be cleansed right after use and the debris must be completely removed when cleaning.

Check

Check on the instruments for faults (fracture, transformation or corrosion). If necessary, assemble the instruments.

Contaminated instruments must be cleansed or disinfected. Transformations that may affect the safety, performance or tolerance of the instruments in other words; bent, damaged (fractured or corroded), or faulty products (discoloration of marking area or loss) must be destroyed.

Packaging

1. Check on the dry status of the instruments and pack in the sterilized wrapping paper.
2. On the sterilized wrapping paper, attach a direction tape to check the date of sterilization. Check the expiration date on the sterilized wrapping paper. Wrapping paper must be able to withstand up to 141°C that coincides with the EN ISO 11607.

Pasteurization

1. The product is packaged cleaned and sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process at a temperature of steam sterilizer at 132°C for 4 minutes Then dry for 20 minutes with a validated cycle according to the standard ISO 176651 following the auto¬clave manufacturer instructions.

2. Instruments and plastic components must be sterilized according to their packaging label.

- Sterilizer must coincide with the requirements of EN 13060 and EN285.
- Sterilization process must regard the ISO 11607.
- Follow the sterilization process and maintenance process of the sterilizer provided by the manufacturer.
- Eciency management
  (proper packaging, no humidity level and sterilization dashboard).

Caution

- The products must not touch the inner part of the sterilization equipment, and the sterilization degree must be lower than 150°C
- If they were not cleansed, not properly dried, or has been corroded, separate them from the rest or remove the faults.
  (Do not sterilize the corroded instruments togetner with the noncorroded products)
- For sterilization, use only salt-free water or distilled water as the solution.
  (Do not use tap water)
- Check if the instruments are fully dried and do not leave them in a place with high moisture.

Storage

Instruments must be stored in a sterilized container in a dry and clean environment. If the packaging is opened or damaged, the instruments' sterilization status cannot be guaranteed

LABELING SYMBOLS

Symbols may be used on some international package labeling for easy identification.

LOT	Batch code
	Date of manufacture
	Non-Sterile
REF	Catalogue number
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use
	Do not use if package is damaged
Rx Only	Prescription only

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