

INSTRUCTIONS FOR USE FOR SURGICAL INSTRUMENTS

CAUTION

READ THE SPECIFIC IMPLANT-PROSTHETIC LOADING PROTOCOL CAREFULLY BEFORE USING THE PRODUCT

MATERIALS: The drills and instruments of the 3DIEMME surgical kits are made of stainless steel for surgical instruments AISI 420B, 4197 and 17-4 PH (according to ASTM F899 standard "Standard Specification for Wrought Stainless Steels for Surgical Instruments").

INTENDED USE: Surgical instruments suitable for the creation of the implant site for the insertion of a dental implant. **The drills must be used ONLY in GUIDED SURGERY interventions**, for the reason that the length of the drills is designed considering the presence and thickness of the surgical template.

WARNINGS: The use, manipulation and clinical application of the 3DIEMME surgical kit instruments must be performed exclusively by qualified doctors, maxillofacial surgeons, dentists and implantologists, with the necessary qualification according to the legislation in force in each Country.

- Work with plenty of irrigation of physiological precooled solution to avoid overheating and consequent bone necrosis and to maintain a perfect visibility of the operating field.
- The surgical alveolus drilling system is sequential, and each drill has a laser mark of the drill diameter.
- It is recommended to use the drills on maximum 15 patients and to check thoroughly the cutting part before every use. The use of worn-out drills could compromise the osseointegration process of the implant.

The surgical instruments are supplied NON-STERILE and MUST BE STERILISED BEFORE USE. Using or reusing a surgical instrument not adequately cleaned and sterilised exposes doctors, operators and patients to serious risk of infection and cross-infection.

CLEANING AND STERILISATION: The entire cleaning and sterilisation process of the instruments must be carried out by qualified personnel under the supervision of the implantologist, using autoclaves in perfect operating condition and periodically overhauled, to ensure correct sterilisation.

The instruments used in the surgical operation must always be disinfected before cleaning.

1- Clean the blood remains, secretions and bone particles immediately from the surgical instruments, the surgical tray and the drills. It is necessary not to let them adhere in order to facilitate the following cleaning. Leave everything to soak in a container with a special cleaning solution for surgical instruments (detergent product with trienzymatic formula: Protease, Lipiasis, Amylase, with bactericidal properties, active on BMR, Yeasticide, active according EN 14476 on PRV, BVDV, Herpes Virus, Vaccinia Virus, HIV-1. Effective on all enveloped viruses). to avoid the deposit of blood and tissues residues.

2- Thoroughly rinse all the material with tap water for at least 3 minutes and brush in case it is necessary, with a soft bristle brush, to remove residues and remains of visible bone fragments. Pay special attention to the sharp edges of surgical drills to avoid minor injuries.

3- Place all the material in an ultrasonic bath for at least 5 minutes. Place the drills individually in the bath to prevent the contact between one drill and the other ruining the cutting edge.

4- Rinse all the material again for at least one minute with tap water, then individually dry the instruments and observe meticulously if they have any residue or bone fragment and if so, repeat the previous steps again until all the instruments, the surgical tray and the drills are totally clean.

5- Wash all the material with ethyl alcohol to remove the remains of soap, as well as the minerals that may have left the water, thus avoiding stains or premature corrosion of the instruments and drills.

6- Carefully dry the material and place it properly on the surgical tray before sterilising it.

All new 3DIEMME instruments and surgical accessories are supplied non-sterile and must be removed from their original packaging for cleaning and sterilisation before their first use.

1 - Place all the instruments on a surgical tray and this latter inside the surgical box and close it properly.

2 - Wrap the surgical box in a double bag for autoclaving.

3 - Sterilise in a steam autoclave according to the autoclave manufacturer's specifications (minimum 20 minutes at temperatures between 132 and 135°C).

CAUTION

• The sterilization cycles lead to a progressive deterioration of the surgical instruments, so it is necessary to periodically overhaul all the instruments to check their perfect state (including unused instruments).

- Be sure to disassemble the torque wrench and ratchets correctly and clean before sterilising them once the surgery is complete.
 - Check, before each use, the proper functioning of each instrument that must be used, replacing all the instruments that are in a bad condition.
- The instruments must be disinfected before their disposal.
- Follow the manufacturer's instructions regarding cleaning, maintenance and sterilisation of the instruments.
 - Do not remove the surgical box from the autoclave until the drying cycle is complete.

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