GIESSE DENTAL IMPLANTS

ACCESSORIES CE 1936

INSTRUCTIONS FOR USE

16016 COGOLETO (GE) VIA Maluea, 3 PAD. 18
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sales@giessetechnology.it www.giessetechnology.it

Warnings

1: The use of the device is limited to medical personnel only, specially trained for dental implantology such as specialist surgeons or licensed dentists.

2: The device, at the end of its life cycle, must be disposed of in accordance with the legal requirements in force in the country of use.

3: Cleaning, disinfection and sterilization of these devices are recommended, before each use.

Description

Medical devices for dental use, used for the preparation of the implant hole. The use is therefore the responsibility of qualified and specialized personnel.

Indications for Use

Pilot drill
Cylindrical geometry shaped, used, for all implant diameters, always as the first tip for the initial preparation of the implant hole. The insertion depth can be discovered through reference notches.

Drills
Sharp surgical instruments, used for the preparation of the implant hole. They are available in different shapes (cylindrical, conical, tapered, cortical), depending on the phase in which they are to be used and the TWIN line to which they belong.
They are available in diameters and lengths that vary depending on the implant chosen by dentistry.
The insertion depth can be discovered through reference notches.
They can be prepared to be connected to depth stops (stop for drills).
Refer to the surgical sequences that can be requested to the sales office of Giesse Technology Srl.
The consumption of the drills depends on bone density. It is recommended to check the status of the instrument at the end of each use.
Drills are recommended for up to 15 uses, an indicative number recommended following tests carried out by the manufacturer and considering the possible effects of the autoclave on the efficiency of cutting cutters in the long term.

Handpiece bone tap
Used to prepare the bone for implant spirals. They are present in some surgical kits related to specific implants of the TWIN line.

The materials used to manufactures the above devices are Titanium grade 5 and/or AISI 630.

Precautions

The product has been designed and manufactured exclusively for the conditions laid down, any other use is to be considered improper and dangerous.
Avoid lever movements that involve risks of fracture of the instruments.
Avoid applying a force that stops the rotation of the instrument. Work intermittently to avoid overheating of the area affected by the cut.

Since the tools are reusable, follow these reccomendations:

- do not use abrasive agents for cleaning and washing before sterilization.
- carry out sterilization:

✓ dry: with "metal cycle" at 160° for 120 minutes (with the tools inserted in two bags of material coupled medical paper - plastic film, suitable for sterilization).

✓ steam: For the United States: seal the device in an envelope* and steam sterilize it at 132°C (237.6°F) for 3 minutes; respect drying times of the devices.
Outside the United States: seal the device in an envelope* and steam sterilize it at 132°-135°C (237.6°F-243°F) for 3 minutes; respect drying times of the devices.
Alternative for United Kingdom: seal the device in an envelope* and steam sterilize it at 134°-135°C (241.2°F-243°F) for 3 minutes; respect drying times of the devices.

* envelope of material coupled medical paper - plastic film, suitable for sterilization.

These devices can be steam sterilized even when placed inside the autoclavable container (kit). In this case, seal the kit (with the tools placed inside in the appropriate holes) in a filter paper sheet suitable for steam sterilization and follow the above indications.

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Where the requirements for steam sterilisation are stricter than those set out above, comply with the requirements laid down by local or national standards in this field.
The dentist is responsible for verifying/controlling his sterilization system.
For good functionality, the accessories must be used exclusively for the preparation of the implant site of Giesse dental implants.
The use of non-sterile devices can cause the onset of infections.

Surgical procedure:

- Make the chosen engraving during the planning of the specific clinical case (all thickness or half thickness).
- Place a surgical mask to transfer the implants in the mouth, where previously established during the preparatory study of the case.
- Start drilling the cortical, with the help of the lanceolate guide tip. Carry out a small hole at the recommended maximum speed, which will allow you to drive the insertion position of the next drills.

It allows you to create an accurate invitation for subsequent steps, defining the correct axial position.
It is important to carry out this phase optimally, as the direction and good location of the plant will be decided here, premises that, combined with the others, are fundamental to achieving long-term success.
Both long and short conical cutters are used at different speeds depending on the bone density available. An alternating light movement is recommended, from top to bottom, to facilitate the discharge of bone chips and allow better cooling. Heat generation should not exceed 39°C. During the surgical technique it is recommended to use the sterile physiological solution for injectable preparations, pre-cooled at a temperature of 4 ° C.
To prepare the ideal channel it is necessary to ream the bone with drills of increasing diameter working at the recommended speed until the use of the last drill. In type III and IV bone it is recommended to use drills of smaller diameter as bone retention is of a smaller degree. Drills are characterized by notches which indicate the depth. It is important that the coils near the neck of the implant are always placed in the cortical.

For the recommended speed, please refer to surgical sequences, which can be requested to the Commercial Office of Giesse Technology Srl.

Guarantees and limitations

GIESSE TECHNOLOGY Srl assures the first purchaser of this GIESSE medical device that the latter has been produced, packaged and tested with reasonable care and that it is free of processing defects and in the materials of use for a period of two years from the date of the first purchase. GIESSE TECHNOLOGY Srl guarantees the product provided that the package is not damaged or improperly handled. Defects resulting from the improper use of this product are not covered by this warranty. In addition, the warranty does not apply in case of improper use and in any case does not comply with the provisions contained in the instructions of use, shocks, falls, exposure to moisture or other conditions also environmental or unsuitable agents, or in any case in which the defect of the product is caused by fact or act that is not attributable, directly or indirectly, to GIESSE TECHNOLOGY Srl , as well as in case of removal, abrasion, alteration or impossibility of identification of the batch number of the product. Under no circumstances will GIESSE TECHNOLOGY Srl be held liable to the buyer for any direct or indirect damage resulting from the manipulation or use of the product, nor for the choice of patients. Liability under this warranty will be limited to the replacement of the defective product or, at the sole discretion of GIESSE TECHNOLOGY Srl, to the reimbursement of the net price paid.

LOT	LOT CODE	REF	CATALOGUE CODE (PRODUCT ITEM NO.)
LATEX	LATEX FREE		WARNING, REFER TO INSTRUCTIONS FOR USE
	MANUFACTURER	CE 1936	CE MARKED MEDICAL DEVICES ACCORDING TO DIRECTIVE DISPOSITIVI 93/42/CEE