Re - usable instruments - Instructions for use

Warnings

1: This device must be used exclusively by medical staff with a specific training in dental implantology, such as specialist surgeons or licensed dentists.

2: At the end of its life cycle, the device must be disposed of in compliance with the applicable laws of the country of use.

3: These devices are placed on the market unsterilized. Non-disposable devices: it is recommended, before each use, cleaning, disinfection and sterilization of instruments. Failure to comply with this warning could cause harm to patients.

Product identification

The devices covered by these instructions are class I instruments: WRENCHES (ratchet wrench - torque wrench), CONNECTIONS (ratchet, contrangle), HANDABLE DRIVERS FOR SCREW, STRAUMANN MOUNTER POSITIONING TOOL, HANDPIECE BONETAP, BOX in Radel (sterilizable container for instruments).
These are reusable, non-sterile medical devices intended for temporary use (continuous duration of less than 60 minutes).
Risk classification as per Directive 93/42/EEC:

- wrenches, connections, handable drivers for screw, Straumann mounter positioning tool, handpiece bonetap: they are class I, according to rule 6 of Annex IX Directive 93/42/EEC;
- box in Radel, steam sterilizable container for instruments: risk class I, according to rule 1 of Annex IX Directive 93/42 / EEC, since it is a non-invasive, reusable medical device, proposed on the market in non-sterile packaging.

Description

These medical devices, used for the preparation of implant - prosthetic work, are reusable and offered in non-sterile packaging.

Wrenches: available in two models, ratchet and torque.
Torque wrenches show incisions of the different torque scale: 15, 20, 25, 30, 35 Ncm.
Depending on the dental device to be implanted, choose and fix one of the measure by screwing the device till the incision. When the torque strength is reached, wrench head springs.
In any case, with dental implants do not force over than 35 Ncm torque and with screws over than 20-25 Ncm. Excessive torque may weaken screws and the entire implant.
Made of AISI 630.

Connections: they are screwdrivers, manual drivers, available in different lengths and sizes depending on whether they should be used with implants, screws, abutments and so as not to come into contrast with any adjacent teeth. They can be connected to the contrangle equipment at the specialist's study. Made of AISI 630.

Straumann mounter positioning tool: manual tool made of AISI 630.

Handpiece bonetap: sharp tool manufactured in AISI 630 or Titanium grade 5.

Box in Radel: autoclavable container equipped with lid and appropriate housings (holes) and supports (in biocompatible silicone) for surgical instruments.

It's strongly recommended the use of surgical gloves when operating with dental medical devices, in order to avoid contaminations.
Each instrument has its own label complete with code, production lot, name of the device and measures when necessary.
In case of order of the device as part of a surgical kit, the kit itself is labeled.

Intended use

Wrenches: perform tightening functions and are available in two models, ratchet and torque.

Connections: they are screwdrivers, handable drivers, having the function of tightening cap screws, retention and healing screws.

Straumann mounter positioning tool: manual device to keep the mounters of the systems in a firm position during the unscrewing of the tightening screws, in order to avoid unscrewing / loosening of the systems themselves during the removal of the screws from the mounters.

Handpiece bonetap: it is used to prepare the bone for the housing of implant threads. It is manual, especially used with very compact or cortical bone.

All instruments available in different shape and lengths: always verify features and availability on catalogue or directly with GiEsse Sales Dept.
Generally, avoid lever movements which can cause device breaks and, therefore, damages to patients.
Ratchet connection and handpiece driver enable to pick implant (and / or screw) directly from inner couvette and move it inside oral cavity, avoiding fall risk inside the mouth. Same result when moving a screw.
Do check instruments with regularity and replace those which have lost their mechanical features to firmly clamp devices and /or to thread / work properly.

Box in Radel: container with a lid used to house surgical instruments and facilitate their storage and steam sterilization.

Contraindications

These devices are contraindicated in:

- ✓ patients clinically unfit to undergo an oral surgical procedure
- ✓ patients with contraindications for treatment with implants or prosthetic components Giesse Technology Srl (see the Instructions for Use of implants and components)
- ✓ patients with allergies or hypersensitivity to Titanium Grade 5 and / or AISI 630.

Important indications

- ⇨ It is advisable to sterilize these instruments before use, according to the indications in the "Sterilization" section.
- ⇨ Each device is complete with alpha-numeric batch of manufacture: it is important to store this data to ensure the traceability of the device for the duration of its use.
- ⇨ For the success of the implant treatment, collaboration between dental technician and dental doctor is necessary.
- ⇨ It is also necessary that compatible Giesse Technology devices are used, in order to avoid connection problems.
- ⇨ It is essential to periodically check the state of conservation of instruments.
- ⇨ Instruments have been designed and manufactured to be used under foreseen conditions: any other different use is to be considered improper and dangerous.

Sterilization

Being reusable, it is strongly recommended as follows:

- do not use abrasive tools to clean and wash, before sterilization
- sterilize.

Medical devices described in this document can be sterilized:

- DRY HEAT - insert medical devices in two envelopes of coupled material medical paper - plastic film and sterilize as follows: time 2 hours, temperature 160 ° C ± 5 ° C
- STEAM - insert medical devices in an envelope of coupled material medical paper - plastic film suitable for sterilization OR insert medical devices inside the autoclavable box and enclose the box in a sheet of filter paper suitable for steam sterilization. Proceed according to this mode: time 3 minutes, 132°C ±3°C, pressure 2 bar (or time 3 minutes, 135°C ±3°C pressure 2 bar).

Make sure to comply with device drying time.
Whereas steam sterilization stricter requirements are foreseen, local or national rules must be followed.
Odontologist should verify his own sterilization system and is responsible for it.
Non sterilized devices use may cause infections.

Intended users and patient groups

Professional (non-lay) users: dental professionals.

Patients: subjects of a dental implantology treatment.

Clinical benefits and unwanted side effects

Clinical benefits: the devices covered by these Instructions for Use are used to make an implant system, therefore the final advantage is the replacement of missing teeth.

Unwanted side effects: those related to invasive treatment by dental implantation. See the instructions for use of implants and prosthetic components.

Warning about serious accidents

If, during the use of this device or in conjunction with its use, a serious accident occurs, it must be reported to the manufacturer Giesse Technology Srl and to the national authority in charge. The manufacturer's contact details are published in www.giessetechnology.it, as well as at the bottom of these instructions for use.

Preservation

Store these devices in the manufacturer's original packaging, complete with the label with traceability data, in a dry, clean place protected from the sun's rays.

Guarantees and limits

GIESSE TECHNOLOGY Srl guarantees to the direct purchaser of this device that this product is manufactured, packaged and tested with reasonable accuracy, that it is free of manufacturing defects, and that the materials used are flawless. This is guaranteed for a period of two years from the date of first purchase. This warranty is void if the product is repaired, altered, modified or improperly stored, installed or maintained. The warranty does not cover any defects due to improper use. The warranty does not cover improper use, failure to comply with the instructions, impacts, drops, exposure to moisture or to any other improper environmental conditions or agents, as well as any other defects caused by events or actions that cannot be, either directly or indirectly, ascribed to GIESSE TECHNOLOGY Srl. Removal, scraping and alteration of the lot number, or impossibility to identify it, will void the warranty. Under no circumstances, will GIESSE TECHNOLOGY Srl be held liable by the purchaser for any direct or indirect damages, either deriving from handling or use of the product, or resulting from patient selection. Liability, as per this warranty, shall be limited to the replacement of faulty products, or - at the sole discretion of GIESSE TECHNOLOGY Srl - to the refund of the net price paid

Manufacturer

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	Batch Code		Article number
	Do not use if the packaging is not intact		Warning, Consult Instructions for Use
	Manufacturer		Class I medical devices according to 93/42/CEE Directive
	Device to be sold to or on the order of a dental professional		