Instruments Risk Class I for mechanical use

Instructions for Use

⚠ Warning

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

2: Do not use if the packaging is not intact.

3: Instruments are placed on the market in non-sterile status.

Product identification

The devices covered by these instructions are class I instruments: laboratory analogs and impression transfers.
They are tools used for the preparation of implant - prosthetic work.
Transfer: When used in the oral cavity, their duration of use is transient (continuous use for less than 60 minutes). They are class I medical devices according to rule 5 Annex VIII Regulation EU MDR 745/2017.
Analog: They are class I medical devices according to rule 1 Annex VIII Regulation UE MDR 745/2017.

Product description

Lab Analog: it is used to reproduce, in laboratory models, the exact position of the implant connection transferred by the transfers. It is made of Ti Gr 5 material. Does not come into contact with the patient. Disposable.

Impression Transfer: they facilitate the transfer of an intra- oral position of an implant or an abutment from the patient's arch to the relative position on a model in the dental laboratory, to support the realization of an implant rehabilitation. Transfer screw included. Made of Ti Gr 5 material. Disposable.

The summary of the devices available and the related compatible systems is present in the catalog in force: each plant line includes the class I instruments to be used, compatible by type of connection and diameter, the instruments (such as screwdrivers, ratchets, keys, etc.), the prosthetic components (straight, inclined, ball stumps, etc.) and the surgical kit (cutters , lances, tappers, stop cutters, shoulder trainers, etc.).

When handling these instruments, it is recommended the use of surgical gloves for individual protection from contamination.
Each instrument travels with a label indicating its code, denomination, color code (if any) and the pictograms listed below.

Intended use

Transfer
It is used to transfer the exact position of the implant itself in terms of inclination and height in order to allow the laboratory to carry out the implant - prosthetic work.

Analog
It is used to replicate an implant on a plaster model for the construction of the prosthesis in the laboratory.
Does not come into contact with the patient.

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.

Important indications

- ⇨ 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 the instruments used with analogues and transfers.
- ⇨ Due to the small size of the transfer, pay the utmost attention to prevent it from being ingested or aspirated by the patient.

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		CE marked Class I medical devices
	Device to be sold to or on the order of a dental professional		Disposable