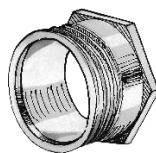


## INSTRUCTIONS FOR USE

Rev. 03 – March 2024

EN



RealGUIDE Sleeve is a metal ring that is manually inserted into a 3D printed surgical guide, specifically designed for a Patient and based on the Doctor's project made in RealGUIDE software. The device is intended for all patients who need implant-prosthetic intervention both for totally edentulous patients and for patients with partial edentulism.

### Materials

RealGUIDE Sleeves are made of stainless steel KLEINOX 4598 or in Titan grade 5 TiAl6V4 ELI.

### Intended Use

RealGUIDE Sleeves are intended to:

- Drive in depth and inclination the surgical drills to prepare the bone for the dental implant insertion;
- Drive in depth, inclination and phase the implant mounts, connected to the implants through a fixation screw, so that the dental implants, virtually placed in the software, are transferred correctly into the Patient's mouth;
- Drive in depth and inclination the eventual fixation tools used by the surgeon to keep the surgical guide in position in case of totally edentulous patients.

### Storage

The goods are sent in a protective packaging in order to prevent damage being caused during storage. Store the products at room temperature.

### Cleaning and disinfection Instructions

Once inserted in the surgical guide, sleeves are cleaned together with the guide.

### Methods for Use













Glue the sleeve (**check the sleeve compatibility with the planned implant before performing surgery**) in the surgical guide hole paying attention to the profile orientation (if available).

### Warnings

- RealGUIDE Sleeves are supplied non-sterile and must be cleaned before use (see Cleaning Instructions). Using a surgical instrument not adequately cleaned exposes doctors, operators and patients to serious risk of infection and cross-infection.
- This product is for single use and doesn't need maintenance. In fact, the use of the surgical guide could deform the sleeve's hole (if drills are not inserted on axis with the sleeve).
- The present device must be used only by qualified doctors: maxillofacial surgeons, dentists and implantologists, with the necessary qualification according to the applicable law in each Country.

If any serious incident and/ or complaint occurs using a sleeve, please contact 3DIEMME or your distributor accordingly. Our company will conduct a proper analysis procedure and will report the event when applicable to the competent authority of the Member State in which the user and/or patient is established.

After terminating the procedure, or in case the device needs to be disposed of, it must be treated as biological waste and disposal must follow the clinic's requirements and disposal instructions.

|   |                                  |   |                                 |
|---|----------------------------------|---|---------------------------------|
|  | Caution                          |  | Prescription only (USA market)  |
|  | Consult instructions for use     |  | Batch Code                      |
|  | CE Marking                       |  | Manufacturer                    |
|  | Non-sterile                      |  | Medical Device                  |
|  | Catalogue Number                 |  | Do not reuse                    |
|  | Do not use if package is damaged |  | Swiss Authorised Representative |

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