3DIEMME S.r.l.
Via Risorgimento, 9
22063 Cantù (CO) - Italia
www.3diemme.it
support@3diemme.it
+39 0317073353

INSTRUCTIONS FOR USE

EN

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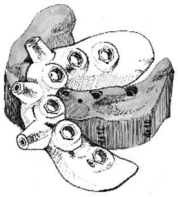

RealGUIDE Surgical Guide is a medical device modelled from a virtual project realized through RealGUIDE software to perform a guided surgery. It is supplied with its working model with the holes correspondent to the implants analogs of the planned implants.
The device is intended for all patients who need implant-prosthetic intervention both for totally edentulous patients and for patients with partial edentulism.

Materials
This surgical guide is made of biocompatible resin (acrylic).
Stainless steel, PEEK or titanium alloy sleeves are used within the surgical guide.

Intended Use
The present surgical guide can be used to drive surgical drills in depth and orientation according to the implant planning realized in RealGUIDE software or to execute osteotomies according to the doctor's planning and to guide the surgical kit that is going to be used.

Storage
The surgical guides should be kept dry and stored in a place that does not expose to direct sunlight.

Cleaning and disinfection Instructions
- If possible, employ ultrasonic cleaning with water and a mild detergent. Wash carefully with saline solution;
- Before surgery, clean the surgical guide using a high-level disinfectant (*) at room-temperature for a maximum time of 20 minutes, according to the product's instructions. Rinse with sterile saline solution and dry with sterile cloths. Do not expose to heat and direct light.

WARNING: the surgical guide could deform if sterilized with heat-based methods.

Methods for Use
- Before surgery, please check the surgical guide fitting on the anatomy model provided with the guide. If possible (except for post-extractive cases), verify the guide stability directly in the patient's mouth. In case of instability, DO NOT use the guide for surgery and contact 3DIEMME.
- It is recommended, during implant planning, to verify the compatibility between the selected sleeves and the surgical kit that you intend to use. Incompatibility between the sleeves and the surgical kit may affect the surgical intervention.
- Before surgery, it is advisable to verify the sleeves stability on the surgical guide and to perform a go/no-go test with the drilling instruments of the surgical kit that will be used.
- During surgery, pay particular attention to the surgical guide positioning since an error at this stage may affect the entire surgical treatment.
- If provided, it is advisable to follow the drill report supplied by 3DIEMME with the surgical guide. In absence of the report, please refer to the instructions of the surgical kit that will be used.

Warnings
- The surgical guide is supplied non-sterile and must be cleaned before use (see Cleaning and disinfection Instructions).
- Heat-based methods for sterilization are not recommended since they could deform the surgical guide.
- 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.
- This product shouldn't be used on those patients for which an implant-prosthetic rehabilitation is not recommended.
- This product is for single use and must be used only for the patient for whom it has been designed. The use of the surgical guide could deform the sleeve's hole (if drills are not inserted on axis with the sleeve) and the surgical intervention could modify the patient's anatomy which could then result incompatible with the designed surgical guide.

If any serious incident and/ or complaint occurs using a surgical guide, 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.

(*) After disinfection with SUPERACETIC 10 detergent, the surgical guide has a total mean microbial load <4.0 x 10^0 (STERIS S.p.A. certificate of analysis n.2402).

⚠	Caution	℞ Only	Prescription only (USA market)	UDI	Unique device identifier
eIFU	Consult instructions for use (electronic)	LOT	Batch Code		Keep away from sunlight
CE	CE Marking		Manufacturer		Keep dry
	Non-sterile	MD	Medical Device		
REF	Catalogue Number		Do not reuse		
	Do not use if package is damaged	CH REP	Swiss Authorised Representative		

CE