Instructions for use

Surgical Guides

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Device description

Personalized surgical guides are instruments intended to guide the surgeon in making cuts and drilling holes at specified angles and locations during osteotomies and, where applicable, subsequent placement of implants. These personalized guides are created based on a pre-operative plan created by a technical physician and a surgeon, based on Computed Tomography (CT) data and/or Magnetic Resonance Imaging (MRI) data of the patient. Surgical guides are made from 3D-printed PA2200 (PA12) and are single-use only.

Surgical Guides are designed to fit the patient's anatomy in a pre-operatively defined position and the guides can be fixed in this position during the procedure. Cutting guides and drilling/positioning guides assist in the correction of bone deformities and ensure precise fixation of bone pieces or implants. Often, multiple surgical guides are used in a single procedure. Surgical Guides are provided in a non-sterile packaging and intended to be cleaned and sterilized before use.

Intended purpose

The 3DMM surgical guides are intended to be used as personalized guides for cutting or drilling at specified positions, angulations, and depths during osteotomies and, where applicable, subsequent placement of implants.

Indications for use

Patients in need of an osteotomy and, where applicable, subsequent implant placement.

Contraindications

- The surgical guides must not be used in surgical procedures where the procedures themselves are contraindicated.
- The surgical guides must not be used for people with a documented or suspected allergy or sensitivity to the material of the device (PA12/nylon).
- The surgical guides must not be used outside the scope of a pre-approved surgical plan.

Instructions for use

The product is delivered by the manufacturer NON-STERILE and needs to be cleaned, disinfected and sterilized before use.

The product should only be used by persons with the required knowledge, training and experience. The user must understand the details in the surgical plan and the product as a whole.

Before use, the product must be checked for completeness and potential damage. The patient number stated on the product label should match the patient number stated in the surgical plan. If these numbers do not match, the product must not be used.

Each surgical guide is prepared during the preoperative surgical plan. The product should only be used for short-term use (<24h) in or on the body. The used surgical guides must be disposed of according to the hospital's specific collection procedure for this type of waste. After the expiry of the product's lifetime, the product must not be used and must be correctly disposed.

Each surgical guide is prepared during preoperative planning and is only to be used in accordance with the surgical plan.

⚠ Warnings and precautions

CLEANING & STERILISATION	*Surgical guides are delivered non-sterile. The user is responsible to follow the instructions for cleaning and sterilizing the product as described in the Instructions for Use.*
CLEANING AGENT	*Do not use any type of alcohol for cleaning the product before sterilization. Only neutral or mild alkaline cleaning and disinfection agents are permitted (pH < 11).*
DISPOSAL	*The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious/sharp items.*
GUIDE IDENTIFICATION	*Surgical guides are not to be used when the patient number on the guide does not match the patient number in the surgical plan. Usage of the wrong surgical guide can pose serious health hazards to the patient. In case of multiple surgical guides in one surgery, the guides are numbered in accordance with the surgical plan.*
HANDLING DEVICE	*Do not use damaged surgical guides. In case of return shipments, either return unused products or provide a decontamination certificate for used products.*
INTRAOPERATIVE PROCEDURE	*Surgical guides must not be modified. In case of damage, breakage or excessive heat during the procedure, all fragments must be removed from the patient body. Rinse the surgical site to remove particles or cool down the site. No excessive pressure should be applied to the surgical guide.*
INSPECTION	*Inspect surgical guides after removal on damage or breakage. Make sure all fragments are removed from the patient body, as remaining fragments can cause serious harm to the patient.*

PACKAGING INTEGRITY	*Surgical guides are not to be used when:* *-the patient number stated on the label and surgical guide does not match the patient number in the surgical plan.* *-the surgical guide is damaged.* *-the primary packaging (inner zip-lock bag) is damaged or opened.* *Contact 3DMM +31(0)852 017 406 in these cases, as soon as possible.*
PLACEMENT	*Surgical guides must be fitted on the specific location and orientation as described in the surgical plan. The guide must be properly secured and stabilized to avoid dislocation and positioning errors during use.*
POTENTIAL ADVERSE EFFECTS	*The following potential adverse effects may occur during the procedure with surgical guides:* *<u>General surgery / procedure related risks</u>* • *Wound infections* • *Wound dehiscence* • *Intermuscular venous thrombosis* • *Hematoma* • *Intraoperative fractures* • *Nerve injury* • *Edema* *<u>(Possible) device related risks</u>* • *Persistent pain* • *Dislocation* • *Bone nonunion / delayed union* • *Malalignment*
PRE-OPERATIVE SCAN	*If the patient anatomy has changed between the creation of the pre-operative scan and the surgery, the guide must not be used.*
REMOVAL	*Surgical guides must always be removed and are not intended for usage longer than 24 hours.*
RETURN SHIPMENTS	*In case of return shipments, only send decontaminated surgical guides.*
SINGLE USE ONLY	*Surgical guides are single use only. Reprocessing or reuse of the surgical guide can cause serious harm to the patient. The product must not be reprocessed or reused.*
STORING CONDITIONS	*Surgical guides must be stored and handled in a dry and clean environment, protected from direct sunlight and in a temperature between 5°C and 30°C.*
SURGICAL PLAN	*Surgical guides must be used in accordance with the surgical plan.*

Potential adverse effects

General surgery / procedure related risks

- Wound infections
- Wound dehiscence
- Intermuscular venous thrombosis
- Hematoma
- Intraoperative fractures
- Nerve injury
- Edema

(Possible) device related risks

- Persistent pain
- Dislocation
- Bone nonunion / delayed union
- Malalignment

Material specification

The product is made of Polyamide 12/nylon.

Packaging

The products are double packed in zip-lock bags in a carton box. Do not use the product if both zip-lock bags are damaged and contact Oceanz 3D Medical Models.

Surgical guides are not to be used when:

- the patient number stated on the label and surgical guide does not match the patient number in the surgical plan.
- the surgical guide is damaged.
- the primary packaging (inner zip-lock bag) is damaged or opened.

Contact Oceanz 3D Medical Models +31(0)852 017 406 in these cases, as soon as possible.

Recommended storage and handling conditions

The products shall be stored and handled with care in an environment that is:

- dry and clean
- protected from direct sunlight
- at a temperature between 5 °C and 30 °C

Disposal

The disposal of this medical product requires no special measures. Be sure to observe all national/local regulations and guidelines when disposing of the packaging material and potentially infectious/sharp items.

Automatic cleaning and disinfection

The cleaning process must be carried out using a validated procedure according to ISO 15883-1 in a washer-disinfector (W/D). The cleaning must be performed with a mild alkalic cleaning agent approved for surgical instruments in accordance with the instructions for use of the supplier.

Load products so that cannulations and holes can drain. The trays must not be overloaded to guarantee optimal rinsing. The following cleaning process has been validated with the cleaning agent Neodisher MediClean Forte® (Dr. Weigert).

Method	Time	Temp.	Medium
Pre-rinsing	1 min	Not temperated	Water
Cleaning	5 min	55 °C	1% detergent
Neutralization	2 min	Not temperated	Water
Rinsing	1 min	Not temperated	Water
Thermal disinfection	5 min	90 °C	RO or DI water
Drying	25 min	100 °C	

RO=Reversed Osmose Water; DI=Demi Water

Caution: Do not use any type of alcohol for cleaning the product before sterilization. Only neutral or mild alkaline cleaning and disinfection agents are permitted (pH < 11).

Do not reclean.

Recleaning of surgical guides can result in the product not being clean, and/or not meeting performance specifications and/or altered material properties.

Inspection

Inspect the product for visible damage. Do not use the product if there is visible damage such as cracks and deformations.

Sterilization

Before starting sterilization of the product, the product must be loaded in a general purpose sterilization tray and packaged in a paper sterilization wrap according to EN 868-2.

The sterilization process must be carried out using the following steam sterilization procedure in a sterilizer which complies with EN 285.

Method	Moist heat sterilization according to ISO 17665-1
Cycle	Fractionated pre-vacuum dynamic air removal
Temperature	134 °C
Exposure Time	3 minutes
Cool Time	30 minutes (minimum, in chamber)
Drying Time	60 minutes (minimum, at room temperature)

Do not resterilize.

Surgical guides are single use only. Reprocessing or reuse of the surgical guide can cause serious harm to the patient. The product must not be reprocessed or reused. Re-sterilization of surgical guides can result in the product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Drying

The integrity of packaging and containers should be visually checked after removal from the sterilizer. Damaged packaging and containers should be treated as non-conforming products. Drying should be carried out in an environment in which particles and microbial contamination are controlled.

Product complaints

If the device ever "malfunctioned" and/or may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the patient number and serial number, your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested. Any serious incident that has occurred about the device should also be reported to the competent authority of the Member State in which the user and/or patient is established.

For questions, please contact Oceanz 3D Medical Models at info@3dmedicalmodels.nl or call +31(0)852 017 406.

End-user information

More information about the product can be found at the website of Oceanz 3D Medical Models: https://www.3dmedicalmodels.nl/
Patient specific information can be found in the surgical plan.

Instructions for use

Further copies of the Instructions for use can be found on the website of Oceanz 3D Medical Models: https://www.3dmedicalmodels.nl/ or requested at info@3dmedicalmodels.nl.

Explanation symbols used in end-user information

The purpose of the used symbols is described below.

 Manufacturer	 Distributor	 Caution
 Use-by Date	 Medical device	 Consult instructions for use
 Do not re-use	 Keep away from sunlight	 Non-sterile
 Do not use if the package is damaged	 Date of manufacture	 Keep dry
 Serial number	 Batch code	 Quantity
 Health care centre or doctor	 Patient number	 Date of medical procedure
 Temperature limit		