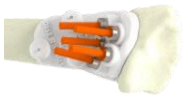
Surgical Guides & Anatomical Models - ENGLISH


Surgical Guide


Surgical Guide


Anatomical Models

Instructions for use

1 Symbols

Symbols may be used on the package label and card. The following table provides the definition of these symbols.

Do not reuse		Do not re-sterilize	
Caution, consult accompanying documents.		Use by date	
Consult instructions for use.		Non- sterile	
Catalogue number		Batch code	
Do not use if package is damaged.		Manufacturer	
Medical Device Name		Keep dry.	
Manufacturing Date		Double sterile barrier system	
Prescription Only		Temperature limits	
Keep away from sunlight.		Humidity Limits	
Quantity of devices		Patient Information Website	
Implant Date		Healthcare institution	
Patient ID number. Product is intended for this patient only.		Patient Name	
Sterilized using low temperature hydrogen peroxide plasma.			

Table 1: Explanation Symbols

2 Description

These instructions for use do not include all of the information necessary for use of the products. Additional, case-specific information can be found in the respective documents (“MedX – Design Steps” "Surgical Guidelines", " Compliance Statement Custom Made Devices"), which are supplied with each case and can be viewed online on the MedX portal in the case overview.

3 Materials

Surgical Guides are made from PA2200 (Polyamide/Nylon 12) and or Ti6Al4V *(Titanium 6 Aluminium 4 Vanadium)*, Anatomical Models are made from PA2200 (Polyamide/ Nylon 12)

4 Indications

A Surgical Guide or a Surgical Guides are intended to be used as a tool to transfer the virtual surgical plan of a bone resection and or drill plan onto the patient’s bone in theatre.

- Preparation of a bone graft
- Resection of bone
- Reduction of a fracture
- Preparation of cut planes in the bone
- Preparation of drill holes for screw fixation
- Temporary *(during surgery)* repositioning of bone parts until final implant fixation

Anatomical Models are intended to be used to visualize the patient’s bony anatomy before or during surgery. But a not allowed to be within the sterile circle in the operation theatre.

4.1 Contraindications

Surgical Guides are contraindicated under any of the following conditions:

- Active infection and sepsis
- Degenerative bone disease which would render the device or the treatment unjustifiable
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to usage.
- Patients with limited blood supply, insufficient quantity or quality of bone, insufficient soft tissue quantity or quality, or latent infection
- Distant foci of infection which can spread to the surgical site
- Uncooperative patients or patients with neurologic or psychiatric/psychologic dysfunction who are incapable or unwilling to follow postoperative instructions.

4.2 Instructions for clinical use

- Read these instructions for use in their entirety before beginning surgery. Also read the individual surgery guidelines that accompany each specific case.
- Confirm the Xilloc Surgical Guide product label for: patient ID and expiration date.
- Make the patient aware of the Instructions For Patient on the patient information website. www.xilloc.com/ifp.
- Confirm the Xilloc Surgical Guides intact double pouch sterility barrier before beginning surgery or opening the Xilloc Surgical Guide packaging.

- A Surgical Guide or a Surgical Guides are intended to be used as a tool to transfer the digital bone resection and drill plan onto the patient's bone in theatre. In case an Xilloc Implant that has been delivered at the same time, read their Instructions For Use before starting the operation. The Surgical Guide must never be implanted.
- The Xilloc Surgical Guide is manufactured to fit the patient's resection site. Fixation locations may be provided to temporarily fixate the Surgical Guide to the bone. We recommend flat head Ø 2.0 mm *(max Ø2.4 mm rescue screw)* titanium screws.
- Drill sleeves in the Surgical Guides are for the drill sizes defined in the Surgical Guidelines and or MedX.
- Cutting Slots in the Surgical Guides are for the cutters defined in the Surgical Guidelines and or MedX.
- Check if fixation screws are required and provided.
- Open the sterile package containing the Surgical Guide corresponding to the procedure being performed.
- It is not recommended to drill in or adapt the Surgical Guide during surgery. But if the shape of the Surgical Guide must be adjusted or an additional hole is required, use sterile "cutting"/ "drilling" instruments, such as rongeurs or nippers. Use of high-speed rotating instruments should be used with caution to avoid overheating the polymer. After shaping or sizing, rinse the Surgical Guide in sterile saline solution.
- In case a Surgical Guide is used together with an Implant. Fill in the required details on the Implant Card en provide this to the patient.

4.3 Possible adverse effects and complications

- Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularisation, or infection can cause the device to loosen.
- Sensitivity to device materials, or allergic reaction to a foreign body.
- Inadequate healing.
- Generation of particle debris during surgical procedure
- Inappropriate use of screws or drill bits

Apart from these adverse effects there are always possible complications associated with any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the Surgical Guide. If an adverse effect occurs, healthcare professionals and/or the patient are obligated by law to inform the manufacturer and patient's home country's National Healthcare authority/Medicine Agency.

- While rare, temporary contact of foreign materials during surgery may result in sensitivity reactions.
- Peripheral neuropathies have been reported in conjunction with surgical procedures involving usage of various types of Surgical Guides. Subclinical nerve damage occurs more frequently, usually as a result of surgical exposure/trauma.
- Infection can lead to failure of the procedure.

5 Warnings

- The surgeon must be thoroughly knowledgeable not only of the medical and surgical aspects of the Surgical Guides.
- Correct placement of the Surgical Guides is of great importance. Improper placement may render the surgery unsuccessful.
- Correct handling of the Surgical Guides is extremely important. The Surgical Guides should not be shaped or bent. Bending, scratches and notches add to the risk of particle release and Surgical Guides breakage.
- The manufacturer does not recommend cutting of the Surgical Guides, because this may result in the Surgical Guides breaking and particles being released from the Surgical Guides.
- Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful treatment. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure since these patients may ignore instructions and activity restrictions.
- The patient is to be made aware and warned of general surgical risks, complications, possible adverse effects, and to follow the instructions of the treating physician.
- The patient is to be advised of the need to come in for regular postoperative follow-up examinations for as long as they are necessary to ensure recovery.

THIS SURGICAL GUIDE HAS BEEN DESIGNED TO FIT THE BONE EXISTING AT THE TIME OF THE CT SCAN AND SURGICAL GUIDE FABRICATION. CHANGES IN THE PATIENT'S ANATOMY OCCURRING AFTER THE CT SCAN AS WELL AS THE USE OF THE SURGICAL GUIDE AFTER SUCH CHANGES MAY RESULT IN A SUBOPTIMAL FIT ONTO THE BONE.

- Improper selection, placement, positioning, and fixation of the Surgical Guide can cause a subsequent undesirable result. The surgeon is to be familiar with the Surgical Guide and the surgical procedure prior to performing surgery.
- To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
- Do not reuse Surgical Guides. While the device may appear clean and undamaged, a used Surgical Guide may be contaminated as the material is highly absorbent. Discard any unused portion.

Caution: Law (EU) restricts this device to sale by or on the order of a physician.

6 Precautions

Do not reuse Surgical Guides. While a Surgical Guide may appear undamaged, previous stress may have created imperfections that would reduce the service life of the Surgical Guide. Do not treat patients with Surgical Guides that have been even momentarily placed in a different patient. Use a Xilloc Surgical Guides only on the patient, for whom it

is designed. Pay attention to the correct positioning of the Surgical Guide according to preoperative planning.

Instruments are available for each Surgical Guide system to aid in the accurate placement, cutting and drilling. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. It is recommended that all instruments be regularly inspected for wear and disfigurement.

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

7 Accessories

- 3D-models of patient's bone are called Anatomical Models. These can be used as tools to plan the surgery. The Anatomical Models are a non-sterile instrument.
- If requested Xilloc can sell or supply a loaner fixation kit.
- The screwdriver, which has been designed, for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved.
- Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the Surgical Guide or screwdriver.
- Excessive torque can cause the screw to fracture.
- Twist drills are labelled for single use only.
- When using twist drills, appropriate cooling is necessary to aid in the prevention of injury to bone, skin and tissue. It should be combined with low-speed drilling to prevent risks of bone demineralization, possible loosening of the bone screw and injury to the patient.
- The manufacturer's instructions for the hand piece used with the twist drill must be followed. The manufacturer of the hand piece may recommend proper speeds to avoid failures such as breakage of the twist drill.
- Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
- Breakage of twist drills may result in injury to the patient, the user, or third party.
- Drill guides and cannulas are provided to assist the operating surgeon in guiding the twist drill and to aid in the protection of the patient, user and third parties. Drill guides and cannulas should be properly irrigated to prevent risks of injury to the patient.

8 Sterility

- The Xilloc Surgical Guide can be supplied STERILE or NON-STERILE.
- Do not use the product if the sterile packaging is damaged. The Xilloc Surgical Guide is sterilised using VH2O2.
- The Anatomical Model is supplied NON-STERILE. Do not use the Anatomical Model within the sterile OR circle.

9 MR

Not Applicable.

10 Storage

Do not use if this product has not been stored in accordance with the following storage conditions:

- Temperature: 15–28 °C
- Humidity: 0–80% relative humidity, non-condensing

11 Manufacturer

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