

Xilloc Surgical Guides & Anatomical Models

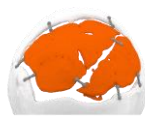
Instructions for use – ENGLISH



Surgical Guide



Anatomical Models



1 Device Description

The Xilloc Surgical Guides are Surgically invasive devices intended for transient use (<60 min).

Anatomical Models are non-invasive devices and are intended for anatomy visualization during surgery.

The Surgical Guides & Anatomical Models are designed and constructed with specific characteristics (e.g., size, shape, material) as prescribed by a healthcare provider for a specified patient. It is typically manufactured from a three-dimensional (3-D) CAD model based on computed tomography (CT) images and manufactured from Polyamide. The Surgical Guides can be made from multiple pieces, which can be fixated with fixation screws in pre-positioned fixation holes.

The principle of operation is to remove a tumor and or transplant an autograft. The Surgical Guides may be fixated with the use of disposable screws.

2 Clinical benefits

The following performance/benefits to the patient are intended to be achieved with the Surgical Guides & Anatomical Models:

- The Surgical Guides are manufactured to fit the patient's anatomy and allows for accurate pre drilling of screw fixation holes and or resecting bone parts.
- The Surgical Guides & Anatomical Models are transferring the virtual surgical plan onto the operation room and anatomy of the patient.
- A vascularized or non-vascularized bone graft may be applied for a primary reconstruction improving clinical outcome of the procedure.
- Anatomical Models are intended for anatomy visualization during surgery to enable proper placement of Surgical Guides and or custom-made implants.

3 Intended purpose

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.

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.

It is intended to be used by surgeons with good knowledge of the specific operative technique, in a standard operating environment.

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.

5 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.

6 Instructions for Use

Instruction for use can be found in the Surgical Technique.

7 Potential adverse effects

As with any major surgical procedure, there are risks involved in orthopedic surgery. Potential risks identified with the use of this system include, but are not limited to:

- 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
- Infection can lead to failure of the procedure.

Intraoperative and early postoperative complications can include:

- dehiscence of the incision,
- infection.

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.

8 Warnings and precautions

Intended users

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.

Improper selection, placement, positioning, and fixation of the Surgical Guide can cause a subsequent undesirable result. The surgeon must be thoroughly knowledgeable not only of the medical and surgical aspects of the Surgical Guide but also the mechanical properties of the Surgical Guide as well as must have read and understood the surgical technique.

Patient education

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.

Make the patient aware of the Instructions For Patient on the patient information website. www.xilloc.com/ifp.

Packaging

Check for each component that the primary packaging is undamaged by visual inspection for breaches of packaging. The packaging should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used.

During the surgical procedure keep components in their sterile package as long as possible until the moment they are required in the surgical implantation step. Components are individually packed and supplied in such manner that this is feasible.

Use by date and Patient ID

Check for if the use-by-date is not expired and if the correct patient ID is present.

Fixation screws

Check if the correct fixation screws are available. Screws are not included and have to be provided by the hospital.

Single use

Do not reuse Surgical Guides & Anatomical Models. Do not treat patients with Surgical Guides that have been even momentarily placed in a different patient. Use Xilloc Surgical Guides & Anatomical Models only on the patient,

for whom it is designed. Pay attention to the correct positioning of the Surgical Guides according to preoperative planning.

Surgical Guides fit

This device has been designed to fit the bone/tumor/defect 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 Guides after such changes may result in a suboptimal fit within the defect.

Surgical Guides handling

Correct handling of the Surgical Guide is extremely important. The Surgical Guide should not be shaped or bent. Bending, scratches and notches add to the risk of particle release and Surgical Guide breakage.

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.

Surgical Guides placement

Correct placement of the Surgical Guide is of great importance. Improper placement may harm surrounding tissues.

Perpendicular fixation

Use the perpendicular fixations holes in order to fixate the Surgical Guides to the bone. The manufacturer does not recommend drilling additional holes to these edges or anywhere in the Surgical Guide.

Powered instruments

Using a powered instrument for drilling an irrigation while drilling is mandatory.

Wound closure

To prevent dehiscence at the incision site, a firm primary closure of the incision is required.

Instrument wear

Instruments are available for each Surgical Guide system to aid in the accurate temporary Surgical Guide fixation onto the patient's anatomy. 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.

Disposal

Dispose all components and materials according local regulations.

9 Material specifications

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)

10 Packaging

Packages for each of the components should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used and should be returned to Xilloc.

11 Recommended storage and handling conditions

The products shall be stored and handled with care. The primary and secondary packaging shall remain intact at all times. The products shall be stored and handled in an environment that is:

- dry and clean
- protected from direct sunlight
- not in close proximity of heat sources.

12 Combination devices

- The Xilloc Surgical Guides & Anatomical Models can be complementary to custom-made implant. In case of a custom-made implant that has been delivered at the same time, read their Instructions For Use before starting the operation.

13 Sterilization

The Xilloc Surgical Guides & Anatomical Models are supplied **STERILE**.

Do not use the Xilloc Surgical Guides & Anatomical Models if the sterile packaging is damaged. Xilloc Surgical Guides & Anatomical Models are sterilized using VH2O2.

Do not re-sterilize the Xilloc Surgical Guides & Anatomical Models.

14 Product complaints

If the Surgical Guide or Anatomical Model 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 component(s) name and number, lot number(s), 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 in relation to the device should also be reported to the competent authority of the Member State in which the user and/or patient is established.

15 MR safety






















The Xilloc Surgical Guides & Anatomical Models have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Xilloc Mandibular Reconstruction in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Fixation method has not been taken into account, used screws can contain additional MR safety information.

In all cases, the Healthcare Professional is responsible for the MR conditions, MR imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

16 Explanation of non-harmonized symbols used in end-user information

The following symbols are not described in harmonized standards or Common Specifications and therefore their purpose is described below.

	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		Keep dry.
	Manufacturing Date		Double sterile barrier system
	MR Safe		Patient Information Website
	Keep away from sunlight.		Health care centre or doctor
	Quantity of devices		Patient Identification
			Patient number
			Sterilized using vaporized hydrogen peroxide

17 Manufacturer

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