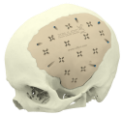
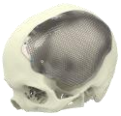
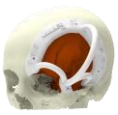
Cranial Reconstructions - ENGLISH



PEEK



Titanium



1 Stage

Instructions for use

1 Symbols

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

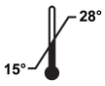
	Do not reuse		Do not re-sterilize
	Caution, consult accompanying documents.		Use by date
	Consult instructions for use.		Non- sterile
	Catalogue number		Batch code
	Do not use if package is damaged.		Manufacturer
	Medical Device Name		Keep dry.
	Manufacturing Date		Double sterile barrier system
	Prescription 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.

Cranial Reconstructions are intended for bone replacement or augmentation for treatment of patients whose present conditions, in the surgeon’s opinion, cannot be treated satisfactorily using other treatment methods. Cranial Reconstructions are used for augmenting and contouring bone regions during surgery, possibly including reconstruction of orbital floor. The implant is static and does not contain any added factors to enhance bone ingrowth. The implant is surgically implanted and fixed in place with titanium screws. All Xilloc Cranial Reconstruction have been designed based on the recipe of the operating surgeon and have been approved by the operating surgeon prior to manufacture of the Cranial Implant.

3 Materials

Cranial Reconstructions are made from either PEEK *(Poly Ether Ether Ketone)* and or Ti6Al4V *(Titanium 6 Aluminium 4 Vanadium)*.

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

Cranial Reconstructions are intended for reconstruction and augmentation in craniofacial procedures intended to fill voids or defects in bone resulting from; disease, traumatic injury, surgical trauma, neoplasm resection, infected craniotomy flaps or neurosurgical operations. These devices can be used in aesthetic reconstructive procedures where augmentation or change in bony contours is desired. It is indicated for non-load bearing applications for all patient age groups, and for use with an intact dura, with or without duraplasty.

4.1 Contraindications

This device is 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 implantation
- 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 implant 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 Cranial Reconstruction 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 Cranial Reconstruction intact double pouch sterility barrier before beginning surgery or opening the Xilloc Cranial Reconstruction packaging.
- The Xilloc Cranial Reconstruction is manufactured to fit the patient's defect site. InterFix locations are provided as premade screw holes for fixation. In some cases, the implant is designed to exceed the region of the bone defect by 0–15 mm. In order to allow the implant to be fixed over the bone with perpendicular screws, the implant edge is minimum 6 mm. The manufacturer does not recommend drilling additional holes to these edges or anywhere in the implant.
- Check if fixation screws are provided.
- Reconstruction can be made with several implants which overlap each other, but all of them must be fixed to the remaining bone defect edge.
- The fixation screws are installed through the holes at the edges of the implant. We recommend flat head self-drilling 1.5 to 2.0 mm diameter titanium screws for the attachment. The number of screws should be determined by the operating surgeon based on the size and shape of the implant.
- XSuture may be use to tack-up the dura mater form the inside of the implant, and muscle, soft tissue on the outside.
- XSuture fits a curved needle of Ø 4 mm x 0.6 thick to Ø 22 mm x 0.6 thick.
- InterFix, during the VSP the InterFix fixation screws are being scheduled. 7 mm is the minimum length and thickness. 13 -15 mm is the maximum advisable length. Ø2.0 is the recommended screw thickness, with a maximum of Ø2.4 thickness
- Open the sterile package containing the device corresponding to the procedure being performed.
- It is not recommended to drill in or adapt the implant during surgery. But if the shape of the implant 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 implant in sterile saline solution.
- 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.
- Pain, discomfort, abnormal sensation, or palpability due to the presence of the implant.
- Increased fibrous tissue response around the implant.
- Inadequate healing.
- Generation of particle debris during surgical procedure
- Inappropriate use of screws or drill bits
- Hematoma and seroma.

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 implant. 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, implantation of foreign materials may result in sensitivity reactions.
- Peripheral neuropathies have been reported in conjunction with surgical procedures involving implantation of various types of Implants. Subclinical nerve damage occurs more frequently, usually as a result of surgical exposure/trauma.
- Implants can loosen or migrate due to loss of fixation or trauma.
- Infection can lead to failure of the procedure.

Intraoperative and early postoperative complications can include:

- fracture of the implant,
- fracture of bone or soft tissue damage,
- extrusion of the implant,
- dehiscence of the incision,
- prominence or disfigurement at the implant site
- infection.

Late postoperative complications can include:

- fracture of the device due to traumatic injury,
- loosening or migration due to loss of fixation or trauma, and prominence or disfigurement over time at or near the implant site.

5 Warnings

- It is unlikely for the implant to migrate in the treatment of a bone defect. This is because the implant must always be fixed to the cranial bone with screws.
- Implants are subject to repeated stress in use, which can result in fatigue fracture.
- If the healing of a bone is delayed, unsuccessful or incomplete, the implant may migrate.
- Patient-dependent factors such as each patient's activity level and adherence to loading instructions have an effect on the attachment and/or migration of the implant.
- The surgeon must be thoroughly knowledgeable not only of the medical and surgical aspects of the implant but also the mechanical properties of the implants.

- Correct placement of the implant is of great importance. Improper placement may harm surrounding tissues, for example the dura mater. The skin above the implant must be in good condition before surgery and incision above the implant should be avoided.
- Correct handling of the implants is extremely important. The implants should not be shaped or bent. Bending, scratches and notches add to the risk of particle release and implant breakage.
- The manufacturer does not recommend cutting of the Implant, because this may result in the Implant breaking and particles being released from the Implant.
- Implants can loosen, fracture, migrate, or cause pain. If there is need for implant removal, the implants can be removed. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management should follow implant removal.
- 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 fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing or an accident directed to the device.
- 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.

These implants are used for augmenting and contouring bone. They are not intended or designed for full or partial load bearing. Do not use these devices for replacement of bone within articulating surfaces. Patients who engage in contact sports or other activities that risk facial injury are to be warned that facial injury may lead to damage of the implant and a subsequent failure of treatment. The patient is to be warned that the device does not replace normal healthy bone and that traumatic injury could necessitate surgical treatment. The patient must be advised of surgical risks and the possible adverse effects. THIS DEVICE HAS BEEN DESIGNED TO FIT THE DEFECT EXISTING AT THE TIME OF THE CT SCAN AND IMPLANT FABRICATION. CHANGES IN THE PATIENT'S ANATOMY OCCURRING AFTER THE CT SCAN AS WELL AS THE USE OF THE IMPLANT AFTER SUCH CHANGES MAY RESULT IN A SUBOPTIMAL FIT WITHIN THE DEFECT.

- Improper selection, placement, positioning, and fixation of the Implant can cause a subsequent undesirable result. The surgeon is to be familiar with the implant and the surgical procedure prior to performing surgery.
- Implants placed, positioned, and fixated over or near air containing sinuses could result in infection.
- Using a powered instrument, an appropriately sized pilot hole must be placed at least 4mm from the perimeter of the implant before inserting any screw. Irrigation while drilling is recommended.
- To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
- Rapid remodeling of the pediatric skull may cause the skull to change significantly between the time of the CT scan and the time implants are ready. The custom implant may no longer optimally fit the defect.
- Do not reuse Implants. While the device may appear clean and undamaged, a used implant 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 implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient. Use a Xilloc Cranial Reconstruction only on the patient, for whom it is designed. Pay attention to the correct positioning of the Implant according to preoperative planning.

Instruments are available for each implant system to aid in the accurate implantation of internal fixation devices. 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 skull are called Anatomical Models. These can be used as tools to plan the surgery. The Anatomical Models are a non-sterile instrument.
- A 1 stage Surgical Guide or a 1 Stage Complex surgical guides set can be delivered as part of the order, if requested. This can be used as a tool to plan a bone resection the digital bone resection and drill holes plan onto the patient's bone in theatre. In case of a Surgical Guide that has been delivered at the same time, read their Instructions For Use before starting the operation. The Surgical Guide must never be implanted.
- For 1 Stage Complex a template of the implant, the Implant Fitter is delivered as part of the order. The

Implant Fitter can be delivered sterile but must never be implanted.
- 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 implant 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 Cranial Reconstruction implants can be supplied STERILE or NON-STERILE.
- Do not use the products if the sterile packaging is damaged. Xilloc Cranial Reconstructions Implants are sterilised using VH2O2.
- The Xilloc Surgical Guide can be supplied STERILE or NON-STERILE. Do not use the Surgical Guide if the sterile packaging is damaged. The Xilloc Surgical Guide is sterilised using VH2O2.
- The Implant Fitter can be supplied STERILE or NON-STERILE. Do not use the Implant Fitter if the sterile packaging is damaged.
- The Anatomical Model is supplied NON-STERILE. Do not use the Anatomical Model within the sterile OR circle.

9 MR

XILLOC CRANIAL RECONSTRUCTION IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT:

The PEEK Cranial Reconstruction Implant alone is composed of a non-conducting, non-magnetic material containing Poly Ether Ether Ketone (PEEK). Xilloc has rationalized the non-clinical effects based on the scientifically relevant characteristics of the PEEK material in a Magnetic Resonance environment. The PEEK implant is determined to be MR Safe in accordance with EN 62570 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Safe refers to an item that poses no known hazards in all MR environments.

For the Titanium Cranial Reconstruction Implant the effects of the MR environment have not been determined. This device has not been tested for heating or migration in the MR environment.

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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The Netherlands