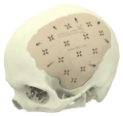
Xilloc Cranial Reconstruction

Instruction for Use - ENGLISH



PEEK

Titanium

1 Device description

The Xilloc Cranial Reconstruction is an implantable device intended for cranial bone replacement or augmentation of the cranium. The implants 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 polyetheretherketone (PEEK) or titanium (Ti). An implant can be made from multiple pieces, which can be fixated with fixation screws in pre-positioned fixation holes. The implant is static and does not contain any added factors to enhance bone ingrowth. The principle of operation is to fill voids or defects in cranial bone by placing cranial reconstructions. The outside of the dura is stitched to the inside of the implant and the implant is fixated with the use of screws.

2 Clinical benefits

The following performance/benefits to the patient are intended to be achieved with the Xilloc Cranial Reconstruction:

- The Xilloc Cranial Reconstruction is manufactured to fit the patient's cranial defect in such a way that no intraoperative adjustments are required and an aesthetically satisfying result is obtained.
- The Xilloc Cranial Reconstruction will result in good aesthetic outcomes.
- The Xilloc Cranial Reconstruction results in cerebral protection, neurologic improvement and improvements in quality of life.
- Use of the Xilloc Cranial Reconstruction results in reduced hospitalization time compared to autologous bone.
- The Xilloc Cranial Reconstruction results in a lower complication rate as compared to autologous bone.

3 Intended purpose

Xilloc Cranial Reconstruction 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 reconstruction, augmenting and contouring bone regions during surgery. It is intended to be used by (neuro-) surgeons with good knowledge of the specific operative technique, in a standard operating environment.

4 Indications

Xilloc 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.

5 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.

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 orthopaedic surgery. Potential risks identified with the use of this system include, but are not limited to:

- Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularisation
- Wound-related complications (e.g., wound dehiscence)
- Infection (superficial, deep, systemic, abscess formation)
- CSF leakage
- Cardio-/vascular related complications (e.g., bleeding, hematoma, middle and posterior cerebral infarction).
- Seizures
- Seroma formation
- Hydrocephalus / pneumocephalus
- Muscle atrophy (e.g., temporal hollowing)
- Reduced vigilance
- Subgaleal air collection

- Step/fissure formation
- CSF shunt complications
- Neurologic complications (e.g., neurologic deficits, dysesthesias)
- Increased cranial pressure
- Pain, discomfort, abnormal sensation, or palpability due to the presence of the implant
- Wrong implantation
- Generation of particle debris during surgical procedure
- Increased fibrous tissue response around the implant
- Implant exposure
- Implant fracture
- Implant migration
- Implant loosening
- Inadequate implant fitting
- Unsatisfactory aesthetic outcome
- Allergic reaction to materials

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 Implant can cause a subsequent undesirable result. 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 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.

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 about surgical risks and the possible adverse effects.

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.

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.

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 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.

Implant fit

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.

Implant handling

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.

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.

Implant placement 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. Implants placed, positioned, and fixated over or near air containing sinuses could result in infection.
Powered instruments Using a powered instrument, an appropriately sized pilot hole must be placed at least 4 mm from the perimeter of the implant before inserting any screw. Irrigation while drilling is recommended.
Tangential or perpendicular fixation 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 extending over the bone has a minimum length of 6 mm. The manufacturer does not recommend drilling additional holes to these edges or anywhere in the implant.
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 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.
Disposal Dispose all components and materials according local regulations.

9 Material specifications

The Xilloc Cranial Reconstruction components are all manufactured from medical grade PEEK (Poly Ether Ether Ketone, ASTM 2026) or Ti6Al4V (Titanium 6 Aluminum 4 Vanadium, ISO 5832-3) .

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

- 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. 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.

13 Sterilization

The Xilloc Cranial Reconstruction implants can be supplied STERILE or NON-STERILE.

Do not use the implant if the sterile packaging is damaged. Xilloc Cranial Reconstructions Implants are sterilized using VH2O2.

NON-STERILE delivered implants need to be sterilized on site using the following procedure:

<u>Cleaning process</u>

Prior to implementation, clean the product with mild detergent (4<pH<10). An automated cleaning process running standard parameters is adequate.

<u>Repacking process</u>

- Wear medical gloves
- Perform packaging in a clean room
- Repack in double sterile barrier system

<u>Packing guidelines</u>

The product must be packed in a suitable double sterile barrier system. The sterile barrier system must meet the following criteria:

- EN 868 and ISO 11607
- Suitable for steam sterilization (steam permeable)
- Temperature resistance to 138°C
  Note: To prevent damaging of the sterile barrier system, place the products with the sharp edge down in a PP sterilization tray

Sterilization accessories and packaging must be appropriate for the content of the package and for the sterilization process.

Apply the accompanying identification labels to the sterilization packaging. The remaining extra label is for your registration purposes.

Use a double sterile barrier system that fits well and make sure the permeable sides are on the same side. Fill the pouches up to 3/4th of their volume, so the sterilization medium can permeate freely during the sterilization process. Seal the first pouch and apply the accompanying identification labels, place it in the second pouch, seal it and also apply the identification labels to this pouch.

Seal process

Use the right combination of temperature and pressure to seal the double sterile barrier system.

Sterilization

Use the following procedures subject to the applicable national requirements:

Fractionated vacuum method with triple fractionation and sufficient product drying

Steam sterilization in accordance with EN 13060 or EN 285 and validated in accordance with ISO 17665-1

Sterilization time and temperature: at least 3 minutes holding time at 134°C

Attention points

- Be careful with the edges of the product, they can be sharp; ensure they do not damage the packaging.
  - The pouches should not tear, nor should fibers detach, as this poses a contamination risk.
    Note: To prevent damaging of the sterile barrier system, place the product with the sharp edge down in a PP sterilization tray.
- Re-sterilization: Before re-sterilizing, contact Xilloc to discuss the options.
- When re-sterilization is required, ensure that the product is:
  - Not damaged
  - Not contaminated
  - Still fits on the defect in the anatomical model

NOTE

The user is responsible for validating the automated cleaning process devices according to the applicable national requirements. Taking into account any differences with regard to the automated cleaning process.

The user is responsible for validating sterilization devices according to the applicable national requirements. Taking into account any differences with regard to sterilization chambers, packaging methods and loading configurations. The same applies if a procedure that differs from our recommendations is used. It is essential that a SAL (Sterility Assurance Level) of 10^{-6} is reached.

14 Product complaints

If the implant 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 Cranial Reconstruction (PEEK and Titanium) has 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 Cranial 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.

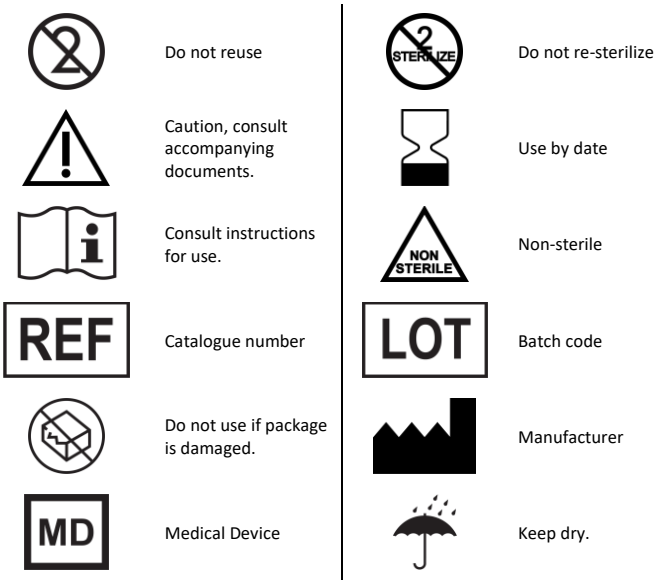
PEEK Cranial Reconstruction Implant is composed of a non-conducting, non-magnetic material containing Polyether ether ketone, based on scientifically relevant characteristics of the PEEK material it has been rationalized that PEEK Cranial Reconstruction poses no known hazards in all MR environments and is considered MR Safe.

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 therefor their purpose is described below.



	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
	Implantation date		Patient number
		Sterilized using vaporized hydrogen peroxide	

17 Manufacturer

Xilloc Medical Int B.V.

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