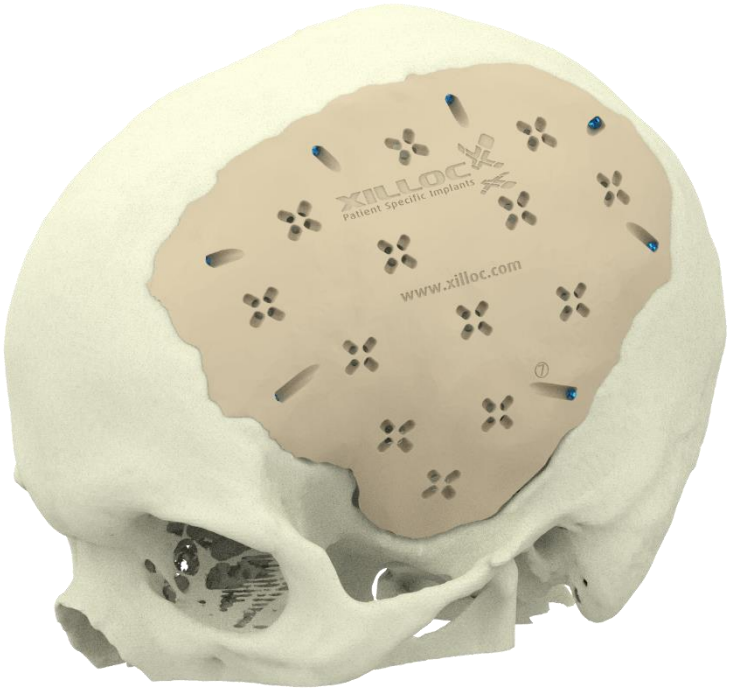
Surgical Technique – Cranial Reconstruction



Manufacturer:

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The information presented in this brochure is intended to demonstrate Xilloc product. Always refer to the package insert, product label and/or user instructions before using any Xilloc product. Surgeons must always rely on their own clinical judgment when deciding which products and techniques to use with their patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Xilloc Implant representative if you have questions about the availability of Xilloc products in your area.

Xilloc Medical - ST - EN - Cranial Reconstruction - V1.0

Surgical Technique – Cranial Reconstruction

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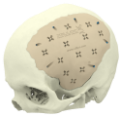
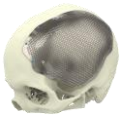
1 Introduction

All Xilloc Cranial Reconstruction products have been designed based on the recipe of the operating surgeon and have been approved by the operating surgeon prior to manufacture of the Xilloc Cranial Reconstruction.



PEEK



Titanium

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

1.1 Product 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.

1.1.1 Features

Xilloc Cranial Reconstruction are surgically implanted and fixed in place with titanium screws. The implant is static and does not contain any added factors to enhance bone ingrowth. Xilloc Cranial Reconstruction can be provided with additional features:

- XSutures: X-shaped suspension holes in the implant to stitch the dura and/or the temporal muscle to the implant.
- InterFix technology: tangential implant fixation method of cranial reconstruction plates

1.2 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.

1.3 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.

2 Indications and contra-indications

2.1 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.

2.2 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.

3 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.
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.

4 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.

5 Procedure overview

	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.

5.1 Packaging inspection

⚠	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.

5.2 Surgical steps

1) The incision is made around the cranial defect (leaving sufficient space between the defect and incision), the scalp is pulled back from the defect by carefully detaching it from the tissues below, and the defect edge is revealed.
2) Cleaning of the defect edge.
3) Open the sterile package containing the device corresponding to the procedure being performed.
4) Fitting of the implant (Figure 1).

⚠	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.

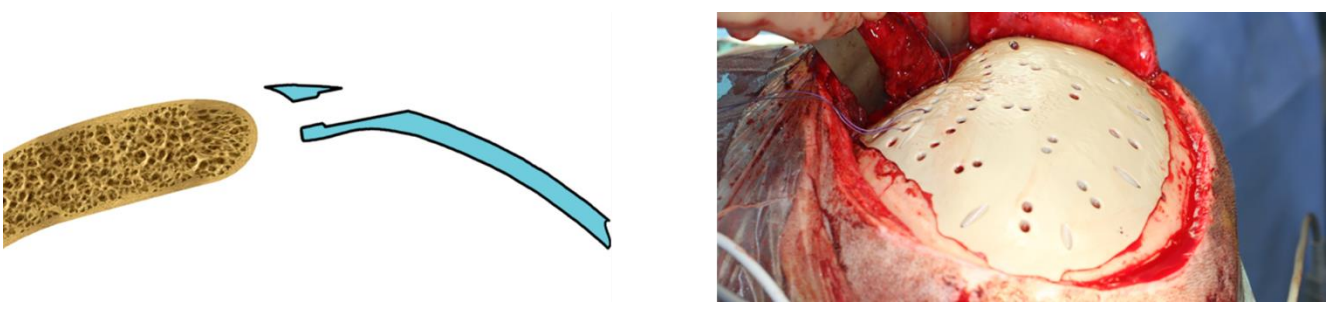


Figure 1: Placement of inlay PEEK implant.

5) Drilling holes in the defect edge through the pre-fabricated InterFix holes (Figure 2).
Note: Drill the correct diameter hole for the screws to be used. Do not drill too deep, just to get through the cortical layer is sufficient.

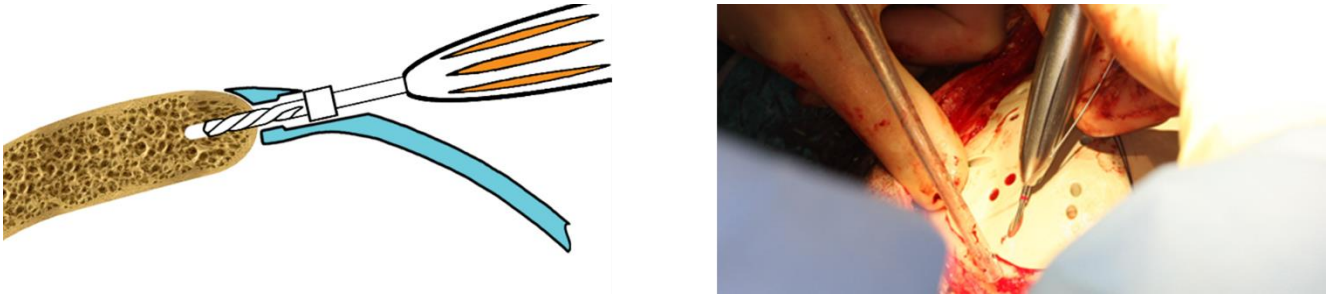


Figure 2: Drilling of holes in defect edge for inlay PEEK implant fixation using InterFix.

6) Stitching the dura to the inside of the implant through the XSuture (Figure 3) or implant Mesh.

Note: XSuture fits a ½ circle curved needle of diameter 0.6 mm and chord length of 4 mm up to 22 mm.

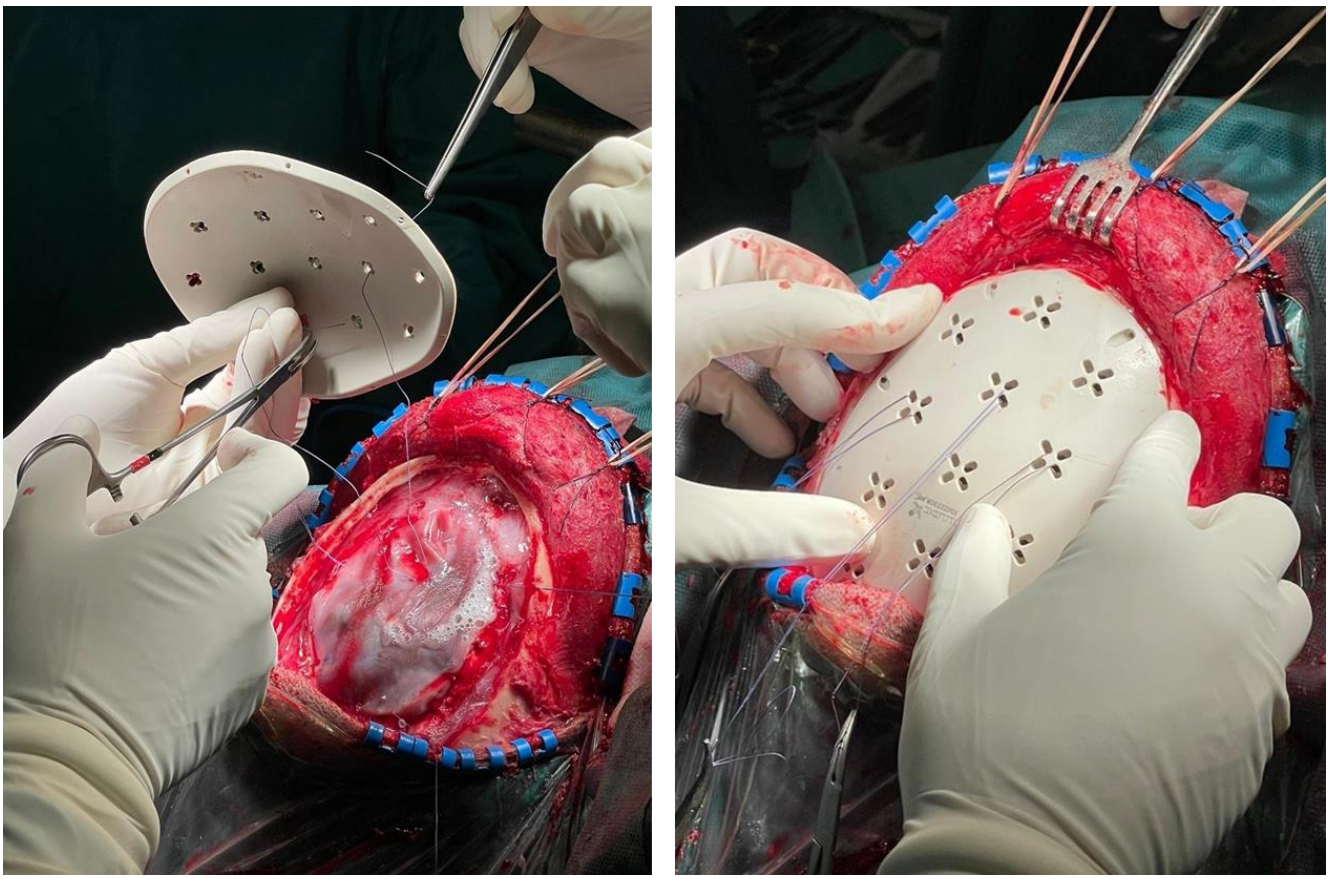


Figure 3: Stitching the dura to the inside of the inlay PEEK implant through the XSuture.

7) The appropriate fixation screws are installed tangentially through the pre-fabricated InterFix holes at the edges of the implant (Figure 4).
Note: We recommend flat head self-tapping titanium screws with a diameter of 1.5 or 2.0 mm for the fixation, minimal screw length is 7 mm and maximal screw length is 15 mm. The number and size of the screws is determined by the surgeon based on the design of the implant.
Emergency screws with a larger diameter are available if the used screw does not grip into the hole.
Fasten the screws only 90% initially. When all screws are placed, fasten the screws to 100% in a criss-cross / diagonal sequence.

⚠	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.

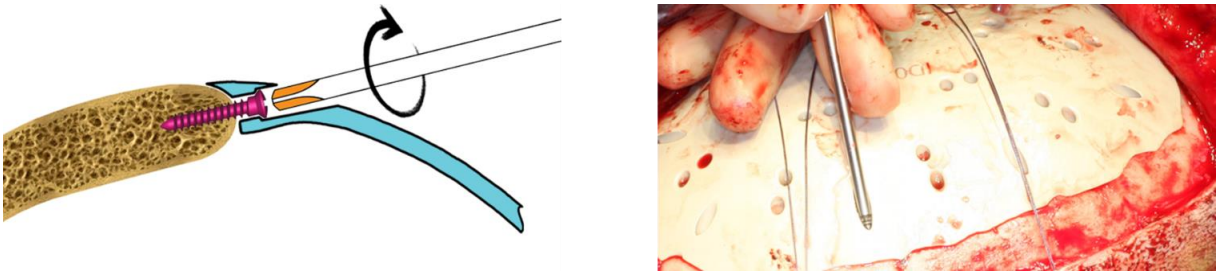


Figure 4: Fixation of inlay PEEK implant using InterFix.

8) Placing of the onlay implants requires perpendicular fixation, with short screws, after cleaning the defect edge and perpendicular drilling (Figure 5).

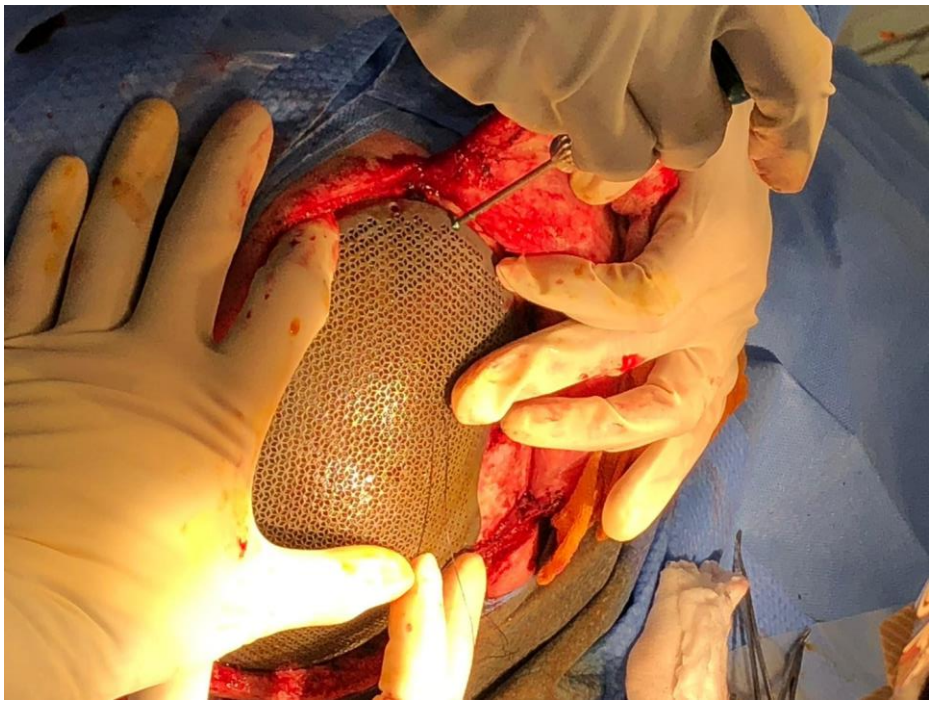


Figure 5: Placing onlay Titanium implant using perpendicular fixation.

9) Stitching the temporal muscle to the outside of the implant through the XSuture (Figure 6) or implant Mesh.

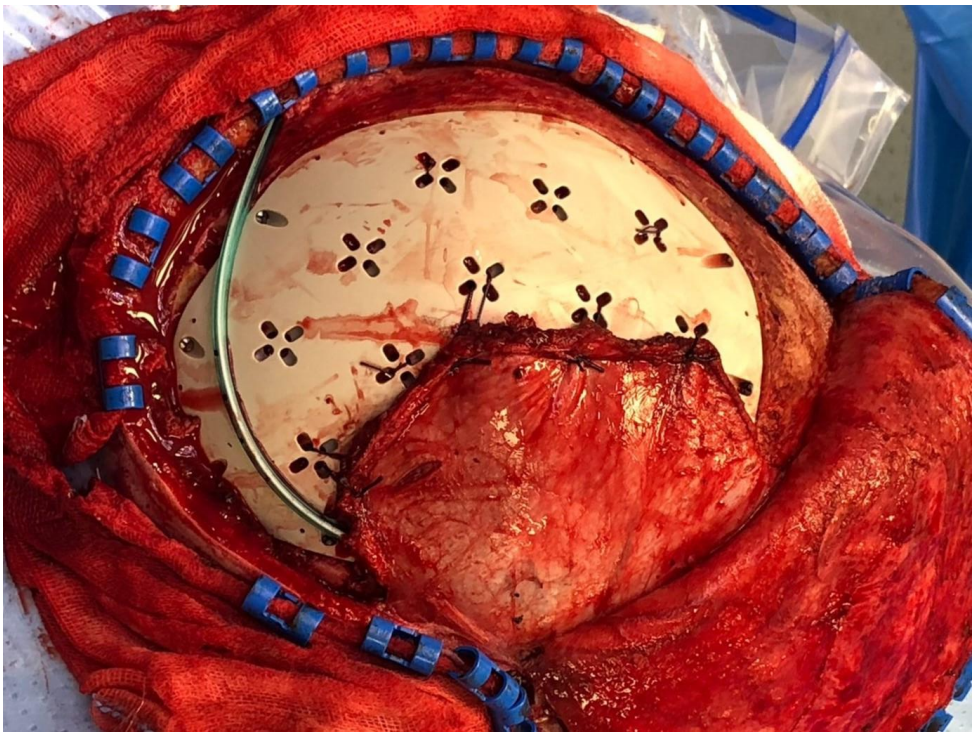


Figure 6: Stitching of the Temporal muscle to the outside of the inlay PEEK implant.

10) Reconstruction can be made with several implants which overlap each other, but all of them must be fixed to the remaining bone defect edge and in some case the parts are connected through screws (Figure 7).

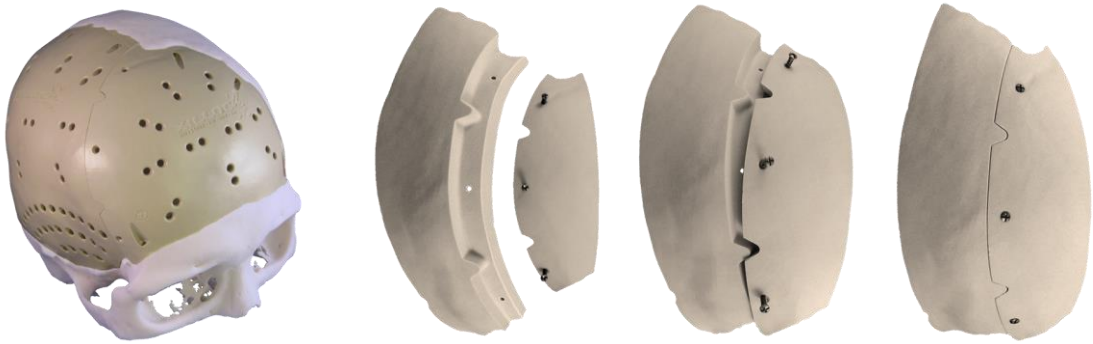


Figure 7: Fixation of overlapping implants

11) Close the defect using preferred approach.

⚠	Disposal	Dispose all components and materials according local regulations.

6 Removal of 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.

7 Implant card

Additional information on the implant card and how it should be completed can be found in that is delivered with the implant (Implant Card (IC) Xilloc - Patient Specific Implants).

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9 Ordering information

Ordering of custom Xilloc Cranial Reconstruction can be performed through our online ordering portal at https://medx.xilloc.com.