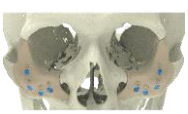
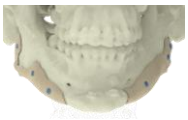
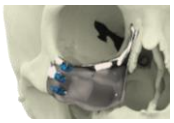
Xilloc Facial Augmentation

Instructions for Use – ENGLISH

PEEK



Titanium

1 Device Description

The Xilloc Facial Augmentation is an implantable device intended for facial bone replacement or augmentation of the maxillofacial area. 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 reconstruct voids or defects by placing a Facial Augmentation implant. 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 Facial Augmentation:

- The Xilloc Facial Augmentation is manufactured to fit the patient's facial defect in such a way that no intraoperative adjustments are required.
- The Xilloc Facial Augmentation will result in good aesthetic outcomes.
- The Xilloc Facial Augmentation results in improvements in quality of life.

3 Intended purpose

Facial 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. Facial Reconstructions are used for augmenting and contouring facial bone regions during surgery, possibly including reconstruction of orbital floor and its S-curve during surgery.

4 Indications

Xilloc Facial Augmentations are intended for reconstruction and augmentation in Facial Augmentation procedures intended to fill voids or defects in bone resulting from; disease, traumatic injury, surgical trauma, neoplasm resection or infected bone grafts.

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)
- Cardio-/vascular related complications (e.g., bleeding, hematoma, middle and posterior cerebral infarction).
- Seroma formation
- Muscle atrophy
- Reduced vigilance
- Step/fissure formation
- 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 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 Facial Augmentation 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.

Implant placement
Correct placement of the implant is of great importance. Improper placement may harm surrounding tissues. The skin above the implant must be in good condition before surgery and incision above the implant should be avoided.

Perpendicular fixation
Us the perpendicular fixations holes in order to fixate the implant to the bone. Fixation holes can be made locking and or nonlocking, this input can be given during the design phase of the implant. 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 Facial Augmentation Implants are all manufactured from medical grade Ti6Al4V (Titanium 6 Aluminum 4 Vanadium, ISO 5832-3) and or from PEEK *(*, ASTM 2026*).*

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 mandibula are called Anatomical Models. These can be used as tools to plan the surgery. The Anatomical Models are sterile instruments.
- A Surgical Guide or set of Surgical Guides can be delivered as part of the order, if requested. This can be used as a tool to plan a bone resection and or pre drill holes for fixation screws. 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.

13 Sterilization

The Xilloc Facial Augmentation implants are supplied STERILE.

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

Do not re-sterilize the implant.

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 Facial Augmentation (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 Facial Augmentation 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.

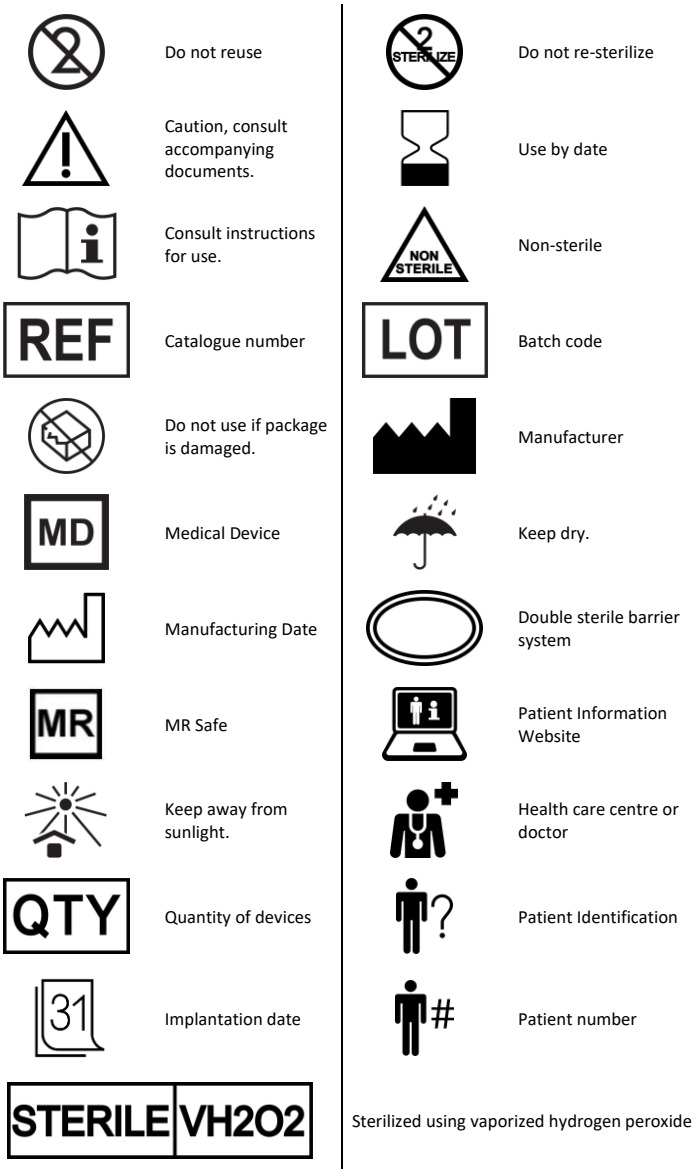
PEEK Facial Augmentation Implant is composed of a non-conducting, non-magnetic material containing Polyether ether ketone, based on scientifically relevant characteristics of the PEEK material it has been rationalized that PEEK Facial Augmentation poses no known hazards in all MR environments and is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



17 Manufacturer

Xilloc Medical Int B.V.

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The Netherlands