

Xilloc Mandibular Reconstructions

Instructions for use – ENGLISH



Surgical Guide



Anatomical Model



Implant + Graft

1 Device Description

The Xilloc Mandibular Reconstruction is an implantable device intended for mandibular bone replacement or augmentation of the mandibula and or maxilla. 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 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 (tumor removal) voids or defects with an autograft and fixating this by placing a mandibular reconstruction 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 Mandibular Reconstruction:

- The Xilloc Mandibular Reconstruction is manufactured to fit the patient's mandibular defect in such a way that no intraoperative adjustments are required.
- A vascularized or non-vascularized bone graft may be applied for a primary reconstruction improving clinical outcome of the procedure.
- The Xilloc Mandibular Reconstruction results in improvements in quality of life.

3 Intended purpose

Xilloc Mandibular Reconstruction are intended for bone replacement with autografts and augmentation for treatment of patients whose present conditions, in the surgeon's opinion, cannot be treated satisfactorily using other treatment methods. Mandibular Reconstructions are used for autograft reconstruction, augmenting and contouring bone regions during surgery. It is intended to be used by (CMF) surgeons with good knowledge of the specific operative technique, in a standard operating environment.

4 Indications

Mandibular Reconstruction Implants are intended for the use in cranio-maxillofacial-, trauma- and reconstructive surgery.

Clinical applications may include:

- Comminuted fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures
- Primary and secondary mandibular reconstruction, used with vascularized or non-vascularized bone graft
- Temporary bridging until delayed secondary reconstruction
- Maxillary reconstruction with bone graft
- Maxillary trauma
- Revision procedures where other treatments or devices have failed

Mandibular mobility is impaired for most of these patients, due to anatomical changes or surgically caused scarification. This often results in pain, difficulties in speech, and impaired oral function.

Mandible, Hemi: Includes any smaller implant on a single surface of the mandible. May come in the form of Left or Right

Mandible, Angle-to-Angle: Includes a single implant that starts at one angle and continues to the other angle

Mandible, Condyle-to-Condyle: Includes a single implant that starts at one condyle and continues to the other condyle continues to the other angle.

Maxilla: Includes any implant on the maxilla.

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

- Poor bone formation, bone necrosis 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 fracture site and/or the implant.
- Inadequate healing.
- Non-union or delayed union, which may lead to breakage of the implant.
- Migration, bending, fracture or loosening of the implant.
- Decrease in bone density due to stress shielding.
- Generation of particle debris during surgical procedure
- Inappropriate use of screws or drill bits
- Poor joint mechanics
- 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.

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 Mandibular 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.

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

Use the perpendicular fixation 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 Mandibular Reconstruction Implants are all manufactured from medical grade Ti6Al4V (Titanium 6 Aluminum 4 Vanadium, ISO 5832-3).

Surgical Guides and Anatomical Models are made from PA2200 (Polyamide/Nylon 12) and or Ti6Al4V (Titanium 6 Aluminium 4 Vanadium).

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 Mandibular Reconstruction implants are supplied STERILE.

Do not use the implant if the sterile packaging is damaged. Xilloc Mandibular Reconstruction 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 Mandibular Reconstruction (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 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
	Implantation date		Patient number
	Sterilized using vaporized hydrogen peroxide		

17 Manufacturer

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