



**Patient Specific Implants**

Anatomical Models  
Surgical Guides



Get **aHead** with Patient Specific Implants

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“BEFORE MY CUSTOM IMPLANT I COULD CRY  
OF FRUSTRATION, NOW I CAN CRY OF HAPPINESS”

“YOUR CONCERN AND COMPASSION FOR MY SON  
WILL NEVER BE FORGOTTEN”

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Get **aHead** with Patient Specific Implants

## A passion for helping patients

Every patient is unique and at Xilloc we believe that every patient should get individualized care, especially when it comes to implants.

Therefore, we provide patient-specific implants and services to assist surgeons in helping individual patients in the best possible way.

To improve the quality of life for patients  
by providing custom products to doctors

Xilloc designs and produces patient specific implants on the prescription of the surgeon, meaning that we create what you envision! This makes Xilloc the company for all your patient-specific needs; custom implants, anatomical models, surgical guides and patient-specific services.



## The flexibility and service of a small company the experience and quality of a big company

Because of the tailor-made nature of our business, Xilloc Medical BV focusses on the individual client needs, ensuring that the individual product for your patient has our full attention and dedication.

Having successfully made custom implants for over 10 year within the Maastricht University Medical Centre we officially founded Xilloc Medical in August 2011. Now also surgeons and patients from outside the Maastricht University Medical Centre can benefit from our know-how and expertise on patient specific technology.

Since its launch Xilloc was awarded “most innovative starter of 2011 in The Netherlands” and received numerous other business awards. The ambitious entrepreneur, Maikel Beerens, is blending the necessary ingredients to provide Xilloc Medical with a solid basis in Europe and from there to spread its wings on a global scale.

“For me it is a moral obligation to contribute to the quality of a patient’s life, by providing tailor-made products”

Maikel Beerens





## Having suffered for six years, knowing it could have been less than one.

August 2004. Marc, a healthy and fit 21 year old is riding his bicycle when dumb luck struck his path. Out of nowhere a woman popped up and in his attempt to avoid her he lost control over his bicycle, and fell to the ground with his head first.

The impact caused traumatic brain injury, which can lead to a host of physical, cognitive, emotional and behavioural effects. Although people can recover completely, permanent disability or even death can occur as a result.

After being held in a coma for one and a half weeks, Marc recalls having trouble speaking, concentrating and remembering the accident. To help him with these difficulties, he received physical, speech, recreation and occupational therapy. In September of that same year, Marc was supposed to start his bachelor studies.

Due to the accident, this was no longer possible. He instead entered an intensive re-integration program and soon after he started applying for jobs. However, it was clear that Marc was not able to keep up with the pace of everyday life. As a result, he lost his new job the following year. Within his social life, he also had to accept new changes; the many operations limited the time he could spend with friends. And so he was robbed of the opportunity to keep and to make new friends at work or while studying for a degree.

### Too many surgeries

During his hospitalization, two parts of his skull were removed to give his brain space and prevent brain herniation and consequently death. In November 2004, three months after the accident the neurosurgeons reimplanted the original bone parts removed during the first surgery, what is supposed to be a standard procedure. However, one and a half year later, one of these reimplanted bone parts failed and was completely resorbed by Marc's body. This resulted in a major deformation on the right side of his face and skull. In April 2006, this side of his skull was reconstructed using bone cement, not satisfying Marc with the aesthetic result.

### Happy end

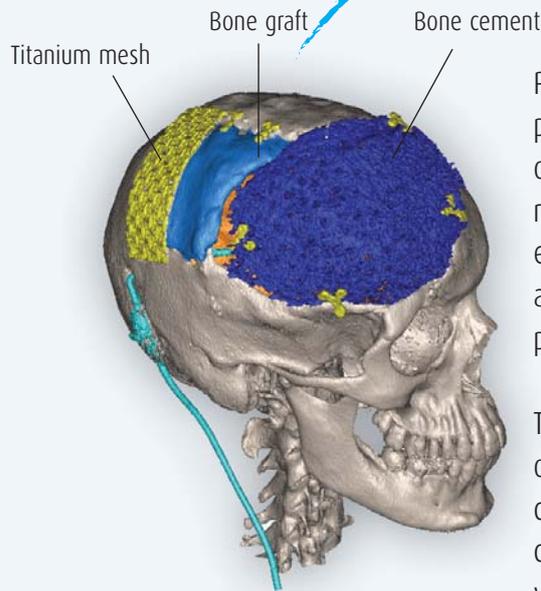
In April 2008, the second bone part resorbed as well, leaving the left side of his face and skull deformed. In search for a more aesthetic reconstruction, in April 2010, he finally received his patient-specific implant to correct his deformation. After six years of struggle for Marc, he was able to enjoy life again and live up to his potential. This story illustrates that the standard procedure described above should be replaced with a patient-specific implant treatment. In Marc's case, this would have implied less surgery, less trauma and a happier life that could have started six years earlier! Marc is convinced that all future cases should use a patient-specific implant to lessen the major impact on patients' private lives. Thanks to the Department of CranioMaxillo- Facial Surgery at Maastricht University Medical Centre and Xilloc, Marc was able to get his custom-made implant. He can now enjoy and appreciate the beauty of life as we all do.



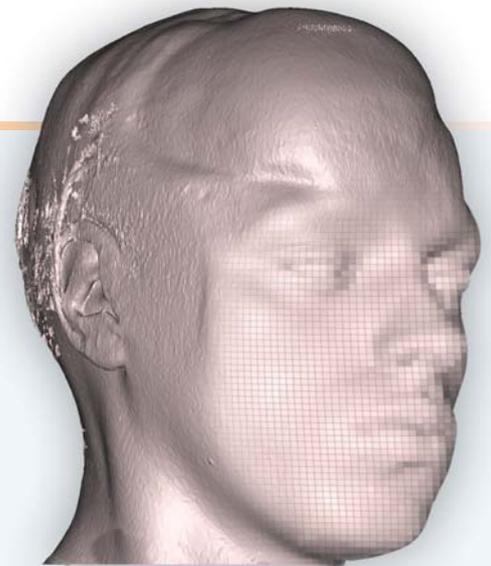
"With my implant I got my life back"

Marc Jacob

## 6 - The indications



People of all ages can face health problems that require them to undergo osteotomies. The bone defects that remain after craniotomies create emotional, functional, physical and aesthetic disturbances that change patients' lives.



The reconstruction of large/complex osseous defects still presents great challenges. And little is known on the best way to approach these challenges. For example if we take the reconstruction of large skull defects which is a truly complicated craft, with surgeons manually shaping, modelling and placing bone cement, bone grafts or titanium meshes. This

in turn means long, high-risk and complex operations with poor safety and aesthetic results with correspondingly long hospitalisation times for the patient. The custom made implants provided by us, ensure better patient and physician satisfaction, in the reconstruction or augmentation of bone defects that no other treatment can foresee in.

### Reconstruction

Patients who have suffered a (complex and/or traumatic) defect, can require a custom reconstruction. Custom implants are also used when there is no suitable standard implant available or when a standard implant has failed. Examples are reconstructions of the cranium, mandible, orbita.

### Cosmetic

Patients requesting custom skeletal augmentations to enhance their appearance and reconstruct a congenital or traumatic pathology. Examples are augmentations of the mandibular angles, the zygomatic areas, chin.

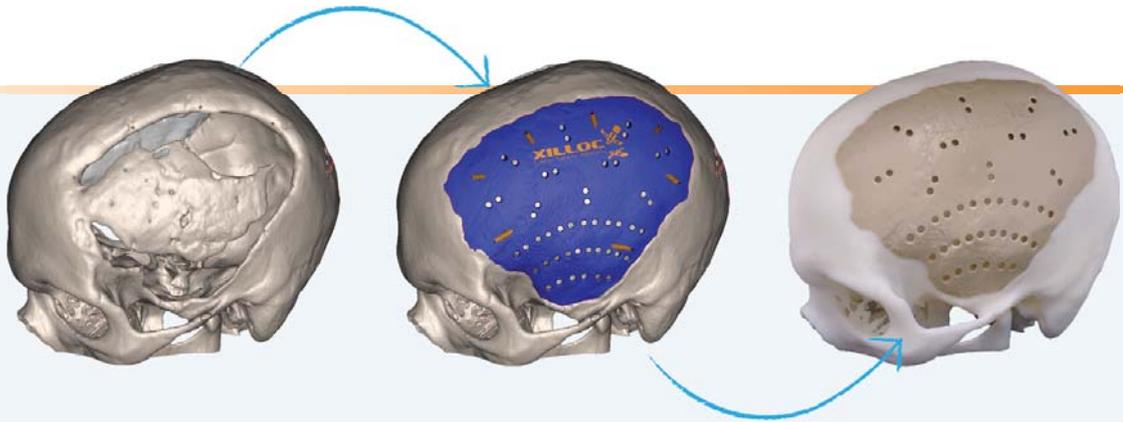
### Surgical disciplines

Our patient specific implants are commonly used by surgeons in various fields such as:

-  **Neuro**
-  **Orthopaedic**
-  **CranioMaxilloFacial**
-  **Trauma**
-  **Plastic**
-  **Surgeons**

### Frequent indications

-  Calvarial reconstructions after decompressive craniectomy; tumour or aneurysm surgery
-  Resorption of bony tissues
-  Mandible, maxilla, zygoma, orbita (floor) reconstructions or augmentations
-  Bone and joint reconstructions and custom plates anywhere in the body



## The benefits of a perfect fit

A patient specific implant is designed to match the anatomy of the patient and therefore it has a perfect fit, which makes the PSI really easy to place.

- 

**Surgery is quick, easy & safe**  
The implant just falls into place, no adjustments to the implant, nor the patient's bone are needed; just fixate it and you're done. This significantly reduces surgery time.
- 

**Aesthetically superb result**  
Using state of the art modelling technology for the design of the implants we ensure an anatomically correct reconstruction, with an unrivaled aesthetic result.
- 

**Reduced infection risk**  
Another advantage of the reduced surgery time is a reduced risk of infection.
- 

**Peace of mind**  
The surgery and the implant have been pre-planned virtually together, eliminating any surprise in the OR. Combine the use of a PSI with an anatomical model to be fully prepared.
- 

**Long-term costs are lower**  
The reduced surgery time results in faster recovery, thus shorter hospitalization. Revision surgery is rare due to the extremely high success rate. This results in the patient returning home sooner and resuming work faster.
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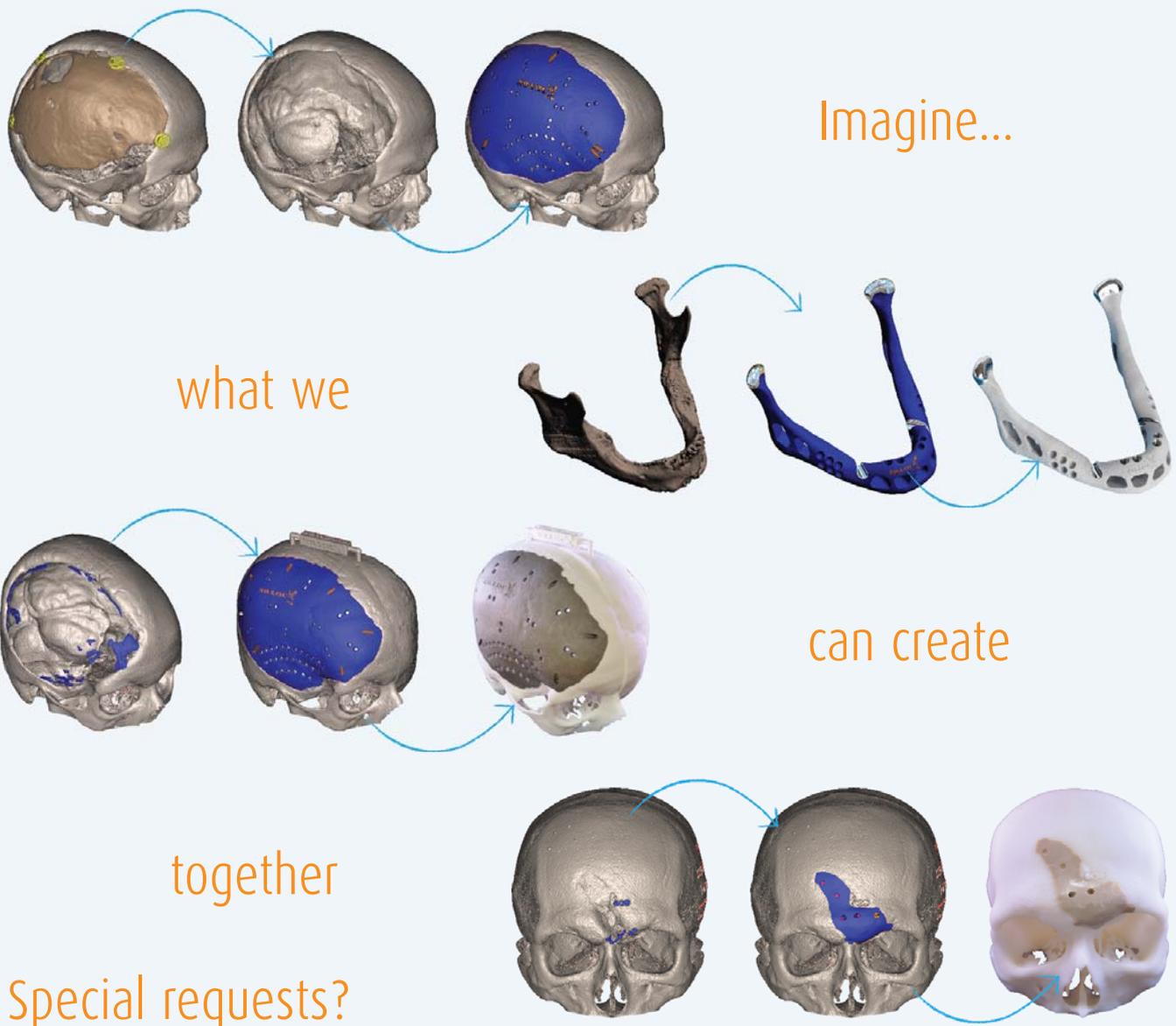
**The patient is happy**  
Eventually, that's what it is all about: to help patients, improve their quality of life and put a smile on their face!

"Xilloc's patient specific implants help the surgeon to perform on the highest level in defect reconstruction with alloplastic implants."

Prof. Dr. Dr. Kessler - MUMC

## Customize your custom

With your medical expertise and the technical know-how of our medical engineers together we create what you envision. You give us your input on implantation approach (shape, spacings, holes, fixation, material and more). We then take care of the design and the appropriate production method to realize your custom implant. We employ state-of-the-art production methods, like high speed milling and 3D printing to reach the perfect end result.



For any specific requests, do not hesitate to contact us. Virtually anything is possible. For example a (hydroxyapatite) coating, porosity or special type of fixation. Just ask us for the possibilities.

## Unique implants are our specialty

At Xilloc, we only create patient-specific products; every patient is unique and we treat a him/her as such. So rest assured, the custom implant for your patient has our undivided attention.



### ◆ The specialist in customs

Having 10 years of experience in creating custom implants, Xilloc has gathered a lot of expertise from which you benefit. We are ready to assist and advise you from start to finish, with our in depth knowledge and expertise on design, biomaterials, anatomy, manufacturing and more, so you get the best possible custom product for your patient.



### ◆ Perfect fit guaranteed

Using our experience, we know how to make an implant fit perfectly. Combined with our unique fixation technique, this makes our implants really Plug and Play. Although most of the biomaterials we offer can be modified during surgery, up to now this has never been necessary in order to make a custom implant fit.



### ◆ Unique, fast and aesthetic fixation

Our patented InterFix technology fixates the implant with tangential screws. The screw holes, direction and depth are all preplanned and the holes are included in the implant. In the OR, you only have to drill through these holes before you fix the implant with 2 to 9 screws. This results in a fast fixation. Because the screw heads are covered by the implant surface, they are not palpable which gives an aesthetic result.



### ◆ Choose the best biomaterial

We have multiple excellent biomaterials in our portfolio, so we can select the best material depending on the application and on your preference.



### ◆ Fast online ordering, fast delivery

Via our online ordering system MedX (developed in-house), ordering custom products is easy and saves you from having to send CD's or DVD's and filling out and faxing order forms. No more hassle with paperwork. Our system makes ordering really fast and as a result, you have more time for your patient and you will have your custom implant sooner.



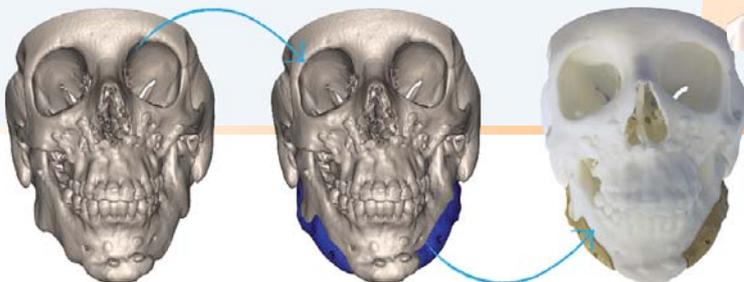
### ◆ Models and guides too

Besides custom implants, you can rely on Xilloc for any patient-specific request. If you want an anatomical model or a surgical guide, Xilloc is your partner. No need to contact multiple/different suppliers.



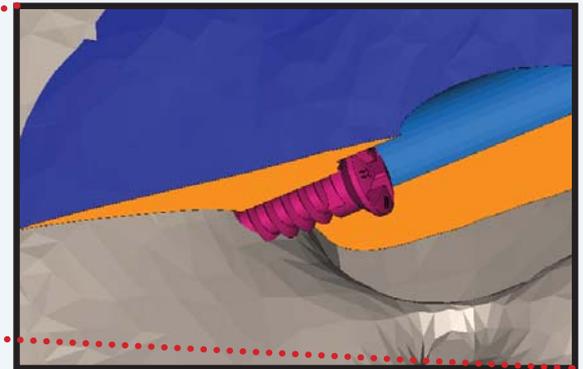
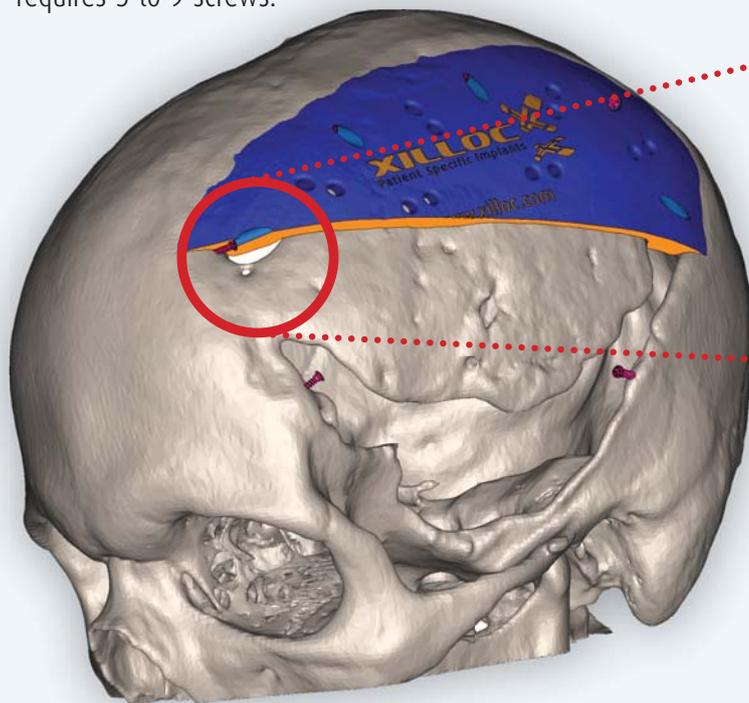
“The highest quality of Patient Specific Implants”

Prof. Dr. Poukens - Orbis



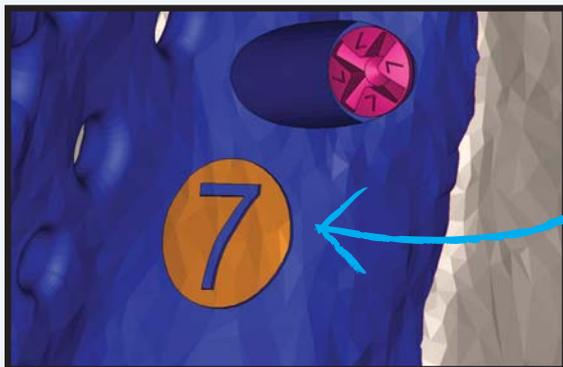
## InterFix

Xilloc's unique InterFix technology gives you preoperatively planned screw positions, screw direction and depth. InterFix eliminates the need for plating and requires only a few screws. During surgery, you place the custom implant into the defect, you drill holes tangentially into the cortical bone guided by the pre-made screw holes and to lock the implant, you fix screws into the holes. A large cranial defect typically only requires 5 to 9 screws.

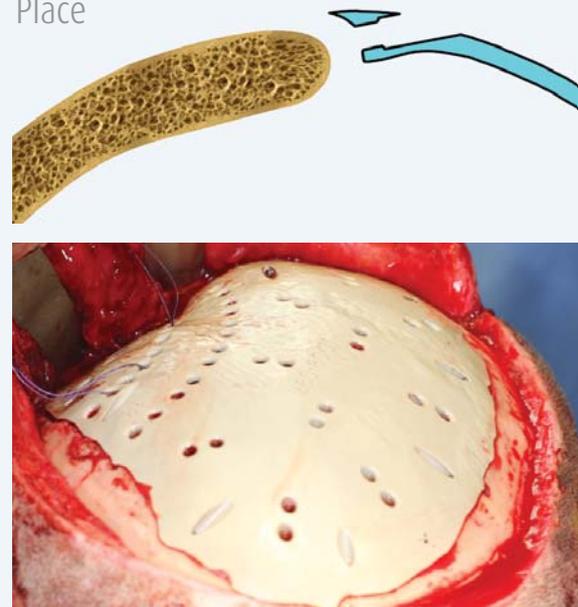


Tangential fixation is a real revolution: it's easy, it's fast and it reduces the time I spend in surgery a great deal"  
Surgeon

When the screw length is critical we provide advice on the maximum screw length to be used and engrave it next to the fixation holes. For example, the symbol 7 is engraved here, which indicates a maximum screw length of seven millimeters.



Place



## A unique fixation

Xilloc developed a unique fixation method. We allow you to fix your custom implant with a tangential fixation. We include fixation holes in the implant guiding your drill and screws.

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**Only a few screws**  
No need for many screws and plates to fix an implant. Typically a large custom cranial plate requires only 7-9 screws for a solid fixation. An orbital implant only 2-3.
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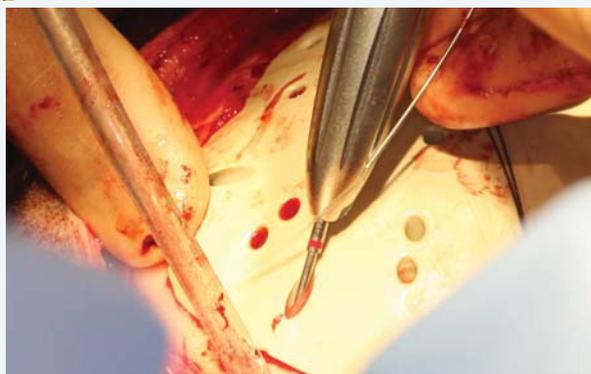
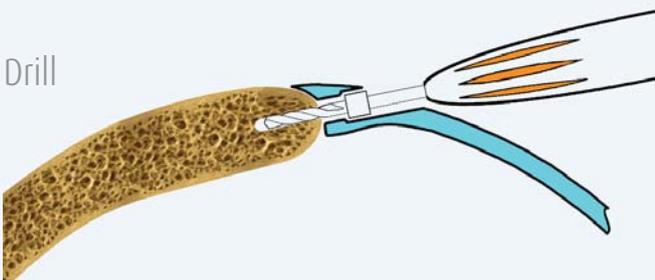
**Surgery is quick and easy**  
Place. Drill. Fixate. Easy and quick. The custom implant falls into place, you drill through the fixation holes and then screw the implant into place. Since you only need a few screws, the implant is fixated before you know it.
- 

**The right position, the right angle, the right depth**  
We use virtual surgery planning to determine the best positions and directions for screw fixation, where the bone is thickest. On top of that, we advise on the optimal screw length and indicate the maximal screw length at positions where you should avoid critical structures.
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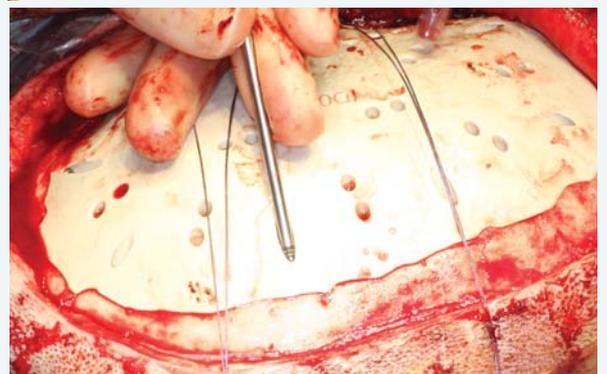
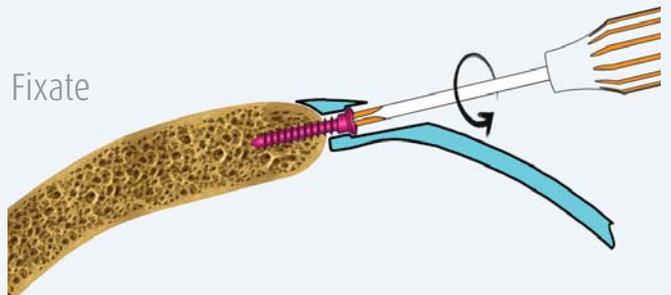
**Aesthetic fixation**  
The screws used to fix the implant fall into the implant. As a result, the fixation is not visible, nor palpable and guarantees an optimal aesthetic reconstruction.
- 

**Use your own screw set**  
Inform us on the screw set you use in the OR and we make sure they fit in your custom implant.

Drill



Fixate



### Biomaterials

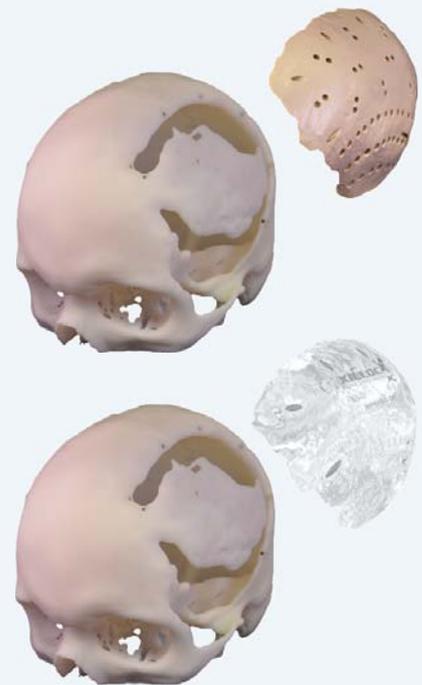
Since different applications have different material requirements and surgeons have different material preferences, Xilloc offers a variety of choice in biomaterials. We can assist you in choosing the right biomaterial for your patient.

#### PEEK

Excellent high-performance polymer biomaterial with physical properties comparable to cortical bone. PEEK is lightweight and can be sterilized with all common methods. PEEK is currently the material most used for facial reconstructions. PEEK is radiolucent and compatible with MRI.

#### PMMA

PMMA has a long track record as a biomaterial in bone cement and intra-ocular lenses. The PMMA from which we produce our implants is pre-polymerized, so no adverse toxicity and heat effects occur, associated with the hardening of bone cement. PMMA is completely transparent, thus allowing you to see possible hematomas underneath the implant. Preferred sterilization method is EtO. PMMA radiolucent and compatible with MRI.



	Cortical bone	PEEK
Strength	++	++
Sterilization	Steam 134°, EtO, gamma	Steam 134°, EtO, gamma
Imaging compatibility	+++	+++
Material modification*	Drill bits	Drill bits

\*) We design our implants to be a perfect fit, and so far they never needed to be modified. Nevertheless we indicated if the material can be adapted in the OR and how.



### Titanium

Ti6Al4V is a titanium alloy, successfully used in load-bearing orthopedic applications (e.g. hip stems), since it is very strong, much stronger than cortical bone. Titanium exhibits osseointegration and can be sterilized with all common methods. Compatible with MRI, yet incompatible with CT. Titanium is too strong to be modified in the OR.



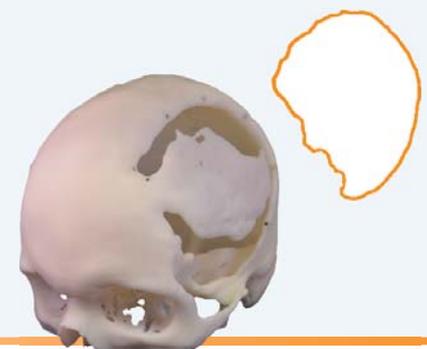
### UHMW-PE

Biomaterial with a long track record in load-bearing and moving (joints) orthopedic applications (e.g. acetabular cups). UHMW-PE is very tough, has a high impact strength, and low friction coefficient. Although tough, it can be cut/chipped with a scalpel. Can only be sterilized with gamma or EtO. UHMW-PE is radiolucent and compatible with MRI.

Titanium	UHMWPE	PMMA
+++	+	++
Steam 134°, EtO, gamma	gamma, EtO	EtO, gamma
+	+++	+++
-	Scalpel	Drill bits

### Your preferred material

Besides our current offering, Xilloc is continuously looking for biomaterials. Contact us if you prefer a biomaterial that is not in our list.



## The worlds first 3D printed full mandible replacement

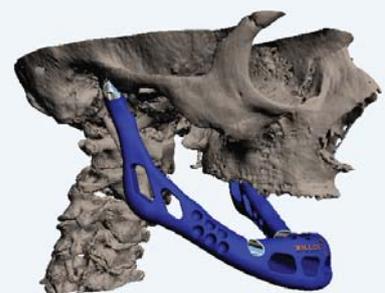
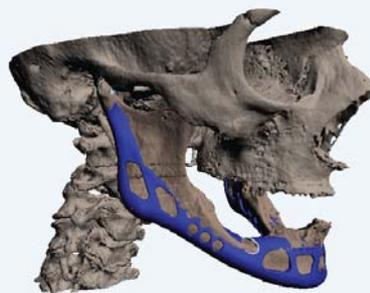
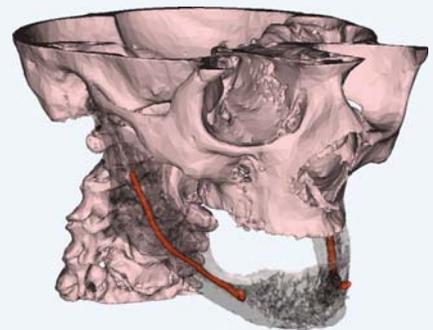


### 1) The challenge

By an unfortunate accident an 83 year old lady suffered from a chin injury which caused severe osteomyelitis in her lower jaw. After careful consideration, Prof. Dr. Jules Poukens decided to remove the full jaw, including the condyles. The aim was to replace the full jaw by a patient specific implant, same size and similar shape as the original jaw maintaining all vital functions.

### 2) The approach

In close collaboration with the surgeon, our design team accurately translated his prescription into a 3D design: Creating smooth condyles for joint functionality without contra implants on the condylar fossa. Preparing dental slots for the future placement of the suprastructures. Two ducts were embedded to preserve and host the mandibular nerve. To reduce the weight and to allow for stitches, the implant features various holes. The whole implant was designed to be placed within the periosteum and therefore sharp edges were removed.



### 3) The technology

3D printing was used to produce the complete mandible in Ti6Al4V, after which it was polished at the condyles and nerve ducts. A hydroxyapatite plasma-spray coating was applied over the remaining surface to stimulate attachment of the periosteum. Holes in the dental arch were equipped with screw-thread.



#### 4) The surgery

The surgery went very smooth and the complete titanium mandible was implanted into the periosteum in only 4 hours. All the vital functions such as speaking, breathing, eating and nerve sensing, were maintained. They would have been lost forever using conventional methods.



#### 5) The result

One day post-operative, the patient started chatting already. One year post-op, she received her dental suprastructure, so she can smile again and have the steak she craved for!



X-Ray



Finished with a smile



"Xilloc made me smile again"

Bertha Buttner

#### Worldwide media attention

Featured press BBC - Forbes - Wired - CBS News and many more. Over 100.000 youtube views and 3.000.000 shares. Just recently, the innovative implant received the "2012 AM Award" by the Additive Manufacturing Network in Belgium.



## A physical model of your patient's anatomy

We can provide accurate 3D images of the anatomy of your patient to reveal often hidden facts. Often you want a physical model in your hands that appeals to your sense of touch. That way, you can get a good feel of the anatomy and pathology of the patient and you will avoid unpleasant surprises in the operation room.



### Shorten your surgery time

Having an anatomical model will allow you to do many things before even stepping into the operating room. The more you do in advance, the less you have to do during surgery.



### Prepare for (complex) surgery

Before you go into surgery, you can use an anatomical model to prepare yourself. You can use an anatomical model to draw your surgical plan upon. Or you can cut and drill in your model. We can also highlight certain bone fragments on the model.



### Collaborate with your surgical team

An anatomical model is also a great communication tool. You can show it to your fellow surgeons and colleagues to get their ideas and feedback.



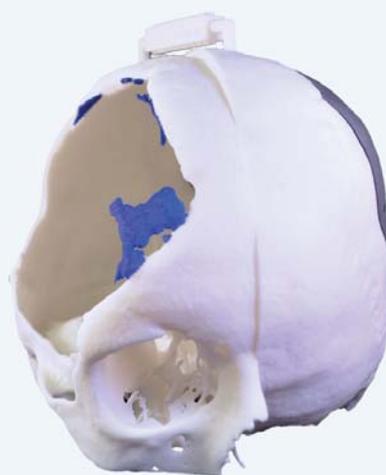
### Pre-bend your plates

Use the anatomical model to already bend your plates to the patient's skeletal structure before surgery, so you don't have to do that anymore in the operating room.



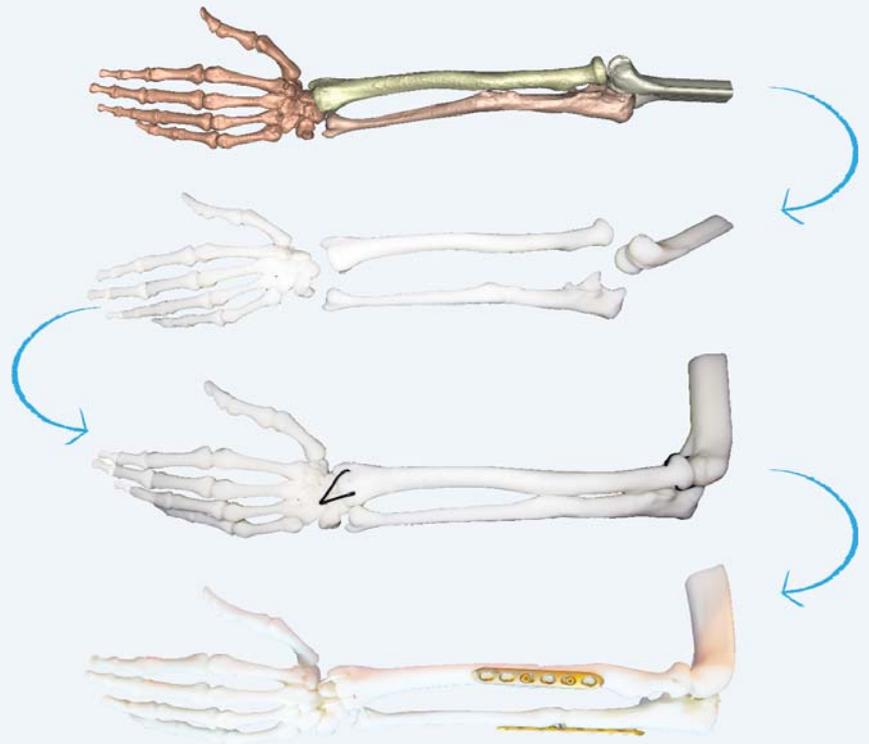
### Validate your custom implant

If you are going to implant a patient-specific implant, you can test the perfect fit on the anatomical model. Also, we can deliver a model implant; that way you don't have to test with the real implant, but you can get a (blue) model implant.



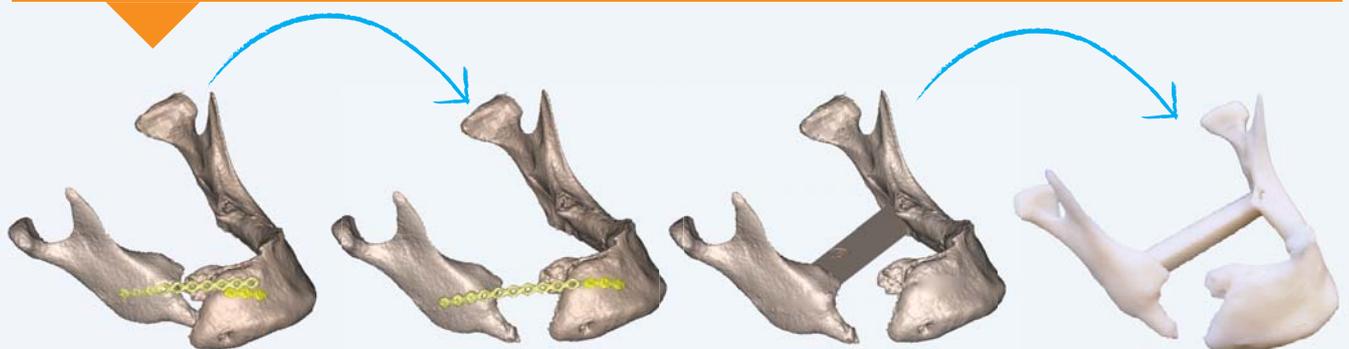
“Xilloc Medical’s Anatomical Model and service enabled us to reveal facts and eliminate the problem”

Prof. Dr. Brink - MUMC



“Xilloc’s assistance enabled us to perfectly reposition the two mandibular parts, to place the fibula to bridge the defect and anatomically reconstruct the patient.

Dr. Poort - MUMC



Patient situation

Mandible repositioned

Preparation for production

Tangible Anatomical Model

### Take your planning to the operating room

A virtual surgery plan is only valuable when you can translate it accurately to the operating room. An effective way to do so is using surgical guides. On request we can assist you with a full pre-operative surgical plan, including the cutting planes and drill holes and their respective angles. To transfer this plan to the actual procedure, we design surgical guides. A surgical guide or template is a small customized tool that guides your saw and/or drill in the planned direction. It fits exactly on a predetermined part of the patient's bone, making sure you cut and drill at the right place, under the right angle and to the right depth.

Use a surgical guide to:

- Cut away a well defined piece of bone. E.g. a piece that contains a tumor.
- Position bone parts in the right way. E.g. to fit a fibula graft into the patient's mandible.



#### Well prepared

With surgical guides, you know that your pre-operative virtual plan can be executed accurately. So you can plan your surgery in great detail in advance. When placing a fibula graft for example, "backward" planning can be used to find the best position of the remaining mandible parts. Then you know the void that needs to be filled with the graft. And subsequently the pieces of fibula you will need as well as the angles in between these fibula pieces.



#### Stay with the plan

Surgical guides are a simple yet elegant solution to accurately transfer your surgical plan to the OR. These small, personalized tools are designed to perfectly fit on the bony structures of your patient. They fit in only 1 place, in only 1 way (in only 1 patient). Once in place, they guide your saw and your drill to cut and drill on the right spot and in the direction you had planned. Or they help you to position and fix bone parts in the right position and under the right angle.



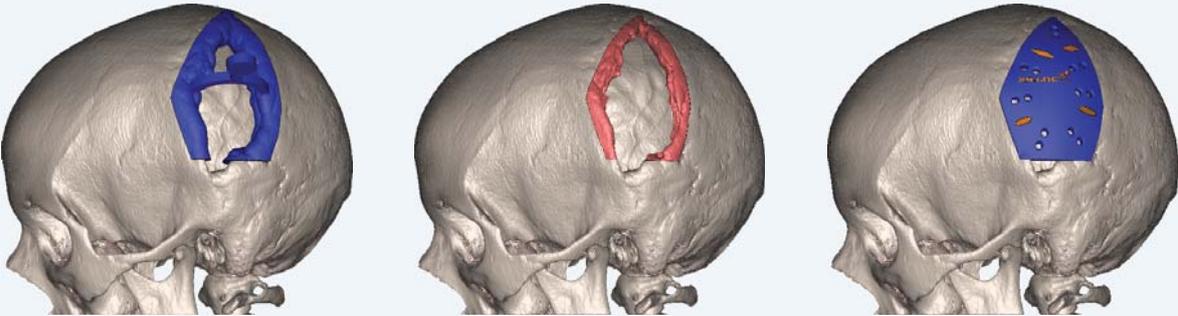
#### Shorter, more precise surgery

Being well prepared and being able to accurately execute that plan in an easy and quick way, will allow you to shorten your surgery time and to perform cutting and drilling more precise. More precise surgery should in turn lead to a more predictable and better outcome.



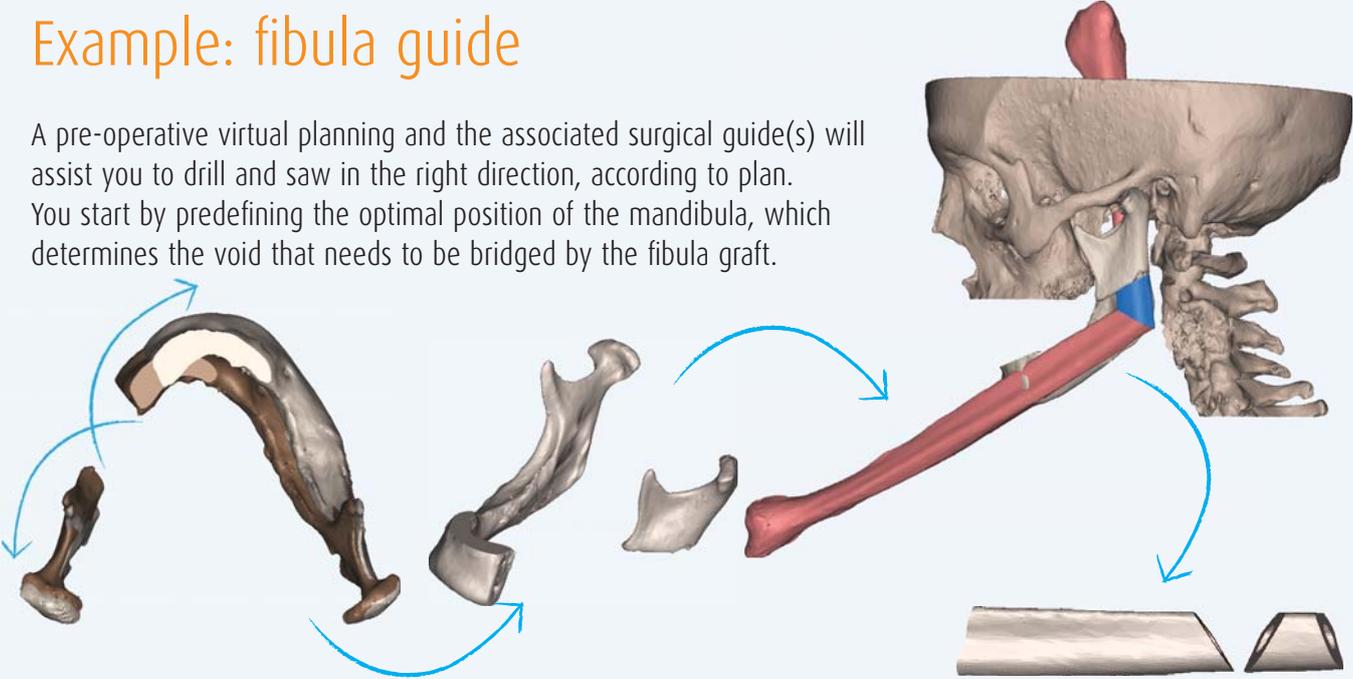
## Example: cranial guide

A guide for redefining the defect edge or used for the removal of bone tumours and subsequently closing the created defect with a custom implant. All in one surgery.

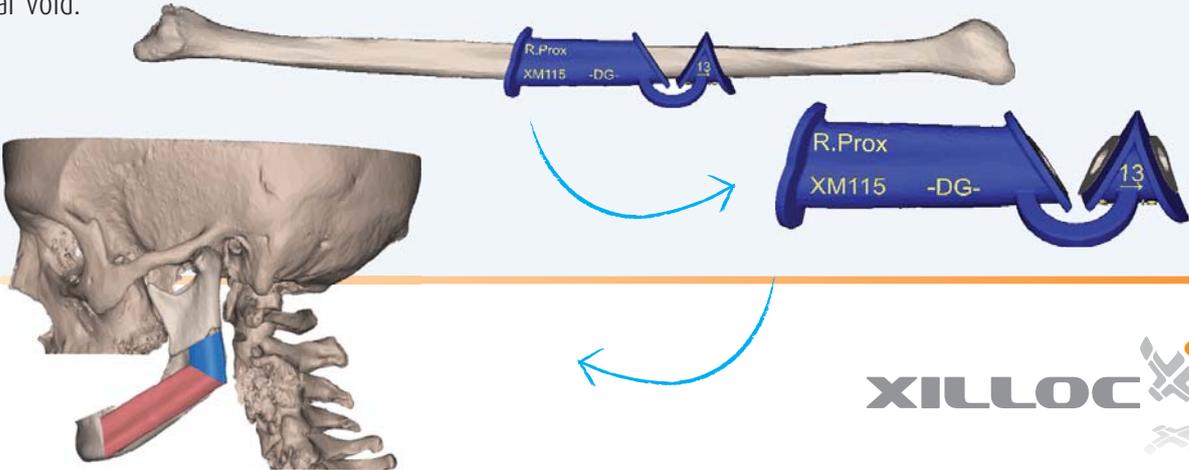


## Example: fibula guide

A pre-operative virtual planning and the associated surgical guide(s) will assist you to drill and saw in the right direction, according to plan. You start by predefining the optimal position of the mandibula, which determines the void that needs to be bridged by the fibula graft.



The guide is designed in such way that it matches the patient's anatomy perfectly and only fits on the predetermined part of the fibula. For the surgeon to know where to open the patient's leg, we indicate the approximate position, in centimetres distance from the distal fibula end. This is done by engraving a number in the guide, number 13 in the example below. After cutting along the four planes the parts can be assembled to fit the mandibular void.



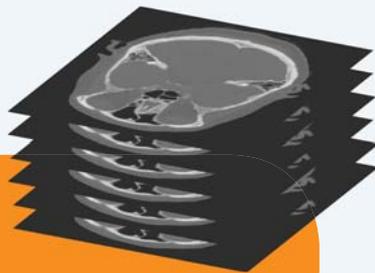
## Online ordering system: MedX

Xiloc, as a specialist in patient specific products, developed MedX; an online ordering system, completely fine-tuned to the process of ordering custom products online. No need for filling out unnecessary paperwork; MedX is easy to use, fully secure and an interactive 3D review of your cases. Create your free account today. Go to: [medx.xiloc.com](http://medx.xiloc.com)



3 small steps to get your: Patient Specific Implants  
Anatomical Models  
Surgical Guides

### 1. Scan



It all starts with a proper CT or CBCT scan.

We provide you with our scan protocol. In general, a scan with 1mm slice distance is sufficient for high quality 3D models, that we can use to make custom implants that fit perfectly.

### 2. Upload



Through our online ordering system MedX, you can securely upload the DICOM data to us and provide us with case details.

We will then send you a quotation that you can easily approve online.



## Delivery

Delivery time for Patient Specific Implants and Surgical Guides is 3 weeks by default. Anatomical Models take 5 working days. Delivery can be faster with our Express Service. Contact us for the possibilities. Our products are delivered non-sterile, shipped with sterilization guidelines.



## iPad app

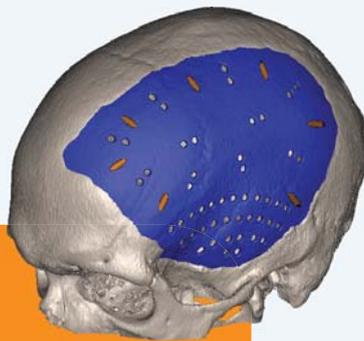
### Your implant at your fingertips

A free iPad app is available in the App Store. It contains 3 demo cases upon installation, but you can link it to your MedX account. The app then functions as an extension of MedX, in which you can view your custom implants and examine them in 3D. Use it to show the implant to your patient or your colleague.



### 3. Your input

To ensure you get the perfect implant we work in close collaboration with you. In the design process there are 2 input/validation steps. Necessary to comply with the regulations and for your own comfort.



### Receive your custom

The patient specific implant is delivered with detailed instructions which should be read carefully.



#### NOTE:

For MedX we recommend using Firefox or Chrome on PC and Safari or Firefox on Mac as browser. Unfortunately Internet Explorer does not support the latest medical security and 3D-protocols.

## Services

Next to our patient-specific products, Xilloc offers a range of patient-specific services, to enable a complete, individualized solution for you.



### Segmentation

If you only require a 3D model of the anatomy of your patient, you can rely on our segmentation skills.



### Virtual surgery planning

We can assist you in your preparation for surgery. Using virtual surgery planning, we can decide upfront on cut-, implant- and screw directions and depth.



### Design

In case you want to produce the implant yourself, we can take care of the design for you.



### Production

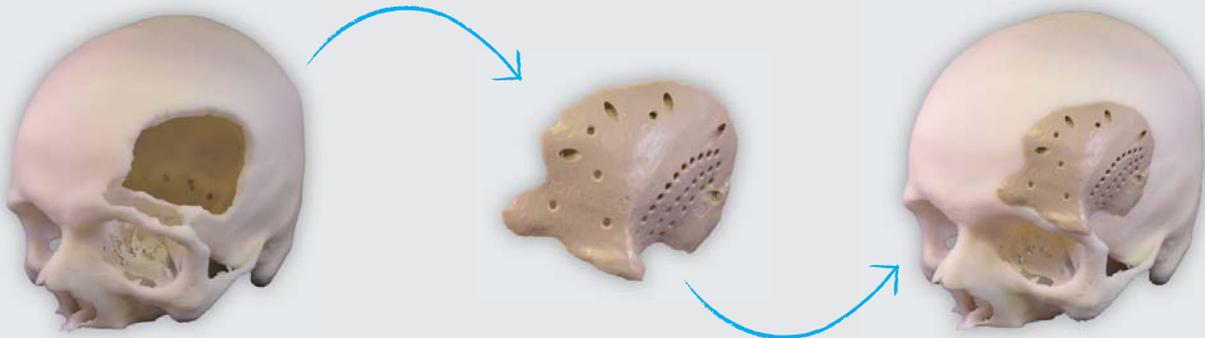
When you have designed an implant yourself, rely on Xilloc to produce it in the best material and the highest quality.

### Quality

Since we are dealing with invasive medical products, quality is our number one priority. Our work complies to the ISO 13485 and our Patient Specific Implant protocol. Our MedX system is secured with the latest online security protocols, so your patient data is perfectly safe with us. To keep improving our products and our service, we highly value your feedback.

### CE mark

Medical Device directive 93/42/EEC states that patient specific implants are categorized as; "Custom made devices, which means: any device specifically made in accordance with a fully qualified medical practitioner's written prescription who gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient." ... "Custom-made devices being placed on the market to be put into service cannot bear the CE marking"



## Research and development

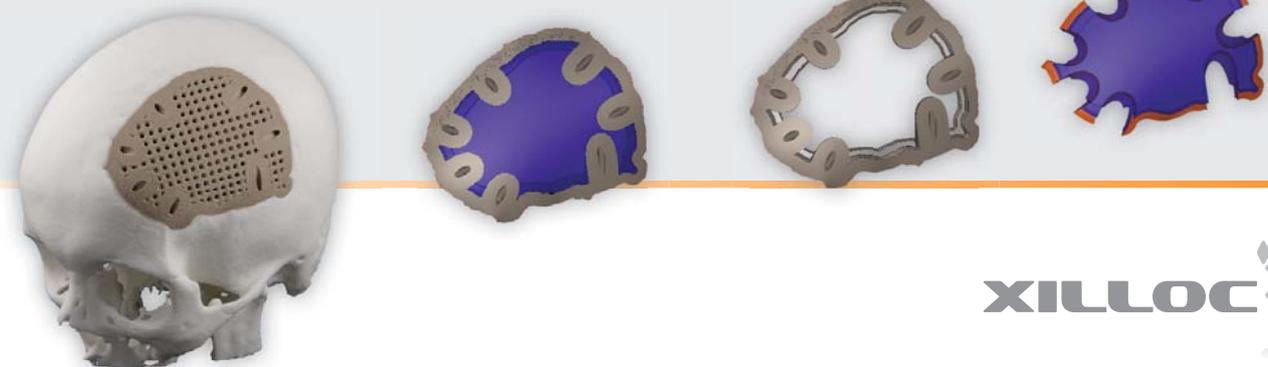
At Xilloc, we are constantly looking for ways to improve our custom products and services to provide a faster and easier implant and fixation. We aim for improved biomaterials and to develop other applications and different patient-specific products.

As a university spinoff, from within the premises of Maastricht Instruments B.V., Xilloc is always ready to discuss our potential participation in research projects.

## Scientific publications

The following articles have currently been written about our implants:

1. Cranioplasty with customized titanium and PEEK implants in a mechanical stress model  
Lethaus B, Safi Y, ter Laak-Poort M, Kloss-Brandstätter A, Banki F, Robbenmenke C, Steinseifer U, Kessler P.  
J Neurotrauma. 2012 Apr 10;29(6):1077-83. Epub 2011 Dec 14.
2. A treatment algorithm for patients with large skull bone defects and first results  
Lethaus B, Ter Laak MP, Laeven P, Beerens M, Koper D, Poukens J, Kessler P.  
J Craniomaxillofac Surg. 2011 Sep;39(6):435-40. Epub 2010 Nov 4.
3. Reconstruction of a maxillary defect with a fibula graft and titanium mesh using CAD/CAM techniques  
Lethaus B, Kessler P, Boeckman R, Poort LJ, Tolba R.  
Head Face Med. 2010 Jul 19;6:16.
4. Craniofacial Trauma – Diagnosis and management  
Hardt Nicolas, Kuttenger Johannes  
2010, XVII, 278 p. 260 illus., 247 in color.
5. A classification of cranial implants based on the degree of difficulty in computer design and manufacture.  
Poukens J, Laeven P, Beerens M, Nijenhuis G, Sloten JV, Stoelinga P, Kessler P.  
Int J Med Robot. 2008 Mar;4(1):46-50.





## Why choose Xilloc for your patient(-specific needs)?

- ❖ Patient-specific is our core, so you and your patient have our full dedication
- ❖ Ordering online is easy and fast, no more hassle with paperwork
- ❖ Short delivery times, plan your surgery and we get you your implant asap
- ❖ Guaranteed perfect implant fit
- ❖ Unique fast and aesthetic fixation method
- ❖ Choose your preferred biomaterial
- ❖ One company for all your patient-specific needs: implants, models and guides

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