



**LITHOZ**<sup>®</sup>

We are ceramic 3D printing.

# **A Guide to 3D-Printed Ceramic Bone Replacement**

**Preclinical and Clinical Results**  
*Based on LCM-Printed Implants*

# LCM Ceramic 3D Printing – a Safe and Established Route Towards Biocompatible Implants

## How to Overcome the Challenge of Bone Replacement

Bone regeneration remains one of the most demanding challenges in modern medicine. Whether in orthopaedics, trauma surgery, neurosurgery, or oral and maxillofacial reconstruction – bone defects require materials that not only restore volume but also actively support the regeneration of living bone tissue.

For complex bone defects, 3D printing of ceramics has opened new possibilities – enabling precise reconstruction without the use of metals and allowing shapes and structures tailored exactly to each patient's anatomy. Beyond complex cases, it also opens new opportunities for stock implants through the creation of controlled porosity, this feature offers optimized integration and healing performance.



Mandibular angle implant with porous inner structure made of hydroxyapatite material LithaBone HA 480. Left image shows titanium screws for fixation and part of the dense hull has been removed to reveal the inner trabecular-like structure. Right image shows the bone-facing inner structure with defined interconnected porosity and the screw-holes through which the implant is fixed within the defect.

**Lithography-based Ceramic Manufacturing (LCM) allows you to produce patient-specific, bioresorbable ceramic implants, as a clinically proven method for bone regeneration.**

Calcium phosphates are well-established materials for bone regeneration, with hydroxyapatite (HA) and tricalcium phosphate (TCP) being the most widely used.<sup>1</sup> For LithaBone Lithoz uses raw materials that comply with the ASTM material standards F1088 and F1185.

The biocompatibility of Lithoz materials has been demonstrated in numerous pre-clinical and clinical studies:

- Tricalcium phosphate (LithaBone TCP 300)<sup>2-5</sup>
- Hydroxyapatite (LithaBone HA 400)<sup>6-9</sup>
- Hydroxyapatite (LithaBone HA 480)<sup>5</sup>

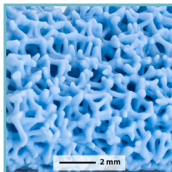
LithaBone HA 480 consists of the same ceramic powder as LithaBone HA 400, thus an equivalent biocompatibility can be concluded.

# The Architecture of Bone Regeneration

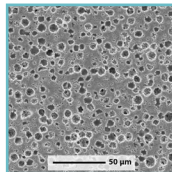
## Designing Optimal Porosity

Porosity is crucial for tissue ingrowth, nutrient supply, and cell attachment. The success of ceramic bone substitutes strongly depends on their pore architecture. **Lithography-based Ceramic Manufacturing (LCM)** enables precise control of macro-, meso-, and micro-porosity, combining mechanical stability with biological performance. Thanks to additive manufacturing, not only the size but also the shape of the pores and the entire interconnected structure can be freely tailored to meet the desired requirements. Interconnected open-porous structures can be achieved without extra effort.

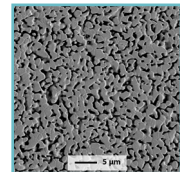
Porosity optimisation has been extensively studied using Lithoz materials and is widely documented in scientific literature.<sup>2, 6-15</sup>



Pore size: 20 - 2000  $\mu\text{m}$   
Pore type: Macroporous ceramics  
Porosity by CAD



Pore size: 2 - 20  $\mu\text{m}$   
Pore type: Mesoporous ceramics  
Porosity by addition of porogenic materials



Pore size: 0.1 - 2  $\mu\text{m}$   
Pore type: Microporous ceramics  
Porosity by sintering conditions  
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## LithaBone Materials are Osteoconductive and Osteoinductive

This is particularly important for the treatment of critical-size bone defects, but also beneficial in smaller defects, as it provides guidance for new bone growth. Preclinical<sup>7-9, 11-18</sup> and clinical proof<sup>2, 19</sup> for osteoconductivity of LithaBone materials has been published over the last years.

Beyond guiding growth, LithaBone materials have been found to actively stimulate bone regeneration by creating a bioactive microenvironment. Several studies have shown osteoinductive behaviour of LithaBone materials without the addition of external growth factors such as BMPs.<sup>2, 17</sup>

”

*In the present study, a hydroxyapatite graft was used .... It is biocompatible, osteoconductive and has osteoinductive properties, has appropriate porosity for the diffusion of nutrients, and the invasion of vascularization of the surrounding tissue.”*  
**Sarlo et al.**<sup>20</sup>

”

*It is an ideal osteoconductive and osteoinductive personalized bone substitute implant... Moreover, since it resembles the in-organic content of bone (apatite), the  $\beta$ -TCP gap-PSI will undergo resorption and remodelling into native bone tissue after its implantation.”*  
**Swennen et al.**<sup>3</sup>

# Bioresorption: From Implant to Bone

## Introduction

Successful bone regeneration requires a balance between material stability and biological resorption. 3D-printed LithaBone scaffolds are designed to gradually degrade while being replaced by newly formed, vital bone. A process that mirrors natural bone remodelling.

## Resorption - Mechanism

After implantation, osteoclasts attach to the ceramic surface and start to resorb calcium phosphates by releasing localised acids and enzymes. This controlled degradation releases ions, which in turn stimulate osteoblast activity and new bone formation within and around the scaffold pores.<sup>17</sup>

Another major advantage is that bone growth only occurs where it is needed. It could be shown by Swennen et al. that, due to bioresorption, even implants placed inaccurately by the surgeon the final fit after healing is excellent and compensates perfectly for the initial flaw.<sup>3</sup>

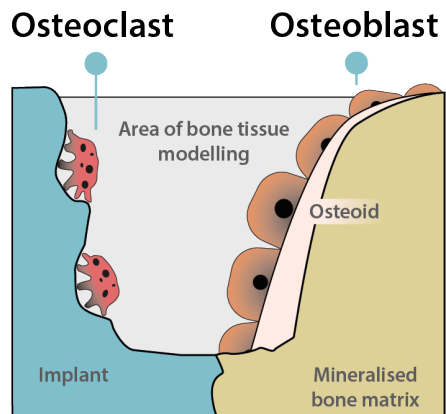
In an interesting article, Ghayor et al. provided deeper insights into resorption and osteoclastic effects.<sup>14</sup>

## 5 Year Follow Up Results - over 90 % Success Rate

A long-term clinical study confirmed the outstanding stability and biocompatibility of LithaBone TCP 300 patient-specific implants in bilateral sagittal split osteotomy (BSSO).

Over a follow-up period of 5 years,  $\beta$ -TCP implants made of LithaBone TCP 300 showed controlled resorption and complete integration with new vital bone, restoring a natural mandibular contour and preventing antegonial notching.<sup>3,21</sup> It showed a success rate of higher than 90% and no wound healing issues or surgical site infections occurred.<sup>3</sup>

3D-printed LithaBone HA 400 (hydroxyapatite) implants have been successfully used to reconstruct critical-sized cranial defects. One-year follow-up showed safety, efficacy, and mechanical properties comparable to native bone, supporting their use as an alternative to alloplastic materials in cranioplasty.<sup>9</sup>



Schematic simplified depiction of osteoclastic bone and calcium phosphate implant remodelling: Osteoclastic cells resorb bone and/or the implant while osteoblastic cells form new bone, which will mature eventually to mineralised bone matrix.

# Clinical Considerations

As for example used in numerous successful clinical cases by **KLS martin** GROUP

## Mechanical Properties

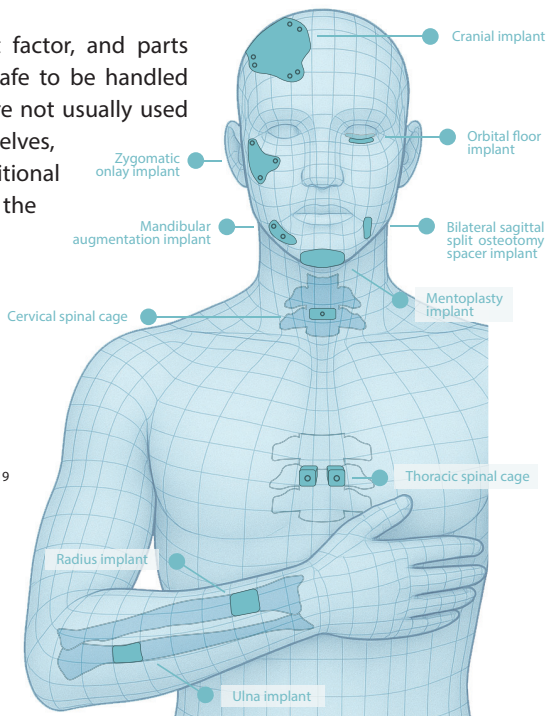
Mechanical strength is an important factor, and parts made from LithaBone materials are safe to be handled during surgical procedures. As they are not usually used for load-bearing applications by themselves, they are typically accompanied by additional measures to support the defect during the healing phase.

## Fixation of the Implant

Fixation of bone replacement has been conducted successfully by titanium screws<sup>20</sup> and polymeric pins by ultrasonic welding (SonicWeld RX®, KLS-Martin, Tuttlingen, Germany),<sup>9,19</sup> which are also resorbable and therefore don't need a second surgery for removal after healing. Furthermore, Swennen et al. found that the implants can be intra-operatively adapted with standard surgical tools.<sup>3</sup>



Zygomatic onlay graft made of LithaBone HA 480 fixed with a polymeric, resorbable pin.



Schematic model with Lithography-based Ceramic Manufacturing (LCM) printed implants.

## Sterilisation of the Implant

Thanks to the high temperatures of the sintering process, which is an essential part of the implant production, the parts are already sterile after manufacturing. However, since the parts must be handled and packaged,

subsequent sterilisation is typically conducted. LithaBone parts have been successfully sterilised by gamma irradiation,<sup>2-4, 9, 20, 25</sup> a validated and widely established method in medical device manufacturing. Also autoclaving and ethylene oxide sterilization have been reported.<sup>6</sup>

## Regulatory Clearance

*A necessary prerequisite for clearance of Lithoz' LCM technology by Brazilian Health Regulatory Agency Anvisa for medical devices is the non recirculation of material, made possible by its unique bottom-up print procedure, ensuring maximal efficient material use.*

## Cleanroom Production of All Material Products

Lithoz has set a new quality benchmark for ceramic-based slurries used in medical applications. An ISO Class 8 cleanroom ensures that the highest purity and quality requirements are consistently met during manufacturing.

## 100% Quality Control in an ISO 13485 Environment

Our comprehensive 100% quality control ensures that every product fulfils the highest demands for our medical customers. Documentation according to cGDP (current Good Documentation Practice) guarantees full traceability and results in a Certificate of Conformity (CoC) for each product.

Embedded in a certified quality (management) system, complying with ISO 13485, ISO 9001 and 21 CFR Part 820 (FDA) covering both development and production, these measures meet the stringent reliability and predictability requirements of all products.



More on Lithoz  
Medical Materials  
and Applications



More on Lithoz  
Certified Quality  
Management System

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