aXOpore® OTO

Patient Specific Implant (PSI)

PCL-TCP Regenerative Implant

For Segmental Defect

Osteopore®

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aXOpore® OTO

Patient Specific Implant

Osteopore's 3D printed scaffold, made to fit, bioresorbable implant used in the treatment of critical-sized segmental defects.

aXOpore® OTO PSI's patented interconnected pores mimics the natural cancellous bone microstructure to promote tissue and vascular ingrowth.

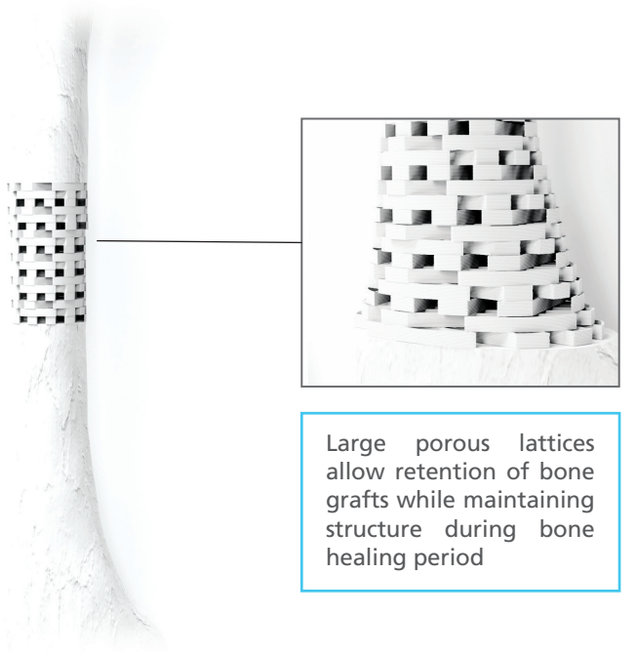
Homogeneous composite of Polycaprolactone –Tricalcium Phosphate (PCL-TCP), provides sufficient mechanical strength, is biodegradable and provide osteoconductive properties.

Suitable for bone reconstruction of severely injured patients up to 10cm. Compatible with fixation devices such as Intramedullary nails, Plates and Screws and Ilizarov frame etc.

aXOpore® OTO Patient Specific Implant

PT60-S	up to 5cm/sterile
PT60-M	> 5 cm to 10 cm/sterile

aXOpore® OTO PSI is supplied, in whole or in parts of a sub-assembly.
The product is packaged sterile and ready-to-use.



Large porous lattices allow retention of bone grafts while maintaining structure during bone healing period

Figure 1.1: **aXOpore® OTO PSI** manufactured in compliance with current Good Manufacturing Practice (cGMP), EN ISO 13485, and is provided sterile by gamma irradiation in accordance with EN ISO 11137.

Advantages of using aXOpore®[1]

Pain free full weightbearing achieved within 12 months

aXOpore® enables early partial weightbearing when implanted with a stable fixation.

Promising short-medium term results

High patient satisfaction and functional limb restoration.

CLINICAL EVIDENCE

aXOpore® OTO PSI is safe and effective. Clinical studies published on reputable journals suggest new bone formation on long bone applications.

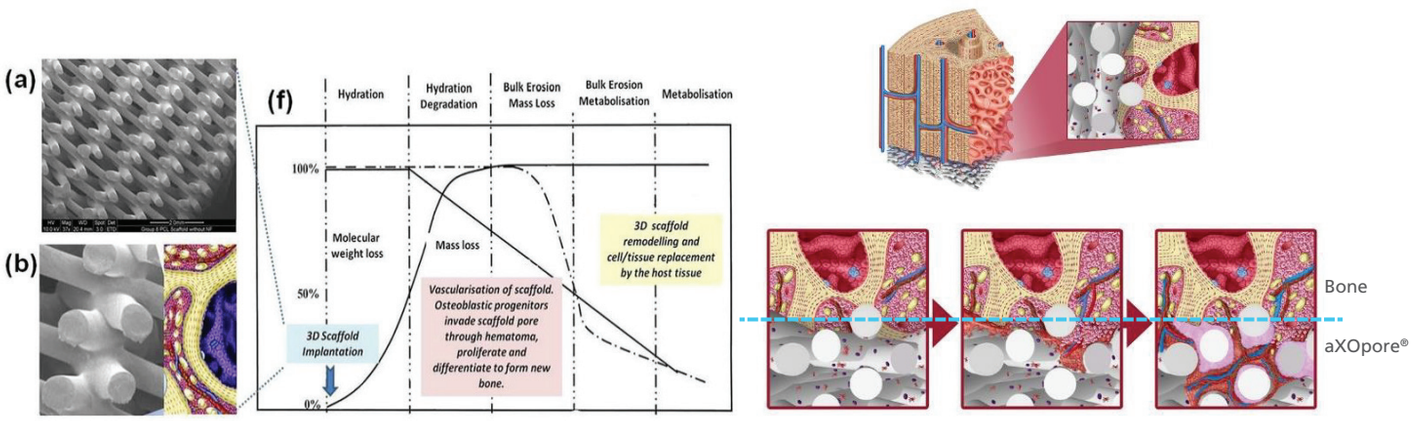


Figure 2.1: **aXOpore® OTO PSI** degrades over time to facilitate bone regeneration while replaced by new host tissue [2]

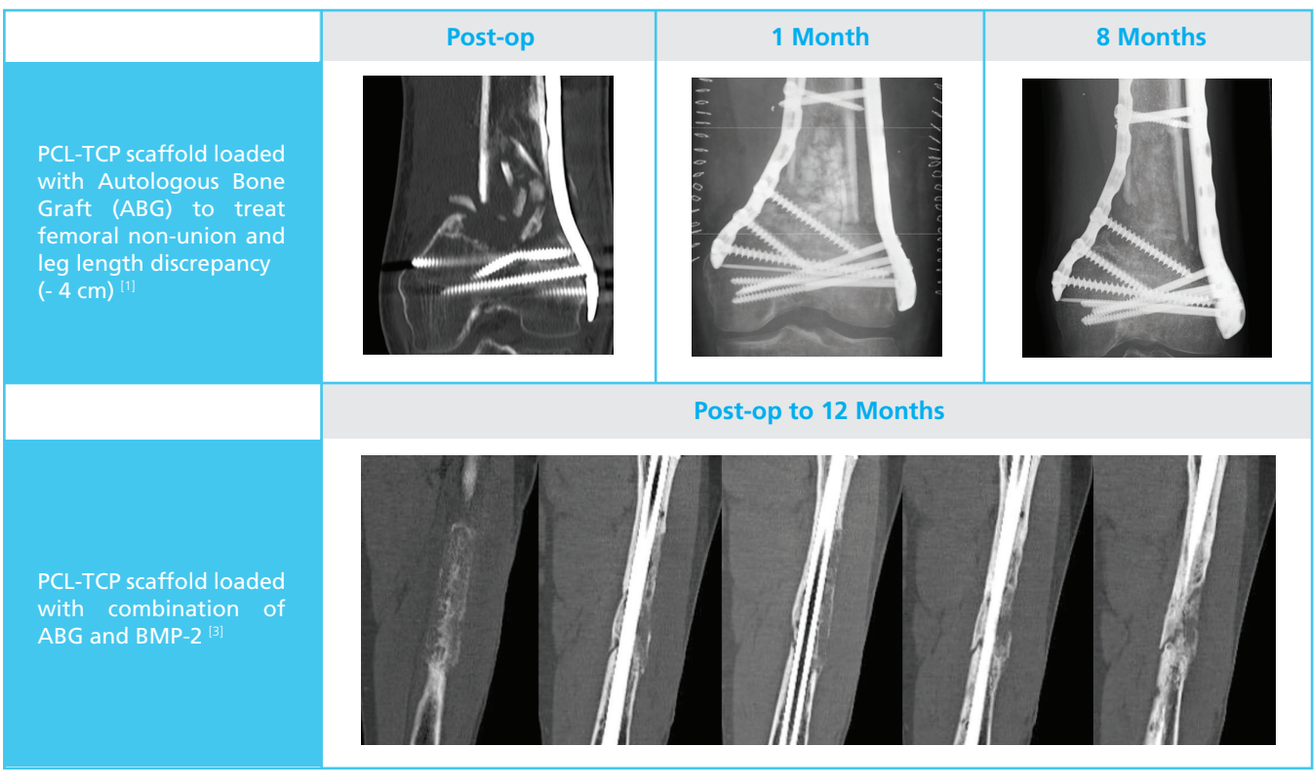


Figure 2.2: Anteroposterior view of patients treated with **aXOpore® OTO PSI**

1. Ordering Information

aXOpore® OTO PSI is for patients only when the treating physician deems there is reasonable time to perform surgical planning, customisation, and manufacturing of a customised implant.

When considering the use of **aXOpore® OTO PSI**, please ensure that you request information on the amount of time needed to manufacture, sterilise, and ship the implant from Osteopore sales representative and logistics.

2. Contraindications

i. Do not use in patients with conditions including: latent or active infections, systemic disorders which will hinder wound healing, or with insufficient quantity or quality of bone stock.

ii. Do not use in contaminated surgical areas.

iii. Do not use in patients with septic reactions.

iv. Not indicated for load bearing anatomical sites.

v. Do not use in areas exposed to outside environment.

ORDERING PROCESS

aXOpore® OTO Patient Specific Implant – a fully customisable solution designed and manufactured to meet your patient's specific clinical needs.

Step 1 **Surgeon request**	Fill the Patient Specific Implant – Long Bone Form. Sales assists surgeon and radiologist with upload of request form and CT scan via secure portal.
Step 2 **CT scan**	Use CT Protocol to obtain CT scan of defect post primary surgical procedure. Apply metal artifacts reduction if metal fixation device is present.
Step 3 **Reconstruction of CT scan via 3D modelling**	Upon receipt of Form and CT scan of defect. Design and Engineering Team to check the details provided. Design and Engineering Team to organise an online or on-site consultation with surgeon to confirm bone defect morphology and surgical approach.
Step 4 **Design and 3D print scaffold prototype**	Scaffold design evaluation and printability check. Surgeon approves design. Hospital issues purchase order based on approved design using registered product codes.
15 WORKING DAYS FROM DESIGN CONFIRMATION	
Step 5 **Manufacturing and sterilisation**	Manufacturing starts upon receipt of approved design and purchase order. Final product will be packed in foil pouch and sterilised*.
Step 6 **Delivered**	Sales and Logistics will provide tracking information and delivery confirmation to hospital/surgeon

* Do not resterilise

3. CT Scan Parameters

Matrix (minimum)	512 x 512
Slice thickness	0.6mm to 1mm
Reconstructed slice increment	0.6mm to 1mm
Reconstructed algorithm	Bone or High Resolution
Gantry tilt	0°
Accepted media	CD[*1] or wireless file transmission[*2]
Patient information	Anonymised for patient privacy

[*1]Please mail the CD to: 2 Tukang Innovation Grove, #09-07 JTC MedTech Singapore 618305
Attention to: Customer Service (CMF/Orthopaedic)

[*2] Please email to: cmdsolutions@osteopore.com
Please indicate the desired area of reconstruction in the email (e.g. OTO tibial defect, OTO femoral defect, OTO calcaneum defect, etc.).

Osteopore® only accepts uncompressed DICOM data

References

1. Laubach, M et al. (2022). Clinical translation of a patient specific scaffold guided bone regeneration concept in four cases with large long bone defects. Journal of Orthopaedic Translation, 34(April), 73–84.
2. Woodruff, M. A. et al. (2012). Bone tissue engineering: From bench to bedside. Materials Today, 15(10), 430–435.
3. Kobbe, P et al. (2020). Convergence of scaffold guided bone regeneration and RIA bone grafting for the treatment of a critical sized bone defect of the femoral shaft. European Journal of Medical Research, 25(1),1–12.

Manufactured by

Osteopore®
Empowering Natural Tissue Regeneration

Osteopore International Pte Ltd

www.osteopore.com

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