

aXopore®

Custom-Made Device (CMD)

PCL-TCP Regenerative Implant

Registered with MHRA

For Critical-Sized Segmental Defect



Osteopore®

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aXOpore® CMD

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

aXOpore® CMD 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 20cm. Compatible with fixation devices such as Intramedullary nails, Plates and Screws and Ilizarov frame etc.

aXOpore® Custom-Made Device

PT60-S	2 cm to 5 cm/sterile
PT60-M	> 5 cm to 10 cm/sterile
PT60-L	> 10 cm to 20 cm/sterile

aXOpore® CMD is supplied, in whole or in parts of a sub-assembly.

The product is packaged sterile and ready-to-use.

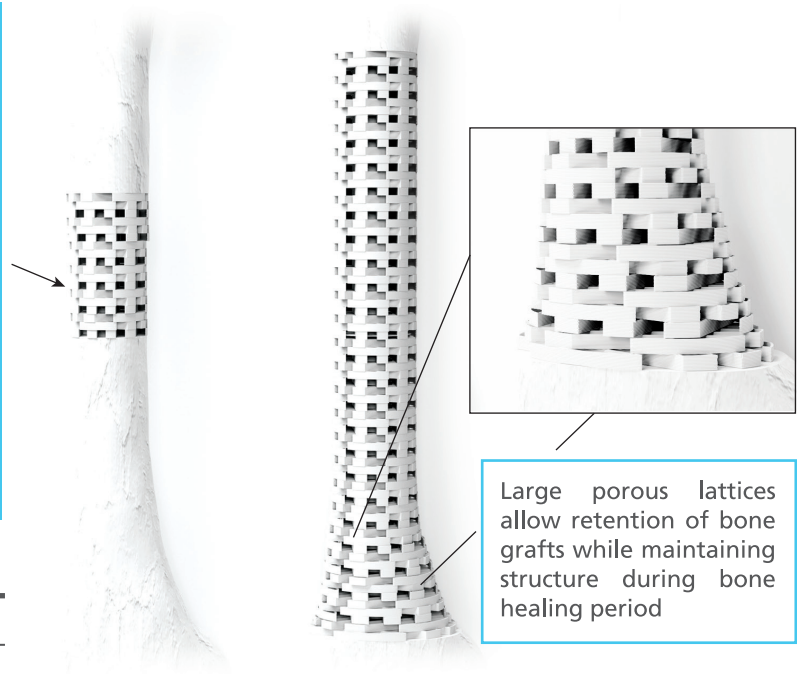


Figure 1.1: aXOpore® CMD is manufactured in compliance with current Good Manufacturing Practice (cGMP, EN ISO 13485) and provided sterile by gamma irradiation (gamma irradiation, EN ISO 11137)

Advantages of using aXOpore®^[1]



Pain free full weightbearing achieved within 12 months

aXOpore® enable early partial weightbearing when implanted with a fixation device.



Promising short-medium term results

High patient satisfaction and functional limb restoration.

CLINICAL EVIDENCE

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

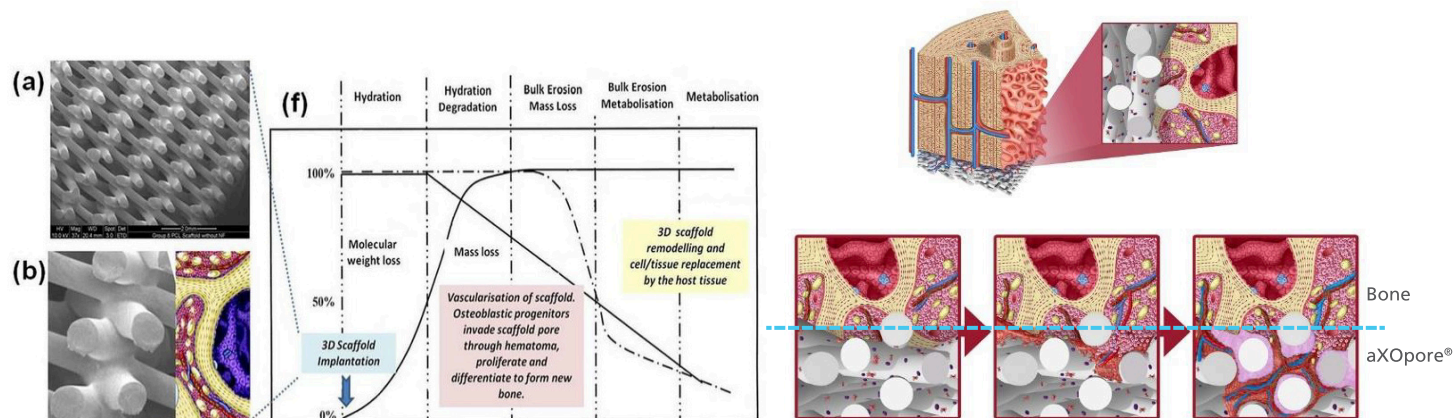


Figure 2.1: aXOpore® CMD degrades over time to facilitate bone regeneration while replaced by new host tissue [2]

	Post-op	1 Month	8 Months
PCL-TCP scaffold loaded with Autologous Bone Graft (ABG) to treat femoral non-union and leg length discrepancy (- 4 cm) [1]			
	Post-op to 12 Months		
PCL-TCP scaffold loaded with combination of ABG and BMP-2 [3]			

Figure 2.2: Anteroposterior view of patients treated with aXOpore® CMD

Ordering Information

aXOpore® CMD 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® CMD, 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.







aXOpore® CMD is registered with the Medicines & Healthcare products Regulatory Agency (MHRA) for supply in Great Britain.

2. Contraindications

- 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.
- Do not use in contaminated surgical areas.
- Do not use in patients with septic reactions.
- Not indicated for load bearing anatomical sites.
- Do not use in areas exposed to outside environment.

ORDERING PROCESS

aXOpore® CMD – a fully customisable solution designed by Osteopore’s multi-disciplinary team led by physicians.

	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 Protocol

Matrix (minimum)	512 x 512
Slice thickness	1mm or less
Feed per rotation	1mm or less
Reconstructed slice increment	1mm or less
Reconstructed algorithm	Bone or High Resolution
Gantry tilt	0°
Accepted media	CD or wireless file transmission

aXOpore® 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

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