

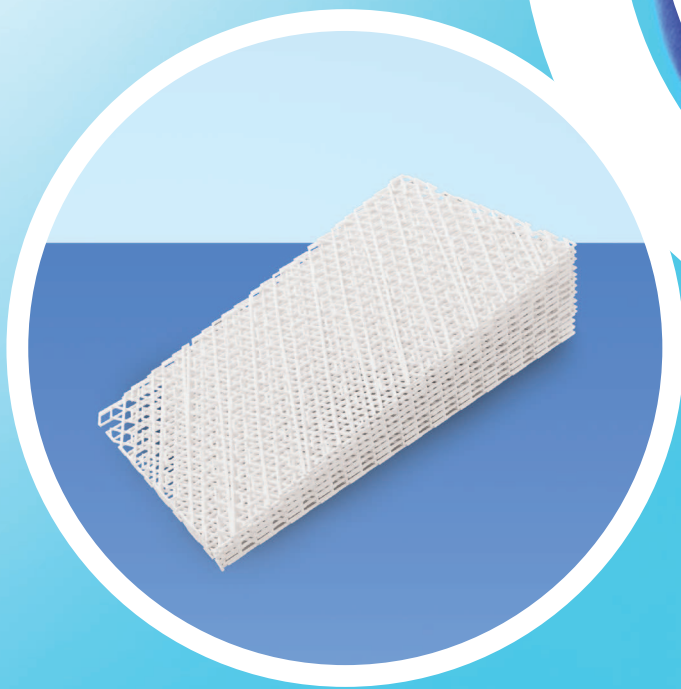
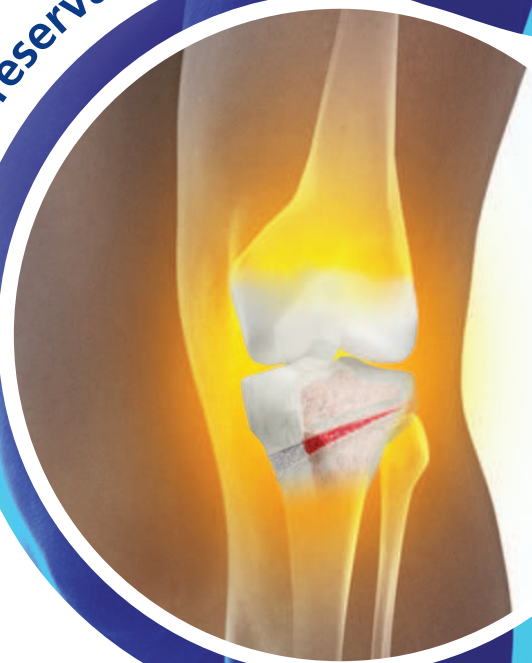
aXOpore[®] OTO

High Tibial Osteotomy (HTO) Wedge

PCL-TCP Regenerative Implant

- Osteoconductive
- Bioresorbable
- Supports early weight bearing
- Quick and easy implantation

For Knee Preservation Surgery



Osteopore[®]

aXCOpore[®] OTO HTO Wedge is favorable with patient's bone



VS



Biomimetic

Body readily accepts HTO Wedge and begin forming new vasculature within its interconnected pores upon implantation.

HTO wedge begins to resorb within 12 months post-implantation, concurrent with the process of osteogenesis.



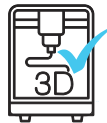
Not optimised for bone regeneration

The risk of nonunion in auto/allo-grafts can arise from poor integration with the patient's bone, often due to compromised blood supply and graft instability^[1].

Bioceramics may exhibit reduced strength retention as they resorb, thereby limiting their suitability for load-bearing applications.

Readily accessible and safe

HTO Wedge is highly reproducible by 3D printing in an EN ISO 13485 certified facility.



Donor site morbidity and limited in source

Additional injury is created during harvesting of host's graft. Thus, increasing the risks of post-op complications.

Fully synthetic

HTO Wedge does not contain any human or animal tissues and is non-toxic. Water and CO₂ are byproducts.



Higher risks of disease transmission

Allografts may pose a risk of disease transmission and potential bone infections.

Time saving and easy to use

HTO Wedge is made to fit on most osteotomy gaps. It is sterile and ready to be used.



Time consuming and inconsistent fit

The harvesting and preparation of auto/allo-grafts are time-consuming and labor-intensive. Optimal fit varies from surgeon to surgeon.

Advantages of using aXCOpore[®] OTO



Supports early full weight bearing

Progression from partial to full weight bearing is viable with satisfactory alignment at 4 weeks postoperatively^[2].



Promising short-medium term results

High patient satisfaction and functional limb restoration^[3].

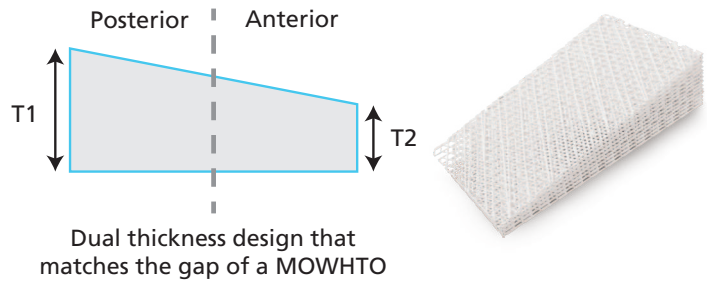
PRODUCT FEATURES

- aXOpore® OTO is a composite of Polycaprolactone - Tricalcium phosphate
- Recommended for Medial Opening Wedge High Tibial Osteotomy (MOWHTO)
- If required, aXOpore® OTO HTO Wedge can be trimmed with a blade to ensure a proper fit
- No soaking of arterial blood is required

PRODUCT CODE Thickness T1,T2 (mm)

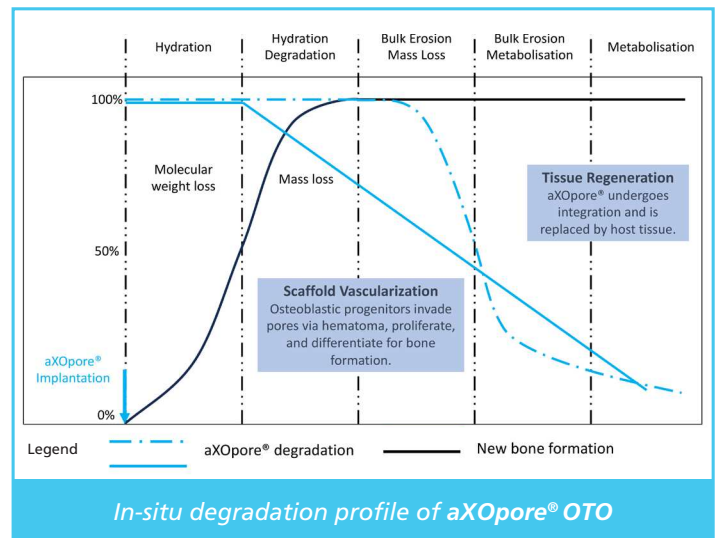
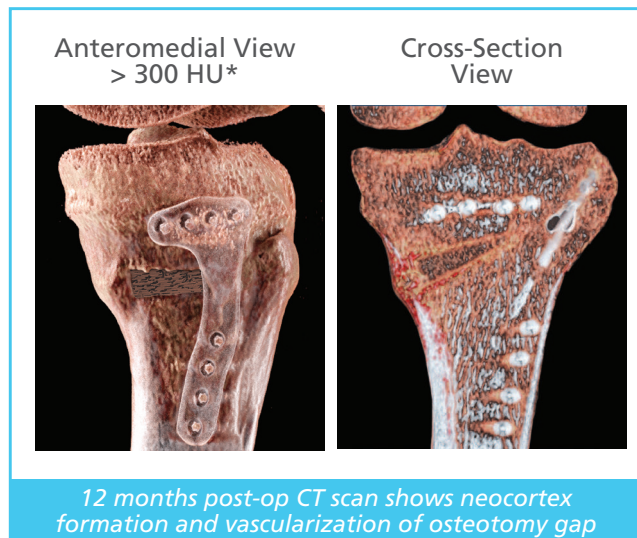
PT41 40 x 25 x 6 x 4 mm	6,4
PT41 40 x 25 x 8 x 6 mm	8,6
PT41 40 x 25 x 10 x 8 mm	10,8
PT41 40 x 26 x 12 x 10 mm	12,10
PT41 50 x 28 x 14 x 12 mm	14,12
PT41 60 x 30 x 16 x 14 mm	16,14

IMAGE

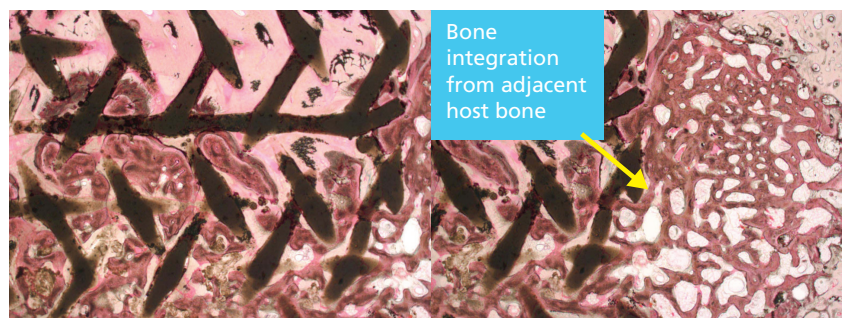


CLINICAL EVIDENCE

HTO Wedge degrades over time and is replaced by new host tissue to facilitate bone regeneration^[4].



*Thresholding was applied to isolate cortical bones only (Left). Vascularised aXOpore® OTO HTO Wedge remains within the bone gap (Right).

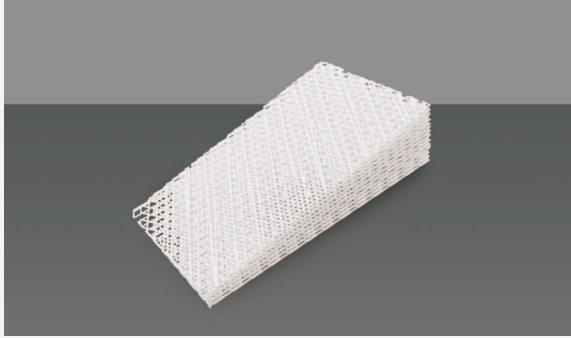


Microscopic images at six months in a micropig model indicate new bone growth within aXOpore® OTO interconnected pores (dark brown) and bone integration from nearby host tissue^[5].

SURGICAL TECHNIQUE GUIDE

1 Select HTO Wedge

Preoperatively, select a HTO wedge that matches the thickness of the correction gap. The HTO wedges are available in 6 sizes (6mm, 8mm, 10mm, 12mm, 14mm and 16mm).



2 Preparation of HTO Wedge

The wedge can be implanted before or after fixation. Trimming of the wedge intraoperatively to ensure fit is viable. Maintain bone gap with a bone spreader until definitive fixation is achieved.



3 Gently pack into osteotomy gap

With a forceps or by hand, insert the narrow part of the wedge first. The pre-constructed HTO Wedge is then press fit into the osteotomy gap.

Note: The HTO wedge may be oriented to fit the larger posterior gap or as deemed appropriate in an opening wedge osteotomy.



4 Closure of Surgical Site

The technique, method and product used to achieve closure of surgical site should follow the current standard of care.

During reparative phase, bone marrow will fill up the free spaces within the porous scaffold to achieve osteogenic potential.



References

1. Andrzejowski, P. et al. (2019). The 'diamond concept' for long bone non-union management. *Journal of Orthopaedics and Traumatology*, 20(1).
2. Wong, S.Y.W., Razak, H.R.B.A. et. al. (2023). Technical Note For The Novel Osteopore® Wedge In Medial Opening Wedge High Tibial Osteotomy [Unpublished manuscript]
3. Laubach, M et al. (2002). 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), 72-84.
4. Woodruff, M. A. et al. (2012). Bone tissue engineering: From bench to bedside. *Materials Today*, 15(10), 430-435.
5. Lim, H. C. et al. (2011). High tibial osteotomy using polycaprolactone-tricalcium phosphate polymer wedge in a micro pig model. *Journal of Bone and Joint Surgery - Series B*, 93 B(1), 120–125.