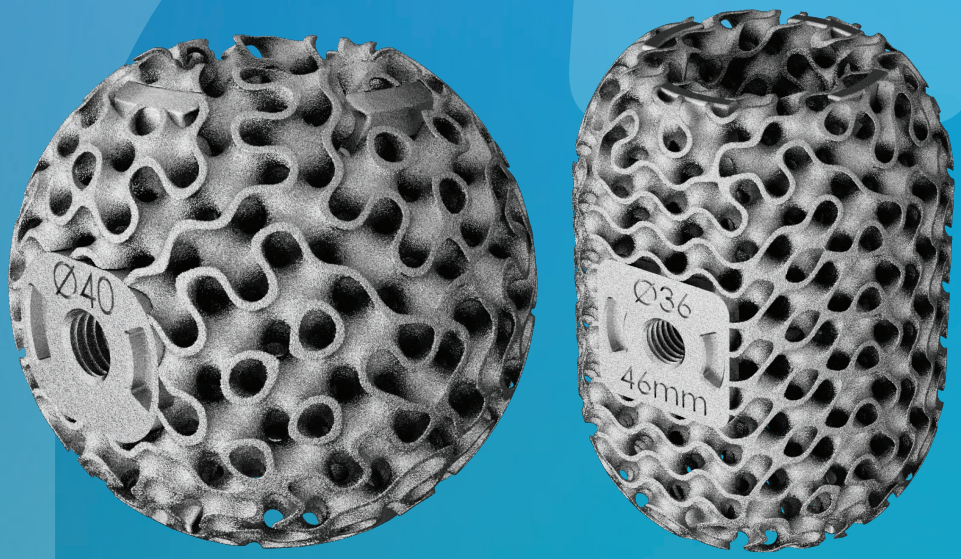
Surgical Technique



Ossera™ AFX System

Dome and Pill Implants

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Indications for Use

Ossera™ AFX System

The Ossera™ AFX System is intended to be used as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The Ossera™ AFX System is intended for use as an accessory to the DynaNail TTC Fusion System. The Ossera™ AFX System is not intended for standalone use. The Ossera™ AFX System is intended for use with autograft and/or allogenic bone graft.

Implant Overview

The Ossera™ AFX is available in a variety of shapes and sizes, designed to maximize bony contact of the native anatomy and provide a structural element to maintain leg length and promote fusion across a void in a TTC salvage procedure. Each Ossera™ AFX includes a 15mm central cannulation, sized to provide circumferential clearance for the largest diameter DynaNail TTC Fusion Nail, which is a 12mm diameter DynaNail. The Ossera™ AFX features interconnected TIDAL porous structure to provide structural graft containment and promote bony incorporation across the fusion surfaces.

The Ossera™ AFX Dome and Pill implants feature convex proximal and distal surfaces, wherein the distal surfaces are intended to terminate within the body of the talus. The Dome is substantially spherical in shape, while the Pill has convex end sections with an elongated central body. When using the Dome or Pill, the proximal and distal bone surfaces are prepared with a convex reamer, sized to mate with the convex surfaces of the Dome and Pill. Subsequent preparation of the subtalar joint for fusion is required as the implants should not cross the subtalar joint.

Ossera™ AFX implant shape and size selection is dictated by the anatomy, taking into account the amount of bone resected, desired limb length and soft tissue closure. Bone resection should be limited to the affected anatomy to minimize the resulting bone void. The ideal implant will have maximum bony contact on the proximal and distal surfaces while ensuring soft tissue closure may be performed without excessive tension on the soft tissue envelope during closure. Anterior-posterior and medial-lateral implant dimensions should not overhang the cortical margins of the respective bone by more than 2mm in any direction. The Dome and Pill may be used when a concave resection is preferred to minimize the amount of bone removed around the terminal ends.

Surgical Technique: Dome and Pill Implants

1. A direct lateral, anterior lateral or lateral extensile incision is made and dissection is taken down to expose the fibula and the ankle joint complex. Removal of prior hardware may dictate additional incisions.
2. Remove any prior hardware in the vicinity of the fusion that would prevent appropriate reduction or insertion of the Ossera™ AFX and DynaNail construct.
3. If present, perform a fibular osteotomy at the level of the affected anatomy about the ankle joint complex.

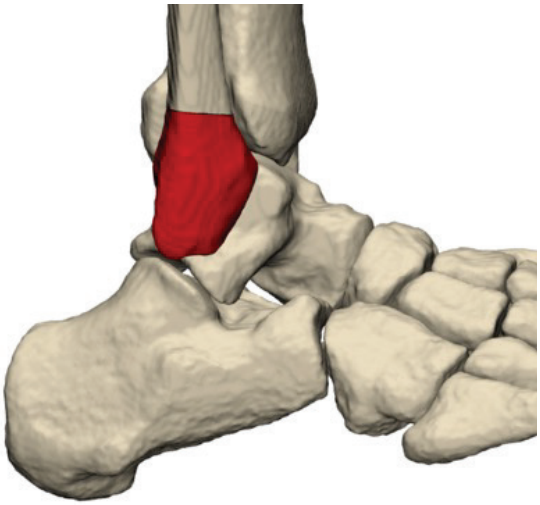

Fig. 1

4. Excise the fibula.
5. Prepare the implantation site using an appropriately sized convex reamer.

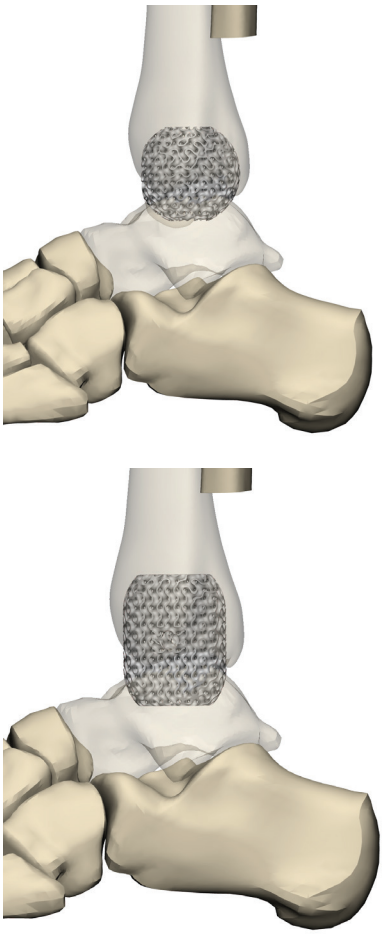

Fig. 2

NOTE: At final implantation, the distal aspect of the Dome or Pill should terminate in the talus.

5.1 If using a convex reamer in conjunction with a Dome implant, place the reamer in the center of the desired bone to be resected. Ream using flouroscopy to confirm adequate depth and size of the reamer. The reamer may collect bone which can be further used to pack the Ossera™ AFX prior to insertion of the definitive implant. After resecting the affected anatomy, the subtalar surface will require subsequent preparation – per the surgeon's preferred technique – to remove cartilage and subchondral bone for fusion, as the reamer and implant should not cross the subtalar joint.

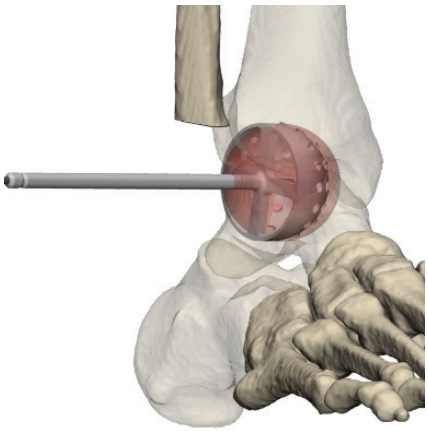

Fig. 3

NOTE: It is recommended to begin reaming with the appropriately sized convex reamer for the smallest intended implant size.

5.2 If using a convex reamer in conjunction with a Pill implant, place the reamer in the center of the desired proximal bone to be resected. Ream using flouroscopy to confirm adequate depth and size of the reamer. Remove the guide wire, then repeat the reaming procedure for the distal aspect of the resection. The reamer may collect bone which can be further used to pack the Ossera™ AFX prior to insertion of the definitive implant. After resecting the affected anatomy, the subtalar surface will require subsequent preparation – per the surgeon's preferred technique – to remove cartilage and subchondral bone for fusion, as the reamer and implant should not cross the subtalar joint.

6. Trials, identically sized to the corresponding implant, are available for each size and shape of Ossera™ AFX offered. Sequential trialing may be performed to assess multiple implant configurations prior to selecting the definitive implant.

6.1 If reaming was performed, the trial footprint should match the reamed anatomy. The trial footprint should provide adequate bone coverage between the trial and anatomy, maximizing cortical bone contact where applicable, without extending beyond the bone margins to avoid interaction with the adjacent soft tissues. The trial height should provide bone contact both proximally and distally to ensure adequate apposition of the Ossera™ AFX to bone. With the trial in place, approximate soft tissue closure to ensure the implant will not require excessive tension on the soft tissue envelope.

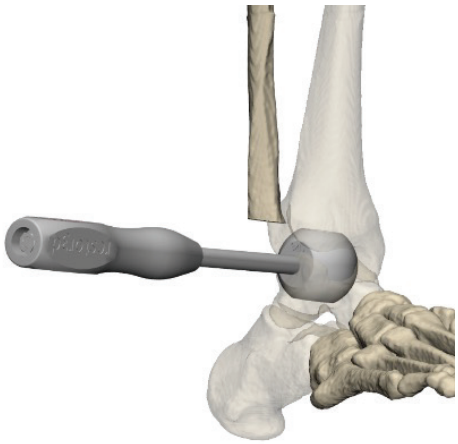

Fig. 4

7. Use trial to verify size, shape, and Ossera™ AFX alignment. The ideal implant will maintain the maximum cortical coverage at each end, where possible. Verify alignment of the trial's central hole with the tibial canal under fluoroscopy.

7.1 All Ossera™ AFXs and respective trials contain a 15mm central through hole that is compatible with all DynaNail IM nail diameters. IM Nail implant selection should be carried out according to the DynaNail Surgical Technique Guide and Instructions For Use. Select the DynaNail of appropriate length to ensure the proximal transverse screws are at least 2cm proximal to the Ossera™ AFX in the tibia, while accommodating for placement of the two distal nail screws in the calcaneus.

8. With the Ossera™ AFX implant trial in place, insert the DynaNail guide wire through the calcaneus and into the tibial canal under fluoroscopy guidance according to the DynaNail Surgical Technique Guide and Instructions For Use, which will determine nail trajectory. Confirm the guidewire is centered within the tibial canal and the trial's central hole in the anterior and lateral views.

9. Retract the guidewire distally from the tibia and trial until the trial can be removed. Remove the trial and insert the guidewire back into the tibia using the prior entry point.

10. Advance the DynaNail reamer in 0.5mm increments, until tibial cortical contact is made, under fluoroscopic guidance to confirm adequate construct alignment and position.

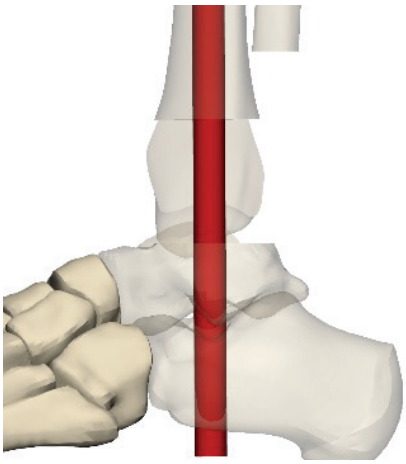

Fig. 5

11. With the definitive Ossera™ AFX implant selected, screw the inserter into the lateral insertion hole of the Ossera™ AFX. Autograft, allograft or synthetic bone graft material may be packed into the porous lattice and along the circumference of the central hole near each end of the Ossera™ AFX. When the nail is advanced through the central hole of the Ossera™ AFX, the bone graft will help to prevent contact between the Ossera™ AFX and the nail.

12. Place the Ossera™ AFX into the surgical site such that the central hole of the Ossera™ AFX is aligned with the reamed tibial canal in the anterior and lateral views as verified under fluoroscopy. Use the inserter attached to the Ossera™ AFX to maintain implant position during nail insertion to minimize contact of the nail with the central hole of the Ossera™ AFX.

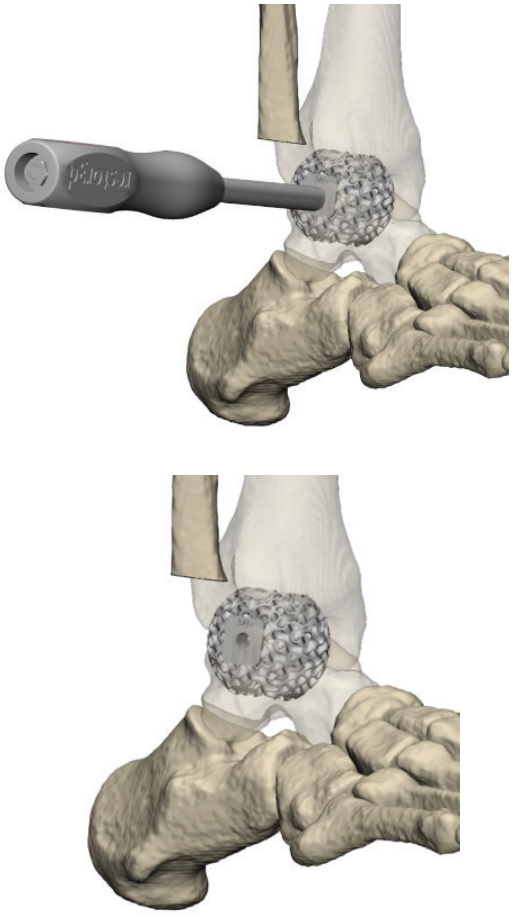

Fig. 6

13. The ™ Ossera™ AFX is indicated for use with the DynaNail TTC Fusion Nail. Follow the manufacturer's Instructions For Use to gradually advance and fixate the DynaNail, taking care, as described above to confirm coaxiality of the DynaNail and the Ossera™ AFX to limit intramedullary contact between the Nail and the Cage. Minor adjustments of the Ossera™ AFX placement may be made using the inserter to position the cage so that it is not contacting the nail. Confirm final alignment in the anterior and lateral views under fluoroscopy.

WARNING: Appropriate surgical technique should be followed to limit contact between the Ossera™ AFX and DynaNail TTC Fusion System construct. Contact between the implants may result in component wear, which could lead to adverse local tissue reactions, implant loosening and osteolysis.

14. Additional bone graft may be placed external to the Ossera™ AFX posteriorly, anteriorly and laterally, as dictated by the patient's anatomy.

15. Close the incision with the surgeon's preferred technique.

Surgical Technique: Removal Implant

1. In the event the implant construct must be removed, remove the fixation screws and DynaNail IM Nail per manufacturer's instructions for use.
2. Osteotomes may be used to loosen the bone-implant interface of the Ossera™ AFX.
3. The inserter may be threaded into the Ossera™ AFX to aid in removal.

Ordering Information:

Ossera™ AFX Dome & Pill Implants

PART NUMBER	DESCRIPTION
7000-0010-A	Ankle Cage Implant- Dome, 2 implant options
7000-0010-B	Ankle Cage Implant- Dome, 3 implant options
7000-0010-C	Ankle Cage Implant- Dome, 4 implant options
7000-0040-A	Ankle Cage Implant- Pill, 2 implant options
7000-0040-B	Ankle Cage Implant- Pill, 3 implant options
7000-0040-C	Ankle Cage Implant- Pill, 4 implant options

Instrumentation

PART NUMBER	DESCRIPTION
7000-0045	Ankle Cage Trial Kit

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CAUTION: Federal law restricts this device to sale by or on the order of a physician. Prior to use of a restor3d device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use.

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