Surgical Technique

Ossera™ AFX System

Cylinder, Half Pill and Rectangle 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. 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 Cylinder and Rectangle implants feature flat planar proximal and distal surfaces. When using the Cylinder or Rectangle, the proximal and distal bone surfaces are prepared with an orthopedic saw blade to create planar mating proximal and distal surfaces with the flat proximal and distal surfaces of the Cylinder or Rectangle. When performing planar saw cuts, ensure the ankle complex is in neutral alignment with the foot plantigrade and the saw cuts are parallel to each other.

The Ossera™ AFX Half Pill features a convex distal surface and horizontal planar proximal surface. When using the Half Pill, the distal bone surface is prepared with a convex reamer sized to mate with the distal spherical surface of the Half Pill, while the proximal bone surface is prepared with an orthopedic saw blade to create a planar mating surface with the flat proximal surface of the Half Pill.

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 Cylinder, Rectangle and Half Pill may be used when a horizontal bone resection is required about both terminal ends (Cylinder and Rectangle) or one terminal end (Half Pill) of the implant. The Half Pill may be used when a concave resection is preferred to minimize the amount of bone removed around one terminal end (Half Pill) of the implant.

Surgical Technique: Cylinder and Half-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.

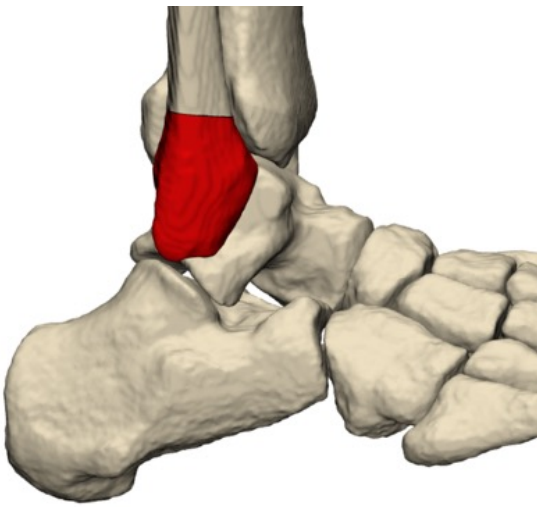


Fig. 3

4. Excise the affected anatomy and prepare the bony surfaces for fusion using an appropriately sized convex reamer and/or saw blade according to the selected implant shape.

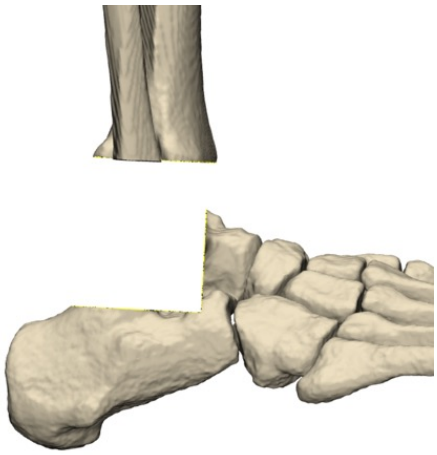


Fig. 4

4.1 If using the distractor and flat cut guides in conjunction with the Cylinder implant, insert a flat cut guide into each of the distractor jaws. (fig. 4.1a). Turn the distractor thumbscrew clockwise to expand the distractor jaws to the desired proximal and distal resection margins. (fig. 4.1b).

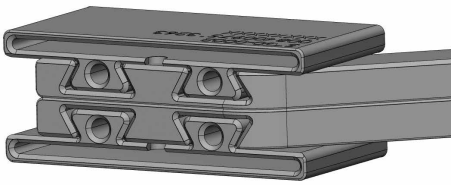


Fig. 4.1a

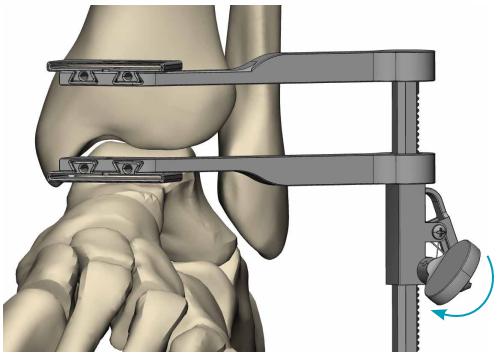


Fig. 4.1b

4.2. Under power, fixate each cut guide with two 2.4mm k-wires placed bicortically. (fig 4.2). X-rays may be used to confirm coronal and sagittal alignment of the cut guides.

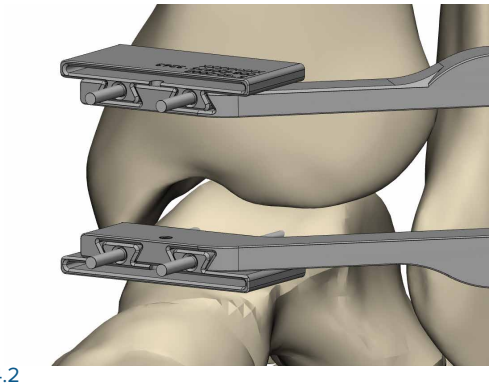


Fig. 4.2

4.3. Leaving the k-wires in place, slide the distractor off the flat cut guides. Under power, perform the resections using an osciallating saw. (fig. 4.3).

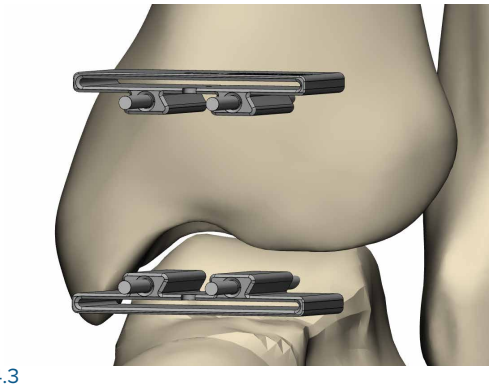


Fig. 4.3

Alternatively, the flat cut guides may be pinned with 2.4mm guidewires at the desired proximal and distal resection margins without using the distractor.

TIP: A single 2.4mm guidewire may be inserted through a hole in the proximal flat cut guide and used to confirm coronal alignment of the desired proximal cut plane under fluoroscopy prior to placing the remaining guidewires.

4.4. If using the flat cut guide in conjunction with the Half Pill implant, place the flat cut guide at the desired proximal resection margin. Insert two 2.4mm guidewires through the holes in the flat cut guide. (fig. 4.4). Use the flat cut guide to direct saw blade for proximal resection.

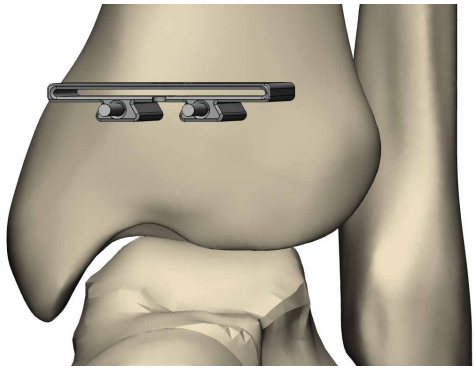


Fig. 4.4

TIP: A single 2.4mm guidewire may be inserted through a hole in the flat cut guide and used to confirm alignment of the desired proximal cut plane under fluoroscopy prior to placing the second guidewire.

4.5. If using a convex reamer in conjunction with a Half Pill implant, place 1.6mm guidewire in the center of the desired distal bone to be reamed. Ream using fluoroscopy to confirm adequate depth and size of the reamer. (fig. 4.5).

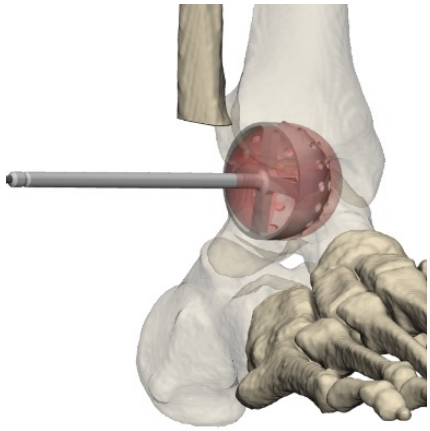


Fig. 4.5

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

5. 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.

5.1. If an off-the-shelf trial is used, attach the inserter to appropriate size trial by placing the prongs of the inserter into the corresponding lateral slots in the trial and rotating the knob clockwise while holding the handle. To remove the inserter, rotate the knob counterclockwise while holding the handle. (fig. 5.1).

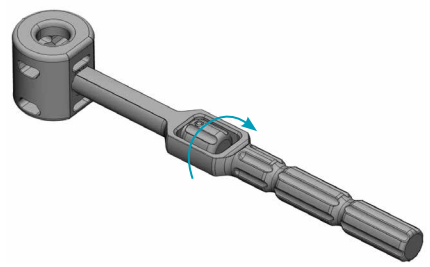


Fig. 5.1

5.2 If reaming was performed for a Half Pill implant, 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. (fig. 5.2). 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.

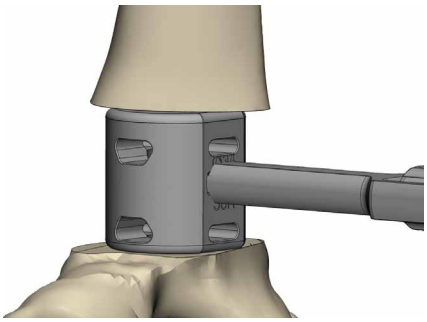


Fig. 5.2

6. 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.

6.1 All Ossera™ AFX implants 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.

7 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.

8. 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.

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

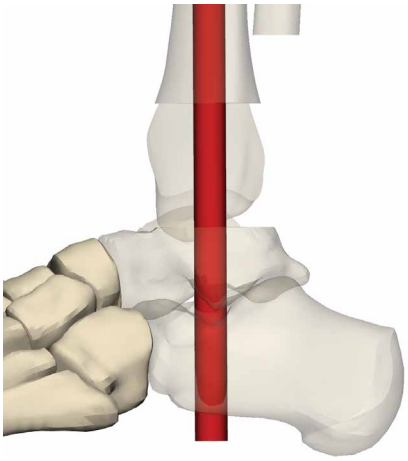


Fig. 9

10. With the definitive Ossera™ AFX implant selected, screw attach the inserter into the lateral insertion hole ofto the Ossera™ AFX by placing the prongs of the inserter into the corresponding lateral slots in the implant and rotating the knob clockwise while holding the handle. (fig. 10). 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.

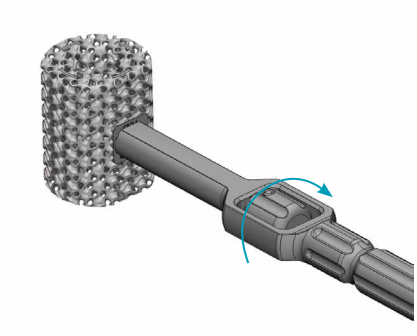


Fig. 10

11. 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. 11).

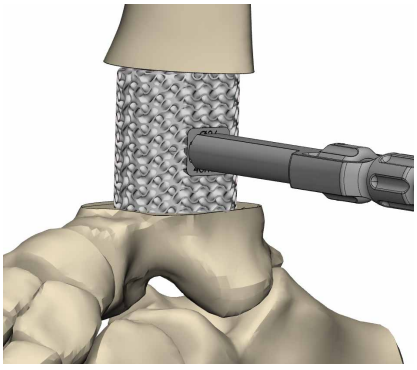


Fig. 11

12. 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. Remove the inserter from the Ossera AFX™ by rotating the knob counterclockwise while holding the handle.

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.

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

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

Surgical Technique: Rectangle Implants

15. A direct anterior 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.

16. Remove any prior hardware in the vicinity of the fusion that would prevent appropriate reduction or insertion of the Ossera™ AFX and DynaNail construct.

17. Prepare the bony surfaces for fusion using a saw blade and/or standard orthopedic instrumentation.

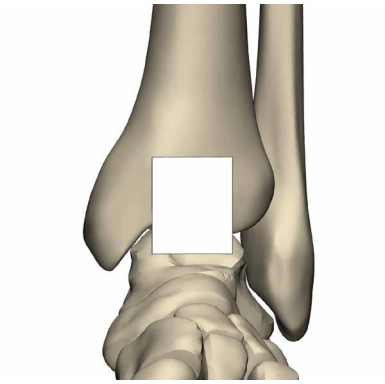


Fig. 17

18. 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.

18.1 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. (fig. 18.1). 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.

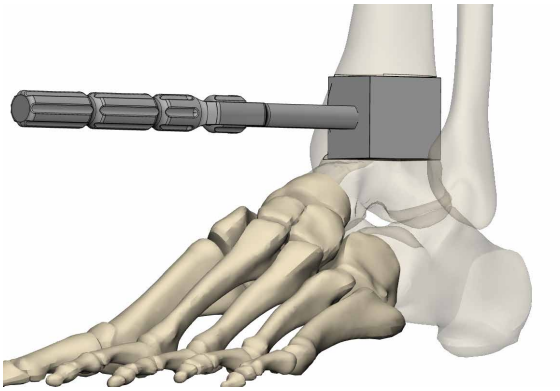


Fig. 18.1

19. 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.

19.1 All Ossera™ AFX 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.

20. 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.

21. 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.

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

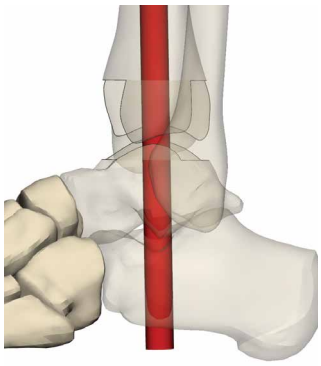


Fig. 22

23. With the definitive Ossera™ AFX implant selected, attach the inserter to the Ossera™ AFX by placing the prongs of the inserter into the corresponding anterior slots in the implant and rotating the knob clockwise while holding the handle. 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.

24. 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. 24).

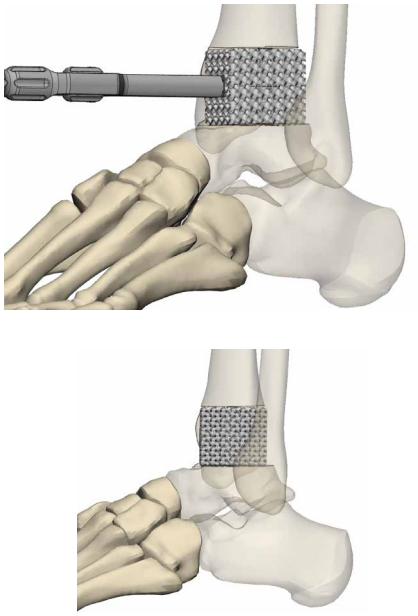


Fig. 24

25. 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. Remove the inserter from the Ossera AFX™ by rotating the knob counterclockwise while holding the handle.

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.

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

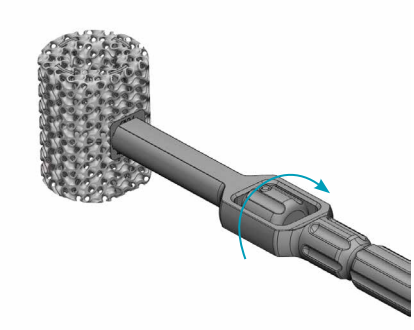
27. Close the incision with the surgeon's preferred technique.

Surgical Technique: Removal Implant

28. In the event the implant construct must be removed, remove the fixation screws and DynaNail IM Nail per manufacturer's instructions for use.

29. Osteotomes may be used to loosen the bone-implant interface of the Ossera™ AFX.

30. The inserter may be threaded into the Ossera™ AFX to aid in removal by turning the thumbscrew clockwise. (fig. 30).



Ordering Information:

Ossera™ AFX Cylinder, Half Pill, & Rectangle Implants – Made To Order

PART NUMBER	DESCRIPTION
7000-0030-A	Ankle Cage Implant- Cylinder, 2 implant options
7000-0030-B	Ankle Cage Implant- Cylinder, 3 implant options
7000-0030-C	Ankle Cage Implant- Cylinder, 4 implant options
7000-0050-A	Ankle Cage Implant- Half Pill, 2 implant options
7000-0050-B	Ankle Cage Implant- Half Pill, 3 implant options
7000-0050-C	Ankle Cage Implant- Half Pill, 4 implant options
7000-0020-A	Ankle Cage Implant- Rectangle 2 implant options
7000-0020-B	Ankle Cage Implant- Rectangle, 3 implant options
7000-0020-C	Ankle Cage Implant- Rectangle, 4 implant options

Ossera AFX Cylinder Implants – Off The Shelf

PART NUMBER	DESCRIPTION
1740-3426	Ossera AFX™, Cylinder, 34D x 26H
1740-3432	Ossera AFX™, Cylinder, 34D x 32H
1740-3436	Ossera AFX™, Cylinder, 34D x 36H
1740-3440	Ossera AFX™, Cylinder, 34D x 40H
1740-3632	Ossera AFX™, Cylinder, 36D x 32H
1740-3636	Ossera AFX™, Cylinder, 36D x 36H
1740-3640	Ossera AFX™, Cylinder, 36D x 40H
1740-3832	Ossera AFX™, Cylinder, 38D x 32H
1740-3836	Ossera AFX™, Cylinder, 38D x 36H
1740-3840	Ossera AFX™, Cylinder, 38D x 40H
1740-4032	Ossera AFX™, Cylinder, 40D x 32H
1740-4036	Ossera AFX™, Cylinder, 40D x 36H
1740-4040	Ossera AFX™, Cylinder, 40D x 40H

Instrumentation

PART NUMBER	DESCRIPTION
7000-0045	Ankle Cage Trial Kit
5801-0002	Drill Tip K-Wire Kit (Qty 2)
6202-165	Single Trocar Guidewire, 1.6mm x 5"
5801-4111	Sagittal Saw Blade, Conmed, 2 implant options
5801-4105	Sagittal Saw Blade, Stryker, 2 implant options

Notes

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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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