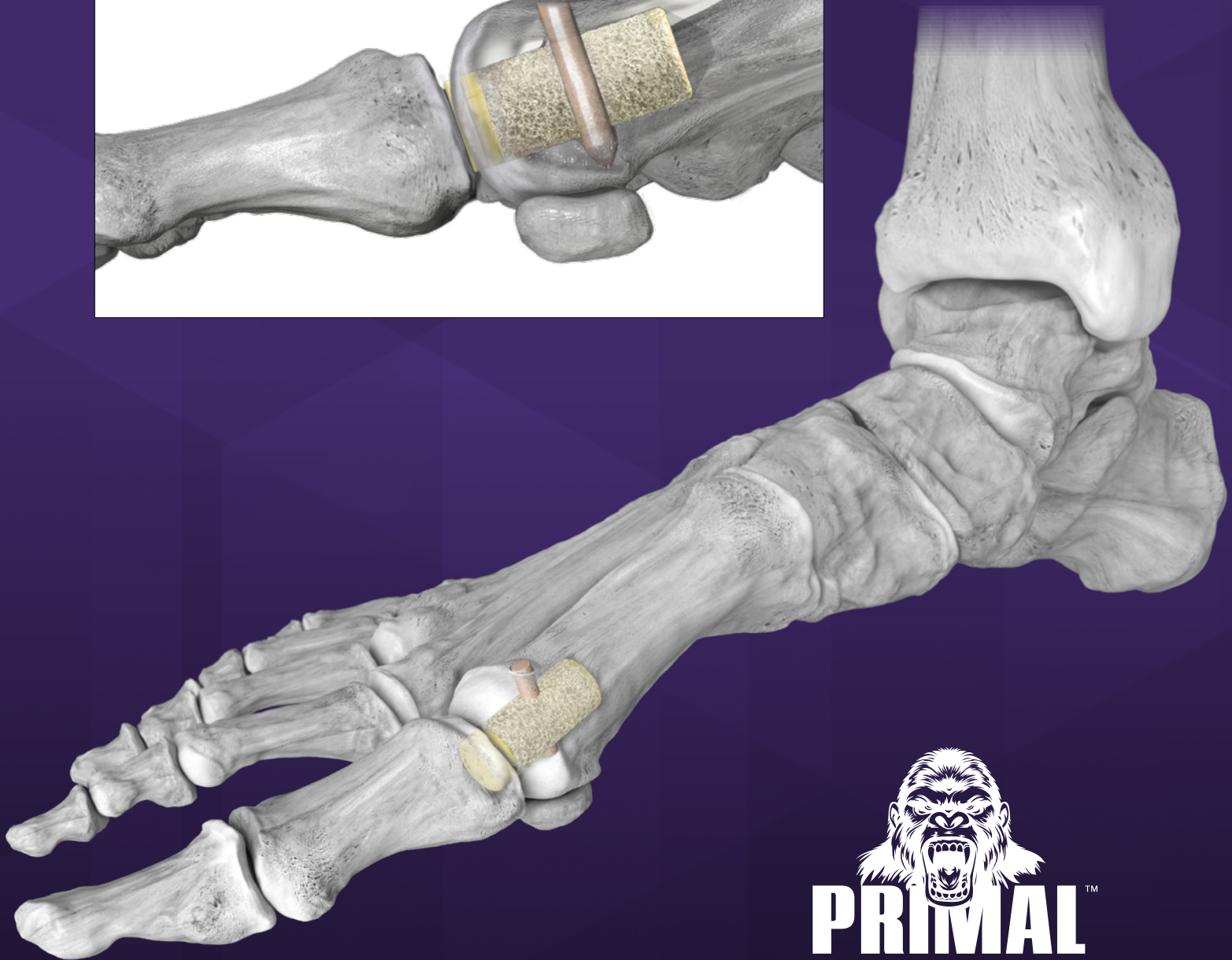
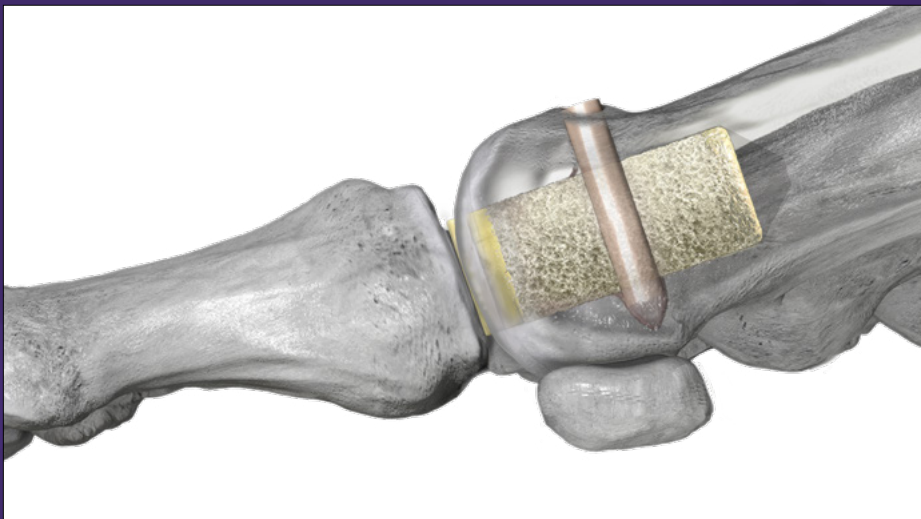


Paragon²⁰

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SURGICAL TECHNIQUE GUIDE

Primal OCD™ Osteochondral Defect (OCD) System



PRODUCT DESCRIPTION:

The Primal™ Osteochondral Defect (OCD) Cartilage Repair System is a joint-preserving cartilage repair system designed for the treatment of isolated osteochondral defects of the first metatarsal head. The system combines an osteochondral allograft plug with purpose-built instrumentation to provide controlled defect preparation, precise implant delivery, and stable fixation while preserving surrounding native anatomy.

Designed specifically for the unique anatomy of the first metatarsophalangeal joint, the Primal™ OCD System provides surgeons with a reproducible, stepwise technique for preparing the defect, sizing the implant, and achieving surface-flush implantation. Dedicated instrumentation includes a Flush Guide, implant-specific reamers, cortical pin guide, implant inserter, and fixation instruments that work together to support accurate implant placement while helping control implant depth and orientation throughout the procedure.

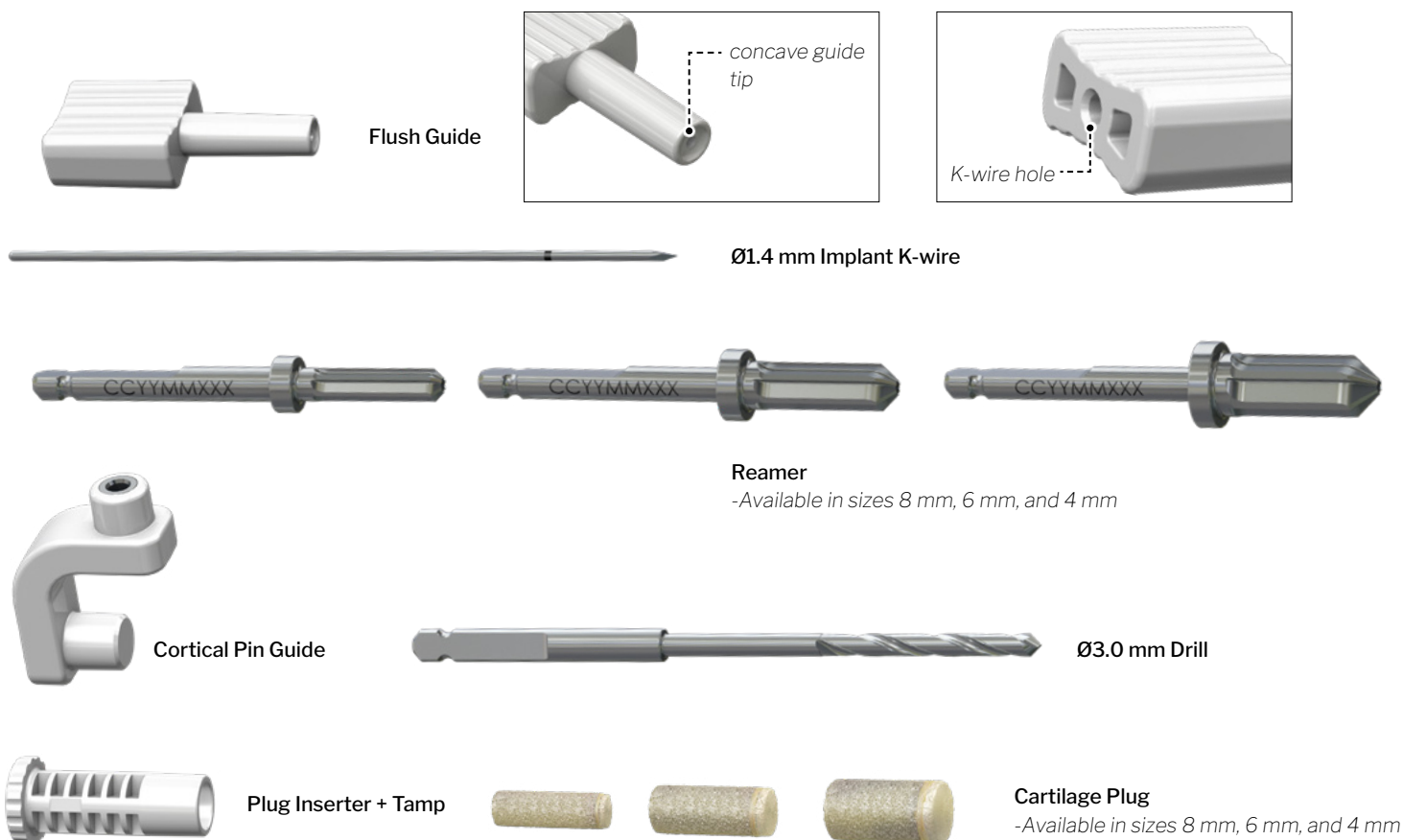
The system utilizes sterile packaged cartilage-containing osteochondral allograft plugs available in 4 mm, 6 mm, and 8 mm diameters, allowing surgeons to select an implant size that best matches the isolated defect while minimizing unnecessary resection of healthy bone and cartilage. Following implantation, fixation is achieved using either a threaded K-wire (4 mm construct) or a cortical bone dowel (6 mm and 8 mm constructs), creating a stable construct designed to resist implant migration and support maintenance of implant position.



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FEATURED INSTRUMENTATION:

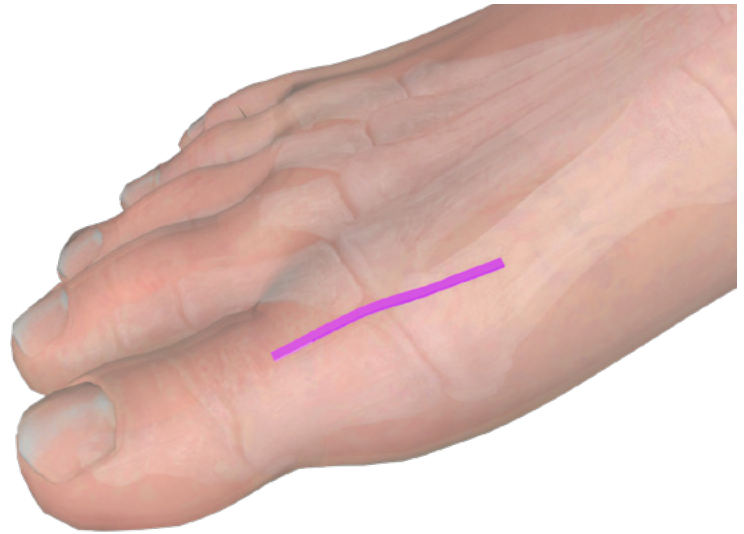
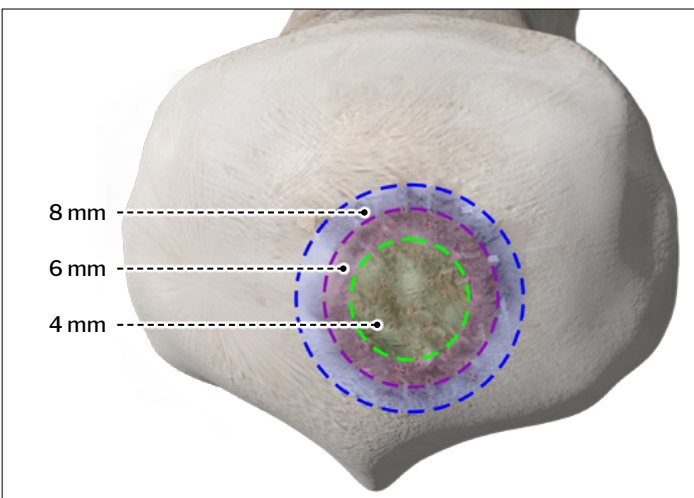


Surgical Technique - Osteochondral Deficit Repair

INCISION EXPOSURE:

Supine patient positioning with fluoroscopy available is recommended for this procedure. A dorsomedial incision over the 1st metatarsophalangeal joint is made.

Soft tissue dissection is continued to expose the 1st metatarsophalangeal joint. Release the soft tissue to obtain exposure of the articular surfaces of the 1st metatarsal head and hallux proximal phalanx base.

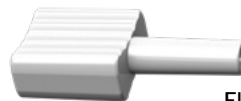


Assess defect diameter visually and/or with a ruler to determine appropriate implant size (4 mm, 6 mm, 8 mm offerings)

K-WIRE PLACEMENT:

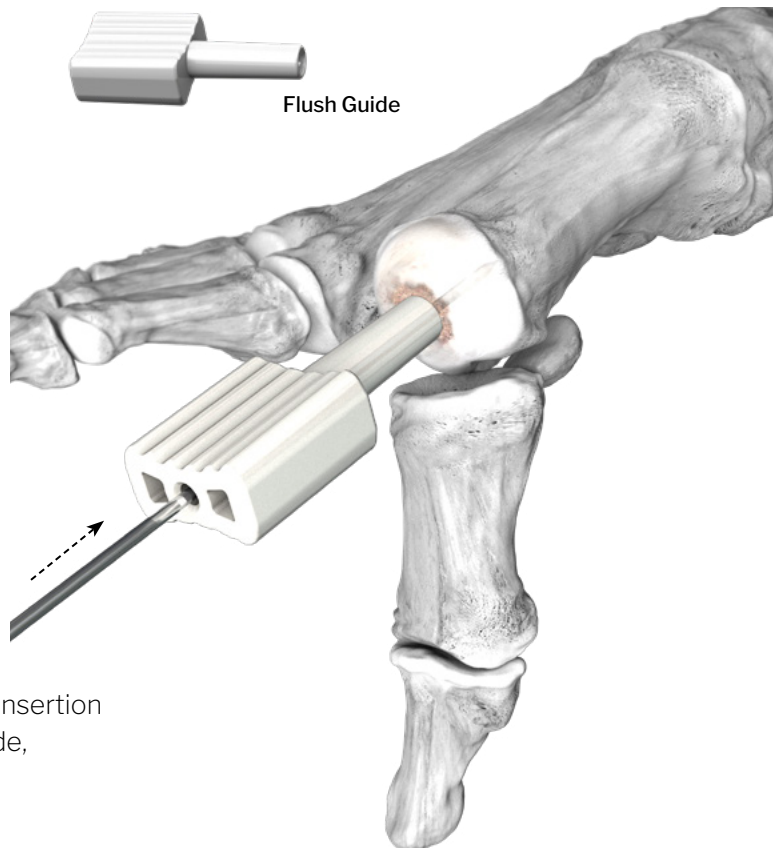


Ø1.4 mm Implant K-wire



Flush Guide

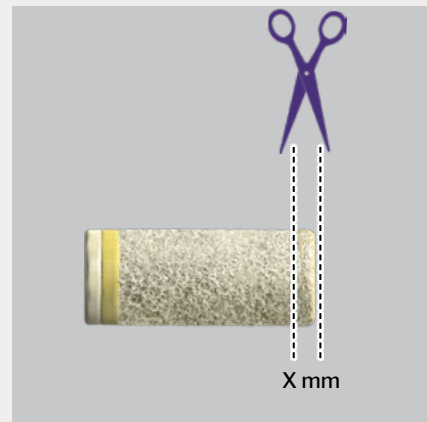
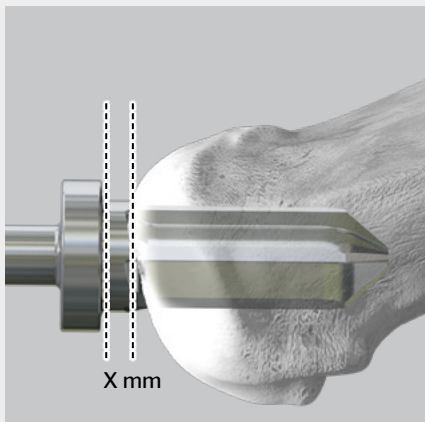
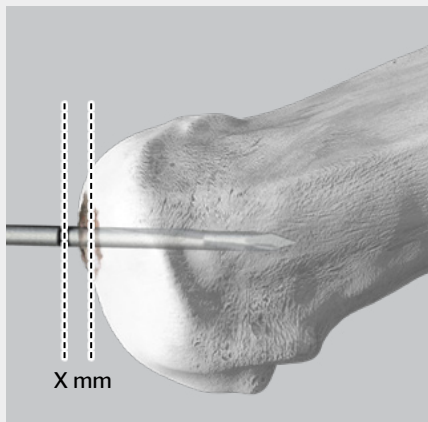
Place the tip of the Flush Guide flush onto the lesion on the metatarsal head. Holding the guide in place, drive the Ø1.4 mm implant K-wire through the hole in the back of the guide and into the metatarsal head until stable, avoiding the metatarsal cortices while inserting deep enough until the laser mark on the K-wire is flush or subflush to the metatarsal surface.



If the defect location makes it difficult to achieve such insertion depth, see the Note box on next page. Remove the guide, leaving the K-wire in place.

K-WIRE PLACEMENT:

- NOTE:** If the defect location makes it difficult to appropriately insert the K-wire deep enough into the metatarsal head, additional steps will be needed to facilitate insertion of a shortened implant.
- Insert the K-wire until the cortex is reached. Measure the distance from the laser mark to the metatarsal head surface, then:
1. Ream only until the depth stop is that same distance from the metatarsal head.
 2. Remove that length from the non-cartilage end of the implant before insertion.



IMPLANTATION AND PREPARATION:



Reamer

Slide the reamer sized appropriate to the implant size to be used over the K-wire and ream into the metatarsal head up to the depth stop on the reamer. Remove the reamer and K-wire.



Cortical Pin Guide

Insert the plug portion of Cortical Pin Guide into the reamed tunnel oriented such that the Guide hole is positioned dorsally on the metatarsal head, pivoting the guide if necessary. Ensure that the plug portion is fully inserted in the tunnel and the distal guide arm contacts the metatarsal head.



IMPLANTATION AND PREPARATION:

4 mm implantation VS. 6 mm and 8 mm implantation



Using either the Ø3.0 mm Drill for 6 mm or 8 mm implants, or the Threaded K-wire for 4 mm implant, drill through the guide hole and into the dorsal surface of the metatarsal head, through the dorsal cortex and into the reamed implant hole. Remove the drill/threaded K-wire and Cortical Pin Guide.

For 4 mm Implant:



For 6 mm or 8 mm Implant:



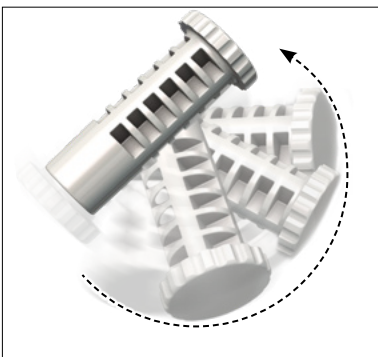
Load the Cartilage Plug into the Plug Inserter such that the cartilage side is inside the inserter, if not done already.



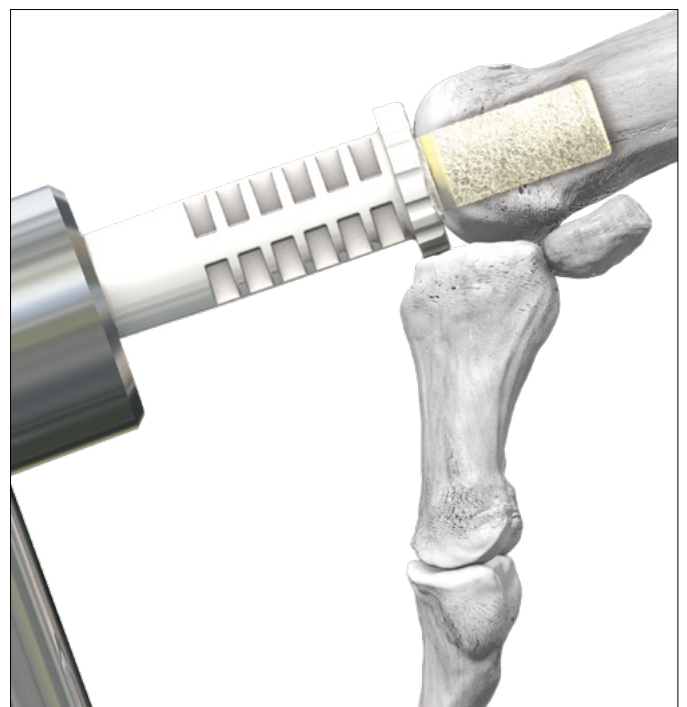
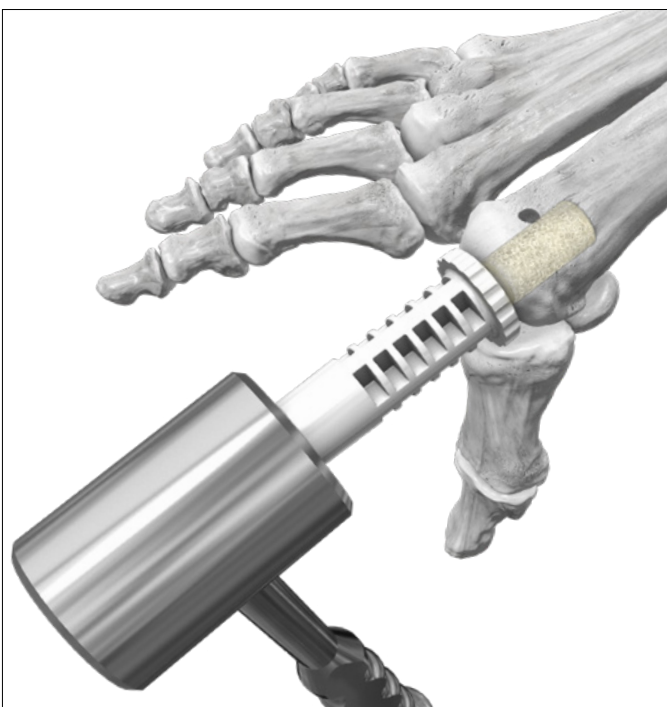
IMPLANT INSERTION AND FIXATION:

Use the inserter to guide the Cartilage Plug into the reamed hole until the inserter contacts the metatarsal surface, lightly tamping if necessary.

Remove the inserter, then flip around.

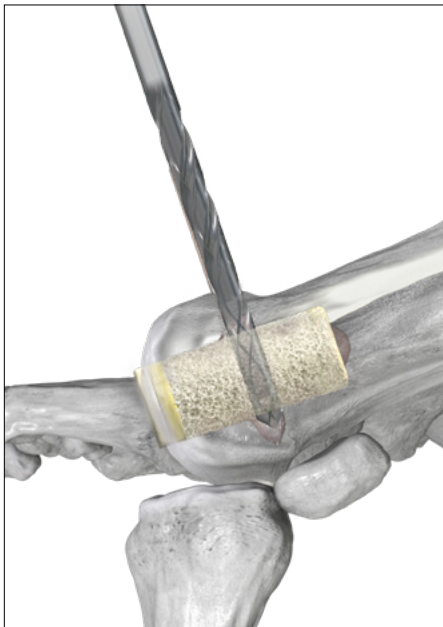


Use flat end as a tamping surface to help fully seat the implant in the reamed hole. Make sure that the cartilaginous end of the plug is as flush against the metatarsal head surface as possible, per surgeon's preference.

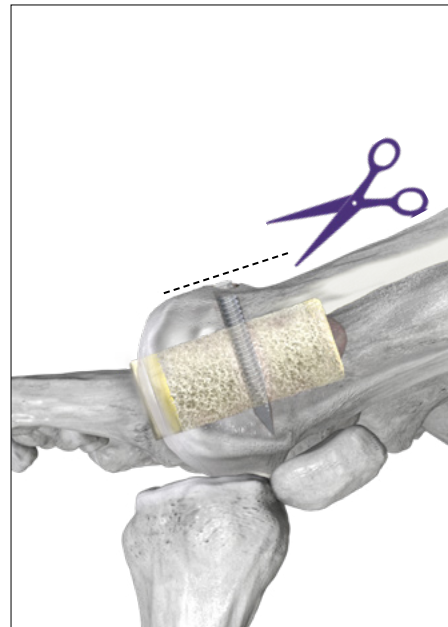
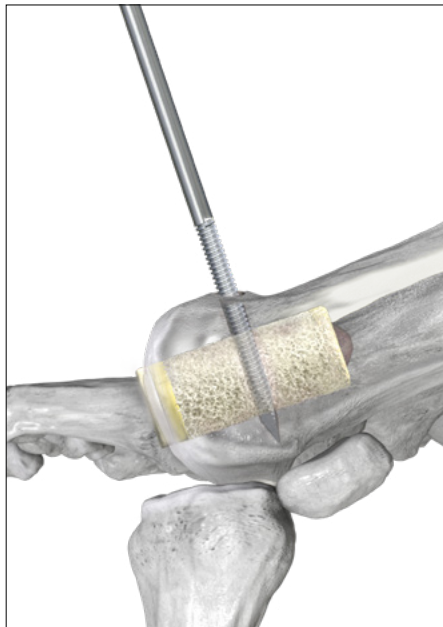


IMPLANT INSERTION AND FIXATION:

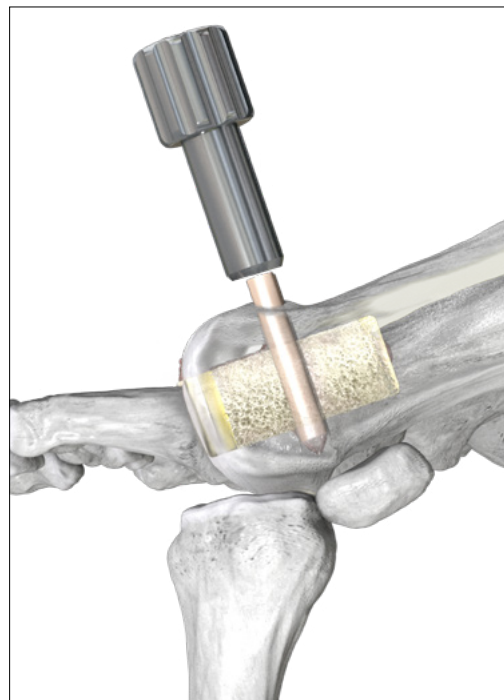
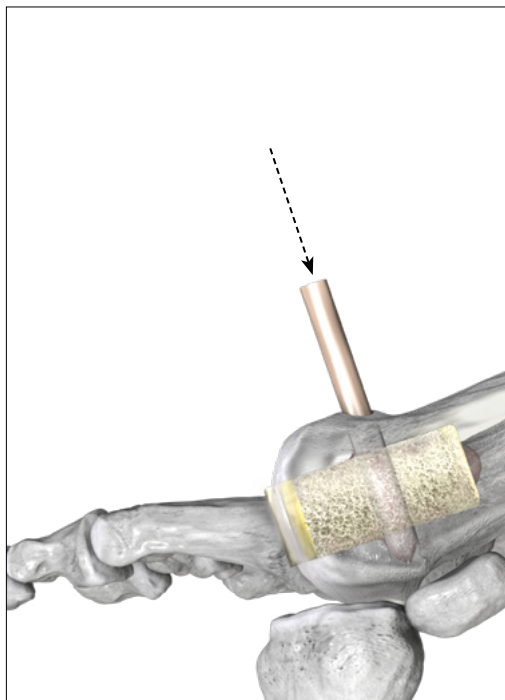
For 6 mm or 8 mm Implant:



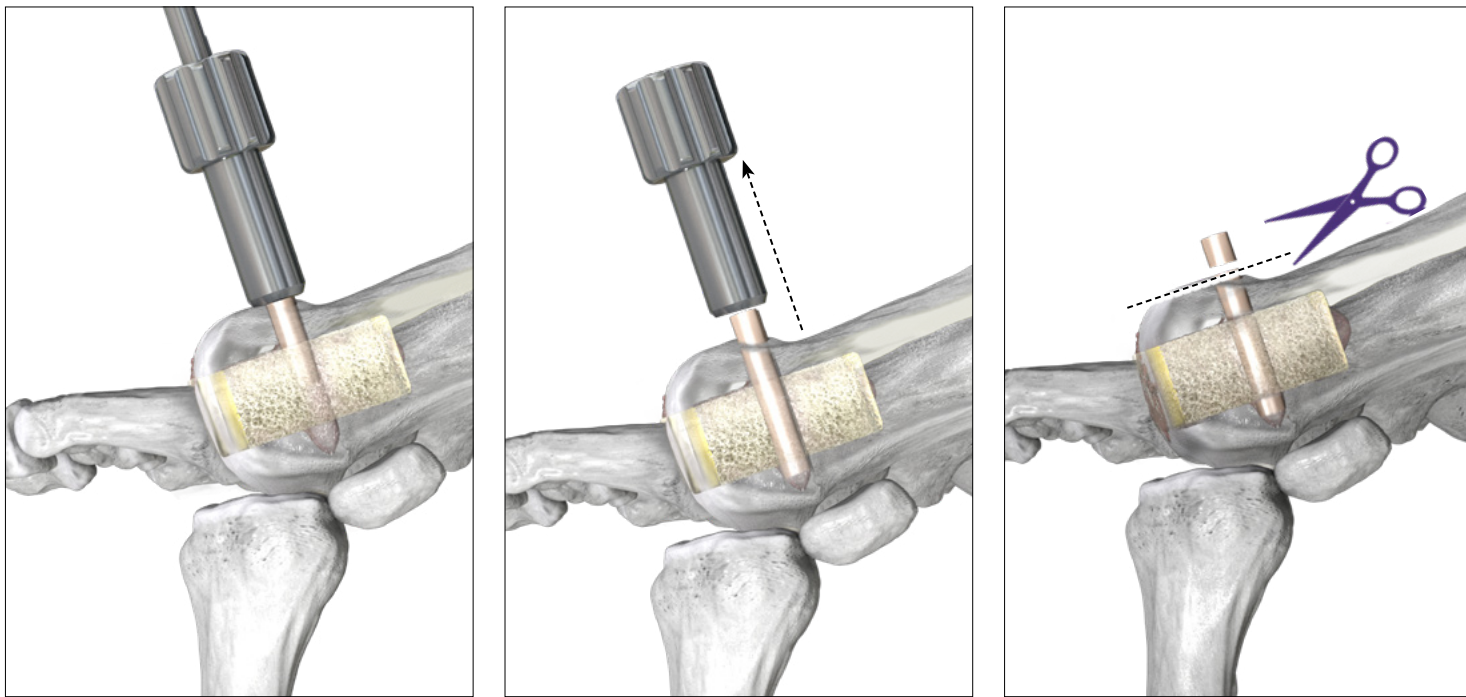
For 4 mm Implant:



Insert the same drill or threaded K-wire used previously into the dorsal hole. Drill/insert plantarly through the plug until the plantar cortex is reached, without violation. Remove the drill, if used. If using 4 mm implant and threaded K-wire, trim the K-wire flush with the metatarsal surface and the procedure is complete.



If using 6 mm or 8 mm implant, manually insert the tip of the cortical dowel into the dorsal hole enough that it remains stable. Slide the Dorsal guide over the cortical dowel down until it contacts the bone

IMPLANT INSERTION AND FIXATION: _____

Insert the Dowel Tamp in the guide, then tamp the end of the Dowel Tamp to guide insertion. Trim off any excess dowel so that the dorsal surface is flush with the metatarsal.

CLOSURE: _____

Proceed to incision closure and/or concomitant procedures.

SYSTEM REMOVAL: _____

For cases using the 4 mm implant, the K-wire can be removed by pulling dorsally from the metatarsal surface until fully removed.

INSTRUMENT KITS:



Primal OCD Instrument Kit, Ø4.0 mm:

[P69-900-0004-SK]

- ▶ K-wire Flush Guide
- ▶ Primal OCD K-wire, Ø1.4mm x 10cm
- ▶ K-wire, Ø1.4mm x 10cm, Threaded
- ▶ OCD Plug Reamer, 4mm
- ▶ Fixation Targeting Guide for 4mm Plug
- ▶ Cartilage Plug Inserter and Tamp, 4mm
- ▶ Cortical Dowel Drill, 3.0mm
- ▶ Cortical Dowel Tamp
- ▶ Cortical Dowel Tamp Guide

Primal OCD Instrument Kit, Ø6.0 mm:

[P69-900-0006-SK]

- ▶ K-wire Flush Guide
- ▶ Primal OCD K-wire, Ø1.4mm x 10cm
- ▶ K-wire, Ø1.4mm x 10cm, Threaded
- ▶ OCD Plug Reamer, 6mm
- ▶ Fixation Targeting Guide for 6mm Plug
- ▶ Cartilage Plug Inserter and Tamp, 6mm
- ▶ Cortical Dowel Drill, 3.0mm
- ▶ Cortical Dowel Tamp
- ▶ Cortical Dowel Tamp Guide



Primal OCD Instrument Kit, Ø8.0 mm:

[P69-900-0008-SK]

- ▶ K-wire Flush Guide
- ▶ Primal OCD K-wire, Ø1.4mm x 10cm
- ▶ K-wire, Ø1.4mm x 10cm, Threaded
- ▶ OCD Plug Reamer, 8mm
- ▶ Fixation Targeting Guide for 8mm Plug
- ▶ Cartilage Plug Inserter and Tamp, 8mm
- ▶ Cortical Dowel Drill, 3.0mm
- ▶ Cortical Dowel Tamp
- ▶ Cortical Dowel Tamp Guide

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INSTRUCTIONS FOR USE: PRIMAL OCD™ OSTEOCHONDRAL DEFECT (OCD) SYSTEM:

Indications, Contraindications, Warnings and Precautions relevant to the use of the Primal™ OCD System are contained in the Instructions for Use document of the Primal™ OCD System , P69-IFU-0001.

MR SAFETY INFORMATION:

The Primal™ OCD System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Primal™ OCD System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.



SURGICAL TECHNIQUE GUIDE

Primal OCD™ Osteochondral Defect (OCD) System

P69-STG-0001 RevA [2026-08-XX]

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