LOWER EXTREMITIES

REUSABLE INSTRUMENTATION

CARTIVA®

Synthetic Cartilage Implant

SURGICAL IMPLANTATION TECHNIQUE

First Metatarsal Phalangeal Joint

THE DIFFERENCE IS MOVING.™

TABLE OF CONTENTS

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

INTRODUCTION

CARTIVA® Synthetic Cartilage Implant (SCI) is intended to treat focal chondral or osteochondral defects of the articular cartilage surface associated with joint pain or decreased range of motion. The implant, a cylindrical device made from an elastic biomaterial, may be used as a replacement for damaged cartilage and bone without requiring the destruction or removal of a patient's healthy tissue. It is intended for use during a single surgical procedure. The procedure is similar to that used for osteochondral autograft or allograft transplantation; a part is placed into a pre-drilled hole to resurface the damaged area of cartilage/bone.

CARTIVA SCI is made from a proprietary biomaterial. The device, which is classified as a hydrated polymer, consists of water in similar proportion to human tissue. This organic polymer-based biomaterial is capable of withstanding repetitive loading typical of normal walking conditions, and its mechanical properties are similar to articular cartilage. CARTIVA SCI provides an alternative to tissue-based treatments without exposing the patient to the risk of viral transmission or an inflammatory response because it does not contain substances derived from human or animal tissue.

CARTIVA SCI is supplied in a range of sizes for selection by the physician. The device is supplied sterile and is packaged as a single unit.

For a comprehensive list of indications, contra-indications, warnings and precautions, see the product Instructions for Use.

The following procedure is furnished as an example for informational purposes only where CARTIVA is used in the treatment of osteoarthritis of the first metatarsophalangeal joint. Each surgeon must evaluate the appropriateness of the procedure based on his or her own surgical training and experience.

INDICATIONS

The CARTIVA Synthetic Cartilage Implant is intended for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

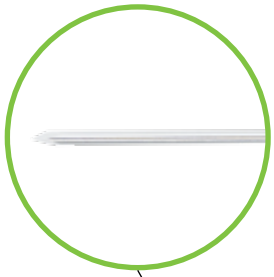
CONTRAINDICATIONS

The CARTIVA SCI should not be implanted in subjects with the following conditions:

- Active infection of the foot
- Known allergy to polyvinyl alcohol
- Inadequate bone stock due to significant bone loss, avascular necrosis, and/or large osteochondral cyst (> 1 cm) of the metatarsophalangeal joint
- Lesions of the first metatarsal head greater than 10 mm in size
- Diagnosis of gout with tophi
- Physical conditions that would tend to eliminate adequate implant support (e.g., insufficient quality or quantity of bone resulting from cancer, congenital dislocation, or osteoporosis), systemic and metabolic disorders leading to progressive deterioration of bone (e.g., cortisone therapies or immunosuppressive therapies), and/or tumors of the supporting bone structures

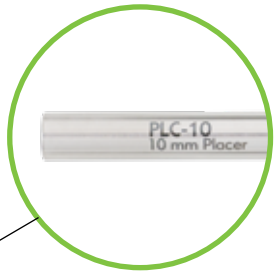
CARTIVA® INSTRUMENTATION

CARTIVA is implanted using dedicated instrumentation designed to provide the surgeon with an implant that is well-seated through a press-fit implantation.



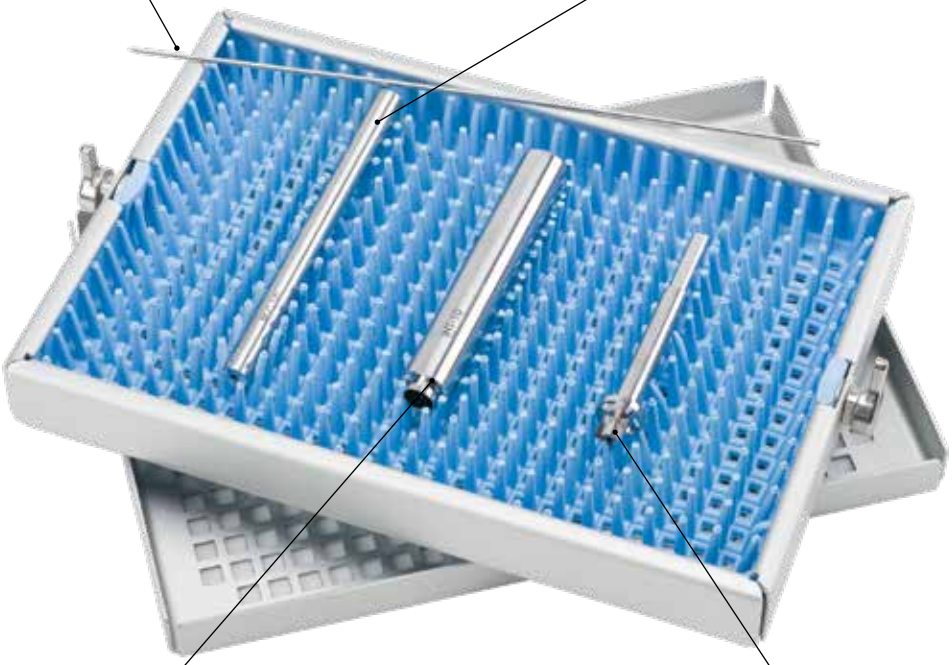
Guide Wire

2.0 mm non threaded.



Placer

Allows surgeon to target optimal implant position to address worst area of wear.



Instrumentation

Specific to the size of the device (8 mm or 10 mm) being implanted.

Introducer

Compresses CARTIVA prior to implantation.

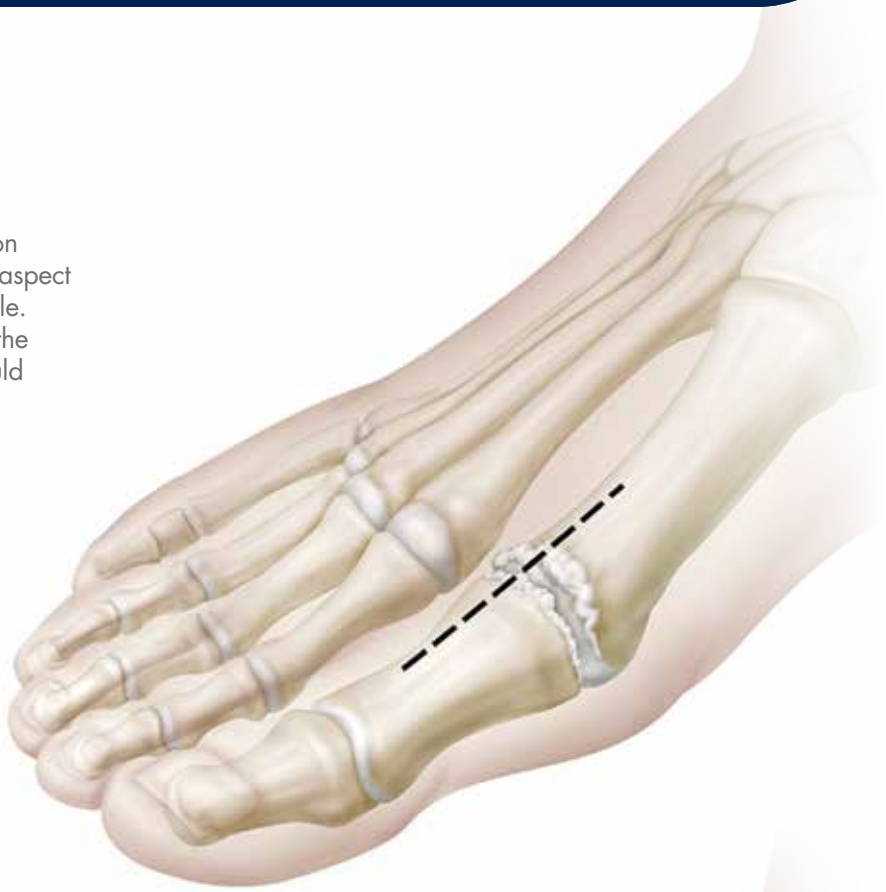
No fixation required.

Metatarsal Drill Bit

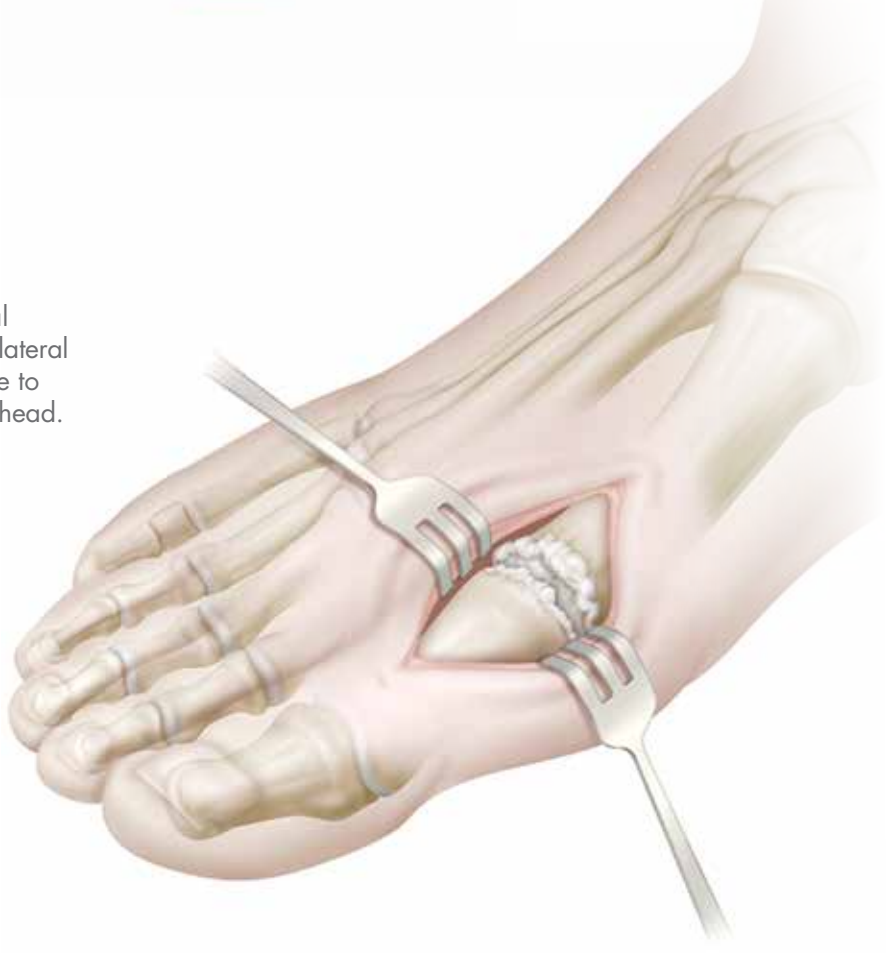
Stop to ensure proper height of press-fit implant.

EXPOSING THE MTP JOINT

Make a small straight dorsal or straight medial incision approximately 4 cm long along the dorsal or medial aspect of the first MTP joint to provide exposure of the capsule. Care should be taken to avoid nerve damage along the dorso-medial aspect of the joint. The EHL tendon should also be protected during the dorsal approach.

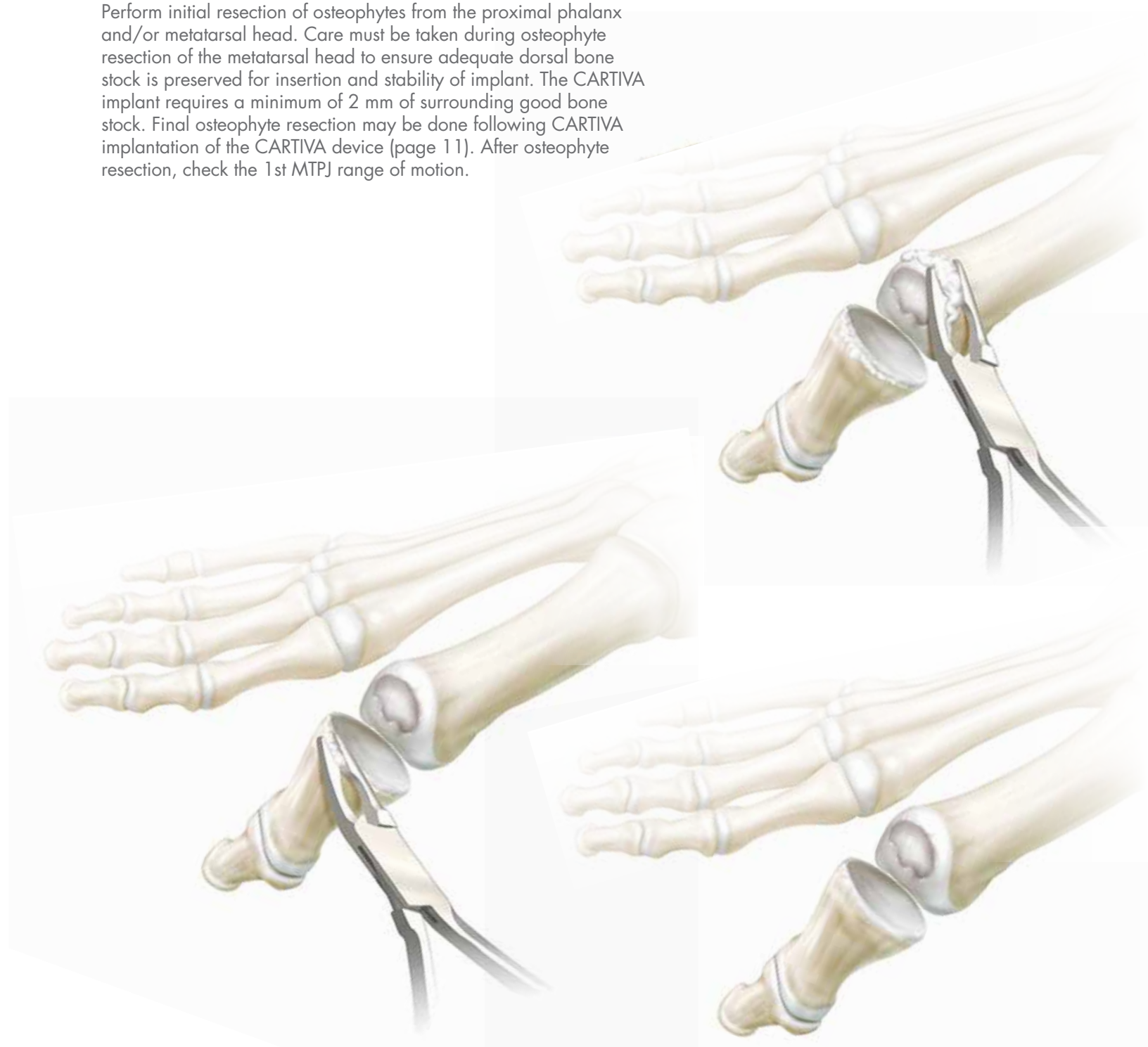


- Expose the entire joint to gain access to the central metatarsal head, which may require release of the lateral and medial soft tissues, to ensure enough exposure to allow implantation perpendicular to the metatarsal head.



OSTEOPHYTE RESECTION

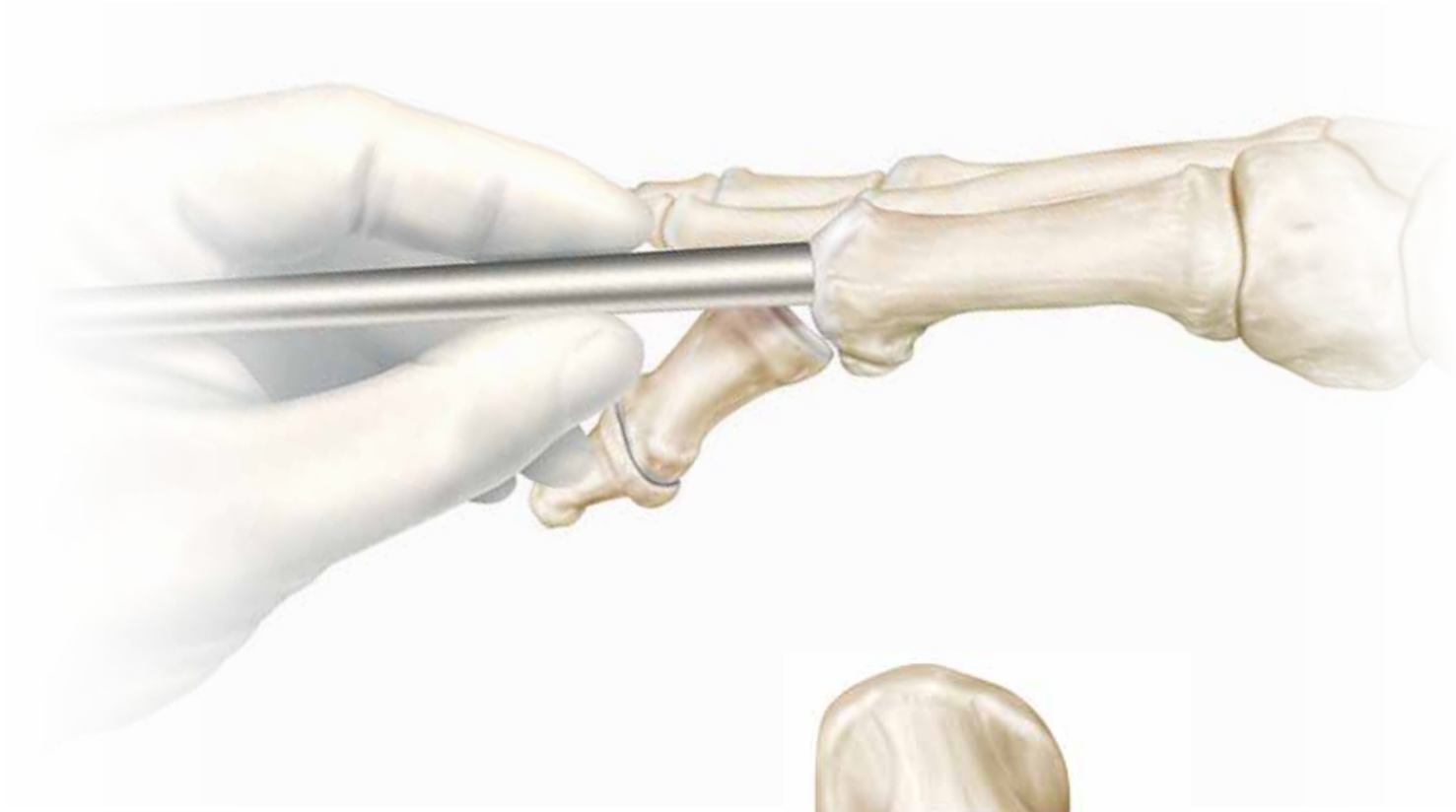
Perform initial resection of osteophytes from the proximal phalanx and/or metatarsal head. Care must be taken during osteophyte resection of the metatarsal head to ensure adequate dorsal bone stock is preserved for insertion and stability of implant. The CARTIVA implant requires a minimum of 2 mm of surrounding good bone stock. Final osteophyte resection may be done following CARTIVA implantation of the CARTIVA device (page 11). After osteophyte resection, check the 1st MTPJ range of motion.



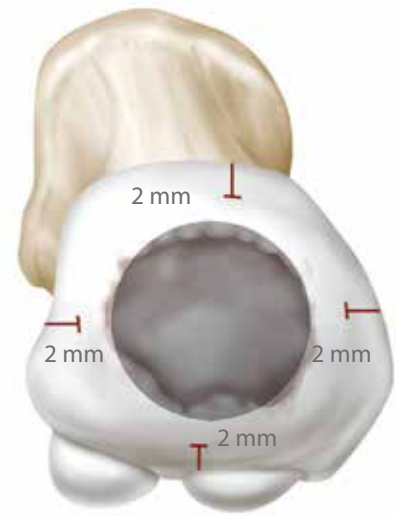
- Visualize any osteochondral defect(s) or cartilage degeneration of the metatarsal head to determine the target implantation site.

IDENTIFYING THE TARGET IMPLANT POSITION AND LOCATION

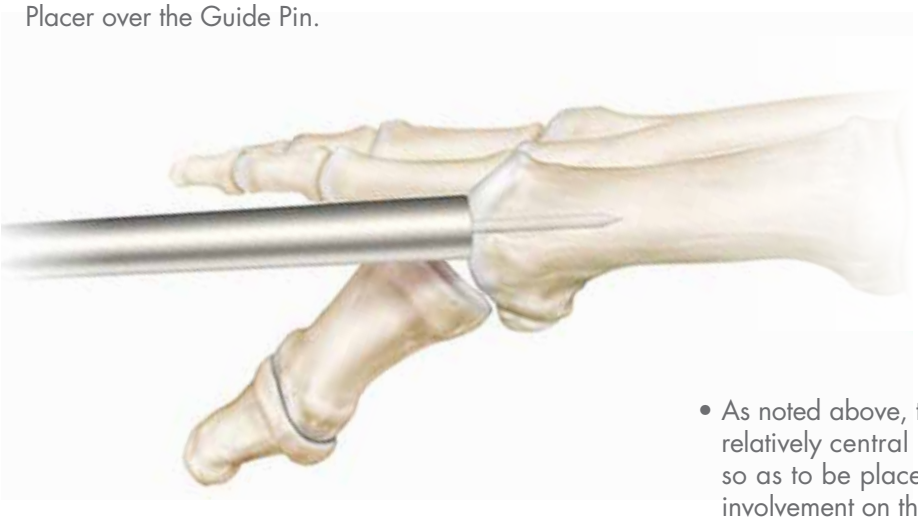
Using the concave end of the Placer, ensuring it is centered in the medial/lateral plane, create a perpendicular angle to the metatarsal head to identify the target implantation site. The Placer should be positioned relatively central but can be slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head.



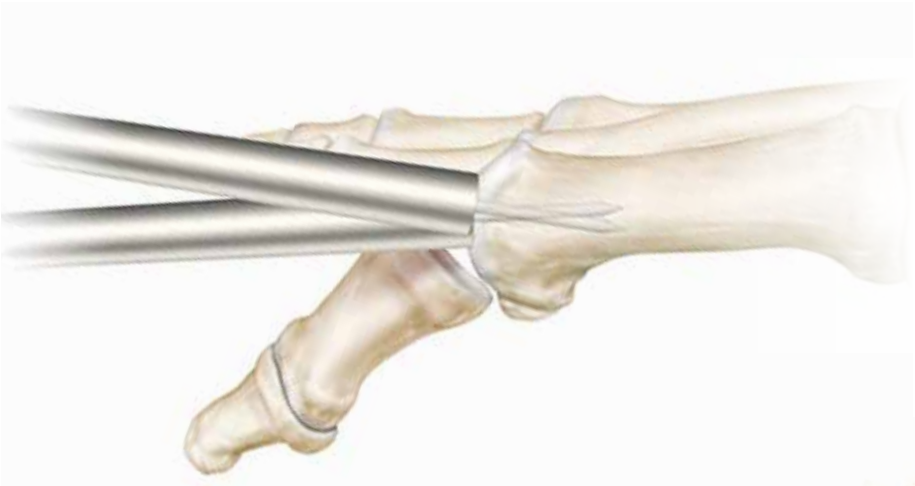
- CARTIVA requires a minimum of 2 mm of surrounding good bone stock.



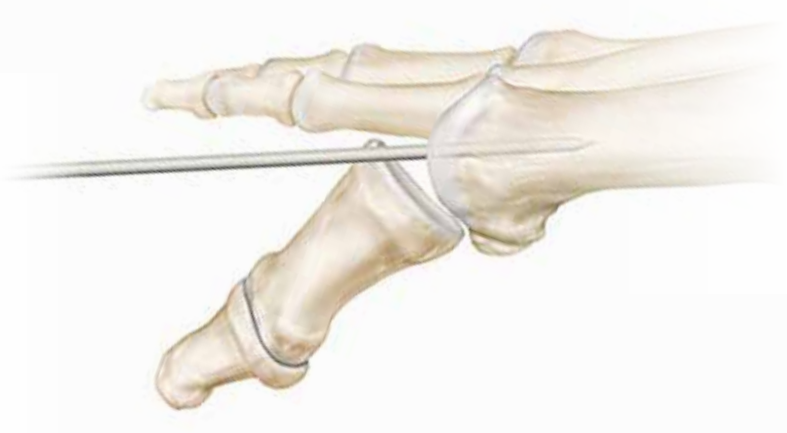
- Insert the Guide Pin into drill and slide the Placer over the Guide Pin.



- As noted above, the Placer should be positioned relatively central but can be slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head.



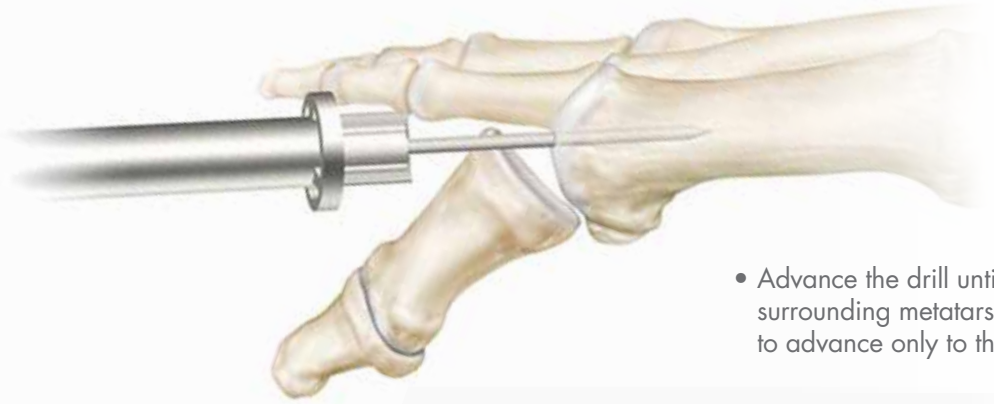
- With the Placer and Guide Pin in the drill, position the Guide Pin perpendicular to the central aspect of the metatarsal head. Advance the Guide Pin into the center of the defect such that it is securely seated within the defect before removing the Placer.



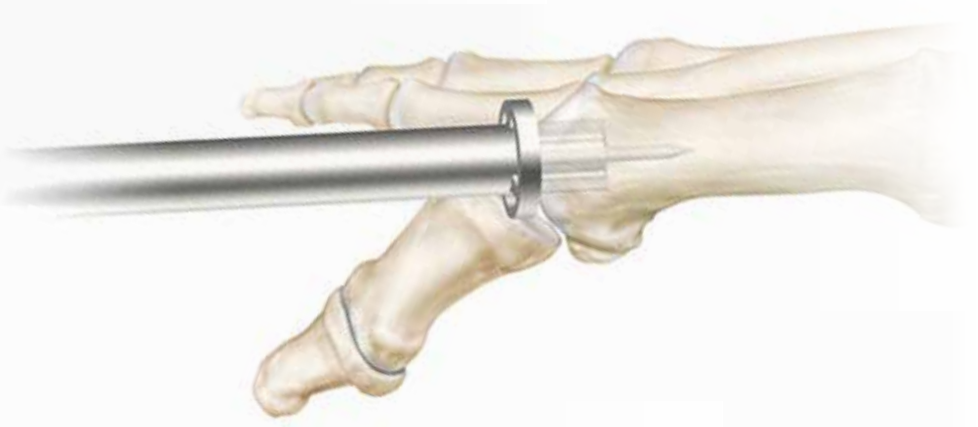
- Remove the Placer, while leaving the Guide Pin in place in the metatarsal head. Fluoroscopic imaging can be used to confirm the correct angle of guide wire placement.

CREATING THE METATARSAL HEAD CAVITY

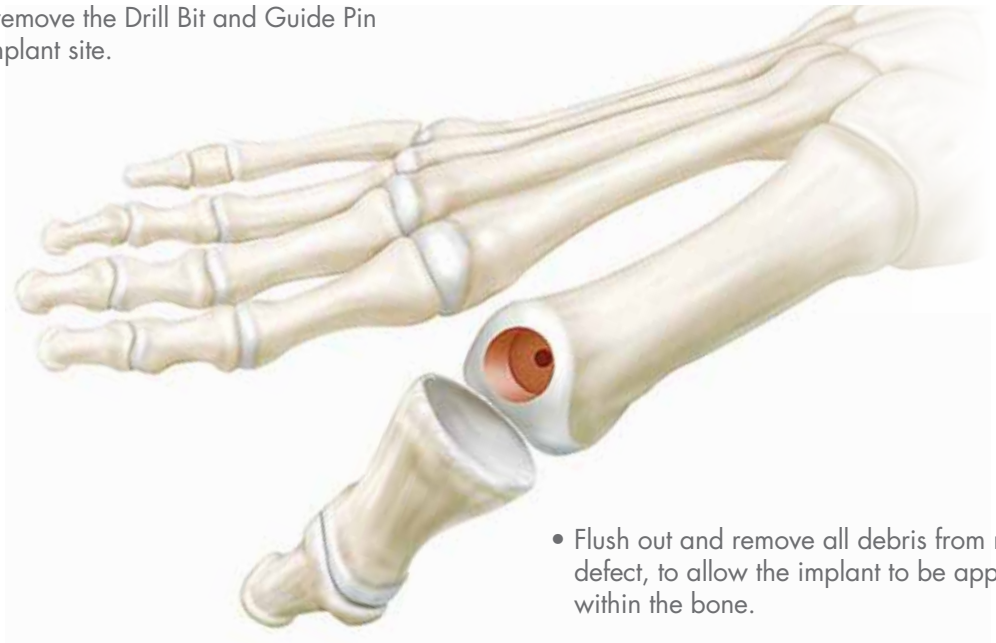
- The cannulated Drill Bit requires a minimum 1/4" drill chuck. Attach to a standard surgical drill driver. Slide the cannulated Drill Bit over the Guide Pin.



- Advance the drill until the post/stop is flush with the surrounding metatarsal head surface. Care should be taken to advance only to the drill stop using light pressure.



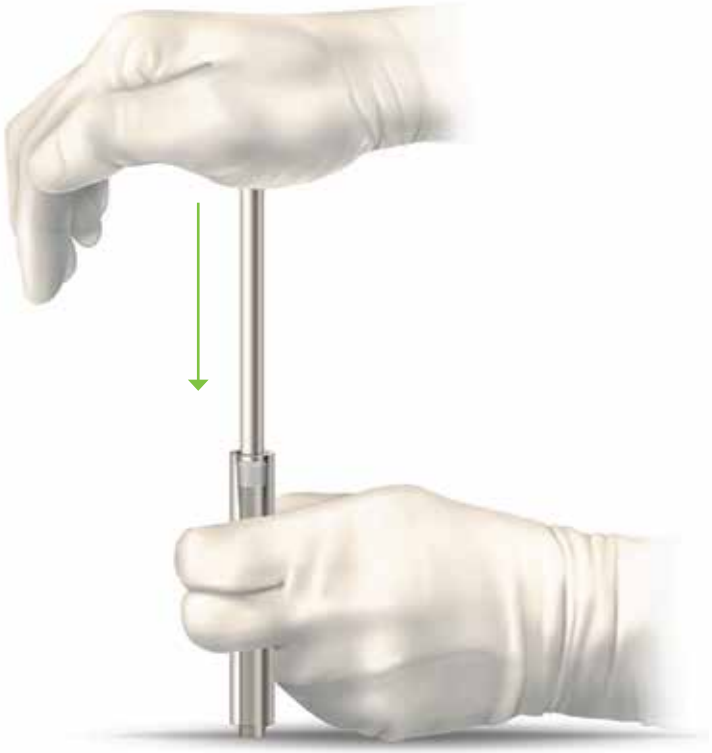
- Carefully, remove the Drill Bit and Guide Pin from the implant site.



- Flush out and remove all debris from metatarsal head defect, to allow the implant to be appropriately seated within the bone.

PREPARING THE IMPLANT FOR INSERTION

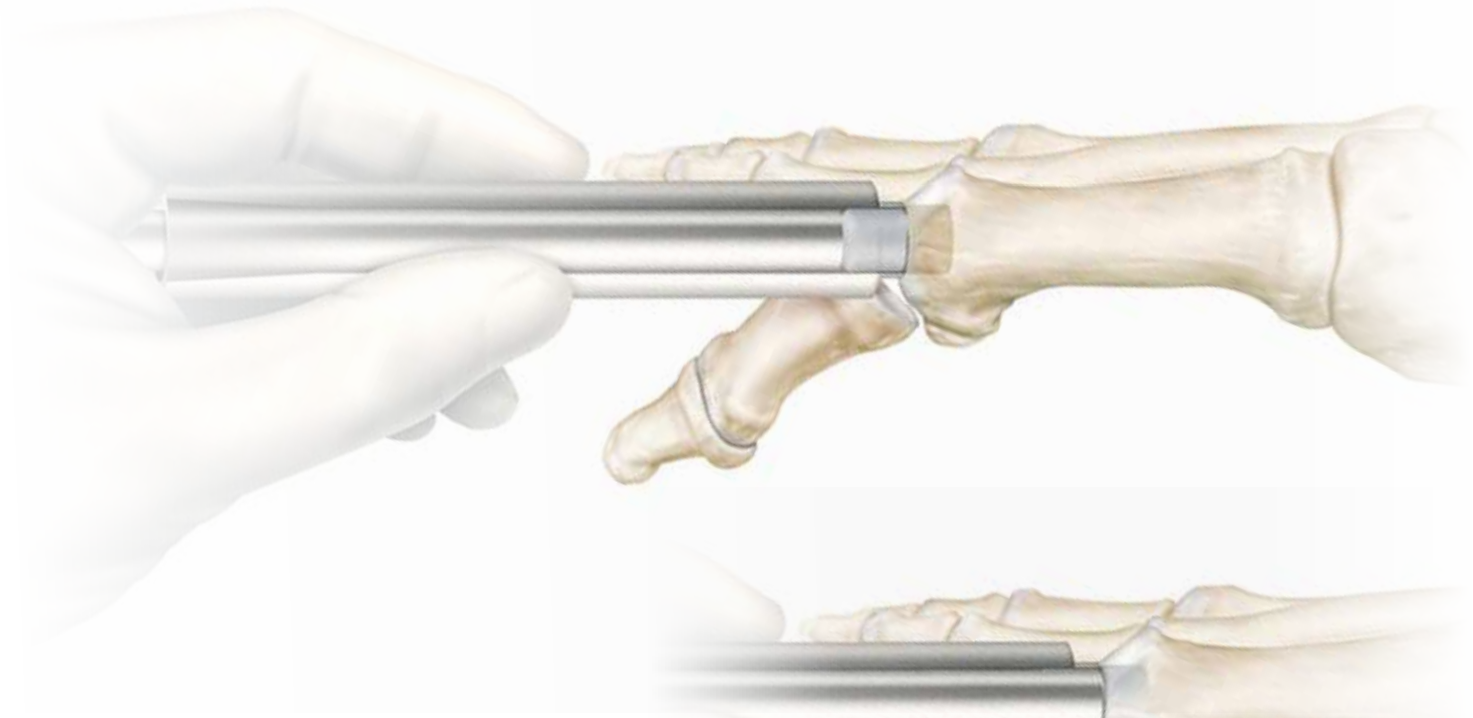
Remove the CARTIVA implant from the sterile packaging using smooth forceps. Moisten Introducer tube with sterile saline. Insert the implant into the Introducer tube at the "wide" end of the Introducer, with the flat end or bottom of the implant facing downward towards the floor, so that the "round" or "convex" portion of the implant is facing upwards towards the ceiling. The goal is for the flat side of the implant to be placed in the bottom of the joint cavity and the round or convex portion of the implant to be the bearing surface against the opposing proximal phalanx.



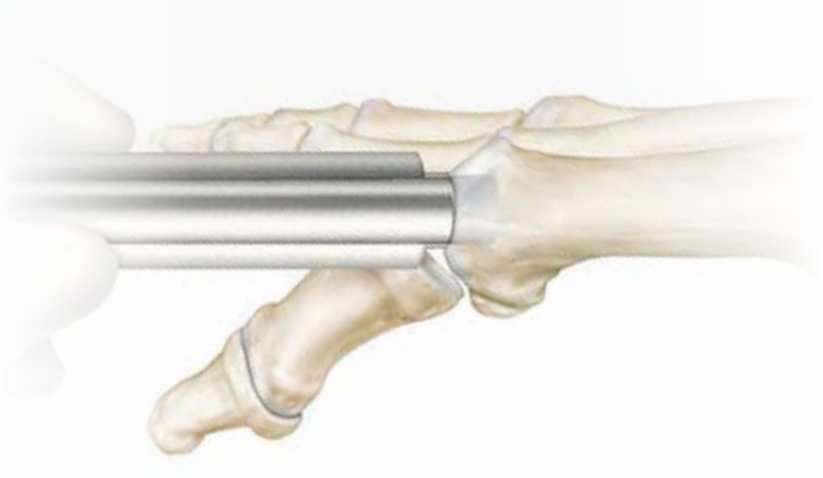
- Firmly grasp the Introducer tube, with the "narrower" or "lip" end firmly placed against a hard flat non-shedding surface. Use the small flat end of the Placer to press the implant to the distal end of the Introducer tube.

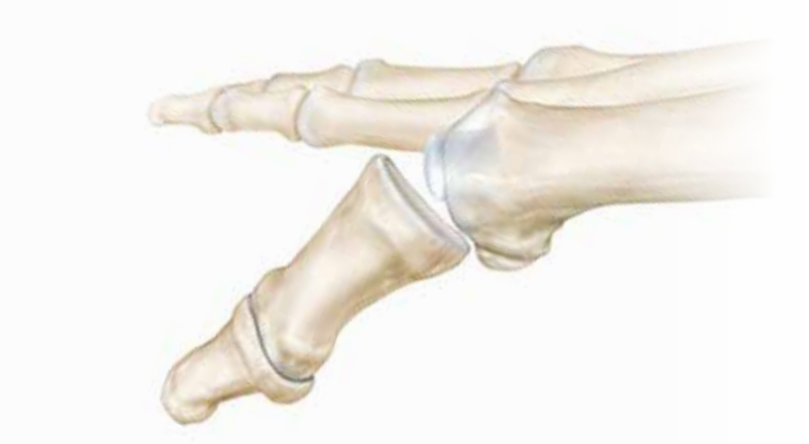
IMPLANT INSERTION

- Place the distal end of the Introducer tube at the implant site, but not into the defect, perpendicular to the metatarsal head.



- Carefully, press down on the Placer, while maintaining the distal end at the implant site, to press fit the implant into the metatarsal head defect.

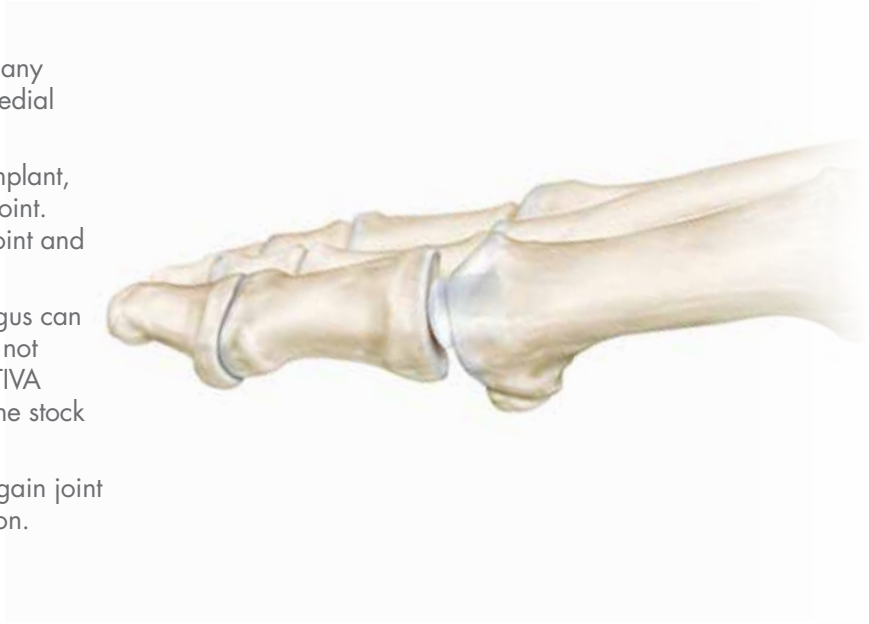




- The implant will be clearly visible following implantation.
- The implant will sit slightly proud (~1.5 mm) in the metatarsal head following implantation. No more than one implant should be used in the metatarsal head.

CAPSULE REPAIR

- Visualize the area and complete final resection of any remaining osteophytes from dorsal, lateral, and medial aspects of metatarsal head.
- Confirm range of motion of the joint against the implant, ensuring there is no restriction or limitation of the joint. Ensure all bone debris is free and clear from the joint and the wound.
- Procedures for the management of mild hallux valgus can be conducted if the concomitant procedure would not compromise the ability to properly place the CARTIVA implant or compromise circumferential cortical bone stock in the metatarsal head.
- Repair as necessary any soft tissues transected to gain joint exposure, and close the capsule in standard fashion.
- Close the skin incision using standard fashion and bandage joint appropriately.



POST-OPERATIVE MANAGEMENT

Subjects receiving the CARTIVA implant should have their wound bandaged and placed in a stiff soled shoe. Weight bearing may begin immediately as tolerated by the subject, as there are no specific weight bearing restrictions for the device. Range of motion exercises should begin immediately to avoid stiffness.

EXPLANT INFORMATION

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Contact Information Located Below

Wright has made these surgical implantation technique guidelines available for informational purposes only and to illustrate an uncomplicated procedure. Proper surgical procedures and techniques are the responsibility of the surgeon, who must evaluate the appropriateness of the procedures described, based upon his/her own personal medical training, experience and the needs of the individual patient. Prior to the use of CARTIVA Synthetic Cartilage Implant, the surgeon should refer to the product instructions for use (IFU) for a comprehensive list of indications, contra-indications, warnings and precautions.

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