HYALEX ORTHOPAEDICS

HYALEX Slalom™ MTP Hemiarthroplasty System

Surgical Technique

MKT-00011-US Revision 7 14/APR/2026

HYALEX Slalom™ MTP Hemiarthroplasty System

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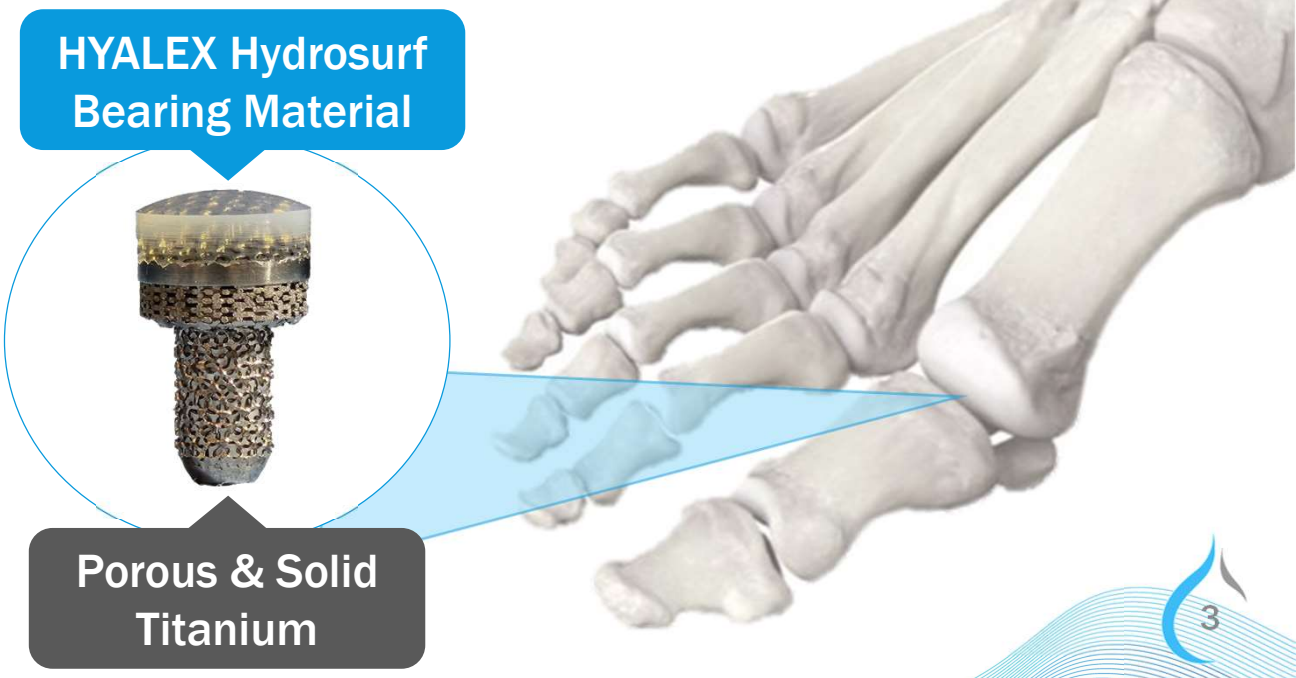
HYALEX Slalom™ MTP Hemiarthroplasty System

Introduction

The HYALEX Slalom ™® MTP Hemiarthroplasty System is intended for use in the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock. The system is comprised of a sterile HYALEX Slalom MTP Hemiarthroplasty Implant and associated instrumentation.

The HYALEX Slalom MTP Hemiarthroplasty Implant is offered in 10mm and 12mm diameters, accommodating a wide range of patient anatomy while preserving viable bone stock. It is comprised of porous and solid titanium, along with proprietary HYALEX Hydrosurf™ Bearing Material, which is a durable synthetic material that has been engineered to replicate the structure and function of native cartilage.

The HYALEX Slalom MTP Hemiarthroplasty Implant restores articulation within the dorsal central region of the metatarsal head, where cartilage damage associated with hallux rigidus commonly occurs. A bone-sparing approach minimizes removal of healthy tissue while optimizing joint mechanics.



HYALEX Slalom™ MTP Hemiarthroplasty System

Indications for Use

The HYALEX Slalom™ MTP Hemiarthroplasty Implant is intended to be implanted to replace the distal metatarsal surface of the great toe for treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus, hallux limitus, or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is intended for single use and for use without bone cement.

Intended Use

The HYALEX Slalom MTP System is intended for use in the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock.

Contraindications

- Known allergy to polyurethanes, bone cement, acrylic, or titanium.
- Inadequate bone stock.
- Cartilage lesions on the phalanx of ICRS Grade 3 – 4 opposite the area intended for treatment.
- Any known systemic cartilage and/or bone disorder, such as but not limited to osteoporosis, chondrodysplasia or osteogenesis imperfecta.

Preoperative Planning

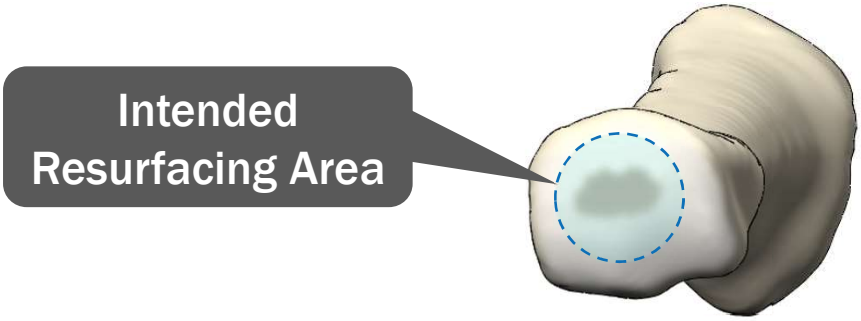
Thorough preoperative planning and patient selection based on anatomy, activity level, and radiographic findings should be performed. Patient selection factors include:

- Need to obtain pain relief and improve function
- Patient age as a potential for early-age revision of total joint arthroplasty
- Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions
- Failure of previous conservative treatment options in correcting deformity and achieving pain relief

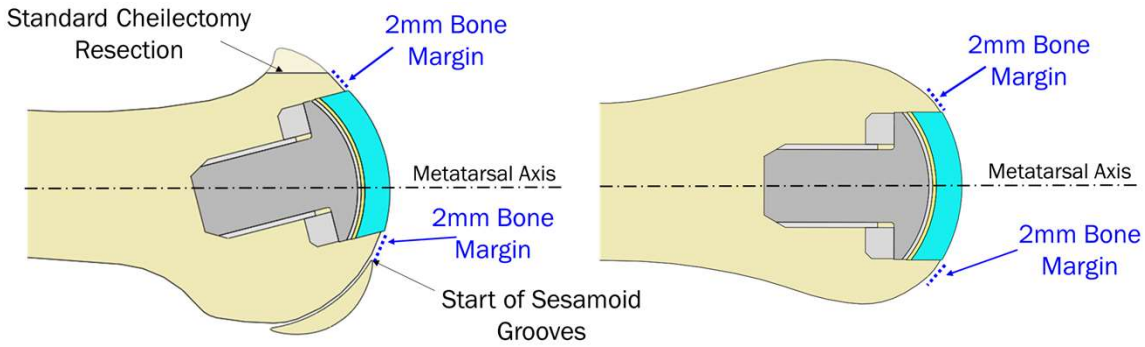
Alternative instruments for fusion, osteotomy, or cheilectomy should also be available in the operating room, and the surgeon should be prepared and capable of performing these alternative procedures if implant sizing is found unsuitable.

HYALEX Slalom™ MTP Hemiarthroplasty System

Key Placement Guidelines



- ❑ At least 2mm of healthy bone must be maintained around the implant to ensure stability.
- ❑ If a cheilectomy is required, modest removal of bone spurs and excess bone is recommended to ensure adequate bone stock for implant insertion and stability.
- ❑ Implant placement must remain dorsal to the sesamoid grooves and should be placed at or above the crista.



Lateral View

Dorsoplantar View

HYALEX Slalom™ MTP Hemiarthroplasty System

Surgical Approach

- Utilize a standard dorsal medial approach, ensuring careful retraction to avoid neurovascular structures and extensor tendons.

- Expose the entire joint to gain access to the central region of the metatarsal head. Release of the lateral and medial soft tissues or sesamoid bones may be required.

- Inspect the opposing phalanx cartilage, ensuring it does not exceed ICRS Grade II degeneration.

NOTE: If the opposing phalanx cartilage is determined to be greater than ICRS Grade II, consider alternative treatments.

- A curved osteotome, freer or McGlamry elevator can be used to release any observed plantar adhesions.

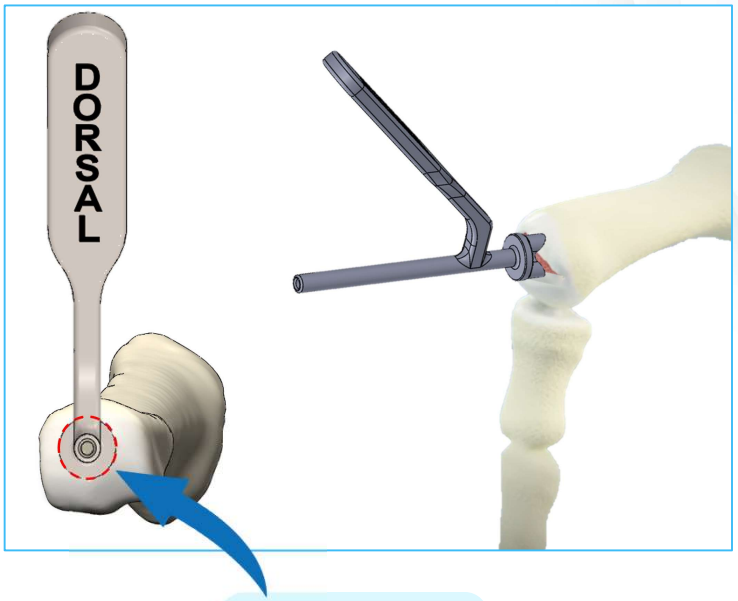
- Care should be taken to avoid damage to the metatarsal-sesamoid articulation.

Performing Cheilectomy (If Necessary)

A cheilectomy may be performed at any step of the procedure, if necessary. If a cheilectomy is performed, modest removal of bone spurs and excess bone is advised to maintain at least 2mm of healthy bone stock, ensuring implant stability.

HYALEX Slalom MTP Hemiarthroplasty Implant Sizing

- Select the Pin Guide that fully covers the damaged area.
- Orient the handle in the dorsal direction and hold the Pin Guide feet firmly against the cartilage surface.
- Confirm that placement meets all Key Placement Guidelines.
- Visually confirm that all three feet of the Pin Guide are contacting the cartilage to ensure that Pin placement is normal to the joint surface.



Implant Diameter

NOTE: If it is determined that neither HYALEX Slalom MTP Hemiarthroplasty Implant diameter is appropriate for the patient anatomy, or if correct alignment and orientation cannot be achieved, the device should not be used, and alternative treatment should be considered, such as cheilectomy, osteotomy, or arthrodesis.

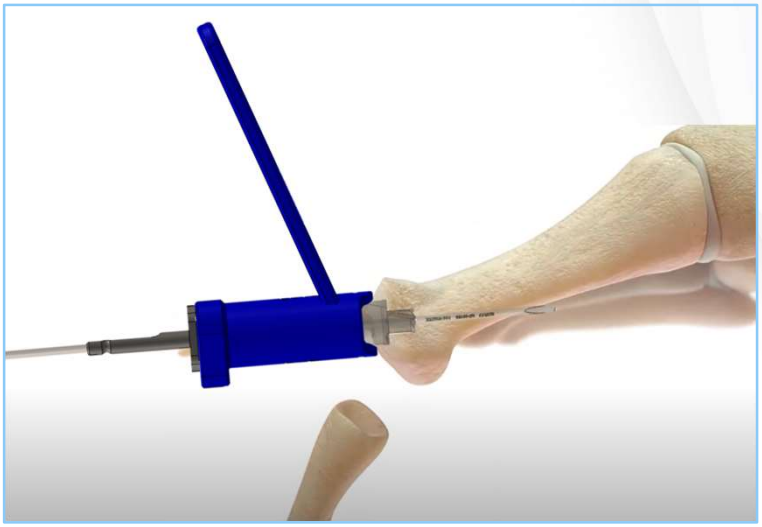
Placing the Pin

- Using a surgical drill, insert the Pin, through the Pin Guide, into the subchondral bone until the third black indicator mark is fully embedded in the Pin Guide. If the Pin remains unstable at this depth (~30mm), continue drilling to the next indicator line or until the Pin achieves stability.
- Visually confirm that all three feet of the Pin Guide are contacting the cartilage to ensure that Pin placement is normal to the joint surface.
- Confirm correct Pin placement radiographically before proceeding. If the Pin is not appropriately placed within the damaged area and perpendicular to the cartilage, remove the Pin and place again.
- Remove the Pin Guide.

TIP: Etch marks on Pin are spaced by 10mm.

Drilling the Implant Site

- Select the Drill Bit diameter that matches the Pin Guide used in the previous step.
- Place the Drill Guide over the Pin and hold it firmly against the metatarsal surface with the handle oriented dorsally.
- Position the Drill over the pin and drill under saline irrigation, using the high-speed setting to prevent thermal injury. Drill until the shoulder of the Drill Bit contacts the Drill Guide, ensuring proper depth.



TIP: The Drill Guide is used to ensure appropriate drill depth. To obtain proper implant seating depth, avoid excessive drill pressure.

TIP: The Pin is used to ensure appropriate alignment over the damaged area. To maintain proper orientation, avoid excessive pressure on the Pin.

- Leaving the Pin in place, remove the Drill and Drill Guide and irrigate the site with the Pin still in place to clean out any bone chips and cartilage debris.

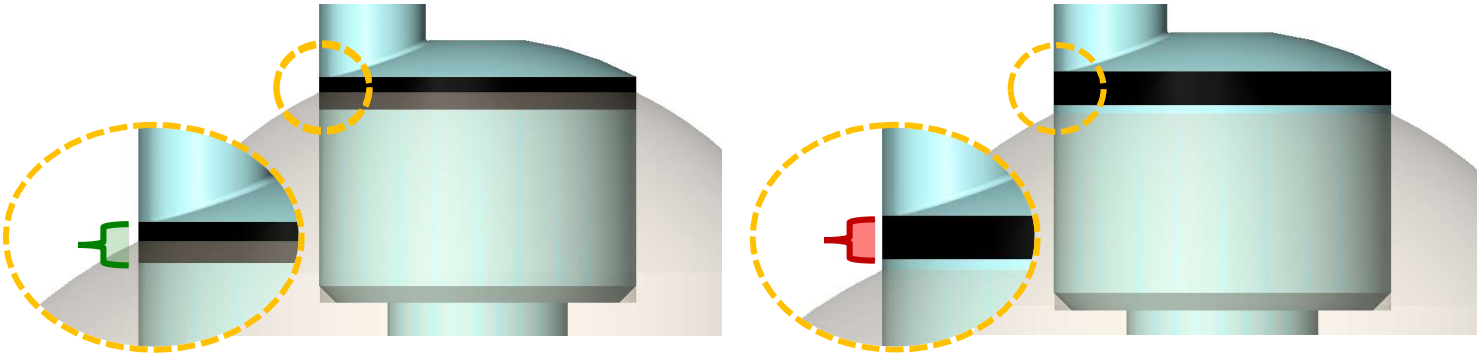
Trialing

- Obtain the Trial that matches the intended HYALEX Slalom MTP Hemiarthroplasty Implant diameter. Place the Trial over the Pin and place into the prepared site. It should slide freely into the drilled site.

- Assess that the dorsal and plantar edges of the cartilage are within the black etched band of the Trial through

✓ **Proper Trial placement, dorsal and plantar cartilage edges are within the etched band.**

✗ **Trial placed proud, indicated by dorsal and plantar cartilage edges beneath the etched band.**

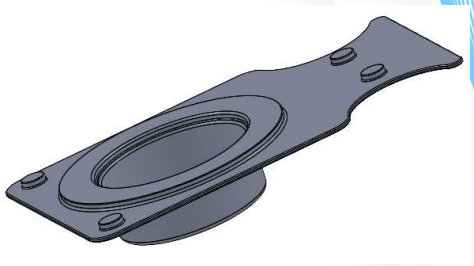


TIP: If the Trial is proud, assess that there is no bone or soft tissue preventing the Trial from seating properly.

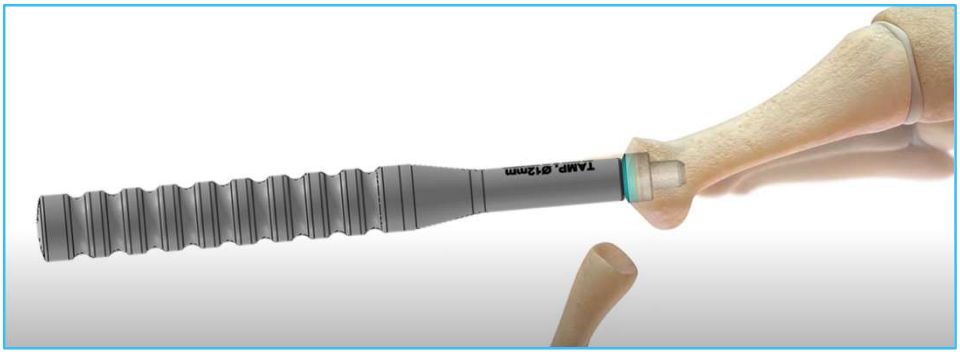
- If satisfied with the prepared site, remove the Trial and Pin. Proceed to implant insertion.
- If the Trial does not insert freely or sits proud, remove the Trial and redrill with the same Drill Bit and Drill Guide while keeping the Pin in place.

TIP: Avoid excessive pressure during redrilling, as this may result in the implant being seated too deep. Only light pressure is required.

Inserting the HYALEX Slalom Hemiarthroplasty Implant



- Select the packaged Implant size that matches the prepared site diameter.
- Open the Implant packaging tray. **Note:** Outer tray is a sterile barrier. Inner tray is for implant protection only.
- Pour off the saline solution and visually inspect the Implant for any damage to the surface.
- Align Implant axially with the prepared site. Using hand pressure, insert the post of the Implant into the site until the cap of the implant is engaged with the bone.
- Confirm that the cap of the implant is perpendicular to the joint surface.
- Seat the implant with a surgical mallet, holding the Tamp against the articular surface of the Implant.



NOTE: The Implant articulating surface is slippery. Take care to minimize the possibility of the Tamp slipping off the Implant during final seating.

Assessing the HYALEX Slalom MTP Hemiarthroplasty Implant Placement

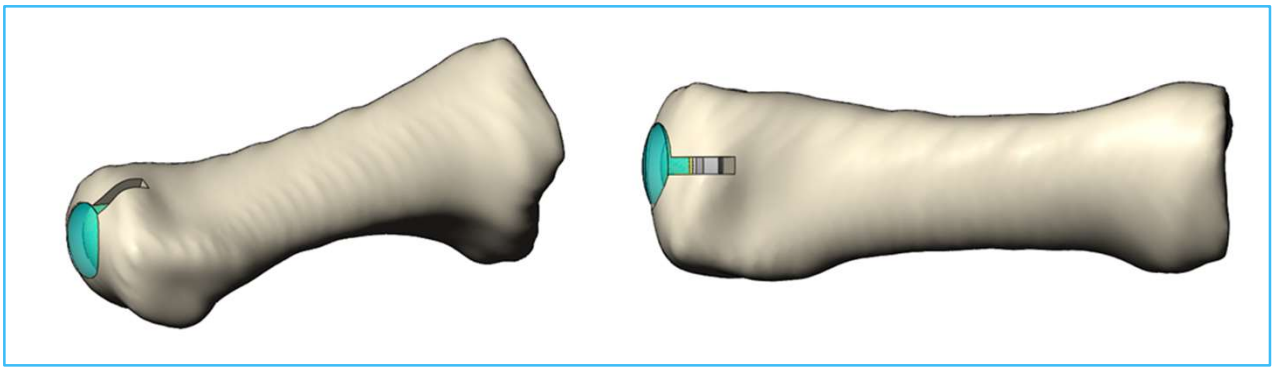
- Verify that the dorsal and plantar edges of the implant are flush or slightly proud, consistent with trial feedback.

WARNING: Do not cut, trim, or modify the HYALEX Slalom MTP Hemiarthroplasty Implant in any way, as this may result in damage to the articular surface.

Intraoperative Implant Removal (If Required)

The following steps should be taken ONLY in cases where a HYALEX Slalom MTP Hemiarthroplasty Implant must be removed during the primary surgery.

- Create a window on the dorsal aspect of the metatarsal head. The window should be wide enough to fit a narrow osteotome and should extend to the base of the HYALEX Slalom MTP Hemiarthroplasty Implant cap.



- Using an osteotome at the base of the HYALEX Slalom MTP Hemiarthroplasty Implant cap, apply axial force to extract the implant.