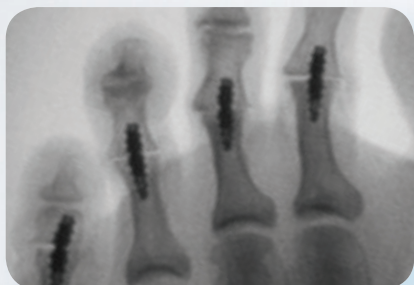




The ToeMATE® Hammertoe Correction System

is an easy to implant bone screw system intended for the correction of hammertoe deformity. It is provided in a complete packaged and sterile kit.



- Proven, strong & stable fixation
- X-Small, Small & Large tapered screws with conical design
- Straight & 10° plantar flexed implant options
- Provided in a complete packaged & sterile kit

Description

The Arthrosurface® ToeMATE® Hammertoe Correction System consists of two intramedullary bone screws, a taper lock pin and a set of instruments used for implant site preparation and delivery. The implants are offered in three size options, x-small, small and large. The taper lock pin provides a press fit connection between the two screws with light contact pressure and is available in straight and angled configurations. The implant components are manufactured using implant grade titanium alloy and cobalt-chrome alloy.

Materials

Intramedullary Bone Screws:	Titanium Alloy (Ti-6Al-4V)
Taper Lock Pin:	Cobalt-Chrome Alloy (Co-Cr)

Indications

Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.
- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Contraindications

Absolute contraindications include:

- Previous or current infection at or near the implantation site.
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response.
- Patients having malignant primary or metastatic tumors that may preclude adequate bone support or screw fixation.
- Patients with known allergies or hypersensitivity to implant grade titanium alloy and/or cobalt-chrome alloy typically used in prosthetic devices.

Relative contraindications include:

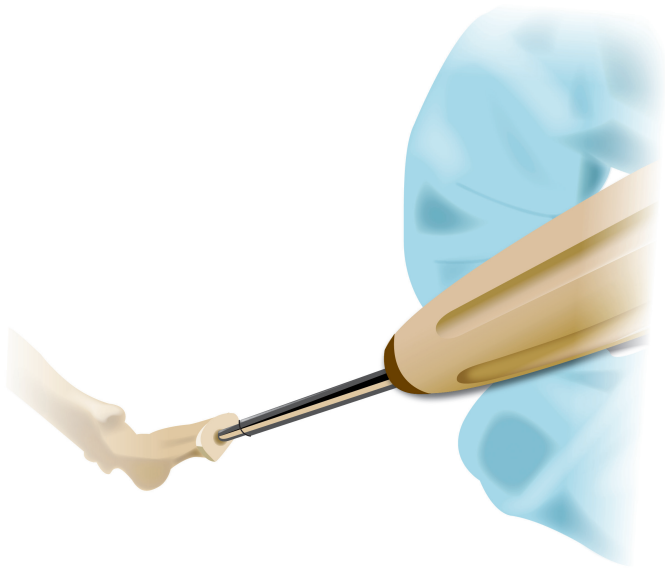
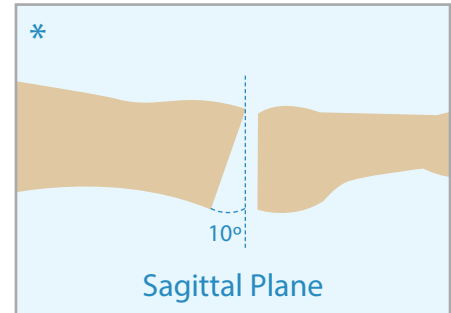
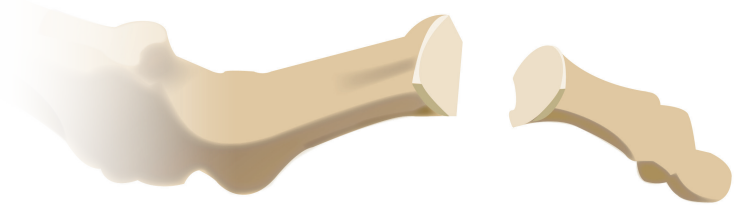
- Poor bone quality or quantity that may lead to inadequate stabilization/fusion of the joint complex.
- Metabolic disorders that may impair the formation or healing of bone.
- Infections at remote sites which may spread to the implant site.
- Rapid joint destruction or bone resorption visible on roentgenogram.

**Reference IFU package insert for warnings, precautions, possible adverse effects & complications.*

Surgical Technique

1. Resect articular surfaces of the proximal interphalangeal joint (PIPJ) i.e. proximal phalanx head and middle phalanx base, perpendicular to longitudinal axis of those bones.

***Note:** If plantar flexion is desired, resect one of the two surfaces at 10° and use the angled taper lock pin.

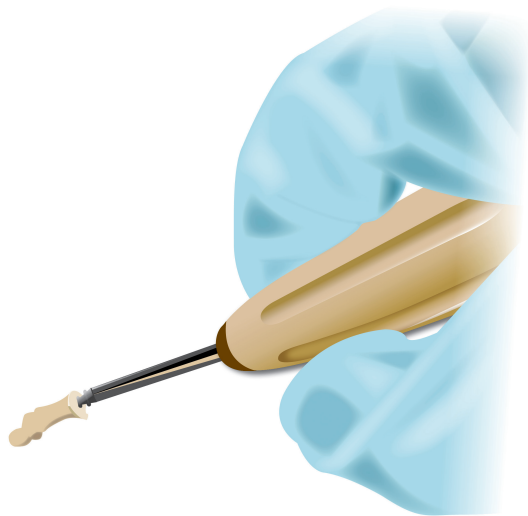
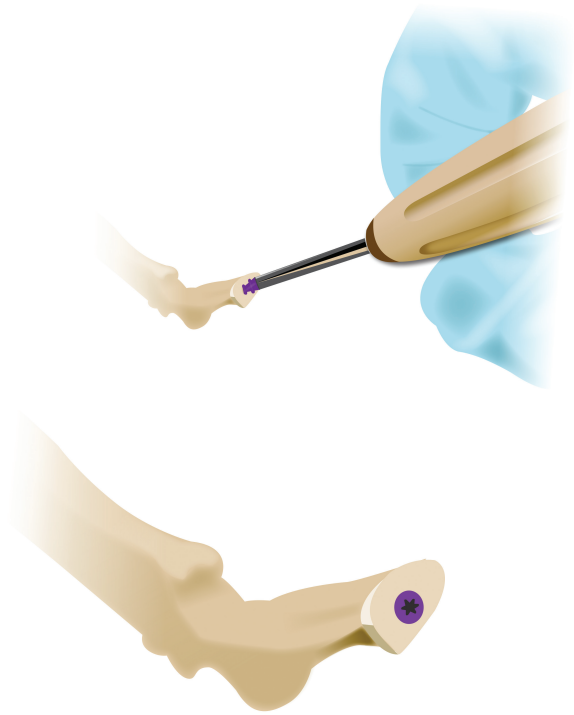


2. Create pilot holes in the proximal and middle phalangeal bones by driving the **Hand Drill** in the central canal, along the long axis of the bones. If using the x-small implant, use the provided **Guide Pin** to create the pilot hole.

3. Insert **Proximal Screw (Purple)** using the **Screw Driver** provided. Insertion is complete when the drive end of the implant is flush with the resected bone surface.

Note: Each 1/4 turn of the **Screw Driver** will move the implant 0.5mm.

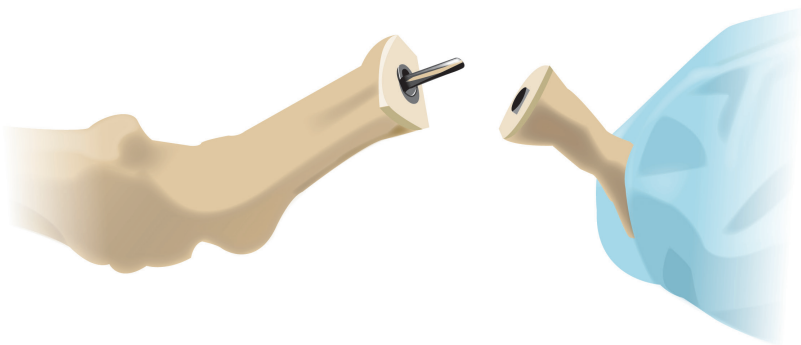
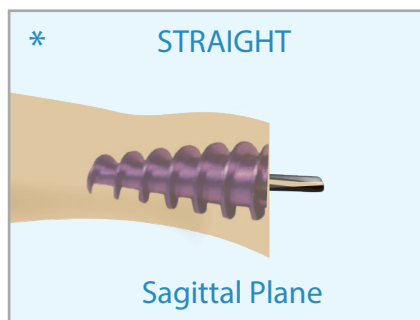
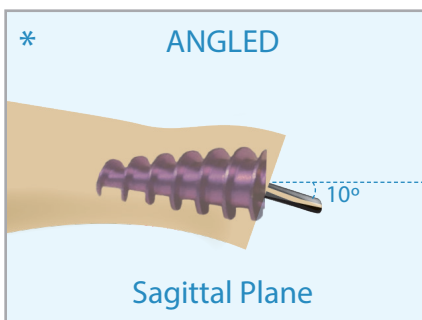
Note: Select the Implant size based on the size of the patient's toes. The X-Ray Template can be used to determine the appropriate size.



4. Similarly, insert **Distal Screw (Gold)** in middle phalanx until its drive end is flush with the resected bone surface.

5. Deliver the **Taper Lock Pin** into the proximal screw using the **Taper Delivery Tool**. Lightly tap the tool using a mallet to secure it within the screw.

***Note:** Use the angled taper lock pin to place the toe in 10° plantar flexion. See Step 1 above.

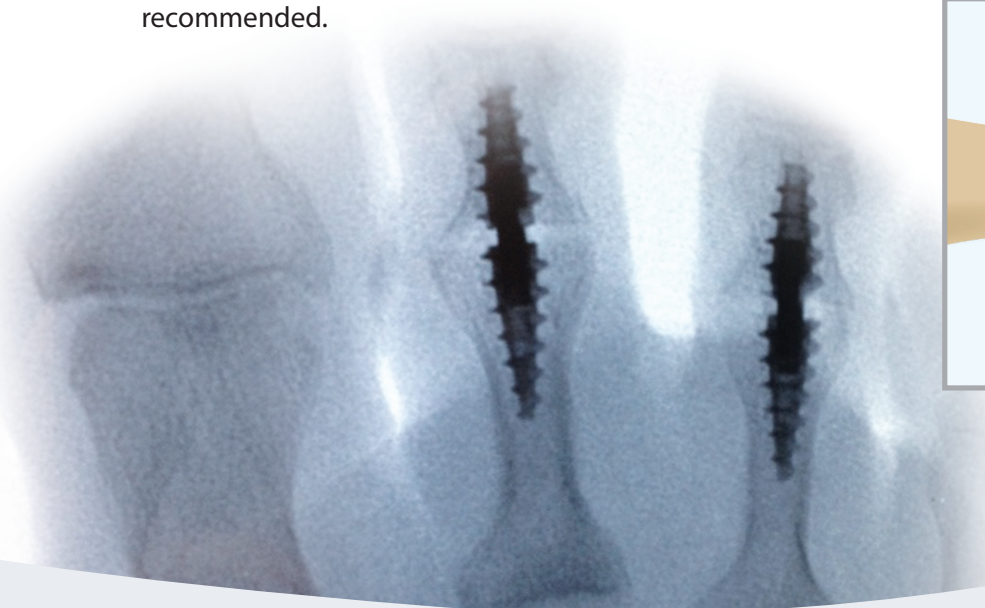
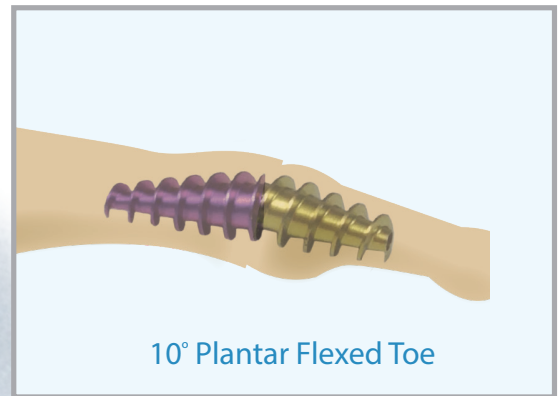
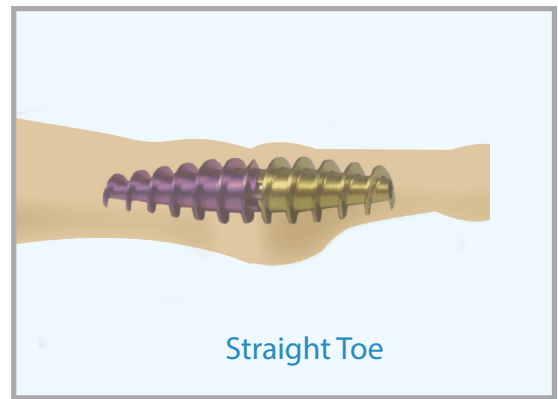


6. Grasp the middle phalanx and place the **Distal Screw** over the exposed half of the **Taper Lock Pin** on the **Proximal Screw**.

Tip: Axial position of the **Proximal** and **Distal Screws** can be adjusted to achieve the desired bone to bone apposition. Each 90° clockwise rotation of the **Screw Driver** will advance the screw further into the bone by 0.5 mm, and vice versa.

7. Use firm pressure to press the middle phalanx onto the proximal phalanx once desired bone to bone apposition is achieved. Place **Thimble** over the toe and lightly tap it using a mallet to secure the **Taper Lock Pin** within the screws.

8. Physically probe the PIPJ to check for stability and screw interface retention following final implant delivery. Verification via intra-operative fluoroscopy is recommended.



Implant Removal Protocol

1. In case of a non-union, open the joint space using a transverse or longitudinal incision.
2. Distract the phalangeal bones using standard osteotomes to separate the implant components and expose the opposing joint surfaces.
3. Implants can be removed using the **Screw Driver** if permissible, or with the use of surgical pliers.
4. A corticotomy or dorsal window can be created to expose the implant. Following exposure, elevate the tip proximally with a curette or elevator, grasp and twist or pull out directly.

System Catalog

Instrument Package (LARGE)

9H00-T020	Drill Screw Driver (White) Thimble
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Instrument Package (SMALL)

9H00-T040	Drill Screw Driver (Blue) Thimble
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Instrument Package (XTRA SMALL)

9H00-T060	Guide Pin Screw Driver (Teal) Thimble
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Implant Package (LARGE - Ø 4.7mm)

9H00-T010	Screw, Proximal (Purple), L: 11mm Screw, Distal (Gold), L: 9mm Screw, Distal (Blue), L: 6.5mm Taper Lock Pin (0° & 10°) Delivery Tool (White)
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Implant Package (SMALL - Ø 3.8mm)

9H00-T030	Screw, Proximal (Purple), L: 9mm Screw, Distal (Gold), L: 7mm Taper Lock Pin (0° & 10°) Delivery Tool (Blue)
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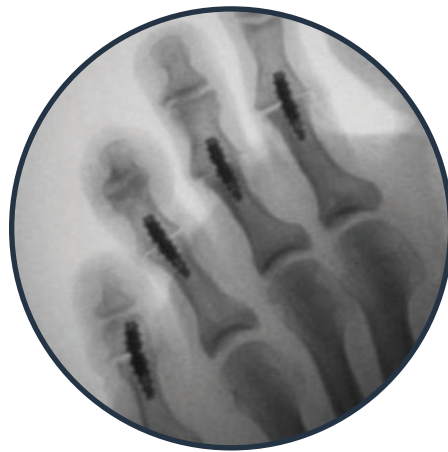
Implant Package (SMALL - Ø 3.2mm)

9H00-T050	Screw, Proximal (Purple), L: 9mm Screw, Distal (Gold), L: 7mm Taper Lock Pin (0° & 10°) Delivery Tool (Teal)
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**Arthrosurface also currently provides
the following products:**

CheckMATE Fusion Plate • AlignMate Lapidus Arthrodesis System • ToeMATE Hammertoe System



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This pamphlet and information is intended for markets where regulatory approval has been granted.