INTEGRA
LIMIT UNCERTAINTY

An den Sicherheitsverantwortlichen für Medizinprodukte/die Zentralapotheke

Saint Priest, 08.04.19

Betreff: **DRINGEND – FIELD SAFETY NOTICE – SICHERHEITSMELDUNG**

Medizinprodukte: ***Integra® MGT-890-10MT - MGT Movement Metatarsal Sz. 10; MGT-890-20MT - MGT Movement Metatarsal Sz. 20; MGT-890-30MT - MGT Movement Metatarsal Sz. 30; MGT-890-40MT - MGT Movement Metatarsal Sz. 40***

Verantwortlicher Hersteller: *Ascension Orthopedics, Inc. – 11101 Metric Blvd, Austin, Texas 78758 USA*

EG-Vertr.: *INTEGRA LIFESCIENCES (Frankreich) SAS – Immeuble Séquoïa 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST*

Betroffene Chargen:
Alle zwischen 2013 und heute verkauften Chargen

Sehr geehrte Kundin, sehr geehrter Kunde,

Integra LifeSciences hat kürzlich einen Widerspruch zwischen der Gebrauchsanweisung (IFU) und der Operationstechnik für Europa, den Nahen Osten und Afrika für das Integra® Movement™ Great Toe System hinsichtlich der Verwendung des Zements für die Total-Arthroplastikverfahren festgestellt.

Es sind zwei Verfahren für das Integra Movement Great Toe System indiziert (IFU LC-04-890-005 Rev G).

„Hemi-Arthroplastik:
Das Integra Movement Großzehsystem als Hemi-Arthroplastik besteht aus einer Metatarsalkomponente und einer Phalangealkomponente und ist zur Oberflächenerneuerung des Metatarsalköpfchens oder der Basis der proximalen Phalanx des großen Zehs bestimmt. Die metatarsalen und phalangealen Komponenten werden als Hemi-Arthroplastiken zur unzementierten Gelenkbehandlung bei Patienten mit Arthritis im Großzeh-Metarsalgelenk eingesetzt, wenn ein guter Knochenbestand vorliegt. Zu den Indikationen gehören:
• Hallux valgus oder Hallux limitus
• Hallux rigidus
• Instabiles oder schmerzhaftes Metatarso-Phalangeal- (MTP-) Gelenk
Totalarthroplastik:
Die Integra Movement Großzehsystem-Totalarthroplastik ist ein zweiteiliges Implantat, das zur Verwendung als Prothese des Metatarso-Phalangealgelenks (MTP) bestimmt ist. Das Medizinprodukt ist nur zur zementierten Verwendung bestimmt. Zu den Indikationen gehören:
• Schmerzhafte degenerative metatarso-phalangeale Gelenkveränderung
• Hallux rigidus Stadium 3 und 4
• Hallux valgus und Hallux rigidus
• Hallux limitus mit schmerzhafter Arthrofibrose
• Revisionen nach moderater proximaler Phalanxresektion“

FSN-R-HHE-152-290319

Integra LifeSciences Services (France)
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪ 69800 Saint Priest ▪ France
33 (0)4 37 47 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ **integralife.com**
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

Aus Vorsichtsgründen und zur Gewährleistung der Patientensicherheit hat der verantwortliche Hersteller Ascension Orthopedics, Inc. daher die Operationstechnik für Europa, den Nahen Osten und Afrika des Integra® Movement™ Great Toe Systems LC-04-890-006 Rev. B (Anhang 1) aktualisiert. Die folgenden Abschnitte der Operationstechnik wurden überarbeitet, um zusätzliche Hinweise und genauere Anweisungen zur richtigen Technik aufzunehmen:
Total Great Toe Operationstechnik Seite 12

Sie erhalten diese dringende Sicherheitsmeldung, da aus unseren Unterlagen hervorgeht, dass Sie eine Lieferung **der unten aufgeführten Produkte** erhalten haben.

Beschreibung des betroffenen Produkts	Produktnummer
MGT Movement Metatarsal Sz. 10	**MGT-890-10MT**
MGT Movement Metatarsal Sz. 20	**MGT-890-20MT**
MGT Movement Metatarsal Sz. 30	**MGT-890-30MT**
MGT Movement Metatarsal Sz. 40	**MGT-890-40MT**

Bitte stellen Sie sicher, dass diese Sicherheitsmitteilung und deren Anhang allen betroffenen Benutzern des Integra® Movement™ Great Toe Systems zur Verfügung gestellt werden.

Bitte unterschreiben und senden Sie das beigefügte „Bestätigungs- und Rücksendeformular" an uns zurück, um zu bestätigen, dass Sie diese Sicherheitsinformation erhalten haben und die Absicht haben, diese vollständig einzuhalten. Darüber hinaus bestätigen Sie, dass diese Benachrichtigung an jeden betroffenen Verbraucher weitergeleitet wurde.

Der Erhalt dieses Formulars dient Integra als Bestätigung, dass diese Informationen tatsächlich übermittelt wurden.

Wir empfehlen auch, dass Sie eine Kopie dieser Mitteilung und eine unterzeichnete Kopie des Formulars zur Kenntnisnahme in Ihren Unterlagen aufbewahren.

Die zuständigen nationalen Behörden können Prüfungen von Sicherheitsmeldungen dieser Art durchführen, um zu überprüfen, dass unsere Kunden informiert wurden und den Zweck der Sicherheitsmaßnahme verstehen.

Die zuständige nationale Aufsichtsbehörde wurde auf diese Sicherheitsmaßnahme hingewiesen.

Wir danken Ihnen für Ihre Kooperation bei dieser Sicherheitsmaßnahme und für das Einsenden des beigefügten Formulars zur Kenntnisnahme und Rücksendung.

Bei jeglichen Fragen oder Anliegen kontaktieren Sie uns bitte unter der folgenden E-Mail-Adresse: emea-fsca-recon@integralife.com

Mit freundlichen Grüßen

Angélique AUBERT
Compliance Coordinator
Europa, Naher Osten & Afrika

Anlage: Bestätigungs- und Rücksendeformular (1 Seite) + Anhang 1

Integra LifeSciences Services (France)
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INTEGRA
LIMIT UNCERTAINTY

BESTÄTIGUNGSFORMULAR

Medizinprodukte:
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Betroffene Chargen:
Alle zwischen 2013 und heute verkauften Chargen

März 2019

Bitte senden Sie das Formular zurück an:

Per Fax: +33 (0)4 37 47 59 30
Oder per E-Mail: emea-fsca-recon@integralife.com
Mit diesem Formular bestätige ich Folgendes:

Ich habe die in der Integra-Vertriebs-Sicherheitsinformation bezüglich des Integra® Movement™ Great Toe Systems enthaltenen Informationen erhalten, gelesen und verstanden.

Ich bestätige, dass diese Vertriebs-Sicherheitsmitteilung und deren Anlage an alle betroffenen Benutzer verteilt wurden.

Name des Kunden	Datum
Anschrift	Stadt/Bundesland/PLZ
Telefonnummer	Unterschrift

FSN-R-HHE-152-290319

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ENG

Integra®

Movement™ Great Toe System

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

Products for sale in Europe, Middle-East and Africa only

Table of Contents

Indications

Hemi-Arthroplasty

The Integra Movement™ Great Toe System hemi-arthroplasty consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemi-arthroplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock.

Indications include:

- Hallux valgus or Hallux limitus,
- Hallux rigidus,
- Unstable or painful metatarsal/phalangeal (MTP) joint.

Total Arthroplasty

The Integra Movement™ Great Toe System total arthroplasty is a two-piece implant that is intended to be used as prosthesis for the metatarsophalangeal joint (MTP). The device is intended for cemented use only.

Indications for use include:

- Painful degenerative metatarso-phalangeal joint change,
- Hallux rigidus stages 3 and 4,
- Hallux valgus and hallux rigidus,
- Hallux limitus with painful arthrofibrosis,
- Revisions after moderate proximal phalanx resection.

Contraindications

- Active local or systemic infection,
- Destruction of the 1st metatarsal head or 1st proximal phalanx base or poor bone quality which prevents adequate fixation of the implant,
- Loss of musculature, neuromuscular compromise, or vascular deficiency in the affected toe.

System Features

- Total and hemi resurfacing implants for both sides of the joint in one instrument set,
- Total implant components can be mismatched for an anatomical fit,
- Cannulated system,
- Conical reaming maintains tissue attachments and sesamoid apparatus while allowing for minimal bone resection and pathway for revision,
- Dorsal metatarsal cut guide allows for precise cheilectomy of dorsal osteophytes when implanting the metatarsal component.

ESSENTIAL PRODUCT USE INFORMATION: For additional important information pertaining to the use of this product, please see product package insert. This information was current at the time of printing, but may have been revised after that date.

Hemi Proximal Phalanx Surgical Technique

As the manufacturer of this device, Ascension Orthopedics, Inc. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

Step 1 • Initial Incision & Exposure

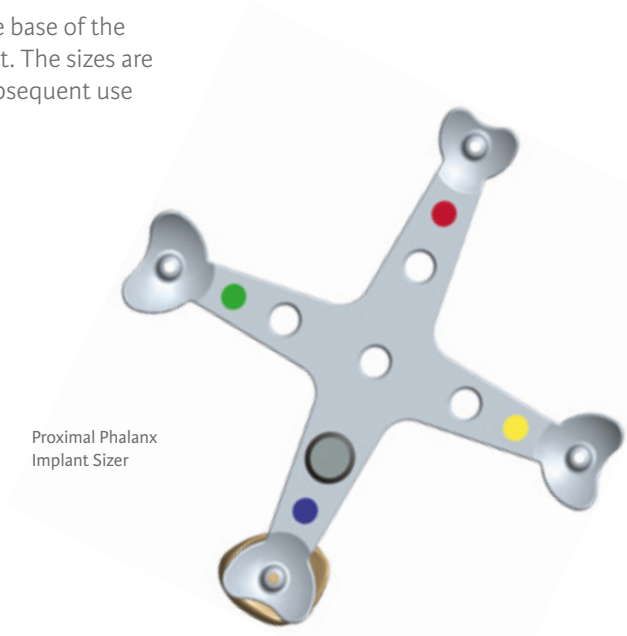
1-1 Exposure of an arthritic first MTP joint requires a skin incision of adequate length. A dorsal skin incision medial to the tendon of extensor hallucis longus is recommended. Begin proximal at the midpoint of the first metatarsal, and extend distally over the MTP joint onto the great toe.

The skin incision is deepened by sharp dissection, with electrocautery of any bleeders. The skin and subcutaneous tissues are reflected, and a lineal capsulotomy may be performed in line with the initial skin incision, once again staying medial to the tendon of extensor hallucis longus. Subperiosteal dissection is usually begun over the base of the proximal phalanx and proceeds proximal and plantar within the confines of the joint. The medial and lateral collateral ligaments are severed with subperiosteal dissection of the first metatarsal. The entire first metatarsal phalangeal joint should be mobilized in order to gain access for subsequent instrumentation. Do not detach the aponeurotic attachments of the flexor expansion from the base of the proximal phalanx.

Hallux rigidus is characterized by "squaring-off" the joint surfaces and peripheral osteophytes. Adequate resection of all osteophytes around the metatarsal head should be performed including dorsal remodeling of the metatarsal head to provide a gentle slope to allow adequate dorsiflexion once the implant is inserted.

Step 2 • Phalangeal Sizing

2-1 The Proximal Phalanx Implant Sizer is utilized to compare to the base of the proximal phalanx and determine the appropriately sized implant. The sizes are color-coded and the selected size color should be noted for subsequent use throughout the remaining technique.



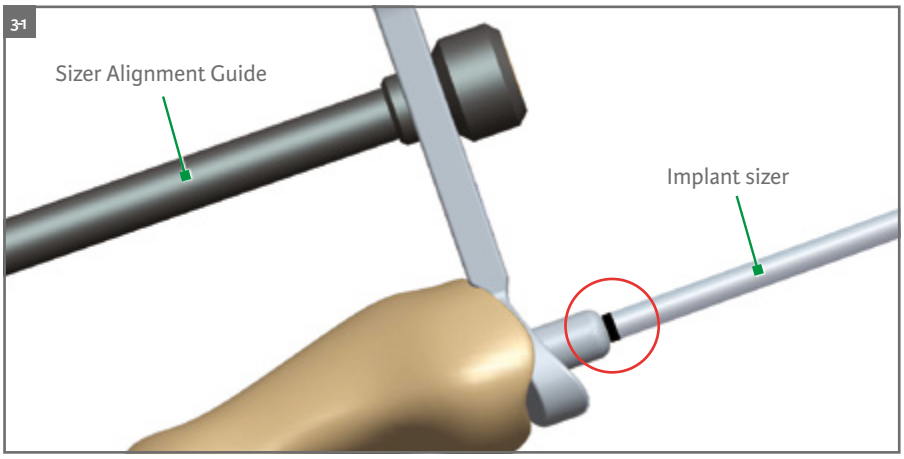
Proximal Phalanx
Implant Sizer

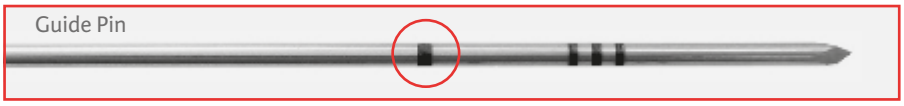
Step 3 • Guide Pin Placement

3-1 Once the appropriate size is determined, thread the Sizer Alignment Guide into the phalangeal Implant Sizer at the area color coded for the implant size selected. Place the Implant Sizer within the wound, lying on the phalangeal articular surface with the Alignment Guide overlying (parallel) the long axis of the hallux.

Place the 2 mm Guide Pin on a drill and drive the Pin into the phalanx through the central hole of the phalangeal Sizer.

Insert the Pin ONLY to the point where the laser mark is flush with the cannulated boss of the Implant Sizer. Placement of the Guide Pin, centrally within the phalanx, should be confirmed by fluoroscopy. The Sizer is then removed and the Guide Pin left in place.





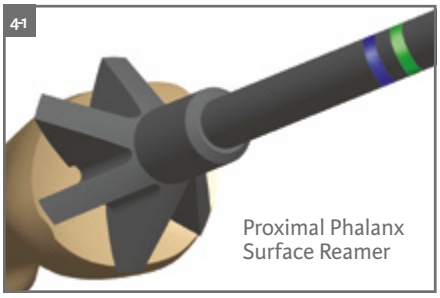
First laser mark flush with top of cannulated boss

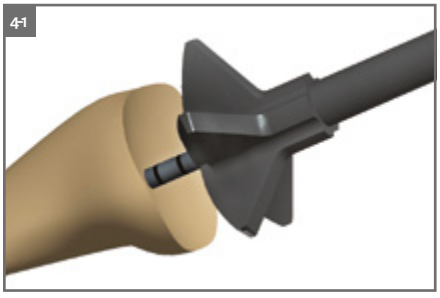
If dorsal osteophytes limit placement of the Sizer, removal of the osteophytes may be performed with a rongeur.

Step 4 • Phalangeal Reaming

4-1 Select the corresponding color-coded Proximal Phalanx Surface (convex) Reamer. Adequate retraction is necessary to prevent the Reamer from damaging the joint capsule or the metatarsal head. The Reamer is placed on a drill and then placed over the Guide Pin. Spin the Reamer prior to engaging bone and gently advance the Reamer against the phalangeal articular surface. Advance the Reamer until the first laser marking is exposed.

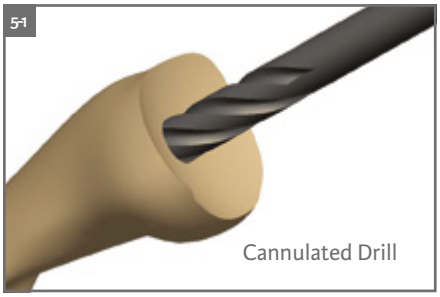
If further decompression is desired, reaming to the second laser marking may be performed. Please note that the laser markings are shown in 2 mm increments. While reaming, continually raise the Reamer from the bone to visualize progress towards exposure of the laser markings. It may be necessary to clear debris or irrigate the wound for better visualization of the laser mark. It is recommended to use irrigation while reaming to avoid overheating of bone.





Step 5 • Center Drill

5-1 Place the 4.5 mm Cannulated Drill bit over the Guide Pin. Advance the Drill until half of the cutting edges are sunk into the base of the proximal phalanx. The Guide Pin is then removed and a rongeur may be used to remove any peripheral debris and osteophytes. Irrigate the wound to remove all debris.

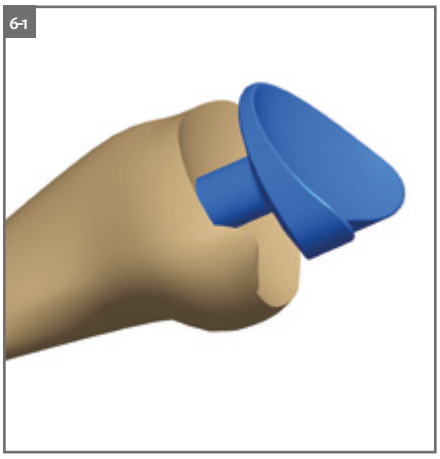


Step 6 • Trial Implant Insertion

6-1 Select the corresponding color-coded Hemi Proximal Phalanx Trial and insert it into the drill hole. If the Trial does not seat properly, use of the Proximal Phalanx Impactor or additional resection of peripheral osteophytes may be performed.

Once the Trial is seated, place the toe and MTP joint through range of motion. Fluoroscopy may be utilized to confirm correct placement. If adequate range of motion is not achieved, repeat steps 4 to 6.

Once again, irrigate the wound prior to insertion of the final implant.

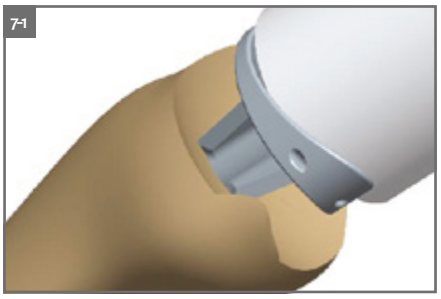


Hemi Proximal Phalanx Trial

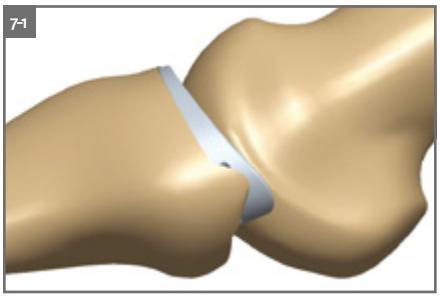
Step 7 • Implantation

7-1 Select the Hemi Proximal Phalanx Implant size that corresponds to the color used during trialing.

Insert the implant and impact it with the phalangeal Impactor and mallet until the implant is fully seated. Assess range of motion and reconfirm positioning with fluoroscopy.



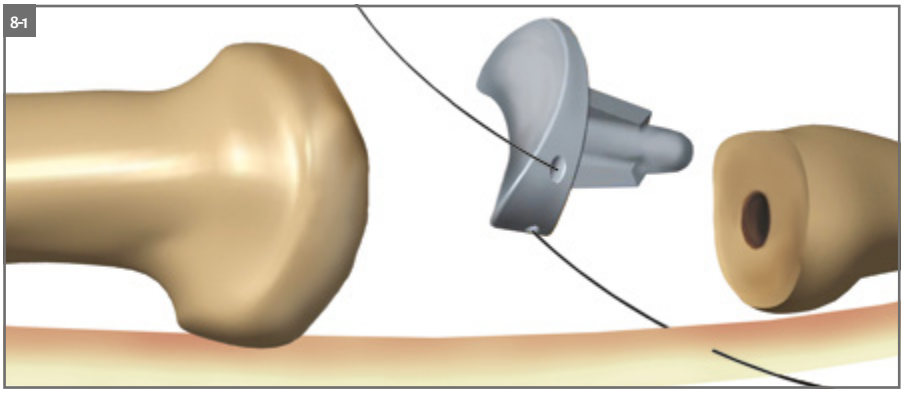
Proximal Phalanx Impactor



Step 8 • Reattaching the Flexor Apparatus

8-1 In case the flexor brevis apparatus is violated on either the medial, lateral, or both components, there are reattachment areas on the plantar medial and lateral portion of the implant.

The surgeon may use the suture holes with their suture of choice. Size 2-0 suture will easily fit into these holes.



Step 9 • Closure

9-1 Closure may be performed via surgeon preference with particular attention to capsular repair with the toe held in a straight and neutral position.

Hemi Metatarsal Surgical Technique

As the manufacturer of this device, Ascension Orthopedics, Inc does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

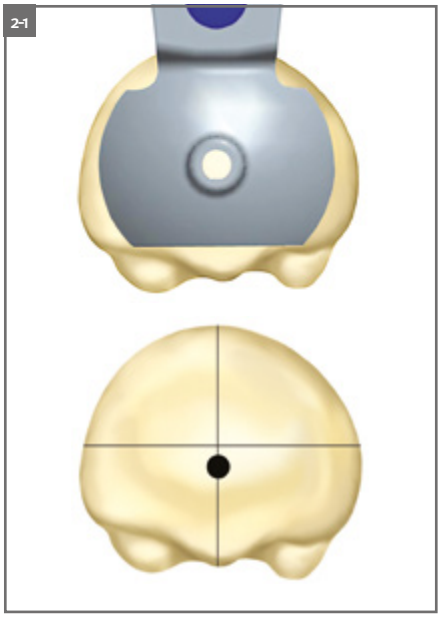
Step 1 • Initial Incision & Exposure

1-1 Exposure of an arthritic first MTP joint requires a skin incision of adequate length. One should consider a longer incision when performing this procedure for the first time. A dorsal skin incision medial to the tendon of the extensor hallucis longus is recommended, beginning proximal at the midpoint of the first metatarsal, extending distally over the MTP joint onto the great toe.

The skin incision is deepened by sharp dissection, with electrocautery of any bleeders. The skin and subcutaneous tissues are reflected, and a lineal capsulotomy may be performed in line with the initial skin incision, once again staying medial to the tendon of the extensor hallucis longus. Subperiosteal dissection is usually begun over the base of the proximal phalanx, and proceeds proximal and plantar within the confines of the joint. The medial and lateral collateral ligaments are severed with subperiosteal dissection of the first metatarsal. The entire first metatarsal phalangeal joint should be mobilized in order to gain access for subsequent instrumentation. During this process, cheilectomy of the first metatarsal may begin, but should be somewhat limited. Do not detach the aponeurotic attachments of the flexor expansion from the base of the proximal phalanx.

Step 2 • Metatarsal Sizing

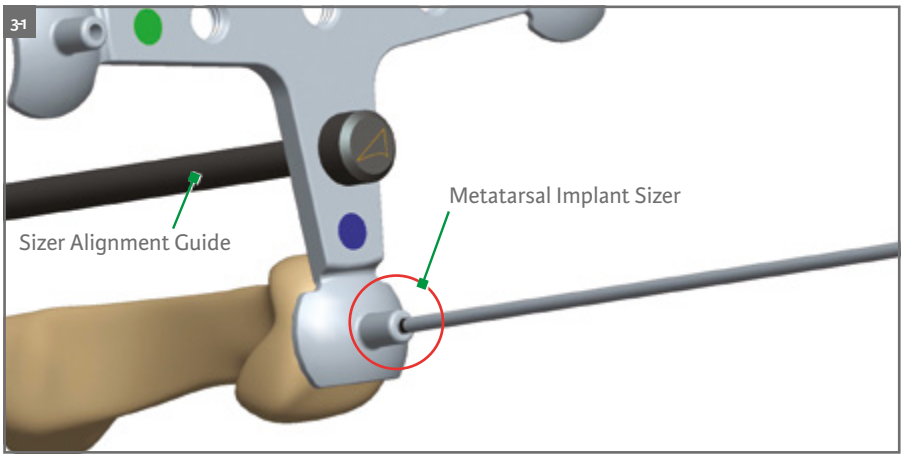
2-1 With the hallux plantar flexed, place the Metatarsal Implant Sizer against the metatarsal head. Determine the correct size by assuring the head is adequately covered. Disregard the peripheral osteophytes while assessing the appropriate size. The plantar aspect of the Sizer should be positioned 0-1 mm superior to the most dorsal aspect of the sesamoidal grooves. Note the color on the handle of the size chosen, as it will be used throughout the procedure.



Metatarsal Implant Sizer

Step 3 • Guide Pin Placement

3-1 Thread the Sizer Alignment Guide through the Sizer into the hole just above the chosen color-coded marking. Press the Sizer against the metatarsal head with the Alignment Guide parallel to, and above, the metatarsal shaft. This step will help the placement of the Guide Pin into the center of the canal. Once proper alignment is achieved, insert the 2.0 mm Guide Pin through the cannulated boss of the Metatarsal Sizer. The Guide Pin is inserted until the first laser mark is flush with the top of the cannulated boss. Confirm alignment of the Guide Pin within the first metatarsal using fluoroscopy. Accurate placement of the Pin, centrally within the first metatarsal and parallel to the long axis, is critical for proper alignment of the implant stem. After confirmation is achieved, remove the Metatarsal Sizer from the Guide Pin.



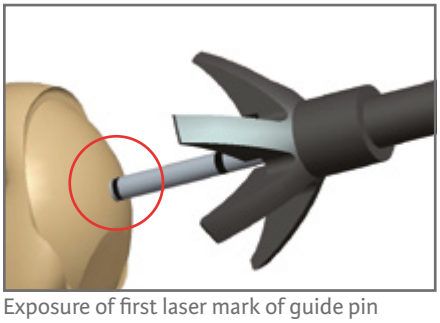
First laser mark flush with top of cannulated boss.

Step 4 • Metatarsal Reaming

4-1 Select the corresponding color-coded Metatarsal Surface (concave) Reamer. Adequate retraction is necessary to prevent the Reamer from damaging the joint capsule or the proximal phalanx. The Reamer is placed on a drill and then placed over the Guide Pin. Spin the Reamer prior to engaging bone and gently advance the Reamer against the metatarsal head surface.

Advance the Reamer until the first laser marking is exposed. If further decompression is desired, reaming to the second laser marking may be performed. Please note that the laser markings are shown in 2 mm increments. While reaming, continually raise the Reamer from the bone to visualize progress towards exposure of the laser markings. It may be necessary to clear debris or irrigate the wound for better visualization of the laser mark. It is recommended to use irrigation while reaming to avoid overheating of bone.

Metatarsal Surface Reamer

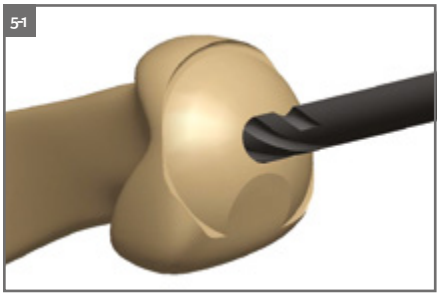


Exposure of first laser mark of guide pin

Step 5 • Center Drill

5-1 Once reaming is completed and the desired laser line is visualized, remove the Reamer and place the 4.5 mm Cannulated Drill over the Guide Pin. Advance the Drill until the full length of the cutting edges are sunk into the metatarsal head.

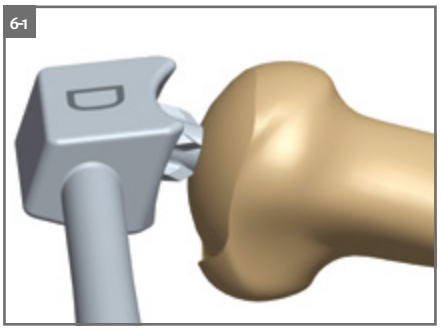
Subsequently, remove the Guide Pin. A rongeur may be used to remove any peripheral osteophytes although we recommend waiting as dorsal bony prominence and osteophytes will be removed during the next step.



Cannulated Drill

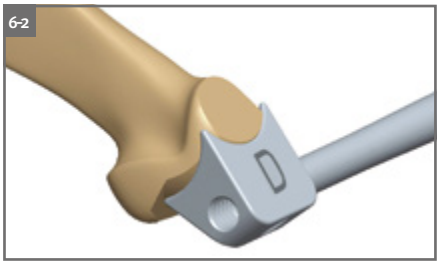
Step 6 • Dorsal Preparation

6-1 The Metatarsal Dorsal Cutting Guide is assembled so that the handle is placed medially and the cutting surface, labeled “D,” is oriented dorsally to allow access of a sagital saw. Visually confirm that the bottom of the Cutting Guide is parallel to the cristae. This will ensure proper implant orientation. Place the Cutting Guide into the previously drilled hole and tap until seated against the metatarsal head.



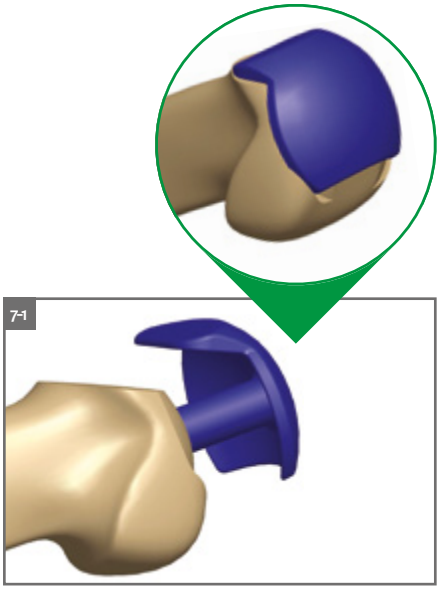
Metatarsal Dorsal Cutting Guide

6-2 Using a sagital saw, place the saw blade flush with the dorsal aspect of the Cutting Guide and perform the osteotomy/exostectomy. Gently remove the Cutting Guide. The surgeon may lightly tap the Guide with a mallet to facilitate removal of the Guide.



Step 7 • Trial Implant Insertion

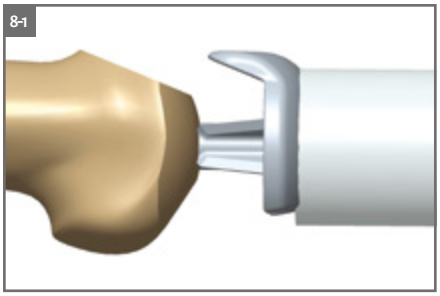
7-1 Select the corresponding color-coded Metatarsal Trial and insert into the prepared site with the flange oriented dorsally. Assess Trial position and contact with the metatarsal. Remove any peripheral bone with the Trial still in place. This can be accomplished with a rongeur or power saw. Once completely seated, place the toe through a range of motion. Fluoroscopy may be utilized to confirm positioning. If range of motion is limited, place the Guide Pin through the drill hole and repeat steps 4 to 6 to allow for further joint decompression.



Metatarsal Trial

Step 8 • Implantation

8-1 Select the Metatarsal Implant size that corresponds to the color used during trialing. Insert the Metatarsal Implant with the flange positioned dorsally. Seat the implant using the Metatarsal Impactor and tap with a mallet. Impact the implant until it is fully seated. Reassess range of motion and reconfirm position with fluoroscopy.



Metatarsal Impactor

Step 9 • Closure

9-1 Closure may be performed via the surgeon’s preference with particular attention to capsular repair, with the toe held in a straight and neutral position.

Total Great Toe Surgical Technique

As the manufacturer of this device, Ascension Orthopedics, Inc does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

NOTE:
In case of Total Arthroplasty, implants are indicated for cemented use only.

Step 1 • Initial Incision & Exposure

1-1

Exposure of an arthritic first MTP joint requires a skin incision of adequate length. One should consider a longer incision when performing this procedure for the first time. A dorsal skin incision medial to the tendon of the extensor hallucis longus is recommended, beginning proximal at the midpoint of the first metatarsal, extending distally over the MTP joint onto the great toe.

The skin incision is deepened by sharp dissection, with electrocautery of any bleeders. The skin and subcutaneous tissues are reflected, and a lineal capsulotomy may be performed in line with the initial skin incision, once again staying medial to the tendon of the extensor hallucis longus. Subperiosteal dissection is usually begun over the base of the proximal phalanx, and proceeds proximal and plantar within the confines of the joint. The medial and lateral collateral ligaments are severed with subperiosteal dissection of the first metatarsal.

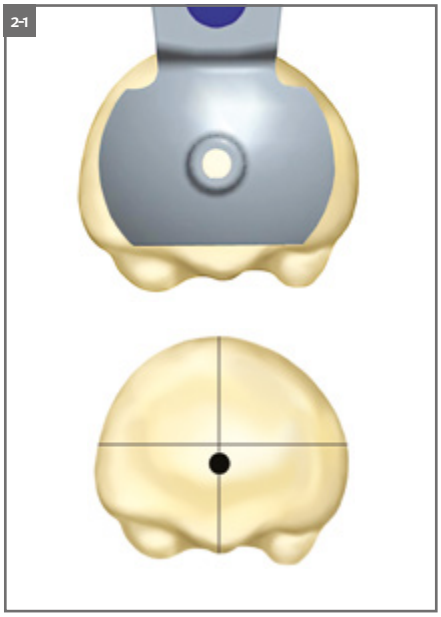
The entire first metatarsal phalangeal joint should be mobilized in order to gain access for subsequent instrumentation. During this process, cheilectomy of the first metatarsal may begin, but should be somewhat limited. Do not detach the aponeurotic attachments of the flexor expansion from the base of the proximal phalanx.

Hallux rigidus is characterized by “squaring-off” the joint surfaces and peripheral osteophytes. Adequate resection of all osteophytes around the metatarsal head should be performed including dorsal remodeling of the metatarsal head to provide a gentle slope to allow adequate dorsiflexion once the implant is inserted.

Preparation of the metatarsal head prior to the base of the phalanx is recommended, however, it is the choice of the surgeon as to which side of the joint to prepare first.

Step 2 • Metatarsal Sizing

2-1



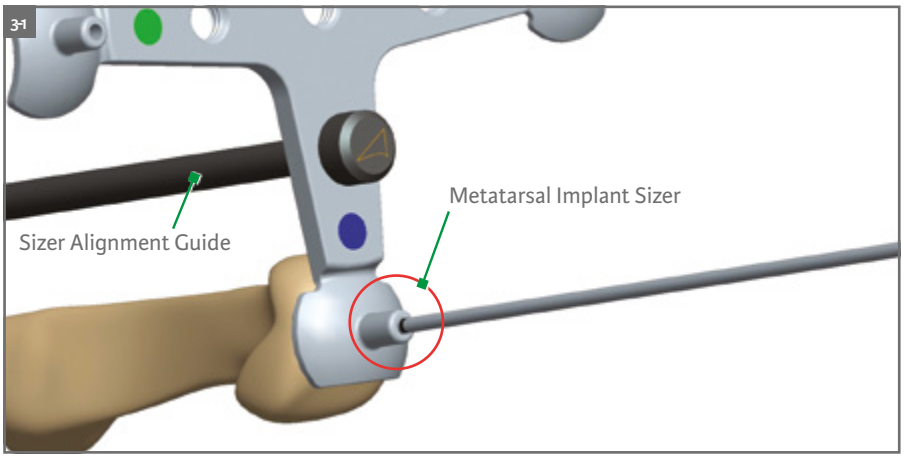
Metatarsal Implant Sizer

Prior to sizing the metatarsal head, please note the system allows for mismatching of any metatarsal size with any phalangeal size implant. Therefore, determine implant sizing based upon the true anatomic size for each side of the joint.

With the hallux plantar flexed, place the Metatarsal Implant Sizer against the metatarsal head. Determine correct size by assuring the head is adequately covered. Disregard the peripheral osteophytes while assessing the appropriate size. The plantar aspect of the Sizer should be positioned 0-1 mm superior to the most dorsal aspect of the sesamoidal grooves. Note the color on the handle of the size chosen, as it will be used throughout the procedure.

Step 3 • Metatarsal Guide Pin Placement

3-1 Thread the Sizer Alignment Guide through the Metatarsal Implant Sizer into the hole just above the chosen color-coded marking. Press the Sizer against the metatarsal head with the Alignment Guide parallel to, and above, the metatarsal shaft. This step will help the placement of the Guide Pin into the center of the canal. Once proper alignment is achieved, insert the 2.0 mm Guide Pin through the cannulated boss of the Metatarsal Sizer. The Guide Pin is inserted until the first laser mark is flush with the top of the cannulated boss. Confirm alignment of the Guide Pin within the first metatarsal using fluoroscopy. Accurate placement of the Guide Pin, centrally within the first metatarsal and parallel to the long axis, is critical for proper alignment of the implant stem. After confirmation is achieved, remove the Metatarsal Sizer from the Guide Pin.



First laser mark flush with top of cannulated boss

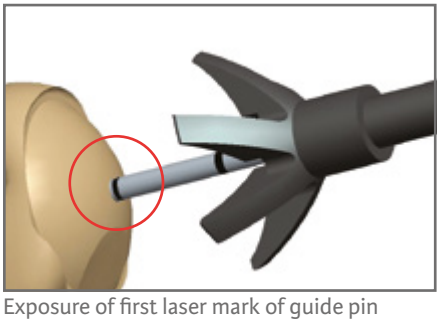
Step 4 • Metatarsal Reaming

4-1 Select corresponding color-coded Metatarsal Surface (concave) Reamer. Adequate retraction is necessary to prevent the Reamer from damaging the joint capsule or the proximal phalanx.

The Reamer is placed on a drill and then placed over Guide Pin. Spin Reamer prior to engaging bone and gently advance the Reamer against the metatarsal head surface. Advance until the second laser marking is exposed. If further decompression is desired, reaming to the third laser marking may be performed. Please note that laser markings are shown in 2 mm increments.

While reaming, continually raise the Reamer from the bone to visualize progress towards exposure of the laser markings. It may be necessary to clear debris or irrigate the wound for better visualization of the laser mark. It is recommended to use irrigation while reaming to avoid overheating of bone.

Metatarsal Surface Reamer

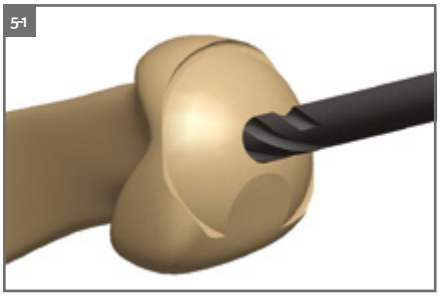


Exposure of first laser mark of guide pin

Step 5 • Center Drill

5-1 Once reaming is completed and the desired laser line is visualized, remove the Reamer and place the 4.5 mm Cannulated Drill over the Guide Pin. For cement application, advance the Drill until the full length of the cutting edges are sunk into the metatarsal head.

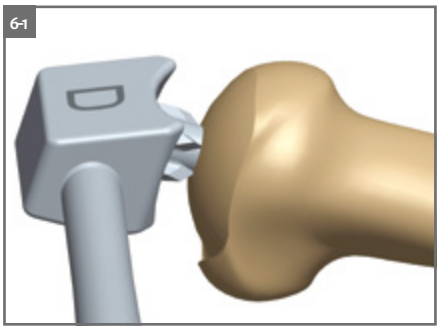
Subsequently, remove the Guide Pin. A rongeur may be used to remove any peripheral osteophytes, although we recommend waiting, as dorsal bony prominence and osteophytes will be removed during the next step.



Cannulated Drill

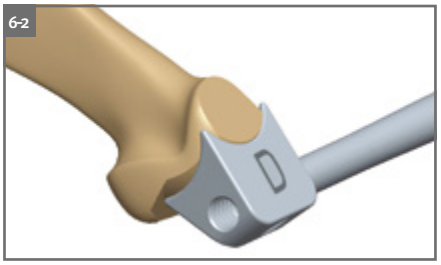
Step 6 • Dorsal Preparation of Metatarsal

6-1 The Metatarsal Dorsal Cutting Guide is assembled so that the handle is placed medially and the cutting surface, labeled "D," is oriented dorsally to allow access of a sagital saw. Visually confirm that the bottom of the Cutting Guide is parallel to the cristae. This will ensure proper implant orientation. Place the Cutting Guide into the previously drilled hole and tap until seated against the metatarsal head.



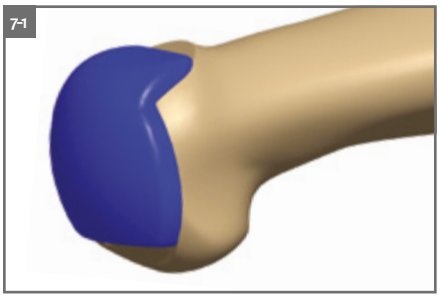
Metatarsal Dorsal Cutting Guide

6-2 Using a sagital saw, place the saw blade flush with the dorsal aspect of the Cutting Guide and perform the osteotomy/exostectomy. Gently remove the Cutting Guide. The surgeon may lightly tap the Guide with a mallet to facilitate removal of the Guide.



Step 7 • Metatarsal Trial Implant Insertion

7-1 Select the corresponding color-coded Metatarsal Trial and insert into the prepared site with the flange oriented dorsally. Assess Trial position and contact with the metatarsal. Remove any peripheral bone with the Trial still in place. This can be accomplished with a rongeur or power saw. Fluoroscopy may be utilized to confirm positioning. Remove the Metatarsal Trial and proceed with preparation of the proximal phalanx.



Metatarsal Trial

Step 8 • Phalangeal Sizing

8-1 The Proximal Phalanx Implant Sizer is utilized to compare to the base of the proximal phalanx and determine the appropriately sized implant. The sizes are color-coded and the selected size color should be noted for subsequent use throughout the remaining technique.

Please note that phalangeal sizing is NOT restricted to the size used on the metatarsal head. The phalangeal component and the metatarsal component are congruent when mismatched with any size.

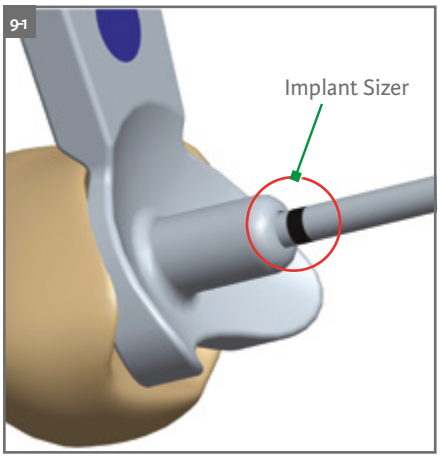
Proximal Phalanx Implant Sizer

Step 9 • Phalangeal Guide Pin Placement

9-1 Once appropriate size is determined, thread the Sizer Alignment Guide into the phalangeal Implant Sizer at the area color coded for the implant size selected. Place the Sizer within the wound, lying on the phalangeal articular surface with the Alignment Guide overlying (parallel) the long axis of the hallux.

Place the 2 mm Guide Pin on a drill and drive the Pin into the phalanx through the central hole of the phalangeal Implant Sizer.

Insert the pin ONLY to the point where the laser mark is flush with the cannulated boss of the Sizer. Placement of the Guide Pin, centrally within the phalanx, should be confirmed by fluoroscopy. The Sizer is then removed and the Guide Pin left in place. If dorsal osteophytes limit the placement of the Sizer, removal of the osteophytes may be performed with a rongeur.

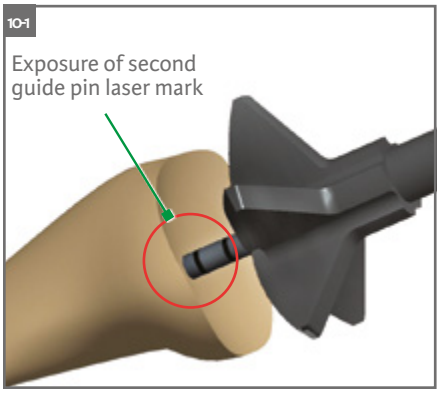


First laser mark flush with top of cannulated boss

Step 10 • Phalangeal Reaming

10-1 Select the corresponding color-coded Proximal Phalanx Surface (convex) Reamer. Adequate retraction is necessary to prevent the Reamer from damaging the joint capsule or the metatarsal head. The Reamer is placed on a drill and then placed over the Guide Pin. Spin the Reamer prior to engaging bone and gently advance the Reamer against the phalangeal articular surface.

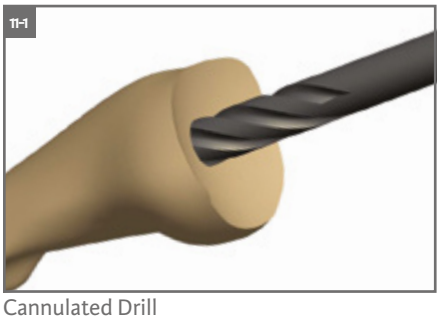
Advance the Reamer until the second laser marking is exposed. If further decompression is desired, reaming to the third laser marking may be performed. Please note that the laser markings are shown in 2 mm increments. While reaming, continually raise the Reamer from the bone to visualize progress towards exposure of the laser markings. It may be necessary to clear debris or irrigate the wound for better visualization of the laser mark. It is recommended to use irrigation while reaming to avoid overheating of bone.



Proximal Phalanx Surface Reamer

Step 11 • Center Drill

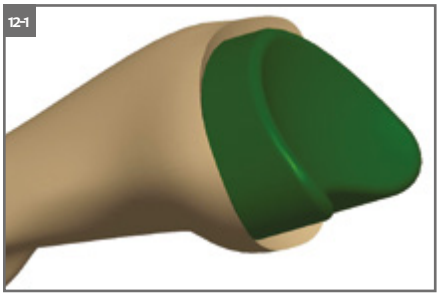
11-1 Place the 4.5 mm Cannulated Drill over the Guide Pin. For cement application, advance the Drill until half of the cutting edges are sunk into the base of the proximal phalanx. The Guide Pin is then removed and a rongeur may be used to remove any peripheral debris and osteophytes. Irrigate the wound to remove all debris.



Cannulated Drill

Step 12 • Phalangeal Trial Implant Insertion

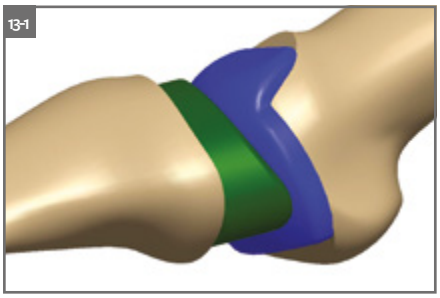
12-1 Select the corresponding color-coded Total Phalangeal Trial and insert it into the drill hole. If the Trial does not seat properly, use of the Proximal Phalanx Impactor or additional resection of peripheral osteophytes may be performed. Utilize fluoroscopy to confirm correct placement.



Total Proximal Phalanx Trial

Step 13 • Total Trial Evaluation

13-1 Reinsert Metatarsal Trial and assess range of motion. If adequate range of motion is not achieved, repeat steps 4 to 6 for metatarsal decompression and/or steps 10 to 11 for phalangeal decompression of the joint. Irrigate wound prior to insertion of the final implant.

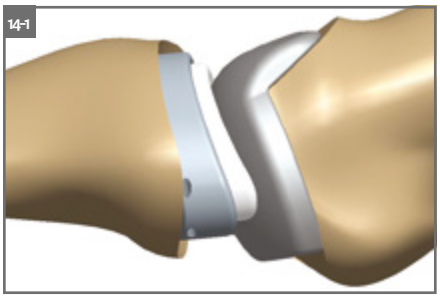


Step 14 • Final Implantation

14-1 Select the implant sizes that correspond to the colors used during trialing. Mix cement using manual or syringe application. The cap of the syringe is left in place and its end cut with scissors. The tip is inserted, and the cement pressurized into the drill holes. Cement on the metatarsal and phalangeal surfaces should be avoided.

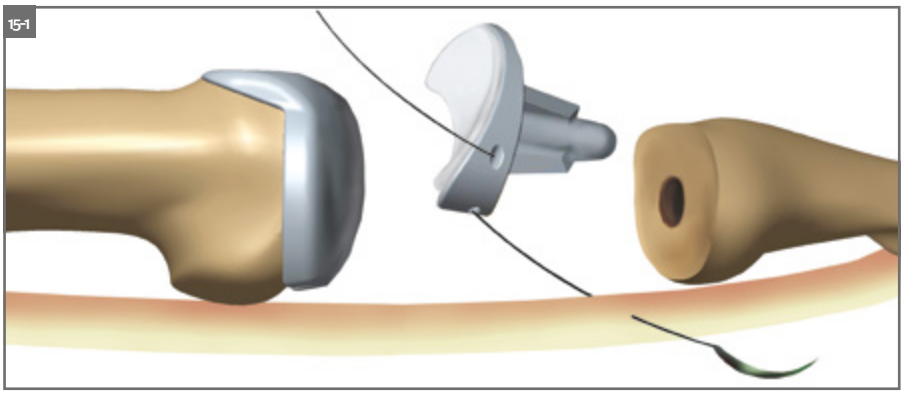
Apply cement to cover the entire backside of the metatarsal implant. Insert and seat the implant using the Metatarsal Impactor and tap with a mallet. Impact the implant until it is fully seated. Next, apply cement to cover the entire backside of the phalangeal implant. Insert and seat the implant using the Proximal Phalanx Impactor, and tap with a mallet. Impact the implant until it is fully seated. Pressure should be maintained on both implants until the cement has hardened.

With both implant components fully seated, assess range of motion and reconfirm positioning with fluoroscopy.



Step 15 • Reattaching the Flexor Apparatus

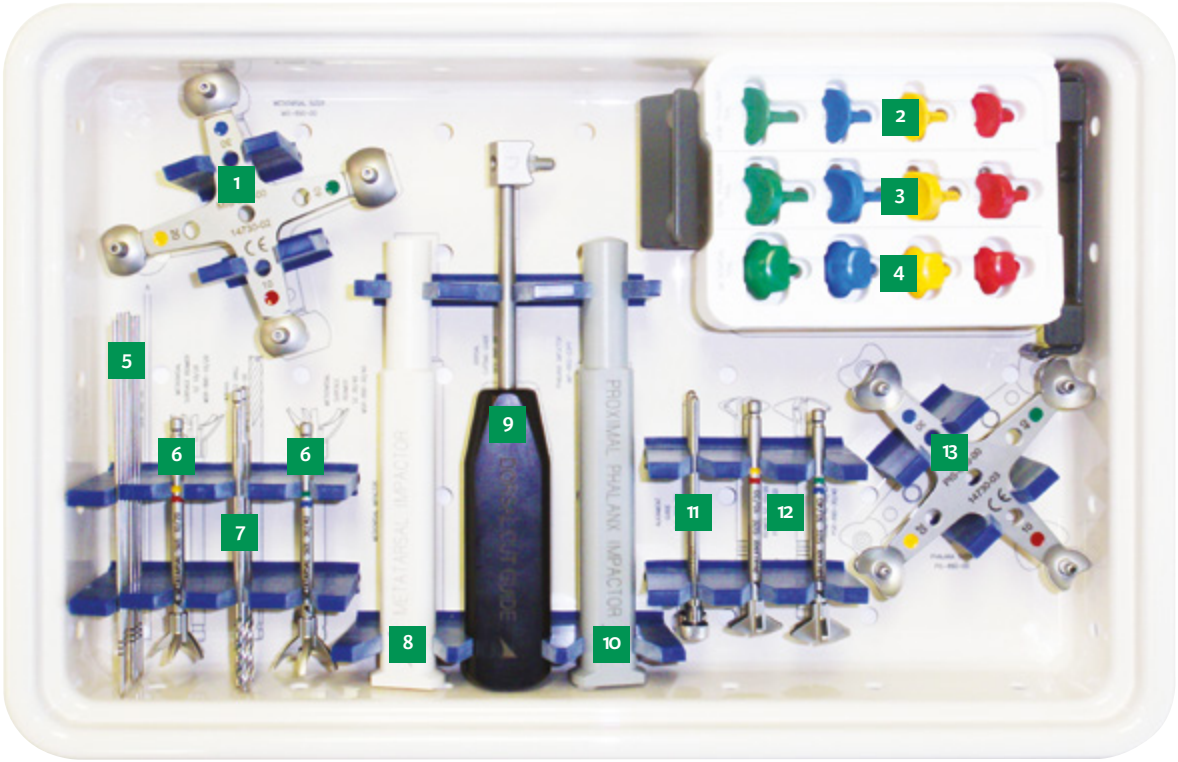
15-1 In case the flexor brevis apparatus is violated on either the medial, lateral, or both components, there are reattachment areas on the plantar medial and lateral portion of the phalangeal implant. The surgeon may use the suture holes with suture of choice. Size 2-0 suture will easily fit into these holes.



Step 16 • Closure

16-1 Closure may be performed via surgeon preference with particular attention to capsular repair with the toe held in a straight and neutral position.

Movement™ Great Toe Instrumentation



Instruments

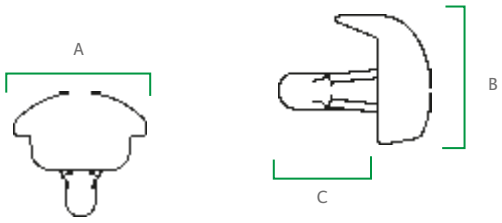
#	Reference	Description
1	MIS-890-00	Metatarsal Implant Sizer
2	TRL-890-XXPPH*	Hemi Proximal Phalanx Trials
3	TRL-890-XXPPT*	Total Phalangeal Trials
4	TRL-890-XXMT*	Metatarsal Trials
5	GDW-890-00	Guide Pins
6	MSR-890-XX/XX*	Metatarsal Surface Reamers
7	DRL-890-00	Cannulated Drill
8	IMP-890-00MT	Metatarsal Impactor
9	DCG-890-00	Metatarsal Dorsal Cutting Guide
10	IMP-890-00PP	Proximal Phalanx Impactor
11	ALG-890-00	Sizer Alignment Guide
12	PSR-890-XX/XX*	Proximal Phalanx Surface Reamers
13	PIS-890-00	Promixal Phalanx Implant Sizer

Container

Reference	Description
CSA-000-06	Generic Symmetry Case Lid
CSA-890-02	MGT Base (Case)
CSA-890-03	MGT Trial Caddy
CSA-890-04	MGT Trial Caddy Lid

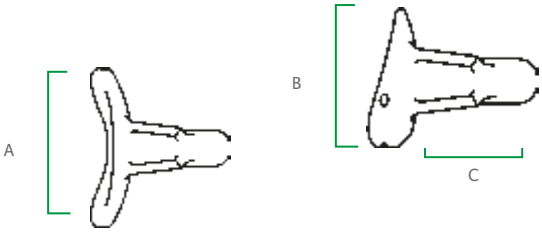
* Please refer to next page for complete references

Movement™ Great Toe Implant Dimensions



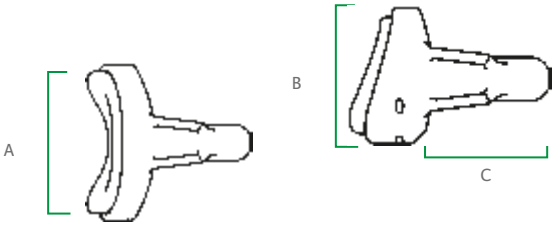
Metatarsal size (mm)

Reference	Width A	Height B	Stem length C
MGT-890-10MT	15.8	14.7	14.4
MGT-890-20MT	17.4	15.0	15.4
MGT-890-30MT	18.8	15.7	16.4
MGT-890-40MT	20.3	16.1	17.4



Hemi Proximal phalanx size (mm)

Reference	Width A	Height B	Stem length C
MGT-890-10PPH	15.4	11.8	9.0
MGT-890-20PPH	16.8	12.5	10.0
MGT-890-30PPH	18.3	13.2	11.0
MGT-890-40PPH	19.6	13.9	12.0



Total Proximal phalanx size (mm)

Reference	Width A	Height B	Stem length C
MGT-890-10PPT	15.4	11.8	9.0
MGT-890-20PPT	16.8	12.5	10.0
MGT-890-30PPT	18.3	13.2	11.0
MGT-890-40PPT	19.6	13.9	12.0

Movement™ Great Toe Implants

Reference	Description
MGT-890-10PPH	Hemi Proximal Phalanx, Size 10
MGT-890-20PPH	Hemi Proximal Phalanx, Size 20
MGT-890-30PPH	Hemi Proximal Phalanx, Size 30
MGT-890-40PPH	Hemi Proximal Phalanx, Size 40
MGT-890-10PPT	Total Proximal Phalanx, Size 10
MGT-890-20PPT	Total Proximal Phalanx, Size 20
MGT-890-30PPT	Total Proximal Phalanx, Size 30
MGT-890-40PPT	Total Proximal Phalanx, Size 40
MGT-890-10MT	Hemi Metatarsal, Size 10
MGT-890-20MT	Hemi Metatarsal, Size 20
MGT-890-30MT	Hemi Metatarsal, Size 30
MGT-890-40MT	Hemi Metatarsal, Size 40

Movement™ Instrumentation

Reference	Description
MIS-890-00	Metatarsal Implant Sizer
PIS-890-00	Proximal Phalanx Implant Sizer
GDW-890-00	Guide Pin, 2.0 mm X 125 mm
MSR-890-10/20	Metatarsal Surface Reamer, Size 10/20
MSR-890-30/40	Metatarsal Surface Reamer, Size 30/40
PSR-890-10/20	Proximal Phalanx Surface Reamer, Size 10/20
PSR-890-30/40	Proximal Phalanx Surface Reamer, Size 30/40
DRL-890-00	Cannulated Drill, 4.5 mm
DCG-890-00	Metatarsal Dorsal Cutting Guide
TRL-890-10MT	Metatarsal Trial, Size 10
TRL-890-20MT	Metatarsal Trial, Size 20
TRL-890-30MT	Metatarsal Trial, Size 30
TRL-890-40MT	Metatarsal Trial, Size 40
TRL-890-10PPH	Hemi Proximal Phalanx Trial, Size 10
TRL-890-20PPH	Hemi Proximal Phalanx Trial, Size 20
TRL-890-30PPH	Hemi Proximal Phalanx Trial, Size 30
TRL-890-40PPH	Hemi Proximal Phalanx Trial, Size 40
TRL-890-10PPT	Total Phalangeal Trial, Size 10
TRL-890-20PPT	Total Phalangeal Trial, Size 20
TRL-890-30PPT	Total Phalangeal Trial, Size 30
TRL-890-40PPT	Total Phalangeal Trial, Size 40
IMP-890-00MT	Metatarsal Impactor
IMP-890-00PP	Proximal Phalanx Impactor
ALG-890-00	Sizer Alignment Guide

Integra
Movement™ Great Toe System

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