

For Intramedullary Fixation of
the Medial Column of the Foot

6.5 mm Midfoot Fusion Bolt

Surgical Technique



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MR Information

The 6.5 mm Midfoot Fusion Bolt System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the 6.5 mm Midfoot Fusion Bolt System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

 Image intensifier control

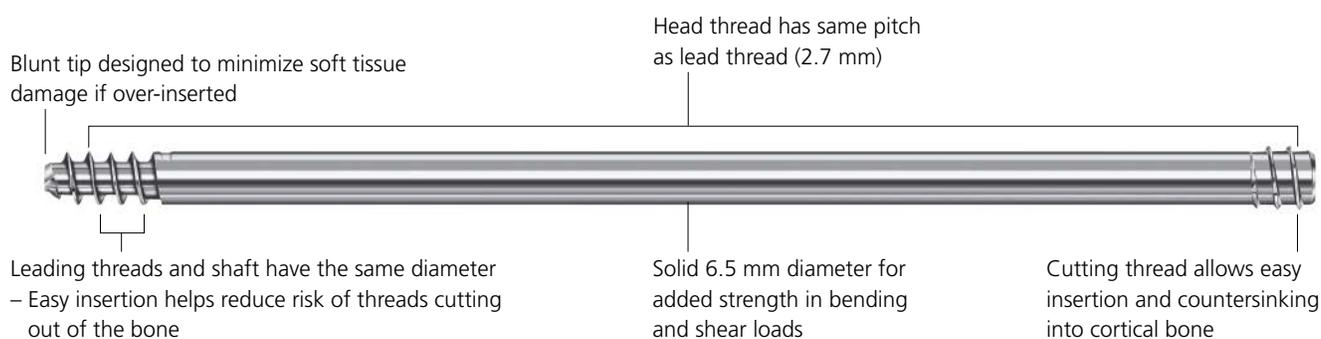
6.5 MM MIDFOOT FUSION BOLT

The Midfoot Fusion Bolt is a solid intramedullary implant that can be used to fuse the medial metatarsocuneiform, naviculocuneiform, and talonavicular joints. Other uses of the Midfoot Fusion Bolt are fusion of the lateral column, calcaneocuboid, and 4th metatarsocuboid joint. The Midfoot Fusion Bolt is designed to achieve permanent fusion of these joints in patients suffering from gross instability such as Charcot neuroarthropathy with or without collapse of the midfoot. The Midfoot Fusion Bolt aids in the fusion of the joints of the midfoot. Fusion of the midfoot can provide stabilization and alignment, enhancing the possibility of a functional foot and increasing the likelihood of limb salvage.^{1,2}

The 6.5 mm Midfoot Fusion Bolt is:

- A solid bolt, highly resistant to bending and shear loads
- Headless, for complete countersinking
- Able to achieve compression
- Available in 50 mm–160 mm lengths
- Available in stainless steel and titanium

Features



1. Johnson JE. Operative treatment of neuropathic arthropathy of the foot and ankle. *J Bone Joint Surg Am.* 1998;80-A:1700–1709.
2. Simon SR, Tejwani SG, Wilson DL, Santner TJ, Denniston NL. Arthrodesis as an early alternative to nonoperative management of charcot arthropathy of the diabetic foot. *J Bone Joint Surg Am.* 2000;82-A(7):939-50.

Functional principle of threads in Midfoot Fusion Bolt

Step 1. Midfoot Fusion Bolt insertion

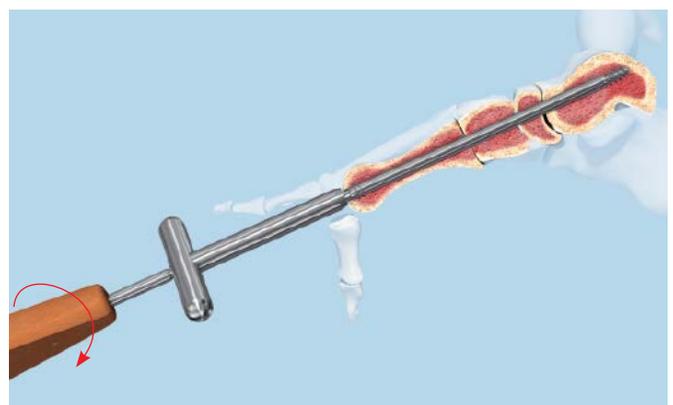
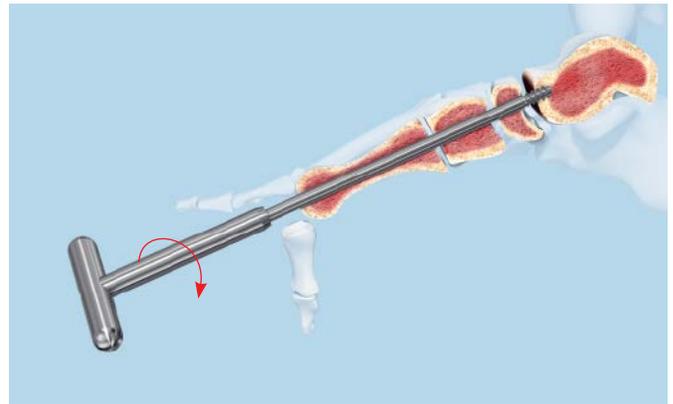
Insertion of the Midfoot Fusion Bolt with the compression T-handle.

Step 2. Closure of gap and compression

As the compression T-handle contacts the bone, it acts like a screwhead and allows closure of the gap by compression.

Step 3. Countersinking

Once the desired amount of compression is achieved, the bolt head is countersunk by holding the T-handle and turning the bolt into the bone with the screwdriver.



AO PRINCIPLES

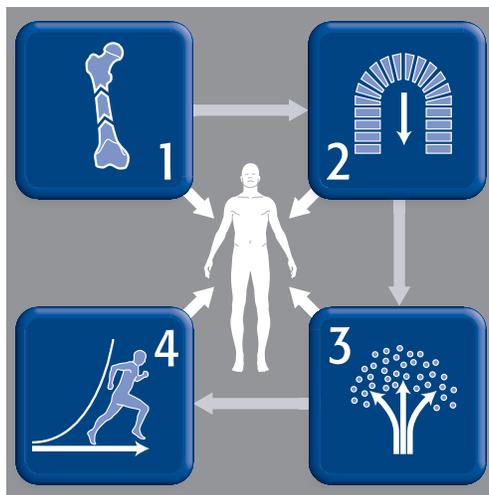
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.^{1,2}

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.



Stable fixation

Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply

Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

1. Müller ME, Allgöwer M, Schneider R, Willenegger H. *Manual of Internal Fixation*. 3rd ed. Berlin, Heidelberg, New York: Springer-Verlag; 1991.
2. Rüedi TP, RE Buckley, CG Moran. *AO Principles of Fracture Management*. 2nd ed. Stuttgart New York: Thieme; 2007.

INDICATIONS

The DePuy Synthes 6.5 mm Midfoot Fusion Bolt is indicated for fracture fixation, osteotomies, nonunions, and fusions of large bones in the foot and ankle.

Warnings:

- **The Midfoot Fusion Bolt is not to be used as a standalone implant and needs to be used with supplemental fixation, such as additional screws and plates across the arthrodesed joints.**
- **The surgeon must use proper clinical judgment and assess the benefit/risk before using this product in patients with Peripheral Vascular Disease or with serious and life threatening co-morbidities.**



PREOPERATIVE PLANNING

Evaluation of x-rays

For good preoperative planning it is important to have the following x-rays:

- Weight-bearing in three projections: Lateral, AP, 45° oblique AP
- AP of ankle
- Comparative x-rays of both sides

Preoperative examination and evaluation

Estimate the balance of the foot and the function of the vital tendons, especially the length of the Achilles tendon and gastrocnemius.

A gastrocnemius slide or percutaneous tendo-Achilles lengthening is needed as equinus contracture causes abnormally high stresses across the midfoot.

PREPARATION

1

Position patient

Place the patient in the supine position, with a roll under the affected hip to position the foot in neutral (toes straight up in a resting position).



2

Perform gastrocnemius slide or percutaneous tendo-Achilles lengthening

A gastrocnemius slide or percutaneous tendo-Achilles lengthening is usually needed to relieve stresses across the midfoot.

3

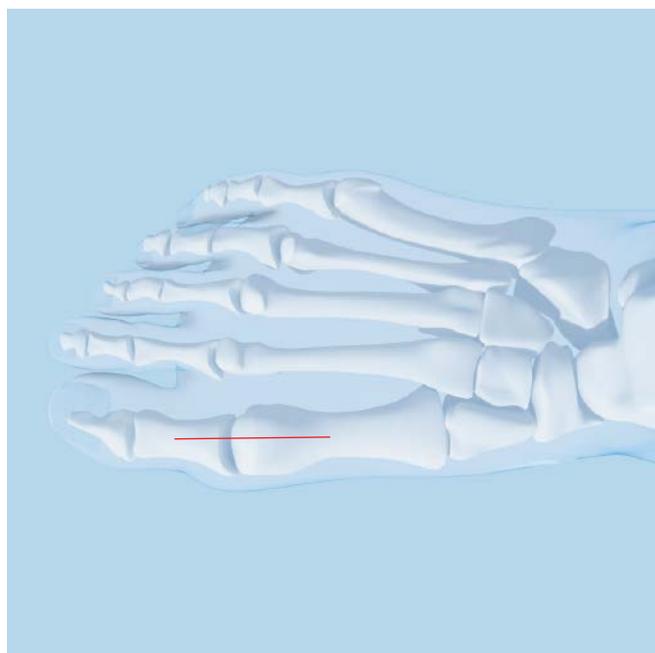
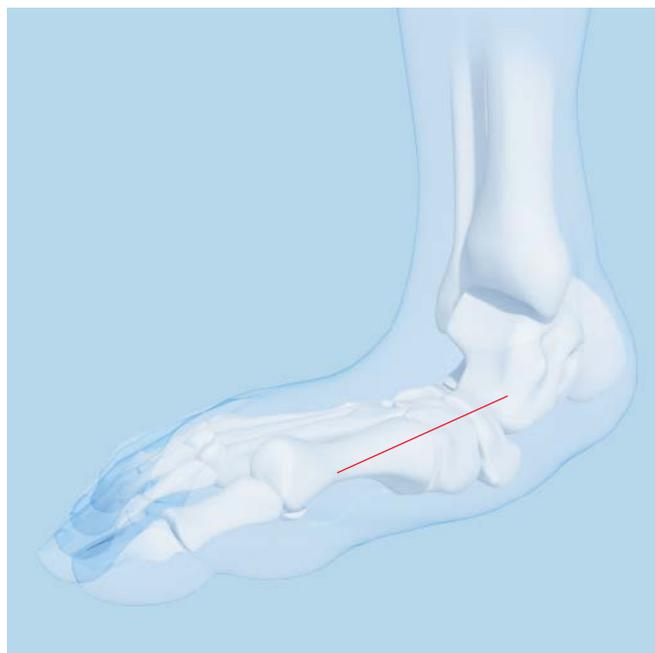
Approach

Two or three incisions are usually needed to expose and prepare the joints to be fused.

Make a medial utility incision to expose and denude the talonavicular, navicular cuneiform, and tarsometatarsal joints. Take care to avoid the tibialis anterior tendon.

Make a dorsal straight incision over the first metatarsal phalangeal joint (MPJ) to expose the joint. This allows access for the drill bit and midfoot fusion bolt through the first metatarsal articular surface.

Note: At this stage of the procedure a subtalar fusion may be performed, if necessary.



4

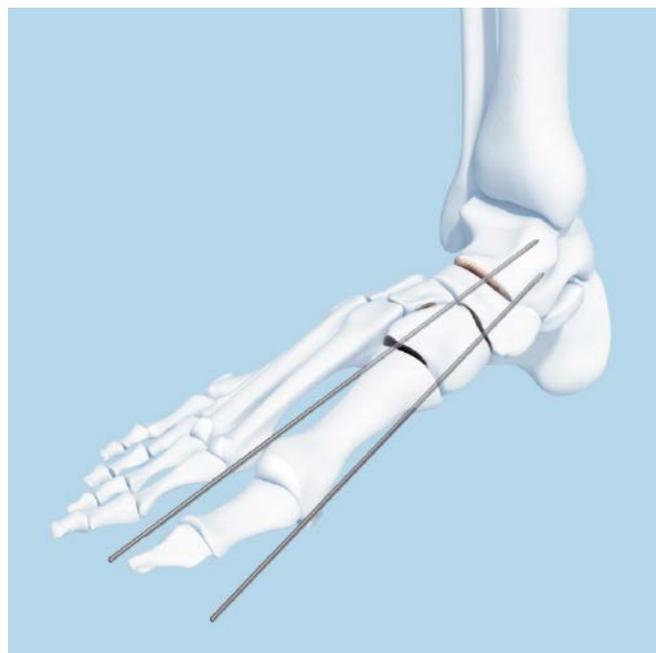
Prepare joints

Instrument

| | |
|---------|--|
| 292.20* | 2.0 mm Kirschner Wire, trocar point, 150 mm |
|---------|--|

Expose and prepare all the joints for fusion. Correct deformities with resections, where necessary. These corrections should be performed to the estimated final shape of the foot. Place temporary K-wires to hold the joints in place, taking care not to place them in the path of the final implant.

Note: If desired add graft before provisionally fixing the joints with K-wires.



5

Prepare metatarsal

Access the first metatarsal head through the dorsal incision.

*Also available.

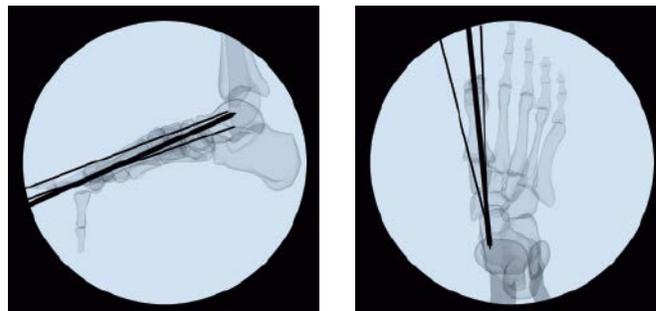
IMPLANTATION

1

Insert guide wire

Instruments

| | |
|------------|--|
| 02.227.001 | 2.8 mm Non-Threaded Guide Wire, trocar point, 300 mm |
| 312.05 | 12.0 mm/8.5 mm Protection Sleeve |
| 312.08 | 8.5 mm/2.8 mm Wire Sleeve |



- Insert the 2.8 mm guide wire, under image intensifier control, through the upper center of the first metatarsal head close to the dorsal cortex and straight across the tarsometatarsal, the navicular cuneiform, and the talonavicular joints into the talus. Insert the guide wire to the depth required.

Note: Measurement is to the tip of the guide wire.



Alternative: reverse technique

Instruments

| | |
|------------|---|
| 02.227.001 | 2.8 mm Non-Threaded Guide Wire, trocar point, 300 mm |
| 312.05 | 12.0 mm/8.5 mm Protection Sleeve |
| 312.08 | 8.5 mm/2.8 mm Wire Sleeve |

Insert the 2.8 mm guide wire under image intensifier control, through the upper center of the first metatarsal head, close to the dorsal cortex and straight across the tarsometatarsal, the navicular cuneiform, and the talonavicular joints, into the talus. Continue inserting the guide wire through the posterior of the talus making sure it exits posterior, avoiding the subtalar joint. From the back of the foot, readjust the guide wire position in the metatarsal head to allow measurement of the desired length of the midfoot fusion bolt.

2 Measure for bolt length

Instrument

319.70 Cannulated Screw Measuring Device, for 6.5 mm and 7.3 mm Cannulated Screws

Place the measuring device over the guide wire and to the bone. Selected bolt length should reflect joint spaces, depth of countersink, and desired position of the leading tip of the bolt.



Alternative: reverse technique

Instrument

319.70 Cannulated Screw Measuring Device for 6.5 mm and 7.3 mm Cannulated Screws

Place the measuring device over the guide wire and to the bone. Selected bolt length should reflect joint spaces, depth of countersink, and desired position of the leading tip of the bolt.



3 Drill

Instruments

| | |
|------------|--|
| 03.111.002 | 5.0 mm Three-Fluted Cannulated Drill Bit, quick coupling, 300 mm, 200 mm calibration |
| 357.047 | 6.5 mm Cannulated Drill Bit, quick coupling, 330 mm |

When the reduction is complete, insert the 5.0 mm drill bit over the guide wire.

- Under image intensification, drill to the final desired position of the bolt.

Note: The length of the bolt can also be checked with the calibrations on the 5.0 mm drill bit.

- Verify under image intensification that the drill bit follows the correct path and does not penetrate the end of the talus.

It is recommended to over-drill the diameter of the bone with the 6.5 mm cannulated drill bit, especially in hard bone.

Precaution: If overdrilling, do not drill the entire length of the bolt, as this will prevent purchase of the leading bolt threads.



3

Drill

Alternative: reverse technique

Instruments

| | |
|------------|--|
| 03.111.002 | 5.0 mm Three-Fluted Cannulated Drill Bit, quick coupling, 300 mm, 200 mm calibration |
| 357.047 | 6.5 mm Cannulated Drill Bit, quick coupling, 330 mm |

When the reduction is complete, insert the 5.0 mm drill bit over the guide wire.

- Under image intensification, drill to the final desired position of the bolt.

Note: The length of the bolt can also be checked with the calibrations on the 5.0 mm drill bit.

- Verify under image intensification that the drill bit follows the correct path.

It is recommended to over-drill the diameter of the bone with the 6.5 mm cannulated drill bit, especially in hard bone.

Precaution: If overdrilling, do not drill the entire length of the bolt, as this will prevent purchase of the leading bolt threads.



4

Remove guide wire

Remove the guide wire to allow insertion of the solid midfoot fusion bolt.

If stability is not maintained, add supplemental K-wires, ensuring that the wires are not in the path of the bolt.

5

Select midfoot fusion bolt

Select the midfoot fusion bolt. Bolt length should reflect joint spaces, depth of countersink, and desired position of the leading tip of the bolt (Step 6).

Notes:

- **It is important that the midfoot fusion bolt is inserted well into the body of the talus.**
- **If there is excessive joint space, this should be considered when choosing the bolt.**

6

Attach midfoot fusion bolt to T-handle

Instrument

| | |
|------------|----------------------------------|
| 03.111.001 | T-Handle for Midfoot Fusion Bolt |
|------------|----------------------------------|

Connect the midfoot fusion bolt to the T-handle and finger-tighten.

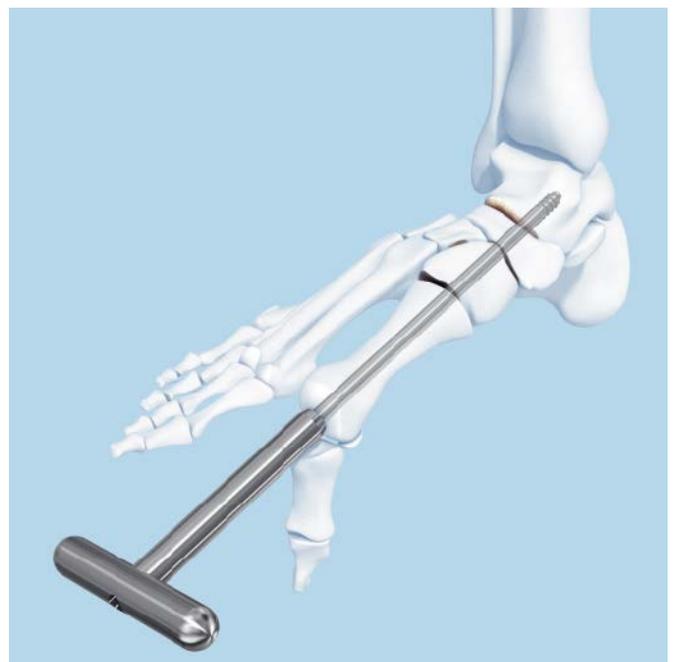
7

Insert midfoot fusion bolt

- Insert the midfoot fusion bolt into the metatarsal head. Use image intensification to visualize and control bolt insertion.

Place allograft or autograft in the prepared joints, if required.

- Turn the T-handle until it reaches the cartilage of the joint.



Alternative: reverse technique

- ① Insert the midfoot fusion bolt. Use image intensification to visualize and control bolt insertion.
- Place allograft or autograft in the prepared joints, if required.
- ② Turn the T-handle until it reaches the posterior of the talus.



8

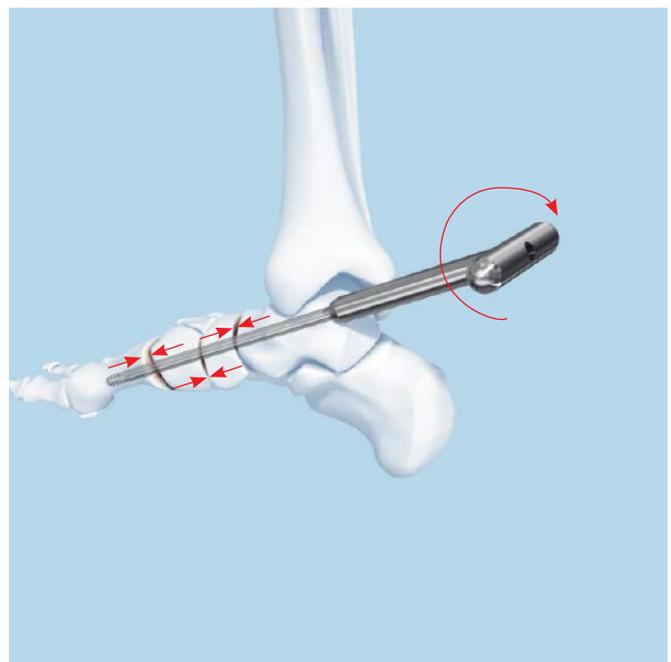
Compress joints

- ① Under image intensification turn the T-handle until the desired compression is achieved.



Alternative: reverse technique

- ① Under image intensification turn the T-handle until the desired compression is achieved.



9

Countersink midfoot fusion bolt

Instrument

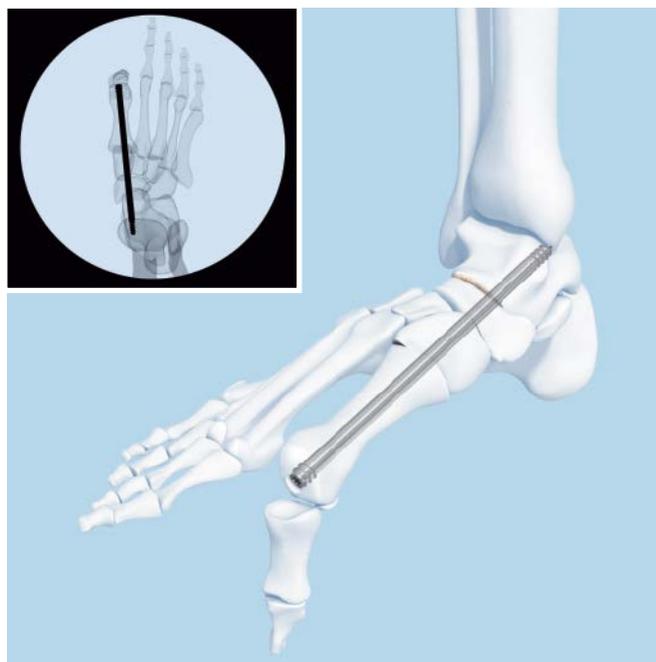
| | |
|---------|--|
| 314.164 | Screwdriver STARDRIVE™, T25, with groove, 240 mm |
|---------|--|

Place the STARDRIVE™ Screwdriver through the cannulation in the T-handle and engage the screwdriver in the head of the bolt.

Hold the T-handle stationary and use the screwdriver to countersink the threaded head of the midfoot fusion bolt into the metatarsal.

Note: The top of the thread is even with the bone surface when the groove in the screwdriver aligns with the top of the T-handle. Check the length of the midfoot fusion bolt, making sure that it is inserted well into the body of the talus.

Precaution: If the bolt is short, there is a risk of cut-out along the plantar aspect of the distal talus when full weight-bearing starts.



9

Countersink midfoot fusion bolt

Alternative: reverse technique

Instrument

| | |
|---------|--|
| 314.164 | Screwdriver STARDRIVE, T25, with groove, 240 mm |
|---------|--|

Place the STARDRIVE Screwdriver through the cannulation in the T-handle and engage the screwdriver in the head of the bolt.

Hold the T-handle stationary and use the screwdriver to countersink the threaded head of the midfoot fusion bolt into the posterior of the talus.

SUPPLEMENTAL FIXATION

The Midfoot Fusion Bolt is to be used with supplemental fixation, such as additional screws and plates across the arthrodesed joints.

DePuy Synthes offers a wide selection of plates and screws which cover a correspondingly extensive variety of indications. For this reason this technical guide does not cover specific indications or the selection of a plate type for specific clinical situations. For treatment of these subjects, please refer to "AO Principles of Fracture Management" courses offered by the AO (www.aofoundation.org), and the corresponding professional literature.



POSTOPERATIVE TREATMENT AND IMPLANT REMOVAL (OPTIONAL)

Postoperative treatment

Immobilization in a well-padded splint for the first two weeks. During this time a dependent position should be avoided. The dressing is removed at two weeks, the wound is evaluated and gentle range of motion of the ankle and first metatarsophalangeal joints is initiated. Full weight-bearing between 10 to 12 weeks based on radiographic evidence of healing.

Implant removal (optional)

Instruments

| | |
|------------|---|
| 03.111.001 | T-Handle for Midfoot Fusion Bolt |
| 314.164 | STARDRIVE Screwdriver, T25, with groove, 240 mm |

Clear tissue ingrowth from the STARDRIVE Recess at the end of the bolt. Screw the bolt out until the head is no longer engaged in the bone. Attach the T-handle, place the STARDRIVE Screwdriver through the cannulation in the T-handle, and engage the screwdriver in the head of the bolt. Holding the T-handle, turn the screwdriver counterclockwise to partially engage the bolt in the T-handle. Remove the screwdriver. While pulling gently, turn the T-handle counterclockwise.

IMPLANTS

6.5 mm Midfoot Fusion Bolts[◊]

| Stainless Steel | Titanium | Length (mm) |
|-----------------|------------|-------------|
| 02.111.150 | 04.111.150 | 50 |
| 02.111.155 | 04.111.155 | 55 |
| 02.111.160 | 04.111.160 | 60 |
| 02.111.165 | 04.111.165 | 65 |
| 02.111.170 | 04.111.170 | 70 |
| 02.111.175 | 04.111.175 | 75 |
| 02.111.180 | 04.111.180 | 80 |
| 02.111.185 | 04.111.185 | 85 |
| 02.111.190 | 04.111.190 | 90 |
| 02.111.195 | 04.111.195 | 95 |
| 02.111.200 | 04.111.200 | 100 |
| 02.111.205 | 04.111.205 | 105 |
| 02.111.210 | 04.111.210 | 110 |
| 02.111.215 | 04.111.215 | 115 |
| 02.111.220 | 04.111.220 | 120 |
| 02.111.225 | 04.111.225 | 125 |
| 02.111.230 | 04.111.230 | 130 |
| 02.111.235 | 04.111.235 | 135 |
| 02.111.240 | 04.111.240 | 140 |
| 02.111.245 | 04.111.245 | 145 |
| 02.111.250 | 04.111.250 | 150 |
| 02.111.255 | 04.111.255 | 155 |
| 02.111.260 | 04.111.260 | 160 |



[◊] Available nonsterile and sterile packed.
Add "S" to catalog number for sterile product.

For detailed cleaning and sterilization instructions, please refer to www.synthes.com/cleaning-sterilization or sterilization instructions, if provided.

INSTRUMENTS

02.227.001 2.8 mm Non-Threaded Guide Wire,
trocar point, 300 mm



03.111.001 T-Handle for Midfoot Fusion Bolt



03.111.002 5.0 mm Three-Fluted Cannulated Drill Bit,
quick coupling, 300 mm, 200 mm calibration



312.05 12.0 mm/8.5 mm Protection Sleeve



312.08 8.5 mm/2.8 mm Wire Sleeve



314.164 STARDRIVE Screwdriver, T25, 240 mm,
with groove



319.70 Cannulated Screw Measuring Device, for
6.5 mm and 7.3 mm Cannulated Screws



338.49 Large Quick Coupling



357.047 6.5 mm Cannulated Drill Bit, quick coupling,
330 mm



6.5 MM MIDFOOT FUSION BOLT SETS

Stainless Steel (01.111.150) and Titanium (01.111.151)

Graphic Case

60.111.150 6.5 mm Midfoot Fusion Bolt Graphic Case

Implants

6.5 mm Midfoot Fusion Bolts, 2 ea.

| Stainless Steel | Titanium | Length (mm) |
|-----------------|------------|-------------|
| 02.111.150 | 04.111.150 | 50 |
| 02.111.155 | 04.111.155 | 55 |
| 02.111.160 | 04.111.160 | 60 |
| 02.111.165 | 04.111.165 | 65 |
| 02.111.170 | 04.111.170 | 70 |
| 02.111.175 | 04.111.175 | 75 |
| 02.111.180 | 04.111.180 | 80 |
| 02.111.185 | 04.111.185 | 85 |
| 02.111.190 | 04.111.190 | 90 |
| 02.111.195 | 04.111.195 | 95 |
| 02.111.200 | 04.111.200 | 100 |
| 02.111.205 | 04.111.205 | 105 |
| 02.111.210 | 04.111.210 | 110 |
| 02.111.215 | 04.111.215 | 115 |
| 02.111.220 | 04.111.220 | 120 |
| 02.111.225 | 04.111.225 | 125 |
| 02.111.230 | 04.111.230 | 130 |
| 02.111.235 | 04.111.235 | 135 |
| 02.111.240 | 04.111.240 | 140 |
| 02.111.245 | 04.111.245 | 145 |
| 02.111.250 | 04.111.250 | 150 |
| 02.111.255 | 04.111.255 | 155 |
| 02.111.260 | 04.111.260 | 160 |



Instruments

| | |
|------------|--|
| 02.227.001 | 2.8 mm Non-Threaded Guide Wire, trocar point, 300 mm, 8 ea. |
| 03.111.001 | T-Handle for Midfoot Fusion Bolt |
| 03.111.002 | 5.0 mm Three-Fluted Cannulated Drill Bit, quick coupling, 300 mm, 200 mm calibration |
| 312.05 | 12.0 mm/8.5 mm Protection Sleeve |
| 312.08 | 8.5 mm/2.8 mm Wire Sleeve |
| 314.164 | STARDRIVE Screwdriver, T25, with groove, 240 mm |
| 319.70 | Cannulated Screw Measuring Device, for 6.5 mm and 7.3 mm Cannulated Screws |
| 338.49 | Large Quick Coupling |
| 357.047 | 6.5 mm Cannulated Drill Bit, quick coupling, 330 mm |

Also Available

| | |
|------------|---|
| 60.111.152 | Lid for 6.5 mm Midfoot Fusion Bolt Graphic Case |
| 60.111.154 | Instrument Tray for 6.5 mm Midfoot Fusion Bolt Graphic Case |
| 292.20 | 2.0 mm Kirschner Wire, trocar point, 150 mm |
| 310.63 | 5.0 mm Cannulated Drill Bit, large quick coupling, 300 mm |

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To order (Canada): 855-946-8999

Note: For recognized manufacturer, refer to the product label.

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