

PROstep[®] MIS Joint Fusion

Operative technique

PROstep[®] MIS Joint Fusion

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important:

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Introduction

The PROstep MIS joint fusion system is intended for minimally invasive joint preparation and joint fusion. The system is provided as a single-use sterile packs and is comprised of blades, elevators, wires, drivers, arthrodesis burrs, awls, high-flow irrigation sleeves, drills, depth gauges, compression sleeves and 4mm PROstep MICA screws and 5mm PROstep Chamfer screws.

PROstep MIS Chamfer Screws diameter and lengths

Diameter	Screw lengths
5mm	30mm, 32mm, 34mm, 36mm, 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm, 56mm, 58mm, 60mm, 65mm, 70mm, 75mm, 80mm
4mm	20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm, 34mm, 36mm, 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm, 56mm, 58mm, 60mm



 $PROstep \ MICA \ 4mm \ screw$



PROstep 5mm Chamfer screw

Indications and contraindications

Indications

The PROstep MIS 5mm Chamfer Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Arthrodesis of the first metatarsal cuneiform joint to reposition and stabilize metatarsus primus varus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

The PROstep MIS 4mm MICA Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or bi-cortical osteotomies in the foot
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Arthrodesis of the first metatarsal cuneiform joint to reposition and stabilize metatarsus primus varus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

Contraindications

There are no product-specific contraindications.

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 operative technique and the package insert is available on the website listed.

System basics

- Instruments for minimally invasive joint arthrodesis include multiple shape and diameter arthrodesis burrs, fenestration awl and high-flow irrigation sleeves.
- PROstep 4mm MICA and PROstep 5mm Chamfer screws offer the simplicity of self-tapping cannulated screws in multiple diameters.
- All PROstep MICA and Chamfer screws are manufactured from titanium alloy (Ti6Al4V) to provide consistent strength.
- Cannulated drill bits are included for use in hard cortical bone, when an oblique approach is desired, or when bicortical fixation is required.
- 4mm and 5mm Compression Packs include an over-drill, compression sleeve and sleeve driver to facilitate a lag technique for reduction of large gaps.

Patient positioning and setup

Operating room setup

Position the table and ancillary equipment in a manner that allows the surgeon to easily utilize the burr, perform fluoroscopy, visualize the fluoroscopy monitor and, if utilized, perform arthroscopy and view the arthroscopy monitor. The PROstep Power Box should be positioned towards the head of the bed. The arthroscopy tower should be positioned on the patient's left or right towards the head of the bed.

NOTICE

Patient positioning based on right-handed surgeon.



C-arm setup

The exact setup will vary depending on the joint being fused and surgeon preference. Utilization of a mini C-arm is appropriate for smaller joints (Interphalangeal, MTP, TMT and NC). At times it may be utilized for arthrodesis of larger joints (TN, CC, ST and ankle) if preferred by the surgeon. The mini C-arm will be brought in from the right side for a forefoot or midfoot fusion and a large C-arm can be brought in from either side.

A bump may be used to elevate the operative leg making visualization with fluoroscopy easier when obtaining a lateral image with a large C-arm.

A tourniquet may be utilized during the procedure but should be deflated when any burrs are used to cut or burr holes into bone. The tourniquet can be left up when performing a traditional arthroscopic fusion and burring "under water."

Irrigation

Assemble the appropriate irrigation sleeve (58PM2SLV for the PROstep handpiece NSK Primado 2 or 58TPXSLV for Stryker TPX handpiece) over the tip of the available power system handpiece and place an arthrodesis burr into the collet through the irrigation sleeve cannula. Connect the irrigation tubing (PD-IT) to chilled saline and to the irrigation sleeve. Set the irrigation flow rate to 100%. Adequate distraction may be applied to enable the cannula to enter the joint. A craniotomy pouch may be utilized to catch the irrigation fluid. If performing full "wet arthroscopy", the irrigation sleeves may not be necessary.



Irrigation sleeve with Arthrodesis Burr (58PM2SLV)

Operative technique

PROstep MIS Joint Fusion

Step 1: Incision

Make a skin incision of appropriate size; this will vary depending upon the joint. Bluntly dissect down to protect superficial sensory nerves and surrounding vital structures. Do not strip periosteum needlessly. Make a small capsular incision.



Figure 1 First tarsal metatarsal fusion

Step 2: Distraction

Place distraction and when applicable use a noninvasive distractor. Example: ankle, subtalar joint, talonavicular joint.

Use an invasive pin spreader or similar device when needed. Example: subtalar, talonavicular, naviculocuneiform, calcaneocuboid, metatarsal phalangeal joints.



Figure 2 First MTP fusion

Step 3: Joint preparation

Pass a freer-elevator along the joint surface to examine the contour of the joint. Use the appropriately sized arthrodesis burr for cartilage removal. The correct trajectory and positioning of the burr can be confirmed with fluoroscopy or arthroscopy. Utilize a sweeping motion to perform cartilage removal; the non-dominate hand should be used to feel the position of the burr. This will prevent exiting the joint and injuring the surrounding structures.



Figure 3 Examining the joint contour

Part no.	Description	Recommendation
58CC2008	Cartilage Burr, Cylinder, 2x8	Small joint arthrodesis (ex: hammertoe)
58CC3012	Cartilage Burr, Cylinder, 3x12	Arthrodesis of most joints (ex: MPT, TMT)
58CC4016	Cartilage Burr, Cylinder, 4x16	Large joint arthrodesis (ex: ankle, subtalar)
58CC4008	Cartilage Burr, Flame, 4x8	Joint concavities (ex:base of proximal phalanx)

The cartilage flame burr (58CF4008) may be used for curved joint surfaces and when getting close to the periphery of the joint. This burr may be used for the anterior ankle, anterior subtalar, talonavicular and first MTP joint.

NOTICE

With typical bone quality and without excessive force or speed, the cartilage burr will tend to scrape away cartilage and bounce off the subchondral cortical bone, preserving the natural joint geometry as much as possible.



Figure 4 Use of non-dominant hand to feel position of burr

Confirmation of cartilage removal should be performed by one or more of the following techniques:

- Arthroscopy using a 2.7 mm, 30 degree scope or nano scope.
- Direct visualization of the joint; a larger incision may be needed to ensure adequate visualization and complete cartilage removal.
- Passing a sharp elevator or curette over the articular surfaces to confirm complete cartilage removal. This option is best learned alongside the other two true visualization methods before implementing as the primary method.



Figure 5 Using wet scope to assess cartilage removal from navicular

Any loose cartilage fragments that may remain in the joint space should be removed using a pituitary rongeur or similar instrument such as a hemostat. This step is important to avoid suboptimal joint fusion.

If any reshaping of the subchondral bone is needed, perform this reshaping with the appropriate size sculpting burr or 3.1x13mm wedge burr (58RW3113).



58RW3113 Longer 3.1x13mm wedge burr



Figure 6 After using the cartilage removal burr, a sharp elevator confirms complete cartilage removal



Figure 7 Hemostat used to remove a piece of cartilage

Part no.	Description	Recommendation
58SC2008	Sculpting Burr, Cylinder, 2x8	Small joint arthrodesis (ex: hammertoe)
58SC3012	Sculpting Burr, Cylinder, 3x12	Arthrodesis of most joints (ex: MPT, TMT)
58SC4016	Sculpting Burr, Cylinder, 4x16	Large joint arthrodesis (ex: ankle, subtalar)

Step 4: Joint fenestration

Once the cartilage is removed, the subchondral bone must be perforated in a controlled manner. The 4mm cortical spherical burr (58RSPH40) can be utilized to perforate the joint surface while maintaining the integrity of the subchondral bone. The fenestration awl (58FENAWL) can also be used to microfracture the subchondral bone while maintaining subchondral integrity. A small drill with a protective sleeve can also be used to drill the subchondral bone while maintaining subchondral integrity. Adequate subchondral preparation should be visually confirmed. Maintaining the integrity of the subchondral bone enables a boost in stability of the final fixation construct when utilizing fully threaded screws and minimizes bone length reduction.



58RSPH40 cortical burr-sphere-4mm burr



Preparing the bone at the base of the proximal phalanx for a first MTP fusion



Figure 9 Preparing the navicular



58FENAWL fenestration awl



Figure 10
Preparing the base of the proximal phalanx



Figure 11 Excellent subchondral bleeding

Step 5: Fixation

Appropriate screw diameter selection is based on the procedure to be performed and the available bone volume or bone interface area.

Appropriate K-wire(s) (57S90004 or DSDS1014S for 4mm MICA Screw, 1.8mm wire from 57DRDEP5 for 5mm Chamfer Screw) are advanced across the fusion site. Verify the desired positioning of the wire(s) fluoroscopically.



DSDS1014S Skive Resistant K-wire

Measure screw length by using the depth gauge (found in 57DRDEP5 or standalone in 57DEPTHG). Slide the tip of the depth gauge over the K-wire and down to the surface of the bone, ensuring the gauge is seated flush to the bone. The gauge measurement indicates the depth from the surface of the bone to the tip of the K-wire.





The PROstep MICA Screw and PROstep 5mm Chamfer Screw systems have been designed to be self-drilling and self-tapping. However, in some situations such as hard cortical bone, bicortical fixation or when an oblique approach is desired, drilling may be necessary. This will decrease the risk of distraction while using fully threaded screws. Under power, drill just past the osteotomy or fusion site.

NOTICE

57DRDEP5 contains 1.8mm K-wires (4), depth gauge and 3.5mm pilot drill needed to implant the 5mm Chamfer screw.



Figure 12

Temporary K-wire and compression screw placement for first MTP fusion.

Optional over-drilling for lag technique

If there is a large distance between the bones, a lag technique may be performed using the appropriate compression pack (57COMPR4 for 4mm MICA Screws, 57COMPR5 for 5mm Chamfer Screws). Use the included over-drill to drill the near (superficial) bone but stop prior to entering the far (deep) bone.

NOTICE

The 5mm compression pack (57COMPR5) contains a 5mm over-drill, compression sleeve, and a rectangular driver for the compression sleeve. The 4mm compression pack (57COMPR4) contains a 4mm over-drill, compression sleeve, a rectangular driver for the compression sleeve and an extended length 2.5mm hex driver. If you plan to use this pack, you do not need to open a regular 2.5mm MICA hex driver. The compression sleeve will not work with regular length 2.5mm hex driver.

Screw placement without lag technique

Load the appropriate driver (57S02025 for 4mm MICA screws, 57DRVT20 for 5mm Chamfer screw) into the cannulated AO driver handle. Place the screw over the K-wire and use the Driver to advance the screw into the bone, until the head is completely countersunk within the bone.

Screw placement with lag technique

Load the rectangular sleeve driver into the cannulated AO driver handle. Assemble the selected screw onto the corresponding compression sleeve (found in 57COMPR4 or 57COMPR5). Place the screw-sleeve assembly over the K-wire and use the sleeve driver to advance the assembly into the bone. Continue to tighten until the appropriate reduction and compression is achieved. Then, using the appropriate screwdriver (2.5mm Hex driver from compression pack for 4mm MICA screw, 57DRVT20 for 5mm Chamfer Screw), drive the screw into the bone and out of the compression sleeve while holding the sleeve from turning. Once the head threads of the screw are completely buried in the bone, the reduction/compression will be locked in and the compression sleeve will be removeable.

Depending on the stability of the first screw, procedure type and patient-related factors (obesity, post-operative compliance issues), multiple screws may be used for additional fixation.



57COMPR5 Compression Pack for 5mm Screw



57S02025 2.5mm Hex Driver



Figure 13 Final fixation of first MTP fusion

Remove the K-wire(s) and perform surgical closure.

Procedure-specific tips

General procedure

- 1. Locate the joint fluoroscopically (or manually for subtalar and for ankle).
- 2. For incision details, see procedure-specific information below.
- 3. Bluntly dissect down to protect the superficial sensory nerves.
- 4. Incise the capsule. Do not strip the periosteum needlessly nor the capsule excessively.
- 5. Place distraction as appropriate (pin spreader or non-invasive distractor).
- 6. Examine the contour of the joint by passing a freer elevator over the surface.
- 7. Use cartilage burrs (cylinder and flame as appropriate) to remove the cartilage from all joint surfaces. See procedure-specific information below for detailed recommendations.
- 8. Use fluoroscopy and palpation with non-dominant hand to guide the burr.
- 9. Confirm adequate cartilage removal (dry arthroscopy, direct visualization, use of curette or sharp elevator).
- 10. Perforate but maintain integrity of the subchondral bone with a spherical 4mm cortical burr (58RSPH40), fenestration awl (58FENAWL), or drill bit.
- 11. Place fixation as appropriate (reference Fixation section in Operative Technique for placing 4mm MICA or 5mm Chamfer Screws).

First metatarsophalangeal fusion

- 1. Make a 1cm incision medial or lateral to the EHL tendon.
- 2. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint. Change to the 4x8mm cartilage flame burr (58CF4008) to remove remaining cartilage from curved surfaces on both sides of the joint.

Hallux interphalangeal fusion

- 1. Make a 1cm incision medial or lateral to the EHL tendon.
- 2. Use a 2x8mm cartilage burr (58CC2008) to remove cartilage from both sides of the joint.

Proximal interphalangeal fusion

- 1. Make a 1cm incision medial or lateral to the EDL tendon, or direct midline medial or lateral aspect of the toe.
- 2. Use a 2x8mm cartilage burr (58CC2008) to remove cartilage from both sides of the joint.
- 3. If needed use a 2x8mm sculpting (58SC2008) burr or 3.1x13mm wedge burr (58RW3113) to remove bone from the distal aspect of the proximal phalanx until adequate correction of the hammertoe deformity is achieved.

First tarsal-metatarsal fusion

- 1. Make a 1cm incision medial to the EHL tendon, direct midline medially or plantar medial. The incision will be dictated by the type of fixation being utilized.
- 2. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint.

Lesser tarsal-metatarsal fusion

- 1. Make a 1cm incision dorsally over the joint. "Cheat" lateral for the second TMT to avoid the DPN and DP artery, or incise directly over the third TMT joint.
- 2. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint.

Navicular-cuneiform fusion

- 1. Make a 1cm incision dorsally over the joint.
- 2. If fusing all three joints incisions are placed over the medial and lateral side of joint. This placement is to protect the dorsal neurovascular bundle making care to avoid any dorsally the intermediate cuneiform.
- 3. Bluntly dissect down to protect the superficial sensory nerves, dorsalis pedis artery and veins and tendons. Stay as far away from the artery as possible.
- 4. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint.

Calcaneal-cuboid fusion

- 1. Make a 1cm incision dorsal lateral over the joint.
- 2. Bluntly dissect down to protect the superficial sensory nerves. Take care to avoid the sural nerve and its branches as well as the peroneal tendons. The incision should be above the tendons.
- 3. Place distraction plantar-lateral or further dorsal-lateral than the incision. Keep in mind the curved joint surface and avoid placing the pins intraarticularly.
- 4. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint.

Talar-navicular fusion

- Make a 1-2cm incision medially over the joint. The incision should be dorsal to the posterior tibial tendon. Make
 a second incision just medial or just lateral to the tibialis anterior tendon. If placement is lateral to the tendon
 take extreme care to protect the DPN and dorsalis pedis artery. Making a slightly larger incision and using
 small soft tissue retractors may help with this. Both incisions are used for instrumentation and visualization
 interchangeably.
- 2. Place distraction medially with a pin spreader. Keep in mind the curved joint surface and avoid placing the pins intraarticularly.
- 3. Use a 3x12mm cartilage burr (58CC3012) to remove cartilage from both sides of the joint. Change to the 4x8mm cartilage flame burr (58CF4008) to remove cartilage from curved surfaces both on the talus and the navicular.

Subtalar fusion

- 1. Use standard arthroscopy portals; usually an anterior and central portal are adequate, if doing the fusion with a true "wet" arthroscopic technique. Use a small sinus tarsi incision from the tip of the fibula towards the base of the fourth metatarsal for a mini-open approach.
- 2. Place distraction using a pin spreader with one pin in the talus and one in the anterior calcaneus.
- 3. Use a 3x12mm cartilage burr (58CC3012) to remove remaining cartilage from both sides of the joint.
- 4. Add in an MIS calcaneal sliding osteotomy if necessary to obtain optimal alignment.

Ankle fusion

- 1. Use standard arthroscopy portals; usually an anterior medial and anterolateral portal are adequate, if doing the fusion with a true "wet" arthroscopic technique. Make a 2cm direct anterior approach if doing the fusion with a "mini-open" technique.
- 2. The interval is between the extensor hallucis longus and the tibialis anterior. Care must be taken to retract and protect the deep peroneal nerve and dorsalis pedis artery. Use retractors and isolate all vital structures.
- 3. Small accessory incisions can be made anterior medial and anterior lateral to remove the cartilage from the medial and lateral gutters respectively. Medially, take care to protect the saphenous vein and nerves. Laterally, take care to protect the superficial peroneal nerve.
- 4. Use a 3x12mm cartilage burr (58CC3012) or 4x16mm cartilage burr (58CC4016) to remove cartilage from both sides of the joint. Change to the 4x8mm cartilage flame burr (58CF4008) to remove cartilage from the curved surface of the anterior tibia.

Explant information

Removal of the 4mm MICA Screws may be performed by using the 2.5mm hex driver (57S02025 or 2.5mm hex driver from 57COMPR4).

Removal of the PROstep MIS 5mm Chamfer Screws may be performed by using the T20 Driver (57LPDT20 or 57DRVT20).

If 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.

Ordering information

Part no.	Description
57S1MI07	PROstep Instrument Pack
58PM2SLV	Irrigation sleeve for PM2
58TPXSLV	Irrigation sleeve for TPX
58CC2008	Cartilage burr – cylinder 2mm x 8mm
58SC2008	Sculpting burr – cylinder 2mm x 8mm
58CC3012	Cartilage burr – cylinder 3mm x 12mm
58SC3012	Sculpting burr – cylinder 3mm x 12mm
58CC4016	Cartilage burr – cylinder 4mm x 16mm
58SC4016	Sculpting burr – cylinder 4mm x 16mm
58CF4008	Cartilage burr – flame 4mm x 8mm
58RSPH40	Cortical burr – sphere

Part no.	Description
58RW3113	Cortical burr – wedge 3.1mm x 13mm
58FENAWL	Curved fenestration awl
57DRDEP5	Drill and depthing pack 5mm
57DRVT20	Sterile T20 driver
57COMPR5	Compr pack for 5mm screw
57COMPR4	Compr pack for 4mm screw
DSDS1014S	1.4mm MICA Wire
57DEPTHG	Depth gauge standalone
57S00030	Drill for 4mm MICA Screw
57S02025	Driver for 4mm MICA Screw
57S1HNDL	Cannulated AO handle

PROstep MIS 5mm Chamfer Screws

Part no.	Description
57S05030	PROstep MIS 5mm x 30mm Chamfer Screw
57S05032	PROstep MIS 5mm x 32mm Chamfer Screw
57S05034	PROstep MIS 5mm x 34mm Chamfer Screw
57S05036	PROstep MIS 5mm x 36mm Chamfer Screw
57S05038	PROstep MIS 5mm x 38mm Chamfer Screw
57S05040	PROstep MIS 5mm x 40mm Chamfer Screw
57S05042	PROstep MIS 5mm x 42mm Chamfer Screw
57S05044	PROstep MIS 5mm x 44mm Chamfer Screw
57S05046	PROstep MIS 5mm x 46mm Chamfer Screw
57S05048	PROstep MIS 5mm x 48mm Chamfer Screw

Part no.	Description
57S05050	PROstep MIS 5mm x 50mm Chamfer Screw
57S05052	PROstep MIS 5mm x 52mm Chamfer Screw
57S05054	PROstep MIS 5mm x 54mm Chamfer Screw
57S05056	PROstep MIS 5mm x 56mm Chamfer Screw
57S05058	PROstep MIS 5mm x 58mm Chamfer Screw
57S05060	PROstep MIS 5mm x 60mm Chamfer Screw
57S05065	PROstep MIS 5mm x 65mm Chamfer Screw
57S05070	PROstep MIS 5mm x 70mm Chamfer Screw
57S05075	PROstep MIS 5mm x 75mm Chamfer Screw
57S05080	PROstep MIS 5mm x 80mm Chamfer Screw

Ordering information (continued)

Part no.	Description
57S34020	PROstep 4mm x 20mm MICA Screw
57S34022	PROstep 4mm x 22mm MICA Screw
57S34024	PROstep 4mm x 24mm MICA Screw
57S34026	PROstep 4mm x 26mm MICA Screw
57S34028	PROstep 4mm x 28mm MICA Screw
57S34030	PROstep 4mm x 30mm MICA Screw
57S34032	PROstep 4mm x 32mm MICA Screw

PROstep 4mm MICA Screws

Part no.	Description
57S34034	PROstep 4mm x 34mm MICA Screw
57S34036	PROstep 4mm x 36mm MICA Screw
57S34038	PROstep 4mm x 38mm MICA Screw
57S34040	PROstep 4mm x 40mm MICA Screw
57S34042	PROstep 4mm x 42mm MICA Screw
57S34044	PROstep 4mm x 44mm MICA Screw
57S04046	PROstep 4mm x 46mm MICA Screw
57S04048	PROstep 4mm x 48mm MICA Screw
57S04050	PROstep 4mm x 50mm MICA Screw
57S04052	PROstep 4mm x 52mm MICA Screw
57S04054	PROstep 4mm x 54mm MICA Screw
57S04056	PROstep 4mm x 56mm MICA Screw
57S04058	PROstep 4mm x 58mm MICA Screw
57S04060	PROstep 4mm x 60mm MICA Screw

Notes	

Notes

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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