Smart Toe II
Intramedullary Implant

Operative Technique
This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis 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.

A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilised before use. Follow the appropriate instructions for use (IFU). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions.

See package insert for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.
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Memometal Nitinol Features

The Smart Toe implant is made of body temperature activated shape memory Memometal NiTinol, an alloy made approximately of 50% nickel and 50% titanium.

The implant has to be stored under 0°C (32°F) for a minimum of 2 hours before implantation. The implant has to be taken out of the freezer only after site preparation is complete and ready for implantation. The implant is designed to recover its shape progressively after implantation, to adapt its opening to patient anatomy.

Example of patients with Smart Toe implants size 19 showing adaptation to site

P1 Intramedullar canal

<2.5mm

>3mm

Implant at 0°C

Implant at 37°C
Indications, Precautions & Contraindications

**Indications**

The MEMOMETAL INTRAMEDULLARY BONE FASTENER (SMART TOE /X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bone fusion.

**Contraindications**

- Acute or chronic infections, local or systemic
- Surgical procedures other than those mentioned in the Indications section
- Do not use on patients allergic to the components of the product or having known allergies. Not indicated for patients with nickel sensitivity
- The combination of this implant with implants of another origin is contraindicated.

**Precautions**

Stryker Osteosynthesis systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique. Detailed information is included in the instructions for use being attached to every implant.

**Warning Information:**

- Never re-sterilise SmartToe implants. Any application of extensive heat would compromise the biomechanical features of the devices possibly resulting in implant failure.
- SmartToe implants are not intended for immediate postoperative weight bearing. Be sure that the postoperative loading of the internal fixation is reduced to a minimum (e.g. with application of a Forefoot Off-loading Shoe) until bone consolidation is confirmed by follow up X-ray examination (normally after 4 - 6 weeks).
- See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.
Smart Toe II Intramedullary Implant

Potential Advantages

- Flat design resists rotation for control of the arthrodesis position
- One piece implant
- 2 angulations available: 0° or 10°
- No post-op implant exposure
- Positioning Rod is designed to ensure proper implant placement

Storage

The Smart Toe has to be stored at 0°C (32°F) or below for 2 hours or more prior to implantation. The implant has to be taken out of the freezer only after site preparation is complete and ready for implantation.

Sterilisation

The Smart Toe implants are delivered sterile. The instrumentation has to be sterilised before use. Refer to the indications for use for more information.

Never resterilise Smart Toe implants. Any application of extensive heat would compromise the biomechanical features of the devices possibly resulting in implant failure.

One set of ancillaries for all references

1. XJA005001
   Colour Code and Sizing guide pad
2. XPI003001
   Implant holding Forceps
3. XDB002001
   Positioning Rod
4. XFO102001
   Medial (P2) and Distal (P3) stop drill bit
5. XFO112001
   Proximal (P1) drill bit diameter 2mm
6. XFR001001
   Surfacing Reamer
7. XRP001001
   Medial Broach for sizes 16 to 22
8. XRP001003
   Small Medial (P2) Broach for size 15

Optional

XRP001002
Proximal Broach (P1)

Note:
Detailed information is included in the instructions for use being attached to every implant. See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.
Operative Technique

PIP Arthrodesis

**Step 1 - Choosing the implant**
Use the provided template and a pre-operative X-Ray to select the most appropriate size to the patient’s morphology.

**Step 2 - Exposure**
A standard linear incision is used to expose the interphalangeal joint.

**Step 3 - Proximal Phalanx (P1) Preparation**
Resect the head of P1 (approximately 2-3mm). Then, prepare the housing of the implant with the 2mm Drill Bit (XFO12001). Drill until the cutting flutes are buried.

*Note:
   - If the housing in P1 seems too narrow for the closed shape of the implant: Remove more bone by using the drill several times to enlarge the housing.
   - If the cortical bone is stiff, it is possible to use the P2 Short broach (XRP001003) to prepare the housing. To avoid the risk of fracture, introduce the broach manually following the axis of the phalanx.
   - In case of retraction of the joint space, make a plantar plate section to facilitate the distraction, and facilitate the Smart Toe implantation, in particular for the sizes 21 and 22.*
Operative Technique

PIP Arthrodesis

Step 4 - Distal Phalanx (P2) Preparation
Drill P2 using the Stop Drill Bit (XFO102001). Then, manually denude the cartilage using the provided Surfacing Reamer (XFR001001).

Step 5 - Middle Phalanx (P2) Preparation

Smart Toe size 15:
Insert the Middle Phalanx P2 Short broach (XRP001003) which has a yellow dot, up to the stop.

Smart Toe size 16, 19 and 20:
Insert the Middle Phalanx P2 broach (XRP001001) up to the laser mark.

Smart Toe size 21 and 22:
Insert the Middle Phalanx P2 broach (XRP001001), up to the stop.

Note:
Introduce the broach manually. If it is not sufficient, always tap gently on the broach to avoid any risk of fracture. The broach must always be parallel to the transverse plane of the phalanx. It is very important not turn the broach.
Operative Technique

**PIP Arthrodesis**

**Step 6 - Implantation in Proximal Phalanx (P1)**

At this point, the implant can be removed from cold storage (0°C / 32°F or below).

Use the Forceps (XPI003001) to remove the Smart Toe from its support. Insert the oblong shaped side of the implant in P1 until the forceps touch the proximal phalanx. Do not remove the forceps at this stage.

**Note:**

If it is difficult to insert the Smart Toe implant, use a graft remover and a hammer to assist implantation. If positioning rod is required, please refer to the following page.

**Step 7 - Implantation in Middle Phalanx (P2) and closure**

Manually reduce middle phalanx over the distal legs of the implant. Forceps must stay engaged until the middle phalanx is partially reduced over the implant.

Remove the forceps and manually compress the joint for approximately 1 minute.

Suture the extensor tendon to avoid the formation of a mallet toe.

**Note:**

To facilitate the shape memory process, the phalanges can be bathed in a warm sterile solution, between 37°C (98.6°F) to 40°C (104°F).
**Operative Technique**

**Positioning Rod Option**

**Step 1**
Prepare bone surfaces and implant housing according to the usual Smart Toe technique, and remove the Smart Toe from its support with the forceps (XPI003001).

**Step 2**
If the surgeon desires to use the positioning rod option, insert the implant in P1, not too deep, in order to let the hole be accessible for the rod. Otherwise follow the usual technique.

**Step 3**
Insert the positioning rod (XDB002001) into the hole, without removing the forceps.
Operative Technique

**Step 4**
Insert the implant in P2 while maintaining the positioning rod and the forceps in place.

**Step 5**
Manually reduce middle phalanx over the distal legs of the implant. Forceps must stay engaged until the middle phalanx is partially reduced over the implant.
Remove the forceps and compress the two phalanges while maintaining the positioning rod in place.

**Step 6**
Remove the positioning rod and finish the compression of the two phalanges for approximately 1 min.
Operative Technique

DIP Arthrodesis

Step 1 Exposure

Make a dorsal incision. Cut the extensor transversely, leaving a distal central strip free. Perform a dorsal arthrolysis, cutting the internal and external ligaments. If necessary, a plantar flexor tenolysis procedure may be used.

Step 2 Distal Phalanx (P3) Preparation

Resect the base of P3 to reach the cancellous bone using a small bone reamer.

Drill with the Stop Drill Bit.

Note:
- Depending on surgeon’s preference, it is possible to stop drilling before the Stop, to avoid risk of deviation in P3.
Operative Technique

Step 3 Medial Phalanx (P2) Preparation

Resect the head of P2 to reach the cancellous bone using a small bone reamer, retaining as much bone as possible.

Drill with the Stop Drill Bit (XFOI02001).

Use the Middle Phalanx P2 broach (XRPO01001) up to the laser mark.

Note:
The position and direction of the PIP and DIP implants are reversed. Take care to insert the implant in the appropriate way.
Operative Technique

DIP Arthrodesis

Step 4 Implantation in Distal Phalanx (P3)
At this point, the implant can be removed from cold storage (0°C / 32°F or below). Use the Forceps (XPI003001) to remove the Smart Toe from its support. The forceps hold the triangular base of the Smart Toe implant.

Insert the distal part into P3 until the forceps come into contact with P3. Continue to hold the forceps closed.

Step 5 Implantation in Medial Phalanx (P2) and Closure
Manually reduce middle phalanx over the proximal legs of the implant.
Forceps must stay engaged until the middle phalanx is partially reduced over the implant.
Remove the forceps and manually compress the joint for approximately 1 minute.

Note:
To facilitate the shape memory process, the phalanges can be bathed in a warm sterile solution, between 37°C (98.6°F) to 40°C (104°F).

Postoperative Care

Smart Toe implants are not intended for immediate postoperative weight bearing. Be sure that the postoperative loading of the internal fixation is reduced to a minimum (e.g. with application of a forefoot off-loading shoe) until bone consolidation is confirmed by follow up X-Ray examination (normally after 4-6 weeks).
### Smart Toe Product Range

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<td></td>
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#### Arthrodeseis line

<table>
<thead>
<tr>
<th>Neutral 0°</th>
<th>ST0-15P</th>
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<th>ST0A-20P</th>
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**Implants are delivered sterile** - They need to be placed in the freezer (0°C /32°F, or below) for 2 hours or more prior to implantation.
## Ordering Information – Instruments

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<td>Medial (P2) and Distal (P3) stop drill bit</td>
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<td>XDB002001</td>
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<td>XRP001003</td>
<td>Small Medial (P2) Broach for size 15</td>
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<td>XRP001001</td>
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<td>XFR001001</td>
<td>Surfacing Reamer</td>
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<td>Implant holding Forceps</td>
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<td>Colour Code and Sizing guide pad</td>
</tr>
<tr>
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<td>Tray without Instruments</td>
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<td>Proximal Broach</td>
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Optional:

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This document is intended solely for the use of healthcare professionals.

A healthcare professional 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 healthcare professionals be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A healthcare professional must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

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