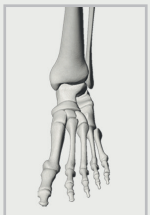


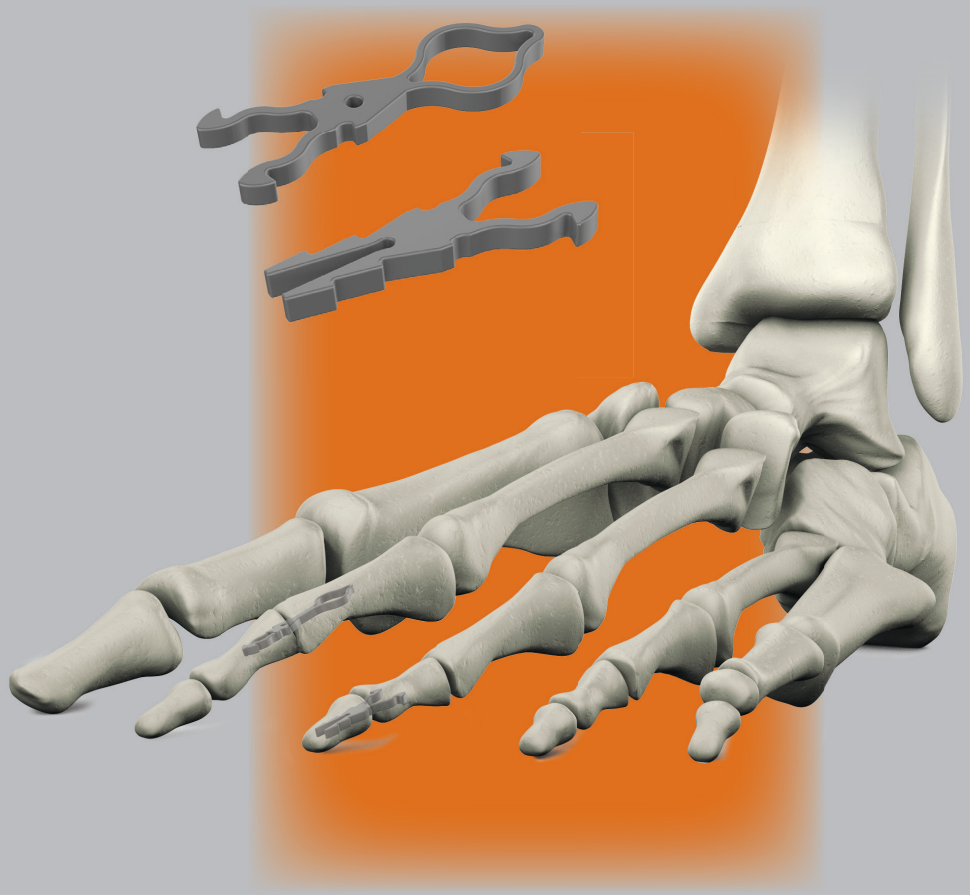
stryker

Smart Toe II

Intramedullary Implant

Operative Technique

Foot & Ankle



Smart Toe II

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.

⚠WARNING

- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.

⚠WARNING

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.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.

⚠WARNING

- 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 due to medical reasons.

Contents

Features

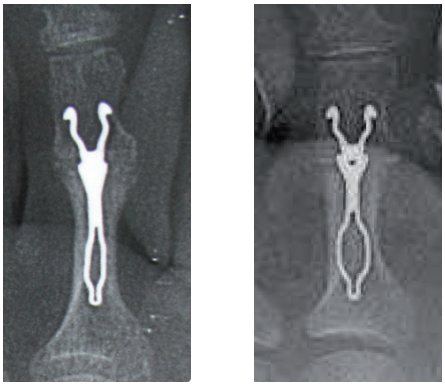
Memometal Nitinol Features

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

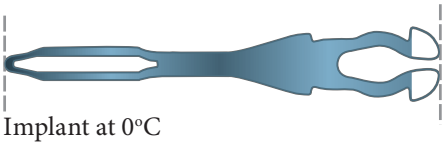
The implant is designed to recover its shape progressively after implantation, to adapt its opening to patient anatomy.

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

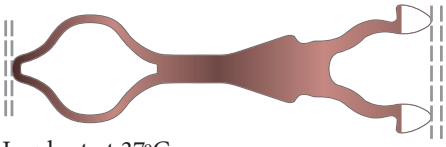
P1 Intramedullar canal



<2.5mm **>3mm**



Implant at 0°C



Implant at 37°C

Indications & Contraindications

Indications

The Smart Toe II is indicated for interphalangeal fusion of the toes.

⚠CAUTION

The Smart Toe II implants have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of Smart Toe II implants in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Contraindications

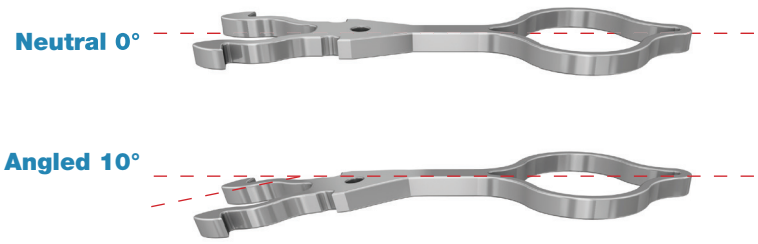
Acute or chronic infections, local or systemic

- 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.

Smart Toe II Intramedullary Implant

Potential Advantages

- Flat design resists rotation to help control 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

⚠ CAUTION

The Smart Toe II 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.

Sterilization

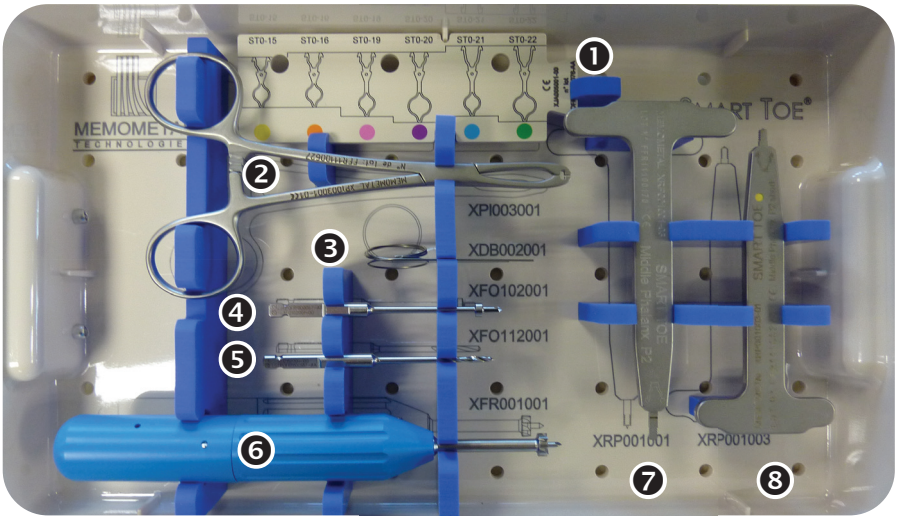
⚠ WARNING

- The Smart Toe II implants are delivered sterile.
- The instrumentation has to be sterilized before use. Refer to the Instructions for Use for more information.

⚠ WARNING

Never re-sterilize Smart Toe II 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
Color Code and Sizing guide pad

2. XPI003001
Implant holding Forceps

3. XDB002001
Positioning Rod

4. XFO102001
Middle (P2) and Distal (P3) stop drill bit

5. XFO112001
Proximal (P1) drill bit diameter 2mm

6. XFR001001
Surfacing Reamer

7. XRP001001
Middle Broach for sizes 16 to 22

8. XRP001003
Small Middle (P2) Broach for size 15

Optional

XRP001002
Proximal Broach (P1) (picture on page 16)

Operative Technique

All of the following steps are shown for the PIP arthrodesis but are valid for IP arthrodesis as well.

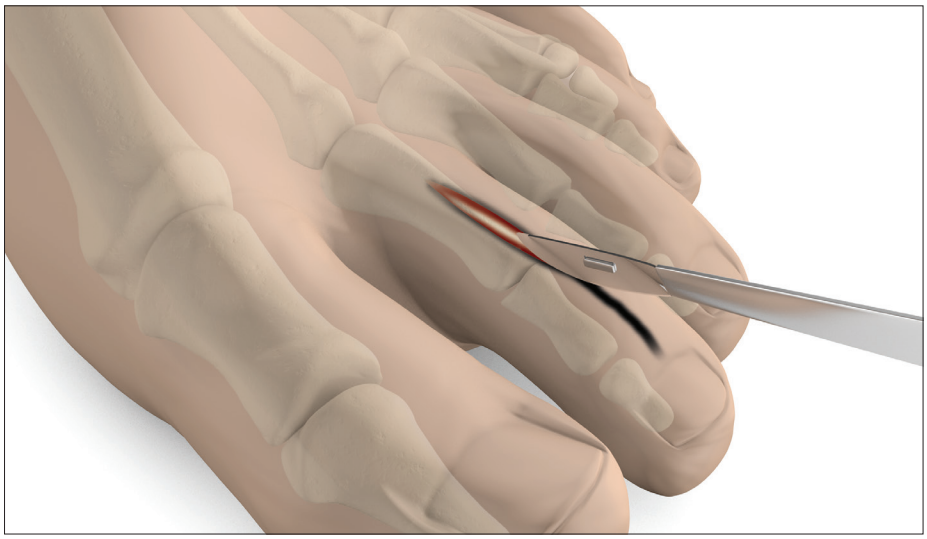
PIP/IP Arthrodesis

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.

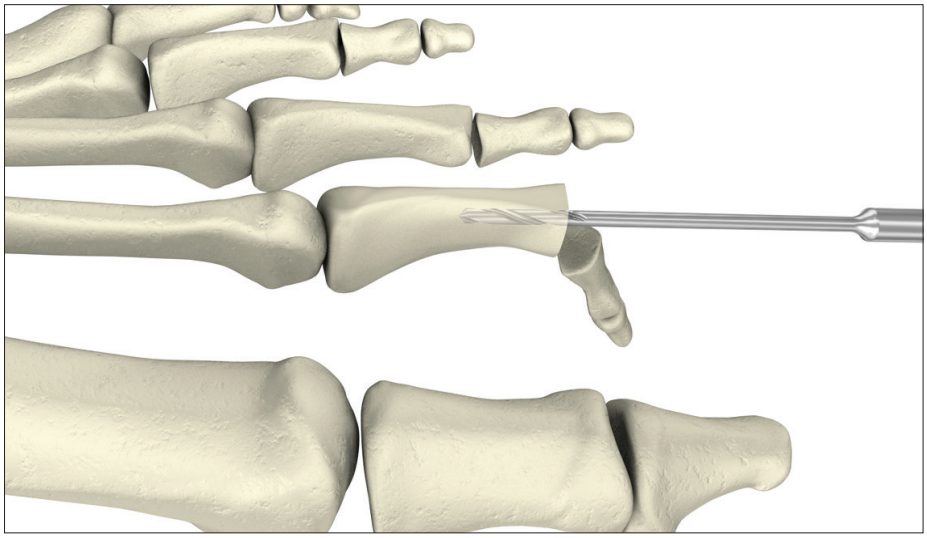
Step 2 - Exposure

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 (XFO112001). Drill until the cutting flutes are buried.



NOTICE

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.

⚠CAUTION

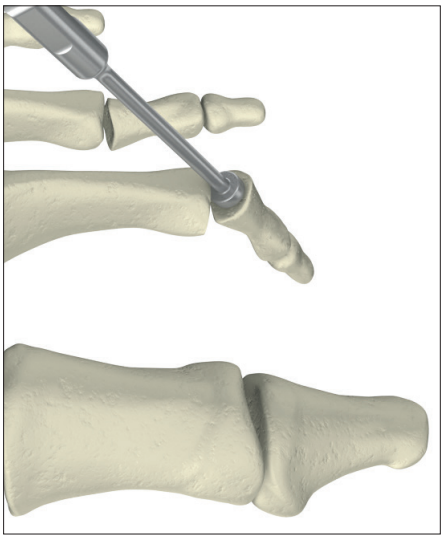
- If the cortical bone is dense, it is possible to use the P2 Short broach (XRP001003) to prepare the housing.
- To avoid the risk of fracture, introduce the broach manually following the axis of the phalanx.
- In case of retraction of the joint space, make a plantar plate incision to facilitate the distraction, and facilitate the Smart Toe II implantation, in particular for the sizes 21 and 22.

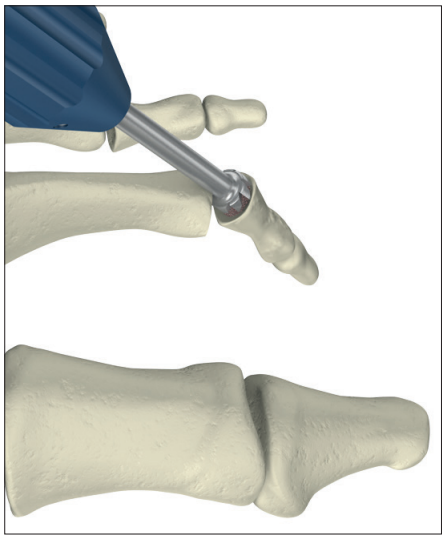
Operative Technique

PIP/IP Arthrodesis

Step 4 – Middle Phalanx (P2) Preparation

Drill P2 using the Stop Drill Bit (XFO102001). Then, manually denude the cartilage using the provided Surfacing Reamer (XFR001001).



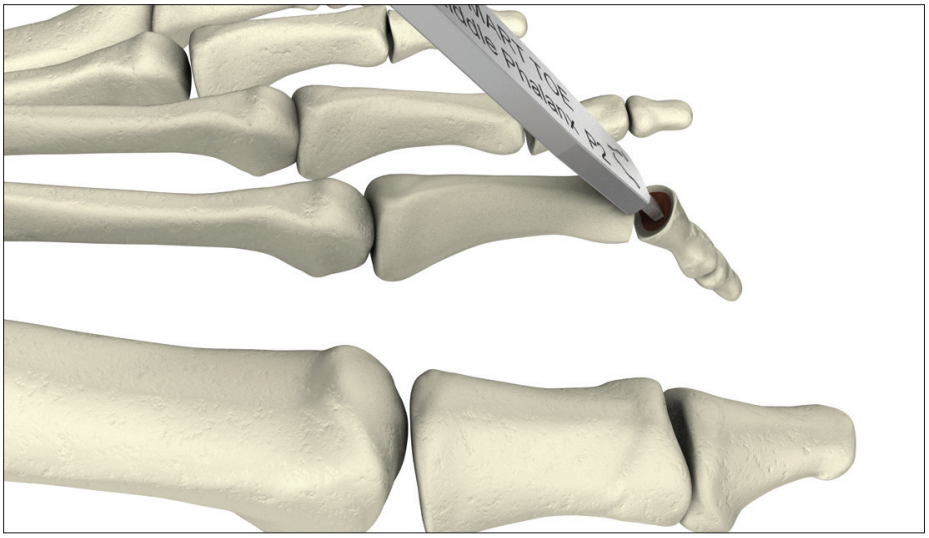


Step 5 - Middle Phalanx (P2) Preparation

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

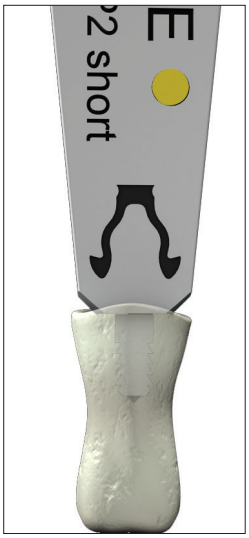
Smart Toe II size 16, 19 and 20:
Insert the Middle Phalanx P2 broach (XRP001001) up to the laser mark.

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



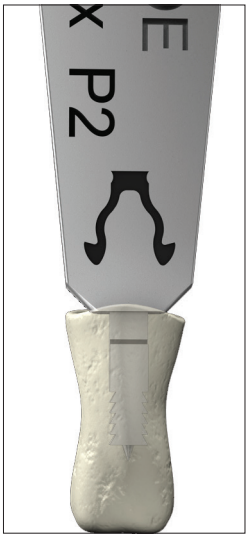
⚠ CAUTION

- 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 to turn the broach.



Size 15

Size 16, 19, 20



Size 21 & 22

Operative Technique

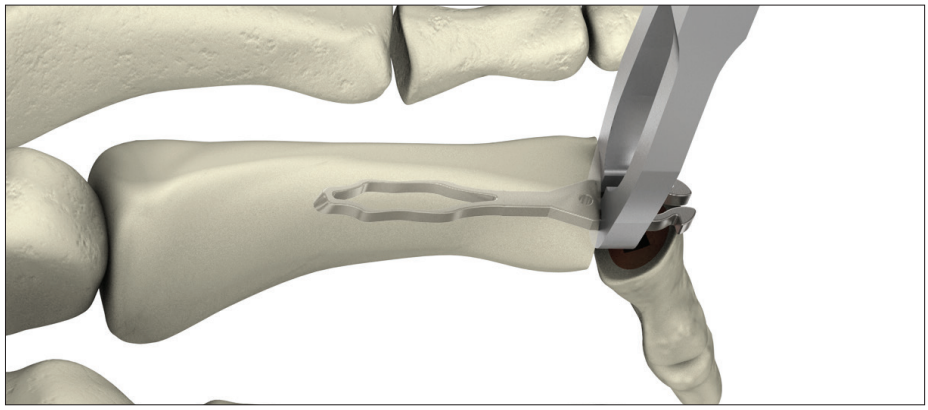
PIP/IP Arthrodesis

Step 6 - Implantation in Proximal Phalanx (P1)

Use the Forceps (XPI003001) to remove the Smart Toe II 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.

NOTICE

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

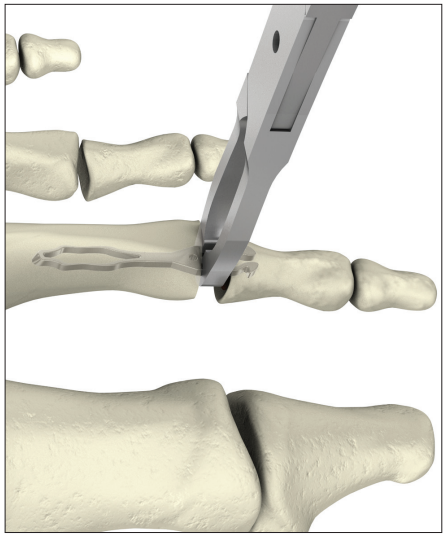


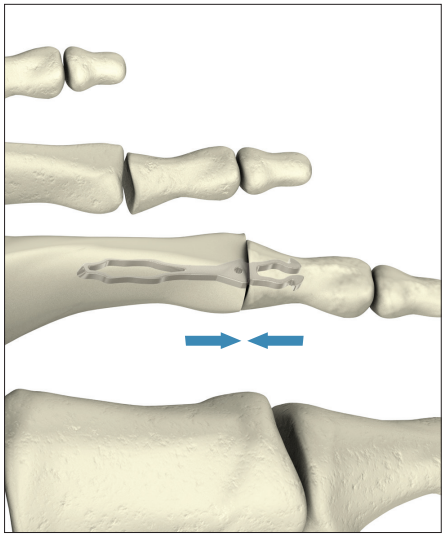
Step 7 - Implantation in Middle Phalanx (P2) and closure

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.





NOTICE

To facilitate the shape memory process after implantation, the patient's toe can be bathed in a warm sterile solution, between 37°C (98.6°F) to 40°C (104°F).

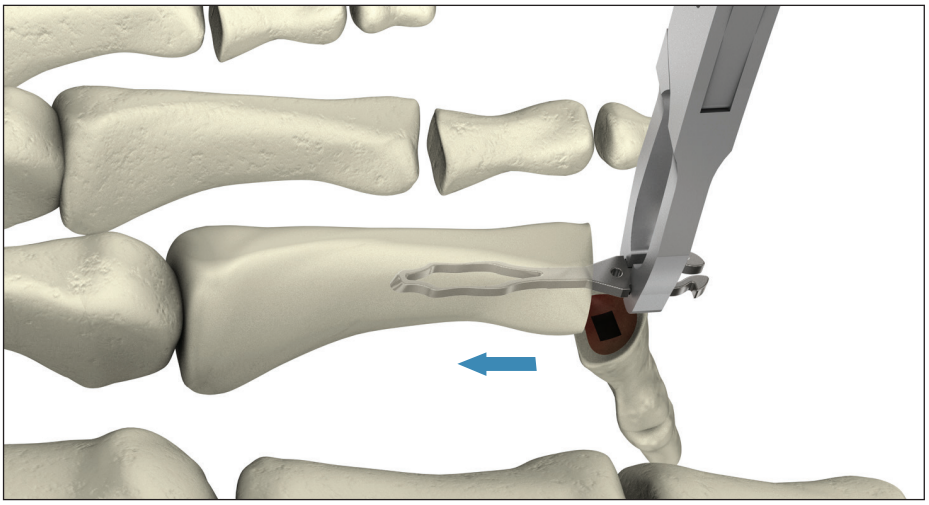
Operative Technique

Positioning Rod Option

All of the following steps are shown for the PIP arthordesis but are valid for IP arthrodesis as well.

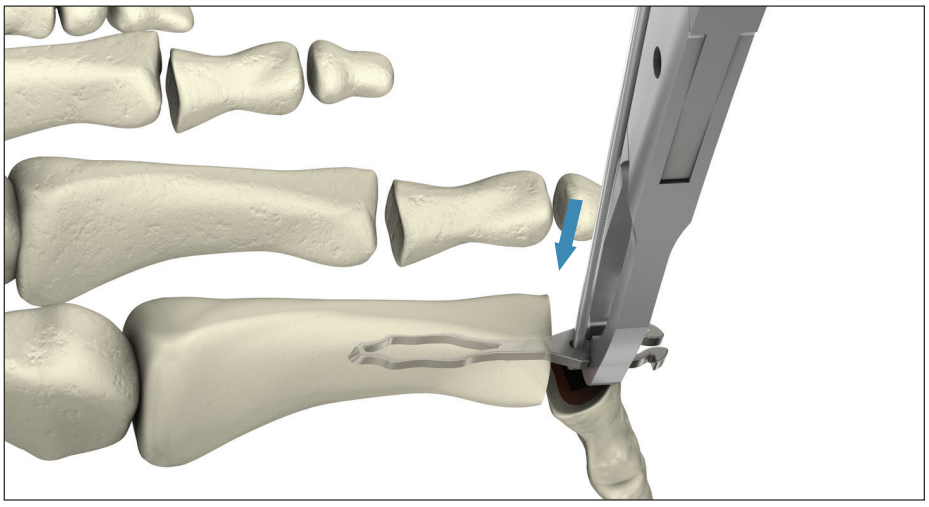
Step 1

Prepare bone surfaces and implant housing according to the usual Smart Toe II technique, and remove the Smart Toe II 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.



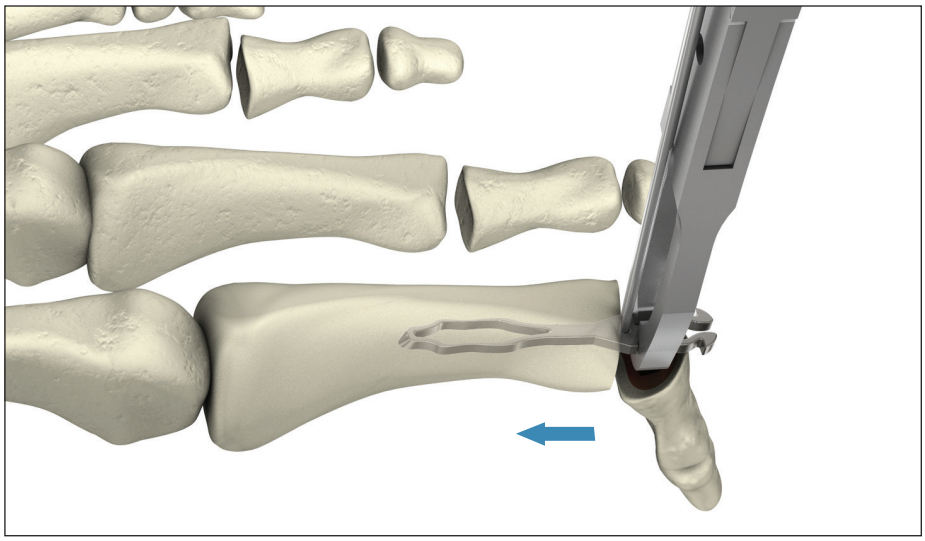
Step 3

Insert the positioning rod (XDB002001) into the hole, without removing the forceps.

Operative Technique

Step 4

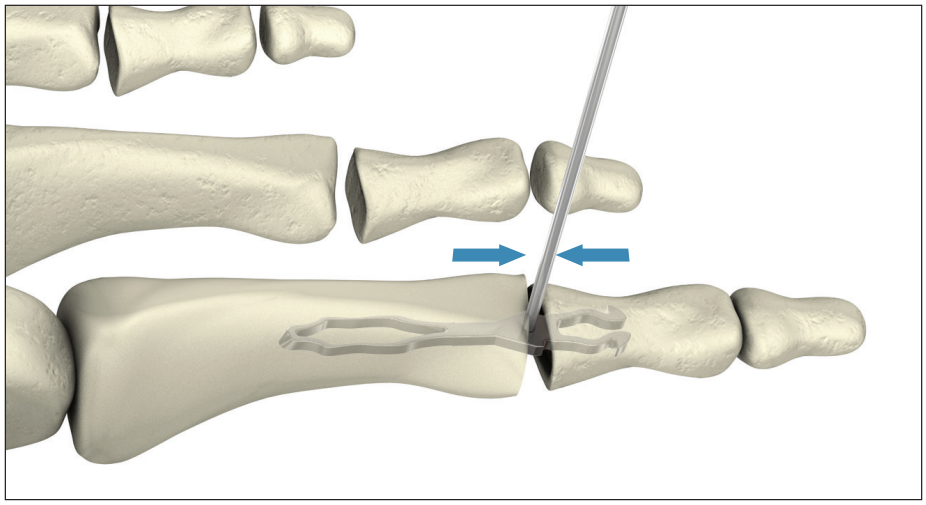
Insert the implant in P2 while maintaining the positioning rod and the forceps in place.



Step 5

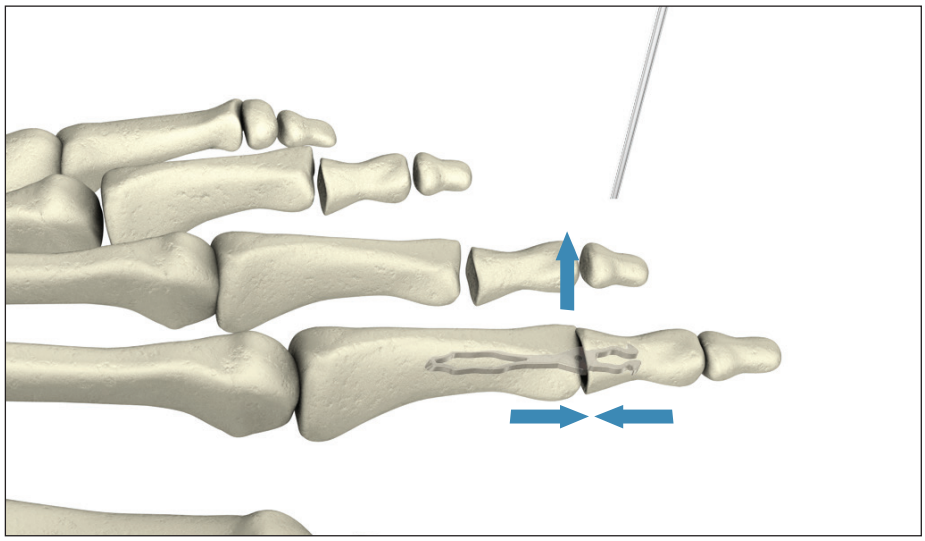
Manually reduce middle phalanx over the distal legs of the implant. Forceps must stay engaged until the middle phalanx is partially reduced over the implant.

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 1min.

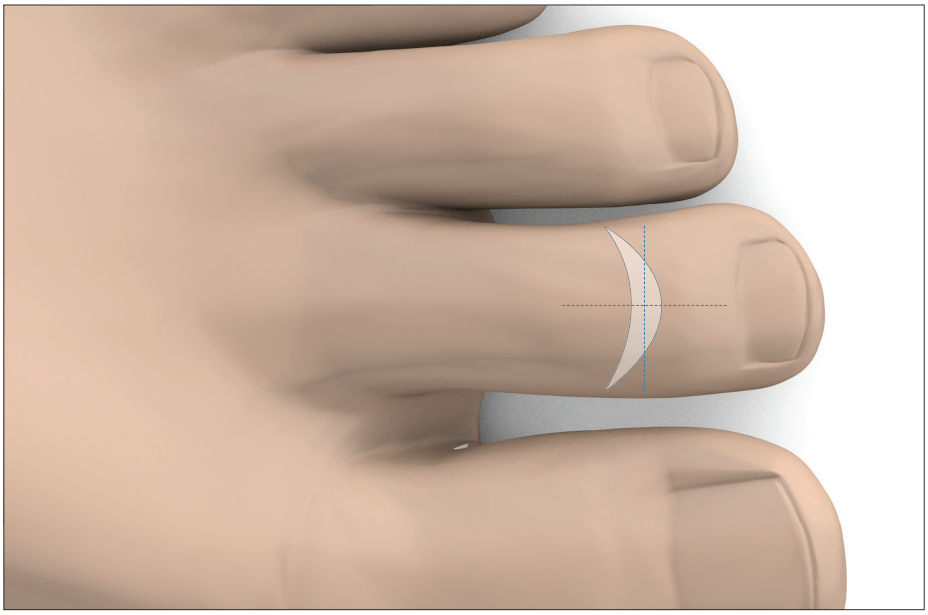


Operative Technique

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.



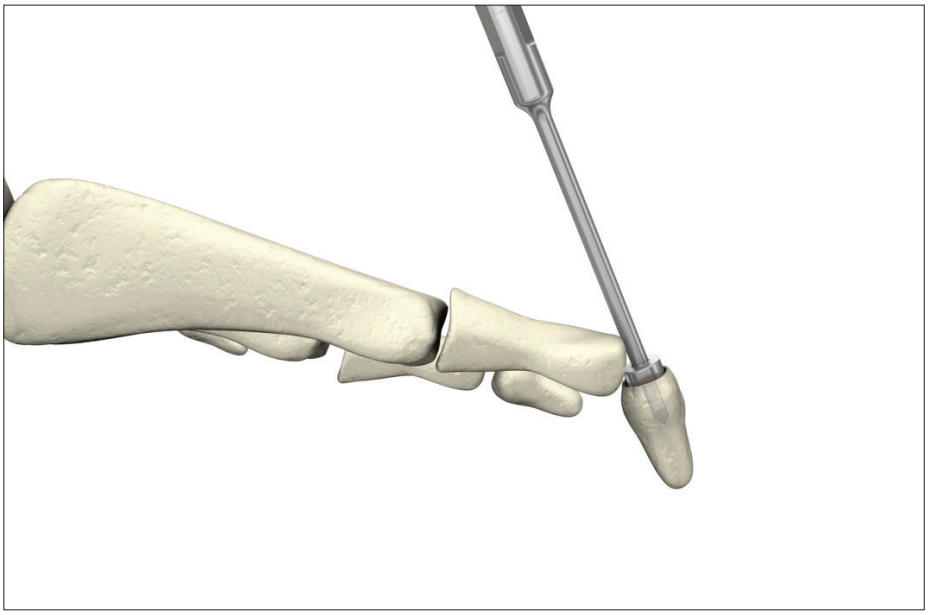
Step 2 Distal Phalanx (P3) Preparation

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

Drill with the Stop Drill Bit.

NOTICE

Depending on surgeon's preference, it is possible to stop drilling before the Stop, to avoid risk of deviation in P3.



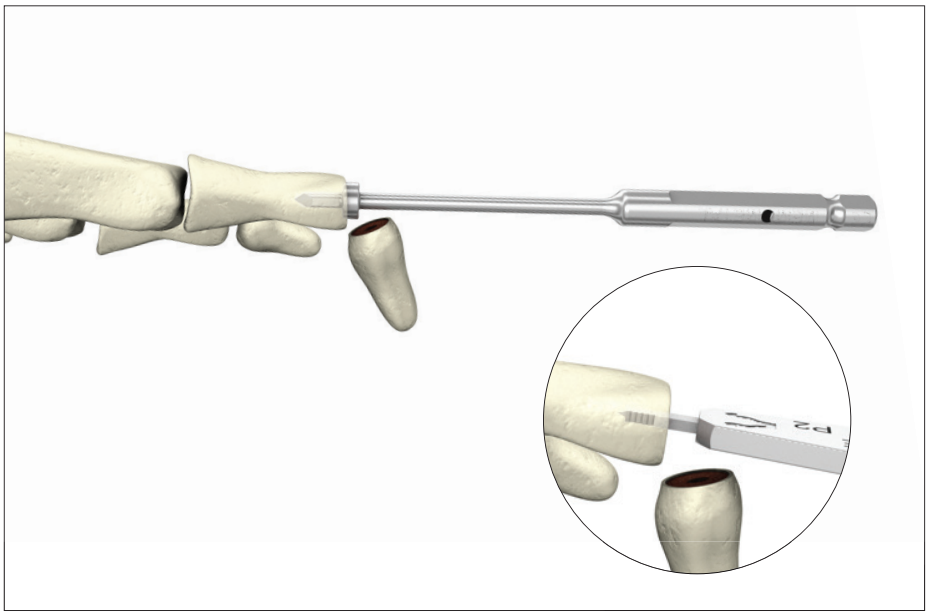
Operative Technique

Step 3 Middle Phalanx (P2) Preparation

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

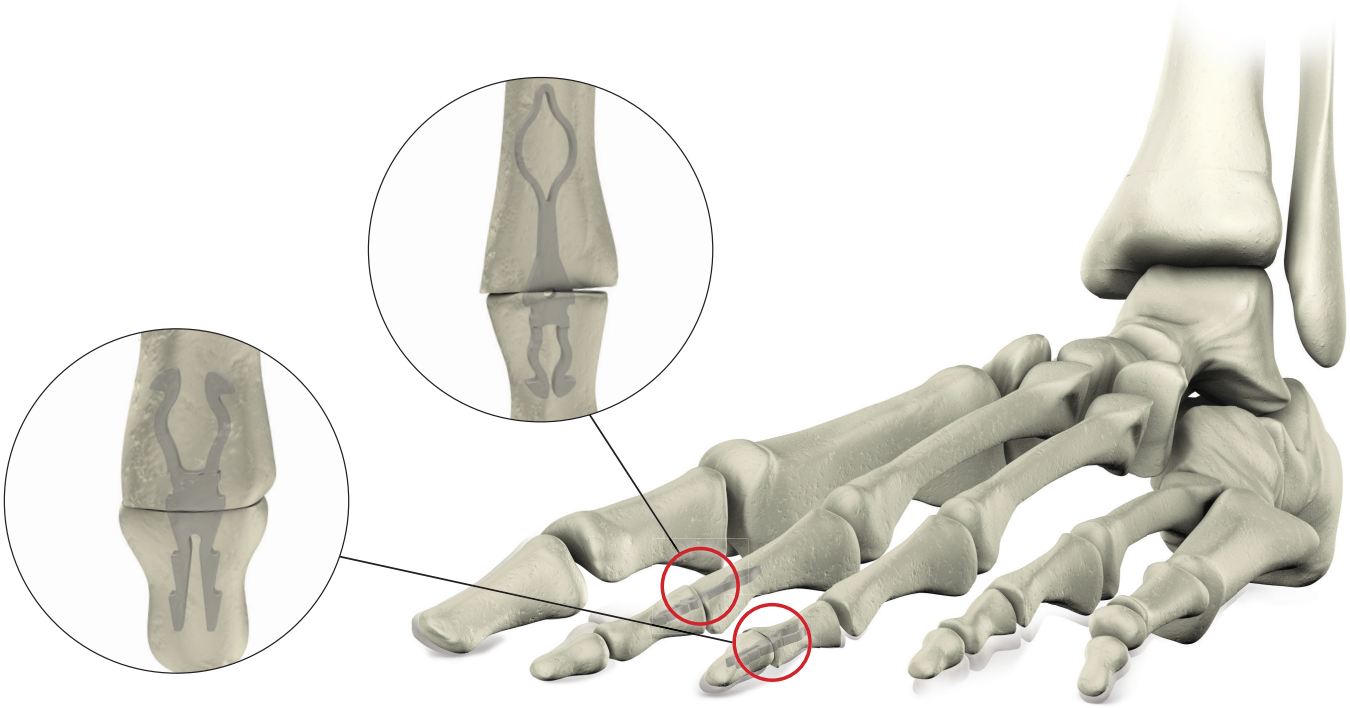
Drill with the Stop Drill Bit (XFO102001).

Use the Middle Phalanx P2 broach (XRP001001) up to the laser mark.



⚠CAUTION

Use the correct implant for PIP and DIP arthrodeses. Take care to insert the implant in the appropriate way.



Operative Technique

DIP Arthrodesis

Step 4 Implantation in Distal Phalanx (P3)

Use the Forceps (XPI003001) to remove the Smart Toe II from its support. The forceps hold the triangular base of the Smart Toe II 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 Middle Phalanx (P2) and Closure

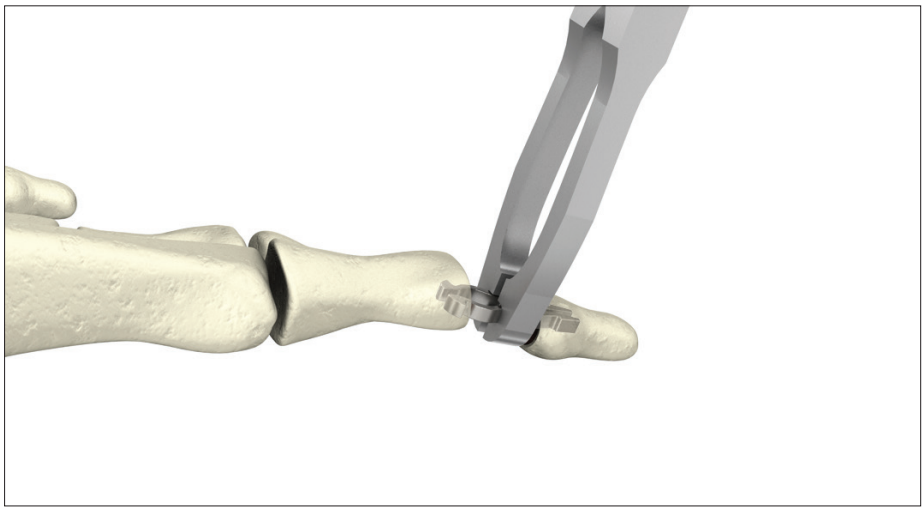
Manually reduce middle phalanx over the proximal legs of the implant.

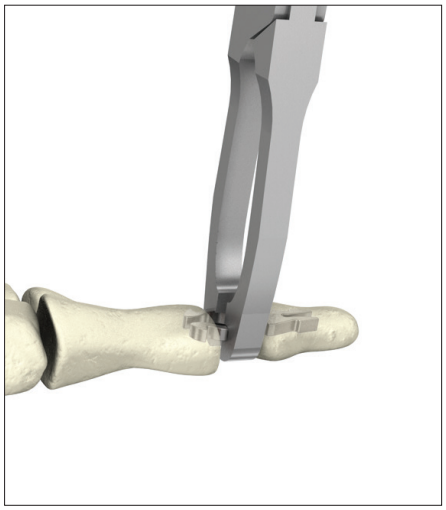
Forceps must stay engaged until the middle phalanx is partially reduced over the implant.

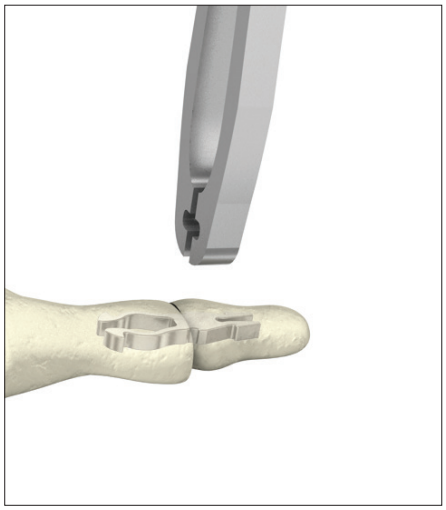
Remove the forceps and manually compress the joint for approximately 1 minute.

NOTICE

To facilitate the shape memory process after implantation, the patient's toe can be bathed in a warm sterile solution, between 37°C (98.6°F) to 40°C (104°F).







Postoperative Care

⚠CAUTION

Smart Toe II implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. 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 fusion is confirmed by follow up X-ray examination.

Removal Procedure

Before fusion:

Use the same approach as fitting and remove the implant reversing the implanting process.

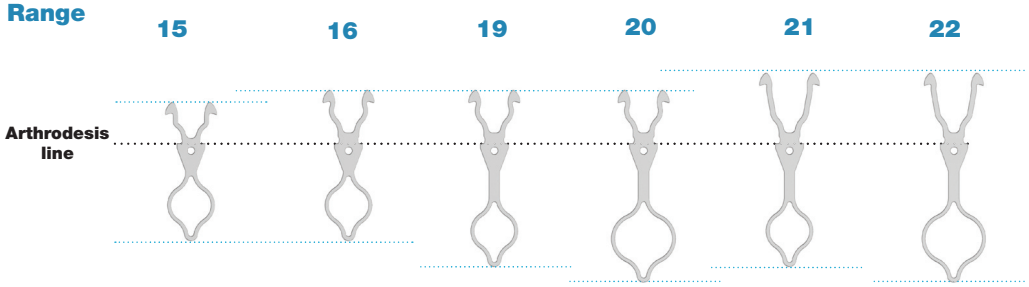
After fusion:

Make a dorsal or lateral window with a reamer or a saw and remove the implant. If necessary use cerclage on the arthrodesis.

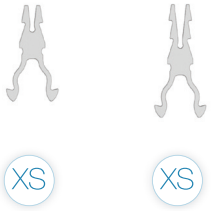
It is possible to use a cold saline solution (approx. 5°C/41°F) to cool the Smart Toe II. It makes the implant softer and consequently easier to extract.

Smart Toe II Product Range

PIP/IP Range



DIP Range



ST0XS-11 ST0XS-13

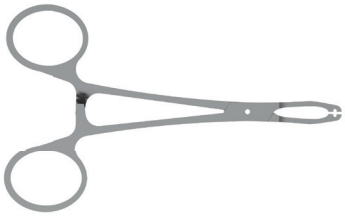
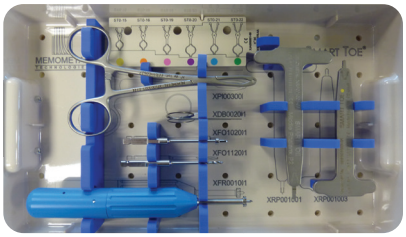
Neutral 0°

	ST0-15P	ST0-16P	ST0-19P	ST0-20P	ST0-21P	ST0-22P
Color Code:	0	0	0	0	0	0

Angled 10°

	ST0A-15P	ST0A-16P	ST0A-19P	ST0A-20P	ST0A-21P	ST0A-22P
Color Code:	10	10	10	10	10	10

System Components – Instruments

	REF	Description
	XFO112001	Proximal (P1) drill bit
	XFO102001	Middle (P2) and Distal (P3) stop drill bit
	XDB002001	Positioning Rod
	XRP001003	Small Middle (P2) Broach for size 15
	XRP001001	Middle Phalanx (P2) Broach for sizes 16 to 22
	XFR001001	Surfacing Reamer
	XPI003001	Implant holding Forceps
	XJA005001	Color Code and Sizing guide pad
	XPL005003 XSEST0200	Tray without Instruments Tray with Instruments
	**Optional:** XRP001002	 Proximal Broach

The information in the section is not intended to be used for sales and/or promotional purposes. This information is solely intended to be used as a reference for clinical usage

Notes

Notes

Notes

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.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Instructions for Cleaning, Sterilization, Inspection and Maintenance (OT-RG-1), Patient Information Leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

If saving the Instructions for Use, Operative Techniques and the Instructions for Cleaning, Sterilization, Inspection and Maintenance from the above mentioned websites, please make sure you always have the most up to date version prior to use.

This document is applicable to US and Canada.

Content ID: ST2-ST-1, Rev. 2, 11 - 2022

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