X Fuse
Superelastic Implant

Operative Technique
• Distal Interphalangeal Joint Arthodesis
Disclaimer

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.

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

See package insert (Instruction for Use) (V15011 and V15013) 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.

Reference

Distal Interphalangeal Joint Arthrodesis Using Nitinol Intramedullary Fixation Implants: X-Fuse Implants for DIP Arthrodesis.

“Techniques in Hand and Upper Extremity Surgery - Volume 17, Number 3, September 2013.”

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Indications & 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 bones fusion.

Contraindications
The X Fuse is contra-indicated for patients with nickel sensitivity, or with anatomical inadequacy. For all contra-indications, please refer to the indications for use.

- 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

The combination of this implant with implants of another origin is contraindicated.

MEMOMETAL INTRAMEDULLARY MEMORY BONE FASTENERS are single-use bone fixation appliances intended to be permanently implanted. Intramedullary bone fasteners are made of superelastic nickel titanium alloy.

Precautions
Stryker 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. Detailed information is included in the instructions for use, attached to every implant.

X Fuse
Sterilization
The X Fuse implants are delivered sterile. The instrumentation has to be sterilized before use. Refer to the indications for use for more information.

Never resterilize X Fuse implants.
Any application of extensive heat would compromise the biomechanical features of the devices, possibly resulting in implant failure.
Operative Technique

Size Selection
Select the appropriate implant size by using the template provided. In most cases, Small and Standard sizes are suitable for DIP 2 to 5 rays, and Large and X Large sizes for IP of the thumb.

⚠️ Then choose the appropriate kit of instruments (Small + Standard kit or Large + X Large) depending on the implant size chosen.

Insertion Approach
Make a dorsal longitudinal incision over the joint, with longitudinal sectioning of the extensor tendon.

Resect the head of P2 and base of P3 and resect the periarticular osteophytes with a ronger.

Proximal (P2) Preparation
Ream manually the bone surface in order to obtain a flat surface.

Open the P2 medullary canal with a 2mm diameter drill bit.
Operative Technique

Use the centromedullary reamer to enlarge the canal and finish with the P2 rasp. Start rasp can be used as an option to centromedullary reamer.

Select the appropriate rasp according to the implant size. **Insert the rasp until the stop for standard, large and X large sizes and insert the rasp until the laser mark for small size.** Apply only gentle side to side translational movement while inserting the rasp. Avoid sweeping or any rotational movement.

**Note:**

In the case of stiff bone, use the P3 rasp as an intermediary reamer.

Make a test with the trial implant in P2.

Distal (P3) Preparation

Ream manually the bone surface in order to obtain a flat surface.

Drilling of the distal part with a 2mm diameter drill bit. Ø1.5 drill bit for very small distal phalanx (Small X Fuse).
Operative Technique

**Distal (P3) Preparation**

Use the centromedullary reamer to enlarge the canal. Finish with the P3 rasp.

Select the appropriate rasp according to the implant size. **Insert the rasp until the stop for standard, Large and X large sizes and insert the rasp until the laser mark for small size.**

Apply only longitudinal translational movement while inserting the rasp. Avoid sweeping or any rotational movement.

Make a test with the trial implant in P3.
**Operative Technique**

**Testing with the trial implant**

Before inserting the definitive implant, check the angle with the trial implants (0°, 15° or 25°) and select the corresponding definitive implant.

Fully flex the prepared DIP joint for complete exposure.

Insert the proximal part of the trial implant, and then the distal part.

Check that the trial implant is well positioned and that the angulation of the joint is satisfactory via radiographic confirmation.

Remove the trial implant.

**Insertion of the final implant**

Use the prehension forceps to compress the proximal legs of the implant.

Insert the implant into P2 up to the stop on the prehension forceps.
**Operative Technique**

Impact using the impactor provided. Position the central area of the implant along the line of arthrodesis.

To impact the implant with the impactor and insert it fully, the forceps must be removed.

Use the prehension forceps to compress the legs on the distal side then advance P3 towards P2 over the compressed implant.

Manually compress P3 onto P2.

**Testing and Closure**

Manually check for stability.

If small gaps exist bone grafts may be interposed.
Final radiographic image is obtained in all planes prior to closure.

Closure may include tenodermodesis, (closure of the skin and the extensor tendon as a unit).

A soft dressing with splint is applied for 7-10 days following surgery with a thermoplastic DIP splint, which is used for 6-8 weeks until there is clinical and/or radiographic evidence of healing.
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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