4Fusion®
Shape Memory Implant

Operative Technique
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 performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

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 have not been tested unless specified otherwise in the product labeling.

See package insert (Instruction for Use) V151082 and V15097 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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**Indications, Precautions & Contraindications**

**Indications**

The Memometal Memory Staples (MemoClip, EasyClip and 4Fusion) are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

**Precautions**

Stryker Osteosynthesis systems have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

**Storage**

The 4Fusion 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**

The 4Fusion implants are delivered sterile. The instrumentation has to be sterilized before use. Refer to the instructions for use for more information.

**Warning Information**

Never re-sterilize 4Fusion implants. Any application of extensive heat would compromise the biomechanical features of the devices possibly resulting in implant failure.

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.

**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
- The combination of this implant which implants of another origin is contraindicated
Access, Denervation and Scaphoidectomy

Make a dorsal incision between the 3rd and 4th compartments.

Expose the radial and mid carpal joint and perform scaphoidectomy, osteophytosectomy and arthrolysis.

Correct the malalignment of the first row (front and sagittal) of the carpus onto the second row.

Stabilize the arthrodesis using two K-Wires between capitate and lunate and between hamate and triquetral.

The K-Wires should be angled laterally to avoid interference with the reamer.
Operative Technique

Reaming

Position the reaming guide on the four bone surfaces (in the middle of the line) and impact it gently with a mallet.

Make sure the guide is properly secured in the bone to avoid guide movement during reaming.

Carefully ream up to 2mm. The bone removed from reaming can be used as bone graft.

Remove the reaming guide and drill the joint surfaces with 3.5mm drill for bone graft placement.

Place the bone graft into the drilled joint.
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Drilling

Place the drill guide in the reamed zone. There are markings with a hand sign on the guides to aid in drill guide placement. The axis of the patient’s hand should be in line with the hand on the guide.

Use the 2.0mm graduated drill bit to drill the four bones. The leg length of the implant is determined using the graduations in the drill bit to achieve bi-cortical fixation.

After each hole is drilled, place the positioning pin into the drilled hole to prevent the guide from moving.
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Implantation of the 4Fusion

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

The implant is delivered with a plastic retainer and impactor assembly as shown in the picture.

Prior implantation take the foam off the implant.

Place the four legs of the implant over the drilled holes. The retainer used in the implant should be in line with the axis of the patient’s hand. This axis represents the main compression axis of the implant.

Remove the retainer prior to insertion.
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Implantation of the 4Fusion

The implant is ready for insertion. Using the cylindrical graft ejector in the set, impact the impactor to insert the implant into the bone until the stop.

Tilt the joint and remove the impactor from the implant.

Impact the implant with the tamp flush to the bone to achieve bi-cortical contact.

The staple must be stapled to the cortical surface, especially on the four corners.
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Testing
Joint can be tested for hardware impingement during flexion and extension using radiographs.

Closing and Post–Operative Care
Orthosis is performed at about 4 weeks.
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 package insert, 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.

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The products listed above are CE marked

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