stryker

Synchfix™ EVT

Syndesmotic fixation device

Operative technique

Important

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.

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.

⚠ CAUTION

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.

⚠ WARNING

The licensed healthcare professional and operating room team must be thoroughly familiar with the operating technique, the instruments, as well as the range of implants to be applied. Complete information and labeling on these subjects must be readily available at the workplace.

The following guidelines are furnished for information purposes only.

Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience.

All instructions for use and labeling must be read carefully prior to clinical use.

Users of this device are encouraged to contact their (Stryker) representative concerning any and all missing documents (e.g., Instructions for Use, Operational Technique, etc.), in the case of damaged products (intra and/or pre operative), or if they require a more comprehensive explanation of the technique to be used with this device. Contact information can be found in this document and the package insert.

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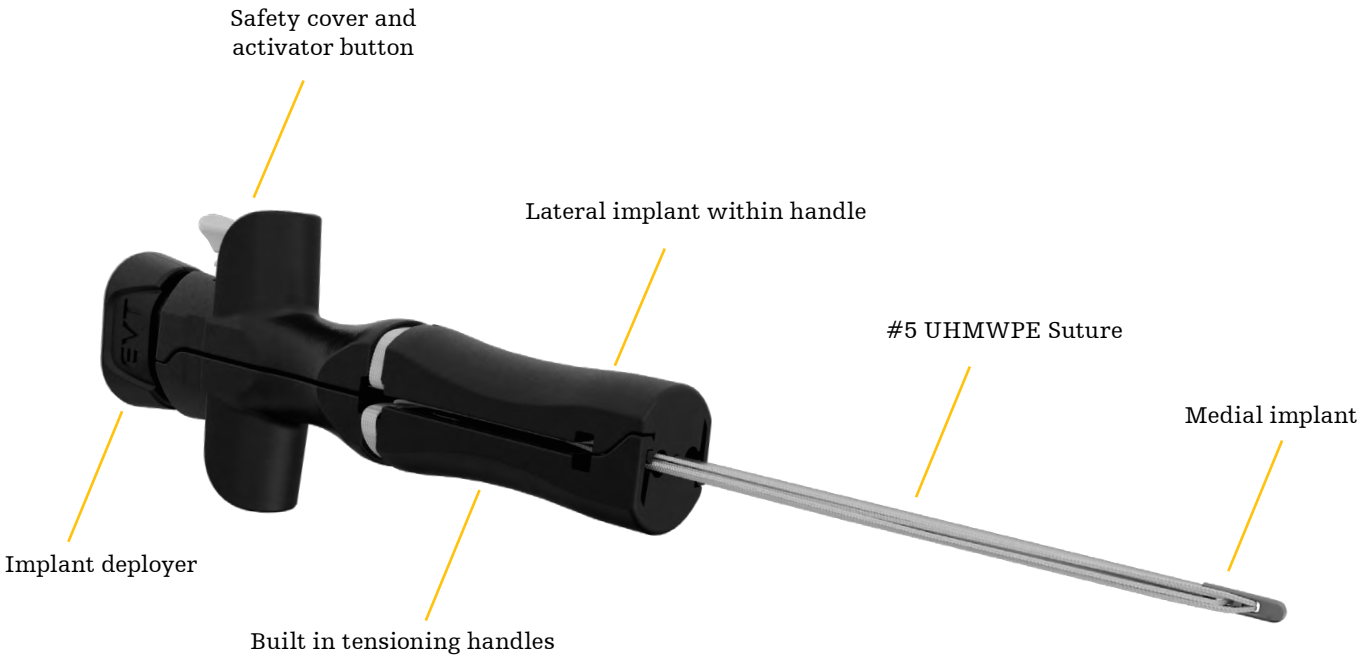
Introduction

The Synchfix EVT syndesmotic fixation device provides a seamless user experience with an ergonomic handle and a low-profile titanium medial implant. Designed for standalone use or compatibility with 3.5mm non-locking screw hardware, it ensures precise, knotless, and secure dynamic fixation across the syndesmosis joint. Its all-in-one integrated design incorporates built-in tensioning handles for a streamlined and efficient technique.

Synchfix EVT Inserter



All of the instruments contained in the Synchfix EVT syndesmotic fixation device kit are disposable.

Indications and Contraindications

Indications

Synchfix EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as, Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

Contraindications

The physician's education, training, and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area;
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site;
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and / or fixation of the devices;
- Material sensitivity, documented or suspected;
- Patients having inadequate tissue coverage over the operative site;
- Implant utilization that would interfere with anatomical structures or physiological performance;
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care;
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

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

Magnetic Resonance Imaging (MRI) Information

The Synchfix EVT is MR Conditional. A patient implanted with a Synchfix EVT implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	Synchfix EVT
Static Magnetic Field Strength (T)	1.5 T and 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (W/kg)	2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 1 hour (or 60 minutes) of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produced an image artifact.

⚠CAUTION

The MRI safety information provided is based on testing which included compatible systems listed in the Instructions for Use. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the system, this could result in additional MRI effects and the information provided above may not apply.

General Considerations

Syndesmotic reduction

⚠ CAUTION

The reduction of the syndesmosis is necessary before fixation, and it should be verified through fluoroscopy, arthroscopic confirmation, direct visualization during open reduction, or a combination of depending on the surgeon's preference and the severity of the injury.

Ankle fractures

Anatomic fixation of unstable and/or displaced fractures in the distal two-thirds of the fibula enables restoration of proper fibular length and rotational alignment. In higher fibula fractures, such as Maisonneuve injuries, treatment often includes fibular shaft open reduction and internal fixation (ORIF) combined with syndesmotic stabilization, depending on the specific injury pattern. The procedure may utilize one or multiple Synchfix EVT implants based on the extent of syndesmosis disruption and the surgeon's preference.

In-plate Surgical Technique

Step 1: Incision and bone prep

Stabilize any associated fractures prior to drilling. Through a lateral incision, use the 3.5mm drill bit (solid or cannulated) to create a pathway through the plate hole, fibula, and tibia — drilling all four cortices at or slightly above the tibial incisura. The drill trajectory should allow for fixation in the center of the tibia. **(Figure 1)**

Optional: The use of a drill guide.

NOTICE

Flexible fixation should be at the centroidal axis of the syndesmosis, which minimizes the likelihood of mal-reduction.

Figure 1

Optional: A guide wire with insert and cannulated 3.5mm drill bit can also be used to confirm accurate positioning. **(Figure 2)**

NOTICE

When using a cannulated drill, trajectory can be confirmed by obtaining fluoroscopic imaging with the temporary K-wire in place. Proper positioning is indicated when the K-wire is centered within the fibular diaphysis.

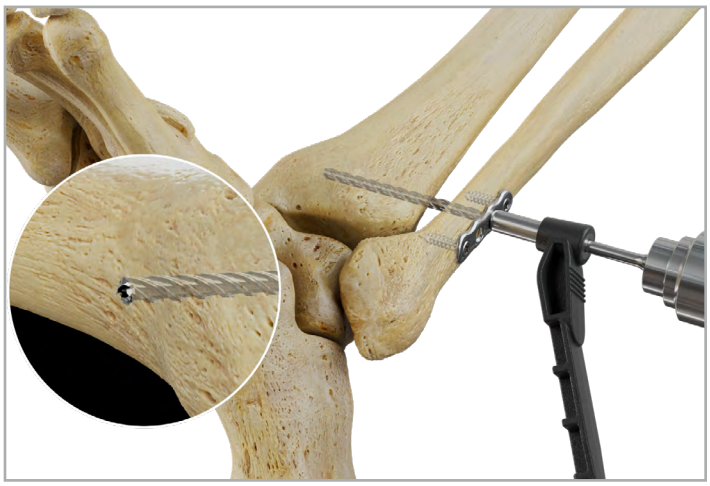


Figure 2

Step 2: Implantation of construct

Position the gray safety cover on the black inserter handle anteriorly (this will help align the medial button with the axis of the tibia after deployment). Advance the Synchfix EVT implant system through the fibula and tibia bone tunnel, passing through all four cortices. **(Figure 3)**

NOTICE

Use fluoroscopy in the anterior-posterior view to ensure that the distal end of the most proximal translucent window on the shaft of the inserter is aligned with the edge of the cortex.

Figure 3

In-plate Surgical Technique (continued)

Step 3: Deploy implant

A. Lift the gray safety cover up to expose the activator button. **(Figure 4)**

B. Press the gray activator button once, to activate the deployer. **(Figure 5)**

C. Using the palm of your hand, squeeze the black implant deployer into the handle to deploy and flip the medial implant. **(Figure 6, 7, & 8)**

Figure 4

Figure 5

NOTICE

Fully advance the deployer until it contacts the back of the handle. This indicates the medial implant is fully deployed.

Figure 6

Figure 7

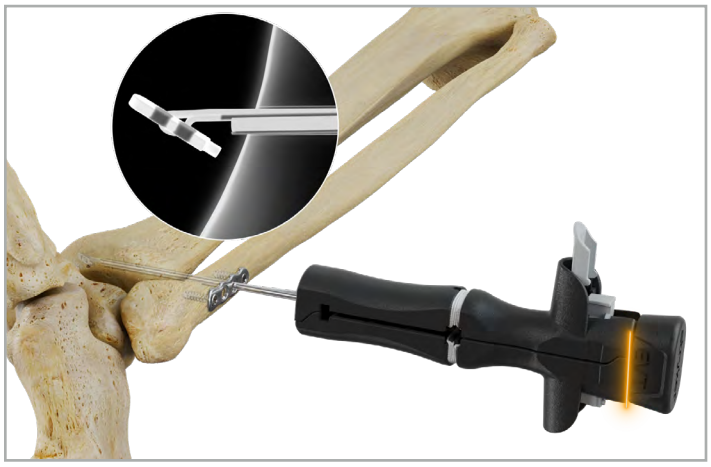


Figure 8

D. After deployment, pull back on the inserter handle and check under fluoroscopy to confirm that the medial implant is fully deployed and seated flat against the medial tibial cortex. **(Figure 9)**

Figure 9

In-plate Surgical Technique (continued)

Step 4: Remove inserter

A. After deploying the medial implant, press the gray activator button a second time to release the implant deployer from the Synchfix EVT inserter. **(Figure 10)**

B. Slide the medial implant deployer fully out of the Synchfix EVT inserter to disengage the tensioning handles, then discard it. **(Figure 11)**

C. Grip the Synchfix EVT inserter with both hands and rotate each half of the handle in opposite directions (one counterclockwise and the other clockwise) to separate the halves and prepare for tensioning. **(Figure 12)**

Figure 10

Figure 11

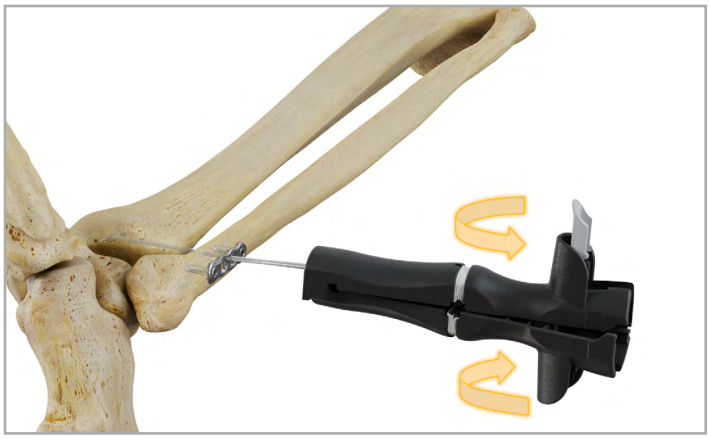


Figure 12

In-plate Surgical Technique (continued)

Step 5: Final tensioning and fluoro check

A. To begin final tensioning, grasp the two built-in tensioning handles, holding one in each hand. **(Figure 13)**

NOTICE

For optimal lateral button advancement, pull the tensioning handles straight back toward the operator, alternating tension from one side to the other to gradually "walk" the lateral button down to the plate until fully seated.

B. After seating the button, pull the two suture strands outward, keeping them in the same plane as the plate surface, until the desired tension is achieved. **(Figure 14)**

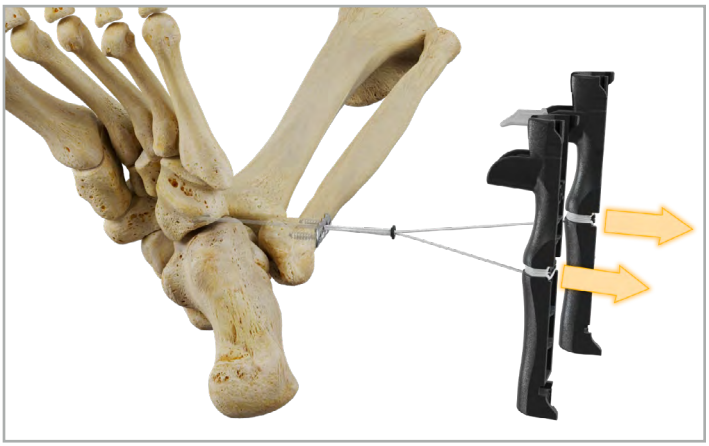


Figure 13

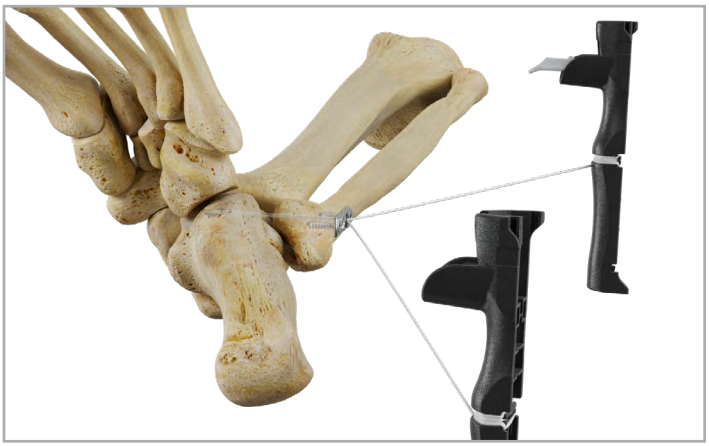


Figure 14

In-plate Surgical Technique (continued)

Step 6: Trim

⚠CAUTION

Once the desired tension is reached, the suture may be carefully cut at the edge of the outer diameter of the lateral implant leaving at least 2mm of suture tail to ensure the implant sutures remain intact and undamaged.

NOTICE

The Synchfix EVT device uses a self-locking (knotless) suture, so tying a knot over the lateral implant is not necessary.

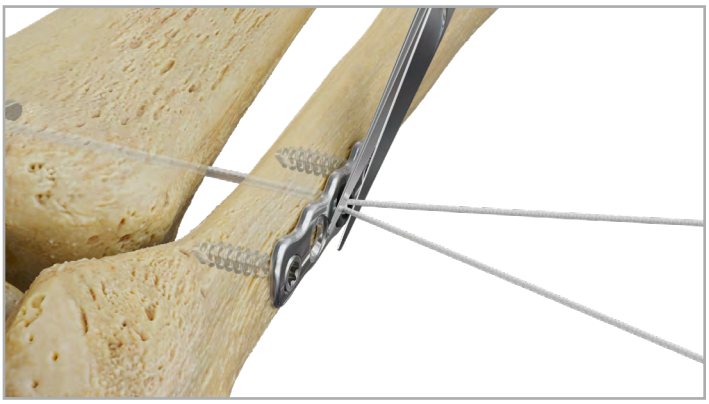


Figure 15

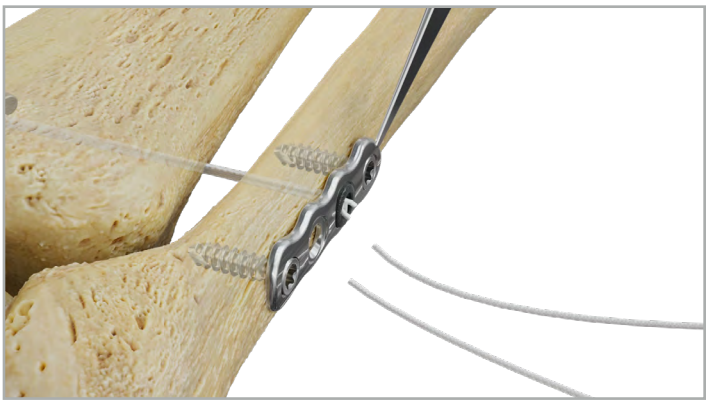


Figure 16

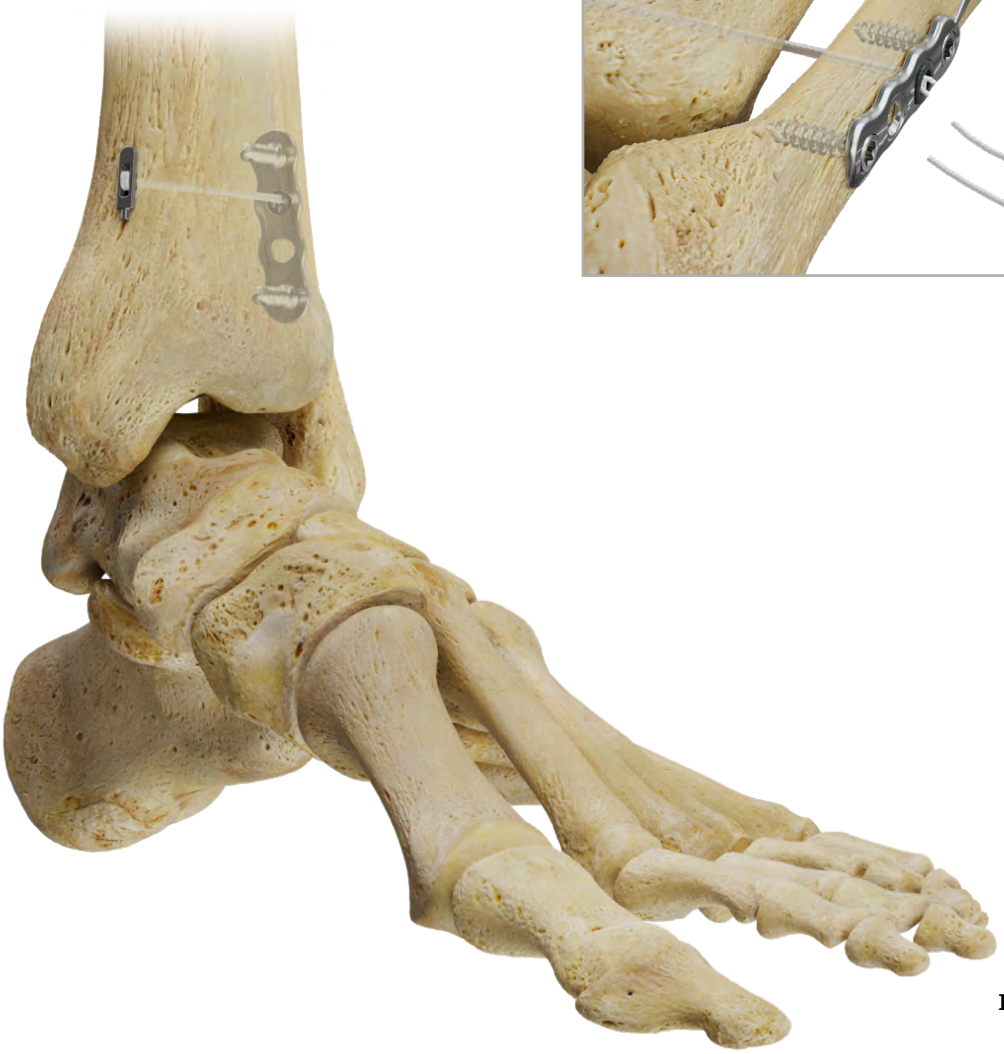


Figure 17

Non-plate Surgical Technique

The Synchfix EVT syndesmotic fixation device may be used without plate fixation by following the previously outlined steps.

The use of a washer is recommended. **(Figure 18)** Prior to completing the previously outlined **steps 1-6**, slide the Synchfix EVT lateral implant washer over the medial implant inserter and suture lines prior to inserting the medial implant through the bone tunnel.

If using a drill guide without a plate, ensure the toothed side is positioned against the bone to provide stable interface during drilling.

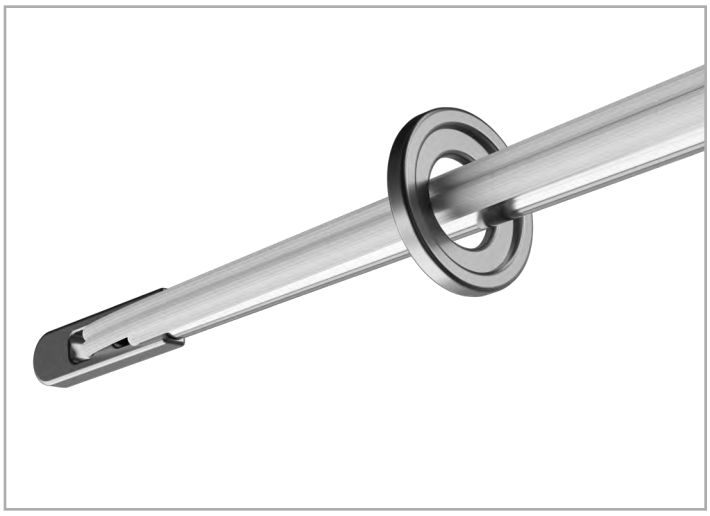


Figure 18

Removal

Explant information

Removal of the Synchfix EVT syndesmotic fixation device, like all flexible syndesmotic fixation, should not be required in most instances and is therefore left to the discretion of the surgeon. If removal is deemed necessary, then a small incision on the lateral and medial side is needed to expose the medial and lateral implants. Once both ends of the construct are exposed, cut the suture and remove the medial implant, followed by the lateral implant and remaining suture.

Ordering Information

Synchfix EVT syndesmotic fixation device sterile packed, single-use implant/instrument kit

Part number	Description
86SYN205	Synchfix EVT inserter with implant construct
	Drill guide
	1.6mm guide wire
	Guide wire adapter for drill guide
	3.5mm solid and cannulated drills
	Washer

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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. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate Stryker's products. 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 of Stryker's products. 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 representative if you have questions about the availability of Stryker's products in your area.

The Instructions for Use, Operative Techniques, Patient Information Leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

Please make sure you always have the most up to date version of these documents prior to use..

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