AutoFIX System
Cannulated Compression Screw

Operative Technique

- 2.0mm
- 2.5mm
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.

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) (V15138 and V15183) 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. AutoFIX sterile implants are sold OUS only.
Indications & Contraindications

Indications
The AutoFIX System is indicated in the treatment of fractures, non-unions, pseudoarthrosis and degenerative changes as well as corrective osteotomies geared towards a functionally stable osteosynthesis in small bones.

Contraindications
Do not use the AutoFIX System in cases of:

- Osteopenic bone
- Inadequate bone quantity and/or bone quality
- Foreign body sensitivity to implant material
- Acute or chronic systemic or localized infections
- Any medical or surgical condition precluding the potential benefit of surgery
- Dependency on pharmaceutical drugs, drug abuse or alcoholism
- Lack of patient cooperation or mental illness
- Immuno-suppression

Note:
- Extreme rotation speed during screwing and countersinking may lead to increased heat generation
- Applying excessive torque during screwing may cause damage to the screw head and screwdriver tip, which can lead to difficult screw extraction. Extensive bone damage may also be a result, requiring additional surgical measures such as supplementary surgery, change in surgical method and/or revision surgery
- Pay attention to avoid any unexpected soft tissue irritation especially during cutting, countersinking, and screw/K-Wire insertion

Warnings & Precautions
Please see package insert for Warnings, Precautions, Adverse Effects, and other essential product information.
Implant & Instrumentation

Technical Specifications

AutoFIX 2.0mm & 2.5mm Headless Cannulated Compression Screws are designed for use on articular surface of joints and areas with minimal soft tissue coverage.

The entire AutoFIX Screw System offers 5 diameters and a large range of length with 1mm, 2mm and 5mm increments. The present document concerns only to the 2.0mm & 2.5mm AutoFIX Screws.

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*Available OUS Only
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The AutoFIX Screw System is intended to be used for various indications, for which the following procedural steps would apply. The operative technique contains examples of the radial head indication but can be applied in a similar manner for the other approved indications.

Planning and preparation with clear identification and classification of the fracture, osteotomy, or fusion site should be established pre-operatively using the proper methods and visualization. Pertinent surgical incisions are made to expose the implantation site. Then, if necessary an osteotomy can be preformed.

The present operative technique applies to the Ø2.0mm / Ø2.5mm AutoFIX System. The operative technique for the Ø3.0mm / Ø4.0mm AutoFIX System, and the Ø6.5mm AutoFIX System is similar, except of the K-Wire and the Countersink diameters, and the Screwdriver Torx used.

Step 1 Stabilization

Reduce fracture by means of:
open reduction, external indirect manipulation, or by means of K-Wire (“joy stick”) manipulation. Provide surgical exposure for implant.

Use the central hole of the K-Wire Guide to place the provided K-Wire down the center of the intended implant path under fluoroscopic guidance (Fig. 1).

Use image intensification to control reduction and K-Wire placement.

Note:
The K-Wire should not overpass the second cortex to obtain valuable measurement.
The placement and positioning of the K-Wire is crucial. The top of the K-Wire should engage the subchondral bone at the far cortex of the fracture and the screw should be placed perpendicular to the fracture line (Fig. 2).

Place an additional guide wire into one of the 6 adjacent parallel path holes located around the circumference of the guide (Fig. 3). This second wire helps to stabilize the fragment and prevents the fragment from spinning when the self threading implant engages the near cortex of the fragment. After the second wire is placed, remove the multi-position wire guide. Deflect the second wire as necessary (Fig. 4).
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Step 2 Screw Length Identification

Advance the depth gauge over the K-Wire and position directly against the bone. Select the appropriate screw length.

Deduct 2mm from the measured length to ensure complete burial of the screw head (Fig. 5).

Length adjustment is particularly important if the tip is close to an articular surface.

Note:
- The depth gauge should be placed perpendicularly to the bone surface. In the case of an angulated measurement, subtract appropriately to ensure a well seated screw head
- The guide K-Wire should not pass through the second cortex
- Insertion of a too long screw could lead to soft tissue damages and/or damages of the joint surface

Step 3 Countersink

Countersinking is performed manually with the Cannulated Countersink.

Insert the Cannulated Countersink Ø2.0mm / Ø2.5mm into the Quick Connect Handle and position over the central K-Wire.

Countersink the proximal cortex to facilitate screw insertion (Fig. 6). Remove Cannulated Countersink from Handle.

Note:
- If the K-Wire is stuck in the cannulated instrumentation, use the Cleaning Stylet to remove the K-Wire.
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**Step 4 Screw Placement**

Insert the Cannulated Screwdriver Torx T7 into the Quick Connect Handle.

Use the StickFIT Driver Blade to remove appropriate implant from the screw caddy and verify size with the built in measuring gauge (Fig. 7).

Slide the screw over central K-Wire and insert the screw in a clockwise manner (Fig. 8). Once the proximal threads contact the near cortex, every full revolution of the Screwdriver Handle compresses a Ø2.0mm Screw 0.2mm and a Ø2.5mm Screw 0.3mm (Fig. 9).

Use image intensification to check positioning and prevent over insertion.

Remove the K-Wire and verify the screw is flush with or below the surface of the cortical bone or articular cartilage (Fig. 10).

Finally, proceed to normal surgical closure.

**Note:**

Although theses implants are self-drilling, some downward pressure is required during initial insertion.
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Tips:
• The general rule for screw use as applied to internal fixation is that fragments must be a minimum of 3 times the diameter of the implant head (Ø9mm for 2.0mm implant and Ø10mm for 2.5mm implant)
• It is possible to use more than one implant in a given fracture by repeating these steps. Two screws may prevent fragment rotation, as well as allow for additional strength and holding ability but it is up to the individual surgeon's discretion to maintain proper distances between implants
• If screw extraction is desired, Solid Screwdriver Remove Torx T7 is provided in the tray

Note:
Pay attention to not put the two screws in contact. Two screws touching each other can lead to screw damage / failure due to excessive screwing torque and could generate unexpected metal fragments.

Fig. 10
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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