stryker

CableFIX® Xpress
Carpometacarpal Fixation System

Operative technique

CableFIX® Xpress
Carpometacarpal Fixation System

Contents

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.

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

For additional information please refer to the instructions for use (IFU), Ref. V15215 delivered with each instrument. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Indications and contraindications

Indications

CableFIX is a suture button implant designed to stabilize the thumb metacarpal following removal or partial resection of the trapezium. The Cable FIX is an adjunct in the healing process when used in conjunction with a biologic reconstruction of the ligament at the base of the thumb metacarpal for treatment of carpometacarpal (CMC) arthritis and instability.

Contraindications

- Active infection.
- Poor bone quality.
- Osteoporotic bone that is susceptible to fracture.
- Conditions that limit the patient's ability or willingness to follow postoperative instructions with the healing regimen.
- Foreign body sensitivity or hyper reactivity.
- Physical conditions that retard the healing process.
- Surgical procedures not indicated for the device.
- Skeletally immature bone/patients may not be suitable.

Precautions

Unless otherwise specified, the Stryker GmbH non-active devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the non-active implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Operative technique

Operative technique

Ulnar knot technique

Step 1:

Make a 1cm incision over the dorsal-ulnar metaphysis of the proximal 2nd metacarpal. Retract the extensor tendons and use blunt dissection to expose the dorsal-ulnar cortex of the 2nd metacarpal.

It is highly recommended that the supplied 1.3mm k-wire is advanced from the dorsal-ulnar aspect of the 2nd metacarpal in an ulnar to radial direction. This facilitates a central placement of the k-wire within the 2nd metacarpal. The ideal exit point of the 1st metacarpal is 5 to 10mm distal from the basal joint surface, just volar to the radial ridge. This will ensure that the 2-hole round plate will be well covered by the thenar musculature. In the sagittal plane, the k-wire should be centrally placed within both metacarpals.

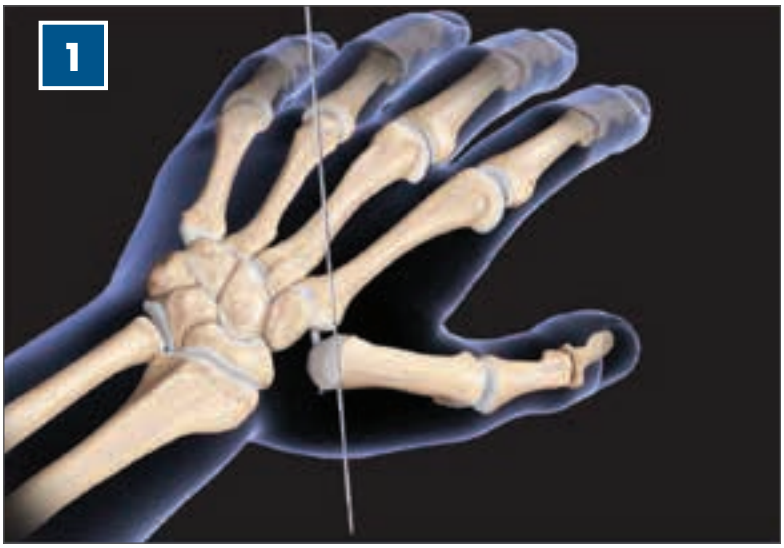

Fig. 1

Via fluoroscopy, confirm k-wire placement intra-operatively in both AP and lateral planes leaving the k-wire in position.

Make a 1cm incision at the exit point of the k-wire. Use blunt dissection to expose the radial cortex of the 1st metacarpal.

Optional PTFE

Optional: If the position of the k-wire or anatomy does not allow for drilling ulnar to radial, utilize the PTFE tube technique below.

Position the supplied 2.7mm cannulated drill bit over the k-wire and drill radial to ulnar, exiting the ulnar cortex of the 2nd metacarpal.

Withdraw the drill bit from the 1st metacarpal cortex side leaving the k-wire in position.

With the k-wire in position, advance the PTFE tube over the k-wire through the 1st and 2nd metacarpals. Remove k-wire leaving the PTFE tube in position within both metacarpals.

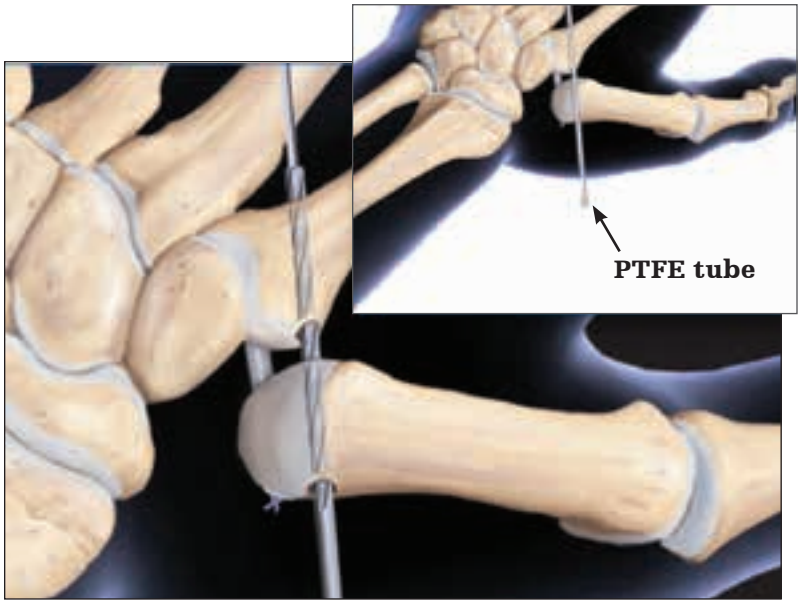

Fig. 1B

Operative technique

Step 2:

Position the supplied 2.7mm cannulated drill bit over the k-wire and drill ulnar to radial, exiting the radial cortex of the 1st metacarpal. Do not remove the drill bit.

With the cannulated drill bit still in position, remove the k-wire.

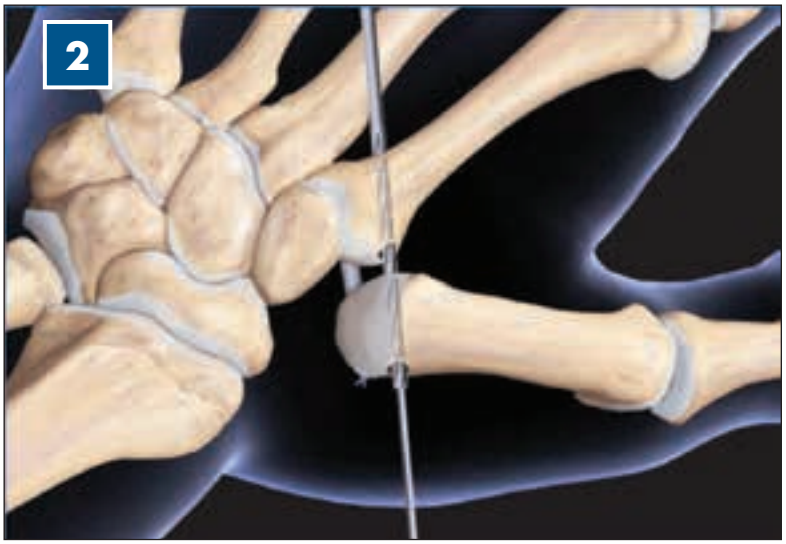

Fig. 2

Step 3:

Insert guide wire of implant assembly into the radial end of the cannulated drill bit or optional PTFE tube and advance ulnarly. Withdraw the drill bit from the 2nd metacarpal cortex. This will position the guide wire of the implant assembly, on the ulnar side of the 2nd metacarpal.

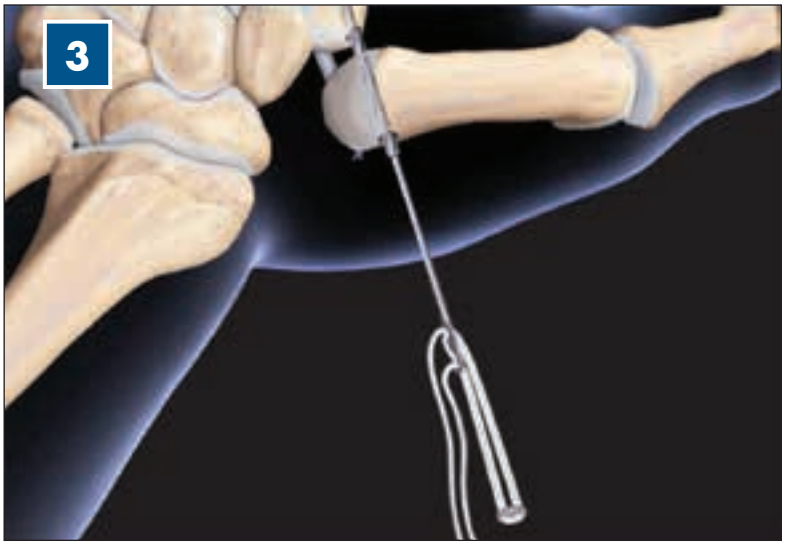

Fig. 3

Operative technique

Step 4:

Gently pull the guide wire implant assembly ulnarly until the 2-hole round plate is seated firmly on the cortex of the 1st metacarpal and the guide wire implant assembly is completely withdrawn on the ulnar side of the 2nd metacarpal cortex.

Hold the oblong plate close to the guide wire with a hemostat, then bend the guide wire and detach from the oblong plate. Dispose of the guide wire.

Confirm that the 2-hole round plate is seated firmly against the 1st metacarpal cortex and deep to the thenar musculature.

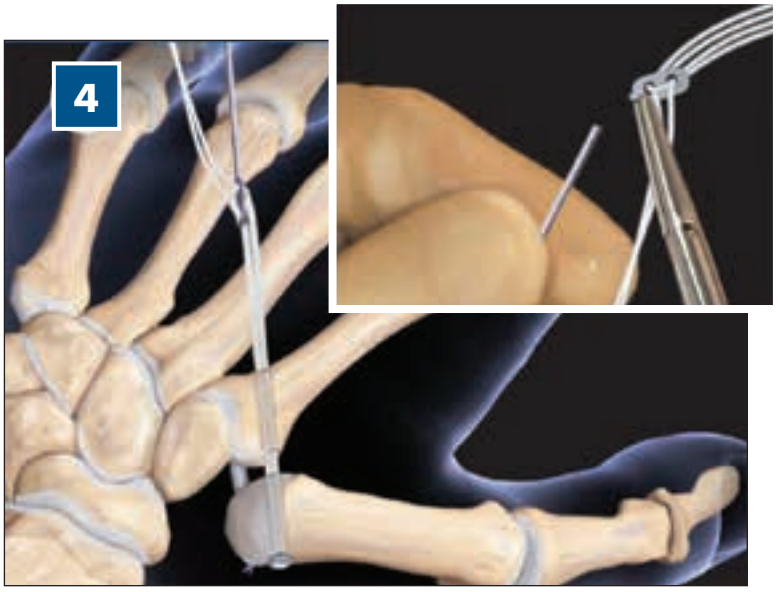

Fig. 4

Step 5:

Reduce the 1st metacarpal subluxation to the desired position in relation to the 2nd metacarpal and have assistant hold reduction.

Gradually begin tensioning both strands of suture until the oblong plate is seated firmly against the cortex of the 2nd metacarpal and does not impinge the extensor tendons.

Fig. 5

Operative technique

Step 6:

Under tension, secure 4 surgeon knots over the 2nd metacarpal 2-hole oblong bone plate. Trim the suture in a standard manner.

Close the surgical sites.

Fig. 6

Post operative management

Remove the dressing, splint, and sutures at 1 week to 10 days post-op.

Fabricate a thumb spica splint holding the thumb in a slightly abducted position.

Discontinue splint at 4 weeks and begin controlled thumb motion and gentle strengthening exercises.

Operative technique

Radial knot technique

Step 1:

Make a 1cm incision over the dorsal-ulnar metaphysis of the proximal 2nd metacarpal. Retract the extensor tendons and use blunt dissection to expose the dorsal-ulnar cortex of the 2nd metacarpal.

It is highly recommended that the supplied 1.3mm k-wire is advanced from the dorsal-ulnar aspect of the 2nd metacarpal in an ulnar to radial direction. This facilitates a central placement of the k-wire within the 2nd metacarpal. The ideal exit point of the 1st metacarpal is 5 to 10mm distal from the basal joint surface, just volar to the radial ridge. This will ensure that the 2-hole oblong plate will be well covered by the thenar musculature. In the sagittal plane, the k-wire should be centrally placed within both metacarpals.

Via fluoroscopy, confirm k-wire placement intra-operatively in both AP and lateral planes leaving the k-wire in position.

Make a 1cm incision at the exit point of the k-wire. Use blunt dissection to expose the radial cortex of the 1st metacarpal.

Step 2:

Position the supplied 2.7mm cannulated drill bit over the k-wire and drill radial to ulnar, exiting the ulnar cortex of the second metacarpal. Do not remove the drill bit.

Fig. 1

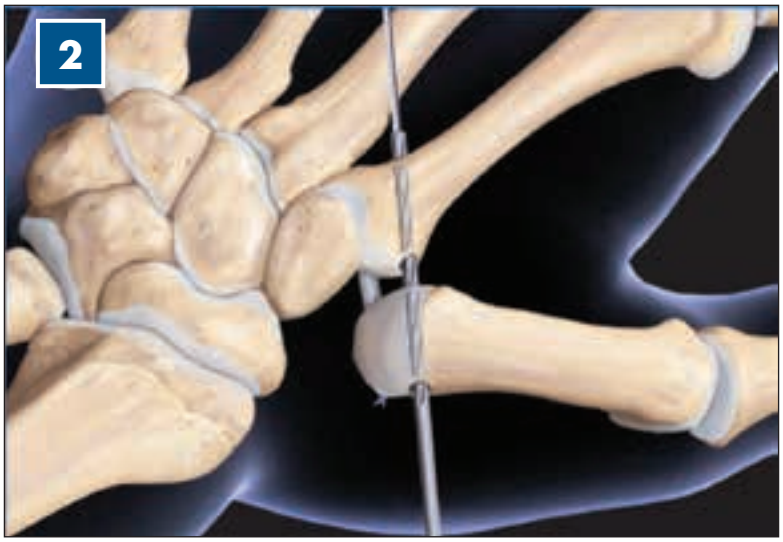

Fig. 2

Operative technique

Step 3:

With the cannulated drill bit still in position, remove the k-wire.

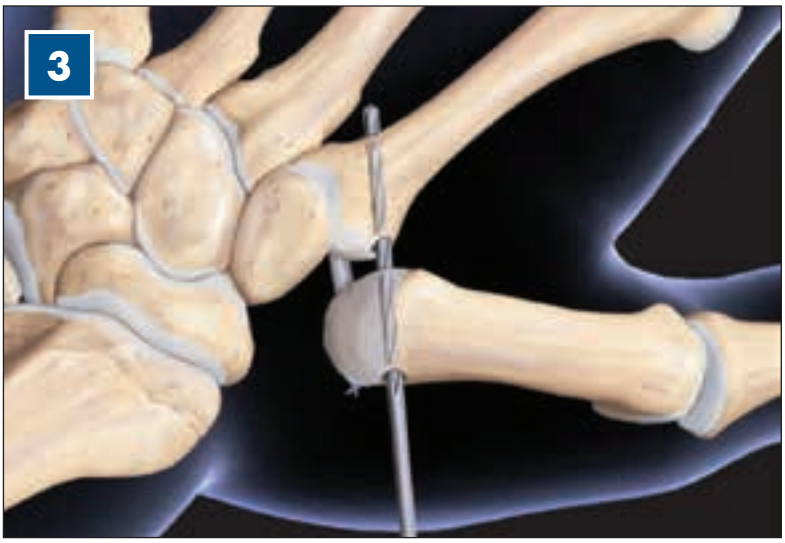

Fig. 3

Step 4:

Insert guide wire of implant assembly into the ulnar end of the cannulated drill bit and advance radially. Withdraw the drill bit from the 1st metacarpal cortex. This will position the guide wire of the implant assembly on the radial side of the 1st metacarpal.

Fig. 4

Operative technique

Step 5:

Gently pull the guide wire implant assembly radially until the 2-hole round plate is seated firmly on the cortex of the 2nd metacarpal and the guide wire implant assembly is completely withdrawn on the radial side of 1st metacarpal cortex.

Hold the oblong plate close to the guide wire with a hemostat, then bend the guide wire and detach from the oblong plate. Dispose of the guide wire.

Confirm that the 2-hole round plate is seated firmly on the 2nd metacarpal cortex and does not impinge the extensor tendons.

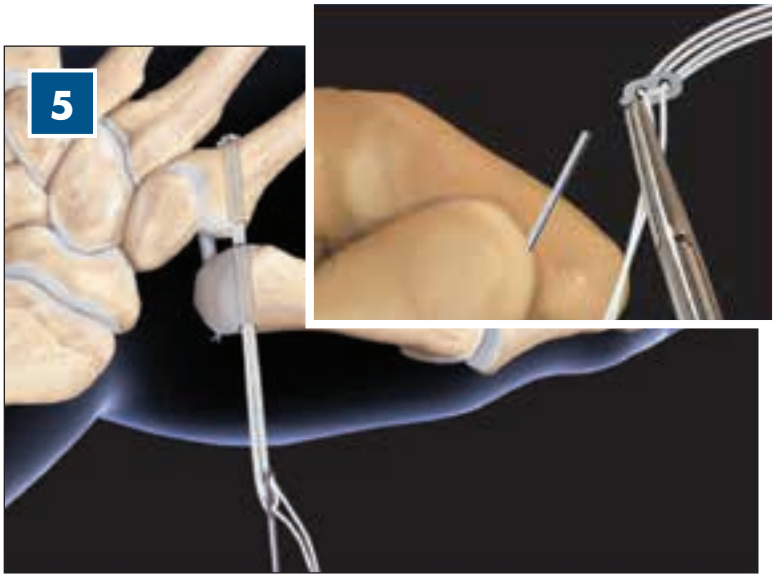

Fig. 5

Step 6:

Reduce the 1st metacarpal subluxation to the desired position in relation to the 2nd metacarpal and have assistant hold reduction.

Gradually begin tensioning both strands of suture until the oblong plate is seated firmly against the cortex of the 1st metacarpal deep to the thenar musculature.

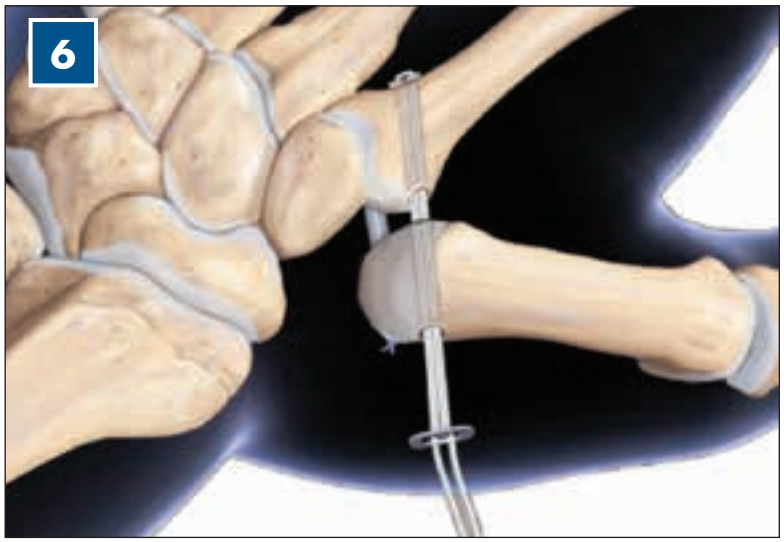

Fig. 6

Operative technique

Step 7:

Under tension, secure 4 surgeon knots over the 1st metacarpal 2-hole oblong bone plate. Trim the suture in a standard manner.

Close the surgical sites.

Fig. 7

Post operative management

Remove the dressing, splint, and sutures at 1 week to 10 days post-op.

Fabricate a thumb spica splint holding the thumb in a slightly abducted position.

Discontinue splint at 4 weeks and begin controlled thumb motion and gentle strengthening exercises.

Notes:

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Trauma & Extremities

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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