CoFix®

Posterior MIS Fusion System

SURGICAL TECHNIQUE

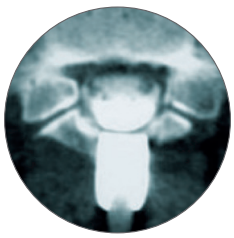
CoFix® DESIGN

The CoFix® implant is intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine. The unique implant design allows for stabilization after decompression to promote fusion and offers an alternative to pedicle screw fixation when used with an interbody fusion device.

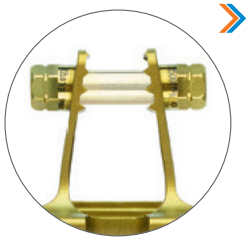
Altogether, the features of the CoFix® implant are designed to provide posterior stabilization and post-surgical decompression until fusion is achieved.

Interlaminar Positioning

The CoFix implant is positioned on the strongest bony structure of the posterior column, the lamina. Insertion at the level of the facet joints is designed to allow the implant to counteract the majority of posterior column forces to maintain foraminal height and unload the facet joints.



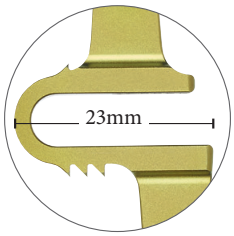
Implant Fixation



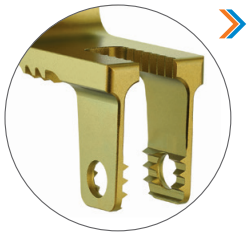
The implant wings, screws and sleeves are designed to allow for a low profile, tissue-friendly, anatomical fit. The implant wings can be adjusted to the morphology of the spinous processes and fixated with the screws and sleeves.

Large Contact Surface

Large implant footprint provides coverage of the spinous processes and the laminae. This allows for load distribution and reduced stresses on the anatomical structures.



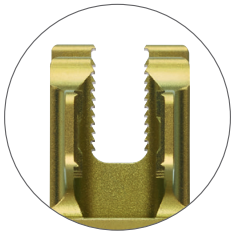
Serrated Teeth



Serrated teeth both inside the wings and on the superior and inferior arm of the CoFix implant provide primary fixation.

Posterior Notch

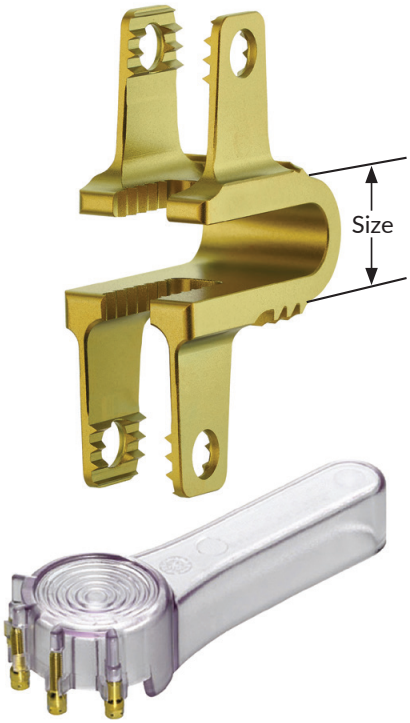
Allows for placement of bone graft to support fusion.



PRODUCT INFORMATION

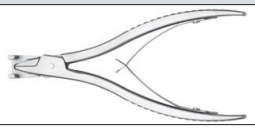
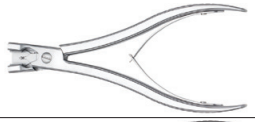
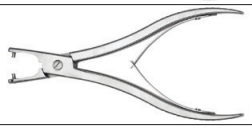
Implants

Color Code	Size	Article Number
	16mm	RQI 00016
	14mm	RQI 00014
	12mm	RQI 00012
	10mm	RQI 00010
	8mm	RQI 00008



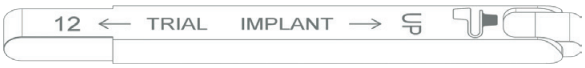
- Material: All CoFix implants consist of titanium 6-aluminum 4-vanadium alloy (ISO 5832-3).
- The CoFix implant is delivered sterile packed and includes a disposable application tool for the screws and sleeves.

Instruments

Part Number	Instrument	
UAT 10100	Bending Plier	
UAT 10200	Crimping Plier	
RAT 20100	Punching Plier	
RAT 20130	Cleaning Tool	
RAT 20120	Probe	
RAT 20222	LIS Screw Inserter	
RAT 20204	Screwdriver	
RAT 20300	Wrench	

Trials

Color Code	Size	Article Number
	16mm	RDT 00016
	14mm	RDT 00014
	12mm	RDT 00012
	10mm	RDT 00010
	8mm	RDT 00008

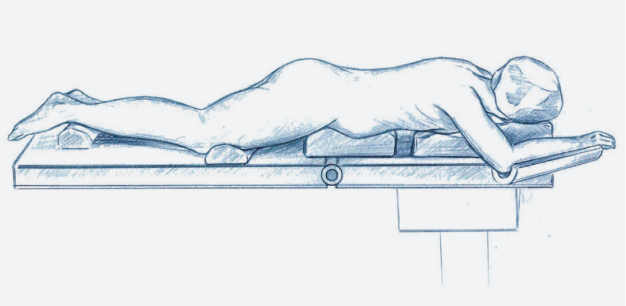


SURGICAL TECHNIQUE

Step 1: Preparation

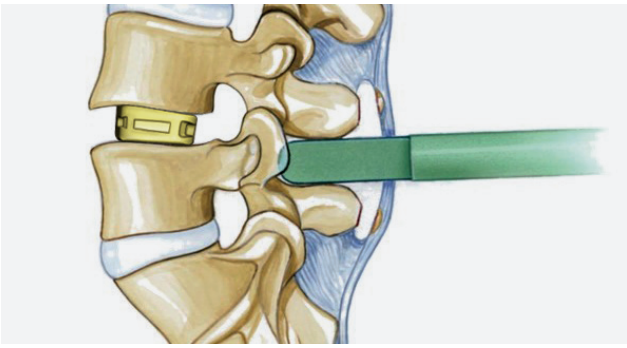
- The patient is placed in prone position on a surgical frame, avoiding hyperlordosis of the spinal segment(s). A routine (midline) skin incision is performed. The muscle is sharply dissected lateral to the supraspinous ligament. The paraspinal muscles are stripped off the laminae.

  The interspinous ligament is sacrificed and any bony overgrowth of the spinous process that may interfere with insertion is resected. The ligamentum flavum is resected and a decompression is performed, relieving all points of neural compression.



Step 2: Implant Site Preparation

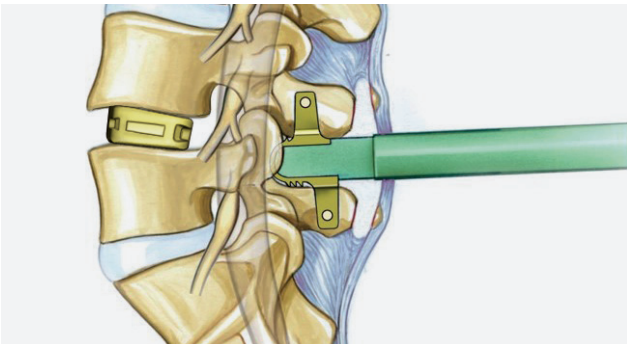
- Trials are utilized to define the appropriate implant size. The trial instrument is placed to evaluate proper contact with the spinous processes avoiding any facet distraction. Some bony resection of the spinous process may be needed to ensure optimal contact of the implant.



Step 3: Implant Insertion

- The implant is introduced via impaction utilizing a mallet. Prior to insertion the wings may need to be opened slightly using the bending pliers to ensure appropriate depth of insertion (Figure 1). Proper depth is determined by passing a beaded tip probe between the implant and the dura to ensure a 2–3 mm separation.

  By deeply inserting the CoFix implant at the level of the facet joints, the implant counteracts the majority of posterior column forces.



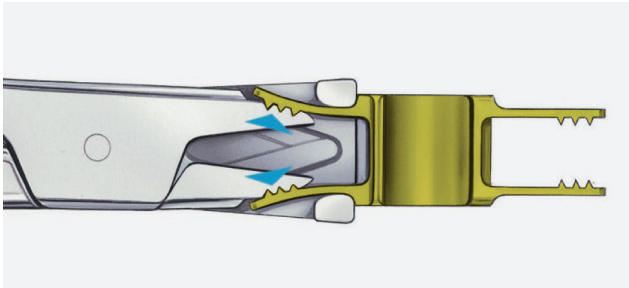
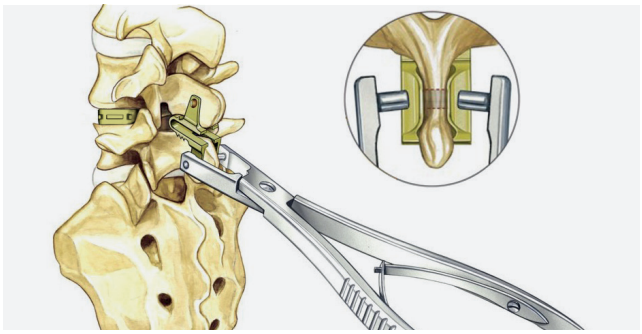


Figure 1

- Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the crimping pliers (Figure 2). Then punching pliers are utilized to create a hole in each spinous process for later introduction of the CoFix screws and sleeves.

  Prior to insertion of the CoFix screws and sleeves, it is recommended to clean the holes using the probe. The CoFix screws and sleeves are attached to the LIS screw inserter and applied into the spinous processes using the screw driver. A tight fit is required for controlled fixation. The teeth of both wings should be firmly engaged into the cortices of the spinous processes.



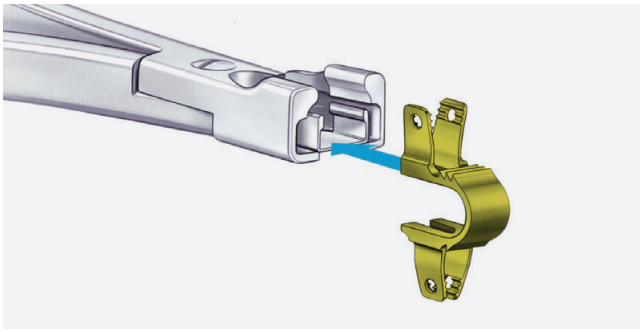
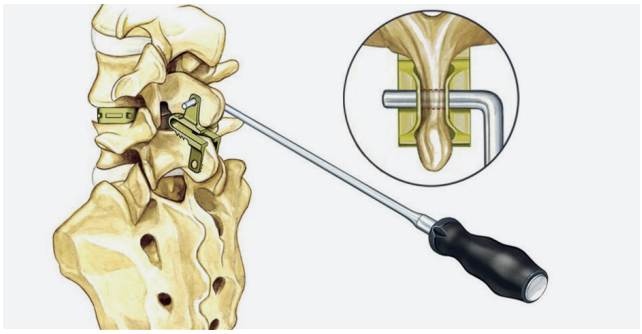


Figure 2

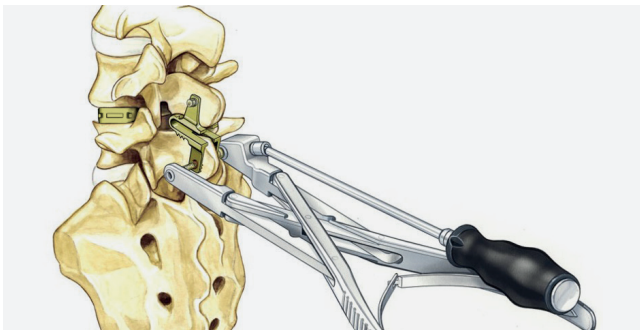
Step 4: Fusion Technique

- After insertion of the CoFix implant and the application of the screws and sleeves, the posterior fenestration can be filled with bone graft. Arthrodesis is performed utilizing standard fusion techniques such as posterolateral or interbody fusion.



Step 5: Wound Closure

- A surgical drain may be placed as per surgeons' preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.



INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

XTANT MEDICAL

888-886-9354
cs@xtantmedical.com
xtantmedical.com

STG-000025 (A) 3/23