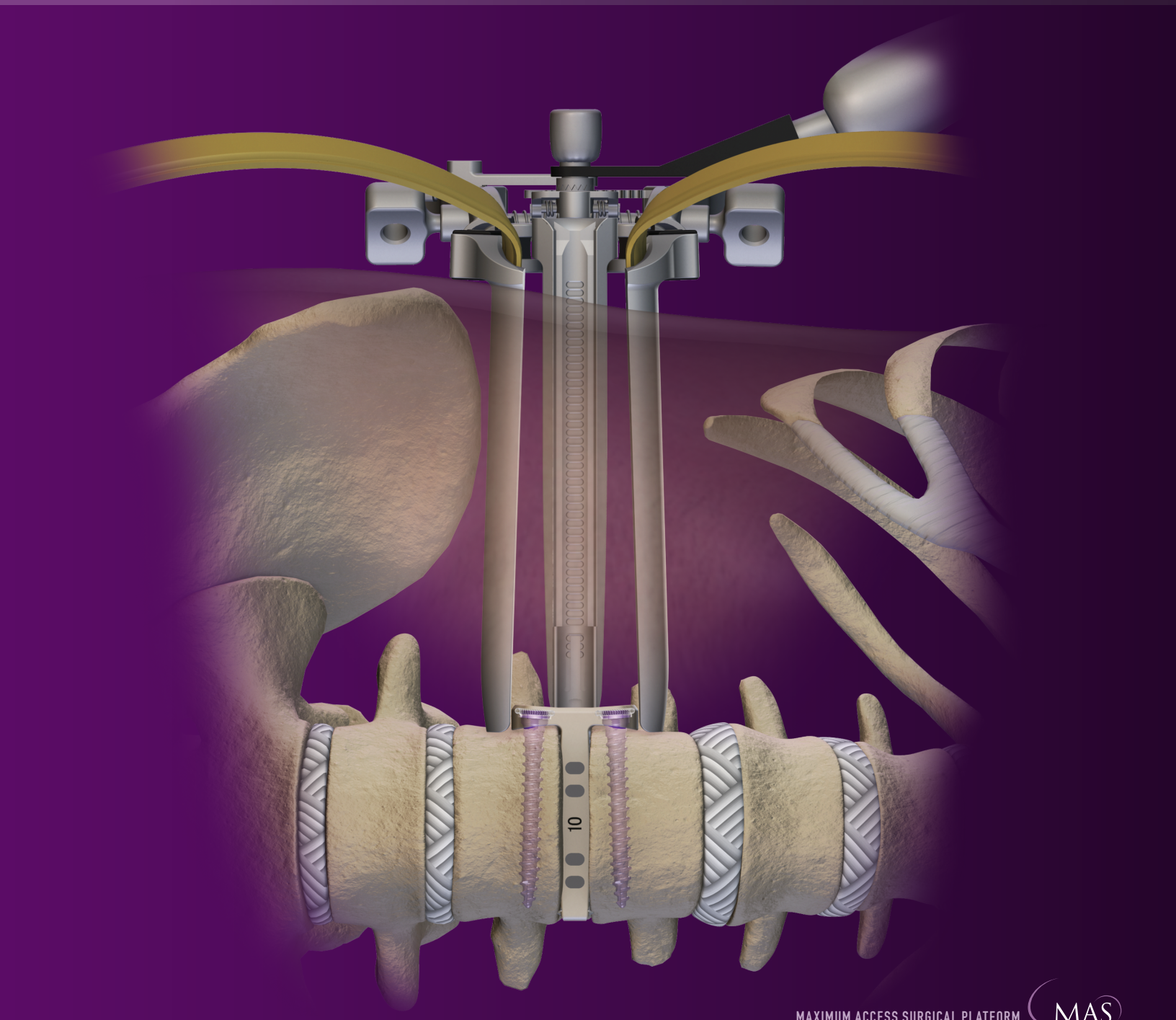
NuVasive

CoRoent

CoRoent XL-F Technique Guide



MAXIMUM ACCESS SURGICAL PLATFORM MAS

CONTENTS

PREFACE

Fellow Colleagues:

The XLIF technique has delivered thousands of outstanding patient outcomes since its inception in 2003, allowing surgeons to achieve results that were previously not possible with the existing conventional methods. When performing the XLIF procedure, surgeons have greatly appreciated the efficiency and reproducibility of the approach. Equally important, the surgeon is able to deliver an exceptionally large interbody implant to help with successful fusion.

When designing the CoRoent XL-F implant system, our goal was to create an interbody implant, supported by supplemental fixation, that would enable the pinnacle of support and stability in an XLIF procedure. In the process, we focused on maintaining the efficiency and reproducibility of the XLIF procedure. After extensive clinical evaluation and multiple design iterations, the finished product is an elegant and highly effective interbody implant system with integrated, self-locking screws. After placing the low-profile interbody implant, the CoRoent XL-F system simply requires delivering two self-locking screws through the implant.

The CoRoent XL-F system is a milestone in the advancement of lateral approach spine surgery, and we are confident that you will appreciate the simplicity, efficiency, and excellent patient outcomes made possible with this unique and thoughtfully designed XLIF implant system.

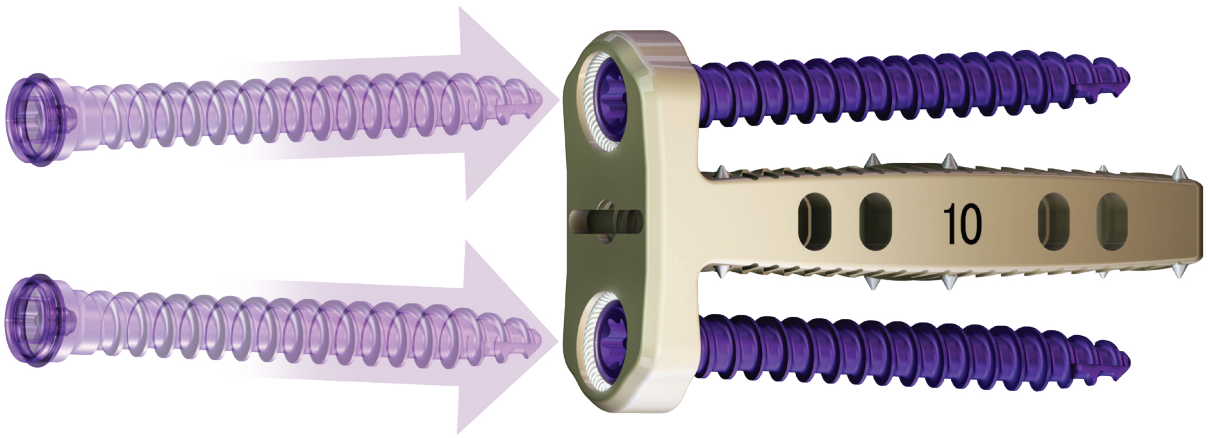
Best regards,

Jim A. Youssef, M.D.
Spine Colorado
Durango, CO

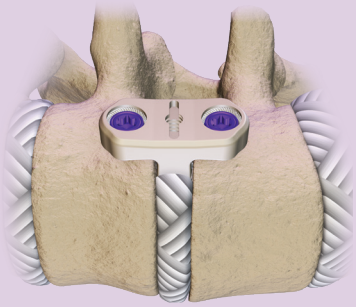
William Blake Rodgers, M.D.
Spine Midwest, Inc.
Jefferson City, MO

SYSTEM OVERVIEW

CoRoent XL-F

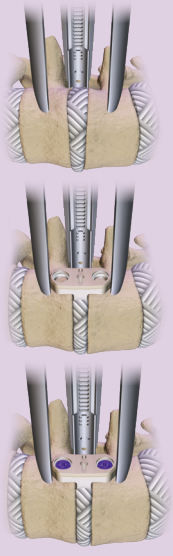


Stable



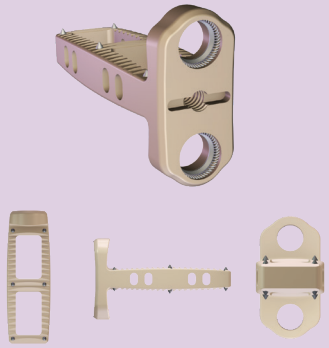
- Extra-large surface area for maximum support.
- Integrated screws for unparalleled stability.

Efficient

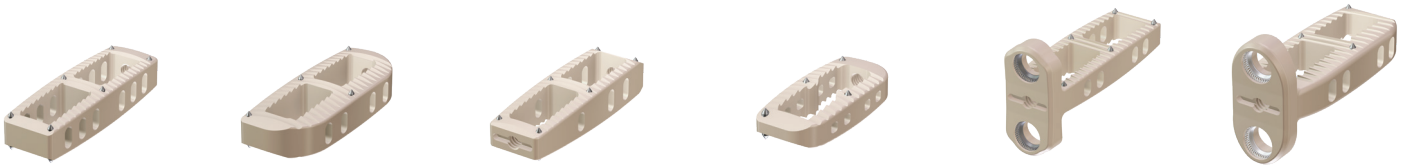


- Access target anatomy using established XLIF approach.
- Deliver CoRoent XL-F interbody implant.
- Place CoRoent XL-F self-locking screws.

Unique



- The first XLIF interbody implant with integrated screws.
- Low-profile, strong, and anatomically accommodating design.



XL Fusion | **XL-W** Support | **XL-CT** Alignment | **XL-T** Thoracic | **XL-F** Stability | **XL-FW** Support + Stability

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

STEP 1:
PREOPERATIVE PLANNING

Before the surgery, it is important to be cognizant of current or planned adjacent-level hardware. If necessary, the CoRoent XL-F system provides a variety of implants and instruments to aid in effective placement.

Similar to traditional XLIF procedures, CoRoent XL-F implants should be placed in the center of the disc space from a medial/lateral perspective, and in the middle of the disc space from an anterior/posterior perspective. For accurate transpsoas implant placement, it is important to use NVM5 Dynamic Nerve Detection.

STEP 2:
ACCESS AND APPROACH OVERVIEW

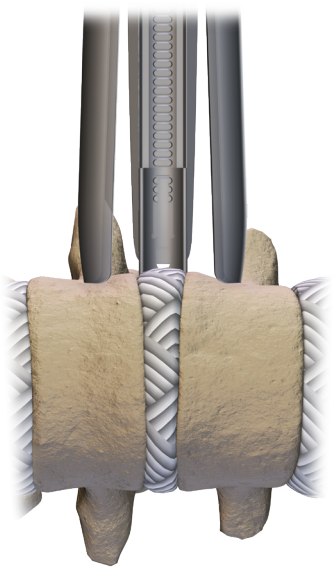
Using the established XLIF approach through the MaXcess Retractor, access the disc space *(Figs. 1, 2)* and perform a thorough discectomy, making sure to release the contralateral annulus.

Note that the access driver only needs to be opened enough to allow room for a thorough discectomy. Increased retraction may be necessary during trialing and/or implant insertion.

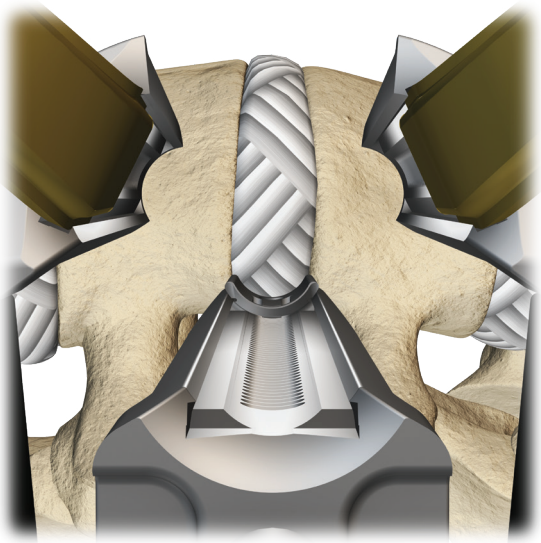
For more information on access and approach, refer to the XLIF Surgical Technique (9500138).

Dynamic Nerve Detection | Free Run EMG

NVM5 Dynamic Nerve Detection and Free Run EMG functionalities used with MaXcess are critical to a safe and reproducible XLIF procedure.



(Fig. 1)



(Fig. 2)

INSTRUMENTS/IMPLANTS USED

MaXcess Retractor | XLIF Instruments

STEP 3:

OSTEOPHYTE REMOVAL (OPTIONAL)

If osteophyte removal is required to properly seat the implant, use the Bone Mill *(Fig. 3)* or Osteophyte Removal Tool to prepare the vertebral bodies for desired implant placement.

Tip

"The dense osteophytic bone may provide high-quality screw purchase. For this reason, I remove only the most severe osteophytes before implant placement."

– Dr. William Blake Rodgers

Tip

Dynamic Nerve Detection

"I always use the NVM5 Ball Tip Probe activated with Dynamic Nerve Detection to check for nerves underneath where the Bone Mill, Trial, or implant will eventually sit."

– Dr. Jim Youssef

(Fig. 3)

INSTRUMENTS/IMPLANTS USED

21 Osteophyte Removal Tool

24 Bone Mill Guide

22 Bone Mill

26 Bone Mill Guide T-handle

STEP 4:
TRIAL AND IMPLANT PLACEMENT

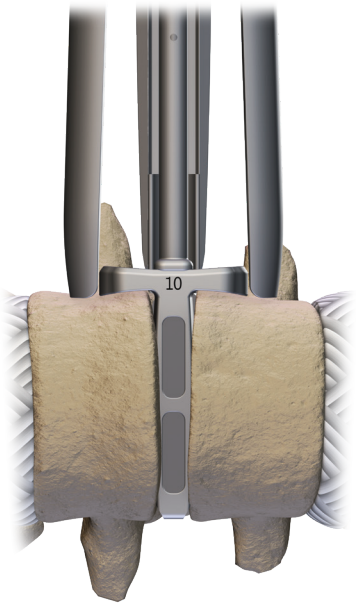
Connect the selected Trial to the Trial Inserter by tightening the thumb-wheel lock *(Fig. 4)*. Under A/P fluoroscopy, gently impact the Trial into the disc space *(Fig. 5)*. Proper anterior/posterior positioning of final Trial placement should be verified using lateral fluoroscopy.

Use sequential trialing within the disc space to help prevent endplate damage.

Note

CoRoent XL-F Trials match the implants in shape and size and are available in standard and lordotic options.

(Fig. 4)



(Fig. 5)

Tip

"Removing one or both of the MaXcess disposable light cables often helps me advance the Trial and implant through the Retractor, especially in small exposures."
– Dr. William Blake Rodgers

INSTRUMENTS/IMPLANTS USED

42 Trial Inserter
37 Trial

STEP 4:
TRIAL AND IMPLANT PLACEMENT (CONT.)

If satisfied with placement and fit of the Trial, the corresponding implant should be selected, filled with graft material, and attached to the proper size Implant Inserter *(Fig. 6)*. Implant Inserters come in sizes 8-18mm and must be used for effective implant placement.

Gently impact the implant into the disc space using A/P fluoroscopy and NVM5 Free Run EMG. In final position, the implant should rest in the middle of the disc space from an anterior/posterior perspective *(Fig. 7)*. From a medial/lateral perspective, the implant should extend to the contralateral ring apophysis *(Fig. 8)*.

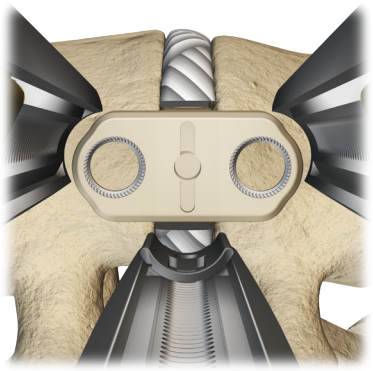
Note

If release of the Anterior Longitudinal Ligament is in the surgical plan, please refer to the XLIF ACR Surgical Technique (9501350).

Tip

"I always use lateral fluoroscopy after Trial and implant placement to check for oblique positioning. This allows me to plan for screw placement, as I do not want the screws angled excessively anterior or posterior."

– Dr. Jim Youssef



(Fig. 7)

(Fig. 6)

Note

The canted coils and implant marker rods aid in visual confirmation of implant positioning in both A/P and lateral fluoroscopy.

(Fig. 8)

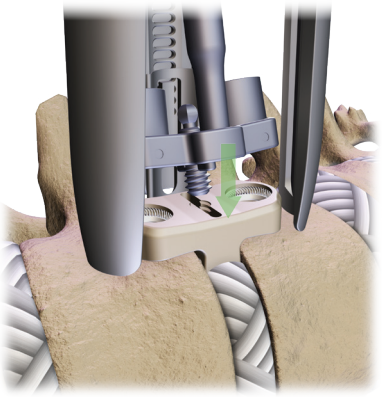
INSTRUMENTS/IMPLANTS USED

43 Implant Inserter
28 Implant
1 Implant Block
10 Tamp

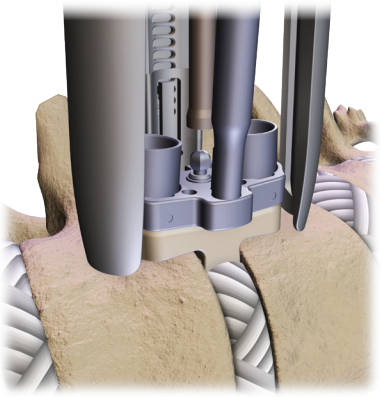
STEP 5:
DTS GUIDE PLACEMENT

Select the DTS Guide that corresponds with the height of the implant. Assemble the DTS Guide by inserting the DTS Guide Handle into the keyhole engagement feature. Secure into position by inserting the DTS Guide Retainer through the Guide Handle and fully threading it into the DTS Guide, ensuring the knurled cap is flush with the top of the Handle *(Fig. 9)*.

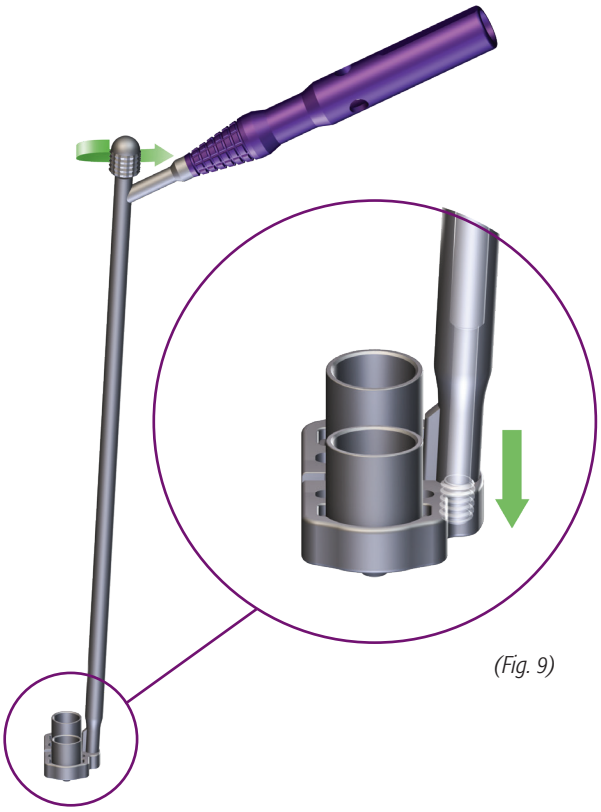
With the Guide Handle facing anterior, use the DTS Bolt Driver to attach the DTS Guide to the implant *(Figs. 10–12)*.



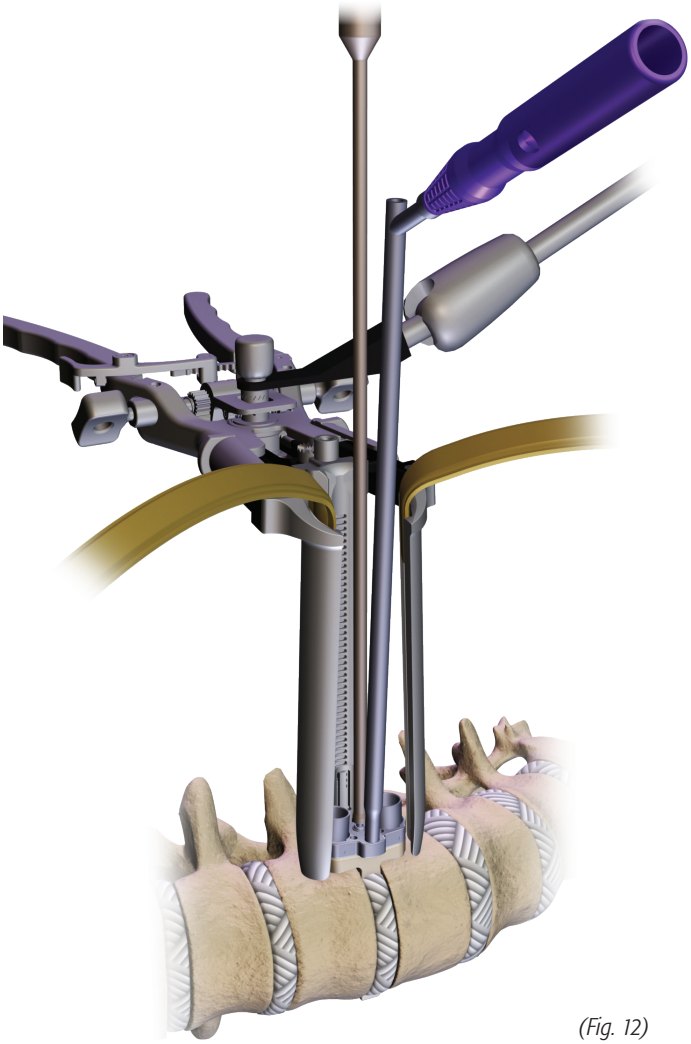
(Fig. 10)



(Fig. 11)



(Fig. 9)



(Fig. 12)

INSTRUMENTS/IMPLANTS USED

13	11	12	17
DTS Guide	DTS Guide Handle	DTS Guide Retainer	DTS Bolt Driver

NUMBERS REFERENCE INSTRUMENT/IMPLANT TRAYS

STEP 6:
PILOT HOLE PREPARATION

According to surgeon preference and anatomical requirements, a selection of Drills, Taps, and Awls are available for pilot hole preparation through the DTS Guide. Before hole preparation with the Drill and Tap, place the Variable-Angle Centering Sleeve or Fixed-Angle Centering Sleeve over the Guide barrel. The Drill Guide Awl can be used directly through the DTS Guide.

Using a select combination of the Awl, Drill, and Tap, prepare a pilot hole for subsequent screw delivery *(Fig. 13)*. Before making the next hole, deliver the desired length screw.

Note

In order to ensure desired screw trajectory, use A/P fluoroscopy during initial Drill or Awl advancement for visual confirmation of the pilot hole path.

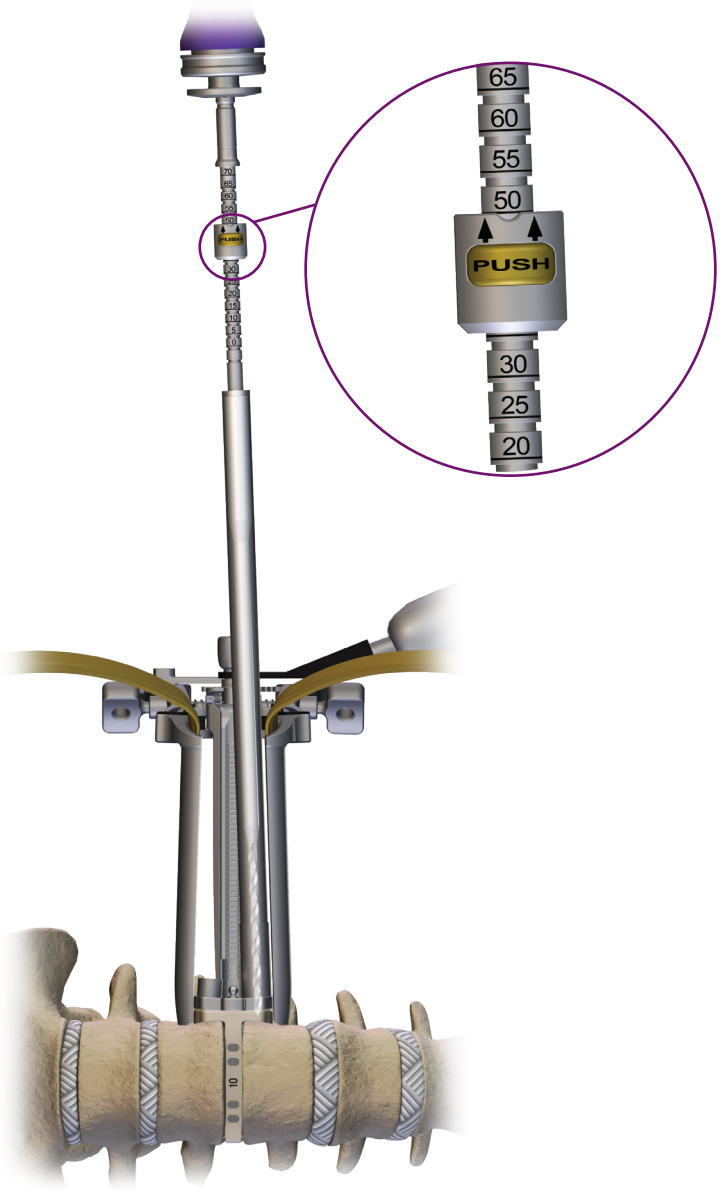
(Fig. 13)

Note

If divergent screw placement is desired, the Guides may be angled from parallel to 8°. Use the Fixed-Angle Centering Sleeve for a predefined 4° screw trajectory.

Note

During pilot hole preparation, use the adjustable-depth stops to avoid excessive advancement of instruments (Fig. 14).



(Fig. 14)

INSTRUMENTS/IMPLANTS USED

13	16	15	20	18	19
DTS Guide	Fixed-Angle Centering Sleeve	Variable-Angle Centering Sleeve	Drill Guide Awl	Drill - 5.5mm	Tap - 5.5mm

STEP 7:
SCREW PLACEMENT

Screw length is determined using interbody graft length and pilot hole depth for reference. Additional length may be needed if bicortical purchase is desired. Select the desired length variable- or fixed-angle 5.5mm screw and insert the tip of the Starter Screwdriver into the hexalobe engagement feature on the screw head. Turn the knurled section on the Starter Screwdriver clockwise to thread the Screwdriver into the screw and secure it into position *(Fig. 15)*.

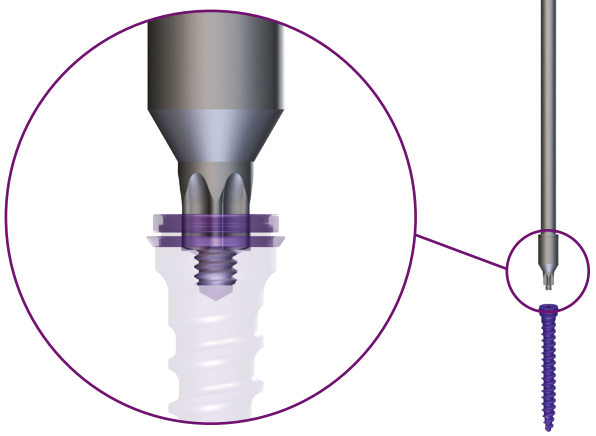
If using the DTS Guide, insert the Starter Screwdriver into the Centering Sleeve and place the screw *(Fig. 16)*. Once the screw has advanced ¾ of its path, detach the Starter Screwdriver and use the Final Screwdriver to advance the screw to its final position *(Fig. 17)*. The Final Screwdriver provides increased strength and tactile response for final screw placement and coil lock confirmation.

Note

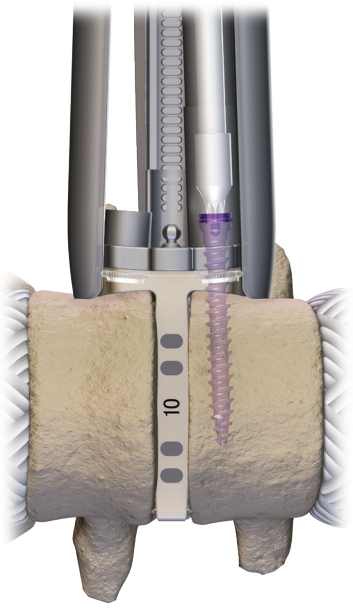
According to patient requirements, 6.5mm rescue screws are available in both variable- and fixed-angle options.

Note

The CoRoent XL-F implant system provides 25-70mm variable- and fixed-angle screws for maximum surgical accommodation.



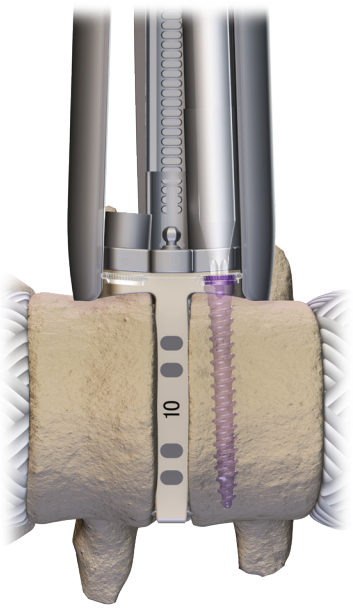
(Fig. 15)



(Fig. 16)

Note

Once the screw is 75% seated, the Starter Screwdriver must be removed to allow final placement with the Final Screwdriver.



(Fig. 17)

INSTRUMENTS/IMPLANTS USED

13	16	15	6	7	9	8	4	5
DTS Guide	Fixed-Angle Centering Sleeve	Variable-Angle Centering Sleeve	XL-F Screw Variable - 5.5mm	XL-F Screw Fixed - 5.5mm	Starter Screwdriver	Final Screwdriver	XL-F Screw Variable - 6.5mm (rescue)	XL-F Screw Fixed - 6.5mm (rescue)

NUMBERS REFERENCE INSTRUMENT/IMPLANT TRAYS

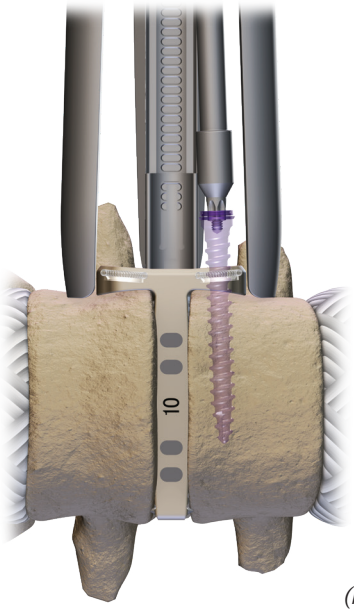
STEP 8:
FREE-HAND SCREW PLACEMENT (OPTIONAL)

As an alternative to pilot hole preparation and screw delivery through the DTS Guide, instrumentation is available for free-hand screw placement. Using the free-hand technique, place the tip of the Self-Centering Awl directly into one of the implant screw holes. When engaged, it will sit firmly inside the implant. Advance the Awl into the vertebral body until the desired depth is reached *(Fig. 18)*. Remove the Awl and use the Starter Screwdriver to insert the desired length screw directly through the implant *(Fig. 19)*. When ¾ of the screw has passed through the implant tab, detach the Starter Screwdriver and use the Final Screwdriver to advance the screw into the locked position *(Fig. 20)*.

Note

Awl depth should be closely monitored using both A/P fluoroscopy and the markings on the Awl shaft. For maximum safety when using the Self-Centering Awl, utilize the Awl's adjustable-depth stop to avoid excessive advancement of the instrument.

(Fig. 18)



(Fig. 19)

Note

Once the screw is 75% seated, the Starter Screwdriver must be removed to allow final placement with the Final Screwdriver.

(Fig. 20)

INSTRUMENTS/IMPLANTS USED

25	6	7	9	8	4	5
Self-Centering Awl	XL-F Screw Variable - 5.5mm	XL-F Screw Fixed - 5.5mm	Starter Screwdriver	Final Screwdriver	XL-F Screw Variable - 6.5mm (rescue)	XL-F Screw Fixed - 6.5mm (rescue)

NUMBERS REFERENCE INSTRUMENT/IMPLANT TRAYS

STEP 9:
FINAL PLACEMENT CONFIRMATION

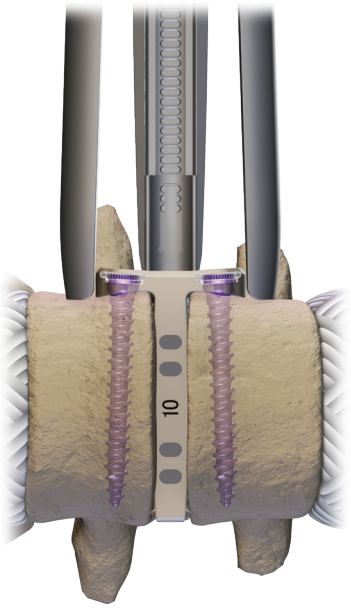
Check final placement. The implant should rest fully across the disc space under A/P fluoroscopy with the screws extending near parallel to the endplates *(Fig. 21)*. In lateral fluoroscopy, the implant should be centered in the intervertebral space from an anterior/posterior perspective *(Fig. 23)*.

Coil Lock Confirmation

Proper screw locking is confirmed by the canted coil covering the entire circumference of the screw head *(Figs. 22, 23)*. In addition, there may be a noticeable audible click and tactile sensation upon locking.

Screw and Implant Removal

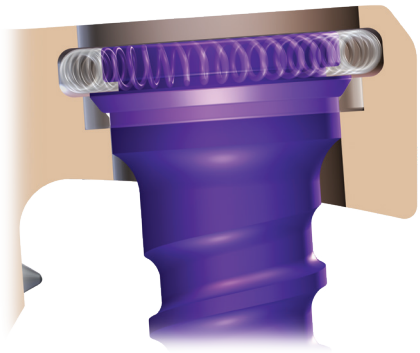
If screw removal is necessary, use the Screw Extractor to safely extract the screw from the vertebral body. The implant can also be safely removed from the intervertebral space using the Implant Inserter and a slap-hammer.



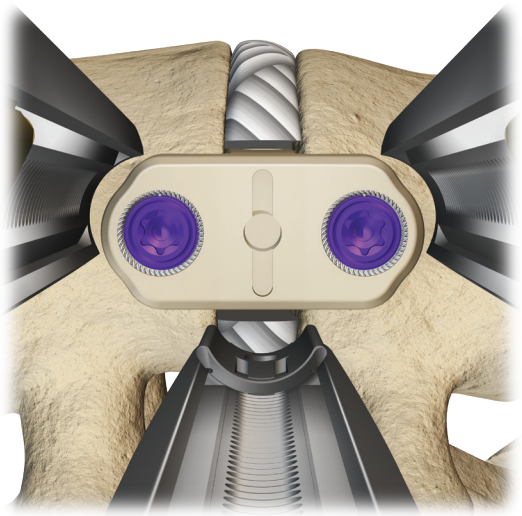
(Fig. 21)

STEP 10:
SUPPLEMENTAL FIXATION

Similar to the entire CoRoent XL family of interbody implants, CoRoent XL-F is intended to be used with supplemental internal spinal fixation.



(Fig. 22)



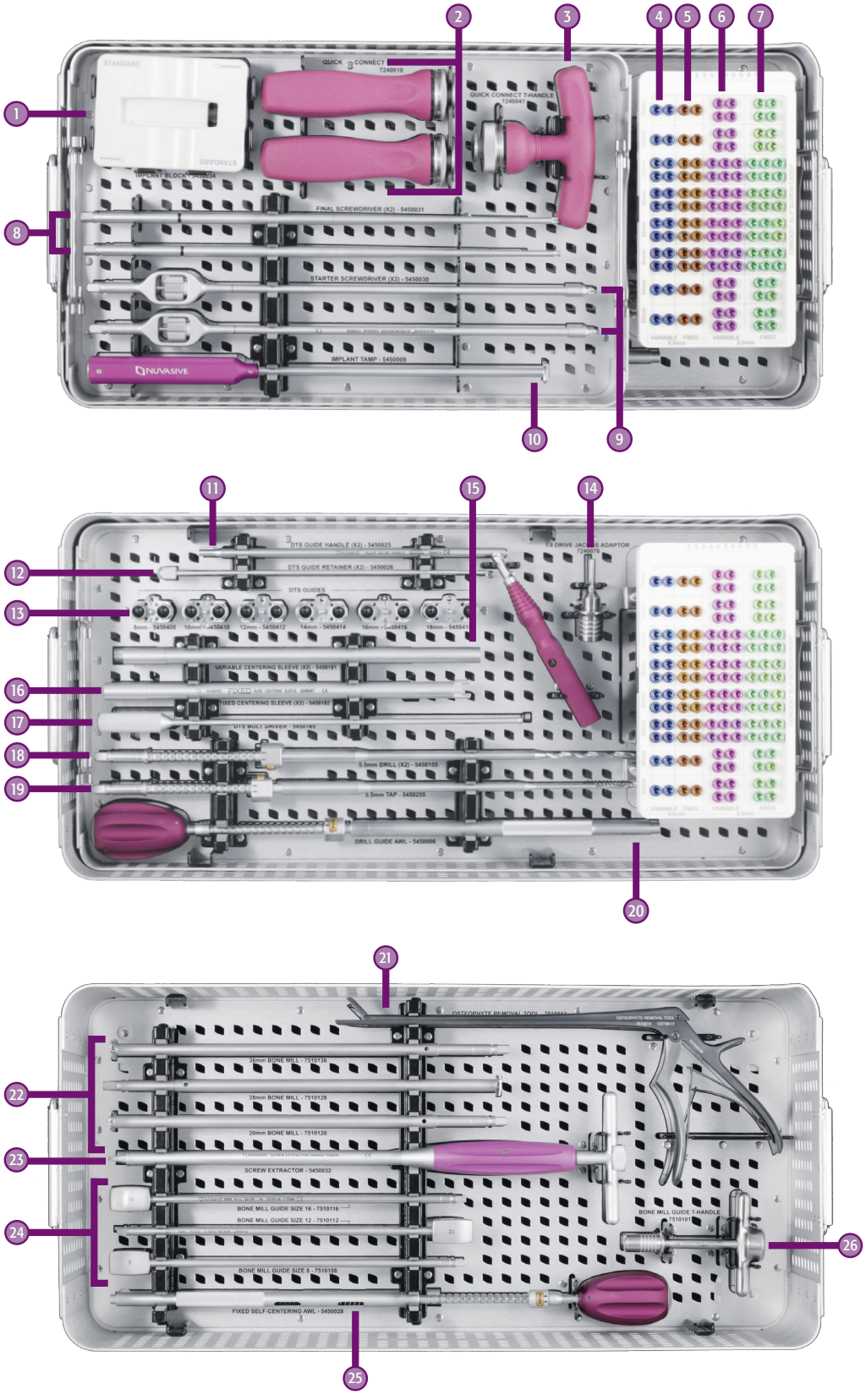
(Fig. 23)

INSTRUMENTS/IMPLANTS USED

23 Screw Extractor

43 Implant Inserter

COROENT XL-F INSTRUMENT TRAY

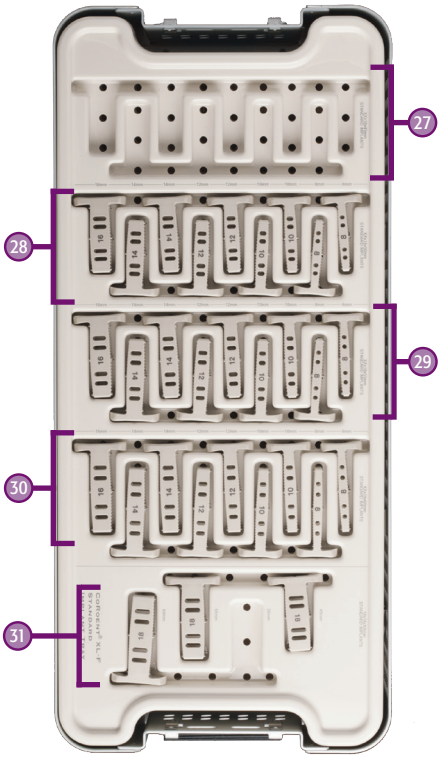


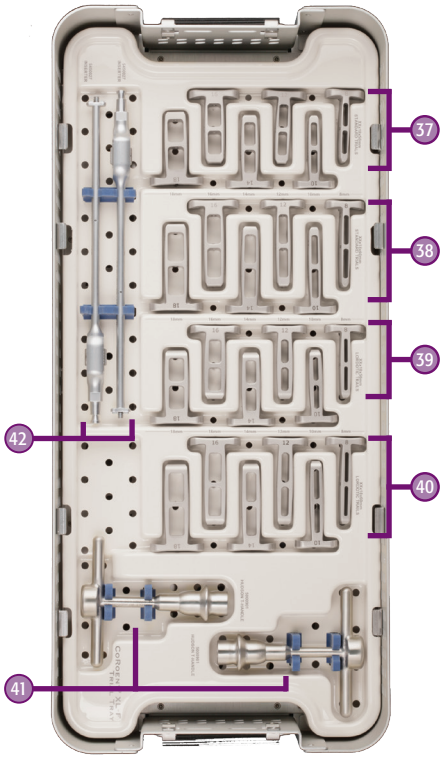
COROENT XL-F INSTRUMENT TRAY

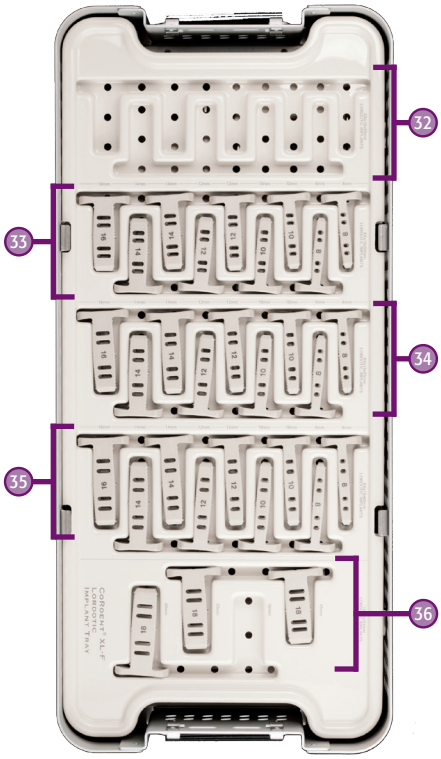
	DESCRIPTION	CATALOG #
1	CoRoent XL-F Implant Block	5450034
2	Quick Connect Straight Handle	7240010
3	Quick Connect T-handle	7240041
4	6.5 x 25mm CoRoent XL-F Screw - Variable	5486525
	6.5 x 40mm CoRoent XL-F Screw - Variable	5486540
	6.5 x 45mm CoRoent XL-F Screw - Variable	5486545
	6.5 x 50mm CoRoent XL-F Screw - Variable	5486550
	6.5 x 55mm CoRoent XL-F Screw - Variable	5486555
	6.5 x 60mm CoRoent XL-F Screw - Variable	5486560
	6.5 x 65mm CoRoent XL-F Screw - Variable	5486565
	6.5 x 70mm CoRoent XL-F Screw - Variable	5486570
5	6.5 x 25mm CoRoent XL-F Screw - Fixed	5476525
	6.5 x 40mm CoRoent XL-F Screw - Fixed	5476540
	6.5 x 45mm CoRoent XL-F Screw - Fixed	5476545
	6.5 x 50mm CoRoent XL-F Screw - Fixed	5476550
	6.5 x 55mm CoRoent XL-F Screw - Fixed	5476555
	6.5 x 60mm CoRoent XL-F Screw - Fixed	5476560
	6.5 x 65mm CoRoent XL-F Screw - Fixed	5476565
	6.5 x 70mm CoRoent XL-F Screw - Fixed	5476570
6	5.5 x 25mm CoRoent XL-F Screw - Variable	5485525
	5.5 x 40mm CoRoent XL-F Screw - Variable	5485540
	5.5 x 45mm CoRoent XL-F Screw - Variable	5485545
	5.5 x 50mm CoRoent XL-F Screw - Variable	5485550
	5.5 x 55mm CoRoent XL-F Screw - Variable	5485555
	5.5 x 60mm CoRoent XL-F Screw - Variable	5485560
	5.5 x 65mm CoRoent XL-F Screw - Variable	5485565
	5.5 x 70mm CoRoent XL-F Screw - Variable	5485570
7	5.5 x 25mm CoRoent XL-F Screw - Fixed	5475525
	5.5 x 40mm CoRoent XL-F Screw - Fixed	5475540
	5.5 x 45mm CoRoent XL-F Screw - Fixed	5475545
	5.5 x 50mm CoRoent XL-F Screw - Fixed	5475550
	5.5 x 55mm CoRoent XL-F Screw - Fixed	5475555
	5.5 x 60mm CoRoent XL-F Screw - Fixed	5475560
	5.5 x 65mm CoRoent XL-F Screw - Fixed	5475565
	5.5 x 70mm CoRoent XL-F Screw - Fixed	5475570
8	Final Screwdriver	5450031
9	Starter Screwdriver	5450030
10	CoRoent XL-F Tamp	5450009

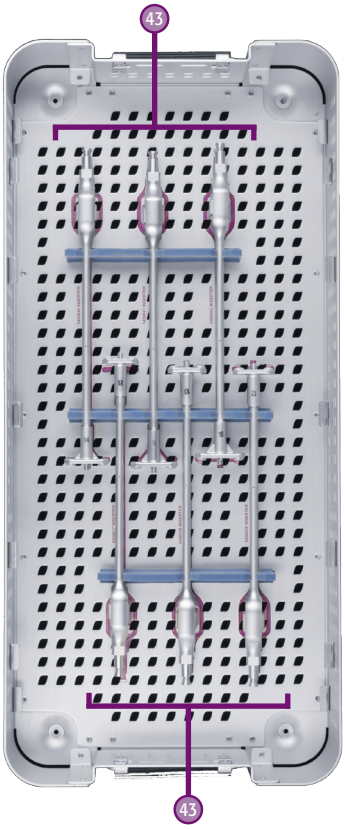
	DESCRIPTION	CATALOG #
11	DTS Guide Handle	5450025
12	DTS Guide Retainer	5450026
13	DTS Guide - 8mm	5450408
	DTS Guide - 10mm	5450410
	DTS Guide - 12mm	5450412
	DTS Guide - 14mm	5450414
	DTS Guide - 16mm	5450416
	DTS Guide - 18mm	5450418
14	1/4-Drive Jacobs Adaptor	7240076
15	Centering Sleeve - Variable-Angle	5450101
16	Centering Sleeve - Fixed-Angle	5450102
17	DTS Bolt Driver	5450165
18	Drill - 5.5mm	5450155
19	Tap - 5.5mm	5450255
20	Drill Guide Awl	5450006
21	Osteophyte Removal Tool	7510013
22	Bone Mill - 20mm	7510120
	Bone Mill - 28mm	7510128
	Bone Mill - 36mm	7510136
23	Screw Extractor	5450032
24	Bone Mill Guide - Size 8	7510108
	Bone Mill Guide - Size 12	7510112
	Bone Mill Guide - Size 16	7510116
25	Self-Centering Awl	5450028
26	Bone Mill Guide T-handle	7510101

COROENT XL-F IMPLANT TRAY









COROENT XL-F IMPLANT TRAY

	DESCRIPTION	CATALOG #
27	8 x 18 x 45mm CoRoent XL-F Implant	7860845
	10 x 18 x 45mm CoRoent XL-F Implant	7861045
	12 x 18 x 45mm CoRoent XL-F Implant	7861245
	14 x 18 x 45mm CoRoent XL-F Implant	7861445
	16 x 18 x 45mm CoRoent XL-F Implant	7861645
28	8 x 18 x 50mm CoRoent XL-F Implant	7860850
	10 x 18 x 50mm CoRoent XL-F Implant	7861050
	12 x 18 x 50mm CoRoent XL-F Implant	7861250
	14 x 18 x 50mm CoRoent XL-F Implant	7861450
	16 x 18 x 50mm CoRoent XL-F Implant	7861650
29	8 x 18 x 55mm CoRoent XL-F Implant	7860855
	10 x 18 x 55mm CoRoent XL-F Implant	7861055
	12 x 18 x 55mm CoRoent XL-F Implant	7861255
	14 x 18 x 55mm CoRoent XL-F Implant	7861455
	16 x 18 x 55mm CoRoent XL-F Implant	7861655
30	8 x 18 x 60mm CoRoent XL-F Implant	7860860
	10 x 18 x 60mm CoRoent XL-F Implant	7861060
	12 x 18 x 60mm CoRoent XL-F Implant	7861260
	14 x 18 x 60mm CoRoent XL-F Implant	7861460
	16 x 18 x 60mm CoRoent XL-F Implant	7861660
31	18 x 18 x 45mm CoRoent XL-F Implant	7861845
	18 x 18 x 50mm CoRoent XL-F Implant	7861850
	18 x 18 x 55mm CoRoent XL-F Implant	7861855
	18 x 18 x 60mm CoRoent XL-F Implant	7861860
32	8 x 18 x 45mm CoRoent XL-F Lordotic Implant	7870845
	10 x 18 x 45mm CoRoent XL-F Lordotic Implant	7871045
	12 x 18 x 45mm CoRoent XL-F Lordotic Implant	7871245
	14 x 18 x 45mm CoRoent XL-F Lordotic Implant	7871445
	16 x 18 x 45mm CoRoent XL-F Lordotic Implant	7871645
33	8 x 18 x 50mm CoRoent XL-F Lordotic Implant	7870850
	10 x 18 x 50mm CoRoent XL-F Lordotic Implant	7871050
	12 x 18 x 50mm CoRoent XL-F Lordotic Implant	7871250
	14 x 18 x 50mm CoRoent XL-F Lordotic Implant	7871450
	16 x 18 x 50mm CoRoent XL-F Lordotic Implant	7871650
34	8 x 18 x 55mm CoRoent XL-F Lordotic Implant	7870855
	10 x 18 x 55mm CoRoent XL-F Lordotic Implant	7871055
	12 x 18 x 55mm CoRoent XL-F Lordotic Implant	7871255
	14 x 18 x 55mm CoRoent XL-F Lordotic Implant	7871455
	16 x 18 x 55mm CoRoent XL-F Lordotic Implant	7871655
35	8 x 18 x 60mm CoRoent XL-F Lordotic Implant	7870860
	10 x 18 x 60mm CoRoent XL-F Lordotic Implant	7871060
	12 x 18 x 60mm CoRoent XL-F Lordotic Implant	7871260
	14 x 18 x 60mm CoRoent XL-F Lordotic Implant	7871460
	16 x 18 x 60mm CoRoent XL-F Lordotic Implant	7871660
36	18 x 18 x 45mm CoRoent XL-F Lordotic Implant	7871845
	18 x 18 x 50mm CoRoent XL-F Lordotic Implant	7871850
	18 x 18 x 55mm CoRoent XL-F Lordotic Implant	7871855
	18 x 18 x 60mm CoRoent XL-F Lordotic Implant	7871860

	DESCRIPTION	CATALOG #
37	8 x 18 x 50mm CoRoent XL-F Trial	6931508
	10 x 18 x 50mm CoRoent XL-F Trial	6931510
	12 x 18 x 50mm CoRoent XL-F Trial	6931512
	14 x 18 x 50mm CoRoent XL-F Trial	6931514
	16 x 18 x 50mm CoRoent XL-F Trial	6931516
	18 x 18 x 50mm CoRoent XL-F Trial	6931518
38	8 x 18 x 60mm CoRoent XL-F Trial	6931708
	10 x 18 x 60mm CoRoent XL-F Trial	6931710
	12 x 18 x 60mm CoRoent XL-F Trial	6931712
	14 x 18 x 60mm CoRoent XL-F Trial	6931714
	16 x 18 x 60mm CoRoent XL-F Trial	6931716
	18 x 18 x 60mm CoRoent XL-F Trial	6931718
39	8 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930508
	10 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930510
	12 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930512
	14 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930514
	16 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930516
	18 x 18 x 50mm CoRoent XL-F Lordotic Trial	6930518
40	8 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930708
	10 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930710
	12 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930712
	14 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930714
	16 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930716
	18 x 18 x 60mm CoRoent XL-F Lordotic Trial	6930718
41	Hudson T-handle	1001992
42	CoRoent XL-F Trial Inserter	5450027
43	Implant Inserter - Size 8	5450037
	Implant Inserter - Size 10	5450038
	Implant Inserter - Size 12	5450039
	Implant Inserter - Size 14	5450040
	Implant Inserter - Size 16	5450041
	Implant Inserter - Size 18	5450042

INSTRUCTIONS FOR USE

DESCRIPTION

The NuVasive CoRoent XL-F System is manufactured from PEEK-Optima LT-1 conforming to ASTM F2026, MP35N conforming to ASTM F562, and titanium alloy conforming to ASTM F136 and ISO 5832-3. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

INDICATIONS FOR USE

The NuVasive CoRoent XL-F System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion.

The CoRoent XL-F System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to L5, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non operative treatment. The system is intended to be used with supplemental internal spinal fixation systems (e.g., pedicle or facet screws) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

CONTRAINDICATIONS

Contraindications include but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

It is important to select the appropriate length screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

Based on bench testing, resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the implant for greater sagittal correction, when used with supplemental fixation per the indications, and aid in preventing potential end plate damage.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or non-union. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Additional care should be taken at the lower levels of the lumbar spine due to the obstruction of anatomical structures, such as the iliac crest and iliac vessels, surgical access for the subject device at the these levels may not be feasible.

PATIENT EDUCATION: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

SINGLE USE: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

MAGNETIC RESONANCE (MR) SAFETY: The CoRoent XL-F System has not been evaluated for safety and compatibility in the MR environment. The CoRoent XL-F System has not been tested for heating or migration in the MR environment.

COMPATIBILITY: Do not use the CoRoent XL-F System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POSTOPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

NOTES

To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:
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