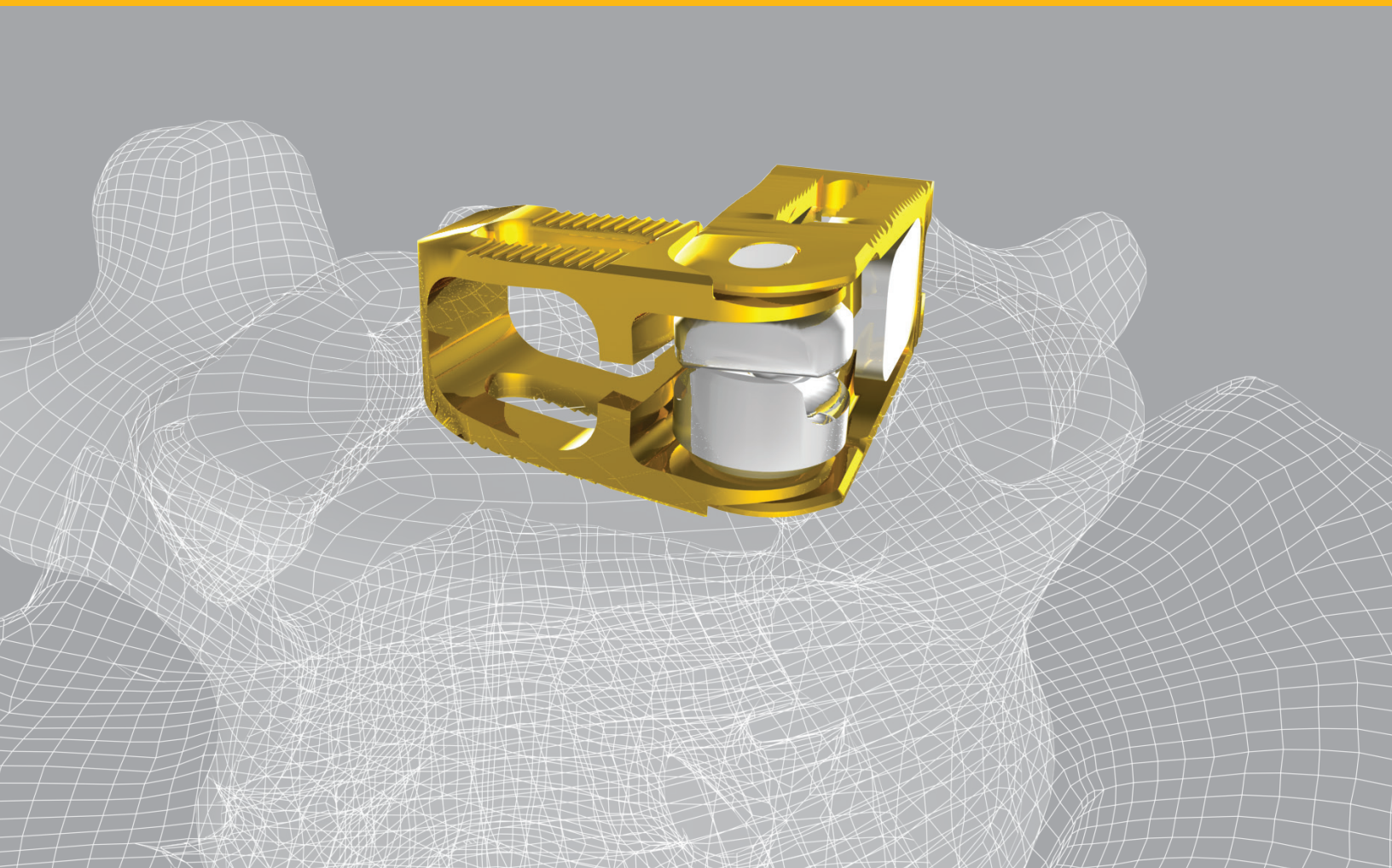
CoreLink
The Source for Spine™

FLXFIT®15 EXPANDABLE POSTERIOR LUMBAR FUSION SYSTEM

Surgical Technique Guide



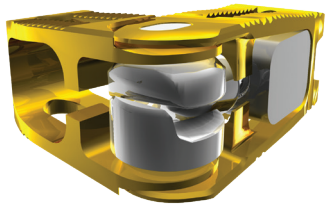
THE FLXFIT15 ADVANTAGE

FLXfit15 is a revolutionary posterior lumbar fusion device designed to maximize lordosis correction by offering up to 15 degrees of controlled in-situ expansion for sagittal balance restoration. The articulating footprints streamline device insertion and maximize anterior lumbar support and endplate surface coverage.

TABLE OF CONTENTS

FLXFIT15 PRODUCT OVERVIEW

The FLXfit15 devices are manufactured from medical grade Titanium (Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)) alloy for surgical implant applications (UNS R56401).



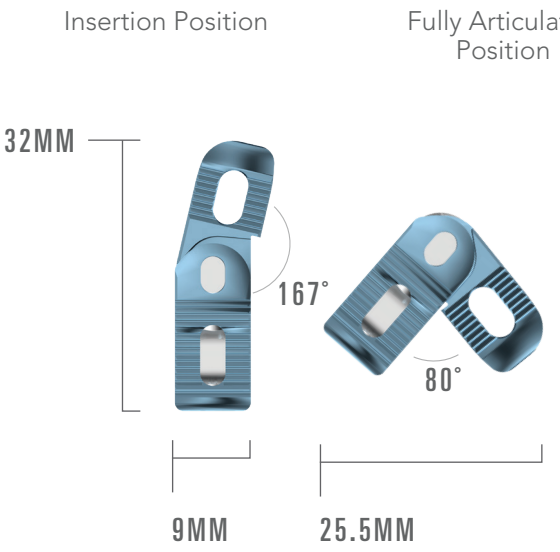
SYSTEM FEATURES

- Allows for controlled, in-situ lordotic expansion with a minimal insertion profile. Up to 15 degrees/4mm of anterior height restoration beyond the device's height at insertion.
- Articulating design streamlines open or MIS TLIF approach insertion, navigation in disc space, and wide endplate surface contact.
- Bullet-nosed to facilitate ease of insertion.
- Inferior and superior surfaces of the cages include teeth intended to resist cage migration.
- Open device architecture enables graft material packing to promote fusion.
- Single instrument with easy two–step procedure for insertion and expansion of the implant.

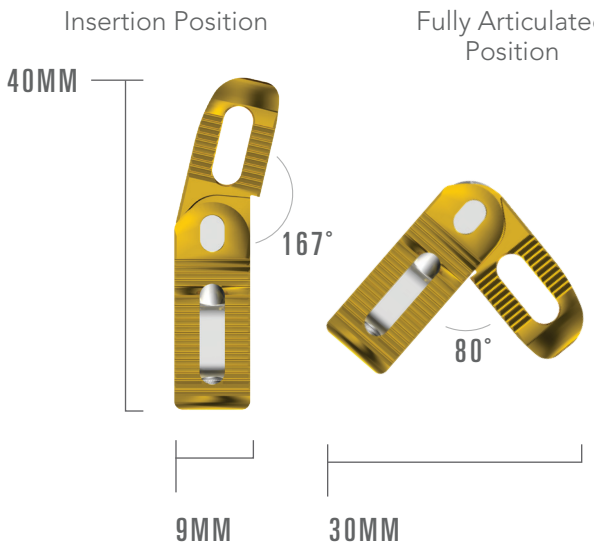
FOOTPRINT DIMENSIONS

The FLXfit15 system includes two footprints and primary heights ranging from 8mm – 13mm prior to expansion:

32MM x 9MM



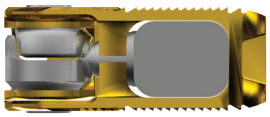
40MM x 9MM



FLXFIT15 PRODUCT OVERVIEW

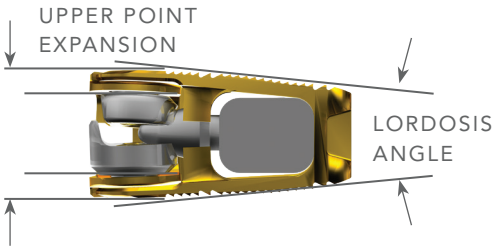
UNEXPANDED

UNEXPANDED / SIDE IMAGE



EXPANDED

EXPANDED / SIDE IMAGE



PRE-OPERATIVE PLANNING AND PREPARATION

Pre-operative planning is recommended for the precise identification and selection of the proper size and length of FLXfit15 implants.

PATIENT POSITIONING

The patient is positioned prone, which promotes suitable exposure. Proper attention is taken to restore sagittal alignment.

ACCESS AND EXPOSURE

LOCATE THE CORRECT OPERATIVE LEVEL

- Locate the correct operative level with fluoroscopic views.
- FLXfit15 can be used in MIS or open procedures.

OPEN TLIF OR PLIF APPROACH

- Make a standard MIS or open incision.
- Retract the muscle layer to view the desired segment.

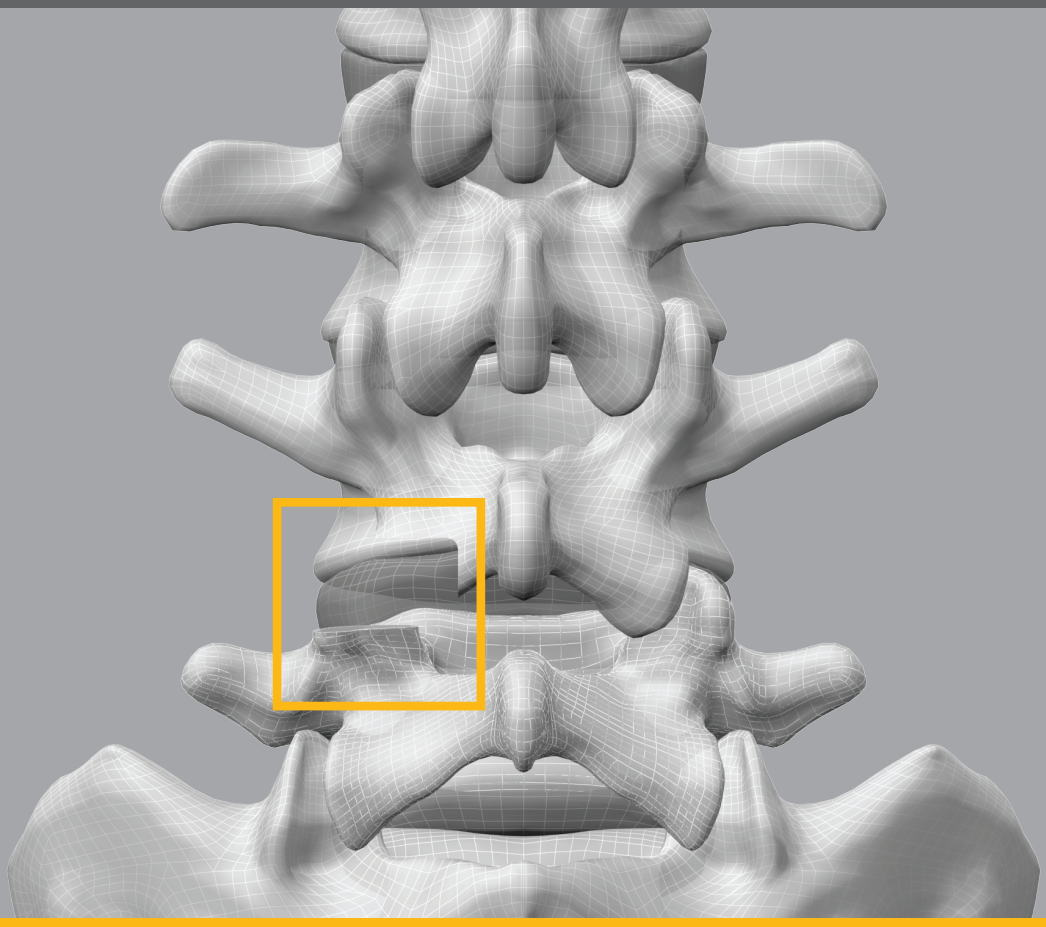
CUT TRANSFORAMINAL WINDOW

- Prepare a window to remove respective facet bone to allow access to the desired disc level.

OPTIONAL: RETRACTION WITH AN OPEN TRANSFORAMINAL APPROACH

- Make a standard open incision, retract the muscle layer to view the desired segment.
- Distract the segment if desired.
- Position a Lamina Spreader at the base of the spinous processes of the appropriate levels.
- Distract carefully until required distraction is achieved.

OPEN TLIF OR PLIF APPROACH



DISCECTOMY

Through an incision above the pedicle, access the foramen and remove disc material, using any of the standard discectomy instruments. See the Product Listing on page 30 for a complete listing of disc prep instruments.

The annulus must be preserved to provide additional support for FLXfit15 and to prevent migration of bone graft into the spinal canal.

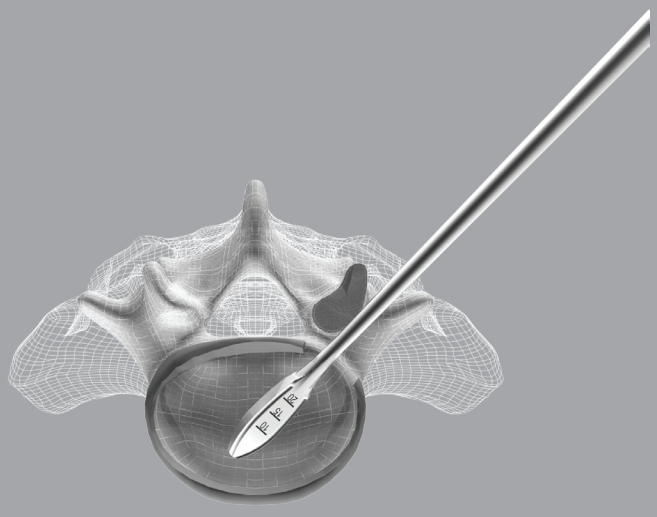
NOTES:

- Make sure to clean the disc space medially and on the contralateral side to allow for full insertion of FLXfit15.
- When the use of a mallet is necessary, it must be used gradually and gently to avoid damage to adjacent structures.
- Spreaders may be used for distraction on the contralateral side.
- Shavers may be used for disc space height measurement.

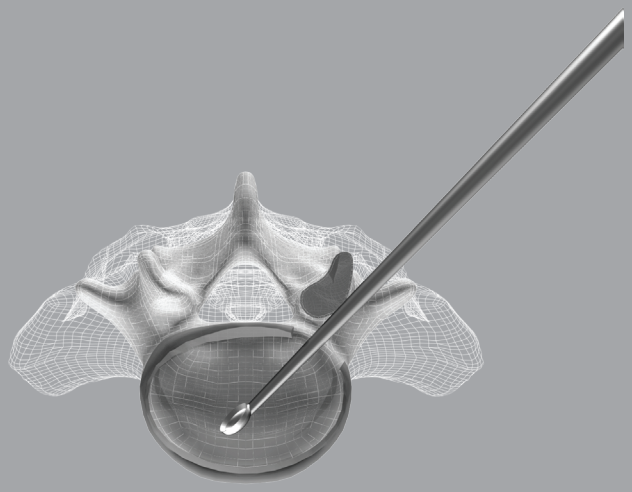
CAUTION:

- Provide enough lateral exposure to the disc to minimize dural retraction.
- Avoid any penetration of the cortical bone when roughening the surfaces of the vertebral endplates.
- Shavers must be introduced progressively (from 8mm to 13mm).

DISC SHAVER IN DISC SPACE



CURETTE IN DISC SPACE



DISC SPACE PREPARATION

PREPARE ENDPLATES

When the discectomy is completed, use the rasp to remove the superficial cartilaginous layers of the endplates to expose the bleeding bone.

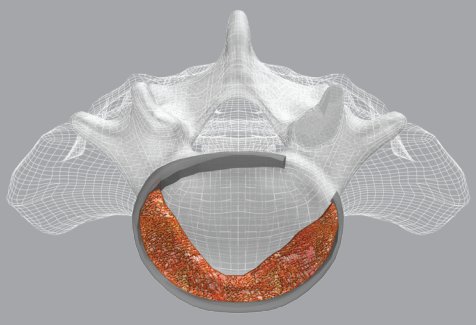
CAUTION:

Excessive exposure of the subchondral bone or excessive removal of the endplate will weaken the vertebral endplate and will result in device subsidence and a loss of segmental stability.

OPTIONAL: PACK DISC SPACE

Before the FLXfit15 is implanted, the anterior disc space may be filled with autogenous bone graft leaving enough space for the Trials to be positioned in the appropriate place. Post-packing the posterior disc space with autograft is recommended.

DISC SPACE PACKED



TRIALS FOR IMPLANT SIZE

ASSEMBLY OF FLXFIT15 INSERTER FOR TRIALING

The same inserter is used to insert the trials and FLXfit15 cage.

Pre-operative Inserter assembly is required.

Post-operative Inserter disassembly is required prior to instrument cleaning and sterilization.

The FLXfit15 Inserter components include:

- Lock/Unlock Slide
- Inner Shaft
- Outer Shaft with attached 90° Handle*

LOCK/UNLOCK SLIDE

INNER SHAFT

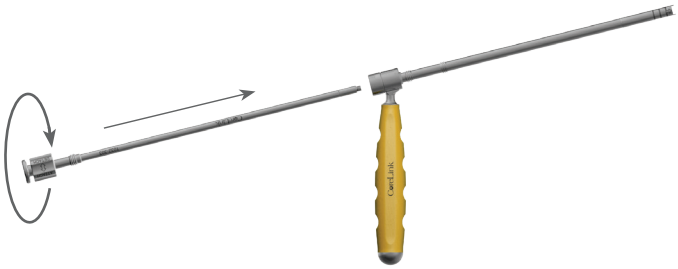
OUTER SHAFT

STRAIGHT INSERTER AVAILABLE UPON REQUEST

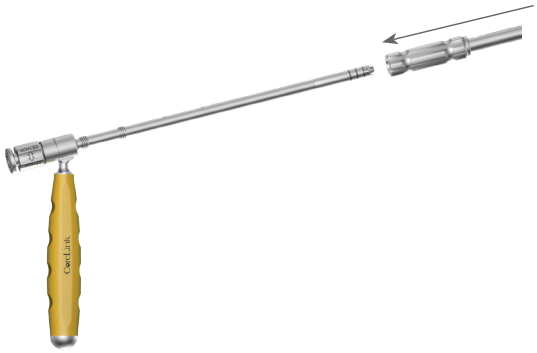
ASSEMBLY OF FLXFIT15 INSERTER FOR TRIALING (CONTINUED)

The FLXfit15 Inserter must be assembled before connection to the Trial.

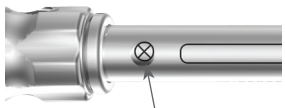
1. Slide the Inner Shaft through the Outer Shaft and then turn clockwise until the Inner Shaft is completely threaded into the Outer Shaft.



2. Slide the Lock/Unlock Slide over the Outer Shaft, making sure that the flat area on the distal tip of the Lock/Unlock Slide is aligned correctly by viewing the black line on the Inner Shaft through the small window opening on the Lock/Unlock Slide.

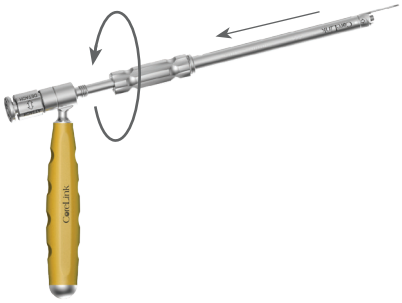


MARKINGS ON INNER INSERTER SHAFT



Make sure the Inner Shaft's black line is viewed through the opening

3. Slide the Lock/Unlock Slide until it stops and rotate the knob counterclockwise until completely tightened into the second set of internal threads.



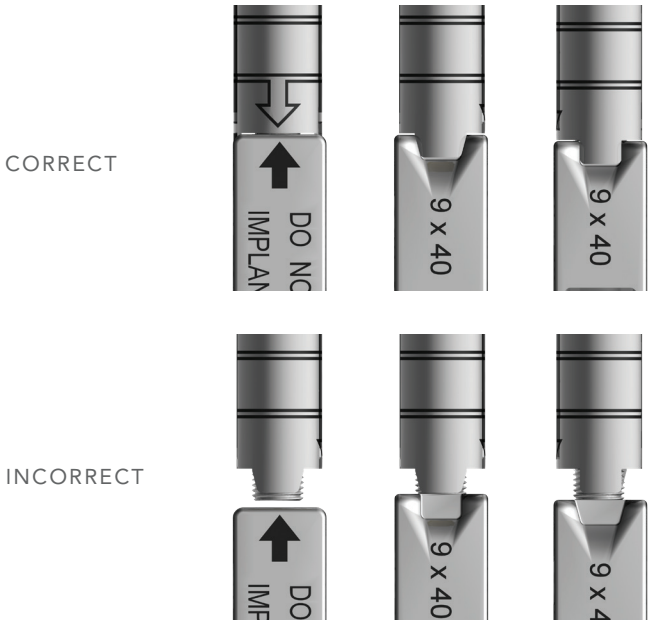
CONNECTING TRIAL TO THE FLXFIT15 INSERTER

1. Ensure that the FLXfit15 Inserter is in its unlocked position. The unlock mark will appear in the Slide window. This will ensure the Lock Slide is out of the way.

2. Choose the appropriately sized Trial. The appropriate size may be selected by measuring the disc space height using a Shaver.

3. Attach the appropriately sized Trial to the FLXfit15 Inserter by turning the Inner Shaft clockwise until its tip threads into the proximal end of the Trial.

   Note: Align the arrows and the notches on the Trial and Inserter. The contact surfaces between the implant and the Inserter should have no gap.



4. Turn the Implant Unlock/Lock Slide Knob clockwise and advance the Lock Slide forward until it stops against the Trial.

   Note: The Trial cannot articulate once the Lock/Unlock Slide is in the Locked position. The Lock mark should appear in the Outer Shaft's window.

TRIAL INSERTION

Insert the Trial into the disc space, ensuring that the orientation of the Trial is correct by verifying that the line marked on the Lock/Unlock Slide faces the sagittal plane. The distal tip of the Trial should be orientated medially. Maintain 10 – 45 degrees inclination between the FLXfit15 Inserter and the sagittal plane during Trial insertion. Forty degrees is recommended.

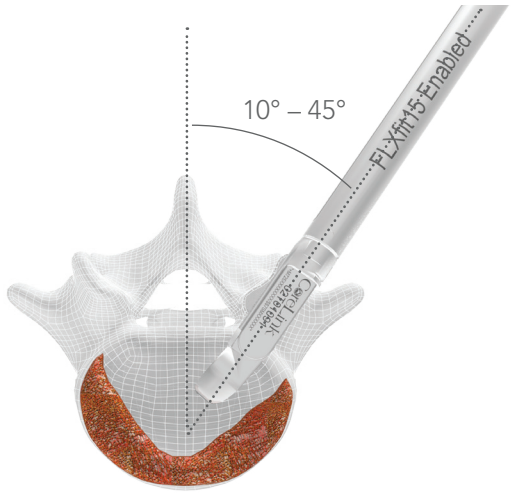
Controlled and light malleting on the Inserter may be required to advance the Trial into the intervertebral disc space. Use fluoroscopy to confirm position and fit of the Trial. Use the Lateral view to observe the Trial markers and the A/P view to ensure optimal medial positioning.

NOTES:

- Make sure that the Trial is inserted while its upper and lower surfaces are parallel to the vertebrae endplates.
- Do not apply excessive force on the instruments.
- Firm connection between the Trial and Inserter should be checked before insertion, by applying manual pressure on the lateral side of the Trial with the thumb. Trial should not pivot during insertion.
- Use soft tissue retractor to protect soft tissue.
- Use fluoroscopy during the insertion to confirm anterior positioning of the Trial.

IMPORTANT:

Monitor the advancement of Trial with radiographic imaging. Be cautious to avoid annulus damage.



TRIAL/CAGE INSERTION ANGLE

LOCK/UNLOCK SLIDE WITH BLACK SAGITTAL ETCHED LINE VISIBLE

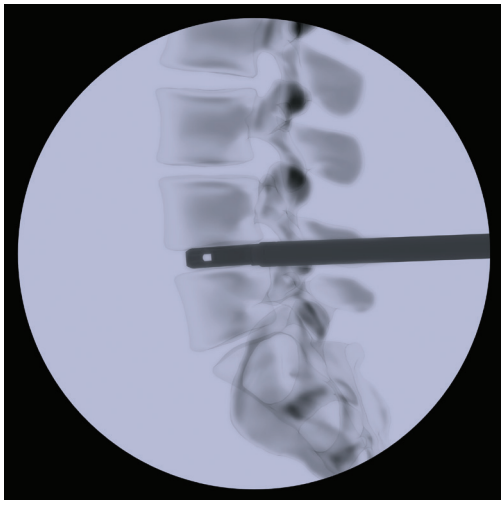
TRIAL POSITIONING

Unlock the Trial's articulation by turning sleeve counterclockwise while pulling it back all the way until it stops. The Unlock mark should appear in the window.

NOTE:

Before unlocking the Trial, confirm with fluoroscopy that the Trial articulation point has passed beyond the annulus entry point.

Controlled and light malleting on the Inserter may be required to pivot the Trial into final position. Use fluoroscopy to confirm fit and position of the Trial.



LATERAL FLUORO IMAGE PRIOR TO TRIAL ARTICULATION

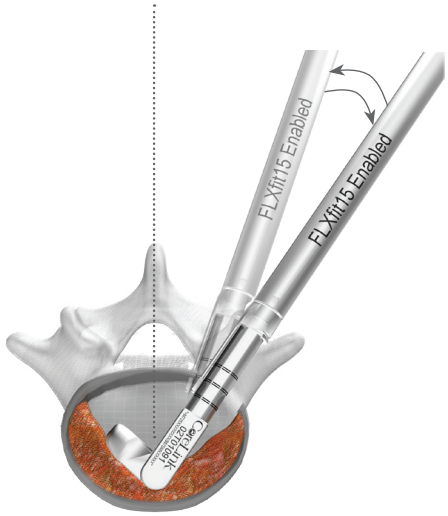
TRIAL POSITIONING (CONTINUED)

Each Trial has a middle notch and distal opening for position confirmation.

If the Trial appears and/or feels too small or too large, try the next smaller or larger size height until the most secure fit is achieved.

If Trial does not articulate freely into place, turn the Inserter handle medially to initiate pivoting upon impaction.

After pivoting is initiated, the Inserter handle must be turned back to an angle of 10 – 45 degrees from the sagittal plane to pivot the Trial into final position.



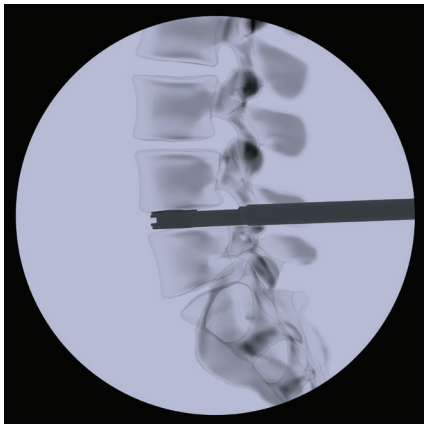
TRIAL ARTICULATED IN DISC SPACE

WARNING:

- **Do not implant the Trial.**
- **Never detach Trial from Inserter while in situ.**

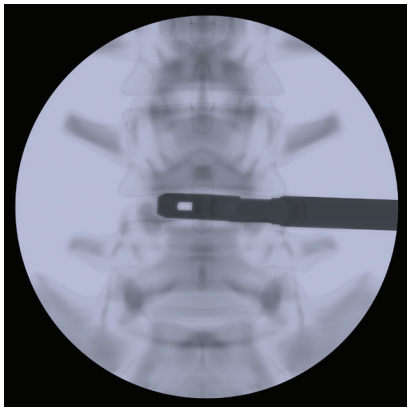
NOTES:

- Ensure that the Trial is positioned as the implant will be placed.
- Optimal placement is obtained when the articulation point is anterior and center in the disc space.
- Due to variations in radiographic magnification, the Trials only provide an estimate of the ideal implant size radiographic fit.
- The Trial has no height expansion and provides an indication to implant positioning and length.
- The implant will expand after insertion ensuring a tight fit and lordotic angle correction.
- If Trial is not well positioned within the disc space, remove Trial and further prepare the disc space.

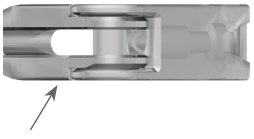


LATERAL FLUORO IMAGE - MIDDLE NOTCH VISIBLE (TRIAL ARTICULATED)

SIDE VIEW OF ARTICULATED TRIAL (ARROW TOWARD VISIBLE NOTCH)



A/P FLUORO IMAGE OF TRIAL IN THE DISC SPACE - DISTAL OPENING VISIBLE

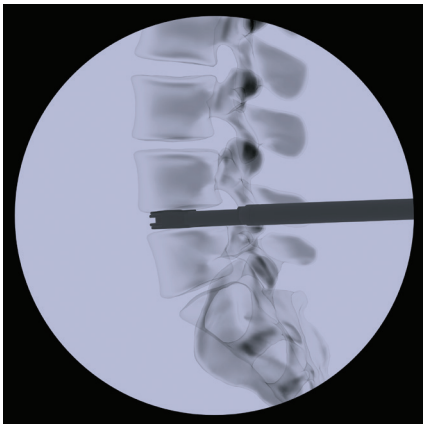


ANTERIOR VIEW OF ARTICULATED TRIAL (ARROW TOWARD VISIBLE OPENING)

CORRECT TRIAL POSITIONING

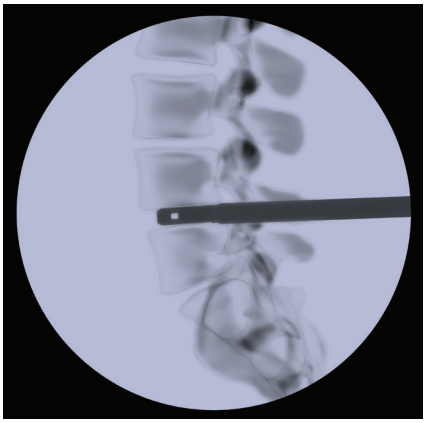
Correct positioning of Trial must be confirmed with fluoroscopy. "Correct" positioning is observed through the Trial's window marking near the anterior part.

CORRECT

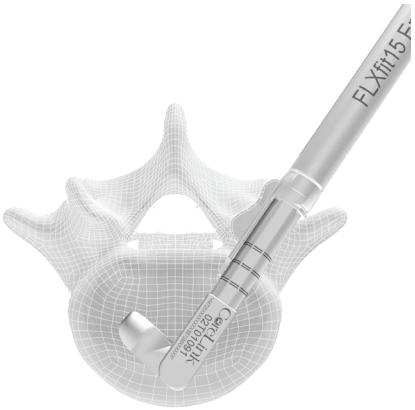


LATERAL FLUORO SHOT OF CORRECT TRIAL POSITION (TRIAL ARTICULATED)

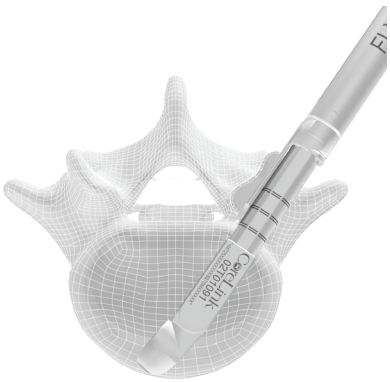
INCORRECT



LATERAL FLUORO SHOT OF INCORRECT TRIAL POSITION (TRIAL NOT ARTICULATED)



AXIAL VIEW OF CORRECT TRIAL POSITION (TRIAL ARTICULATED)



AXIAL VIEW OF INCORRECT TRIAL POSITION (TRIAL NOT ARTICULATED)

TRIAL REMOVAL

IMPORTANT:

The FLXfit15 Inserter's Lock/Unlock Slide must be in the unlock position to remove the Trial from the intervertebral disc space.

If needed, slide the Slide Hammer onto the end of the implant Holder Knob.

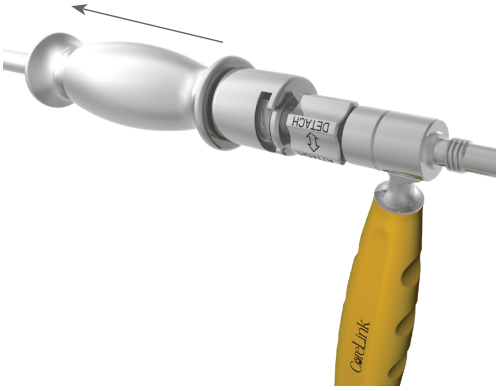
While holding the Inserter handle with one hand, apply an upward force to the Slide Hammer with the other hand. Repeat this procedure until the Trial is removed.

To detach the Trial from the Inserter, turn the Inner Shaft counterclockwise until the Trial is free.

WARNING:

Never detach Trial from Inserter while in situ.

TRIAL AND SLIDE HAMMER CONNECTION



TRIAL REMOVAL WITH SLIDE HAMMER

IMPLANT PREPARATION

SELECT IMPLANT

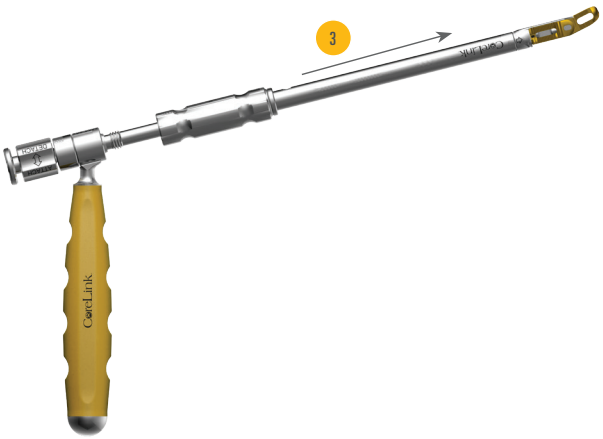
Select the FLXfit15 implant that corresponds to the height and length measured using the Trial in the previous steps.

CONNECT IMPLANT TO THE FLXfit15 INSERTER

The same Inserter used during trialing will be used again to insert the implant.

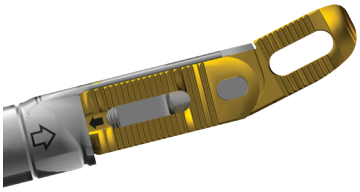
1. Ensure that FLXfit15 Inserter is in the unlock position. The unlock mark will appear in the Outer Slide window.
2. Attach the implant to the Inserter by turning the Inner Shaft clockwise until implant is attached.
3. Rotate and slide the Lock Slide clockwise and forward until it stops against the implant. The lock mark should appear in the Slide window.

CONNECTING CAGE TO INSERTER



CAGE ATTACHED TO INSERTER

When the Lock/Unlock Slide contacts the implant, the implant cannot articulate.



CAGE ATTACHED TO INSERTER WITH LOCK SLIDE IN THE LOCKED POSITION

LOCK/UNLOCK MARK IN SLIDE WINDOW

IMPORTANT:

- Ensure that the arrow on the end of the Inserter aligns with one of the arrows on the implant. There should be no gap between the tip of the inserter and the implant.

CORRECT

INCORRECT

PACK IMPLANT WITH AUTOGENOUS BONE GRAFT

Autogenous graft packing is done manually. It is important to fill the implant until the material protrudes from its windows to ensure maximum contact with the vertebral endplates.

IMPLANT INSERTION AND EXPANSION

INSERT IMPLANT

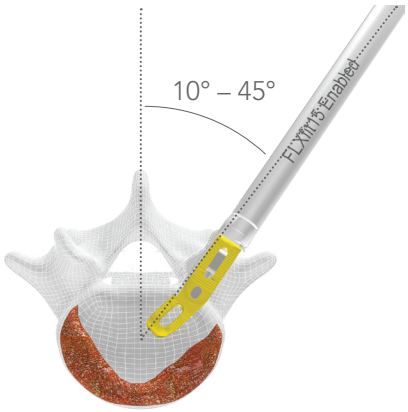
Confirm secure connection between implant and Inserter.

Insert the implant into the disc space, ensuring that the orientation of the implant is correct by verifying that the line on the Lock Slide faces the sagittal plane.

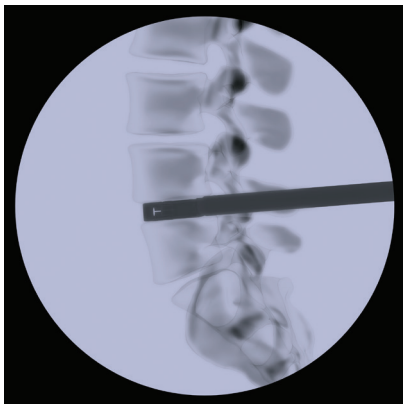
The implant tip should be orientated medially. Maintain 10 – 45 degrees inclination between the Inserter handle and the sagittal plane during implant insertion.

Controlled and light malleting on the Inserter may be required to advance the implant into the intervertebral disc space.

Use fluoroscopy to confirm position and fit of the implant.



CAGE AND INSERTER ENTERING IN DISC SPACE



LATERAL FLUORO IMAGE OF CAGE
IN DISC SPACE PRIOR TO ARTICULATION

CAUTION:

- Make sure that the implant is inserted while its upper and lower surfaces are parallel to the vertebral endplates.
- Do not apply excessive force on the instruments.
- FLXfit15 Inserter can be checked manually by applying pressure on the lateral side of the implant with the thumb. Implant should not pivot.
- Use soft tissue retractor to protect soft tissue.
- Use fluoroscopy during the insertion to confirm anterior and midline position of the implant.

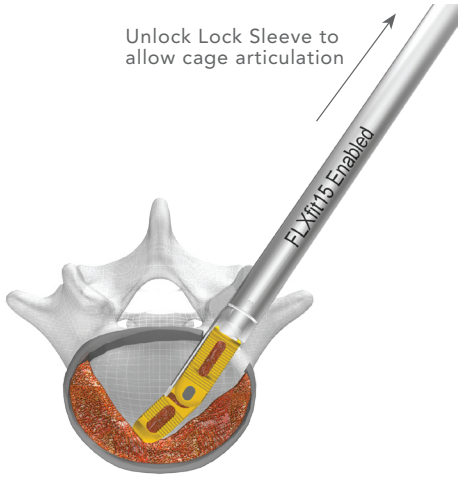
IMPORTANT:

- Maintain 10 – 45 degrees inclination between the FLXfit15 Inserter handle and the sagittal plane during implant insertion.
- Monitor the advancement of cage with radiographic imaging. Be cautious to avoid annulus damage.

POSITION IMPLANT

Confirm implant positioning with fluoroscopy to make sure the articulation has passed beyond the annulus line. Unlock implant articulation by turning Lock Sleeve in counterclockwise direction, pulling it back all the way to the handle until it stops. Unlock mark should appear in the window.

Ensure implant Lock Sleeve is turned counterclockwise until it stops to avoid FLXfit15 Inserter Outer Tube deformation.



CAGE AND INSERTER ENTERING INTO DISC SPACE

Controlled and light malleting on the Inserter may be required to pivot the implant into final position.

Use fluoroscopy during the articulation procedure to confirm fit and position of the implant.

Avoid torque and/or bending of Inserter.

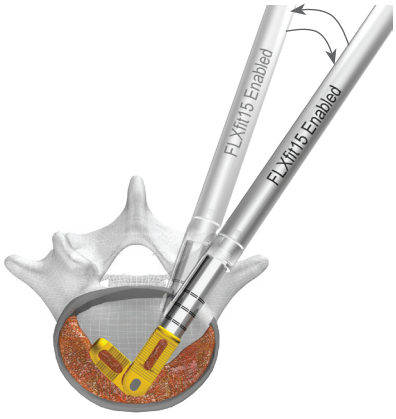
NOTE:

If autograft is placed into the disc space after Trialing and before implantation, the implant may not reach the same position as the Trial.

ARTICULATION OF FLXFIT15 CAGE

If implant does not pivot freely into place, medialize the FLXfit15 Inserter handle to initiate articulating upon impaction gently malleting throughout.

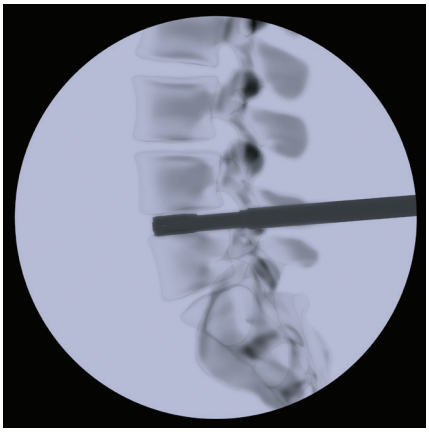
After pivoting is initiated, the FLXfit15 Inserter handle must be turned back to an angle of 10 – 45 degrees from the sagittal plane to pivot the implant into final position.



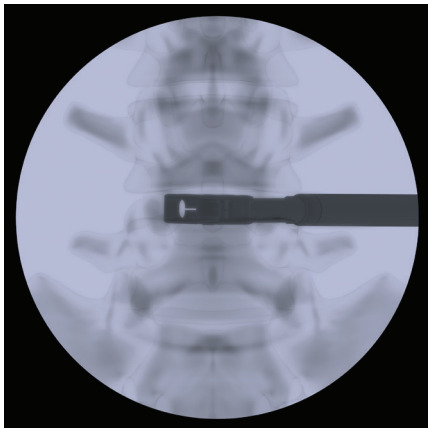
CAGE ARTICULATED IN DISC SPACE

IMPORTANT:

- Implant articulation point should be recessed inside the disc space before articulating the cage.
- Maintain 10 – 45 degrees inclination between the FLXfit15 Inserter handle and the sagittal plane during cage insertion.
- Make sure to keep Inserter handle neutral during implant insertion. Any unnecessary torque on handle may result in damage to implant during insertion.
- Confirm implant position with lateral and A/P views before expansion. Implant should be positioned anterior and midline in the disc space.



LATERAL FLUORO IMAGE OF IMPLANTED FLXFIT15 CAGE PRIOR TO EXPANSION WITH INSERTER ATTACHED



A/P FLUORO IMAGE OF FLXFIT15 CAGE IMPLANTED WITH INSERTER ATTACHED

NOTE:

If the implant has been released from the Inserter and needs to be repositioned, the Inserter can be reconnected to the implant in order to reposition the implant. Repositioning of the implant can only be performed before the expansion. If repositioning is necessary after implant expansion, you must contract the implant, remove it, and use another implant.

CAUTION:

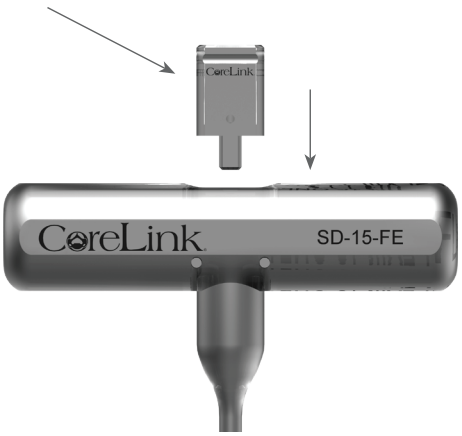
If an interspinous distractor was used, make sure to release distraction before confirming the final positioning and the height of the cage with fluoroscopy.

IMPLANT EXPANSION

To expand FLXfit15, the T-handle Expander with single-use Cartridge must be used. The implant must only be expanded after it is in final position.

The Cartridge is designed to prevent over torquing of the Expander and cage. Ensure Cartridge is pre-loaded into the T-handle Expander prior to use.

CARTRIDGE



T-HANDLE EXPANDER

CARTRIDGE INSERTED

NOTE:

To check if a Cartridge has been previously used, load the Cartridge in the Expander and lightly spin the T-handle Expander Shaft. If the shaft spins, the Cartridge has previously been broken and should be thrown away. An intact Cartridge will not turn freely.

Insert the FLXfit15 Expander through the bore in the proximal end of the FLXfit15 Inserter.

Turn the T-handle Expander clockwise to expand the cage.

FINAL ASSEMBLY OF INSERTER, EXPANDER AND IMPLANT

EXPANSION TABLE

The table below outlines the lordosis achieved at each turn of the T-handle Expander. Implant expansion adds anterior height and lordosis correction.

NUMBER OF TURNS	ADJUSTED LORDOSIS	UPPER POINT EXPANSION	ADJUSTED LORDOSIS	UPPER POINT EXPANSION
	32MM IMPLANT		40MM IMPLANT	
0–2 IDLE	0°	0.0MM	0°	0MM
1	1.5°	0.3MM	1.5°	0.4MM
2	3.0°	0.6MM	3.0°	0.8MM
3	4.5°	0.9MM	4.5°	1.2MM
4	6.0°	1.1MM	6.0°	1.6MM
5	7.5°	1.3MM	7.5°	2.0MM
6	9.0°	1.6MM	9.0°	2.4MM
7	10.5°	2.0MM	10.5°	2.8MM
8	12.0°	2.3MM	12.0°	3.2MM
9	13.5°	2.6MM	13.5°	3.6MM
10	15.0°	3.0MM	15.0°	4.0MM

NOTE – Numbers in the table are approximate and should be used as a reference only.

A minimum of three full turns is needed to achieve articulation locking.

Verify implant expansion using fluoroscopy. Remove the Expander once satisfied with lordotic correction or Cartridge torques out.

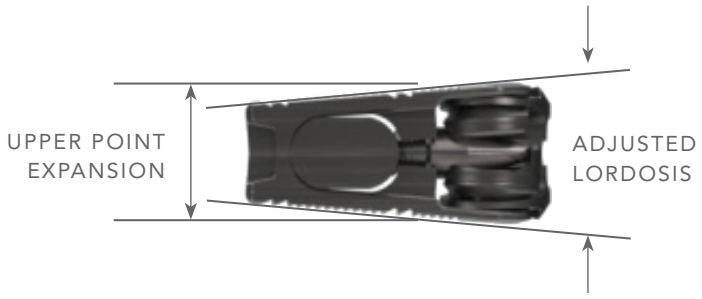
CAUTION:

- Do not use excessive torque for expansion.
- Maximum number of turns is ten (10). Do not rotate the expander more than ten turns.
- The FLXfit15 implant must never be contracted back after expansion, except in the case of cage removal.
- Do not mallet on FLXfit15 Inserter/implant after expansion for repositioning.
- Cartridge is a single-use item. Only use each cartridge once for either expansion or contraction.

IMPORTANT:

FLXfit15 is a single-use device. If for any reason you decide to remove an implant intra-operatively, do not reuse this implant.

Only one cycle of expansion/contraction is allowed. If for any reason you decide to contract the implant after expansion, do not reuse this implant.



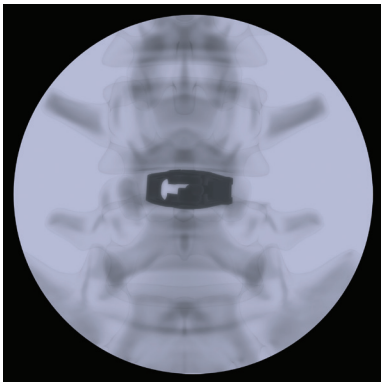
IMPLANT IMAGING

Use fluoroscopy to verify the final position of the implant. In A/P fluoroscopic image, the distal opening on the FLXfit15 implant should be visible.

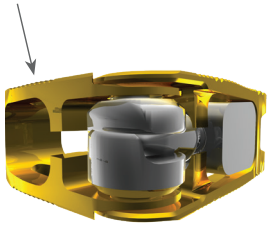
In lateral fluoroscopic image, a small opening and a tooth should be visible once expansion has occurred.

IMPLANT / INSERTION DISCONNECTION

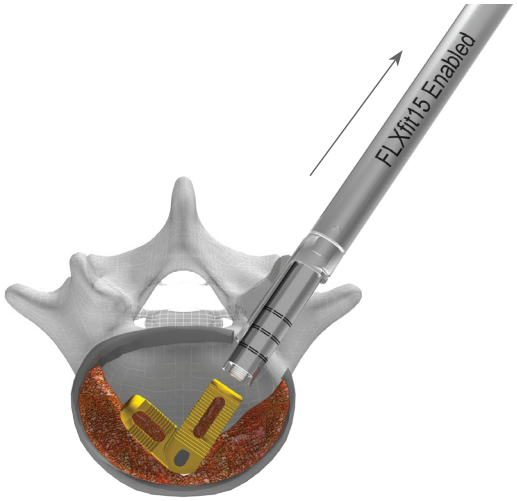
To detach the implant from Inserter, turn the Inner Shaft counterclockwise until it is free. The FLXfit15 Inserter can now be removed from the implant.



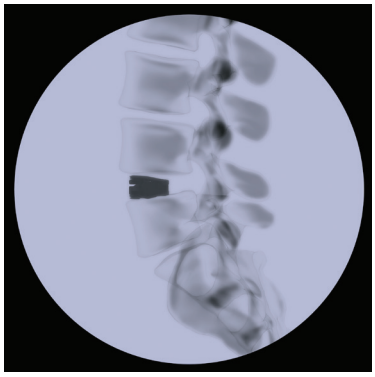
A/P IMAGE OF IMPLANTED FLXFIT15 (DISTAL OPENING VISIBLE)



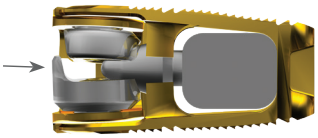
ANTERIOR VIEW OF EXPANDED CAGE (ARROW TOWARD VISIBLE OPENING)



INSERTER DETACHMENT



LATERAL FLUORO IMAGE OF IMPLANTED FLXFIT15 (SMALL OPENING AND TOOTH VISIBLE, DEMONSTRATING EXPANSION)

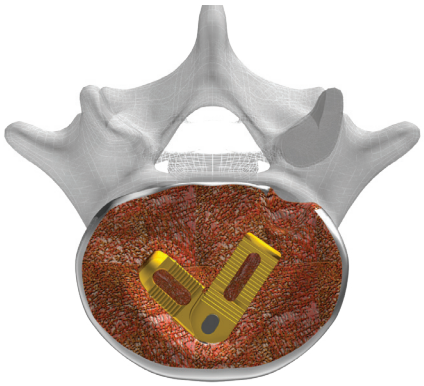


LATERAL VIEW OF EXPANDED CAGE (ARROW TOWARD VISIBLE OPENING)

POSTERIOR SUPPORT

PACK DISC SPACE

After the FLXfit15 is implanted and expanded, fill the posterior disc space and the lateral disc space with bone graft to create optimal conditions for fusion.

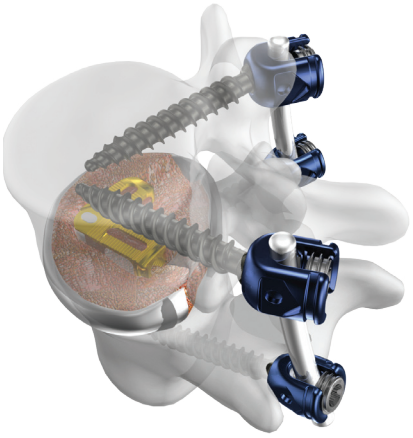


FLXFIT15 IN DISC SPACE

SUPPLEMENTAL FIXATION

FLXfit15 is intended to be used with supplemental posterior fixation, such as CoreLink Tiger® Pedicle Screw System.

It is important to check the lordosis restoration at the operated levels in the lumbar spine according to anatomical parameters of the patient.



FLXFIT15 WITH TIGER PEDICLE SCREW SYSTEM

IMPLANT REMOVAL

Disassemble the Inserter to its three separate parts.

ENGAGEMENT WITH IMPLANTED CAGE:

Locate the internal threads of implanted cage with Inner Shaft. Turn clockwise until a firm connection has been made.

CONTRACTION OF IMPLANTED CAGE:

Insert T-handle Expander and rotate counterclockwise.

Ensure full engagement of the Expander with the implant. Rotate the Expander handle counterclockwise to fully contract the implant. Verify contraction of cage with fluoroscopy.

Remove the Expander after completing the contraction.

CAGE REMOVAL:

Make sure that the neural elements are protected during cage removal.

Connect the Slide Hammer to the Inner Shaft and use a Dural Retractor to protect the nerve while removing the implant from the disc space.

INSTRUCTIONS FOR USE

CORELINK FLXFIT®15 LUMBAR CAGE SYSTEM

OPERATING SURGEON – IMPORTANT INFORMATION

IMPORTANT NOTE:

The user of this system must read and acknowledge the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision at corelinksurgical.com/ifu or by scanning the barcode on the product labeling.

PHYSICIAN NOTE

The physician must convey the important medical information in this document to the patient.

DESCRIPTION

FLXfit & FLXfit15 are expandable, articulating TLIF interbody fusion devices (IBFD), both used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. The FLXfit & FLXfit15 are available in a range of sizes with height expansion which accommodates lordotic curve up to 15°. A bullet-nose design facilitates self-distraction and ease of insertion and teeth on the inferior and superior surfaces of the devices assist in stabilization of the construct. The open architecture of the devices allows them to be packed with autogenous bone graft material, i.e. autograft.

Implants in the FLXfit Lumbar Cage System are manufactured from the following materials:

- Medical grade Titanium Alloy (Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)) Alloy for Surgical Implant Applications (UNS R56401)).

INDICATIONS FOR USE:

The FLXfit & FLXfit15 Intervertebral body fusion devices are indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The FLXfit & FLXfit15 devices are intended to be used with supplemental spinal fixation system and with autogenous bone graft.

CONTRAINDICATIONS:

This device is not intended for cervical spine use.

Contraindications for use of FLXfit and FLXfit15 include, but are not limited to:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
8. Suspected or documented allergy or intolerance to implant's materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or Pseudarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Hemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

Note: This list may not include all of complications cause by the surgical procedure itself.

Additional surgery may be required to correct these potential adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS:

PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances could compromise the result. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical technique, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke will have reduced incidence of bone fusion. These patients must be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by CoreLink. It is therefore mandated that CoreLink implants are not used with instruments from any other source.

Never, under any circumstances, reuse a FLXfit or FLXfit15 implant. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

The CoreLink FLXfit & FLXfit15 Cage System has not been evaluated for safety and compatibility in the MR environment. The CoreLink FLXfit & FLXFit15 Cage System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CoreLink FLXfit & FLXfit15 Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications must be selected.
2. Patient conditions and/or predispositions such as those addressed in the contraindications must be avoided.
3. Care must be taken in the handling and storage of the device(s). They must not be scratched or damaged. Devices must be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon must be familiar with the various devices before use and must personally verify that all devices are present before the surgery begins.
6. The size of device for the case must be determined prior to the beginning of the surgery. An adequate inventory of implant sizes must be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual instruments may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.
8. Prior to use, instruments must be inspected for signs of wear, damage and proper function. If you suspect an instrument is damaged, please contact CoreLink for a replacement.
9. Follow the Cleaning and Sterilization procedures below.

CLEANING AND STERILIZATION

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments must not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments).

Manual Cleaning Instructions:

1. Completely submerge the instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution must be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices.
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

NOTE: Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

AUTOMATED CLEANING INSTRUCTIONS:

1. Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
2. Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection.

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	2-minute prewash with cold tap water
2	1-minute enzyme spray with hot tap water
3	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
4	15-second hot tap water rinse
5	2-minute thermal rinse (80-93°C/176-200°F)
6	10-second purified water rinse (64-66°C/146-150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:

- The washer manufacturer's instructions must be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the implant surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

STERILIZATION INSTRUCTIONS

Implants and instruments of the CoreLink FLXfit & FLXfit15 Lumbar Cage System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, testing has shown that effective sterilization may be achieved as follows:

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

Instruments and implants must be sterilized in the steam sterilization cases provided by CoreLink. Instrument and implant sets must be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used.

REUSABLE RIGID STERILIZATION CONTAINERS

The FLXfit & FLXFit15 Lumbar Cage System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10-6 sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the FLXfit & FLXfit15 Lumbar Cage System is not recommended.

IMPORTANT SYSTEM CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion of implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. However, the presence of dissimilar metals in contact accelerates corrosion. For instance, where titanium and stainless steel are in contact, the stainless steel is subject to corrosive attack. Corrosion may accelerate failure of implants through fatigue fracture. Corrosion also causes metal compounds to be released into the body. To minimize effects from corrosion, implant components that encounter other metal objects, must be made from like or compatible metals.
2. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain disc height restoration until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
3. I**mplant Selection.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.
4. **Patient Considerations.** The following must be considered when evaluating whether a patient is a candidate for such a procedure:
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she must not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, drug abuse, or mental conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **Degenerative diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
   - **Implant sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implants to become displaced or damaged and may cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
- **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
- **Implant Removal.** Spinal implants of this type may require removal if the desired clinical and surgical outcomes are not obtained. The surgeon must carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon must provide postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. Although uncommon, permanent implantation of this device may result in the following: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury; and (7) Risk of additional injury from postoperative trauma.
- **Do Not Reuse Implants.** An implant previously implanted must never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

INTRAOPERATIVE

1. The instructions in any available FLXfit & FLXFit15 surgical technique guide must be carefully followed.
2. Verify the integrity of the sterile wraps or containers. Never use items where a sterile barrier is damaged. Prepare the surgical site for implant introductions.
3. At all times, extreme caution must be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
4. Breakage, slippage, or misuse of instruments or implants will cause injury to the patient or operative personnel.
5. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
6. Proper selection of the shape, size, and design of the implant by the surgeon and subsequent placement during surgery are extremely important. Refer to the FLXfit Lumbar Cage System Cage System Surgical Technique Guide for specific instructions related to the surgical procedure.
7. The surgeon must be thoroughly familiar not only with the medical aspects of the FLXfit & FLXfit15 but must also be aware and instruct the patient on the use and limitations of implants.

POSTOPERATIVE

Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
2. The patient must be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices must be revised and/or removed immediately before serious injury occurs.

5. Any retrieved devices must be treated in such a manner that reuse in another surgical procedure is not possible.

REVISION SURGERY AND IMPLANT REMOVAL

The implants of the FLXfit & FLXFit15 System are intended for permanent implantation and are not required to be removed. However, removal may be advisable in the following situations:

- Implant migration or breakage
- Non-union
- Pain due to the implant
- Infection

Implant removal must be performed using the supplied FLXfit & FLXfit15 System instruments. Implant removal must be performed by first securely attaching the system-specific removal instruments to the implants, then carefully removing them from the surgical site ensuring any surrounding anatomical structures are not damaged

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, must notify the distributor or CoreLink, LLC. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor/CoreLink, LLC must be notified immediately. If any CoreLink, LLC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor/ CoreLink, LLC must be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

CAUTION: Under federal law, this device may only be sold by or on the order of physician.

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indications the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4

LIMITED WARRANTY AND DISCLAIMER

CORELINK PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/ REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company.

For further information contact:

CoreLink, LLC
2072 Fenton Logistics Park
St. Louis, MO 63026
(888) 349-7808

STANDARD FLXFIT15 IMPLANTS AND INSTRUMENT KIT

KIT ORDER #K5000330

IMPLANTS

QTY	CATALOG NUMBER	CAGE DESCRIPTION	AUTOGENOUS GRAFT VOLUME (CC)
2	AT3208	32MM x 9MM x 8MM	.45
2	AT3209	32MM x 9MM x 9MM	.52
2	AT3210	32MM x 9MM x 10MM	.58
1	AT3211	32MM x 9MM x 11MM	.67
1	AT3212	32MM x 9MM x 12MM	.74
1	AT3213	32MM x 9MM x 13MM	.81
2	AT4008	40MM x 9MM x 8MM	.63
2	AT4009	40MM x 9MM x 9MM	.71
2	AT4010	40MM x 9MM x 10MM	.84
1	AT4011	40MM x 9MM x 11MM	.96
1	AT4012	40MM x 9MM x 12MM	1.05
1	AT4013	40MM x 9MM x 13MM	1.20

INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
6	SD-15-FU	FLXFIT15 CARTRIDGE (SINGLE-USE)
1	02T01082	TRIAL 8MM (32MM)
1	02T01083	TRIAL 9MM (32MM)
1	02T01084	TRIAL 10MM (32MM)
1	02T01085	TRIAL 11MM (32MM)
1	02T01086	TRIAL 12MM (32MM)
1	02T01087	TRIAL 13MM (32MM)
1	02T01090	TRIAL 8MM (40MM)
1	02T01091	TRIAL 9MM (40MM)
1	02T01092	TRIAL 10MM (40MM)
1	02T01093	TRIAL 11MM (40MM)
1	02T01094	TRIAL 12MM (40MM)
1	02T01095	TRIAL 13MM (40MM)
2	SD-15-FE	T-HANDLE CAGE EXPANDER
2	1032-302	LOCK/UNLOCK INSERTER SLIDE (COMPATIBLE WITH 90° HANDLE)
2	1032-303	INNER INSERTER SHAFT (COMPATIBLE WITH 90° HANDLE)
2	1032-301	90° INSERTER HANDLE*
1	08G00017	SLIDE HAMMER
1	09P00013	8MM DISC SHAVER (BITAPERED)
1	09P00014	9MM DISC SHAVER (BITAPERED)
1	09P00015	10MM DISC SHAVER (BITAPERED)
1	09P00016	11MM DISC SHAVER (BITAPERED)
1	09P00017	12MM DISC SHAVER (BITAPERED)
1	09P00018	13MM DISC SHAVER (BITAPERED)
2	15G00002	T-HANDLE (HUDSON CONNECTION)

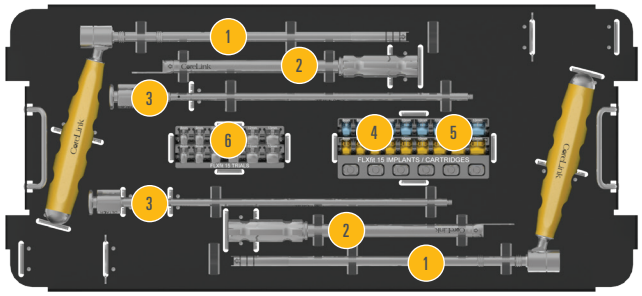
NOTE: Straight inserter available on request.

SPECIAL ORDER INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	1032-108	QUICK RELEASE STRAIGHT INSERTER (OUTER SHAFT WITH MOLDED HANDLE AND LOCK/UNLOCK SLIDE)
1	1032-103	INNER SHAFT

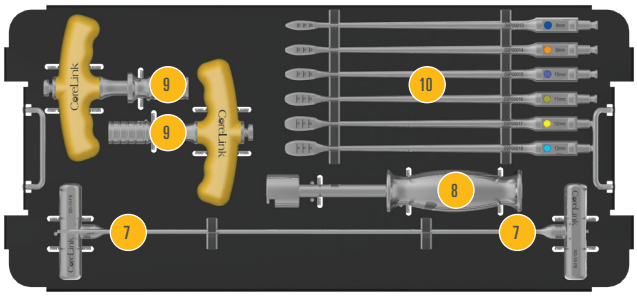
TOP TRAY

1. 90° Inserter Handles
2. Lock/Unlock Slides
3. Inner Inserter Shafts
4. Cartridges
5. Implants
6. Trials



BOTTOM TRAY

7. T-handle Expanders
8. Slide Hammer
9. T-handles
10. Disc Shavers (8mm - 13mm)



DISC PREP KIT

KIT ORDER #K5000009

POSTERIOR LUMBAR DISC PREP INSTRUMENT SET		
QTY	CATALOG NUMBER	DESCRIPTION
1	09P00042	FLIP-UP DISTRACTOR, 8MM PLIF
1	09P00043	FLIP-UP DISTRACTOR, 9MM PLIF
1	09P00044	FLIP-UP DISTRACTOR, 10MM PLIF
1	09P00045	FLIP-UP DISTRACTOR, 11MM PLIF
1	09P00046	FLIP-UP DISTRACTOR, 12MM PLIF
1	09P00047	FLIP-UP DISTRACTOR, 13MM PLIF
1	09P00048	FLIP-UP DISTRACTOR, 14MM PLIF
1	09P00049	FLIP-UP DISTRACTOR, 15MM PLIF
1	09P00025	OSTEOTOME – 8MM STRAIGHT
1	03P00060	RASP – ANGLED PLIF
1	04P00011	CUP CURETTE, 6MM x 10MM STRAIGHT
1	04P00012	CUP CURETTE, 6MM x 10MM OFFSET LEFT
1	04P00013	CUP CURETTE, 6MM x 10MM OFFSET RIGHT
1	04P00014	CUP CURETTE, 6MM x 10MM ANGLED
1	04P00015	CUP CURETTE, 6MM x 10MM BACK DOWN
1	04P00018	RING CURETTE, 6MM ROUND-ANGLED 45 DEGREES

SPECIAL ORDER MIS TLIF DISC PREP KIT

KIT ORDER #K50000120

MIS TLIF DISC PREP INSTRUMENT SET		
QTY	CATALOG NUMBER	DESCRIPTION
KERRISONS		
1	7900-201	2MM, 40 DEGREE
1	7900-202	3MM, 40 DEGREE
1	7900-203	4MM, 40 DEGREE
PITUITARIES		
1	7900-208	2MM STRAIGHT, 170MM WORKING LENGTH
1	7900-209	2MM UP ANGLED, 170MM WORKING LENGTH
1	7900-211	MICRO – 2MM STRAIGHT, 170MM WORKING LENGTH
1	7900-212	MICRO – 2MM UP ANGLED, 170MM WORKING LENGTH
1	7900-217	4MM STRAIGHT, 170MM WORKING LENGTH
1	7900-218	4MM UP ANGLED, 170MM WORKING LENGTH
CURETTES		
1	7900-227	3MM STRAIGHT, BAYONETED
1	7900-228	3MM REVERSE, BAYONETED
1	7900-229	3MM DOWN BITING, BAYONETED
1	7900-230	3MM DOWN ANGLED, BAYONETED
1	7900-234	4MM STRAIGHT, BAYONETED
1	7900-235	4MM REVERSE, BAYONETED
1	7900-236	4MM DOWN BITING, BAYONETED
1	7900-237	4MM DOWN ANGLED, BAYONETED
1	7900-239	4MM ANGLED RIGHT, BAYONETED
1	7900-240	4MM ANGLED LEFT, BAYONETED
1	7900-262	SERRATED – 4MM STRAIGHT, BAYONETED
1	7900-263	SERRATED – 4MM REVERSE, BAYONETED
2	7900-269	SERRATED – 6MM STRAIGHT, BAYONETED
1	7900-270	SERRATED – 6MM REVERSE, BAYONETED

MIS TLIF DISC PREP INSTRUMENT SET (CONTINUED)		
QTY	CATALOG NUMBER	DESCRIPTION
INSTRUMENTS		
1	7900-280	SUCTION TUBE STYLET
1	7900-285	SUCTION TUBE – 8 FRENCH
1	7900-287	SUCTION TUBE – 10 FRENCH
1	7900-289	KNIFE HANDLE – BAYONETED
1	7900-290	MICRO NERVE HOOK – BALL TIP, 2MM
1	7900-294	PENFIELD – 3, PUSH, BAYONETED
1	7900-295	PENFIELD – 3, PULL, BAYONETED
1	7900-298	WOODSON PROBE – 60 DEGREE, BAYONETED
1	7900-300	COBB ELEVATOR – 10MM
1	7900-301	MICRO NERVE HOOK – FORWARD
1	7900-302	MICRO NERVE HOOK – REVERSE
1	7900-305	NERVE ROOT RETRACTOR, 6MM
1	7900-307	OSTEOTOME – 6MM
1	7900-309	RING CURETTE – 6MM STRAIGHT, BAYONETED
1	7900-310	RASP – STRAIGHT, BAYONETED

NOTE: MIS Tube, Table Arm, and Retractor Sets are additionally available. Contact CoreLink Customer Service for more information.

NOTES

NOTES

CoreLink®

The Source for Spine™

INSIGHT | PERFORMANCE | VALUE

CoreLinkSurgical.com 888.349.7808

Designed and manufactured in St. Louis, MO 63026

CL-FORM-251, Rev. 6