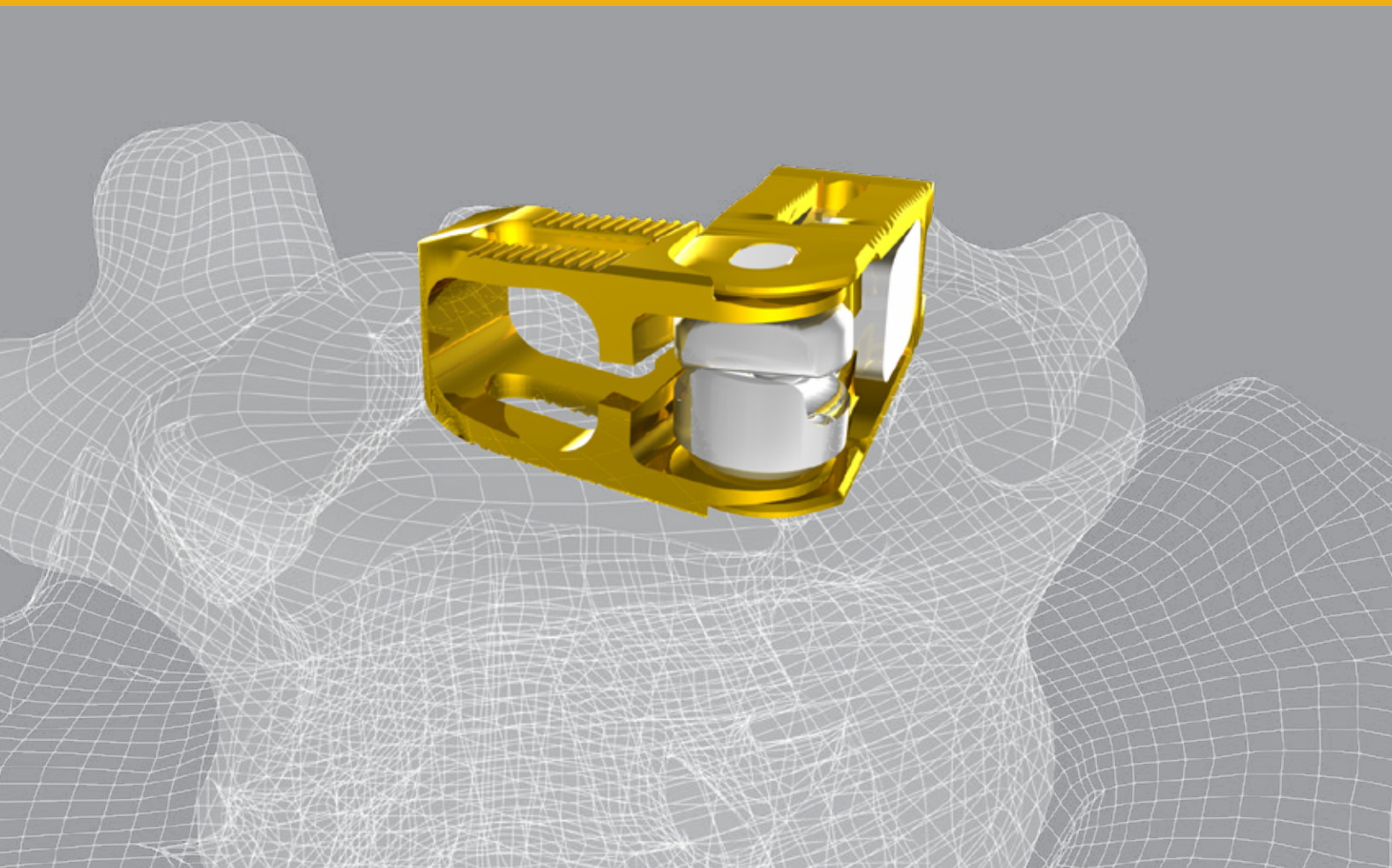
CoreLink
The Source for Spine™

# FLXfit®15 EXPANDABLE POSTERIOR LUMBAR FUSION SYSTEM

Surgical Technique Guide



# THE FLXfit®15 ADVANTAGE

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

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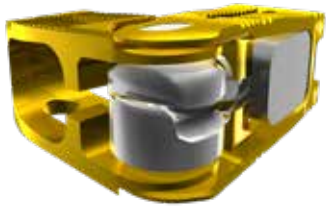
# FLXfit®15 PRODUCT OVERVIEW

The FLXFit15 devices are manufactured from medical grade Titanium (Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)) alloy for surgical implant applications (UNS R56401).



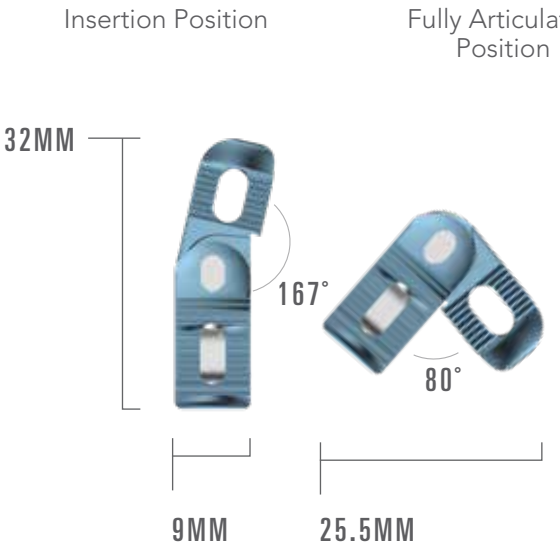
## SYSTEM FEATURES

- Allows for controlled, in-situ lordotic expansion with a minimal insertion profile. Up to 15°/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 optimize 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.

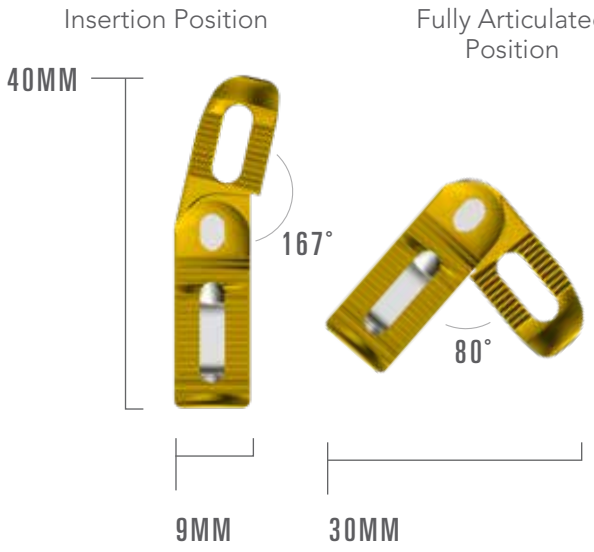
## FOOTPRINT DIMENSIONS

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

### 32MM x 9MM



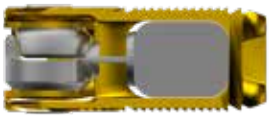

### 40MM x 9MM



# FLXfit®15 PRODUCT OVERVIEW

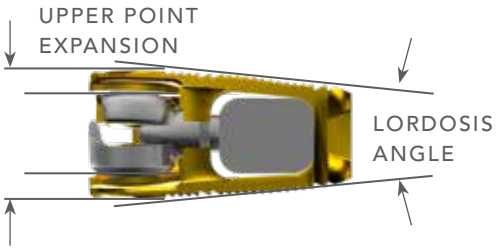
### UNEXPANDED

### 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.
- FLXfit®15 can be used in MIS or Open procedures.

### OPEN TLIF OR PLIF APPROACH

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

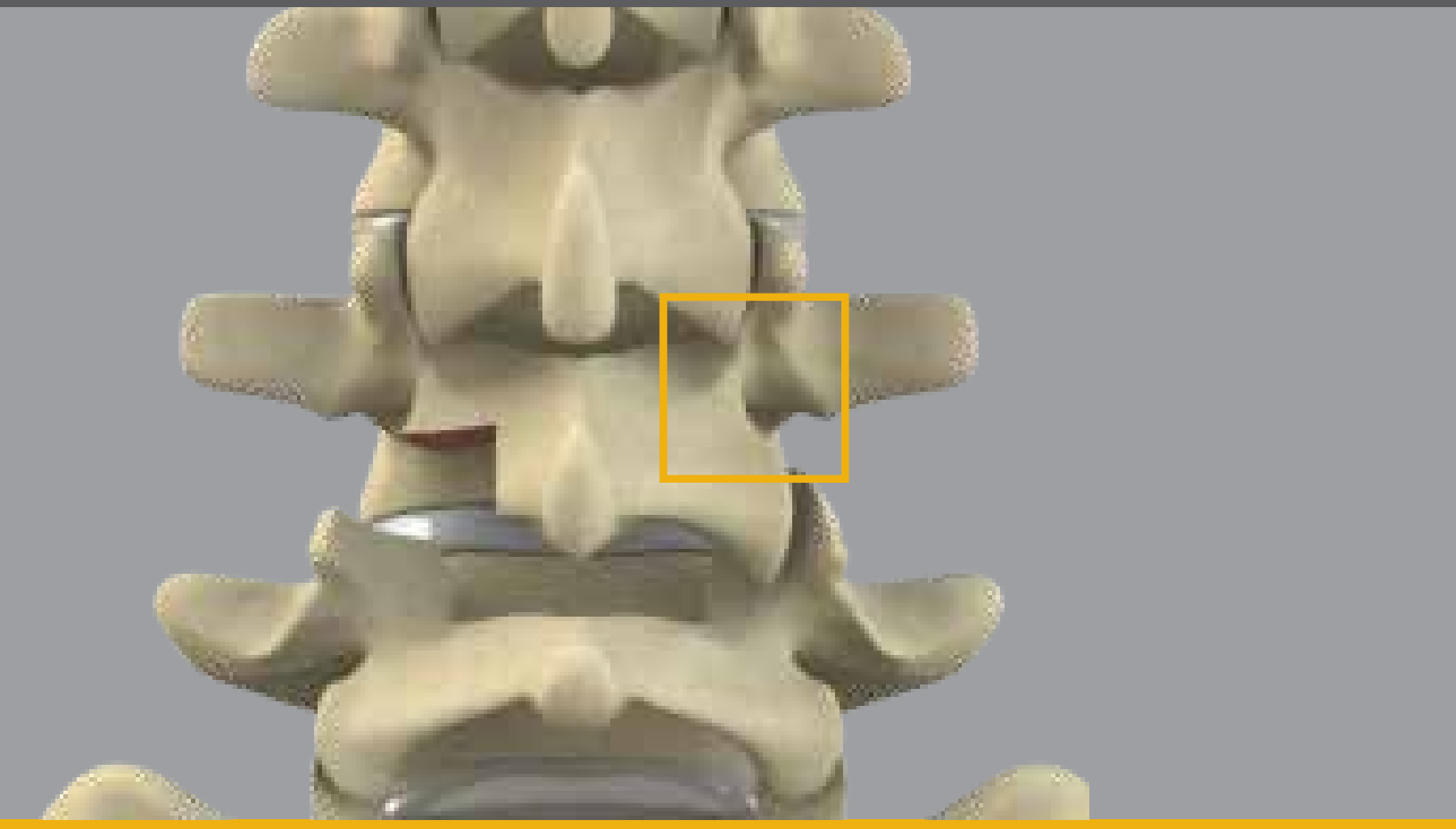
### CUT TRANSFORAMINAL WINDOW

- 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 28 for a complete listing of disc prep instruments.

**The annulus must be preserved to provide additional support for the FLXfit®15 and to prevent migration of bone graft into the spinal canal.**

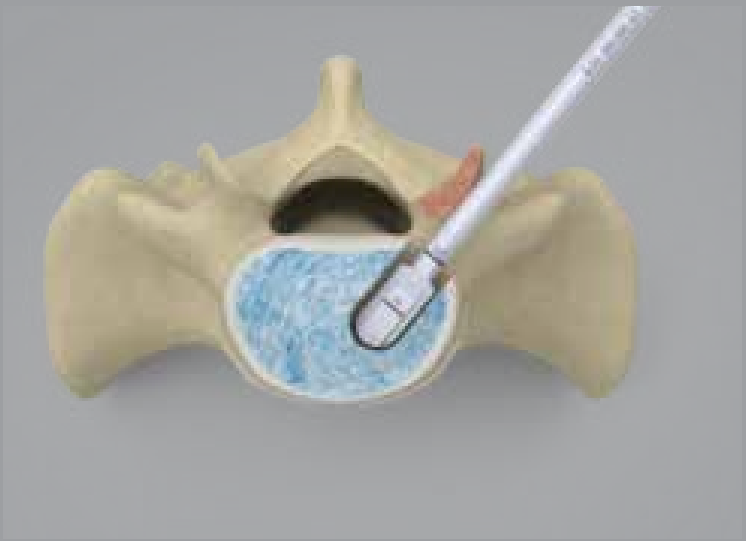
### NOTES:

- Make sure to clean up the space medially and on the contra–lateral side to allow for full insertion of FLXfit15.
- Avoid direct blows to instruments for which the use of a hammer is not specifically indicated to avoid damage to adjacent structures.
- When the use of a hammer is necessary, hammering must be performed gradually by gentle blows 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.

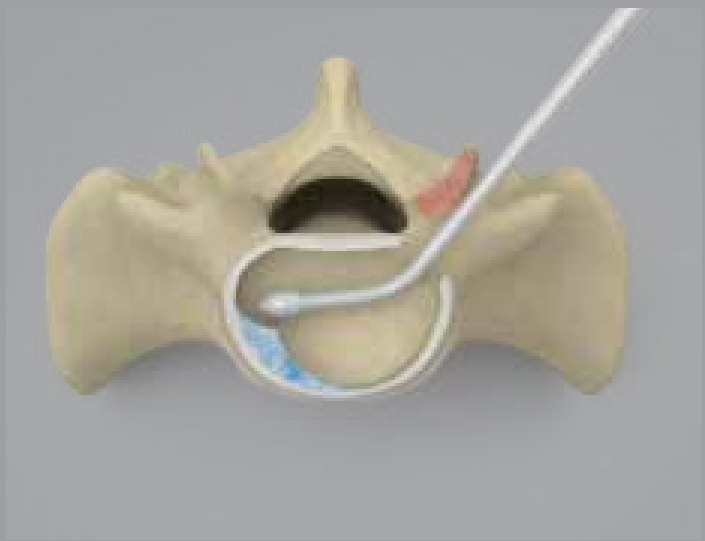
### IMPORTANT:

- 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.

### IMPORTANT:

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

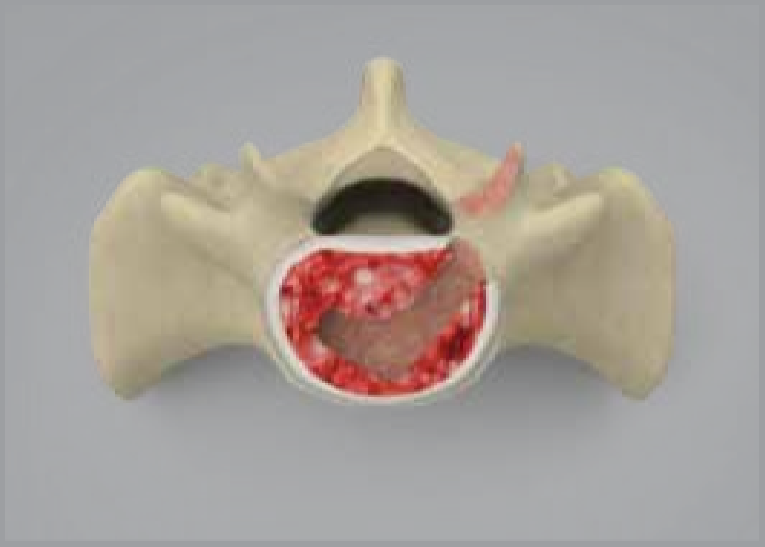
### OPTIONAL: PACK DISC SPACE

Before the FLXfit®15 is implanted, the disc space could be filled with some autogenous bone graft leaving enough space for the Trials to be positioned in the appropriate place.

### NOTE:

Repeat the trialing stage to verify that the path was not blocked.

## DISC SPACE PACKED



# TRIALS FOR IMPLANT SIZE

## ASSEMBLY OF FLXfit®15 INSERTER AND TRIALS

Pre–operative Inserter assembly is required. Post–operative Inserter disassembly is required prior to instrument cleaning and sterilization.

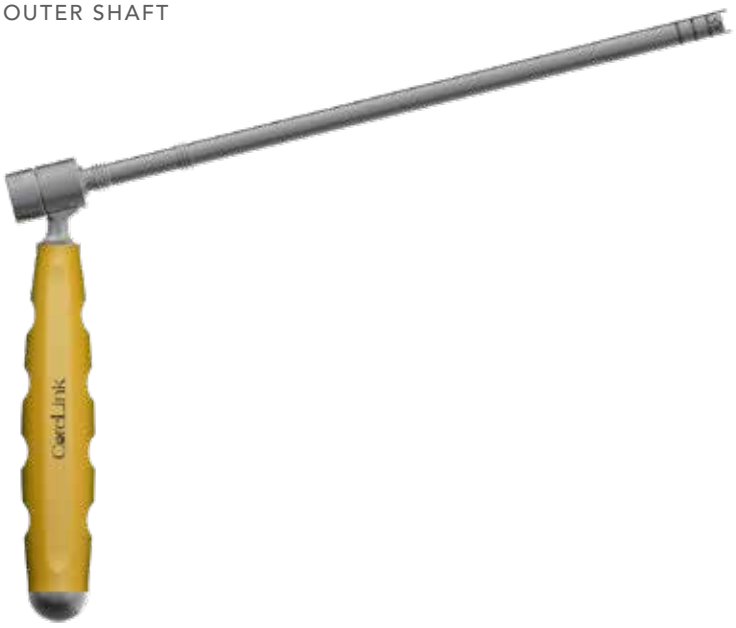
The FLXFit Inserter components include:

- Lock/Unlock Slide
- Inner Shaft
- Outer Shaft with Attached 90–degree Handle

LOCK/UNLOCK SLIDE

INNER SHAFT

OUTER SHAFT



# ASSEMBLY OF FLXfit®15 INSERTER AND TRIALS (CONTINUED)

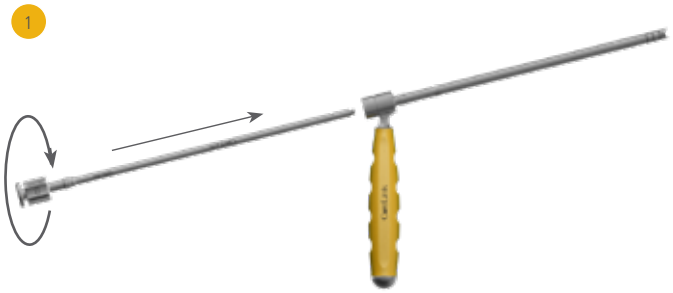
The FLXfit15 Inserter must be assembled before connection to the Trial.

1. Slide the Inner Shaft through the Outer Shaft and then turn the Implant Holder Knob 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 Sleeve is aligned by viewing the black line on the Inner Shaft through the small window opening on the Outer Shaft.
3. Slide the Implant Lock Knob until it stops and rotate the knob counter clockwise until completely tightened into the second set of internal threads.

**NOTE:**

For disassembly turn the Implant Lock Knob clockwise until it's free to move and then slide it out. Pull back the Implant holder knob and turn it counterclockwise.

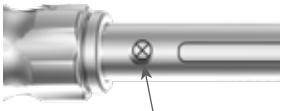
1



2

3

MARKINGS ON OUTER INSERTER SHAFT



Make sure the outer inserter's black line is viewed through the opening

# CONNECTING TRIAL TO THE FLXfit®15 INSERTER

1) Ensure that the FLXfit15 Inserter is in its unlock position. The unlock mark will appear in the Outer Shaft's window.
2) Choose the appropriate sized Trial. The appropriate size may be selected by measuring the disc space height using a Shaver.
3) Attach the appropriate size Trial to the FLXfit15 Inserter by turning the Implant Holder Knob clockwise until it the Inner Shaft's tip threads into the proximal end of the Trial.

   **Note:** Take care to 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) Rotate the Implant Lock Knob clockwise and advance the Lock Slide 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).

# INSERT TRIAL

Insert the Trial into the disc space, ensuring that the orientation of the Trial is correct by verifying that the line mark on the Lock/UnLock Slide tube faces the sagittal plane. The distal tip of the Trial should be orientated medially. Maintain 10° – 45° inclination between the FLXfit®15 Inserter and the sagittal plane during Trial insertion. 40° is recommended.

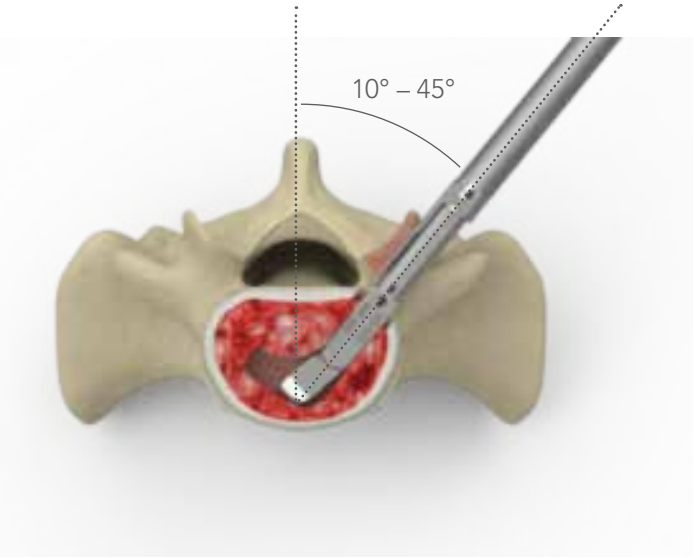
Controlled and light hammering on the Inserter may be required to advance the Trial into the intervertebral disc space. Use fluoroscopy to confirm position and fit of the Trial. Lateral view is normally enough using the tracking markers but AP view is recommended in case of doubt on the optimal medial position.

**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 of the Trial to Inserter should be checked before insertion, by manually applying pressure on the lateral side of the Trial with the thumb. Trial should not pivot.
- 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 by imaging and be cautious to avoid annulus damage.




# TRIAL POSITIONING

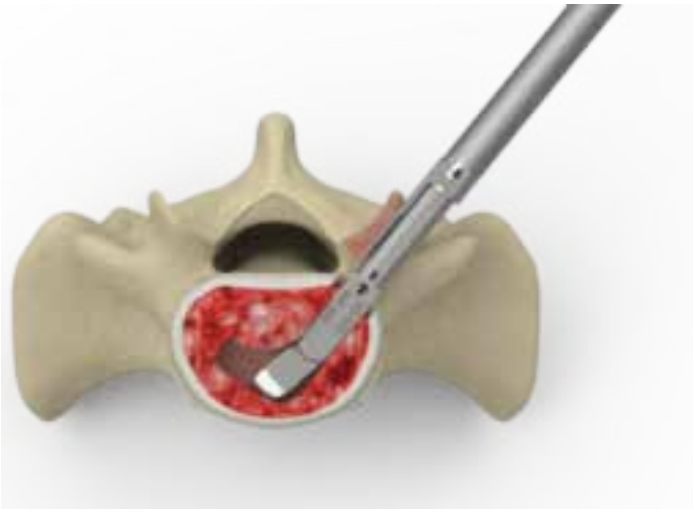
Turn the Implant Lock Knob counter clockwise, while pulling it back all the way and then continue to rotate until it stops. The Unlock mark should appear in the window.

**NOTE:**

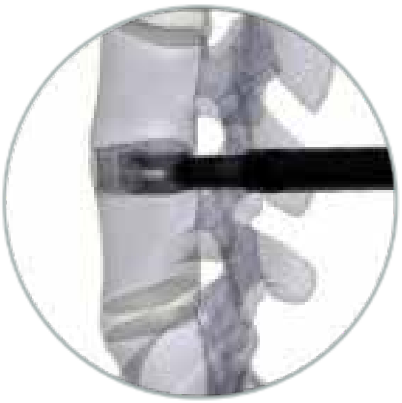
Before unlocking the Trial, confirm by fluoroscopy that the Trial articulation point has passed beyond the annulus entry point.

Ensure the Implant Lock Knob is turned counterclockwise until it stops to avoid Trial or Outer Shaft deformation.

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



TRIAL IMAGE IN DISC SPACE

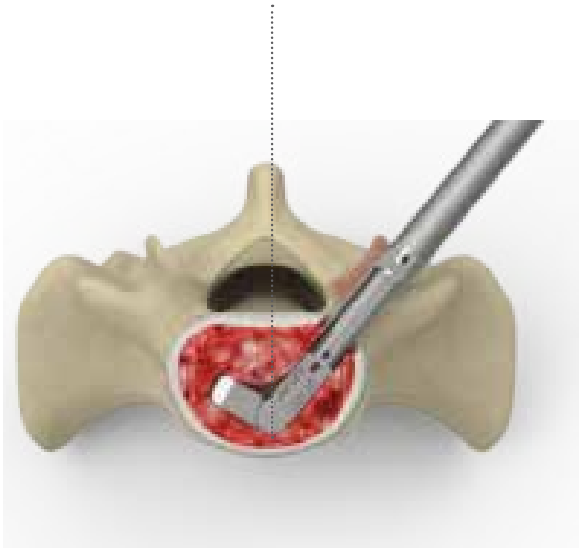


LATERAL FLUORO IMAGE

# TRIAL POSITIONING (CONTINUED)

Use fluoroscopy during the articulation procedure to confirm fit and position of the trial spacer. Each Trial has a medial/lateral and an anterior/posterior opening for position control.

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



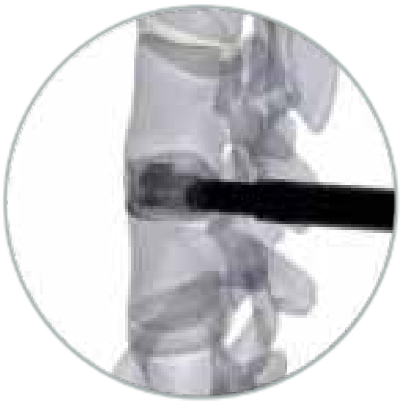
TRIAL ARTICULATED IN DISC SPACE

## IMPORTANT:

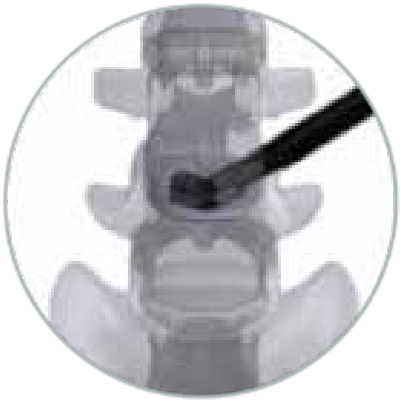
- Maintain 10° – 45° inclination between the Inserter handle and the sagittal plane during Trial insertion.
- Do not detach the Trial in the disc space.
- In any case, do not implant the Trial.

## NOTES:

- Ensure that the Trial is positioned where the implant will be placed eventually.
- Optimal placement is obtained when the articulation point is at the anterior section at the center of the disc space.
- Due to variations in radiographic magnification, the Trials only provides an estimate of the ideal implant size radiographic fit.
- **Remember: The Trial has no height expansion and provides an indication to implant positioning and length. The actual implant will expand after insertion allowing tight fit and lordosis angle correction.**
- If Trial is not well positioned within the disc space, remove Trial and continue cleaning of the disc space.



LATERAL FLUORO IMAGE–TRIAL ARTICULATED



AP FLUORO IMAGE OF TRIAL IN THE DISC SPACE

# OPTIONAL: MANUALLY POSITION TRIAL

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° from the sagittal plane to pivot the Trial into final position.

## CORRECT TRIAL POSITIONING

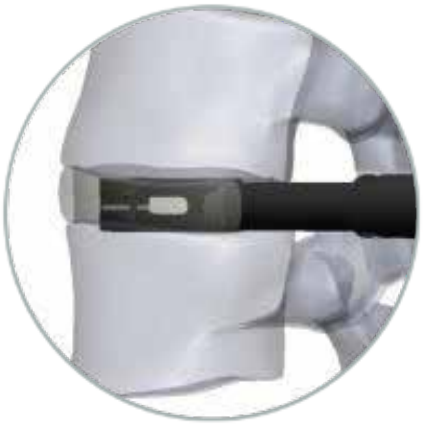
Correct positioning of Trial is indicated by lateral fluoroscopy. "Correct" positioning is observed through the Trial's window marking near the anterior part.

AP FLUORO IMAGE OF TRIAL
IN THE DISC SPACE

CORRECT

LATERAL FLUORO SHOT OF CORRECT
TRIAL POSITION

INCORRECT



LATERAL FLUORO SHOT OF INCORRECT
TRIAL POSITION

# REMOVE TRIAL

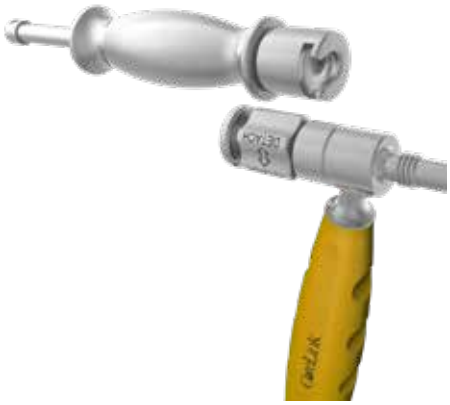
**IMPORTANT:**

The FLXfit®15 Inserter 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, turn counterclockwise the Implant Holder Knob until the Trial is free.



SLIDE HAMMER AND INSERTER CONNECTIONS

TRIAL ARTICULATED IN DISC SPACE

# IMPLANT PREPARATION

## SELECT IMPLANT

Select the FLXfit®15 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 its unlock position. The unlock mark will appear in the outer shaft window.
2. Attach the implant to the Inserter by turning the Implant holder knob clockwise until it stops.
3. Turn and push forward the Implant lock knob clockwise until it stops against the Implant. The lock mark should appear in the Outer tube window.


CONNECTING CAGE TO INSERTER

CAGE ATTACHED TO INSERTER

MARKINGS ON OUTER INSERTER SHAFT

## NOTE:

When the Lock/Unlock Slide contacts the Implant, the Implant can't pivot.

## IMPORTANT:

- Ensure that the arrow on the end of the Inserter aligns with the one on the implant. The contact surfaces between the implant and the Inserter should have no gap.

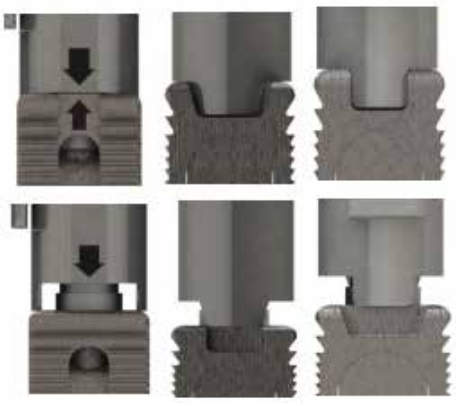
## PACK IMPLANT WITH AUTOGENOUS BONE GRAFT

Graft packing is done manually. Impact the autogenous bone graft into the implant. It is important to fill the implant until the material protrudes from its perforations to ensure optimal contact with the vertebral endplates.


CAGE ATTACHED TO INSERTER

CORRECT

INCORRECT



# IMPLANT INSERTION AND EXPANSION

## INSERT IMPLANT

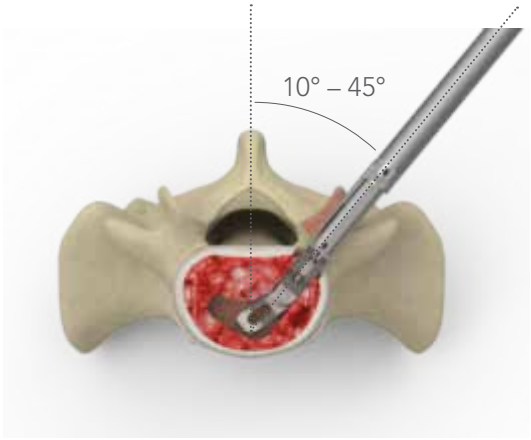
Recheck the firm connection of implant to Inserter.

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

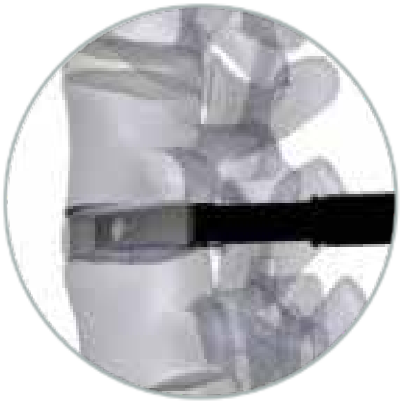
The implant tip should be orientated medially. Maintain 10° – 45° inclination between the Inserter handle and the sagittal plane during implant insertion.

Controlled and light hammering 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

## NOTES:

- 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 position of the implant.

## IMPORTANT:

- Maintain 10° – 45° inclination between the FLXfit15 Inserter handle and the sagittal plane during implant insertion.

## POSITION IMPLANT

Confirm implant positioning by fluoroscopy to make sure the articulation has passed beyond the annulus line. Turn the Implant lock knob counterclockwise, pull it back all the way and then continue to rotate until it stops. Unlock mark should appear in the window.

Ensure Implant lock knob is turned counterclockwise until it stops to avoid FLXfit15 Inserter outer tube deformation.

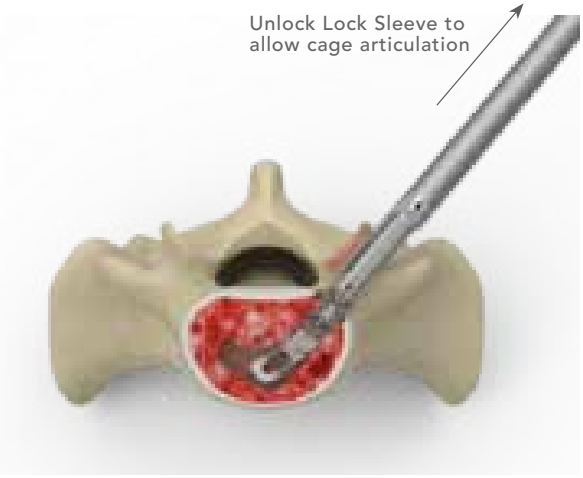
Controlled and light hammering on the Inserter may be required to pivot the implant into final position.

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

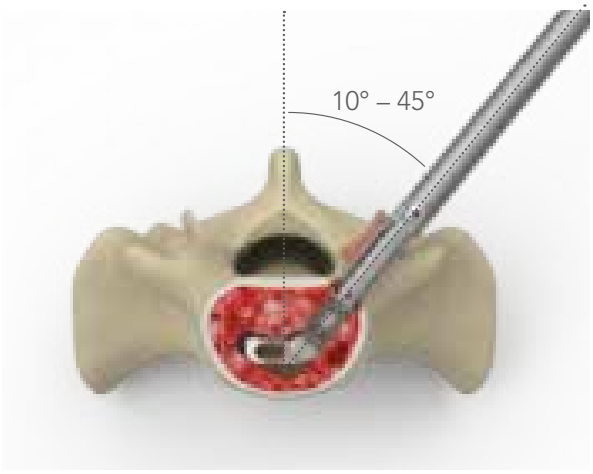
If torque and/or bending are required, apply them gently on the Inserter.

## NOTE:

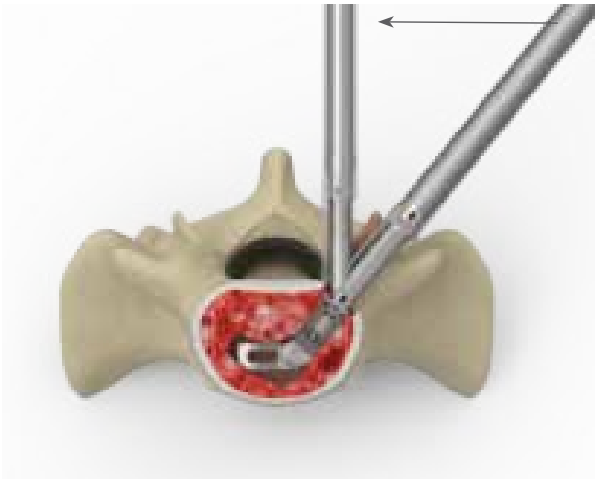
If bone graft is placed into the disc space after Trialing and before implantation, the implant may not reach the same position as the Trial.




CAGE AND INSERTER ENTERING INTO DISC SPACE




CAGE IN DISC SPACE PRIOR TO ARTICULATION



CAGE ARTICULATED IN DISC SPACE

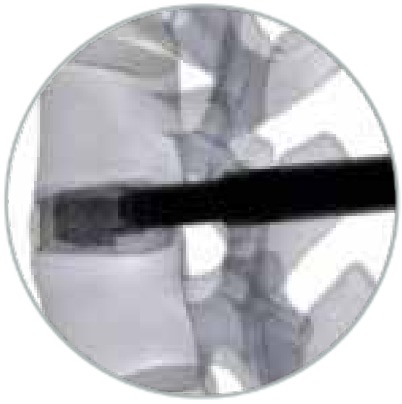
## ARTICULATION OF FLXFIT15 CAGE

If implant does not pivot freely into place, turn the FLXfit15 Inserter handle medially to initiate pivoting upon impaction.

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

**IMPORTANT:**

- Maintain 10° – 45° inclination between the FLXfit®15 Inserter handle and the sagittal plane during Trial insertion.
- Confirm implant position by AP view before expansion. Implant should be positioned at the anterior section, at the center of the disc space.



LATERAL FLUORO IMAGE OF IMPLANTED FLXFIT15 CAGE

A/P FLUORO IMAGE OF FLXFIT15 CAGE IMPLANTED

# OPTIONAL: MANUAL POSITIONING OF IMPLANT

### IMPORTANT:

Maintain 10° – 45° inclination between the FLXfit15 Inserter handle and the sagittal plane for final implant insertion.

### 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, please contact the implant, remove it and use another implant.

### CAUTION:

If an interspinous distractor was used, do not forget to release distraction before confirming the positioning and the height of the cage while operating under fluoroscopic control.

# EXPAND IMPLANT

Implant is expanded by turning the T-Handle Expander counter clockwise. The Implant must be expanded after it is positioned in-situ.

Ensure that the T-Handle Expander has single-use Cartridge preloaded. This Cartridge is designed to prevent over torqueing of the Expander device.

**NOTE:**

To check if a Cartridge has been previously used, load the Cartridge in the Expander and lightly spin the 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 hole in the proximal end of the FLXfit15 Inserter.


CARTRIDGE


CARTRIDGE INSERTED

FINAL ASSEMBLY OF INSERTER, EXPANDER AND IMPLANT

# EXPANSION TABLE

| NUMBER OF TURNS | FLXfit®15 | | | |
|---|---|---|---|---|
| | ADJUSTED LORDOSIS | UPPER POINT EXPANSION | ADJUSTED LORDOSIS | UPPER POINT EXPANSION |
| DEVICE LENGTH | AT32## | | AT40## | |
| 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.

Turn the Expander handle clockwise to expand the implant.

A minimum of 3 full turns is needed to achieve articulation locking.

## NOTE:

Implant expansion adds height, lordosis correction according to the expansion table.

Verify implant expansion using fluoroscopy. Remove the Expander.

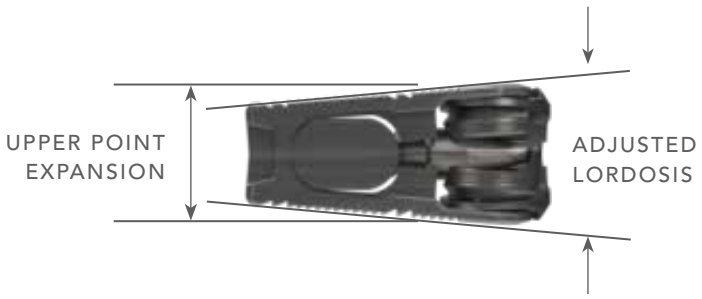
## CAUTION:

- Do not use excessive torque for expansion.
- Max. number of turns is ten (10). Do not rotate the expander more than 10 turns.
- The FLXfit®15 implant must never be contracted back after expansion, except in the case of cage removal.
- Do not hammer on FLXfit15 Inserter/implant after expansion for repositioning.
- Replace Expander or its Cartridge in case of breakage.

## IMPORTANT:

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

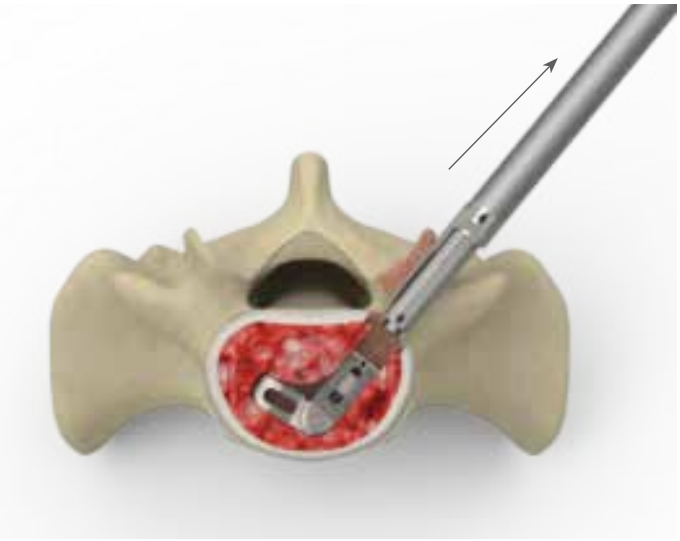
Only one cycle of Expansion-Contraction is allowed. If for any reason you decide to contract the implant after expansion, do not reuse this implant.



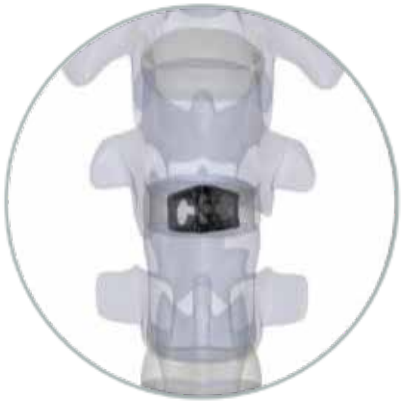
## DETACH IMPLANT

Use fluoroscopy to verify the final position of the implant. With a medial/lateral fluoroscopic image, lateral opening of the FLXfit®15 implant should be visible.

To detach the implant, turn the implant holder knob counterclockwise until it's free. The FLXfit15 Inserter can now be removed from the implant.



INSERTER DETACHMENT



A/P IMAGE OF IMPLANTED FLXFIT15

LATERAL FLUORO IMAGE OF IMPLANTED FLXFIT15

# POSTERIOR SUPPORT

## PACK DISC SPACE

After the FLXfit®15 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

The FLXfit15 is intended to be used with supplemental posterior fixation, such as CoreLink Tiger® Pedicule 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.

Insert the T-Handle Expander into the Inner Shaft.

### ENGAGEMENT WITH IMPLANTED IMPLANT:

Locate the internal threads of implanted implant, turn the Implant Holder Knob clockwise until a firm connection has been made.

### CONTRACTION OF IMPLANTED IMPLANT:

Then rotate the Implant Holder Knob counterclockwise two turns.

Ensure full engagement of the Expander with the Implant. Rotate the Expander handle counterclockwise to fully contract the implant.

Remove the Expander after completing the contraction.

### CAGE REMOVAL:

Rotate the Inner Shaft clockwise until firm connection with the implant is achieved.

Make sure that the neural elements are protected during the procedure.

### CAUTION:

Confirm implant contraction before removal using Fluoroscopy.

Connect the Slide Hammer to the FLXfit15 Inner Shaft and use a Dural Retractor to protect the nerve while pulling out the implant from the Disc space.

FLXfit15 implant will begin release itself to its fully un-articulated position while it is removed outside.

# INSTRUCTIONS FOR USE

## CORELINK FLXfit®15 LUMBAR CAGE SYSTEM

OPERATING SURGEON – IMPORTANT INFORMATION

### IMPORTANT
Before using this product, read the following information carefully.

### PHYSICIAN NOTE
The physician should convey the important medical information in this document to the patient.

**Caution:** Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) that has appropriate training or experience.

### DESCRIPTION:
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 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. The devices are manufactured from medical grade Titanium (Wrought Titanium6Aluminum–4Vanadium ELI (Extra Low Interstitial)) Alloy for Surgical Implant Applications (UNS R56401)).

### INTENDED USE:
The 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.

### INDICATIONS
Please refer to FLXfit15 – Transforaminal Lumbar Interbody Cage Surgical Technique Guide.

### CONTRAINDICATIONS:
This device is not intended for cervical spine use. Contraindications 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.

### 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.

### WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may 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 have been shown to have a reduced incidence of bone fusion. These patients should 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 Expanding Orthopedics. In the interests of patient safety, it is therefore recommended that Expanding Orthopedics 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 FLXfit & FLXfit15 have not been evaluated for safety and compatibility in the MR environment. The FLXfit & FLXfit15 have not been tested for heating or migration in the MR environment.

### PREOPERATIVE
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.

6. The size of device for the case should be determined prior to the beginning of the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless supplied sterile, all devices should be cleaned and sterilized before use.

## INTRAOPERATIVE

1. The instructions in any available FLXfit®15 surgical technique guide should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
5. 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 FLXfit15 Lumbar Cage System Cage System Surgical Technique Guide for specific instructions related to the surgical procedure.
6. 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

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 should 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 should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. The patient should 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 should be revised and / or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

## PACKAGING

Packages containing implants or instruments should be intact upon receipt. Do not use if the seal is broken. Surgical cases serve to hold devices on customized trays during sterilization, and subsequent storage and transportation. Prior to use, all packages of implants and instruments should be checked for completeness and to ensure that there is no damage. Damaged packages, implants or instruments should not be used and should be returned to the distributor or EOI.

## CLEANING AND STERILIZATION

Implants and instruments of the FLXfit & FLXfit15 Lumbar Cage System are supplied clean and non–sterile and must be cleaned and sterilized prior to use. Remove all packaging materials, including protective tip covers where applicable, and perform cleaning and sterilization prior to introduction into a sterile, operative field, according to routine hospital procedures. All re–usable instruments must be disassembled (if applicable) and cleaned thoroughly before sterfield, according to routine hospital procedures. All re–usable instruments must be disassembled (if applicable) and cleaned thoroughly before sterilization. Cleaning and disinfection of instruments and cases may be done manually or automatically as follows or according to an equivalent standard cleaning process:

1. Submerse the device in an enzymatic detergent safe for use with metals. Soak the device for 20 minutes.
2. As applicable, scrub the device with a soft–bristle brush including all lumens and holes. Use a small coarse–bristle brush to clean the internal channels. Agitate the device in the solution while scrubbing and maneuver any movable parts to loosen any trapped soil.
3. Rinse in warm (50°–60°C) tap water for 3 minutes.
4. Place the device in a batch containing warm (50°–60°C) tap water. Agitate the device by hand for at least 1 minute. Replace the water and repeat 2 additional times.
5. Ultrasonically clean the device for 10 minutes in (20°–25°C) neutral pH detergent.
6. Rinse the device with distilled, reverse osmosis or deionized water for at least 3 minutes.
7. Dry the device with fiber–free cloth or allow drying. Please note that cleaning solutions such as those containing formalin, glutaraldehyde and bleach may damage some devices and should not be used. Cleaning with alkaline solutions should be avoided if other alternatives are available. EOI has validated steam sterilization in the provided surgical cases using one of the following processes using only "FDA–cleared" sterilization wraps. Hospitals may follow equivalent protocols:

| Method | Cycle | Temperature | Exposure Time | Dry Time |
|---|---|---|---|---|
| Steam | Pre–Vacuum | 270°F(132°C) | 4 minutes | 15–30 min. |
| Steam | Gravity | 270°F(132°C) | 15 minutes | 20–30 min |

All products should be treated with care. Improper handling may lead to damage and/or possible improper functioning of the device.

## 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, should 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 should 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 should 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.

## 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 THAT TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/ REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK FOR CURRENT INFORMATION AT 888–349–7808.

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

## INFORMATION

In cases of product complaints, or for further information, please contact:

St. Louis, MO 63026

corelinksurgical.com | p: (888) 349–7808

CoreLink
The Source for Spine™

# FLXfit® 15 PRODUCT LISTING

KIT ORDER #K5000329

## STANDARD FLXfit15 PRODUCT LISTING

| 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 |

## STANDARD FLXfit15 INSTRUMENTS LISTING

| 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 EXPANDER FLXfit15 |
| 2 | 1032-302 | LOCK/UNLOCK SLIDE (COMPATIBLE WITH 90° INSERTER OUTER SHAFT) |
| 2 | 1032-303 | INSERTER-INNER SLEEVE (COMPATIBLE WITH 90°INSERTER OUTER SLEEVE) |
| 2 | 1032-301 | INSERTER-OUTER SLEEVE WITH 90° 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 |

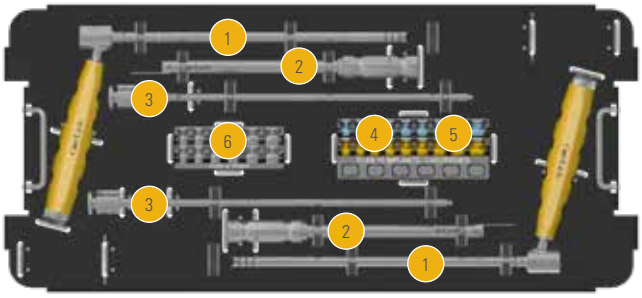
NOTE: Straight inserter available on request.

# FLXfit® 15 IMPLANTS AND INSTRUMENT KIT

KIT ORDER #K5000329

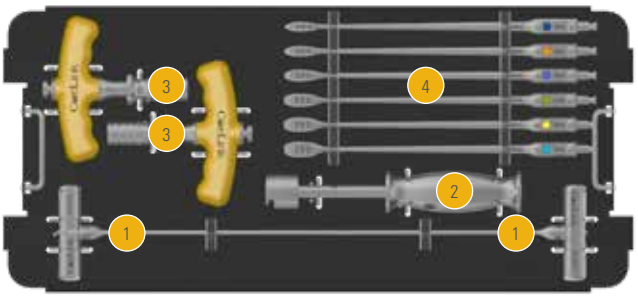
## TOP TRAY

1. Inserter-Outer Sleeve with 90° Handle: #1032-301
2. Lock/Unlock Slide: #1032-302
3. Inserter-Inner Sleeve: #1032-303
4. Cartridges: #SD-15-FU
5. Implants
6. Trials




## BOTTOM TRAY

1. T-Handle Expander: #SD-15-FE
2. Slide Hammer: #08G00017
3. T-Handle: #15G00002
4. Disc Shavers



# DISC PREP PRODUCT LISTING

KIT ORDER #K5000009

| FOUNDATION 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 |

## KIT ORDER #K50000120

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

CoreLink®

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CL–Form–251, Rev. 3