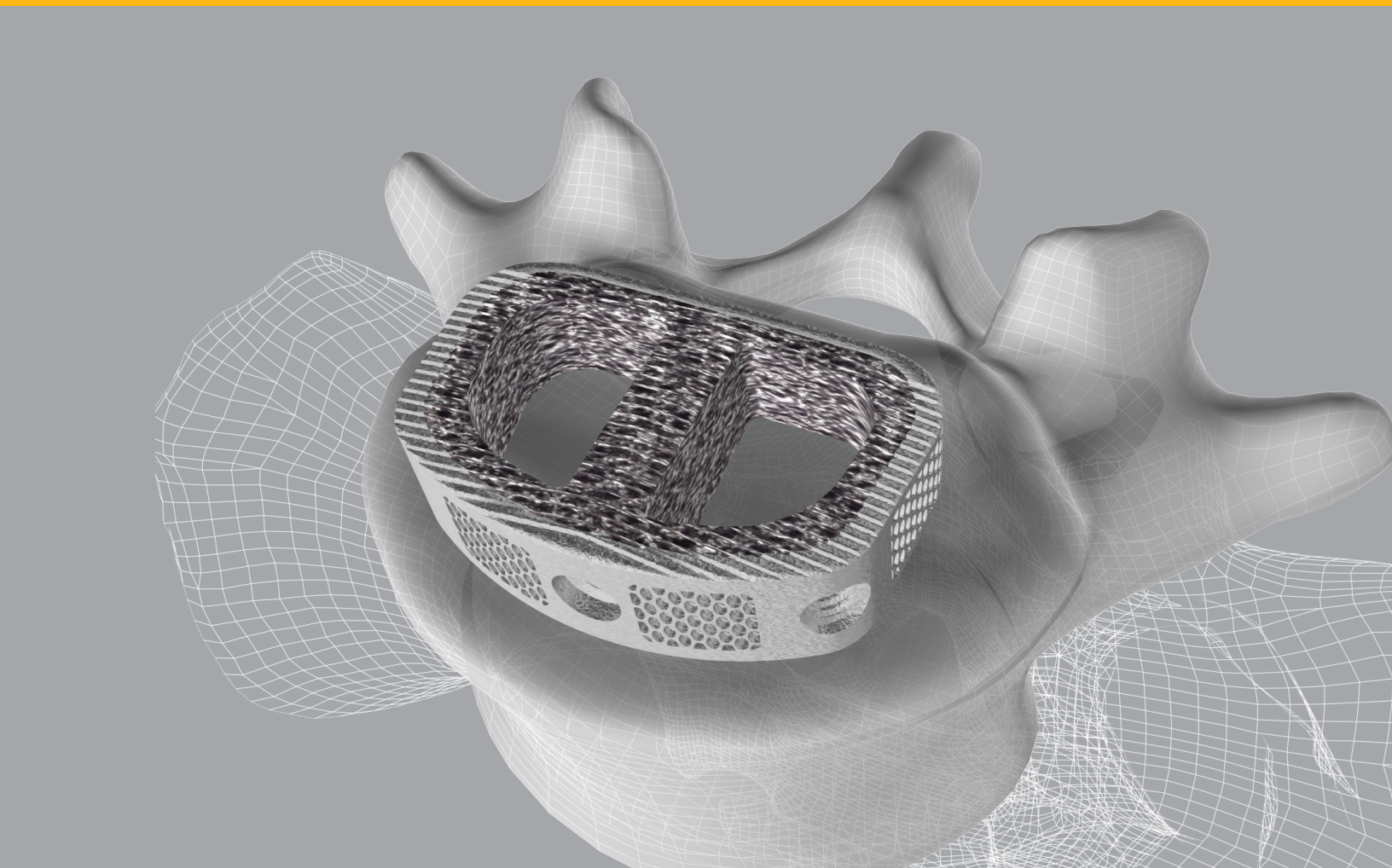
CoreLink
The Source for Spine™

F3D ANTERIOR LUMBAR INTERBODY CAGE SYSTEM

Surgical Technique Guide



F3D ANTERIOR LUMBAR INTERBODY SYSTEM ADVANTAGE

The F3D Anterior Lumbar Interbody System incorporates proven implant geometry, and the revolutionary properties of Mimetic Metal® technology. The F3D family of interbodies offer a wide range of footprint, height, and lordotic options, and are created through a proprietary 3D printing and finishing process.

FEATURES

- Directional lattice framework enables dual-zone micro deflection, designed for load sharing and minimized stress shielding
- Increased osteoblast function compared to PEEK and machined titanium shown in cell culture*
- Greater bony on-growth and in-growth compared to machined titanium shown in an in-vivo sheep model*
- Hydrophilic trabecular endplates designed for optimal blood flow
- Streamlined support structure minimizes density, allowing high quality imaging

**Data on file, pre-clinical data may not be representative of clinical results*

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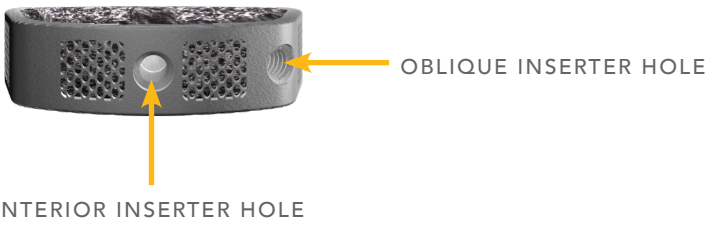
IMPLANT OVERVIEW

The F3D Anterior Lumbar Interbody System consists of anterior lumbar interbody devices made from titanium alloy (6A1-4V ELI). Two different lordosis and two different footprints are available in the standard system.

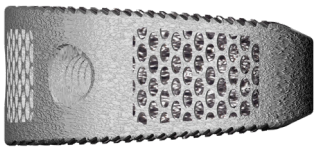
Standard ALIF interbody heights are offered in 1mm increments from 10mm to 17mm. The heights are measurements of the tallest aspect of the anterior surface of the device.

See **Product Listing** details on page 10 for the Posterior Height and specific Graft Volume.



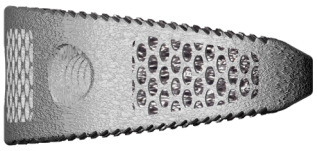
LORDOTIC OPTIONS

8° (SIDE VIEW)



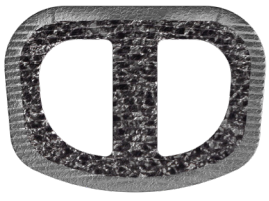
HEIGHT

15° (SIDE VIEW)



FOOTPRINT OPTIONS

25MM X 35MM



Graft Volume –
1.96cm^3 to 4.48cm^3

27MM X 40MM

Graft Volume –
2.61cm^3 to 6.27cm^3

30MM X 45MM

Graft Volume –
3.41cm^3 to 8.13cm^3
Special Order

For a current, complete list of all sizing options, contact CoreLink Customer Service.

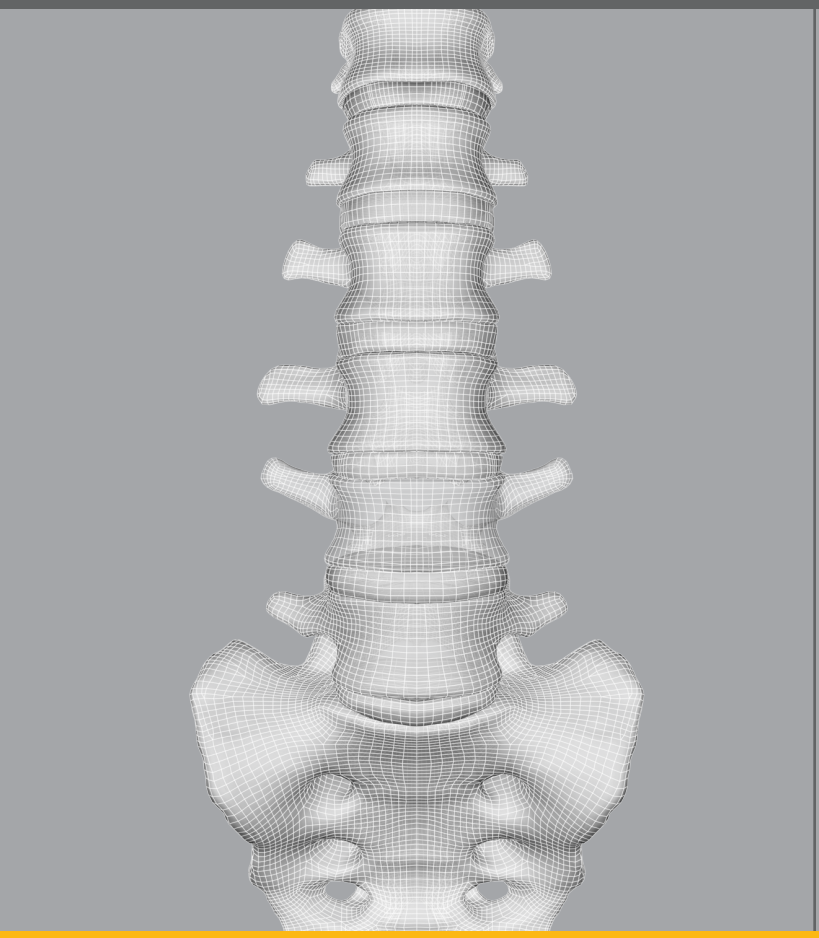
PATIENT POSITIONING AND APPROACH

The patient is put under anesthesia and positioned supine. The operative area is prepared and draped in the standard fashion. An incision is made at the appropriate level(s). Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of the implant(s).

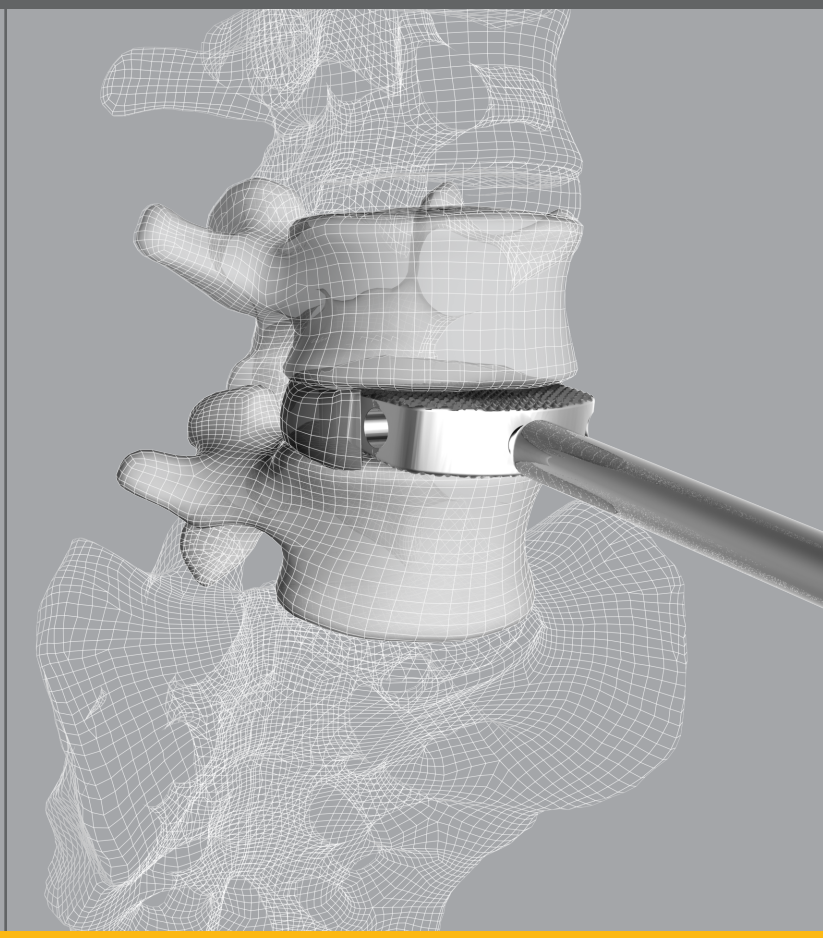
DISCECTOMY AND ENDPLATE PREPARATION

Remove the intervertebral disc and osteophytes as needed. A variety of disc preparation instruments are provided as well as modular trialing rasps to help to decorticate the endplates.

ANTERIOR LUMBAR SPINE



ANTERIOR LUMBAR TRIALING RASP



DISTRACTION

Adequate distraction helps to restore disc height and decompress neural foramen.

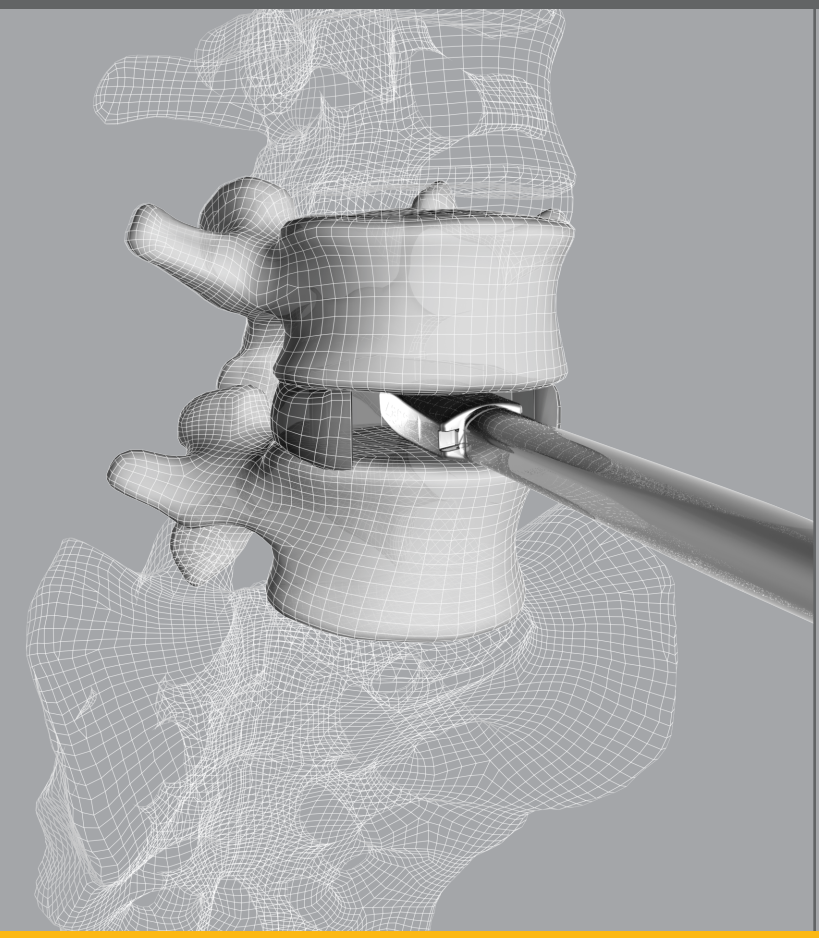
Modular Trials (provided in 1mm increments) may be used to dilate the disc space and to determine the appropriately sized spacer.

Disc Spreaders are also available from Customer Service upon request. To use the Disc Spreaders, first attach the T-handle to the Spreader Shaft, then pull back on the collar of the Shaft to connect the Spreader. Once connected, release the Shaft collar and confirm connection.

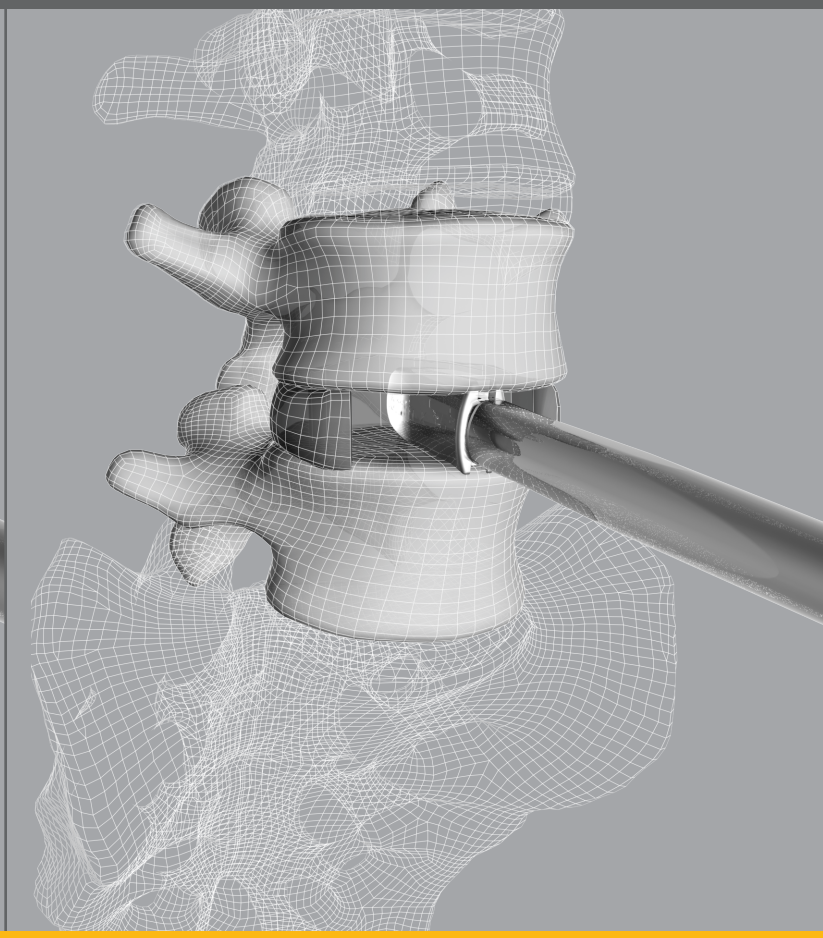
Pulling or handling the Spreader Shaft during rotation of the Spreader must not be performed and could result in instrument failure and/or patient injury. Only rotate the Spreader by using the T-handle. Once rotated, the Handle and Shaft may be removed if desired during disc preparation.

Starting with the shortest Disc Spreader, insert into the disc space and rotate 90 degrees. Repeat the process with incrementally larger Disc Spreaders (10mm-17mm) until adequate distraction has been achieved.

DISC SPREADER – FLAT



DISC SPREADER – FLIPPED UP



IMPLANT SIZING

The supplied Anterior Lumbar Trials have a line-to-line dimensional match with the implants and should be used to determine the height of the cage that will best fit the prepared disc space. A secure fit is desirable to maintain height and promote fusion. Radiographic images may be used to verify proper fit.

Remove Trial from caddy before attaching to Inserter. Thread Trial onto Inserter by hand. Take care not to cross thread Inserter and Trial. Discontinue threading if any resistance is felt as it is an indication of cross threading.

Confirm that the Trial Inserter shoulder is fully seated within the Trial head. When fully connected no Inserter threads are visible and a tight connection is achieved.

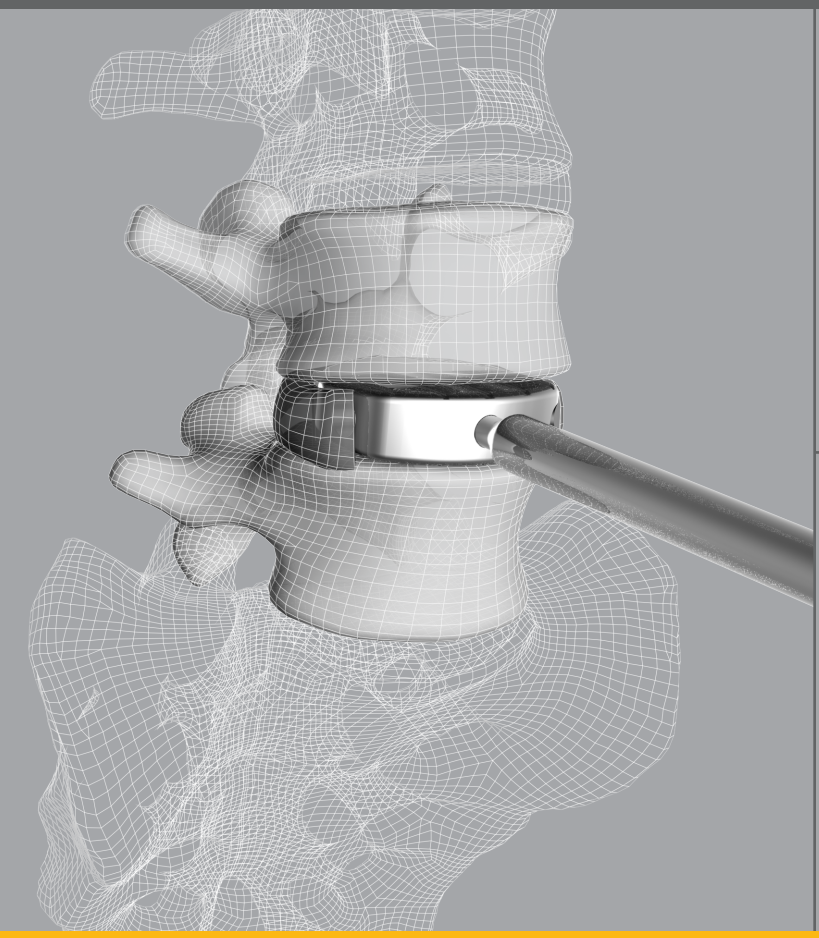
Mallet may be necessary on Inserter's proximal strike cap during trialing steps.

If needed, the Slide Hammer may be used to remove the Trial while loaded on the inserter. **Never detach the Trial from the Trial Inserter in the disc space.**

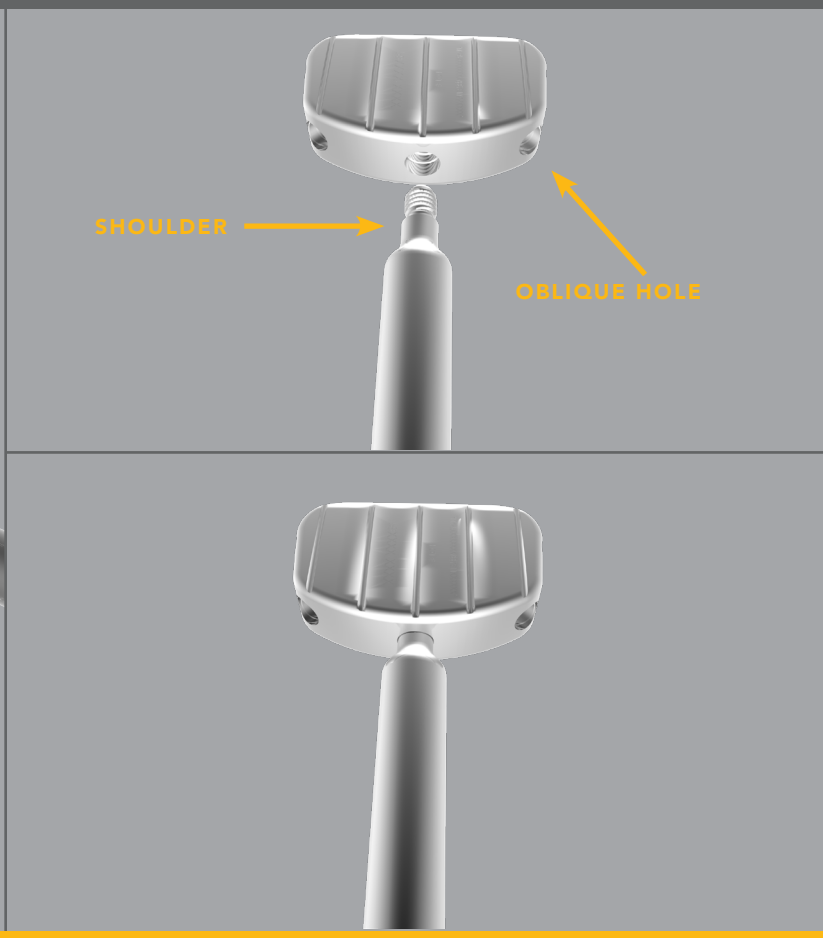
The F3D ALIF cages may feel different than the trials upon insertion into the disc space due to the increased surface roughness of F3D implants.

SLIDE HAMMER CONNECTED TO TRIAL INSERTER

ANTERIOR LUMBAR TRIAL



TRIAL INSERTER SHOULDER



IMPLANT INSERTION

Select the appropriate F3D Anterior Lumbar cage. Thread the implant onto the Cage/Trial Inserter by hand. Take care not to cross thread Inserter and cage. Discontinue threading if any resistance is felt as it is an indication of cross threading.

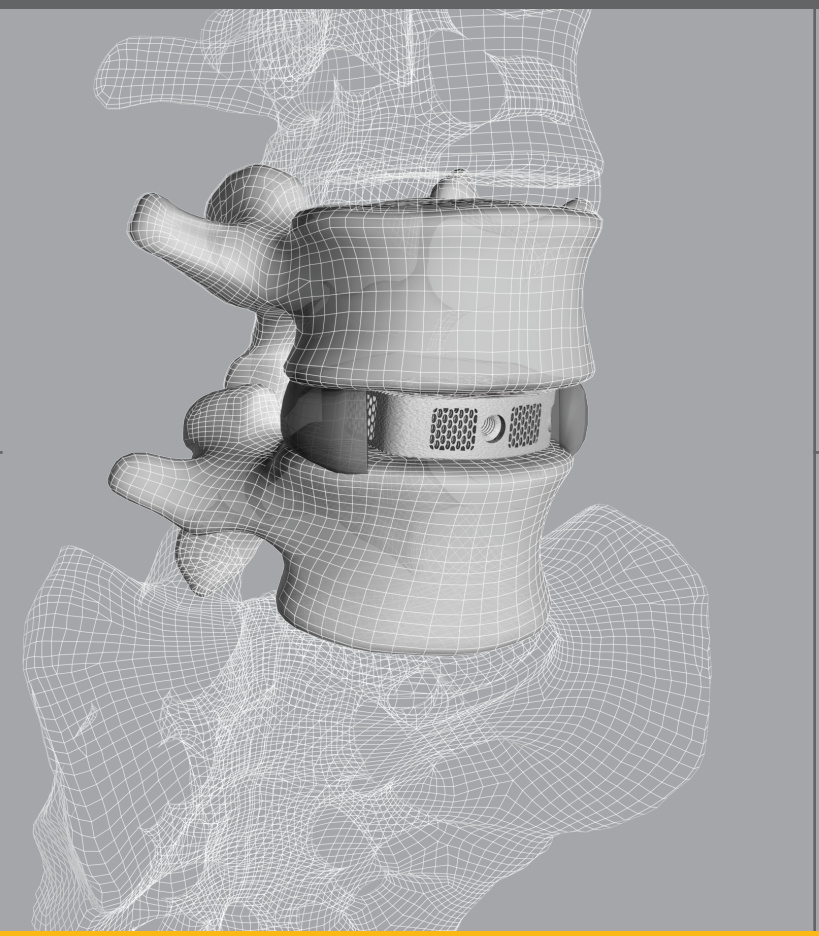
Confirm that the Inserter shoulder is fully seated within the cage. When fully connected, no Inserter threads are visible and a tight connection is achieved. Insert into the prepared intervertebral disc space. Impaction with Mallet may be necessary on Inserter's proximal strike cap during implant insertion. Radiographic images may be used to verify implant size and placement.

INSERTER WITH IMPLANT

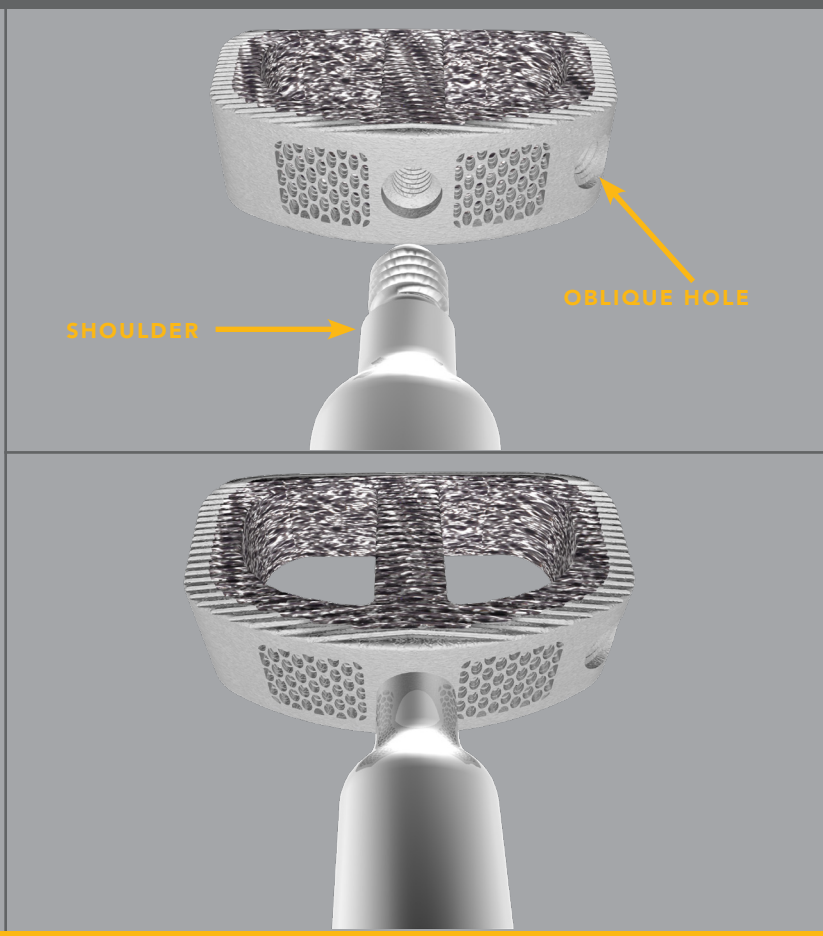
IMPLANT REMOVAL

To remove or revise the implant, reverse all steps of implantation.

IMPLANT INSERTED INTO THE INTERVERTEBRAL DISC SPACE



INSERTER AND ANTERIOR CAGE CONNECTION THREADING



INSTRUCTIONS FOR USE

CORELINK F3D ANTERIOR LUMBAR INTERBODY SYSTEM

OPERATING SURGEON – IMPORTANT INFORMATION

F3D LUMBAR SERIES INTERBODY SPACERS

This IFU applies to the following product families:

F3D ALIF Anterior Lumbar Interbody System

F3D Lateral Lumbar Interbody System

F3D Curved Lumbar System

F3D Straight Lumbar Interbody System

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.

DESCRIPTION

The F3D Lumbar Series Interbody System is an additively manufactured implant comprising of lumbar interbody spacers. They are designed to provide mechanical support to the lumbar spine while arthrodesis occurs. The lumbar lines feature a wide variety of lordosis and footprint options with fully porous architectures and varying pore sizes to offer increased room for bone growth with mechanical stability.

Implants in the F3D Lumbar Series of intervertebral body fusion devices are manufactured from the following materials:

- Medical grade titanium alloy (Ti6AL4V ELI as per ASTM F-136)

Do not use any of the F3D Lumbar Series Interbody System components with components from any other manufacturer or system unless specifically allowed to do so in this or any other CoreLink document. None of the F3D Lumbar Series Interbody implants or implant components should be reused under any circumstances. The instruments provided with the F3D Lumbar Series Interbody System are provided specifically for the implantation of the F3D Lumbar Series implants.

Please refer to the applicable F3D Lumbar Series Interbody System Surgical Technique for additional important information about specific CoreLink implants, in addition to the information described herein.

INDICATIONS

The F3D Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain 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). F3D Lumbar implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

Contraindications of the F3D Series of intervertebral body fusion devices include:

- Active system infection.
- Local infection at the site of surgery.
- Allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis as it may prevent adequate fixation and lead to collapse of the vertebral bodies around this and any other orthopaedic implant.
- Presence of fracture or tumor of the vertebral body.
- Prior fusion at the level(s) to be treated.
- Any condition not described in the Indications for Use.

Other relative contraindications include:

- Conditions that place great stress on the implant or the interface with the endplates of the vertebral bodies, such as severe obesity, may lead to collapse of the vertebral bodies around the device. The treating surgeon must weigh the benefits versus risks of using the device in order to device what is in the best interest of the patient.
- A patient's occupation or activity level or mental capacity. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Bending and/or breakage of any or all devices.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Fracture, damage or penetration of any spinal bone.
- Post-operative change in normal spinal curvature, loss of correction, height.
- Pain, skin penetration, irritation, fibrosis caused by skin pressure by implant components.
- Bursitis.
- Fracture, microfracture, resorption, damage or penetration of any spinal bone at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological, gastrointestinal, and/or reproductive systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, sterility, consumption, sexual dysfunction etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Death.

Additional surgery might become necessary to correct adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS

WARNING: The safety and effectiveness of lumbar interbody fusion device systems have been established only for spinal conditions with acute and chronic instabilities or deformities of lumbar and sacral/iliac spine (L2-S1): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-implant interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implant components and the development of the fusion mass about the implant components. Instruct the patient that implant components may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.

This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

Altering an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the F3D Lumbar Series Interbody Systems surgical technique manual for descriptions of appropriate implant handling and insertion techniques.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

In addition to the warnings and precautions discussed above, patients must be informed about general surgical risks prior to surgery.

PRECAUTIONS: The implantation of the F3D Lumbar Series of intervertebral body fusion devices is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from CoreLink by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the F3D Lumbar Series Interbody Systems rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by CoreLink.

The F3D Lumbar Series Interbody Systems have not been evaluated for safety and compatibility in the MR environment. The F3D Lumbar Series Interbody Systems have not been tested for heating, migration, or image artifact in the MR environment. The safety of the F3D Lumbar Series Interbody Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREPARATION AT POINT OF USE

The implants of the F3D Lumbar Series Interbody Systems are provided sterile. The surgical instruments provided with the F3D Lumbar Series Interbody Systems are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. 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.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. If an instrument is suspected to be damaged, please contact CoreLink for a replacement.

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 should 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 instrument in a lukewarm neutral pH enzyme solution and allow it to soak 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 should 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.
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 should be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the instrument 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

- Sterile Implants: Implants of the F3D Lumbar Series are provided "STERILE" via gamma irradiation and intended for single patient use only. DO NOT RESTERILIZE THIS PRODUCT. Sterility can only be assured if packaging is intact.
- Non-sterile Instruments: Instruments of the F3D Lumbar Series are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. 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 should be sterilized in the steam sterilization cases provided by CoreLink.

INSTRUCTIONS FOR USE (CONTINUED)

Instrument sets must be wrapped in 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 F3D Lumbar Series Interbody System Instruments, provided in a perforated steam sterilization case, may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the systems, 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)
Full Cycle 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 F3D Lumbar Series Interbody Systems 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 implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The F3D Lumbar Series Interbody System implants are available in titanium alloy. It is imperative that the F3D Lumbar Series Interbody System implants do not come into contact in-vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment. Corrosion may accelerate failure of implants. Corrosion also causes metal compounds to be released into the body.
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. **Implant Selection.** Appropriate implant selection and placement are critical factors that affect implant life. Strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to maximize implant longevity. 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. Care must be taken to protect the components from being marred, nicked, or notched. Alterations will product defects which may become the point for eventual implant breakage. Inspection and trial assembly are recommended to determine proper working order of the system. If any components are damaged in any way, do not use them and return them to CoreLink.
4. **Patient Considerations.** The following should 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 should 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.
   - **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, please 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. 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. 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 should carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon should 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.

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

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

SYMBOLS GLOSSARY

SYMBOL	DESCRIPTION	ISO15223 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
	Use-by-Date – Indicates the date after which the medical device is not to be used.	5.1.4
	Lot Number – Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacturer's catalogue number so that the medical device can be identified	5.1.6
	Sterilized via Irradiation – Indicates a medical device has been sterilized using irradiation	5.2.4
	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 – Indicates 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

F3D ALIF IMPLANTS STANDARD

KIT ORDER #K5000309

25MM X 35MM IMPLANTS				
QTY	CATALOG NUMBER	DESCRIPTION	POSTERIOR HEIGHT (MM)	GRAFT VOLUME (CC)
1	3AF2535-0810	25MM X 35MM X 10MM, 8°	5.1	2.5
1	3AF2535-0811	25MM X 35MM X 11MM, 8°	6.1	2.8
2	3AF2535-0812	25MM X 35MM X 12MM, 8°	7.1	3.0
2	3AF2535-0813	25MM X 35MM X 13MM, 8°	8.1	3.3
2	3AF2535-0814	25MM X 35MM X 14MM, 8°	9.1	3.6
2	3AF2535-0815	25MM X 35MM X 15MM, 8°	10.1	3.9
1	3AF2535-0816	25MM X 35MM X 16MM, 8°	11.1	4.2
1	3AF2535-0817	25MM X 35MM X 17MM, 8°	12.1	4.5
1	3AF2535-1510	25MM X 35MM X 10MM, 15°	2.0	2.0
1	3AF2535-1511	25MM X 35MM X 11MM, 15°	3.0	2.2
1	3AF2535-1512	25MM X 35MM X 12MM, 15°	4.0	2.5
1	3AF2535-1513	25MM X 35MM X 13MM, 15°	5.0	2.8
1	3AF2535-1514	25MM X 35MM X 14MM, 15°	6.0	3.0
1	3AF2535-1515	25MM X 35MM X 15MM, 15°	7.0	3.3
1	3AF2535-1516	25MM X 35MM X 16MM, 15°	8.0	3.6
1	3AF2535-1517	25MM X 35MM X 17MM, 15°	9.0	3.9
1	14C00378	F3D – SOFT CASE		

KIT ORDER #K5000310

27MM X 40MM IMPLANTS				
QTY	CATALOG NUMBER	DESCRIPTION	POSTERIOR HEIGHT (MM)	GRAFT VOLUME (CC)
1	3AF2740-0810	27MM X 40MM X 10MM, 8°	4.8	3.5
1	3AF2740-0811	27MM X 40MM X 11MM, 8°	5.8	3.9
2	3AF2740-0812	27MM X 40MM X 12MM, 8°	6.8	4.3
2	3AF2740-0813	27MM X 40MM X 13MM, 8°	7.8	4.7
2	3AF2740-0814	27MM X 40MM X 14MM, 8°	8.8	5.1
2	3AF2740-0815	27MM X 40MM X 15MM, 8°	9.8	5.5
1	3AF2740-0816	27MM X 40MM X 16MM, 8°	10.8	5.9
1	3AF2740-0817	27MM X 40MM X 17MM, 8°	11.8	6.3
1	3AF2740-1510	27MM X 40MM X 10MM, 15°	1.5	2.6
1	3AF2740-1511	27MM X 40MM X 11MM, 15°	2.5	3.0
1	3AF2740-1512	27MM X 40MM X 12MM, 15°	3.5	3.4
1	3AF2740-1513	27MM X 40MM X 13MM, 15°	4.5	3.8
1	3AF2740-1514	27MM X 40MM X 14MM, 15°	5.5	4.2
1	3AF2740-1515	27MM X 40MM X 15MM, 15°	6.5	4.6
1	3AF2740-1516	27MM X 40MM X 16MM, 15°	7.5	5.0
1	3AF2740-1517	27MM X 40MM X 17MM, 15°	8.5	5.4
1	14C00378	F3D – SOFT CASE		

For a complete list of F3D implant options, contact CoreLink Customer Service.

F3D ALIF IMPLANTS SPECIAL ORDER

KIT ORDER #K5000376

30MM X 45MM IMPLANTS

QTY	CATALOG NUMBER	DESCRIPTION	POSTERIOR HEIGHT (MM)	GRAFT VOLUME (CC)
1	3AF3045-0810	30MM X 45MM X 10MM, 8°	4.4	4.7
1	3AF3045-0811	30MM X 45MM X 11MM, 8°	5.4	5.3
2	3AF3045-0812	30MM X 45MM X 12MM, 8°	6.4	5.9
2	3AF3045-0813	30MM X 45MM X 13MM, 8°	7.4	6.4
2	3AF3045-0814	30MM X 45MM X 14MM, 8°	8.4	7.0
2	3AF3045-0815	30MM X 45MM X 15MM, 8°	9.4	7.6
1	3AF3045-0816	30MM X 45MM X 16MM, 8°	10.4	8.1
1	3AF3045-1510	30MM X 45MM X 10MM, 15°	1.7	3.4
1	3AF3045-1511	30MM X 45MM X 11MM, 15°	2.7	4.0
1	3AF3045-1512	30MM X 45MM X 12MM, 15°	3.7	4.5
1	3AF3045-1513	30MM X 45 MM X 13MM, 15°	4.7	5.1
1	3AF3045-1514	30MM X 45 MM X 14MM, 15°	5.7	5.7
1	3AF3045-1515	30MM X 45 MM X 15MM, 15°	6.7	6.3
1	3AF3045-1516	30MM X 45 MM X 16MM, 15°	7.7	6.8
1	14C00378	F3D – SOFT CASE		

30M X 45MM TALL IMPLANTS

QTY	CATALOG NUMBER	DESCRIPTION	POSTERIOR HEIGHT (MM)	GRAFT VOLUME (CC)
1	3AF3045-0818	30MM X 45MM X 18MM, 8°	12.4	9.3
1	3AF3045-0819	30MM X 45MM X 19MM, 8°	13.4	9.8
1	3AF3045-0820	30MM X 45MM X 20MM, 8°	14.4	10.4
1	3AF3045-0821	30MM X 45MM X 21MM, 8°	15.4	11.0
1	3AF3045-1518	30MM X 45MM X 18MM, 15°	9.7	8.0
1	3AF3045-1519	30MM X 45MM X 19MM, 15°	10.7	8.5
1	3AF3045-1520	30MM X 45MM X 20MM, 15°	11.7	9.1
1	3AF3045-1521	30MM X 45MM X 21MM, 15°	12.7	9.7

Tall 30mm x 45mm Implants are shipped individually.

KIT ORDER #K5000431

25MM X 35MM / 27MM X 40MM TALL IMPLANTS

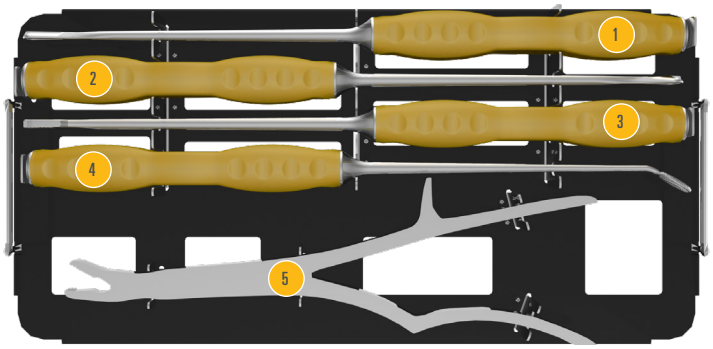
QTY	CATALOG NUMBER	DESCRIPTION	POSTERIOR HEIGHT (MM)	GRAFT VOLUME (CC)
1	3AF2535-0818	25MM X 35MM X 18MM, 8°	13.1	4.8
1	3AF2535-0819	25MM X 35MM X 19MM, 8°	14.1	5.1
1	3AF2535-0820	25MM X 35MM X 20MM, 8°	15.1	5.3
1	3AF2535-0821	25MM X 35MM X 21MM, 8°	17.4	5.6
1	3AF2535-1518	25MM X 35MM X 18MM, 15°	10.0	5.0
1	3AF2535-1519	25MM X 35MM X 19MM, 15°	11.0	4.5
1	3AF2535-1520	25MM X 35MM X 20MM, 15°	12.0	4.8
1	3AF2535-1521	25MM X 35MM X 21MM, 15°	13.0	5.1
1	3AF2740-0818	27MM X 40MM X 18MM, 8°	12.8	6.7
1	3AF2740-0819	27MM X 40MM X 19MM, 8°	13.8	7.1
1	3AF2740-0820	27MM X 40MM X 20MM, 8°	14.8	7.5
1	3AF2740-0821	27MM X 40MM X 21MM, 8°	15.8	7.9
1	3AF2740-1518	27MM X 40MM X 18MM, 15°	9.5	5.8
1	3AF2740-1519	27MM X 40MM X 19MM, 15°	10.5	6.2
1	3AF2740-1520	27MM X 40MM X 20MM, 15°	11.5	6.6
1	3AF2740-1521	27MM X 40MM X 21MM, 15°	12.5	7.0
1	14C00378	F3D – SOFT CASE		

DISC PREP INSTRUMENT KIT STANDARD

KIT ORDER #K5000303

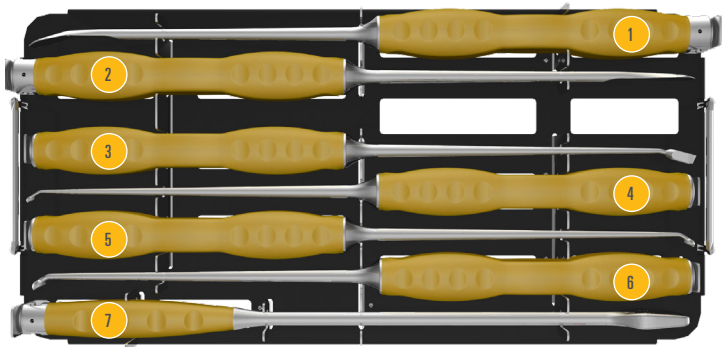
DISC PREP TRAY 1 – TOP TRAY

1. Uterine Currette – 25mm x 11mm: #7818-003*
2. Uterine Currette – 25mm x 17mm: #7818-004*
3. Flat Rectangular Rasp, single-sided, 12mm x 30mm: #03A00534
4. Domed Rasp, angled 30°: #03A00535
5. Rongeur Double Action, 14 inch with teeth, 8mm: #7900-101



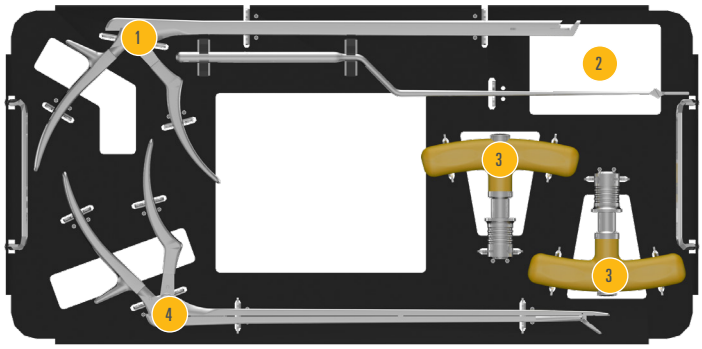
TRIAL TRAY 2 - MIDDLE TRAY

1. Angled Cobb Elevator – 22mm: #09A00142
2. Straight Cobb Elevator – 22mm: #09A00143
3. Box Curette – 8mm x 20mm, angled 15°: #04A00009*
4. Cup Curette – 4mm x 6mm oval, angled 15°: #04A00002
5. Cup Curette – 6mm x 8mm oval, angled 15°: #04A00004
6. Cup Curette – 8mm x 10mm oval, angled 15°: #04A00006*
7. Wedge Distractor: #5830-200*



DISC PREP TRAY 3 – BOTTOM TRAY

1. Kerrison Ronguer:
   325mm x 4mm Straight – #7803-604
   325mm x 6mm Straight – #7803-606
2. Bayoneted or Straight Knife Handle: #17815-002/#7815-003
3. T-handle – non-ratcheting, 1/4 inch – qty 2: #8025-100
4. Pituitary Ronguer:
   325mm x 4mm Straight – #17A00014
   325mm x 6mm Straight – #17A00015



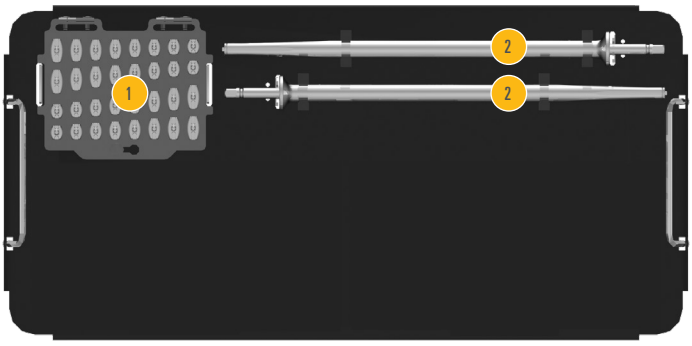
SPECIAL ORDER

KIT ORDER #K5000304

DISC SPREADER INSTRUMENT TRAY

1. Disc Spreaders – 8° and 15°, 10mm – 17mm
2. Disc Spreader Shaft – qty 2: #4801-100*

*** NOTE: Disc Spreaders and Disc Spreader Shafts to be used with T-Handles in the Disc Prep Set (Disc Prep Set Order # K5000303)**



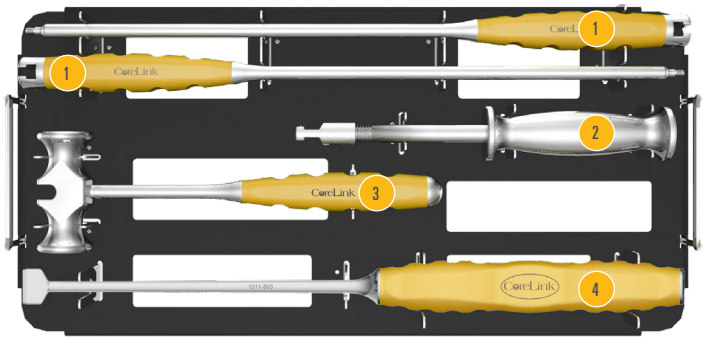
*Special Order. Straight Cup Curettes also available upon request. Contact Customer Service for Special Order items.

INSTRUMENT AND TRIAL KIT STANDARD

KIT ORDER #K5000305

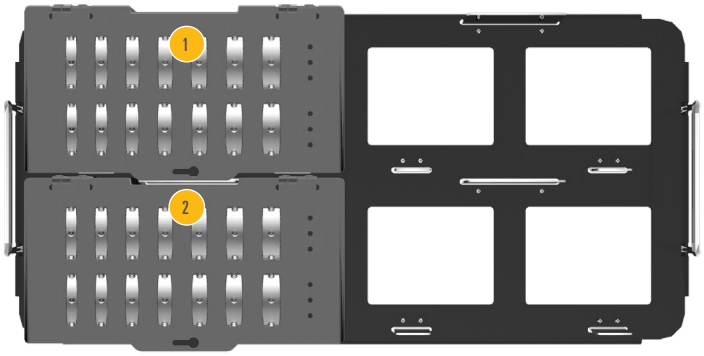
TRIAL TRAY 1 – TOP TRAY

1. Cage / Trial / Trial Rasp Inserters: 2 qty #01A00038
2. Large Slide Hammer: #08G00001
3. Large Mallet: #1011-500
4. Straight Tamp: #1011-503



TRIAL TRAY 2 – BOTTOM TRAY

1. 25mm x 35mm Trials, 8° and 15°, 10mm – 17mm (1mm increments)
2. 27mm x 40mm Trials, 8° and 15°, 10mm – 17mm (1mm increments)



TRIAL RASPS SPECIAL ORDER

KIT ORDER #K5000381

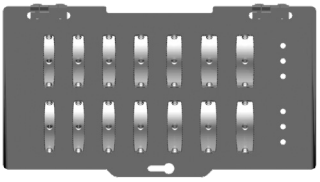
TRIAL RASP CADDIES

1. 25mm x 35mm Trial Rasps – 8° and 15°, 10mm – 17mm (1mm increments)
2. 27mm x 40mm Trial Rasps – 8° and 15°, 10mm – 17mm (1mm increments)

KIT ORDER #K5000355

30MM X 45MM TRIAL RASP CADDY

30mm x 45mm Trial Rasps – 8° and 15°, 10mm – 17mm (1mm increments)



TRIALS SPECIAL ORDER

TRIAL CADDIES	
KIT ORDER#	DESCRIPTION
353	30MM X 45MM – 8° AND 15°; STANDARD HEIGHTS (10MM-16MM)
365	25MM X 35MM TALL – 8° AND 15° (18MM - 21MM)
366	27MM X 40MM TALL – 8° AND 15° (18MM - 21MM)
367	30MM X 45MM TALL – 8° AND 15° (18MM - 21MM)

For a complete list of F3D implant options, contact CoreLink Customer Service.

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CoreLinkSurgical.com 888.349.7808

Designed and manufactured in St. Louis, MO 63026

CL-FORM-243, Rev. 4