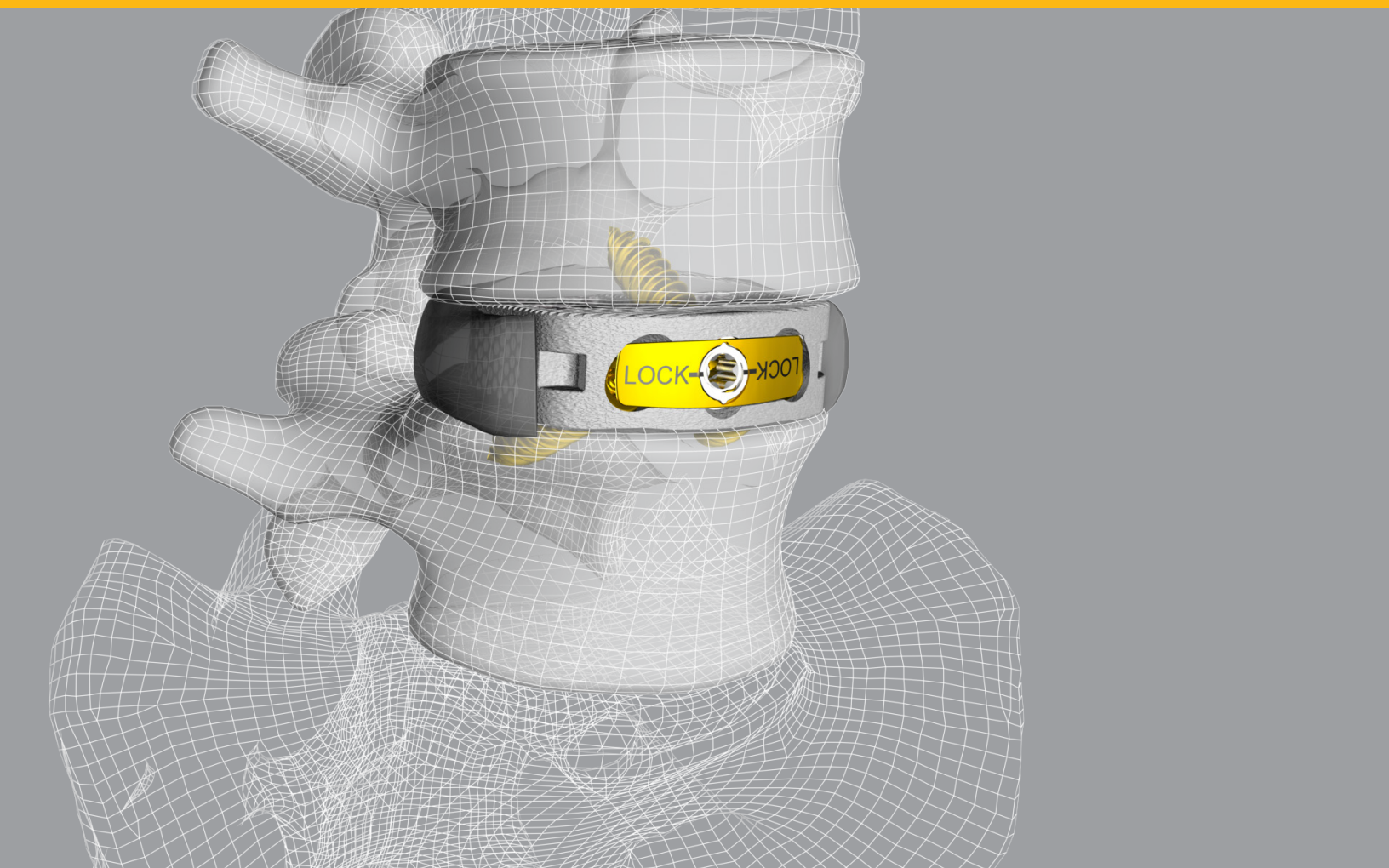
CoreLink
The Source for Spine™

M3 STAND-ALONE ALIF SYSTEM

Surgical Technique Guide



THE M3 ADVANTAGE

The CoreLink M3 Stand-alone Anterior Lumbar Interbody Fusion System features a versatile, three-screw design and a comprehensive array of straight and angled instruments. When paired with M3 screws and lock, the M3 Stand-alone ALIF ensures solid enduring screw fixation and surgeon peace of mind.

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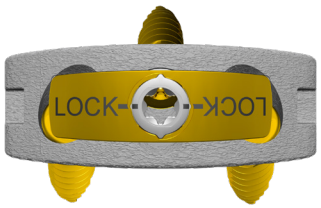
PRODUCT OVERVIEW

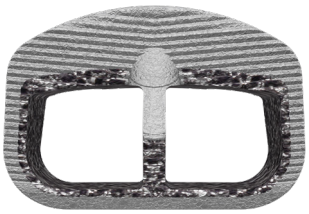
M3 is an integrated ALIF system comprised of a 3D printed spacer, three diverging bone screws, and an anterior locking plate.



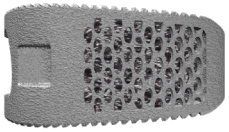
SYSTEM FEATURES

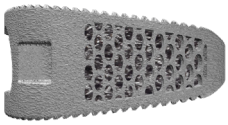
- Patented Mimetic Metal® technology is designed to emulate key characteristics of natural bone to provide an optimal structure and environment for healing
- Reliable and sturdy locking mechanism provides visual and tactile confirmation
- Large open spacer graft windows for increased autograft volume
- Versatile straight and angled instrumentation for difficult ALIF access situations
- Self-centering awl options with retractable tips to prevent vascular injuries

FOOTPRINT DIMENSIONS



LORDOSIS OPTIONS


8°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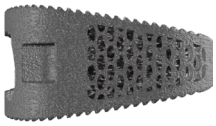
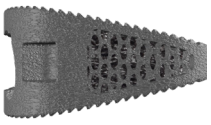
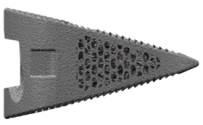

20°
Special Order


25°
Special Order


30°
Special Order

CONTACT CORELINK CUSTOMER SERVICE FOR SPECIAL ORDER OPTIONS.

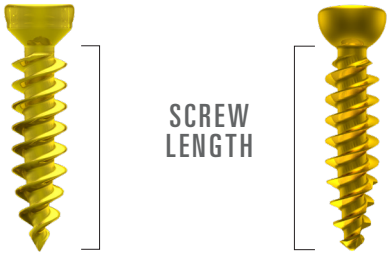
NOTE: STANDARD INTERBODY HEIGHTS ARE OFFERED IN 1MM INCREMENTS FROM 10MM TO 17MM

PRODUCT OVERVIEW (CONTINUED)

SCREW OPTIONS

FIXED ANGLE SCREW (DENOTED BY BLACK LINE)

VARIABLE ANGLE SCREW

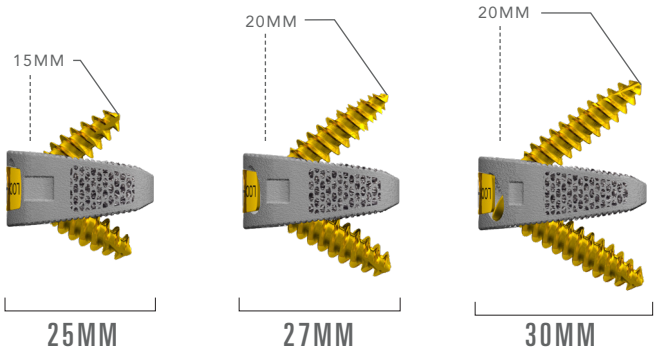


M3 screw length is a measurement of the smooth and threaded portion of the screw shank. The screw head is 3.85mm and the smooth portion of the shank is 1mm. Screw tip depth varies slightly based on screw trajectory.

RECOMMENDED SCREW/SPACER COMBINATION

CAGE	SCREW
25MM X 35MM	15MM SCREW
27MM X 40MM	20MM SCREW
30MM X 45MM	20MM SCREW

15mm is preferred screw length for 25mm x 35mm cage; 20mm screw may also be used



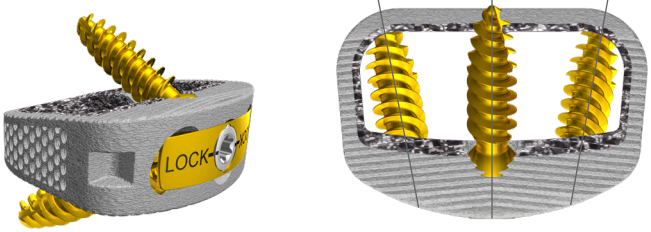
NOTE: SELF-TAPPING SCREWS ARE STANDARD, SELF-DRILLING SCREWS ARE SPECIAL ORDER

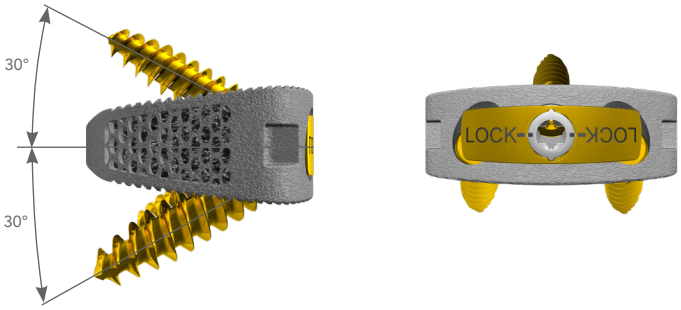
SCREW ANGULATION

Positioning the screws outside of the acceptable angle ranges will result in complications during screw seating. See page 34 for more information on pairing dimensions and variable screw trajectories.

FIXED ANGLE TRAJECTORIES

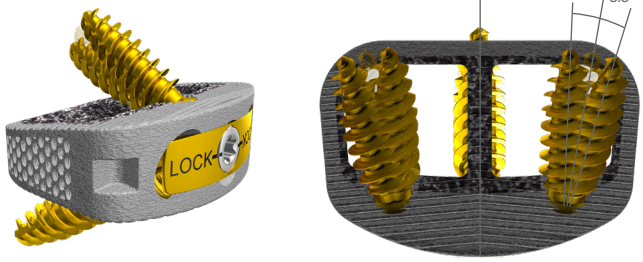
- Center Screw Hole
  - 30° Cranial
- Lateral Screw Holes
  - 30° Caudal x 11° Lateral

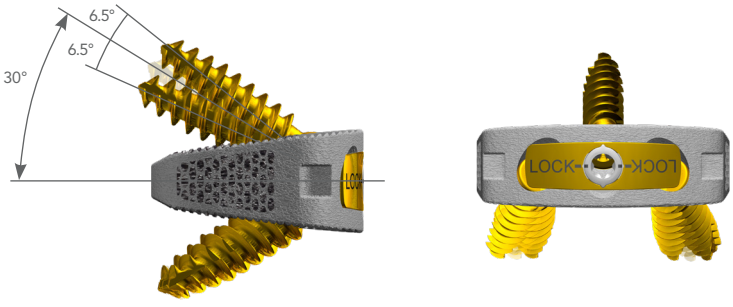




VARIABLE ANGLE TRAJECTORIES

- Center Screw Hole
  - 30° +/- 6.5° Cranial
- Lateral Screw Holes
  - 30° Caudal x 11° Lateral +/- 6.5°





PATIENT POSITIONING AND APPROACH

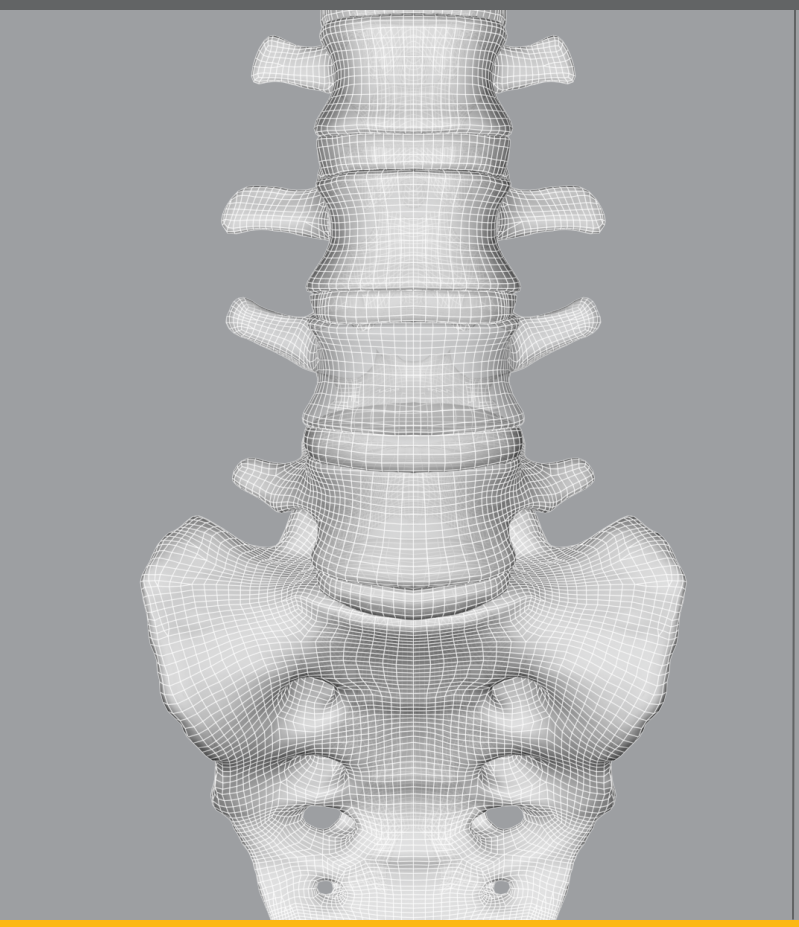
The patient is put under anesthesia and positioned supine. The operative area is prepared and draped in the standard fashion. An incision is made at the appropriate level(s). Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of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

DISCECTOMY AND ENDPLATE PREPARATION

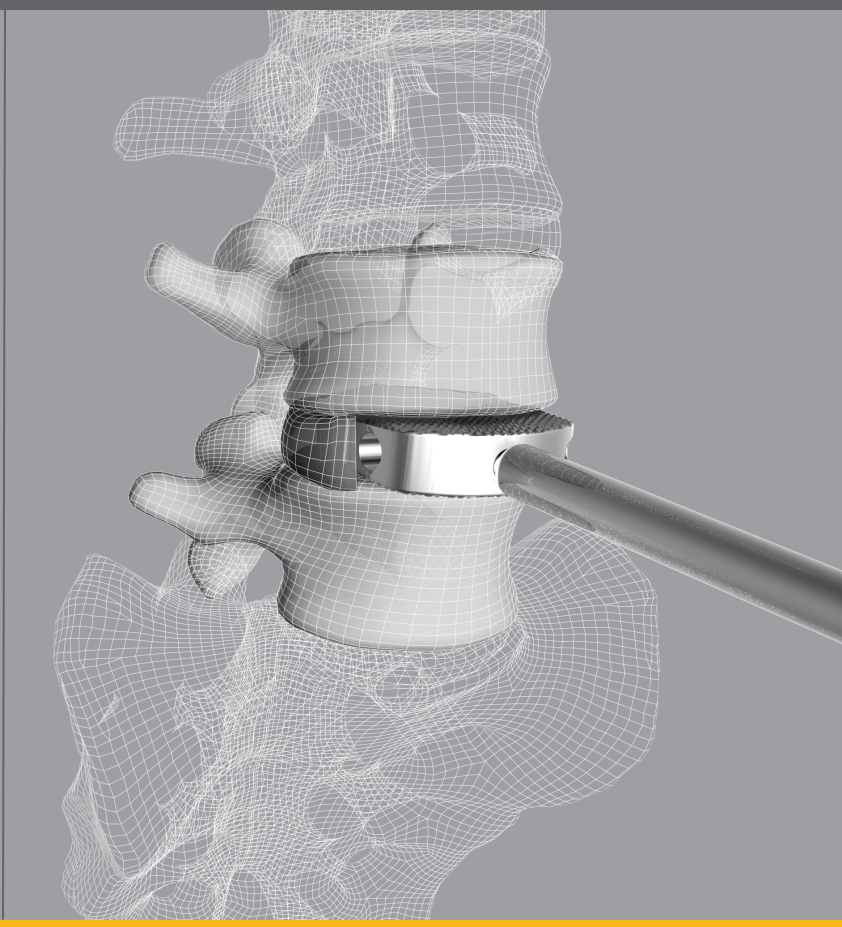
Remove the intervertebral disc and osteophytes as needed. A variety of disc preparation instruments are provided as well as modular trialing rasps to help to decorticate the endplates.

Modular Trialing Rasps are special order.

ANTERIOR LUMBAR SPINE



ANTERIOR LUMBAR TRIALING RASP



DISTRACTION

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

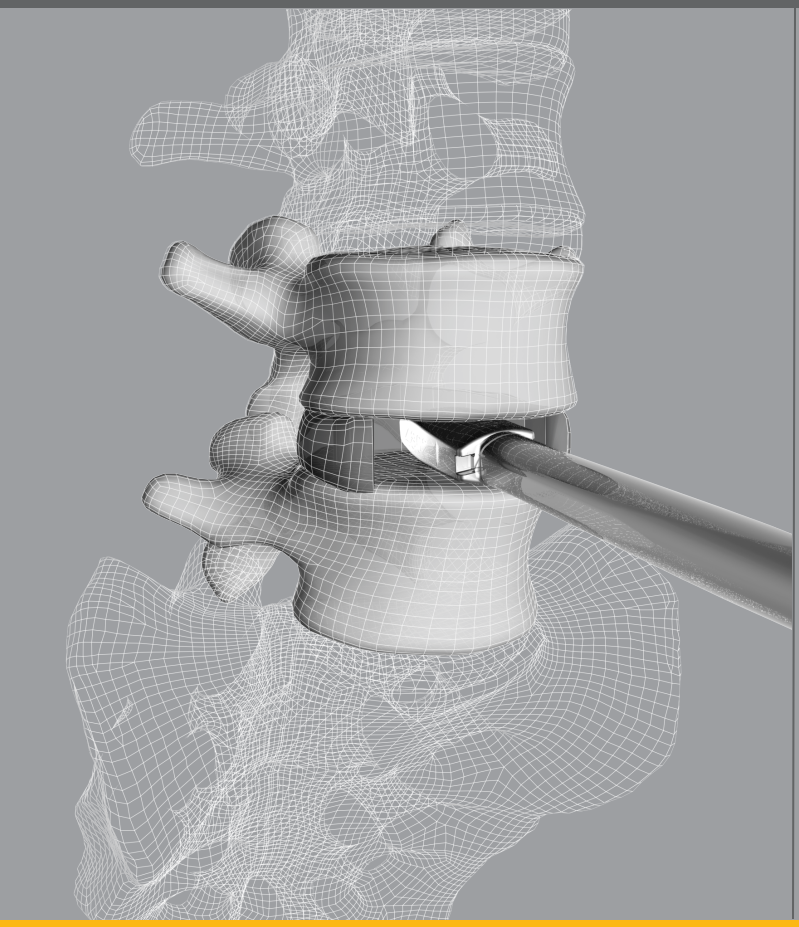
Modular Disc Spreaders are available as special order items. Disc Spreaders are available in 8 and 15 degrees from 10mm-17mm heights. To assemble Disc Spreader instrument, first attach T-handle to Spreader Shaft. Align the opening on Spreader Shaft with the post on Modular Spreader. Pull back Shaft collar and then release collar for a secure connection to Spreader.

Pulling or handling the Spreader Shaft during rotation of the Spreader must not be performed and will 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.

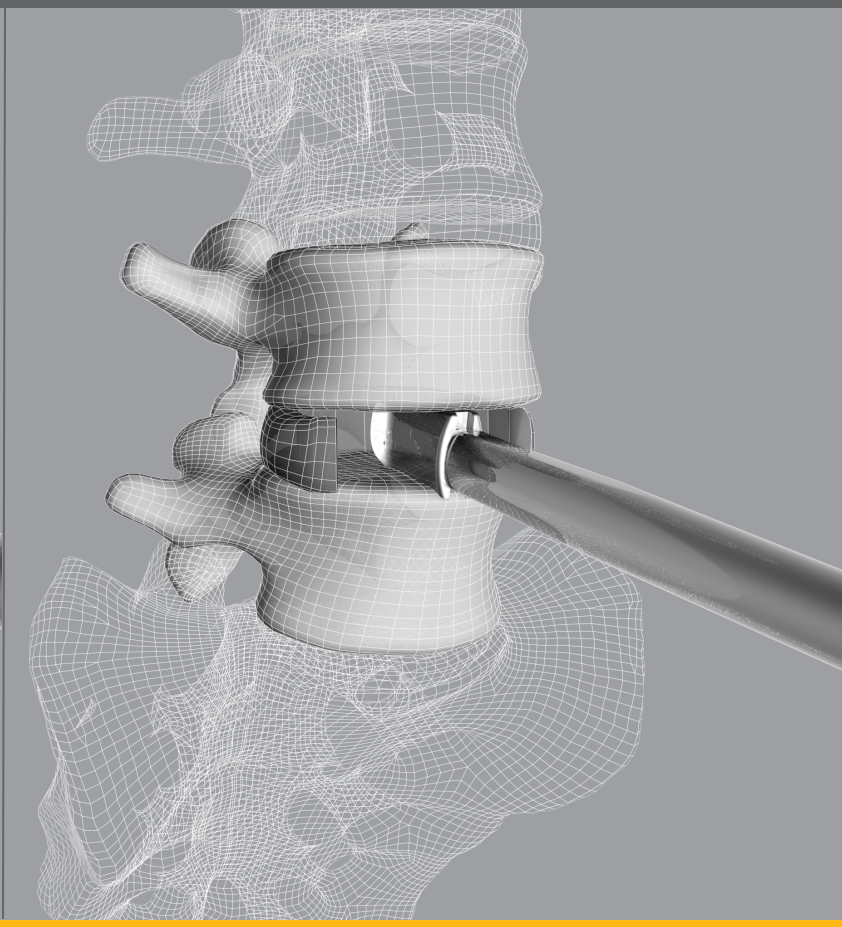
Starting with the shortest Disc Spreader, insert into the disc space and rotate 90 degrees. Repeat the process with incrementally larger Disc Spreaders until adequate distraction has been achieved.

Modular Trials may be used to dilate the disc space and to determine the appropriately sized spacer.

DISC SPREADER – INSERTION POSITION



DISC SPREADER – ROTATED 90 DEGREES



SPACER SIZING

The modular, smooth Trials have a line-to-line dimensional match with the spacer and must be used to determine the height of the spacer that will best fit the prepared intervertebral space. A secure fit is desirable to maintain height and promote fusion. Radiographic images must be used to verify proper fit.

The M3 spacers may feel different than the Trials upon insertion into the disc space due to the increased surface roughness of the M3 implant.

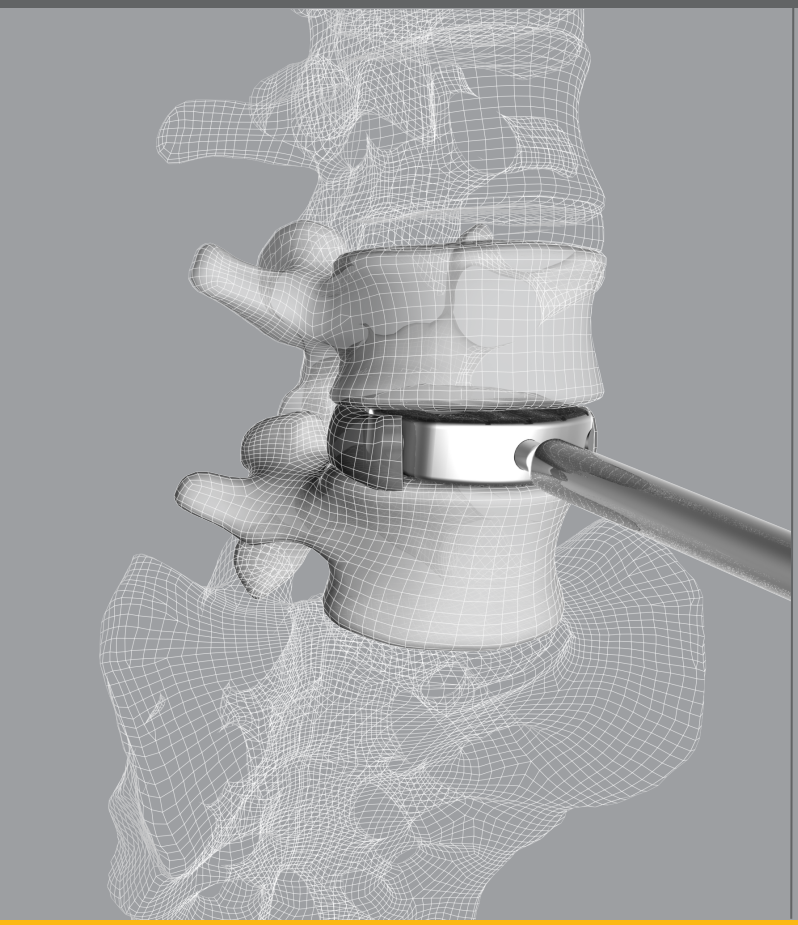
To use, thread the Trial onto the Trial Inserter and insert the Trial into the desired disc space.

Repeat the process with incrementally taller Trials until appropriate fit has been achieved.

If necessary, the Slide Hammer may be used to remove the Trial from the disc space.

SLIDE HAMMER CONNECTED TO TRIAL INSERTER

ANTERIOR LUMBAR TRIAL



M3 SPACER INSERTION

Select and pack the appropriately sized M3 spacer with autograft material.

The Inserter is compatible with all M3 spacers regardless of footprint, lordosis, or height. Check to ensure Inserter's connection feature is in the neutral position by rotating the Locking Knob counterclockwise. Center the Inserter midline on the anterior surface of the spacer. Rotate the Locking Knob on the M3 inserter clockwise a quarter turn for secure connection to spacer.

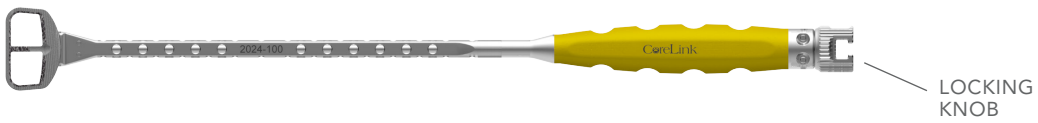
Pay careful attention to spacer orientation prior to insertion to ensure correct cephalad and caudal screw orientation.

During Inserter and cage assembly, align etched dots on Inserter with the double screw side of cage. This will remind the surgeon about screw orientation prior to cage insertion.

Radiographic images must be used to verify implant size and placement.

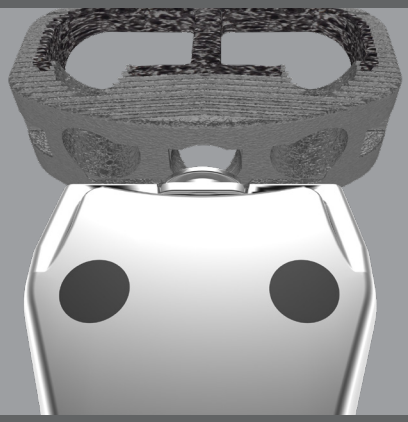
The Tamp can be used to reposition the spacer in the disc space. **Do not use Inserter to reposition spacer.**

If necessary, the Slide Hammer can be used with the Inserter to remove the spacer.

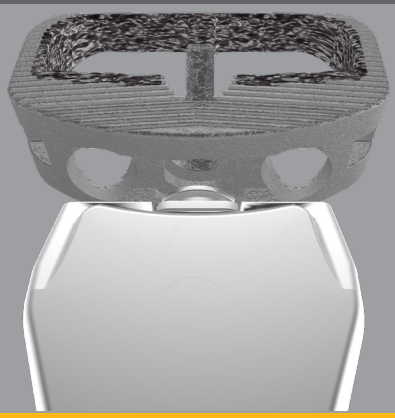


INSERTER CONNECTED TO M3 SPACER

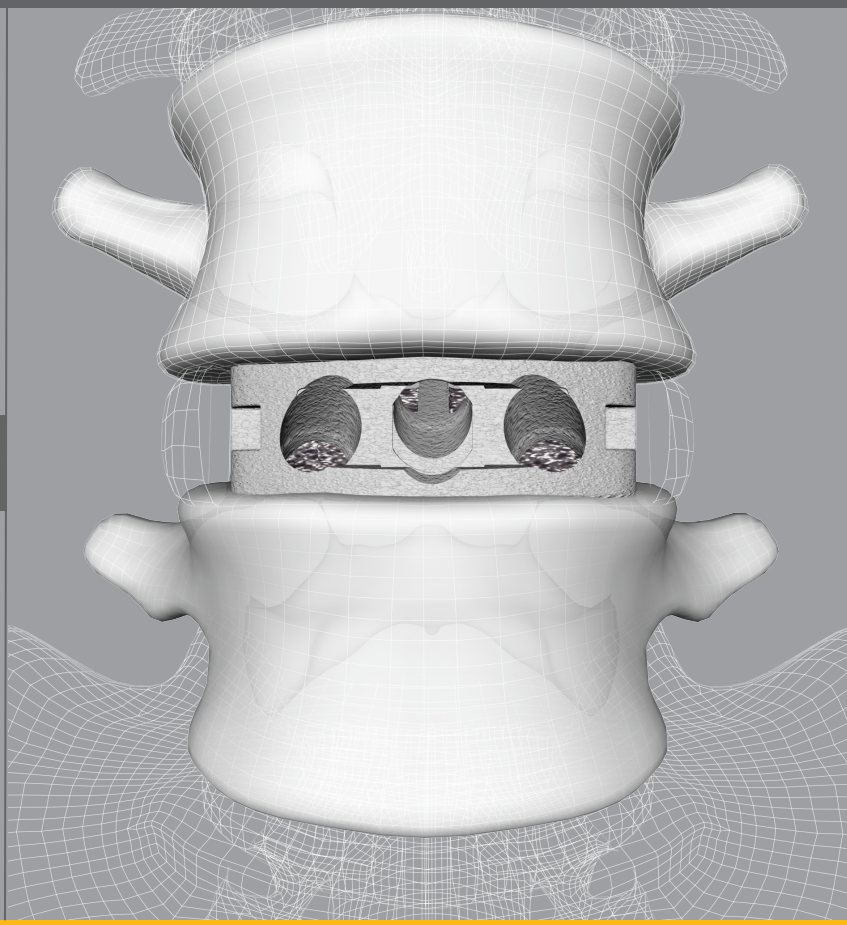
TWO SCREWS CEPHALAD, ONE SCREW CAUDAL



ONE SCREW CEPHALAD, TWO SCREWS CAUDAL



SPACER IN DISC SPACE



SCREW HOLE PREPARATION

AWL OPTIONS

The Awl options have a protective sleeve to help prevent accidental vessel injury. The 15mm Awl is intended to puncture cortical bone. The Awl Tip will extended approximately 2.5mm shorter than the tip of a 15mm screw.

15MM AWL OPTIONS INCLUDE:

- Straight Awl with fixed and variable tips
- Curved Awl with fixed and variable tips

NOTE: Contact Customer Service if different solutions are needed

AWL ASSEMBLY

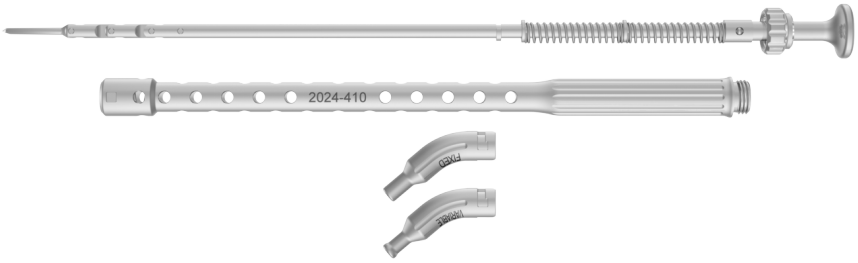
Straight Awl Components:

- Straight Awl Inner Shaft (2024-408)
- Outer Awl Sleeve (2024-410)
- Straight Fixed Awl Tip (2024-405)
- Straight Variable Awl Tip (2024-404)
- Side Handle (8500-100)*

Curved Awl Components:

- Curved Awl Inner Shaft (2024-409)
- Outer Awl Sleeve (2024-410)
- Curved Fixed Awl Tip (2024-407)
- Curved Variable Awl Tip (2024-406)
- Side Handle (8500-100)*

*Not shown

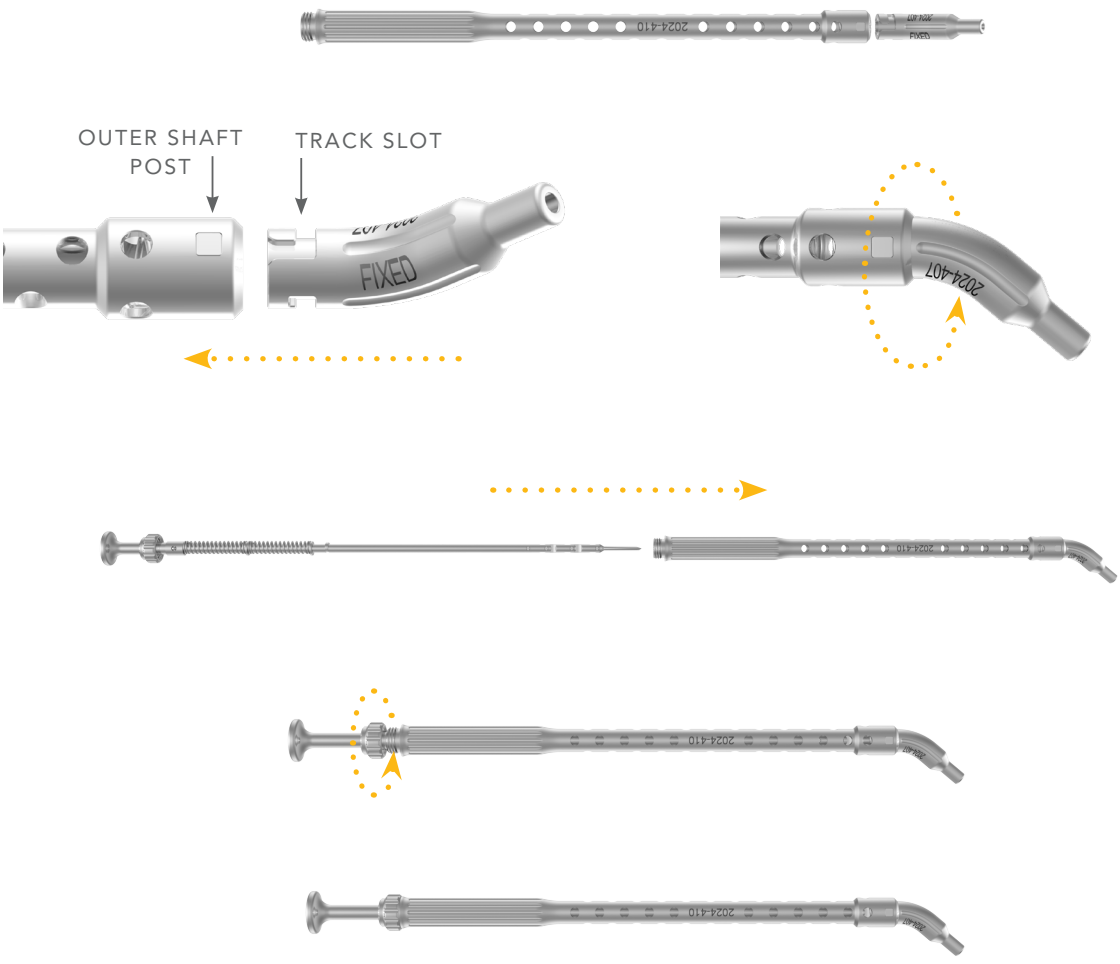


The Fixed and Variable Awl Tips match the Fixed and Variable Screw angles as outlined on page 2.

SCREW HOLE PREPARATION (CONTINUED)

AWL ASSEMBLY (CONTINUED)

Align Outer Shaft post with track slot on Awl Tip. Insert Awl Tip and apply pressure while rotating Awl Tip a quarter turn counterclockwise to secure connection. Verify that a tight connection is achieved.



FULLY ASSEMBLED AWL

AWL USE

Insert Awl into the target screw hole and then provide gentle impaction on the handle strike cap. Before making the next new pilot hole, insert the screw to prevent accidental spacer migration.

Fixed Awl Tip must be fully seated in screw pocket to provide fixed trajectory. Position Awl Shaft slightly away from trajectory direction to ensure proper cephalad/caudal angulation and to avoid shallow Awl and Screw trajectories.

STANDARD DRILL OPTIONS (15MM, 20MM)

Attach T-handle or Straight Handle to the proximal end of the desired Drill.

- Ball-jointed Drill (2024-115 and 2024-116)
- All Drills have a 3mm outer diameter

Insert the Drill with Drill Guide into the target screw hole. Set Handle to "Lock" or "Forward Ratchet" to drill pilot hole. Radiographic images must be used to confirm drill trajectory and length.

The Straight and Ball-jointed Drills **must be used with one of the system's Guide options:**

- Single-barrel Variable Adjustable Drill Guide (2024-113)
- Single-barrel Fixed Adjustable Drill Guide (2024-109)

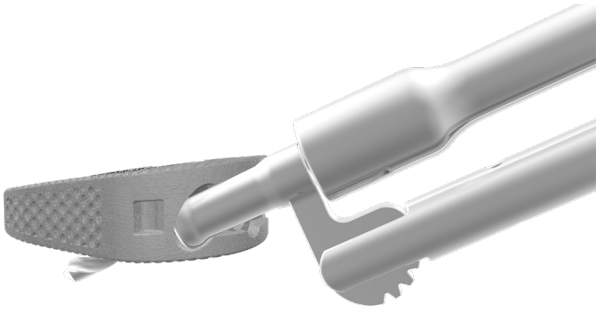
BALL-JOINTED DRILL

SCREW HOLE PREPARATION (CONTINUED)

DRILL GUIDE OPTIONS

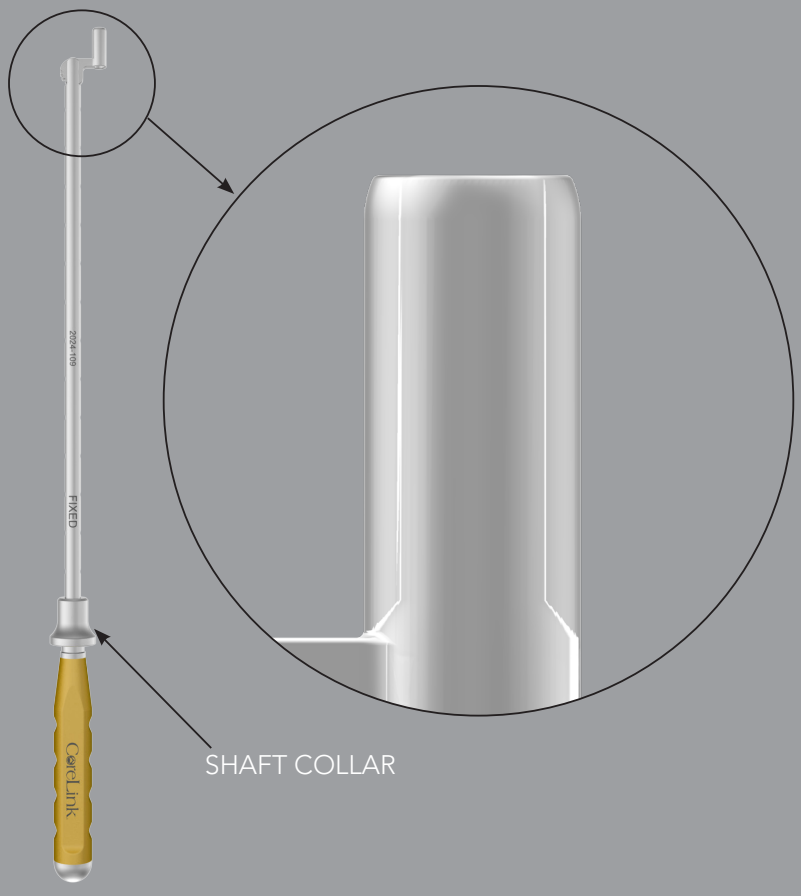
The Single-barrel Guides provide either fixed or variable angulation. See page 2 for screw angulations.

Both Drill Guides have an adjustable shaft. Pulling back on the shaft collar will allow adjustments.

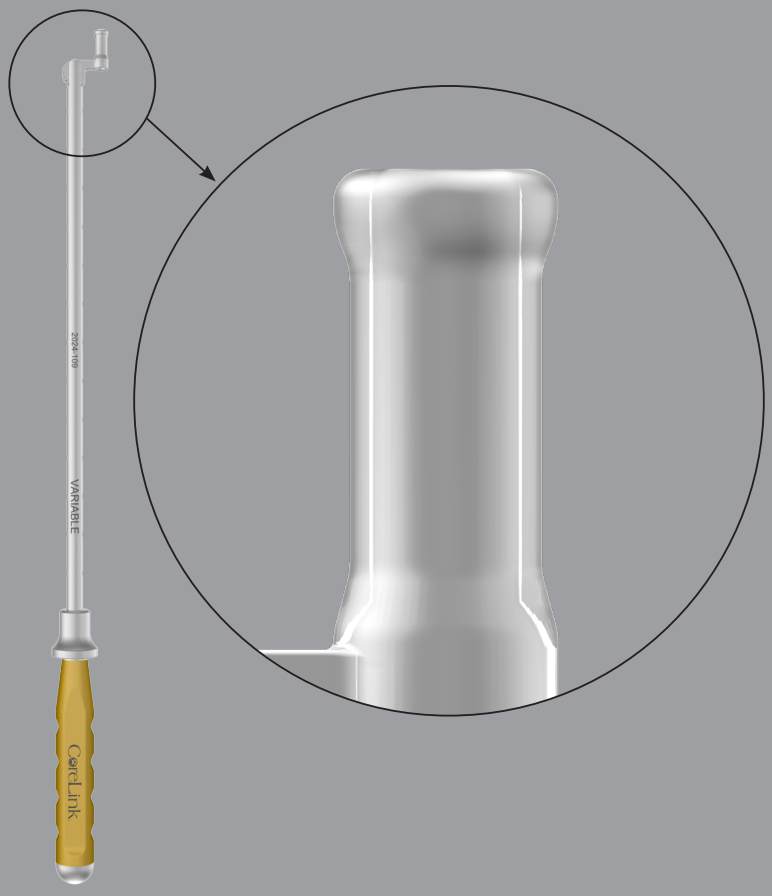


SINGLE-BARREL VARIABLE ANGLE DRILL GUIDE WITH 20MM BALL-JOINTED DRILL

FIXED GUIDE (2024-109)



VARIABLE GUIDE (2024-113)



TAP OPTION

Attach T-handle or Straight Handle to the proximal end of the desired Ball-jointed Tap (2024-118). Insert the Tap into the target screw hole. Set the Handle to "Lock" or "Forward Ratchet" to tap pilot hole.

Radiographic images must be used to confirm Tap length and trajectory. Total Tap length is 30mm.

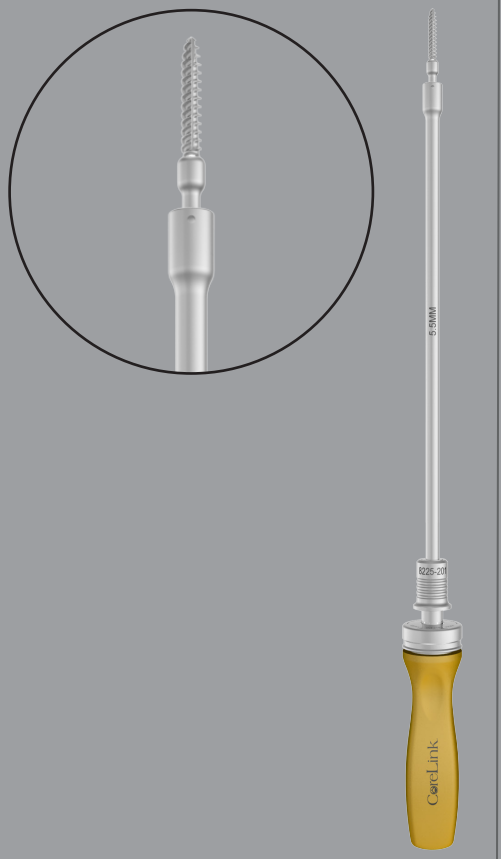
SCREW DRIVER OPTIONS (#20 HEXALOBE)

Attach T-handle or Straight Handle to the proximal end of the desired Driver. Drivers have a #20 Hexalobe stab-and-grab tip.

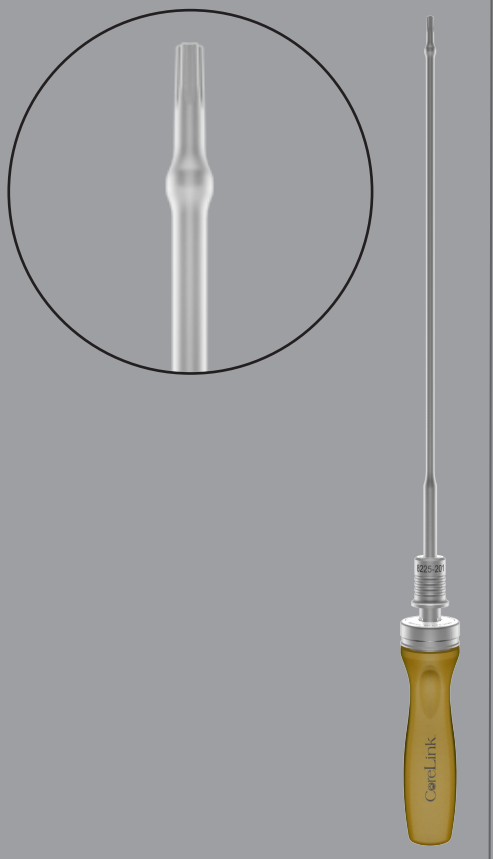
- Straight Screw Driver (2024-104)
- Ball-jointed Screw Driver (2024-111)
- Slim Angled Driver Bits: Standard 15mm (2124-115) and Long 40mm (2124-140) options. See page 12 for Slim Angled Instrument assembly).

Insert the Driver with desired screw into the target screw hole. See spacer/screw pairing recommendation on page 2. Set the Straight Handle to "Lock" or "Forward Ratchet." Radiographic images must be used to confirm screw trajectory.

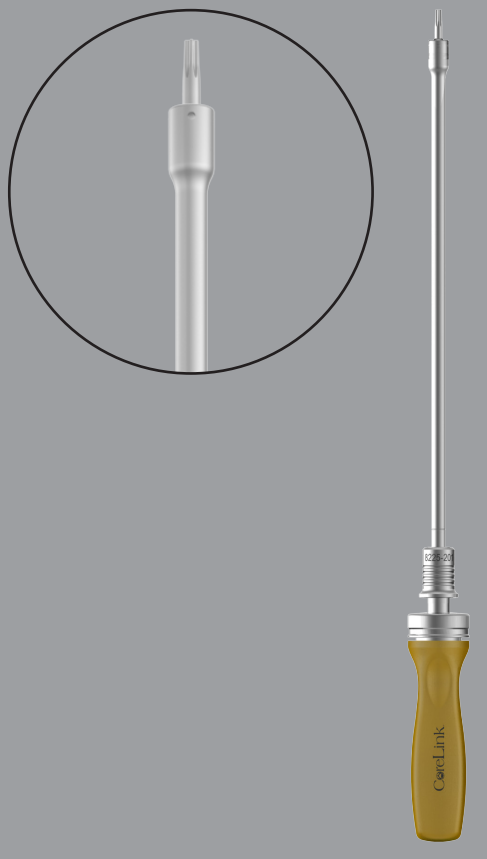
BALL-JOINTED TAP



STRAIGHT DRIVER



BALL-JOINTED DRIVER



FIXED SLIM ANGLED INSTRUMENT ASSEMBLY

The Fixed Slim Angled Instrument provides a 40 degree fixed angle to accommodate steep angles during screw placement.

Slim Angled Instrument Components:
Outer Sleeve (2124-102)
Inner Shaft (2124-102)
Short Driver Bit (2124-115)
Long Driver Bit (2124-140)
Straight Handle (8225-201)*
Side Handle (8500-100)*

OUTER SLEEVE

INNER SHAFT

SHORT DRIVER BIT
15MM

LONG DRIVER BIT
40MM

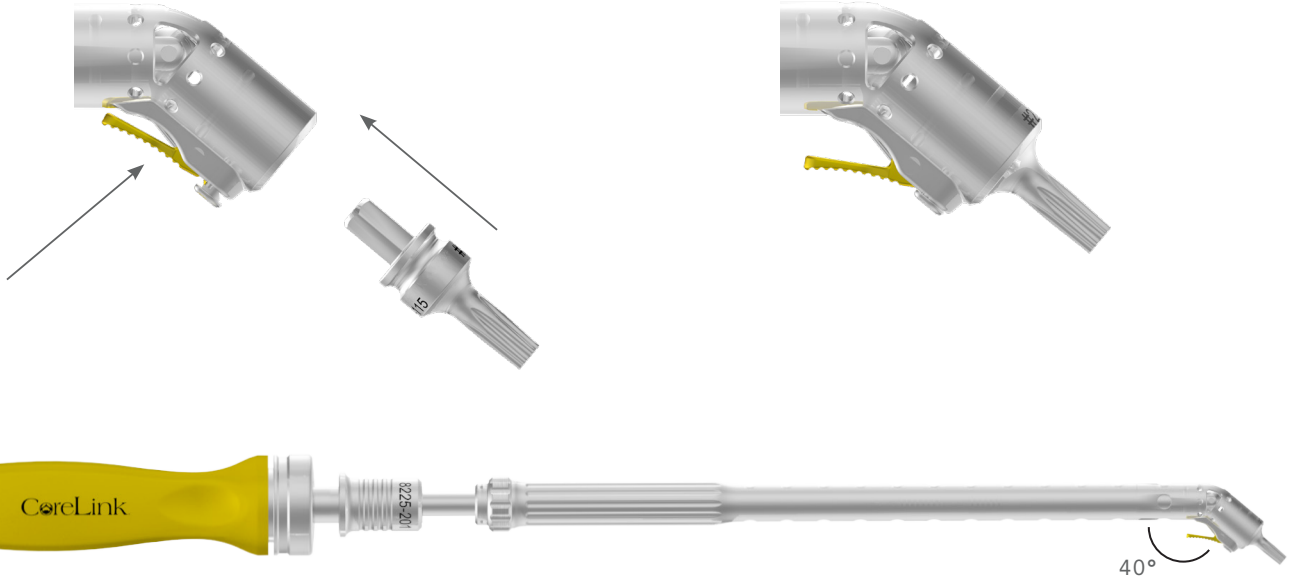
Drill and Tap bits also available as Special Order items

*NOT PICTURED

1. Insert the inner shaft into outer sleeve and dial down until tight connection is complete.

2. Attach ratcheting Straight Handle or T-handle to the proximal end of the Inner Drive Shaft. Set the handle to "Lock" or "Forward Ratchet" to advance drill, tap, or screw.

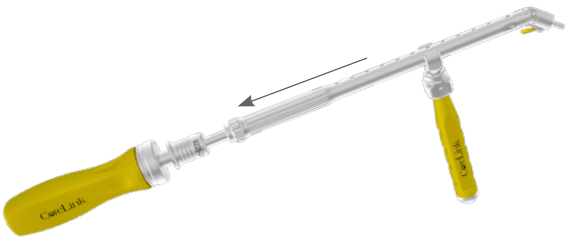
3. Insert the post end of bit into the opening on the outer sleeve while pressing the gold button on the underside of the sleeve. Release button and check to ensure bit is secure.

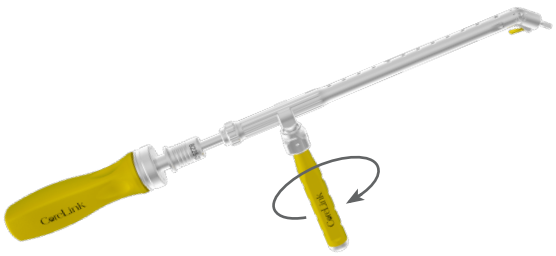


FIXED SLIM ANGLED INSTRUMENT FULLY ASSEMBLED

FIXED SLIM ANGLED INSTRUMENT ASSEMBLY (CONTINUED)

If additional stability is needed, use the Side Handle (8500-100) with the Slim Angled Instrument. To attach Side Handle, rotate the knob on the C-handle counterclockwise and slide the C-shaped section of the Side Handle from the Slim Angled Instrument's smooth section toward its ridged section of the outer Shaft body. Once the desired handle position is determined, rotate the knob on C-handle clockwise until secure.





FIXED SLIM ANGLED INSTRUMENT DISASSEMBLY

After usage, fully disassemble the Slim Angled Instrument prior to cleaning and sterilization. To disassemble, first remove the Side Handle, disconnect the straight handle, remove bit, and separate inner shaft from outer sleeve.

ANTI-BACK-OUT LOCK

Ensure all three screws are completely seated in their final position prior to attaching Lock Plate. Lock cannot attach to spacer if screw heads are proud.

The Lock is compatible with any spacer size regardless of its footprint, height, and lordosis.

Assemble the Lock Driver Shaft (2024-102) and small, yellow Lock Handle (8020-10). Make sure the Lock is in the Unlocked position prior to taking Lock from the caddy. The Lock Driver Shaft has a stab-and-grab #20 hexalobe distal tip that can be used to lift Lock from the caddy.

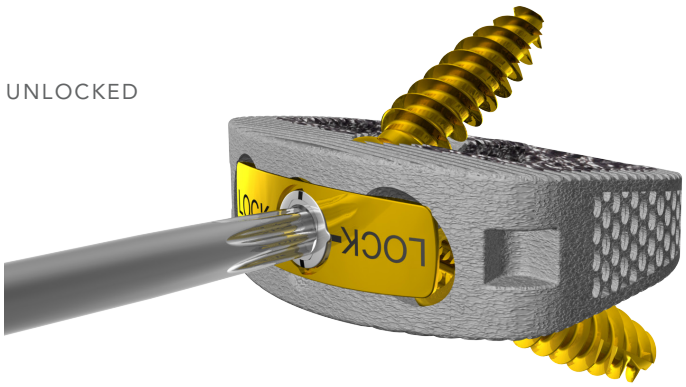
Align the Lock with the internal pocket on the M3 spacer.

Once in position, turn the Lock Driver Shaft clockwise 90 degrees. This will align the marking on the inner lock ring with the markings on the exterior gold portion on the lock. The M3 Lock will provide tactile and visual locking confirmation.

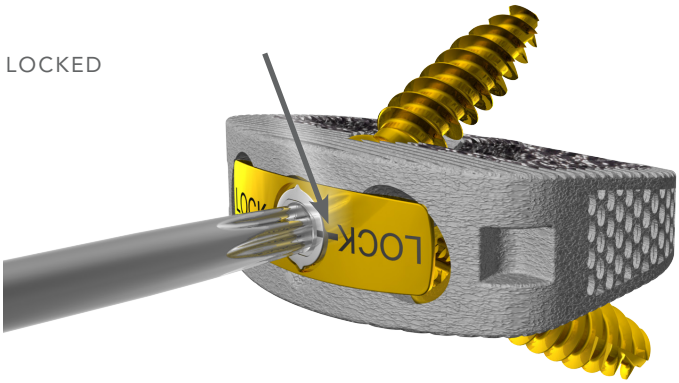
The Lock Handle is NOT a torque handle. Thus, the Lock can visually provide a false positive if misused. During final inspection, physically check to make sure the Lock is attached to the spacer.

User must always visually confirm that the laser etched line on the inner hexalobe feature lines up with the word "Lock."

UNLOCKED



LOCKED



IMPLANT REMOVAL

Reverse the spacer insertion steps by removing the spacer Lock and screws. This system also includes a Screw Removal Driver (2024-103) to be used if the standard screw removal methods are insufficient. Insert the Screw Removal Driver into the screw head's internal threaded feature and turn is clockwise. Once connected to screw, rotate counterclockwise until screw is removed from bone.

If the screw has stripped in the bone, it may be necessary to pull back slightly on the Screw Removal Driver while turning counterclockwise.

Attach the spacer Inserter to the spacer and remove the spacer. If necessary, Slide Hammer may be used to remove the spacer from disc space.

DTS (DRILL/TAP/SCREW) FIXED ANGLE GUIDES

(SPECIAL ORDER)

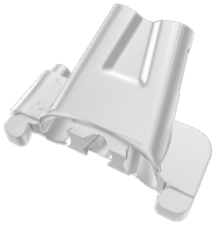
The M3 System includes Fixed Angle Drill/Tap/Screw (DTS) Guides with compatible U-jointed and Straight instrumentation including Drills, Taps, Screw Drivers, and Screw Removal Drivers.

The DTS Guides provide a fixed screw trajectory of 30 degrees in the sagittal plane (for the center and lateral screws) and 11 degrees in the axial plane for the lateral screws.

The DTS Guides are designed to attach to spacer prior to insertion into the disc space. When using the DTS guide, the anterior surface of the spacer must be in line with the cortical rim, as shown below.

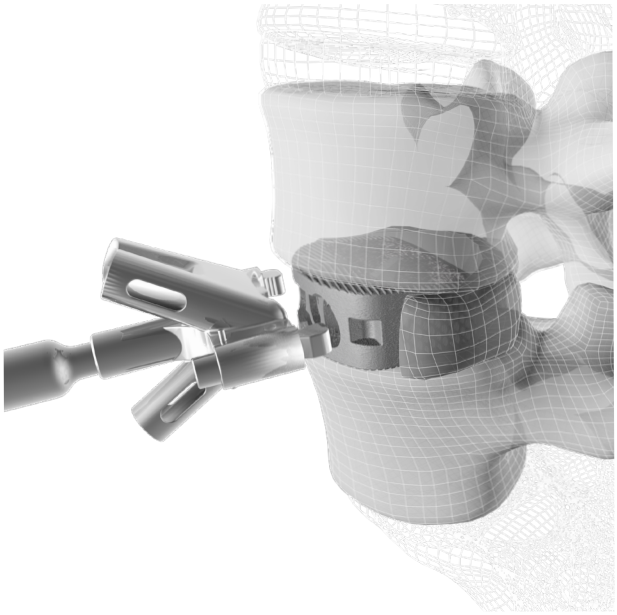
DTS GUIDE COMPONENTS:

GUIDE INSERTER IN TRIAL SET
(01A00038)



EXAMPLE DTS GUIDE
IN DTS GUIDE SET
(1240-013)

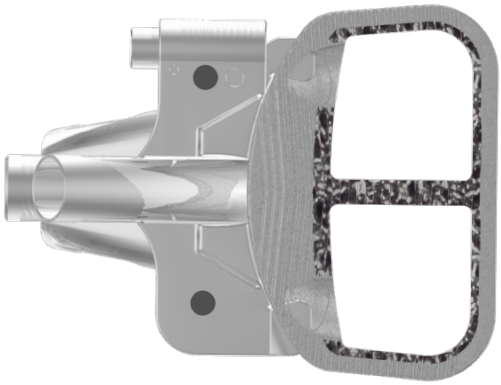
LOCK DRIVER WITH HANDLE IN M3 INSTRUMENT SET
(2024-102 AND 8020-100)



DTS GUIDE REATTACHING TO SPACER IN LINE WITH CORTICAL RIM

DTS GUIDE ASSEMBLY:

1. Use appropriately sized DTS Guide that pairs with specified M3 Spacer. The Guides are in spacer-specific footprints and heights. Align dots on DTS Guide with screw holes on spacer to ensure correct assembly.



ALIGN ETCHED DOTS WITH SCREW HOLES

2. Use Lock Driver (2024-102) to tighten the lateral pin on the DTS Guide for secure attachment to spacer.

DTS GUIDE LATERAL PIN TURN CLOCKWISE TO TIGHTEN

3. Confirm secure connection between DTS Guide and spacer.

   Thread Trial/DTS Guide Inserter (#01A00038) into the center post on the DTS Guide. The Guide Inserter is in the Trial kit.

4. Once assembled, insert spacer into the disc space. Radiographic images must be used to confirm spacer position prior to drill, tap, or screw steps. Address each screw hole in sequential order (drill, tap, screw) prior to moving on to next screw hole to prevent cage migration.

DTS GUIDE ATTACHED TO IMPLANT

Caution must be used when inserting the M3 spacer with attached DTS Guide. Once the spacer is fully in the disc space, do not attempt to reposition or remove the spacer with the DTS Guide attached to the spacer. Axial motions, such as prying, will result in accidental detachment of Guide from spacer, damage to the implant, and may cause injury.

Repositioning Spacer: If the spacer needs to be repositioned, remove the DTS Guide and use the M3 Tamp to move the spacer. If the anterior face of the spacer is positioned past the anterior rim of the adjacent vertebral bodies, the DTS Guide may not reattach to the spacer in situ.

Spacer Removal: If the spacer needs to be removed from the disc space, remove the DTS Guide and attach the Spacer Inserter and Slide Hammer to remove the spacer. Removal of the spacer with the DTS Guide attached will result in implant damage and patient injury.

DRILL/TAP/SCREW DRIVER INSTRUMENTS

The DTS Guide set includes a series of Straight and U-jointed instruments that are compatible with the M3 DTS Guides. All instruments in the DTS Guide trays have a ¼ inch drive shaft and are compatible with the Straight Ratcheting Handles (8225-211) in the standard M3 instrument tray. Use of radiographic imaging is necessary to confirm trajectory and length of instruments and final screw placement.

DRILL OPTIONS:

- Straight Drills in 15mm and 20mm (1011-115, 1011-120)
- U-jointed Drills in 15mm and 20mm (1011-215, 1011-220)
- 15mm Drill Bit for Slim Angled Instrument (2124-315)*
- 20mm Drill Bit for Slim Angled Instrument (2124-320)*

TAP OPTIONS:

- 30mm Straight Tap (1011-550)
- 30mm U-jointed Tap (1012-550)
- 30mm Tap Bit for Slim Angled Instrument (2124-550)*

Radiographic verification must be used to ensure appropriate tap depth is achieved. Care must be taken to avoid over-tapping pilot hole length.

ADDITIONAL DRILL GUIDES:

The Drill Guide set also includes a set of Single-barrel Drill Guides that are compatibles with the Straight and U-jointed Drills. They are not compatible with the Ball-jointed Drills in the M3 Instrument Set.

- Fixed Drill Guide (1011-300)
- Variable Drill Guide (1011-301)

SCREW DRIVER OPTIONS:

- Straight Screw Driver* (2024-104)
- U-jointed Screw Driver (2024-105)
- Long 40mm Driver Bit* (2124-140) *

SCREW REMOVAL INSTRUMENT OPTIONS:

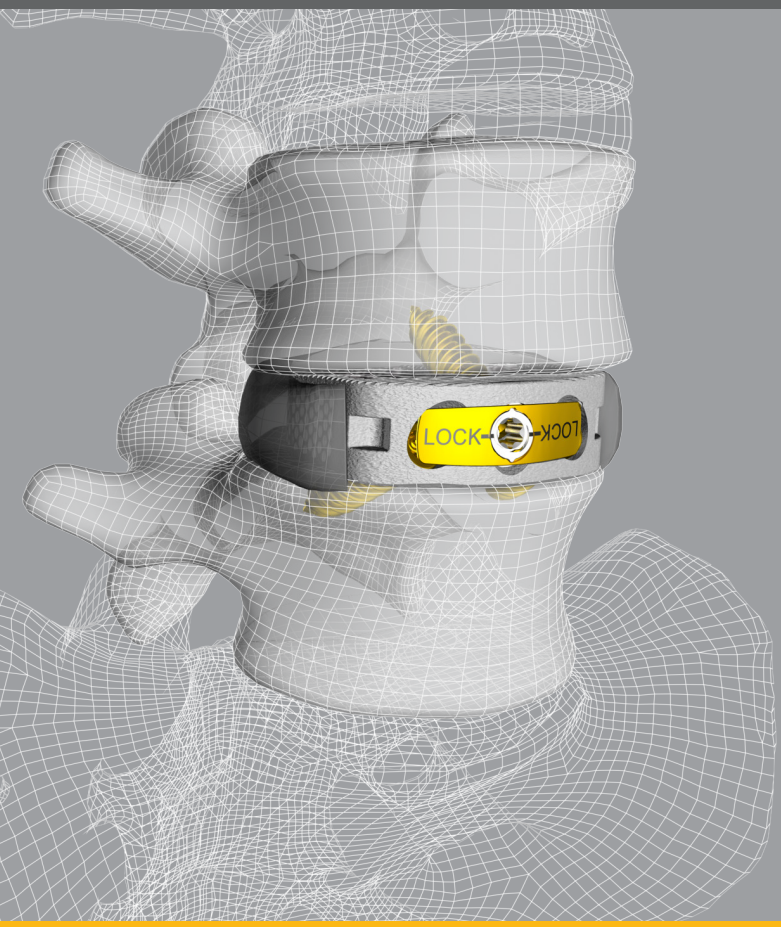
- Straight Screw Removal Instrument* (2024-103)
- U-jointed Screw Removal Driver (2024-127)

*Available in standard M3 Instrument Tray. Use of Slim Angled Instruments and Drill, Tap, and Driver Bits at certain levels may be difficult due to patient anatomy or inadequate exposure. Caution must be taken.

REMOVAL OF DTS GUIDE FROM SPACER

To disconnect the DTS Guide from the implanted spacer, turn the lateral pin on the Guide counterclockwise with Lock Driver. Ensure all screws are completely seated in their final position prior to attaching Lock to the anterior surface of the spacer. The Lock cannot attach to the spacer if screw heads are proud. Refer to page 15 for M3 Lock details.

FINAL CONSTRUCT



INSTRUCTIONS FOR USE

CORELINK M3 STAND-ALONE ANTERIOR LUMBAR INTERBODY FUSION SYSTEM

This IFU applies to the following product family:

M3 Stand-alone ALIF Anterior Lumbar 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 M3 Stand-alone Anterior Lumbar System is an internal spinal fixation system compromised of a spacer, three screws, and a lock assembly. The purpose of the M3 Stand-alone device is for anterior lumbar interbody fusion. It is designed to provide support to the lumbar spine while arthrodesis occurs. The M3 Stand-alone Anterior Lumbar System is available in a variety of lordosis and footprint options with a porous architecture to offer increased room for bone growth and mechanical properties to suit the individual pathology and anatomical conditions of the patient.

Implants in the M3 Stand-alone Anterior Lumbar System are manufactured from the following materials:

- Medical grade titanium alloy (Ti6AL4V ELI as per ASTM F-136 and ISO 5832-2)

Do not use any of the M3 Stand-alone Anterior Lumbar 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 M3 Stand-alone Anterior Lumbar System implants or implant components should be reused under any circumstances. The instruments provided with the M3 Stand-alone Anterior Lumbar System are provided specifically for the implantation of the M3 Stand-alone Anterior Lumbar System implants.

Please refer to the applicable M3 Stand-alone Anterior Lumbar System Surgical Technique for additional important information about specific CoreLink implants, in addition to the information described herein.

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use). Such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

INDICATIONS

The M3 Stand-alone Anterior Lumbar System is a standalone interbody fusion system indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The device may be used with supplemental fixation.

Hyper-lordotic implants (≥20° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The system is indicated to be used with autograft bone. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

When used as a stand-alone device the M3 implants are intended to be used with the bone screws and lock provided. When using a 3-screw implant, all three (3) screws must be used. The accompanying lock must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, or none of the provided screws, then the additional supplemental fixation in the lumbar spine must be used to augment fixation.

CONTRAINDICATIONS

Do not use the M3 Stand-alone Anterior Lumbar System in the presence of an active systemic infection or infections localized to the site of the proposed implantation. Use of implants in this setting may lead to future infection and implant failure. Other relative contraindications include:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Severe osteoporosis as it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis, osteopenia).
- Obesity.
- Certain degenerative diseases.
- Foreign body sensitivity.
- A patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. 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 and non-union.

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 M3 Stand-alone Anterior Lumbar System 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 M3 Stand-alone Anterior Lumbar System 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 M3 Stand-alone Anterior Lumbar System 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 M3 Stand-alone Anterior Lumbar System has not been evaluated for safety and compatibility in the MR environment. The M3 Stand-alone Anterior Lumbar System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the M3 Stand-alone Anterior Lumbar System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREPARATION AT POINT OF USE

The components of the implants of the M3 Stand-alone Anterior Lumbar System are provided in sterile (interbody cage) and non-sterile (fixation screws and locking plates) configurations. The surgical instruments provided with the M3 Stand-alone Anterior Lumbar System 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.

INSTRUCTIONS FOR USE (CONTINUED)

- 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:** Interbody spacer components of the M3 Stand-alone Anterior Lumbar System 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 Implants:** Fixation screw and locking plate components of the M3 Stand-alone Anterior Lumbar System is 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.
- **Non-sterile Instruments:** Instruments of the M3 Stand-alone Anterior Lumbar System is 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. 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 M3 Stand-alone Anterior Lumbar System 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 M3 Stand-alone Anterior Lumbar System is not recommended.

IMPORTANT SYSTEM CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The M3 Stand-alone Anterior Lumbar System implants are available in titanium alloy. It is imperative that the M3 Stand-alone Anterior Lumbar 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.

The osteosynthesis achieved with M3 Stand-alone Anterior Lumbar System must obligatorily be accompanied by an arthrodesis on the concerned vertebras. The M3 Stand-alone Anterior Lumbar System is only intended to secure the surgical result until bony fusion has occurred, or for one year at the latest.

ADDITIONAL PRECAUTIONS

1. **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. Although the physician is the expert intermediary

between the company and the patient, the important medical information given in this document must be conveyed to the patient.

2. **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: (1) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (2) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
3. **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.
4. **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.

POSTOPERATIVE IMMOBILIZATION

Until X-rays confirm that sufficient fusion mass has developed, external immobilization (such as bracing or casting) is recommended.

Please inform the patient to reduce stress on the implants to reduce complications from fixation failure.

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.

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Use-by-Date – Indicates the date after which the medical device is not to be used.	5.1.4
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	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 – Indications the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4

For further information contact:

CoreLink.
The Source for Spine™

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

STANDARD INSTRUMENT PRODUCT LISTING

KIT ORDER #K5000383

INSTRUMENT KIT

QTY	CATALOG NUMBER	CAGE DESCRIPTION
1	2024-115	BALL-JOINTED DRILL, 15MM
1	2024-116	BALL-JOINTED DRILL, 20MM
1	2024-109	FIXED ANGLE ADJUSTABLE DRILL GUIDE
1	2024-113	VARIABLE ANGLE ADJUSTABLE DRILL GUIDE
1	2024-118	BALL-JOINTED TAP, 5.5MM
1	2024-100	M3 CAGE INSERTER
1	2024-102	LOCKING DRIVER SHAFT
1	2024-103	SCREW REMOVAL DRIVER
1	2024-104	STRAIGHT #20 HEXALOBE SCREW DRIVER
1	2024-111	BALL-JOINTED #20 HEXALOBE SCREW DRIVER
2	2124-102	SLIM ANGLED INSTRUMENT
2	2124-115	ANGLED INSTRUMENT SHORT DRIVER BIT, 15MM
1	2124-140	ANGLED INSTRUMENT LONG DRIVER BIT 40MM
2	8225-211	1/4" DRIVE MOLDED STRAIGHT RATCHETING HANDLE
1	8500-100	UNIVERSAL INSTRUMENT SIDE HANDLE
1	8020-100	LOCK DRIVER HANDLE
1	2024-404	STRAIGHT VARIABLE AWL TIP
1	2024-405	STRAIGHT FIXED AWL TIP
1	2024-406	CURVED VARIABLE AWL TIP
1	2024-407	CURVED FIXED AWL TIP
1	2024-408	STRAIGHT AWL INNER SHAFT
1	2024-409	CURVED AWL INNER SHAFT
2	2024-410	OUTER AWL SLEEVES

M3 SCREWS AND LOCK

QTY	CATALOG NUMBER	CAGE DESCRIPTION
5	LK300-1000	M3 LOCK
9	10355-15	5.5MM x 15MM, VARIABLE SELF-TAPPING
9	10355-20	5.5MM x 20MM, VARIABLE SELF-TAPPING
9	10355-25	5.5MM x 25MM, VARIABLE SELF-TAPPING
0*	10355-30	5.5MM x 30MM, VARIABLE SELF-TAPPING
9	10555-15	5.5MM x 15MM, FIXED SELF-TAPPING
9	10555-20	5.5MM x 20MM, FIXED SELF-TAPPING
9	10555-25	5.5MM x 25MM, FIXED SELF-TAPPING
0*	10555-30	5.5MM x 30MM, FIXED SELF-TAPPING
9	10365-15	6.5MM x 15MM, VARIABLE SELF-TAPPING
9	10365-20	6.5MM x 20MM, VARIABLE SELF-TAPPING
9	10365-25	6.5MM x 25MM, VARIABLE SELF-TAPPING
0*	10365-30	6.5MM x 30MM, VARIABLE SELF-TAPPING
9	10565-15	6.5MM x 15MM, FIXED SELF-TAPPING
9	10565-20	6.5MM x 20MM, FIXED SELF-TAPPING
9	10565-25	6.5MM x 25MM, FIXED SELF-TAPPING
0*	10565-30	6.5MM x 30MM, FIXED SELF-TAPPING

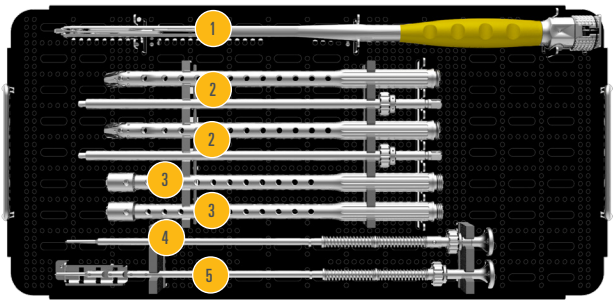
*Special Order. CONTACT CORELINK CUSTOMER SERVICE FOR SPECIAL ORDER ITEMS SUCH AS ADDITIONAL HEIGHT AND LORDOSIS OFFERING AND SELF-DRILLING SCREWS

STANDARD INSTRUMENT KIT

KIT ORDER #K5000383

TOP TRAY

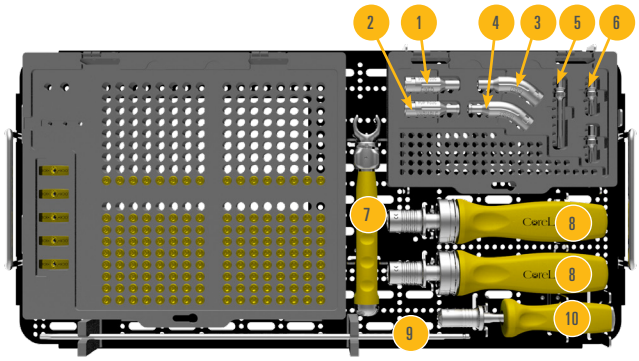
1. Cage Inserter
2. Slim Angled Instruments
3. Outer Awl Sleeves
4. Straight Awl Inner Shaft:
5. Curved Awl Inner Shaft



MIDDLE TRAY

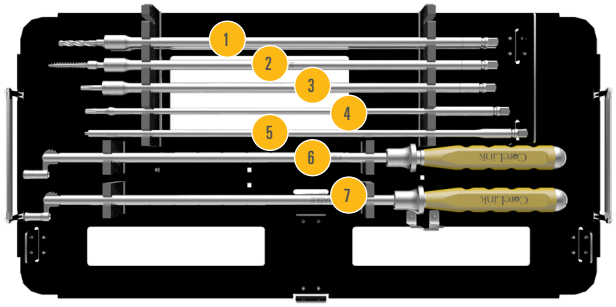
1. Straight Variable Awl Tip
2. Straight Fixed Awl Tip
3. Curved Variable Awl Tip
4. Curved Fixed Awl Tip
5. Long Driver Bit
6. Short Driver Bit
7. Angled Instrument Side Handle
8. 1/4" Drive Molded Straight Ratcheting Handles*
9. Locking Driver Shaft
10. Locking Driver Handle

**T-handles are in the ALIF Disc Prep set (Kit Order #5000303)



BOTTOM TRAY

1. Ball-jointed Drills, 15mm & 20mm
2. Ball-jointed Tap, 5.5mm
3. Ball-jointed #20 Hexalobe Screw Driver
4. Straight #20 Hexalobe Screw Driver
5. Screw Removal Driver
6. Fixed Angle Adjustable Drill Guide
7. Variable Angle Adjustable Drill Guide



STANDARD M3 SPACER PRODUCT LISTING

KIT ORDER #K5000314

25MM X 35MM

QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS2535-0810	25MM X 35MM X 10MM, 8°	5.1	2.5
1	3AS2535-0811	25MM X 35MM X 11MM, 8°	6.1	2.7
2	3AS2535-0812	25MM X 35MM X 12MM, 8°	7.1	3.0
2	3AS2535-0813	25MM X 35MM X 13MM, 8°	8.1	3.3
2	3AS2535-0814	25MM X 35MM X 14MM, 8°	9.1	3.6
2	3AS2535-0815	25MM X 35MM X 15MM, 8°	10.1	3.9
1	3AS2535-0816	25MM X 35MM X 16MM, 8°	11.1	4.2
1	3AS2535-0817	25MM X 35MM X 17MM, 8°	12.1	4.5
1	3AS2535-1510	25MM X 35MM X 10MM, 15°	2.0	2.0
1	3AS2535-1511	25MM X 35MM X 11MM, 15°	3.0	2.2
1	3AS2535-1512	25MM X 35MM X 12MM, 15°	4.0	2.5
1	3AS2535-1513	25MM X 35MM X 13MM, 15°	5.0	2.8
1	3AS2535-1514	25MM X 35MM X 14MM, 15°	6.0	3.0
1	3AS2535-1515	25MM X 35MM X 15MM, 15°	7.0	3.3
1	3AS2535-1516	25MM X 35MM X 16MM, 15°	8.0	3.6
1	3AS2535-1517	25MM X 35MM X 17MM, 15°	9.0	3.9

KIT ORDER #K5000315

27MM X 40MM

QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS2740-0810	27MM X 40MM X 10MM, 8°	4.8	3.5
1	3AS2740-0811	27MM X 40MM X 11MM, 8°	5.8	3.9
2	3AS2740-0812	27MM X 40MM X 12MM, 8°	6.8	4.3
2	3AS2740-0813	27MM X 40MM X 13MM, 8°	7.8	4.7
2	3AS2740-0814	27MM X 40MM X 14MM, 8°	8.8	5.1
2	3AS2740-0815	27MM X 40MM X 15MM, 8°	9.8	5.5
1	3AS2740-0816	27MM X 40MM X 16MM, 8°	10.8	5.9
1	3AS2740-0817	27MM X 40MM X 17MM, 8°	11.8	6.3
1	3AS2740-1510	27MM X 40MM X 10MM, 15°	1.5	2.6
1	3AS2740-1511	27MM X 40MM X 11MM, 15°	2.5	3.0
1	3AS2740-1512	27MM X 40MM X 12MM, 15°	3.5	3.4
1	3AS2740-1513	27MM X 40MM X 13MM, 15°	4.5	3.8
1	3AS2740-1514	27MM X 40MM X 14MM, 15°	5.5	4.2
1	3AS2740-1515	27MM X 40MM X 15MM, 15°	6.5	4.6
1	3AS2740-1516	27MM X 40MM X 16MM, 15°	7.5	5.0
1	3AS2740-1517	27MM X 40MM X 17MM, 15°	8.5	5.4

CONTACT CORELINK CUSTOMER SERVICE FOR SPECIAL ORDER ITEMS SUCH AS ADDITIONAL HEIGHT AND LORDOSIS OFFERING AND SELF-DRILLING SCREWS

SPECIAL ORDER M3 SPACER PRODUCT LISTING

KIT ORDER #K5000351

30MM X 45MM, 8° AND 15°				
QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS3045-0810	30MM X 45MM X 10MM, 8°	4.4	4.7
1	3AS3045-0811	30MM X 45MM X 11MM, 8°	5.4	5.3
2	3AS3045-0812	30MM X 45MM X 12MM, 8°	6.4	5.9
2	3AS3045-0813	30MM X 45MM X 13MM, 8°	7.4	6.4
2	3AS3045-0814	30MM X 45MM X 14MM, 8°	8.4	7.0
2	3AS3045-0815	30MM X 45MM X 15MM, 8°	9.4	7.6
1	3AS3045-0816	30MM X 45MM X 16MM, 8°	10.4	8.1
1	3AS3045-0817	30MM X 45MM X 17MM, 8°	11.4	8.7
1	3AS3045-1510	30MM X 45MM X 10MM, 15°	1.7	3.4
1	3AS3045-1511	30MM X 45MM X 11MM, 15°	2.7	4.0
1	3AS3045-1512	30MM X 45MM X 12MM, 15°	3.7	4.5
1	3AS3045-1513	30MM X 45MM X 13MM, 15°	4.7	5.1
1	3AS3045-1514	30MM X 45MM X 14MM, 15°	5.7	5.7
1	3AS3045-1515	30MM X 45MM X 15MM, 15°	6.7	6.3
1	3AS3045-1516	30MM X 45MM X 16MM, 15°	7.7	6.8
1	3AS3045-1517	30MM X 45MM X 17MM, 15°	8.7	7.4

KIT ORDER #K5000363

30MM X 45MM, 20°, 25°, AND 30°				
QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS3045-2014	30MM x 45MM x 14MM, 20°	2.0	4.7
1	3AS3045-2016	30MM x 45MM x 16MM, 20°	4.0	5.9
1	3AS3045-2018	30MM x 45MM x 18MM, 20°	6.0	7.0
1	3AS3045-2020	30MM x 45MM x 20MM, 20°	8.0	8.1
1	3AS3045-2516	30MM x 45MM x 16MM, 25°	2.3	4.9
1	3AS3045-2518	30MM x 45MM x 18MM, 25°	4.3	6.0
1	3AS3045-2520	30MM x 45MM x 20MM, 25°	6.3	7.2
1	3AS3045-3018	30MM x 45MM x 18MM, 30°	2.5	5.1
1	3AS3045-3020	30MM x 45MM x 20MM, 30°	4.5	6.2

SPECIAL ORDER M3 SPACER PRODUCT LISTING (CONTINUED)

KIT ORDER #K5000357

25MM X 35MM / 27MM X 40MM, 20° AND 25°				
QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS2535-2014	25MM x 35MM x 14MM, 20°	3.6	2.6
1	3AS2535-2016	25MM x 35MM x 16MM, 20°	5.6	3.2
1	3AS2535-2018	25MM x 35MM x 18MM, 20°	7.6	3.8
1	3AS2535-2020	25MM x 35MM x 20MM, 20°	9.6	4.4
1	3AS2740-2014	27MM x 40MM x 14MM, 20°	3.1	3.6
1	3AS2740-2016	27MM x 40MM x 16MM, 20°	5.1	4.4
1	3AS2740-2018	27MM x 40MM x 18MM, 20°	7.1	5.2
1	3AS2740-2020	27MM x 40MM x 20MM, 20°	9.1	6.0
1	3AS2535-2514	25MM x 35MM x 14MM, 25°	2.3	2.2
1	3AS2535-2516	25MM x 35MM x 16MM, 25°	4.3	2.8
1	3AS2535-2518	25MM x 35MM x 18MM, 25°	6.3	3.4
1	3AS2535-2520	25MM x 35MM x 20MM, 25°	8.3	3.9
1	3AS2740-2514	27MM x 40MM x 14MM, 25°	11.1	3.0
1	3AS2740-2516	27MM x 40MM x 16MM, 25°	13.1	3.8
1	3AS2740-2518	27MM x 40MM x 18MM, 25°	15.1	4.6
1	3AS2740-2520	27MM x 40MM x 20MM, 25°	17.1	5.4

KIT ORDER #K5000361

25MM X 35MM / 27MM X 40MM, 30°				
QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS2535-3016	25MM x 35MM x 16MM, 30°	2.0	2.4
1	3AS2535-3018	25MM x 35MM x 18MM, 30°	4.0	2.9
1	3AS2535-3020	25MM x 35MM x 20MM, 30°	6.0	3.5
1	3AS2740-3016	27MM x 40MM x 16MM, 30°	1.6	3.2
1	3AS2740-3018	27MM x 40MM x 18MM, 30°	3.6	4.0
1	3AS2740-3020	27MM x 40MM x 20MM, 30°	5.6	4.8

KIT ORDER # K5000422

TALL SPACERS, 18MM - 21MM, 8° AND 15°				
QTY	CATALOG NUMBER	CAGE DESCRIPTION	POSTERIOR HEIGHT (MM)	AUTOGENOUS GRAFT VOLUME (CC)
1	3AS2535-0818	25MM X 35MM X 18MM, 8°	13.1	4.8
1	3AS2535-0819	25MM X 35MM X 19MM, 8°	14.1	5.1
1	3AS2535-0820	25MM X 35MM X 20MM, 8°	15.1	5.3
1	3AS2535-0821	25MM X 35MM X 21MM, 8°	17.1	5.6
1	3AS2740-0818	27MM X 40MM X 18MM, 8°	12.8	6.7
1	3AS2740-0819	27MM X 40MM X 19MM, 8°	13.8	7.1
1	3AS2740-0820	27MM X 40MM X 20MM, 8°	14.8	7.5
1	3AS2740-0821	27MM X 40MM X 21MM, 8°	15.8	7.9
1	3AS3045-0818	30MM X 45MM X 18MM, 8°	12.4	9.3
1	3AS3045-0819	30MM X 45MM X 19MM, 8°	13.4	9.8
1	3AS3045-0820	30MM X 45MM X 20MM, 8°	14.4	10.4
1	3AS3045-0821	30MM X 45MM X 21MM, 8°	15.4	11.0
1	3AS2535-1518	25MM X 35MM X 18MM, 15°	10.0	5.0
1	3AS2535-1519	25MM X 35MM X 19MM, 15°	11.0	4.5
1	3AS2535-1520	25MM X 35MM X 20MM, 15°	12.0	4.8
1	3AS2535-1521	25MM X 35MM X 21MM, 15°	13.0	5.1
1	3AS2740-1518	27MM X 40MM X 18MM, 15°	9.5	5.8
1	3AS2740-1519	27MM X 40MM X 19MM, 15°	10.5	6.2
1	3AS2740-1520	27MM X 40MM X 20MM, 15°	11.5	6.6
1	3AS2740-1521	27MM X 40MM X 21MM, 15°	12.5	7.0
1	3AS3045-1518	30MM X 45MM X 18MM, 15°	9.7	8.0
1	3AS3045-1519	30MM X 45MM X 19MM, 15°	10.7	8.5
1	3AS3045-1520	30MM X 45MM X 20MM, 15°	11.7	9.1
1	3AS3045-1521	30MM X 45MM X 21MM, 15°	12.7	9.7

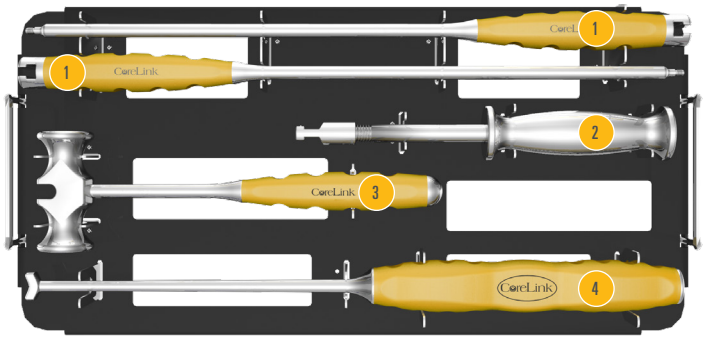
CONTACT CORELINK CUSTOMER SERVICE FOR SPECIAL ORDER ITEMS SUCH AS ADDITIONAL HEIGHT AND LORDOSIS OFFERING AND SELF-DRILLING SCREWS

STANDARD M3 TRIAL KIT

KIT ORDER #K5000305

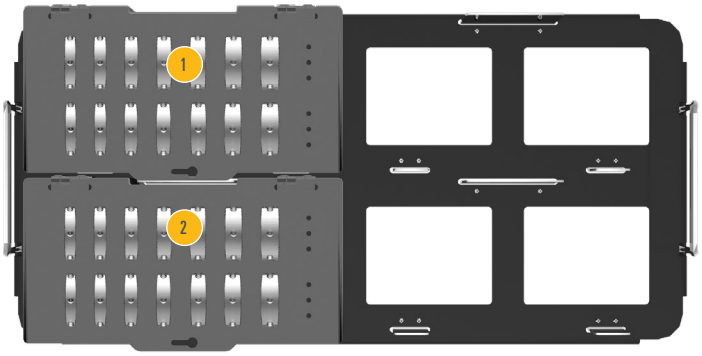
TRIAL TRAY 1 – TOP TRAY

1. ALIF Inserters: Qty 2 #01A00038
2. Slide Hammer: #08G00001
3. Mallet: #1011-500
4. 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)



SPECIAL ORDER TRIAL CADDIES

30MM X 45MM TRIALS
KIT ORDER #K5000353

- 8° and 15°, 10mm – 17mm (1mm increments)

30MM X 45MM HYPERLORDOTIC TRIALS
KIT ORDER #K5000364

- 20°, 25°, and 30°, 16mm – 20mm (2mm increments)

20° TRIALS
KIT ORDER #K5000358

- 25mm x 35mm, 14mm – 20mm (2mm increments)
- 27mm x 40mm, 14mm – 20mm (2mm increments)

25° TRIALS
KIT ORDER #K5000360

- 25mm x 35mm, 14mm – 20mm (2mm increments)
- 27mm x 40mm, 14mm – 20mm (2mm increments)

30° TRIALS
KIT ORDER #K5000362

- 25mm x 35mm, 16mm – 20mm (2mm increments)
- 27mm x 40mm, 16mm – 20mm (2mm increments)

TALL TRIALS 25MM X 35MM
KIT ORDER #K5000365

- 25mm x 35mm, 18mm – 21mm (1mm increments)

TALL TRIALS 27MM X 40MM
KIT ORDER #K5000366

- 27mm x 40mm, 18mm – 21mm (1mm increments)

TALL TRIALS 30MM X 45MM
KIT ORDER #K5000367

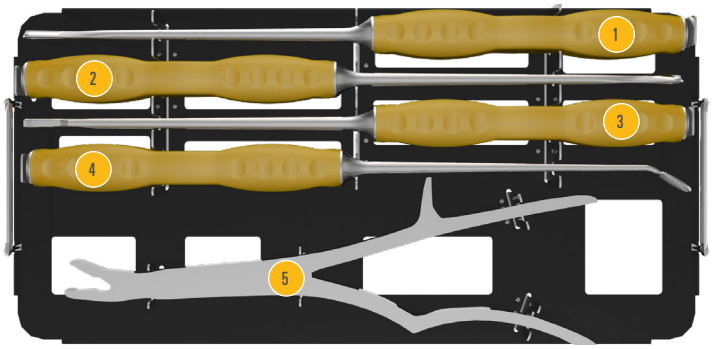
- 30mm x 45mm, 18mm – 21mm (1mm increments)

ALIF DISC PREP INSTRUMENT KIT

KIT ORDER #K5000303

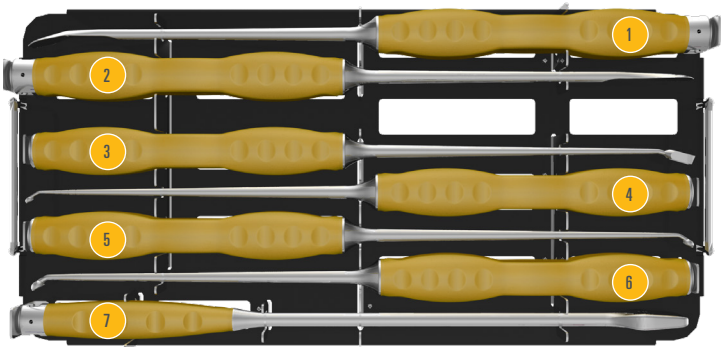
DISC PREP TRAY 1 – TOP TRAY

1. Uterine Ring Currette 25mm x 11mm: #7818-003*
2. Uterine Ring Currette 25mm x 17mm: #7818-004*
3. Flat Rectangular Rasp: #03A00534
4. Domed Rasp: #03A00535
5. Rongeur Double Action: #7900-101



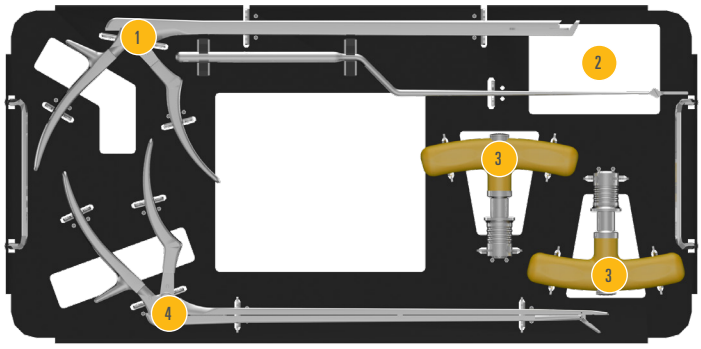
TRIAL TRAY 2 - MIDDLE TRAY

1. Angled Cobb Elevator: #09A00142
2. Straight Cobb Elevator: #09A00143
3. Box Curette: #04A00009*
4. Cup Curette 4mm x 6mm: #04A00002
5. Cup Curette 6mm x 8mm: #04A00004
6. Cup Curette 8mm x 10mm: #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 or 7815-003
3. T-handles Qty 2: #8025-100
4. Pituitary Ronguer:
   325mm x 4mm Straight: #17A00014
   325mm x 6mm Straight: #17A00015



REQUEST INDIVIDUALLY

QTY	CATALOG NUMBER	CAGE DESCRIPTION
1	5025-115	STRAIGHT ALIF CUP CURETTE, 4X6
1	5025-120	STRAIGHT ALIF CUP CURETTE, 6X8
1	5025-215	STRAIGHT ALIF CUP CURETTE, 8X10
1	4000-117	RATCHETING ALIF DISTRACTOR
1	4000-118	RATCHETING ALIF DISTRACTOR LEFT TIP
1	4000-119	RATCHETING ALIF DISTRACTOR RIGHT TIP

*Special Order. Contact Customer Service for special order items.

SPECIAL ORDER INSTRUMENT PRODUCT LISTING

KIT ORDER #K5000369

SELF-DRILLING SCREWS VARIABLE AND FIXED		
QTY	CATALOG NUMBER	CAGE DESCRIPTION
9	10255-15	5.5MM X 15MM, VARIABLE
9	10255-20	5.5MM X 20MM, VARIABLE
9	10255-25	5.5MM X 25MM, VARIABLE
0*	10255-30	5.5MM X 30MM, VARIABLE
9	10265-15	6.5MM X 15MM, VARIABLE
9	10265-20	6.5MM X 20MM, VARIABLE
9	10265-25	6.5MM X 25MM, VARIABLE
0*	10265-30	6.5MM X 30MM, VARIABLE
9	10455-15	5.5MM X 15MM, FIXED
9	10455-20	5.5MM X 20MM, FIXED
9	10455-25	5.5MM X 25MM, FIXED
0*	10455-30	5.5MM X 30MM, FIXED
9	10465-15	6.5MM X 15MM, FIXED
9	10465-20	6.5MM X 20MM, FIXED
9	10465-25	6.5MM X 25MM, FIXED
0*	10465-30	6.5MM X 30MM, FIXED

REQUEST INDIVIDUALLY

AWLS AND ADAPTERS		
QTY	CATALOG NUMBER	CAGE DESCRIPTION
1	5025-115	SLIM STRAIGHT AWL, 15MM
1	5025-120	SLIM STRAIGHT AWL, 20MM
1	5025-215	SLIM ANGLED AWL, 15MM
1	5025-220	SLIM ANGLED AWL, 20MM
1	2024-107	INSERTER HANDLE ADAPTER

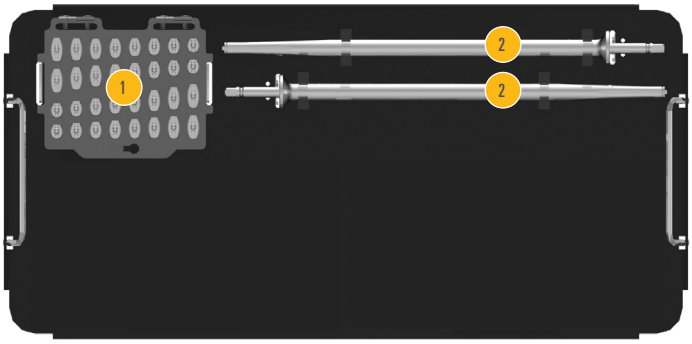
*Special Order. Contact Customer Service for special order items.

DISC SPREADER INSTRUMENT KIT (SPECIAL ORDER)

DISC SPREADER INSTRUMENT TRAY
KIT ORDER #K5000304

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

NOTE: DISC SPREADERS AND DISC SPREADER SHAFT TO BE USED WITH T-HANDLES IN THE DISC PREP SET (DISC PREP SET ORDER #K5000303)



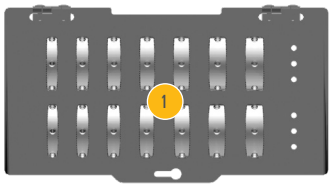
TRIAL RASPS (SPECIAL ORDER)

TRIAL RASPS 25MM X 35 MM / 27MM X 40MM
KIT ORDER #K5000381

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)

TRIAL RASPS 30MM X 45MM
KIT ORDER #K5000355

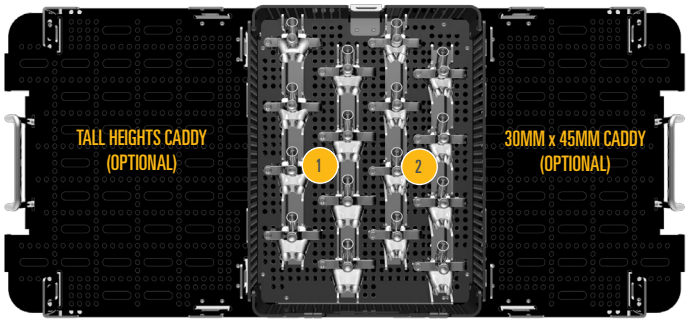
1. 30mm x 45mm Trial Rasps – 8° and 15°, 10mm – 17mm (1mm increments)



FIXED DTS GUIDE INSTRUMENT KIT (SPECIAL ORDER)

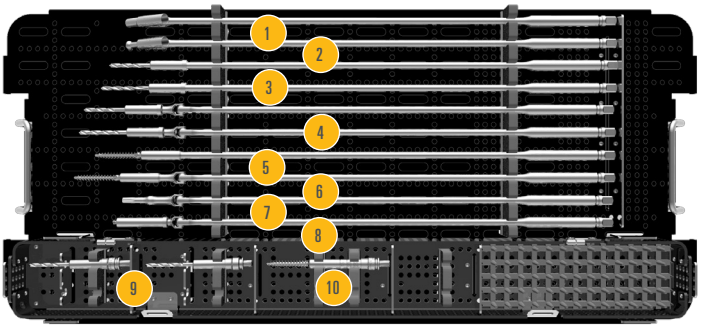
KIT ORDER #K5000316

TOP TRAY



1. DTS Guides: 25mm x 35mm, 10mm - 17mm
2. DTS Guides: 27mm x 40mm, 10mm - 17mm

BOTTOM TRAY



1. Fixed Angle Drill Guide: #1011-300
2. Variable Angle Drill Guide: #1011-301
3. Straight Drills – 1/4" Drive:
   3mm x 15mm: #1011-115
   3mm x 20mm: #1011-120
4. U-jointed Drills – 1/4" Drive:
   3mm x 15mm: #1011-215
   3mm x 20mm: #1011-220
5. 5.5 Straight Tap, 1/4" Drive: #1011-550
6. U-jointed Tap – 1/4" Drive: #1012-550
7. U-jointed Screw Driver: #2024-127
8. U-jointed Screw Removal Tool: #2024-127
9. Angled Instrument Drill Bits:
   3mm x 15mm: #2124-315
   3mm x 20mm: #2124-320
10. Angled Instrument, 5.5mm Tap Bit: #2124-550

CADDIES (SPECIAL ORDER)

30MM X 45MM FIXED DTS GUIDE CADDY
KIT ORDER #K5000317

- 30mm x 45mm, 10mm – 17mm

TALL FIXED DRILL GUIDE CADDY
KIT ORDER #K5000401

- 25mm x 35mm, 18mm – 21mm
- 27mm x 40mm, 18mm – 21mm
- 30mm x 45mm, 18mm – 21mm

M3 CAGE AND VARIABLE SCREW PAIRING

Pay attention to cage, awl lengths, and screw lengths at various angles to avoid injury.

The measurements in the tables show the distance of the Awl and Screw tips in reference to the posterior edge of the cage at the range of possible variable angles: the most shallow angle (23.5 degrees), the nominal angle (30 degrees), and the most extreme angle (36.5 degrees).

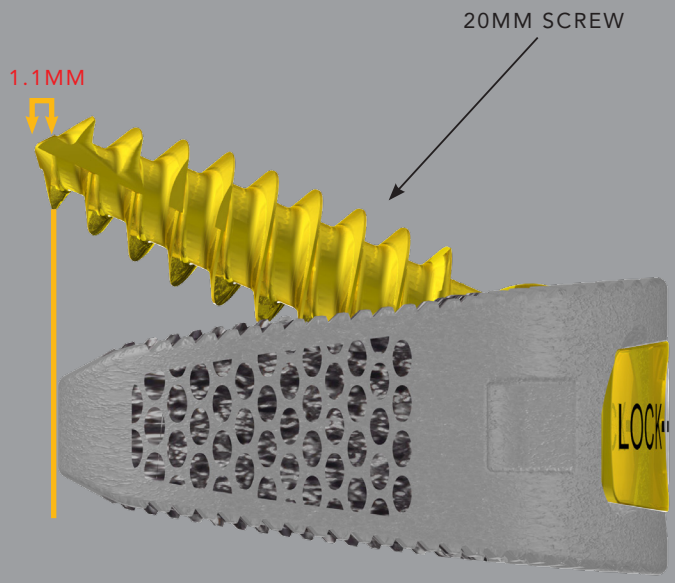
The measurements in green show the combinations where the Awl/Screw tips do not bypass the posterior margin of the cage. The measurements in red show the combinations in which the Awl/Screw tips do bypass the posterior margin of the cage.

Additional information on M3 cage and screw pairings can be found on page 2.

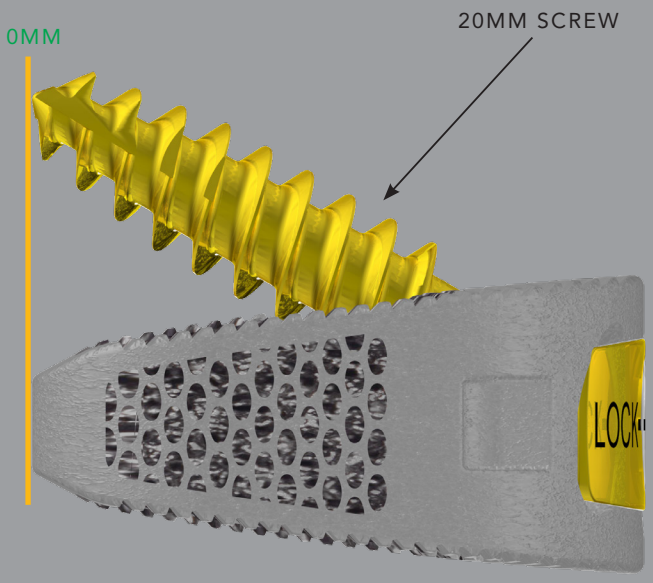
25MM X 35MM
CEPHALAD & CAUDAD TRAJECTORIES

SCREW/AWL LENGTHS	SHALLOW ANGLE (23.5°)	NOMINAL ANGLE (30°)	EXTREME ANGLE (36.5°)
15MM*	1.4MM	2.3MM	3.5MM
20MM	3.1MM	1.9MM	.5MM
25MM	7.7MM	6.2MM	4.5MM
30MM	12.3MM	10.6MM	8.5MM

27MM X 40MM - SHALLOW TRAJECTORY (23.5°)



27MM X 40MM - NOMINAL TRAJECTORY (30°)

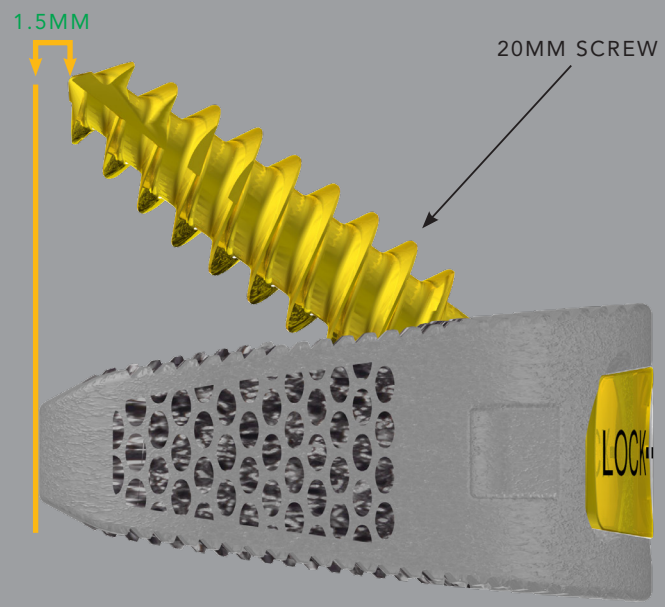


27MM X 40MM CEPHALAD & CAUDAD TRAJECTORIES			
SCREW/AWL LENGTHS	SHALLOW ANGLE (23.5°)	NOMINAL ANGLE (30°)	EXTREME ANGLE (36.5°)
15MM*	3.4MM	4.3MM	5.5MM
20MM	1.1MM	0MM	1.5MM
25MM	5.7MM	4.2MM	2.4MM
30MM	10.3MM	8.6MM	6.5MM

30MM X 45MM CEPHALAD & CAUDAD TRAJECTORIES			
SCREW/AWL LENGTHS	SHALLOW ANGLE (23.5°)	NOMINAL ANGLE (30°)	EXTREME ANGLE (36.5°)
15MM*	6.4MM	7.3MM	8.5MM
20MM	1.8MM	3MM	4.5MM
25MM	2.7MM	1.2MM	0.5MM
30MM	7.3MM	5.6MM	3.5MM

30mm Screws are Special Order.
*Standard M3 Awl is 15mm. Awl is 0.2mm undersized in length from the 15mm Screw.

27MM X 40MM - EXTREME TRAJECTORY (36.5°)



NOTES

NOTES

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