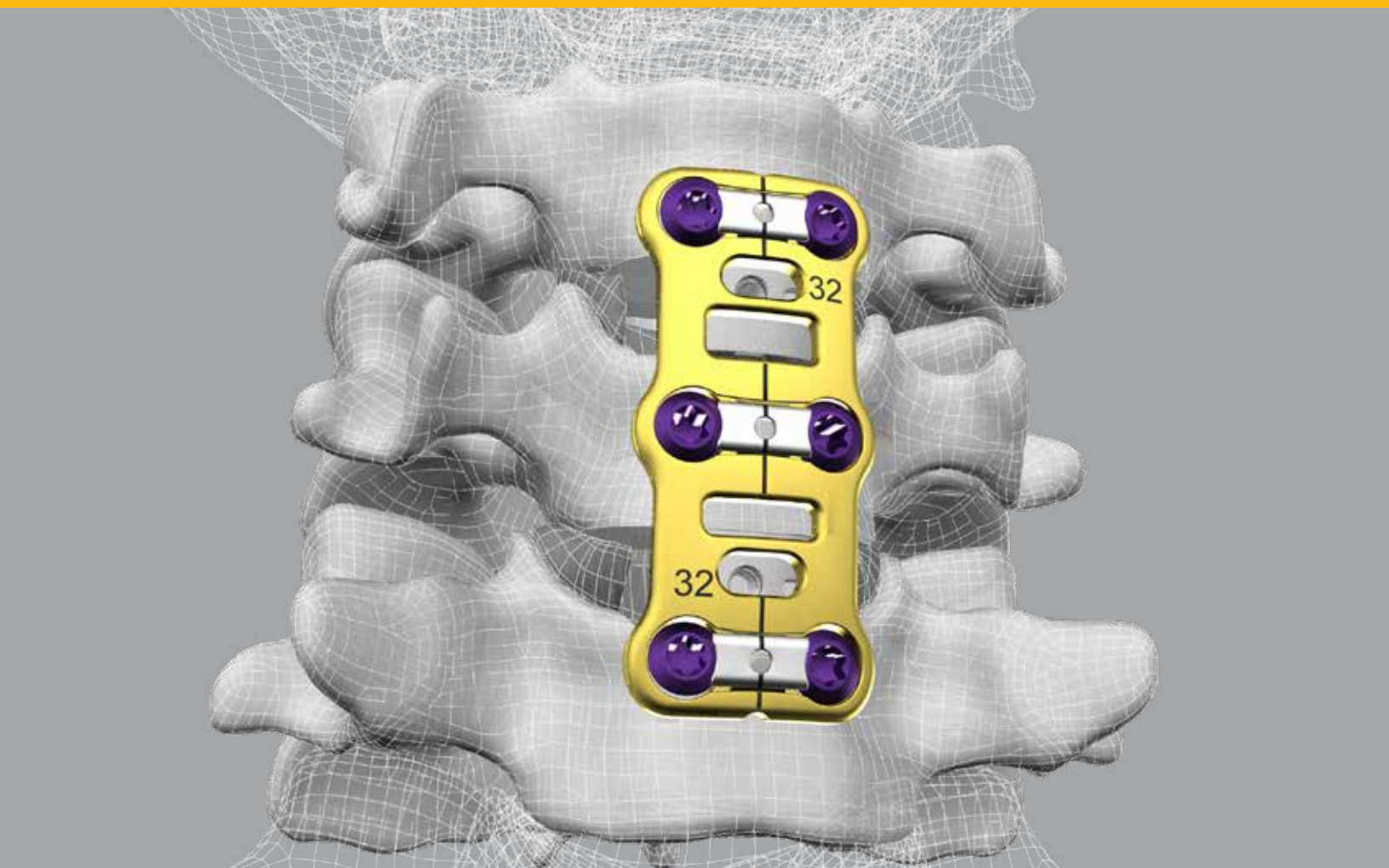
CoreLink
The Source for Spine™

TERRACE® & SURESIZE® ACDF SYSTEM

Surgical Technique Guide



THE TERRACE & SURESIZE ADVANTAGE

When used together, the **Terrace Anterior Cervical Plate and SureSize Interbody Cage Systems** assist with precise one-level plate sizing* and simple, secure, and adjustable temporary plate fixation. These complimentary systems are designed to help your ACDF go faster and show better.

SureSize interbodies offer a choice of material (F3D printed titanium and CL5 PEEK) along with a range footprints and sizes to best suit individual patient anatomy.

Terrace provides an efficient and user-friendly solution for anterior cervical plating. The low-profile plate incorporates an automatic locking mechanism to prevent screw back-out and enhance operating room efficiency. The variable angle screws provide a large cone of angulation, making it the perfect plate for those looking to customize their screw trajectories.

* The SureSize system provides recommendation for minimum length 1-level plates (10mm-16mm) based upon disc space height.

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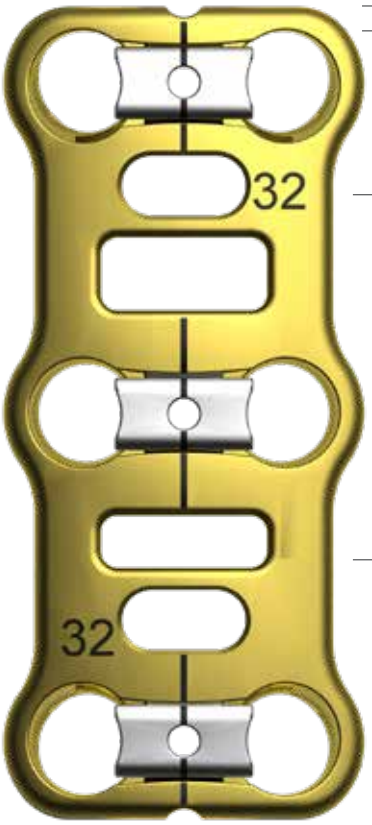
TERRACE PLATE OVERVIEW

The Terrace Anterior Cervical Plate features automatic locking mechanisms that prevent screw back-out and provide visual confirmation that the screws are secure. All Terrace plates are pre-lordosed and have a thin profile.

The Terrace system is compatible with F3D printed titanium and CL5 PEEK interbody cage systems, along with many others. However, when used with the SureSize interbody system, additional plate fixation and alignment benefits are provided.

ANTERIOR VIEW



1.15MM≈
BETWEEN SCREW HOLE AND EDGE OF PLATE

FIXATION PIN SLOT

14.5MM
AT NARROWEST POINT

17.5MM
AT WIDEST POINT

PROFILE VIEW

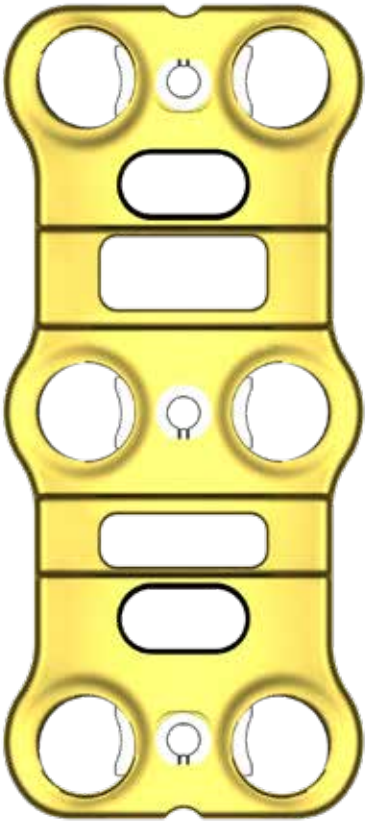
SCREW HOLE ANCHOR RINGS

2.2MM
PRIMARY PLATE PROFILE (THICKNESS OF PLATE)

1.9MM
AT BEND ZONES

2.5MM PROFILE AT SCREW HOLE ANCHOR RINGS

POSTERIOR VIEW

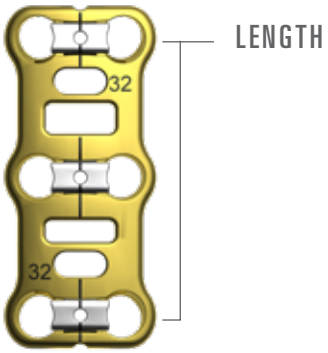


TERRACE PLATE LENGTH OPTIONS

Terrace is available in multiple lengths ranging from 10mm-110mm for one to five levels of fixation. The length of the plates correspond with the distance from the center of cephalad holes to the center of the caudal holes.

PLATES		LENGTH (MM)																
LEVEL	I	10	11	12	13	14	16	18	20	22	24	26	28	30				
	II	24	26	28	30	32	34	36	38	40	42	44	46					
	III	40	42	44	46	48	50	52	54	56	58	60*	62*	64*	66*	68*	70*	
	IV*	60	64	68	72	76	80	84	88	92	96	100						
	V*	75	80	85	90	95	100	105	110									

*Special Order

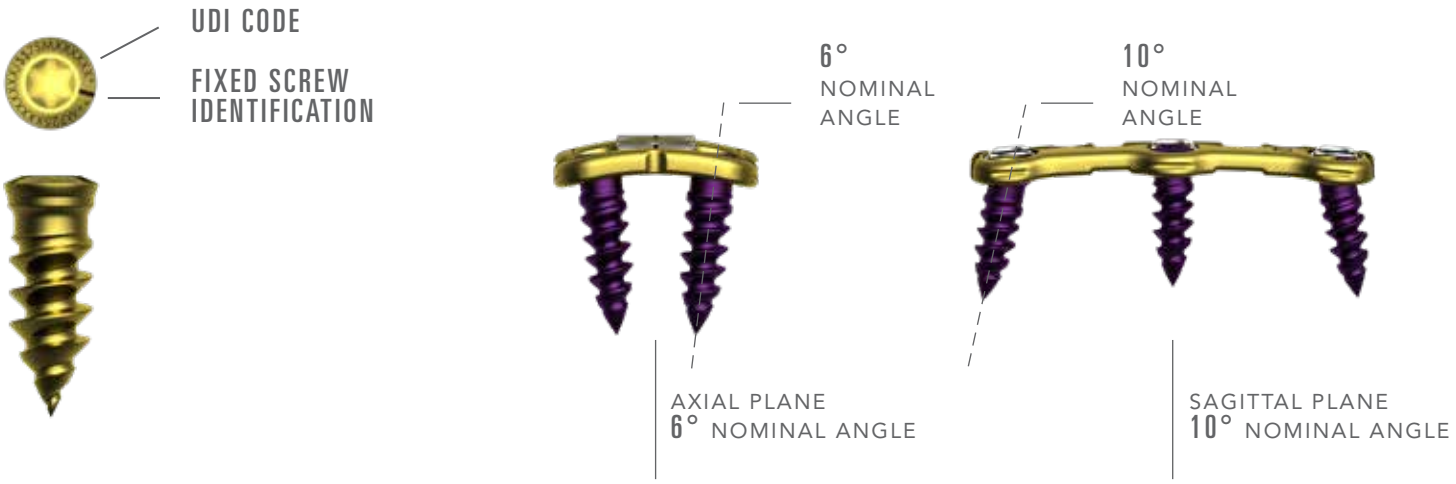


TERRACE SCREWS

The screws are available with diameters of 4mm and 4.5mm. They are color coded for identification of the bone/screw interface (12mm-20mm).

FIXED ANGLE SCREWS

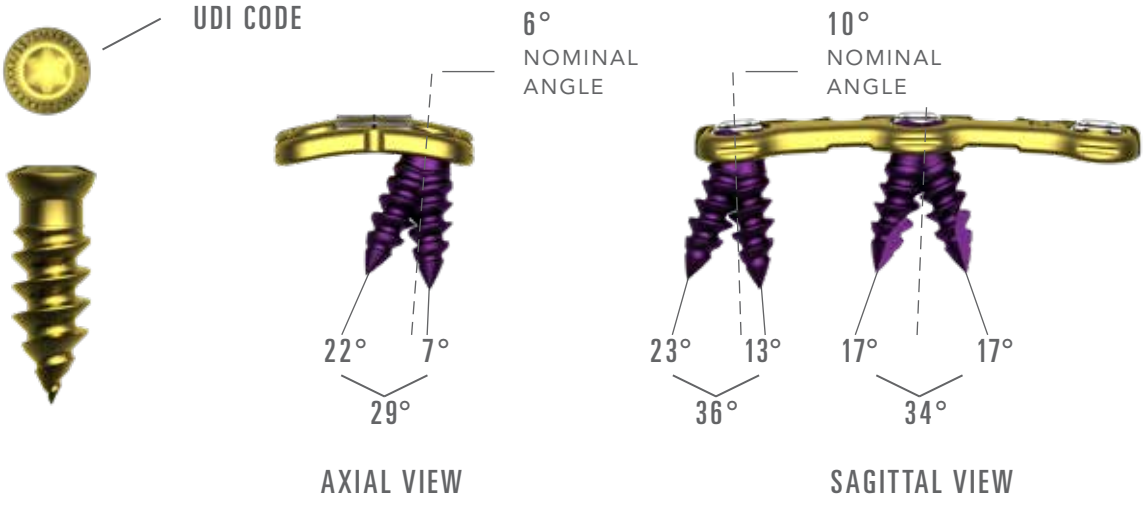
The Fixed Angle Screws can be identified by the laser marked line on the head. They provide six degrees of angulation in the axial plane and 10 degrees of angulation (for the cephalad and caudal screws) in the sagittal plane.



VARIABLE ANGLE SCREWS

On the axial plane, the range of angulation is 29 degrees (22 degrees medial and seven degrees lateral). On the sagittal plane, the end screws have a 36 degrees range of angulation (23 degrees cephalad and 13 degrees caudal). The center screws have a 34 degrees range of angulation (17 degrees cephalad and 17 degrees caudal).

CAUTION: When using variable angle screws, it is important to position their trajectory away from the construct's disc space.

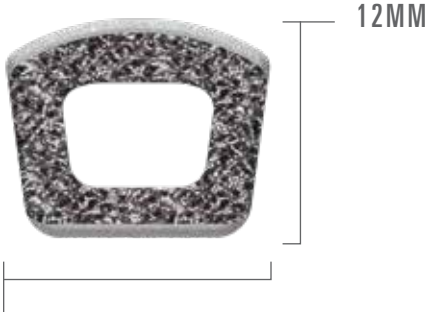


NOTE: If not using SureSize interbodies, turn to page 9 for Plate Positioning.

SURESIZE INTERBODY OVERVIEW

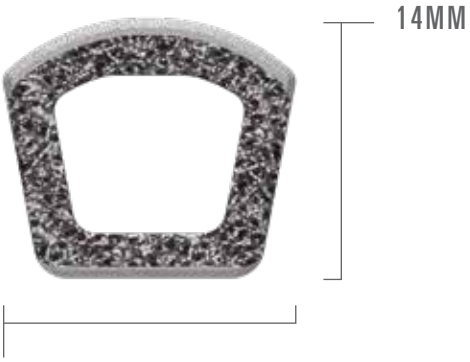
The SureSize cervical interbody cages are available in CL5 PEEK or F3D printed titanium featuring Mimetic Metal technology. F3D cages are pictured below. For details about Mimetic Metal, consult the Mimetic Metal document (CL-FORM-236-01).

The SureSize system includes two, seven degree lordotic axial footprints and heights ranging from 6mm-12mm (1mm increments).



14.5MM

STANDARD CERVICAL CAGE



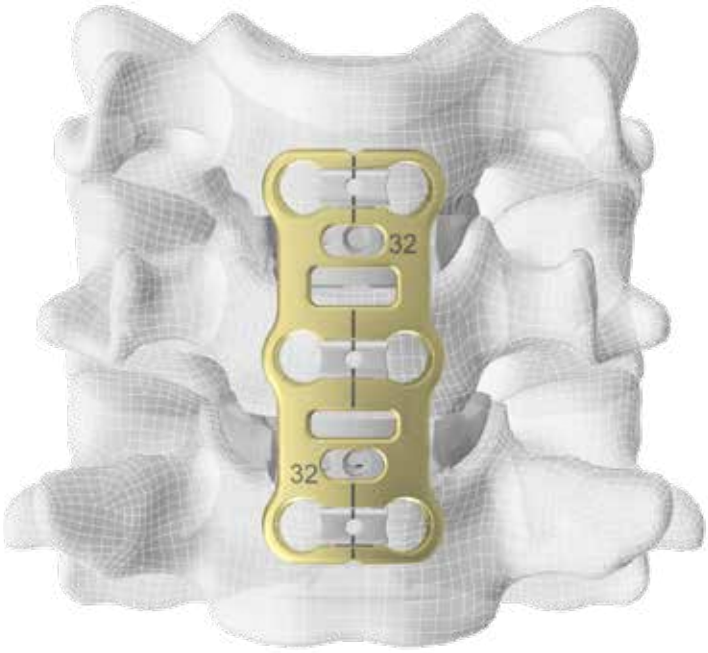
16.5MM

LARGE CERVICAL CAGE

The SureSize interbody cage has a dual-purpose hole for both cage insertion and temporary plate fixation directly to the interbody (when aligned with the superior fixation slot of a Terrace anterior cervical plate).

STANDARD LORDOSIS:
7°

3MM
DISTANCE FROM CENTER OF HOLE TO CEPHALAD EDGE



PATIENT POSITIONING

The patient is put under anesthesia and placed in the supine position. The operative area is then prepped and draped in the standard fashion, and 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).

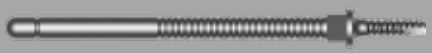
DISTRACTION

Distraction of the vertebral bodies may be accomplished using standard methods. Distraction pins are available in lengths of 12mm, 14mm and 16mm as a special order through Customer Service.

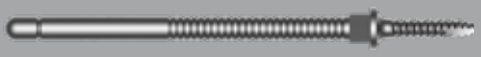
DISTRACTION PINS

SDP-012 (12MM)

SDP-014 (14MM)

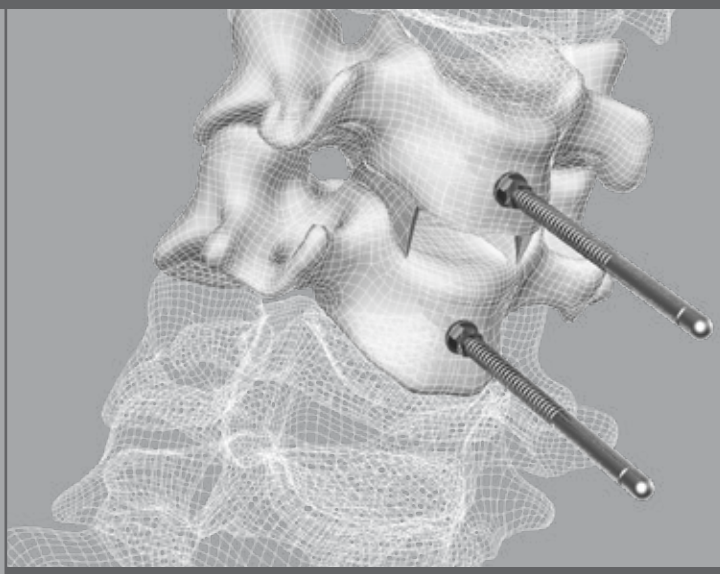


SDP-016 (16MM)

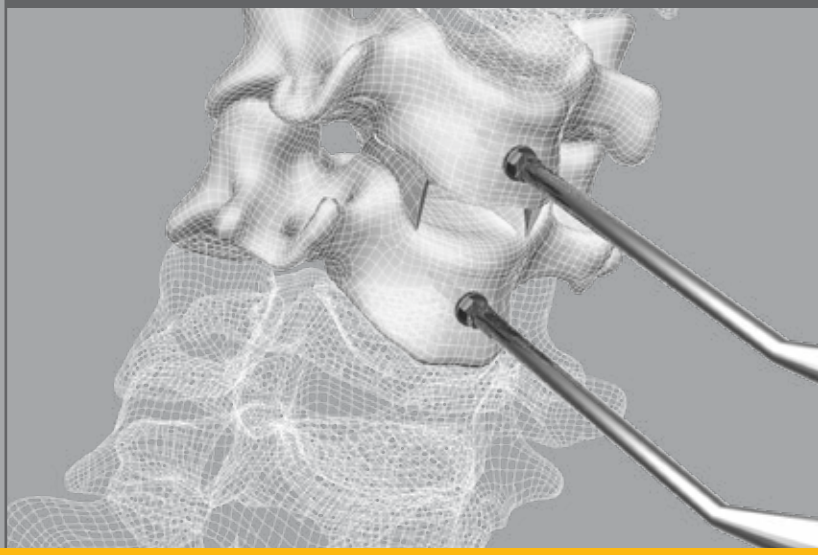


Sterile, individually packaged pins are available in boxes of 10.

DISTRACTION PINS PLACED IN VERTEBRAL BODIES



DISTRACTOR PLACED OVER DISTRACTION PINS



DISCECTOMY AND ENDPLATE PREPARATION

Remove the intervertebral disc and osteophytes as needed, leaving the lateral annulus intact. Cervical rasps in heights of 6mm to 12mm (available as special order) may be used to reveal the cartilaginous endplates and to prep the disc space for fusion. The height of the rasp matches that of the corresponding SureSize implant and trial.

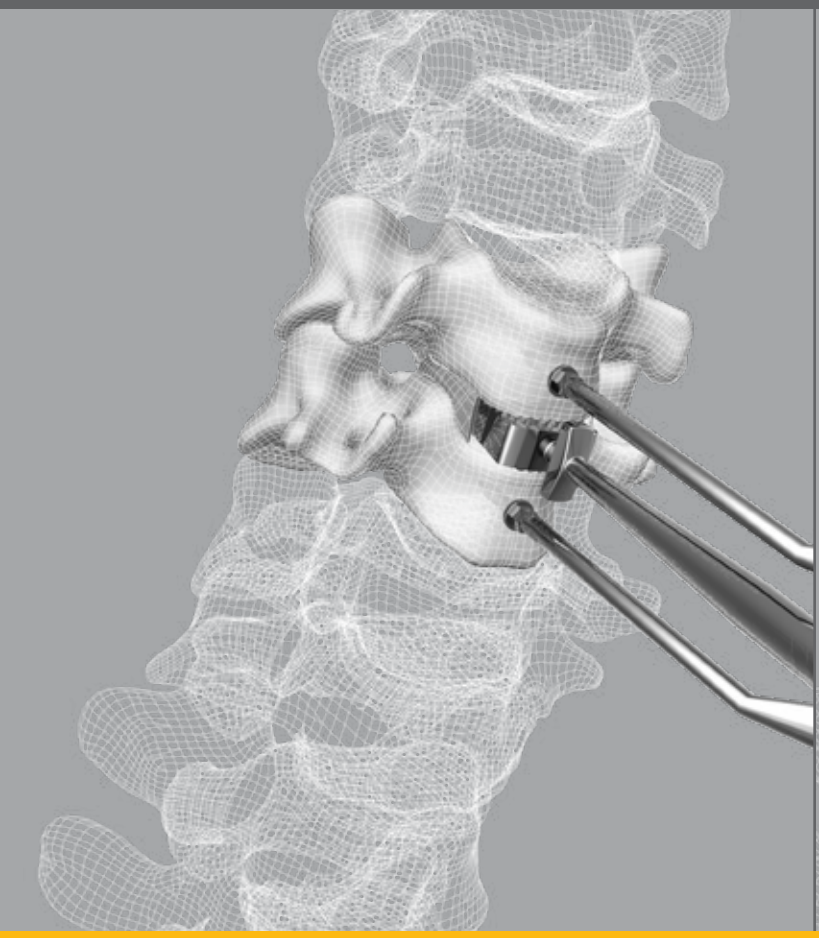
INTERBODY SIZING

The supplied Cervical Trials have a height profile that matches line-to-line to the implant height and may be used to determine the implant height that best fits the prepared intervertebral space. A secure fit is desirable to maintain disc height and promote fusion. Radiographic images may be used to verify implant size.

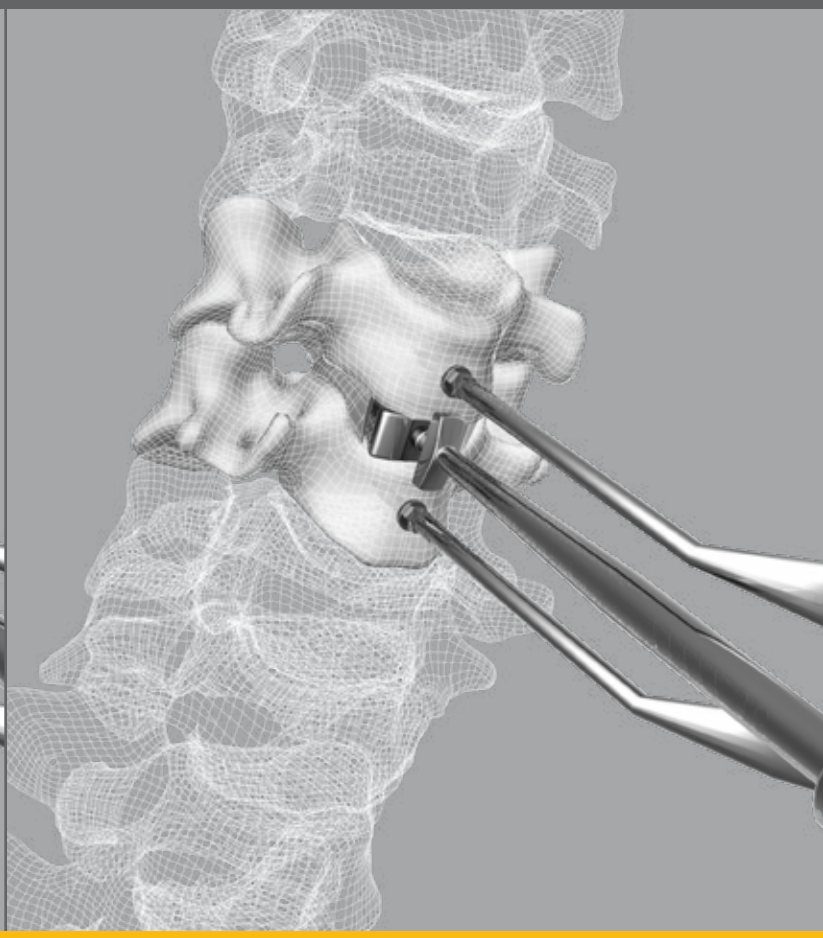
Select the appropriate SureSize implant and pack with the graft material.

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

CERVICAL RASP



CERVICAL TRIAL



INSERTER LOADING

After selection of the appropriate SureSize interbody, align the larger and smaller protrusions on the distal end of the inserter with the larger and smaller indentations on the anterior face of the SureSize cage.

Once correctly oriented and aligned, thread the inserter into the interbody.

INTERBODY ORIENTATION AND INSERTION

The SureSize interbody must be properly oriented to enable alignment of the cage's off-set inserter/fixation pin hole with the fixation pin slot in the Terrace plate.

- At the most superior level of the construct, orient the inserter so the text "Superior-This Side Up" is cephalad.
- Either orientation is acceptable for center and inferior end interbodies.

INTERBODY INSERTION

SPECIAL NOTE: PAY ATTENTION TO THE WAY IN WHICH THE INTERBODY AND INSERTER ARE ATTACHED AND ORIENTED TO ENSURE CORRECT ENGAGEMENT AND DEVICE FUNCTION.

SUPERIOR CAGE INSERTION

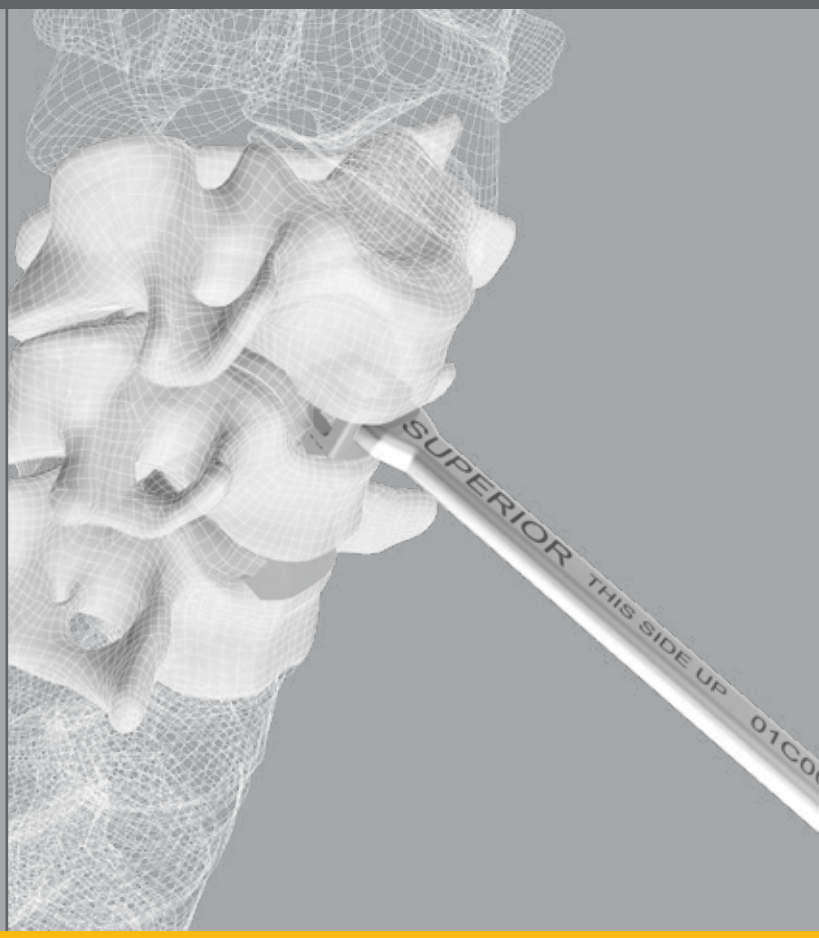


PLATE LENGTH SELECTION

After proper exposure and preparation of the appropriate cervical levels, select the minimum length plate suitable for patient anatomy.

The optimal plate size for 1-level ACDFs utilizing both SureSize and Terrace is indicated in the table to the right.

SURESIZE CAGE	1-LEVEL TERRACE PLATE
6MM	10MM
7MM	11MM
8MM	12MM
9MM	13MM
10MM	14MM
12MM	16MM

IN THE TABLE ABOVE, THE CORRESPONDING 1-LEVEL PLATE WILL ALWAYS BE 4MM LARGER THAN THE CAGE SIZE CHOSEN.

TERRACE PLATE

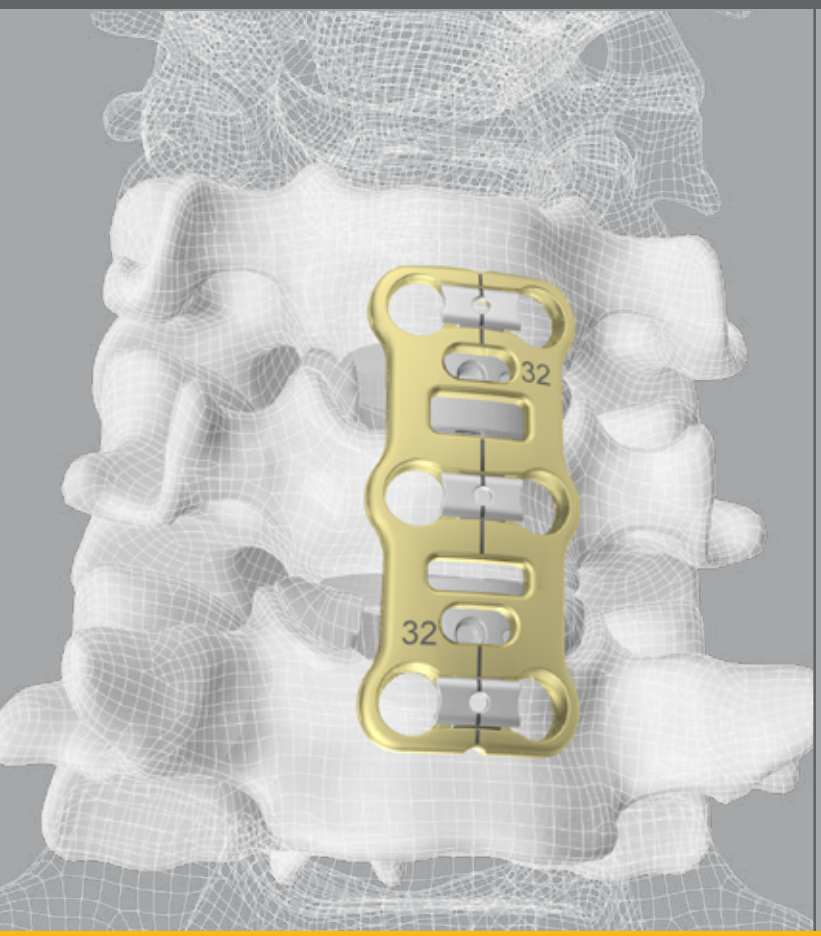


PLATE POSITIONING

The superior screw holes should be positioned in the inferior third of the superior vertebral body. Similarly, the inferior screw holes should be positioned in the superior third of the inferior vertebral body.

PLATE BENDING

Once the appropriately sized plate is chosen, determine if the plate is properly contoured. All plates are pre-lordosed. Additional contouring may be accomplished using the Plate Bender.

WARNING: Only bend over the designated bend zone(s) using the Plate Bender, failure to do so will result in plate damage and device failure. Do not implant if bent and ensure there is no damage to the locking plate mechanism. Never repeat or reverse bend a plate or post-operative failure will occur.

PLATE POSITIONING

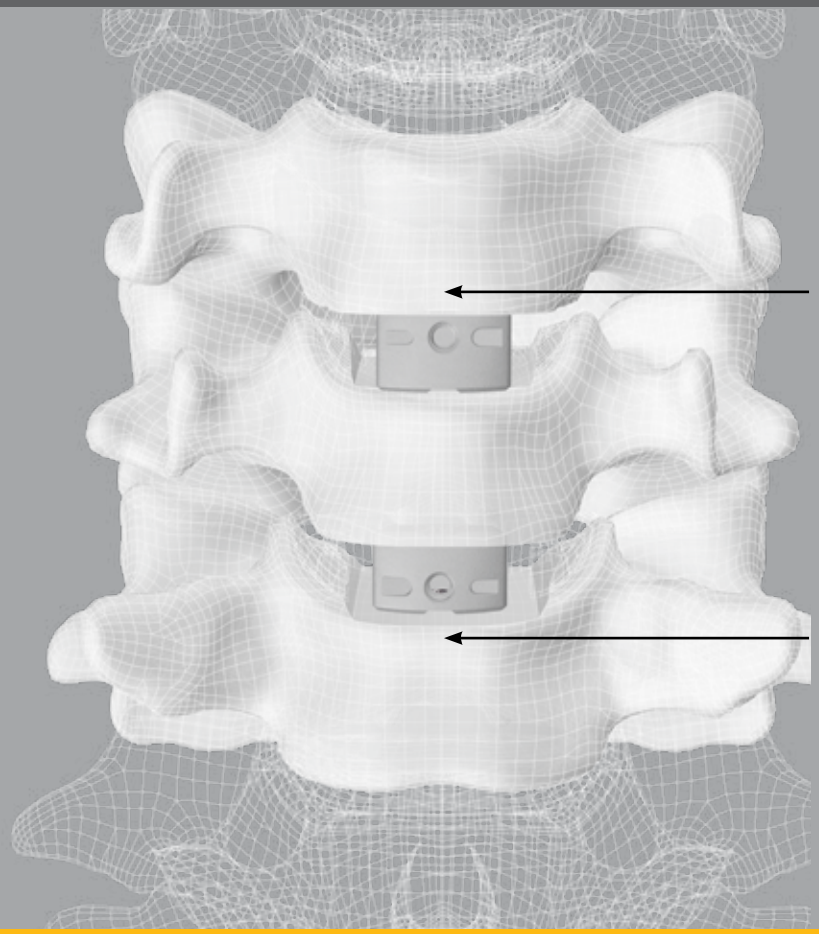
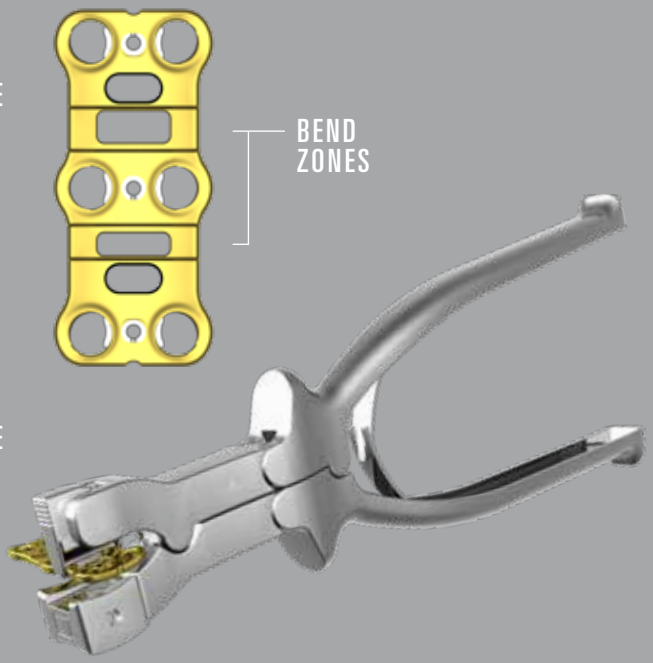


PLATE BENDING

The following plates must NEVER be bent:

- One-level Plates: 10mm, 11mm, 12mm, 13mm
- Two-level Plates: 24mm, 26mm, 28mm, 30mm



SURESIZE TEMPORARY PLATE FIXATION

Use the Plate Holder to position the plate on the cervical spine during temporary plate fixation.

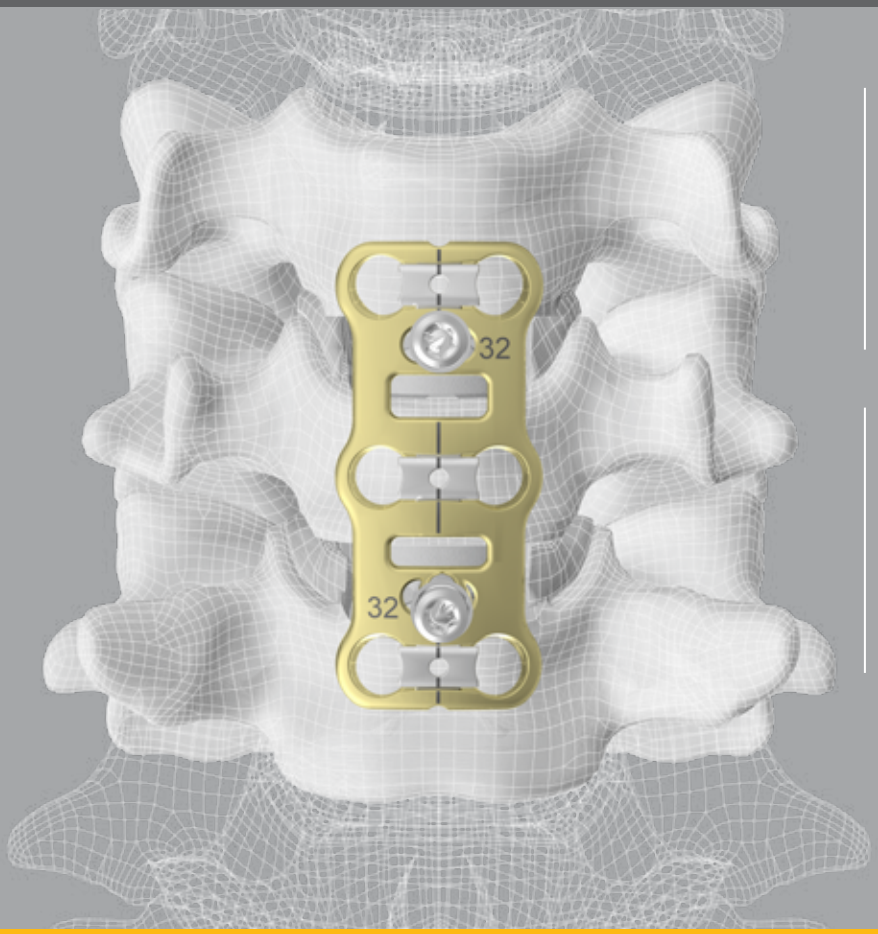
SureSize temporary fixation pins fit through the Terrace fixation pin slot and thread directly into the SureSize dual-purpose inserter/fixation hole with the Screw Driver (#2020-101).

Temporary fixation of the plate to the interbody allows for easier adjustment of the plate alignment prior to screw insertion.

The Spring Loaded Fixation Pin (#6020-110) allows for connection to recessed interbodies.

Traditional Temporary Fixation Pins (threaded and non-threaded) are also provided should fixation through the plate screw holes into cortical bone be desired. These pins should be placed with the provided Fixation Pin Inserter (#5020-201).

PLATE WITH FIXATION PINS



SURESIZE FIXATION PIN OPTIONS

BOTH SURESIZE OPTIONS ARE THREADED

STANDARD
#6020-109

SPRING LOADED
#6020-110

TRADITIONAL FIXATION PIN OPTIONS

NON-THREADED
#6020-111

THREADED
#6020-112

TERRACE DRILL GUIDES

	SCREW HOLE COMPATIBILITY	FUNCTIONALITY DRILL	TAP	SCREW	AXIAL ANGULATION	SAGITTAL ANGULATION
VARIABLE, SINGLE-BARREL	ANY	●	○	○	VARIABLE	VARIABLE
VARIABLE, DUAL-BARREL	ANY	●	○	○	6° MEDIAL	VARIABLE
FIXED, DUAL-BARREL, END	SUPERIOR AND INFERIOR (OUTER) SCREW HOLES	●	●	●	6° MEDIAL	10°
FIXED, DUAL-BARREL, CENTER	CENTRAL (INNER) SCREW HOLES	●	●	●	6° MEDIAL	10°

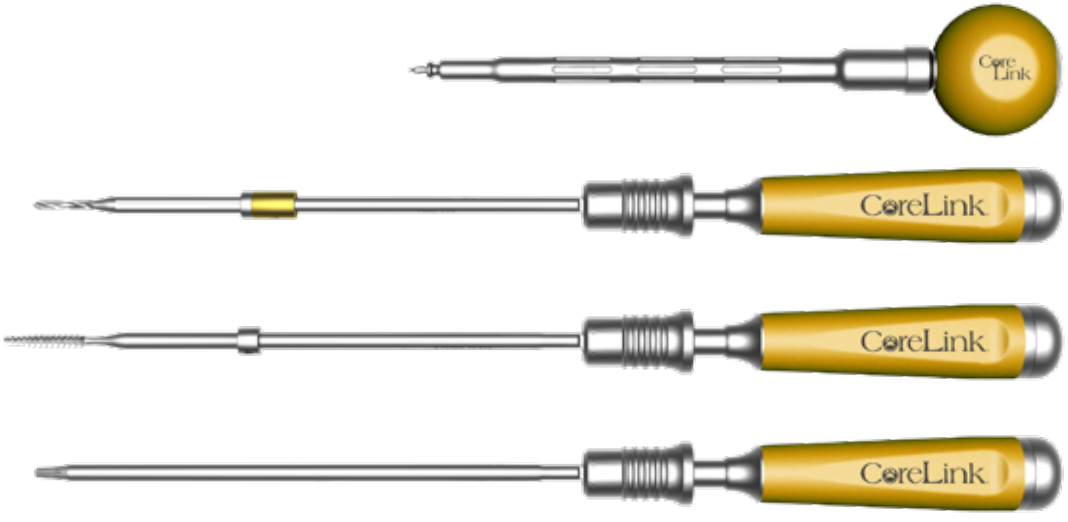
The variable, single-barrel drill guide handle must be positioned toward the midline of the plate for easy insertion and removal. The Fixed End and Center DTS Guides features a unique design function that provides snap-on engagement with the lateral edges of the Terrace plate.

SCREW HOLE PREPARATION & SCREW INSERTION

Use the awl, drills, and taps to prepare the screw holes. Drill bits are available with preset stops at 12mm, 14mm, and 16mm and are to be used with the drill guides. The tap has a 4mm diameter. All drill bits and taps are compatible with the AO Adapter Handle. An adapter that enables usage of power is additionally available as a special request from Customer Service.

The awl must be used with the self centering sleeve or through one of the drill guides to prevent damage to the plate. When used with the sleeve, the awl tip extends 6mm.

Use radiographic images to determine the appropriate screw length.



LOCKING MECHANISM

As each screw is advanced into place, its head will temporarily displace the locking mechanism, allowing the screw to pass. Once the screw head has sufficiently advanced, the locking mechanism will return to position, partially covering the screw head and preventing the screw from backing out. Confirm that the locking mechanism is in the "locked" position by visual verification that the confirmation lines are aligned. In addition, the hole in the locking mechanism will be in line with the confirmation lines on the plate.

NOT LOCKED

LOCKED

WARNING: Make sure lock is returned to the Locked position before placing the contralateral screw. Failure to do so will result in difficulty seating the contralateral screw.

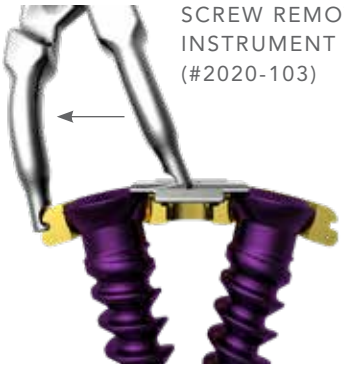
PLATE REMOVAL

To remove the Terrace Plate, use the Screw Removal Instrument (#2020-108) by positioning one of the instrument's distal tips through the small hole at the center of locking mechanism. The other distal tip should be positioned on the outside flat edge of the plate. Compress the Removal Tool to slide the Lock out of the way and then secure the instrument ratchet.

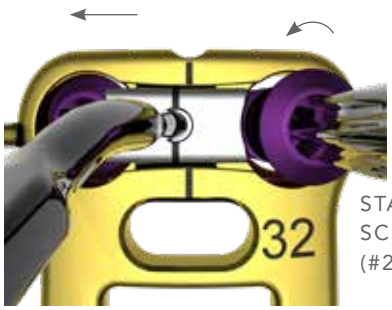
Once the locking mechanism has been slid away, use the Standard Screw Driver (standard hexalobe #10) with a counterclockwise rotation to remove that screw. Repeat the steps to remove other screws as necessary.

The system also includes a Screw Removal Driver (#2020-103) to be used if the standard plate removal methods are insufficient.

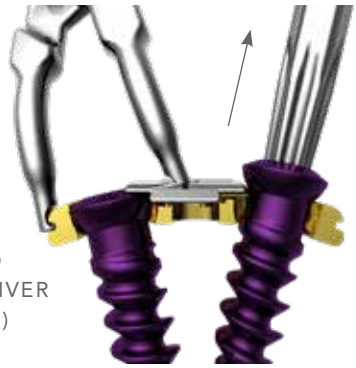
WARNING: Turn in a counterclockwise direction and this will destroy the screw hexalobe.



SCREW REMOVAL INSTRUMENT (#2020-103)



STANDARD SCREW DRIVER (#2020-101)



INSTRUCTIONS FOR USE

CORELINK CL5 CERVICAL SERIES INTERBODY SPACERS

OPERATING SURGEON – IMPORTANT INFORMATION

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

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

DESCRIPTION

The CL5 Cervical series of intervertebral body fusion devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various fixed heights and shapes for placement in the cervical spine. There are different cages designed for specific regions of the spine approaches to the spine. Each cage has a hollow center to allow placement of graft material inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the end-plates and prevent expulsion

Implants in the CL5 Cervical series of intervertebral body fusion devices are manufactured from the following materials:

- Medical grade PEEK (per ASTM F2026)
- Medical grade Tantalum (per ASTM F560)

Do not use any of the CL5 Cervical Interbody Fusion Device 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 CL5 Cervical Interbody implants or implant components should be reused under any circumstances. The instruments provided with the CL5 Cervical Interbody Fusion Device System are provided specifically for the implantation of the CL5 Cervical Interbody Fusion Device System implants.

Please refer to the applicable CL5 Cervical Series Interbody System Surgical Technique for additional important information about specific CoreLink implants, in addition to the information described herein.

INDICATIONS

CL5 Cervical Interbody Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. CL5 Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. CL5 Cervical implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

Contraindications of the CL5 Cervical series of intervertebral body fusion devices include:

- Active systemic 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 orthopedic 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 system 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.

WARNING: The safety and effectiveness of Cervical interbody fusion device system have been established only for spinal conditions with acute and chronic instabilities or deformities of the cervical spine (C2-T1): 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.

INSTRUCTIONS FOR USE (CONTINUED)

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 CL5 Cervical Series Interbody 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 CL5 Cervical 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 CL5 Cervical Series Interbody 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 CL5 Cervical Series Interbody System have not been evaluated for safety and compatibility in the MR environment. The CL5 Cervical Series Interbody System have not been tested for heating, migration, or image artifact in the MR environment. The safety of the CL5 Cervical Series Interbody 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 implants and instruments of the CL5 Cervical Series Interbody 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 devices 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 in the CL5 Cervical Series Interbody System 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 you suspect an instrument is 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 at 45-50 kHz to aid in thorough cleaning of devices
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

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

Automated Cleaning Instructions:

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

Typical Automated Washer Cycle for Surgical Instruments

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

Notes:

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

Sterilization Instructions

Implants and instruments of the CL5 Cervical Series Interbody System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

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

Sterilizer type: Pre-vacuum

Preconditioning Pulses: 3

Minimum Temperature: 132°C (270°F)

Full Cycle Time: 4 Minutes

Minimum Dry Time: 30 Minutes (allow for cool-down)

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

REUSABLE RIGID STERILIZATION CONTAINERS

The CL5 Cervical Series Interbody System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer system JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10-6 sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

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

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container system. 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 CL5 Cervical Series Interbody System is not recommended.

IMPORTANT CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion of implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. However, the presence of dissimilar metals in contact accelerates corrosion. For instance, where titanium and stainless steel are in contact, the stainless steel is subject to corrosive attack. Corrosion may accelerate failure of implants through fatigue fracture. Corrosion also causes metal compounds to be released into the body. To minimize effects from corrosion, implant components that encounter other metal objects, must be made from like or compatible metals.
2. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain alignment 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, placement, and fixation 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 must be considered when evaluating whether a patient is a candidate for such a procedure.
   - **Weight**. An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or Activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she 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 for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

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. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implants to become displaced or damaged and may cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
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: (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.
3. **Handle Implants with Care.** Never alter the implants from the original provided condition. Care must be taken to avoid any notching, scratching or reverse bending of the implant component or other operation that may produce defects in surface finish and internal stresses which may become a potential site for eventual breakage of the implant. Alterations to this implant will significantly decrease the fatigue strength and may cause early failure.
4. **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.
5. **Do Not Reuse Implants.** An implant previously implanted should 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 a 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
	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
	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

INSTRUCTIONS FOR USE

F3D CERVICAL SERIES INTERBODY SPACERS

OPERATING SURGEON – IMPORTANT INFORMATION

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

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

DESCRIPTION

The F3D Cervical Series Interbody System is an additively manufactured implant comprising of cervical interbody spacers. They are designed to provide mechanical support to the cervical spine while arthrodesis occurs. The cervical line has a partially porous construction and an open architecture with a large variety of footprints and lordosis angles to help optimize implant fit.

Implants in the F3D Cervical 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 Cervical 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 Cervical Series Interbody implants or implant components should be reused under any circumstances. The instruments provided with the F3D Cervical Series Interbody System are provided specifically for the implantation of the F3D Cervical Series implants.

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

INDICATIONS

The F3D Cervical Interbody Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. F3D Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. F3D Cervical implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

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

- Active systemic 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 System 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 Cervical Interbody Fusion Device System have been established only for spinal conditions with acute and chronic instabilities or deformities of

Cervical spine (C2-T1): 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

INSTRUCTIONS FOR USE (CONTINUED)

deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the F3D Cervical Series Interbody 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 F3D Cervical 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 Cervical Series Interbody 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 F3D Cervical Series Interbody System have not been evaluated for safety and compatibility in the MR environment. The F3D Cervical Series Interbody System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the F3D Cervical Series Interbody 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 implants of the F3D Cervical Series Interbody System are provided sterile. The surgical instruments provided with the F3D Cervical Series Interbody 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.
- 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 Cervical 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 Cervical 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. 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 Cervical Series Interbody System Instruments, provided in a perforated steam sterilization case, may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the System, when processed in Aesculap SterilContainer System 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 System. 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 Cervical Series Interbody 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 F3D Cervical Series Interbody System implants are available in titanium alloy. It is imperative that the F3D Cervical 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 a 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

INSTRUCTIONS FOR USE

TERRACE ANTERIOR CERVICAL PLATE SYSTEM

OPERATING SURGEON – IMPORTANT INFORMATION

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

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

DESCRIPTION

The Terrace Anterior Cervical Plate System is an implant system used to provide temporary immobilization and stabilization of the cervical spine while fusion occurs. The Terrace System consists of plates and screws in various configurations which can be assembled to create a construct that meets the needs of the patient. Screws are provided in fixed and variable configurations in a variety of lengths and diameters. Plates can be further contoured intraoperatively with instruments provided to obtain necessary spinal curvature.

Implants in the Terrace System are manufactured from the following materials:

- Medical grade titanium alloy (Ti6Al4V as per ASTM F136).
- Nitinol nickel-titanium alloy (NiTi as per ASTM F-2063).

The screws are anodized to facilitate size selection. Changes or variation in color during use or preparation do not affect implant quality.

CoreLink provides Surgical Technique Manuals demonstrating the use of CoreLink implants and instruments. Please contact your CoreLink sales representative to obtain copies of these Surgical Technique Manuals. Reference the Terrace Anterior Cervical Plate System Surgical Technique Manual for additional important information about specific CoreLink implants, in addition to the information described herein.

INDICATIONS

The Terrace Anterior Cervical Plate System is intended for anterior fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the evolution of cervical fusions in patients with degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

CONTRAINDICATIONS

Do not use the Terrace Anterior Cervical Plate 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, 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 may be required to correct these potential adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS

WARNING: The safety and effectiveness of anterior cervical plating systems have been established only for the following spinal conditions with acute and chronic instabilities or deformities of cervical spine (C2-T1): 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, lordosis, 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 in any of several modes. These modes include, but are not limited to, bone-metal interface failure, rod fracture or deformation, and/or bone failure.

Spinal implants of this type may be removed after sufficient bone fusion develops. However, please inform the patient that a second surgical procedure may be necessary and that there are risks associated with a second surgical procedure. 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.

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.

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.

INSTRUCTIONS FOR USE (CONTINUED)

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 Terrace Anterior Cervical Plate 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 Terrace Anterior Cervical Plate 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 anterior cervical plate 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 Terrace Anterior Cervical Plate 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 Terrace Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. Terrace Anterior Cervical Plate System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Terrace Anterior Cervical Plate 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 implants and instruments of the Terrace Anterior Cervical Plate 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 devices 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 in the Terrace Anterior Cervical Plate System 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 you suspect an instrument is 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 instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution 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 at 45-50 kHz to aid in thorough cleaning of devices.
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

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

Automated Cleaning Instructions:

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

Typical Automated Washer Cycle for Surgical Instruments

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

Notes:

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

Sterilization Instructions

Implants and instruments of the Terrace Anterior Cervical Plate System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

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

Sterilizer type: Pre-vacuum
Preconditioning Pulses: 3
Minimum Temperature: 132°C (270°F)
Full Cycle Time: 4 Minutes
Minimum Dry Time: 45 Minutes (allow for cool-down)

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

REUSABLE RIGID STERILIZATION CONTAINERS

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

Required Sterilization Cycle

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

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

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

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

Flash sterilization of the Terrace Anterior Cervical Plate System is not recommended.

IMPORTANT SYSTEM CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion of implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. However, the presence of dissimilar metals in contact accelerates corrosion. For instance, where titanium and stainless steel are in contact, the stainless steel is subject to corrosive attack. Corrosion may accelerate failure of implants through fatigue fracture. Corrosion also causes metal compounds to be released into the body. To minimize effects from corrosion, implant components that encounter other metal objects, must be made from like or compatible metals.
2. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Non-union.** Implants of this type are temporary devices that are used to align and maintain vertebral body position 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 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.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.
4. **Patient Considerations.** The following 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 for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, 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. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implants to become displaced or damaged and may cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
- **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (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.
- **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 should 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 the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

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

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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
	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
	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

TERRACE PLATE PRODUCT LISTING

KIT ORDER #K5000203

1–LEVEL PLATES

QTY	CATALOG NUMBER	DESCRIPTION
1	24100-010	10MM
1	24100-011	11MM
1	24100-012	12MM
1	24100-013	13MM
1	24100-014	14MM
1	24100-016	16MM
1	24100-018	18MM
1	24100-020	20MM
1	24100-022	22MM
1	24100-024	24MM
1	24100-026	26MM
1	24100-028	28MM
1	24100-030	30MM

2–LEVEL PLATES

QTY	CATALOG NUMBER	DESCRIPTION
1	24200-024	24MM
1	24200-026	26MM
1	24200-028	28MM
1	24200-030	30MM
1	24200-032	32MM
1	24200-034	34MM
1	24200-036	36MM
1	24200-038	38MM
1	24200-040	40MM
1	24200-042	42MM
1	24200-044	44MM
1	24200-046	46MM

3–LEVEL PLATES

QTY	CATALOG NUMBER	DESCRIPTION
1	24300-040	40MM
1	24300-042	42MM
1	24300-044	44MM
1	24300-046	46MM
1	24300-048	48MM
1	24300-050	50MM
1	24300-052	52MM
1	24300-054	54MM
1	24300-056	56MM
1	24300-058	58MM
1	24300-060	60MM*
1	24300-062	62MM*
1	24300-064	64MM*
1	24300-066	66MM*
1	24300-068	68MM*
1	24300-070	70MM*

4–LEVEL* PLATES

QTY	CATALOG NUMBER	DESCRIPTION
1	24400-060	60MM
1	24400-064	64MM
1	24400-068	68MM
1	24400-072	72MM
1	24400-076	76MM
1	24400-080	80MM
1	24400-084	84MM
1	24400-088	88MM
1	24400-092	92MM
1	24400-096	96MM
1	24400-100	100MM

5–LEVEL* PLATES

QTY	CATALOG NUMBER	DESCRIPTION
1	24500-075	75MM
1	24500-080	80MM
1	24500-085	85MM
1	24500-090	90MM
1	24500-095	95MM
1	24500-100	100MM
1	24500-105	105MM
1	24500-110	110MM

*3-level (60mm-70mm), 4–level, and 5–level plates available for special request.

TERRACE SCREW PRODUCT LISTING

KIT ORDER #K5000203

VARIABLE CERVICAL SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
VARIABLE SELF-DRILLING		
10	20140-12	4.0MM X 12MM
10	20140-14	4.0MM X 14MM
10	20140-16	4.0MM X 16MM
10	20145-12	4.5MM X 12MM
10	20145-14	4.5MM X 14MM
10	20145-16	4.5MM X 16MM
VARIABLE SELF-TAPPING		
10	20240-12	4.0MM X 12MM
10	20240-14	4.0MM X 14MM
10	20240-16	4.0MM X 16MM
6	20240-18	4.0MM X 18MM
6	20240-20	4.0MM X 20MM
6	20245-12	4.5MM X 12MM
6	20245-14	4.5MM X 14MM
6	20245-16	4.5MM X 16MM
6	20245-18	4.5MM X 18MM
6	20245-20	4.5MM X 20MM

FIXED CERVICAL SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
FIXED SELF-DRILLING		
10	20340-12	4.0MM X 12MM
10	20340-14	4.0MM X 14MM
10	20340-16	4.0MM X 16MM
6	20345-12	4.5MM X 12MM
6	20345-14	4.5MM X 14MM
6	20345-16	4.5MM X 16MM
FIXED SELF-TAPPING		
10	20440-12	4.0MM X 12MM
10	20440-14	4.0MM X 14MM
10	20440-16	4.0MM X 16MM
6	20440-18	4.0MM X 18MM
6	20240-20	4.0MM X 20MM
6	20445-12	4.5MM X 12MM
6	20445-14	4.5MM X 14MM
6	20445-16	4.5MM X 16MM
6	20445-18	4.5MM X 18MM
6	20445-20	4.5MM X 20MM

STANDARD TERRACE PLATE KIT

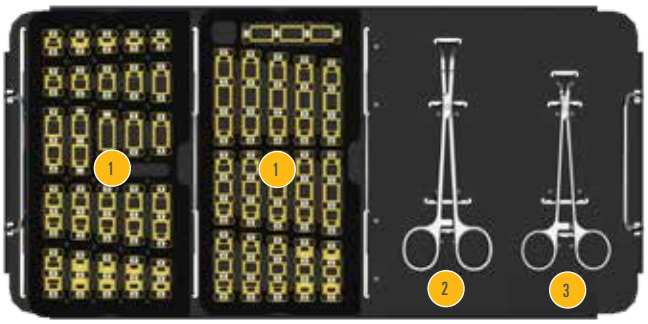
KIT ORDER #K5000203

TOP TRAY

1. 1, 2, 3-level Plates
2. Plate Holder: #4010-105
3. Revision Instrument: #2020-108

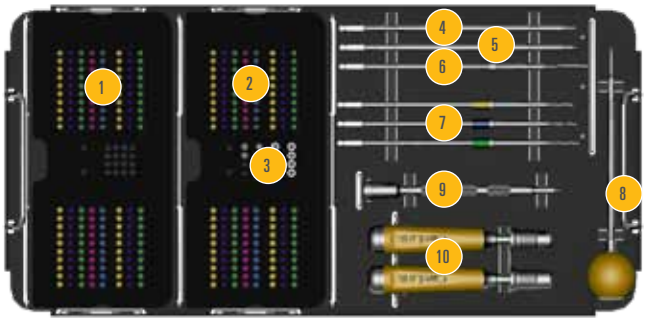
1 & 2-LEVEL PLATES

3-LEVEL PLATES



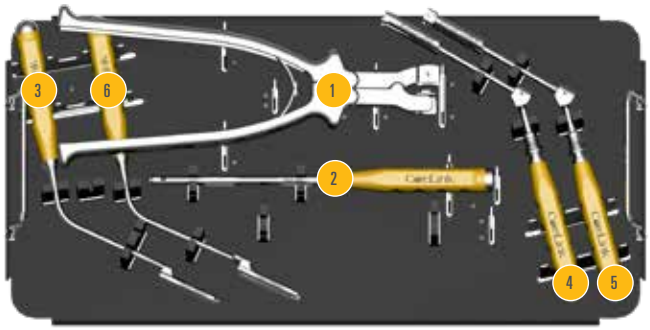
MIDDLE TRAY

1. Fixed Screws
2. Variable Screws
3. Temporary Fixation Pins:
   2 qty x #6020-109 (Standard SureSize)
   2 qty x #6020-110 (Spring Loaded SureSize)
   4 qty x #6020-111 (Traditional Non-threaded)
   4 qty x #6020-112 (Traditional Threaded)
4. Self Retaining Screw Driver:
   #10 Hexalobe: 2 qty x #2020-101
5. Screw Removal Tool:
   #10 Hexalobe: #2020-103
6. Tap – 4mm: #1020-040
7. Drills:
   12mm 2 qty x #1020-112mm
   14mm 2 qty x #1020-114mm
   16mm 2 qty x #1020-116mm
8. Awl: #5020-105
9. Awl Sleeve: #5020-106
10. Handle-AO Connection: 2 qty x #8020-100



BOTTOM TRAY

1. Plate Bender: #7020-200
2. Fixation Pin Inserter: #5020-201
3. Dual-Barrel Drill Guide – Variable: #1120-207
4. Single-Barrel Drill Guide – Variable: #1120-104
5. Dual-Barrel DTS Guide – End: #1120-205
6. Dual-Barrel DTS Guide – Center: #1120-206



Individual instruments may vary from those imaged above.

SURESIZE INTERBODY OFFERINGS

STANDARD FOOTPRINT
(14.5MM X 12MM), 7° LORDOSIS

PEEK KIT ORDER #K5000259

F3D-TI KIT ORDER #K5000261

INSTRUMENT SET CONTENTS STANDARD FOOTPRINT		
QTY	PEEK CATALOG NUMBER / TITANIUM CATALOG NUMBER	ANTERIOR CAGE HEIGHT
3	ZCL0706 / 3CZ1412-0706	6MM
3	ZCL0707 / 3CZ1412-0707	7MM
3	ZCL0708 / 3CZ1412-0708	8MM
3	ZCL0709 / 3CZ1412-0709	9MM
3	ZCL0710 / 3CZ1412-0710	10MM
3	ZCL0711 / 3CZ1412-0711	11MM
3	ZCL0712 / 3CZ1412-0712	12MM

LARGE FOOTPRINT
(16.5MM X 14MM), 7° LORDOSIS

PEEK KIT ORDER #K5000260

F3D-TI KIT ORDER #K5000262

INSTRUMENT SET CONTENTS LARGE FOOTPRINT		
QTY	PEEK CATALOG NUMBER / TITANIUM CATALOG NUMBER	ANTERIOR CAGE HEIGHT
3	ZLCL0706 / 3CZ1614-0706	6MM
3	ZLCL0707 / 3CZ1614-0707	7MM
3	ZLCL0708 / 3CZ1614-0708	8MM
3	ZLCL0709 / 3CZ1614-0709	9MM
3	ZLCL0710 / 3CZ1614-0710	10MM
3	ZLCL0711 / 3CZ1614-0711	11MM
3	ZLCL0712 / 3CZ1614-0712	12MM

SURESIZE INSTRUMENT KITS

STANDARD INSTRUMENT KIT

KIT ORDER #K5000263

INSTRUMENT SET CONTENTS STANDARD KIT	
CATALOG NUMBER	DESCRIPTION
01C00039	SURESIZE INTERBODY INSERTER
07C00007	TAMP
02C00048	STANDARD 7° TRIALS (6MM-12MM)
02C00049	
02C00050	
02C00051	
02C00052	
02C00053	
02C00054	
02C00146	LARGE FOOTPRINT SIZER (16.5MM X 14MM)

LARGE INSTRUMENT KIT

KIT ORDER #K5000264

INSTRUMENT SET CONTENTS LARGE KIT	
CATALOG NUMBER	DESCRIPTION
01C00039	SURESIZE INTERBODY INSERTER
07C00007	TAMP
02C00195	LARGE 7° TRIALS (6MM-12MM)
02C00196	
02C00197	
02C00198	
02C00199	
02C00200	
02C00201	

NOTES

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CL-FORM-242, Rev. 6