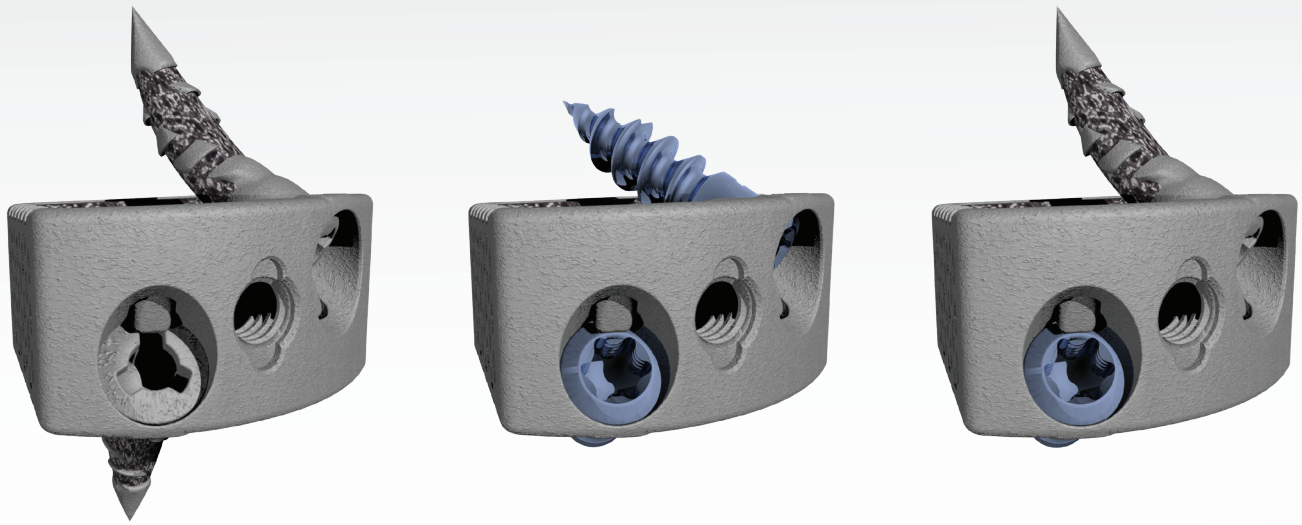
CoreLink
The Source for Spine™

F3D-C2 STAND-ALONE CERVICAL SYSTEM

WITH FUSATION™ ANCHOR TECHNOLOGY

Surgical Technique Guide



F3D-C2 STAND-ALONE CERVICAL SYSTEM

The **F3D-C2 Stand-alone Cervical System** is an interbody fusion system comprised of a spacer with two screws and/or Fusation™ anchors secured by a locking mechanism integrated within the cage. The system features versatile fixation, proven implant geometry, and the osteoconductive benefits of Mimetic Metal®.

TABLE OF CONTENTS

SYSTEM OVERVIEW

INTRODUCTION

The F3D-C2 Stand-alone Cervical System includes traditional screws as well as porous Fusation anchors for surgical versatility and solid implant fixation. Mimetic Metal 3D printing technology is incorporated into the cage and anchor components.

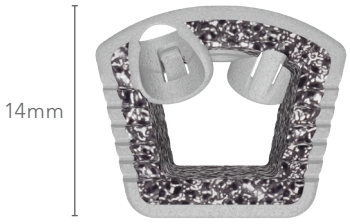
FEATURES

- Directional lattice framework enables dual-zone micro deflection, designed for load sharing and minimized stress shielding
- Large, open spacer graft windows for increased graft volume
- Zero-step locking mechanism
- Cage is compatible with two reliable fixation options:
  - Screws
  - Anchors designed to facilitate easier fixation and minimization of the surgical corridor to reduce soft tissue retraction and disruption

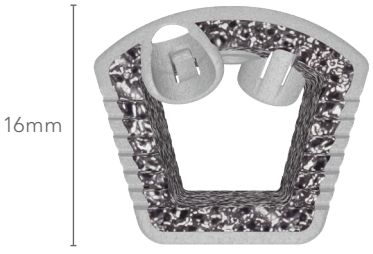
FOOTPRINT DIMENSIONS

14.5mm x 12mm

16.5mm x 14mm



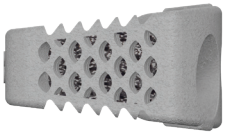
18.0mm x 16mm*



LORDOSIS

7°

13°*

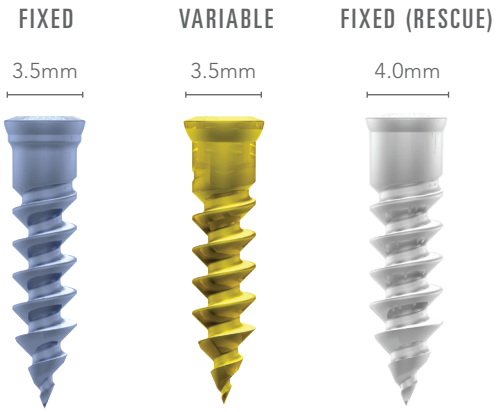


*Special order. Contact CoreLink Customer Service for additional sizes & options.

SYSTEM OVERVIEW (CONTINUED)

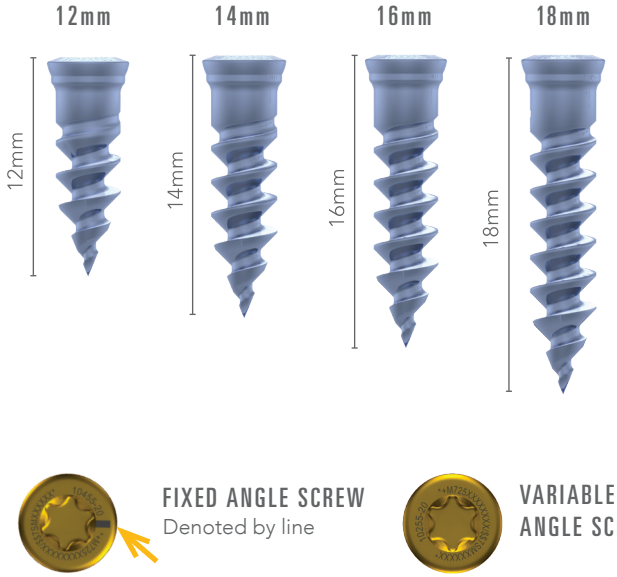
SCREW DIAMETERS

Screws are available in both a fixed and variable configuration for the 3.5mm screw, and a fixed trajectory for the 4.0mm rescue screw. The screws are self-drilling-self-tapping.



SCREW LENGTH

Screws are available in 12mm, 14mm, 16mm, and 18mm lengths.



FIXED ANGLE SCREW
Denoted by line

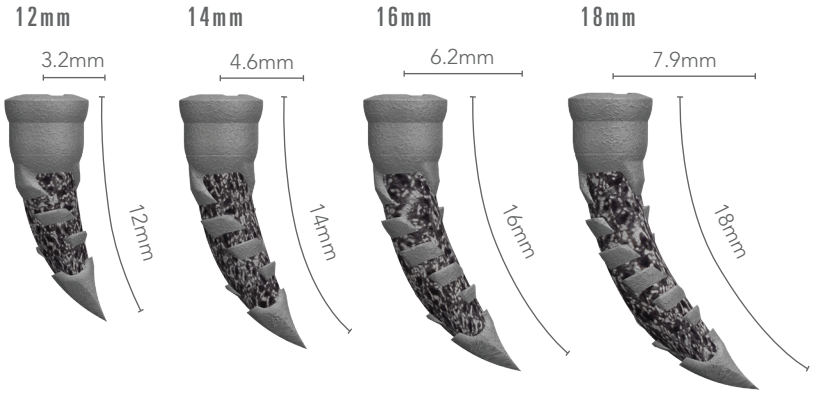
VARIABLE
ANGLE SCREW

ANCHOR DIAMETERS

Anchors are available in a 3.5mm diameter.

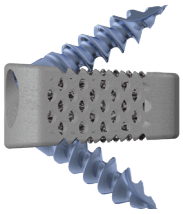
ANCHOR LENGTH

Anchors are available in 12mm, 14mm, 16mm, and 18mm lengths. **The anchors are measured by their arc length**.



RECOMMENDED SCREW & ANCHOR / CAGE COMBINATION

CAGE	SCREW/ANCHOR LENGTH
14.5mm x 12mm	12mm or 14mm
16.5mm x 14mm	14mm or 16mm
18.0mm x 16mm	16mm or 18mm



Note: The screw size indicates the full length of the screw from end to end. In a fixed trajectory the tip of the screw should align with the posterior aspect of the cage when fully seated. Refer to the chart on page 23.

ANGULATION

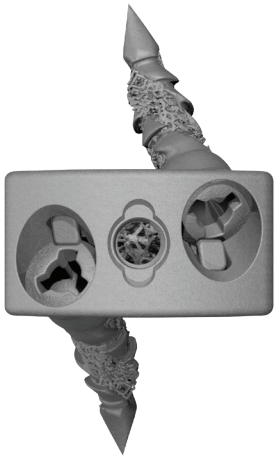
FIXED ANGLE TRAJECTORIES

- Fixed cephalad/caudal angulation of 35°
- Fixed medial angulation of 20°

VARIABLE ANGLE TRAJECTORIES*

- 35° + 15° cephalad/caudal
- 20° +/- 6.5° medial/lateral variability

**Anchors not available in variable configuration.*



PATIENT POSITIONING AND APPROACH

The patient is anesthetized and positioned supine. The operative area is prepared and draped in the standard fashion. An incision is made at the appropriate level and the vertebral bodies to be fused are exposed.

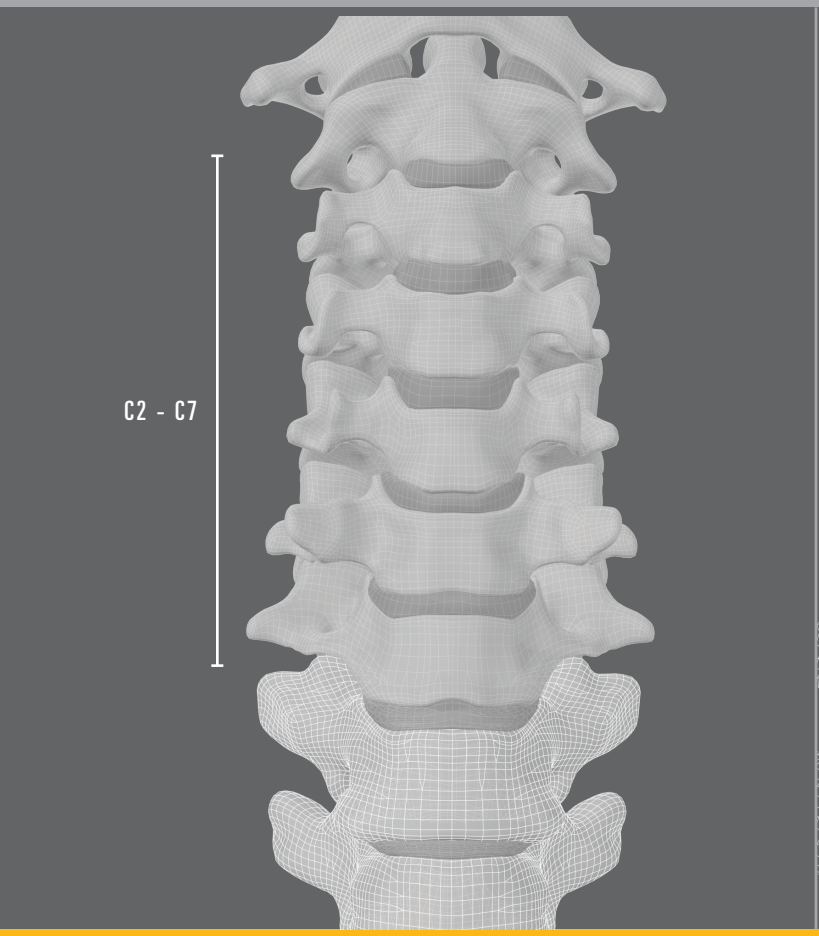
Utilize radiographic guidance with C-arm fluoroscopy throughout the procedure to ensure correct placement of the implant(s).

DISCECTOMY AND ENDPLATE PREPARATION

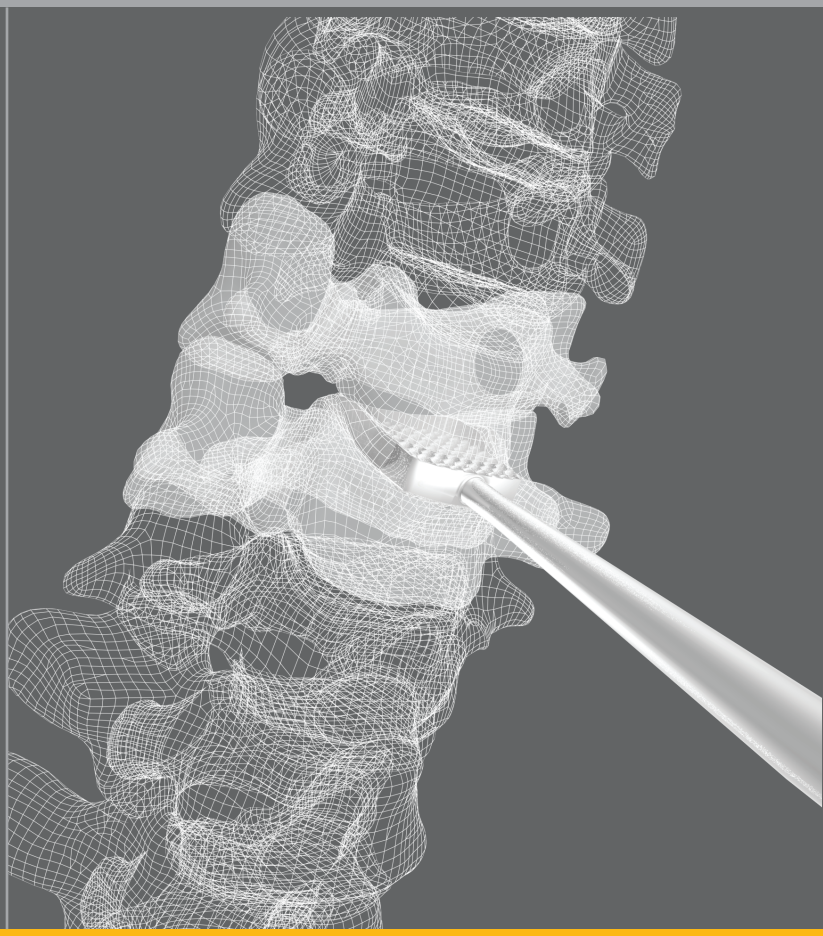
Access the operative site and retract the tissue using preferred instrumentation and distraction techniques. The intervertebral disc and osteophytes are removed as indicated. A complete discectomy, nerve and spinal cord decompression, and endplate preparation are completed using preferred instrumentation.

The F3D-C2 Stand-alone Cervical System includes a variety of surgical instruments to facilitate site preparation, such as a universal rasp to help decorticate the endplate.

ANTERIOR CERVICAL SPINE



CERVICAL RASP



IMPLANT SIZING

Trial sizers are available to determine the appropriate dimensions for the interbody once the disc space is prepared.

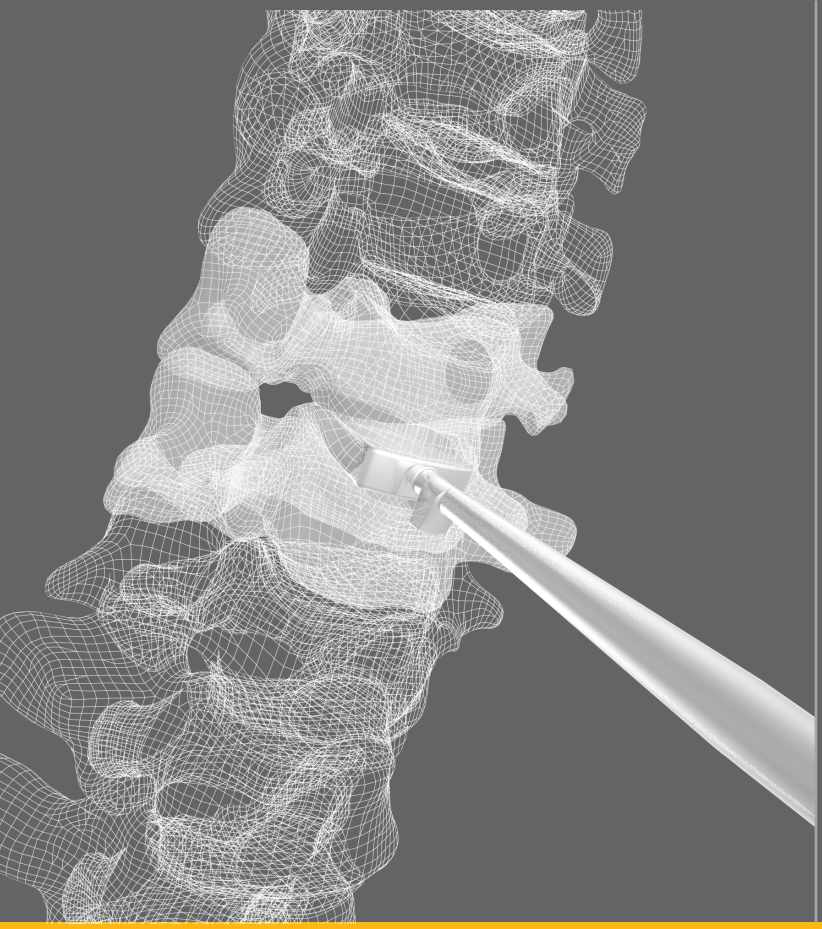
Trials are used to determine spacer footprint, height, and lordosis that best fits the prepared intervertebral space.

Carefully insert the selected trial into the prepared disc space. A secure fit is desirable to maintain height and promote fusion. It is recommended to start with a smaller height and advance to the appropriate height. A mallet can be used to aid insertion. Radiographic images are used to verify proper fit.

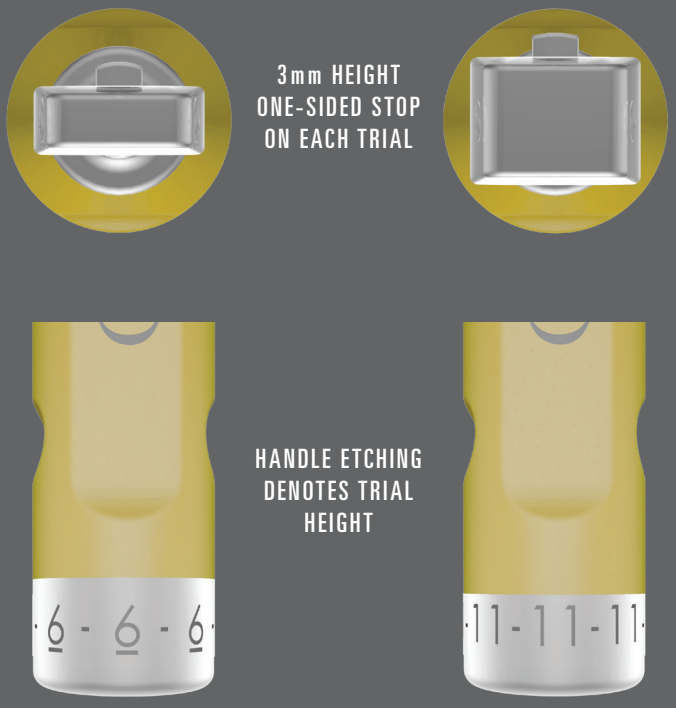
Trials are true to exact size. The trials have stops that are 2mm proximal from the trial head.

Implants can then be inserted via attachment to the dual-barrel drill/tap/screw (DTS) guide or with a freehand technique, as described in the following pages.

USING THE TRIAL



TRIAL SIZING



SCREW FIXATION TECHNIQUE
IMPLANT LOADING: FREEHAND INSERTER

The freehand inserter can be used once the desired size of implant has been chosen. This inserter is for freehanding screws only and does not accommodate the DTS guides in the kit

FREEHAND INSERTER/CAGE ASSEMBLY

1. Assemble the freehand inserter by sliding the inner shaft through the outer sleeve of the inserter. **The inner sleeve must be threaded into the outer sleeve.**

2. Thread the distal tip of the inserter through the anterior face of the implant by rotating the proximal knob of the internal shaft clockwise until snug.

   Note: Do not overtighten the inner shaft as it may cause the outer sleeve to not rotate freely in the case where the stops on the outer shaft must be repositioned.

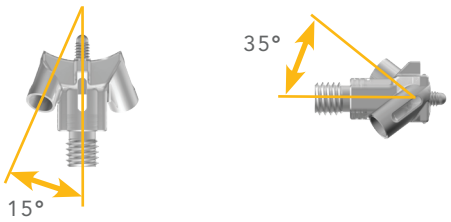
   The freehand inserter has a 12mm tall stop (only functions as a stop up to 10mm tall implants).

   Rotate the outer sleeve to position the stops perpendicular to the anterior margin of the cage so they do not interfere with the screw holes.

IMPLANT LOADING: DUAL-BARREL DTS GUIDE

The system includes fixed angle DTS guides with compatible U-jointed and straight instrumentation including drills, taps, screw drivers, and screw removal drivers. (All gold instruments are compatible with the DTS guides.)

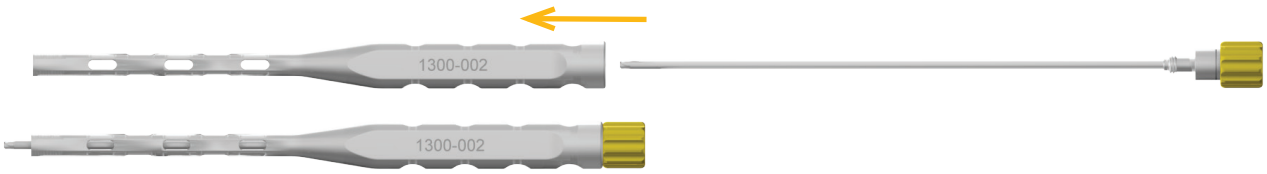
The DTS guides provide a fixed screw trajectory of 35 degrees in the sagittal plane and 15 degrees medial. The DTS guides are designed to attach to spacer prior to insertion into the disc space. When using the DTS guide, the anterior surface of the spacer must be in line with the cortical rim.



DTS GUIDE INSERTER/CAGE ASSEMBLY

1. Assemble the DTS inserter by inserting the inner shaft through the outer sleeve of the inserter. The inner sleeve must be threaded into the outer sleeve.

   A gold shaft indicates usage with the DTS guide. A silver shaft indicates usage with the freehand inserter.

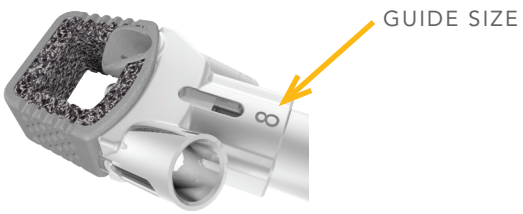


2. Place the DTS inserter over the appropriate DTS guide in the caddy and rotate the outer sleeve of the inserter clockwise to secure the DTS guide onto the inserter.

3. Line up the DTS guide in the appropriate orientation with the implant such that the barrels of the DTS guide are aligned with the screw holes in the implant.

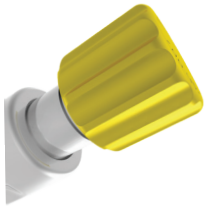
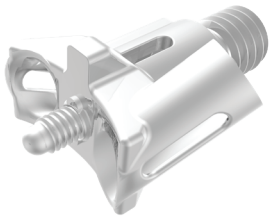
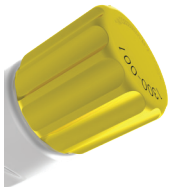
Note: The DTS guides change based on height only and do not change with footprint or lordosis variance.

IMPORTANT: EACH HEIGHT IMPLANT IS DESIGNED TO BE USED WITH THE SPECIFIC HEIGHT DTS GUIDE AS MARKED. IMPLANTS CANNOT BE IMPLANTED WITHOUT THE CORRESPONDING SIZE GUIDE. FAILURE TO DO SO WILL RESULT IN IMPLANT DAMAGE OR AN INABILITY TO CORRECTLY PLACE THE DEVICE.



IMPLANT LOADING: DUAL-BARREL DTS GUIDE (CONTINUED)

4 Once the DTS guide is in the proper orientation, advance the inner shaft of the inserter forward. Once engaged, rotate the proximal knob clockwise until the implant is secured onto the assembly.

	GUIDE	GUIDE WITH IMPLANT	PROXIMAL END OF SHAFT
INCORRECT			
CORRECT			

SPACER INSERTION

Once the implant has been loaded onto the inserter, fill and pack the implant with autograft.

Gently impact the inserter/implant assembly into the prepared disc space. Confirm implant size and placement utilizing radiographic imaging. A tamp is provided should repositioning of the implant in the disc space be desired.

The cage may feel different than the trials upon insertion into the disc space due to the increased surface roughness of the F3D-C2 implants.

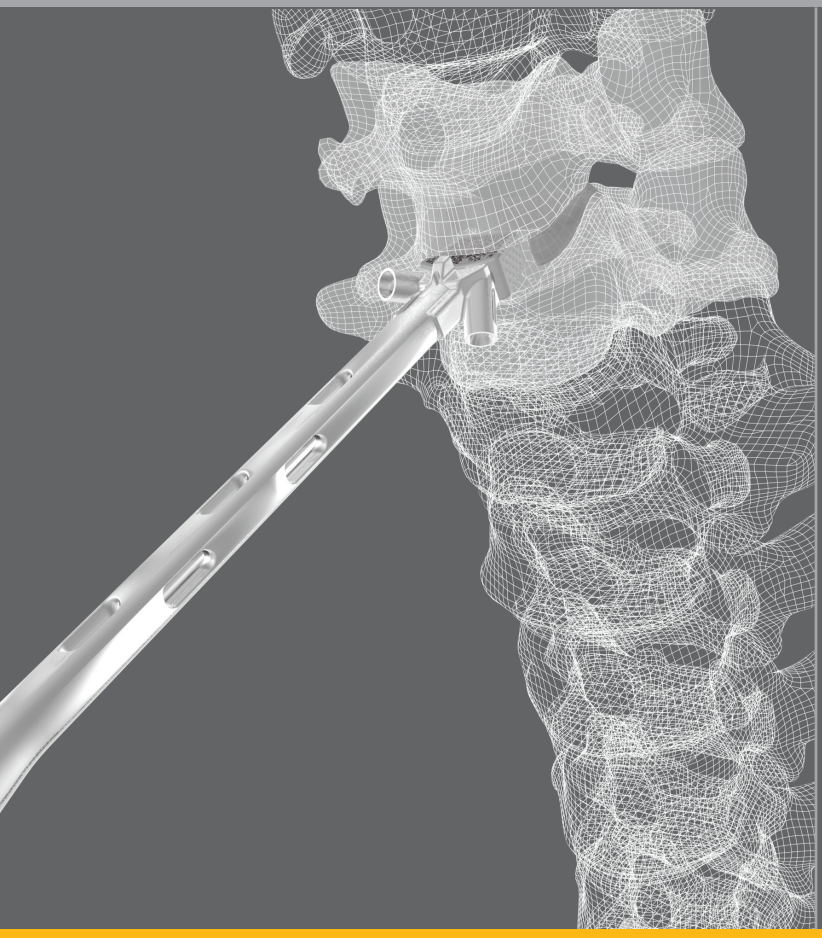
Caution must be used when inserting the spacer with the attached DTS guide. Once the spacer is fully in the disc space, do not attempt to reposition or remove the spacer with the DTS guide attached to the spacer.

Axial motions, such as prying, will result in accidental detachment of the DTS guide from the spacer, damage to the implant, and may cause injury.

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

Note: Implant should be flush with anterior vertebral bodies.

SPACER INSERTION WITH DTS GUIDE AND INSERTER ATTACHED



TAMP

SCREW HOLE PREPARATION

An awl or drill may be used to initiate the screw pathway. Taps are available upon request.

The F3D-C2 Stand-alone Cervical System has multiple awl and drill options for guided or freehand techniques. The awl options have a protective sleeve to help prevent accidental vessel damage.

Insert awl into the target screw hole and provide gentle impaction on the handle. Before making the next new pilot hole, insert the screw to prevent accidental spacer migration. When using the freehand awl, it is recommended to awl with the inserter still attached and the stops of the inserter contacting the anterior margin of the vertebral bodies. This will prevent cage migration during awling.

Awls are intended to puncture the cortical bone.

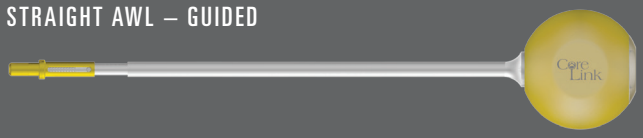
Note: Awls at full extension will protrude a total of 10mm.

WARNING: Do not attempt to maneuver the cage with the awl in place or repeatedly impact the freehand awl into the cage. This may result in bending or breaking of the awl tip in the vertebral body or damage to the cage.

AWLS

STRAIGHT AWL – FREEHAND

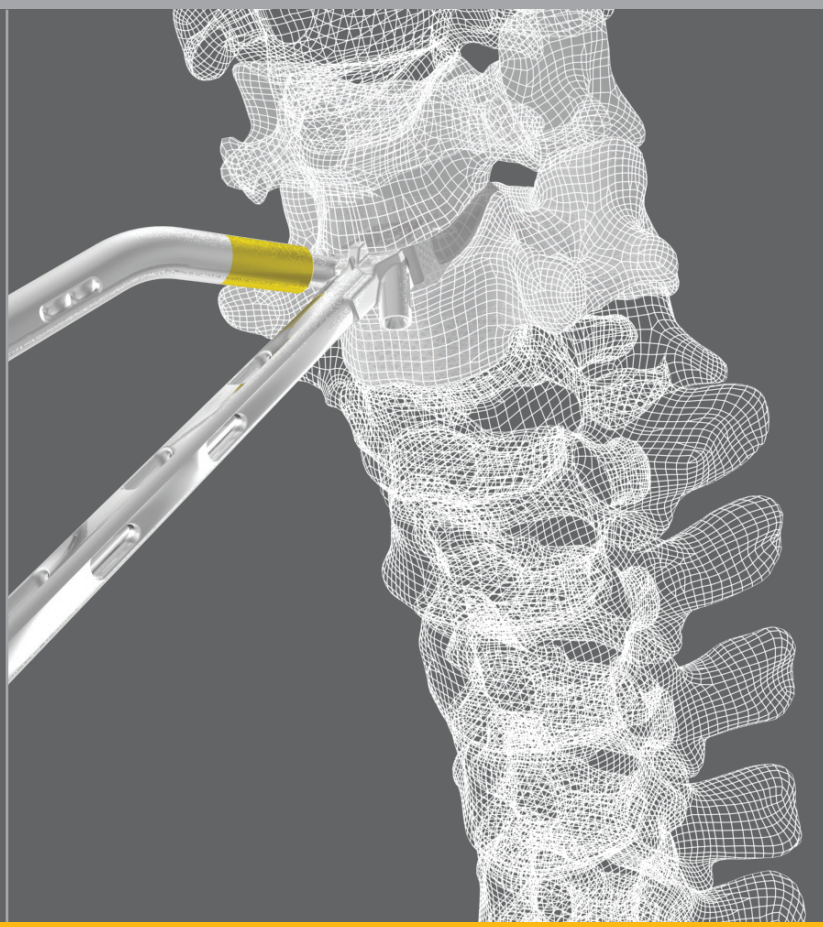
STRAIGHT AWL – GUIDED



ANGLED AWL – FREEHAND

ANGLED AWL – GUIDED

ANGLED AWL THROUGH DUAL-BARREL GUIDE

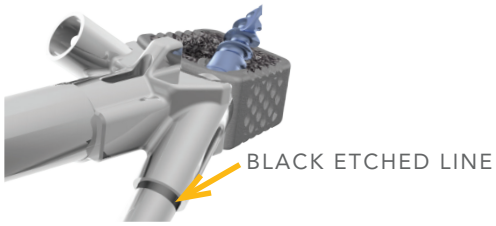


SCREW INSERTION

Both straight and angled drivers are available for both guided and freehand techniques. Insert the desired length and diameter of screw through either the DTS guide assembly or through the prepared screw hole if using the freehanded technique.

ARTICULATING DRIVERS

STRAIGHT DRIVER

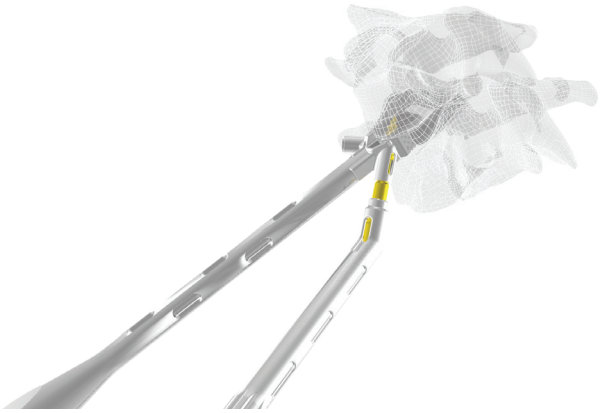


The line on the straight driver will align with DTS guide barrel when the screw is past the locking tab.

To ensure the screw is in the locked position, take note of the tab on the implant and ensure the screw head has advanced past the anti-back-out tab.

All drill and driver options specific to the DTS guides are gold coated. Do not use the freehand bits with the DTS guides or vice versa to avoid complications.

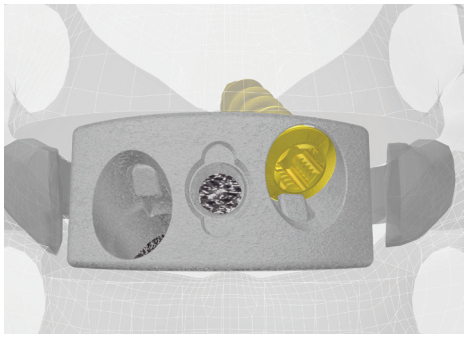
DRIVER AND DTS GUIDE

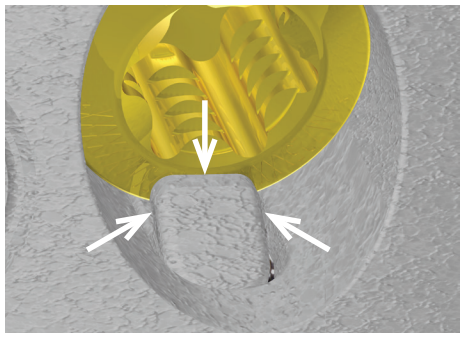


FREEHAND

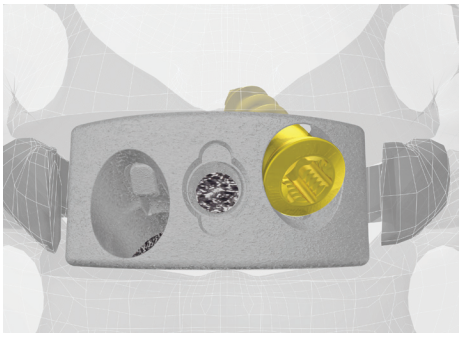
DUAL-BARREL DTS GUIDE

FULLY SEATED WITH TAB CLOSE UP





NOT FULLY SEATED



Note: The sides and top of the tab should be visible when the screw is fully seated.

Note: Both the DTS and freehand inserter can be removed from the field of view at any point. To do this, rotate the proximal knob of the inserter counterclockwise to disconnect the inserter from the implant.

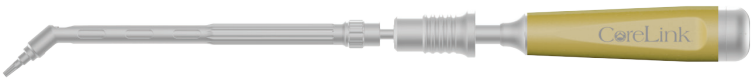
UNIVERSAL INSTRUMENT ASSEMBLY

A modular universal angled instrument is available that contains an interchangeable drill, driver, tap and revision bits for use with either the DTS guide or freehand technique. This instrument assembly offers more stability than a standard articulating instrument.

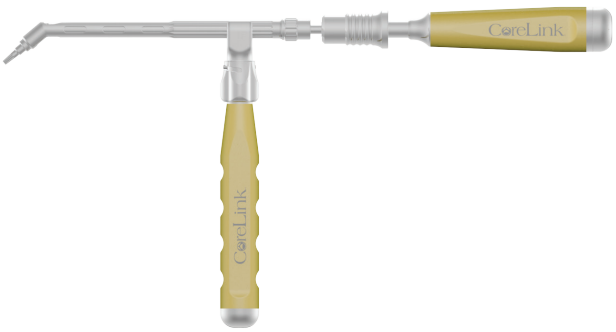
1. Load the appropriate universal angled instrument bit into the distal end of the shaft by placing it through the back end.

2. Slide the inner shaft through the outer shaft and rotate the proximal knob clockwise to secure the inner shaft.

3. Connect the proximal shaft to the handle.



Note: If additional stability is desired, a side handle attachment is available that can be used to slide and lock onto the shaft of the universal angled instrument. Side handle attachment is also compatible with the system's awls.

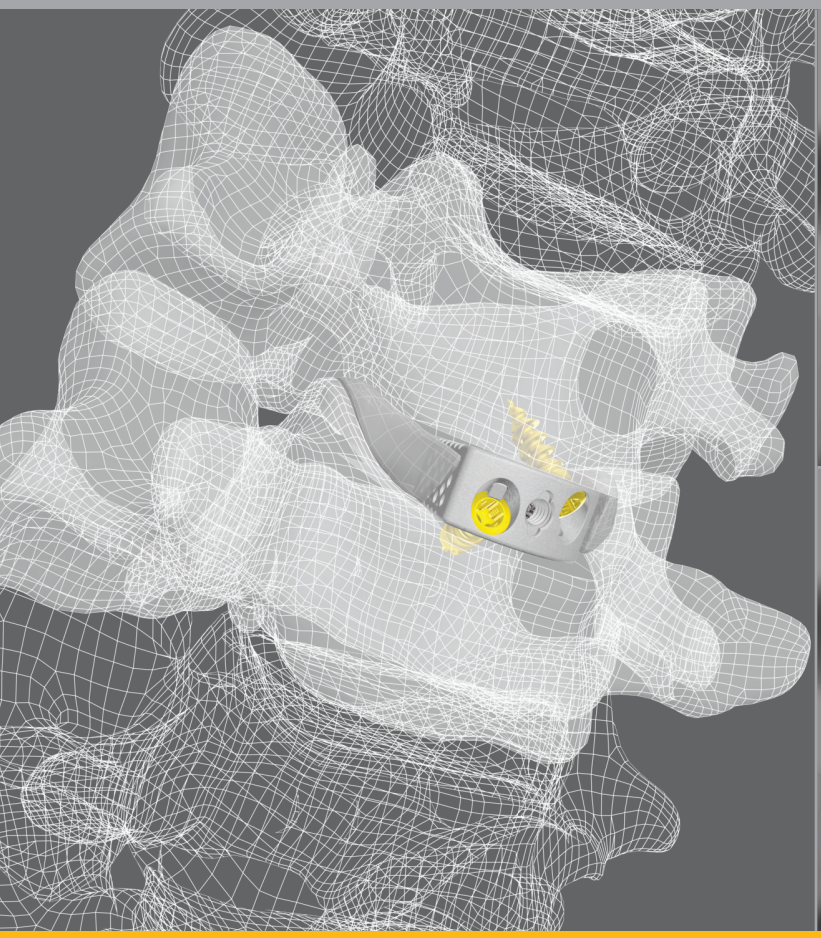


FINAL CONSTRUCT WITH SCREWS

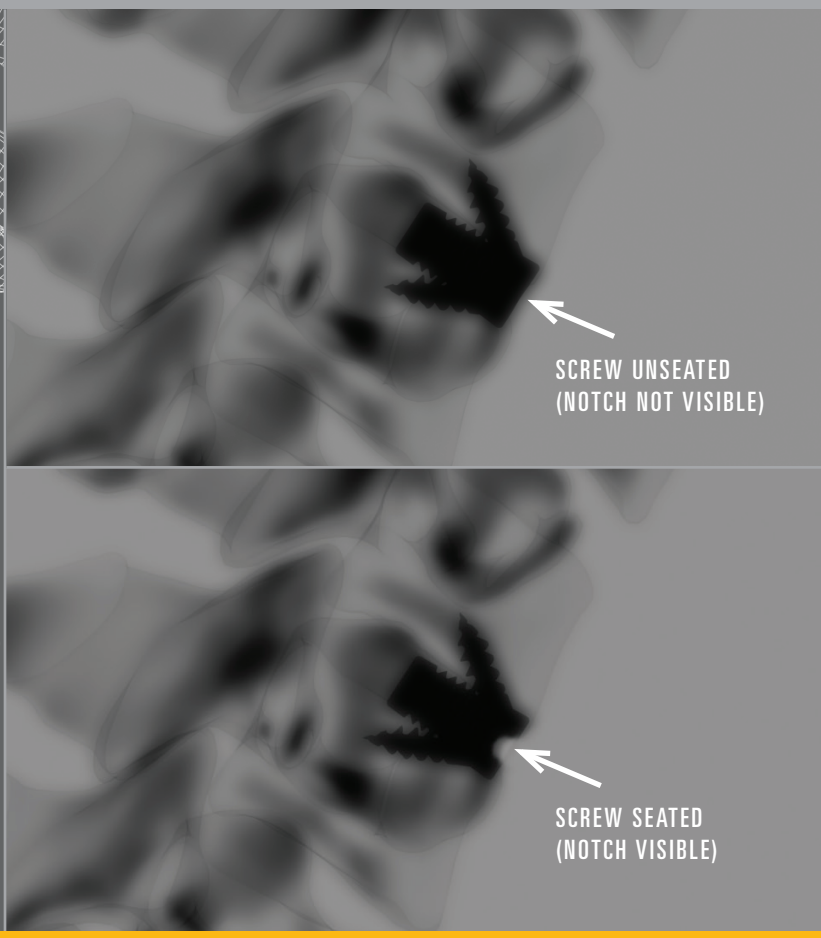
The final construct is shown below with the screws fully seated and advanced past the anti-back-out tab.

Lateral fluoroscopy can be used to confirm if screws are fully seated past the anti-back-out tab. When the screws are fully seated, a C-shaped notch is visible on the ventral surface of the implant. Direct visualization of the locking tab is the best way to confirm that the screws are past the anti-back-out tab. Refer to page 12 for a close view of tab engagement.

FINAL CONSTRUCT WITH SCREWS



LATERAL SCREW PLACEMENT CONFIRMATION



SCREW REMOVAL

Should removal of the implant be necessary, there are three removal tool options available.

The first is a reverse threaded screw removal driver. To use, insert the reverse threaded screw removal driver into the screw head's internal threaded feature and rotate counterclockwise. Continue counterclockwise rotation until the screw is removed from the implant. Once the screws are removed from the implant, the implant inserter can be reattached to the cage to aid in removal.

Alternatively, there is an additional removal option that is available with an auger-style tip design. This is available as a straight auger instrument, a freehanded auger bit, and a DTS guide auger bit. The bits are to be used with the universal angled instrument.

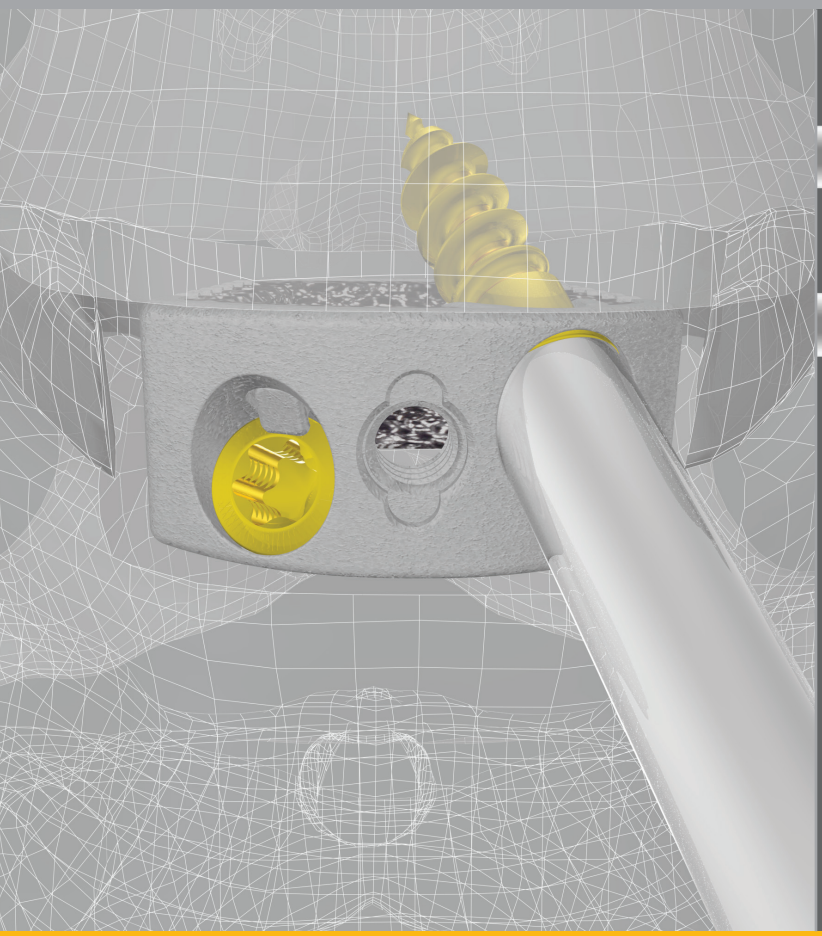
The straight auger instrument can be used either on the screw or through the threaded hole on the anterior surface of the cage. The auger-style bits are intended for only screw removal.

Caution: Use of the auger removal tool will result in permanent damage to the screws and cage.

Removed implants must not be reused or re-implanted.

Note: If the spacer needs to be removed from the disc space, the freehand inserter should be used to reattach to the spacer. Removal of the spacer with the DTS guide inserter attached will result in implant damage and patient injury.

REMOVAL TOOL ON SCREW



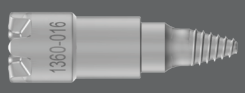
REMOVAL TOOLS

REVERSE THREAD SCREW REMOVAL TOOL

AUGER-STYLE REMOVAL TOOL

FOR USE WITH THE UNIVERSAL INSTRUMENT:

FREEHAND AUGER-STYLE BIT



DTS GUIDE AUGER-STYLE BIT

FUSATION™ ANCHOR FIXATION TECHNIQUE
OVERVIEW

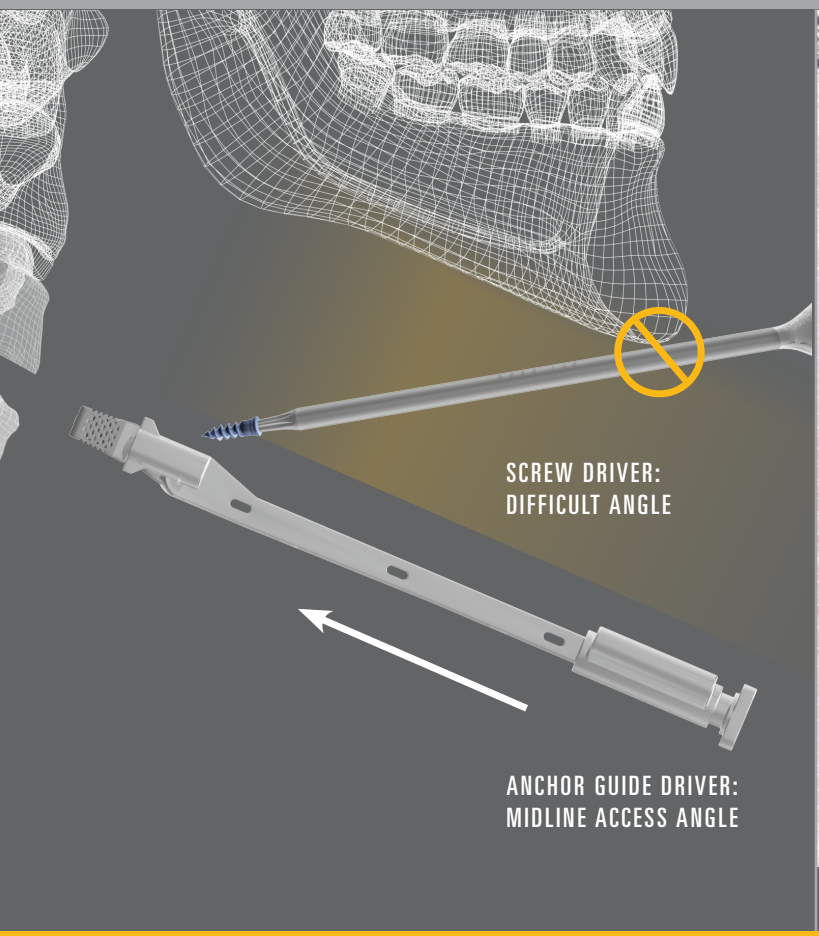
The F3D-C2 Stand-alone Cervical System includes anchors in addition to screws that can be used independently, or interchangeably, depending on surgeon preference.

Anchors minimize the surgical corridor, in turn reducing soft tissue retraction and disruption. Additionally, the anchor's low profile inserter allows for inline anchor implantation. This minimally invasive approach provides easier access to the disc space with interfering patient anatomy, such as at C2-C3 and C6-C7 where the patient's chin or sternum may cause access challenges.

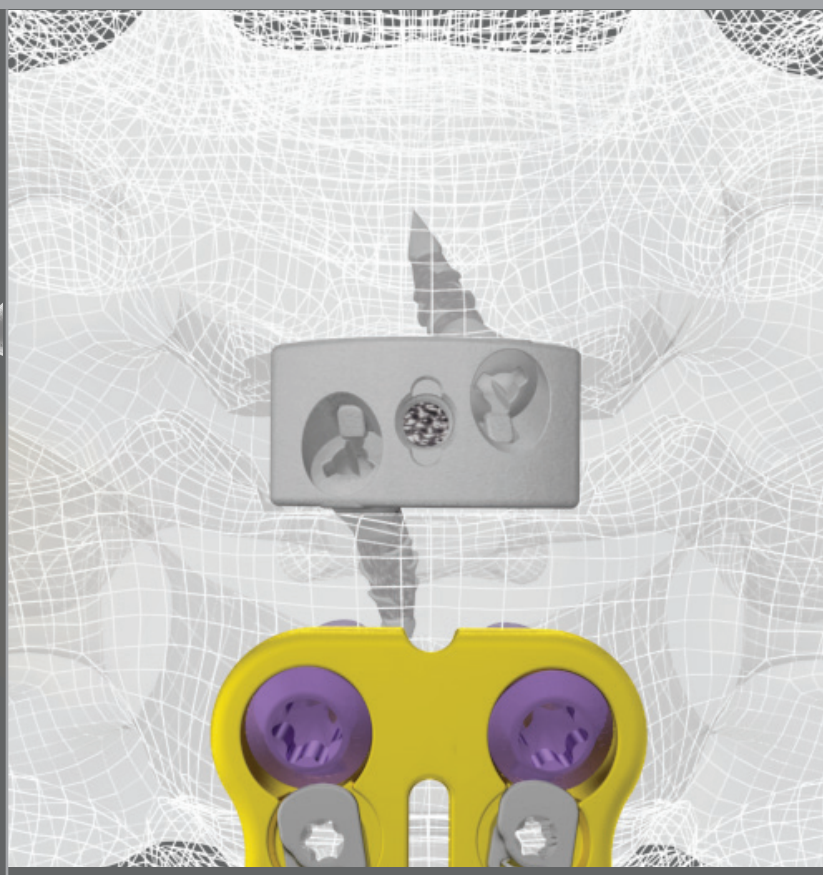
Anchors allow for a more medial trajectory than screws, simplifying fixation around existing hardware.

The F3D-C2 Stand-alone Cervical System includes a comprehensive array of instruments for anchor insertion. The guided technique is recommended for the anchor fixation method, however—surgical constraints may not allow for guide use. In those cases, the non-guided "basic" anchor fixation technique may be necessary. (See page 16)

MINIMIZED WORKING CORRIDOR



MEDIAL TRAJECTORY TO EASE FIXATION



*Supplemental fixation is required when anchor is in use

FREEHAND ANCHOR FIXATION

The Freehand Method for anchor insertion uses the Freehand cage inserter.

AWLING TECHNIQUE

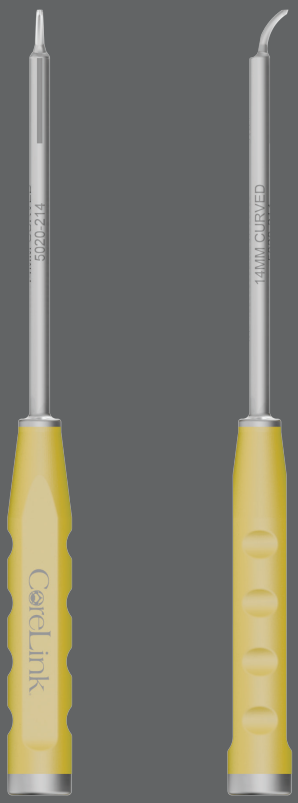
It is recommended to awl and fixate the anchors with the inserter still attached and the stops of the inserter contacting the anterior margin of the vertebral bodies. This will prevent cage migration.

The F3D-C2 Stand-alone Cervical System includes several awl options designed to pilot the hole ahead of anchor insertion:

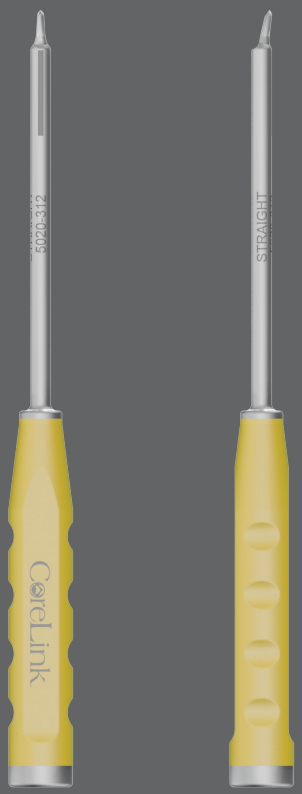
- 7mm straight awl
- 12mm curved awl
- 14mm curved awl
- 16mm curved awl

The curved awls are available in four lengths that match the exact length of the various anchor lengths. The curved awls and anchors are measured by their arc length.

CURVED AWL



STRAIGHT AWL



The 7mm straight awl is designed to only be used to puncture cortical bone. It is not intended to match the final curved anchor path.

The awls are slightly undersized compared to the anchor to create a pilot hole. The curved awls should be used to create a hole using a 20° medial trajectory. Each awl has a straight black line etched on its shaft to indicate position of the awl tip. Make sure to use the etched line for visual confirmation of final awl tip position.

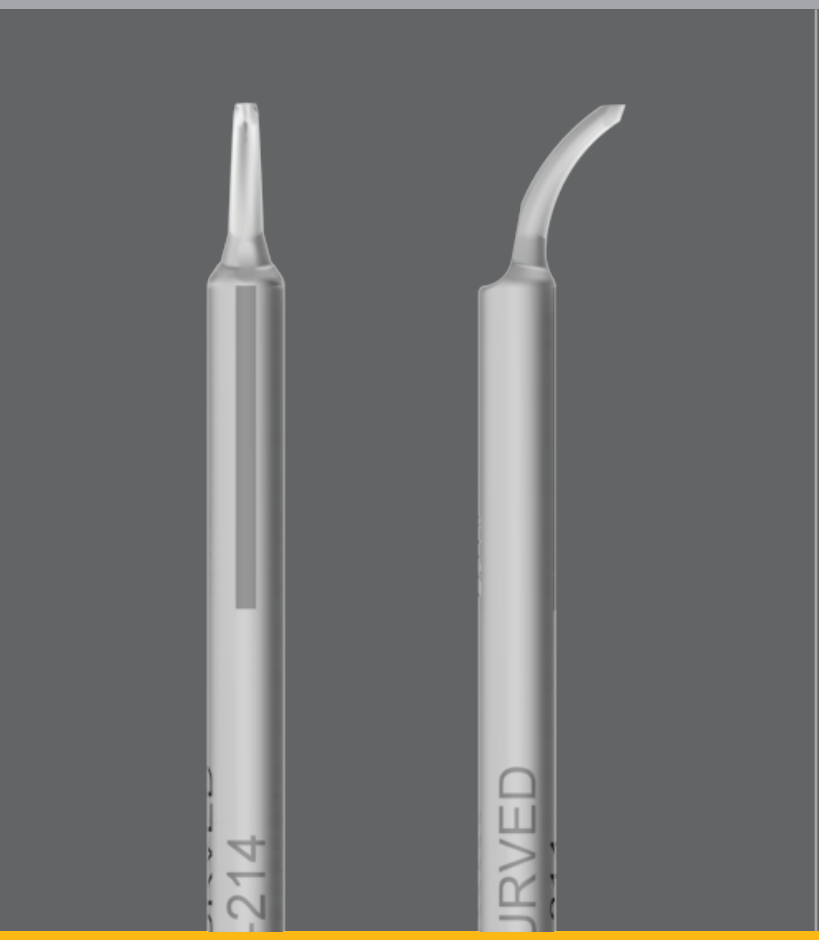
It is recommended that the awls are used under fluoroscopy to ensure proper placement. Care must be taken to center the awl within the cage to protect the locking mechanism and match the intended anchor trajectory.

Once the cage is implanted, select the correct curved awl length by using the cage and anchor size pairing recommendation (refer to page 3). For example, if using a 14.5mm x 12mm cage, the recommended awl and anchor length is 12mm or 14mm. If only a pilot hole is needed, then select the 7mm straight awl.

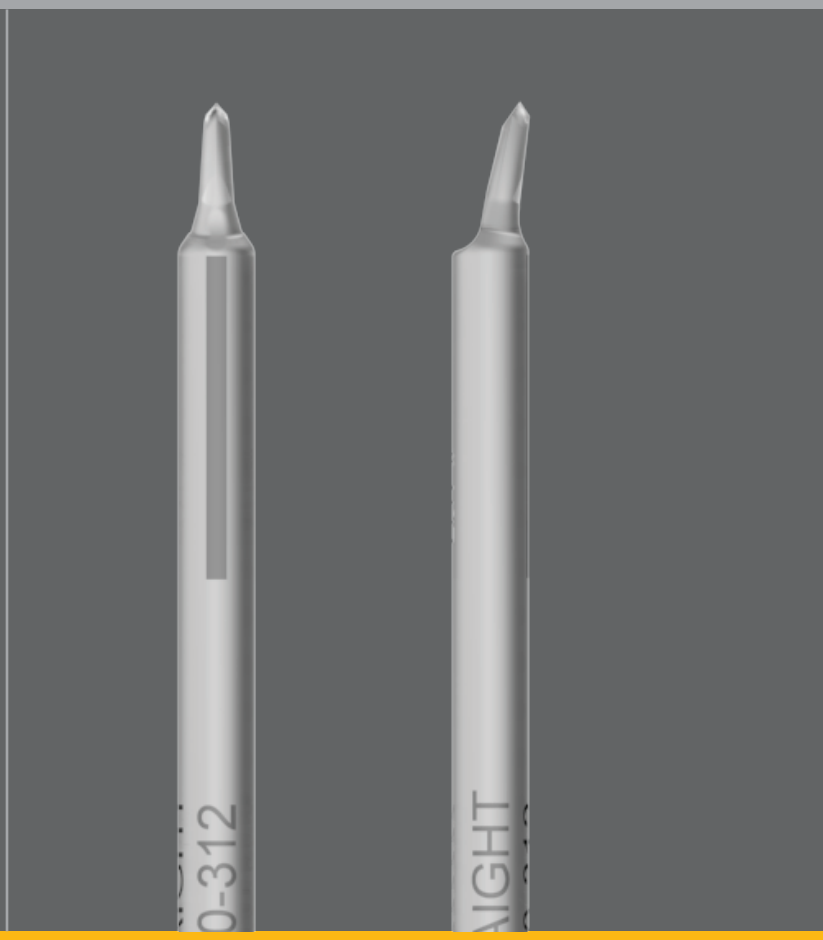
Insert awl into the target anchor hole and provide gentle impaction with the mallet on the strike cap on the awl handle. The awl can be impacted straight into the surgical site and will guide itself caudal or rostral—the handle will need to move in a subtle swooping motion.
Before making the next new pilot hole, insert the anchor to prevent accidental cage migration.

WARNING: Do not attempt to maneuver the cage with the awl in place or repeatedly impact the awl into the cage. This may result in bending or breaking of the awl tip in the vertebral body or damage to the cage. If awl gets stuck in bone, use slot on mallet to act as a slide hammer.

CURVED AWL TIP



STRAIGHT AWL TIP



FREEHAND ANCHOR INSERTER ASSEMBLY

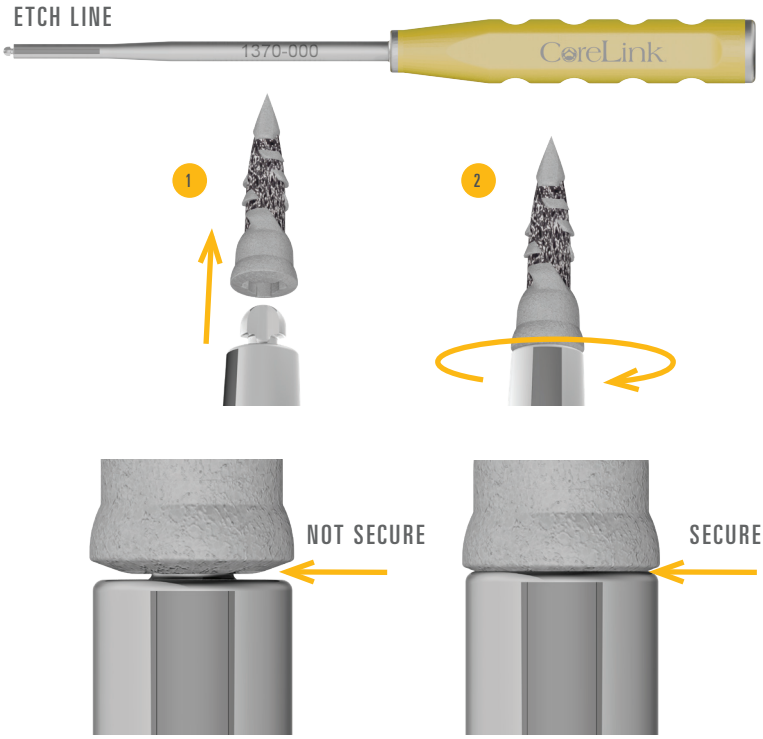
1. To attach the anchor inserter to the anchor, first hold anchor with tip pointed upwards. Position the inserter's black line slightly to the left of the anchor tip.

2. Push inserter tip into the tri-lobe feature in anchor head. Gently rotate inserter clockwise until etched line on inserter lines up with the tip of the anchor. **There should be no space between the anchor head and the shoulder of the anchor driver.** Connection between the anchor and anchor driver should be secure prior to anchor fixation.

3. Insert anchor into the target hole with proper orientation and provide gentle impaction with the mallet on the strike cap on the anchor driver. **Make sure to use the etched line as guidance for the preferred final anchor position.** It is recommended that the anchor positions are confirmed with fluoroscopy to ensure proper placement. Turn inserter gently counter-clockwise to disconnect from implanted anchor head. Repeat steps for anchor or screw fixation for the second cage hole.

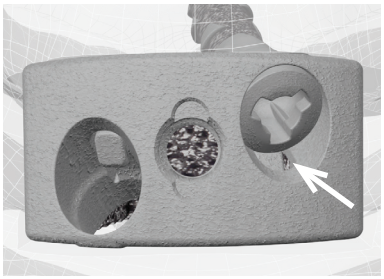
4. To ensure the anchors are in the locked position, visually take note of the tab on the implant and ensure the anchor head has advanced past the anti-back-out tab. Lateral fluoroscopy can be used to confirm if the anchors are fully seated past the anti-back-out tab. When the anchors are fully seated, a C-shaped notch is visible on the anterior surface of the implant. Direct visualization of the locking tab is the best way to confirm the anchors are secure. If additional impaction on the anchor is needed, seat the inserter tip into the anchor head but **DO NOT try to reattach it**. In situ reattachment may cause damage to the inserter tip.

FREEHAND ANCHOR INSERTER

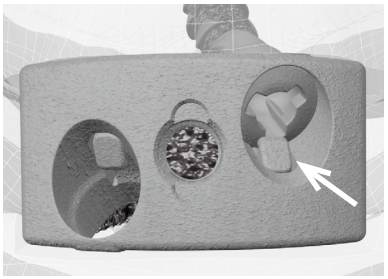


LOCK CONFIRMATION

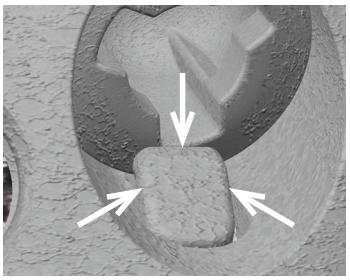
ANCHOR UNSEATED



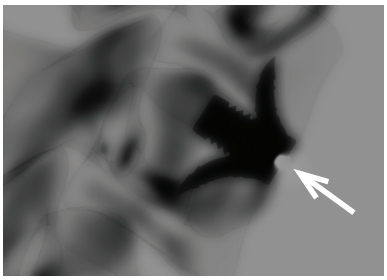
ANCHOR SEATED



ANCHOR SEATED (TAB VISIBLE)



ANCHOR SEATED (NOTCH VISIBLE)



GUIDED ANCHOR FIXATION

Two variations of anchor insertion guides are standard in the system including:

Single-Sided Anchor Guides

- Use to implant a single anchor at a time
- Use if working corridor is limited
- Use if hybrid approach with anchor and screw is preferred

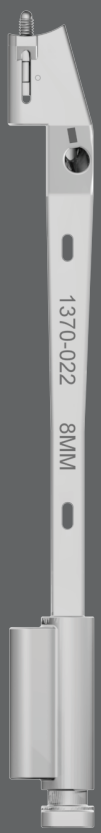
Double-Sided Anchor Guides

- Use to implant two anchors—one anchor at a time
- Saves intraoperative time

Both guide variations are cage-height specific (6mm-12mm in height). In addition, both guide systems use cage inserters and have a stop that is flush with the edge of the guide and cage interface. Both variations attach to the interbody in the same fashion and use the same guide impactor to position the anchors.

SINGLE-SIDED ANCHOR GUIDES

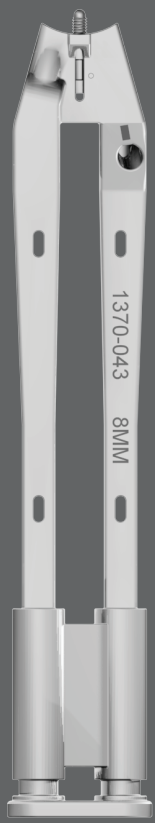
TOP



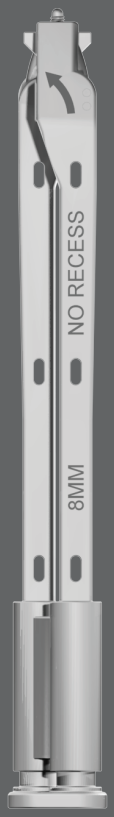
SIDE

DOUBLE-SIDED ANCHOR GUIDES

TOP



SIDE



IMPLANT LOADING: ANCHOR GUIDES

Once the implant has been chosen after trialing, attach the implant to the matching height specific anchor guide.

1. Align implant with distal end of guide.
2. Use standard screwdriver and cervical handle (from the F3D-C2 screw instrument set) to turn set screw on center of guide to attach implant to the anchor guide. Confirm secure attachment. Medial barrel should be used to guide driver into guides' set screw during attachment and detachment of cage.
3. Once the proper implant has been loaded onto the anchor guide/inserter assembly, pack the implant with preferred allograft or autograft material.
4. Select proper length anchor based on patient anatomy, cage size, and length pairing recommendation (see page 3). Additional measurements and screw to anchor comparisons can be found on page 33.
5. Position anchor into port by hand. Seating the anchor into the port is a two step process. First, push the anchor into the port as far as it will go using the anchor insertion tool. Then, release the tool, and push the anchor into the port the rest of the way. The etched line on the anchor insertion tool must always be in line with the etched line on the guide.
6. Ensure that the anchors are fully seated in the port. When seated, there should be a slight tactile feel, and the insertion tool will be flush to the guide, as shown in the image on the right.
7. Once the anchor(s) are secure within the guides, gently impact the inserter/implant assembly into the prepared disc space. Confirm implant size and position utilizing fluoroscopy.

   Note: The internal features within the anchor ports hold the anchors in place.

Note: The Anchor Guides change based on height only and do not change with footprint or lordosis differences

DRIVER ALIGNMENT WITH MEDIAL BARREL

ANCHOR PORTS

ANCHOR INSERTION TOOL

ANCHOR INSERTION INTO PORT

ANCHOR SEATED IN PORT

ANCHOR HOLE PREPARATION AND INSERTION

Once the cage is in position, the pre-loaded anchor(s) is ready for deployment.

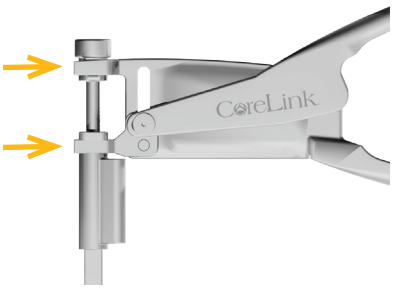
1. Insert the impactor into the proximal end of the guide. Rotate impactor shaft until its flat is aligned with the flat on the guide, and it slides easily into the guide. The word "medial" is also on the impactor shaft to assist in correct alignment.
2. Mallet slightly on the impactor to get the anchor path started. Attach the impact assist to the guide handle and impactor shaft by sliding the prongs around the top grooves on impactor and guide handle, as shown in the image.

   Note: The impact assist must be attached with the "This Side Up" etching visible.
3. Gently mallet on impactor's strike cap to advance the anchor. During impaction, squeeze the impact assist's handles to assist with advancement of anchor.
4. Once impactor's strike cap is flush with guide handle, the anchor is fully deployed. Verify anchor deployment with fluoroscopy prior to detaching guide.
5. If using the single anchor guide, remove guide from implanted cage.
   - Load desired anchor into the anchor port on the same guide as described and shown previously. Rotate anchor guide 180° for correct guide and interbody alignment for implantation of anchor into the second hole.
6. If using the double-sided anchor guide, the second anchor was previously loaded so the guide should stay attached to the implant.
   - Insert the impactor into the second hole on the guide handle to drive the second anchor into position. Use same technique as before with the impact assist instrument.
7. Visually confirm that the anchors' heads are past the locking mechanism on the cage. See page 18 for verification instructions.

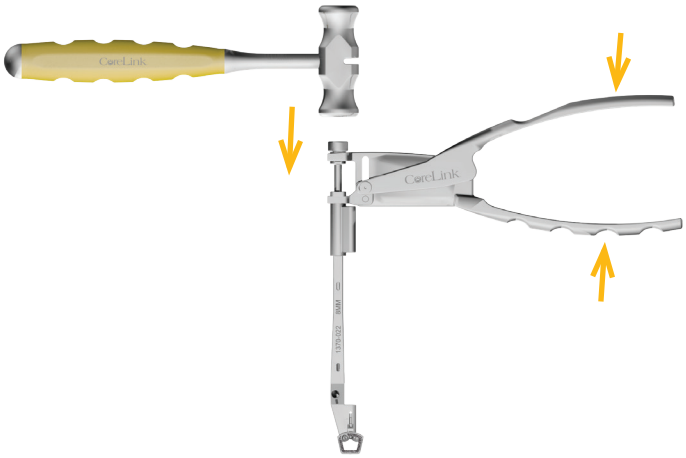
IMPACTOR

IMPACTOR INSERTION INTO GUIDE

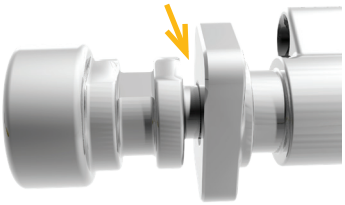
IMPACT ASSIST INSTRUMENT ATTACHMENT



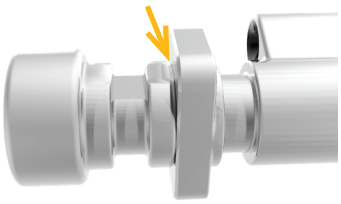
IMPACTION AND MALLETING



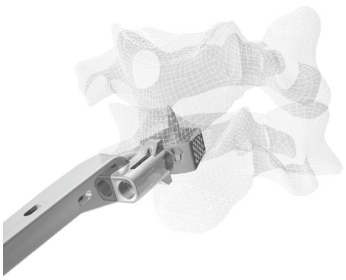
ANCHOR NOT DEPLOYED



ANCHOR DEPLOYED



SECOND ANCHOR PLACEMENT



FINAL CONSTRUCT WITH ANCHORS

The final construct is shown below with the anchors and/or screws fully seated and advanced past the anti-back-out tab.

When used with one or more Fusation anchors, the F3D-C2 Cervical Stand-alone System is intended for use at one level and requires additional supplemental fixation such as posterior cervical screw fixation.

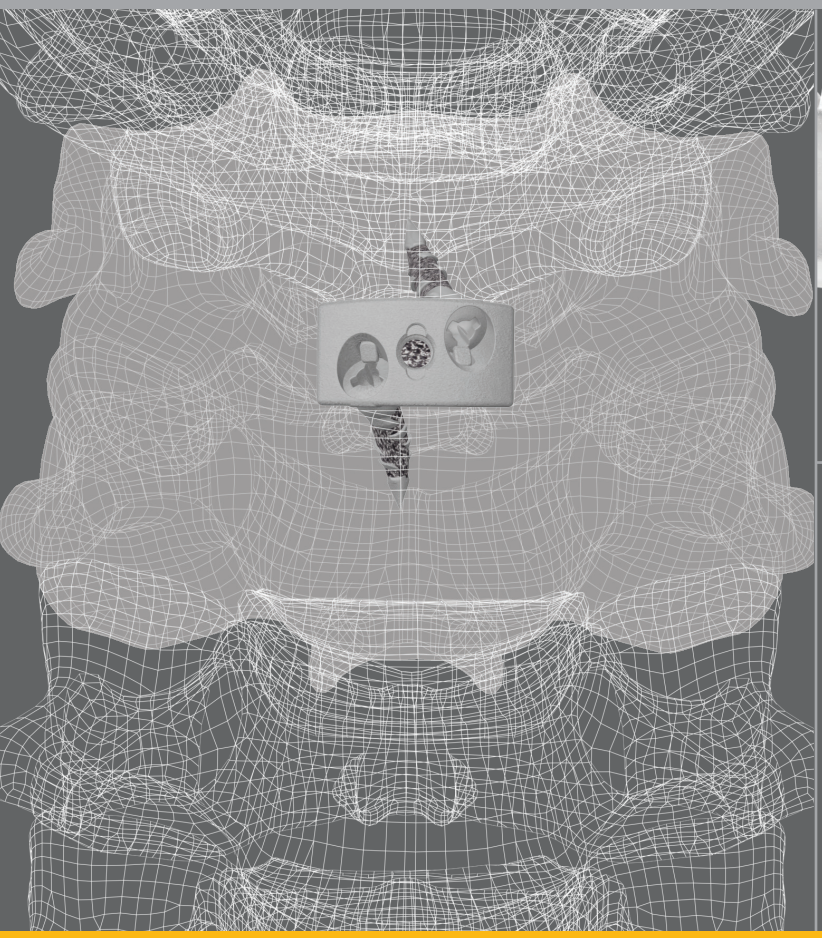
ANCHOR REMOVAL

The anchor removal instrument has a tri-lobed tip that mates with the anchor head's internal tri-lobe. Position removal tool's groove handle toward midline to attach, then position instrument in anchor head. Turn instrument tip clockwise approximately 60° until the tip connects to the anchor. **WARNING: Overturning will result in breakage of the removal instrument.**

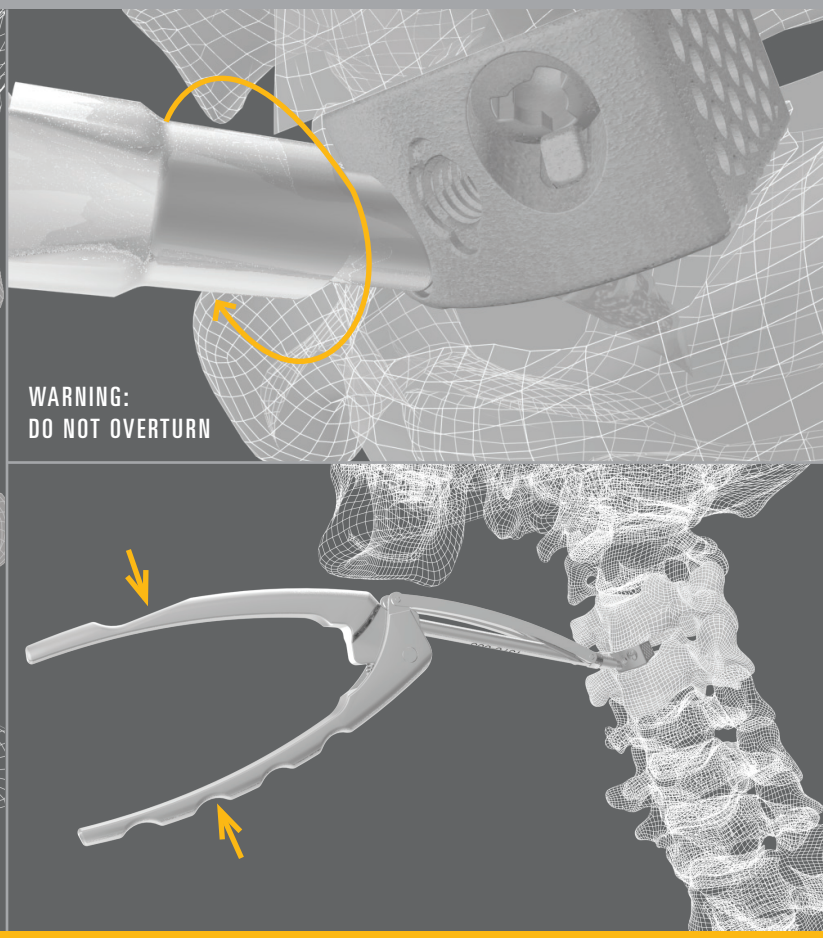
When the instrument is connected successfully to the implanted anchor, a subtle stop should be felt during the clockwise turn. To verify, slightly pull back to feel for resistance. If felt, a connection is achieved and the anchor can be extracted. Once connected, squeeze handle to extract implanted anchor.

Repeat for second implanted anchor, if applicable.

FINAL CONSTRUCT WITH ANCHORS



ANCHOR REMOVAL



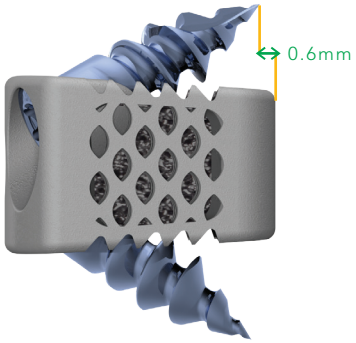
CAGE DEPTH TO SCREW/ANCHOR LENGTH COMPARISON

The measurements in the tables below show the distance of the screw and anchor tips in reference to the posterior edge of the cage at the fixed angle. Examples shown below.

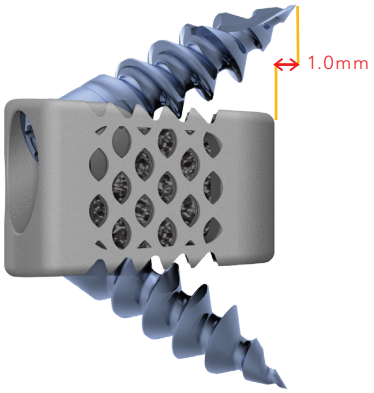
DISTANCE FROM SCREW TIP TO POSTERIOR EDGE OF CAGE				
CAGE DEPTH	SCREW LENGTH 12mm	SCREW LENGTH 14mm	SCREW LENGTH 16mm	SCREW LENGTH 18mm
12mm	0.6mm	1.0mm	2.6mm	4.2mm
14mm	2.6mm	1.0mm	0.6mm	2.2mm
16mm	4.6mm	3.0mm	1.4mm	0.2mm

Note: Red measurements indicate screw overhang at nominal angle.

12mm CAGE DEPTH & 12mm SCREW LENGTH



12mm CAGE DEPTH & 14mm SCREW LENGTH



DISTANCE FROM ANCHOR TIP TO POSTERIOR EDGE OF CAGE				
CAGE DEPTH	ANCHOR LENGTH 12mm	ANCHOR LENGTH 14mm	ANCHOR LENGTH 16mm	ANCHOR LENGTH 18mm
12mm	2.2mm	1.8mm	1.6mm	1.8mm
14mm	4.2mm	3.8mm	3.6mm	3.8mm
16mm	6.2mm	5.8mm	5.6mm	5.8mm

Note: No anchors bypass the posterior edge of the cage. Adjacent level vertebral body height must be taken into consideration when selecting anchor length.

DISTANCE FROM CAGE ENDPLATE TO IMPLANTED ANCHOR TIP			
ANCHOR LENGTH 12mm	ANCHOR LENGTH 14mm	ANCHOR LENGTH 16mm	ANCHOR LENGTH 18mm
7.4mm	9.4mm	11.4mm	13.4mm

12mm CAGE DEPTH & 16mm ANCHOR LENGTH

INSTRUCTIONS FOR USE

CORELINK F3D-C2 STAND-ALONE CERVICAL SYSTEM

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

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

DESCRIPTION

The F3D-C2 Cervical Stand-alone System is an internal spinal fixation system consisting of additively manufactured titanium alloy interbody devices, additively manufactured titanium alloy anchors, and machined titanium bone screws. It is designed to provide mechanical support to the cervical spine while arthrodesis occurs. The F3D-C2 Cervical Stand-Alone System is available in a variety of lordosis and footprint options with a porous architecture to offer increased room for bone growth and mechanical properties to suit the individual pathology and anatomical conditions of the patient.

Implants in the F3D-C2 Stand-alone Cervical System are manufactured from the following materials:

- Medical grade titanium alloy (Ti6AL4V ELI as per ASTM F-136 and ISO 5832-3, ASTM F-3001)

Do not use any of the F3D-C2 Cervical Stand-alone 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-C2 Cervical Stand-alone System implants or implant components should be reused under any circumstances. The instruments provided with the F3D-C2 Cervical Stand-alone System are provided specifically for the implantation of the F3D-C2 Cervical Stand-alone System implants.

Please refer to the applicable F3D-C2 Cervical Stand-alone System Surgical Technique for additional important information about specific CoreLink implants, in addition to the information described herein.

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

INDICATIONS

The F3D-C2 Cervical Stand-alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels depending on the assembly. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D-C2 Cervical Stand-alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) depending on the assembly. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment.

The F3D-C2 Cervical Stand-alone System is an interbody fusion device intended to be used with two titanium alloy screws and/or Fusation™ anchors which accompany the implants. When used with screws, the F3D-C2 Cervical Stand-alone System is intended for use at one or two levels of the cervical spine (C2-T1) and requires no additional fixation. When used with one or more Fusation™ anchors, the F3D-C2 Cervical Stand-alone System is intended for use at one level of the cervical spine (C2-T1) and requires additional supplemental fixation such as posterior cervical screw fixation.

CONTRAINDICATIONS

Contraindications of the F3D-C2 Stand-alone Cervical System 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 decide 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 the F3D-C2 Cervical Stand-alone System has 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,

INSTRUCTIONS FOR USE (CONTINUED)

fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.

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

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

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

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

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

Altering an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the F3D-C2 Cervical Stand-alone 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-C2 Cervical Stand-alone System is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from CoreLink by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the F3D-C2 Cervical Stand-alone 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-C2 Cervical Stand-alone System have not been evaluated for safety and compatibility in the MR environment. The F3D-C2 Cervical Stand-alone System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the F3D-C2 Cervical Stand-alone 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-C2 Cervical Stand-alone System are provided sterile. Additionally, the titanium bone screws may be alternatively provided non-sterile and require reprocessing the supplied surgical instrumentation. The surgical instruments provided with the F3D-C2 Cervical Stand-alone 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. All instruments that are fully or partially dismantlable must be disassembled prior to cleaning.

This includes the following:

- Removal of all detachable handles from each instrument
- Removing the DTS Guide Inserter from the DTS Guides and removal of the inner shaft from the outer shaft
- Removing the inner shaft from the Inserter
- Removal of the inner shaft and driver bits from the Fixed Angle instruments
- Removal of the Anchor Guides and inner impactor from the Anchor Guide Inserter

Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients.

Instruments must be placed into their respective locations in the sterilization tray to ensure proper steam sterilization. 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. This includes inspecting the tips of awls, drivers, drills, and taps for wear, threaded regions of inserters Anchor Guides and DTS Guides, and the inner shafts of any dismantlable instruments. If an instrument is suspected to be damaged it must not be used and CoreLink must be contacted 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 and reassemble all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions

- **Sterile Implants:** Implants of the F3D-C2 Stand-alone Cervical System are provided "STERILE" via gamma irradiation and intended for single patient use only. DO NOT RESTERILIZE THIS PRODUCT. Sterility can only be assured if packaging is intact.
- **Non-sterile Implants and Instruments:** Instruments of the F3D-C2 Stand-alone Cervical System are provided non-sterile. Titanium bone screw implants may be provided in a non-sterile configuration. 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
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 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-C2 Stand-alone Cervical 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
Temperature: 132°C (270°F)
Full Cycle Time: 4 Minutes
Minimum Dry Time: 30 Minutes (allow for cool-down)

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

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERSEDE 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-C2 Stand-alone Cervical 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-C2 Stand-alone Cervical System implants are available in titanium alloy. It is imperative that the F3D-C2 Stand-alone Cervical 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.

INSTRUCTIONS FOR USE (CONTINUED)

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
(888) 349-7808

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Use-by-Date – Indicates the date after which the medical device is not to be used.	5.1.4
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Sterilized via Irradiation – Indicates a medical device has been sterilized using irradiation	5.2.4
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4

F3D-C2 INSTRUMENT PRODUCT LISTING – STANDARD

SCREW INSTRUMENT KIT ORDER #K5000408

INSERTER / DUAL-BARREL DTS GUIDES

QTY	CATALOG NUMBER	DESCRIPTION
1	1300-003	FREEHAND INSERTER – INNER SHAFT
1	1300-004	FREEHAND INSERTER – OUTER SHAFT
1	1300-001	DUAL-BARREL DTS GUIDE INSERTER – INNER SHAFT
1	1300-002	DUAL-BARREL DTS GUIDE INSERTER – OUTER SHAFT
1	1300-006	DUAL-BARREL DTS GUIDE – 6mm
1	1300-007	DUAL-BARREL DTS GUIDE – 7mm
1	1300-008	DUAL-BARREL DTS GUIDE – 8mm
1	1300-009	DUAL-BARREL DTS GUIDE – 9mm
1	1300-010	DUAL-BARREL DTS GUIDE – 10mm
1	1300-011	DUAL-BARREL DTS GUIDE – 11mm
1	1300-012	DUAL-BARREL DTS GUIDE – 12mm

UNIVERSAL ANGLED INSTRUMENT

QTY	CATALOG NUMBER	DESCRIPTION
2	1360-000	INNER SLEEVE
2	1360-001	OUTER SLEEVE
2	1360-002	#10 HEXALOBE DRIVER BIT – FREEHAND
2	1360-006	FREEHAND DRILL BIT – 12mm
2	1360-010	DUAL-BARREL DTS GUIDE DRILL BIT – 12mm
2	1360-003	#10 HEXALOBE DRIVER BIT – DUAL-BARREL GUIDE
1	8600-100	ANGLED INSTRUMENT SIDE HANDLE ATTACHMENT

AWLS

QTY	CATALOG NUMBER	DESCRIPTION
1	1330-001	STRAIGHT – FREEHAND W/ SLEEVE
1	1330-003	FIXED ANGLE – FREEHAND W/ SLEEVE
1	1330-002	STRAIGHT – DUAL-BARREL DTS GUIDE W/ SLEEVE
1	1330-004	FIXED ANGLE – DUAL-BARREL DTS GUIDE W/ SLEEVE

STRAIGHT INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	1310-012	DRILL – 12mm WITH STOP
1	2020-118	SCREW DRIVER – #10 HEXALOBE - SLIM

ARTICULATING INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	1380-001	FREEHAND ARTICULATING DRIVER
1	1380-002	DTS ARTICULATING DRIVER

REMOVAL INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	2020-122	SCREW REMOVAL TOOL – #10 HEXALOBE - SLIM
1	2020-117	REVERSE THREAD AUGER SCREW REMOVAL TOOL
1	1360-016	FREEHAND BIT - REVERSE THREAD AUGER SCREW REMOVAL
1	1360-017	DUAL-BARREL DTS GUIDE BIT - REVERSE THREAD AUGER SCREW REMOVAL

ADDITIONAL INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	07C00037	TAMP, CURVED CERVICAL – DELRIN TIP
1	03C00789	CERVICAL RASP – 14.5mm X 12mm X 5.5mm X 0°, DOMED/FLAT
2	8020-100	AO DRIVE MOLDED CERVICAL HANDLE – NON RATCHETING

Contact CoreLink Customer Service for additional sizes and options

F3D-C2 INSTRUMENT PRODUCT LISTING - STANDARD (CONTINUED)

SCREW INSTRUMENT KIT ORDER #K5000408

TRIALS

QTY	CATALOG NUMBER	DESCRIPTION
14.5mm X 12mm, 7°, DOUBLE STOP		
1	02C00690	6mm
1	02C00691	7mm
1	02C00692	8mm
1	02C00693	9mm
1	02C00694	10mm
1	02C00695	11mm
1	02C00696	12mm
16.5mm X 14mm, 7°, SINGLE STOP		
1	02C00195	6mm
1	02C00196	7mm
1	02C00197	8mm
1	02C00198	9mm
1	02C00199	10mm
1	02C00200	11mm
1	02C00201	12mm

CADDIES

QTY	CATALOG NUMBER	DESCRIPTION
1	14C00555	SCREW CADDY
1	14C00562	DUAL-BARREL DTS GUIDE CADDY
1	14C00566	UNIVERSAL BIT CADDY

CONTAINERS

QTY	CATALOG NUMBER	DESCRIPTION
1	14C00550	BASE
1	14C00551	INNER TRAY 1
1	14C00552	INNER TRAY 2
1	14C00564	INNER TRAY 3
1	14G00500	LID

F3D-C2 INSTRUMENT PRODUCT LISTING - NON-STANDARD

TAPS - SPECIAL ORDER		
QTY	CATALOG NUMBER	DESCRIPTION
1	1360-005	DUAL-BARREL DTS GUIDE BIT - TAP*
1	1360-004	FREEHAND BIT - TAP*
1	1320-001	STRAIGHT TAP*

TRIAL KIT ORDER #K5000523

TRIALS		
QTY	CATALOG NUMBER	DESCRIPTION
14.5mm X 12mm, 13°, DOUBLE STOP		
1	02C01688	6mm
1	02C01689	7mm
1	02C01690	8mm
1	02C01691	9mm
1	02C01692	10mm
1	02C01693	11mm
1	02C01694	12mm
16.5mm X 14mm, 13°, DOUBLE STOP		
1	02C01702	6mm
1	02C01703	7mm
1	02C01704	8mm
1	02C01705	9mm
1	02C01706	10mm
1	02C01707	11mm
1	02C01708	12mm

TRIAL KIT ORDER #K5000524

TRIALS - NON-STANDARD		
QTY	CATALOG NUMBER	DESCRIPTION
18mm X 16mm, 13°, DOUBLE STOP		
1	02C01730	6mm
1	02C01731	7mm
1	02C01732	8mm
1	02C01733	9mm
1	02C01734	10mm
1	02C01735	11mm
1	02C01736	12mm

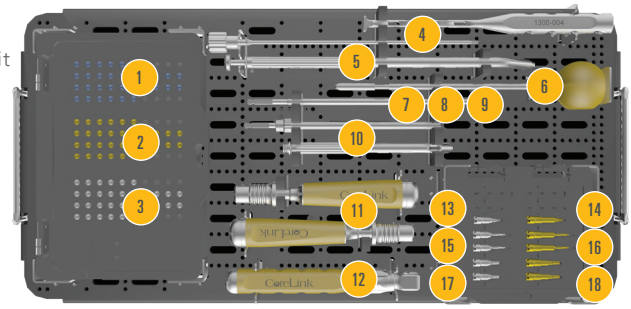
SCREW INSTRUMENT KIT ORDER #K5000408

TOP TRAY

1. 3.5mm Fixed Screws
2. 3.5mm Variable Screws
3. 4.0mm Fixed Screws
4. Freehand Inserter
5. Curved Fixed Angle Awl – Freehand
6. Straight Fixed Awl – Freehand
7. Straight Screw Driver
8. Freehand Articulating Driver
9. DTS Guide Articulating Driver
10. Universal Angled Instrument Outer and Inner Shaft
11. AO Cervical Handles
12. Universal Angled Instrument Side Handle

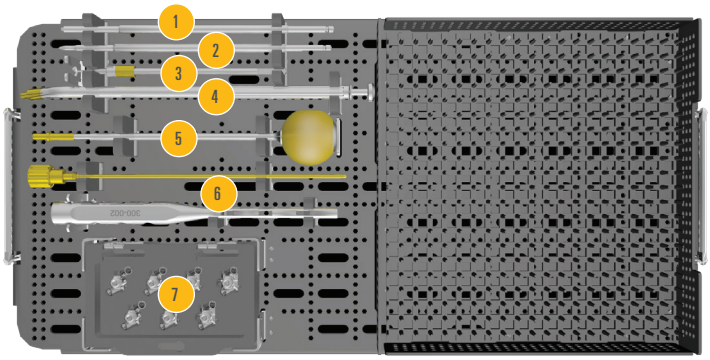
Drill & Driver Bits

13. Freehand Screw Removal Auger Bit
14. DTS Guide Screw Removal Auger Bit
15. Freehand Drill Bit (Qty 2)
16. DTS Guide Drill Bit (Qty 2)
17. Freehand Driver Bit (Qty 2)
18. DTS Guide Driver Bit (Qty 2)



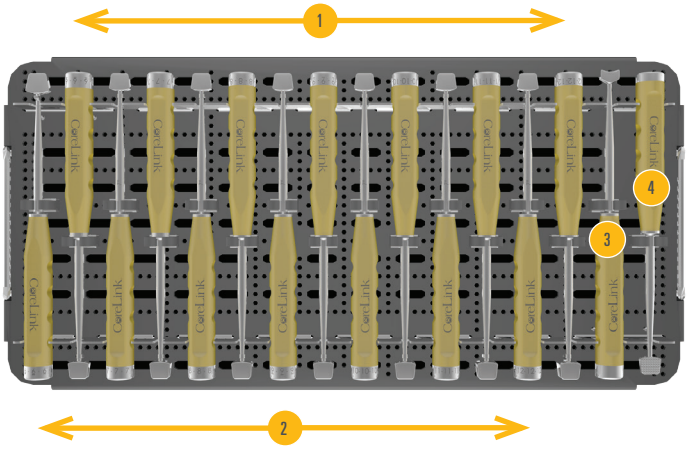
MIDDLE TRAY

1. Reverse Thread Removal Tool
2. Screw Removal Auger Style Tool
3. 12mm Straight Drill
4. Curved Fixed Angle Awl – DTS Guide
5. Straight Awl–DTS Guide
6. DTS Guide Cage Inserter
7. DTS Guide Caddy



BOTTOM TRAY

1. 14.5mm x 12mm 7° Trials, 6 - 12mm
2. 16.5mm x 14mm 7° Trials, 6 - 12mm
3. Cervical Tamp
4. Cervical Rasp



Contact CoreLink Customer Service for additional sizes and options

F3D-C2 ANCHOR INSTRUMENT PRODUCT LISTING – STANDARD

ANCHOR KIT ORDER #K5000477

ANCHOR INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
SINGLE-SIDED GUIDE		
1	1370-020	6mm – FLUSH STOP
1	1370-021	7mm – FLUSH STOP
1	1370-022	8mm – FLUSH STOP
1	1370-023	9mm – FLUSH STOP
1	1370-024	10mm – FLUSH STOP
1	1370-025	11mm – FLUSH STOP
1	1370-026	12mm – FLUSH STOP
DOUBLE-SIDED GUIDE		
1	1370-041	6mm – FLUSH STOP
1	1370-042	7mm – FLUSH STOP
1	1370-043	8mm – FLUSH STOP
1	1370-044	9mm – FLUSH STOP
1	1370-045	10mm – FLUSH STOP
1	1370-046	11mm – FLUSH STOP
1	1370-047	12mm – FLUSH STOP

ANCHOR INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
2	1370-011	GUIDE IMPACTOR
1	1370-005	GUIDE IMPACT ASSIST
1	1370-006	ANCHOR REMOVAL TOOL
1	1370-000	ANCHOR INSERTER (NON-GUIDED/FREEHAND)
1	1370-009	ANCHOR INSERTION TOOL (FOR GUIDES)
1	5020-212	CURVED ANCHOR AWL – 12mm
1	5020-214	CURVED ANCHOR AWL – 14mm
1	5020-216	CURVED ANCHOR AWL – 16mm
0*	5020-218	CURVED ANCHOR AWL – 18mm
1	5020-312	STRAIGHT ANCHOR AWL – 7mm
1	1370-016	MALLET

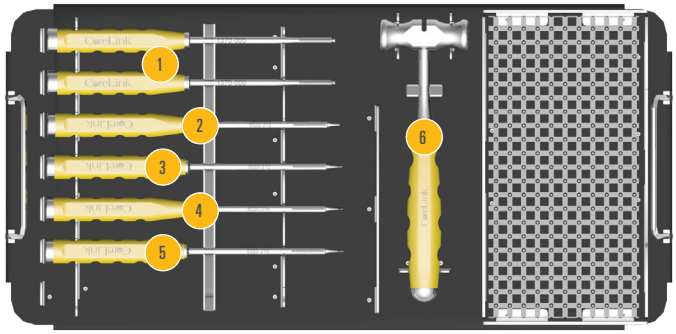
CONTAINERS

QTY	CATALOG NUMBER	DESCRIPTION
1	14C00675	ANCHOR INSTRUMENT TRAY – BASE
1	14C00676	INSTRUMENT TRAY – TOP TRAY
1	14C00677	INSTRUMENT TRAY – BOTTOM TRAY
1	14C00679	SINGLE-SIDED ANCHOR GUIDE CADDY
1	14C00680	DOUBLE-SIDED ANCHOR GUIDE CADDY

ANCHOR INSTRUMENT KIT ORDER #K5000477

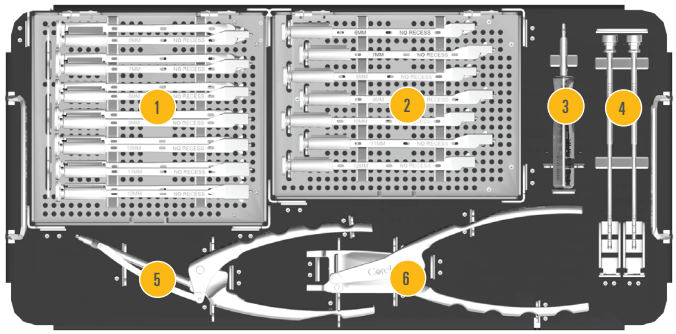
TOP TRAY

1. Anchor Drivers (Qty 2)
2. Straight Awl 7mm
3. Straight Awl 12mm
4. Straight Awl 14mm
5. Straight Awl 16mm
6. Mallet



BOTTOM TRAY

1. Double-Sided Guide Caddy
2. Single-Sided Guide Caddy
3. Anchor Installation Tool
4. Guide Impactors (Qty 2)
5. Anchor Removal Tool
6. Guide Impact Assist



F3D-C2 IMPLANT PRODUCT LISTING – STANDARD

CAGE KIT ORDER #K5000410

14.5mm X 12mm, 7°				
QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
3	3CS1412-0706	6mm	4.6mm	0.1cc
3	3CS1412-0707	7mm	5.6mm	0.2cc
3	3CS1412-0708	8mm	6.6mm	0.2cc
3	3CS1412-0709	9mm	7.6mm	0.4cc
2	3CS1412-0710	10mm	8.6mm	0.3cc
2	3CS1412-0711	11mm	9.6mm	0.4cc
2	3CS1412-0712	12mm	10.6mm	0.4cc
1	14C00378	CAGE TOTE		

CAGE KIT ORDER #K5000411

16.5mm X 14mm, 7°				
QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
3	3CS1614-0706	6mm	4.3mm	0.3cc
3	3CS1614-0707	7mm	5.3mm	0.3cc
3	3CS1614-0708	8mm	6.3mm	0.4cc
3	3CS1614-0709	9mm	7.3mm	0.5cc
2	3CS1614-0710	10mm	8.3mm	0.6cc
2	3CS1614-0711	11mm	9.3mm	0.6cc
2	3CS1614-0712	12mm	10.3mm	0.7cc
1	14C00378	CAGE TOTE		

SELF-DRILLING-SELF-TAPPING SCREWS*		
QTY	CATALOG NUMBER	DESCRIPTION
FIXED		
6	20635-12	3.5mm X 12mm
10	20635-14	3.5mm X 14mm
10	20635-16	3.5mm X 16mm
6	20635-18	3.5mm X 18mm
6	20640-12	4.0mm X 12mm
10	20640-14	4.0mm X 14mm
10	20640-16	4.0mm X 16mm
6	20640-18	4.0mm X 18mm
VARIABLE		
6	20535-12	3.5mm X 12mm
10	20535-14	3.5mm X 14mm
10	20535-16	3.5mm X 16mm
6	20535-18	3.5mm X 18mm

ANCHOR KIT ORDER #K5000472

FUSATION ANCHORS		
QTY	CATALOG NUMBER	DESCRIPTION
4	3CN01-3512	12mm
6	3CN01-3514	14mm
6	3CN01-3516	16mm
4	3CN01-3518	18mm
1	14C00693	ANCHOR TOTE

NOTE: CAGES AND ANCHORS ARE STERILE-PACKAGED

*Screws in the F3D-C2 Instrument Tray

**Special order. Contact CoreLink Customer Service for additional sizes & options.

F3D-C2 IMPLANT PRODUCT LISTING - NON-STANDARD

CAGE KIT ORDER #K5000525

14.5mm X 12mm, 13°

QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
2	3CS1412-1306	6mm	3.4mm	0.1cc
2	3CS1412-1307	7mm	4.4mm	0.2cc
2	3CS1412-1308	8mm	5.4mm	0.2cc
2	3CS1412-1309	9mm	6.4mm	0.3cc
1	3CS1412-1310	10mm	7.4mm	0.3cc
1	3CS1412-1311	11mm	8.4mm	0.4cc
1	3CS1412-1312	12mm	9.4mm	0.4cc
1	14C00378	CAGE TOTE		

16.5mm X 14mm, 13°

QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
2	3CS1614-1306	6mm	2.9mm	0.3cc
2	3CS1614-1307	7mm	3.9mm	0.3cc
2	3CS1614-1308	8mm	4.9mm	0.4cc
1	3CS1614-1309	9mm	5.9mm	0.4cc
1	3CS1614-1310	10mm	6.9mm	0.5cc
1	3CS1614-1311	11mm	7.9mm	0.6cc
1	3CS1614-1312	12mm	8.9mm	0.6cc
1	14C00378	CAGE TOTE		

CAGE KIT ORDER #K5000412**

18mm X 16mm, 7°

QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
3	3CS1816-0706	6mm	4.1mm	0.7cc
3	3CS1816-0707	7mm	5.1mm	0.8cc
3	3CS1816-0708	8mm	6.1mm	1.0cc
3	3CS1816-0709	9mm	7.1mm	1.1cc
2	3CS1816-0710	10mm	8.1mm	1.2cc
2	3CS1816-0711	11mm	9.1mm	1.4cc
2	3CS1816-0712	12mm	10.1mm	1.5cc
1	14C00378	CAGE TOTE		

CAGE KIT ORDER #K5000526

18mm X 16mm, 13°

QTY	CATALOG NUMBER	HEIGHT DESCRIPTION	POSTERIOR HEIGHT	GRAFT VOLUME
F3D-C2 STAND-ALONE CERVICAL CAGES				
3	3CS1816-1306	6mm	2.9mm	0.2cc
3	3CS1816-1307	7mm	3.9mm	0.3cc
3	3CS1816-1308	8mm	4.9mm	0.4cc
3	3CS1816-1309	9mm	5.9mm	0.5cc
2	3CS1816-1310	10mm	6.9mm	0.6cc
2	3CS1816-1311	11mm	7.9mm	0.6cc
2	3CS1816-1312	12mm	8.9mm	0.7cc
1	14C00378	CAGE TOTE		

NOTES

NOTES

CoreLink®

The Source for Spine™

INSIGHT | PERFORMANCE | VALUE

CoreLinkSurgical.com 888.349.7808

Designed and manufactured in St. Louis, MO 63026

CL-FORM-319, Rev. 6