

F3D-C2 STAND-ALONE

CERVICAL CAGE SYSTEM
WITH FUSATION™ ANCHOR TECHNOLOGY



THE F3D-C2 STAND-ALONE CERVICAL SYSTEM

The F3D-C2 Stand-alone Cervical System is a cervical interbody fusion system comprised of a spacer with two bone screws and/or Fusation anchors secured by a locking mechanism integrated within the cage. The system features versatile spacer fixation options, innovative instruments that streamline implantation at the most challenging levels, and the biocompatible benefits of Mimetic Metal®.

SYSTEM OVERVIEW

Mimetic Metal facilitates

IN-GROWTH & ON-GROWTH*

LATERAL LATTICE

for graft containment and load sharing

VFRSATILITY:

Screw or anchor



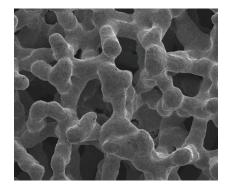
IN-LINE INSERTION:

Minimizing tissue retraction and maximizing surgical efficiency

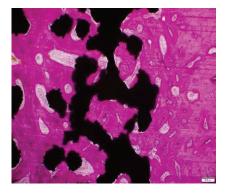
ANTI-BACKOUT MECHANISM

MIMETIC METAL

The F3D-C2 spacer and anchors feature CoreLink's proprietary Mimetic Metal technology. Mimetic Metal's structure is a balance of porosity and strength. It combines a lattice framework and inner trabecular pores to emulate the structural, functional, and physiological properties of bone. Mimetic Metal allows for greater bony on-growth and in-growth compared to machined titanium shown in an in-vivo sheep model*.



Mimetic Metal Up-Close 500 Micron Pores

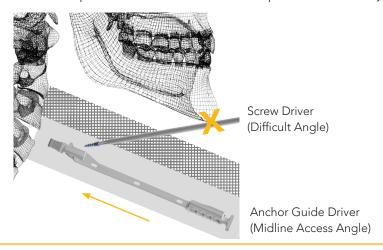


Histology of Mimetic Metal at 12 Weeks

^{*}Data on file, pre-clinical data may not be representative of clinical results.

IN-LINE INTEGRATED FIXATION

Fusation anchors are an ideal alternative to traditional fixation screws for surgical scenarios when screw instrumentation is limited. This limitation may be caused by patient anatomy, commonly seen when the patient's chin or sternum limits access to certain levels of the cervical spine. The anchor instrumentation provides a minimally invasive anterior surgical working corridor.



SURGICAL VERSATILITY

The system includes F3D-C2 cervical bone screws and/or Fusation curved anchors, providing multiple options to fixate the spacer to vertebral bodies.

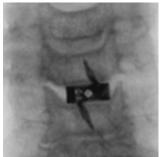


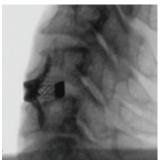




RADIOGRAPHIC IMAGING

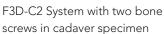
Streamlined support structure minimizes density, allowing high quality imaging.

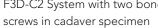




F3D-C2 System with two Fusation anchors in cadaver specimen[†]







IMPLANT OVERVIEW

MIMETIC METAL TITANIUM SPACERS

Footprints:

- 14.5mm x 12mm
- 16.5mm x 14mm

Anterior Heights:

• 6mm - 12mm (1mm increments)

Lordotic Options:

• 7 degrees



14.5mm



16.5mm

SCREW OPTIONS

Screws:

• Diameters: 3.5mm or 4.0mm

· Lengths: 12mm - 18mm (2mm increments)

• Self-drilling-self-tapping

• Variable* and fixed



3.5MM FIXED



3.5MM VARIABLE



4.0MM FIXED

FUSATION CERVICAL ANCHOR OPTIONS

Anchors:

• Diameter: 3.5mm

• Lengths: 12mm - 18mm (2mm increments)



12MM



14MM



16MM



18MM

Note: Additional sizes and lordosis options may be available upon request; *Variable in 3.5mm only

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 TM 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 TM 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.

For product information, including indications for use, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the product Instructions For Use (IFU) and information on the CoreLink website. To obtain a copy of the current Instructions for Use (IFU) for full prescribing and risk information, please call CoreLink Customer Service at (888) 349-7808 or visit corelinksurgical.com/ifu.

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