NEURO® STRUCTURES

PorOsteon® PHUSION METAL® TECHNOLOGY

Cavetto® Phusion Metal®

CERVICAL INTERBODY CAGE SYSTEM

SURGICAL TECHNIQUE GUIDE

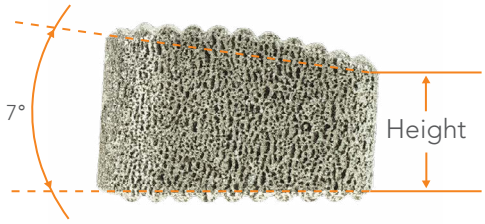
Made in the USA

neurostructures.com

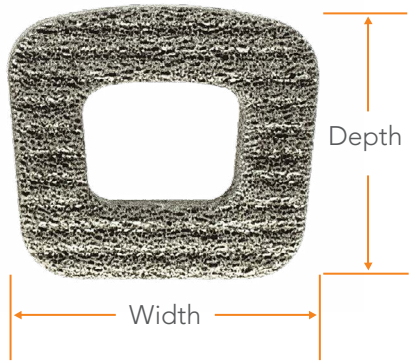
Cavetto® Phusion Metal®

This is intended as a guide only. There are multiple techniques for the delivery of Cervical Cages as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Lordotic Angulation & Height



Footprint



Cage Size

		Depth (mm) x Width (mm)	
Diameter		12.5 x 14.5	14.5 x 16.5
Height (mm)	5	✓	✓
	6	✓	✓
	7	✓	✓
	8	✓	✓
	9	✓	✓
	10	✓	✓

1 Preparation & Sizing

The Rasps can be used to prepare the site and determine the appropriate implant size.

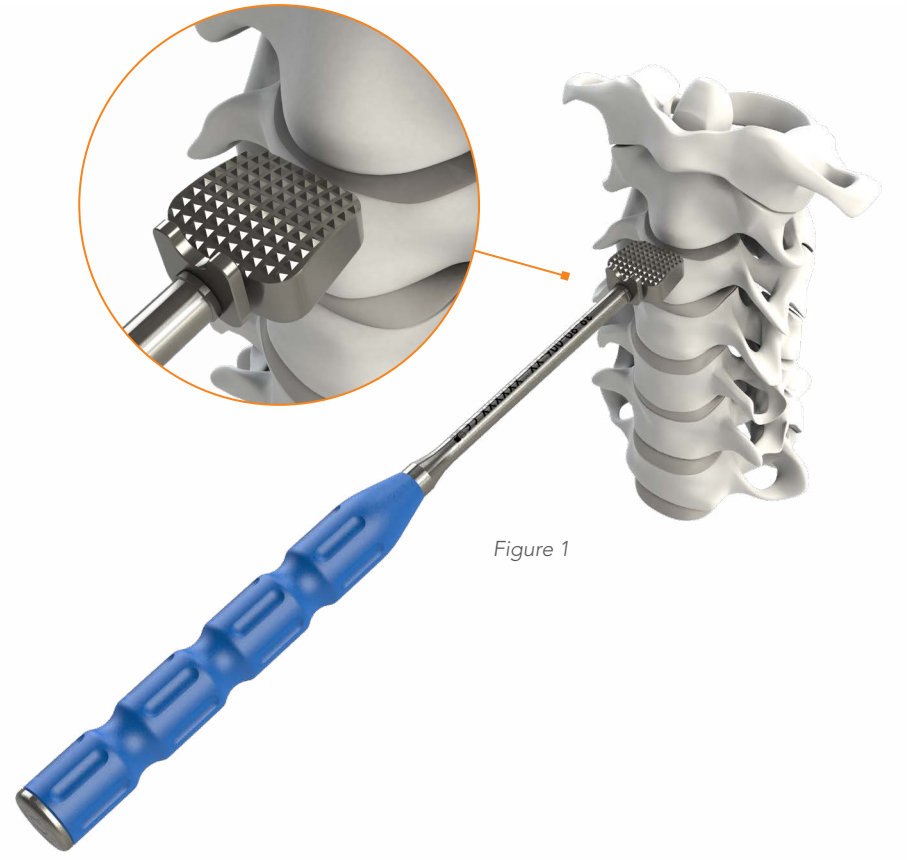


Figure 1

Rasp

Figure 2

It is recommended that preoperative planning be used to help determine the proper entry point and trajectory. Identify the operative levels using A/P and lateral fluoroscopy.

The Trials can be used to determine the appropriate implant size.

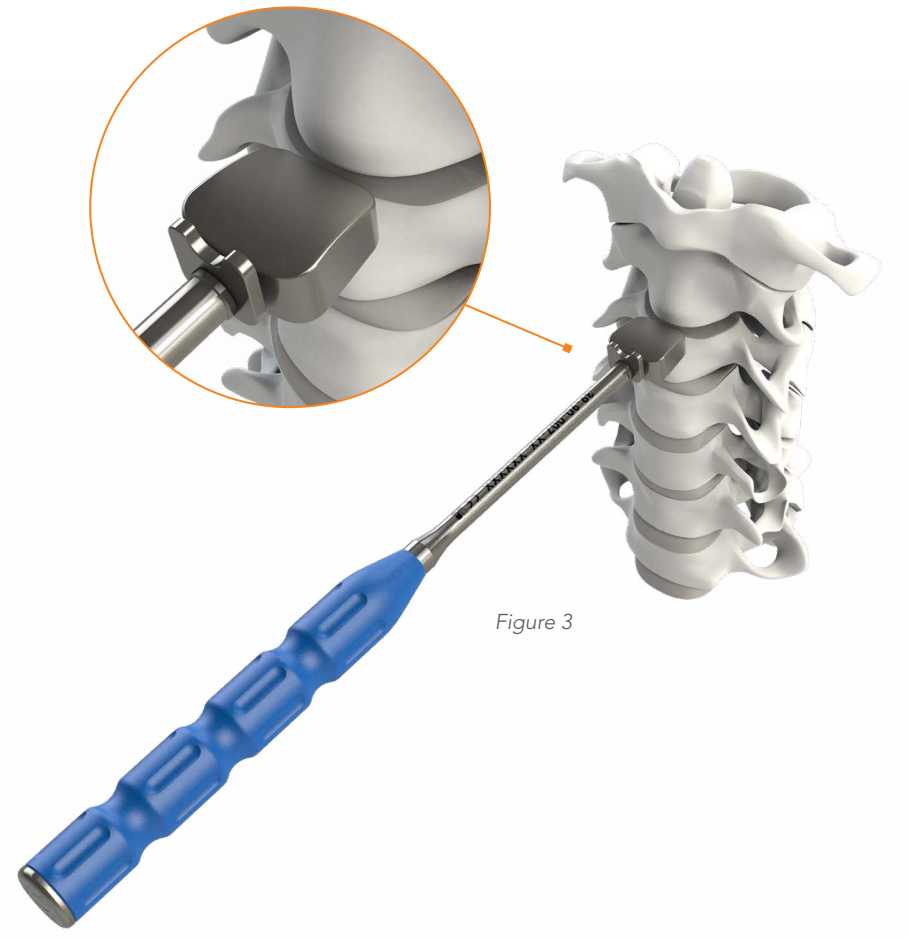


Figure 3

Trial

Figure 4

2 Implant Preparation

Select implant based on trial fit.

Connect the implant to the appropriate Inserter by pushing the implant onto the two pins.

Then insert the implant and Inserter into the Inserter Handle. Once the Inserter is fully seated into the Inserter Handle, the pins will be locked into the implant.

Rotate the knob on the end of the Inserter Handle clockwise to lock Inserter Handle onto the Inserter.

Figure 5

3 Implant Delivery

Insert the implant into the disc space.

To release the implant from the Inserter, first rotate knob on Inserter Handle counter-clockwise to release Inserter Handle from Inserter.

Once the grip on implant has loosened, both the Inserter and Inserter Handle can be removed together.

Caution: Confirm placement before removing the instruments.

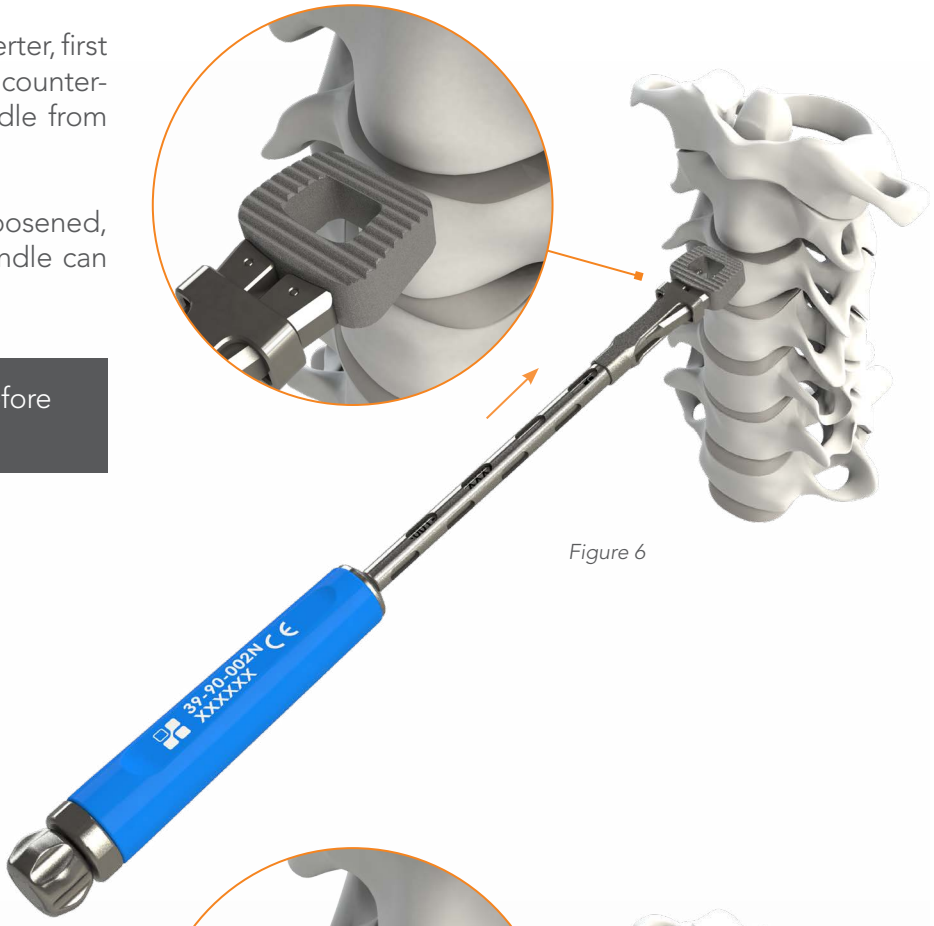


Figure 6

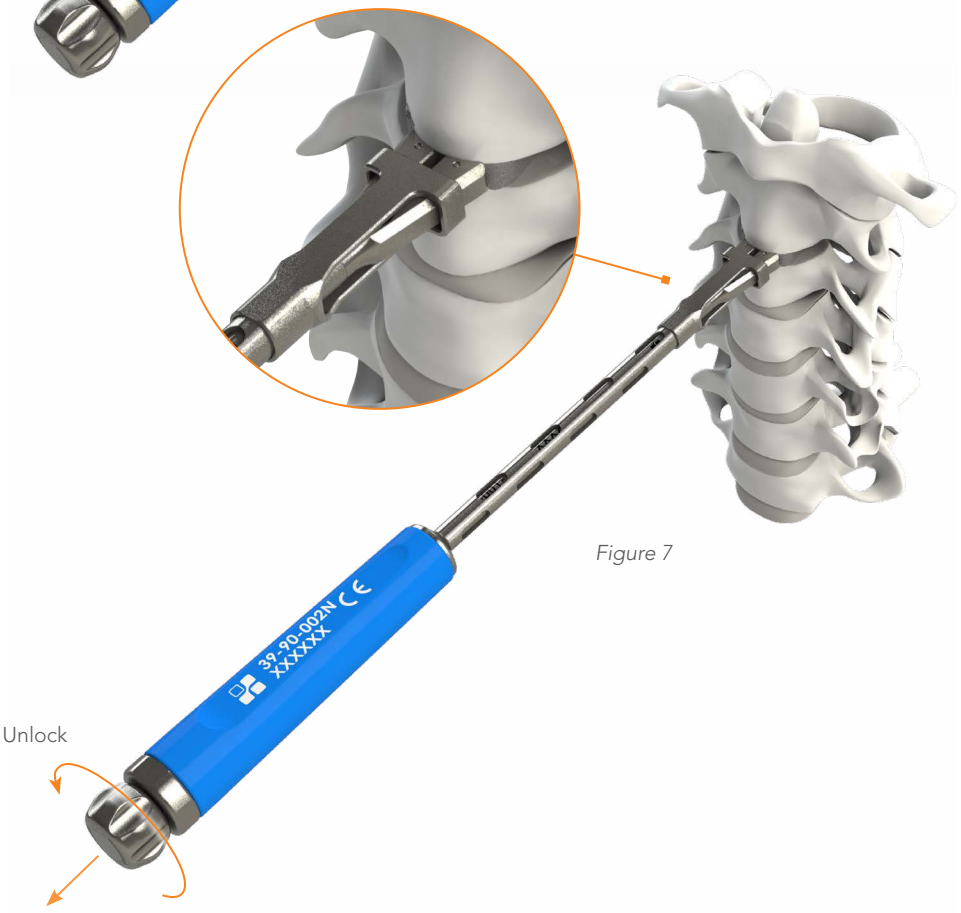


Figure 7

4 Implant Positioning

After the implant has been inserted, you can use the Implant Pusher to position the implant.

Caution: Confirm implant placement under fluoroscopy.

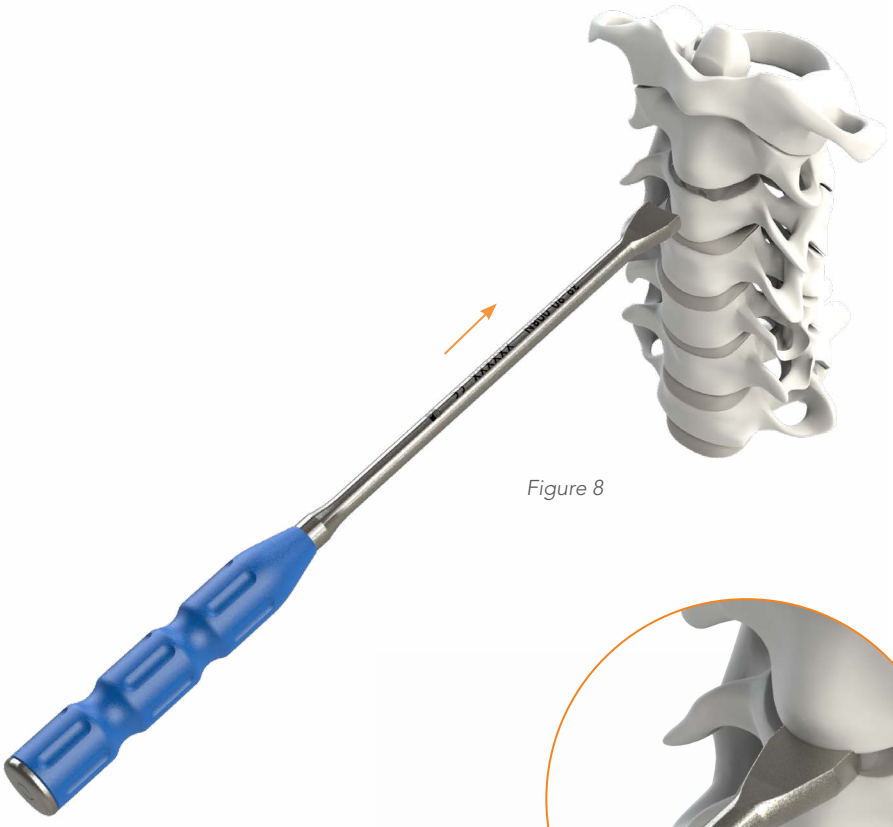


Figure 8

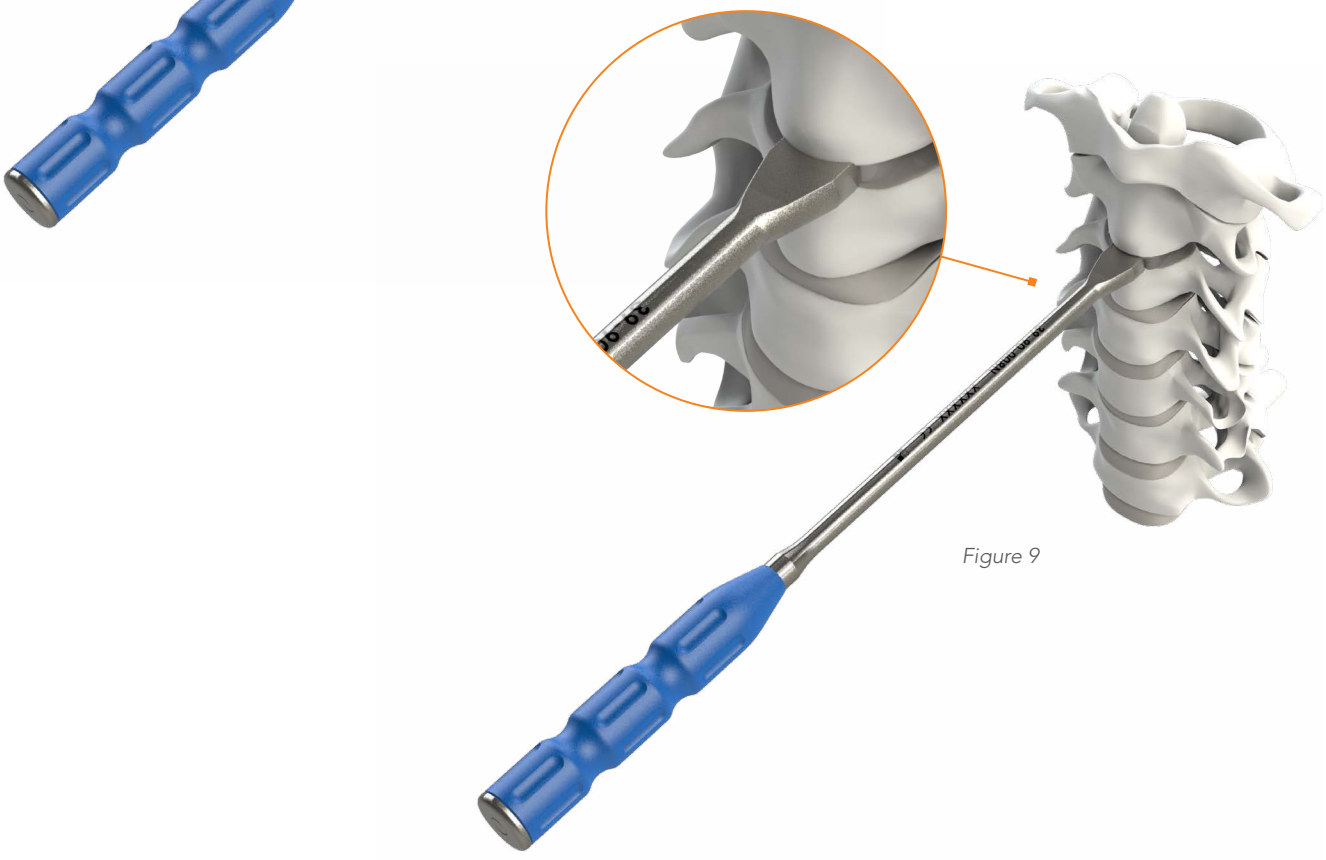


Figure 9

5 Final Position

Implant should be positioned in the middle of the disc space.

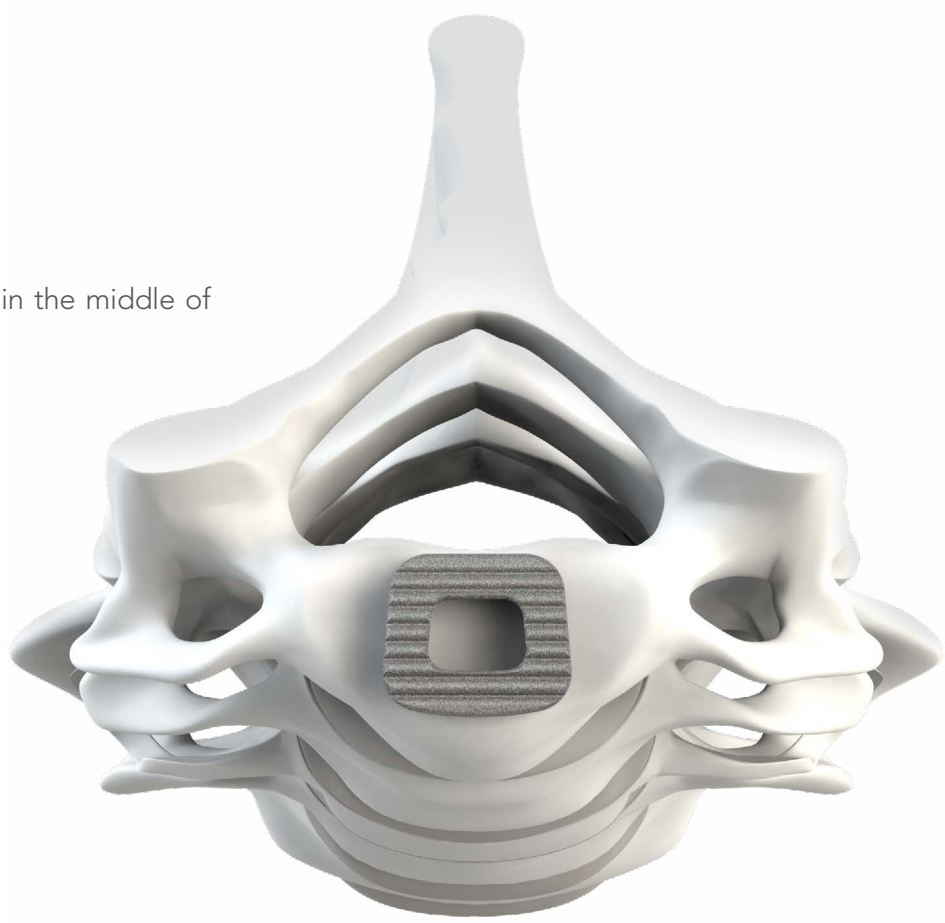


Figure 10

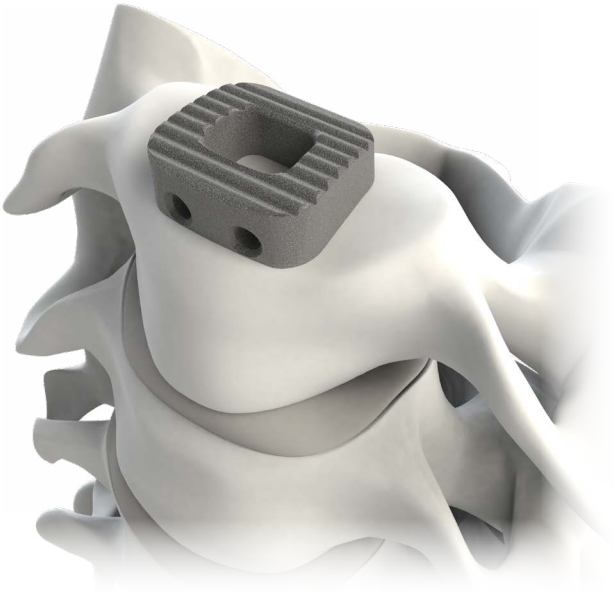


Figure 11

6 Implant Removal

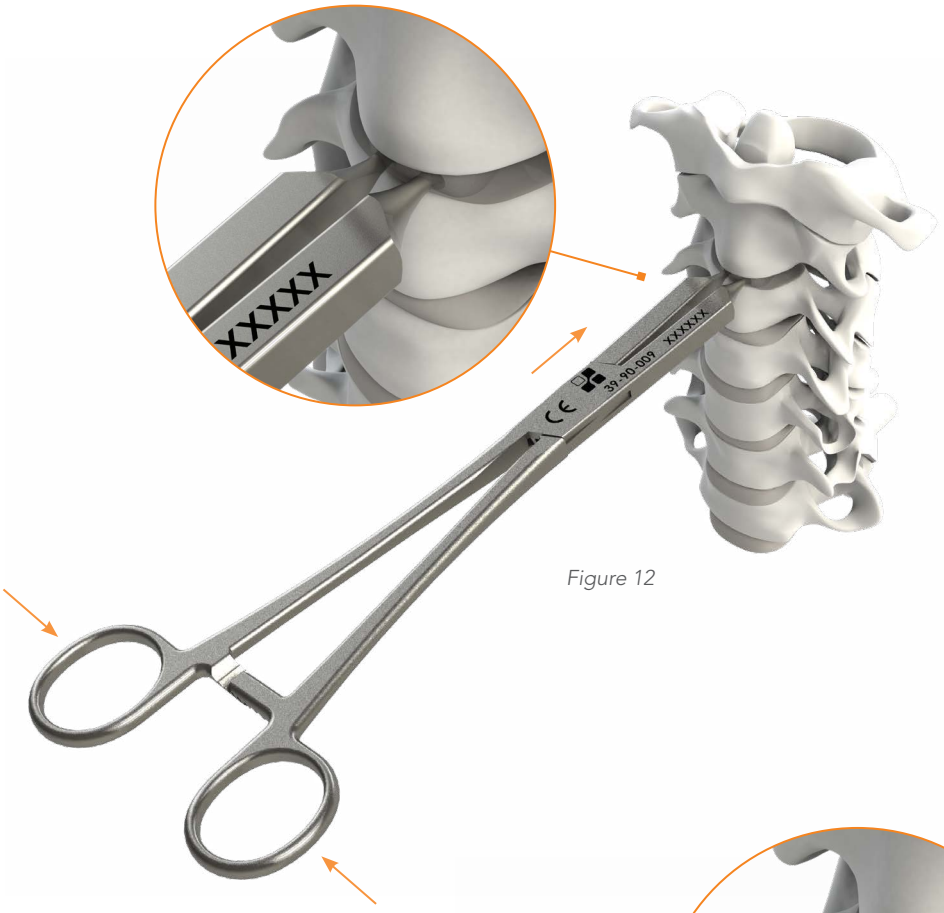


Figure 12

If for any reason the implant needs to be removed, the Implant Remover tool can be used.

Attach the Implant Remover to the front of the implant by pushing it into the pin holes. Once the Implant Remover is fully engaged with the implant, compress the Implant Remover to lock the implant onto it then gently pull the implant straight out.

Compress the Remover to lock implant

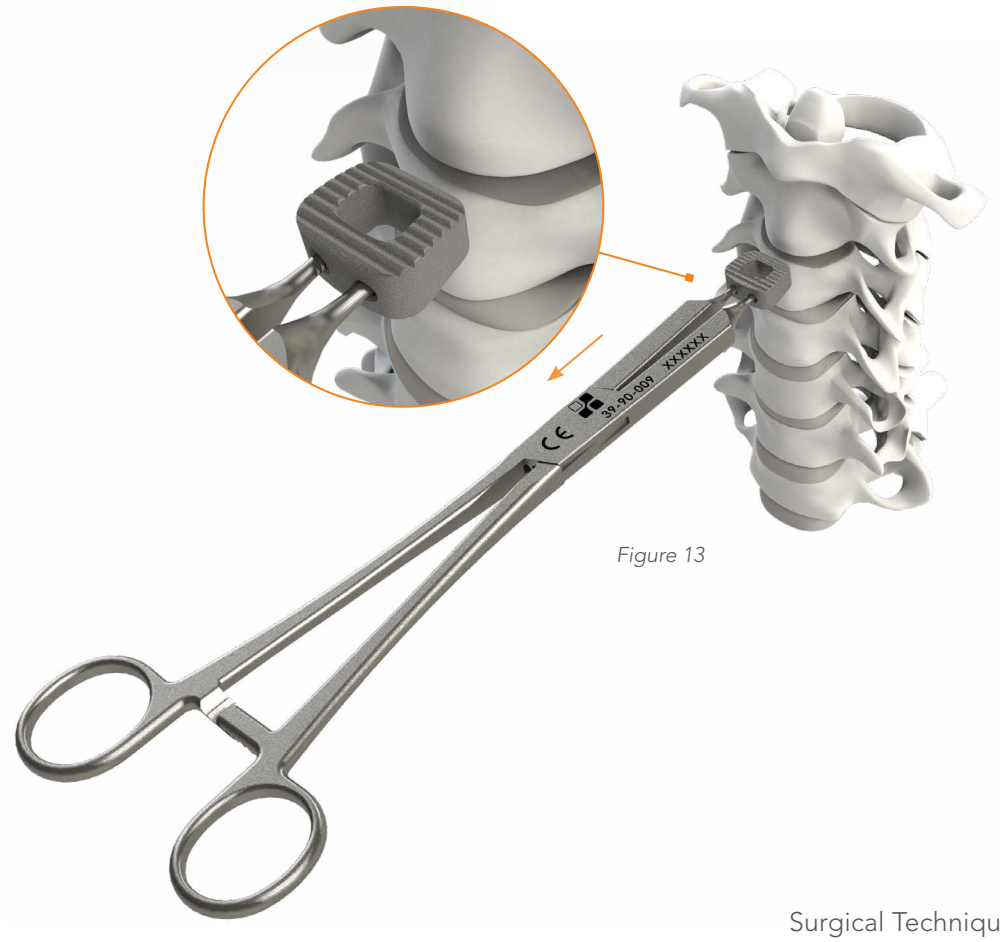


Figure 13

7 Instruments

39-90-001-01
Inserter
12.5mm x 14.5mm

39-90-001-07
Inserter
14.5mm x 16.5mm

39-90-002
Inserter Handle

39-90-006-XX
Rasp with Handle

39-90-007-XX
Trial with Handle

39-90-008
Implant Pusher

39-90-009
Implant Remover

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EC REP
Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Part Number	Depth (mm)	Width (mm)	Height (mm)	Convexity (mm)	Lordosis (°)
ACDF001-01	12.50	14.50	5.0	1.0	7.0
ACDF001-02	12.50	14.50	6.0	1.0	7.0
ACDF001-03	12.50	14.50	7.0	1.0	7.0
ACDF001-04	12.50	14.50	8.0	1.0	7.0
ACDF001-05	12.50	14.50	9.0	1.0	7.0
ACDF001-06	12.50	14.50	10.0	1.0	7.0
ACDF001-07	14.50	16.50	5.0	1.2	7.0
ACDF001-08	14.50	16.50	6.0	1.2	7.0
ACDF001-09	14.50	16.50	7.0	1.2	7.0
ACDF001-10	14.50	16.50	8.0	1.2	7.0
ACDF001-11	14.50	16.50	9.0	1.2	7.0
ACDF001-12	14.50	16.50	10.0	1.2	7.0

Instructions for Use

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Description

The Cavetto® Phusion Metal® Cervical Cage is an intervertebral fusion device intended to act as a disc spacer and hold bone graft to promote fusion in the cervical spine. The Cavetto Phusion Metal Cervical Cage is manufactured from a porous titanium nickel intermetallic material. The Cavetto Phusion Metal Cervical Cage is offered in a variety of shapes and sizes to accommodate variations in patient anatomy. As with all orthopedic implants, do not re-use these implants.

Indications

The Cavetto Phusion Metal Cervical Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Cavetto Phusion Metal Cervical Cage is intended for use at one level in the cervical spine, from C3 to C7, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Cavetto Phusion Metal Cervical Cage is to be used in patients who have had six weeks of nonoperative treatment. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone and supplemental fixation, such as an anterior plating system.

Contraindications:

General contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
9. Suspected or documented metal allergy or intolerance.
10. Any case needing to mix metals from different components.
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any case not described in the indications.
13. Any patient unwilling to cooperate with postoperative instructions.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.

Possible Adverse Effects:

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

1. Early or late loosening of the components. Implant migration.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
4. Infection.
5. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
6. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
7. Loss of neurologic function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, presthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
8. Caudaequina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
9. Scar formation possibly causing neurological compromise around nerves and/or pain.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Bone loss or decrease in bone density, possibly caused by stress shielding.
12. Subsidence of the device into vertebral body(s).
13. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
14. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
15. Non-union (or pseudoarthrosis). Delayed union. Mal-union.
16. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
17. Graft donor site complications including pain, fracture, infection, or wound healing problems.
18. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
19. Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warning and Precautions

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This device system is not intended to be the sole means of spinal support. The Cavetto Phusion Metal Cervical Cage must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without autograft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Consider preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction prior to surgery. Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage to the connection mechanism will reduce instrument stability.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Preoperative:

The selection of the proper size, shape and design of the implant for each patient is crucial to planning the success of the procedure. The Cavetto Phusion Metal Cervical Cage is subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

1. Use care in handling and storing these components. Do not scratch or damage them. Protect implants and instruments during storage especially from corrosive environments.
2. Since mechanical parts are involved, be familiar with the various components before using the equipment and personally assemble the devices to verify that all parts and necessary instruments are present before surgery.
3. Determine the type of construct to be assembled for the case prior to surgery. Have an adequate inventory of implant sizes available at the time of surgery, including sizes larger and smaller than those expected to be used.
4. Unless packaged sterile, clean and sterilize all parts before use. Have additional sterile components available in case of an unexpected need.

Intraoperative

1. Carefully follow the instructions in any available applicable surgical technique manual.
2. At all times, use extreme caution around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Do not use bone cement since it will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

Postoperative:

Postoperative directions and warnings to the patient and patient compliance are extremely important.

1. Give the patient detailed instructions on the device's use and limitations. If partial weight bearing is recommended or required prior to firm bony union, warn the patient that device bending, loosening, or breakage can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation maybe increased if the patient is active or if the patient is debilitated, demented, or otherwise unable to use crutches or other weight supporting devices. Warn the patient to avoid falls or sudden jolts in spinal position.
2. For optimal surgical results, do not expose the patient or device to mechanical vibrations that may loosen the device construct. Warn the patient of this possibility, and instruct the patient to limit physical activities, especially lifting and twisting motions and any type of sport participation. Advise the patient not to smoke or consume excess alcohol during the bone graft healing process.
3. Advise the patient not to bend at the point of spinal fusion, and teach the patient to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By fatigue, these stresses can cause eventual loosening, or breakage of the device. It is important that union immobilization is established and confirmed by roentgenographic examination. Where there is a non-union, or if the device loosens and/or breaks, the device should be revised immediately before serious injury occurs.

MRI Compatibility:

The Cavetto Phusion Metal Cervical Cage has not been evaluated for safety and compatibility in the MR environment. The Cavetto Phusion Metal Cervical Cage has not been tested for heating or migration in the MR environment.

The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

Packaging

Packages for each of the components should be intact upon receipt. Check all components for completeness and for lack of damage prior to use. Do not use damaged packages or products; return them to NeuroStructures, Inc.

Sterility

The AAMI guidelines for the various sterilization cycles have been tested to meet a Sterility Assurance Level (SAL) of 10^{-6}. NeuroStructures, Inc. has validated the sterilization parameter for the Cavetto Phusion Metal Cervical Cage using the biological Indicator (BI) overkill method half cycle method.

Unless otherwise indicated, the Cavetto Phusion Metal Cervical Cage has been sterilized by a minimum of 25 kGy (2.5 MRads) of E-beam irradiation and is supplied packaged in protective double Tyvek pouches. This sterilization is validated by AAMI TIR33:2005 Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization and Sterilization of health care products – Radiation sterilization-Substantiation of 25 kGy as a sterilization dose-Method VDmax to an SAL of 10^{-6}. Inspect packages for punctures and other damage prior to surgery.

Cleaning Instructions of Reusable Instruments

The cleaning instruction is applicable to the reusable instruments and trials.

Trials/Provisionals and other instruments are used to determine sizing before the sterile package needs to be opened. Trials/ Provisionals and instruments should be sterilized in accordance with institution sterilization protocols and procedures.

Instruments must be thoroughly cleaned after assembly and before re-stocking. The components are placed in a sterilization tray for steam sterilization. Recommended procedure for thorough cleaning are as follows:

Steps	Process
1	Prepare neutral pH enzyme and cleaning agent per institution / hospital practice for cleaning reusable metallic and plastic instruments.
2	Submerge instrument(s) in enzyme solution and soak for twenty (20) minutes or more.
3	Use soft bristled brush to gently clean instruments to remove foreign matter and stains; particular attention should be paid to crevices, lumens, matted surfaces, and other hard to clean areas. Lumen should be cleaned with long, wire bristle brush (e.g., pipe cleaner brush).
4	Remove instruments from enzyme solution and rinse in purified water for a minimum of three (3) minutes. Thoroughly flush lumens, crevice and other areas that are hard to clean.
5	Prepare neutral pH cleaning (detergent) solution and place in sonication unit.
6	Completely submerge device in cleaning solution and sonicate for minimum of then (10) minutes. Prefer 45-50kHz for the sonication unit.
7	Rinse Instruments in purified water for minimum of three (3) minutes. Thoroughly flush lumen, crevice and other hard to clean areas.
8	Repeat step 6 and 7 with freshly prepared cleaning solution.
9	Dry instruments with a clean disposable and absorbent, lint free wipe.

Inspect the instruments for the following criteria:

- Dryness of the instruments.
- Ensure the instruments are free from lint residue, wetness, strain, foreign material.

Note: Inspect lumens, crevices, holes, channels, tightly mated components, rough surfaces, and other hard to reach areas to flush out residue.

Should the instruments contain foreign matter or stains, the instrument should be submitted for re-cleaning per above procedure. Should one or more instruments fail the cleaning procedure a second time, it should be discarded and replaced with a new instrument.

After cleaning and restocking of the instrument, and prior to sterilization and use again in surgery, all instruments should be visually examined for the following:

- Functionality
- Usability
- Wear and tear

Instruments exhibiting damage that may compromise function must be discarded and replaced. Visual evidence of metallic corrosion, material degradation, and/or significant mechanical damage qualifies as failure to pass visual inspection. Instruments that fail the visual inspection should be discarded per institution/hospital procedures, and replaced as soon as possible to ensure function of the instrument set. Enzyme solution should be changed when it becomes grossly contaminated (blood and/ or turbid).

Instruments of the Cavetto Phusion Metal Cervical Cage are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters.

Sterilization Type	Pre-vacuum
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	20-30 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap
Wrap:	KIMGUARD (K082554/ K881471)/ KIMGUARD ONE-STEP (K092167/ K091685/ K082177) or other FDA cleared wrap

Sterilization Type	Gravity Displacement
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	15 Minutes
Minimum Dry Time:	15-30 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap
Wrap:	KIMGUARD (K881471)/ KIMGUARD ONE-STEP (K092167) or other FDA cleared wrap

Further Information

NeuroStructures, Inc. has complied with the mitigation measures for the Cavetto Phusion Metal Cervical Cage device as provided in FDA Class II Special Controls Guidance Document: Intervertebral body Fusion Device. Specifically, NeuroStructures, Inc. has established biocompatibility via ISO 10993 testing, evaluation in a large animal model of spinal fusion, and extensive review of the scientific literature. Sterility of reusable instruments and the Cavetto Phusion Metal Cervical Cage device has been assured per industry standards described in this document. Biomechanical and large animal testing shows the device will perform as intended and labeled. The potential for injury to bone structures such as vertebral endplates, reoperation, and non-union are described here in the sections Warnings and Precautions and Potential Adverse Effects.

The implants should not be used with components of other systems.

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

NeuroStructures, Inc., 199 Technology, Suite 110, Irvine, CA 92618, 800-352-6103.

www.neurostructures.com

NEUROSTRUCTURES, INC. DOES NOT RECOMMEND RESTERILIZATION OF IMPLANTABLE MEDICAL DEVICES.

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