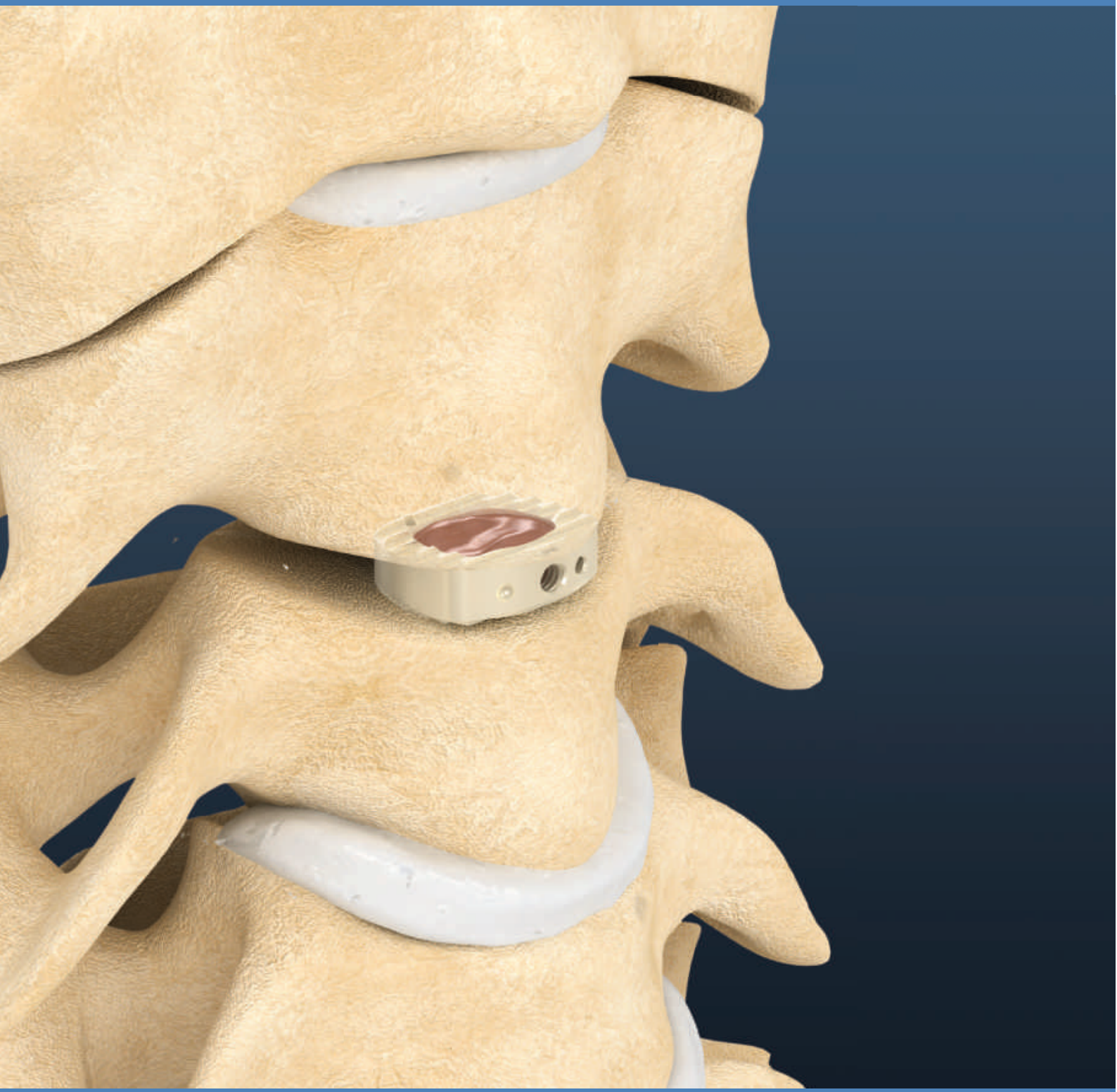
Cervical Product

4CIS® Marlin *PEEK Cage*

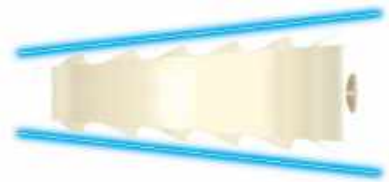


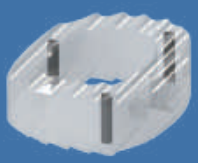
4CIS® *Marlin*

4CIS® Marlin ACIF Cage System is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have six weeks of non-operative therapy in advance. The 4CIS® Marlin ACIF Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach. It is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine, such as Anterior Cervical Plate system.

Anatomical Shape

Lordotic Shape

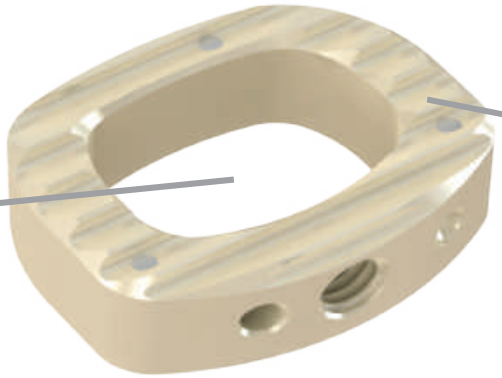




Vertical radiopaque Tantalum marker

For easy and exact implant positioning and localization

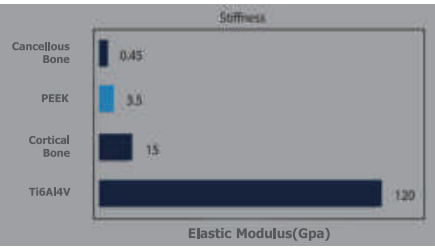
Graft Window
Optimized ratio between contact area and opening



Serrated Profile
for high primary stability

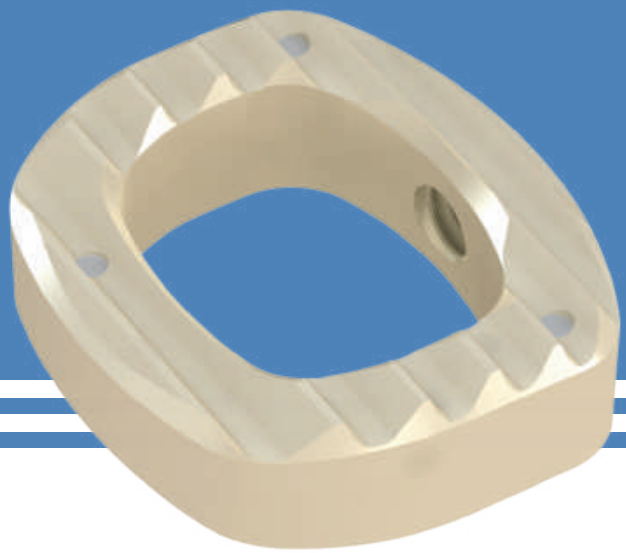
PEEK (Poly-Ether-Ether-Ketone) Properties

- Biocompatibility
- Radiolucency
- PEEK cage are more than simple spacers permitting vascularization between vertebral endplates, they mediate physiological loading of the bone graft. Its elasticity close to that of cancellous and cortical bone, insures an optimal mechanical behavior contributing to successful fusion.

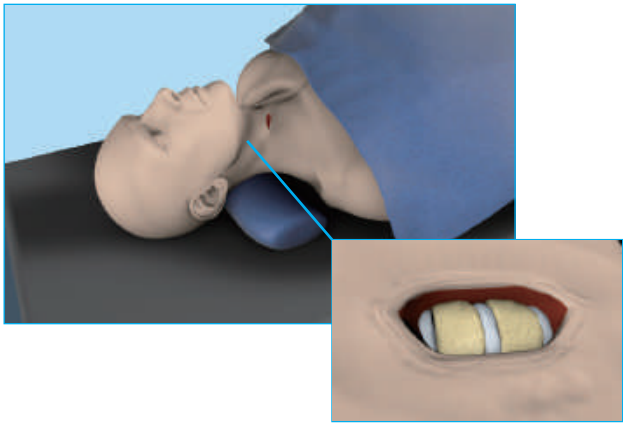


The Indications include the following;

- Intervertebral disc prolapse
- Disc herniation
- Mechanical instability
- Calcification of the posterior structures
- Osteochondrosis
- Spinal canal stenosis



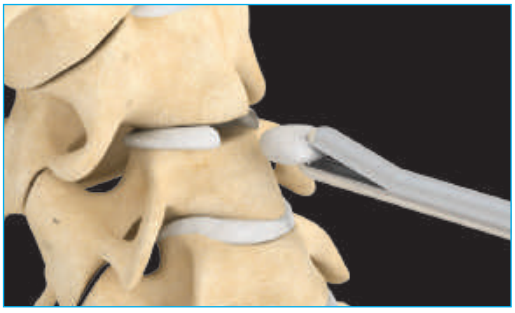
1. Exposition



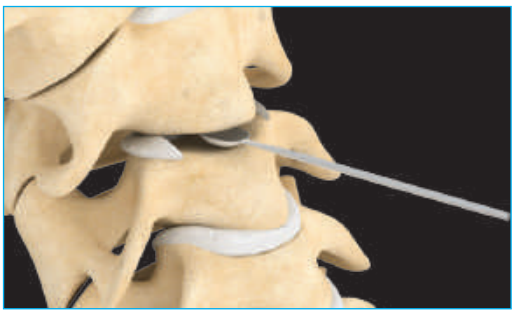
The patient is placed in the supine position.

The anterior aspect of the vertebral bodies cephalad and caudal to the segment involved are exposed.

2. Discectomy

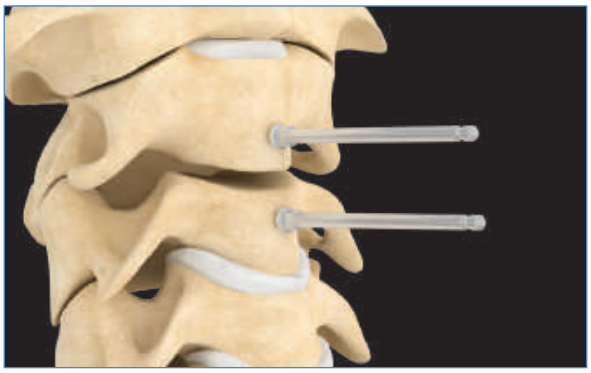


Curettes and pituitary forceps are used to remove disc material and the cartilaginous endplates.

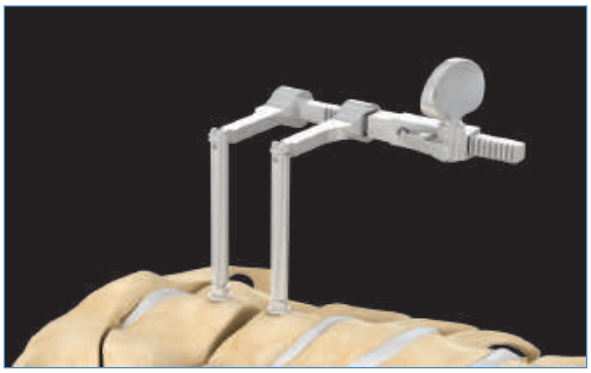


After completion of the disc removal, the end-plates of the vertebrae are prepared with curette or high-speed burr.

3. Distraction

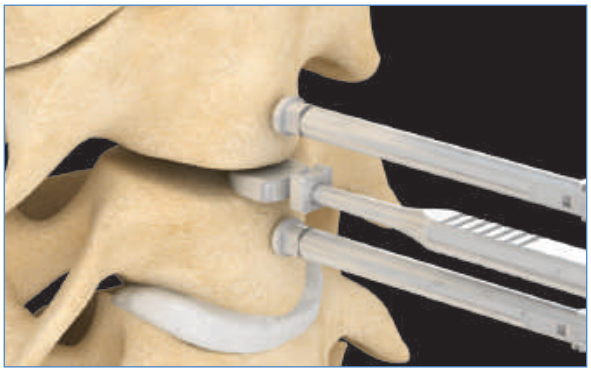


The Caspar Pins and Caspar Retractor may be used to widen interbody disk space. To achieve this two pins are driven, one into the superior and the other into the inferior vertebrae using Caspar Pin driver.
It is recommended that pins should be driven at least 5.0mm away from the endplates.



Following decompression of the disc space and neural elements, a freehand technique can be used to prepare the end plates for insertion space.

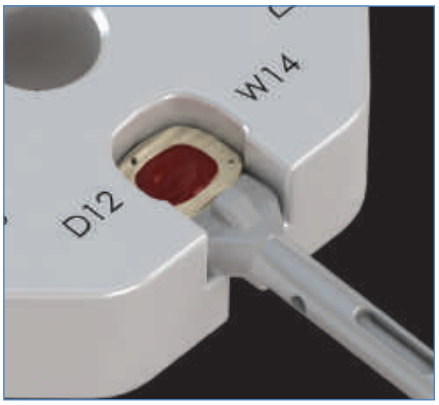
4. Cage Size Selection



Starting with the smallest trial, sequentially larger trials are placed into the disc space. The trial that produces the most satisfactory fit in the disc space is selected.

5. Cage Preparation

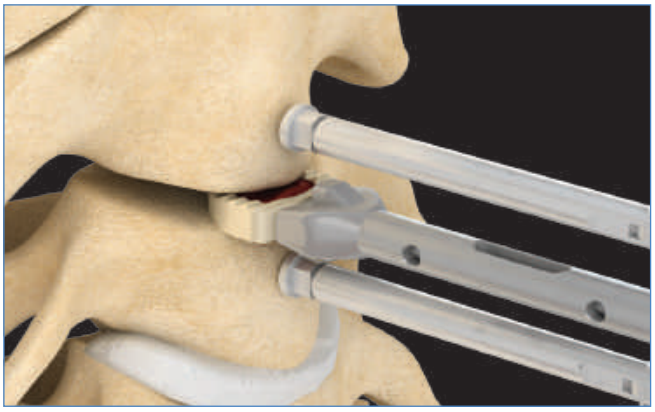
The chosen cage is mounted onto ACIF Cage Holder making sure that the positioning knob is aligned in the hole beside the threads In the cage.

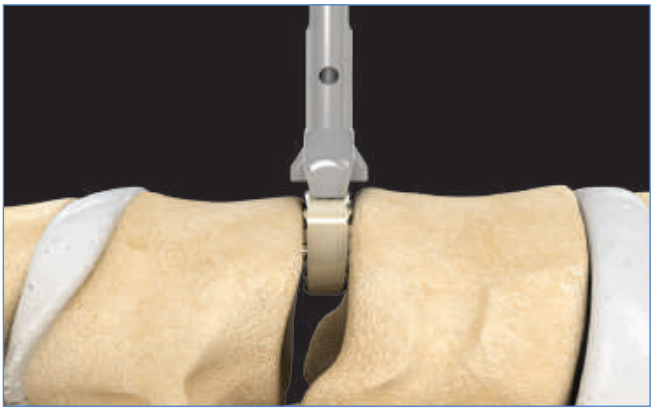


Place the cage in the ACIF Bone Graft Holder corresponding to the cage depth. (12mm or 14mm)

The cage may be filled with bone or a bone substitute using ACIF Bone Graft Handle.

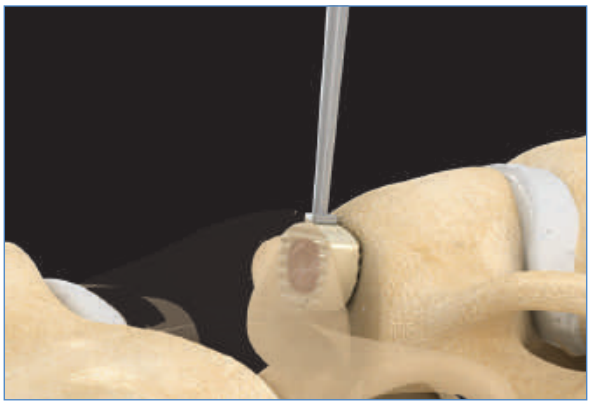
6. Cage Insertion



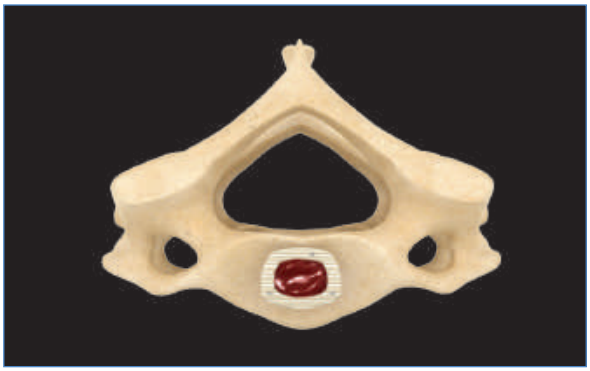


The cage mounted onto the ACIF Cage Holder is impacted into the disc area using the mallet. The ACIF Cage Holder comes with a stopper for maximal safety during insertion.

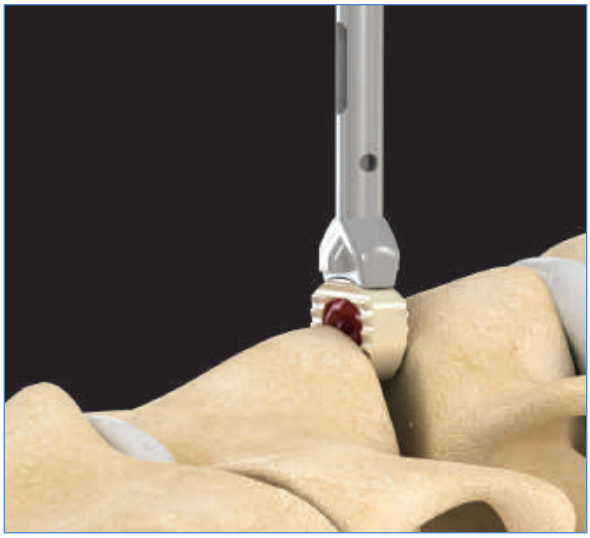
Once the implant is in the desired position, disengage the implant from the Inserter by rotating the handle counter-clockwise until it's released.



When the ACIF Cage Holder has been withdrawn, the implant position may be adjusted using the ACIF Cage Impactor.

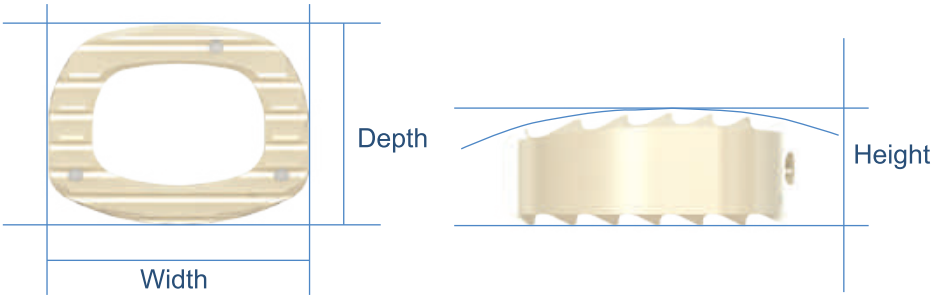


7. Removal



The Cage can be removed using ACIF Cage Holder by surgeon's decision.

Implants



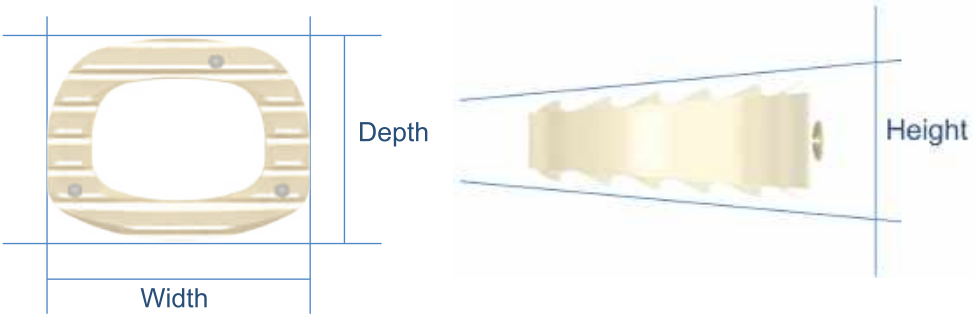
Anatomical Cage (Non_sterilized)

Cat' No.	Size(WxDxHmm)	Remark
MPU0-C125	12x12x5	Standard
MPU0-C126	12x12x6	Standard
MPU0-C127	12x12x7	Standard
MPU0-C128	12x12x8	Standard
MPU0-C129	12x12x9	Standard
MPU0-C12A	12x12x10	Standard
MPU0-C12B	12x12x11	Option
MPU0-C12C	12x12x12	Option
MPU0-E125	14x12x5	Standard
MPU0-E126	14x12x6	Standard
MPU0-E127	14x12x7	Standard
MPU0-E128	14x12x8	Standard
MPU0-E129	14x12x9	Standard
MPU0-E12A	14x12x10	Standard
MPU0-E12B	14x12x11	Option
MPU0-E12C	14x12x12	Option
MPU0-E145	14x14x5	Standard
MPU0-E146	14x14x6	Standard
MPU0-E147	14x14x7	Standard
MPU0-E148	14x14x8	Standard
MPU0-E149	14x14x9	Standard
MPU0-E14A	14x14x10	Standard
MPU0-E14B	14x14x11	Option
MPU0-E14C	14x14x12	Option
MPU0-G145	16x14x5	Standard
MPU0-G146	16x14x6	Standard
MPU0-G147	16x14x7	Standard
MPU0-G148	16x14x8	Standard
MPU0-G149	16x14x9	Standard
MPU0-G14A	16x14x10	Standard
MPU0-G14B	16x14x11	Option
MPU0-G14C	16x14x12	Option

Anatomical Cage (Sterilized)

Cat' No.	Size(WxDxHmm)	Remark
MPE0-C125	12x12x5	Standard
MPE0-C126	12x12x6	Standard
MPE0-C127	12x12x7	Standard
MPE0-C128	12x12x8	Standard
MPE0-C129	12x12x9	Standard
MPE0-C12A	12x12x10	Standard
MPE0-C12B	12x12x11	Option
MPE0-C12C	12x12x12	Option
MPE0-E125	14x12x5	Standard
MPE0-E126	14x12x6	Standard
MPE0-E127	14x12x7	Standard
MPE0-E128	14x12x8	Standard
MPE0-E129	14x12x9	Standard
MPE0-E12A	14x12x10	Standard
MPE0-E12B	14x12x11	Option
MPE0-E12C	14x12x12	Option
MPE0-E145	14x14x5	Standard
MPE0-E146	14x14x6	Standard
MPE0-E147	14x14x7	Standard
MPE0-E148	14x14x8	Standard
MPE0-E149	14x14x9	Standard
MPE0-E14A	14x14x10	Standard
MPE0-E14B	14x14x11	Option
MPE0-E14C	14x14x12	Option
MPE0-G145	16x14x5	Standard
MPE0-G146	16x14x6	Standard
MPE0-G147	16x14x7	Standard
MPE0-G148	16x14x8	Standard
MPE0-G149	16x14x9	Standard
MPE0-G14A	16x14x10	Standard
MPE0-G14B	16x14x11	Option
MPE0-G14C	16x14x12	Option

Implants



Lordotic Cage 5° (Non_sterilized)

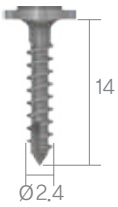
Cat' No.	Size(WxDxHmm)	Remark
MPU5-C125	12x12x5	Standard
MPU5-C126	12x12x6	Standard
MPU5-C127	12x12x7	Standard
MPU5-C128	12x12x8	Standard
MPU5-C129	12x12x9	Standard
MPU5-C12A	12x12x10	Standard
MPU5-C12B	12x12x11	Option
MPU5-C12C	12x12x12	Option
MPU5-E125	14x12x5	Standard
MPU5-E126	14x12x6	Standard
MPU5-E127	14x12x7	Standard
MPU5-E128	14x12x8	Standard
MPU5-E129	14x12x9	Standard
MPU5-E12A	14x12x10	Standard
MPU5-E12B	14x12x11	Option
MPU5-E12C	14x12x12	Option
MPU5-E145	14x14x5	Standard
MPU5-E146	14x14x6	Standard
MPU5-E147	14x14x7	Standard
MPU5-E148	14x14x8	Standard
MPU5-E149	14x14x9	Standard
MPU5-E14A	14x14x10	Standard
MPU5-E14B	14x14x11	Option
MPU5-E14C	14x14x12	Option
MPU5-G145	16x14x5	Standard
MPU5-G146	16x14x6	Standard
MPU5-G147	16x14x7	Standard
MPU5-G148	16x14x8	Standard
MPU5-G149	16x14x9	Standard
MPU5-G14A	16x14x10	Standard
MPU5-G14B	16x14x11	Option
MPU5-G14C	16x14x12	Option

Lordotic Cage 5° (Sterilized)

Cat' No.	Size(WxDxHmm)	Remark
MPE5-C125	12x12x5	Standard
MPE5-C126	12x12x6	Standard
MPE5-C127	12x12x7	Standard
MPE5-C128	12x12x8	Standard
MPE5-C129	12x12x9	Standard
MPE5-C12A	12x12x10	Standard
MPE5-C12B	12x12x11	Option
MPE5-C12C	12x12x12	Option
MPE5-E125	14x12x5	Standard
MPE5-E126	14x12x6	Standard
MPE5-E127	14x12x7	Standard
MPE5-E128	14x12x8	Standard
MPE5-E129	14x12x9	Standard
MPE5-E12A	14x12x10	Standard
MPE5-E12B	14x12x11	Option
MPE5-E12C	14x12x12	Option
MPE5-E145	14x14x5	Standard
MPE5-E146	14x14x6	Standard
MPE5-E147	14x14x7	Standard
MPE5-E148	14x14x8	Standard
MPE5-E149	14x14x9	Standard
MPE5-E14A	14x14x10	Standard
MPE5-E14B	14x14x11	Option
MPE5-E14C	14x14x12	Option
MPE5-G145	16x14x5	Standard
MPE5-G146	16x14x6	Standard
MPE5-G147	16x14x7	Standard
MPE5-G148	16x14x8	Standard
MPE5-G149	16x14x9	Standard
MPE5-G14A	16x14x10	Standard
MPE5-G14B	16x14x11	Option
MPE5-G14C	16x14x12	Option

Instruments

5901-0094 Caspar Pin



5901-0093 Caspar Pin Driver

5901-0056 Caspar Retractor
increment(2.4mm) per one click distraction

5901-0134 4CIS® Marlin ACIF Bone Graft Handle

5901-0135 4CIS® Marlin ACIF Bone Graft Holder

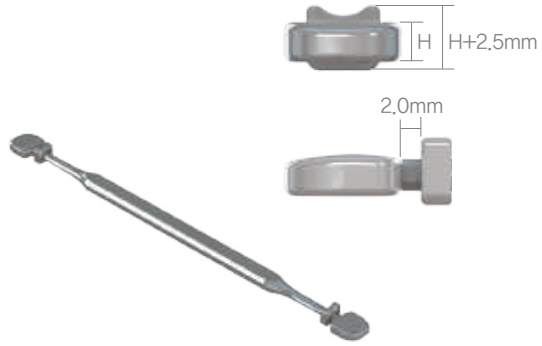
5901-0136 4CIS® Marlin ACIF Cage Inserter
5901-0369 4CIS® Marlin ACIF Cage Inserter

5901-0054 4CIS® Marlin ACIF Cage Impactor

5901-0169 4CIS® Marlin Rasp L - Lollipop
5901-0170 4CIS® Marlin Rasp S - Lollipop

Instruments

5901-0137	4CIS® Marlin Trial 12x12, H5
5901-0138	4CIS® Marlin Trial 12x12, H6
5901-0139	4CIS® Marlin Trial 12x12, H7
5901-0140	4CIS® Marlin Trial 12x12, H8
5901-0141	4CIS® Marlin Trial 12x12, H9
5901-0142	4CIS® Marlin Trial 12x12, H10
5901-0143	4CIS® Marlin Trial 12x12, H11
5901-0144	4CIS® Marlin Trial 12x12, H12



5901-0145	4CIS® Marlin Trial 14x12, H5
5901-0146	4CIS® Marlin Trial 14x12, H6
5901-0147	4CIS® Marlin Trial 14x12, H7
5901-0148	4CIS® Marlin Trial 14x12, H8
5901-0149	4CIS® Marlin Trial 14x12, H9
5901-0150	4CIS® Marlin Trial 14x12, H10
5901-0151	4CIS® Marlin Trial 14x12, H11
5901-0152	4CIS® Marlin Trial 14x12, H12

5901-0153	4CIS® Marlin Trial 14x14, H5
5901-0154	4CIS® Marlin Trial 14x14, H6
5901-0155	4CIS® Marlin Trial 14x14, H7
5901-0156	4CIS® Marlin Trial 14x14, H8
5901-0157	4CIS® Marlin Trial 14x14, H9
5901-0158	4CIS® Marlin Trial 14x14, H10
5901-0159	4CIS® Marlin Trial 14x14, H11
5901-0160	4CIS® Marlin Trial 14x14, H12

5901-0161	4CIS® Marlin Trial 16x14, H5
5901-0162	4CIS® Marlin Trial 16x14, H6
5901-0163	4CIS® Marlin Trial 16x14, H7
5901-0164	4CIS® Marlin Trial 16x14, H8
5901-0165	4CIS® Marlin Trial 16x14, H9
5901-0166	4CIS® Marlin Trial 16x14, H10
5901-0167	4CIS® Marlin Trial 16x14, H11
5901-0168	4CIS® Marlin Trial 16x14, H12

9901-5035	Anatomical Cage Caddy

9901-5036	Lordotic Cage Caddy

9901-5034	Instrument Container

Instruments (Optional)

5901-0061	Blade Retractor increment(1.6mm) per one click distraction	
5901-0057	Caspar Blade Ejector	
5901-0062	Blade, 45mm	
5901-0063	Blade, 50mm	
5901-0064	Blade, 55mm	
5901-0065	Blade, 60mm	
5901-0066	Blade, 65mm	

Important Product Information

Spinal Fusion System
4CIS® Marlin ACIF Cage System

A. DEVICE DESCRIPTION

The 4CIS® Marlin ACIF Cage System cages are single component devices used to restore height of disc space by anterior approach and to facilitate cervical interbody fusion with maintaining physiological lordotic angulation of cervical spine. To allow maximum preservation and ensure ample contact surfaces with bony endplate, a variety of shapes and sizes are available and each device has three tantalum markers for ease of visualization on radiographs. The vertical square teeth on the top and the bottom surface prevent subsidence of the cage into the vertebral body while they increase the anchoring and prevent slipping or expulsion. To make solid fusion of intervertebral body, hollow space in the implant allows bone graft material to be filled. The implant has safety proven structure and material (Poly-ether-ether-ketone and Titanium alloy) to promote biological synostosis and assures mechanical safety against load. All EtO sterilized implants meet pyrogen limit specifications.

B. INDICATION FOR USE

4CIS® Marlin ACIF Cage System is indicated for use in cervical intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at the levels from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have six weeks of non-operative therapy in advance. The 4CIS® Marlin ACIF Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach. It is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine, such as Anterior Cervical Plate system.

C. CONTRAINDICATIONS

The 4CIS® Marlin ACIF Cage system is not designed, intended or sold for uses other than those indicated. Should not be used if patient has or shows following conditions.

1. Any abnormality present which affects the normal process of bone fusion including, but not limited to;
- Rapid joint disease, disc disease, osteomalacia, or osteoporosis involving the spine
- Bone absorption, osteopenia, primary or metastatic tumors involving the spine
- Certain metabolic disorders affecting osteogenesis
2. Any medical or surgical condition which would preclude the potential benefit of spinal surgery with implantation including, but not limited to;
- Presence of tumors, congenital abnormalities leading grossly distorted anatomy, elevation of sedimentation rate unexplained by other diseases
- Elevation of white blood cell count (WBC), or marked left shift in the WBC differential count
- Radio- or chemotherapy for cancer, kidney dialysis
3. Unstable burst and compression fractures of vertebral body
4. Active systemic infection or infection localized to the site of operation or adjacent to the spine or spinal structures
5. Marked local inflammation
6. Immature patient
7. Pregnancy
8. Spinal Tumors
9. Major spinal instabilities
10. Suspected or documented allergy, intolerance or oversensitive to any of the implant materials.
11. Old age, mental defect, alcoholic, medicinal poisoned or neurological disk muscle disorder which may cause fail during surgery, complications after surgery or disability of following post-operative instructions.
12. Anomalous neural anatomy
13. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
14. Any patient unwilling to co-operate with postoperative instructions.
15. Fever or leukocytosis.
16. Morbid obesity who can show abnormal reaction caused failure of fusion which places unsafe load level on the device during the healing period or failure of the device itself due to excess weight near surgery area. Obesity is defined according to the W.H.O. standards.
17. Diagnosis result came out to be other than indication for use and physician judge that the product cannot be used on the patient.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
19. Any case not needing a bone graft and where fusion is not required.
20. Severe burn or cicatrix near the surgery area.
21. Open wounds.
22. Any case not described in the indications. These contra-indications are relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

D. POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

Include but are not limited to:

1. Inappropriate or improper surgical placement of other fixation device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
2. Bone loss or decrease in bone density, possibly caused by stress shielding or unbalanced physical pressure.
3. Heterotopic bone formation.
4. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
5. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
6. Scar formation possibly causing neurolovascular compromise around nerves and/or pain.
7. Vertebral endplate injury or subsidence of the device into vertebral body(ies).
8. Bursitis, hemorrhage, hematoma, thrombus, occlusion, seroma, edema, embolism, stroke, excessive bleeding, myocardial infarction, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
9. Superficial or deep-set infection and inflammatory phenomena at the implantation site
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures also have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.
10. Soft tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
11. Neuropathy, neurological deficits (transient or permanent), monoplegia, reflex deficits, arachnoiditis, and/or muscle loss.
12. Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the dev elopment or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
13. Neurological damage (a breach of the dura mater, lesion of a spinal root) from surgical trauma
14. Delayed union(late bone fusion), Non- union(cessation of any potential growth of the fused portion of the spine or no visible fusion mass or pseudoarthrosis) or Mal-union
15. Loss of spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Change in mental status.
18. Death.
19. Bronchopulmonary disorders or development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
20. Implant migration, bending, and/or breakage may result from inadequate implantation, latent infection, premature loading of the device or trauma.
21. Damage or transformation of the product, collapse of vertebra body because of dislocation or expulsion of the implant before bone fusion, which requires another surgical procedure.
22. Damage or transformation of the product due to heavy physical exercise or pressure.
23. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
24. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
25. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the auto-graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
26. Gastrointestinal complications, Genitourinary disorders
27. Intraoperative fissure, fracture, or perforation of the spine may occur due to implantation of bone graft.
28. Graft donor site complications including pain, fracture, infection, or wound healing problems.

Other than above listed events may occur. The surgeon must warn the patient of these adverse events as deemed necessary. And when some of the events may require for additional surgical procedure.

E. WARNINGS AND CAUTIONS

1. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.
2. Do not use this product other than its indication. Cannot be inserted other than indicated area and cervical vertebrae is not allowed.
3. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.
4. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result
in premature rupture. Such reuse may also result in infection in the patient.
5. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
6. Sterilized implants have shelf life. Therefore, USE-BY DATE must be checked and never use expired implants.
7. All instruments are delivered non-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed
by the manufacturer.
8. A wrong choice of implant size may cause damage to the product and may become the reason of unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, and area of vertebral checked by X-ray.
Please refer to "the choice of implant".
9. It cannot be used with other product without validation regarding safety and effectiveness. If it is used with other product, Solco Biomedical Co.,Ltd do not take any responsibility.
10. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.

Important Product Information

11. It is important for surgeon and medical staff to be well-informed of the following information and give it to patient before the procedure, in order to be warned of the potential consequences and ensure success of the surgical implantation:
- Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished,
alcoholic, obese, or patients with muscle weakness or nerve paralysis.
- To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
- The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
- Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
- These implants do not present any known risk of interference with other medical equipment.
- Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.
1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
2. The benefit of spinal fusions utilizing any interbody fusion device has not been adequately established in patients with stable spines.
3. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are pre-requisites.
5. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
6. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor
candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion as someone who should be advised of the consequences of the fact that an increased incidence of non-union has been reported with such patients
7. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.
8. Non-sterilized implants must be placed on a tray for use.q
9. Never reuse the implant under any circumstances. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise
device performance and patient safety.
10. The compatibility needs to be verified before use with other product.
11. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product maybe damaged from loads due to scratches not visible with naked eyes.
12. The use of implants may interfere with the anatomical structure or physiological performance of the patient. It should be reviewed carefully about radiological diagnosis and its side effects before the procedure.
13. The 4CIS® Marlin ACIF device has not been evaluated for safety and compatibility in the MR environment. The 4CIS® Marlin ACIF device has not been tested for heating or migration in the MR environment
14. As a surgical device, The 4CIS® Marlin ACIF device is not for sale to a physician but to a surgeon.
15. CAUTION: Federal law restricts this device to sale by or on the order of a physician.

F. SURGICAL PROCEDURE
1. Pre-operative preparations
a. This Instructions for Use has to be read with the related surgical technique before use these implants.
b. Inspection and tentative assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage or preparation for the surgery.
c. Non-sterilized implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
d. All instruments are deliverednon-sterilized and therefore, must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
e. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
f. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients must be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient must understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it.
g. Patients must be advised of all above potential complications and adverse side effects as risks. For example, patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients must be advised of this fact and warned of the potential consequences.
h. The type of construct to be assembled for the case should be determined by surgeon prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
i. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the to verify that all parts and necessary instruments are present before the surgery begins.
2. The choice of Implant
a. Product's design and size must be selected by surgeon considering patient's weight, amount of exercise, and area of segment to be operated. Accurate decision to determine transplant size and operation techniques must be made by surgeon. Mistake to select wrong product may damage the product and cause unsuccessful urgery. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation. operation spot, use appropriate surgical instrument to incise skin.
b. Operation must be made by surgeon and must consider the patient's condition (Quality of bone, pathology, safety of spine).
c. This product should be inserted according to surgical technique manual and special medical literature. Then Surgeon should use proper surgical instrument according to surgical method and purpose.
d. In order to avoid damage, make sure there is enough space for inserting the implant in the intervertebral body.
e. For successful internal fusion, cage needs to be filled with bone graft. Allograft and synthetic bone graft are also available. But cancellous bone from iliac crest is most suitable.
f. If cage is not firmly connected with cage holder, it is possible to be broken.
g. The surgical approach for the cage insertion to the patient should be from anterior to posterior.
h. Do not make any modification to the device during surgery and do not exert excessive external forces when inserting the product.
i. It is advised not to move patient from surgery area until the implant and adjacent bones are fully fixed by surgical implantation.
4. Post-operative
a. The product cannot always withstand activity and load levels equal to those placed on normal and healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result. Physician and/or surgeon are required to give a notice to the patient of this information as well as temporary restrictions such as limit on physical activities and few other restrictions to avoid re-surgery due to damage of product.
b. Reprocessing implants and instruments is required after surgical use as instructed by the manufacturer. Cleaning, sterilization, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
5. Removal
a. Inserted product is united with bone graft to help growing of bone transplant. Therefore, the product should not be removed unless it has to be removed because of complication or side effect.
b. Before removing the product, risk of an additional surgery to patient and difficulty of removing the product should be considered.
c. To remove the product surgeon can use the included cage holder in the tray and an additional instrument.

G. PACKAGING
1. Non-sterilized implants and instruments are individually packed by transparent PE bag. The packing should be removed and FDA-cleared sterilization packaging materials should be used for packing before sterilization.
2. Sterilized implants are individually packed and the packing should not be damaged before usage.
3. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

H. CLEANING
In accordance with the reprocessing manual, Instrument should be cleaned and sterilized before use. Implant should not be cleaned and only non-sterilized implant should be sterilized before use. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
1. Cleaning before sterilization If the packing is not damaged, the instruments do not need to be washed. Otherwise, they must be washed with a damp gauze pad or wipe to remove all gross visible soil. The cleaning has to be done before sterilization; ultrasonic?wash with water soluble neutral cleaner is advised. Cleaner's composition and cleaning method must follow by the reprocessing manual. The solution must be within pH range 6-8.
2. Avoid cleaning the product in high temperature for long period.
3. Use of corrosive object including abrasive sponges and metal brushes must be avoided.
4. Verify that the product is in operating condition without any foreign substance in them after cleaning.
5. Unacceptable cleaning agents
It is inadequate to use strong acidic or basic cleaning solution such as sulphuric acid, nitric acid, or chloric acid. Sodium hydroxide (NaOH) is also prohibited.
6. Cautions when cleaning Forbid using abrasion product or instrument. After cleaning, product's capability and condition, existence of foreign substance in implant should be checked. For this each hospital's cleaning instrument and method need to be verified.

Important Product Information

I. Drying
Surgical instrument and product should be dried without any water before sterilization.

J. STERILIZATION
All EtO sterilized implants meet pyrogen limit specifications. All non-sterilized implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. For storage before sterilization and surgery, use sterilized storage tray. To achieve a sterility assurance level of not less than 10-6, all non-sterile implants and instruments must be autoclave sterilized using the following validated cycle parameter.
- S.A.L(sterility assurance level) : 10^{-6}
- Minimum Cycle Times

The individual products are recommended to be steam sterilized by the hospital in a gravity displacement
1. For gravity-displacement steam sterilization

Item	Temperature	Exposure time	Drying Time
Wrapper instrument	132°C(270°F)	15 min	30 min
Unwrapped nonporous item	132°C(270°F)	3 min	0 min

2.For Pre-vaccuum steam sterilization

Item	Temperature	Exposure time	Drying Time
Wrapper instrument	132°C(270°F)	4 min	30 min
Unwrapped nonporous item	132°C(270°F)	3 min	N.A

* Sterilize using the clear wrap recommended by the FDA.
* EtO sterilized products are sterilized and do not need to be sterilized separately. If different sterilization method is used, verification is equired to show that the sterilization method is valid enough to be safe for usage. Depend on sterilization method, hospital should check the certification and needs to check sterilization time and temperature regularly.
If sterilization is done with paper filter, filter should be changed every time it's used. If water is remained on sterilized tray and product you need to sterilize and dry all of them again.

K.STORAGE
1. If non used product is exposed to waste, it must be sterilized and dried for storage. Product must be stored in dry room temperature and must be away from direct ray of light.
2. The product must be stored away from contact with metal or abrasive materials or corrosive environments to prevent damages such as cracks, scratches nick or notch. Also, the product maybe damaged from loads due to scratches not visible with naked eyes.

L.COMPLAINTS
If you are unsatisfied with the product or have complaints, please contact our representative. Especially if you suspect the product is having problems, please notify us immediately.
If our products have caused damage, side effect, fatal injury to patient, please contact us immediately with the provider's information via fax, telephone, or letter. For all other complaints, please provide us product catalog number, lot number, your contact information including your name and telephone number, and detailed information about problems you are having. For more information, please contact us.

SYMBOL TRANSLATION

Symbol	Description	Symbol	Description
	"DO NOT REUSE"		"MANUFACTURER"
LOT	"BATCH CODE" or "LOT NUMBER"		"DATE OF MANUFACTURE"
REF	"CATALOGUE NUMBER"		"WARNING"
	"NON STERILE"		"CAUTION, CONSULT ACCOMPANYING DOCUMENT"
Mat :	"MATERIAL"	QTY	"QUANTITY"
	"CONSULT INSTRUCTIONS FOR USE"	EC REP	"AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	"USE-BY DATE"		"KEEP AWAY FROM SUNLIGHT"
CE	"ALLOWED BUSINESS ACTIVITY IN EEA"		"METHOD OF STERILIZATION USING STEAM OR DRY HEAT"
	"DO NOT USE IF PACKAGE IS DAMAGED"		"KEEP DRY"
	"UPPER LIMIT OF TEMPERATURE"	Rx only	"PRESCRIPTION ONLY"
	Sterilized using ethylene oxide		

CT-A-001-0401 MFG:07/2019 REV:4

4CIS® Marlin

Anterior Cervical Interbody Fusion
Cage System

FIRST GOLD CORP.

http://fgsolco.com/

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