Alamo C

Part Numbers	Description
1412I-005	14mm x 12mm x 5mm x 0° Alamo C
1412I-006	14mm x 12mm x 6mm x 0° Alamo C
1412I-007	14mm x 12mm x 7mm x 0° Alamo C
1412I-008	14mm x 12mm x 8mm x 0° Alamo C
1412I-009	14mm x 12mm x 9mm x 0° Alamo C
1412I-010	14mm x 12mm x 10mm x 0° Alamo C
1412I-011	14mm x 12mm x 11mm x 0° Alamo C
1412I-012	14mm x 12mm x 12mm x 0° Alamo C

Part Numbers	Description
1714I-705	17mm X 14mm X 5mm X 7° Alamo C
1714I-706	17mm X 14mm X 6mm X 7° Alamo C
1714I-707	17mm X 14mm X 7mm X 7° Alamo C
1714I-708	17mm X 14mm X 8mm X 7° Alamo C
1714I-709	17mm X 14mm X 9mm X 7° Alamo C
1714I-710	17mm X 14mm X 10mm X 7° Alamo C
1714I-711	17mm X 14mm X 11mm X 7° Alamo C
1714I-712	17mm X 14mm X 12mm X 7° Alamo C

Part Numbers	Description
1412I-705	14mm x 12mm x 5mm x 7° Alamo C
1412I-706	14mm x 12mm x 6mm x 7° Alamo C
1412I-707	14mm x 12mm x 7mm x 7° Alamo C
1412I-708	14mm x 12mm x 8mm x 7° Alamo C
1412I-709	14mm x 12mm x 9mm x 7° Alamo C
1412I-710	14mm x 12mm x 10mm x 7° Alamo C
1412I-711	14mm x 12mm x 11mm x 7° Alamo C
1412I-712	14mm x 12mm x 12mm x 7° Alamo C

Part Numbers	Description
2016I-005	20mm X 16mm X 5mm X 0° Alamo C
2016I-006	20mm X 16mm X 6mm X 0° Alamo C
2016I-007	20mm X 16mm X 7mm X 0° Alamo C
2016I-008	20mm X 16mm X 8mm X 0° Alamo C
2016I-009	20mm X 16mm X 9mm X 0° Alamo C
2016I-010	20mm X 16mm X 10mm X 0° Alamo C
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Part Numbers	Description
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2016I-711	20mm X 16mm X 11mm X 7° Alamo C
2016I-712	20mm X 16mm X 12mm X 7° Alamo C

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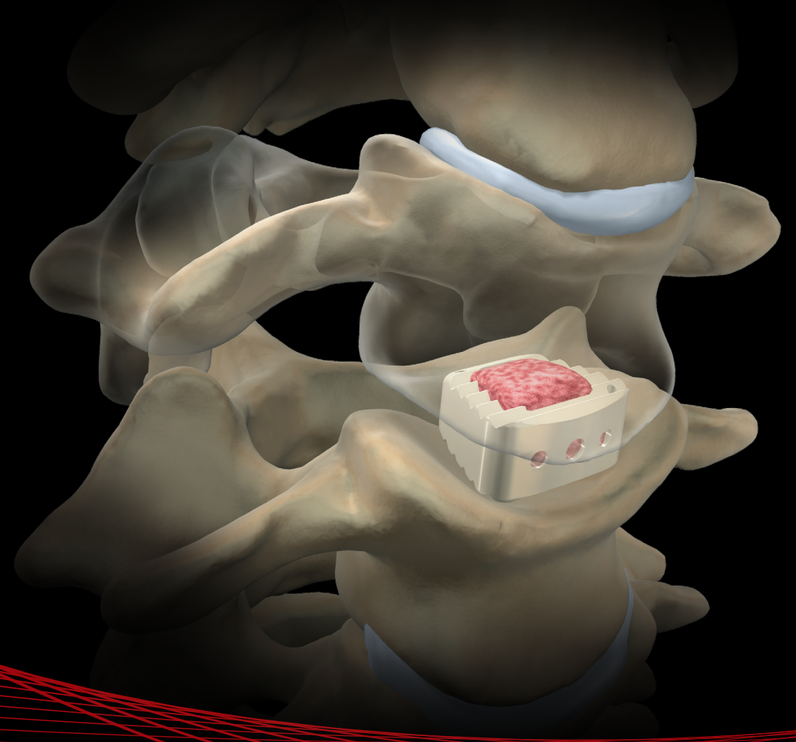
MKT-100 Rev. F

Alamo C



Cervical Interbody System
Surgical Technique

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Alamo C

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Table of Contents

Indications for Use:

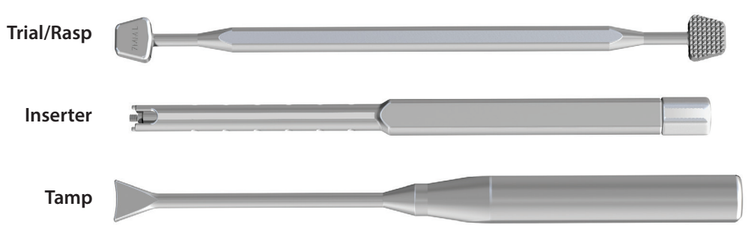
The Alamo C is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with an intervertebral cage. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via an open, anterior approach.

Device Description:

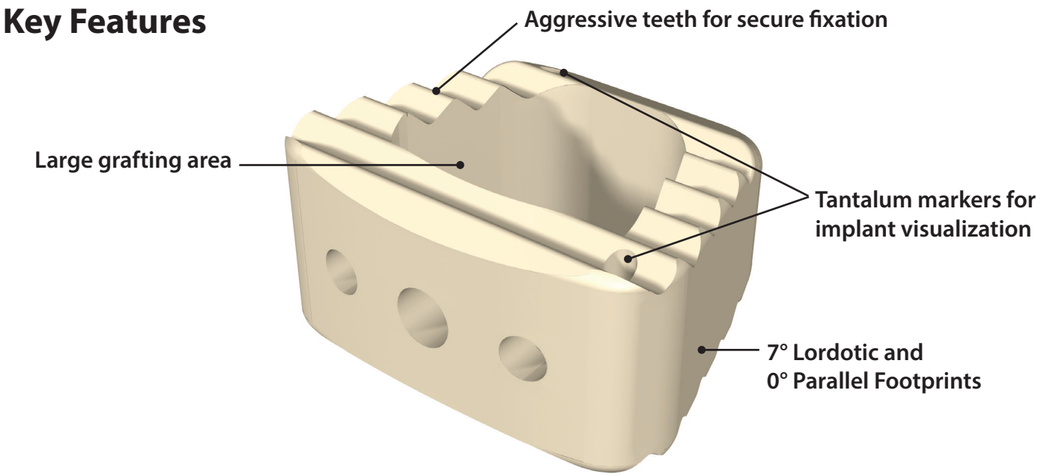
The Alamo C is designed for use as a cervical intervertebral body fusion device. The device is manufactured from PEEK Optima® LT1 per ASTM F2026 and includes tantalum markers per ASTM F560 for radiographic visualization.

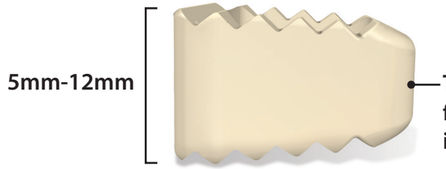
The profile of the device is rectangular with a hollow core for bone graft to promote bone integration and fusion between the endplates. The device is available in various heights to accommodate variability among patients and the inferior and superior surfaces are designed with teeth to prevent back out and migration.

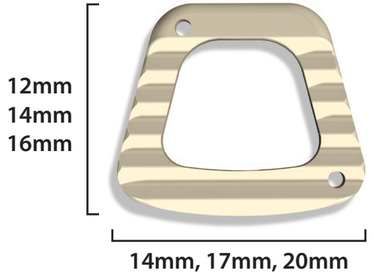
Instruments

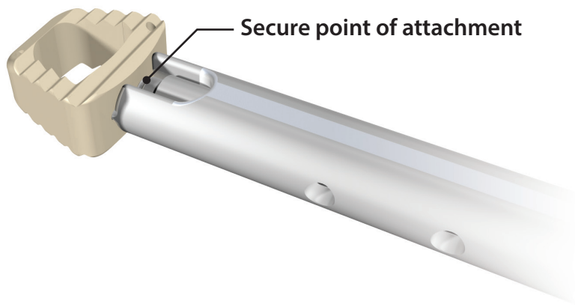


Key Features









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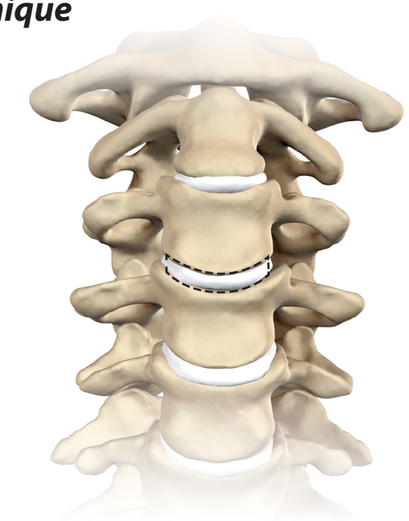
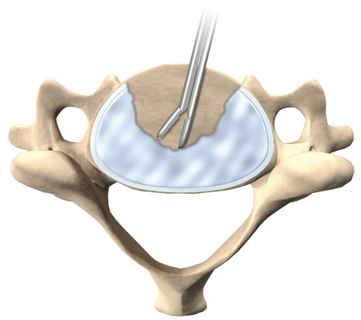
Alamo C
Cervical Interbody System
Surgical Technique



Step 1: Preoperative Planning
The appropriate Alamo C height should be estimated prior to surgery. In order to achieve maximal segment stability, it is essential to choose the largest possible implant that can be safely inserted without disturbing the surrounding neural elements.

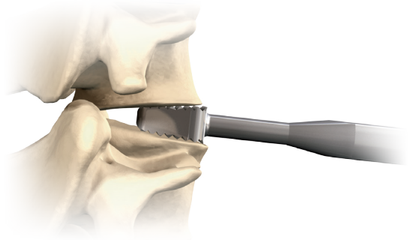
Step 2: Creating Disc Space Access
Patient is placed in the supine position. The anterior cervical spine is exposed via the standard surgical approach.



Step 3: Disc Space Preparation
Perform a standard discectomy using instrumentation for an anterior cervical discectomy and fusion procedure.

Using the Rasp end of the Double Ended Trial/Rasp for the estimated device height, scrape the cartilaginous layers from the surface of the adjacent vertebral end plates until bleeding bone is attained.

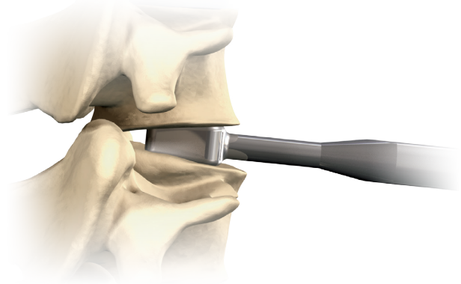
Sufficient cleaning of the end plates is important for vascular supply to the bone graft. However, excessive cleaning may result in the removal of bone underlying the cartilaginous layers and weaken the end plates.



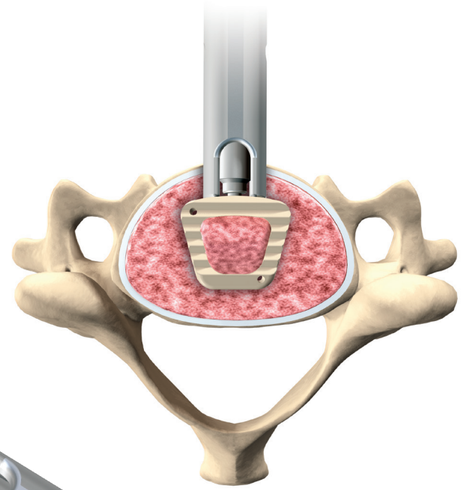
Step 4: Device Height Determination
Select the trial that corresponds to the preoperative estimated height and best matches the prepared end plates. Each trial has a height and lordotic or parallel indicator.

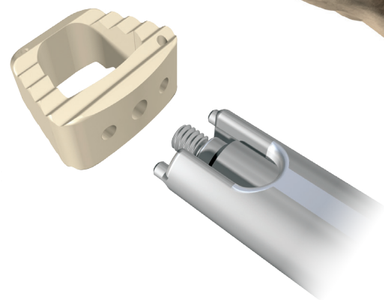
Insert the trial into the disc space. Apply gentle impaction and ensure that the trial fits tightly and accurately between the end plates.

Using the largest possible device maximizes segment stability through the tension in the longitudinal ligament and annulous fibrosus.



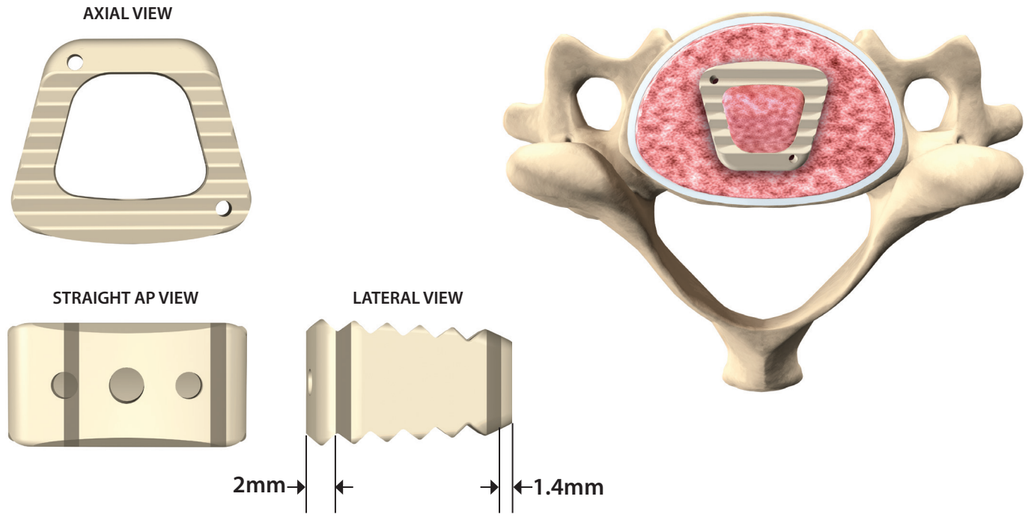
Step 5: Device Insertion
Select the implant that corresponds to the trial. Attach the implant to the inserter by aligning the lateral pins with the flat surface of the implant and turning the handle to expose the internal threaded shaft. The threaded tip will engage with the central thread of the implant for secure attachment. Pack the grafting area of the implant with autologous bone graft. Insert the implant into the prepared intervertebral space. Gentle impaction on the inserter will assist in correct positioning. Release the inserter by turning the handle counter-clockwise to disengage from the implant. If additional positioning is required, the Tamp may be used with a mallet to move the implant to the desired location.





Step 6: Verifying Implant Placement

Remove all instruments and verify the optimal position using fluoroscopy. The diagrams below demonstrate the location of the X-ray markers as the view is rotated from a lateral to anteroposterior (AP) view.



Step 7: Supplemental Fixation

Use of a FDA cleared anterior cervical plate is required for supplemental fixation with this device.

Step 8: Removal or Revision

The device can be removed by breaking the fused bone/device interface with a cutting tool such as an Osteotome or Chisel. Once the device is loose, attach the inserter and pull the device from the disc space. If additional force is required, a strong forceps instrument such as Kocher forceps or a hemostat can be used to retrieve the device.

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Precautions:

Only patients that meet the criteria described in the indications should be selected and the implantation of the interbody fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions which may impact the performance of the system.

Care should be taken in the handling and storage of the implant. The implants should not be scratched, notched or damaged during surgery. Alterations will produce defects in surface finish and internal stresses, which may become the focal point for eventual breakage of the implant.

The Alamo C has not been evaluated for safety and compatibility in the MR environment.
The Alamo C has not been tested for heating or migration in the MR environment.

The use of dissimilar metals is prohibited as rapid corrosion can occur. Components of this system should not be used with components of any other system or manufacturer.

Contraindications:

Contraindications include, but are not limited to:

1. Any case where there is active systemic infection, infection localized to the site of the proposed implantation
2. A patient with rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication because it may limit the amount of fixation and thus preclude the use of this or any other spinal instrumentation system
3. A patient that does not meet the criteria described in the indications
4. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
5. An overweight or obese patient as these patients can produce additional loads on the device that can cause failure of the device or subsidence
6. Any patient that is non-compliant with post-operative instructions
7. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used
8. Pregnancy
9. Signs of local inflammation
10. Fever or leukocytosis
11. Any case where the patient's occupation, activity level, or lifestyle can place undue stress on the implant that leads to failure. Specifically patients with mental illness, alcoholism, or drug abuse

Potential Adverse Effects:

Possible adverse events or complications include, but are not limited to:

1. Bone loss or decrease in bone density due to stress shielding
2. Non-union (pseudoarthrosis), delayed union
3. Bending and/or breakage of the implant
4. Posterior or anterior implant migration and/or subsidence
5. Allergy or foreign body sensitivity to any of the implant material
6. Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of the implant 7.

Infection

8. Pain, discomfort, or abnormal sensations due to the presence of the device
9. Post-operative change in spinal curvature, loss of correction, height and/or reduction
10. Loss of neurological function including complete or incomplete paralysis, dysesthesia, hyperesthesia, paraesthesia, appearance or radiculopathy
11. Death
12. Erosion of blood vessels due to the proximity of the device leading to hemorrhage and/or death

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSCIAN.
Please refer to the Instructions For Use included with the product for complete instructions, indications, contraindications, and warnings.