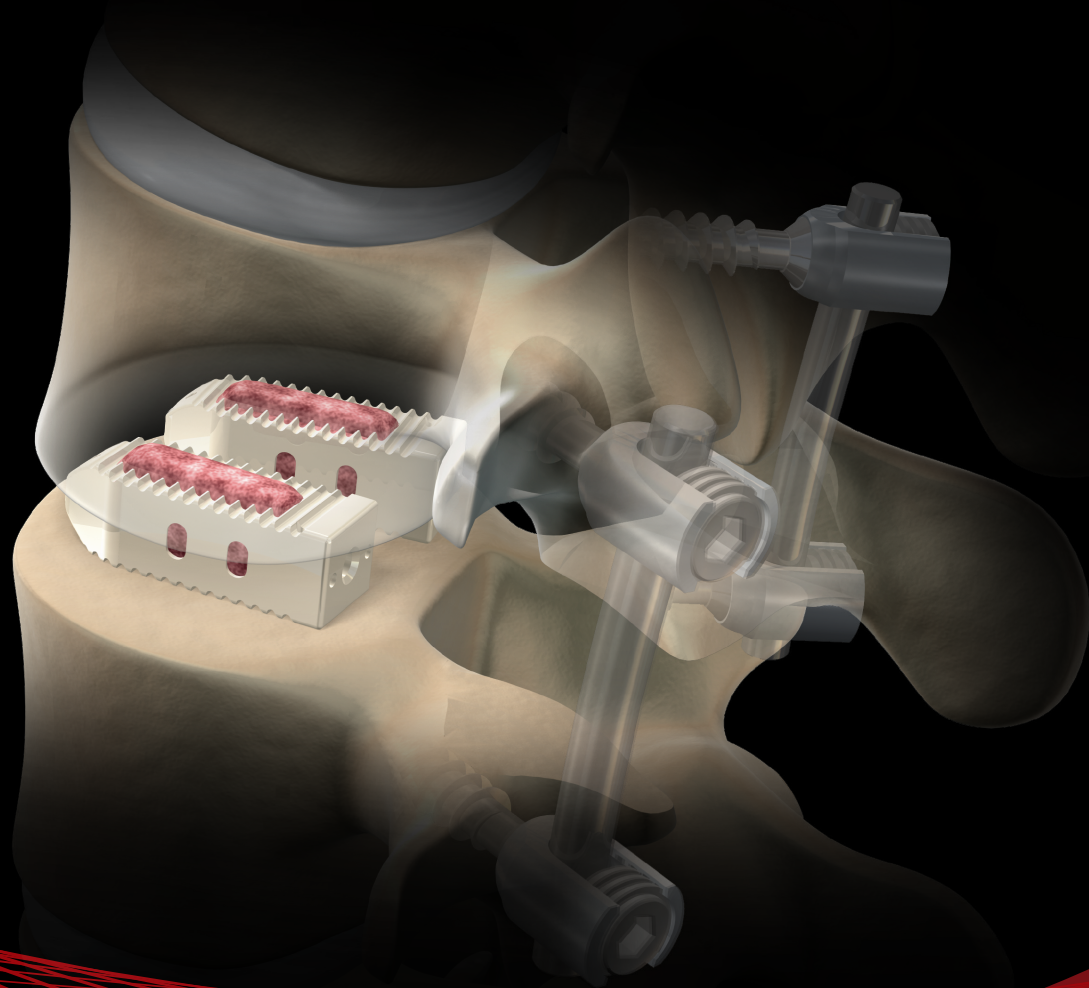


Alamo[®] P



*Posterior Lumbar Interbody System
Surgical Technique*



AllianceSpine[™]

Inspiring Solutions Through Innovation

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Indications for Use:

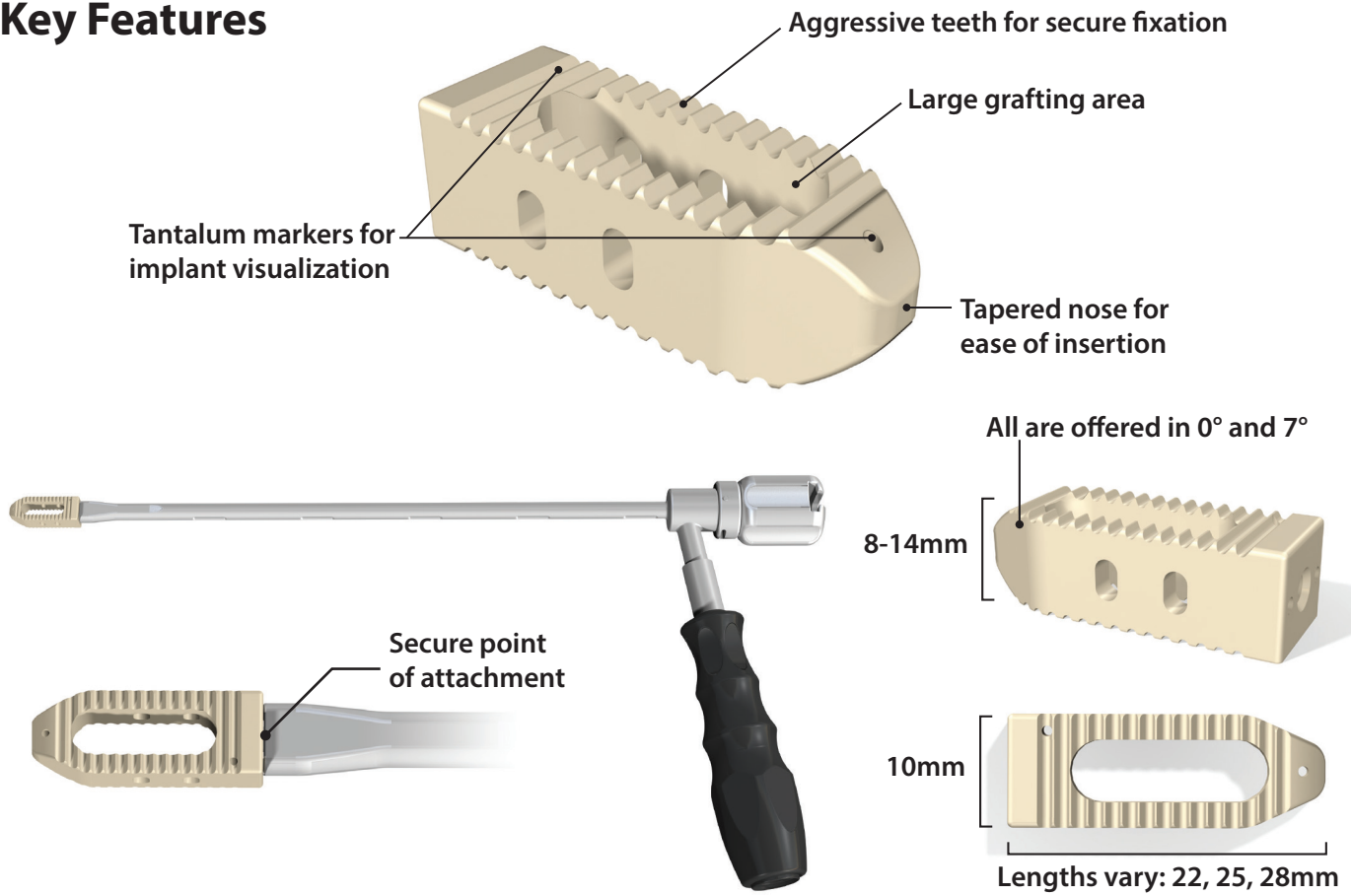
The Alamo[®] P is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral cage. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is to be implanted via a posterior approach.

Device Description:

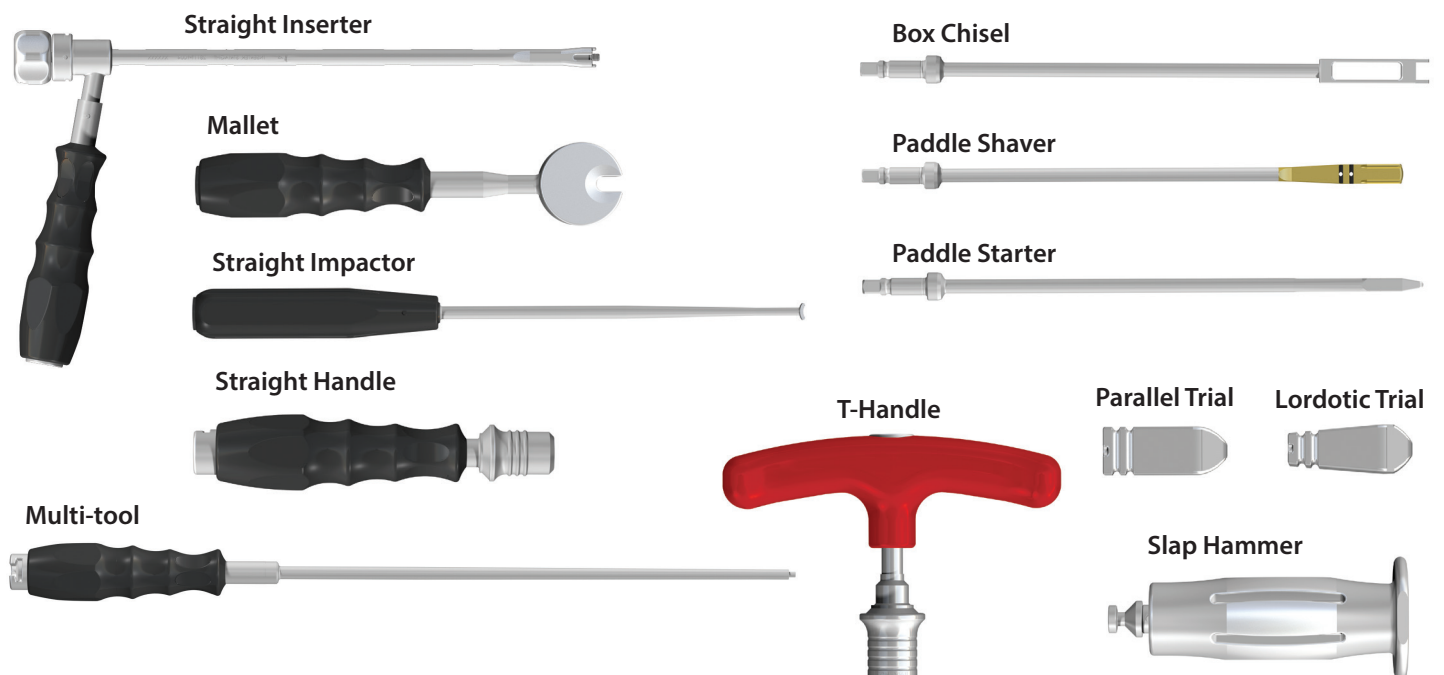
The Alamo[®] P is used for spinal fusion surgery to provide support and structural stability at the fusion site following discectomy. The device is manufactured from PEEK Optima[®] LT1 per ASTM F2026 and includes tantalum markers per ASTM F560 for radiographic visualization.

The device footprint has a hollow centre to accommodate bone graft and is implanted via a posterior (PLIF) surgical approach. The device is available in various heights to accommodate variability among patients and the inferior and superior surfaces are designed with ridges to improve fixation and stability and prevent back out and migration.

Key Features



Instruments



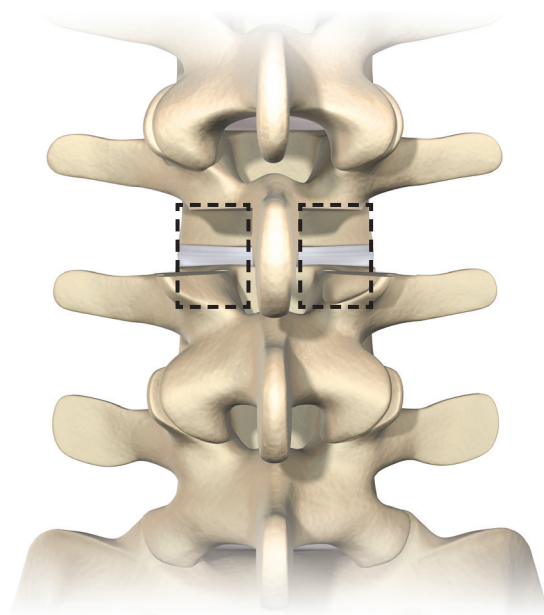
Alamo[®] P Posterior Lumbar Interbody System Surgical Technique

Step 1: Preoperative Planning

The appropriate Alamo[®] P 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.

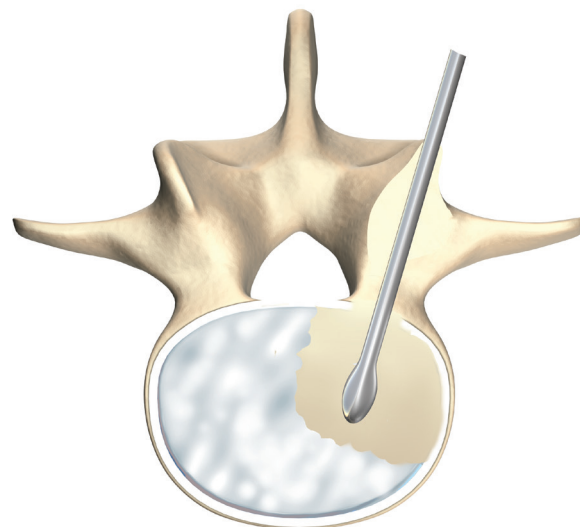
Step 2: Creating Disc Access

Patient is placed in the prone position. From the midline laterally, dissect the skin, subcutaneous tissues, and the paraspinal muscles in order to locate the spinous process, lamina, dura, facets and nerve roots at the appropriate level(s). Perform a laminotomy and carefully retract the dura to expose the disc space.



Step 3: Disc Space Preparation

Using the appropriate instruments, remove the disc material. A Box Chisel may be used to enlarge the entry and remove posterior osteophytes. Scrape the cartilaginous layers from the surface of adjacent vertebral endplates until bleeding bone is obtained. Use caution to avoid damage to the endplates.



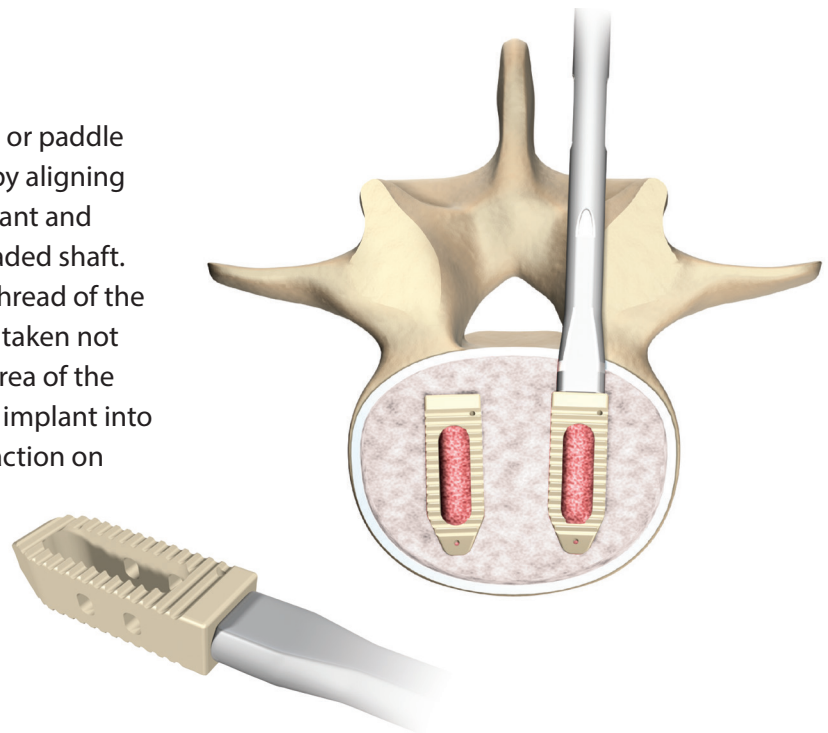
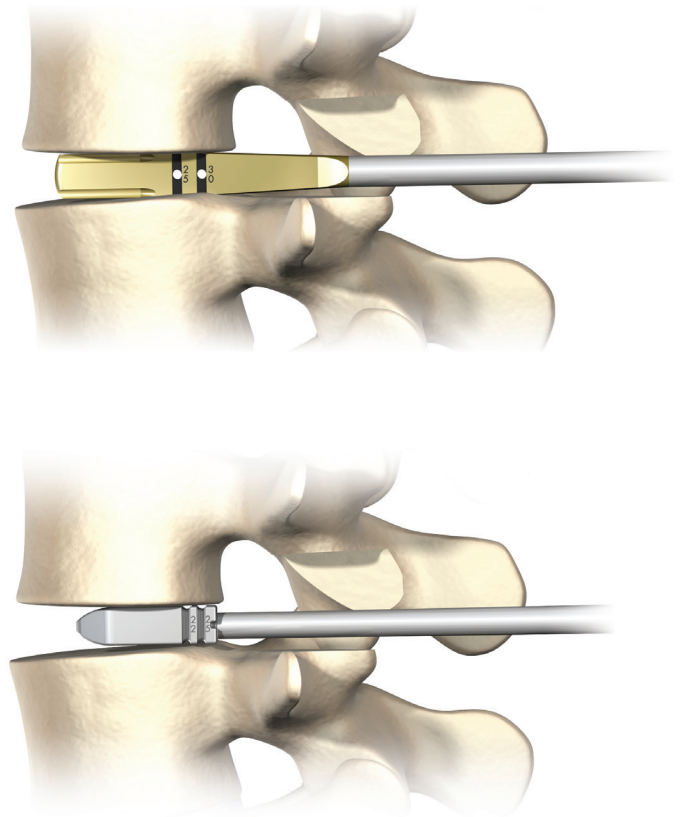
Step 4: Device Height Determination

Select the paddle shaver that corresponds to the preoperative estimated height and the prepared endplates. Holes with laser marks for depth indication are cut into the paddle shaver at 25mm and 30mm. Insert the paddle shaver into the disc space and rotate until desired height is achieved. Use caution to avoid damage to the endplates. Confirm height and position under fluoroscopy.

Select the trial that corresponds to the preoperative estimated height and paddle shaver if applicable. The 28mm trial has grooves for depth indication at 22mm and 25mm. Attach the trial to the Multi-tool or the Inserter and insert the trial into the disc space. Apply gentle impaction to ensure that the trial fits tightly and accurately between the endplates. Confirm height, depth, and position under fluoroscopy. Care must be taken to protect the nerve roots while placing paddle shavers, trials, and implants.

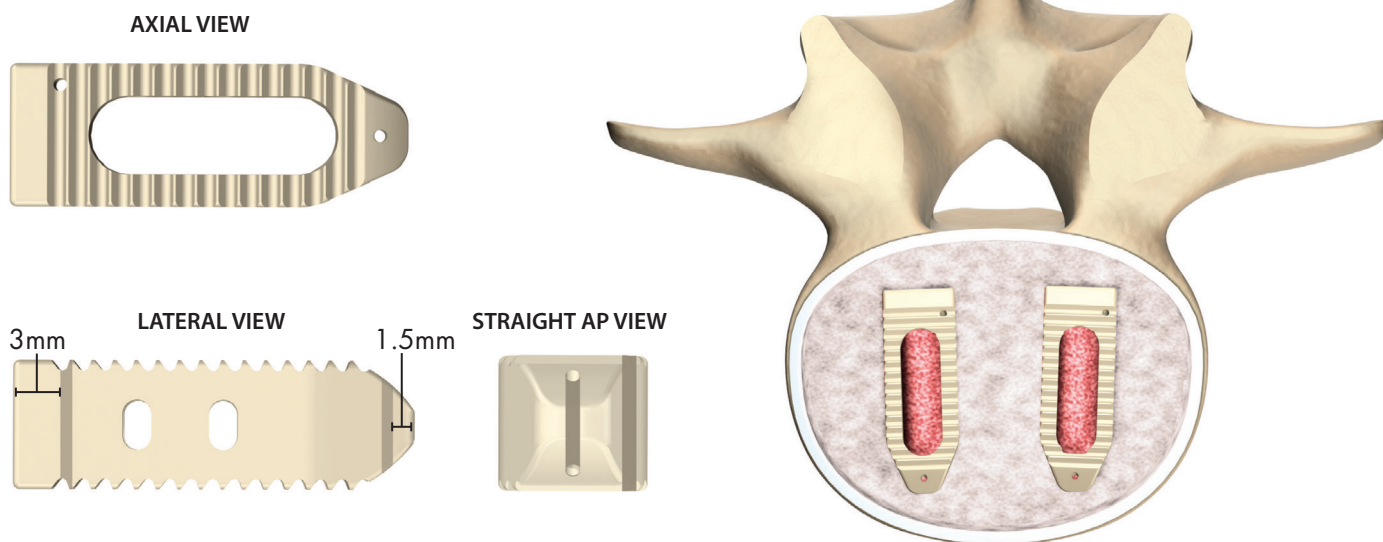
Step 5: Device Insertion

Select the implant that corresponds to the trial or paddle shaver size. 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. Care should be taken not to over tighten the inserter. 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

A FDA cleared pedicle screw system 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 assistance is required, the Slap Hammer can be used to retrieve the device.

Precautions:

Only patients that meet the criteria described in the indications should be selected and the interbody fusion device should be implanted only by experienced spinal surgeons with specific training in the use of this device due to the 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 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 the surface finish and internal stresses, which may become the focal point for eventual breakage of the implant. The Alamo® P has not been evaluated for safety, compatibility, heating, or migration in the MR environment. The use of dissimilar metals is prohibited as rapid corrosion may occur. Components of this system should not be used with components of any other system or manufacturer. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

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 and 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 the spinal implant surgery such as the presence of tumors, congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell 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 which 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.
12. Prior fusion at the level(s) to be treated.

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 and anterior implant migration and/or subsidence
5. Allergy and foreign body sensitivity to any of the implant material
6. Tissue, nerve damage, irritation, and/or pain caused by improper positioning and placement of 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 PHYSICIAN.

Please refer to the Instructions For Use included with the product for complete instructions, indications, contraindications, and warnings.

Alamo® P

Part Numbers	Description
2210I-008	22mm x 10mm x 8mm x 0° Alamo P
2210I-009	22mm x 10mm x 9mm x 0° Alamo P
2210I-010	22mm x 10mm x 10mm x 0° Alamo P
2210I-011	22mm x 10mm x 11mm x 0° Alamo P
2210I-012	22mm x 10mm x 12mm x 0° Alamo P
2210I-013	22mm x 10mm x 13mm x 0° Alamo P
2210I-014	22mm x 10mm x 14mm x 0° Alamo P

Part Numbers	Description
2210I-709	22mm x 10mm x 9mm x 7° Alamo P
2210I-710	22mm x 10mm x 10mm x 7° Alamo P
2210I-711	22mm x 10mm x 11mm x 7° Alamo P
2210I-712	22mm x 10mm x 12mm x 7° Alamo P
2210I-713	22mm x 10mm x 13mm x 7° Alamo P
2210I-714	22mm x 10mm x 14mm x 7° Alamo P

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Part Numbers	Description
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2810I-714	28mm x 10mm x 14mm x 7° Alamo P



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