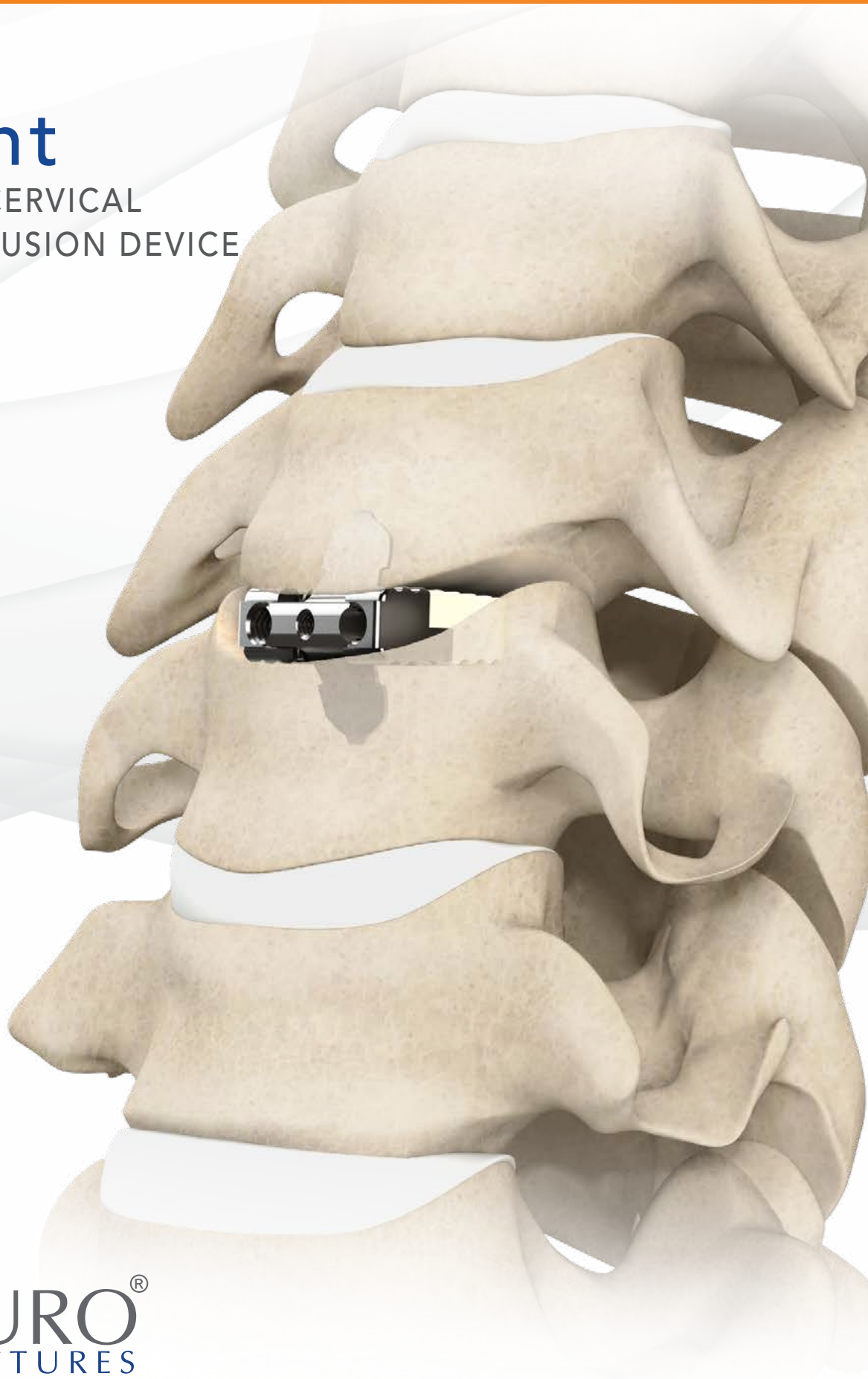
Trident

ANCHORED CERVICAL INTERBODY FUSION DEVICE



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Surgical Technique Guide

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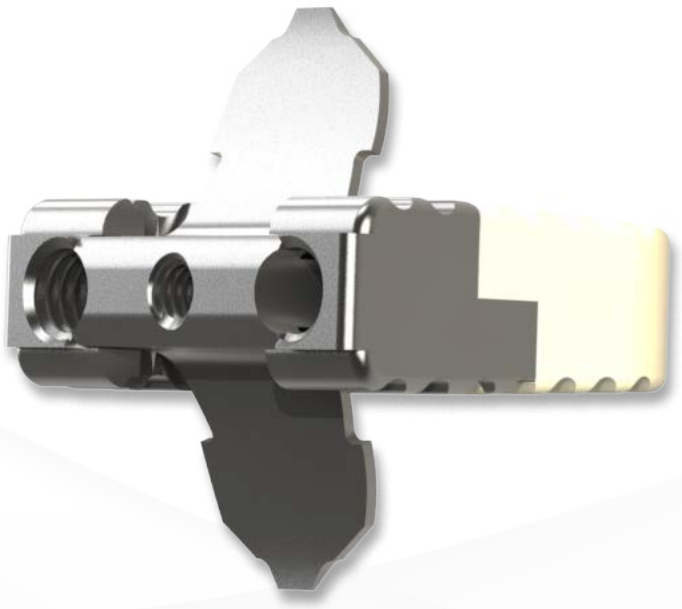


Overview

Trident Anchored Cervical Interbody Fusion device or Trident (ACI) is a novel cervical product.

Looking at the current medical device market we realized that other leading products in this segment had distinct drawbacks. So Trident was developed to meet all the same clinical needs while removing the major drawback of removability. The Trident ACI is easy to implant and can be easily removed, if necessary.

Trident is a cervical implant with an integrated anchor. The device is to be used with supplemental fixation, i.e. an anterior cervical plate. The implant is titanium with a PEEK radiolucent spacer and has an anchor component.

System Features

- One Tool & One Step Deployment
- Anchor is Retractable for Easy Implant Removal
- Zero Profile Construct
- PEEK Spacer Provides Modulus of Elasticity Similar to Bone
- Provides Adequate Space for Autogenous Bone Graft
- No Additional Locking Components Required
- Available in Full Titanium

Implant Geometry

- Implant Made of Titanium with PEEK Radiolucent Spacer
- Tantalum Radiopaque Markers per ASTM F560
- Anchor is Made of Titanium
- Implant is Offered in a 5° Lordotic Profile

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 warnings.

Indications for Use

The Trident Anchored Cervical Interbody Fusion device (ACI) has been cleared under the OVE product classification – Intervertebral Fusion Device with Integrated Fixation, Cervical.

Trident Anchored Cervical Interbody Fusion device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Product Features

Footprints: 12 x 14mm and 14 x 16mm

Heights: 5mm through 10mm, 1mm increments

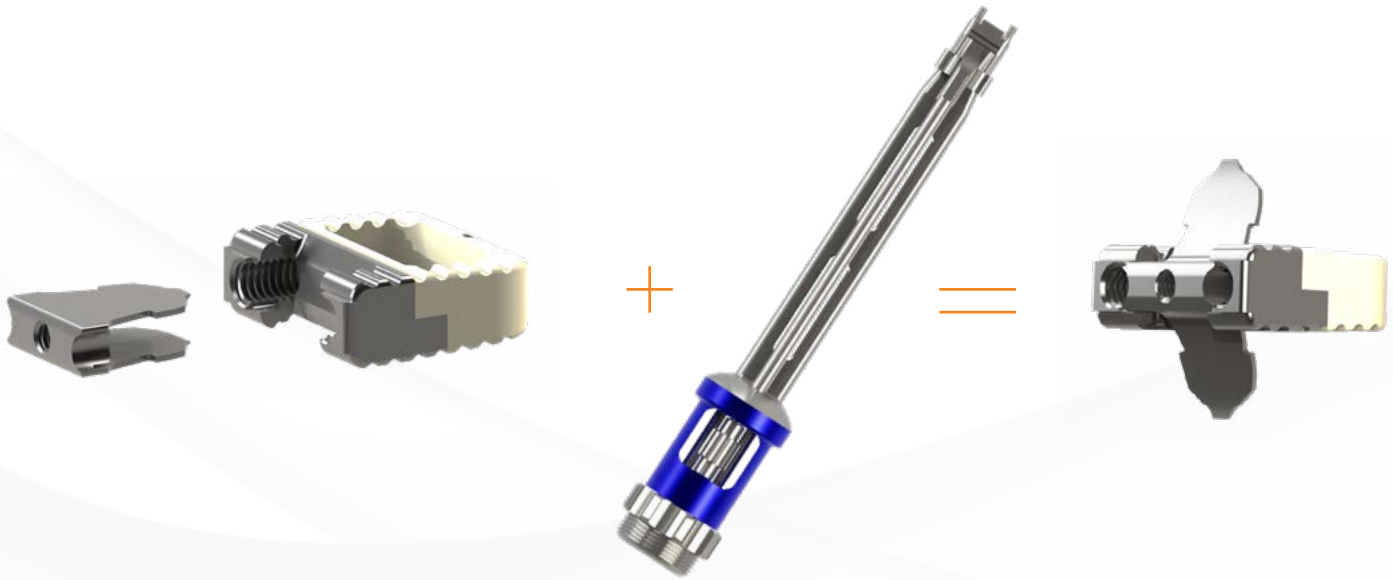
Lordosis: 5°

Anchors: Short and Long

Packaging: Gamma sterilized, pre-packaged Implants and Anchors packaged separately

Marking: **Implant** | Product marked with catalog number, footprint, lot number, lordosis and height

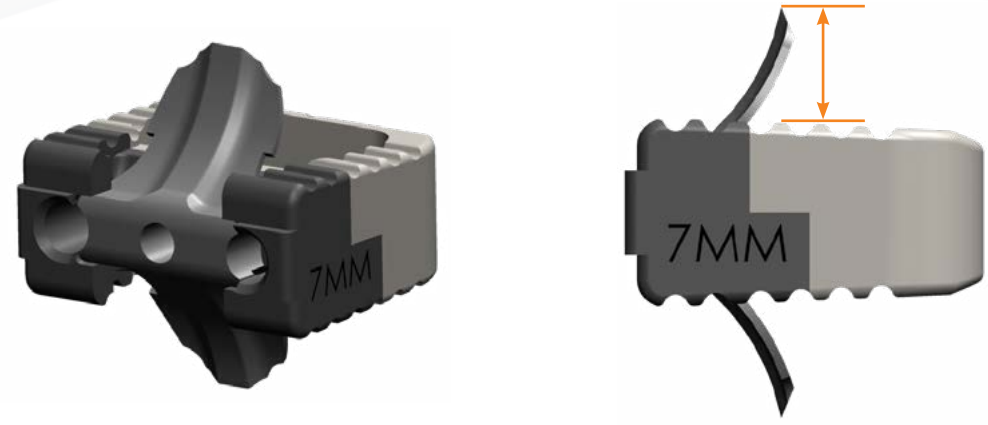
Anchor | Product marked with catalog number and lot number



1 ANCHOR SELECTION

The Trident Anchored Cervical Interbody system comes with short and long anchors. All anchor sizes are packaged separately from the implants.

Implant Height (mm)	5	6	7	8	9	10
Anchor Size	22-9211-SHORT			22-9212-LONG		
Anchor Height (mm)	5.5	5.0	4.5	5.5	5.0	4.5

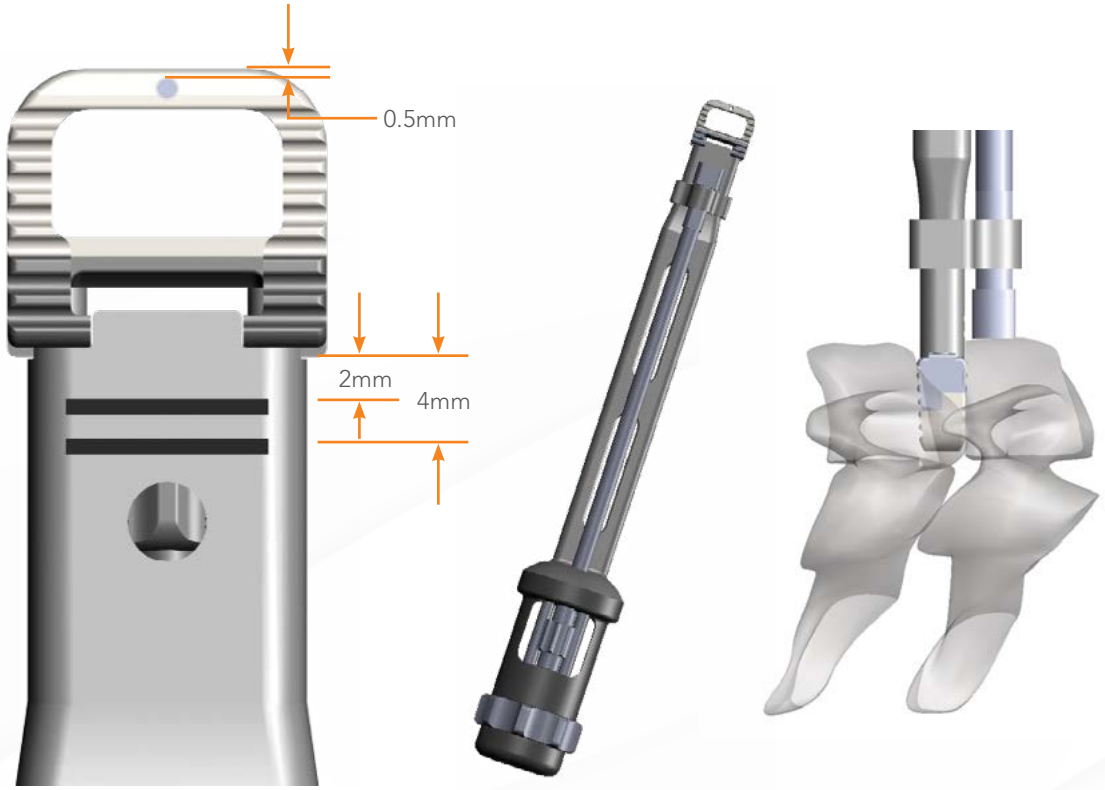


2 IMPLANT PREPARATION

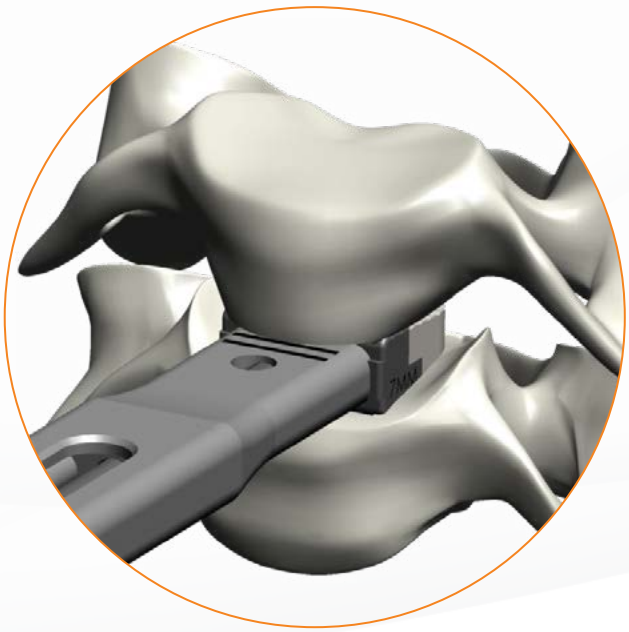
Assemble implant and anchor to inserter by turning geared ring

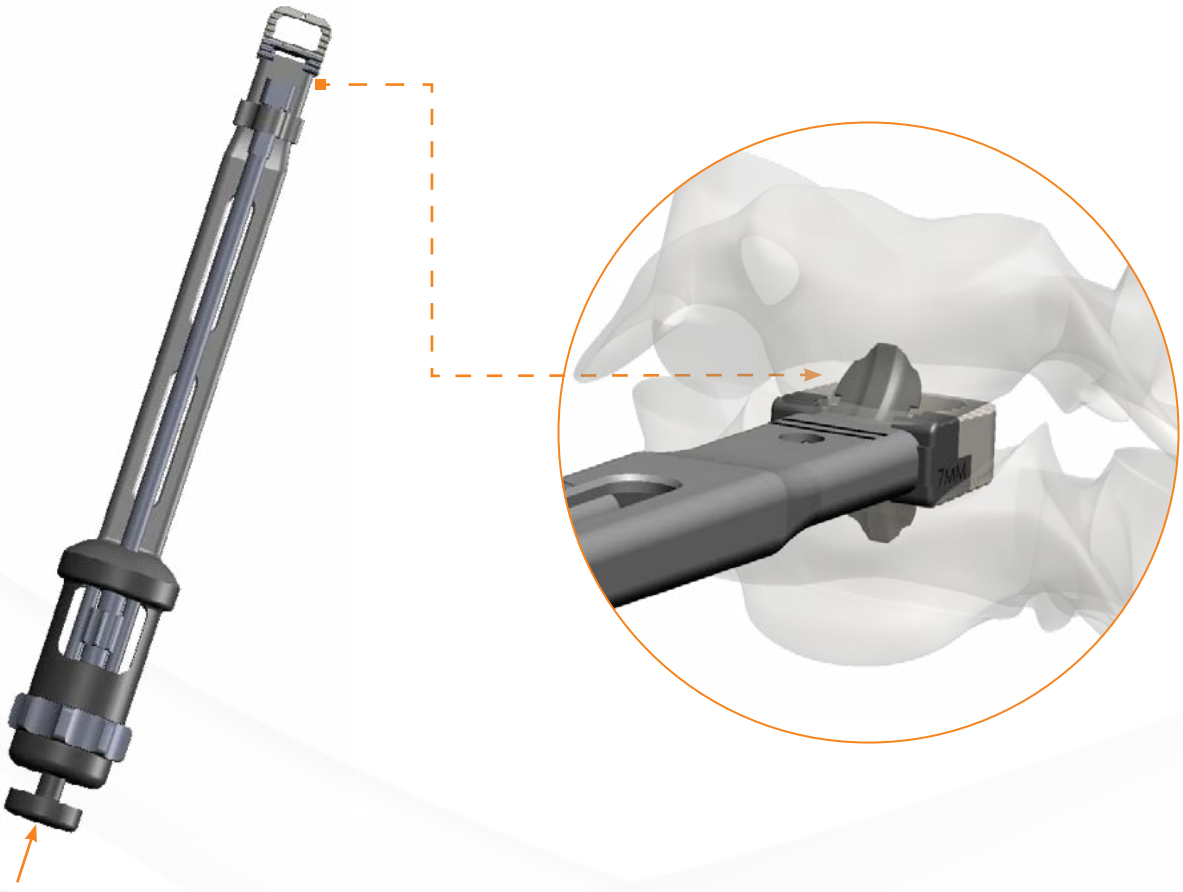
Pack cage with autogenous bone graft

Tamp implant into position



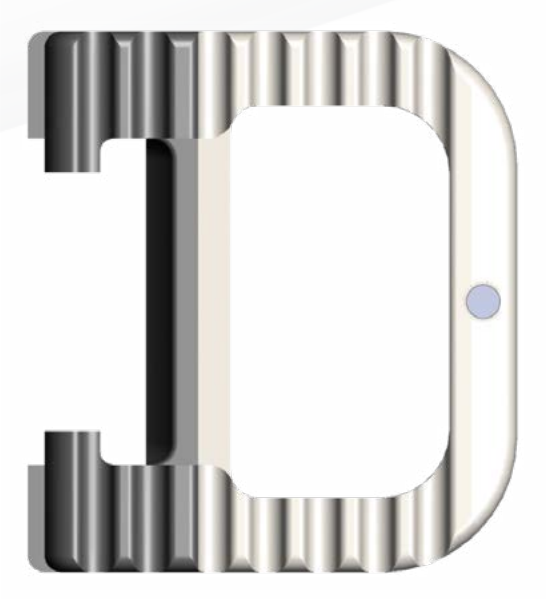
3 ANCHOR BLADE DEPLOYMENT

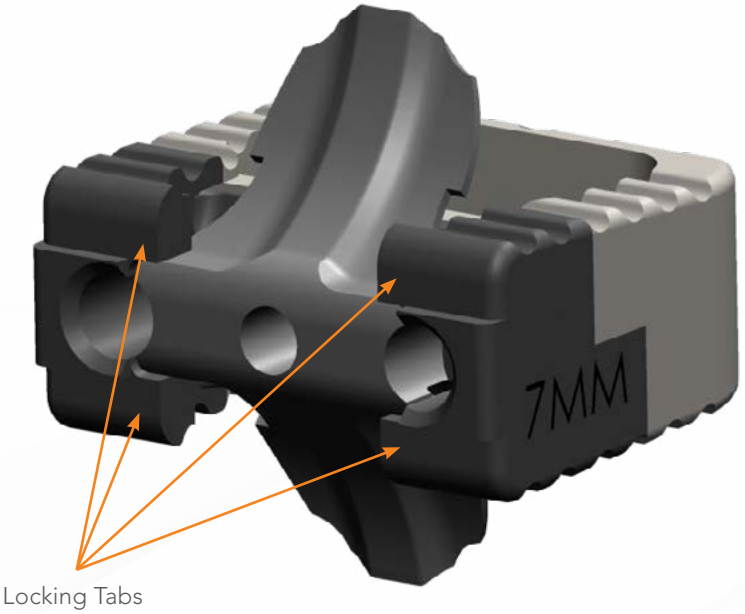




4 IMPLANT LOCKING

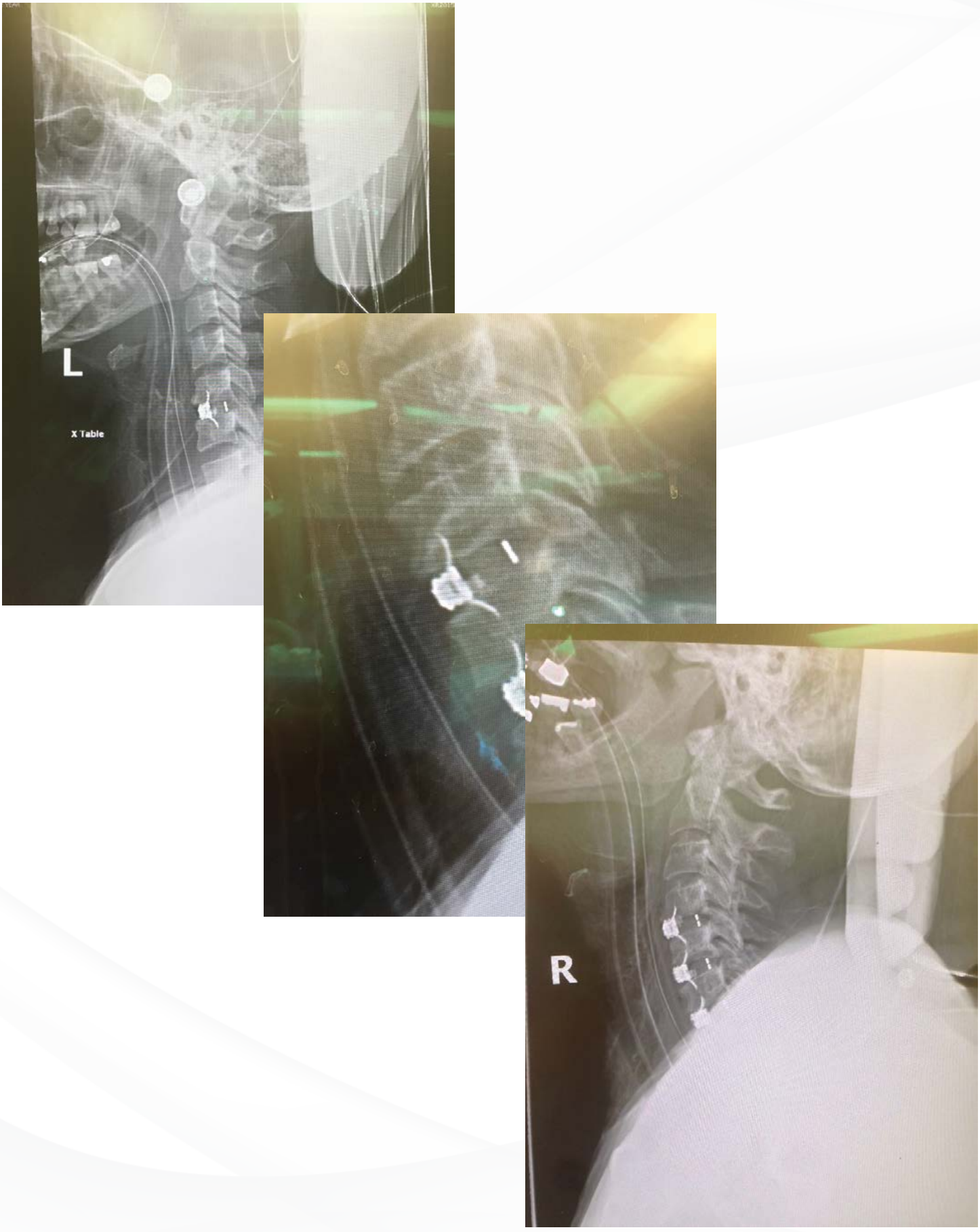
Once deployed, the anchor locks to the implant. The anchor blades are directed under the locking lugs on the implant and due to the plastic deformation of the blades no additional locking components or steps are necessary.





Locking Tabs

5 X-RAY IMAGES



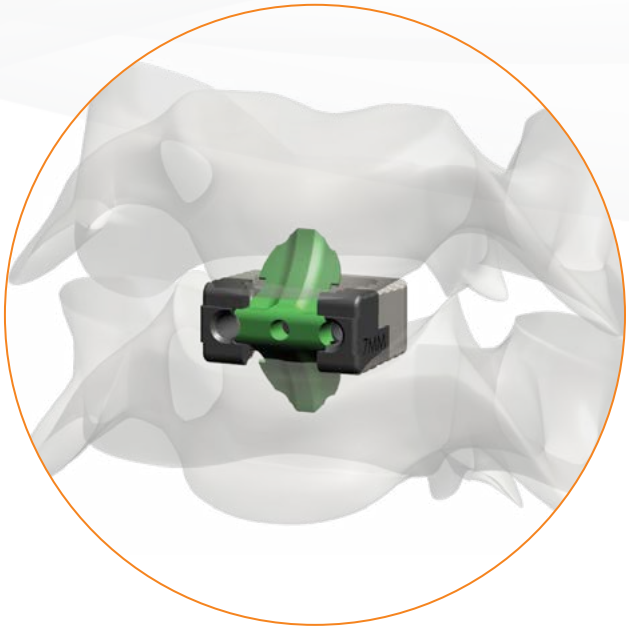
6 REMOVAL

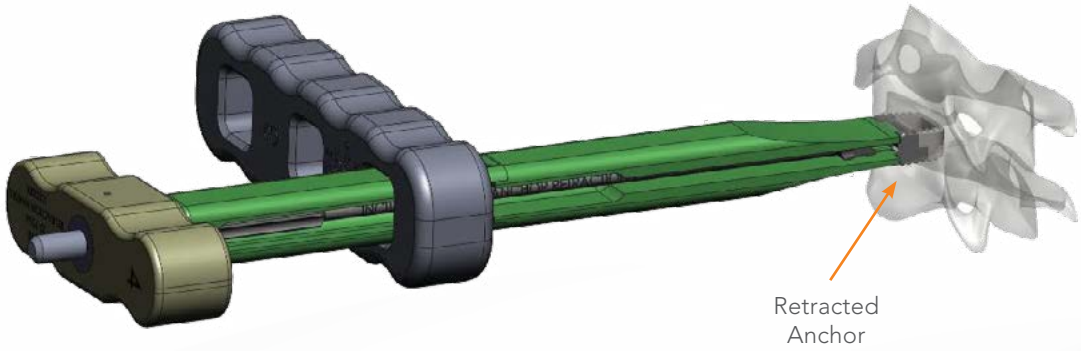
Use of Retraction Tools

Set of tools that assemble in-situ

Give the ability to easily remove the anchor and implant, if desired

Works intra-and post-operatively





7 COMPETITIVE PRODUCTS

Screw-Based Devices | Disadvantages

Multi-step implantation

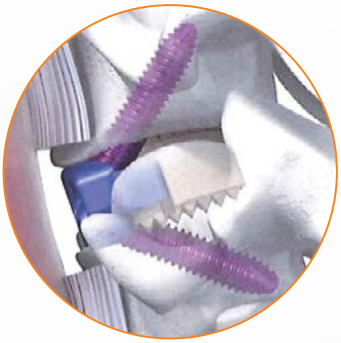
Large, oblique access needed at implantation site

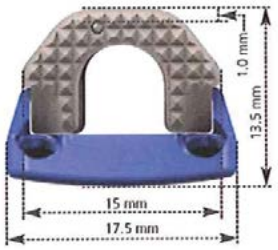
Screw loosening

Globus Medical
Coalition

K2m
Chesapeake (all Ti)

Synthes/JNJ
Zero-P

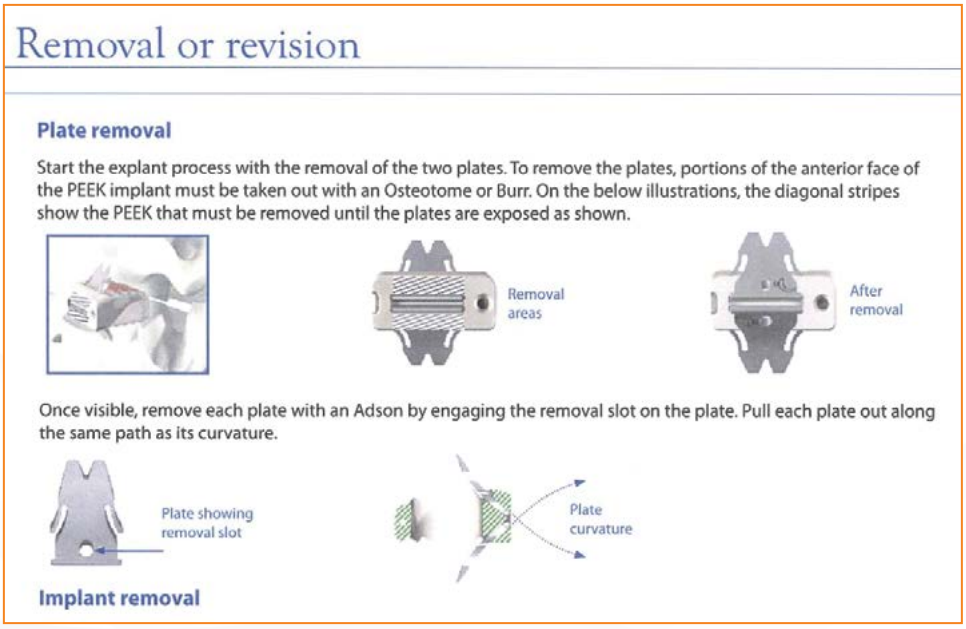




Non screw-based devices (LDR) | Disadvantages

Multi-step implantation, must load 2nd blade and use two tamps

No ability to retract the anchor blades -must remove PEEK material with high-speed burr & then pull each blade out (see below)



Removal or revision

Plate removal

Start the explant process with the removal of the two plates. To remove the plates, portions of the anterior face of the PEEK implant must be taken out with an Osteotome or Burr. On the below illustrations, the diagonal stripes show the PEEK that must be removed until the plates are exposed as shown.

Removal areas

After removal

Once visible, remove each plate with an Adson by engaging the removal slot on the plate. Pull each plate out along the same path as its curvature.

Plate showing removal slot

Plate curvature

Implant removal

8 CLINICAL EXPERIENCE

Product cleared through 510k for sale in US Market

K122008

K130306

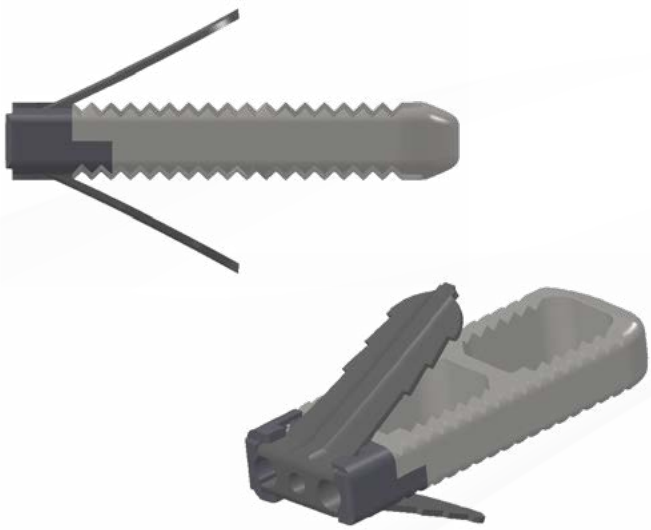
Device currently being sold in US through several distribution channels

Trident ACI device has been successfully implanted in over 3000 patients

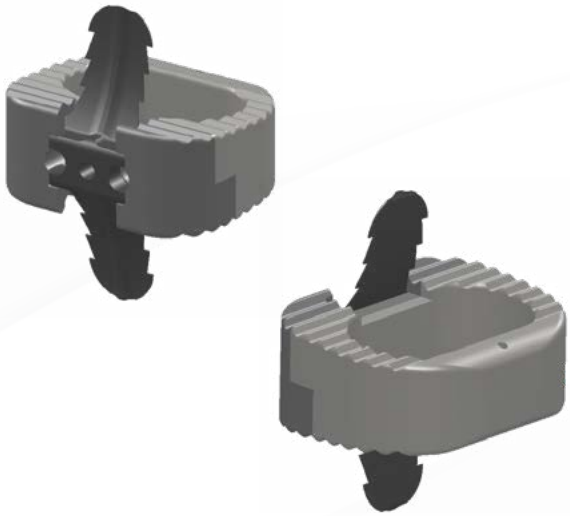
Technology is subject of granted US Patent 8,460,388 and covers multiple spinal approaches (i.e.–cervical & lumbar, anterior, lateral, posterior)

9 FUTURE PRODUCT EXTENSIONS

Since US Patent does cover multiple spinal approaches, Pantheon Surgical has completed limited modeling and prototyping of devices for additional approaches:



Anchored lateral Device



Anchored ALIF Device

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