OSSEUS

SURGICAL TECHNIQUE GUIDE 2017

RED · RUBY

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OSSEUS

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Disclaimer:
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.

FEATURES & BENEFITS

SYSTEM FEATURES:

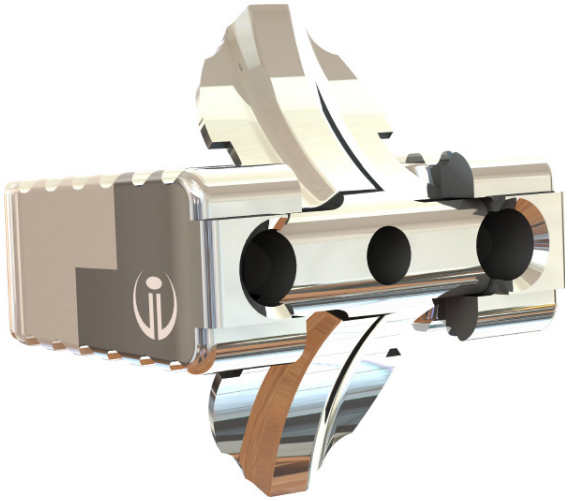
- Single step implantation
- Anchor is retractable for easy implant removal
- Zero profile construct
- PEEK Optima® LT1 spacer provides modulus of elasticity similar to bone
- Provides adequate space for autogenous bone graft

PRODUCT DESCRIPTION:

The Red Ruby Anchored Cervical Interbody Fusion Device (ACI) 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.

IMPLANT GEOMETRY:

- Implant made of Titanium with PEEK Optima® LT1 radiolucent spacer
- Tantalum radiopaque markers per ASTM F560
- Anchor is made of Titanium
- Implant is offered in 5, 6, 7, 8, 9 and 10mm heights
- Implant is offered in a 5° lordotic profile
- Footprint: 14mm depth x 16mm width
- Implant and Anchor are sterile packaged seperately



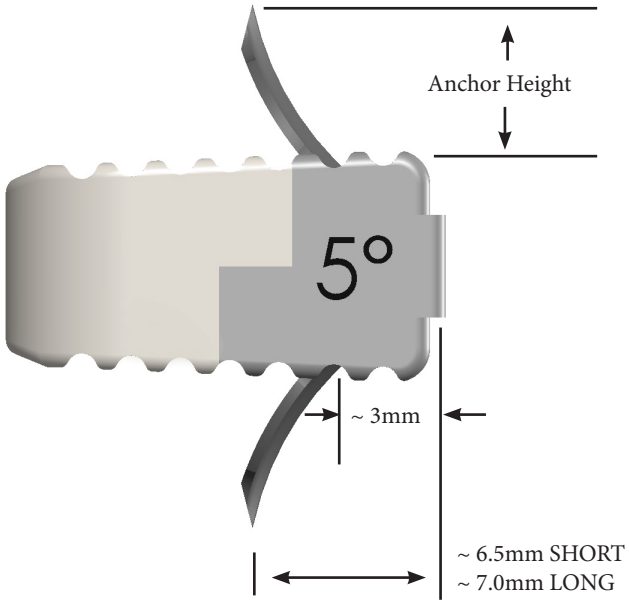
FEATURES & BENEFITS

MATERIALS:

- Spacer: PEEK Optima® LT1 (polyetheretherketone)
- Ramp: 6AL-4V ELI Titanium
- Markers: Tantalum per ASTM F560
- Anchor: 6AL-4V ELI Titanium

IMPLANT SPECIFICATIONS:

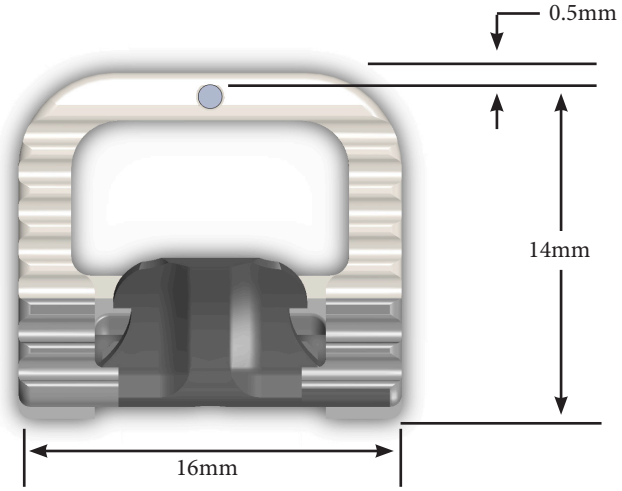
Implant Height (mm)	Graft Volume (cc)
5	.40
6	.48
7	.55
8	.62
9	.70
10	.77



ANCHOR SPECIFICATIONS:

Implant Height (mm)	**5**	**6**	**7**	**8**	**9**	**10**
Anchor Size	Short			Long		
Anchor Height (mm)	5.5	5.0	4.5	5.5	5.0	4.5

Note: It is at the surgeon's discretion which anchor is chosen for a given implant height.



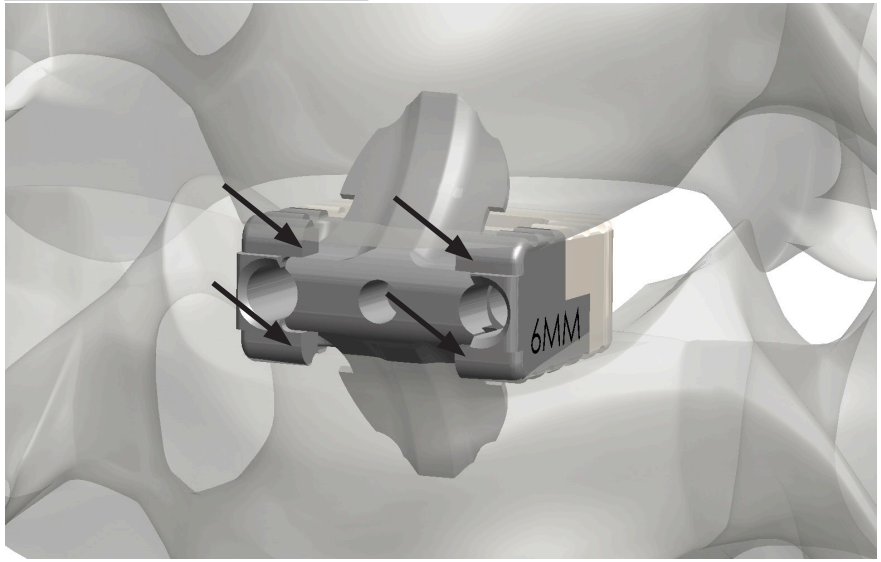
FEATURES & BENEFITS

ANCHOR BLADE DEPLOYMENT:

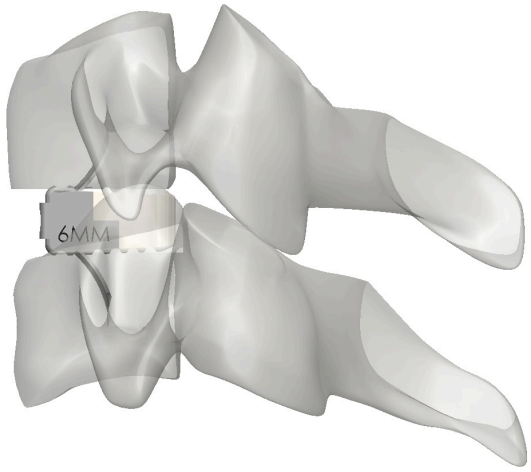
An ACI inserter is used to insert the implant and advance the seperate anchor component into the adjacent vertebral bodies. During advancement, the titanium anchor moves toward the posterior of the implant deflecting under the constraint of the ramp. Upon continued deformation, the anchor members curve out of the profile of the implant and can then pierce adjacent vertebral bodies. The anchor blades are plastically deformed in this manner and therefore retain their curvature post-deployment.

The implant includes four locking lugs (shown below) that interface with the anchor, once deformed. The anchor deploys under these lugs, thereby fixing the anchor to the implant. The locking lugs serve as a backstop that prevents separation of the anchor from the implant unless the anchor is physically retracted with the retraction tools. The retraction tools provide the needed mechanical advantage to overcome the curved shape of the anchor and pull it back under the locking tabs enabling its removal. This functionality has been designed into the ACI inserter.

LOCKING FEATURES:



LATERAL VIEW:



FEATURES & BENEFITS

INSTRUMENTATION OVERVIEW:

The ACI Instrument System includes the following:

- Trial Sizers
- ACI Inserter, 22-93002
- ACI Retraction Tools

The ACI inserter enables the surgeon to place the device and deploy the anchor members in one controlled step. The inserter hs been designed to disassemble for thorough cleaning. Please refer to the “Instructions for Use” for disassembly and assembly instructions.

ACI Inserter, 22-93002

The ACI retraction tools can be easily assembled to the device to facilitate removal once the ACI inserter has been separated from the implant.

SURGICAL TECHNIQUE GUIDE

SURGICAL APPROACH:

- Patient positioning should allow for anterior cervical access
- The affected level(s) should be identified with fluoroscopy
- A standard exposure should be used to gain access to the operative disc level
- The ACI can be inserted from a direct anterior approach. No oblique access is necessary necessary for fixation. The intervertebral disc should be exposed such that there is sufficient space for placement of the intended width implant.
- Perform a discectomy on the operative level using standard surgical technique
    - Care should be taken to retain as much of the posterior and lateral annulus as possible
    - The vertebral endplates should be prepared in a manner consistent with standard surgical tecniques. Excessive disruption of the endplates should be avoided to ensure proper stability of the implanted segment.

Note: Please reference the full “Instructions for Use” for indications and contraindictions.

TRIAL SELECTION:

- Trial spacers should be used to select the appropriate implant size to properly restore the disc height.
    - Trials are color coded as follows:

5mm

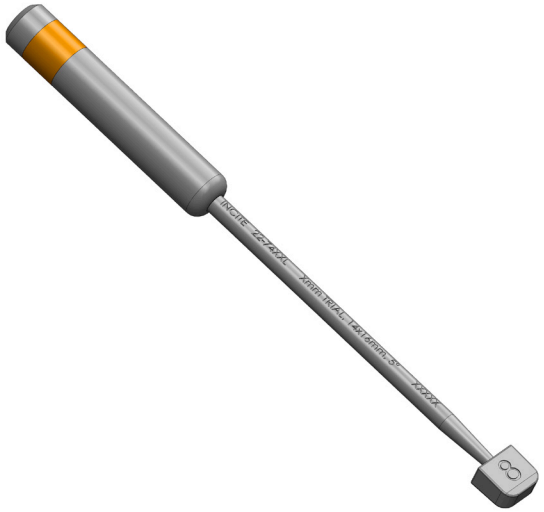
6mm

7mm

8mm

9mm

10mm



- Once the desired trial is selected, insert the trial in the disc space and confirm the appropriate size using fluoroscopy.

Note: The implant should not be used as a trial.

FOR ACI INSERTER 22-93002:

Anchor Loading:
Two anchor lengths are available to match the implant heights. The desired anchor blade height can be selected using the following table:

Implant Height (mm)	5	6	7	8	9	10
Anchor Size	Short			Long		
Anchor Height (mm)	5.5	5.0	4.5	5.5	5.0	4.5

- Place the selected anchor into the distal end of the Inserter, 22-93002.

Figure 1

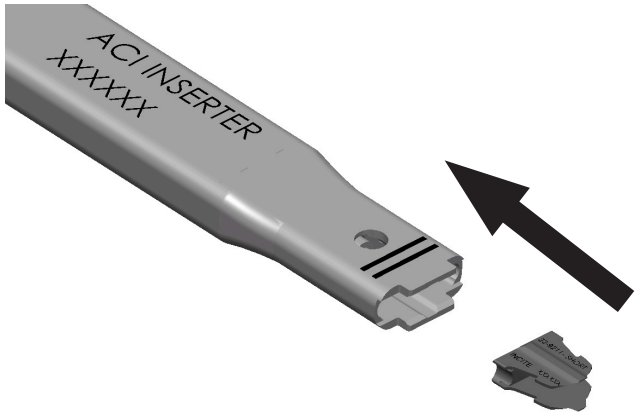


Figure 2

IMPLANT LOADING:

- Attach the selected implant based on trialing. This is accomplished by lining up the features on the anterior aspect of the implant with the slots in the distal end of the inserter.

Figure 1

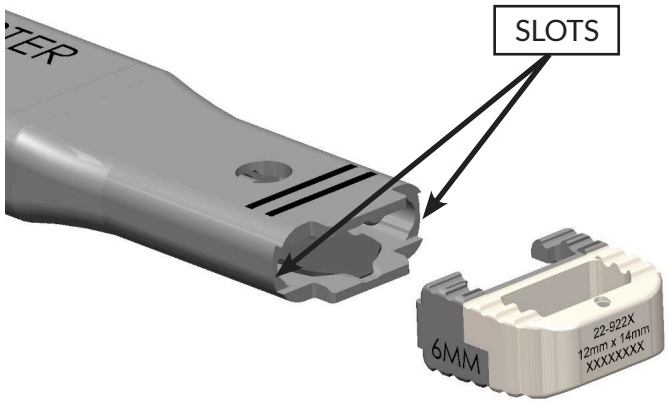
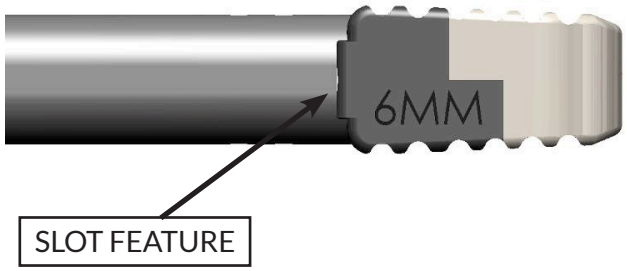
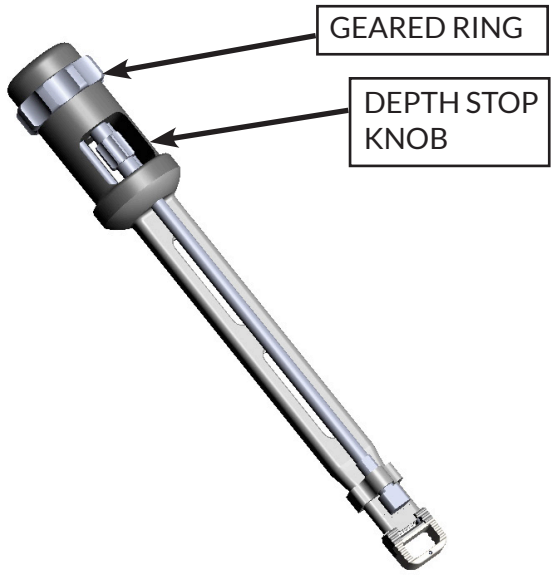


Figure 2

Figure 3

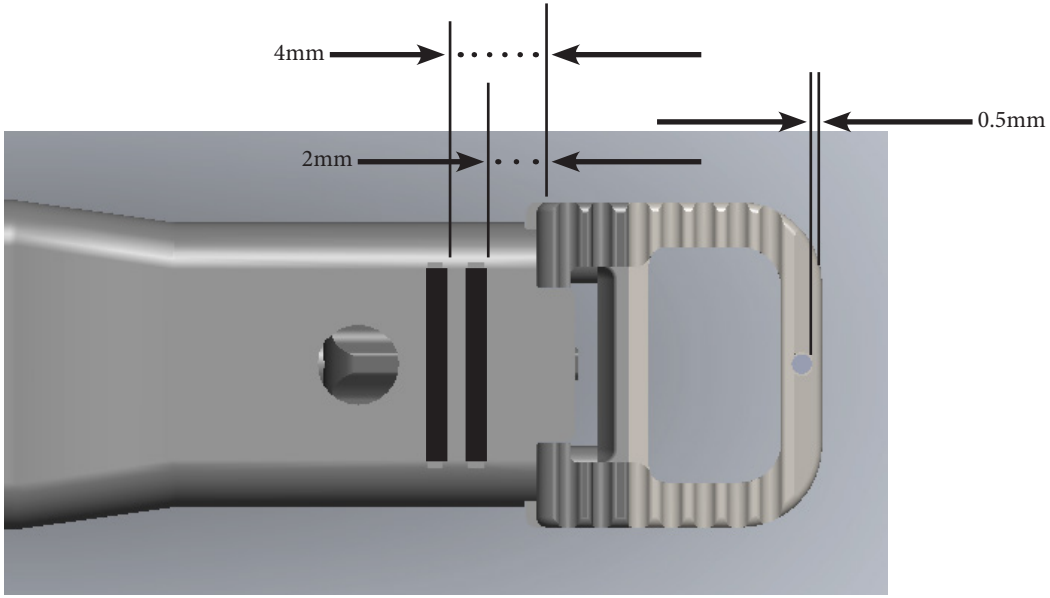


- Turn the geared ring to thread the posts into both sides of the implant. The geared ring should be turned clockwise until the implant fits snugly against the distal portion of the inserter.



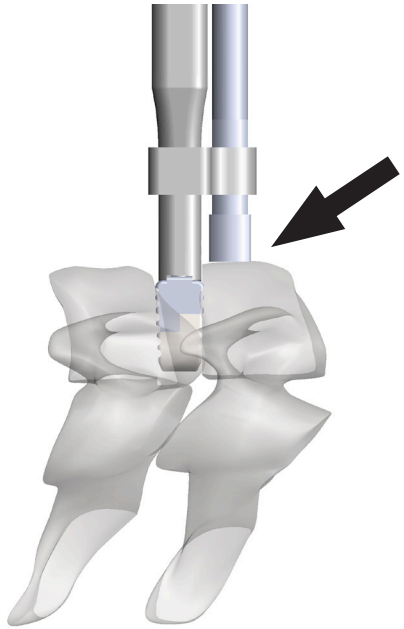
- Adjust the depth stop for the approximate desired countersunk depth. Setting the depth stop to the front of the distal marked line equals a countersunk depth of 2mm.

- **Note:** Depth markings have been included on the Inserter. Radiopaque markers have been incorporated into the implant to allow visualization of the posterior portion of the implant, once inserted.

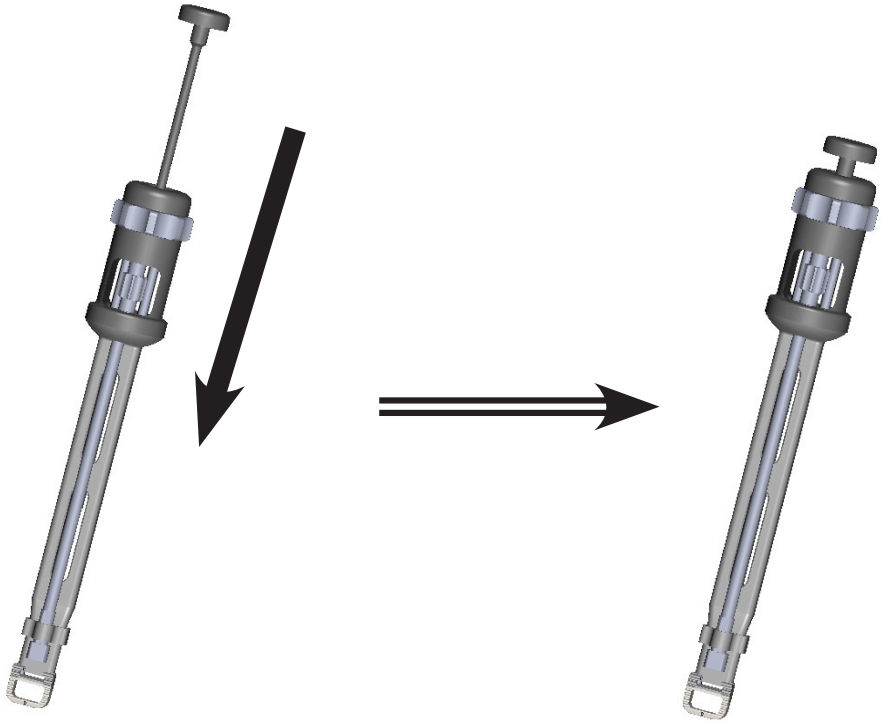


- Bone grafting material should now be packed into the open graft window in the PEEK spacer.

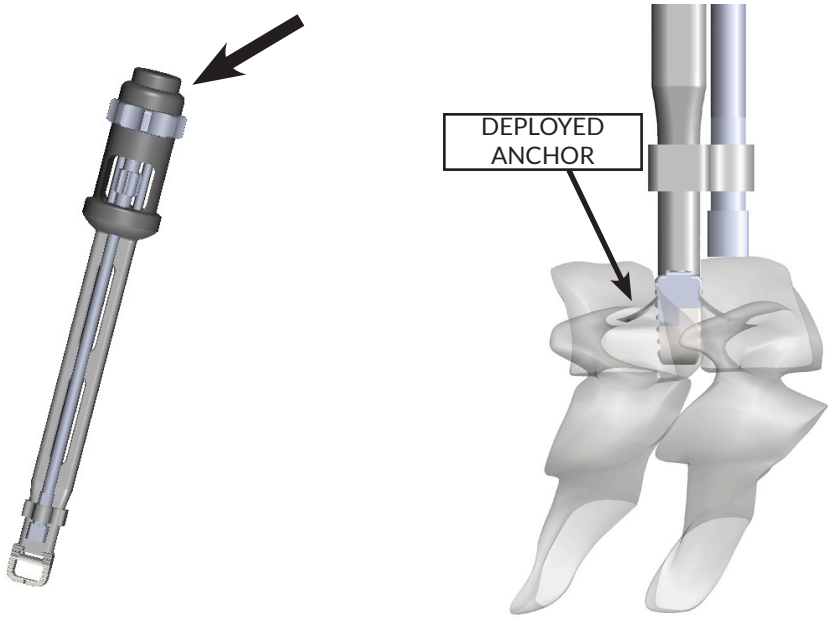
- Impact the implant into the desired position. Ensure that the depth stop foot is against the vertebral body as shown below.



- Place the anchor driver into the inserter.



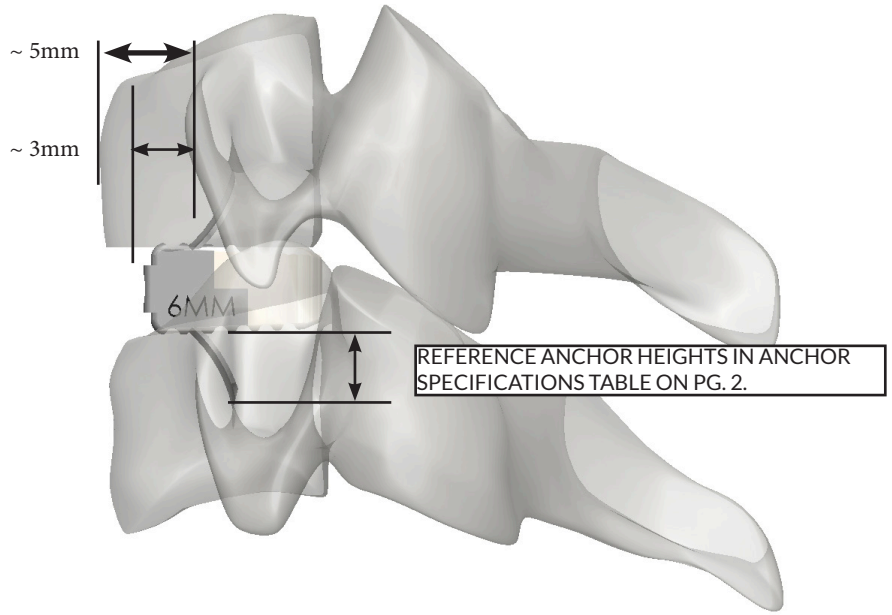
- Deploy the anchor by light impaction on the anchor driver. When the anchor driver is proximal to the inserter handle as shown below, the anchor is fully deployed.



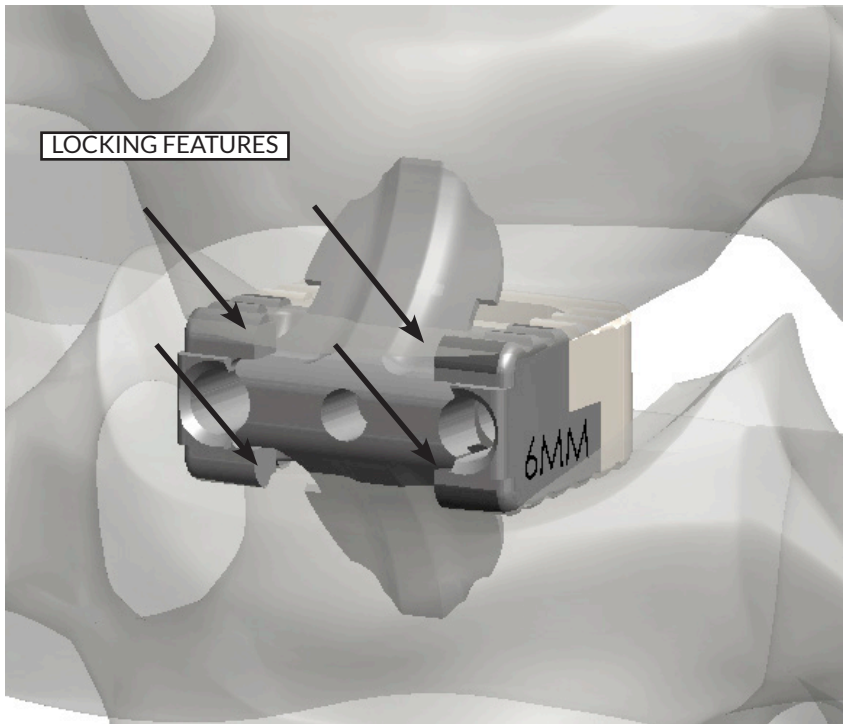
- Loosen the geared ring counter-clockwise and remove the implant inserter.
- If implant removal is necessary, use the retraction tools as outlined further in this surgical technique guide.

VERIFICATION OF DEVICE POSITION

- The final implant/anchor position may be verified using fluoroscopy or an intraoperative lateral x-ray.

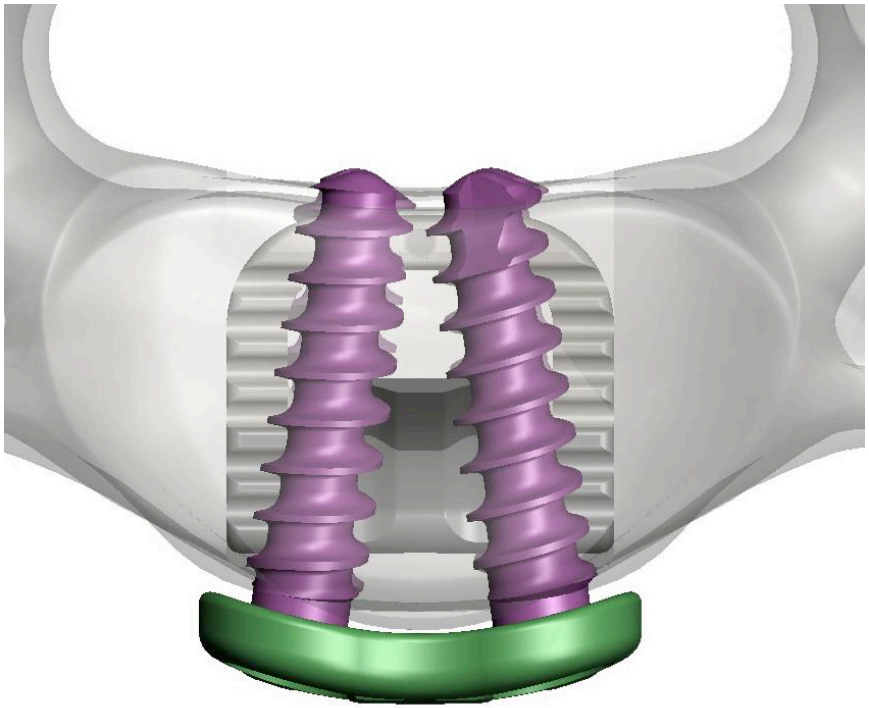


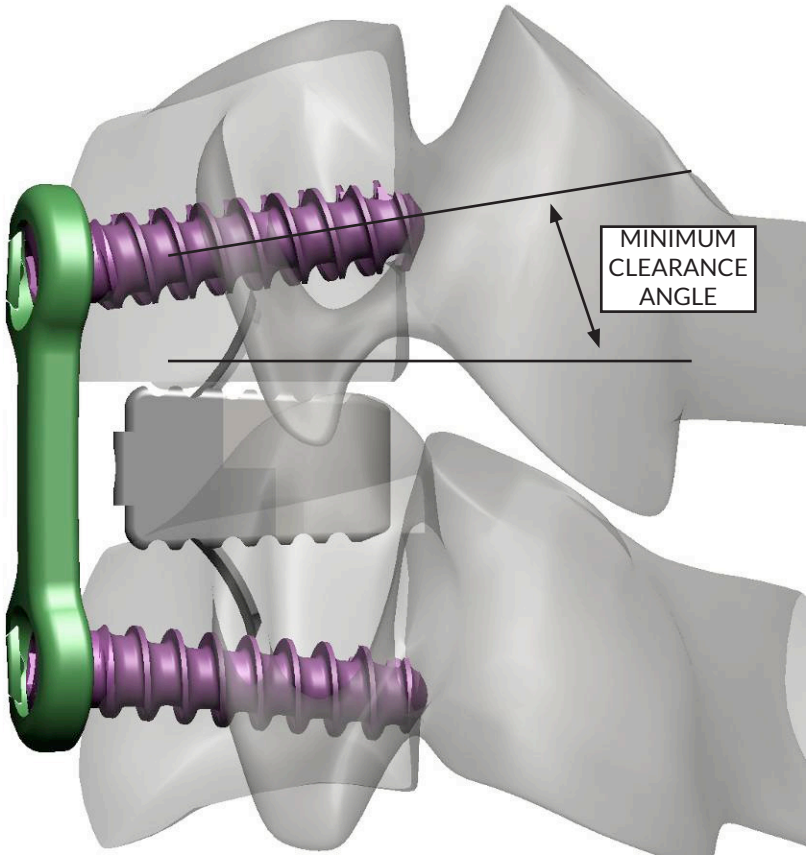
- Once deployed, the anchor locks to the implant. The anchor blades are directed under the locking lugs on the implant and due to the plastic deformation of the blades no additional locking components or steps are necessary.



ANTERIOR CERVICAL PLATE IMPLANTATION:

- An anterior cervical plate is required for supplemental fixation per the indications for use.
- Once the implant position is verified to be satisfactory, the cervical plate can be implanted with its associated screws.
    - Red Ruby ACI devices that are 5, 6, and 7mm in height utilize the short anchor blade. For these implants, an anterior cervical plate with a minimum length of 16mm can be used when 4.5mm diameter screws are used, provided the screws are implanted away from the implant at an angle that is equal to 8°.
    - Red Ruby ACI devices that are 8, 9, and 10mm in height utilize the long anchor blade. For these implants, an anterior cervical plate with a minimum length of 18mm can be used when 4.5mm diameter screws are used, provided the screws are implanted away from the implant at an angle that is equal to 9°.
      Note: Screws with a length of 16mm are shown for reference only. Screw length should be chosen by the surgeon to be appropriate based on the anatomy of the patient.
    - The clearance angle noted above assumes that the screws are aligned medially as shown below and the implant is recessed approximately 2mm.
    - Use of smaller diameter screws and alignment away from the medial line of the vertebrae will provide additional clearance from the anchor blades.




MINIMUM
CLEARANCE
ANGLE

- Once the appropriate length plate is chosen, it can be implanted using standard surgical technique.

Figure 1

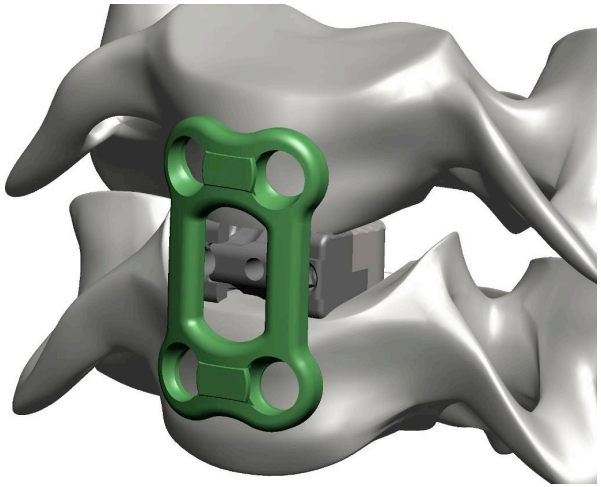


Figure 2

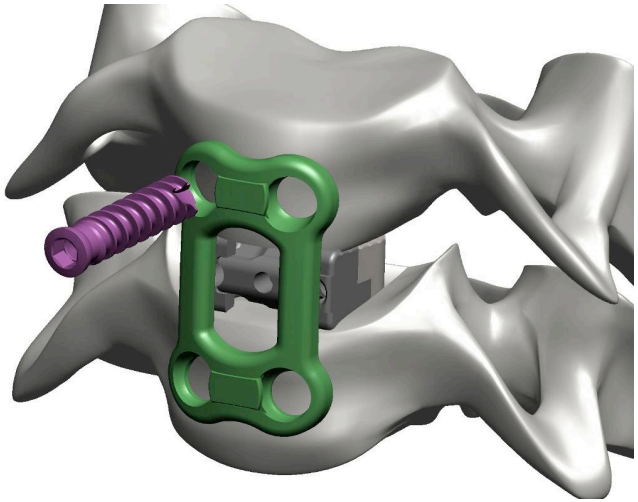
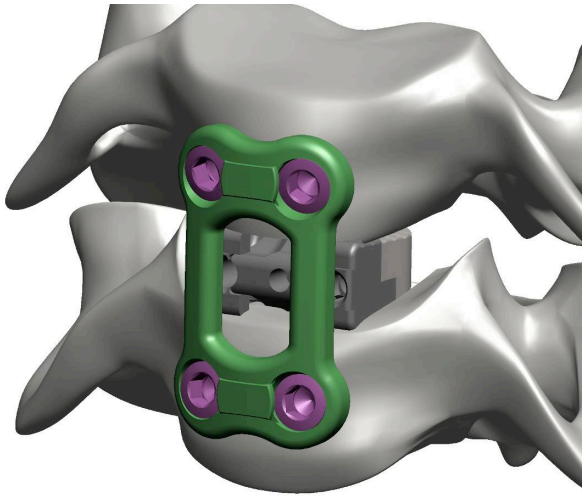
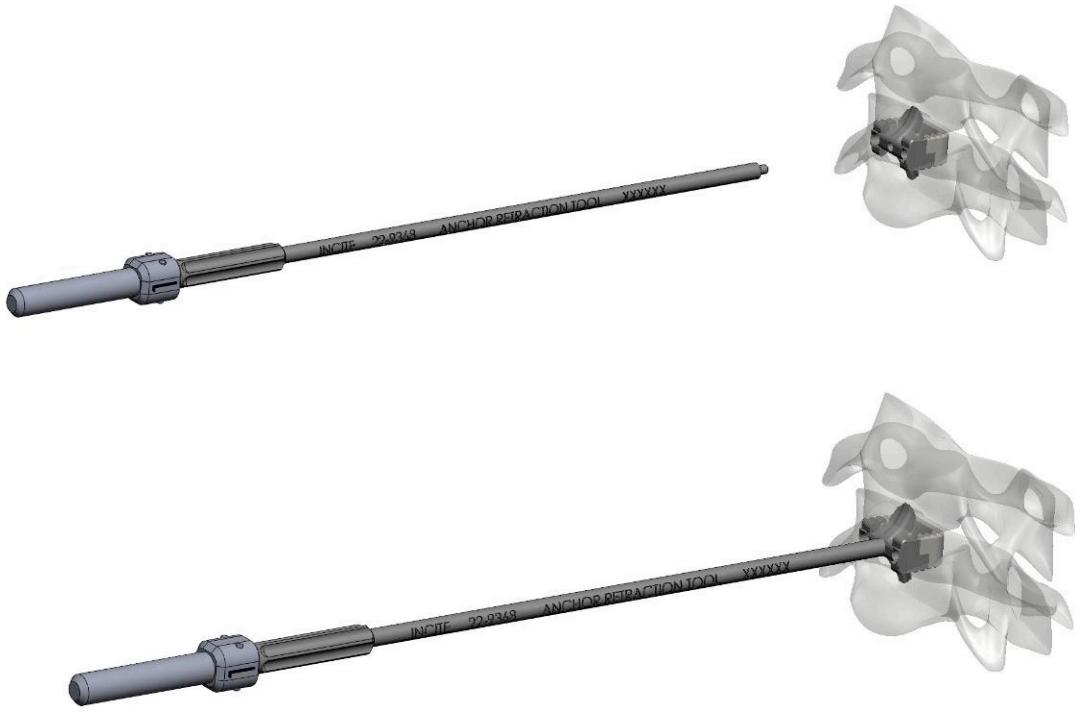


Figure 3

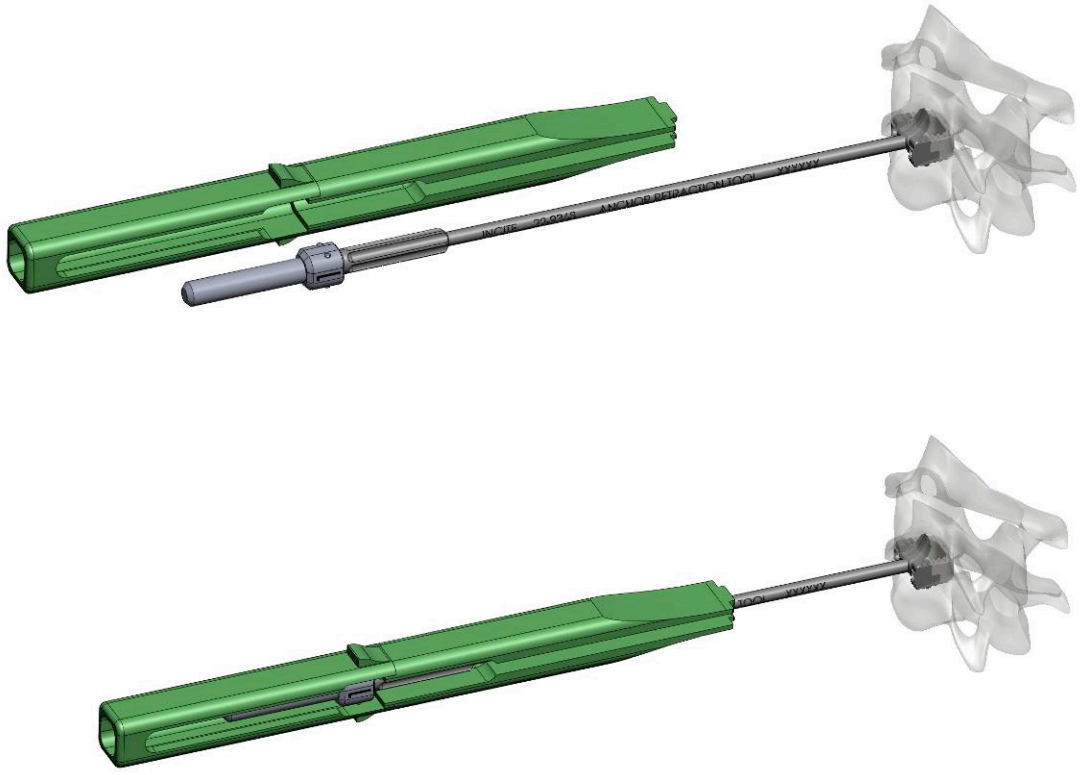


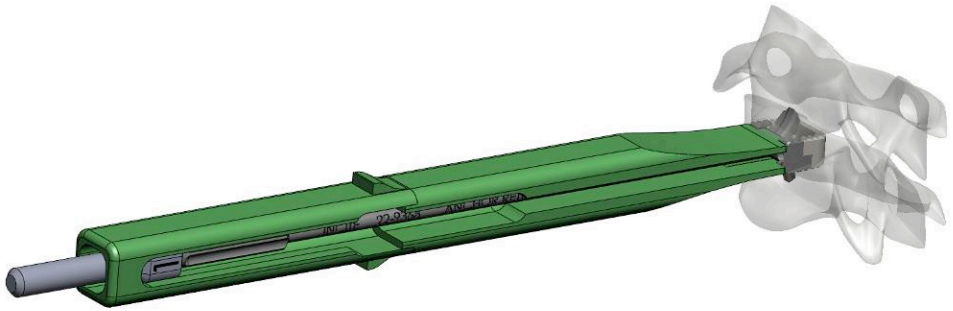
Post-Operative Management:
Management of the patient post-operatively should be consistent with the surgeon's standard of care.

IMPLANT REMOVAL with RETRACTION TOOLS (if necessary):
Step 1:
Thread the distal end of the anchor retraction tool, 22-9368, into the center hole on the anchor.
This tool has been marked with a "1."

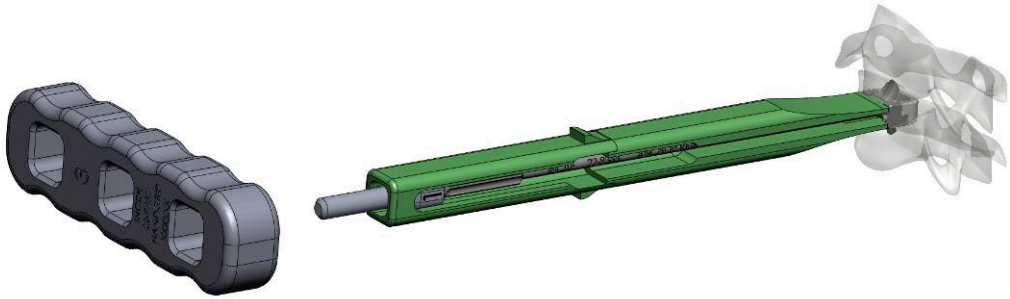


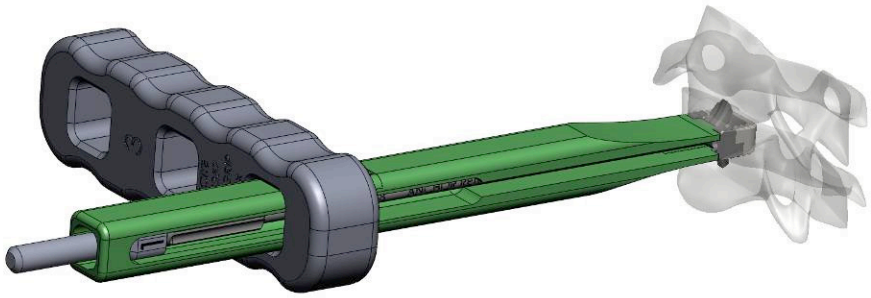
Step 2:
Assemble the retraction sleeve, 22-9360, marked with a “2” onto the anchor retraction tool. The square feature on the proximal end fits within the lateral slot of the retraction sleeve. Slide the retraction sleeve down shaft until it seats onto the implant.



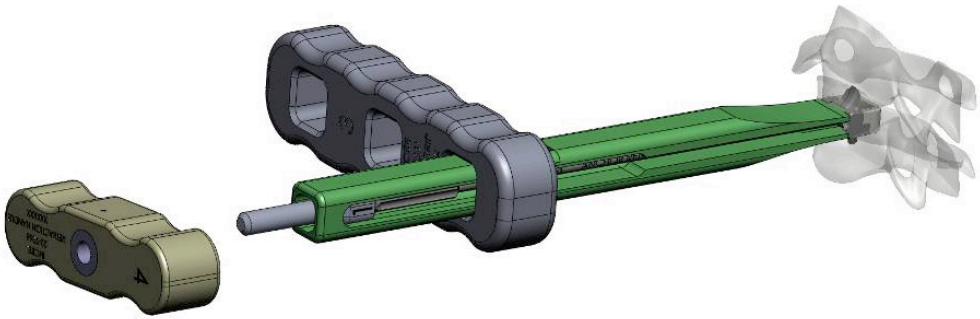


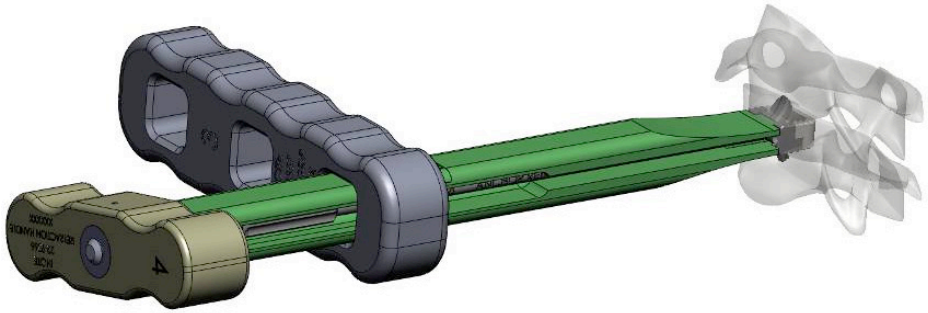
Step 3:
Assemble the handgrip, 22-9357, marked with a “3” onto the retraction sleeve. The handgrip may be assembled using any of the slots. The square slots permit assembly in any desired orientation to the sterile field.



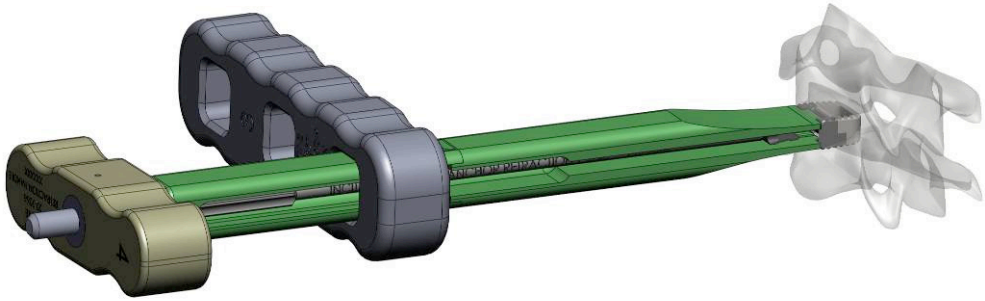


Step 4:
Thread the retraction handle, 22-9366, marked with a “4” onto the threaded portion of the anchor retraction tool. The retraction handle should be oriented with the metal ring away from the retraction sleeve.

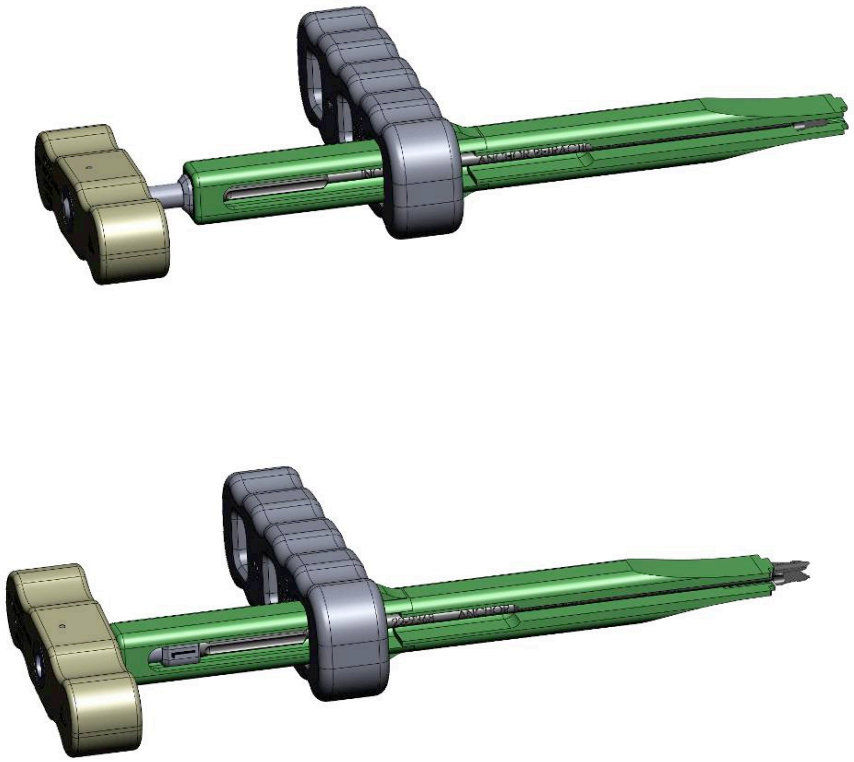




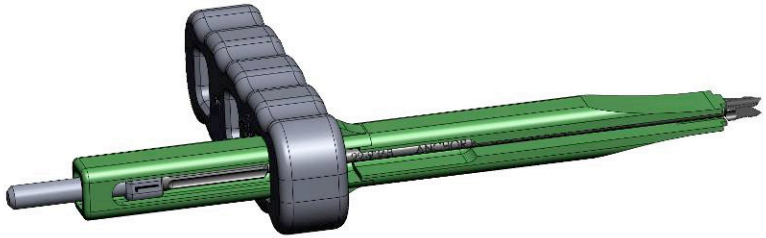
Step 5:
While holding the handgrip, turn the retraction handle clockwise to retract the anchor. Once the limit of the stroke is reached the anchor will be free of the implant and can be removed from the surgical site.

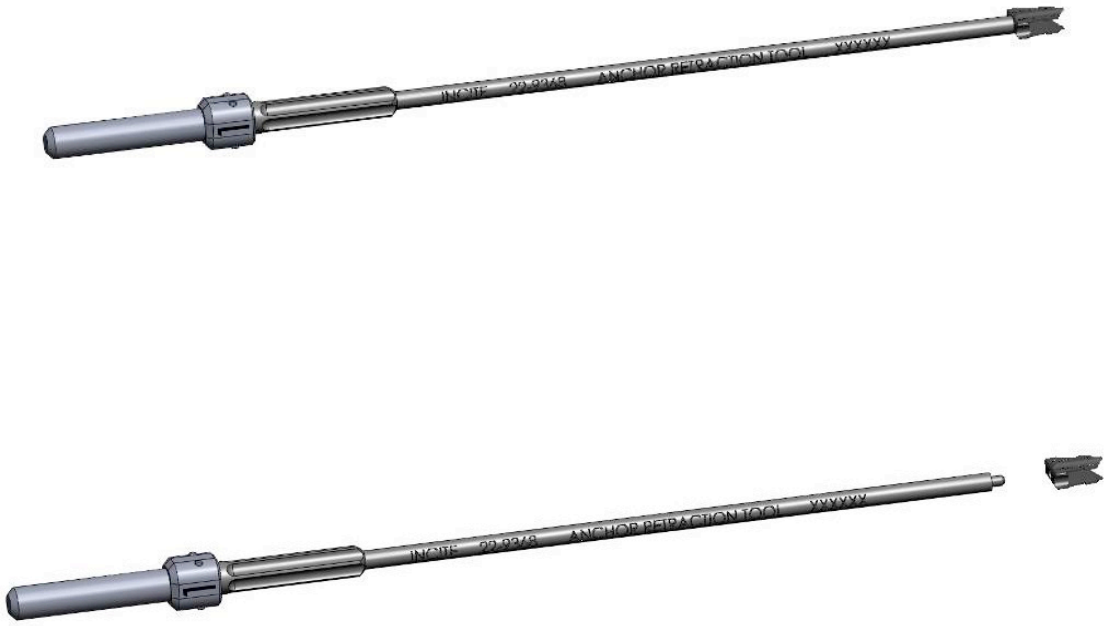


Step 6:
To release the anchor, unthread the retraction handle partway and use it to push the anchor retraction tool distally, thereby releasing the anchor from the retraction sleeve.



Step 7:
Unthread and remove the retraction handle by turning it counter-clockwise. Then remove the handgrip. The retraction sleeve can be removed by sliding it proximally and then off of the anchor retraction tool. With the retraction sleeve removed, the anchor may be easily unthreaded from the anchor retraction tool.




INVUITY
ANCHOR RETRACTION TOOL
INVUITY
ANCHOR RETRACTION TOOL

Step 8:
Thread into one of the side holes on the implant using the implant removal tool, 22-9361, marked with a “5.” Once threaded into the implant, the tool can be used to remove the implant from the surgical site.

Figure 1

Figure 2

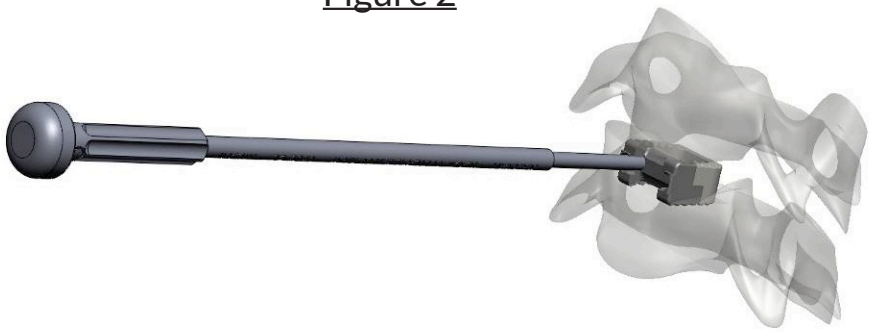
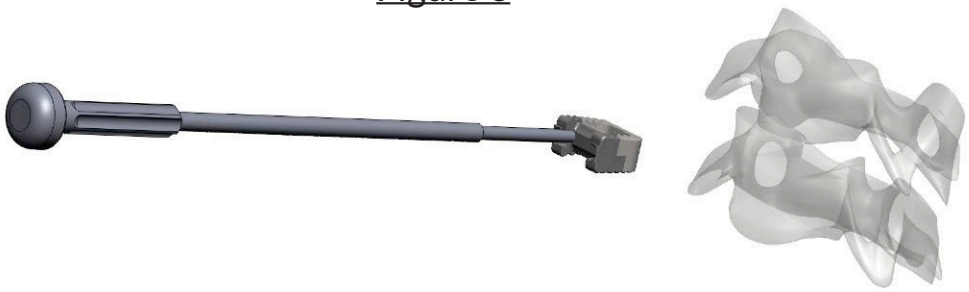


Figure 3



IMPORTANT PRODUCT INFORMATION

RED RUBY ANCHORED CERVICAL INTERBODY (ACI) IMPLANTS:

- Implants and anchors are packaged seperately and are supplied pre-packaged and sterile via gamma irradiation.

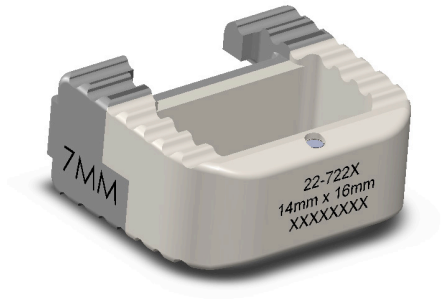
14mm depth x 16mm width - 5° Lordotic

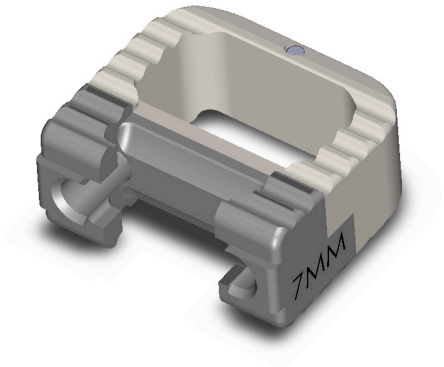
Part Number	Description
2200-7220	5mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°
2200-7221	6mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°
2200-7222	7mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°
2200-7223	8mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°
2200-7224	9mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°
2200-7225	10mm Red Ruby Anchored Cervical Interbody Implant, 14x16mm, 5°

IMPORTANT PRODUCT INFORMATION

Anchors

Part Number	Description
2200-9211	Anchor, Anchored Cervical Interbody, Short
2200-9212	Anchor, Anchored Cerivcal Interbody, Long





IMPORTANT PRODUCT INFORMATION

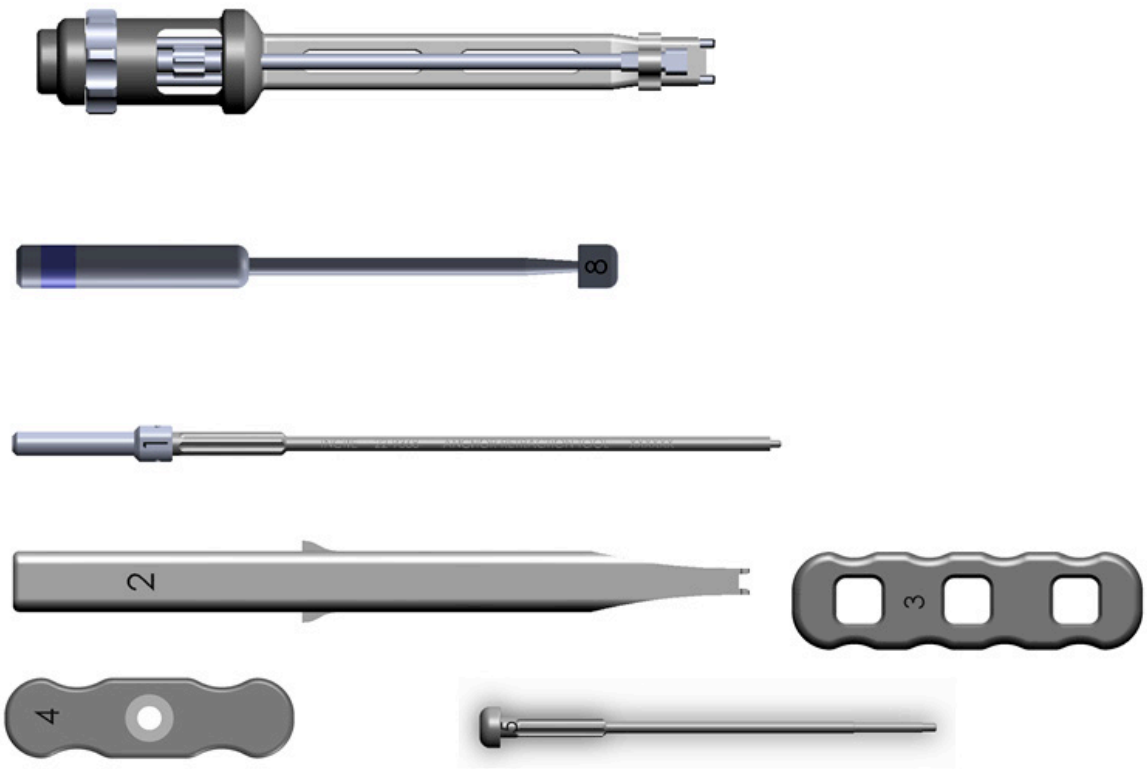
RED RUBY ACI INSTRUMENTS:

- Instruments are supplied NON-STERILE
- Instruments must be steam-sterilized prior to use (refer to Instruction for Use for validated steam sterilization cycle).

Instrumentation

Catalog Number	Description
2200-93002	ACI Implant Inserter
2200-7405L	Trial, 5mm, 14x16mm, 5°
2200-7406L	Trial, 6mm, 14x16mm, 5°
2200-7407L	Trial, 7mm, 14x16mm, 5°
2200-7408L	Trial, 8mm, 14x16mm, 5°
2200-7409L	Trial, 9mm, 14x16mm, 5°
2200-7410L	Trial, 10mm, 14x16mm, 5°
2200-9368	Anchor Retraction Tool
2200-9360	Retraction Sleeve
2200-9357	Handgrip
2200-9366	Retraction Handle
2200-9361	Implant Removal Tool

IMPORTANT PRODUCT INFORMATION



IMPORTANT PRODUCT INFORMATION

1. **DO NOT USE IMPLANT AS A TRIAL -** This may damage the implant. Trials are undersized by 0.5mm to ensure proper fit.
2. **SIZING OF IMPLANT -** Too large of an implant may "fishmouth" the disc space. Ideal fit results in continuous contact between the endplate and the implant superior and inferior surfaces.
3. **PLACEMENT OF CASPAR PINS -** Place the caspar pins at least 5mm off midline. This will ensure that the anchor blades do not hit the pins when deployed. If using distraction, release the tension to properly trial.
4. **INSERTION AND DEPLOYMENT -** After trialing, re-engage distraction to insert the implant. Release distraction before deploying anchor.
5. **ALIGNMENT -** Align the axis of the inserter with the endplates. Once the implant is impacted into position, the inserter should naturally find its alignment.
6. **IMPLANT DEPTH -** Take a lateral image prior to anchor deployment. Radiopaque markers are 0.5mm from the posterior edge of the implant. Determine anterior placement based on titanium implant face. Implant should be countersunk to ensure proper blade deployment.
7. **SINGLE USE DEVICE -** The implant and anchor should not be re-used. The device is only meant to be used once. If removal of device is necessary, a new implant and anchor must be used.

Red Ruby ACI is manufactured by Incite Innovation, LLC and distributed by Osseus Fusion Systems, LLC.

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Revision A

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