INSTRUCTIONS FOR USE

Incite Anchored Cervical Interbody Fusion Device

Caution: United States Federal law restricts this device to sale by or on the order of a physician.

Description:

The Incite 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. An insertion tool is used to implant the device and actuate the anchor members in one step. The anchor members pierce the vertebral superior and inferior endplates simultaneously. The implant has one large chamber for packing autogenous bone graft. The implant also includes radiopaque tantalum markers for implant visualization once implanted.

Indications

The Incite Anchored Cervical Interbody 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.

Contraindications:

- spinal fractures
- spinal tumor
- osteoporosis
- infection

Materials:

The spacer is manufactured from PEEK-Optima® LT1 (ASTM F2026). The anchor and ramp components are manufactured from Ti-6AL-4V ELI (ASTM F136). The radiopaque markers consist of tantalum pins (ASTM 560) that are press-fit into small holes on the posterior portion of the PEEK spacer.

Packaging:

The implant and anchor are supplied separately in sterile double packaging. The packaging prevents product contamination in normal conditions of handling and transport. It is necessary to check the integrity of the packaging before use.
The ACI instrumentation is supplied non-sterile. It must be cleaned and sterilized prior to use.

Instructions for Use:

- The instructions for using the ACI and associated instrumentation are described in the ACI Surgical Technique Guide. Before implanting the ACI, the site must be carefully prepared to avoid implant subsidence or implant migration.
- Components of this system should not be used with components of any other system or manufacturer, with the exception of the anterior cervical plate. Please refer to the Incite Anchored Cervical Interbody Device Surgical Technique Guide for recommendations on plate and screw sizing.
- The implant must be filled with autogenous bone graft in order to create a fusion across the motion segment.

Precautions:

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. **Please read** the Surgical Technique Guide prior to implanting this device.
- Patients who smoke have been shown to have an increased risk of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting of significant loads, or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the device. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
- Sale of this product is restricted to physicians.

Possible Adverse Effects:

- Possible adverse effects associated with general surgery include complications from anesthesia, infection, hematoma and death.
- Possible adverse effects associated with the implantation of the ACI implant may include: fracture of another vertebrae during placement, device breakage, device migration, material sensitivity or allergic reaction, spinal cord impingement, bone resorption, loss of disc height, soft tissue damage, damage to large blood vessels, neurological complications, trauma to nerve root or dura, and pseudoarthrosis.
- The adverse effects listed above are possible adverse effects known to potentially occur for procedures that may involve this type of implant and surgical approach.

Warning:

- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- Potential risks associated with the use of this system, which may require additional surgery, include device component failure (bending, loosening or fracture), loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, overdistraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, or expulsion.
- The device can break if it is subjected to increased loading associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant.
- Care should be taken to avoid interference between the anchor blades and the screws used with the required anterior cervical plate. Please refer to the Incite Anchored Cervical Interbody Device Surgical Technique Guide for recommendations on plate and screw sizing.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it or small defects may exist which may lead to fracture of the implant.
- The Incite Anchored Cervical Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. The Incite ACI device has not been tested for heating or migration in the MR environment."

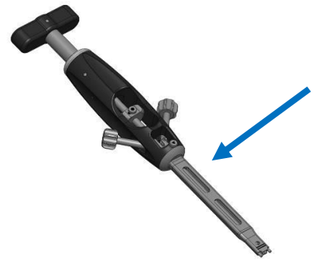
Cleaning:

There are two inserters for use with the Incite Anchored Cervical Interbody Device. Follow the cleaning instructions below for the desired inserter.

Cleaning Procedure for ACI Instrumentation:

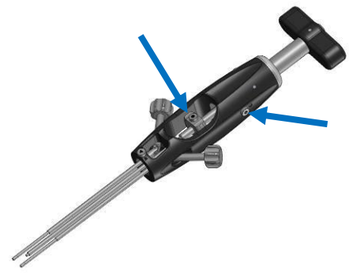
Inserter, 22-9300:

1) Instruments should be cleaned initially directly after use to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
2) The ACI Inserter must be disassembled for thorough cleaning. This is accomplished by:
   a) Loosen the thumbscrew with the ▲ on the front of the handle as shown below.

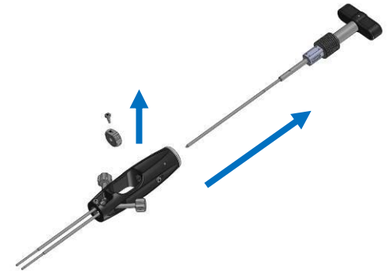


   b) Slide front-end off of instrument as shown below:

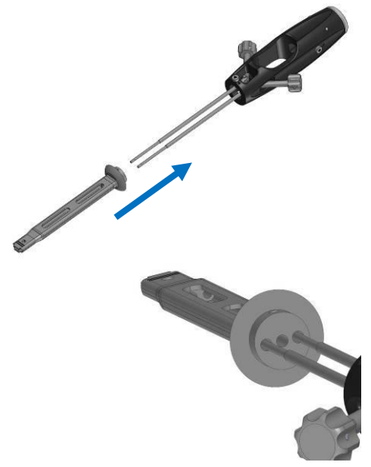
   c) Remove the thumbscrew marked with a ● located on the Center Knob and loosen the thumbscrew marked with a ● on the Handle as shown below:



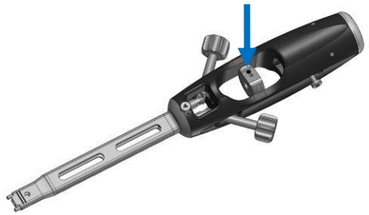
   d) Using the T-Handle, unthread the Center Shaft using a counterclockwise motion. The Center Shaft can be disassembled completely from the handle once the screw thread is disengaged. The Center Knob will be separate from the Handle.

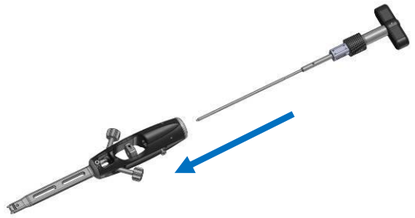


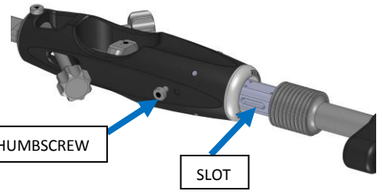
3) Submerge the disassembled components in an enzymatic detergent safe for use with metal devices. Prepare the detergent according to the manufacturer's recommendations. Soak the device(s) for twenty (20) minutes in the protein solubilizing detergent.
4) Thoroughly scrub the submerged device components with a soft bristled brush until all visible soil has been removed, for at least a period of one (1) minute. Agitate the device(s) in the solution while scrubbing and actuate any moving parts. Lumens or other hard to reach areas should be cleaned with a soft-bristled brush.
5) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes. Thoroughly flush lumens, holes and other difficult to reach areas. Actuate any moving parts while rinsing the device.
6) Ultrasonically clean the device components for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative), preferably at 45-50 kHz. Prepare the detergent according to the manufacturer's recommendations.
7) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes until there is no sign of blood or soil in the rinse stream. If blood or soil are present rinse for an additional three minutes until is no sign of blood or soil in the rinse stream.
8) Repeat steps 4 and 5 with a freshly prepared detergent solution.
9) Dry the disassembled device components with a clean, absorbent, disposable, lint-free cloth.
10) Repeat this cleaning procedure if the devices appear to be soiled after initial cleaning.
11) The ACI Inserter can be reassembled using the following steps:
   a) Slide the Front-End over the two side shafts. The side shafts should slide into the holes on the outside of the Front-End as shown below. Secure with thumbscrew with triangle symbol ▲.



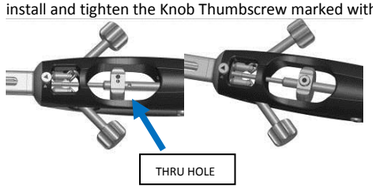
   b) Place Knob into the Handle window and slide Center Shaft through Handle and Knob as shown. The slot in the square component should align with the thumbscrew as shown.





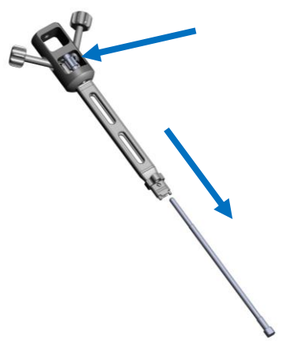


c) Tighten the Thumbscrew with the ● on the Handle.
d) Locate the thru hole on the Center Shaft. Align the Knob with the hole, install and tighten the Knob Thumbscrew marked with ● .



Alternate Inserter, 22-93001:

1) Instruments should be cleaned initially directly after use to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
2) The ACI Inserter must be disassembled for thorough cleaning. This is accomplished by:
   a) Turn Depth Stop Adjustment Knob continuously until Depth Stop Shaft can be removed from instrument:



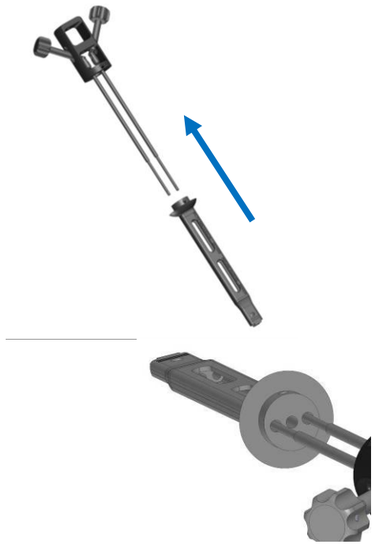
b) Remove Depth Stop Knob and slide Depth Stop Sleeve off of Front-End:

c) Loosen the thumbscrew with the ▲ on the front of the handle as shown below.

d) Slide front-end off of instrument as shown below:

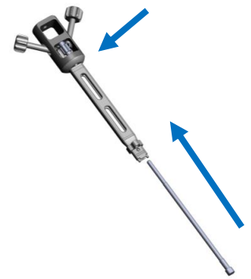
e) Remove U-Joint Assemblies from Body.

3) Submerge the disassembled components in an enzymatic detergent safe for use with metal devices. Prepare the detergent according to the manufacturer's recommendations. Soak the device(s) for twenty (20) minutes in the protein solubilizing detergent.
4) Thoroughly scrub the submerged device components with a soft bristled brush until all visible soil has been removed, for at least a period of one (1) minute. Agitate the device(s) in the solution while scrubbing and actuate any moving parts. Lumens or other hard to reach areas should be cleaned with a soft-bristled brush.
5) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes. Thoroughly flush lumens, holes and other difficult to reach areas. Actuate any moving parts while rinsing the device.
6) Ultrasonically clean the device components for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative), preferably at 45-50 kHz. Prepare the detergent according to the manufacturer's recommendations.
7) Rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices, for example, RO, DI and/or distilled water for a minimum of three (3) minutes until there is no sign of blood or soil in the rinse stream. If blood or soil are present rinse for an additional three minutes until is no sign of blood or soil in the rinse stream.
8) Repeat steps 4 and 5 with a freshly prepared detergent solution.
9) Dry the disassembled device components with a clean, absorbent, disposable, lint-free cloth.
10) Repeat this cleaning procedure if the devices appear to be soiled after initial cleaning.
11) The ACI Inserter can be reassembled using the following steps:
    a) Assemble U-Joint Assemblies into Body.
    b) Slide the Front-End over the two side shafts. The side shafts should slide into the holes on the outside of the Front-End as shown below. Secure with thumbscrew with triangle symbol ▲ .



c) Slide the Depth Stop Guide onto the Front-End:

d) Place the Depth Stop Shaft through the Guide and thread it into the Depth Stop Knob. The flats on the Depth Stop Shaft should fit into the flats on the Depth Stop Sleeve.



Sterilization:
The ACI implant and anchor are supplied sterile, having been irradiated by gamma radiation with a minimum dose of 25 kGy.

The product is sterile for a period of 3 years provided that the packaging stays intact.

The ACI implant and anchor are single use and should not be resterilized.

All ACI surgical instruments are supplied NON-STERILE and in an instrument tray. The instruments may be steam sterilized in the sterilization tray using the following validated cycle:

Method:	Steam
Cycle:	Pre-vacuum
Temperature:	132°C
Exposure Time:	4 min full cycle
Drying Time:	20 Minutes

Note:

1) The cycle conditions noted above were validated and are considered adequate to achieve an SAL of 10^{-6}.
2) These parameters are consistent with ANSI/AAMI ST79:2010/A2:2011 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

FDA cleared wraps are recommended when sterilizing ACI instrumentation. Only sterile instruments should be used in surgery. Instruments should be properly cleaned and sterilized prior to use. Soiled instruments must be properly cleaned prior to sterilization to ensure the product is sterile.

Storage & Transport:
There are no special storage or transport conditions.

SYMBOL LEGEND	DESCRIPTION
⚠	Caution, refer to accompanying documents
LOT	Batch code
	Do Not Re-Use
REF	Catalogue Number
STERILE R	Sterilized via irradition
2002-03	Use by, expressed as: YYYY/MM

Manufactured by:
Incite Innovation LLC
1500 Main Street, Suite 2410
Springfield, MA 01115-5707
413-382-0210 Phone
413-382-0211 Fax