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InCorporate CORPECTOMY SYSTEM
IMPLANTS AND INSTRUMENTS

This package insert covers the InCorporate Corpectomy System and Manual Surgical Instruments that are used for the implantation of this system.

GENERAL INFORMATION

The InCorporate Corpectomy System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The implants have ridges or teeth in both the superior and inferior directions, which resist migration. The implants have cavities to accept packing of autograft and/or allograft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery. The materials used in the implant are listed on the packages. Implants are made from either PEEK (polyetheretherketone) radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively or Titanium Alloy (Ti6Al4V ELI) as specified in ASTM F136. To ensure radiographic visibility for inspecting the implant position, they contain marker pins made of x- ray opaque implant material (Tantalum).

INDICATIONS

The InCorporate Corpectomy System is a vertebral body replacement system indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). InCorporate Corpectomy System is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

CONTRAINDICATIONS

1. Fractures
2. Scoliosis
3. Active infection
4. Allergy to tantalum, PEEK or Titanium Alloy (Ti6Al4V ELI)
5. Bone tumors in the region where the implant would have to be anchored
6. Unwillingness or inability of the patient to follow the instructions for postoperative treatment
7. Any medical or surgical condition that could preclude the potential success of the implantation
8. Pregnancy
9. Osteoporosis or similar loss of bone density
10. Systemic or metabolic diseases
11. Drug abuse or alcoholism
12. Generally poor condition of the patient
13. Morbid obesity
14. Psychosocial issues; inadequate co-operation by the patient
15. Fever or leukocytosis
16. Any case not needing a fusion
17. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
18. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result
20. Any case that requires the mixing of metals from two different components or systems
21. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
23. Prior fusion at the level to be treated
24. All cases that are not listed under indications

WARNINGS

Implants provided sterile are sterilized through gamma irradiation. Do not re-sterilize implants provided sterile. Devices provided non-sterile must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced surgeon with training in the use of spinal devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Correct selection of the implant is extremely important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing**.**

Implants Can Break When Subjected to The Increased Loading Associated with Delayed Union or Nonunion. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

MAGNETIC RESONANCE ENVIRONMENT

The InCorporate Corpectomy System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.

4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. All implants and instruments should be inspected prior to use. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
5. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

MAGNETIC RESONANCE ENVIRONMENT

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POSSIBLE ADVERSE EFFECTS

Potential adverse effects may include, but are not limited to the following:

1. Early or late loosening of any or all of the components
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Implant material sensitivity, or allergic reaction to a foreign body.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, paraesthesia, and/or the development or continuation of pain, numbness, spasms, or sensory loss
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.

10. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
11. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain,
13. Bursitis.
14. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
15. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Inability to perform the activities of daily living.
19. Death.
20. Spinal cord impingement or damage.
21. Reflex sympathetic dystrophy.
22. If a pseudo-arthrodesis occurs coupled with the InCorporate Corpectomy Cage, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
23. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery

SINGLE USE
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death. All implants are single use.

STERILITY
All devices provided sterile have been gamma irradiation sterilized and are for single use only. Do not re-sterilize sterile devices. All devices provided non-sterile must be sterilized prior to use. Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by Spinal Elements.

SHELF LIFE
The product expiration date is indicated by the hourglass symbol on the product label. **Caution**: Do not use sterile devices if the packaging providing the sterile barrier has been compromised. Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to Spinal Elements.

CLEANING AND MAINTENANCE

All devices must be free of packaging material prior to reprocessing. All instruments must be free of bio-contaminants prior to reprocessing. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

CLEANING AND MAINTENANCE
Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.

Disassemble all components to provide maximum exposure for cleaning.
All devices must be processed manually prior to automated cleaning.
Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.
Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents.
Caution: Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. An automated system may be used as a follow-up method to manual cleaning.

AUTOMATED CLEANING INSTRUCTIONS
All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING
1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3. Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)

AUTOMATED CLEANING
4. Transfer the instruments into the automated washer for processing. Position the instruments to allow for proper drainage. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	300 seconds	Cold tap water	N/A
Wash 1	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
Wash 2	300 seconds	65.5°C	Endozime AW Plus or equivalent per manufacturer's instructions
PURW Rinse	10 seconds	82.2°C	N/A
Drying	7 minutes	115.5°C	N/A

5. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
6. Visually examine devices to ensure all visible soil has been removed.
7. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.

MANUAL CLEANING INSTRUCTIONS
Follow the instructions listed below for manual cleaning prior to sterilization.
1. Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at <43°C.
2. Immerse in Endozime® AW Plus enzymatic detergent (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations and clean thoroughly for at least 14 minutes at <43°C. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.
3. Rinse thoroughly for 2 minutes with warm distilled, de-ionized, or reverse osmosis water. (27°-44°C)
4. Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.

Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear.
Note: If any damage or wear is noted that impairs the function of the instrument, contact your Spinal Elements representative for a replacement.

STERILIZATION

Devices provided non-sterile and must be sterilized before use. Non-sterile devices should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	273°F (134°C)	4 minutes	30 minutes

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAM ST 79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Information

REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Caution, Consult Accompanying Documents		Do Not Re-Use
STERILE R	Sterilized using irradiation		Use-by date

NON STERILE — Device Not Sterile

℞ Only — Prescription Only

ifu.spinalelements.com — Instruction for Use are provided electronically at ifu.spinalelements.com

Patent: patent.spinalelements.com

CAUTION: Federal Law (USA) restricts these devices for sale by or on the order of a physician.