Gemini-C Hybrid Cervical Interbody System

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CAUTION: USA law restricts this device to sale by or on the order of physician.

DESCRIPTION

The Osseus Fusion Systems' Gemini-C Hybrid Cervical Interbody System is used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. This system includes three design configurations: 1) PEEK, 2) Titanium alloy (Ti-6Al-4V ELI), and 3) Hybrid PEEK/Titanium alloy. The implants are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of autogenous bone graft.

The Gemini-C Hybrid Cervical Interbody System is designed to be used in conjunction with supplemental spinal fixation.

The PEEK Gemini-C component is made from SOLVAY ZENIVA ZA-500 PEEK (ASTM F2026), the Titanium Gemini-C configuration is made from Ti-6A-4V ELI alloy (ASTM F136), and the Hybrid PEEK/Titanium, and the Hybrid PEEK/Titanium Gemini-C is manufactured from SOLVAY ZENIVA ZA-500 PEEK (ASTM F2026) and Ti-6A-4V ELI (ASTM F136).

INDICATIONS

The Gemini-C Hybrid Cervical Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels within the cervical spine at disc levels from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. This device is intended for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. anterior cervical plate such as the White Pearl Preferred Angle Anterior Cervical Plate). Patients should have had at least six weeks of non-operative treatment prior to treatment with intervertebral cages.

CLEANING/DISINFECTION

Preparation for cleaning:

Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h).

For this use only running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency, be suitable for the disinfection of instruments and be compatible with the instruments. For manual removal of impurities only a soft brush or a clean soft tissue is to be used, in no case metal brushes or steel wool.

Rinse all lumens five (5) times by application of a single-use syringe (minimum volume 10ml).

Manual cleaning:

1. Soak instruments for a minimum of one (1) minute in Enzol® or other enzymatic detergent prepared according to manufacturer's recommendations at 1 oz/gal using warm tap water.
2. Following soak time, a soft-bristled brush (M16) and a properly sized lumen brush are used to thoroughly clean the instruments, including cannulas, holes, hinged mating surfaces, joints, and crevices, and where possible, use a twisting action.
3. Rinse thoroughly under water quality of reverse osmosis or distilled water.
4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

Devices with challenging design features (cannulations, T-handle interfaces, hinged instruments, instruments with crevices):

1. Immerse instrument and soak for a minimum of five (5) minutes in Enzol® or other enzymatic detergent prepared according to manufacturer's recommendations at 1 oz/gal using warm tap water.
2. Use a soft-bristled brush (M16) and a properly sized lumen brush to remove additional soil from challenging design features:
   a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
   b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
   c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
   d. Scrub crevices using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm Enzol® or other enzymatic detergent.
4. Rinse thoroughly with water quality of reverse osmosis or distilled water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

Automatic Washing:

Pre-cleaning:

Devices <u>without</u> challenging design featuress:

- Pre-cleaning is not required for used reusable medical devices and containment devices that do not have dried-on soil. They can be placed directly into the automatic washer for cleaning.

Devices with challenging design features:

1. Enzol® or other enzymatic detergent is prepared according to manufacturer's recommendations at 1 oz/gal using warm tap water. Immerse instruments in prepared detergent and soak for five minutes. Following soak time, a soft-bristled brush (M16) and a properly sized lumen brush are used to thoroughly clean the instruments, including cannulas, holes, hinged mating surfaces, joints, and crevices, and where possible, use a twisting action.
2. Sonicate in fully opened position for a minimum of ten (10) minutes in warm Enzol® or other enzymatic detergent prepared at 1 oz/gal using warm tap water.
3. Rinse under water quality of reverse osmosis or distilled water.

Automatic Washing Cycle:

1. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain).
2. Run the automatic wash cycle - Minimum cycle parameters:
   - five-minute prewash in cold taper water
   - five-minute enzyme wash in tap water at 43° C minimum temperature
   - five-minute detergent wash at 55° C minimum temperature
   - one-minute rinse in tap water at 45° C minimum temperature
3. Check instruments for visible soil (see "Verifying cleaning"). Repeat cleaning if soil is visible and re-inspect.

Verifying cleaning:

1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood. **Note: Rinse the instruments thoroughly under water quality of reverse osmosis or distilled water following hydrogen peroxide testing.**
3. Repeat cleaning if not visibly clean and re-inspect.

Inspection and function testing:

Device/Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play.."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

Maintenance:

- For devices with hinged/mating surfaces, surgical-grade lubricant should be added to the hinged area while in the open position.
- If the any of instruments exhibit any of the flaws listed above adequately dispose of the devices.

STERILIZATION

Implants and instruments of the Gemini-C Hybrid Cervical Interbody System are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Cycle:	Pre-Vacuum
Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	40 Minutes
Condition:	Wrapped
Wrap:	The wrap should be FDA cleared for the proposed cycle specifications

USAGE

PRECAUTION: The implantation of the Gemini-C Hybrid System should be performed only by experienced spinal surgeons with specific training in the use of this anterior cervical system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable, not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical limitations of surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the implant and be warned regarding weight bearing and body stresses on the device prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need for an additional surgery to remove the device. Refer to the individual system surgical technique manual for additional important information. A surgical technique can be obtained from the local representative or Osseus Fusion Systems, LLC.
Gemini-C Hybrid components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI, and may cause galvanic corrosion.

The Gemini-C Hybrid Cervical Interbody System has not been evaluated for safety and compatibility in the MR environment. The Gemini-C Hybrid Cervical Interbody System has not been tested for heating or migration in the MR environment. The safety of Gemini-C Hybrid Cervical Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include implant fracture or bone failure. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

CONTRAINDICATIONS

- spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system)
- reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
- fractures

- tumours
- scoliosis
- Active infection
- Allergy to titanium, titanium alloy or PEEK
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented allergy or intolerance to composite materials
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Spondylolisthesis unable to be reduce to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated

INFORMATION TO THE PATIENTS

The surgeon must discuss with the patient all physical and psychological limitations inherent to the use of implants, including the rehabilitation stage, physiotherapy and the use of orthopedic devices, according to medical prescription. The surgeon must warn about the risk of physical activities.

Patients with vigorous work or activities (lift weight, run, jump, or any excessive muscular work) that require a compressive resistance in the spine must be warned about the necessity of a substitution in future, to avoid the risks of fail. Smokers show a tendency of failure in the bone fusion and must be warned about this condition. Patients with degenerative disease in advanced stage can be susceptible to a shorter life time of the fixation system so this surgical technique is faced as a palliative technique.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. 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.

2. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase.

3. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

   A. **The patient's weight.** An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

   B. **The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

   C. **A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

   D. **Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

   E. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique manual is available for detailed instructions on the correct use of the Gemini-C Hybrid Cervical Interbody System. The contents of this manual alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

Note: A further surgery might become necessary to correct adverse effects.

This list may not include all complications caused by the surgical procedure itself.

1. Fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
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, and paresthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malposition of implant adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Symbol	Used For	Symbol	Used For
	Single use only		Catalog number
	Lot number		Use by YYYY-MM-DD or YYYY-MM
	See package insert for labeling limitations		Do not use if package is damaged or open
	Non-sterile. To be sterilized prior to use.		CAUTION: USA law restricts this device to sale by or on the order of physician.

POST MARKETING ASSISTANCE

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