CURITEVA®

SAGE™ CERVICAL INTERBODY FUSION SYSTEM
INSTRUCTIONS FOR USE

DESCRIPTION:

The SAGE Cervical Interbody Fusion System consists of interbody fusion cages that are generally box-shaped with an open central chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device. Implants are available in a range of sizes and footprints to accommodate varying anatomical conditions.

The system implants are manufactured from PEEK (per ASTM F2026) with Tantalum markers (per ASTM F560), or Titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. The PEEK implants are available with or without a medical grade commercially pure titanium (CpTi) plasma coating (per ASTM F1580) on the superior and inferior toothed surfaces. (NOTE: Not all implant material options are available in all markets.)

INDICATIONS FOR USE:

The SAGE Cervical Interbody Fusion System 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 (C2 – T1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) and supplemental spinal fixation systems that have been cleared for use in the cervical spine. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the device.

CONTRAINDICATIONS:

Contraindications for the SAGE Cervical Interbody Fusion System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- 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.
- Any case not described in the indications for use.
- Reuse or multiple uses.

CAUTIONS, PRECAUTIONS, WARNINGS and POSSIBLE ADVERSE EFFECTS:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.

Do not use components of the SAGE Cervical Interbody Fusion System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the SAGE Cervical Interbody Fusion System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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 the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The SAGE Cervical Interbody Fusion 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 SAGE Cervical Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

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. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects, including but not limited to:

- Early or late loosening of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery
- Non-union (pseudarthrosis), mal-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

GENERAL:

Single Use Only: Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Patient Education: It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of

the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

CLEANING OF SYSTEM COMPONENTS:

All system components, including implants, reusable instruments and trays, must be thoroughly clean before sterilization and introduction into a sterile surgical field. Implants should be cleaned separately from soiled instruments to avoid cross-contamination. If an implant has been in contact with the patient, body fluids or tissues or is damaged, it may NOT be reprocessed and MUST be properly discarded.

Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer / disinfector systems are not recommended as the sole cleaning method. An automated system may be used in addition to the following validated manual cleaning procedure.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments/trays; these solutions should not be used. Also, certain instruments may require disassembly before cleaning. All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

1. Thoroughly clean all system components as soon as possible after use (within a maximum of 2 hours post-operation is recommended). Do not allow blood and debris to dry on the instruments/trays.

2. Disassemble instruments as required. Ensure that the inserter threaded shaft has been properly unthreaded and removed from the inserter prior to cleaning.

3. The following table describes the required steps for thoroughly cleaning the system components:

Step	Agent	Time (mm:ss)
1. Rinse 1	Tap Water	As Needed
2. Clean 1	Enzol® Enzymatic Detergent Solution (or equivalent)	3:00
3. Rinse 2	Tap Water	1:00
4. Clean 2	Enzol® Enzymatic Detergent Solution (or equivalent)	10:00
5. Rinse 3	Deionized Water	1:00
6. Dry	Unaided Eye	As Needed
7. Inspect	Unaided Eye	As Needed

Manual Cleaning Procedure:

Step 1 – Rinse 1

- Thoroughly rinse component(s) under cool running tap water (< 35°C) to remove gross soil.

Step 2 – Clean 1

- Add one (1) ounce (30 mL) of detergent to one (1) gallon (3.8 L) of tap water. Fully immerse component(s) for at least three (3) minutes and flush detergent through all channels until evidence of organic material is removed. While submerged, use a soft bristle brush intended for use with surgical components to gently remove visible debris. Pay close attention to threads, crevices, channels, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of detergent per one (1) gallon (3.8 L) of warm tap water (< 55°C). Fully immerse component(s) in the detergent for at least one (1) minute.

Step 3 – Rinse 2

- Thoroughly rinse component(s) under cool running tap water (< 35°C) including all hard to reach areas to remove detergent for at least one (1) minute.

Step 4 – Clean 2

- Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water (< 55°C) to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse component(s) in the solution and sonicate for ten (10) minutes.

Step 5 – Rinse 3

- Remove component(s) from sonication unit and thoroughly rinse with deionized (DI) water including all hard to reach areas to remove detergent for at least one (1) minute.

Step 6 – Dry

- Dry component(s) using a clean, soft lint-free towel and/or filtered, pressurized air (20 psi).

Step 7 – Inspect

- Visually inspect each component for evidence of organic material. If any contamination is present, repeat the cleaning steps as necessary.

Instrument Care and Handling:

Before each use, instruments should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear or have other irregularities, DO NOT use.

Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Refer to ASTM standard F1744, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.

STERILIZATION:

All SAGE Cervical Interbody Fusion System components are provided non-sterile in a convenience caddy/tray(s) and must be sterilized prior to use. All implants and instruments must be inspected for damage and free of packaging material and bio-contaminants prior to sterilization. All system components, including the implant caddies, must be properly placed back into the convenience tray prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameters:

Method: Saturated steam
Sterilizer Type: Pre-vacuum
Temperature: 270°F (132°C)
Duration: 4 minutes
Drying Time: 30 minutes

It is the end user's responsibility to use only sterilizers and sterilization packaging materials/accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used, but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation. Do not stack trays during sterilization.

Product Complaints:
The customer or health care professional should report any dissatisfaction with the product quality, labeling, packaging or performance to Curiteva immediately. Furthermore, if any of the implanted system components "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of a patient, Curiteva should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the product description(s), part number(s), and lot number(s) should be provided along with the nature of the complaint, as well as the name and address of the individual filing the complaint.

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⚠ **CAUTION:** Federal Law (USA) restricts this device to use by or on the order of a physician.