Instructions for Use
Vusion® CS Plus

Manufacturer
Ortho Development® Corporation
12187 South Business Park Drive
Draper, UT 84020
Phone 801-553-9991
Fax 801-553-9993
www.odev.com

DESCRIPTION

The Vusion® CS Plus is intended to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The Vusion CS Plus device consists of a Polyetheretherketone (PEEK-OPTIMA® LT1, ASTM F2026) and contain tantalum markers (tantalum per ASTM F560), which allow radiographic confirmation of proper positioning. The system offers implants in various heights, widths, depths, and lordosis angles. The center of the device is hollow to allow for packing of autogenous bone graft.

INDICATIONS

The Vusion CS Plus device is intended for spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

This device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine.

This device is intended to be used in patients who have had six weeks of non-operative treatment.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
1. Metal/polymer sensitivity/allergies to the implant materials.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit a beneficial surgical outcome.
3. Patients resistant to following post-operative restriction on movement especially in athletic and occupational activities.
4. Grossly distorted anatomy caused by congenital abnormalities.
5. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
7. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
8. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
9. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
10. Prior fusion at the level to be treated.
11. Any case not described in the indications for use.
12. Reuse or multiple use.

WARNINGS AND PRECAUTIONS

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 this product 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.

Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

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

Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of adjacent vertebrae, neurological injury, and/or vascular or visceral injury.

Patients should be informed of the potential risks identified with the use of this device as well as postoperative weight bearing activity levels, which may require additional surgery. The device is designed as a load sharing device and is to be used to obtain normal alignment until normal healing and/or fusion occurs. If delayed union or nonunion occurs the implant may be subjected to increased loads which may result in device component fracture.

When using the Vusion CS Plus system, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system.

Never, under any circumstances, reuse a Vusion CS Plus device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

Vusion CS Plus has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. Vusion CS Plus has not been tested for heating or migration in the MR environment.

ADVERSE EFFECTS

Potential adverse effects include, but are not limited to:

1. Late union or non-union (pseudorthrosis).
2. Loss of proper spinal curvature, correction, height, and/or reduction.
3. Loss of fixation (implant migration).
4. Early or late loosening of any or all of the components.
5. Skin or muscle sensitivity, soft tissue injury, vertebral endplate injury, vascular or visceral injury.
6. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
7. Foreign body or allergic reaction, or sensitivity to the materials used to manufacture the implant.
8. Infection.
9. Disassembly, bending, and/or breakage of any or all of the components.
10. Decrease in bone density and/or bone fracture or micro-fracture.
11. Bone graft donor site pain or complication.
12. Loss of neurological function, including paralysis (partial or complete), appearance of radiculopathy, and/or development or continuation of pain, discomfort, numbness, spasms, and/or sensory loss.
13. Dural tears, CSF leakage, meningitis.
14. Herniated nucleus pulposus, disc disruption or disc degeneration at, above, or below the level of surgery.
15. Cessation of any potential growth of the operated portion of the spine.
16. Urinary retention or loss of bladder/bowel controls.
17. Loss of or increase in spinal mobility or function.
18. Epidural bleeding, hemorrhage of blood vessels, and/or hematomas.
19. Cardiovascular disorders, including venous thrombosis, pulmonary embolism, cerebrovascular accident and/or myocardial infarction.

20. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
21. Death.

Adverse effects may necessitate re-operation or revision.

Preoperative
1. Extreme caution should be used around the spinal cord.
2. Mishandling of instruments may cause injury to patient and/or operating personnel..
3. Bone grafts should be used to ensure stability.
4. Notching and scratching of implants should be avoided.
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.

Postoperative
1. For best possible results, patients should be counseled to avoid lifting, physical activities, smoking, consuming alcohol and any other activity that would compromise or delay the healing process.
2. The patients should be warned about bending limitations at the point of surgery.

PACKAGING AND STERILITY
The Vusion CS Plus implants are supplied in sterile or non-sterile packaging. Implants supplied in non-sterile packaging must be sterilized prior to use.

Sterile Vusion CS Plus implants are sterilized by a minimum of 25kGy gamma irradiation at a sterility assurance level of 10^{-6}. Sterile product packaging should be inspected for flaws before opening. In the presence of a packaging flaw, do not use. Do not re-sterilize. Do not use after expiration date.

All instruments should be thoroughly cleaned prior to sterilization. Cases should be placed in two layers of FDA cleared 1-ply polypropylene wrap, such as Kimguard KC600, using sequential wrapping techniques prior to sterilization.

The following Steam Sterilization Cycles must be followed in order to ensure sterility of the implants and instruments:

Implants and instruments:
Pre-vacuum Cycle: 4 minutes at 270° F (132° C)
Dry Time: 60 minutes

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).

PRODUCT HANDLING
Implants should be used only if received with packaging intact. Damaged packaging and implants should not be used and should be returned to Ortho Development Corporation. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development Corporation. If any of the implants or instruments "malfunction" (i.e. do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development Corporation should be notified immediately by phone, fax, or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

INSTRUMENT CARE

Considerations

This guide includes processing instructions for all Ortho Development (ODEV) reusable devices. All ODEV devices may be safely and efficiently reprocessed using either manual or combination manual/automated cleaning instructions outlined. New and used instruments must be thoroughly cleaned per these instructions prior to sterilization and use.

Warnings and Precautions

- Universal precautions should be observed by all hospital personnel that work with contaminated medical devices. Caution should be exercised when handling devices with cutting edges or sharp points.
- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Do not place heavy instruments on top of more delicate instruments.
- Do **NOT** use metal brushes or scouring pads during manual cleaning. These will damage the surface and finish of instruments. Only soft-bristled, nylon brushes and pipe cleaners should be used.
- Do **NOT** allow contaminated devices to dry prior to reprocessing. All subsequent cleaning is facilitated by not allowing blood, body fluid, bone and tissue debris, saline or disinfectants to dry on used devices.
- Saline, and cleaning/disinfection agents containing active chlorine, aldehyde, bromide, bromine, chloride, mercury, iodine or iodide are corrosive and should **NOT** be used.
- Mineral oil or silicone lubricants should not be used because they are difficult to remove, prevent direct contact of the surface with steam during sterilization and coat microorganisms.

Limitations and Restrictions

- Automated cleaning using a washer/disinfector alone may not be effective for cleaning orthopedic instruments. A thorough manual or combination manual/automated cleaning process is recommended.
- Neutral pH enzymatic and cleaning agents are recommended.
- Instrument trays, cases and lids must be cleaned separately. Non-sterile, single use implants are an exception as they may remain in the tray or caddy for reprocessing.
- Repeated processing has minimal effect on ODEV reusable instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended use and not reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Reverse Osmosis (RO) or Deionized (DI) water should be used for final rinsing of the instruments.

CLEANING INSTRUCTIONS

Point of Use

Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a tray of distilled water or cover with damp towels.

Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning

Disassemble the following instruments for cleaning:

259-0001 Vusion CS Plus Inserter

Grasp the instrument and unscrew at the knob. Gently separate the two pieces.

All cleaning agents should be prepared according to the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of manufacturer recommended temperatures is important for optimal performance of the cleaning agents

NOTE: Fresh cleaning solutions should be prepared when the existing solutions become grossly contaminated (turbid and/or bloody).

Table 1: Cleaning/Disinfection Options

Method	Description
Manual (Table 2)	Enzymatic soak and scrub followed by sonication
Combination Manual/Automated (Table 3)	Enzymatic soak and scrub followed by an automated washer/disinfector cycle
Automated (washer/disinfector)	Automated cycle - Not recommended without manual pre-cleaning

Manual Cleaning/Disinfection Procedure

Table 2: Manual Cleaning Steps

Step 1	Use a lint-free cloth dampened in tap water to remove gross soil. While wiping, actuate the instrument through the full range of motion.
Step 2	Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water.
Step 3	Fully immerse the instruments in the detergent and soak for a minimum of 20 minutes. While soaking, the instrument(s) should be actuated to ensure complete penetration of the detergent. Using a soft bristled brush (e.g. M16), remove all visible soil paying attention to crevices and hard to reach areas. Continue to actuate while brushing.
Step 4	Rinse the instrument(s) under running RO/DI water for a minimum of 3 minutes to remove detergent residue. While rinsing, actuate the instrument(s) through its/their full range of motion.
Step 5	Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaner.
Step 6	Fully immerse the instrument(s) and sonicate for a minimum of 10 minutes.
Step 7	Rinse the instrument(s) under running RO/DI water for a minimum of 5 minutes to remove all evidence of detergent residue. While rinsing, actuate the instrument through its full range of motion.
Step 8	Visually inspect the instrument(s) for soil. Dry using a clean, soft cloth and filtered pressurized air (<40psi). If soil is visible, repeat the process.

NOTE: Use of a sonicator at 45-50 kHz will aid in thorough cleaning of the devices.

NOTE: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

Table 3: Combination Manual/Automated Cleaning Steps

Step 1	Use a lint-free cloth dampened in tap water to remove gross soil. Actuate the instrument(s) through the full range of motion.
Step 2	Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water.
Step 3	Fully immerse the instrument(s) in the detergent and soak for a minimum of 20 minutes. While soaking, the instrument(s) should be actuated to ensure complete penetration of the detergent. Using a soft bristled brush (e.g. M16), remove all visible soil paying attention to crevices and hard to reach areas. Continue to actuate the instrument(s) while brushing.
Step 4	Rinse the instruments under running RO/DI water for a minimum of 3 minutes to remove detergent residue. While rinsing, actuate the instrument through its full range of motion.
Step 5	Prepare an enzymatic detergent according to manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaner.
Step 6	Fully immerse the instrument(s) and sonicate for a minimum of 10 minutes.
Step 7	Rinse the instrument(s) under running RO/DI water for a minimum of 5 minutes to remove all evidence of detergent residue. While rinsing, actuate the instrument through its/their full range of motion.

Step 8	Place instrument(s) into the associated tray, then place into a washer/disinfector with the cover and upper tray(s) separate from the lower tray and main case.
Step 9	Remove from the washer and visually inspect for visible soil. If soil is visible, repeat the process.

NOTE: Use of a sonicator at 45-50 kHz will aid in thorough cleaning of the devices.
NOTE: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

Table 4: Recommended Automated Washer/Disinfector Cycle Steps

Step 1	Pre-Wash; Cold Softened Tap Water; 1 minute
Step 2	Enzyme Wash; Hot Softened Tap Water; 1 minute
Step 3	Detergent Wash; Hot Softened Tap Water (66°C set point); 2 minutes
Step 4	Rinse; Hot Softened Tap Water; 1 minute
Step 5	Hot Air Dry (115°C); 7 minutes

Inspection, Maintenance and Testing
Carefully inspect each device to ensure all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Check the action of moving parts to ensure smooth operation throughout the full range of motion.

Hinged, rotating or articulating instruments should be lubricated with a water soluble product intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations.

Hospital Responsibilities for Ortho Development Loaner Instruments
Orthopedic instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper case should be returned to Ortho Development to be discarded. Notify your Ortho Development representative of any instrument problems.

Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Ortho Development. Documentation of decontamination should be provided with instruments being returned to Ortho Development.

Important Notice
The instructions provided have been validated by Ortho Development as being capable of preparing orthopedic instruments for use. It is the responsibility of the hospital to ensure that the reprocessing is performed using the appropriate equipment and materials and the personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

CAUTION
Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

To obtain a surgical technique manual, please request one by contacting Ortho Development Corporation by phone, fax, or written correspondence.

351-1-10686 07/2016