ZIMMER BIOMET

TrellOss™ Porous Ti Interbody System

℞ only

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Commonly Used Symbols for Medical Devices

Note: Refer to the individual package label for symbols applicable to the product.

SYMBOL	DEFINITION
	Manufacturer
	Date of manufacture
	Use by date
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
Ø	Diameter
	Consult instructions for use
	Caution: Consult accompanying documents
MR	MR conditional
NON STERILE	Non-sterile
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
QTY	Quantity per package
LOT	Batch code
REF	Reference
EC REP	Authorized representative in the European Community
℞ only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

INSTRUCTIONS FOR USE **en**

DEVICE DESCRIPTION

The TrellOss Porous Ti Interbody System is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have pores 300-700µm. The inferior/superior aspects of the TrellOss open devices incorporate a large vertical cavity which can be packed with bone graft material. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient.

MATERIALS

The TrellOss Porous Ti Interbody System implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS FOR USE

When used as a cervical intervertebral fusion device, the TrellOss-C Porous Ti Interbody System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a lumbar intervertebral fusion device, the TrellOss-TS and TrellOss-TC Porous Ti Interbody System open devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the TrellOss Porous Ti Interbody System lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a vertebral body replacement device, the TrellOss Porous Ti Interbody System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

CONTRAINDICATIONS

The TrellOss Porous Ti Interbody System contraindications include, but are not limited to:

- The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
- Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- Any condition not described in the Indications for Use.
- Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.

- The TrellOss Porous Ti Interbody System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
- The TrellOss solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
- These devices are provided as single use only implants and are not to be reused or re-implanted regardless of an apparent undamaged condition.
- The TrellOss Porous Ti Interbody System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
- The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Components of this system should not be used with components of any other system or manufacturer.
- Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

POTENTIAL ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems and include, but are not limited to: pseudarthrosis, insufficient bone stock, painful bursa, pressure necrosis, palpable components, early or late loosening of the components; disassembly, bending or breakage of any or all of the components; foreign body (allergic) reaction to the implants; possible infections requiring removal of devices; loss of neurological function, including paralysis, spinal cord impingement or damage.

MRI SAFETY INFORMATION

The TrellOss Porous Ti Interbody 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 TrellOss Porous Ti Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INSTRUMENT CLEANING AND DECONTAMINATION

All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. The following procedure details the requirements to 1) minimize the organic soil transfer from one patient to another 2) prevent accumulation of residual soil through the product's use life, and 3) allow for successful, subsequent sterilization steps.

Instrument Cleaning Warnings and Precautions

Zimmer Biomet Spine surgical instruments are provided non-sterile unless it is explicitly labeled sterile. Instruments provided non-sterile must be sterilized prior to use.

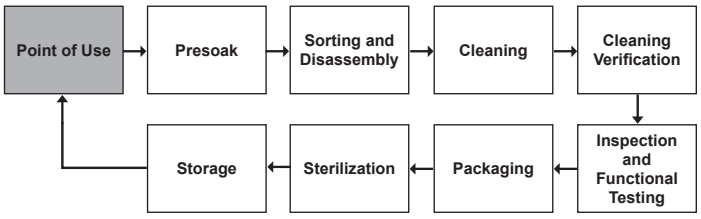
Zimmer Biomet Spine surgical instruments are intended to contact normally sterile tissue or body space during use. Due to this intended use it is considered a critical device and must be thoroughly cleaned and sterilized after each use. Do not allow contaminated devices to dry prior to cleaning and reprocessing as subsequent reprocessing steps are facilitated by not allowing blood, bodily fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments.

Surgical instrumentation of complexity (multiple components, moving components, textured surfaces) requires special attention and must be manually cleaned prior to processing through an ultrasonic cleaner. Avoid highly alkaline conditions and hypochlorite solutions as they can damage and corrode surgical instruments.

Please treat instruments that may have been exposed to Creutzfeldt - Jakob disease (CJD) according the health care facility's standard operating procedure. Sterilization parameters recommended in this document or the device's IFU are not intended and not suitable for inactivation of prions. Contact World Health Organization (WHO) or local regulatory authorities for further information on special CJD inactivation processing procedures.

Cleaning and Decontamination

To assist health care personnel in the decontamination processes and procedures for various types of reusable surgical instruments, this section provides guidelines for the selection and use of available cleaning and microbicidal processes. The cleaning process must be thorough as residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. An outline of the reprocessing procedures is shown below.



Point of Use

Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the device. Prolonged exposure to saline should be avoided to minimize the potential for corrosion.

Presoaking

Presoaking the instruments with an enzymatic solution, such as Enzol® by Advanced Sterilization Products®, for a minimum of 1 minute will moisten and loosen the soil, thus making the cleaning step more efficient. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution. When presoaking the instruments, personnel should refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time.

Sorting and Disassembling

Upon arrival in the decontamination area, contaminated items should be removed from their transport containers, and prepared for cleaning. All instruments should be checked for damage and corrosion prior to cleaning. If a component is lost, damaged, or corroded then contact Zimmer Biomet Spine directly or your local representative.

If the device consists of more than one component, and is designed to be disassembled, the instrument should be disassembled prior to cleaning and disinfection. Non-interchangeable components of assemblies shall be kept together to ensure correct reassembly. Instruments that are complex and/or designed to be disassembled prior to cleaning are provided below.

Inserter Disassembly

- Unthread and separate the inner shaft from outer body.
- The I.D., external grooves of the outer tube, and external thread of the inner shaft should be thoroughly cleaned with a nylon brush.
- The internal and external threads should be thoroughly cleaned with a nylon brush.

Cleaning

For reusable medical devices, the most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms. The factors that contribute to cleanliness are: quality of water; the quality, concentration, and type of cleaner; washing method; rinsing and drying; preparation of the contaminated devices; the time, temperature, load capacity of the equipment being used; and operator performance.

Many types of soil could be present on a device, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to clean. It must be rehydrated and then washed. Ultrasonic cleaning should not exceed temperatures of 140°F (60°C) to prevent coagulation and should be ran for a period of 10 minutes.

Instruments are optimally cleaned in water and detergent solutions at temperatures between 80°F and 110°F (27° to 44°C), but not to exceed 140°F. They should be cleaned with a brush, cloth, or sponge, and a low foaming, pH neutral detergent solution, such as Renu-Klenz™ by Steris Corporation®, or equivalent. Use a soft bristle brush to remove all traces of blood and debris; pay close attention to textured areas, crevices, blind holes, hinges, joints, and cannulated parts.

When cleaning an articulating instrument, fully immerse the instrument in the detergent and remove traces of blood and debris with a soft bristle brush. If the instrument can be articulated, retract and open the instrument in the detergent repeatedly.

Heavy instruments should not be placed on top of delicate instruments and small components should be placed in baskets.

Rinse components under warm or hot flowing water for at least one minute, with direct contact of each surface for a minimum of 10 seconds. Repeat this step using purified water.

Dry the internal areas of instruments using compressed air. When drying instruments with concave features, place the concave surface down to facilitate draining.

Cleaning Verification

Inspect all instruments before sterilizing to ensure the complete removal of all soil from surfaces, tubes, holes, and moveable parts. The ANSI/AAMI ST79 acceptance standard for cleanliness is visibly clean. Some surfaces of an instrument can be visually obstructed and prevents this verification. If a borescope is not available for inspection, checking for blood can be accomplished by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, then blood is present and cleaning must be repeated. Rinse instruments thoroughly after using hydrogen peroxide solution.

Inspection and Functional Testing

Instruments should be inspected for damage and wear. Check for smooth movement of assemblies without excessive play. Locking mechanisms should attach and detach easily. Cutting edges should be free of nicks and have a continuous edge. Long slender instruments should be straight and free of distortion. Instruments should be removed of any excessive moisture with a clean, absorbent, and non-shedding wipe.

Packaging

Instruments should be loaded in the instruments trays that are provided with the sets. When possible, instruments should be placed in the holders in an open position. If packaged individually, a standard packaging material may be used and packed in accordance with local packaging procedures or ANSI/AAMI ST46-1993.

Storage

Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extreme temperature or humidity.

IMPLANT AND INSTRUMENT STERILIZATION

The TrellOss Porous Ti Interbody System implants are supplied STERILE. All sterile products are supplied in protective sterile barrier packaging. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants.

The instruments are supplied NON-STERILE and must be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle has been validated to an SAL of 10^{-6}.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

INSTRUCTIONS FOR USE

The TrellOss Porous Ti Interbody System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to TrellOss Porous Ti Interbody System Surgical Techniques for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please Zimmer Biomet Spine, Inc., Customer Service by email: usbrocustomerservice@zimmerbiomet.com, Tel: +1 800.447.3625, Fax: +1 866.973.9072.

INSTRUCTIONS:

PREOPERATIVE

- Preoperative instructions to the patient are essential. The adverse effects, warnings, precautions and limitations should be understood by the surgeon and explained to the patient prior to the surgery.
- Only patients that meet the criteria described in the indications should be selected.
- Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
- Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.

- The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
- Proper function of the surgical instruments and components should be verified prior to every surgical procedure. All instruments and components must be sterilized before use.

INTRAOPERATIVE

- The primary goal of this surgery is to arthodese selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
- The placement of the TrellOss Porous Ti Interbody System devices should be checked radiographically.
- Care should be taken when positioning the implants to avoid neurological damage. Extreme caution should be used around the spinal cord and nerve roots.

POSTOPERATIVE

- Adequately instruct the patient on postoperative care, use and limitations and potential complications. Successful healing depends on postoperative care and the patient's ability and willingness to follow instructions.
- The patient must be made aware of the limitations of the implant and that physical activity and load bearing may cause premature loosening, bending or fracture of the internal fixation device. The patient should be warned to avoid falls, sudden jolts, mechanical vibrations, and lifting, twisting motions and restrict any type of sport participation. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
- If a nonunion develops, or if the implants loosen, fracture, corrode, migrate, cause pain, or stress, the device(s) should be evaluated, revised and/or removed. Patients with evidence of these conditions should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity, revision or removal considered.
- Periodic x-rays for at least the first year postoperatively are recommended to detect any evidence of nonunion, changes in position, loosening, bending or cracking of components.
- Any retrieved devices must never be reused under any circumstances.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

PRODUCT COMPLAINTS

Communicate suspected deficiencies in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance directly to Zimmer Biomet Spine (email: spinecomplaints@zimmerbiomet.com, phone: +1 844.557.7463). When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, and the patient case number. Sterilize and return all component(s) to your local Zimmer Biomet Spine representative or distributor. Notify Zimmer Biomet Spine immediately of an incident resulting in patient death or serious injury.

FURTHER INFORMATION

If further directions regarding proper use of the instruments is desired, contact Zimmer Biomet Spine, Inc., Customer Service by email: usbrocustomerservice@zimmerbiomet.com, Tel: +1 800.447.3625, Fax: +1 866.973.9072.
