FloSpine
Ti-Largo™ Cervical Interbody System
Package Insert

IMPORTANT

This booklet is designed to assist in using the Ti-Largo™ Cervical Interbody System. It is not a reference for surgical techniques.

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

INDICATIONS

Ti-Largo™ Cervical Interbody Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Ti-Largo™ Cervical Interbody Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Ti-Largo™ Cervical Interbody Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

GENERAL INFORMATION

FloSpine Ti-Largo™ Cervical Interbody Cages are generally box-shaped devices that have various graft windows throughout the geometry. These devices are manufactured from 3D printed Titanium Grade 23 per ASTM F3001. All implants are intended for single use only and should not be reused under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

PACKAGING

Packages for each of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to FloSpine.

CLEANING AND DECONTAMINATION

All instruments must first be cleaned using neutral cleaners before sterilization and introduction into a surgical field or (if applicable) return the product to FloSpine. Cleaning and disinfecting of instruments can be performed with aldehdye-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Refer to the Ti-Largo™ Surgical Instrument Sets Care, Cleaning and Sterilization Instructions for Use for detailed information.

STERILIZATION: IMPLANTS

Unless otherwise indicated, all components have been sterilized by a minimum of 25 kGy (2.5 MRads) of gamma irradiation and are supplied packaged in protective trays or pouches. This sterilization is validated by AAMI TIR33:2005 Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization and Sterilization of health care products - Radiation sterilization-Substantiation of 25 kGy as a sterilization dose - Method VDmax to an SAL of 10^{-6}. Inspect packages for punctures and other damage prior to surgery.

Ti-Largo™ IMPLANTS MUST NOT BE RE-STERILIZED ONCE REMOVED FROM ORIGINAL PACKAGING.

INSTRUMENTS - CLEANING, DECONTAMINATION AND STERILIZATION:

All instruments must be thoroughly cleaned before each sterilization (including first use) and introduction into a sterile field. All devices should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Instruments that are specifically designed for use with the Ti-Largo™ Cervical Interbody System include trials, rasps, mallets, tamps, and implant/interbody inserters. For a list of all instruments, refer to the Ti-Largo™ Cervical Interbody System Surgical Technique.

All instruments must be thoroughly cleaned, decontaminated and sterilized as follows:

1. Decontamination: Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. Pre-Cleaning: No instruments require disassembly. Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. Washing: Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
4. Rinsing: Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. Drying: Allow devices to air dry for a minimum of 20 minutes prior to inspection for moisture and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. Inspection: After cleaning/disinfection, instruments should be visually inspected for contamination. If contamination is still visible, repeat steps 3, 4 and 5. If instruments continue to have visual contamination, they should not be used and should be disposed of.
7. Preparation: After cleaning/disinfection, visually inspect all instruments for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. FloSpine has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

STERILIZATION: INSTURMENTS

Sterility: Ti-Largo™ Cervical Interbody System instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle: Pre-vacuum Steam Sterilization
Minimum Temperature 132° C (270° F)
Exposure 4 Minutes
Drying Time 40 Minutes

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. 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).

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling FloSpine at 561-705-3080.

Caution: Federal Law USA restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE

The Ti-Largo™ Cervical 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 the Ti-Largo™ Cervical Interbody System Surgical technique Manual for complete Instructions for use.

CONTRAINDICATIONS

1. The Ti-Largo™ Cervical Interbody System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice.
2. 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.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.

WARNINGS AND PRECAUTIONS

The use of surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgery. However, these implants are intended only to assist bony healing and are not intended to replace normal body structures. Vertebral Interbody Fusion devices are used to support and maintain alignment while normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants.

1. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and material aspects of surgical implants. Postoperative care is extremely important. The patient should be warned that non-compliance with postoperative instructions could lead to breakage of the implant and/or possibly migration requiring revision surgery to remove the device.
2. The following are specific adverse effects, warnings and precautions, which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should also be explained to the patient prior to surgery.
3. The Ti-Largo™ Cervical Interbody System is used in spinal arthrodesis, or fusion, a surgical procedure to fuse together two or more spinal vertebrae to provide stability to an otherwise unstable spinal column. For optimum results, careful preoperative diagnosis and planning, meticulous surgical technique, and extended postoperative care are essential. It is important that both patient and doctor be fully aware of all possible risks and complications involved in such a procedure.
4. The Ti-Largo™ Cervical Interbody System implants are manufactured from grade 23 titanium ASTM F3001 and are used as vertebral interbody devices.
5. Prior to use, the physician should be trained in the surgical procedure recommended for use of these devices.
6. Do not use Titanium and Stainless Steel components together as the combination has a potential to cause corrosion.
7. The Ti-Largo™ Cervical Interbody System has not been evaluated for safety and compatibility in the MR Environment. The Ti-Largo™ Cervical Interbody Fusion System has not been tested for heating or migration in the MR environment. The Ti-Largo Cervical 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 Ti-Largo Cervical Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE

1. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.
2. Correct selection of the implant is extremely important. The potential for successful healing 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 presents limitations on the size and strength of implants. Internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full load bearing.
3. These devices can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load sharing devices which maintain support until healing occurs. If healing is delayed, or does not occur, the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
4. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt air, etc. Inspection should be made to determine if components have been damaged during storage or previous procedures.
5. Patient conditions and /or predispositions such as those previously addressed, should be avoided.
6. An adequate inventory of implant sizes should be available at the time of surgery.
7. Allergies and other reactions to device materials although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
8. Special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.
9. Before the initial experience, we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device, and/or attend a training course.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebral bodies. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the vertebral interbody fusion implants should be checked radiographically prior to final tightening of the construct.
3. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing. This is particularly important should the device be used to treat an unstable fracture. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device. The patient should understand that a titanium implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
2. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
3. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
4. Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

INQUIRIES or additional information such as to receive a Ti-Largo™ Surgical Technique, to place an order, or to report adverse reactions, contact:
FloSpine Customer Services at:
Phone: 561-705-3080
Fax: 561-705-0720 Email: customer@flospine.com

LOT	Lot Number	NON STERILE	Non-Sterilized, Sterilize Before Use
REF	Item Number	Rx Only	Prescription Device
	Single Use Item, Do Not Reuse	STERILE R	Sterilized By Irradiation
	Refer To Instructions For Use		Expiration Date
	Manufacturer		Do Not Use if Package is Open or Damaged
CONT	Contents	EC REP	Authorized European Representative in the European Community
CE	Mandatory conformity mark for products placed on the market in the European Economic Area (EEA)		Caution, Refer To Package Insert