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INSTRUCTIONS FOR USE
TRIPOD-FIX VERTEBRAL BODY AUGMENTATION SYSTEM

Description

Tripod-Fix Vertebral Body Augmentation System (Tripod-Fix) is designed to be implanted into a collapsed vertebral body for restoration. Tripod-Fix is made of titanium alloy (Ti-6Al-4V ELI) conforming to ISO 5832-3 and ASTM F136. The system is composed of an expansion stent and a fixing screw. The stent is intended to be expanded in the vertebral body to restore the anatomical height mechanically, and the fixing screw is to maintain the structure of the system. Tripod-Fix is to be implanted via a transpedicular approach. All implants are intended for single use only and should not be reused under any circumstances.

- **Expansion Stent (Sterile)**

REF No.	40-465000	40-465800
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Color	Gold	Dark blue
Unexpanded Diameter (mm)	5.0	5.8
Length (mm)	25.0	28.0
Full Expansion Height (mm)	15.0	17.0

- **Fixing Screw (Non-sterile)**

For Expansion Stent 40-465000

REF No.	40-465002	40-465024
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter (mm)	3.0	3.0
Length (mm)	23	25
Advancing Distance* (mm)	0.0-2.0	2.0-4.0

For Expansion Stent 40-465800

REF No.	40-465802	40-465824	40-465846
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter (mm)	3.0	3.0	3.0
Length (mm)	23	25	27
Advancing Distance* (mm)	0.0-2.0	2.0-4.0	4.0-6.0

* Advancing Distance: same as the advancing distance of the implant driver utilized to expand the expansion stent to a certain height

* Fixing Screw is optional

Indications for Use

Tripod-Fix is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5 in skeletally mature patients that may result from osteoporosis (i.e., T-score of <-2.5 SD according to WHO criteria).

Tripod-Fix is intended to be used in combination with Teknimed F20 bone cement or TECRES Mendec® Spine HV system, and to be implanted transpedicularly through a pedicle channel with the minimum diameter given below. Pre-operative CT scan is recommended to confirm the adequacy of the vertebral dimensions.

Expansion Stent REF No.	40-465000	40-465800
Minimum Pedicle Channel Diameter (mm)	5.7	6.5

Contraindications

Tripod-Fix is not indicated for any other application other than that for which it is designed. Contraindications for Tripod-Fix include, but are not limited to

- Patient presenting a loss of vertebral height >50% compared to estimated pre-fracture height
- Sclerotic fracture
- Patient with a prior history of intolerance or of allergic reaction to titanium and/or one of the components of the PMMA cement

- Patient suffering from irreversible coagulopathy or undergoing anticoagulant treatment at the moment of surgery or at least 8 days prior to inclusion
- Active infection (systemic or in the target vertebra)
- Patient suffering from a severe or uncontrolled systemic disease
- Patient presenting a pathological fracture with the presence of a mass within the spinal canal
- Patient presenting neurological damage caused by vertebral fracture
- Patient pregnant or likely to be so or breastfeeding
- Patient vertebral anatomy not compatible with the size of the implant or instrumentation
- Fracture geometry making the insertion of the implant impossible

In addition, please refer to the contraindication listed in the Instructions for Use of the PMMA bone cement to be used with the Tripod-Fix implants.

Possible Side Effects

Patient should be advised of possible side effects before operation. Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to

- Infections
- Haematomas
- Bleedings
- Allergies
- Thrombosis
- Adjacent vertebral fracture
- Rib fractures
- Intolerance to anesthesia
- Cement leaks
- Pulmonary embolism
- Fall in blood pressure
- Cement intolerance
- Temporary aggravation of local pain
- Neurological complications (organic malfunctions, paraesthesia, radiculopathy, spinal canal or neural foraminal compression)

Warnings and Precautions

- The expansion stent of Tripod-Fix is sterilized with gamma radiation. Do not use if the package is open or damaged. Do not resterilize.
- The fixing screw of Tripod-Fix is non-sterile and must be sterilized prior to use.
- Do not use the device after the expiration date indicated on the package label.
- Tripod-Fix should only be used by qualified spinal surgeon trained in the use of surgical instruments and relevant surgical procedures. The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal device.
- The information contained in the package insert is necessary but not sufficient for the use of these devices. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.
- Anyone using Tripod-Fix can obtain a Surgical Technique Manuals by requesting one from a distributor or from Wiltrom Co., Ltd. directly. Those using manuals published more than two years before the surgical intervention are advised to get an updated version.
- Correct selection of the implants is extremely important. Proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. The surgeon is responsible for this choice which depends on each patient.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the system. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
- Since the implant cannot be closed again after opening, the surgeon must check the correct position of the implant in the vertebra before its expansion. It is imperative to open the implant once it is in the correct position.
- Fluoroscopic controls must be used at all times throughout the operation to facilitate implant site preparation, precise positioning and restoration.
- During the implantation, avoid any contact with other materials or instruments which could damage Tripod-Fix.
- The Tripod-Fix has not been tested for heating or migration in the MR environment.
- Tripod-Fix must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

- The fixing screw which has not been used but got contaminated by contact with the blood, tissue, and/or body fluids/materials, should not be used again.
- Wiltrom surgical instruments, driver and cement transfer tube, are unique to the implantation of the Wiltrom spinal implants and must be used to assure accurate implantation.
- Instruments must be examined for wear or damage prior to surgery. Surgeons must verify that the instruments are in good condition and operating order prior to each use during surgery.
- Surgeons must instruct patients regarding appropriate and restricted activities in order to prevent placing excessive stress on the implants. Surgeons must instruct patients to report any unusual changes of the operative site to the physician. The physician should closely monitor the patient if a change at the site has been detected. Postoperative care and the patient's ability and willingness to follow instructions are important.
- Tripod-Fix is not intended to be removed unless the management of a complication or adverse event requires the removal.
- Explanted or soiled devices must be treated as clinical wastes. Waste disposal must be in accordance with the hospital requirements and applicable local regulations.

Information for patients

- Detailed instructions on the limitations of the device should be given to the patient. The patient must be warned of the surgical risks and made aware of possible adverse effects.
- Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
- The patient should be advised not to smoke or consume alcohol, or use the other except steroids and aspirin drugs after the surgery.
- Before an MRI or CT scan, the patient must indicate that he/she has received Tripod-Fix implantation.

Handling Instructions

Selection of implants should be based on vertebral dimensions of the patient (i.e., the inner diameter of the pedicle, the inner anteroposterior diameter of the vertebral body). The desired restoration height should also be considered. Prior to implantation, an adequate space should be created for implant placement. The folded expansion stent is then inserted and expanded to an optimal height with an implant driver. The surgeon can select a fixing screw with an appropriate length according to the advancing distance of the implant driver. With the injection of PMMA bone cement through the same implantation pathway, the restoration can be maintained and the stability of the spine is enhanced by the whole implant system.
The use of 2 implants is recommended. The surgeon may decide to use and expand one single implant based on the fracture type to be treated (e.g., unilateral fracture).

Sterilization Instructions

The expansion stent of Tripod-Fix is to be supplied sterile, and the fixing screw is non-sterile. The sterility of the device can be identified on the package label. The non-sterile products must be sterilized by the hospital before use. All implants and instruments must be free of packaging materials and bio-contaminants prior to sterilization. The specially designed container provided by Wiltrom can be sterilized directly. Unless specified elsewhere, these non-sterile products should be steam sterilized using the process parameters that have been validated to provide a 10^{-6} sterility assurance level (SAL).

- Pre-vacuum cycle
  - Temperature: 132°C/270°F
  - Exposure time: 4 minutes
  - Minimum drying time: 45 minutes
- Gravity displacement cycle
  - Temperature: 121°C/250°F
  - Exposure time: 30 minutes
  - Minimum drying time: 45 minutes

Note: a) Package fixing screws and instrument sets in rigid trays and cases with lids. Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI ST79 double wrap method or equivalent.
b) It is the responsibility of the Hospital to ensure that only the validated sterilizers and qualified sterilization accessories (e.g., sterilization wrap, sterilization pouches, indicators and sterilization cassettes) are used for the selected sterilization cycle.
c) Although the treatment of the instruments, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times the non-sterile implant and instruments can be resterilized.

Packaging, Shelf-life and Storage

Packages for each components of Tripod-Fix should be intact upon receipt.
The shelf-life of the sterile expansion stent is 5 years, and the shelf-life of the non-sterile fixing screw is 10 years. Tripod-Fix should be stored and transported in a cool and dry place at a temperature not exceeding 25°C. The implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc.

Sterilized, packaged fixing screws and instruments should be stored in a designated, limited access area that is well ventilated

and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes. The package should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: a) Maintenance of sterile package integrity is generally event related. If a sterilization wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture or dropped on unsanitized surfaces, the device must be repackaged and sterilized.

b) If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the device resterilized.

Inspection and trial assembly are recommended prior to surgery to determine if any components have been damaged during the storage processes.

Surgical Technique Manuals

The Surgical Technique Manual for the Tripod-Fix can be obtained by requesting one from a distributor or contacting with Wiltrom Co., Ltd. at service@wiltrom.com.tw or 886-3-610-7168.

	The expansion stent of Tripod-Fix has been sterilized using irradiation
	The fixing screw of Tripod-Fix has not been subjected to a sterilization process
	Tripod-Fix is intended for one use on a single patient during a single procedure
	Users need to consult the instructions for use
	Tripod-Fix should not be used if the package has been damaged or opened
Rx Only	Tripod-Fix is for prescription use only
	The upper limit of temperature to which Tripod-Fix can be safely exposed is 25°C
	Tripod-Fix needs to be protected from light sources
	Tripod-Fix needs protection from moisture

Manufacturer:

Wiltrom Co., Ltd.

1 F, No. 26, Sec. 2, Shengyi Rd.
Zhubei City, Hsinchu County, 30261
Taiwan (R.O.C.)

TEL: +886-3-610-7168
FAX: +886-3-658-0006

EU Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd
2595AA, The Hague
Netherlands

TEL: +31-64-416-8999
E-mail: peter@lotusnl.com

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