ZIMMER BIOMET

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RECONSTRUCTIVE INTERPOSITIONAL PEEK TITANIUM WEDGE SYSTEM (RIPTIDE)
PACKAGE INSERT

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

DESCRIPTION OF THE MEDICAL DEVICE:

The implants are:

- The Ti/PEEK RIPTIDE is an implant constructed of Polyetheretherketone (PEEK), medical-grade as described by ASTM F2026, with a titanium plasma spray as described by ASTM F1580.
- The device is open in the transverse plane to allow insertion of autograft or allograft into the device before placement.
- The tantalum sphere markers used for this product are made to the voluntary standard ASTM F560.
- The radiolucent PEEK material allows visualization of the defect site on the radiograph to assess bone growth.
- For all indications, this device is intended to be used with supplemental bone fixation systems that have been cleared for use in the foot (i.e., trauma screw systems, peanut plate systems, and rod systems.)

The Zimmer Biomet RIPTIDE System contains an optional single use sterile instrument kit containing all the instruments necessary for a procedure involving the implantation of a single wedge. These instruments include: an inserter, trials, and a tamp. These components will be provided in a sterilized package to accommodate a range of anatomical sites and are discarded after the procedure is complete, removing the need for any facility reprocessing.

The Zimmer Biomet Ti/PEEK RIPTIDE implants are supplied sterile.

INDICATIONS FOR USE

Reconstructive Interpositional PEEK Titanium Wedge System Indications

The Zimmer Biomet Reconstructive Interpositional PEEK Titanium Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies in the ankle and foot such as:

- Cotton and Evans Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform of Cotton osteotomies
  - Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Midfoot Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation
The Zimmer Biomet RIPTIDE is not intended for use in the spine

MATERIAL

The Zimmer Biomet RIPTIDE devices are constructed from Polyetheretherketone per ASTM F2026 and have a titanium plasma spray per ASTM F1580. Each implant contains Tantalum markers per ASTM F560. The specialized instruments are made primarily of surgical-grade stainless steel (ASTM F899) and titanium.

HOW SUPPLIED

Zimmer Biomet RIPTIDE Instruments are delivered either non-sterile or in a single use sterile instrument kit as specified by the packaging.

Zimmer Biomet RIPTIDE Implants are delivered **sterile** as specified by the packaging. All sterile implants are gamma radiation sterilized. The package should be inspected before use to ensure the sterile barrier has not been compromised. Do not resterilize.

CONTRAINDICATIONS

The operation should not be carried out against the following contraindications:

- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. 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. The size and shape of the human foot present limiting restrictions on the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight-bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand before surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage before use.
3. All instruments must be cleaned and sterilized before surgery.
4. As with all orthopaedic implants, ZIMMER BIOMET RIPTIDE should never be reused under any circumstances.
5. The Zimmer Biomet RIPTIDE should never be used with dissimilar materials.
6. Proper implant selection and patient compliance with postoperative precautions will affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
7. Postoperative care is important. The patient should be instructed on the limitations of his/her implant and should be cautioned regarding weight-bearing and body stress on the appliance before securing healing.

PRECAUTIONS

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Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during post-operative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities. The patient should be advised not to smoke or consume alcohol during the healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening, or breakage of the device(s). Immobilization of the foot surgical site must be maintained until a firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until the bony union is confirmed.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Zimmer Biomet RIPTIDE Device components should ever be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS

1. bending, loosening, or fracture of the implants or instruments.
2. loss of fixation.
3. sensitivity to a metallic foreign body, including possible tumor formation.
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications.
5. Non-union or delayed union.
6. infection.
7. nerve or vascular damage due to surgical trauma.
8. gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency
9. and/or loss of consortium.
10. pain or discomfort.
11. bone loss due to resorption or stress shielding, or bone fracture.
12. hemorrhage of blood vessels and/or hematomas.
13. malalignment of anatomical structures.
14. bursitis.
15. autograft donor site pain.
16. inability to resume activities of normal daily living.
17. reoperation.
18. death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The Zimmer Biomet RIPTIDE has not been evaluated for safety and compatibility in the MR environment. The Zimmer Biomet RIPTIDE implant has not been tested for heating or migration in the MR environment.

DIRECTIONS FOR USE

The operating surgeon is solely responsible for determining an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be met before application:

- All requisite implant components are ready to hand

- Operating conditions are highly aseptic
- The implantation instruments are cleaned and sterilized before use according to the procedures outlined in this document.
- The implantation instruments, including the special Zimmer Biomet RIPTIDE instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:

- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The lifespan of the implant is dependent on a variety of factors that can include but are not limited to body weight, patient compliance with weight-bearing, activity level, etc.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

Implanting the Ti/PEEK devices

- Select the appropriate Ti/PEEK implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments for preparing the implant bed, as well as the implantation instrument.
- To implant the Zimmer Biomet RIPTIDE implants, use only the specialized Zimmer Biomet RIPTIDE instrumentation. Do not use implants or instruments from any other system or manufacturer.
- Apply appropriate care when inserting the implant.
- Check implant height and/or angle using the trial implants.

For complete instructions regarding the proper use and application of all Zimmer Biomet RIPTIDE implants and instruments, please refer to the Zimmer Biomet RIPTIDE Surgical Technique Manual (provided with the system).

CARE AND HANDLING

Some Zimmer Biomet RIPTIDE Instruments provided non-sterile should be stored in the original packaging until cleaned and sterilized. Before use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION section for recommended parameters.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure the safe handling of biologically contaminated devices.

Containment and Transportation

It is recommended that devices are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Remove excess soil with a clean, lint-free, disposable, absorbent cloth.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the devices by placing them under running water and scrubbing them with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other load devices in such a way that the parts can drain.
- At a minimum, use a cycle meeting the following parameters:

Enzyme Wash	Hot (40 - 65 ℃) (104 - 149 ℉) for 3 minutes
Neutral pH Wash	60 ℃ (140 ℉) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 ℃ (194 ℉) for 1 minute
Dry	82 ℃ (180 ℉) for 6 minutes

- Determine if the devices are dry. If they are not dry, dry them with a soft, clean, lint-free cloth.
- After drying, check devices for complete removal of any debris. If necessary, repeat the cycle or use manual cleaning. Replace devices that cannot be cleaned.

Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the devices by placing them under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each device for at least one minute.
- Bathe the devices in the enzymatic solution for 5 minutes; where appropriate, the device shall be rotated and briskly moved in the bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the devices with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint-free cloth.
- After drying, check devices for complete removal of any debris. If necessary, repeat manual cleaning. Replace devices that cannot be cleaned.

Inspection and Function Testing

Visually inspect all devices under normal lighting to ensure the cleaning was effective. Inspect for surface damage and wear. Check for staining, discoloration, corrosion, misalignment, burrs, bent or fractured tips. Where devices interface with other devices, inspect to ensure that the devices properly interface. Mechanically test the working parts to verify that each device functions correctly. Replace any device that is not functioning.

Verify the legibility of all markings. Replace any device that is unreadable.

Repeat the cleaning and/or replace the affected devices as needed to ensure proper operation before proceeding with sterilization.

Device Replacement

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any Tyber Medical instrument.

If your Tyber Medical device is defective or damaged, contact your local Tyber Medical Distributor. In your correspondence please include, at minimum, the following:

- Device Part Number
- Device Lot Number
- Description of defect or damage
- Information on whether the device is available for return

Packaging

Instruments may be loaded into the specified Zimmer Biomet instrument trays or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization

For sterile implants and kits, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage before surgery. If the sterile barrier has been broken, return the component to Zimmer Biomet. Do not re-sterilize.

If not specifically labeled **STERILE**, components are supplied non-sterile. Non-sterile instruments must be cleaned and sterilized before surgery.

Warning: Zimmer Biomet does not recommend that the instruments be sterilized by Flash, EtO, or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, Zimmer Biomet recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum	
Minimum Temp.	132 ℃ (270 ℉)	132 ℃ (270 ℉)	135 ℃ (275 ℉)
Exposure*	15 min	4 min	3 min
Dry Time	20 minutes		

**Tyber Medical has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.*

Zimmer Biomet recommends following ANSI/AAMI ST79, a *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which includes physical monitoring of the cycle, the inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

Zimmer Biomet RIPTIDE implants are provided sterile and cannot be resterilized.

Storage

Zimmer Biomet instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas that protect from dust, insects, chemical vapors, and extreme changes in temperature and humidity.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery.

When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Zimmer Biomet customer service for the return of removed implants.

DISPOSAL

Observe internal hospital/institution procedures, practices, and guidelines, and/or government regulations for proper handling and disposal of the Zimmer Biomet RIPTIDE System devices.

CUSTOMER SERVICE

For further information regarding the Zimmer Biomet RIPTIDE or a copy of the Zimmer Biomet RIPTIDE Surgical Technique Manual, please contact Zimmer Biomet or your local Zimmer Biomet Distributor.

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Symbols Glossary		
Symbol	**Title/Standard**	**Meaning**
REF	ISO 15223-1 5.1.6 Catalogue Number	Indicates the *manufacturer's catalogue number* so that the *medical device* can be identified
LOT	ISO 15223-1 5.1.5 Batch Code	Indicates the *manufacturer's* batch code so that the batch or lot can be identified
	ISO 15223-1 5.1.3 Date of Manufacture	Indicates the date when the *medical device* was manufactured (Country of Manufacture symbol supersedes use of this symbol)
	ISO 15223-1 5.1.4 Use-by date	Indicates the date after which the *medical device* is not to be used
STERILE R	ISO 15223-1 5.2.4 Sterilized using irradiation	Indicates a *medical device* has been sterilized using irradiation
	ISO 15223-1 5.4.2 Do not re-use	Indicates a *medical device* that is intended for one *single use* only
	ISO 15223-1 5.2.8 Do not use if package is damaged and consult instructions for use	Indicates that a *medical device* that should not be used if the package has been damaged or opened and that the user should consult the *instructions for use* for additional information
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the *instructions for use*
	ISO 15223-1 5.1.1 Manufacturer	Indicates the *medical device manufacturer*
UDI	ISO 15223-1 5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information
CC	ISO 15223-1 5.1.11 Country of manufacture	To identify the country of manufacture of products
	ISO 15223-1 5.2.12 Double sterile barrier system	Indicates two *sterile* barrier systems
Rx only	21 CFR 801.109b Prescription Only	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
QTY	Quantity	Indicates the quantity of devices
MATL	Material	Indicates the material of the device
	ISO 15223-1 5.1.9 Distributor	Indicates the entity distributing the medical device into the locale
NON STERILE	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
MD	ISO 15223-1 5.7.7 Medical Device	Indicates the item is a *medical device*