Ref. PCB00019 Rev 04/Nov 2, 2020

ENGLISH / INSTRUCTIONS FOR USE

OSSIO*fiber*® Compression Screw

DESCRIPTION
The OSSIO*fiber*® Compression Screws are cannulated bone screws made of degradable poly (L-lactide-co-D,L-lactide) (PLDLA) reinforced with continuous mineral fibers. The polymer content degrades by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The fibers are made from materials that are found in natural bone. As the OSSIO*fiber*® implants degrade, the load transfers to the surrounding anatomy throughout the healing period of the osteotomy, fusion, or fracture. Substantial degradation takes place within approximately 18 months as shown in pre-clinical studies, thus eliminating the requirement for future hardware removal surgery.

The OSSIO*fiber*® Compression Screws are supplied sterile, for single patient use only, and are available in several sizes.

The OSSIO*fiber*® Compression Screws are designed to be used with commonly available orthopedic surgical tools such as ISO 5835/ISO 9714 compatible instrumentations.

CONTENTS

1 each OSSIO*fiber*® Compression Screw

Please refer to the valid product brochure for the available offerings and product codes.

INDICATIONS
The OSSIO*fiber*® Compression Screws are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization.

CONTRAINDICATIONS
The OSSIO*fiber*® Compression Screw should not be used in situations where internal fixation is otherwise contraindicated, e.g., active or potential infection, limited blood supply, insufficient quantity or quality of bone, or where patient post-operative compliance cannot be guaranteed.

WARNINGS
- Federal law restricts this device to sale by or on the order of a licensed physician.
- The OSSIO*fiber*® Compression Screw is supplied sterile for single patient use only.
- DO NOT use if sterility of the device is in suspicion.
- DO NOT use device if packaging is damaged or previously opened.
- DO NOT reuse, reprocess or re-sterilize. Reusing, reprocessing or re-sterilization could lead to device failure and contamination, which might result in an adverse event for the patient or user.
- DO NOT use device beyond the expiration date.
- DO NOT use device if temperature sensor on packaging is black indicating device has been exposed to temperatures outside of indicated threshold.

PRECAUTIONS
- The surgeon must evaluate each situation individually based on the patient's clinical presentation, including patient weight, age, bone quality, concomitant medications, activity level and preoperative level of health. Incorrect patient selection could lead to increased risk of failure and can be critical to the eventual success of the procedure.
- Incorrect selection, placement, positioning, and fixation of the implant can cause subsequent undesirable results.

- It is strongly recommended that the patient is informed of the surgical risks and possible adverse effects prior to surgery and warned that non-compliance with post-operative instructions can cause failure of the treatment, which could require additional surgery and device removal.
- The surgeon should be familiar with the device and the technique prior to use.
- Prior to use, carefully inspect the implant for damage. DO NOT use if implant is damaged.
- Excessive force, such as bending or flexing, on the implants during procedure may cause breakage or damage to the device or surrounding bone.
- Use only appropriate instrumentation for the chosen implant and procedure.
- Surgeons should use professional judgement for prescription of implant, indications, surgical technique, and patient history to determine appropriate implant size, configuration, instrumentation and surgical site preparation.
- Before closing the surgical incision, the surgeon must ensure proper alignment and adequate fixation.
- DO NOT cut or shape the implant.
- DO NOT use temperature cautery to cut or shape the implants.
- Safety and effectiveness cannot be guaranteed in case of off-label use.
- The effect of the OSSIO*fiber*® Compression Screw Implant on the healing of growth plates has not been evaluated clinically.
- Restricted to use by a licensed professional.
- A controlled 2-year study was performed in an animal model to complete resorption. While there were no macroscopic adverse clinical signals associated with the device, and there was no evidence of pain or distress in the animals throughout the study, animal data may not predict human clinical outcomes. Patients should be advised of potential adverse effects of absorbable implanted devices, including foreign body reactions, such as inflammation and/or pain. These potential adverse effects may occur at various post-operative timepoints, including beyond fracture healing, as the device undergoes resorption.

SURGICAL TECHNIQUE

NOTE: The surgeon must choose the appropriate size OSSIO*fiber*® Compression Screw and appropriate instrumentation that best meet the patient's surgical needs.

Several surgical techniques are commonly available that describe the use of these implants. It is the responsibility of the surgeon to be familiar with the procedure before use of these products.

1. Prepare and stabilize the fixation site in order to achieve good alignment of the fracture/osteotomy
2. Align a drill guide on the bone in the desired trajectory and insert a K-wire to the desired depth
3. The K-wire may be used in conjunction with a depth measuring device to aid in determining appropriate screw length
4. Create a pilot hole over the K-wire with the appropriately sized drill, tap, and countersink instrumentation

   NOTE: A drill and tap can be used with an associated drill guide to maintain an aligned trajectory and protect surrounding tissue

   NOTE: It is recommended to use the tap and countersink instruments on hard bone to ensure proper implant performance

5. Insert the screw with the appropriate inserter type over the K-wire into the prepared hole and thread until the proximal portion of the screw is seated into the bone
6. Confirm desired alignment and adequate fixation and complete procedure by routine closure using preferred technique.

   NOTE: If adequate fixation is not achieved, the implant can be manually removed or drilled through using appropriate instrumentation

ADDITIONAL CONSIDERATIONS

- Use proper local, regional or general anesthesia.
- Maintain a sterile field throughout the procedure.
- Perform proper exposure using standard surgical procedures.
- Thoroughly prepare the surgical site while preserving the neurovascular structures through careful dissection.
- Achieve good alignment/reduction of the fracture/osteotomy.
- Radiographs can be taken before wound closure to assess the alignment/reduction following fixation.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.
- As with any surgical procedure, careful post-operative management is important for optimal healing.
- Provide the patient with detailed instructions for post-operative care.
- Use appropriate additional immobilization (e.g., a suitable cast, brace and/or crutches) during bone healing.

- Antibiotic therapy is at the discretion of the clinician.
- Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of osteotomies and fracture management in reconstructive surgical applications. These implants provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.
- Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the implant. Avoid pull-out of the implant during the procedure. Before closing the wound, the surgeon must ensure proper fit of the implant and adequate fixation.
- The type of procedure will determine the nature of post-operative weight bearing, external immobilization and rehabilitation regimen.
- The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. The patient is to be instructed on the use of external supports, walking aids, and braces that are intended to immobilize the operated site and limit weight or load. The patient is to be made fully aware and warned that the device can break, bend, become loose, migrate or be otherwise damaged as a result of early weight bearing, load bearing, stress, excessive activity and trauma.

IMAGING COMPATIBILITY

X-ray, CT or MRI can be used.
The implant is MR Safe. NOTE: The MRI safety information provided is for the implant only and does not include supplementary devices. If there are supplementary devices (e.g. rigid fixation implants, cast, brace, etc.) present in proximity to the implant, this could result in additional MRI effects and the information provided above may not be applicable.

ADVERSE EFFECTS

The following is a non-exhaustive list of possible complications related to internal fixation methods:

- Infection
- Neurovascular injuries due to surgical trauma
- Implantation of foreign materials can result in an inflammatory response or an allergic reaction. Transient local fluid accumulation may occur in sterile circumstances
- Soft tissue irritation
- Premature bending, loosening, breakage or migration of the implant
- Non-union, delayed union, or inadequate healing
- Pain, discomfort, or abnormal sensation
- Disfigurement due to improper alignment of bone fragments

STERILITY

The OSSIO*fiber*® Compression Screws are sterilized by exposure to ethylene oxide (EtO) gas.

MATERIAL COMPOSITION

The device is made of Poly(L-lactide-co-D,L-lactide) (PLDLA), Silicone dioxide (SiO_2), Calcium Oxide (CaO), Sodium Oxide (Na_2O), Magnesium Oxide (MgO), Phosphorus Pentoxide (P_2O_5) and Boron trioxide (B_2O_3).

STORAGE

Store at room temperature (7 to 30°C / 45 to 86°F) at a normal relative humidity. Do not expose product to temperatures greater than 47°C or 116°F.

MANUFACTURER

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SYMBOLS GLOSSARY

Symbol	Symbol title	Symbol explanatory text	Relevant standard	Symbol reference
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1:2016*	5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2016	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2016	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2016	5.1.6
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2016	5.2.3
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1:2016	5.2.6
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2016	5.2.8
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1:2016	5.3.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2016	5.3.7
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2016	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2016	5.4.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1:2016	5.4.4

RxOnly	Prescription device	Federal law (USA) restricts this device to sale by or on the order of a licensed physician	Alternative to Certain Prescription Device Labeling Requirements; Guidance for Industry, FDA, January 2000,	21 CFR sec. 801.109(b)(1)
MR	MR safe	Indicates an item that poses no known hazards resulting from exposure to any MR environment.	ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.1; Table 2
QTY	Quantity	Indicates quantity of medical devices contained within the packaging	N/A	N/A

* The full title of this standard is: ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements; this note applies to other mentions of this standard in this glossary.