Part No. 030-1269
Rev. U

OSTEOMED

ExtremiFix

Rigid Fixation System

2.0/2.4mm and 3.0/4.0mm Cannulated Screw System

Product Information and Instructions for Use

Description

The *OSTEOMED Cannulated Screw System is* comprised of screws and washers used for bone fixation of the hand and foot following trauma or osteotomy. The System features cannulated screws in the following dimensions:
2.0mm screw diameter – 10mm to 42mm screw length;
2.4mm screw diameter – 10 mm to 50mm screw length;
3.0mm screw diameter – 10mm to 40mm screw length;
4.0mm screw diameter – 12mm to 52mm screw length;
The system instruments include depth gauges, screwdrivers, countersinks, guidewires, and other instruments to facilitate the placement of screws.

Material

The screws and washers are made from Titanium Alloy (ASTM-F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The *OSTEOMED Cannulated Screw Systems* are indicated for bone fixation of hand and foot following trauma or osteotomy. The cannulated screws and washers are intended for single use only. The system drills and guide wires are single use instruments. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications

Use of the *OSTEOMED Cannulated Screw System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.

Warnings

1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments, guide wires and screws are to be treated as sharps.
5. Failure to engage distal cortex with LDA screws may result in screw loosening.
6. Use of screws in high density bone may result in implant and/or instrument fracture or failure upon insertion.
7. It is recommended to remove any fractured implants and/or instruments from patients during surgery. If unable to remove, notify patient.
8. The *OSTEOMED Cannulated Screw System* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating and migration in the MR environment.
9. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The *OSTEOMED Cannulated Screws* are not intended to endure excessive abnormal functional stresses.
- The *OSTEOMED Cannulated Screws* are intended for temporary fixation only until osteogenesis occurs.
- All OsteoMed Cannulated Bone Screws and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the OsteoMed implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Do not use Instruments which are faulty, damaged or suspect, Replace and contact OsteoMed for further instructions regarding disposition and/or repair.
- Use OsteoMed products in a sterile environment.
- Depth Gauge marking tolerance: ± 0.25mm.

Surgical Technique:

1. Place a bone clamp to create the necessary compression across the osteotomy or fusion site (when applicable). Note: This step is very important if bone is dense and in arthrodesis, as the axial force necessary for inserting the cannulated screw could temporarily distract the fragments at the fracture/arthrodesis line.
2. Insert a guide wire to the appropriate depth under image intensification. DO NOT BEND GUIDE WIRE WHEN PLACING IN BONE.
3. Slide the depth gauge over the guide wire until tip bottoms out on bone; the end of the guide wire will indicate the screw length required. Subtract appropriately for any anticipated interfragmentary compression resulting from screw insertion.
4. If necessary, use the countersink to create a recess in the bone for cannulated lag screws. Note: ExtremiFix screws are self drilling and self tapping, but drilling is recommended in cases of dense bone. If significant resistance is felt while inserting the screw, back out the screw and use a larger diameter drill per the table below. Remember to use irrigation when pilot drilling.

Screw diameter	Recommended drill size
2.0mm	2.0/2.4mm drill (Ø1.7mm)
2.4mm	2.0/2.4mm drill (Ø 1.7mm)
3.0mm	3.0/4.0mm drill (Ø2.3mm)
4.0mm	3.0/4.0mm drill (Ø2.3mm) Or 4.0mm drill (Ø2.7mm)

5. Select the appropriate screw diameter and length. Use the screw remover to remove the desired cannulated screw from the screw block. Slide the screw over the K-wire. Optional: If deemed clinically appropriate, place a washer over the K-wire prior to placing the screw.
6. Use the screwdriver stem and screwdriver handle to drive the cannulated screw into bone until the desired compression is achieved.
7. Remove and discard the guide wire.

Surgical Technique for Arthrodesis of the 2nd through 5th digits

1. Expose the joint space dorsal of the proximal interphalangeal joint.
2. Resect the articular surfaces of the proximal interphalangeal joint.
3. Using a pin driver and a .035" double trocar guide wire, insert the guide wire centrally into the middle phalanx, drilling toward the distal phalanx.
4. Position the distal phalanx in the desired position and continue inserting the guide wire, maintaining a central position.
5. Continue driving proximal to distal until the guide wire is protruding through the distal phalanx. Assure that the guide wire is sufficiently exposed to allow for capture with pin driver.
6. With the pin driver, retract the guide wire until the proximal end is only exposed 1 to 2 mm.
7. Extend the digit to obtain proper alignment between the guide wire and the proximal phalanx. Surgeon judgment should be used to ensure sagittal plane stability and toe purchase.
8. Drive the guide wire to engage the proximal phalanx, assuring that the guide wire does not pass into the metatarsophalangeal joint.
9. CAUTION: Intra-operative imaging should be used to verify that metatarsophalangeal joint space is not compromised by guide wire. Verify that guide wire is not bent in any way.
10. Using the appropriate depth gauge, determine screw length.
11. Optional: Countersink, if desired and bone surface is adequate. Do not countersink before measuring.
12. Optional: Drill, if necessary, in dense bone using the cannulated drill.
13. Place screw on guide wire and drive screw until fully seated. Ensure the implant is placed appropriately against the distal phalanx. Avoid entering the MPJ joint with the screw. Engage the distal cortex to ensure thread purchase.
14. Optional: If deemed clinically appropriate, place a washer over the guide wire prior to placing the screw.
15. Remove guide wire and discard.

Alternative Method for Arthrodesis of the 2nd through 5th Digits:

1. Use a .062" guide wire in place of the .035" guide wire.
2. After step 9, replace the .062" guide wire with the .035" guide wire.
3. Ensure that .035" guide wire follow pilot hole created by .062" guide wire.
4. Proceed with Step 10, DO NOT DRILL AS STATED IN OPTIONAL STEP 12.

Screw Removal (if necessary):

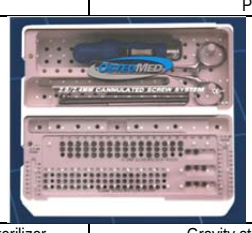
1. Locate implant with intraoperative imaging.
2. Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
3. Engage screw head with driver and rotate counterclockwise until screw is removed.
4. Optional: If screw head is stripped, engage cannula of screw with screw extractor by turning counterclockwise and exerting light pressure. Continue turning counterclockwise until screw is removed.
5. If screw is integrated with bone, core out with trephine.

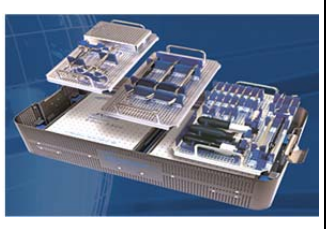
Cleaning

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation:
  1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
  2. Thoroughly rinse all instruments and the sterilization tray with water.
  3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
  4. Steam Autoclave per the following Sterilization Instructions.

Sterility

- Implants are provided non-sterile or sterile packaged (Gamma Sterilized). DO NOT USE IF IMPLANT STERILE PACKAGE IS DAMAGED. DO NOT USE IMPLANTS AFTER EXPIRATION DATE.
- Implants supplied non-sterile must be sterilized prior to use.
- Instruments are supplied non-sterile and must be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED ExtremiFix Cannulated Screw Systems*, the following parameters should be used.

Type of Block or Tray	2.0/2.4mm Cannulated Screw Organizer Block (316-0110) / 3.0/4.0mm Cannulated Screw Organizer Block (316-0010)	
Material	Plastic	Plastic
Tray Configuration		
Type of Sterilizer	Pre-vacuum steam sterilizer	Gravity steam sterilizer
Preconditioning Pulse(s)	3	-
Wrapping Technique/ Tray Preparation	Block wrapped with 2 layers of 1-ply polypropylene wrap	Unwrapped
Minimum Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	10 minutes	40 minutes
Minimum Dry Time	55 minutes	1 minute

Type of Block or Tray	Assembly, Block, 2.0/2.4mm Cannulated Headless (316-1250) Assembly, Block, 3.0/4.0mm Cannulated Headless (316-1350)	ExtremiFix Tray (316-1400)
Materials	Aluminum	Stainless Steel
Tray Configuration		
Type of Sterilizer	Pre-vacuum steam sterilizer	
Wrapping Technique/ Tray Preparation	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential wrapping techniques	Tray wrapped with 2 layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554), with towel placed between the wraps and the bottom of the tray
Preconditioning Pulse(s)	4	3
Minimum Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	4 minutes	10 minutes
Minimum Dry Time	30 minutes	55 minutes
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric Instrumentation		
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.		

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

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CE 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.	STERILE R	Sterile, Method of Sterilization Using Irradiation

Printed in U.S.A.
OSTEOMED August 2014