Part No. 030-1416
Rev. L

OSTEOMED
Rigid Fixation System
Cannulated Screw System
6.5mm and 7.3mm

Product Information and Instructions For Use

Description

The *OSTEOMED 6.5mm/7.3mm Cannulated Screw System* is comprised of screws and washers used for bone fixation following trauma or osteotomy. The system features 6.5mm and 7.3mm diameter cannulated screws in lengths of 40.0mm to 120.0mm with thread lengths of 20mm and 32mm. System instruments include drill guides, depth gauges, screwdrivers, countersinks, taps and drill bits to facilitate the placement of screws. Screw Extractor is available for removal of screws.

Material

The screws 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 System* is indicated for bone fixation following trauma or osteotomy. The *Cannulated Screws and washers* are intended for single use only. The system 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 Systems* are 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. The *OSTEOMED 6.5mm/7.3mm Cannulated Screw System* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
6. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The *OSTEOMED Cannulated Screws are* not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Cannulated Screws are* intended for temporary fixation only until osteogenesis occurs.
5. 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.
6. Carefully inspect the OsteoMed implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
7. OsteoMed recommends the use of OsteoMed products in a sterile environment.
8. Depth Gauge marking tolerance: ± 0.38mm.

Surgical Technique: Open Approach

1. Insert the 2.8 mm Guide Wire (PN 316-0023). Evaluate the placement of the guide wire with intra-operative radiographics. Proper position of the guide wire is critical for screw placement.
2. For parallel screw fixation, parallel guide wires may be placed utilizing the parallel drill guide (PN 316-0018). Place the parallel drill guide over the initial guide pin and rotate it to the desired orientation.
   a. If only a second wire is to be placed: the guide allows a second wire to be placed 8mm away from the first.
   b. If dual screws are to be placed: the guide wires for parallel screw placement should be placed at least 10mm apart to eliminate interference between the screw heads (see laser marking on Parallel Drill Guide, PN 316-0018).

   NOTE: To avoid screw interference, adjustable arm should be placed past the lasermark.
3. Place the Depth Gauge (PN 316-0017) over the guide wire, directly against the cortex to ensure accurate measurement.
   Optional:
   a. Drilling: If drilling is deemed clinically appropriate, place the calibrated cannulated drill (PN 316-0016) over the guide wire and advance the drill 5mm short of the end of the guide wire. The cannulated drill is calibrated in 10mm increments for reference.
   b. Tapping: If tapping is deemed clinically appropriate, place the cannulated tap over the guide wire and advance.
4. Place the cannulated countersink (PN 316-0020) over the guide wire and create a recess in the bone to seat the head of the screw. (Head height = 4 mm)
   NOTE: Overall screw lengths of the 6.5mm and 7.3mm Cannulated Screws are measured from the top of the head to the tip of the screw. The head height (4mm) should be considered when countersinking.
5. Verify screw length using screw length gauge.
6. Place the appropriate screw over the guide wire.
7. Drive the screw.
   Optional: If deemed clinically appropriate, place a washer over the guide wire prior to placing the screw.
   Caution: OsteoMed's 6.5mm/7.3mm Cannulated Screws can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

Surgical Technique: Percutaneous Approach

1. Assemble percutaneous screw sleeve assembly. Place trocar tip through skin incision, directly in contact with bone.
2. Tap the 2.8mm trocar with a mallet to dimple the bone.
3. Remove the 2.8mm trocar and advance the guide pin into the bone through the guide pin sleeve. Evaluate the placement of the guide wire with intra-operative radiographics. Proper position of the guide wire is critical for screw placement.
4. Remove the guide wire sleeve and introduce the depth gauge over the guide wire through the drill sleeve. Place the depth gauge directly against the cortex to ensure a correct screw length reading.
5. Optional*:
   a. Drilling: If drilling is deemed clinically appropriate, place the cannulated drill through the drill sleeve and advance 5mm short of the end of the guide wire. The cannulated drill is calibrated in 10mm increments for reference. Remove the drill sleeve.
   b. Tapping: If tapping is deemed clinically appropriate, place the cannulated tap through the screw sleeve and advance.
6. Place the cannulated countersink over the guide wire and through the screw sleeve to create a recess in the bone to seat the head of the screw. (Head height = 4 mm)
   NOTE: Overall screw lengths of the 6.5mm and 7.3mm Cannulated Screws are measured from the top of the head to the tip of the screw. The head height (4mm) should be considered when countersinking.
7. Verify screw length using screw length gauge.
8. Place the appropriate screw over the guide wire through the screw sleeve; the screwdriver stem is used to advance the screw manually or via a Jacob's chuck.
9. Drive the screw.
   Optional: If deemed clinically appropriate, place a washer over the guide wire prior to placing the screw.
   Caution: OsteoMed's 6.5mm/7.3mm Cannulated Screws can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

Surgical Technique: Screw Extraction

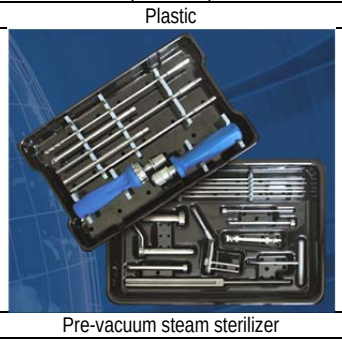
Screw extraction should be performed with the cannulated driver shaft manually. If complications arise during screw extraction, the screw can be removed with the Cannulated Screw Extractor (PN 316-0024). The screw extractor is turned counterclockwise into the cannulation of the screw. The screw extractor will thread into the inner wall of the screw and become bound within the cannulation. When the screw extractor has become bound within the screw, continue to turn the screw extractor counterclockwise to facilitate removal.

Cleaning

- Products must be carefully cleaned prior to sterilization, unless supplied sterile packaged directly from OsteoMed. 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	6.5/7.3mm Cannulated Tray (316-0033)	6.5/7.3mm Cannulated Screw Organizer (316-0600)
Material	Plastic	Aluminum
Tray Configuration		
Type of Sterilizer	Pre-vacuum steam sterilizer	Pre-vacuum steam sterilizer
Wrapping Technique/ Tray Preparation	Tray wrapped with 2 layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554)	
Minimum Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	10 minutes	10 minutes
Minimum Dry Time	35 minutes	35 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.

Storage

Sterile Packaged implants should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering. Sterile implants have a shelf life of 2 years.

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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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

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