Part No. 030-1535
Rev. T

OSTEOMED *ExtremiFix*

Cannulated Headless Screw System

Rigid Fixation System

Product Information and Instructions for Use

Description

The *OSTEOMED* ***ExtremiFix*** *Cannulated Headless Screw System* is comprised of screws in diameters of 2.0mm (10-42mm length), 2.4mm (10-50mm length), 3.0mm (10-40mm length), and 4.0mm (12-52mm length). The system instruments include guide wires, drills, drivers, handle, depth gauge, bone clamp, screw extractor and preparation instruments to facilitate the placement 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* ***ExtremiFix*** *Cannulated Headless Screw System* is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. The screws 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/instrument 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 single use device/instrument if it is used on more than one patient.

Contraindications

Use of the *OSTEOMED* ***ExtremiFix*** *Cannulated Headless Screw System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; in patients with certain metabolic diseases; or in patients where there is insufficient available bone or poor bone quality. 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. It is recommended to remove any fractured implants and/or instruments from patients during surgery. If unable to remove, notify patient.
6. Use of screws in high density bone may result in implant and/or instrument fracture or failure upon insertion.
7. The *OSTEOMED* ***ExtremiFix*** *Cannulated Headless 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.
8. 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

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* ***ExtremiFix*** *Cannulated Headless Screws* are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED* ***ExtremiFix*** *Cannulated Headless Screws* are intended for temporary fixation only until osteogenesis occurs.
5. All *OSTEOMED* ***ExtremiFix*** *Cannulated Headless 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.

Instructions for Use, Cannulated Headless screws

1. Secure proper placement of bone segments to be joined.
   Note: This step is very important if the bone is very dense or in arthrodesis, as the axial force necessary for insertion could temporarily distract the fragments at the fracture/arthrodesis line.
2. Using a wire driver, insert the guide wire toward the distal cortex.
3. CAUTION: Intra-operative imaging should be used to verify proper placement. Verify that guide wire is not bent. When placing more than one screw, ensure that subsequent guide wires do not interfere with other implants.
4. Using the appropriate depth gauge, determine screw length. Subtract any anticipated interfragmentary compression resulting from screw insertion.
   - 4.1 Pre-drilling and proximal cortex drilling:
     - 4.1.1 On softer bone, screws may be inserted without any pre-drilling or proximal cortex drilling.
     - 4.1.2 Pre-drilling is recommended when working with high density bone, especially in a bi-cortical application, using the cannulated drill.

   NOTE: 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 Size	Recommended Drill SIze
2.0 / 2.4mm	2.0/2.4mm drill (Ø 1.7mm)
3.0mm	3.0/4.0mm drill (Ø 2.3mm)
4.0mm	3.0/4.0mm drill (Ø 2.3mm) 4.0mm drill (Ø2.7mm drill)

   - 4.1.3 Use of the proximal cortex drill to skim the proximal cortical surface is recommended. Be sure to accurately measure or the screw may not purchase and the length of the screw may be too long or too short.
   - 4.1.4 When inserting the headless screw in an oblique orientation it may be necessary to drive screw a little further to prevent a portion of the screw from remaining exposed. Note: Use of proximal cortex drill may aid in countersinking the screw.
5. Remove desired screw from screw block. Verify length of screw with screw length gauge.
6. Place screw over guide wire and drive screw until fully seated.
7. Check that screw is seated flush with the surface of the bone.
8. Remove guide wire and discard.

Instructions for Use, Cannulated Headless screws—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 wire 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.
    - 10.1. Pre-drilling and proximal cortex drilling
      - 10.1.1. On softer bone, screws may be inserted without any pre-drilling or proximal cortex drilling
      - 10.1.2. Pre-drilling is recommended when working with high density bone, especially in a bi-cortical application, using the cannulated drill.

    NOTE: 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 Size	Recommended Drill Size
2.0 / 2.4mm	2.0/2.4mm drill (Ø 1.7mm)
3.0mm	3.0/4.0mm drill (Ø 2.3mm)
4.0mm	3.0/4.0mm drill (Ø 2.3mm) 4.0mm drill (Ø2.7mm drill)

      - 10.1.3. Use of the proximal cortex drill to skim the proximal cortical surface is recommended. Be sure to accurately measure or the screw may not purchase and the length of the screw may be too long or too short.
      - 10.1.4. When inserting the headless screw in an oblique orientation it may be necessary to drive screw a little further to prevent a portion of the screw from remaining exposed. Note: Use of proximal cortex drill may aid in countersinking the screw.
11. Remove desired headless screw from screw block.
12. Place screw on guide wire and drive screw until fully seated.
13. Remove guide wire and discard.

Alternate 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 follows the pilot hole created by .062" guide wire.
4. Proceed with Step 11, DO NOT DRILL AS STATED IN OPTIONAL STEP 10.1

Screw Removal: (if necessary)

1. Locate implant with intraoperative imaging.
2. Palpate screw and remove surrounding soft tissue to gain maximum exposure.
3. Insert appropriate guide wire through cannula if possible.
4. Engage screw with driver and rotate counterclockwise until screw is removed.
5. If unable to insert guide wire, engage screw with the solid core driver and rotate counterclockwise until screw is removed.
6. If screw cannot be removed, core out with trephine.

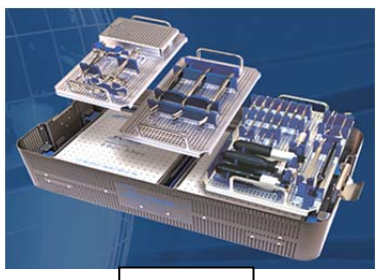
Cleaning

- 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 Sterilization Instructions. Do not reuse single use instruments.

Sterility

- Implants and 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.



316-1400

316-1200

316-1300

Type of Block or Tray	ExtremiFix Tray (316-1400)	2.0/2.4mm ExtremiFix Organizer Block (316-1200) / 3.0/4.0mm ExtremiFix Organizer Block (316-1300)
Material	Stainless Steel	Plastic
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) with towel placed between the wraps and the bottom of the tray	Block 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	15 minutes
Minimum Dry Time	55 minute	40 minutes

316-1250

316-1350

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)	
Material	Aluminum	
Type of Sterilizer	Pre-vacuum steam sterilizer	Pre-vacuum steam sterilizer
Wrapping Technique/ Tray Preparation	Block wrapped with 2 layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) and a towel placed between block and wrap	Block wrapped in Kimberly Clark *1 Step* wrap (Kimguard KC600 – 510(k) K082554)
Minimum Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	8 minutes	5 minutes
Minimum Dry Time	20 minutes	45 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.

OSTEOMED
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service: 800/456-7779
Outside USA: 972/677-4600

EC REP
Shotwell & Carr, LLC
2 St. Paul's Road
Clifton Bristol
BS8 1LT, U.K.
Tel: +44 (0) 117 9738944

CE 0086

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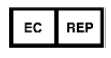
Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents		Authorized Representative in the European Community
	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.		

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