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Ti6 Internal Fixation System Directions for Use

Description

The Ti6 Internal Fixation System is comprised of five types of screws used for bone fixation of the hand and foot following trauma or osteotomy. Available screws and instrumentation are packaged as a single system and organized around the five types of screws described below:

1. The **TS-Series** (Titanium Solid) is a non-cannulated, threaded bone screw which is offered in 2.0, 2.5, 3.0 & 4.0mm diameters with lengths of 6 – 50mm.
2. The **TC-Series** (Titanium Cannulated) is a cannulated, threaded bone screw which is offered 2.0, 2.5, 3.0 & 4.0mm diameters with lengths of 6 – 50mm.
3. The **TH-Series** (Titanium Headless) is a cannulated, dual-thread, headless bone screw which is offered in 2.5 & 3.0mm diameters with lengths of 10 – 34mm.
4. The **TQ-Series** (Titanium QuickSnap) is a snap-off solid core screw which is offered in a 2.0mm diameter with lengths of 8 – 16mm.
5. The **DS-Series** (Dital Screws) is a cannulated, threaded bone screw which is offered 2.0mm diameter with lengths of 24 – 50mm.

The system includes instruments (drill bits, drill guides, guide wires, depth gauges, countersinks, bone clamps, forceps and screwdrivers) to facilitate the placement of the screws.

Material

All Ti6 screws are made from Titanium Alloy (ASTM F-136). The instrumentation is made from titanium and stainless steel.

Indications

The *Ti6 Internal Fixation System* implants (screws) are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants and guide wires are intended for single use only.

These implants are not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Contraindications

Use of the *Ti6 Internal Fixation 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 internal fixation.

Warnings

1. Re-operation to remove or replace implants (screws) 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. All Ti6 implants and guide wires are intended for single use only.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated, non-cannulated, headless, and snap-off screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.

3. The Ti6 screws are not intended to endure excessive abnormal functional stresses.
4. All *Ti6 Internal Fixation System* screws and instrumentation may be required for each surgery. Failure to use dedicated, unique MetaSurg 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.
5. Carefully inspect the screws prior to use. Inspect the instruments before and after each procedure to assure they are in proper operation condition. Instruments which are faulty, damaged or suspect should not be used.
6. MetaSurg recommends the use of MetaSurg products in a sterile environment.

Instructions for Use – TS-Series Screws (Solid Screws)

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 very dense and in arthrodeses, as the axial force necessary for inserting the TS-Series screw could temporarily distract the fragments at the fracture/arthrodeses line.
2. Using the appropriately sized drill bit, drill a pilot hole the correct length through the bone fragments. The drill guide may be used to aid in the placement of the drill and to protect soft tissue.
3. Using the appropriately sized depth gauge, measure the length from the proximal cortex to the distal cortex to determine the proper screw length.
4. Use the appropriately sized countersink to create a recess in the bone.
5. Remove the desired TS-Series screw from the screw caddy. Insert the screw into the pilot hole.
6. Drive screw into bone until the desired compression is achieved.

Instructions for Use – TC-Series Screws (Cannulated Screws)

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 very dense and in arthrodeses, as the axial force necessary for inserting the TC-Series screw could temporarily distract the fragments at the fracture/arthrodeses line.
2. Insert the appropriately sized guide wire to the correct length under image intensification. To avoid bending the guide wire, insert the wire in 5mm – 10mm increments.
3. Slide the appropriately sized depth gauge/countersink over the guide wire until the countersink tip contacts bone. Rotate the countersink back and forth to create the necessary recess in the bone.
4. Measure for the desired screw length by examining the end of the guide wire in relation to the marks on the depth gauge.
5. For 3.0mm & 4.0mm screws in dense cortical bone, pre-drilling the near cortex using the cannulated overdrill is recommended to reduce the axial force necessary for inserting the screw.
6. Use the screw forceps to remove the desired cannulated screw from the screw caddy. Slide the screw over the guide wire.
7. Using the ratcheting screw driver and driver shaft, drive the TC-Series screw into bone until the desired compression is achieved.
8. If the screw meets unusual resistance, remove the guide wire and continue driving the screw.
9. Remove and discard the guide wire.

Instructions for Use – TH-Series Screws (Headless Screws)

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 very dense and in arthrodeses, as the axial force necessary for inserting the TH-Series screw could temporarily distract the fragments at the fracture/arthrodeses line.
2. Insert a guide wire to the correct length under image intensification. Insert the guide wire in 5 to 10mm increments to avoid bending the wire.
3. Slide the depth gauge over the guide wire until the tip contacts bone. Measure the desired screw length by examining the end of the guide wire in relation to the marks on the depth gauge.
4. Use the TH-Series cannulated relief drill to overdrill the proximal cortex to create a pilot hole for the screw. (Use the first notch of the relief drill for 2.5 screws and the second notch for 3.0 screws).
5. Use the screw forceps to remove the desired TH-Series screw from the screw caddy. Slide the screw over the guide wire.

6. Use the appropriately sized screwdriver shaft and screwdriver handle to drive the TH-Series screw into bone until the desired compression is achieved. The head of the screw should rest flush with the proximal cortex.
7. If the screw meets unusual resistance, remove the guide wire and continue driving the screw using the TH series solid screw driver.
8. When removing TH series screws, use the TH series solid screw driver.

Instructions for Use – TQ-Series Screws (QuickSnap Screws)

1. After making the appropriate bone cuts, use a guide wire to initiate a 1mm deep pilot hole that penetrates the proximal cortex.
2. Load the appropriate TQ-Series screw into the 3-prong manual driver or into a K-Wire driver.
3. Drive the screw using the manual driver or K-Wire driver until the distal head is flush with the bone.
4. Tilt the manual driver or K-Wire driver in the opposite angle of the screw direction to snap off the shank.
5. If necessary, use the 3-prong manual driver to finish driving the screw to the desired depth.
6. Important: If the screw shank snaps off prior to completion, engage the 3-prong driver over the remaining screw head to finish driving the screw.

Instructions for Use – DS-Series Screws (Digital Screws)

1. Perform an incision, of the surgeon's choice, over the proximal interphalangeal (PIP) joint. Reflect the soft tissues surrounding the PIP joint to completely expose it for resection. Complete the resection of the PIP joint in preparation for PIP joint fusion.
2. Using the included K-Wire (DW-1111) drive the wire through the center of the middle and distal phalanx and out through the tip of the toe. Retrograde the wire proximal until it is protruding 2mm to 4mm from the resected base of the middle phalanx.
3. Position the toe into the preferred anatomical alignment and drive the wire into the center of the proximal phalanx to the location and depth of the final intended screw location. The use of a mini C-arm may be useful at this point if there is uncertainty as to the location and depth of the wire.
4. Place a small transverse incision (3mm to 4mm long) in the tip of the toe and dissect any soft tissue around the distal tuft. Place the combination countersink depth gage over the wire and lightly countersink the tip of the distal phalanx. (*Note: Countersinking can be skipped if the screw is going to be removed after fusion has occurred.*) With the countersink in place, read the gauge to determine the proper screw length.
5. Select the correct length screw and slide the screw over the wire and into position. Using the included driver and ratcheting handle, drive the screw into position and compress the PIP joint. **Do not over tighten the screw. Damage to the screw or the drive feature of the screw can result from over tightening. In most cases two finger tightening is adequate.**
6. Remove the K-wire and close the incisions with the suture material of choice.

Sterility

The *Ti6 Internal Fixation System* (instruments and screws) are package non-sterile and must be sterilized prior to surgical use.

Pre-Vacuum Steam Sterilization:
Condition: Wrapped
Temperature: 270° F (132° C)
Time: 4 minutes

Gravity Steam Sterilization:
Condition: Wrapped
Temperature: 270° F (132° C)
Time: 15 minutes

Since MetaSurg is not familiar with individual hospital handling methods, cleaning methods and bioburden, MetaSurg cannot assume responsibility for sterility even though the guideline is followed.

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 MetaSurg instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively**