3. Use the AH-Series Cannulated Relief Drill to enlarge the proximal cortex. Important: Drill to the 1st step notch for 2.5mm screws and all the way to the drill base for the 3.0mm screws.
4. Slide the screw and driver shaft over the K-wire, and drive the screw through the bone until the top of the screw sits just below the bone surface. If the screw meets unusual resistance, remove the guide wire and continue driving the screw using the AH series solid screw driver. The AH-Series solid screw driver should also be used for screw removal. If unusual resistance is still experienced, do not attempt to drive the screw.

**AQ-Series Screws (QuickSnap Screws)**

1. Perform the appropriate cuts for the lesser metatarsal procedure, and remodel the dorsal shelf.
2. The surgeon can choose to use the guide wire to initiate a 1mm deep pilot hole that penetrates the proximal cortex. However, the AQ-Series screw is self-drilling and self-tapping.
3. Load the QuickSnap screw into the QuickSnap Driver until the proximal head is engaged by the 3 prongs. **Using a Wire Driver:** The QuickSnap screw is also designed to be driven with a wire driver. Use the 3 prong driver to complete insertion if the screw snaps off before reaching the proximal cortex.
4. While compressing the osteotomy site with manual or clamp pressure, drive the screw until the distal head is flush with the proximal cortex. If unusual resistance is experienced, do not attempt to drive the screw. **Important:** If the screw does not snap off after contacting the outer cortex, it may be necessary to snap it by tilting the driver back and forth.

**AD-Series Screws (Digital Screws)**

1. Perform an incision of the surgeon's choice over the proximal interphalangeal (PIP) joint. Resect the base of the middle phalanx and head of the proximal phalanx to the desired length. Optional resection of the DIP joint can also be performed at this time.
2. Drive the guide 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 2 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 depth of the intended screw location, using image intensification, if necessary. Place a small transverse incision in the tip of the toe, and dissect any soft tissue around the distal tuft. Place the countersink/depth gauge over the wire, and lightly countersink the tip of the distal phalanx.
4. Slide the screw over the wire and drive into position, compressing the PIP joint. In most cases, two finger tightening is adequate. If unusual resistance or jamming of the screw occurs, do not continue to advance the screw. Check and reposition the K-wire so that it is centered in the medullary canal and not engaging the cortical wall. If unusual resistance is still experienced, do not attempt to drive the screw.

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

**Sterility – Capture**

The Capture Internal Fixation System components are provided non-sterile and must be cleaned and sterilized prior to use. The Capture Internal Fixation System (instruments and screws) must be wrapped in FDA cleared wraps, pouches or containers for steam sterilization.
Do not re-use implants, as they are single use only.
Detailed reprocessing instructions are provided in LC-04-0000-0004.

**PRODUCT INFORMATION DISCLOSURE**

INTEGRA LIFESCIENCES CORPORATION ("INTEGRA") HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE PRODUCTS. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

**Symbols Used on Labeling**

| | |
|---|---|
|  | Manufacturer |



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**Integra® Capture™ Internal Fixation System**

**Instructions for Use**

**Description**

The Integra® Capture™ Internal Fixation System is comprised of four 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 four types of screws described below:

1. The AC-Series (Titanium Cannulated) is a cannulated, threaded bone screw which is offered in 2.0, 2.5, 3.0 & 4.0mm diameters with lengths of 2.0 (6-22mm), 2.5 (8-30mm), 3.0 (10-40mm), & 4.0(12-50mm).
2. The AH-Series (Titanium Headless) is a cannulated, dual threaded, headless bone screw which is offered in 2.5mm diameter in lengths of 10 to 22mm and 3.0mm diameter in lengths of 14 to 34mm.
3. The AQ-Series (Titanium QuickSnap) is a snap-off solid core screw which is offered in 2.0mm diameter in lengths of 8 to 16mm and 2.7mm diameter in lengths of 12 to 22mm.

4. The AD-Series (Digital Screw) is a cannulated, threaded bone screw which is offered in a 2.0mm diameter with lengths of 24 to 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 Capture screws are made from Titanium Alloy (ASTM F-136). The instrumentation is made from titanium and stainless steel.

**Clinical Indications**

The Capture 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 are intended for single use only.

**Contraindications**

Use of the Capture Internal Fixation System is contraindicated for:

- 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.
- Patients exhibiting disorders which would cause the patient to ignore the limitations of internal fixation conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, and conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.
- Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implementation.

**Possible Adverse Effects**

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection.
2. Pain, discomfort or abnormal sensations due to the presence of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Migration of the implant: loosening of the implant.
5. Delayed wound healing or deep wound infection resulting in possible removal of the implant.
6. Fracture of the implant due to non-compliance to post-operative regimen, improper implant selection, or non-union.

**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. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Instruments, guide wires and screws are to be treated as sharps.
4. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
5. The Capture screw has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Capture screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
6. No metallic surgical implant should be reused. Any metal implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.

**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 Capture screws are not intended to endure excessive abnormal functional stresses.
4. All Capture Internal Fixation System screws and instrumentation may be required for each surgery. Failure to use dedicated, unique Integra 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 operating condition. Instruments which are faulty, damaged or suspect should not be used.
6. Integra recommends the use of Integra products in a sterile environment.
7. For best results and to ensure proper working condition, after cleaning the Ratchet Handle (AI1006) a non-silicone lubricant should be used per the manufacturer's instructions.

**AC-Series Screws (Cannulated Screws)**

1. After making the appropriate bone cuts, insert the guide wire to the correct depth using image intensification, if necessary. Temporary clamping or manual compression of the bone segments can provide more accurate measurement and improve screw engagement into the far side of the osteotomy site. Drive the guide wire using 15 – 20mm increments to avoid bending the guide wire.
2. For all screw sizes, pre-drilling the proximal cortex can assist with screw insertion in dense bone. Use the optional 2.0/2.5 or 3.0/4.0 cannulated over-drill for this step.
3. Countersink and then measure using the combination countersink depth gauge instrument. Use a reciprocating motion to create the countersink recess and measure after countersinking. Intra-operative radiographs should be taken to confirm proper placement of the guide wire.
4. Slide the AC-Series screw over the guide wire, and drive the screw until it is flush with the bone surface. If the screw meets unusual resistance, remove the guide wire and continue driving the screw. If unusual resistance is still experienced, do not attempt to drive the screw.

**AH-Series Screws (Headless Screws)**

1. After making the appropriate bone cuts, drive the AH-Series guide wire to the correct depth using image intensification, if necessary. Temporary clamping or manual compression of the bone segments can provide more accurate measurement and improve screw engagement into the far side of the osteotomy site. Drive the guide wire using 10 – 15mm increments to prevent bending the wire.
2. Measure for the proper screw length by sliding the AH-Series depth gauge over the K-wire until it reaches the bone surface.