



Instructions For Use

CAUTION: Non-Sterile



CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.

Capture™ High-Torque Screw System

DESCRIPTION

The Capture™ High-Torque Screw System consists of various sizes of cannulated screws. The screws are machined, metallic screws with a cannulation that are self-drilling and self-tapping. Each type is offered in a variety of diameters and lengths and is manufactured from stainless steel and titanium.

INDICATIONS FOR USE

The Capture High-Torque Screw System is intended for the following:

- Fixation of fractures in long bones
- Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow
- Arthrodesis of the foot, wrist and elbow
- Small and long bone osteotomies

CONTRAINDICATIONS

Use of the Capture High-Torque 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 internal fixation.

- Not indicated for fixation to the posterior elements of the cervical, thoracic or lumbar spine.
- Screws are contraindicated in: active infection; 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; conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process; and foreign body sensitivity.
- 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.

- These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

WARNINGS AND PRECAUTIONS

- 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.
- Correct handling of implant is extremely important. Avoid contouring metallic implants whenever possible. If necessary, or allowed by design, the device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
- If metal plates or other metallic devices are to be used together with the cannulated screws, all such devices should be manufactured from a metal that has a similar composition to avert possibility of galvanic corrosion or other metallic reactions.
- Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The patient's anatomy and indication will determine the size of the cannulated screw to be used. The size and shape of the human bones presents limiting restrictions on the size and strength of implants.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant requiring revision surgery to remove the device.
- The use of cannulated screws provides the surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subject to repeated stress in use which can result in metal fatigue.
- Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.
- No partial weight-bearing or nonweight-bearing device can be expected to withstand the unsupported stresses of full weight-bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.

- Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of the weight-bearing or muscle activity. An active patient or a debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.
- While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.
- The Capture High-Torque Screw System may affect image quality (image artifact) depending on the pulse sequence that is used for MR imaging.
- The Capture High-Torque Screw System has not been evaluated for safety and compatibility in the MR environment.
- The Capture High-Torque Screw System has not been tested for heating or migration in the MR environment.

STERILIZATION

The Capture High-Torque Screw System screws are supplied non-sterile and must be sterilized before use. Do not reuse implants. They are single use only.

The Capture High-Torque Screw System Instruments are provided non-sterile, and must be cleaned and sterilized before use. Soak instruments in warm water for a minimum of 10 minutes. Disassemble instruments, as appropriate. Hand wash in a neutral pH (7) or mild detergent. Scrub with a soft bristle brush. Pay careful attention to any threads, pivots, recesses or hard to reach areas on the instruments. If the product is cannulated insert a nylon brush or chenille pipe cleaner into the cannula. Immediately and thoroughly rinse and dry after washing. Visually inspect the instruments under room lighting conditions to ensure instruments are suitable for use and free of debris. Sterilize with steam sterilization.

Ascension Orthopedics, Inc. has completed sterilization validations for our instrument sets. The validation protocols were performed in accordance with [AAMI ST79:2006 Steam Sterilization and Sterility Assurance in Health Care Facilities](#), and [AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization](#). All testing was done using the overkill approach with Geobacillus stearothermophilus spores. The results confirmed a 10⁻⁶ Sterility Assurance Level (SAL) for the sets when using the recommended cycles.

In accordance with our validation results, the following cycles are recommended for wrapped goods:

- **Steam Pre-vacuum:** 4 minutes at 132°C (270°F)
- **Steam Gravity:** 15 minutes at 132°C (270°F) – **DO NOT USE THIS CYCLE FOR FILTERED STERILIZATION CONTAINERS**

A vacuum drying cycle of at least 30 minutes is also recommended.

ADVERSE EVENTS

- Loosening, bending, cracking or fracture of the screw or loss of fixation in bone attributable to nonunion.
- Loss of anatomic position with nonunion or malunion with rotation or angulation.
- Infection, both deep and superficial.
- Allergies and other reaction to the device material.

SURGICAL PROCEDURE

A Surgical Technique brochure is available which outlines the basic procedure for device implantation and the use of specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

TRAINING

It is the responsibility of the surgeon to obtain the necessary training prior to implanting this implant.

Disclaimer of Warranties

Ascension Orthopedics has no control over the conditions under which the device is used, the diagnosis of the patient, or the methods or procedures used for implantation. Therefore, Ascension Orthopedics makes no warranty or guarantee, expressed or implied, of the implant or accessory instruments other than the warranty that at time of manufacture, reasonable care was used in the manufacture of these devices.

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