Trident SI Screw System

Advanced Research Medical, LLC
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System Contents:

- Non-Sterile Implants – Single Use Only
- Non-Sterile Instruments – Reusable

CAREFULLY READ ALL INSTRUCTIONS AND BE FAMILIAR WITH THE SURGICAL TECHNIQUE PRIOR TO USING THIS PRODUCT.
CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DESCRIPTION AND INTENDED USE:
The Advanced Research Medical Trident SI Screw System consists of screws manufactured from Ti-6Al-4V ELI per ASTM F136. The screws are available in a variety of lengths and diameters to accommodate varying patient anatomy.

INDICATIONS FOR USE:
The Advanced Research Medical Trident SI Screw System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS:
Contraindications include but are not limited to:

- Acute or chronic infections diseases of any etiology and localization
- Morbid obesity
- Signs of local inflammation
- Fever or leukocytosis
- Metal/polymer sensitivity/allergies to the implant materials
- Medical or surgical conditions, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of bone graft)
- Any case not needing a bone graft and fusion, or where fracture healing is not required
- Any case requiring the mixing of metals from different components
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support, bone immaturity
- Any case not described in the indications
- A patient unwilling to cooperate with the postoperative instructions
- Alcoholism, smoking, or drug abuse
- Any time implant utilization would interfere with anatomical structures or expected physiological performance

MATERIALS:
Trident SI Screw System Implants are manufactured entirely of Ti-6Al-4V ELI with no markers or wires. Surgical instruments provided with the implants are manufactured from stainless steel, silicone, and polyphenylsulfone (PPSU).

CLEANING OF IMPLANTS AND INSTRUMENTS:

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Immerse the instruments and implants in a neutral pH detergent prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard to clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard to clean areas.
6. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. ARM recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions. It is also recommended to remove implants (in caddies) from kits (cases).

The instruments, case, and caddy can be reprocessed for use. They must be cleaned prior to sterilization. If there are any visual signs of contaminants, soil, or debris, the cleaning steps must be repeated prior to sterilization.

INSPECTION:
Carefully inspect each instrument to ensure all visible blood and soil has been removed.

1. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
2. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact ARM customer service or your representative for a replacement.
3. If corrosion is noted, do not use and contact ARM customer service or your representative for a replacement.

STERILIZATION:
All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been validated:

Method:	**Steam**
Cycle:	**Pre-Vacuum**
Temperature:	**270°F (132°C)**
Exposure Time	**4 minutes**
Number of pulses:	**4**
Dry Time:	**30 minutes**

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.
Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it must be cleaned and re-sterilized after surgery.

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.

- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: Current Verson – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79:Current Verson – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a. A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
   b. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
   c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
   d. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
   e. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
   f. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use radiographic imaging and the guidewire to determine the appropriate implant to use.
3. PREVIOUSLY IMPLANTED DEVICES MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. SCREW TYPES. The Ø6 mm side screws of the Trident SI Screw System are intended to be used only in conjunction with the Ø13 mm main screw.
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
7. MAGNETIC RESONANCE ENVIRONMENT. The Trident SI Screw System 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 the Trident SI Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
9. Paralysis.
10. Death.
11. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:

ARM spinal products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.
If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact ARM for current information.

PRODUCT COMPLAINTS

Any healthcare professional (e.g. customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify:

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When reporting a complaint, please provide the component name, lot number, UDI, your name and phone number, and the nature of the problem.

ARM
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