STS - Subtalar Spacer System
152232-0

The following languages are included in this packet:

English (en)

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

STS - Subtalar Spacer System
(152232-0)

OUTLINE:

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Non-sterile
	For prescription use only

	Do not use if packaging is ripped or damaged.

Abbreviation	Material
Ti-6Al-4V	Titanium Alloy

DESCRIPTION

The STS screw consists of a threaded implant, designed to be inserted between the posterior and middle facets of the subtalar joint and corresponding instrumentation to facilitate insertion. It is important that the instruments and trial implants used are those specifically designed for this device to ensure accurate insertion. The STS screw implant is cylindrical in shape and incorporates a center cannula designed for use with a guide wire to facilitate proper placement of the implant. An internal hex-head allows for maximum torque with minimal risk of stripping. External rounded threads increase ease of insertion.

A. INDICATIONS

The STS screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela.

- Severely pronated foot;
- Walking intemperance;
- Calcaneal stance position greater than 5°;
- Manually correctable deformities;
- Mid-tarsal breech (arch pain);
- Forefoot varus greater than 10°.

B. CONTRAINDICATIONS

The STS Implants are contraindicated for use in patients with the following conditions:

- Active local infection (any evidence of infection);
- Metal sensitivity or allergic reaction to foreign bodies;
- Poor or insufficient bone stock;
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient;
- Other conditions that may place the patient at risk (physiologically).

C. WARNINGS

Safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. Improper selection, placement, positioning, or seating of the implant may result in unusual loading conditions which could affect the long-term service life of the implant. In every case, accepted surgical practices should be followed in postoperative care. The patient should be made aware of the limitations of the subtalar implant and that physical activity and full weight bearing have been implicated in

premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  a. The material composition of the fragment (if known);
  b. The size of the fragment (if known);
  c. The location of the fragment;
  d. The potential mechanisms for injury, e.g., migration, infection;
  e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

These implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

D. 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 specific to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery:

- Infection;

- Pain, discomfort, or abnormal sensations due to presence of the implant;
- Metal sensitivity or allergic reaction to a foreign body
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;
- Bursitis

E. IMPLANT MATERIALS

The STS is manufactured from titanium alloy (Ti -6Al-4V ELI, ASTM F136).

F. STERILIZATION

The system is provided non-sterile and should be steam sterilized at the surgical facility before use. The system must be cleaned prior to sterilization. Clean and inspect all instruments within the system to ensure they are suitable for use. Cracked or bent instruments should be replaced. The system must be steam sterilized using the following process parameters:

Steam Sterilization		
Sterilizer Type	Parameter	Minimum Set Point
Pre-Vacuum	Temperature	132°C (270°F)
	Full Cycle Time	4 minutes
	Dry Time	20 minutes
Sample Configuration: Wrapped tray with a towel placed between tray and wrap		

The use of flash sterilization is not recommended.

Remove all packaging materials prior to sterilization. Only implants and instruments should be used in surgery. Immediately clean and re-sterilize all items removed from the surgical field before handling. Surgical implants shall not be re-used. Any implant once used shall be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

G. PRODUCT HANDLING

Store implants unopened in their respective protective packages until use. Protect the prosthesis from contact with objects, which may damage the surface finish. Inspect each implant prior to use and dispose of implants that exhibit surface or configuration damage. Contouring or clamping of implants should be avoided if possible. It is recommended that implants should not be cut, sharply bent, or re-bent, notched, or scratched. These attentions can produce defects or stresses, which may lead to failure of the implant.

H. CAUTION

Federal Law (United States) restricts this device to sale, distribution, and/or use by or on the order of a physician.