

Instructions For Use

STS - Subtalar Spacer System

Package Insert / Important Medical Information

OrthoPro

THE FOOT AND ANKLE COMPANY

DESCRIPTION OF DEVICE

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.

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°.

CONTRAINDICATIONS

The OrthoPro STS Implant is 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).

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.

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.

IMPLANT MATERIALS

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

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:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	20 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

Sterilizer Type:	Gravity
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	18 Minutes
Minimum 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.

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.

CAUTION:

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

FURTHER INFORMATION

For further information, please contact:

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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.