

# Instructions For Use

## CSS - Cannulated Screw System

### Package Insert / Important Medical Information



#### DESCRIPTION OF DEVICE

The CSS is a cannulated bone screw that consists of a threaded implant and corresponding instrumentation to facilitate insertion. The implants are cylindrical in shape and incorporate a center cannula designed for use with a guide wire to facilitate proper placement of the implant. An internal cruciate-head allows for maximal torque with minimal risk of stripping. These screws are of self-tapping.

#### INDICATIONS

The CSS cannulated bone screw is indicated for bone fractures, osteotomies, arthodeses, osteochondritis and tendon reattachment. These screws are not intended for attachment or fixation to the posterior elements (pedicles) of cervical, thoracic, or lumbar spine.

#### CONTRAINDICATIONS

The OrthoPro CSS 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).

#### WARNINGS

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in postoperative care. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Do not modify implants.

#### 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 CSS 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.