# CSS - Cannulated Screw System
## 152231-0

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

## CSS - Cannulated Screw System

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## 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 |
|---|---|
| LOT | Batch code |
| REF | 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 |
| EC REP | Authorized EC Representative in the European |
| | Non-sterile |
| ℞ Only | For prescription use only |
| | Do not use if packaging is ripped or damaged. |

| Abbreviation | Material |
|---|---|
| Ti6Al4V | Titanium Alloy |

## DESCRIPTION

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.

## A. INDICATIONS

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

## B. CONTRAINDICATIONS

The 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).

## C. WARNINGS

For sale 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.

## D. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness

and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The main goal of surgery with this implant is to establish soft tissue to bone union. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

Avoid flawing implant surfaces to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

**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.

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

**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.

The Cannulated Screw System has not been evaluated for safety and compatibility in the MR environment. The Cannulated Screw System has 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.

See Section II for specific product information.

## E. 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

## F. IMPLANT MATERIALS

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

## G. 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.

## H. 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.

## I. CAUTION

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