

## Packaging Insert



### IMPORTANT MEDICAL INFORMATION

MANUFACTURED FOR:  
ORTHOPEDIATRICS  
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English

**NON STERILE**

### Warnings & Precautions

#### 4.0 Cannulated Screw System

##### Description

The Trauma system includes bone plates and screws for the application of aiding bone fracture repair and healing. The range includes from medical devices from Class IIb (93/42/CEE Directive).

##### Materials

The bone plates and bone screws are made from implant grade 316 L (ISO5832-9) stainless steel.

##### Indications & Usage

- The system is indicated for use in pelvic, small and long bone fracture fixation.
- The system is contra-indicated in patients with active infections in or near the fixation site.

##### Warnings

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
- Use extreme care in the handling and storage of implants. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant system.
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact. The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, we recommend the retrieval of implants as otherwise they will replace the function of the bone and lead to bone reduction and weakening, this is particularly important for young and active patients.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed.
- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

##### Sterilization

- This implant is not sterile when shipped from ORTHOPEDIATRICS.
- All implants must be sterilized before use.
- Remove all implants from their packaging prior to sterilization.
- ORTHOPEDIATRICS implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital, as detailed in OrthoPediatrics Instrument Care, Cleaning, and Sterilization Instructions CI-0001.
- Other sterilization methods and cycles may also be suitable. However, individuals and hospitals are advised to validate whichever method they deem appropriate at their institution and in accordance with the autoclave manufacturer's recommendations.
- ETO sterilization and cold sterilization techniques are not recommended. ORTHOPEDIATRICS disclaims any liability for any problem further to the use of these sterilization methods.

##### Storage and Handling

- Medical devices are sensitive to damage. Implants should be handled with care at all times.
- Surgical implants and the packaging should be checked for defects before use and to verify the appropriate sizing.