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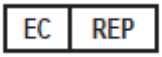
Bone Screws
INSTRUCTION FOR USE

CE
0123

GRAPHICAL SYMBOLS	
	Manufacturer
	LOT number
	Do not re-use
	Non sterile
	Consult instructions before use
	Catalog number
QTY	Quantity
	Date of Manufacture

	Do not use if package is damaged
	Humidity limitation
	European Community Representative
	Material
	Caution, consult accompanying documents

DESCRIPTION

The Bone Screw System is indented for use in conjunction with Trauson's products (e.g. bone plate system) for adjunct fixation. The Bone Screw System is available in various length and designs. The Bone Screw system is made from stainless steel conforming to ISO 5832-1 or titanium alloy conforming to ISO 5832-2.

INTENDED USE

The bone screw system is indicated for fix, stabilize the fracture site, in order to maintain proper occlusion during the fracture healing. Some types of the bone screw can be used together with the bone plates.

INDICATIONS FOR USE

The Bone Screw System including Cortical Screws, Cancellous Screws, Cannulated Screws , Washer, Lag screw, Compression Screw, Locking Screws, and Screw Hole Inserter, is designed to provide fixation for fractures, fusions or osteotomies. In general, these screws are indicated for fractures requiring additional stability.

Indications include:

Cortical screw :

- fracture of cortical bone.

Cancellous screw:

- fracture of can`cellous bone.

Lag screw and compression screw:

- fractures of the proximal femur including intertrochanteric fractures, subtrochanteric fractures, intracapsular and basal neck fractures.
- fractures of the distal femur including intercondylar fractures, supracondylar fractures

Cannulated screw and washer:

- fracture of metaphysis of limbs and fracture of hand, foot, pelvis and sacrum.

Locking screw and filling screw:

- fracture of limbs and pelvis.

CONTRAINDICATIONS

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

1. Any active or suspected latent infection or marked local inflammation in or about the affected area.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
3. Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
4. Material sensitivity, documented or suspected.
5. Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
6. Patients having inadequate tissue coverage over the operative site.
7. Implant utilization that would interfere with anatomical structures or physiological performance.
8. Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
9. Other medical or surgical conditions which would preclude the potential benefit of surgery.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

In many instances, adverse results may be clinically related rather than device related. This list may not include all complications caused by the surgical procedure itself.

1. Delayed union or non-union of the fracture site.
2. These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
3. Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
4. Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.
5. Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
6. Early or late infection, both deep and/or superficial.
7. Deep venous thrombosis.
8. Avascular necrosis.
9. Shortening of the effected bone/fracture site.
10. Subclinical nerve damage may possibly occur as a result of the surgical trauma.
11. Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

WARNINGS AND CAUTIONS

WARNING

1. **NON-STERILE PRODUCTS**: The implants and the instruments to be used must be cleaned carefully in a clean environment and sterilized thoroughly with appropriate temperature and pressure before they are used.
2. **STERILIZED PRODUCTS:** For the products provided sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined. For components provided sterile, ensure that the package is not damaged prior to use.

   PRECAUTION: Do not use implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile.
3. **IMPLANT SELECTION AND SIZING:** The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.
4. **PATIENT SELECTION:** Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for surgery using the Bone Screw System.
5. **HANDLING:** Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the screw surfaces as these may induce premature failure of the component.
6. **PATIENT EDUCATION:** Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
7. **SINGLE USE ONLY:** Reuse of a single use device that has come in contact with blood,

bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

8. **MAGNETIC RESONANCE (MR) SAFETY**: The Bone Screw System has not been evaluated for safety and compatibility in the MR environment. The Bone Screw System has not been tested for heating or migration in the MR environment.
9. **COMPATIBILITY:** Do not use the Bone Screw System with components of other systems. Unless stated otherwise, Trauson's devices are not to be combined with the components of another system.
10. Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.
11. For optimal results, the same type of instruments used for implantation should be used for implant removal.
12. Trauson does not and cannot warrant the use of instruments nor any of the component parts upon which repairs have been made or attempted except as performed by Trauson or an authorized Trauson repair representative. The use of an Instrument for tasks other than those for which they are intended may result in damaged/broken instruments and/or patient injury.
13. If there is any doubt or uncertainty concerning the proper use of instruments please contact Trauson Customer Service. Any available operation brochure will be provided upon request.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Unless stated otherwise, the device is not to be combined with the components of another system.
5. All parts should be cleaned and sterilized before use.

CAUTION

1. Before using this product, the users must read carefully Surgical Technique published by Trauson and are skilled in the operation process of this product.

2. It is not recommended to use Trauson products together with other brands, as it is not verified or validated.

PRE-OPERATIVE

1. The implant is for single use only.
2. Ensure that all components needed for the operation are available in the operation theatre.
3. Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
4. While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

INTRA-OPERATIVE

1. Avoid surface damage of implants.
2. Discard all damaged or mishandled implants.
3. During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, required for precise positioning and fixing is secure.
4. After the procedure check the proper positioning of all implants using the image intensifier.
5. Do not use components of the Trauson product systems in conjunction with components from any other manufacturer's system unless otherwise specified (see operative technique manual).

POST-OPERATIVE

1. Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
2. The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g. X-ray checks) are advisable.
3. The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
4. Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.

INFORMING THE PATIENT

The implantation affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, the surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn patient that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at

some time in the future.
Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the site of operation did not appear to be harmed at the time.
Explain also the need to appear for the postoperative examinations (e.g. X-ray checks) and for the possible explantation of the implant.

PACKAGING

Packages for each of the components should be intact upon receipt. All implant and instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Trauson.

CLEANING AND DECONTAMINATION

Products delivered in non-sterile condition, must be cleaned, disinfected, and sterilized prior to use. For cleaning and sterilization, remove the product from its packaging before cleaning, disinfecting and sterilizing the product. A suitable cleaning, disinfection and sterilization process must be applied by the user. Only pH-neutral cleaning agents should be used. The preparation instructions of the respective cleaning and disinfection agent manufacturer must be considered.

All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.
All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

STERILIZATION

The following sterilization process parameters are validated by Trauson and recommended for sterilization:

Method	Moist heat sterilization according to ISO 17665
Cycle	Saturated steam with fractional forced air removal
Temperature	132-137°C (270-277°F)
Exposure Time	4 minutes (minimum)
Drying Time	30 minutes (minimum, in chamber)

Additionally, the method of sterilization utilized by end users should be validated, as suggested by Trauson.

TRANSPORTATION AND STORAGE CONDITIONS

The relative humidity of transportation and storage is no more than 80%. Keep products in draughty room without corrosive gas.

INFORMATION

To obtain Operation Technique or should any information regarding the products or their uses be required, please contact your local representative or Trauson directly at +86-519-86387075. You may also email: info@trauson.com .