	Instructions for use	Doc. No.: IU/7
	for	Rev. No.: 06
	Bone Plates, Bone Screws, Intramedullary Nails, Pins and Wires – Ti non sterile	Rev. Date: 19JUL2019

For use by an Accredited Orthopaedic Surgeon only

IMPORTANT MEDICAL INFORMATION

1. Purpose:

Bone Plates, Bone Screws, Intramedullary Nails, Pins and Wires are intended to aid in surgical stabilization following operative procedures to treat fractures, enable correction of skeletal deformities or other related interventions. These devices are meant to share load with the bone during the healing and regenerative phase. These devices are subjected to various mechanical forces while in use. The extent to which the device would withstand these forces is limited by the operating surgeon achieving a stable fixation construct, the use of bone graft to supplement the fixation where appropriate, the correct weight bearing regimen prescribed by the operating surgeon based on the progress of healing and the compliance of the patient. These devices are meant to be removed after they have served their intended purpose.

2. Materials:

The Unalloyed or Alloyed Titanium used for these devices comply with the international standards in ISO 5832-2 or ISO 5832-3

3. Preparation:

Before the operation, an operative plan must be drawn up by the operating surgeon, ensuring that –

- All implant components necessary are available in the required quantities
- Aseptic operating conditions are present.
- The required set of instruments is complete, operable and compatible.
- All pertinent documents related to the set of instruments and the implants being used are present and the surgeon and the operating team are, familiar with them.
- The operating surgeon is experienced in performing internal fixation procedures to stabilize fractures using implants and in particular with the specific operative procedure being performed, involving the use of the implant.

4. Indications:

Surgical Stabilization following operative procedures to treat fractures, enable correction of deformities or other related interventions, as per the latest fracture management / deformity correction, treatment protocols

5. Contraindications:


Contraindications for the use of this device include but are not limited to the following:

- Immunological intolerance
- Patients displaying metal sensitivity or allergic reactions to any of the elements in implant grade materials, e.g. Nickel or Chromium
- Presence of degenerative diseases
- Mental illness
- Alcohol and/or drug addiction
- Obesity
- Poor patient compliance
- Expected overloading of the implants

6. Implant Selection and Handling:

- All implant components should be checked for intact packaging on receipt. In case a loaner or consignment set of instruments and implant components is used, all instruments and implants must be carefully checked for completeness and all components should be carefully inspected for absence of damage prior to use.
- Selection of the proper size, shape and design of the implanted device is a crucial parameter for success of the operative procedure and must be ensured by the operative surgeon.



5 	Instructions for use	Doc. No.: IU/7
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- For implants that need to be bent or contoured to conform to the shape of the bone, such contouring must be achieved using bending instruments specially designed for this purpose. Reverse bending which decreases the fatigue life of plates must be avoided. Care should be exercised to ensure that there are no scratches or distortions at the sites of plate holes and that the process of contouring does not cause notches or sharp dents on the implants which may predispose the device to failure
- All pre-operative handling on implants must be done with care to ensure that the handling does not cause scratches, notches or dents on the surface of the implants that may predispose the device to failure.

7. WARNINGS:

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- Because of unbalanced muscle forces, sub trochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
- Subtrochanteric and comminuted trochanteric fractures and osteotomies place increased stresses on bone plates. Plate length should be increased to provide maximal fixation. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time for non- or limited weight bearing should be correspondingly increased until solid bony union occurs.
- The threads of an implanted screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
- Do not mix dissimilar metals. Use only stainless steel screws with stainless steel devices.


8. PRECAUTIONS:

- Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.
- The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

9. ADVERSE EFFECTS

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported.
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
- Leg length discrepancies and subsequent patient limp may occur.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Penetration of a guide wire/screw into the pelvis can occur.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.



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- Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.

10. Implant Removal

Bone Plates, Bone Screws, Intramedullary Nails, Pins and Wires are internal fixation devices. It is intended that these devices assist in the process of stabilizing the operative site during the normal process of healing. Subsequent to healing, these devices do not serve any further functional purpose and need to be removed. Removal is primarily indicated in most cases, as the implants are not intended to transfer or support forces applicable during normal activities. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue.



- Corrosion combined with localized pain or tissue reaction.
- Migration of position of the implant, resulting in injury.
- Postoperative trauma with the risk of additional injury.
- Bending, loosening and/or breakage of implant components, which may make removal more difficult or even impractical.
- Possibly increased risk of infection.
- Bone loss due to stress shielding.
- Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

11. SPECIAL NOTE TO USERS:

Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.

12. PACKAGING AND LABELING:

Packaging must be carefully checked for perforation or other damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. These Implants supplied in unsterile condition are

indicated by  or  on the label which must be properly sterilized by suitable method prior to surgery.

13. CLEANING AND STERILIZATION:

Cleaning (metal components only):


If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Recommended Steam Sterilisation Cycle Parameters:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 Minutes and a minimum vacuum drying time of 30 minutes
- Flash Steam Cycle (Reusable Instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in gravity displacement cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilisation evacuation and pulsing should be carried out in accordance with HTM 2010).



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Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: This is not a recommendation as to the sterilization parameters to be followed. The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's Sterilization equipment and Product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

14. STORAGE CONDITIONS:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

15. IMPORTANT INFORMATION:

The operative surgeon is responsible for carrying out the internal fixation procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant. In case of devices such as pins and wires which while implanted, project outside the patient's body, as a part of an external fixator assembly, it is also the responsibility of the operating surgeon to educate the patient on the possibility of pin tract infection and its associated problems, the importance of maintaining general hygiene and methods of maintaining cleanliness and care of the projecting pins and wires and the external fixator assembly.

Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components or External Fixator Components predispose such components to premature failure.

Implant components from one manufacturer should not be used with those of another. In case such combinations are necessary, they would be possible only if the surgeon can ascertain that all implants being used are manufactured to correct dimensional specifications and tolerances and from chrome-nickel-molybdenum alloyed austenitic stainless steel complying with or compatible to the relevant standards referred to above.

Manufacturing Traceability Records for the device are available for 15years after the manufacturing date mentioned on the label.



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16. Symbols Used in IFUs, Labels and Packaging Materials

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Manufactured by		Use by Date (Date of Expiry) YYYY-MM
	Date of Manufacture YYYY-MM		Consult instructions for use		Do not use if package is opened or damaged
	Caution: check for specific warnings or precautions	REF:	Code Number / Part No.		Non Sterile
	Batch Number		Recycle		Avoid moisture or water contact
	Keep away from heat /sunlight and radioactive sources	R_x only	To be sold only against prescription		

17. Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to adler-in.info@smith-nephew.com

Manufactured by:



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