

ALIANS PROXIMAL HUMERUS NON STERILE



PLAQUES ET VIS NON STERILES

POUR OSTEOSYNTHESE DE L'HUMERUS PROXIMAL

RANGE OF NON STERILE IMPLANTS

OF PROXIMAL HUMERUS LOCKING PLATING SYSTEM



R_Xonly



Registered in
sept. 2002

NEWCLIP TECHNICS

Obtenu en
sept. 2002

44115 Haute-Goulaine FRANCE

T. +33 (2) 28 21 37 12

Ref. NoticeHumerus

F. +33 (2) 40 63 68 37

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www.newcliptechnics.com



Produit à usage unique / Single-use product / Producto desechable / Prodotto monouso / Produto de uso único / Einweg product / Product voor eenmalig gebruik / Engångsprodukt / Tek Kullanımlık Ürün



Lire les instructions avant utilisation / Read instructions before use / Leer las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes da utilização / Vor Verwendung die Anweisungen lesen / De instructies lezen vóór het gebruik / Läs anvisningarna före användning / Kullanmadan önce talimatları okuyunuz



N° lot / Batch n° / N° lote / N° di lotto / N° lote / Chargen-Nr / Batch nr / Partijnummer / Seri no

Date de fabrication / Date of manufacturing / Fecha de fabricación / Data di fabbricazione / Data de fabrico / Datum der Herstellung / Productiedatum / Tillverkningsdatum / Üretim Tarihi



Nom et adresse du fabricant / Manufacturer's name and address / Nombre y dirección del fabricante / Nome e indirizzo del fabbricante / Nome e endereço do fabricante / Name und Adresse des Herstellers / Naam en adres van de fabrikant / Tillverkarens namn och address / Üretici Firmanın adı ve adresi

Description of products

The Alians Proximal Humerus consists of plates and screws constituting a locking internal fixation device. All implants in this range are supplied non sterile with the associated instrumentation.

Material

The implants of the range are made from titanium alloy Ti6Al4V for implantable devices (in accordance with standards ASTM F136 and ISO 5832-3).

Indications

The implants of the Alians Proximal Humerus range are intended for osteosynthesis of fractures and fractures dislocations, osteotomies and non-unions of the proximal humerus in adults.

The sales brochure associated to this range contains a complete list of product references, designations and indications.

Contra-indications

- Serious vascular deterioration, bone devitalization,
 - Pregnancy.
 - Acute or chronic local or systemic infections.
 - Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
 - Insufficient bone quality preventing a good fixation of the implants into the bone,
 - Muscular deficit, neurological deficiency or behavioral disorders, which could submit the implant to abnormal mechanical strains.
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- Allergy to one of the materials used or sensitivity to foreign bodies.
 - Serious problems of non-compliance, mental or neurological disorders, failure to follow post-operative care recommendations.
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- Unstable physical and/or mental condition.

IMPORTANT: When an implantable device is considered the best solution for a patient, and the latter shows one or several contra-indications, the patient must be made fully aware and warned of their potential influence on the successful outcome of the operation. It is recommended that patients be given all useful advice on measures to be take, to reduce the effects of such contra-indications.

Packaging and traceability

All information concerning the traceability of products in this range appears on the packaging, while each device is also identified with a laser-marking for identification.

Precautions

1. An implant shall never be reused. Previous stresses may have created imperfections that can potentially lead to device failure. Each implantable device is designed to be used once only by specialists of orthopaedic and traumatological surgery.
2. Do not use the implant if it has been in contact with another patient. If it has, please dispose of it in compliance with the regulations in force.
3. Instruments must be inspected for wear or damage prior to usage
4. Protect implant appliances against scratching and nicking. Such stress concentration can lead to failure. Do not use an implant if it looks damaged (dents, scratches, stains...).

Warning: Do not modify implants. Do not bend or cut them.

Associated ancillaries and surgical techniques

All the implants of this range must be implanted or removed using specific NEWCLIP TECHNICS ancillaries designed for the purpose. A list and detailed description of these ancillaries is included in the associated sales brochure. In no circumstances should any combination with other devices of a different brand can be done. The various surgical techniques involved in inserting and removing the products in each range are available from the manufacturer or its representative. It is imperative to become familiar with the relevant techniques before use and to comply with the instructions throughout the entire surgical procedure.

Instruments are provided to carry out the implantation of the internal fixation devices. Intraoperative breakages and damages of instruments have been reported. Surgical instruments must only be used for their intended purpose. The instruments subject to excessive force or misuse may break or be damaged. It is imperative to inspect systematically instruments for wear or shocks before use.

Precautions to be taken for obtaining a locked fixation

Osteosynthesis locking screws must be driven into the bone through the plate holes. The system is locked automatically at the end of screwing.

To obtain a perfectly locked fixation of screws and plates, it is imperative to:

- Carry out each drilling before the positioning of a screw, with the help of NEWCLIP TECHNICS threaded guide gauges. The guide gauge and the drill must be of the same diameter. Once the drilling has been done, remove the guide gauge. For some screws references, it is necessary to countersink the bone before the insertion of the screws into the holes. The various surgical techniques involved in inserting the products in each range are available from the manufacturer or its representative. It is imperative to become familiar with the relevant techniques before using an implant and to comply with the instructions throughout the entire surgical procedure.
- Remove any foreign body likely to enter the plate hole.
- Insert the screw in the locking hole. Stop screwing as soon as the locking sensation is obtained.

Screws should be inserted and/or locked into the holes with the appropriate screwdriver. NB: Locking holes can accept, at the surgeon's initiative, locking screws or non locking screws.

Post-operative precautions

Gradual weight-bearing is recommended and will vary according to age, weight and patient's good will and understanding. A periodic follow up is recommended in order to check the condition and the position of the implant, as well as the bone condition. It is recommended to proceed periodically to postoperative radiographies and to compare them to the immediate postoperative condition to detect each potential failure of the implant.

Removal of the implanted device

Implants are subject to stress until bone healing. After the bone has healed, implants are no longer strictly necessary and may then be removed. It is the responsibility of the surgeon to decide when and if the implants must be removed.

Limited warranty and disclaimer

NEWCLIP TECHNICS products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. The manufacturer's liability is limited to the applications and uses specified in this document.

Warning

1. It is essential to check that the device is correctly chosen for the use it was intended for by the manufacturing company.
2. The operating surgeon is responsible for having adequate surgical training, properly selecting patients, and choosing the type of device most appropriate for implantation. The implant type and size is based on pre-operative data and measurements, and is the surgeon's decision. The surgeon must check that there is no biological, biomechanical or other factors that will affect the implantation and the post-operative treatment. The surgeon must be thoroughly knowledgeable on biological, biomechanical or other risks not affecting the implantation and the post-operative treatment. The surgeon must warn the patient that failure to follow post-operative care instructions may have an effect on the service life of the implant and compromise success of treatment.
3. The patient must be made aware and warned that implantable devices have been designed for use in specific, limited conditions; they may have adverse effects and while generally successful, they may also loosen, break, bend or be damaged as a result of loosening fixation systems, stress, patient's activity level or excess load bearing, especially when the device is subjected to increased loading associated with delayed union, non-union or incomplete healing.
4. The surgeon must be aware of the following metallurgical and mechanical aspects of implantable devices:
 - The device can break when subjected to increased loading associated with non-union or delayed union.
 - Implants materials are subject to corrosion when implanted in a constant environment of salts, acids and alkalis. Putting dissimilar metals in contact with each other can accelerate the corrosion process (and may therefore enhance fracture of implants).
 - The placement of the implants must be gradual to avoid unusual wear and tear of implants. Excessive force could indeed create strains that may lead to implant fracture or distortion resulting in adverse side effects.

The implants of this range have not been evaluated for safety and compatibility in the MR environment. This range has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning and sterilization

All non-sterile implants must be cleaned and sterilized prior to use by qualified professionals using the following guideline:

Conditions for use	These devices are sold non sterile. All devices must be cleaned, decontaminated and sterilized after removal of packaging material, before and after use.
Preparation for cleaning	Solutions containing bleach or formaldehyde can damage the units and must not be used. These devices must not come into contact with fluorinated or chlorinated compounds, with fat-based detergents, and, in general, with any product which might modify their chemical component(s). Similarly the use of metallic brushes or other abrasive products is not allowed.
Cleaning	Cleaning may be carried out manually or mechanically according to the specifications provided by the supplier of the equipment to the hospital.
Cleaning - manual	<u>Equipment: aldehyde-free detergent (alkaline or neutral) – brush with soft bristles – purified water</u> Rinse off excess soiling from the device. Apply the detergent according to the detergent manufacturer's instructions, with the brush on all surfaces, ensuring that devices with joints are cleaned in both the open and the closed positions. Particular attention must be applied to threaded areas and to areas which are hard to access. After cleaning, devices must be immediately rinsed carefully and thoroughly with purified water, during at least 1 minute. Ensure that water flows through cannula and difficult access areas.
Cleaning - automated	<u>Equipment: washer/disinfector – alkaline or neutral detergent – purified water</u> Deposit the devices so as to allow the water to flow through difficult access areas. Follow the instructions for concentration, temperature and contact time by the manufacturer of the cleaning agent. The minimum washing cycle is 5 minutes and rinsing 3 minutes.
Disinfection	When washer/disinfector is employed, a final rinse at 95°C for 10 minutes can be performed in order to achieve thermal disinfection.
Drying	The temperature in the drying phase must not exceed 134°C.
Visual inspection	After cleaning (manual or automated), the device must be inspected. If the device is determined to not be visually clean at the end of the cleaning process, the user must repeat the previous cleaning steps, or alternatively, call the manufacturer. If the cleaning process has caused damage to the device, it should not be used and the manufacturer is to be notified.
Sterilization	<u>Recommended method: steam sterilization in autoclave:</u> Before sterilization, Newclip tray should be packaged in a legally marketed FDA-cleared sterilization wrap.

They must be steam-sterilized using the following guideline:

	US Sterilization (only for United States)	EU sterilization (only for Europe)
Sterilizer	Dynamic-air-removal steam sterilizer	
Temperature	270°F / 132.2°C	134°C / 273.2°F
Exposure time	4 min	18 min
Drying time	20 min	20 min

The EU sterilization protocol (134°C - 18 min) is not validated for prion inactivation cycle in the US sterilizers.
The devices can be sterilized repeatedly under these described conditions.

Storage

These devices are subject to damage. We therefore advise that they are handled with care.

Since NEWCLIP is not familiar with individual hospital handling methods, and in particular cleaning, decontamination and sterilization, NEWCLIP cannot assume responsibility for sterility of implants, even though the guidelines have been followed.

Newclip has validated the instructions provided above as being capable of sterilizing its medical devices. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process.

Storage conditions

The implants must be stored in a clean, dry, temperate environment away from direct sunlight.

Factors likely to compromise the success of implantation

- Severe osteoporosis, loss of bone substance.
- Deformity or severe traumatism with loss of bone substance or soft parts.
- Local bone tumour.
- Systemic, metabolic or genetic disorders.
- Infectious diseases.
- Drug addiction and/or tendency to abuse drugs and medication.
- Obesity.
- Intense physical activity (e.g.: competitive sports or strenuous work).

Possible adverse effects

The most frequently reported adverse effects following the fitting of osteosynthesis implants are:

- Pain or discomfort
- Soft tissues irritations, nerve damage due to the implant presence or to surgical trauma,
- Delayed union, pseudarthrosis,
- Damages to vessels, hematoma,
- Loosening, migration, breakage, deformation of all or part of the implant, implant fragmentation which may lead to revision surgery or removal of the implant,
- Infections,
- Cardiovascular disorders, thrombosis, pulmonary embolism,
- Fracture formation, secondary arthritic changes around the implantation site due to a different distribution of mechanical strains,

- Sensitivity to metals or allergic reaction,
- Bone necrosis or osteolysis,
- Excessive growth of fibrous tissue around the site of implantation.

IMPORTANT: These surgical products must be handled, and/or implanted by well-trained, knowledgeable surgeons aware of the present instructions.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) or on the physician's prescription.

NEWCLIP TECHNICS cannot assume responsibility in case of non-respect of the above instructions.