AREX® : SCRU™/ SCRU™ 2 ©
Screws for osteosynthesis
NON STERILE

Instructions
(READ ATTENTIVELY BEFORE USE)

Arex® SCRU™ and SCRU™ 2© device is used for orthopaedic surgical treatment. For best results, a detailed preoperative evaluation, a meticulous surgical technique and adequate postoperative care are necessary.
These implants are CE products since 2003. It is important that the patient and the surgeon are completely aware of risks and possible complications associated to this type of surgery. We advise to the surgeon to attend a training course with a surgeon already experimented with the use of this technique, before starting the use of the Arex® Scru™ and Scru™ 2© device.

1] DESCRIPTION AND COMPOSITION OF THE DEVICE

Arex® SCRU™ and SCRU™ 2© implant is composed of a canulated, compressive,dualpitch, self drilling, self tapping screw. This implant is made of Titanium alloy according to standards ISO 5832-3 and ISO 5832-11 or made of pure Titanium according to standards ISO 5832-2 and Titanium alloy according to standards ISO 5832-3. The material is indicated on the external packaging.

2] INDICATIONS

- Mono and bi-cortical osteosynthesis
- Distal or proximal metatarsal osteotomy
- Weil osteotomy
- Scarf / Chevron osteotomy

For hand surgery SCRU™2 and SCRU™2LP are highly recommanded to perform arthrodesis DIP but also PIP. SCRU™ but also SCRU™2 and SCRU™2LP are also recommanded to eprform carpal arthrodesis.

3] CONTRA-INDICATIONS

The contra-indications include but are not limited to:
- Acute or chronic, local or systemic infections
- Fever
- Known allergy or intolerance to the materials
- Infectious disease
- Systemic and metabolic disorders
- Severe osteoporosis
- Drug or alcohol dependency
- Local bones tumours
- Non cooperative patient or patient with mental illness
- Intense physical activity

The surgeon has to furnish the patient all information concerning the influence of these factors on the operation's success and give advice in order to minimize these risks.

4] ADVERSE EFFECTS / RISKS OF MEDIUM AND LONG-TERME COMPLICATIONS

Potential complications and adverse effects associated with the AREX® SCRU™ device are identical to those encountered with other identical systems and may require an additionnal surgery.
- Thrombosis
- Rupture, Crushing or Recess of the implant
- Infection
- Haematoma
- Allergy due to patient intolerance to the materials used

5] PREVENTION OF POSTOPERATIVE COMPLICATIONS

- Avoid extreme forced positions (flexion/extension)
- Wear orthopaedic shoes prescribed by the surgeon
- Avoid any fall
- Seek immediate medical attention for any infection occurring after the operation

6] RISK OF INTERFERENCE WITH MEDICAL IMAGING

MRI / CT: The patient must mention the implants systematically (Inform the patient about this recommendation) this everythough the TA6V alloy that is used is MRI (Magnetic resonance imaging) compatible.

7] CLEANING / DECONTAMINATION

The implants provided « NON-STERILE » and « for SINGLE USE » must be removed from their original packaging, checked up to guarantee that they have not been damaged, and must be cleaned and decontaminated with appropriate products before their sterilisation. All products which can alter the implants are forbidden.

8] STERILISATION

The implants delivered "Non-sterile" and its ancillaries must be sterilised before use; it is advised to sterilise in a steam autoclave according to the method used in hospitals and clinics (recommended values below).

Method	Cycle	Temperature	Exposure time
Autoclave	Gravity (Prion)	134°C (273°F)	20 min (minimum)

Recommended cycle at the creation date of these instructions, as an indication
However, we advise users to validate their methods used by appropriate laboratory techniques.

9] STORAGE
The implants must be carefully stored, in a clean place, under normal temperature and moisture conditions and, if possible, away from U.V light. Implants must be protected from any corrosive environment.

10] USE
The surgeon must know, thanks to various rachis litteratures, a solid rachis surgical formation, and the documentation released, the Arex® SCRU™ and SCRU™ 2© implantation technik.
The success of the operation is closely related to the respect of indications and the operating technique. Good patient selection and correct follow-up of pre and postoperative instructions by patients are also essential requirements for the success of the operation.
All patients who are considered for implantation of the Arex® SCRU™ and SCRU™ 2© system should be informed about the risks associated with this type of technique and about the limitations regarding their activities after the surgical procedure.

10.1 Preoperative precautions :
- The success of the operation is closely related to a detailed preoperative diagnosis, a self-possession of surgical technique and a post operative medical attention.
- The surgeon should be familiar with the different components of the device, the instruments and the surgical implantation procedure.
- Check before sterilisation that the implants have not been damaged (scratch, impact, etc…)
- Check before sterilisation that an adequate and sufficient range of implants (shapes, sizes) is available to make the surgery.
- Check before sterilisation that all setting instruments are available and functional
- For implants provided sterile verify the sterilisation validity.

10.2 Peroperative precautions :

- Proceed according to the surgical procedure provided by the manufacturer.
- Only NEW and STERILE implants must be used during the surgical procedure
- During manipulation, the surface of the implants should be verified and any contact that might alter their condition should be avoided (scratch, impact, etc…).
- The correct selection of the size of the implant suitable for the patient as well as its positioning are extremely important.
- The surgeon is requested to be extremely careful when placing the implants and to pay particular attention to neurological structures.
- Eliminate all implants which have been in contact with the bone according to the rules in force.
- Components from a different manufacturer or from a different product should not be used in combination with the components of the Arex® SCRU™ and SCRU™ 2© system.

10.3 Postoperative precautions :

- The devices, which have been in contact with a patient, must be isolated and decontaminated before cleaning and possible return to the manufacturer or destruction.
- The surgeon should give the patient detailed instructions regarding his activities after surgery and should ask him to strictly comply with these instructions (avoid extreme forced positions, avoid intense physical activity, come back for postoperative follow-up,…).
- A suitable rehabilitation program must be designed and implemented
- It is recommended that a regular postoperative follow-up is undertaken to control the patient state and the stability of material.
- the respect by the patient of pre and postoperative instructions constitutes an essential condition of successful of the operation.

11] CAUTION

- We decline all liability if our implants are associated with those of a different origin.
- **Single use implant must not under any circumstances be reused, even if it seems free of any defects. First because cleaning and sterilization procedures may not remove all biological debries that could contain pathogenic agent. Moreover cutting and mechanical properties of the device will be affected in case of reuse. Wastes or implants which have been used on the patient must be disposed of according the legisaltion in force and the procedures used in hospitals**
- Arex® SCRU™ and SCRU™ 2© implants must be manipulated and implanted only with Arex® SCRU™ and SCRU™ 2© instruments designed for this effect and according to the surgical technique advocated.
-The Titanium alloy will not be into contact with other implants which are not approved or controlled by the manufacturer.
- Despite the use of a rigorous operation technique, in some cases the implants cannot indefinitely support the backbone and present various failures. These can be a failure at the bone-implant interface, with break down of components or a broken bone. The surgeon and the patient must be aware of this risk. In such a case a supplementary surgery can be necessary.
- Under no circumstances should an implant be modified or altered by the user

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NON STERILE


SEE INSTRUCTIONS FOR USE


DO NOT USE IF PACKAGE IS DAMAGED


KEEP DRY


DO NOT RE-USE

CE 0499