Instructions for Use: Non-Sterile Implants

Instructions for Use RNL-IFU-002 RevD Issue Date: Jun-17

Caution:

Carefully read all the instruction and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

1 GENERAL INSTRUCTIONS

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. Renovo Life implants should only be used with approved devices and accessories.

2 DEVICE DESCRIPTIONS

a) Implants made from titanium in accordance with ISO 5832-2 unalloyed Titanium; ISO 5832–3 Ti6Al4V alloy; ISO 5832-11 Ti6Al7Ni alloy manufactured by Renovo Life, LLC. The surface of these implants is chemically passive: not magnetic.

These implants can be combined with the standardized material provided that its composition lies within the analysis stipulated in the ISO 5832-2 / ISO 5832-3 / ISO 5832-11 standard and the required specifications. The material wrought unalloyed titanium and alloyed titanium is biocompatible and prevents a so-called chrome-nickel allergy by its nature

b) Implants made from stainless steel in accordance with ISO 5832-1 stainless steel; ISO 5832–9 high Nitrogen stainless steel manufactured by Renovo Life, LLC. The surface of these implants is chemically passive: not magnetic.

These implants can be combined with the standardized material provided that its composition lies within the analysis stipulated in the ISO 5832-1 / ISO 5832-9 standard and the required specifications. Material alloys with chrome-nickel (implant steel) components can trigger a so-called chrome-nickel allergy by their nature; there are no other known biocompatible hazards.

c) We indicate that implants can only execute their functions correctly when the following basic rules are observed.

- When selecting implants (bone: plates / screws / pins wires / clips), care must be taken to choose the appropriate implants on the basis of the weight and level of activity of the patient, and the bone fracture to be treated.
- Note that by making the correct choice of biomechanics the forces to be transferred by the implants remain low.
- Extreme deformation of the implants must be avoided; the cautious bending of wires, plates and pins does not, however, lead to implant damage provided it is done with sufficient care.
- Repeated deformation should be avoided at all costs as it will fatigue the implant material.
- The re-use of implants is absolutely forbidden (single use).
- We strongly advise you to inform patients of the advantages and disadvantages of implants.
- Excessive strain as a result of body weight and the level of activity of the patient should be avoided due to the limited strength of the implants. Failure to observe these precautionary measures can have serious consequences for the healing process.

3 INDICATIONS

Renovo Life implants are intended for fixation and/or osteosynthesis of fractures, osteotomies, nonunions, and malunions of various, small, large, long, and short bones. Refer to specific implant surgical techniques for specific intended use statements.

4 CONTRAINDICATIONS

Acute and chronic infections; muscle, nerve or vascular diseases that endanger the affected extremity; a lack of bony tissue or poor bone quality (e.g. severe osteoporosis); local bone tumors. Systemic diseases and metabolic disorders; infections and falls; drug dependence; obesity; highly physical activities together with activities involving extreme vibrations which can lead to overstraining of the implants.

5 NOTES

The user should record and keep all information provided to the patient. It should be checked before use whether the patient tolerates the material to be implanted. The implants described in these instructions for use may only be used (implanted) by surgeons with the appropriate experience.

6 POSSIBLE NEGATIVE EFFECTS (RISKS)

Failure of the fracture to heal, allergy to the material, failure of the product (break, bending), bone deformation and refracture, infection.

7 REMOVAL OF IMPLANTS

The surgeon may elect to remove the implants once the fracture has healed.

8 CLEANING AND STERILIZATION OF UNSTERILE IMPLANTS

a) Implants may be supplied sterile, as indicated on the device's labelling. These implants are sterilized by gamma irradiation. Dispose of these implants if the packaging is damaged. Resterilization of these sterile-supplied implants is strictly prohibited, as it may alter the mechanical integrity of the device.

b) Unless specifically labelled sterile, the implants are supplied non-sterile and must be sterilized prior to use.

c) A complete guide for reprocessing implants may be provided upon request. As a guideline, the following sterilization method is recommended:

STEAM AUTOCLAVE PRE-VACUUM
Condition: Double-Pouched
Temperature: 270° F (132° C)
Time: 4 minutes
Drying Time: 20 minutes

Note: Drying time is subject to variation depending on machine load.

d) The recommendations from the sterilizer's manufacturer should be strictly adhered to. The sterilization process and adjustment of the autoclaves should be checked regularly. If there is residual dampness in the sterilization box after the sterilization cycle, proceed as follows:

- Usage of an FDA-cleared wrap is recommended to ensure that the device is sterile prior to implantation
- Do not open the box immediately after use
- Increase the drying time, unless tests show that the exposure time has been adequate to obtain the required time for sterilization
- Make additional perforations in the box to facilitate the run-off of the residual humidity

e) The recommendations on sterilization are only given as a guideline. Under no circumstances can the manufacturer be held responsible for the sterility of devices sterilized within the hospital.

9 MR COMPATIBILITY STATEMENT

Renovo Life implants made from stainless steel or titanium have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Renovo Life implants in the MR environment is unknown. Scanning a patient who has one or more of these devices may result in patient injury.

10 IMPORTANT NOTES

a) Every time the implants are used or sterilized you must first check that they function perfectly.

b) In the event of failure to observe these instructions or demonstrable violation, no guarantee or compensation for damages can be provided.

11 MAINTENANCE, STORAGE, AND HANDLING

a) Instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray respectively, and in accordance with AS4187:2003.

b) Surgical instruments should be handled and stored with care. Instruments should be carefully stored in an appropriate, dry, clean environment. Instruments must not be stored in contact with, or close to, products that may have a corrosive effect.

12 LIMITED WARRANTY / LIABILITY

Renovo Life 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.

Renovo Life shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Renovo Life neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Renovo Life intends that these implants should be used only by physicians having received appropriate training in orthopaedic surgical techniques.

13 CONTACT INFORMATION

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Renovo Life location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Renovo Life location as listed below:

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Label Symbol Legend