osseoREBAR Nails

For Symbols Glossary, please refer to
https://restor3d.com/resources/instructions

INSTRUCTIONS FOR USE

1. DEVICE DESCRIPTION

The restor3d osseoREBAR Nails consist of cylindrical-shaped implants intended to be used for fracture fixation, osteotomies, arthrodesis, and as bone graft. The restor3d Pin Implants are manufactured from an implant grade titanium alloy. The osseoREBAR Nail is intended to be used with supplemental fixation.

2. INDICATIONS FOR USE

The restor3d osseoREBAR Nail is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone graft in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast, brace).

3. CONTRAINDICATIONS

The restor3d osseoREBAR Nail is contraindicated for use in cases of:

- Infection
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for more conservative treatment
- Growing patients with open physes
- Patients with high levels of activity
- Malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless additional supplemental fixation or stabilization methods are utilized
- Foreign body sensitivity

4. WARNINGS AND PRECAUTIONS

WARNINGS

- The osseoREBAR Nail is supplied sterile for single use only.
- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Do not reuse this device. Reuse of this product may result in infection or other systemic complication that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect the function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage or contamination that could result in implant failure and should be discarded.

- Plates and screws chosen to secure the fracture, fusion, or osteotomy that could contact the implanted osseoREBAR Nail should be manufactured from Titanium (or titanium alloy) to reduce the likelihood of galvanic corrosion.
- It is important that immobilization of the fracture, fusion, or osteotomy site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established to reduce the likelihood of delayed or non-union of the fracture or osteotomy site.
- Some implants may be cut to reduce length as part of the surgical technique. However, additional modifications should not be made. Modified devices may not perform as intended and could result in patient injury.
- Do not use beyond the expiration date listed on the label. The performance, safety, and/or sterility of the device cannot be assured beyond the expiration date.
- In the event that a device is opened and not used, dispose of it according to hospital policy and procedure.

PRECAUTIONS

- Correct selection of implant is extremely important. The potential for success in fracture fixation, osteotomy, or arthrodesis is increased by selecting the proper implant size, shape, and design. The patient's anatomy and indication will determine the size of the osseoREBAR Nail to be used.
- No partial weight-bearing or non-weight-bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant or nonunion of the fracture or osteotomy requiring revision surgery to remove the device. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- The osseoREBAR Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the nail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

5. MRI SAFETY INFORMATION

The osseoREBAR Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the osseoREBAR Nail in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

6. POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from use of the osseoREBAR Nail include, but are not limited to, the following:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant

- Loosening of the implant requiring revision surgery
- Loss of anatomic position with nonunion or malunion
- Bone resorption or over-production
- Allergic reaction to the implant material
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Adverse effects may necessitate re-operation, revision or removal surgery. Implant removal should be followed by adequate postoperative management.

7. IMPLANT MATERIALS

The osseoREBAR Nail is manufactured from an implant grade titanium alloy (Ti-6AL-4V).

8. HOW SUPPLIED

Sterile Implants
The osseoREBAR Nail has been sterilized by gamma radiation and is provided sterile in the unopened, undamaged package. If either the implant or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize sterile implants.**

9. SURGICAL PROCEDURE / DIRECTIONS FOR USE

It is the responsibility of the surgeon to be familiar with the procedure before use of these products. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Generic surgical procedures that are indicated for use with the nail implants include the following:

A) Drilling Across Site

1. Place implant in the wire driver collet for the selected diameter.
2. Drill implant into bone, across the fracture site.
3. Verify implant placement on fluoroscopy.
4. Using standard orthopedic pin cutters, cut the implant at the desired length.
5. Tamp the nail further into the bone to seat flush (if necessary).
6. Place additional immobilization.

B) Fixate & Reduce

1. Place implant in the wire driver collet for the selected diameter.
2. Drill implant into one side of joint or osteotomy site.
3. Drill bone tunnel in opposite side of joint or osteotomy.
4. Use standard orthopedic pin cutters to cut implant to desired length (if necessary).
5. Reduce and fixate implant into opposite side of osteotomy site.

6. Verify implant placement on fluoroscopy.
7. Place additional immobilization.

10. TRAINING

Surgeons may obtain training from a qualified instructor prior to implantation this device to ensure thorough understanding of instrumentation, implantation and removal techniques. Please contact restor3d Customer Service toll-free in the U.S. at 984-888-0593 or email customerservice@restor3d.com to arrange training with a qualified instructor.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Manufacturer: restor3d, Inc.
311 W Corporation St
Durham, NC 27701
Phone: 984-888-0593
Email: customerservice@restor3d.com
www.restor3d.com

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