restor3d Metallic Interference Screw

INSTRUCTIONS FOR USE

1. DEVICE DESCRIPTION

The restor3d Metallic Interference Screw is a cannulated interference screw used to maintain fixation of a bone-tendon-bone graft in an orthopedic procedure. It is constructed from implant grade 3D-printed metal and available in a variety of lengths and diameters to accommodate variations in patient anatomy.

2. COMPATIBILITY

The restor3d Interference screw has a 3.5mm hex interface to allow insertion with a 3.5mm hex driver.

3. INDICATIONS FOR USE

The restor3d Metallic Interference Screw is used to provide bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

The restor3d Interference Screw is intended for use with a standard 3.5mm cannulated hex screwdriver with handle, such as the Apiary Medical Inc. part number gS 86.4495.S

4. CONTRAINDICATIONS

- Surgical procedures other than those listed in the indications for use.
- Insufficient quantity or quality of bone for attachment.
- Blood supply limitations and/or previous infections which may retard healing.
- Foreign-body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Patients with active sepsis or infection.
- Conditions which tend to limit the patient's ability or willingness to restrictive activities or follow directions during the healing period.

5. WARNINGS AND PRECAUTIONS

WARNINGS

- The restor3d Metallic Interference Screw 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.
- Do not use this device for fixation of soft tissue grafts.
- Do not modify the implant. 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

- The restor3d Interference Screw should be used only by those physicians who have been trained in the appropriate procedures. Knowledge of appropriate surgical techniques, instrumentation, proper selection and placement of implants and postoperative patient care and management are essential to a successful outcome.
- Careful selection of screw size, with respect to bone block size, shape and tunnel diameter can reduce the risk of damage or loss of fixation.
- The restor3d Metallic Interference Screw 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 restor3d Metallic Interference Screw in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

6. POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from use of the restor3d Interference Screw include, but are not limited to, the following:

- Infections/tissue irritations, both deep and superficial.
- Allergies and other reactions to the device materials.

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

7. IMPLANT MATERIALS

The restor3d Interference Screw is manufactured from an implant grade metal alloy, either implant grade titanium (Ti-6AL-4V ELI) or cobalt chrome (ASTM F75 Type A). Refer to packaging label to confirm which type of material was used to create your 3D-printed Interference Screw.

8. HOW SUPPLIED

The restor3d Interference Screw 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. As the manufacturer of this device, restor3d does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

1. Prepare the tibial and femoral tunnels in accordance with the accepted surgical technique.
2. If a guidewire is used, position guidewire in appropriate location.
3. Place the bone block securely into the tunnel.
4. Place the restor3D Interference Screw on guidewire.
5. Drive screw with an appropriate hex drive (3.5 mm cannulated hex driver)
6. Remove guidewire after initial insertion

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