restor3d MTP Implant

INSTRUCTIONS FOR USE

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

1. DEVICE DESCRIPTION

The restor3d MTP Implant, made of cobalt-chromium alloy, is used to treat patients with degenerative and post-traumatic arthritis in the first metatarsophalangeal joint to restore joint motion and relieve pain. The restor3d MTP Implant is available in three sizes with varying articulating head dimensions.

Instrumentation to assist in the surgical placement of the MTP Implant is provided. It is important that the provided instruments are used to ensure the appropriate implantation of the implants.

2. INDICATIONS FOR USE

The restor3d MTP Implant is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint. The device is a single use implant intended to be press fit, with optional use of bone cement.

3. CONTRAINDICATIONS

- Surgical procedures other than those listed in the indications for use.
- A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
- Patients with an active local or systemic infection or if the patient is immunocompromised.
- Conditions which tend to retard healing such as blood supply limitations or previous infections.
- Skeletally immature patients where the implanted device would cross open epiphyseal plates.
- Grossly distorted anatomy due to congenital abnormalities.
- Inadequate tissue coverage over surgical site.
- Insufficient quality or quantity of bone, comminuted bone surfaces or pathologic conditions such as cystic change or severe osteopenia that would impair the ability of the restor3d MTP Implant to securely fixate to the bone.
- Inadequate neuromuscular status (e.g. paralysis, inadequate muscle strength).

- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted, and sensitivity ruled out prior to implantation.
- A condition of the toe which may lend itself to a more conservation procedure.
- In conjunction with ancillary fixation.

4. WARNINGS AND PRECAUTIONS

WARNINGS

- The restor3d MTP Implant and supporting instruments are supplied sterile for single use only.
- Do not resterilize the implant or supporting instruments. Resterilization could lead to mishandling and surface damage that could result in fracture and/or particulate debris.
- Do not reuse the implant or supporting instruments. Reuse of these products may result in infection or other systemic complication that may affect the patient's overall health. Additionally, the reuse of these products could adversely affect their function. Any device 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 modify the implant or supporting instruments. Modified devices may not perform as intended and could result in patient injury.

PRECAUTIONS

- The restor3d MTP Implant should be used only by those physicians who have been trained in the appropriate, specialized 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.
- Appropriate selection of restor3d MTP Implant components is extremely important. Carefully select the appropriate device size based on the needs of each individual patient.
- Never attempt to reuse. Once the restor3d MTP Implant and supporting instruments have been removed from the packaging, the devices should be either used or discarded. Never attempt to reuse the implant or supporting instruments, even though they may appear undamaged.
- The surgeon must make the final decision regarding implant removal.
- In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. Extreme care must be taken when removing the device.
- Use only restor3d device components and instruments or equivalent when handling and implanting the restor3d device.
- Confirm fluoroscopy shows proper alignment of the restor3d MTP Implant with the metatarsal bone.

5. MRI SAFETY INFORMATION

The restor3d MTP Implant 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 restor3d MTP Implant 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 restor3d MTP Implant include, but are not limited to, the following:

- Loosening, cracking or fracture of the implant.
- Loss of fixation in bone.
- Fracture of bony structures.
- Deep or superficial infection.
- Degenerative changes or instability at the metatarsophalangeal joint.
- Nerve damage due to surgical trauma or presence of the device.
- Sensitivity, allergies, or other reaction to the device material.
- Tissue reactions including macrophage and foreign body reactions adjacent to implants.
- Malalignment of anatomical structures.
- Pain, discomfort and abnormal sensations due to presence of the implant.
- Hematoma or thrombosis.

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

7. IMPLANT MATERIALS

The restor3d MTP Implants are manufactured from implant grade cobalt-chromium-molybdenum alloy (ASTM F3213). Other materials may be present at trace levels.

8. HOW SUPPLIED

The restor3d MTP Implant and supporting instrumentation have been sterilized by gamma radiation and are provided sterile in unopened, undamaged packages. If either the devices or the packages appear damaged, are beyond the sterility expiration date, or if sterility is questioned for any reason, the devices should not be used. **Do not resterilize sterile implants or supporting instruments.**

9. SURGICAL PROCEDURE

A surgical technique is available, which outlines the procedure for device implantation and the use of surgical instrumentation. 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.

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.

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