Precautions
- Do not re-use 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 function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate debris and should be discarded.
- The Integra Movement Great Toe System has not been evaluated for safety and compatibility in the MR environment, and compatibility and safety in the MR environment are unknown. The Integra Movement Great Toe System has not been tested for heating or migration in the MR environment, and heating or migration effects in the MR environment is unknown.

Indications for Use
Hemi-Arthroplasty
The Integra Movement Great Toe System is a two-piece implant that is intended to be used as a prosthesis for the metatarsophalangeal joint (MTP). The device uses the metatarsal semi-arthroplasty device from above paired with a phalangeal base manufactured from titanium with an Ultra High Molecular Weight Polyethylene (UHMWPE) articulating surface insert. The metatarsal and phalangeal joint replacement devices are intended for cemented use only. Each device is boxed individually and delivered sterile for single use.

Total Arthroplasty
The Integra Movement Great Toe System is a two-piece implant that is intended to be used as a prosthesis for the metatarsophalangeal joint (MTP). The device is intended for cemented use only. Indications for use include:
- Hallux valgus or Hallux limitus
- Hallux rigidus
- Unstable or painful metatarsal/phalangeal (MTP) joint

Contraindications
- Active local or systemic infection;
- Destruction of the 1st metatarsal head or 1st proximal phalanx base or poor bone quality which prevents adequate fixation of the implant;
- Loss of musculature, neuromuscular compromise, or vascular deficiency in the affected toe.

Warnings
The following conditions, singularly or concurrently, tend to place excessive loads on the toe joint prosthesis and, thereby, place the patient at higher risk for failure of the prosthesis. If excessive loading of the affected toe joint cannot be prevented, this toe joint prosthesis should not be used.
1. Excessive activity of the affected joint;
2. Incorrect or recurrent deformity;
3. Incorrect sizing of the implant;
4. Inadequate soft tissue or bony support;
5. Implant malposition.

These conditions — occurring singularly or concurrently — may damage the structural integrity of the device and could result in implant fracture and/or particulate debris. The benefits of toe joint replacement may not meet the patient’s expectations or may deteriorate over time. Pain, swelling, instability, and/or deformity may persist or return after toe joint replacement.

Stability
This implant has been sterilized by gamma radiation and is sterile in the unopened, undamaged package. If either the implant or the package appears damaged or has been opened, or if sterility is questioned for any reason, the implant should not be used. Resterilization of this product is not recommended.

Surgical Procedure
A Surgical Technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation, which will provide optimum implantation and reconstruction results.

Metallic preparation of the implant site and selection of the proper size implant increases the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

Training
Surgeons may obtain training from a qualified instructor prior to implanting the Integra Movement Great Toe System to ensure thorough understanding of the implantation techniques and the instrumentation. Please contact Ascension Orthopedics’ Customer Service at 1 (800) 654-2873, or toll-free in the U.S. at (877) 370-5001, to arrange training with a qualified instructor.

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