Integra® Silicone Toe System

Instructions for Use

℞ ONLY

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

These devices are fabricated from medical grade silicone elastomer. In some implants, this material is internally reinforced with medical grade polyester mesh and/or fibers. The Integra® Silicone FGT Toe device includes a metal grommet component that is fabricated from Commercially Pure Titanium (CP Ti). Suture ties are provided in some implants for temporary stabilization. Polyester mesh or velour external surfaces, when present, promote long-term stabilization through tissue ingrowth.

INTEGRA SILICONE FGT

The Primus Flexible Great Toe (FGT) is a third-generation flexible implant for first metatarsophalangeal joint arthroplasty. It is constructed of durable silicone elastomer and has Commercially Pure Titanium (CP Ti) Grommets. Its anatomically designed hinge allows for free and natural movement of the 1st MP joint. The design incorporates angled osteotomies, allowing for the preservation of the flexor hallucis brevis tendon to function in its natural state.

INTEGRA SILICONE CGT

The Classic Flexible Great Toe (CGT) is a third-generation implant for first metatarsophalangeal joint arthroplasty. It is constructed of durable silicone elastomer and its anatomically designed hinge allows for free and natural movement of the 1st MP joint. The implant requires vertical osteotomies, eliminating the need to use a cutting guide.

INTEGRA SILICONE LMP

The Lesser Metatarsal Phalangeal Implant (LMP) is the first prosthesis designed specifically to supplement lesser metatarsal phalangeal joint arthroplasty. It is constructed of durable silicone elastomer and its anatomically designed hinge allows for free and natural movement of the lesser MP joints.

This device is intended for single use only.

INDICATIONS

The Integra Silicone CGT and FGT devices are indicated for:

- Hallux limitus or hallux rigidus
- Painful rheumatoid arthritis
- Hallux abducto valgus associated with arthritis
- Unstable or painful joint from previous surgery

The Integra Silicone LMP device is indicated for:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain associated with rheumatoid or osteoarthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Kohler's disease
- Hammer toe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state

CONTRAINDICATIONS

General contraindications for the use of these implants for joint reconstruction include:

1. A psychologically unsuitable patient
2. A patient with skin, bone, circulatory and/or neurological deficiency
3. Nonfunctioning and irreparable musculotendinous system
4. Active sepsis
5. Inadequate bone stock

WARNINGS (See also the Patient Counseling Information Section)

Strenuous loading, excessive mobility and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

PRECAUTIONS

This product is provided sterile in an undamaged package and is for ONE-TIME USE ONLY. If either the implant or the package appears damaged, expiration date has been exceeded or if the sterility is questioned for any reason, the implant should not be used. DO NOT clean, re-sterilize or re-use as this may damage or compromise performance of the devices and may expose patient to risk of transmitting infectious diseases.

Implants should only be handled with blunt instruments to avoid scratching, cutting or nicking the device.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful outcome. A complete range of trial sizers is available to aid in bone preparation. 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.

MAGNETIC RESONANCE (MR) STATEMENT

The Integra Silicone Toe System 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 Integra Silicone Toe System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STERILITY

The Integra Silicone Toe System implant components are supplied sterile in an undamaged package. The components are sterilized by ethylene oxide (EO) gas. If either the implant or the package appears to be damaged, the package has been opened, the expiration date has been exceeded or if sterility is questioned for any reason, the implant should not be used.

Do not re-sterilize this product.

Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should 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 Silicone Toe System to ensure thorough understanding of the implantation techniques and the instrumentation.

ADVERSE EVENTS

Potential adverse events reported with toe joint prostheses include pain, loosening, fracture, dislocation or infection. There have been some reports of patients with silicone sensitivity reactions following joint replacement. Implantation of materials such as silicone may result in foreign body reaction adjacent to the implant site. Injury to surrounding nerves, blood vessels, tendons or soft tissue can occur as a consequence of implanting this device.

In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate, synovitis or bone cyst complications in contiguous bone. Contributing factors have been reported to include the use of implants in physically overactive patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with K-wires, subluxated implants, implant over or under-sizing, and uncorrected or recurrent deformity.

STORAGE

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

SURGICAL PROCEDURE

A Surgical Technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation.
It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

PATIENT COUNSELING INFORMATION (See also Warnings)

Providing each patient scheduled for implant surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary. In addition to the patient-related information contained in the Warnings and Adverse Events section, the following information should be conveyed to the patient:

1. Adverse effects may necessitate reoperation, revision or fusion of the involved joint.
2. While the expected life of joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity levels and loads of normal healthy bone for an unlimited period of time.

PRODUCT INFORMATION DISCLOSURE

INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS PRODUCT.

Symbols Used on Labeling

REF	Catalog number		Do not use if package is damaged
LOT	Lot number	MATL cpTi	Commercially pure titanium (cpTi)
	Consult Instructions for Use	℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not re-use		
QTY 1	Quantity		Manufacturer
MATL Si-O-Si	Silicone elastomer (Si-O-Si)		Use-by date (YYYY-MM-DD)
STERILE EO	Sterilized using ethylene oxide		Do not re-sterilize

For further information or complaints, please contact:

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