

Instructions For Use

OrthoFlex Rod - Silicone Toe Implant

Package Insert / Important Medical Information

OrthoPro

THE FOOT AND ANKLE COMPANY

GENERAL PRODUCT INFORMATION

Through the advancement of partial and total joint replacement, the surgeon has been provided a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from silicone and that any joint replacement system cannot be expected to withstand the activity levels and loads as would normal, healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

DESCRIPTION OF DEVICE

The OrthoFlex implant is a flexible double stemmed implant specifically designed for the proximal interphalangeal joint of the lateral toes. It is used as an adjunct to resection arthroplasty in cases of moderate to severe hammertoe deformities of toes 2 through 5.

INDICATIONS

The indications for the OrthoFlex Rod include:

- Semi-rigid or rigid hammertoe deformity associated with degenerative arthritis
- Semi-rigid or rigid hammertoe deformity associated with rheumatoid arthritis
- Revision of a failed arthroplasty or arthrodesis

WARNINGS

In using joint prostheses, the surgeon should be aware of the following:

- All products are manufactured from silicone elastomer.
- The judgment by a surgeon to implant silicone elastomer implants is a risk/benefit decision which must take into account the patient's needs and desire in addition to the surgeon's knowledge of expected results and complications as well as therapeutic alternatives.
- The correct selection and sizing of the prosthesis is extremely important. Selection of the proper size, shape, and design of the prosthesis increases the potential for success in joint replacement. Joint prostheses require careful seating and adequate bone support.
- OrthoPro does not recommend a particular surgical technique when using the implant. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.
- For all implants, a sizing set is available for proper size determination during surgery (supplied sterile and not suitable for implantation).
- In selecting patients for joint replacements, the following factors can be critical to the eventual success of the procedure:
 - Patient's occupation or activity. If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 - Condition of senility, mental illness, or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
 - Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PATIENT SELECTION

- Good condition of the patient
- Adequate skin coverage
- Availability of post-operative therapy
- Possibility of a functional musculotendinous system
- Good neurovascular status
- Adequate bone stock to receive implant
- Cooperative patient

CONTRAINDICATIONS

- Infection
- Physiologically or psychologically inadequate patient
- Possibility for conservative treatment
- Irreparable tendon system
- Inadequate skin, bone, or neurovascular status
- Growing patients with open epiphyses
- Patients with high levels of activity

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with silicone implants include:

- Infection or painful, swollen or inflamed implant site
- Loosening or dislocation of the prosthesis requiring revision surgery
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Allergic reaction(s) to prosthesis material(s)
- Fracture of the implant
- Bone restoration or over-production
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Some degree of particle formation is inevitable with all implants including those made of silicone elastomer. The amount will vary with factors such as patient activity, joint stability or instability post-implantation, implant position and the amount of soft tissue support. The patient's biological response to these particles is variable, but can include local synovitis and bone lysis in contiguous bones.

PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived 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 common. The patient's mental status must also be considered. Willingness and/or ability to follow postoperative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

PRECAUTIONS

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

One of the goals of implant surgery is to minimize production of wear particles. It can never be eliminated because of all the moving parts, e.g., implants that articulate against bone, wear to some degree. In an implant arthroplasty, clinically significant wear can result from normal mechanical forces. Abnormal or excessive force will further increase clinically significant wear.

Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Inadequate soft tissue support
- Excessive motion
- Patient misuse or over activity
- Improperly sized implant
- Implant malposition
- Uncorrected or recurrent deformity
- Intra-operative fixation

Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above
- Stabilize collapse deformities
- Use a properly sized implant
- Identify prior pathology
- Bone graft pre-existing cysts
- Avoid K-wires and sutures through the implant

If complications develop, possible corrective procedures include:

- Implant removal
- Bone grafting of cysts
- Removal of the implant with fusion of the joint
- Synovectomy
- Replacement of the implant

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and OrthoPro's instructions for use, especially during insertion and removal.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with OrthoPro's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - The material composition of the fragment (if known);
 - The size of the fragment (if known);
 - The location of the fragment;
 - The potential mechanisms for injury, e.g., migration, infection;
 - Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

HANDLING AND STERILIZATION

IMPLANTS: This product has been sterilized and should be considered sterile unless the package has been opened or damaged. Remove from package, using aseptic OR technique, only after the correct size has been determined. Handling of the implants should be done with blunt instruments to avoid surface trauma or contamination with foreign bodies. Rinse the implant thoroughly with sterile saline solution before insertion. This product is for single use only. An implant shall never be re-sterilized.

INSTRUMENTS: Surgical instruments should be cleaned and sterilized according to ISO 8828, or AORN recommended practices for in-hospital sterilization should be followed for all components.

RECOMMENDATIONS FOR STEAM STERILIZATION:

- If using a 270°F pulsing vacuum sterilization cycle, double wrap the component in 1-ply polypropylene wrap (Kimguard KC600 or similar wrap) cleared for use by FDA
- Autoclave according to the following parameters:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	20 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap
Sterilizer Type:	Gravity
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	18 Minutes
Minimum Dry Time:	20 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

STORAGE CONDITIONS

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

CAUTION:

Federal Law (United States) restricts this device to sale, distribution, and/or use by or on the order of a physician.

FURTHER INFORMATION

Please contact company for further information, product inquiries, and surgical techniques, or to report any adverse experience.

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