

# 3S Hemi Toe Implant System

## Instructions for Use

900-01-001, Rev B

### **Description**

The 3S Hemi Toe Implant consists of one component to replace the articulation of the proximal phalanx of the first metatarsophalangeal joint, and corresponding instrumentation to facilitate insertion.

The 3S Hemi Toe Implant is fixed by means of a stem, which is inserted into the medullary canal of the phalanx. The profile of the metal base plate articulates with the metatarsal head. Instrumentation is provided to assist in the surgical implantation of this great toe system. It is important that the instruments and trial implants used are those specifically designed for this device to assure accurate installation.

### **Indications**

The 3S Hemi Toe Implant is designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidus, painful hallux valgus, revision of failed previous surgery and painful arthritis.

### **Contraindications**

Contraindications for the use of the 3S Hemi Toe Implant include any condition, which would contraindicate the use of joint replacement in general, including:

Poor bone quality, which may affect the stability of the implant,  
Severe tendon, neurological, or vascular deficiencies, which could compromise the affected extremity,  
Any concomitant disease, which may compromise the function of the implant.

### **Warnings**

For safe and effective use of this implant system, the surgeon should be familiar with the recommended implantation procedure for this device. Improper selection, placement, positioning, or fixation of implant may result in unusual loading conditions, which could affect the long term service of the implant.

In every case, accepted surgical practices should be followed in post-operative care. The patient should be made aware of the limitations of joint reconstruction and cautioned to govern his/her activities accordingly to protect the joint from unreasonable stresses. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture, or wear of the implant.

Patient sensitivity to implant materials should be considered and assessed prior to surgery.

### **Adverse Effects**

Loosening of similar implant components has been reported. Early loosening may result from improper fixation or latent infection. Late loosening may result in bone resorption or pain due to biological complications or mechanical problems.

Dislocation and subluxation of similar implant components have been reported due to improper positioning of the prostheses. Soft tissue laxity can also contribute to these conditions. Metal sensitivity reactions in patients following joint replacement have been reported infrequently. The significance and effects of sensitization await further clinical evidence for evaluation and may be avoided by preoperative sensitivity testing.

Implantation of foreign material in the tissues can result in histological reaction involving various sized macrophages and fibroblasts, or heterotopic bone formation. The actual clinical significance of this effect is uncertain, as similar changes may occur as a normal precursor to, or during, the normal wound healing process.

Peripheral neuropathies may occur, possibly as a result of surgical trauma. Reoperation may be required to repair adverse affects. Infrequent complications, such as infections, have been reported which have resulted in implant revision, arthrodesis or amputation.

### **Implant Materials**

The 3S Hemi Toe Implant is manufactured from cobalt chrome (CoCrMo per ASTM F-799)

### **Packaging and Sterility**

Trilliant 3S Hemi implants are supplied sterile (Gamma Sterilized). Prior to use, inspect package for damage, which may compromise sterility. If damaged, the product must be assumed to be non-sterile.

Surgical implants should not be reused. Any implant once used should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

Trilliant 3S Hemi Surgical Kits are supplied sterile (Gamma Sterilized). Prior to use, inspect package for damage, which may compromise sterility. If damaged, the product must be assumed to be non-sterile.

**DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.**

**Product Handling**

Store implants unopened in their respective protective packages until use. When removing the implant from its package, observe all relevant aseptic instructions. Protect the prosthesis from contact with objects, which may damage the surface finish. Inspect each implant prior to use and return the 3S Hemi Toe Implants that exhibit surface or configuration damage. Contouring or clamping of implants should be avoided if possible. It is recommended that implants should not be cut, sharply bent or re-bent, notched or scratched. These alterations can produce defects or stresses, which may lead to failure of the implant.

Follow all steps outlined in the surgical technique manual to ensure safety and effectiveness of the implant procedure. The surgical technique manual will be made available upon request.



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

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