



HUNTER TENDON IMPLANTS

150814-0

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

HUNTER TENDON IMPLANTS

(150814-0)

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DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
②	Do not re-use
⚠	Caution, consult accompanying documents
📖	Consult operating instructions
🕒	Use by
🌡	Temperature limitation
💧	Keep dry
☀️	Keep away from sunlight
📅	Date of manufacture
🏭	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILEO	Sterilized using ethylene oxide

STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
Rx ONLY	For prescription use only
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

I. 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 metal. In addition, the system will not be as strong, reliable, or durable as a natural human tendon.

The surgeon should be aware of the following:

- A. All products are manufactured from a woven polyester core covered with barium-impregnated **silicone** elastomer.
- B. The **judgement 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. Wright Medical Technology, Inc., can provide a bibliography of articles on the use and complications of silicone elastomer implants to any physician. Please write or call Wright Medical Technology, Inc.
- C. **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success.
- D. Wright Medical Technology, Inc., 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.
- E. **Reshaping of the implant** should be avoided because it can compromise or destroy the structural integrity and the functionality of the implant.
- F. **In selecting patients for tendon replacements, the following factors can be critical to the eventual success of the procedure:**
 - 1. **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 tendon, and the patient should not have unrealistic functional expectations.

2. **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.
3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. INDICATIONS

This device is indicated for use in stage one of the two-stage procedure developed by Dr. James M. Hunter for the reconstruction of flexor and extensor tendons in individuals having significant hand tendon injury. This device is intended to be implanted temporarily in order to encourage the formation of a pseudosynovial sheath, which will later nourish and lubricate an autogenous tendon graft.

See Section II for specific product information.

B. CONTRAINDICATIONS

This device is not intended for any use other than that indicated. Residual antecedent infection is a contraindication for the use of this device. Appropriate surgical and antimicrobial treatment and subsequent wound healing will allow the procedure to be carried out at a later date. A digit that has a scarred tendon bed, borderline nutrition, nerve deficit and severe joint stiffness could possibly be salvaged; however, this should probably be undertaken only in the patient with very special requirements.

See Section II for specific product information.

C. WARNINGS

Synovitis, adhesion, and wound infection have been reported as complications of reconstructive procedures which are similar to the HUNTER Tendon Implants, and therefore, must be assumed to be potential complications of the use of this device. Device migration has also been reported in the use of similar devices, but it is thought to be unlikely in the use of this device.

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
- Fracture of the implant
- Loosening or dislocation of the prosthesis requiring revision surgery
- Bone restoration or over-production
- Allergic reaction(s) to prosthesis material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- 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.

See Section II for specific product information.

D. PRECAUTIONS

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

- It is imperative that this device not be handled with bare fingers or come in contact with lint. Silicone elastomers are very electrostatic and therefore susceptible to contamination by airborne or surface particles. The presence of these contaminants could cause adverse tissue reaction. In the event that the implant is exposed to such contaminants, rinse the device thoroughly with sterile distilled water.
- This device is intended for SINGLE USE ONLY.
- Patient input and motivation are important to the success of this procedure because of the amount of participation required of the patient during the postoperative program of hand rehabilitation.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Resterilization of these devices is not recommended because resterilization of these devices may cause distortion of the device.

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 post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

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

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. 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.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;

- e. 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.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

E. STERILIZATION PROCEDURES

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

Handling of the implant 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 should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

F. STORAGE CONDITIONS

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

II. SPECIFIC PRODUCT INFORMATION

A. HUNTER TENDON ROD & PASSIVE TENDON IMPLANTS

DESCRIPTION

The **HUNTER Tendon Rod Implant** consists of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). This design provides the necessary combination of inert qualities, firmness and flexibility as well as the smooth surface required to induce pseudosynovial sheath formation and insure ease of insertion and gliding through the finger, palm, and forearm.

The **HUNTER Passive Tendon Implant** consists primarily of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). At the distal end of the device is a fixation component made of type 316 stainless steel. A hole in the fixation component accommodates a 2.0 mm stainless steel bone screw (not provided) which is used to secure the device to the phalanx. (See surgical technique for screw specifications). Both the HUNTER Tendon Rod Implants and HUNTER Passive Tendon Implants are double-pouched and are **STERILE** unless the inner package is opened and damaged.

WARNINGS

Stage I is not contraindicated in patients under 5 years of age. However, tendon reconstruction in children requires the use of a 2 to 4 mm reinforced tendon rod without distal fixation component.

B. HUNTER ACTIVE TENDON IMPLANTS

DESCRIPTION

The HUNTER Active Tendon Implant consists primarily of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity) that provides the necessary combination of inert qualities, firmness and flexibility as well as the smooth surface required to induce pseudo-sheath formation and insure ease of insertion and gliding through the finger, palm, and forearm.

At the distal end of the device is a fixation component made of type 316 stainless steel. A hole in the fixation component accommodates a 2.0 mm stainless steel bone screw (not provided) which is used to secure the device to the bone. The hole is angled to help direct the screw into cortical bone. The proximal end is terminated in a loop, permitting surgical attachment of the motor tendon to the device.

The HUNTER Active Tendon Implant is STERILE unless the inner package is opened or damaged.

CONTRAINdications

The current range of device sizes limits this device to use in the mature adult hand. Tendon reconstruction in children requires the use of a 2 mm, 3 mm, or 4 mm reinforced Tendon Rod implant without distal fixation components or proximal loop.

C. HUNTER ACTIVE TENDON IMPLANT BC (BI-CORDAL)

DESCRIPTION

The HUNTER Active Tendon Implant BC consists of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). The rod portion of the device is

4 mm wide and 2 mm thick and varies in length. At the proximal and distal ends of the device are two polyester cords, continuations of the rod's inner core, which provide the means for weave anastomosis to the motor tendon and for attachment to the phalanx, respectively. The cords extend 15 cm beyond the ends of the rod.

The HUNTER Active Tendon Implant BC is double-pouched and is STERILE unless the inner pouch is opened or damaged.

The interval between Stage One (implantation of the device and formation of the pseudosynovial sheath) and Stage Two (removal of the device and autogenous tendon grafting) should be two to six months to permit maturation of the tendon bed to the point where it can nourish and lubricate a tendon graft. The surgeon must determine, on the basis of the findings in the hand, the appropriate time within that period at which to commence Stage Two of the procedure.

INDICATIONS

The HUNTER Active Tendon Implant BC is specifically indicated in cases in which a bone screw distal fixation may be compromised due to the small size and poor quality of the phalanx. It is also indicated for use in patients having small pulleys, which unless opened surgically will not permit insertion of a standard HUNTER Active Tendon Implant.

WARNINGS

The patient should be monitored frequently by clinical examination and radiographs after Stage One surgery to assess progress and adjust treatment program as necessary.

D. HUNTER ACTIVE TENDON IMPLANT DC (DISTAL CORD)

DESCRIPTION

The HUNTER Active Tendon Implant DC consists of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). The rod portion of the device is 4 mm wide and 2 mm thick and varies in length. The proximal end is terminated in a loop, also comprised of a polyester core covered with barium-impregnated silicone elastomer. This loop permits anastomosis of the motor tendon to the device.

At the distal end of the device are two polyester cords, continuations of the rod's inner core, which provide the means for attachment to the phalanx. The cords extend 15 cm beyond the distal end of the rod.

The HUNTER Active Tendon Implant DC is double-pouched and is STERILE unless the inner pouch is opened or damaged.

The interval between Stage One (implantation of the device and formation of the pseudosynovial sheath) and Stage Two (removal of the device and autogenous tendon grafting) should be two to six months to permit maturation of the tendon bed to the point where it can nourish and lubricate a tendon graft. The surgeon must determine, on the basis of the findings in the hand, the appropriate time within that period at which to commence Stage Two of the procedure.

INDICATIONS

The HUNTER Active Tendon Implant DC is specifically indicated in cases in which a bone screw distal fixation may be compromised due to the small size and poor quality of the phalanx. It may also be used, at the surgeon's option, in patients having small pulleys, which unless opened surgically will not permit insertion of a standard HUNTER Active Tendon Implant.

WARNINGS

The patient should be monitored frequently by clinical examination and radiographs after Stage One surgery to assess progress and adjust treatment program as necessary.

E. HUNTER ACTIVE TENDON IMPLANT PC (PROXIMAL CORD)

DESCRIPTION

The HUNTER Active Tendon Implant PC consists of a woven polyester core covered with silicone elastomer (barium-impregnated for radiopacity). The rod portion of the device is 4 mm wide and 2 mm thick and varies in length. At the proximal end of the device are two polyester cords, continuations of the rod's inner core, which provide the means for weave anastomosis to the motor tendon. The cords extend 15 cm beyond the proximal end of the rod. At the distal end of the device is a fixation component made of type 316 stainless steel. A hole in the fixation component accommodates a 2.0 mm stainless steel bone screw (not provided) which is used to secure the device to the bone. The hole is angled to help direct the screw into cortical bone.

The HUNTER Active Tendon Implant PC is double-pouched and is STERILE unless the inner pouch is opened or damaged.

The interval between Stage One (implantation of the device and formation of the pseudosynovial sheath) and Stage Two (removal of the device and autogenous tendon grafting) should be two to six months to permit maturation of the tendon bed to the point where it can nourish and lubricate a tendon graft. The surgeon must determine, on the basis of the findings in the hand, the appropriate time within that period at which to commence Stage Two of the procedure.

INDICATIONS

The HUNTER Active Tendon Implant PC is specifically indicated in cases in which proximal anastomosis must be executed deep in the proximal forearm. It may also be used, at the surgeon's option, in patients having small pulleys, which unless opened surgically will not permit insertion of a standard HUNTER Active Tendon Implant.

WARNINGS

The patient should be monitored frequently by clinical examination and radiographs after Stage One surgery to assess progress and adjust treatment program as necessary.

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