



INSTRUCTIONS FOR FLAT FOOT PROSTHESIS

150849-0

The following languages are included in this packet:

English (en)
Español (es)
Türkçe (tk)

Deutsch (de)
Italiano (it)

Nederlands (nl)
Português (pt)

Français (fr)
中文- Chinese (sch)

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CE 0086*

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP

Wright Medical UK Ltd
3rd Avenue
Letchworth
Hertfordshire, SG6 2JF
UK

* The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.



Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

**WRIGHT MEDICAL
FLAT FOOT PROSTHESIS
(150849-0)**

OUTLINE:

DEFINITIONS












GENERAL PRODUCT INFORMATION

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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
	Batch code
	Catalog number
	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

GENERAL PRODUCT INFORMATION

Through the advancement of surgical hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal and UHMWPE, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after healing occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

In using the Flat Foot Prosthesis, the surgeon should be aware of the following:

- **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. The implants require careful seating and adequate bone support.
- **In selecting patients for surgery, 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 bone, 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.

- **The patient destined to receive the implant must be informed that the security and durability of the implants depends also on his/her behavior, particularly concerning his/her activity and body weight.**
- **It is essential to have all sizes shown in the catalogue in the operating room before the operation in order to choose the most suitable size (see our surgical technique).**

DESCRIPTION

The Flat Foot Prosthesis is a hollow polyethylene cylinder with a proximal collar and a stainless steel screw used for treating hyperpronation of the foot. It is offered in 4 sizes ranging from 6mm-12mm in diameter.

The implants are constructed from Stainless Steel and UHMWPE.

A. PATIENT SELECTION

Use of surgical hardware requires consideration of the following general indications:

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

B. INDICATIONS

Indications include:

- Functionally flat foot
- Foot with congenital vertical talus

The Flat Foot Prosthesis is intended for single use only.

C. CONTRAINDICATIONS

Use of the Flat Foot Prosthesis is contraindicated in cases of neurologic flat foot; in patients with serious ligamentous hyperrelaxation.

Absolute contraindications include:

- overt infection;
- distant foci of infections (which may cause hematogenous spread to the implant site);
- rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- skeletally immature patients;
- cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

- uncooperative patient or patient with neurologic disorders, incapable of following instructions;

- marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
- metabolic disorders that may impair bone formation;
- osteomalacia;
- poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery.

- Infection
- Pain, discomfort or abnormal sensations due to presence of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Migration of the implant; loosening of the implant
- Delayed correction in alignment
- Decrease in bone density due to stress shielding
- Bursitis

E. WARNINGS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- Instruments and implants are to be treated as sharps.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of subtalar implant devices.
- The implants are not intended to endure excessive abnormal functional stresses.
- All Flat Foot implants and instrumentation may be required for each surgery. Failure to use dedicated, Flat Foot instruments and implants for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used. They should be replaced or sent to Wright Medical for disposition and repair.
- Wright Medical recommends the use of Wright Medical products in a sterile environment.

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.

F. 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.

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.

WARNING: DO NOT steam sterilize/resterilize ceramic, plastic, and/or metal/plastic implants.

INSTRUMENTS

Surgical instruments should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

1. Double wrap the component in CSR wrap or a similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

All implants supplied by Wright Medical must not be resterilized by the purchaser. Wright Medical does not take any responsibilities for the use of implants resterilized by the purchaser.

G. STORAGE CONDITIONS

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

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