EN

PHALINX™ HAMMERTOE SYSTEM

151676-3

The following languages are included in this packet:

English (en)
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Svenska (sv)
Français (fr)
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For additional languages, visit our website www.wright.com. Then click on the **Prescribing Use** option.

For additional information and translations please contact the manufacturer or local distributor.

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

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

PHALINX HAMMERTOE SYSTEM (151676-3)

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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
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged
STERILE	Sterile
	Non-sterile
	Do not resterilize
	MR Conditional
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy

CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina
ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
$CaSO_4$	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D
PEEK	Poly Ether Ether Ketone
Al	Aluminum
DBM	Demineralized Bone Matrix

DESCRIPTION

The PHALINX™ Hammertoe System implants are a single piece titanium alloy device. The implants are offered in two designs, straight or 10° angled. The implants have a barb style end and threaded end, both designs are available in four sizes.

A. INDICATIONS

The PHALINX™ Hammertoe System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PHALINX™ Hammertoe Fixation System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

B. CONTRAINDICATIONS

General Surgical Contraindications:

- Infection;
- Physiologically or psychologically inadequate patient;
- Irreparable tendon system;
- Possibility for conservative treatment;
- Growing patients with open epiphyses;
- Patients with high levels of activity.

C. PRECAUTIONS

Pre-operative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical technique prior to performing surgery.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the implant, which can lead to failure of the implant. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Any implant, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as natural human bone. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Additional conditions presenting increased risk of failure include:

1) Uncooperative patient or patient with neurologic disorders, incapable of following instructions.
2) Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the implant cannot be achieved.
3) Metabolic disorders that may impair bone formation.
4) Osteomalacia.
5) Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

6) Pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the implant does not replace normal healthy bone and that the implant can break or become damaged as a result of certain activity or trauma. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intra-operative Precautions

Specialized instruments are available and must be used to assure the accurate implantation of the implant. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

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.

Correct selection of the implant is extremely important. Implants require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

Post-operative Precautions

The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Periodic follow-up is recommended to monitor the position and state of the implant components, as well as the condition of the bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, and cracking of components.

Concerning Magnetic Resonance Environments

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

These implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.

3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition, size, and location of the fragment (if known);
    b. The potential mechanisms for injury, e.g., migration, infection;
    c. Procedures or treatments that should be avoided to reduce the possibility of a serious injury from the fragment.

D. ADVERSE EFFECTS

The following are specific adverse effects, which should be understood by the surgeon and explained to the patient prior to surgery:

- Allergic reactions to materials; metal sensitivity that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL);
- Delayed wound healing; deep wound infection (early or late) which may necessitate removal of the implant. In rare instances arthrodesis of the involved joint or amputation of the limb may be required;
- A sudden drop in blood pressure intra-operatively due to the use of bone cement;
- Damage to blood vessels or hematoma;
- Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;

- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction;
- Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
- Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
- Pain.

E. WARNINGS

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in postoperative care. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Do not modify implants. Do not bend or cut them.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are either provided sterile or non-sterile; the individual product's labeling will determine whether or not it is packaged sterile. Implants that are presented in instrument trays are provided non-sterile. Devices provided sterile are sterilized by gamma radiation. Devices provided sterile should be inspected to ensure that the packaging has not been damaged or previously opened. The implant should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the

manufacturer for instructions. Remove device from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

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 the following: significant degradation in device performance, cross-infection, and contamination.

An implant should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Wright does not take any responsibility for the use of implants resterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- NEVER steam sterilize/re-sterilize ceramic, HA, calcium sulfate, plastic, and/or metal/plastic implants. If sterilization/re-sterilization of a metal component, is required, proceed as described below.

Implants provided non-sterile should be processed according to the recommended parameters for the reusable instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) 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

The minimum recommended steam sterilization conditions for the non-sterile or reusable medical devices associated with this package insert are as follows:

1. Double wrap the component in an FDA-cleared 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 and A1, Table 5, Row 1 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".

G. 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.