Instructions For Use
PhaLinx System
Package Insert / Important Medical Information

DESCRIPTION
The PhaLinx System Implants are a single piece titanium 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.

INDICATIONS
The PhaLinx Hammertoe system is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

CONTRAINDICATIONS
The PhaLinx Implants are contraindicated for use in patients with the following conditions:
- Infection;
- Physiologically or psychologically inadeqate patient;
- Irreparable tendon system;
- Possibility for conservative treatment;
- Growing patients with open epiphyses;
- Patients with high levels of activity.

PRECAUTIONS
Preoperative Precautions
The surgeon must evaluate each situation individually based on the patient's clinical presentation in making decisions regarding the 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 (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.

Intraoperative 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 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.

Postoperative 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 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.
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.

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.

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.

IMPLANT MATERIALS
The PhaLinx implants are manufactured from titanium alloy (Ti -6AI-4V ELI, ASTM F136,).

PACKAGING AND STERILITY
The system is provided non-sterile and should be steam sterilized at the surgical facility before use. The system must be steam sterilized using the following process parameters:

Sterilizer Type:	*Pre-Vacuum*
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*

The use of flash sterilization is not recommended.

Remove all packaging materials prior to sterilization. Only implants and instruments should be used in surgery. Immediately clean and re-sterilize all items removed from the surgical field before handling. Surgical implants shall not be re-used. Any implant once used shall be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

INSTRUMENT CLEANING
The instruments must be cleaned prior to sterilization. Carefully inspect all instruments within the system to ensure they are suitable for use and have not been damaged (i.e. cracks, bends, twisting, dull cutting surfaces, etc.). Devices must be manually cleaned before being processed in the Automatic Washer/Disinfector.

Preparation
It is recommended that devices should be reprocessed as soon as is reasonably practical following use. Soak and/or rinse heavily soiled devices prior to cleaning to loosen any dried soils or debris. Lumens/cannula should be cleared of soil or debris. This can be accomplished through using appropriate sized soft-bristle brushes and inserting the brushes into the cannula using a twisting motion.

Manual Pre-clean
Perform the manual pre-clean using the following steps.
1. *Rinse soiled devices under cold running tap water for one minute or until the visible soil is removed. Use a soft-bristle brush or lumen brush to assist in the removal of soil and debris.*
2. *Fully immerse the instruments in a neutral ph (7.0) enzymatic cleaner made per manufacturer's recommendations using lukewarm tap water.*
3. *Manually clean (scrub) the device using a soft-bristle brush removing all visible soil and debris. Pay particular attention to any threads, pivots, cannula, recesses, blind holes or difficult to reach areas. Be sure to thoroughly clean cannulated products using an appropriate size brush. The brush should be repeatedly run through the entire length of the cannula using a twisting motion. Flush the cannula with water until the rinse stream is clear.*
4. *Rinse the devices thoroughly for 1 minute at room temperature (20°-25°C) water. Water must be purified (deionized (DI), distilled, etc.). Use a syringe, water jet, or pipette to flush cannula, blind holes, and channels.*
5. *If soil or debris are still visible repeat steps 1-4 until all visible soil or debris have been removed from the device.*
6. *Dry the device thoroughly using a clean, soft, lint-free cloth or compressed air (30-40psi).*

Automatic Processing Parameters
After the manual pre-clean has been performed the parts will be processed in the automated cleaner (washer/disinfector) using the following steps.
1. *Place devices into an automatic washer/disinfector and process using the following parameters.*
2. *Pre Wash; Cold Tap Water; 2 minutes*
3. *Enzyme Wash; Hot Tap Water; 1 minute*
4. *Detergent Wash; Hot Tap Water (64°C -66°C): 2 minutes*
5. *Rinse; Hot Tap Water; 15 seconds*
6. *Pure Water Rinse (64°C -66°C); Heated, 10 seconds*
7. *Hot Air Dry; (116°C); 7-30 minutes*

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

The PhaLinx Device has not been evaluated for safety and compatibility in the MR environment.
The PhaLinx device has been tested for heating or migration in the MR environment.

FURTHER INFORMATION
For further information, please contact:
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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.