OSTEOSYNTHETIC IMPLANTS

DESCRIPTION

Compression and neutralization screws available in different diameters and lengths for the Antares, Omnitech Evolutionary and Unima Evo / Neutra Screw Systems. They are manufactured from titanium alloy.

Staples available in different spacings, sections and leg lengths for the Eleos, Pareos and Telya Staple Systems. They are manufactured from stainless steel, pure titanium or Nitinol.

Implants are available sterile and non-sterile. The products do not contain latex.

A. INDICATIONS

Osteosynthetic Implants are only indicated for use in the lower extremities.

Screws: compression screws are recommended for the fixation of bone fractures and for bone reconstruction

OMNITECH EVO AA21	P1 Akin type osteotomies or shortening osteotomies
OMNITECH EVO AA25	Scarf osteotomies Chevron osteotomies P1 Akin type osteotomies or shortening osteotomies
OMNITECH EVO AA30	Scarf osteotomies Chevron osteotomies Partial arthrodeses of the tarsus
OMNITECH EVO AA35	Partial arthrodeses of the tarsus Malleolar fractures
UNIMA EVOLUTION Ø4,5mm	Partial or complete Lisfranc arthrodesis Lapidus intervention (C1-M1) Partial or total arthrodesis of the midfoot Talonavicular or calcaneocuboid arthrodesis Osteosynthesis of the foot
UNIMA NEUTRA Ø4,5mm	Partial or complete Lisfranc arthrodesis Lapidus intervention (C1-M1) Partial or total arthrodesis of the midfoot Talonavicular or calcaneocuboid arthrodesis Metatarsophalangeal arthrodesis (Hallux) Osteosynthesis of the foot
UNIMA EVOLUTION Ø7,3mm	Arthrodesis of the hindfoot, subtalar, talonavicular Talocrural arthrodesis Osteotomy of the calcaneus
UNIMA NEUTRA Ø7,3mm	Arthrodesis of the hindfoot, subtalar, talonavicular Talocrural arthrodesis Osteotomy of the calcaneus
ANTARES Ø3mm	Stabilization of forefoot osteotomies First metatarsal osteotomies for hallux valgus (Scarf, Chevron) Phalangeal osteotomies of the big toe (Akin) Interphalangeal osteotomies Fixation of small bone fragments

Staples: Examples of use:

ELEOS EVOLUTION	Akin osteotomy Shortening osteotomy Metatarsal osteotomy MTP arthrodesis Cuneo-navicular arthrodesis Lisfranc arthrodesis Cuneo-metatarsal arthrodesis Talo-navicular arthrodesis Calcaneal / cuboid arthrodesis
TELYA	Hallux valgus interphalangeus correction Akin Osteotomy Phalangeal pronation correction Wind swept toes
PAREOS	Osteotomy fixation Fracture fixation First metatarsophalangeal joint arthrodesis Lisfranc arthrodesis Arthrodesis of calcaneocuboid, talocalcaneal, talonavicular, cuneo scaphoid joints

B. CONTRAINDICATIONS

The implant must not be fitted in a patient who is currently or who has had in the past:

-Acute or chronic, local or systemic inflammations

-Active infections or inflammations

-An allergy or intolerance to suspected or known metals

-A devitalised bone, severe osteoporosis, loss of bony substance

C. PRECAUTIONS

Pre-operative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. The surgeon should contact Wright for product-specific surgical techniques.

The surgeon should also use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.

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 prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Any joint replacement system, 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 a natural human joint. 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 prosthesis 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.
7. Hypersensitivity or confirmed hypersensitivity to foreign bodies (e.g. stainless steel and nitinol).

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. 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 prosthetic components. 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. Under no circumstances should the implants be deformed. Manipulations should be gradual, so that there is no abnormal strain on the implant.

Correct selection of the prosthesis is extremely important. Joint prostheses 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, or 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 such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

MRI Safety Information

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.

D. ADVERSE EFFECTS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production or bone loss due to stress shielding
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism
- No bone fusion or late fusion

E. HANDLING & STERILIZATION

The medical devices associated with this package insert may be provided sterile or non-sterile; the individual product's labeling will determine whether or not they are packaged sterile. Devices that are presented in trays are provided non-sterile.

Devices provided sterile should be inspected to ensure that the packaging has not been previously 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.

Refer to the instrument instructions for use for detailed cleaning instructions for re-usable instruments.

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.

Wright does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

Devices provided non-sterile should be processed according to the recommended cleaning and sterilization parameters below.

Device Cleaning

1. Disassemble all components as per manufacturer instructions (if appropriate).
2. Rinse with cold tap water to remove any 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 (1.041mm) is recommended.

Device Sterilization

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

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prion Cycle 273°F (134°C)	Exposure Temperature	273°F (134°C)
	Exposure Time	18 minutes

F. STORAGE CONDITIONS

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