BIOARCH™ SUBTALAR IMPLANT SYSTEM

150840-1

The following languages are included in this packet:

English (en)	Deutch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	Türkçe (tk)

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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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
BIOARCH™ SUBTALAR IMPLANT SYSTEM
(150840-1)

OUTLINE

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 aspetic processing techniques
℞ 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 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 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 BIOARCH™ Subtalar implants, 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.

DESCRIPTION

The BIOARCH™ Subtalar implant is a one-piece titanium implant for treating hyperpronation of the foot. It is offered in 5 sizes ranging from 8 mm-12 mm in diameter. Available implants and instrumentation are packaged as a single system.

The system includes instruments (trial sizers, alignment rods, cannulated probe, cannulated insertion driver, and removal driver) to facilitate the placement of the implants.

The implants are constructed from implant grade titanium alloy (Ti-6AL-4V ELI).

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

The BIOARCH™ Subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Indications include:

- Severe pronation
- Calcaneal valgus deformity
- Plantarflexed talus

- Failed correction with long term orthotic treatment
- Congenital and painful flatfoot deformity
- Repair of tarsal coalitions
- Subtalar instability
- Posterior tibial tendon dysfunction
- Paralytic flat foot deformity

The BIOARCH™ Subtalar implants and alignment rods are intended for single use only.

C. CONTRAINDICATIONS

Use of BIOARCH™ Subtalar implant is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; in patients with inadequate bone stock; in patients with superstructural alignment deformities; or in patients with certain metabolic diseases.

D. POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

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, alignment rods 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 BIOARCH™ Subtalar implants and instrumentation may be required for each surgery. Failure to use dedicated, unique BIOARCH™ 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 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. INSTRUCTION FOR USE

Instructions for Use- BIOARCH™ Subtalar Implant

1. Proper surgical techniques are necessarily the responsibility of the medical professional. The following guidelines are furnished only as recommended techniques. Each surgeon must evaluate the appropriateness of the techniques based on his or her own medical training and experience.
2. A small 2-4 cm incision is made on the lateral aspect of the foot over the sinus tarsi area along the relaxed skin tension lines. It is important to avoid the intermediate dorsal cutaneous nerves as well as the sural nerve, which should course superior and inferior to the incision respectively. The deep fascia and capsule overlying the sinus tarsi is identified and incised, allowing entrance into the lateral sinus tarsi. If the cervical ligament is encountered, it may be retracted allowing entry into the sinus tarsi.

   The anterior lateral edge of the posterior facet of the calcaneus should be palpable with instrumentation upon completing the dissection into the tarsal canal. Minimal dissection is performed in the sinus tarsi; a sinus “tarsectomy” is not performed.
3. The cannulated probe instrument is inserted with a gentle, twisting motion to open the sinus tarsi, to dilate the tarsal canal and stretch the interosseous talocalcaneal ligament. The probe is positioned from lateral to medial across the lateral sinus tarsi and into the sinus canalis. The probe tip will gently “tent” the soft tissue on the medial side of the foot. Proper positioning of the probe in the sinus tarsi should result in the

distal aspect of the probe “tenting” near the talonavicular articulation. During this maneuver the interosseous talocalcaneal ligament may be released.

The alignment rod is then placed through the cannulated probe from lateral to medial. Again, the medial tenting should be evident to assure correct placement within the sinus canalis. The probe is then removed.

4. All further instrumentation and implants are cannulated and will be placed over the alignment rod for ease of use and to ensure the implant is placed in the correct location.
5. The appropriate trial sizer is placed into the sinus tarsi from lateral to medial. Range of motion of the subtalar joint and implant placement are examined.

   The appropriate trial sizer should limit abnormal calcaneal eversion. From a neutral calcaneal position, approximately 2-4 degrees of joint eversion is preferred.

   Very important: At this time, intra-operative radiographs are taken to evaluate the placement of the implant (sizer). This is a very important step and should not be avoided.
6. Once the appropriate trial sizer is determined, check the measurement on the scored handle and remove the sizer.

   The equivalent size subtalar implant is placed over the alignment rod. Utilizing the cannulated insertion driver insert the implant into the sinus tarsi to the predetermined length on the scored insertion tool (as referenced by the previous scored trial sizer).
7. Very Important: Intra-operative radiographs are once again taken to evaluate the degree of correction and placement of the implant. On AP view, the leading end of the implant should be 1/3 to 1/2 the distance across the subtalar joint.

If the implant is determined to be too far in a medial or lateral direction the insertion driver can be turned in either direction to adjust positioning.

The insertion driver and alignment rod are removed when satisfactory position of the implant is obtained.

8. The area should be irrigated and the subtalar joint motion should be reevaluated. Significant reduction of excess subtalar joint pronation should now be appreciated. Closure of the capsule, subcutaneous tissue and skin layers are performed and the foot is placed in a mildly compressive dressing.

   Post-operative care, assuming no adjunctive procedures were performed, consists of protective weight-bearing in a below-the-knee walking cast or walking boot for 2-4 weeks. A gradual return to limited activity in 4-6 weeks is permitted as tolerated.

9. Removal: In the case of implant removal, the threaded removal driver is inserted into the threaded proximal end of the implant and turned in a counter-clockwise motion to engage the reverse threads and aid in removal of the implant.

G. HANDLING AND STERILIZATION

The BIOARCH™ Subtalar implants and instruments are packaged non-sterile and must be sterilized prior to surgical use.

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.

Sterilization protocols are as follows:

Pre-Vacuum Steam Sterilization:

Temperature: 270 °F (132 °C)

Time: 15 minutes

Gravity Steam Sterilization:

Temperature: 270 °F (132 °C)

Time: 15 minutes

Since Wright Medical is not familiar with individual hospital handling methods, cleaning methods and bioburden, Wright Medical cannot assume responsibility for sterility even though the guideline is followed.

Ensure that implants are at room temperature prior to implantation.

These recommendations 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 Medical's Cleaning and Handling of Wright Medical Instruments.

H. STORAGE CONDITIONS

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

CAUTION:

- **Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.**
- **Do not attempt a surgical procedure with faulty, damaged or suspect Wright Medical instruments or implants. Inspect all components preoperatively to assure utility.**