BIOFOAM™ ANKLE SPACER BLOCK

150865-1

The following languages are included in this packet:

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Français (fr)
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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

June 2018
Printed in U.S.A.

EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

BIOFOAM™ ANKLE SPACER BLOCKS (150865-1)

OUTLINE

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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
LOT	Batch code
REF	Catalog number
②	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 A	Sterilized using aseptic processing techniques
STERILE GAS	Sterilized using gas plasma
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	Do not use if packaging is ripped or damaged
Abbreviation	**Material**
CPTi	Commercially Pure 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
$CaPO_4$	Calcium Phosphate

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 BIOFOAM™ Ankle Spacer Block is a titanium metal foam block used to fill the structural defect left behind by the removal of a total ankle replacement implant. It is offered in various heights, ML and AP dimensions with a standard slot dimension in order to accommodate the VALOR™ Ankle Fusion Nail.

The BIOFOAM™ Ankle Spacer Block is intended for single use only.

A. INDICATIONS

The BIOFOAM™ Ankle Spacer Blocks are indicated for tibiotalocalcaneal arthrodesis during the salvage of a failed total ankle joint replacement. The BIOFOAM™ Ankle Spacer Blocks are indicated for use with the VALOR™ Ankle Fusion Nail for cases in which there

is adequate bone stock to support the device (i.e., the medial and lateral malleoli are intact).

B. CONTRAINDICATIONS

The BIOFOAM™ Ankle Spacer Block is contraindicated for the following uses:

- use without supplemental fixation (e.g., arthrodesis nail)
- use in segmental defects of the tibiotalar joint with absent or poor quality peripheral bone (e.g., medial malleolus, fibula)

C. WARNINGS

- The BIOFOAM™ Ankle Spacer Block should not be modified or altered in any way (e.g., cut, drilled, sawed, etc.) as this may generate metallic debris and adversely impact bone ingrowth
- The textured surface of the BIOFOAM™ Ankle Spacer Block may damage surgical gloves

D. 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. 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.

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.

Correct selection of the prosthesis is extremely important. 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.

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.

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.

E. ADVERSE EFFECTS

Possible adverse effects typical of many surgical procedures may include:

- 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 prosthesis. On rare occasions, 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.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are provided sterile and are sterilized by gamma radiation. Irradiated devices have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation. Devices provided sterile 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. This is particularly important in handling the devices in this system due to their roughened surfaces. Do not allow roughened surfaces to come in contact with cloth or other fiber-releasing materials.

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 re-sterilized after contact with body tissues or fluids.

INSTRUMENTS

For additional information regarding instruments, see WMT's Cleaning and Handling of Wright Medical Instruments.

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.

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 (U.S.) restricts this device to sale by or on the order of a physician.