BIOPLAN

USE AND MAINTENANCE MANUAL

CE 0426

DISCLAIMER

BRM Extremities Srl declines any responsibility for damage to people or things due to improper use of this product and failure to comply with the indications, warnings, instructions and precautions contained in this user manual.

This manual of use is provided only in paper format and must always go with the medical device BioPlan.

BioPlan is manufactured by:

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SOMMARIO

1 GENERAL INFORMATION

BioPlan is an implantable medical device. It is a subtalar screw manufactured in PEEK or Titanium alloy (Ti6Al4V), designed to offer to the specialistic foot orthopedic surgeon a solution for the flatfoot correction. The device consists on a truncated-conical screw, with a low-profile external thread for the grip in the periosteum that guarantees primary stabilization without causing tissue damage to the patient. The use of the BioPlan screw implies the introduction of the device into the tarsal sinus (a bone cavity interposed between talus and calcaneus) in order to excite the proprioceptors of the hedged ligament and inhibit excessive prone/supination movements.

1.1 INTENDED USE

The device is a permanent implantable screw, to be placed into the tarsal sinus for the flatfoot correction.

1.2 CLASSIFICATION

Classification according to 93/42/CEE Directive, Annex IX rule 8 class IIb.

CAREFUL!

THE DEVICE HAS TO BE USED ONLY BY ORTHOPAEDIC SURGEONS

1.3 USEFUL LIFE

The device is disposable and is provided in sterile form, therefore the useful life is linked to the shelf life of the device, defined in 60 months (according to the primary packaging validation and the sterility maintenance). The device remains in site for more than 30 days.

1.4 INDICAZTION OF USE

The main clinical indications include:

- Essential congenital pronated valgus foot of the child and adolescent
- In association with calcaneal medializing osteotomy with a significant varus of the hindfoot in adult pronated unstable foot
- Over 6 years of age
- Hypermobility of the foot
- Painful symptomatic foot
- Scaphoid and malleolus pain
- Posterior tibial inflammation with tendonitis
- Muscle insufficiency
- Achilles shortening
- Ligamentous laxity
- Foot not aligned

1.5 CONTRAINDICATIONS AND KNOWN SIDE EFFECTS

BioPlan screw implantation is normally contraindicated in the following cases:

- Flat foot rigid or with associated deformities
- Flat foot with forefoot adduction
- Chronic ruptures of the posterior tibial tendon
- Symptomatic arthritis
- Neurological diseases (paraplegia)
- Sepsis in progress.

1.6 SYMBOLOGY

	Below are shown the symbols used for the management of the main warnings for a proper and safe use of the device, in order to make more comfortable and easier the manual reading.

	**Requirement for a correct use** This symbol identifies the presence of information for correct use of the device.
	**Information requirement** This symbol identifies the presence of useful and general information whose reading guides the user to a conscious use of the device and / or to the execution of actions.
CE 0426	This symbol identifies that the device is design and manufactured according to the safe requirements (RES) of the Medical Devices Directive 93/42/CEE (Medical device class IIb, according to classification rule n.8 of the Annex IX).

1.7 PRELIMINARY WARNINGS

Failure to comply with the warnings listed below as well as with the standards and precautions described in this user manual entails the immediate termination of any warranty on the BioPlan device.
BRM Extremities S.r.l. is not responsible for any damage to people or things as a result of failure to comply with the rules or precautions listed below and reported in this user manual.

	LACKS OR NEGLIGENCE IN COMPLIANCE WITH THE FOLLOWING INDICATIONS MAY CAUSE DEVICE MALFUNCTION, DAMAGE AND INJURY TO THE USER OR PATIENT
	DO NOT USE THE DEVICE BEFORE THE READING AND UNDERSTANDING OF THIS USE MANUAL IN ALL ITS PARTS
	NO MODIFICATION OF THE DEVICE AND/OR OF ITS PARTS IS ALLOWED
	THE USE OF THE DEVICE FOR PURPOSES OTHER THAN THOSE INDICATED IN THIS USER MANUAL COULD EXPOSE THE PATIENT AND THE OPERATOR TO HAZARDS

THE DEVICE IS DISPOSABLE.
IT IS STRICTLY FORBIDDEN ITS REUSE AND ANY ACTIVITY OF REPROCESSING; REUSE COULD RESULT IN THE TRANSMISSION OF BIOCONTAMINATING AGENTS.

1.8 PACKAGING CONTENT AND ACCESSORIES

BioPlan is provided sterile and individually packed in double Tyvek envelope inserted into a cardboard box. The cardboard box with adhesive label is sealed with a transparent protective film. The instructions for use as well as the traceability labels intended for the medical record are contained in the box.
BioPlan screws are available entirely in titanium (Ti6Al4V) or in PEEK, with a metallic repere (Ti6Al4V) on the tip, which allows the identification by radiography.
Both versions are available in the following sizes:

- BioPlan Screw Ø 7 mm - L 13 mm
- BioPlan Screw Ø 8 mm - L 14 mm
- BioPlan Screw Ø 9 mm - L 15 mm
- BioPlan Screw Ø 10 mm - L 16 mm
- BioPlan Screw Ø 11 mm - L 17 mm
- BioPlan Screw Ø 12 mm - L 18 mm
- BioPlan Screw Ø 13 mm - L 19 mm

For the correct implantation of the BioPlan screws it is necessary to use the dedicated surgical instruments, manufactured by BRM Extremities S.r.l. and available on request. The use of tools other than those indicated could involve unacceptable risks for the success of the intervention.

THE USE OF ELEMENTS NOT INCLUDED IN THE SYSTEM ABOVE DESCRIBED OR NOT SUPPLIED WITH THE DEVICE COULD AFFECT ITS SAFETY AND EFFECTIVENESS

In the event that all the elements listed above are not included in the pack, contact the manufacturer immediately

2 METHOD OF USE

2.1 INFORMATION FOR THE PATIENT

Before receiving the implant, the patient has to be informed about the following issues, as well as about the possible side effects due to the implantation of the device (Ref. Section 1.4):

Avoid to subject the operated anatomical district to excessive mechanical efforts in the period immediately following the surgery.

The device could not withstand joint instability, as well as exhausting loads and excessive mobility, undergoing to accelerated wear or collapse, following dislocation or breakage of the screw.

Strictly follow the instructions of your doctor in relation to the limitations of movement and activity required after receiving the implant.

In the event that symptoms of infection or evident mobilization of the device are noted, it is necessary to contact the structure that performed the surgery as soon as possible.

The BioPlan Implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the BioPlan Implant in the MR environment is unknown. Scanning a patient who has this device may results in patient injury.

2.2 REMOVAL FROM PACKAGING

CHECK THE INTEGRITY OF THE DEVICE AND OF THE PRIMARY PACKAGING BEFORE PROCEEDING WITH THE OTHER STEPS: IF THE DEVICE OR THE PRIMARY PACKAGING ARE DAMAGED DO NOT USE THE DEVICE AND DISPOSE OF IT ACCORDING TO THE INSTRUCTIONS OF THE "DISPOSAL" CHAPTER.

CHECK THE EXPIRATION DATE OVER THE STERILE SCREWS PACKAGING: IF THE DATE HAS BEEN EXCEEDED DO NOT USE THE DEVICE AND DISPOSE OF IT FOLLOWING THE INSTRUCTIONS OF THE “DISPOSAL” CHAPTER.

The handling of the osteosynthesis screws is intended only for qualified personnel (instrumentalist or otherwise qualified professional nurse). It is recommended to remove the sterile devices from their primary packaging only immediately before their use and as far as possible to handle the screws wearing talc-free gloves so as not to contaminate them.

3 SURGICAL TECHNIQUE

It's recommended to follow the instructions described below, for the implant of BioPlan screw:

1. Make an incision between 1.5 and 2 cm in the soft area near the tarsal sinus, taking care to not damage the intermediate dorsal skin nerves as well as the sural nerve. Identify and incise the subcutaneous tissues in the tarsal canal to gain the access to the sinus of the lateral tarsus: the front lateral edge of the posterior aspect of the calcaneus is now palpable. Perform a minimal dissection in the tarsal sinus.
2. Dilate the tarsal canal (if necessary, using a scissor) to "open the field'' and stretch the interosseous talus-calcaneal ligament. Insert the cannulated probe, in latero-medial direction, through the sinus of the tarsus. If correctly positioned, the tip of the probe will come into contact with the soft tissue on the medial side of the foot, while the distal part should "rest" near the talo-navicular joint.
3. Insert the alignment rod (blunt-tipped wire) through the cannulated probe proceeding in latero-medial direction, making sure of the correct positioning inside the sinus canal. Then remove the probe. The wire will be used as a guide for inserting and positioning instruments and cannulated implants.
4. Insert the first test sizer (the smaller one) into the tarsal sinus by screwing it clockwise along the previously positioned wire and evaluate the mobility of the subtalar joint and the positioning of the sizer. Increase the test size until get a joint eversion, starting from the neutral position, of about 2-4 °. At this stage, intra-operative radiographs should be performed to evaluate the positioning of the test sizer: in an anteroposterior image, the lateral edge of the implant should correspond to the lateral profile of the talus neck. Once the appropriate test sizer has been identified, before removing it, memorize the measurement shown on the graduated handle.
5. It is now possible to insert the BioPlan device of the identified size. Using the cannulated insertion screwdriver, insert the implant into the tarsal sinus until the predetermined depth (shown on the graduated handle, previously used). It is very recommended to verify, through intra-operative radiographs, the degree of correction and the device positioning. Once a satisfactory positioning of the implant has been achieved, the insertion screwdriver and the wire can be removed. Excessive pronation of the joint should now have been significantly limited.
6. Suture the capsule, the subcutaneous tissue and the skin layers. The procedure is complete.

Postoperative therapies: limitation of weight support through a possible foot plaster cast for 2-4 weeks. Gradual resumption of normal activities after about 4-6 weeks.
To remove the implant, insert the extractor screwdriver into the implant and turn it counterclockwise until it engages in the appropriate fenestrated area facilitating the removal of the implant.

4 DISPOSAL

The devices have to be disposed according to the waste management regulation of the Local Management Authority (Special hospital waste). In any case do not disperse the product or its packaging in the environment.

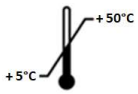
5 ENVIRONMENTAL CONDITIONS

In order to guarantee the maintenance of device sterility and integrity, the following environmental conditions should be respected.

Environmental Conditions	Temperature:	Use	+10 / +40°C
		Storage / transport	+5 / +50°C
	Humidity:	Use	20 / 80% Ur without condensation
		Storage / transport	5 / 95% Ur without condensation
	Atmospheric pressure:	Use	700 at 1020 hPa
		Storage / transport	500 at 1060 hPa

6 SYMBOLS USED ON THE LABEL

	Identification of the manufacturer
	Product reference
	Batch number
	Attention, refer to the user manual. Security information
	Warning, to be sale only on prescription from an authorized health care professional
	Sterilized with ionizing radiation
	Do not resterilize

	Do not use if the packaging is not intact
	Do not reuse
	Consult the instructions for use
	Use by the date indicated
	Keep away from light
	Keep dry
	Storage environment temperature
	Compliant with Council Directive 93/42/EEC and subsequent amendments, DM Class IIb. The 4-digit code indicates the device certification Notified Body.