BURRS FOR PERCUTANEOUS FOOT SURGERY

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.

The burrs for percutaneous foot surgery are manufactured by:

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SUMMARY

1 GENERAL INFORMATION

BRM Extremities S.r.l. burrs are medical devices intended to be used in mini-invasive percutaneous foot surgery. Burrs are available in different head shape and dimensions, both in sterile/disposable and not sterile/reusable (up to 10 uses) version. Burrs are made up in thermally treated AISI 630 stainless steel which guarantees a proper biocompatibility according to the intended use.

1.1 INTENDED USE

The intended use of the burrs is the cutting and/or the milling of the bone tissue (osteotomy), through an exclusively mechanical action, during mini-invasive percutaneous foot surgery.

1.2 CLASSIFICATION

Classification according to the Directive 93/42/CEE Annex IX rule 6 class IIa.

CAREFUL!

THE DEVICE HAS TO BE USE ONLY BY SURGEONS PROPERLY TRAINED IN THE EXECUTION OF MINI-INVASIVE PERCUTANEOUS FOOT SURGERY.

1.3 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**.**
	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 IIa, according to classification rule n.6 of the Annex IX).

1.4 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 Burrs 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

1.5 PACK CONTENTS

Burrs are available in the following configurations:

- Single pack (1 burr) sterile and disposable
- Multiple pack (6 burrs) sterile and disposable
- Single pack (1 burr) not sterile and reusable
- Multiple pack (6 burrs) not sterile and reusable

Regardless of the end configuration, burrs are always individually packed in peelable PET12 / AL9 / PE50 bags and placed in a cardboard box. The secondary packaging always contains this user manual and a series of adhesive labels to be applied on the patient's medical record or on other documents in order to ensure the traceability of the production batch.

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 BURRS TYPES AND THEIR FUNCTIONS

The following kinds of burrs are available:

- Shannon Standard: burr with helical cutting edges (15°), a diameter of 2 mm and a cutting-edge length of 12 mm.
- Shannon Short: burr with helical cutting edges (8°), a diameter of 2 mm and a cutting-edge length of 8,3 mm.

- Shannon Isham: burr with straight cutting edges, a diameter of 2 mm and a cutting-edge length of 12 mm.
- Conical: burr with helical cutting edges (10°), a diameter of 3.1 or 4.1 mm and a cutting-edge length of 13 mm.
- Straight Cylindrical: burr with straight cutting edges, a diameter of 2, 2.5 or 3.1 mm and a relative cutting-edge length of 14, 20 or 22 mm.
- Wedge: burr with helical cutting edges (10°), a diameter of 3.1 or 4.1 mm and a cutting-edge length of 13 mm.
- Rounded Cylindrical: burr with straight cutting edges, a diameter of 3.1 or 4.1 mm and a cutting-edge length of 15 mm.
- Brophy: burr with helical cutting edges (13°), a diameter of 5 mm and a cutting-edge length of 14.8 mm.

The following table provides a non-exhaustive list of possible surgical indications for each type of burrs.

Type	Indication
Short and Standard Shannon	Osteotomy of the minor finger phalanges Exostectomy of the minor fingers Remodeling of bone surfaces Dorsolateral exostectomy of the head of the fifth metatarsal (standard length) Dorsolateral wedge-metatarsal exostectomy (standard length)
Shannon Isham	Osteotomy of the minor finger phalanges and of the first metatarsal (distal e proximal) Akin Osteotomy Exostectomy of the minor fingers Remodeling of bone surfaces Calcaneal spur exostectomy Dorsolateral exostectomy of the head of the fifth metatarsal Dorsolateral wedge-metatarsal exostectomy
Wedge	Decorticalizzazione Bunionectomy of the first metatarsal Calcaneal spur exostectomy Dorsolateral wedge-metatarsal exostectomy Akin Osteotomy
Straight Cylindrical	Bunionectomy of the first metatarsal Calcaneal spur exostectomy Dorsolateral wedge-metatarsal exostectomy
Rounded Cylindrical	Moderate and severe exostectomy of the big toe
Conical	Cheilectomy (the shape allows to easily remove the osteophytes of the metatarsophalangeal joint)
Brophy	Exostectomy of large surfaces

THE CONTENTS PROVIDED IN THIS CHAPTER ARE INTENDED ONLY TO BE INDICATIVE. THE CHOICE OF SURGICAL TECHNIQUE AND APPROPRIATE INSTRUMENTS FOR EACH PATIENT IS UNDER THE RESPONSIBILITY OF THE SURGEON, IN ACCORDANCE WITH ITS PRACTICE, EXPERIENCE, TRAINING, LEVEL OF ACCURACY AND KNOWLEDGE OF MEDICAL LITERATURE. THE PATIENT SELECTION CRITERIA AND THE ASSESSMENT OF THE USABILITY OF BRM EXTREMITIES BURRS WITHIN THE SPECIFIC CASE IT IS RESPONSIBILITY OF THE SURGEON, AFTER AN ADEQUATE ANAMNESIS; EVEN THE INFORMATION TO THE PATIENT ON THE POSSIBLE RISKS ARISING FROM THE USE OF THE MEDICAL DEVICES OBJECT OF THIS INSTRUCTIONS FOR USE IS RESPONSIBILITY OF THE SURGEON, WITH REFERENCE TO THE IMPLEMENTATION OF THE REGULATIONS CONCERNING THE INFORMED CONSENT.

2.2 EXTRACTION 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 PACKAGING OF THE STERILE BURRS: 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 burrs is reserved to qualified personnel (instrumentalist or qualified professional nurse). It is recommended to remove the burrs from their primary packaging only immediately before their use and as far as possible to handle the burrs wearing talc-free gloves in order to not contaminate them.

2.3 BURRS PREPARATION BEFORE USE

2.3.1 STERILE BURRS

Sterile and disposable burrs, when removed from their primary packaging, can be immediately used for the intended use.

2.3.2 NOT STERILE BURRS

Not Sterile and reusable burrs must be washed, disinfected and sterilized before their use, according to the following instructions:

1) Put the burrs in an ultrasonic tank with a mild detergent (for dilution refer to the instructions on the detergent label) and treat for at least 10 minutes.

DURING WASHING DO NOT USE HYDROGEN PEROXIDE (OXYGEN WATER) THAT COULD DAMAGE THE DEVICES.

2) Place the burs in a suitable container (steel or Teflon tray or basket) and rinse with sterile water for injections.
3) Immerse the burs in an ultrasound tank with disinfectant for surgical medical devices: for dilution and contact times, refer to the instructions provided by the manufacturer.
4) Sterilization in Autoclave: the recommended method is to package the items or put them in a suitable surgical tray and sterilize for 5 minutes at 134 ° C and 2.1 bar.
5) Place the sterilized surgical instruments in a tray containing sterile physiological solution during the surgery.

2.4 BURRS USE

To be used the burs have to be inserted into the mandrel of a surgical micromotor (handpiece). Burs stem has been designed in conformity with the EN 1797 technical standard: it is therefore recommended to use a handpiece with a compatible mandrel, making sure that the shank of the bur is well inserted and locked in the mandrel. During burs use, it is necessary to keep the rotation speed below 8000 rpm in order to avoid overheating of the bone tissue with possible consequent damage (tissue necrosis). To limit overheating, other precautions should also be taken, such as spraying saline at the intervention site.

2.5 BURRS TREATMENT AFTER USE

2.5.1 STERILE BURRS

Sterile burrs are disposable therefore they have to be disposed after the use.

DO NOT RESTERILIZE AND DO NOT REUSE THE DISPOSABLE STERILE CUTTERS. IMPROPER REUSE MAY CAUSE THE TRANSMISSION OF SERIOUS INFECTIONS.

2.5.2 NOT STERILE BURRS

Unsterile burrs are reusable up to 10 times. After their use follow the below steps:

1) Wash with a mild detergent in an ultrasonic bath or instrument washer.

DURING WASHING DO NOT USE HYDROGEN PEROXIDE (OXYGEN WATER) THAT COULD DAMAGE THE DEVICES.

2) Proceed with a visual inspection by removing any debris with a soft brush.

3) Proceed by rinsing the burrs in water for sterile injections, preferably in a glass immersed in the ultrasound tank.

4) Let dry the burrs in a protected environment.

5) Place the burrs in the sterilization box.

BEFORE USE AGAIN THE BURS REPEAT THE STEPS FROM 1 TO 5 DESCRIBED IN THE CHAPTER 2.3.2

3 USEFUL LIFE

The useful life of the devices depends on the kind of burrs: the shelf life of sterile burrs is defined in 60 months (with reference to primary packaging validation and the maintenance of the sterility). Refers to the expiration date shown on the package to determine the shelf life of the burs.

Furthermore, sterile burrs are disposable; therefore, they have to be disposed of after their use. Unsterile burrs can be used up to 10 times, corresponding to the max number of sterilization cycles they can be performed.

4 DISPOSAL

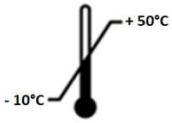
The devices have to be disposed according to the waste management regulation of the Local Management Authority (Special hospital waste). In any case do not disperse the product or its packaging in the environment.

5 ENVIRONMENTAL CONDITIONS

In order to ensure the maintenance of sterility and integrity of the device, 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 code
	Batch number
	Attention, refer to the user manual. Security information
	Sterilized with ionizing radiation
	Do not resterilize
	Do not use if the packaging is damaged
	Do not reuse
	Consult instructions for use
 AAAA/MM	Use by the expiration date
	Not sterile
	Keep away from light
	Keep dry
	Environmental storage temperature
 0426	Compliant with Council Directive 93/42/EEC and subsequent amendments, DM Class IIa. The 4-digit code indicates the device certification Notified Body.