MENDEC CRANIO

Plasticity at your service

p.d. 53

Tecres produces PMMA-based medical devices since 1986.
Mendec Cranio is the acrylic resin optimized for cranioplasty use and it is a sure remedy for the closure of small cranial defects directly *in situ*.

[illegible]

The product can be easily moulded and is perfectly adaptable to precise and safe manipulation.
After the hardening of cement is possible to drill and prepare it for prosthesis fixation with plates and screws or suture wires.

20g įpakavimas

MENDEC Cranio resin is available in 20g package with barium sulphate as radiopaque agent.
The special 3:1 ratio between powder and liquid, and the particular powder-making technique provide important advantages:

Ease of use:
thanks to its special characteristics, the resin reaches an optimal plastic consistency few minutes after mixing. At this point the resin can be manipulated to perfectly fill the defect [3]

Mechanical strength:
PMMA has excellent mechanical properties (elasticity, resistance, lightness) in comparison with other materials

	Compression strength	Bending strength	Bending modulus
Mendec Cranio	101± 5	70 ± 5	3000 ± 150
ISO limit	> 70 MPa	> 50 MPa	> 1800 MPa

Reduced polymerization temperature:
each monomer gram (the liquid component) develops 130 Kcal of heat. Thanks to its special powder, **MENDEC Cranio** needs 30% less liquid with respect to normal acrylic resins, thus reducing the total heat produced during polimerization

Reduced toxicity:
the reduced amount of liquid (MMA) gives a resin with a reduced toxicity

Biocompatibility:
PMMA has been used in clinical practice for more than 70 years, demonstrating its excellent biocompatibility.[1-2]

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

PLASTICITY

Reaches an excellent moulding state shortly after mixing.

PRECISION

Remains malleable for a long time, allowing for a detailed reconstruction of the bone defect.

SAFETY

The consistency of the mass allows it to maintain the shape given before the ending of polymerisation, which can therefore take place on an external support, away from the meninges.[4-5]

Working times at 23°C

Phases:	Mixing	Waiting	Handling and moulding	Hardening
MENDEC Cranio radiopaque	45''±15''	2'30''±30''	8'00''±1'00''	11'00''±2'00''

kietėjimas

Times indicated in the table were obtained under controlled temperature of 23°C +/- 1°C.

temperatūra

Working times at 20°C

Phases:	Mixing	Waiting	Handling and moulding	Hardening
MENDEC Cranio radiopaque	45''±15''	4'±30''	9'00''±1'00''	14'00''±2'00''

Times indicated in the table were obtained under controlled temperature of 20°C +/- 1°C.

p.d.53

Ordering information

Ref	Description	Details
1220/D	MENDEC Cranio radiopaque	20 g
CPSP-02	Bowl and spatula	

S. Tamaitė

2

MENDEC® CRANIO

(EN)

INSTRUCTIONS FOR USE
To the Medical Staff's attention

Akrilinė masė

Skirtas kaukolės defektų atstatymui

PRESENTATION

MENDEC CRANIO is an acrylic resin for repairing cranial defects. It is easy to manipulate and mould, proper for manual application. MENDEC CRANIO is a sterile and single use medical device. The hermetically sealed blister pack contains a sachet and a phial sterilised with ethylene oxide. The liquid is sterilised by means of filtration and the powder by means of ethylene oxide treatment.
Two versions are available: non-radiopaque, and radiopaque.

Composition of MENDEC CRANIO: 20 g sterilių miltelių

p.d. 53

	MENDEC CRANIO *non radiopaque*	MENDEC CRANIO *radiopaque*
POWDER	**20 g** sachet of sterile powder	**20 g** sachet of sterile powder
Polymethylmethacrylate	97.00% w/w	84.30% w/w
Barium sulphate	—	13.00% w/w
Benzoyl peroxide	3.00% w/w	2.70% w/w
LIQUID	**7.9 g** phial of sterile liquid (sterilus skystis)	**6.65 g** phial of sterile liquid
Methylmethacrylate	99.10% w/w	99.10% w/w
N-N dimethyl-p-toluidine	0.90% w/w	0.90% w/w
Hydroquinone	75 ppm	75 ppm

INDICATIONS

MENDEC CRANIO is indicated for repairing cranial defects.

CONTRAINDICATIONS

The use of MENDEC CRANIO must be carefully considered in presence of hypersensitivity to monomer or to any of the other components of the resin. It is not advised in case of active infection.

USE DURING PREGNANCY, BREAST-FEEDING AND IN CHILDREN

There are no tests which demonstrate the utilisation safety of MENDEC CRANIO during pregnancy or breast-feeding. MENDEC CRANIO should not be used in the first three months of pregnancy; for the remaining gestation period, should only be used in life-endangering situations.
The use in children is advised only when it is believed impossible to repair the cranial defect through other forms of intervention.

PRECAUTIONS FOR USE

- Read this instruction booklet very carefully.
- Make sure that the inner package is undamaged and that the components are integral, i.e. the powder should not present yellow or brown discolouring and the liquid should not be syrupy.
- Temperature has a major effect on the preparation characteristics of any acrylic resin. Temperatures of more than 23°C for the product, the preparation accessories and the environment accelerate the various stages in the preparation procedure. Lower temperatures retard the preparation stages. **Before using MENDEC CRANIO it is strongly advised to make sure that the package is stored at a temperature of 23°C ± 1°C for the previous 24 hours.**
- Make sure that the preparation accessories are specifically compatible with the product.
- Do not open the phial of liquid over the mixing bowl to avoid the risk of glass fragments entering the dough.
- Do not mix the resin in a flow of air since this will promote rapid evaporation of the liquid component and consequent variations in the performance of the resin.
- NEVER add other substances or foreign bodies to the acrylic resin.

To ensure safe application of MENDEC CRANIO, surgeons must be aware of the properties of the product, its preparation and handling characteristics, applicational limitations and correct application technique. It is strongly recommended that the surgical team carry out practical trials prior to use in patients under the same instrumental and environmental conditions.
Clinical data demonstrate the need to maintain strictly aseptic surgical techniques. It is important to keep in mind that the possible deep infection of a surgical wound is a serious risk for the successful outcome of the surgical operation.
Prolonged respiration of the vapours may cause drowsiness: excessive exposure to monomer vapours may irritate the respiratory apparatus and the eyes. Avoid monomer contact with the skin and mucous membranes. Cases of contact dermatitis have been observed in susceptible subjects. It is therefore advisable to wear a second pair of surgical gloves and scrupulously observe the instructions for mixing the components in order to reduce the possibility of reactions caused by hypersensitivity. Do not allow the liquid component to come into direct contact with accessories in rubber or elastomers. The vapours of the liquid component may affect soft contact lenses.
The liquid component is flammable and volatile and for this reason the operating theatre must be correctly ventilated. The liquid component and/or its vapours must never be directly exposed to naked flames or heated

R. Tauraitė

materials.
Caution: Acrylic resins reach temperatures higher than physiological temperatures during the exothermic polymerisation reaction.
Following surgery, if any form of infection should arise, patients must immediately consult their doctors to reduce the risk of infection.

PREPARATION AND APPLICATION INSTRUCTIONS

Open the unit container and transfer the powder sachet and phial of liquid on a sterile working surface in the operating theatre. Break open the phial and pour the liquid into the mixing bowl. Open the powder sachet and pour the powder over the liquid.
Caution: never arbitrarily modify the ratios between the liquid and solid components.
Mix with a spatula for some 30 seconds, then leave acrylic resin to rest.
To minimise the inclusion of air bubbles, it is advisable to mix the resin with a spatula from the outside of the bowl towards the centre. All the powder must be moistened by the liquid.
After 3-4 minutes the acrylic resin can be handled and manually moulded by the surgeon. The manipulation period is about 4-5 minutes, after that acrylic resin begins to polymerise. The surgical wound shall be covered with a sterile cotton gauze during the moulding of the artificial skullcap *in situ*. The consistency degree reached by MENDEC CRANIO before the curing allows the removal of the acrylic resin skullcap and the polymerisation on an external support.
Caution: the polymerisation has to be finished on an external support before the implantation.
After the acrylic resin has cured (cooled down to room temperature) it is possible to smooth the acrylic resin edges for a better adaptation.
It is recommended to drill the artificial skullcap to make fixing and suspension holes. The holes for fixation should be done at a distance of at least 0.5 cm from the edge of the device.
Before the implantation, verify that the artificial skullcap is cooled down to room temperature and accurately cleaned with sterile saline. Remove the gauze and clean the surgical site with sterile saline.
Then proceed to fixation with implant grade metal plates or sutures.

TIMING FOR THE PREPARATION AND APPLICATION OF MENDEC CRANIO

Times indicated in the instructions were obtained by performing tests under temperature controlled conditions of 23°C±1°C .
Any **increase in temperature** of the working environment, the product and the prosthesis over 23°C **reduces the waiting and hardening times** of the acrylic resin. Equally, **lower temperatures increase such times.**

9±1 min – 12±2 min

MENDEC CRANIO *non radiopaque*	45"±15"	3'30"±30"	9'00"±1'00"	12'00"±2'00"
Operations	**Mixing**	**Wait period in mixing bowl**	**Handling and modelling**	**Hardening**
MENDEC CRANIO *radiopaque*	45"±15"	2'30"±30"	8'00"±1'00"	11'00"±2'00"

Modeliavin kocteju, p.d 53

WARNINGS

- Store at a temperature below 25°C and protect from light.
- Sterility is assured only if the unit container is not damaged or opened.
- Do not use the product if the powder has a yellowish or brownish colour or if the liquid is syrupy. These two conditions indicate that the product has not been stored correctly.
- Do not re-sterilize and/or re-use the device. It is designed for single-use on a single patient.
  Avoid dividing the product into two or more portions, in order to use it other times. This would be a re-utilization and may lead to an error in the proportion of the powder and liquid components. It can also cause a sterility loss. Re-sterilization should not be carried out since it can cause infection risks for the patient. Re-sterilization can also alter the device's morphology and the mechanical features, causing a malfunction of the same with serious risks for the patient's health.

All residues must be considered waste surgical material and therefore should be eliminated at the end of the operation.

NEGATIVE EFFECTS

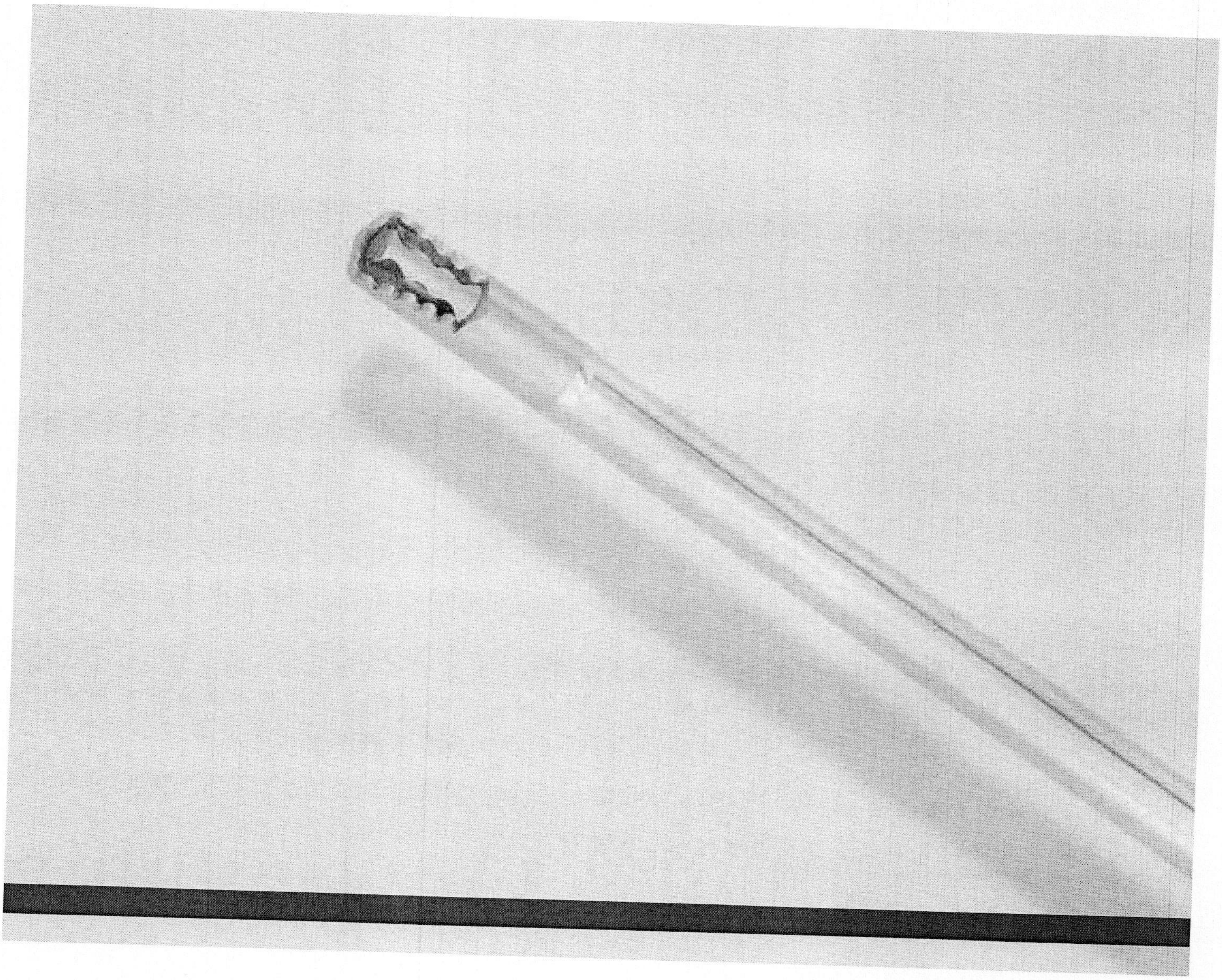
Serious:
Myocardial infarct
Cerebrovascular incidents
Cardiac arrest
Sudden death
Pulmonary embolism
Rejection of the implant
Neurotoxicity

More frequent:
Temporary drop in blood pressure
Haematoma - Haemorrhage
Anaemia
Infection of surface/deep surgical lesions

Other referred reactions:
Loosening of the implant
Breakage of the acrylic resin
Aesthetic damage

V. Taunaitė

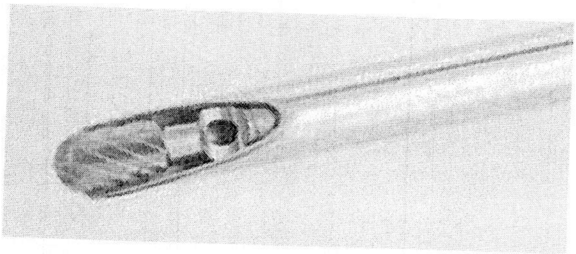
SWITZERLAND
DR MEDICAL
for your arthroscopy solution



ARTHROSCOPY

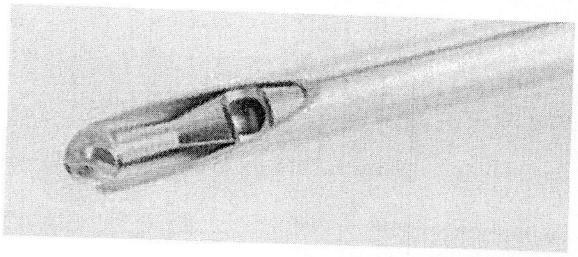
SWITZERLAND
DR MEDICAL
for your arthroscopy solution

DR SHAVER BUR CERATITAN®



DR BARREL BUR®

68.3



DR ROUND BUR®

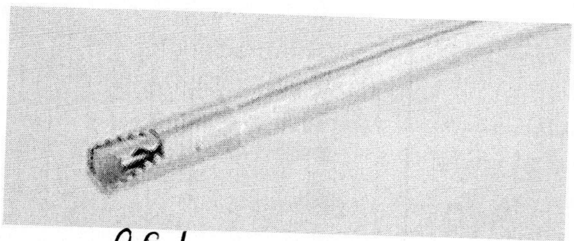
Internal tube coated with CERATITAN® (an anti-bacterial ceramic coating)

- CERATITAN® - coating for highest
    - cut quality
    - cutting performance
    - contrast by visualization
- with 2 aspiration windows (prevents "snowstorm effect")

DR SHAVER BLADE pat.

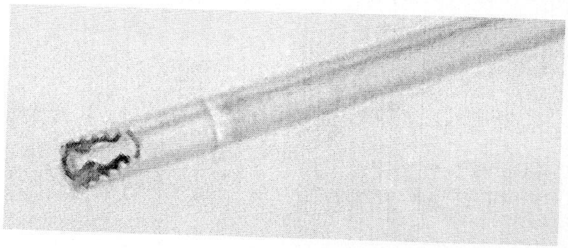
- DR WAVE CUTTER® with 1 double edge
- DR PIT BULL® with 3 double edges
- High cut quality and cutting performance
- Suitable for soft tissue and bone resection (PIT BULL®)
- Milling recommended up to 5000 rpm (maximum 8000 rpm)

- Oscillations up to 5000 rpm
- Either clockwise or anti-clockwise rotation
- Available in straight or 15° curved geometry
- Various lengths: 130mm, 155mm and 174mm
- Available single use and reusable
- Supplied sterile

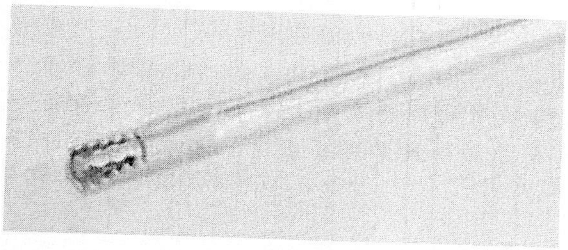


68.4

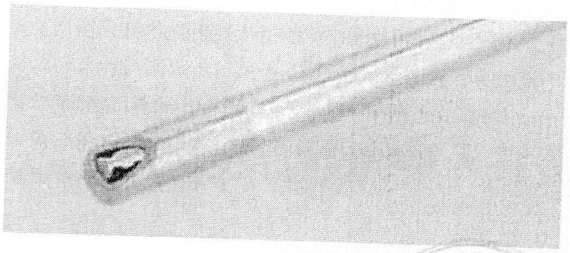
DR WAVE CUTTER®



DR PIT BULL® CERATITAN®



DR PIT BULL®

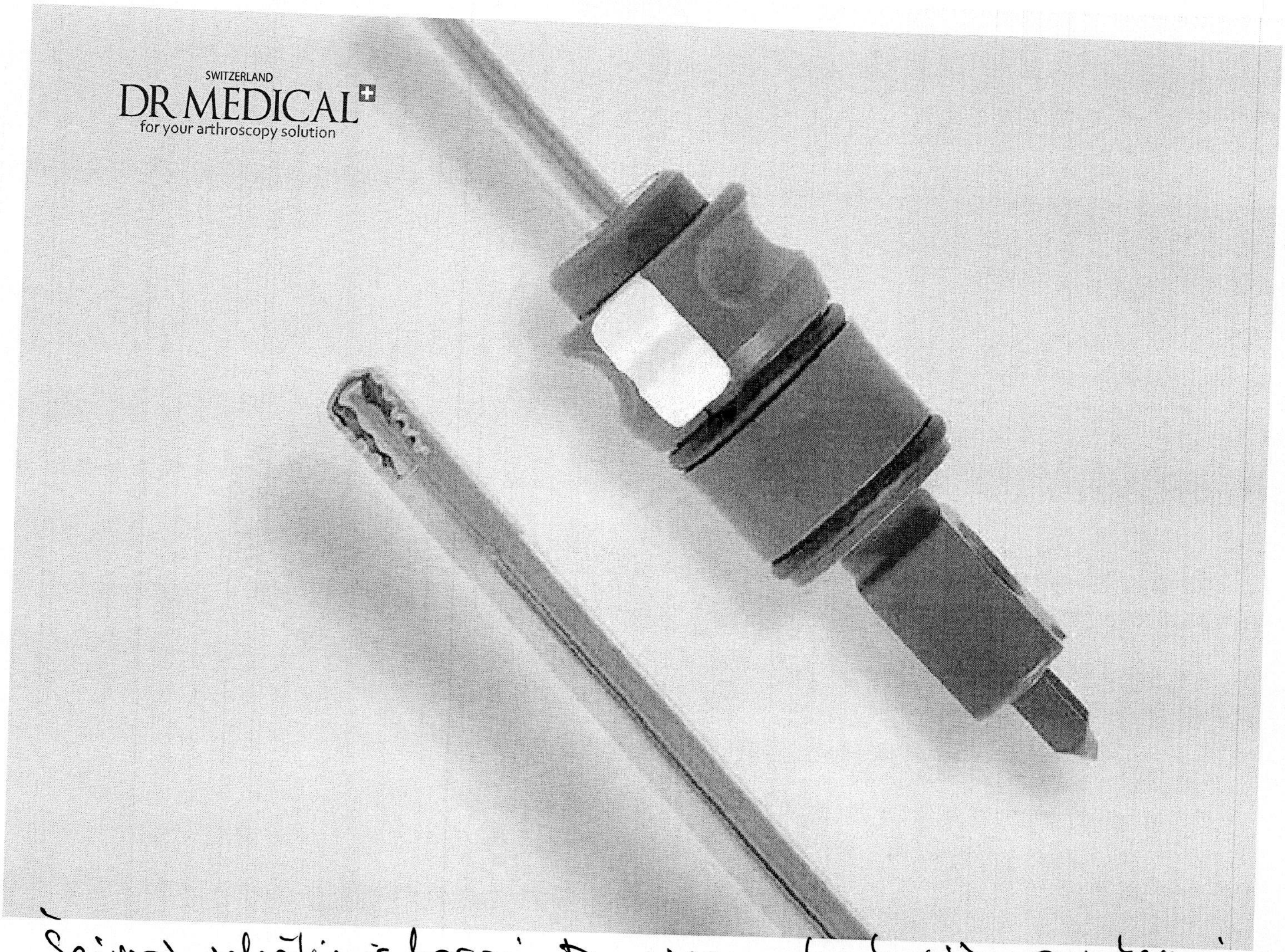


DR SYNOVIA PIT BULL®

68.1 ir 68.2

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

6



Šeiverio geležtės ir borai Dyonics artroskopijos rankenai

SHAVER BLADES & BURS FOR ARTHROSCOPY HANDPIECES **DYONICS S&N**

Vienkartiniai

Single use instruments into sterile packaging with 5 pieces inside

Plastic blue hub

diametras ilgis

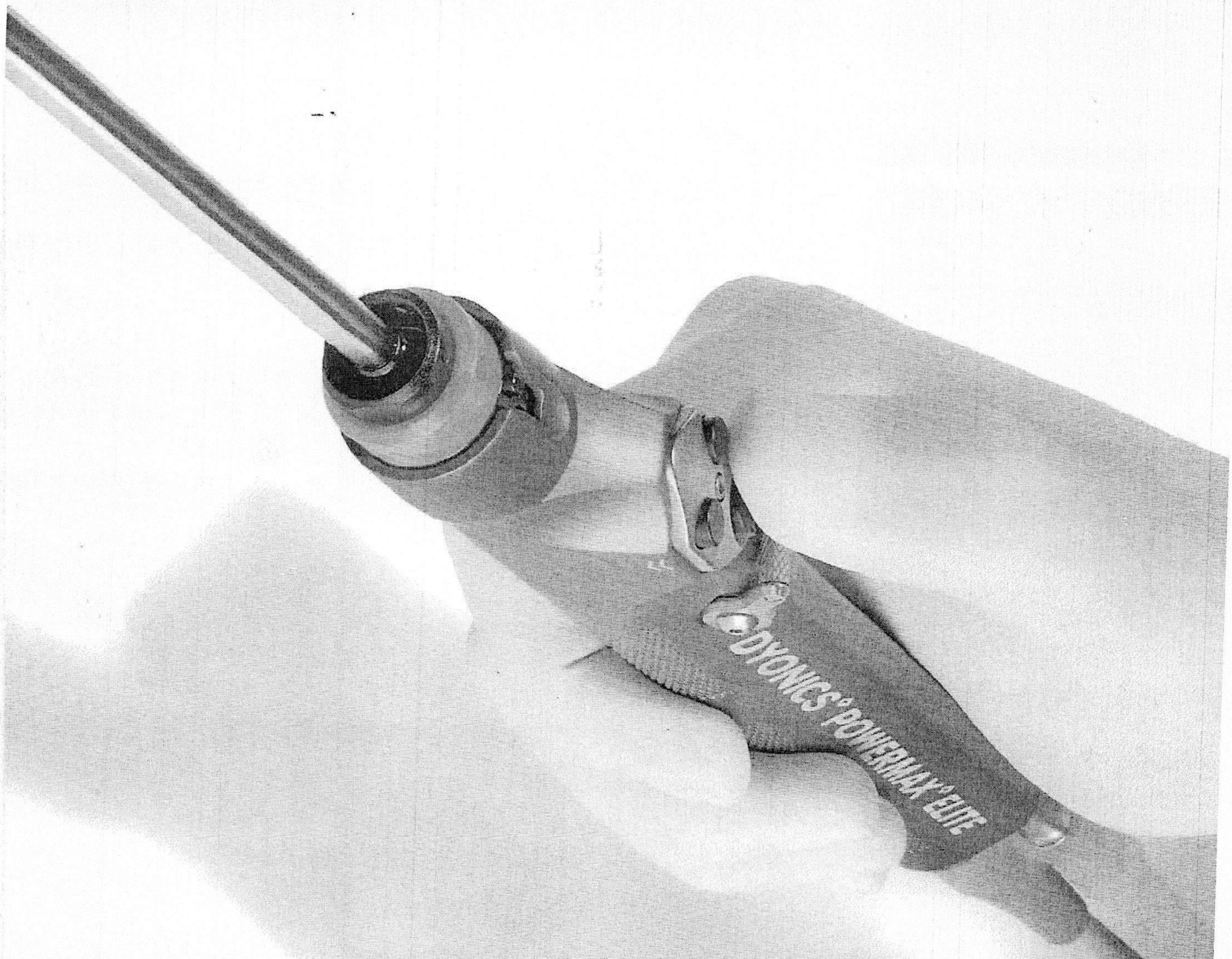
Description	Ø (mm)	L (mm)	No. Ref.	Hub	
DR WAVE CUTTER	Ø 4.0	130	021.101.230	DRSN blue	68.4
DR WAVE CUTTER	Ø 5.0	130	021.201.230	DRSN blue	
DR PIT BULL	Ø 3.0	130	021.301.240	DRSN blue	
DR PIT BULL	Ø 4.0	130	021.101.240	DRSN blue	p.d. 68.1
DR PIT BULL	Ø 5.0	130	021.201.240	DRSN blue	p.d. 68.2
DR PIT BULL	Ø 7.0	130	021.701.240	DRSN blue	
DR PIT BULL, CONCAVE 15°	Ø 4.0	130	021.101.236	DRSN blue	
DR BENDING PIT BULL	Ø 3.0	130	021.301.340	DRSN blue	
DR BENDING TOOL			020.101.103		
DR SYNOVIA PIT BULL	Ø 4.0	130	021.101.241	DRSN blue	
DR SYNOVIA PIT BULL, CONCAVE 15°	Ø 4.0	130	021.101.242	DRSN blue	
DR SYNOVIA PIT BULL, CONCAVE 15°	Ø 4.0	174	021.101.250	DRSN blue	
DR PIT BULL, CONCAVE 15°	Ø 4.0	174	021.101.251	DRSN blue	
DR BARREL BUR	Ø 4.0	130	131.100.220	DRSN blue	p.d. 68.3
DR BARREL BUR	Ø 5.5	130	131.200.220	DRSN blue	
DR ROUND BUR	Ø 4.0	130	121.100.220	DRSN blue	
DR ROUND BUR	Ø 5.5	130	121.200.220	DRSN blue	

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

S. Tomaitė

smith&nephew
DYONICS° POWER
Shaver Handstücke

Alles im Griff



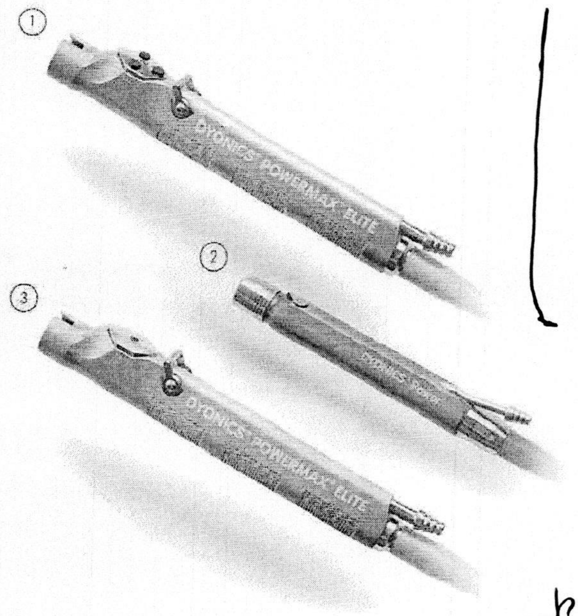
Intelligenz. Komfort. Power.

Die Motoren des DYONICS° POWER Systems zeichnen sich vor allem durch ein außergewöhnlich hohes Drehmoment, ein schnelles Erreichen der vorgewählten Drehzahl sowie eine hohe Leistung aus. Alle Motoren sind mit einer Schneideblatt-erkennung ausgestattet, mit Ausnahme des Minihandstückes.

Die neueste Innovation, das DYONICS POWERMAX° Handstück, ist ca. 50% leichter als unser Standard-produkt und bietet dabei ca. 25% mehr Leistung.

Für die unterschiedlichen Anforderungen in der Arthroskopie stehen Ihnen derzeit insgesamt 4 verschiedene DYONICS POWER Handstücke zur Verfügung.

Alle Handstücke sind mit dem DYONICS POWER System kompatibel.



① DYONICS POWERMAX ELITE mit Handsteuerung
② DYONICS POWER Minihandstück
③ DYONICS POWERMAX ELITE ohne Handsteuerung

Besonderheiten Ultralight Handstück

- Mit diesem Motor können alle geraden Einmalschneideblätter, Fräsen und die Ultralight Einmalschneideblätter betrieben werden.

Besonderheiten POWERMAX ELITE° Handstücke

- Komfortable Steuerung der Betriebsrichtung mittels Druckknöpfen
- Neu gestaltete Absaugregelung
- Nimmt alle Einmalschneideblätter (außer Mini) auf
- Neue Geometrie der Steuerungsknöpfe
- Dual Slot ermöglicht einfaches und schnelles Einrasten und Wechseln der Schneideblätter.

Bestellinformation

Artikel	Beschreibung
7205357	DYONICS POWER Minihandstück
7205971	DYONICS POWER Ultralight Handstück
72200616	DYONICS POWERMAX ELITE mit Handsteuerung
72200617	DYONICS POWERMAX ELITE ohne Handsteuerung

p.d. 68.5

Hinweis: Alle Handstücke mit 3m langem Anschlusskabel

Smith & Nephew GmbH
Endoskopie
Mendelssohnstraße 15d
22761 Hamburg
Tel. (0 40) 7 07 00-200
Fax (0 40) 7 07 00-201

endo.smith-nephew.com
www.smith-nephew.de

9