

Instructions for use of the medical cast cutter saw **OSCIMED 2000, ref. OSC 20101**



Indications and contraindications for use:

Medical device intended for the removal of plaster or synthetic resin immobilisation casts.

All other use is strictly prohibited. In particular, this device is not designed for use where the blade comes into voluntary contact with the patient or for surgical procedures.

Adverse effects:

The adverse effects reported in literature are: cuts, grazes and burns.
Comply with these instructions for use to prevent these adverse effects.

Warnings and safety instructions:



Read the instructions carefully. Failure to comply with the instructions and conditions of use mentioned in this manual may compromise the safety and effectiveness of the device. The manufacturer and distributor cannot be held responsible if the device has been used, modified, repaired and/or subjected to unauthorised technical interventions.

- Read this manual before using the product.
- Please keep this manual with the device of which it is an integral part. Use this device only for its intended purpose.
- When opening the package, check the integrity of the device, paying particular attention to damage to plastic parts.
- Do not use the device in environments where flammable anaesthetic mixtures with air, oxygen or nitrous oxide are present.
- Avoid touching the device with wet hands and avoid contact with liquids.
- The device may only be used by an operator trained to work in a plaster room and who has read these instructions carefully.
- The device is designed for dry use only and should only be used or stored in a dry place.
- Check that the power socket is compatible with the device plug.
- The plug must be inserted into a mains socket that can be easily accessed for quick disconnection if necessary.
- Do not leave the device running unattended.
 - Always remove the power plug before performing any work on the device, or when it is left unattended or within reach of children or persons not responsible for their actions.
- Do not pull or lift the device using the power cable.
- For repair operations, contact only the manufacturer's technical service or a technical assistance centre authorised by the manufacturer and request the use of original spare parts. Do not modify this device without the manufacturer's permission. No electrical and/or mechanical parts contained in the device were designed to be repaired or modified by the user.
- Any modification of the device with respect to its original version is strictly prohibited.
- The manufacturer declines all responsibility for damage caused to persons, animals, or property as a result of failure to comply with these instructions or if the device has been used in an abnormal manner.
- Observe the temperatures indicated in the technical data.
- If a blow to the device results in cracks or if the device or its accessories is damaged, discontinue use immediately and contact your local maintenance service.
- In the event of a serious incident, contact the manufacturer and the competent authority.

Technical Description:

Power supply :

The power supply consists of a cable with a mains plug connected to the transformer, which supplies the saw with direct current voltage.

Electromechanical drive (Saw):

A direct current motor oscillates the saw blade by mechanical transmission. The transmission is manufactured using high-quality, hard-wearing and maintenance-free materials. The motor is controlled by an electronic circuit.. The switch turns the device on and off.

Saw blades:

The saw blade has a central part made of synthetic material (blue for synthetic casts and white for plaster casts).

Saw blades	 Ø 77 mm	 Ø 65 mm	 Ø 65 mm	 Ø 65 mm	 Ø 50 mm	 Ø 50 mm
Stainless steel saw blade for plaster of Paris	-	WP-65	-	WP-65-2	WP-50	WP-50-2
Hardened steel saw blade for synthetic casts	BS-77-2	BS-65	BS-65-LN	-	BS-50	BS-50-2
Hardened steel saw blade with Titan coating for synthetic casts	-	BS-65-GT	-	-	BS-50-GT	-
Hardened steel saw blade with non-stick PTFE coating for synthetic casts	-	BS-65-TF	-	-	-	-

Specifications:

Voltage of the mains power supply	100-240 VAC
Frequency of the mains power supply	50-60 Hz
Power consumption	100 W
Duty cycle	3 minutes on / 20 minutes off
Length of the saw body	210 mm
Overall diameter	46 mm
Weight without power supply box	760 g
Motor rotation speed	13,200 rpm
Blade oscillation angle	6.2°
Useful stroke at the end of a 65 mm diameter blade	3.50 mm
Length of power cable	1.10 m
Length of 24 VDC cable	3.50 m
Noise level	62 dB(A)
Protection against splashing water and dust	IP 52
Storage, transport and use conditions.	Temperature: 0 to 35° C Humidity: 0 to 90% Pressure: 900 to 1080 hPa

Content:

- Medical cast cutter saw
- Power supply box
- Mains power cord
- 2 saw blades

Switching on and off and use:

- Plug the plug of the power cable into the socket.
- To start the saw, simply press the electronically-controlled button; press again to stop the device.
- Use the device in compliance with good clinical practice for cast removal. More specifically, saw the cast by allowing the blade to cut through it without applying excessive pressure or making jerky movements. To avoid cutting the patient, control the depth of the cut by lowering the blade gradually.

Changing the blade:



- Disconnect the power plug from the mains to prevent accidental operation during handling.

- When used in suction mode, remove the suction nozzle to access the blade. CAUTION: the blade is sharp, handle with care.
- Turn the blue lock knob (1) a quarter turn, pull out the knob and remove the blade at a slight angle.
- Attach the new blade (2) to the end of the notched pin and turn the lock knob (1) a quarter turn to lock the blade.



Adjusting the support and depth stop:

Pull the cylindrical endpiece of the stop (3) outwards by a few millimetres to release the notch. Slide the stop vertically to the desired height and release the cylindrical endpiece.

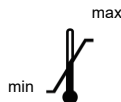
Maintenance-Cleaning:

 Disconnect the mains plug before any maintenance or cleaning operation.

Operation/ Responsible person	Operator	Technical service
Check <u>Frequency:</u> before each use	Check that no electrical cable sheath is damaged, that the movement of the oscillating pin and the switch is not blocked due to a build-up of sawdust. Check the condition of the saw blade, its teeth must be sharp. If the saw is connected to a dust extraction system, check that the suction air flow is not blocked by a build-up of sawdust. In the presence of abnormalities, do not use the device and send it to the technical service.	none
Cleaning <u>Frequency:</u> 3 months	Wipe a damp cloth over the surface of the device (do not use solvents or cleaning products as they may damage the device). Remove any dust from the ventilation slots. Do not immerse the device in water or any other liquid, do not get water on the device.	none
Check <u>Frequency:</u> every year	none	Check the general condition of the device, in accordance with good technical and clinical practice.

Protection against electric shock, standards, labelling:

Meaning of the symbols:

	Caution!		Refer to the instructions for use.
	Device with type B applied part.		Product complies with European directives and standards
	Serial number.		Reference number.
	Manufacturer.		At the end of the life of the device, please contact the competent local authorities or your distributor for waste disposal.
	Class II device with double electrical insulation, without protective grounding.		% Humidity limitation during transport, storage or use.
	Temperature limit for transport, storage or use.		Degree of protection of an electrical device against accidental or deliberate penetration by foreign solids and protection against penetration by liquids. 1 st digit, protection against solids: protected against dust. 2 nd digit, protection against water intrusion drops of water up to 15° from the vertical.
	Legal representative in the European Union		Risk of excessive temperature
	Medical Device		

Regulatory information on electrical safety

Device class:	I
Applicable standard:	IEC 60601-1: 2005 + A1:2012
Protection class, applied part:	Class IIB
Sterilisation:	None

Caution: powered device

The device does not have a power indicator light. If the plug is connected to the mains socket, the device is powered. (In accordance with chapter 15.4.4 of IEC 60601-1).

First fault conditions

In case of failure (short-circuit) of some components of motor's electronic control board, the temperature of the accessible parts exceeds the authorised limits. If this happens, do not touch the device. Switch it off and have it checked.

In the event of continuous use the temperature of the accessible parts exceeds the authorised limits. If this happens, do not touch the device. Switch it off and observe the recommended cycle times in the future.

Regulatory information on electromagnetic compatibility

Classification The device is designed to meet the requirements of IEC 60601-1-2: 2015 regarding electromagnetic compatibility; however, certain equipment may unintentionally emit strong RF signals that may interfere with the device. It should be kept away from all other electrical devices. (In accordance with chapter 7.9.2.2 of IEC 60601-1-2).

Deviations and information on test results:

Note 1: in case of an 8 kV electrostatic discharge in direct contact with the screws of the device. The device will switch off and must be switched on again.

Note 2: in the event of a 5 second power failure the device switches off and switches back on again when the power supply is restored.

Disposal at the end of the product's life:

At the end of the life of the device, please contact the competent local authorities or your distributor for waste disposal.

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Test table:

TEST DESIGNATION	SEVERITY	VERDICT	BASIC STANDARDS / COMMENTS
Harmonics current emission - 230Vac/50Hz Power Supply	Class A	N/A	IEC 61000-3-2 : 2018 EUT isn't powered through a public network
Measurement of voltage fluctuation and flicker - 230Vac/50Hz Power Supply	-	N/A	IEC 61000-3-3 : 2013 EUT isn't powered through a public network
Conducted emission (measurement) - 230Vac/50Hz Power Supply	Group 1 Class A	PASS	CISPR 11 : 2015 / AMD1 : 2016 / AMD2 : 2019 150kHz-30MHz
Measurement of radiated disturbances - Back side - 230 Vac/50Hz - Front side - 230 Vac/50Hz	Group 1 Class A	PASS PASS	CISPR 11 : 2015 / AMD1 : 2016 / AMD2 : 2019 30MHz-1GHz 30MHz-1GHz
Electrostatic discharges immunity - INDIRECT 8kV (VERT.) - INDIRECT 8kV (HORIZ.) - DIRECT 8kV - AIR 2kV - AIR 4kV - AIR 8kV - AIR 15kV	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS Note 1 PASS PASS PASS PASS	IEC 61000-4-2 : 2008
Electrical fast transient/burst immunity - 230Vac/50Hz Power Supply at ±2kV - 24Vdc Power supply (Saw side) at ±2kV - 24Vdc (Adapter side) at ±2kV	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS PASS	IEC 61000-4-4 : 2012 Freq 100kHz Freq 100kHz Freq 100kHz
Radiated, radio-frequency, electromagnetic field immunity - Back side - Back side (spot frequencies) - Lateral side - Lateral side (spot frequencies)	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS PASS PASS	IEC 61000-4-3 : 2006 / AMD1 : 2007 / AMD2 : 2010 80MHz-2.7GHz at 3V/m 80MHz-2.7GHz at 3V/m
Surge immunity - 230Vac/50Hz Power Supply - Level 1 - 230Vac/50Hz Power Supply - Level 2 - 230Vac/50Hz Power Supply - Level 3	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS PASS	IEC 61000-4-5 : 2014 / AMD1 : 2017
Conducted disturbances induced by radio-frequency fields immunity - 230Vac/50Hz Power Supply - 230Vac/50Hz Power Supply (ISM band) - 24Vdc power supply (AC/DC adapter side) - 24Vdc power supply (AC/DC adapter side) (ISM band) - 24Vdc power supply (saw side) - 24Vdc power supply (saw side) (ISM band)	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS PASS PASS PASS PASS	IEC 61000-4-6 : 2013 150kHz-80MHz at 3Veff 6Veff 150kHz-80MHz at 3Veff 6Veff 150kHz-80MHz at 3Veff 6Veff
Power frequency magnetic field immunity - Axis X, Y, Z at 30A/m frequency 50Hz	I.3 (60601-1-2)	PASS	IEC 61000-4-8 : 2009 Tests for information, according to manufacturer, EUT has no sensitive components to H field
Voltage dips and short interruptions immunity - 230Vac/50Hz Power Supply at 0%Un during 10ms - 230Vac/50Hz Power Supply at 0%Un during 20ms - 230Vac/50Hz Power Supply at 70%Un during 500ms - 230Vac/50Hz Power Supply at 0%Un during 5s	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	PASS PASS PASS PASS	IEC 61000-4-11 : 2004 / AMD1 : 2017 Note 2
Immunity to proximity magnetic fields in the frequency range 9kHz to 13.56MHz 30 kHz level 8A/m 134.2 kHz level 65A/m 13.56 MHz level 7.5A/m	I.3 (60601-1-2) I.3 (60601-1-2) I.3 (60601-1-2)	N/A N/A N/A	IEC 61000-4-39 : 2017 According to manufacturer, EUT has no sensitive components to proximity magnetic fields
Measurement of electromagnetic field in comparison of reference level(s) - 1Hz - 400kHz - 100kHz - 3GHz	2.3 µT 27.5V/m	PASS PASS	IEC 62311: 2019 + IEC 62233 : 2005; RECOMMENDATION 1999/519/CE; DIRECTIVE 2013/35/UE

Notes :

[illegible]