EN

POWER DRIVE

Morcellation System for Endoscopic Surgery

7688	PD1
7688	PDU
7688	PDMO
7688	PDG1
7688	PDC
7689	M1
7689	M2
7689	W1
7689	W2

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DE

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EN

WISAP would appreciate any comments from users regarding possible errors or unclear passages in this manual. Since the improvement of our products is an ongoing process, we reserve the right to make design changes without notice.

ES

WISAP agradece expresamente todo tipo de indicaciones que el usuario pueda darnos sobre eventuales errores o vaguedades contenidos en el presente manual. Dado que seguimos perfeccionando constantemente nuestros productos, nos reservamos el derecho a introducir modificaciones técnicas sin previo aviso.

IT

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1 GENERAL INFORMATION

1.1 PREAMBLE

Dear customer,

Thank you for your confidence in WISAP Medical Technology GmbH. This product combines our longstanding experience and thorough workmanship. You have decided for reliable, high-quality WISAP device.

Please read these instructions carefully before you put your new unit into operation for the first time. This will prevent damage that can result from the wrong electrical connection or improper use.

Use the device only for the purposes described in these instructions. We will assume no liability for damage caused by using the unit for purposes other than those for which it was designed.

The high value and quality of our products, even beyond the warranty, can only be guaranteed if all the service work has been carried out by the company WISAP Medical Technology GmbH. This includes, inter alia, SRC / LMC Testing and comparative measurements, maintenance and parts replacement.

The manufacturer reserves the right to modify the appearance and technical performance of the product through continued development of the product.

THIS MANUAL DOES NOT CONTAIN A DETAILED DESCRIPTION OF LAPAROSCOPY AND IS NOT SUITABLE FOR INTRODUCING A BEGINNER TO THIS SURGICAL TECHNIQUE.

INCIDENTS
All serious incidents related to the device must be reported to the manufacturer and the component authority of the Member State in which the user and/or the patient is established.

Your WISAP Team

1.2 SCOPE OF THIS USER MANUAL

This user manual covers the following products:

7688	PD1
7688	PDU
7688	PDMO
7688	PDG1
7688	PDC
7689	M1

7689 M2
7689 W1
7689 W2

1.3 ICONS IN THIS USER MANUAL

DANGER!

Failure to observe this warning leads to serious personal damage or injury.

WARNING!

Failure to observe this warning may lead to serious personal damage or injury.

CAUTION!

Failure to observe this warning may cause minor personal injury and may cause damage to the product.

NOTE!

A note contains valuable information or offers measures with which the handling of the product can be made more efficient and easier.

1.4 ABBREVIATIONS IN THIS USER MANUAL

SRC	Safety-related Checks
LMC	Legal metrological Control

2 SAFETY

2.1 ICONS AND SYMBOLS ON THE MEDICAL PRODUCT

Icons are for user information and are provided by the type label on the back side of the device for example.

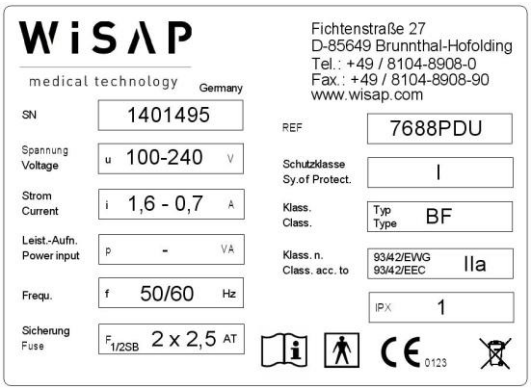
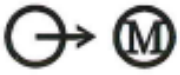


Figure 1: Type Label

Icon, Symbol	Descriptions
ON	Switch „ON “-position
OFF	Switch „OFF “-position
	Connection to the potential equalization
	Motor Status
	Connector to motor
SN	Serial number
REF	Reference number
	Date of manufacture
	Manufacturer
	Accessory of type BF
	Caution
	Consult instruction for use

Icon, Symbol	Descriptions
	Refer to the Manual!
IPX1	Protected against dripping water
IPX7	Protection against the effects of temporary immersion in water
	The device must not be disposed through the normal clinical disposal. For information on disposal, see the appropriate chapter.
CE 0123	CE-marking and identification number of the Notified Body. The product complies with the essential requirements of the Medical Device Directive 93 / 42 / EWG.
MD	Medical Device

2.2 ICONS AND SYMBOLS ON THE PACKAGING

Icon, Symbol	Descriptions
	This Side up
	Keep Dry
	Temperature Limitation
	Non-Sterile
	Do not use if package is damaged
	Atmospheric pressure limitation
	Humidity Limitation

2.3 DANGER

DANGER!

The use of this device is restricted to authorized personnel / physicians only.

DANGER!

This unit may only be operated by properly qualified persons who have been trained in its use. Endoscopic instruments and equipment may only be used by physicians who have completed appropriate training.

DANGER!

Do not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer.

DANGER!

Only use sterilized accessories (motor-drive, gearbox, cutting tubes) for each patient.

DANGER!

After each application, multi-use equipment must be processed before being used again.

DANGER!

Perform morcellation only under permanent view!

DANGER!

The device must never be operated with a defective power cord.

DANGER!

Turn off the power before replacing the fuse and disconnect the power cord from the power supply! Wait until the device has adjusted to the ambient temperature.

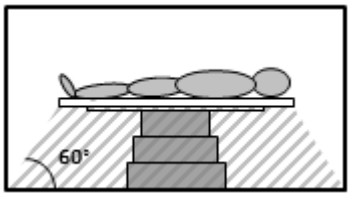
2.4 WARNINGS

WARNING!

The device is not destined for operation in explosive-endangered areas.

WARNING!

When using explosive anaesthetic gases, the device and its accessories are not to be operated in the shown area of 60 degree.



WARNING!

The user is fully responsible for observing the applicable cleaning, disinfection, and sterilization regulations. Errors caused by non-observance of the above regulations are not at the expense of the manufacturer and exclude any warranty and damage claims.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed.

WARNING!

Recognize the prevalence of unsuspected uterine sarcoma in patients under consideration for hysterectomy or myomectomy for the treatment of uterine fibroids and review these options with each prospective surgical patient. Apart from a laparoscopic approach, alternative surgical procedures exist that do not require electric morcellation. Also, some surgeons may recommend closed morcellation in a bag to reduce the risk of inadvertent spread of uterine tissue.

WARNING!

Consider the treatment alternatives for women with symptomatic uterine fibroids and review these options with each prospective surgical patient. Thoroughly discuss the benefits and risks of all treatments with patients.

WARNING!

Use the recognized guidelines to the investigation and management of uterine leiomyomas.

WARNING!

For individual patients for whom, after a careful benefit-risk evaluation, laparoscopic power morcellation is considered the best therapeutic option:

Inform patients that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis.

WARNING!

For individual patients for whom, after a careful benefit-risk evaluation, laparoscopic power morcellation is considered the best therapeutic option:

Be aware that some clinicians and medical institutions now advocate using a specimen “bag” during morcellation to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

WARNING!

Rotation of the cutting blades starts immediately after pressing the actuator button.

WARNING!

Avoid unintentional activation of the motor!

WARNING!

If the drive-motor cannot be stopped by releasing the actuating button, the operative intervention must be terminated immediately. The rotation can be interrupted by detaching the connection cable between the drive-motor and the controlling unit.

WARNING!

For your own safety, and that of your patient, use only original accessories.

WARNING!

Damaged equipment must not be used.
To open the enclosure, repairs, modifications, and calibrations may be performed only by manufacturer or by persons authorized by the manufacturer explicitly.

2.5 CAUTIONS

CAUTION!

Observe all operating instructions and safety warnings listed in this user manual!
Read the instructions carefully before use.

CAUTION!

This device unit may only be installed by the manufacturer or by authorized personnel.

CAUTION!

The device may only be operated in medically utilized rooms, which have been installed according to the guidelines of DIN VDE 0107.

CAUTION!

Before connecting the POWER DRIVE to the mains power supply make sure the supply network follows the specified requirements (power voltage, frequency and fuses).

CAUTION!

Pay attention to the integrity of the packaging of the device. When the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the unit, please contact the manufacturer immediately.

CAUTION!

Opening of the housing (chassis, motor-drive), any repairs and calibrations may only be performed by the manufacturer or by personnel explicitly authorized by the manufacturer!

CAUTION!

Run a visual inspection of the POWER DRIVE before each use. When detecting damage set the unit aside immediately and do not perform any operation with it. Contact the manufacturer immediately.

CAUTION!

Risk of fire, only use rated fuses, see type plate.

CAUTION!

Check the appliance and all accessories for proper operation before each procedure. In case of detected or suspected defects the products are not to be used.

CAUTION!

If a malfunction of the drive motor or gear unit is detected or suspected (e.g., no rotation despite pressed button, mechanical blockage, etc.), the button of the drive motor must not be pressed. Non-observance can lead to serious consequences!

CAUTION!

To ensure safety, the device and its accessories must not be used in the event of a detected or suspected malfunction. The malfunctions must be corrected immediately by the manufacturer or its authorized personnel.

CAUTION!

The selection of the proposed intervention and the required instruments is the sole responsibility of the treating physician, regardless of the instructions given in this manual.

CAUTION!

Place the unit out of the reach of the patient!

CAUTION!

Please make sure that no liquid enters the unit or that the controller unit does not get in touch with liquids.

CAUTION!

The controlling unit must not be sterilized!

CAUTION!

To ensure good dissipation of heat generated during an operation the control unit must not be covered with cloth.

CAUTION!

For detachment of the plug, do not grasp cable! Risk of damage!

CAUTION!

The connection cable to the drive motor must not be kinked, crushed, stretched, or rotated!

CAUTION!

Do not bring the drive motor into proximity of magnetically influenced parts!

CAUTION!

The POWER DRIVE may only be used for horizontal morcellation.

CAUTION!

Handle the cutting tubes carefully, cutting tubes are very sharp!

2.6 NOTES

NOTE!

Report any serious incidents that have occurred in connection with the medical device to the manufacturer and the competent authority at their location.

NOTE!

The user manual must be kept at a well-visible place nearby the unit.

NOTE!

Retain the instructions for use during the service life of POWER DRIVE.

NOTE!

Give this manual to any subsequent owner or user of the Power Drive® 7688.

NOTE!

Install the device onto a plane surface.

NOTE!

For the correct use of this device, it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before you begin the application. This applies both to the first use and if the device is transported to another environment.

NOTE!

Always keep extra sharp cutting tubes ready. Only sharp cutting tubes ensure a proper functionality and the speedy implementation of the procedure!

NOTE!

Have a second motor drive unit in the or in case the main unit breaks down.

NOTE!

In the start-up phase after each activation of the device the controlling unit increases the rotational speed to the maximum level within the first 2 seconds.

2.7 RECOMMENDATIONS FOR HEALTH CARE PROVIDERS

According to FDA, "UPDATE: The FDA recommends performing contained morcellation in women when laparoscopic power morcellation is appropriate", issued: February 25, 2020.

The FDA recommends performing laparoscopic power morcellation for myomectomy or hysterectomy only with a tissue containment system, legally marketed in the U.S. for use during laparoscopic power morcellation and performing these procedures only in appropriately selected patients. Tissue containment systems used during laparoscopic power morcellation are intended to isolate and contain tissue that is considered benign. Based on bench and animal testing, use of a containment system confines morcellated tissue within the containment system.

The FDA continues to recommend limiting the use of laparoscopic power morcellation to certain appropriately selected women undergoing myomectomy or hysterectomy. In addition, FDA recommends that when morcellation is appropriate, only contained morcellation be performed.

- Perform laparoscopic power morcellation with a legally marketed laparoscopic power morcellation containment system when morcellation is appropriate. The containment system should be compatible with the laparoscopic power morcellator.
- The FDA continues to recommend limiting the use of laparoscopic power morcellation to certain appropriately selected women undergoing myomectomy or hysterectomy; and when morcellation is appropriate, only contained morcellation be performed.
- Do not use laparoscopic power morcellators in gynaecologic surgery when the tissue to be morcellated is known or suspected to contain malignancy.
- Do not use laparoscopic power morcellators for removal of uterine tissue containing suspected fibroids in patients who are:
    - post-menopausal or over 50 years of age, or
    - candidates for removal of tissue (en bloc) through the vagina or via a mini-laparotomy incision.
- Tell patients about the risk of occult cancer (cancer that cannot be identified during pre-treatment evaluation) and inform them that use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease their long-term survival.
- Tell patients that the risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age.
- Be aware that uncontained power morcellation has been associated with the spread of benign uterine tissue, such as, parasitic myomas and disseminated peritoneal leiomyomatosis.

2.8 RECOMMENDATIONS FOR COMPATIBLE TISSUE CONTAINMENT BAGS

WARNING!

Uterine tissue may contain unsuspected cancer. The use of laparoscopic morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.
We recommend since the above reason performing laparoscopic morcellation for myomectomy or hysterectomy only with a tissue containment system, which is legally marketed for use during laparoscopic morcellation and performing these procedures only in appropriately selected patients. The probability of an undetected malignant tumour occurring is between 0.01% - 0.09%. The patient must be informed of this probability

The use of a tissue containment system is highly recommended for any application of the PowerDrive. Please note that the operating time increases when using a containment bag.

Wisap does not produce such tissue containment bags itself and is therefore not responsible for possible user errors and risks.
The correct use of the containers can be found in the corresponding instructions from the manufacturer.

Wisap also recommends verifying that the tissue containment bags used meet the requirements of the FDA guidance for containment system used with power morcellators dated May 26, 2023.

Compatibility has been confirmed with the following products:

Trading name	**Manufacturer**	**Compatible with**	
		15mm instrument (7689 M1, 7689 W1)	20mm instrument (7689 M2, 7689 W2)
LapSac Surgical Tissue Pouch	Cook Medical	X	X
Steri-Drape isolation bag	3M	X	X
EcoSac 230	Espiner	X	
Anchor TRS-200	Anchor Surgical	X	
MetraBag	BOWA MEDICAL	X	

3 PRODUCT DESCRIPTION

3.1 INTENDED USE / PURPOSE

7688 PDMO 7688 PDU 7688 PDC 7688 PDG1
The electronically controlled POWER DRIVE combined with the WISAP Gearboxes allows by continuous rotation of the motor drive or additionally intermitted manual rotation the cutting of tissue cylinders from myoma (fibroids) and uterus.

7689 M1 7689 W1 7689 M2 7689 W2
The WISAP cutting tubes family (Trading Name: Morzellator) with sealing caps (7620DK1 included with every morzellator, only sold as spare part) was developed specifically for laparoscopic surgery or pelviscopic / gynecology. With these cutting tubes an intraabdominal, endoscopic, horizontal morcellation of tissue/myoma together with the WISAP PowerDrive is possible. The cutting tubes serves as access for optics, instruments, endobags aso.

7689 M1 7689 W1 7689 M2 7689 W2 & 7688 PDMO 7688 PDU 7688 PDC 7688 PDG1
Optimum morcellation is only ensured in connection with the electronically controlled WISAP POWER DRIVE. Working without fatigue and the resulting maintenance of the surgeon’s fine motoricity ensure rapid and safe operation of the unit.

3.2 INDICATION/CONTRAINDICATION

The electronically controlled POWER DRIVE has especially been developed for intraabdominal, endoscopic, horizontal morcellation of tissue and/or myoma.
While operating with the WISAP POWER DRIVE horizontal morcellation is indicated.

The application of the device and its accessories is not indicated for the following scenarios:

- for treatment of vascularized tissue or use with dissection instruments.
  (Ovaries, tubes, adnexae, myoma and other structures need to be devascularised and dissected prior to morcellation.)
- in case of suspect findings / malignant myoma.
- in case of anatomically narrowing myoma
- in case of non-accessible or hardly accessible anatomic conditions.
- for treatment of patients that use Marcumar (or other anticoagulant agents).

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynaecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- ***peri- or post-menopausal, or***
- ***candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.***

WARNING!

Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices. The probability of an undetected malignant tumour occurring is between 0.01% - 0.09%. The patient must be informed of this probability

(Extract of http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm424123.pdf, 30.05.2016)

WARNING!

Be aware that some clinicians and medical institutions now advocate using a specimen “bag” during morcellation to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

3.3 USER GROUP

The Power Drive may only be operated by surgeons with experience in endoscopic procedures during minimal invasive surgery and gynaecology.

DANGER!

The use of this device is restricted to authorized personnel / physicians only.

3.4 OPERATING PRINCIPLE

The operation is very simple, all system components can be plugged together and are locked in place in their respective position. The motor drive can be turned on by simply pressing the actuator button.

During operative endoscopic interventions, an electronic module controls the rotation/rotational speed of the Macro cutting tubes during the procedure.
The maximum speed of rotation (approx. 120-140 min -1) guarantees optimum cutting of all tissue types/thicknesses.

NOTE!

In the start-up phase after each activation of the device the controlling unit increases the rotational speed to the maximum level within the first 2 seconds.

3.5 BIBLIOGRAPHICAL REFERENCE

SEMM, K.:
- Morcellation at Endoscopy - The Journal for EUROPEAN PRIVATE HOSPITALS, Sommer 1995 Results of the CISH Procedure between 1992-1997 – D-Levine und H.O. Rappold
- Interfascial Subtotal Hysterectomy C*I*S*H* / TUMA, IVH Macro-Morcellation / 1997

3.6 VARIANTS OF THE MEDICAL PRODUCT

The device is usable with different sizes of gear boxes and sizes of cutting tubes. For detailed information about the specifications, please refer to the customer service of WISAP.

A list and further information on possible expansion options can be found in chapter 9.

3.7 COMPONENTS OF THE MEDICAL PRODUCT

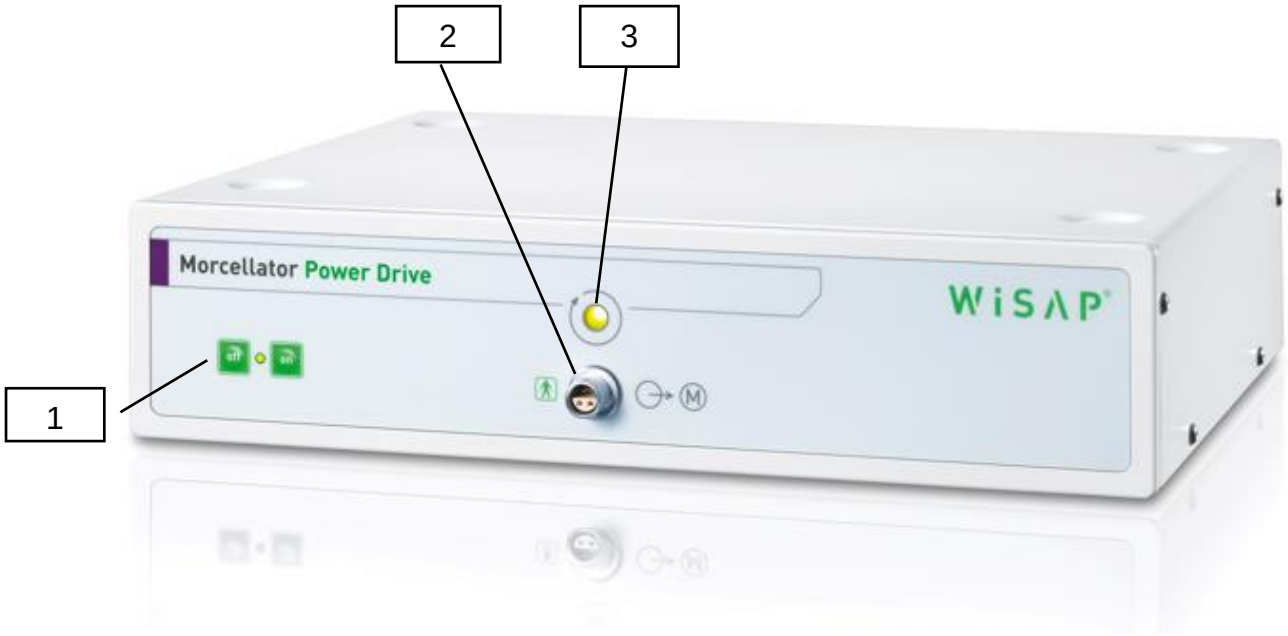


Figure 2: Front Side

Figure 3: Back Side

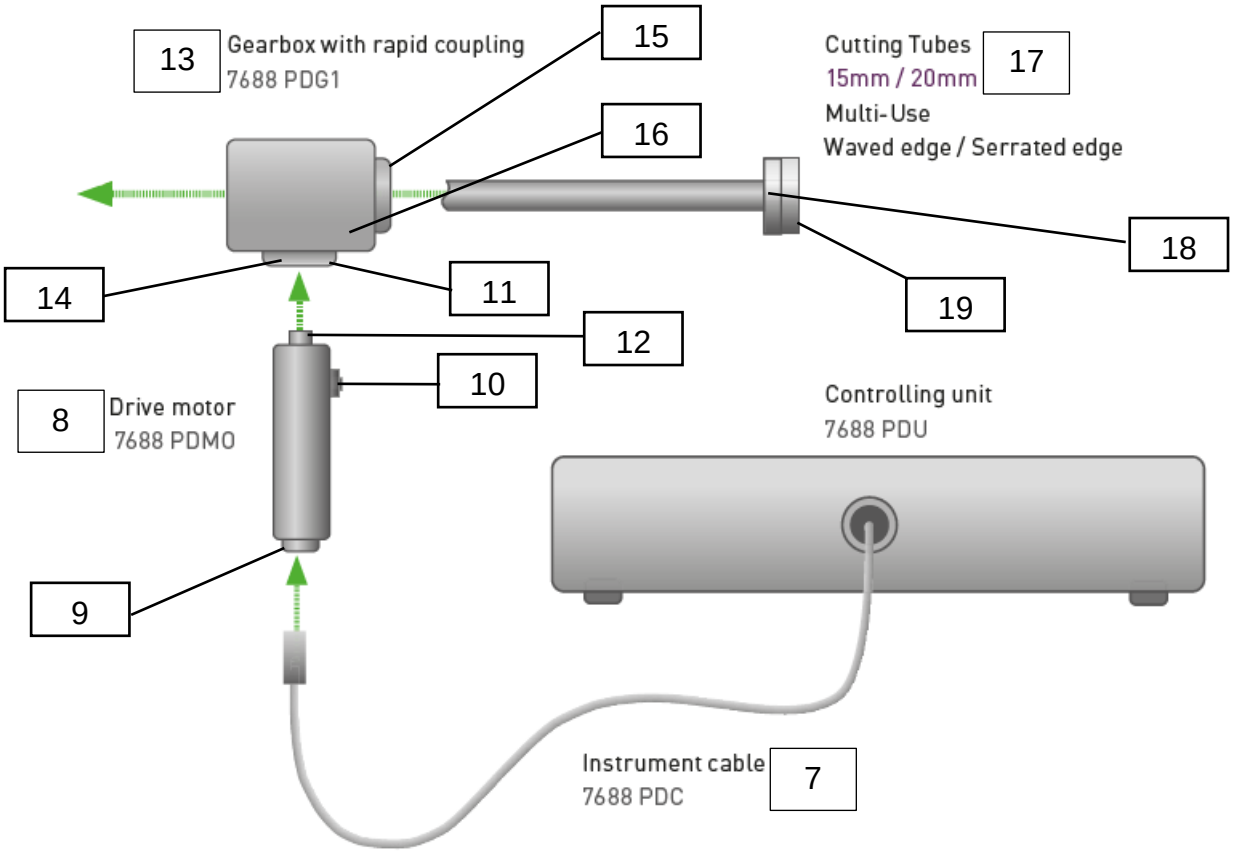


Figure 4: Back Side with accessories (schematic representation)

No.	Component / Element	Function
1	Power switch (ON / OFF)	Mains switch for turning the unit on, ON = I, OFF = O. Small rocker switch illuminates if unit is ON.
2	Connector Socket for motor-drive cable	The motor drive cable is attached to this connector socket. Observe the arrow mark!
3	Operating LED: display for motor drive	Operating display for motor drive – The middle big indicator LED illuminates if voltage is applied at motor drive and this starts rotating the cutting tube.
4	Mains connection with fuse drawer	Mains connection with fuse drawer

CAUTION!

Risk of fire, only use rated fuses, see type plate.

5	Grounding-Pin	For connecting the unit to the central grounding
6	Product Label	Technical data, as well as type (REF) and serial number (SN) of your device are to be found on the product label, which are to be indicated when ordering spare parts or in case of other questions.

7	Motor-drive cable between motor drive and controlling unit	The motor drive is joined with the controlling unit through the connection cable. For such purpose, attach the two plugs of the connection cable to respective receptacle of the controlling unit and to receptacle of the motor drive, whereby the red marking at the plugs and receptacle or positioning groove in the chassis of the motor drive above receptacle must be observed.

CAUTION!

For detachment of the plug, do not grasp cable! Risk of damage!

8	Motor drive	By means of the motor drive, the Morcellator tube is caused to rotate through gearbox.
9	Connector Socket for motor drive cable	To this socket, Motor-drive cable is attached. Observe positioning groove in the chassis above connector socket!
10	Actuator Button	Motor drive can be activated by means of the Actuator Button.
11	Fixation drilling at motor drive	In the fixation drillings of the motor drive the fixation level of the gearbox snaps while assembling.
12	Drive axle	When assembling, make sure that the drive axle engages in the seat of the gear box.
13	Macro Gearbox (7688 PDG1)	Gearbox is suitable for cutting tubes of 15 and 20 mm.
14	Fixation lever (For morcellator tube)	The Fixation lever must be kept pressed while inserting Morcellator tubes. Release fixation lever after insertion of the motor drive and turn Morcellator tubes until it locks in place.
15	Fixation drillings (At morcellator tube)	Upon assembly, fixation lever is tightened in the fixation drillings for morcellator tubes.
16	Cleaning holes	Prior to sterilization, the gearbox must be thoroughly rinsed followed by drying with compressive air.
17	Morcellator tube (D 15, 20mm)	The Morcellator tube 15 mm is destined for use of 10-mm-instruments. The Morcellator tube 20 mm is destined for use of 10-mm-instruments.
18	Fixation drillings at Cutting tube	In the fixation drillings of the cutting tube the fixation level snaps while assembling.
19	Sealing for morcellator tube (D 15, 20mm)	The sealing prevents escape of CO_2 gas during the operation.

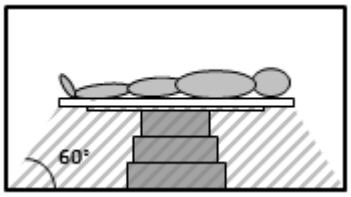
4 PUTTING INTO OPERATION

WARNING!

The device is not destined for operation in explosive-endangered areas.

WARNING!

When using explosive anaesthetic gases, the device and its accessories are not to be operated in the shown area of 60 degree.



CAUTION!

The device may only be operated in medically utilized rooms, which have been installed according to the guidelines of DIN VDE 0107.

NOTE!

Retain the instructions for use during the service life of Power Drive.

4.1 KIND OF DELIVERY

The device and its accessories are carefully packed with different protecting materials. Remove the POWER DRIVE and all its accessories from the packaging.

DANGER!

Only use sterilized accessories (motor-drive, gearbox, cutting tubes) for each patient.

CAUTION!

Observe all operating instructions and safety warnings listed in this user manual!
Read the instructions carefully before use.

CAUTION!

Pay attention to the integrity of the packaging of the device. When the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the unit, please contact the manufacturer immediately.

4.2 SCOPE OF DELIVERY

The standard delivery of the POWER DRIVE set (**7688 PD1**) includes:

Image	Description	Article Number
	Controller-unit	7688 PDU
	Motor-drive	7688 PDMO
	Gearbox Macro	7688 PDG1
	Connection cable (3m)	7688 PDC
	Power-Cord	1110ND2
	User Manual	

4.3 CONDITIONS FOR OPERATION

Operation	+ 5°C bis + 40°C
Storage and Transport	- 10°C bis + 60°C
Humidity	max. 85 % rH
Air Pressure	70kPA – 106kPA

4.4 ASSEMBLING OF THE DEVICE

DANGER!

The device must never be operated with a defective power cord.

CAUTION!

This device unit may only be installed by the manufacturer or by authorized personnel.

CAUTION!

Before connecting the POWER DRIVE to the mains power supply make sure the supply network follows the specified requirements (power voltage, frequency and fuses).

CAUTION!

Check the appliance and all accessories for proper operation before each procedure. In case of detected or suspected defects the products is not to be used.

CAUTION!

To ensure the safety the device and its accessories must no used in case of detected or suspected malfunction. The malfunctions must maintained by the manufacturer or its authorized personal immediately.

CAUTION!

Handle the cutting tubes carefully, cutting tubes are very sharp!

CAUTION!

Do not bring the drive motor into proximity of magnetically influenced parts!

CAUTION!

The connection cable to the drive motor must not be kinked, crushed, stretched or rotated!

NOTE!

Install the device onto a plane surface.

UNPACKING

- Remove The POWER DRIVE and all its accessories from the packaging.
- Place the machine on a stable and level surface.

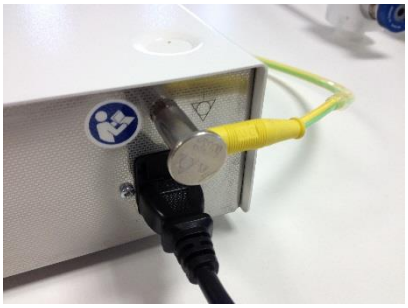
CAUTION!

Pay attention to the integrity of the packaging of the device. When the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the unit, please contact the manufacturer immediately.

GROUNDING THE UNIT

- Grounding pin 5 of the device must be connected via an earthing cable with the central potential equalization of the OR of the equipment trolley upon installation of the appliance.
- The equipment trolley is then additionally to be connected through a grounding cable with the central potential equalization of the OR.

  The device is equipped with a grounding connection pin 5 according to DIN 42801 for connecting a bonding conductor, over which the device must be grounded ("Guidelines for avoiding ignition hazards due to static electricity").



CONNECTING TO THE POWER SUPPLY

- Before connecting the POWER DRIVE to the mains power supply, make sure the supply network follows the Specified requirements (Power Voltage, Frequency and fuses).

- Make sure the Power Switch **1** is set in the OFF-position.
- Now connect the power cable to the device 4 and then connect it to the power supply.

ASSEMBLY OF CONNECTING CABLE AND MOTOR-DRIVE

- Connect the motor-drive cable **7** to the connector socket on the motor drive **9**.
- **Arrows on the motor-drive 9 and the connecting cable 7 indicate the correct positioning before inserting the plug**.

ASSEMBLY OF CONNECTING CABLE AND CONTROLLING UNIT

- Connect the motor-drive cable **7** with the connector socket on the controlling unit.

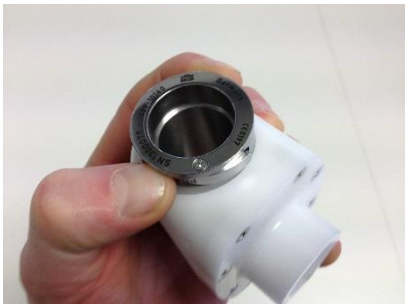
ASSEMBLY (MOTOR-GEARBOX)

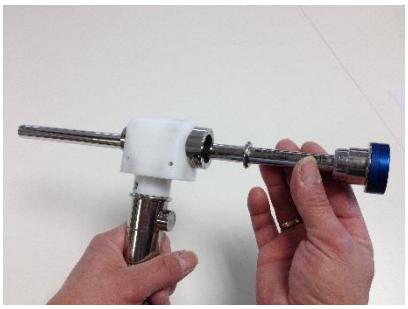
Assembling of gearbox **13** and cutting tube **17** on motor drive **9**:

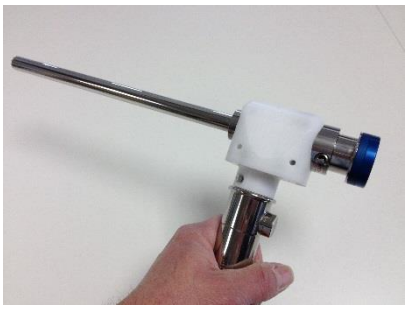
- Push the fixation-lever **14** on the gearbox
- Shift drive axle **12** of the motor drive in the seat of the gear box **13**.
- Bring the gear box **13** with pressed fixation lever **14** in a proper ergonomic position.
- Release the fixation- lever **14**. Twist drive motor **9** in place until fixation lever snaps into place **11** and fixates the gear box in one position.

ASSEMBLY (GEARBOX-CUTTING TUBE)

- Push the fixation lever for the cutting tubes **15**.
- Insert a cutting tube **17** through the lateral opening of the gear box **13** until it stops.
- Release the fixation lever for cutting tubes **15** and twist the cutting tube **17** until it locks in place **18**.







4.5 FIRST PUTTING INTO OPERATION

CAUTION!

Before first use, the cutting tubes, the gearbox and the motor must be sterilised. Additionally the connecting cable can be sterilised.

CAUTION!

Run a visual inspection of this device before each use. When detecting damage set the unit aside immediately and do not perform any operation with it. Contact the manufacturer immediately.

CAUTION!

Please make sure that no liquid enters the Controller unit or that the unit does not get in touch with liquids.

CAUTION!

To ensure good dissipation of heat generated during an operation the control unit must not be covered with cloth.

NOTE!

For the correct use of this device, it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before you begin the application. This applies both to the first use and if the device is transported to another environment.

NOTE!

Have a second motor drive unit in the or in case the main unit breaks down.

4.5.1 Switch ON

• Check that the power switch is in the "**OFF**" position and whether the potential equalization is connected correctly.	
• Insert the power plug of the power cord into a power socket.	
• Turn on the device by pressing the "**ON**"-Switch	The following conditions can be observed: • The indicator LED between OFF and ON lights up
• Before the first intended use, carry out a test in accordance with chapter 12.2	
• Before each use run a functional test in accordance with chapter 12.3.	

4.5.2 Switch OFF

• Turn the device OFF by pressing the OFF button **1**; the LED light between OFF and ON position of the Power Switch **1** ceases.	The following conditions can be observed: • The indicator LED between OFF and ON no longer lights up
• Disconnect the power cord from the power supply by removing the mains plug of the power cord from the power outlet. • Note that the device is only completely disconnected from the power supply when the power cord is unplugged.	
• Disconnect the power cord from the power socket **4** of the control unit of the POWER DRIVE and keep it close to the device.	

4.6 FUNCTIONAL TEST

The execution of the functional test is dictated by the standards of IEC 60601-1. It has to be performed prior to each operative intervention.
Functional test serves for inspection of the POWER DRIVE in conjunction with its accessories.

DANGER!

The device must never be operated with a defective power cord.

NOTE!

In the start-up phase after each activation of the device the controlling unit increases the rotational speed to the maximum level within the first 2 seconds.

Action	Control-points
1. Put the unit into operation	• Morcellator tubes **14** must have sharp edges. • It must be ensured that all system components can be joined as described in the section **4.2**. • It must be possible to have the motor-drive **8**, the gearbox **13** and the morcellator tube **14** locked in place through the fixation levers **11**.
2. Activate the controlling unit by pressing ON of the Power Switch **1**	• LED between OFF and ON button of switch **1** lights up • Indicator LED **3** is completely OFF • Motor drive **8** remains inactive • Cutting tube **14** remains inactive, no rotation is visible
3. Activate motor drive **8** by pressing the Actuator button **10**	• Rotation of the cutting blades **14** starts immediately after pressing the actuator button **10**. • In the start-up phase after each activation of the device the controlling unit increases the rotational speed to the maximum level within the first 2 seconds. • Morcellator tube **14** rotates, while actuator button **10** is kept pressed. • Indicator LED **3** lights up and signalizes activation of motor drive **8**.
4. Turn off motor drive **8** by releasing Actuator Button **10**	• Rotation of cutting tube **14** immediately stops after release, rotation does NOT coast down. • LED **3** OFF

5 OPERATION

DANGER!

This unit may only be operated by properly qualified persons who have been trained in its use. Endoscopic instruments and equipment may only be used by physicians who have completed appropriate training.

DANGER!

Perform morcellation only under permanent view!

DANGER!

Only use sterilized accessories (motor-drive, gearbox, cutting tubes) for each patient.

DANGER!

After each application, multi-use equipment has to be processes before being used again.

CAUTION!

Run a visual inspection of the POWER DRIVE before each use. When detecting damage set the unit aside immediately and do not perform any operation with it. Contact the manufacturer immediately.

CAUTION!

Place the unit out of the reach of the patient!

NOTE!

Please consult the pertinent medical literature for techniques, complications and hazards.

NOTE!

Always keep extra sharp cutting tubes ready. Only sharp cutting tubes ensure a proper functionality and the speedy implementation of the procedure!

5.1 START OF HORIZONTAL MORCELLATION

- Activate the motor drive **8** by pressing the Actuator Button **10**.
- Actuator button **10** must be kept pressed for continuous rotation.

- During the active state of motor drive **8**, the Indicator LED **3** at the controlling unit remains lit.
- After pressing the Actuator Button, the rotational speed is slowly increase to maximum rotation within the first 2 seconds. That feature ensures safety for the patient.

WARNING!

Rotation of the cutting blades starts immediately after pressing the actuator button.

WARNING!

Be aware of the residual risk of inadvertent injury to other organs or tissues

WARNING!

Avoid unintentional activation of the motor!

WARNING!

If the drive-motor cannot be stopped by releasing the actuating button, the operative intervention has to be terminated immediately. The rotation can be interrupted by detaching the connection cable between the drive-motor and the controlling unit.

CAUTION!

In case of detected or suspected malfunction of the drive motor or gearbox (e. g. no rotation despite pressed pushbutton, mechanical blockage, etc.) of the push button of the drive motor must not be operated. Failure to do so could result in serious consequences!

CAUTION!

The POWER DRIVE may only be used for horizontal morcellation.

CAUTION!

Do not bring the drive motor into proximity of magnetically influenced parts!

CAUTION!

The selection of the proposed intervention and the required instruments is the sole responsibility of the treating physician, regardless of the instructions given in this manual.

NOTE!

In the start-up phase after each activation of the device the controlling unit increases the rotational speed to the maximum level within the first 2 seconds.

NOTE!

Have a second motor drive unit in the or in case the main unit breaks down.

5.2 MANUAL MORCELLATION

In case of failure of the drive components, it is advisable to end the surgical procedure manually.

- Remove cutting tube **17** from the surgical access / trocar.
- Press the locking lever **15** and removal of the cutting tube **17.**
- Insert the cutting tube **17** through the opening of a Manual Drive.
- Fixation of the Manual Drive by means of a clamping screw into the holes provided on the cutting tube **17**.
- After mounting the hand wheel check the tight fit!
- Intraoperative application is guaranteed.

CAUTION!

Handle the cutting tubes carefully, cutting tubes are very sharp!

6 HYGIENIC MEASURES

To maintain effectiveness of the unit, maintenance and storage must be thoroughly taken care of. The accessories coming into contact with human tissue need to be sterilized for avoiding infections to the patient.

DANGER!

Only use sterilized accessories (motor-drive, gearbox, cutting tubes) for each patient.

WARNING!

Do not use the sterile gearbox and morcellator engine and accessory again without required cleaning, disinfecting and sterilizing procedure

DANGER!

Accessories that are designed for single use are not safe for a second application. Sterile single use accessories are not designed for processing!

DANGER!

After each application, multi-use equipment must be processes before being used again.

WARNING!

The user is fully responsible for observing the applicable cleaning, disinfection and sterilization regulations. Errors caused by non-observance of the above regulations are not at the expense of the manufacturer and exclude any warranty and damage claims.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed.

WARNING!

For this medical device, 55 reprocessing cycles are validated. Use of the device for more cycles is not validated and is at the user's own risk

Please read the tabular overview in the reprocessing Instruction “RA_Powerdrive-und-Zubehör” on cleaning, disinfection, and sterilisation.

6.1 CLEANING (MANUAL)

6.1.1 Controlling unit

CAUTION!

The controlling unit must not be sterilized! The control unit may only be wiping sterilized!

CAUTION!

Applied parts and accessories may only be cleaned and disinfected if it's disconnected from the PowerDrive control device.

CAUTION!

Please make sure that no liquid enters the unit or that the controller unit does not get in touch with liquids.

6.2 STERILIZATION

6.2.1 Motor-Drive, Connection Cable, Gearbox and Cutting Tubes

The parts to be sterilised should be cleaned, disinfected and dried. Owing to the cavities in the products, a pre-vacuum procedure has to be affected. Please observe the operator manual of the autoclaving unit. All sterilization processes must be carried out according to 17665-1:2006-11

WISAP does recommend the following sterilisation method:
Steam sterilisation at 134°C / 3,0 bar / 90 seconds (half cycle)

WISAP would recommend that the personnel responsible for sterilisation studies the operator manual of the different sterilising units. Please read the instructions for metal articles with lumen and porous articles with lumen. It is important to note that the recommended sterilisation parameters are only valid if the sterilisation equipment has properly been maintained and calibrated.
Other validated sterilisation procedures (complying with ISO 17664-1:2021 and ISO 17664-2:2021 or 17665-1:2006-11) may also be used at the user's own responsibility.

CAUTION!

Before each use, the components must be checked for visual changes. If such changes occur, the manufacturer must be contacted immediately, and the product must no longer be used!

CAUTION!

Sterilize reusable applied parts and accessories before surgery to prevent infection!

7 TROUBLE SHOOTING

Fault Description	Possible Causes	Remedy
• No device functions • LED between the OFF and the ON position of the Power Switch **1** does not light up	• Breakdown of power supply • Defective mains cable • Defective mains fuses • Voltage of power supply is not in conformity with the value on the type label.	• Have supply network checked • Check mains cable, exchange if necessary • Exchange fuses (observe type of fuse, see „Technical Data“) • Have device serviced by manufacturer or authorized dealer
• LED between the OFF and the ON position of the Power Switch **1** lights up, drive motor **9** cannot be switched on by pressing push button **10**, LED **3** lights up while push button **10** is pressed.	• Defect of control unit, connecting cable **7** or drive motor **9**.	• Send unit to manufacturer or authorised dealer for service check.
• LED **3** does not light up when the drive motor **9** is switched on and the cutting tube **17** is rotating.	• Control unit defective	• Send unit to manufacturer or authorised dealer for service check.
• Drive motor **9** and cutting tube **17** run after the push button operation has ended.	• Control unit defective	• Send unit to manufacturer or authorised dealer for service check.
• Drive motor **9** and cutting tube **17** run without actuation of push button **10**, sometimes jerkily.	• Control unit defective	• Send unit to manufacturer or authorised dealer for service check.

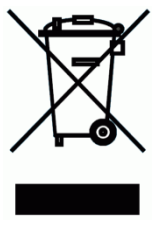
• Gearbox **13** cannot be locked to drive motor **9**.	• Drive axle **12** does not engage correctly in the receptacle of the angular gear **13**, gearbox **13** cannot be connected to the drive motor as far as it will go. • Defective locking lever **14** or worn locking holes **11**.	• When assembling, make sure that the drive axle **12** engages correctly in the mounting of the gearbox **13**. • Send drive motor **9** and gearbox **13** to manufacturer or authorised dealer for service inspection.
• Cutting tubes **17** cannot be locked in the angular gear **13**.	• Defective locking lever **15** or worn locking holes **18**.	• Cutting tubes **17** and angular gear **13** to manufacturer or authorised specialist dealer for service inspection.
• Cutting tubes **17** are difficult or impossible to remove from the trocar.	• Cutting tube **17** flared at the distal end	• Use a new cutting tube **17**
• Limited cutting ability	• Cutting tube 17 worn (blunt)	• Use a new cutting tube **17**
• Engine has no power/performance	• After an overload of the engine, a protective circuit in the control unit intervenes.	• Wait a short time until the protection circuit is deactivated again.

8 DISPOSAL

At the end of product life, the components of this device should be disposed of properly. Pay attention to a careful separation of materials. The materials used do not contain dangerous goods. The housing material is recyclable. The electronics boards should be disposed through an appropriate recycling process.

This device must be disposed of with special care and in a processed condition to avoid microbiological hazards.

In addition, special attention must be paid to the sharp edges of the cutting tubes.



This symbol on the product and/or accompanying documents means, that the product must not be mixed with general household waste. If you want to discard this product, please contact your dealer or supplier for further information.
This symbol applies only to the countries within the EEA (*).

(*) EEA = European Economic Area, which comprises the EU Member States plus Norway, Iceland and Liechtenstein

9 LIST OF ACCESSORIES

The complete list of accessories could be requested from the Customer Service of WISAP.

WARNING!

For your own safety, and that of your patient, use only original accessories.

Please refer to the following table that shows the possible combinations between the different gearboxes, the appropriate cutting tubes and other purchased parts:

Cutting tubes, autoclavable		**Gearbox Macro 7688PDG1**
Ø 15 mm	Serrated Edge	**7689M1**
Ø 15 mm	Waved Edge	**7689W1**
Ø 20 mm	Serrated Edge	**7689M2**
Ø 20 mm	Waved Edge	**7689W2**
Seal, autoclavable		**7620DK1**

10 TECHNICAL DATA

Classification according to	
93/42/EWG	IIa
Type of protection against electric shock	Protection Class I
Degree of protection against electric shock	Device type BF

Ambient Conditions	
Operation	+ 5°C to + 40°C
Storage and transport	- 10°C to + 60°C
Humidity	max. 85 %

Controller Unit 7688 PDU	
Type of protection against ingress of water	IPX1
Operating mode	intermittent duty
mains connection	100 - 240 V ± 10% / 50/60 Hz
Fuses	2 x 2,5 AT
Power consumption	110 VA
Weight	2,7 kg
Dimensions (w x h x d)	350 x 110 x 235 mm

Motor Drive 7688 PDMO	
Type of protection against ingress of water	IPX7
Operating mode:	intermittent duty with electric braking
Operating time / Pause time:	max 30s / min. 10s
Idle speed:	130 min^{-1} ± 15%
Dimensions (W x D)	178 x 42 mm
Diameter:	34 mm
Weight:	0,55 kg

The CE mark is awarded in accordance with EC Directive 93/42/EEC Annex II.

11 OVERVIEW OF ELECTROMAGNETIC COMPATIBILITY (EMC)

Manufacturer's Declaration for Electro-Technical Compatibility acc. to IEC 60601-1-2

for the WISAP mains powered Morcellator POWER DRIVE

Guidance and manufacturer's declaration - electromagnetic emissions		
The device POWER DRIVE is intended for operation in a specified environment as below. The customer or the user of the UNIT should ensure that it is used in such an environment.		
Emission Test	**Accordance**	**Electromagnetic Environment - Guidelines**
HF-Emissions according to CISPR 11	Group 1	The unintended generated RF emissions are very low and it is unlikely that nearby electronic devices to be disturbed. The device is suitable for use in all establishments, including domestic establishments and those directly connected to a public power supply network that supplies buildings used for domestic purposes.
HF- Emissions according to CISPR 11	Class B	
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations Flicker according to IEC 61000-3-3	n.a.	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device POWER DRIVE is intended for use in the electromagnetic environment as specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity testing	**IEC 60601-Test Level**	**Compliance level**	**Electromagnetic Environment - Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / Bursts According to IEC 61000-4-4	± 2 kV für power lines ± 1 kV for input and output lines	± 2 kV ± 1 kV	The power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV Mode voltage ± 2 kV Common mode voltage	± 1 kV ± 2 kV	The power quality should be that of a typical commercial or hospital environment.

voltage dips, short interruptions and voltage variations according to IEC 61000-4-11	< 5 % U_T (> 95 % collapse of U_T) für ½ period 40 % U_T (60 % collapse of U_T) for 5 periods 70 % U_T (30 % collapse of U_T) für 25 periods < 5 % U_T (> 95 % collapse of U_T) for 5 s	In accordance	The power quality should be that of a typical commercial or hospital environment.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3A/m	Magnetic fields at mains frequency should have the typical values, as can be found in the business and hospital environment.
NOTE: U_T is the ac mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The POWER DRIVE is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic - Environment Guidlines**
			Portable and mobile RF communications equipment should be used no closer to any UNIT, including cables, than the recommended separation distance calculated from the equation for the transmission frequency equation. **Recommended separation distance:**
Conducted RF after IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 Veff	d = [3,5/V1] x $\sqrt{P}$ = 1,2 x $\sqrt{P}$
radiated RF disturbances Acc. to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	For 80 MHz to 800 MHz: d = [3,5/E1] x $\sqrt{P}$ = 1,2 x $\sqrt{P}$ at 800 MHz until 2,5 GHz: d = [7/V1] x $\sqrt{P}$ = 2,3 x $\sqrt{P}$
			where P is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of stationary radio transmitters should be in accordance with a site survey, less than the compliance level in each frequency. In the vicinity of equipment. bearing the following symbol interference are possible. 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all cases. The Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A: Field strengths from fixed transmitters, such as Base units of cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted exactly. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

B: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended separation distances between portable and mobile RF communications equipment and the POWER DRIVE.

The POWER DRIVE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device by - depending on the output power of the communications equipment as specified below - to comply.

Nominal power of the transmitter	**Protective distance depending on transmission frequency m**		
W	**150 kHz bis 80 MHz**	**80 MHz bis 800 MHz**	**800 MHz bis 2,5 GHz**
	d = [3,5/V1] x √ P = 1,2 x √ P (at V1 = 3 Veff)	d = [3,5/E1] x √ P = 1,2 x √ P (at E1 = 3 V/m)	d = [7/E1] x √ P = 2,3 x √ P (at E1 = 3 V/m)
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum nominal power in the above table is not specified, the recommended separation distance d can be calculated in meters (m) using the equation of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all cases. The Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 TECHNICAL SERVICE AND MAINTENANCE

12.1 FREQUENCY OF MAINTENANCE

To avoid accidents due to aging or normal wear-and-tear, the unit including accessories need to pass in frequent interval a regular function and safety test according to IEC 60601-1. **Annual maintenance is therefore required.**

CAUTION!

Opening of the housing, any repairs, modifications and calibrations may only be performed by the manufacturer or by personnel explicitly authorized by the manufacturer!

12.2 TESTING BEFORE FIRST INTENDED USE, AFTER MODIFICATION AND MAINTENANCE

Testing prior to the first intended use, any modification and after maintenance is carried out in accordance with DIN EN 62353 ("Medical electrical equipment – Iteration-test and test after repair of medical electrical equipment").

Following tests must be conducted in a regular interval:

- Change Fuses when appropriate
- Check mechanical condition of the unit including the accessories
- Check the tight fit of all electrical equipment including the protective conductor connection
- Check the readability of all functionally important inscriptions and the nameplate
- Check the availability of all necessary documentation (instructions for use)
- Check the function of all controls, sockets and lights on the device
- Check the protective conductor resistance according to DIN EN 62353:2008-08, Section 5.3.2
- Check the leakage according to DIN EN 62353:2008-08, Section 5.3.3.

12.3 FUNCTIONAL TEST (ITERATIVE)

The safety checks are carried out according to DIN EN 62353 ("Medical electrical equipment - Loop test and test after repair of medical electrical equipment"). The safety test is the responsibility of the operator but should regularly (12 month interval) be carried out by the manufacturer or a person authorized by him.

For more details, please see chapter 12.2.

12.4 CHANGING THE FUSES

DANGER!

Turn off the power before replacing the fuse and disconnect the power cord from the power supply! Wait until the device has adjusted to the ambient temperature.

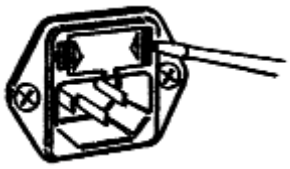
Turn OFF the device by pressing the OFF switch on the front of the device.

Disconnect the power cord from the power supply by removing the mains plug of the power cord from the power outlet.

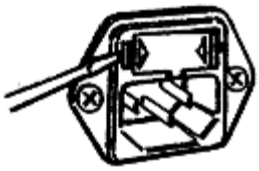
Remove the power cord from the power connector of the device and keep it close to the device.

The fuses are located above the mains socket.

Slide a suitable tool (screwdriver) into the right recess and press the lock to the left, so that the fuse box comes out slightly.

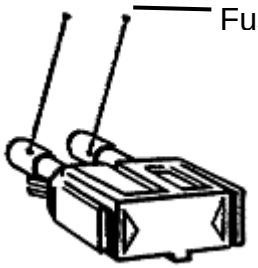


Slide a suitable tool (screwdriver) into the left recess and press the lock to the right, so that the fuse box comes out entirely.



Pull out the fuse box.

Remove the fuse and install the new one(s). Only use fuses with the correct electrical values (specification see chapter 0)



Install the fuse. Correct assembly on both sides is indicated by an audible "click".

12.5 SERVICE / REPAIR / MODIFICATION

All services such as regular maintenance, inspection, repair, modification, calibration, etc., shall be carried out with consideration of the special safety regulations for medical equipment by the manufacturer or by expressly authorized by him shall.

Performed services are filled in the table in chapter 12.7.

12.6 PRODUCT LIFETIME

The lifetime of the medical device is determined by their function and the careful handling of them. For this medical device, 55 reprocessing cycles are validated.

12.7 SERVICE TABLE

Date	Description	Signature

12.8 REPAIR AND RETURNS

If a repair should be required, please advise us or your local dealer. To process your repair as quickly as possible, please request an **RMA NUMBER**.

Pack the cleaned (not contaminated*) device only in its original packaging and return it to us free. Describe the error or malfunction and tell us the contact person for further inquiries.

*) The repair must be shipped devices and accessories must, to protect service personnel and transport security, have been prepared in accordance with the information in this manual.
THE CERTIFICATE OF DECONTAMINATION SHOULD CLEARLY THE ACCOMPANYING THIS PACKAGE.
If this is not possible, the contaminated product must be clearly visible in and double-wrapped in a security film with an indication of the decontamination.
The manufacturer can refuse the acceptance and repair of contaminated products.

13 INSTRUCTION

The unit with serial number: _____ was released to the customer on

_____.

Training was conducted by Mr./Ms.: _____

The following person(s) received training:

_____ Function: _____

_____ Function: _____

14 WARRANTY / LIABILITY

The manufacturer guarantees that the unit and accessories have been carefully checked before leaving the factory. He is only responsible for the safety characteristics under the statutory provisions if all work on the product made by factory authorized service personnel and the equipment and accessories are used exclusively for the intended use after. Authorized service personnel may be strictly trained and certified by the manufacturer.

14.1 WARRANTY

WISAP - Medical Technology granted a 12 month warranty on production- and material faults. Faults or defects caused by mishandling are not covered by warranty.

In case of unauthorized opening, modifications and/or repairs, we cannot be held liable for proper and safe function of the device. All warranty claims are declared null and void then.

- The unit is handled Improperly,
- Operator-errors cause damage to the unit,
- Failure to observe the instructions for use,
- Implementation of changes to the device (modifications, alterations extensions etc.) without written permission,
- Opening of the housing by unauthorized persons,
- Use of non-original accessories,
- Acts of God (such as lightning),
- Transport damage resulting from improper packaging when returning; to avoid transport damages, we advise you to pack the device including all components safe for transport,
- In case of defective packaging Repair costs are invoiced. Even during the warranty period will void any warranty,

If the complaint is unlawful, we are entitled to charge a reasonable fee for inspection and delivery of the unit.

14.2 LIABILITY

We, as manufacturer of this device consider ourselves only liable for safety, reliability and efficiency of the unit, if:

- maintenance, assembly, extensions, readjustment, modifications or repairs have been performed by our service personnel or by personnel authorized by us.
- the electric installation of the respective room corresponds to the standards of VDE 0107
- the instructions in the operator manual are strictly observed when operating the unit.

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