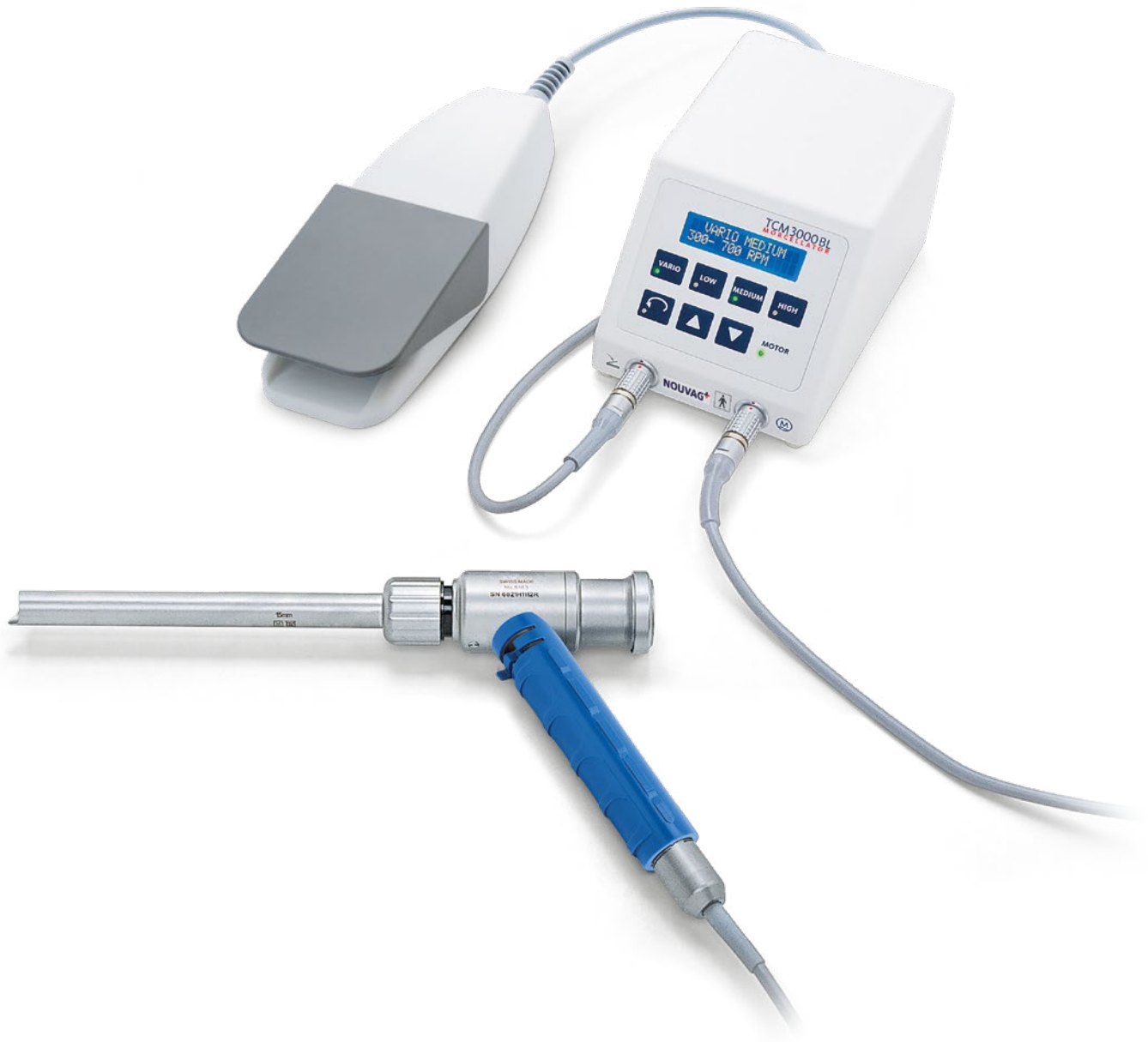
EN

Instructions for use

TCM 3000 BL Morcellator

NOUVAG+



CONGRATULATIONS ON YOUR PURCHASE OF A PRODUCT FROM NOUVAG.

We are pleased that you have chosen a quality product from NOUVAG and thank you very much for the trust you have placed in us.

These instructions for use will familiarize you with the device and its functions so that you can apply and use them correctly.

SYMBOLS

	General warning sign		General mandatory action		Refer to instructions for use
	Manufacturer		Date of manufacture		Use-by date
	Observe accompanying documents		Not for reuse		Separate collection required (WEEE)
	Biological hazard		Autoclavable at 134°C		For thermal disinfection
LOT	Batch code	REF	Catalog number	SN	Serial number
MD	Medical device	EC REP	Authorized representative in the European Community	CE 0197	European Conformity mark
	Water resistance		Equipotentiality		Protective ground
	Type BF applied part		Foot switch		Motor
	Certified by the TÜV Rheinland North America Group	1 min. on/ 1 min. off	INT 1min/1min 1 min. ON / 1 min. OFF, for 8 cycles, afterwards 15 min. OFF		

CONTENT

GENERAL INFORMATION

INDICATIONS

The morcellator set is for the morcellation and extraction of tissue and for removing myomas or the uterus during laparoscopic procedures in gynecology.

PRINCIPLE

For morcellation and extraction of tissue, as well as for removal of myomas or the uterus, during laparoscopic procedures, the control unit is used in conjunction with the morcellator handpiece. For this purpose, a rotating cylindrical tube, which has a cutting edge at the distal end, is introduced into the abdominal cavity, which has been dilated by insufflation. With the gripping forceps inserted through the cutting tube, the tissue pieces to be removed are guided to the rotating cutting tube, cut off piece by piece and removed from the abdominal cavity with the gripping forceps.

This instructions for use describes three different options for removing tissue by a laparoscopic procedure:
Option 1 – Tissue removal by morcellation with protective tube Instruments (forceps) are inserted through a protective tube sealed by a valve system. When removing the forceps from the sealed protective tube, you may need to cover the valve with your thumb to avoid gas loss.
Option 2 – Tissue removal by morcellation with trocar sleeve Instruments (cutter tube, forceps) are inserted through the trocar sleeve. The trocar sleeve contains a valve that prevents gas loss when withdrawing the instruments.
Option 3 – Tissue removal (myomectomy) with myoma drill through the trocar sleeve The myoma drill is inserted through the trocar sleeve (Ø12mm) with separate access. Tissue parts are removed with the morcellator with forceps, Option 1 or Option 2.

> ⚠ For a myomectomy, only the trocar sleeve (REF 5141nou) with a diameter of 12mm may be used together with the myoma drill.

CONTRAINDICATIONS

Relative or absolute contraindications may result from the general medical findings or in special cases in which the patient's risk for motor-driven tools is significantly increased. Ovaries, fallopian tubes, myomata and other structures must be devascularized and dissected before morcellation.

The laparoscopic deployment of morcellators is contraindicated:

- For the treatment of malignant tumors
- For the treatment of vascularized tissue
- For the preparation of tissue
- In gynecologic surgery in which tissue to be morcellated is known or suspected to contain malignacy
- For the removal of uterine tissue containing fibroids in patients who are:
  - Peri or postmenopausal, or
  - Candidates for en bloc tissue removal, for example through the vagina or via a Mini-laparotomy incision.

Cases described in the literature, must be observed.

TARGET GROUP

Women from age 18.

GENERAL INFORMATION

MEDICAL APPLICATION

This product is designed solely for use in medical facilities by medically qualified persons.

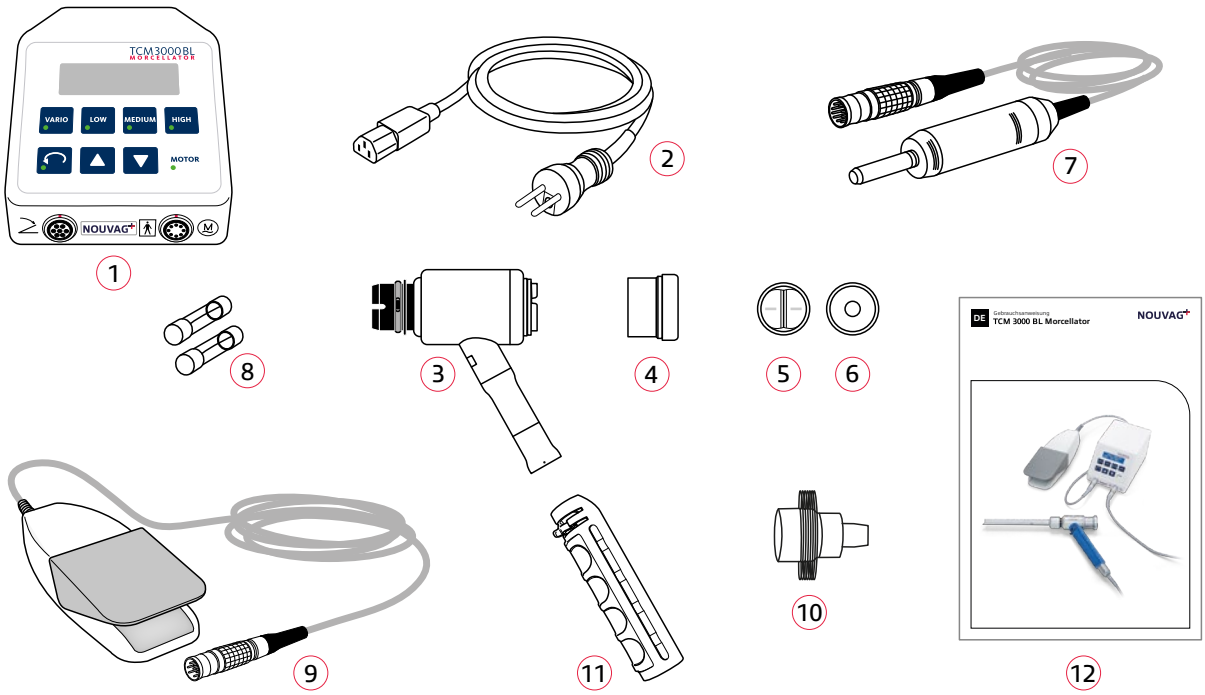
AMBIENT CONDITIONS

	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90 %	max. 80 %
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 – 1'060 hPa	800 – 1'060 hPa

ON RECEIPT

- ¬ The shipping package must contain all parts listed in chapter [SCOPE OF DELIVERY, ACCESSORIES AND SPARE PARTS >6].
- ¬ If parts are damaged or missing, contact NOUVAG.

Immediate control of the drive set «TCM 3000 BL Morcellator» (REF 3287):



1 Control unit (REF 3281) **2** Power cable (country-specific) **3** Gear unit (5163nou) **4** Sealing unit (REF 5136nou) **5** Roof shaped seals (10) (REF 5167nou) **6** Membrane seals for all cutting tube diameters (10) (REF 5166nou) **7** Electronic motor 21 (REF 2090nou) **8** Fuses (2) (REF 21606) **9** VARIO pedal (REF 1507nou) **10** Threaded spray adapter (REF 19584) for lubrication of the electronic motor 21 **11** Handle (REF 5183nou) **12** Instructions for use (REF 31946)

SCOPE OF DELIVERY, ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QUANTITY
3287nou	TCM 3000 BL Morcellator | Set	1
3281	TCM 3000 BL Morcellator control unit	1
1507nou	VARIO foot switch	1
2090nou	Electronic motor 21, 40'000 rpm	1
5163nou	Morcellator gear unit	1
5183nou	Handle complete	1
31946	TCM 3000 BL Morcellator instructions for use	1
19584	Spray adapter with thread, for lubricant spray (REF 2128)	1
19586	Flushing adapter Luer-Lock	1

ALL OPTIONS

REF	DESCRIPTION	QUANTITY
5151nou	Obturator Ø 12 mm	1
5152nou	Obturator Ø 15 mm	1
5154nou	Cutting tube Ø 12 mm	1
5155nou	Cutting tube Ø 15 mm	1
5136nou	Sealing unit Ø 12/15 mm	1
5168nou	Sealing adapter complete	1
5167nou	Roof shaped seal Ø 12/15 mm, PU 10 pcs.	1
5166nou	Instrument membrane sealing Ø 12/15 mm, PU 10 pcs.	1
5192	Tenaculum forceps Ø 13.5/15 mm, FL 420 mm, non detachable, for cutting tube 15 mm	1
5194	Tenaculum forceps Ø 5 mm, FL 420 mm, non detachable	1
5195	Claw forceps Ø 10 mm, FL 420 mm, non detachable	1
5196	Tenaculum forceps Ø 10 mm, FL 420 mm, non detachable	1

OPTION 1

REF	DESCRIPTION	QUANTITY
4144nou	Morcellator Ø 12 mm with protection tube	1
4145nou	Morcellator Ø 15 mm with protection tube	1
5137nou	Protection tube reusable Ø 12 mm	1
5138nou	Protection tube reusable Ø 15 mm	1

OPTION 2

REF	DESCRIPTION	QUANTITY
4147nou	Morcellator Ø 12 mm with trocar sleeve	1
4148nou	Morcellator Ø 15 mm with trocar sleeve	1
5141nou	Trocar sleeve Ø 12 mm	1
5142nou	Trocar sleeve Ø 15 mm	1
5177nou	Gasket for trocar flap Ø 12/15 mm, PU 10 pcs.	1
5180nou	O-ring for trocar sleeve Ø 12/15 mm, PU 10 pcs.	1

SCOPE OF DELIVERY, ACCESSORIES AND SPARE PARTS

OPTION 3

REF	DESCRIPTION	QUANTITY
5193	Drill for myoms Ø 10 mm, Length 330 mm	1
5141nou	Trocar sleeve Ø 12 mm	1

In line with regulations pertaining to hazardous materials, the lubricant spray is not delivered with the control unit but can be ordered separately.

SAFETY INFORMATION

Your safety, the safety of your team, and of course that of your patients is very important to us. It is therefore essential to bear the following information in mind:
Every use of the TCM 3000 BL Morcellator different to the product description defined in Section [INDICATIONS >4], causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices then the devices must be removed from the place of treatment. Avoid any connection or close adjacency to other devices.

EMC MANUFACTURER'S DECLARATION OF CONFORMITY

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurrence of negative environmental factors in the close area of the TCM 3000 BL Morcellator may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is not allowed.
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Use only accessories and cables as specified in the product description. Further observe the EMC manufacturers declaration of conformity.

MODIFICATION AND MISUSE

Modification or manipulation of the TCM 3000 BL Morcellator and its accessories is prohibited. The manufacturer is not liable for any damages resulting from unauthorized modifications or manipulations. The warranty will be canceled.
Use of the TCM 3000 BL Morcellator outside the indications described in Section [INDICATIONS >4] is prohibited. The user or operator is solely responsible for any such use.

ESSENTIAL REQUIREMENTS

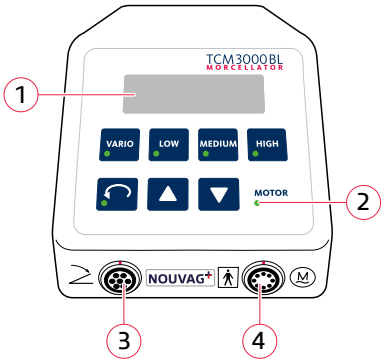
Before using the TCM 3000 BL Morcellator, this instruction manual must be read thoroughly and you must be well acquainted with the functions and handling of the unit.
For protection of the patient, the user and third parties the used products must be prepared as specified in this instructions for use.
The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.
Repairs may only be performed by authorized NOUVAG service technicians
The products described in this manual must be used by trained and qualified medical personnel only in accordance with the requirements and with reference to the manual.
Improper use or repair of the device, or failure to observe these instructions, will relieve us from any obligation arising from warranty provisions or other claims!
Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.
Use the recommended cleaning and care sprays to care for the gear unit. Only use lubricating spray for the electronic motor. The use of other care products can lead to malfunctions and void the waranty.
Uterine tissue may contain unsuspected cancerous tissue. The use of laparoscopic, motor-driven morcellators in hysterectomy and myomectomy, carries the risk of spreading cancerous tissue beyond the uterus, thereby reducing long-term patient survival. This information should be communicated to patients in advance of surgery when the use of motor-driven morcellators is being considered.

DURING USE

The device is not sterile on delivery. All sterilizable parts must be sterilized before use [Instrument preparation >33].
Operate the device only outside the danger zone of explosive, flammable mixtures or gases!
The motor ventilation slots must be kept clear in order to prevent the motor from overheating.
Disregarding the guidelines on intermittent operation (INT 1min/1min: 1 Min. ON / 1 Min. OFF, for 8 cycles, afterwards 15 Min. OFF) may cause burns at contact with the gear unit.
Never operate the clamping mechanisms of the cutting tubes while the system is running. This could result in instrument damage.
Keep hands clear of the cutting tubes when operating the device. Danger of serious injury.
The TCM 3000 BL Morcellator must be operated under the continuous supervision of medically qualified persons only.
Make sure that the operating voltage matches the mains voltage.

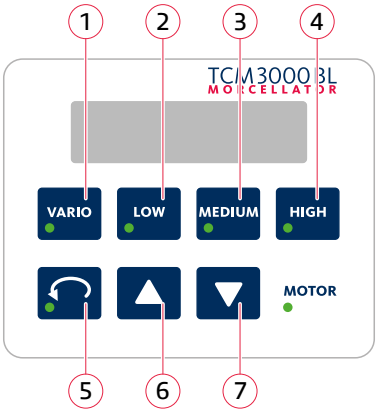
DEVICE OVERVIEW

Front view



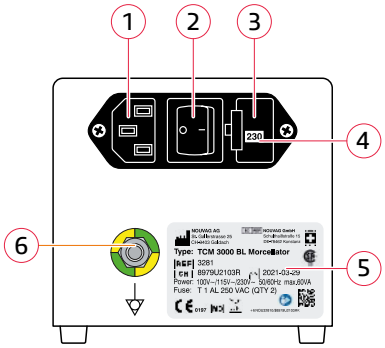
1 Display
2 Motor LED
3 Pedal connection
4 Motor connection (M)

Control panel



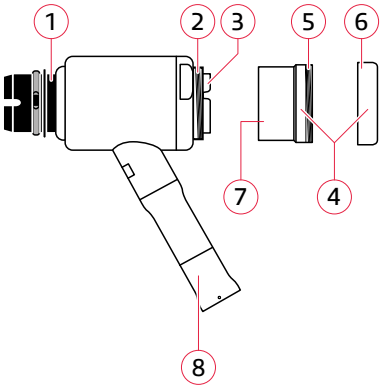
1 Key «VARIO» (variable speed range)
2 Key «LOW» (low speed range)
3 Key «MEDIUM» (medium speed range)
4 Key «HIGH» (high speed range)
5 Key «Changing rotation direction» (When changing the direction of rotation, the device emits a tone signal.)
6 Key «UP» (increase value)
7 Key «DOWN» (reduce value)

Rear view



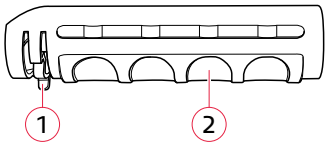
1 Mains connection
2 Power switch ON/OFF
3 Fuse compartment
4 Window with indication of
5 national voltage
6 Type plate with type designation, reference number, serial number, information on power supply and device fuse
7 Potential equalization

Gear unit



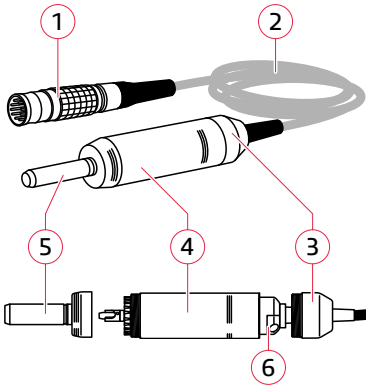
1 Flange for protective tube connection
2 Thread for seal holder
3 Cutting tube holder
4 Sealing unit with membrane screw
5 Thread for membrane screw
6 Membrane screw
7 Sealing unit thread
8 Motor connection coupling

Handle



1 Release lever
2 Handle

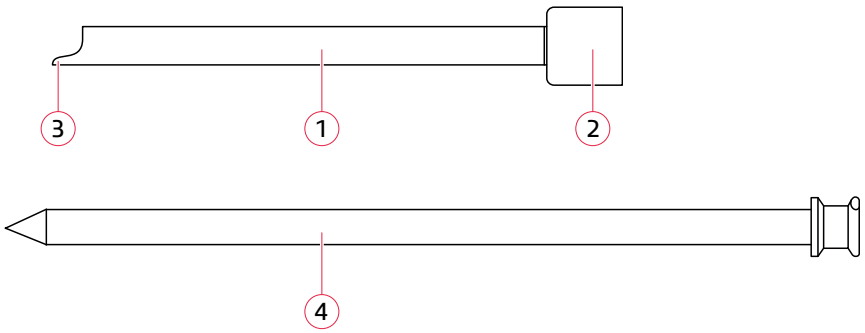
Motor



1 Device connection plug
2 Motor cable
3 Motor cap
4 Motor
5 Handpiece holder
6 Motor connection plug

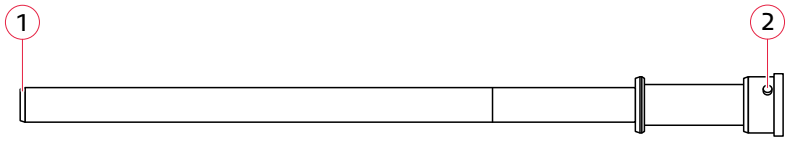
DEVICE OVERVIEW

PROTECTION TUBE WITH OBTURATOR



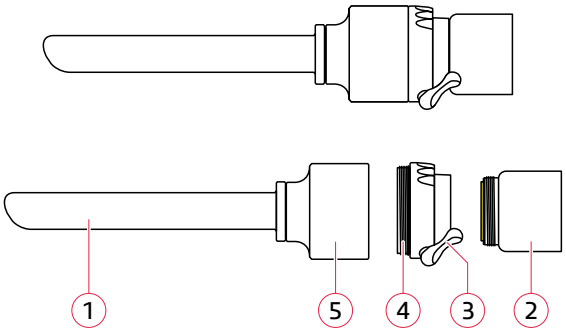
1 Protective tube
2 Locking nut
3 Nose to position tissue
4 Obturator

CUTTING TUBE



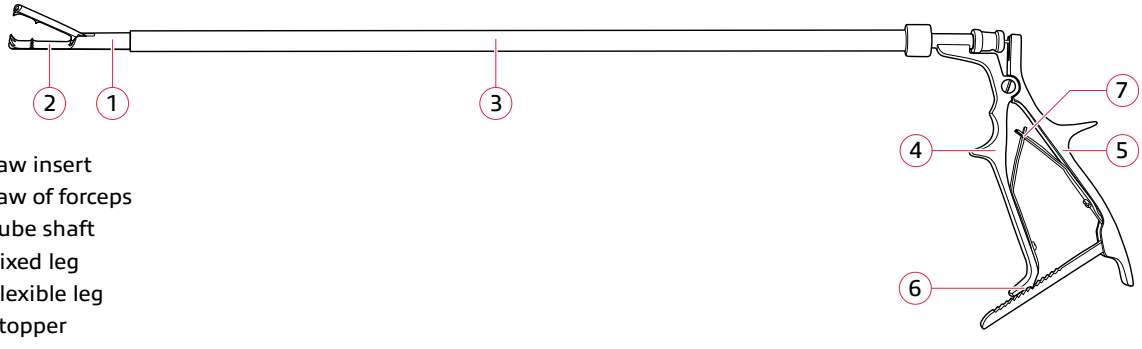
1 Cutting edge
2 Stopper pins

TROCAR SLEEVE



1 Protective tube
2 Seal cap holder
3 Valve actuation
4 Valve body
5 Main body

FORCEPS (OPTIONAL)

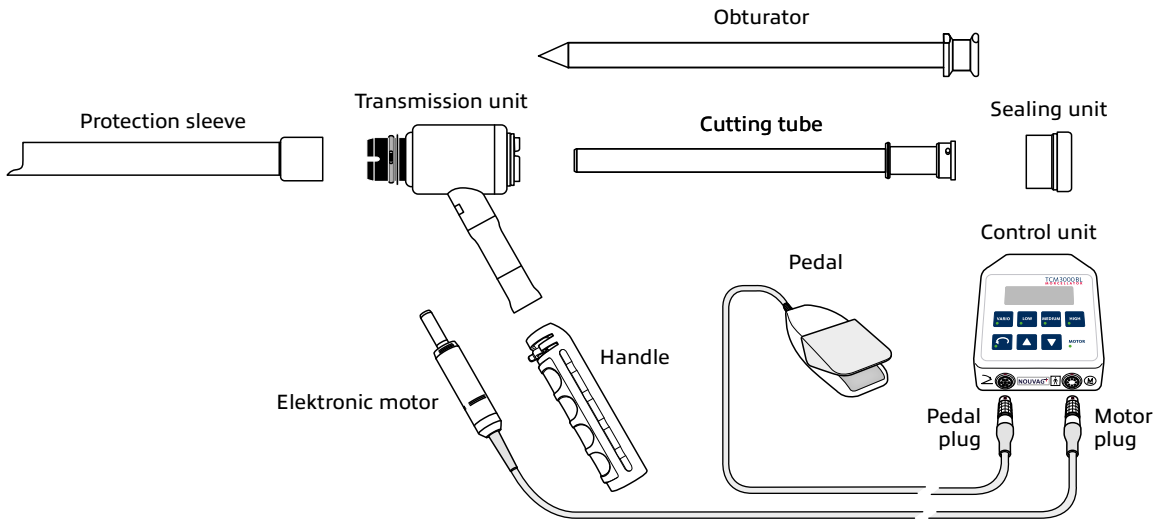


1 Jaw insert
2 Jaw of forceps
3 Tube shaft
4 Fixed leg
5 Flexible leg
6 Stopper
7 Spring component

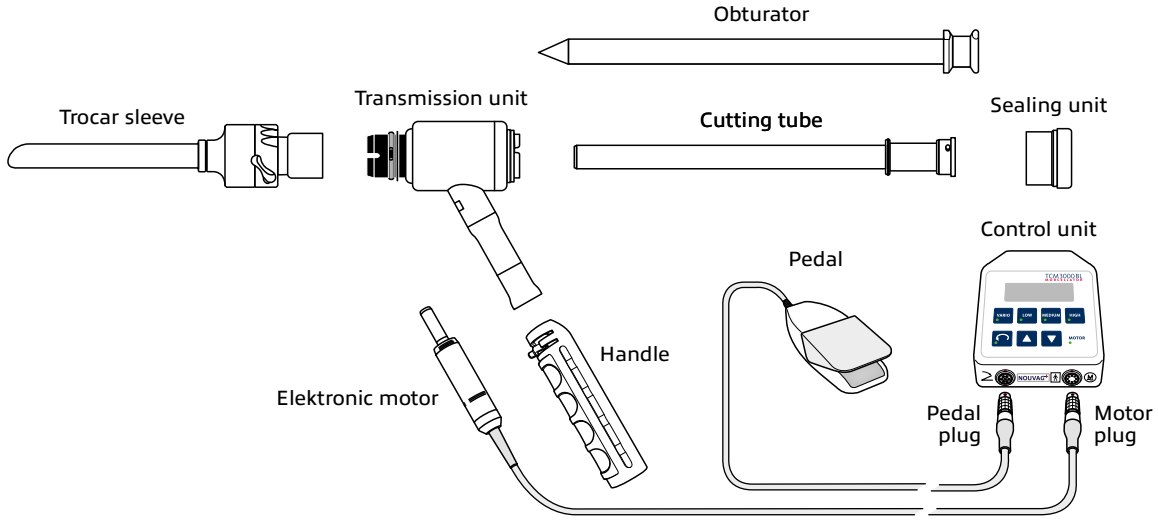
DEVICE OVERVIEW

SYSTEM-CHART TCM 3000 BL MORCELLATOR

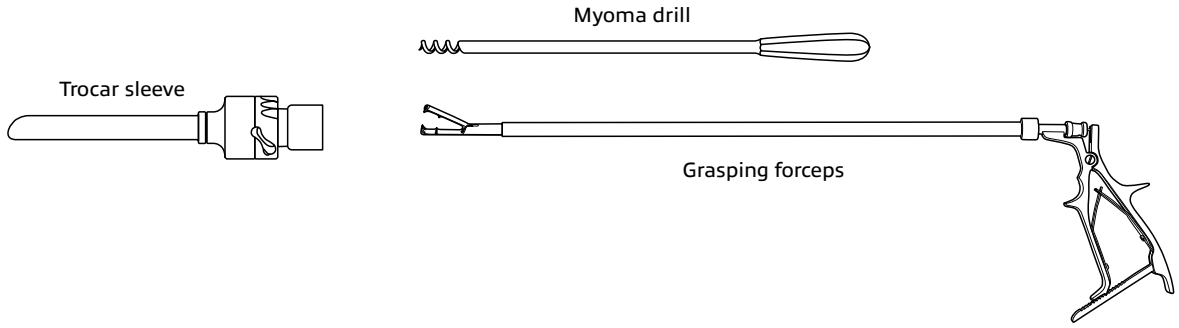
OPTION 1



OPTION 2



OPTION 3



BEFORE USE

The TCM 3000 BL Morcellator and all required accessories and instruments must be placed on a level nonslip surface. Do not allow the operating range of the device with cable to be restricted by limiting factors.
The display, keypad and indicator lights must be fully visible at all times.
It is very important to ensure that no objects can fall on the pedal. The power plug at the rear of the device must be accessible at all times.

POTENTIAL EQUALIZATION CONNECTION ACCORDING TO DIN 42801

At the back of the device a potential equalization plug is installed, according to DIN 42801.
The additional potential equalization has the task of equalizing potentials between different parts of conductive materials that can be touched at the same time, or reducing potential differences.
This connection must be used, to protect the patient, the user and third parties from touch voltages.
The equipotential plug is marked with the following symbol: ⏚

CONNECTION TO THE POWER SUPPLY

⚠ Before plugging the power cable into the power socket for the first time, you must check the supply voltage setting next to the power switch!

In order to prevent the risk of electric shock, the device may only be connected to a power network with a PE protective earth conductor.

If the voltage shown does not correspond to the local mains voltage, the Grey fuse holder must be set to the correct voltage:

1 **Switch the device off.**

2 **Unplug the power cable.**




3 **Use a screwdriver to open the fuse slot.**

4 **Remove the fuse holder.**

5 **Remove the Grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.**

6 **Slide the Grey fuse holder back in and close the fuse slot.**

7 **Check the mains voltage shown on the fuse slot.**

8 **Plug the power cable back into the device.**

DEVICE PREPARATION

⚠ The device is not sterile on delivery. All sterilizable parts must be sterilized before use [INSTRUMENT PREPARATION >33].

If the accessories have already been sterilized: when removing them from the sterile packaging, ensure that the sterile packaging is not damaged and that the sterility indicator confirms sterility and shelf life of the sterile item has not expired.

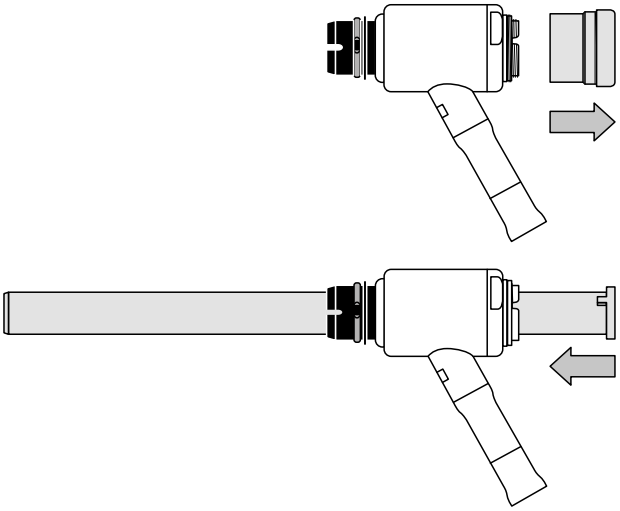
The morcellator must be assembled under sterile conditions (wear gloves and a mask, place morcellator and accessories on a sterile surface). Aseptic regulations must be observed.

BEFORE USE

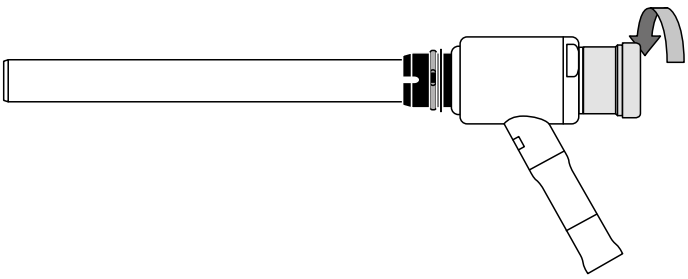
ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1)

There is a risk of injury to tissue by the sharp edge at the distal end of the cutting tube.
Handle the cutting tube carefully.
If the cutting tube is not used, rotate the protective tube to the **«NO CUT»** position.
If the cutting tube is not used, it must be placed on a flat, sterile surface so it cannot fall and cause injury.
Check the cutting tube.
Make sure that the cutting edge of the blade is sharp and undamaged (e.g. no cracks, deformation or burrs).
Use only cutting tubes in perfect condition.

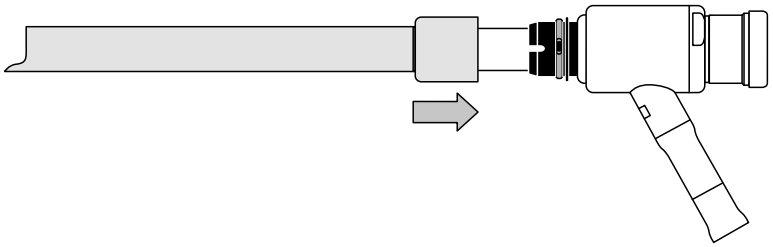
1 **Inserting the cutting tube through the gear unit**
Remove the sealing unit from the gear unit.
Insert the cutting tube through the gear unit.
The two guide pins on the cutting tube must fit into the slot on the flange of the gear unit.



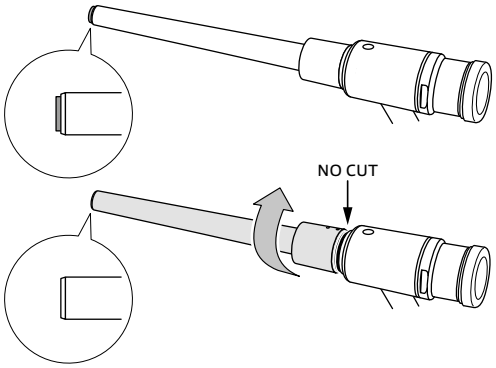
2 **Attaching the cutting tube to the gear unit**
Hold the cutting tube with one hand.
Connect the sealing unit to the gear unit with the bayonet closure with the other hand.



3 **Mounting protective tube**
Select a suitable protective tube.
Push the protective tube over the distal end of the cutting tube.
The guide pin of the protective tube must be in the distal slot of the gear unit.
Lock the protective tube in position with a click.

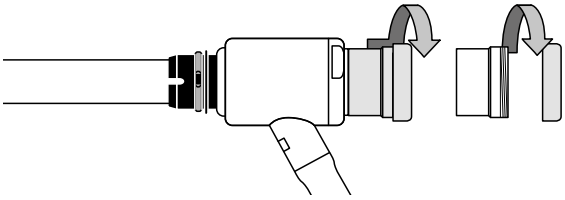


BEFORE USE



4 Protecting the cutting tube

The distal end of the cutting tube is very sharp.
To prevent injury, the cutting tube must be covered at all times when it is not in use.
To cover the cutting tube, rotate the protective tube until the words **«NO CUT»** are visible in the distal slot of the gear unit.
The cutting tube is completely covered by the protective tube.



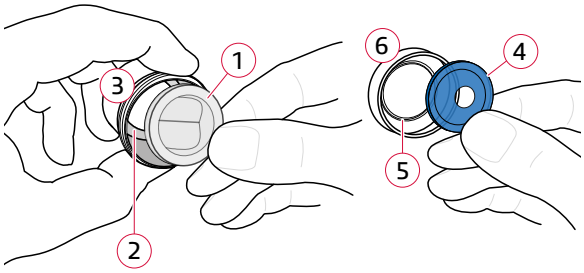
5 Replacing seals

Unscrew the sealing unit from the gear unit.
Unscrew the membrane positioning ring from the sealing unit.
There must be a top seal and a membrane seal.

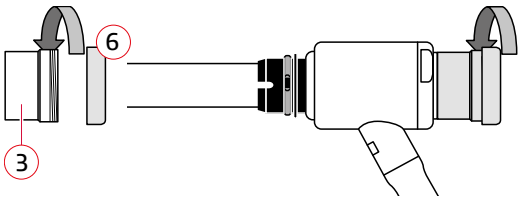
6 Replacing the seals of the sealing unit to use Ø 12/15 mm cutting tubes

Remove the sealing unit from the gear unit.

> Check seals before use.
> Do not use damaged seals (frayed, discolored, yellowed, porous, no longer elastic).

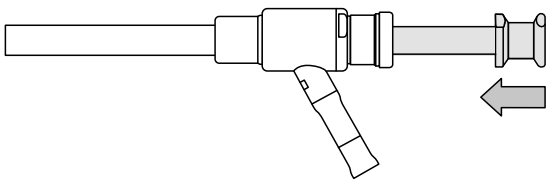


Unscrew the membrane screw from the sealing unit.
Position the edge of the roof shaped seal **(1)** to point to the inside stop **(2)** of the seal holder **(3)** and press the roof shaped seal in.
Position the edge of the membrane seal **(4)** to point to the slot **(5)** of the membrane screw **(6)** and press the membrane seal into the slot.
Screw the membrane screw **(6)** onto the thread of the seal holder **(3)** to the stop and connect the sealing unit to the gear unit.



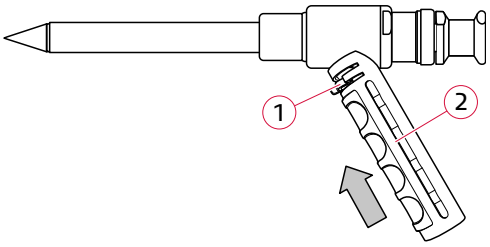
7 Inserting the obturator

Insert the obturator through the sealing unit, gear unit and protective tube up to the stop.



8 Attaching the handle

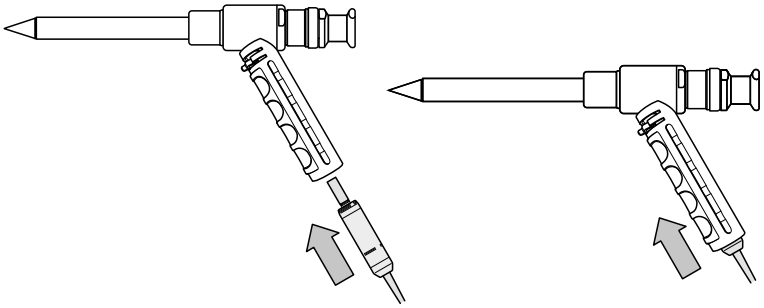
Lift and hold the release lever **(1)** of the handle **(2)**.
Push the handle **(2)** over the motor connection of the gear unit.
Release the handle release lever.
The handle release lever must lock in position.



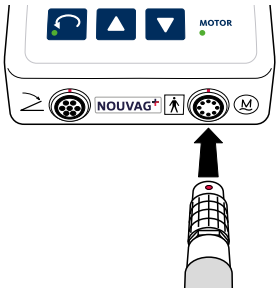
> Do not open the handle release lever to remove the handle during the procedure.

BEFORE USE

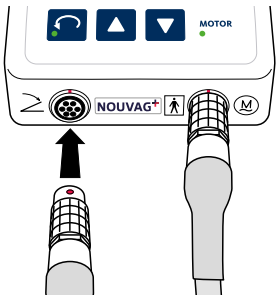
9 **Connecting the motor**
Insert the motor coupling into the bottom end of the handle.
Continue to insert the motor until it locks into the gear unit's motor connection.



Align the red dot on the device connection plug of the motor with the red dot on the motor connection of the control unit.
Plug the motor device connection plug into the motor connection of the control unit. The plug must lock in position.



10 **Connecting the pedal**
Align the red dot on the device connection plug of the pedal with the red dot on the pedal connection of the control unit.
Plug the pedal device connection plug into the pedal connection of the control unit. The plug must lock in position.



FUNCTIONAL CHECK

1 **Check morcellator for loose parts.**
2 **Check that morcellator is correctly assembled.**
3 **Are all labels easily readable?**
4 **Check cutting tube: cutting tube evenly ground, no broken edges or deformations?**
5 **Switch on control unit.**
6 **Switch on motor (press pedal).**
7 **Run motor with morcellator for about 20 seconds; it must reach the set speed.**
8 **If it does not run evenly, switch off motor with morcellator.**

The control unit will only operate if the pedal has been connected to the control unit.

1 **Switch off control unit.**
2 **Check that morcellator is correctly assembled.**
3 **Check that the gear unit runs smoothly; if necessary treat it with the lubricant spray.**
4 **Check that the electronic motor is clean and runs smoothly; if necessary clean it and treat it with the lubricant spray.**
5 **Repeat the function check.**

Risk of injury by motor failure!
Problem: the motor is heating up. Cause: the motor was damaged during preparation.
Remedy: do not continue to use the motor. Always have a spare motor available!

BEFORE USE

ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2)

The trocar sleeve is used instead of the protective tube. The integrated valve flap prevents gas from escaping when instruments are moved in and out.

The nose of the trocar sleeve partially extends beyond the cutting tube to protect organs in the abdominal cavity from the sharp blade. This requires the morcellator to be rotated under visual supervision (endoscopy) so the nose of the trocar sleeve covers the cutting tube blade to protect the organ.

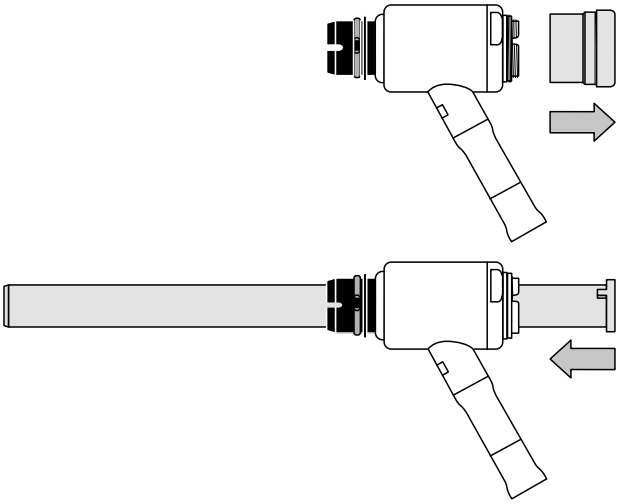
1 **Visual checks**

Check that the unit is sealed, sterile and free from corrosion.
Ensure that it is free from rust, dents and scratches.
The distal end of the obturator must not be damaged.
There must be no signs of damage on the seal valve or seal.

Check the blade. Ensure that the cutting edge of the blade is sharp and free of damage (e.g. tears or burrs).

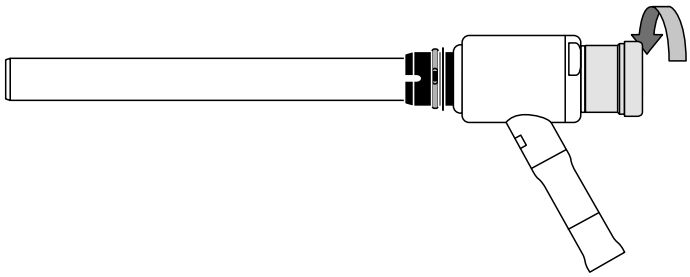
2 **Inserting the cutting tube through the gear unit**

Remove sealing unit from the gear unit.
Insert the cutting tube through the gear unit.
The two guide pins on the cutting tube must fit into the groove on the flange of the gear unit.



3 **Attaching the cutting tube to the gear unit**

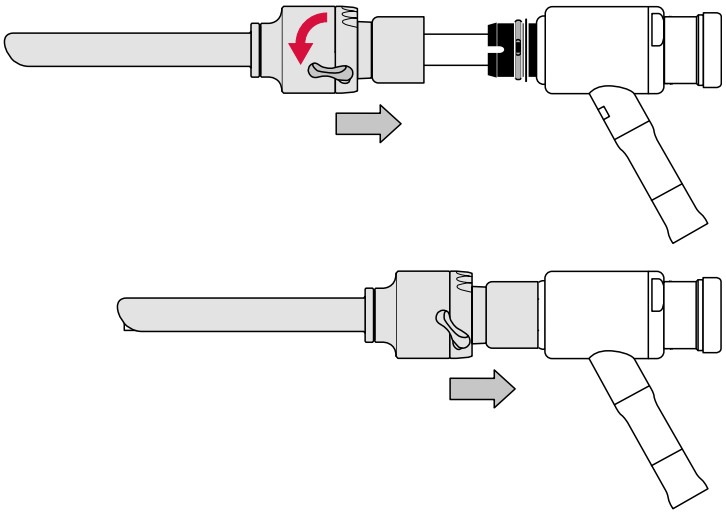
Hold the cutting tube with one hand.
With the other hand screw the sealing unit onto the gear unit.



BEFORE USE

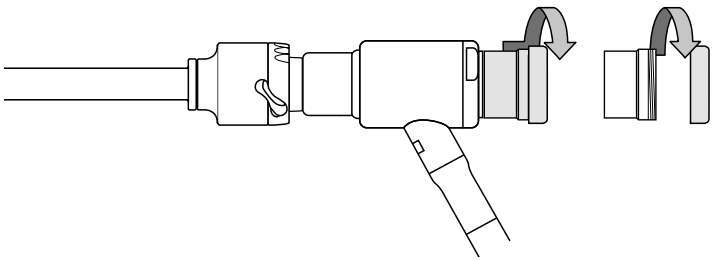
4 Assembling the trocar sleeve

Select a suitable trocar sleeve. Open the trocar sleeve valve by actuating the lever. This prevents damage to the cutting tube by pushing the trocar too far.
Push the trocar sleeve over the distal end of the cutting tube. The guide pin of the trocar sleeve must be in the distal slot of the gear unit.
Click the trocar sleeve into position.



5 Replacing seals

Unscrew the sealing unit from the gear unit.
Unscrew the membrane positioning ring from the sealing unit.
There must be a top seal and a membrane seal.

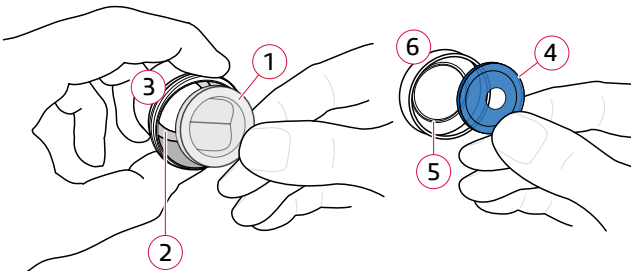


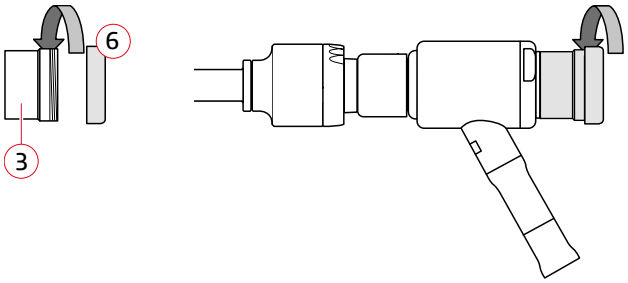
6 Replacing the seals of the sealing unit to use Ø 12/15 mm cutting tubes

Unscrew the sealing unit from the gear unit.

> ⚠ Check seals before use.
> Do not use damaged seals (frayed, discoloured, yellowed, porous, lack of elasticity).

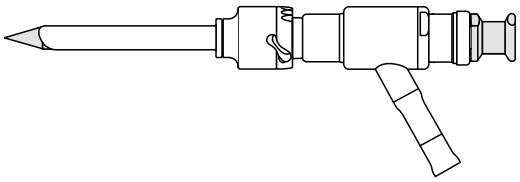
Unscrew the membrane positioning ring from the seal holder.
Face the edge of the top seal **(1)** towards the inside resting edge **(2)** of the seal holder **(3)** and press the top seal into the groove in the thread.
Face the edge of the membrane **(4)** towards the groove **(5)** of the membrane positioning ring **(6)** and press the membrane seal into the groove.
Screw the membrane positioning ring **(6)** into the thread of the seal holder **(3)** until it stops. Then screw the entire sealing unit onto the gear unit.



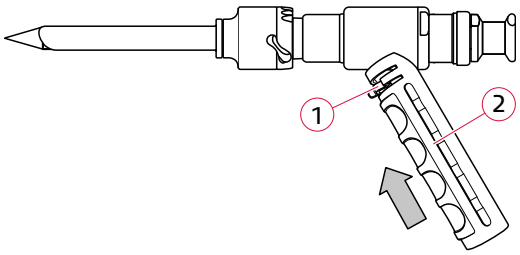


BEFORE USE

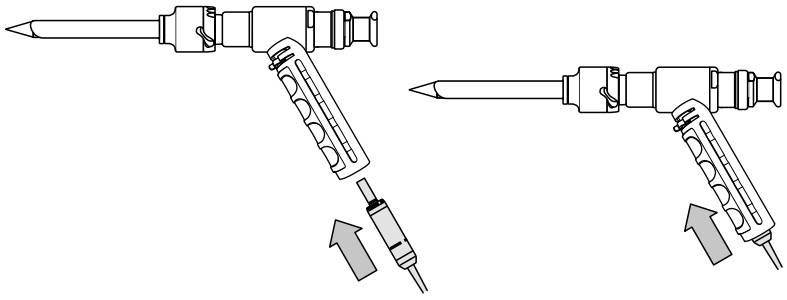
7 **Inserting the obturator**
Introduce the obturator through the sealing unit, gear unit and protective tube until its stops.



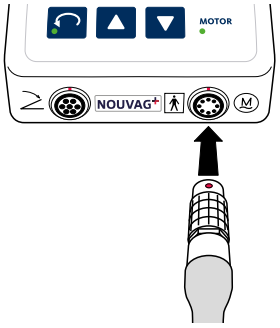
8 **Attaching the handle**
Lift and hold the release lever **(1)** of the handle **(2)**.
Push the handle **(2)** over the motor connection of the gear unit.
Release the handle release lever.
The handle release lever must lock in position.



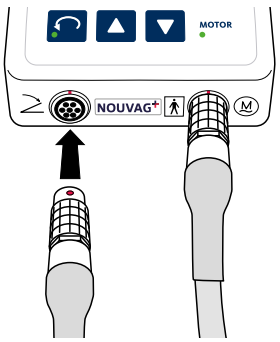
9 **Connecting the motor**
Insert the motor coupling into the bottom end of the handle.
Continue to insert the motor until it locks into the gear unit's motor connection.



Align the red dot on the device connection plug of the motor with the red dot on the motor connection of the control unit.
Plug the motor device connection plug into the motor connection of the control unit. The plug must lock in position.



10 **Connecting the pedal**
Align the red dot on the device connection plug of the pedal with the red dot on the pedal connection of the control unit.
Plug the pedal device connection plug into the pedal connection of the control unit. The plug must lock in position.



BEFORE USE

FUNCTIONAL CHECK

1 **Check morcellator for loose parts.**

2 **Check that morcellator is correctly assembled.**

3 **Are all labels easily readable?**

4 **Check cutting tube: cutting tube evenly ground, no broken edges or bends?**

5 **Switch on control unit.**

6 **Switch on motor (press pedal).**

7 **Run motor with morcellator for about 20 seconds; it must reach the set speed.**

8 **If it does not run evenly, switch off motor with morcellator.**

The control unit will only operate if the pedal has been connected to the control unit.

1 **Switch off control unit.**

2 **Check that morcellator is correctly assembled.**

3 **Check that the gear unit runs smoothly; if necessary treat it with the lubricant spray.**

4 **Check that the electronic motor is clean and runs smoothly; if necessary clean it and treat it with the lubricant spray.**

5 **Repeat the function check.**

Risk of injury by motor failure!
Problem: the motor is heating up. Cause: the motor was damaged during preparation.
Remedy: do not continue to use the motor. Always have a spare motor available!

ASSEMBLING THE FORCEPS (OPTION 3)

Forceps are available in various designs. The pair shown here is not supplied with the morcellator kit; it is an optional accessory. The forceps come with a detailed assembly and preparation guide.

BEFORE USE

CONNECTION TO THE POWER SUPPLY

Connect this device only to a grounded AC mains supply that complies with IEC guidelines. Only connect the device to a power supply that corresponds to the connection values on the type plate on the rear of the device.

Do not switch on the control unit and other equipment until all cables have been connected. Otherwise, the equipment may be damaged.

The device is not splash water protected. Protect the device from liquids. Keep the mains connection socket dry. If liquid enters the device, do not use the device.

CONNECT POWER CABLE

1 **Switch off the power switch on the rear of the device (Position «O»).**

2 **Plug the supplied power cable into the socket on the back of the device.**

3 **Plug the other end of the power cord into the power outlet.**

USE

PRIOR TO USE

Make sure that the product has been correctly prepared and inspected.

> ⚠ The TCM 3000 BL Morcellator control unit has been designed for operation with the morcellation blades as a set. The user is solely responsible if different products are used with the set. Incompatibility may risk injury to patients.

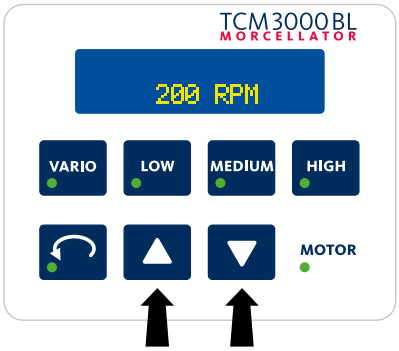
SWITCHING ON AND OFF

1 **Switch on the control unit.**
The display lights up. A short signal tone is emitted.
The control unit displays the speed value «200 RPM» (U/min.).

OPERATING MODE (MOTOR)

The motor is designed for intermittent operation.
(INT 1min/1min: 1 Min. ON / 1 Min. OFF, for 8 cycles, afterwards 15 Min. OFF)

USING THE CONTROL UNIT



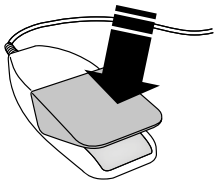
SETTING THE SPEED

The speed can be set manually in stages (within a range of 50 to 1000 rpm).

1 **Press «▲» to increase the speed.**

2 **Press «▼» to reduce the speed.**
The set speed is shown on the display.

STARTING THE MOTOR



1 **Press pedal.**
The blade rotates at the adjusted speed.
The motor LED lights up.

2 **To stop the motor, take your foot off the pedal.**

> ⚠ Risk of injury and damage due to heat! The morcellator may generate heat if operated for a long period.
>
> Remedy:
> Use morcellator only in intermittent mode of «(INT 1min/1min: 1 Min. ON / 1 Min. OFF, for 8 cycles, afterwards 15 Min. OFF)».
>
> Stop the morcellator immediately if one or more components of the morcellator set become very warm.
>
> Precaution when changing parameters. Unusual behavior of the instruments while operating may provoke false reactions and jeopardize the patient.
>
> Each setting must be checked and the new behavior of the instrument must be familiarized with.

USE

AVAILABLE SPEED MODES

- ¬ «LOW» (low, 100 – 400 rpm)
- ¬ «MEDIUM» (medium, 300 – 700 rpm)
- ¬ «HIGH» (high, 500 – 1000 rpm)

ACTIVATING MODE SETTING

1 **Press «VARIO» to activate mode setting.**
The «VARIO» LED lights up.
The «LOW» LED lights up. (default setting)
The display shows «VARIO LOW, 100 – 400 rpm».

SELECTING MODE

1 **Press «LOW», «MEDIUM» or «HIGH» to select the corresponding mode.**
The display shows the mode and the corresponding speed range that can be selected with the pedal.
The corresponding LED lights up.

STARTING THE MOTOR

1 **Press pedal.**
The motor LED lights up.
The blade rotates at a speed within the range, set by how far down the pedal is pressed.

2 **To stop the motor remove foot from pedal.**

EXIT MODE SETTING

1 **Press «VARIO».**

CHANGING DIRECTION OF ROTATION

1 **To change the direction of rotation, press «».**
The device confirms the change of rotation direction with a signal tone and on the display it is symbolized with two arrows.
The display shows the mode and the corresponding speed range that can be selected with the pedal.
The corresponding LED lights up.

The values shown on the display are speed ranges that can be called up using the pedal.
In operation the display does not show any current speed values.

The values described can deviate from the actual values by a maximum of ± 10 %.

USE

PROCEDURE

Risk of death or serious injury!
Unsupervised cutting may injure the abdominal wall and organs and can cause the death of the patient.

Remedy:
Before every procedure make sure that an endoscopic procedure is preferable to a conventional procedure.

Use only the products described in this manual.

During the procedure, use the protective tube or trocar sleeve as a precautionary measure. Refer to Section [Assembling the morcellator kit with the protective tube (option 1) >14] and [Assembling the morcellator kit with the trocar sleeve (option 2) >17].

Use the morcellator under visual control (endoscope) only.

Use the morcellator only for the morcellation of tissue that has been fully prepared and is clearly visible. NOUVAG accepts no liability for any other applications.

NOUVAG also recommends the use of a second gripper or a similar retaining device to prevent uncontrolled movement of large morcellator pieces of tissue. This will require an additional percutaneous access.

Fix the morcellator in a ventrolateral position to prevent movements inside the uterus.

Prevent movement towards the lateral blood vessels, kidneys and retroperitoneum.

Use the gripping forceps to pull the tissue to be morcellated to the rotating blade.

Risk of injury due to gas loss!
Gas loss may occur during the procedure. This can lead to a subsidence of the abdominal wall.

Select an inflator with a sufficient flow rate to prevent sagging of the abdominal wall.

Using the morcellator with the protective tube, following Option 1: When removing or replacing instruments, immediately close the proximal opening of the seal unit with your thumb.

Use with the trocar sleeve, following Option 2: Pull the morcellator complete with cutting tube out of the trocar sleeve. The trocar sleeve valve closes to prevent gas loss.

After removing the morcellated tissue, insert the morcellator into the trocar sleeve and repeat the process.

The morcellator system is designed for removing tissue with the greatest possible safety. For this purpose the system is fitted with a valve flap.

The morcellation without the protection tube or trocar sleeve is prohibited!

Tissue escapes the gripper!
Tissue may escape the gripper during the procedure and fall into the abdominal cavity.

Causes:
The tissue is not gripped tightly enough or the type of gripper is not suitable.

Remedy:
Grip the tissue at a different position.

Press the jaws of the gripper together as tightly as possible.

Risk of injury due to frictional heat!
When using on patients, the user must urgently ensure that as little frictional heat as possible is generated. High speeds and high contact pressure can lead to thermal narcotization of the tissue.

USE

The distal end of the cutting tube is extremely sharp.

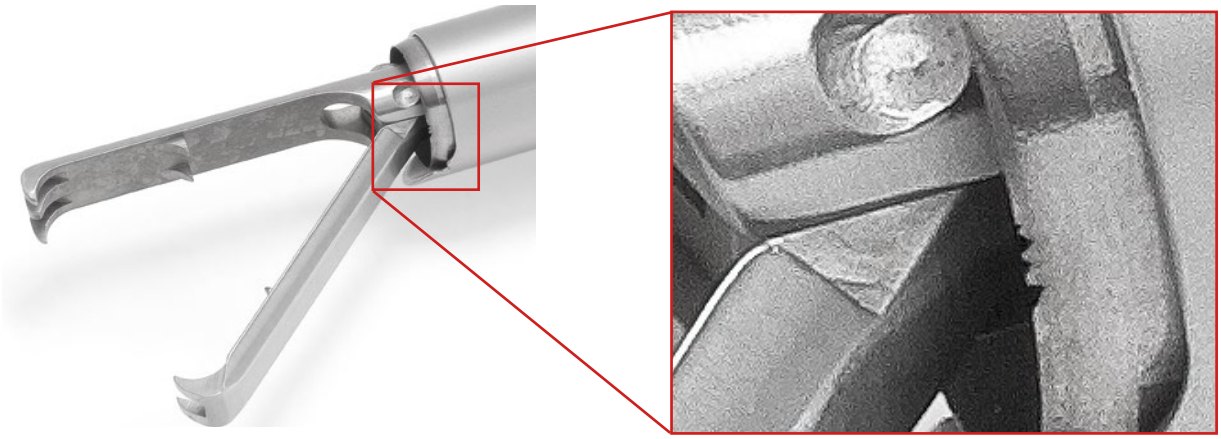
Precautions:
Handle the cutting tube particularly cautiously and carefully.

Where possible, have the morcellator with protective tube in protected position **«NO CUT»**, particularly if the cutting tube is not used for any period.

Insert and remove the protection tube and cutting tube under visual control (endoscopy).

When inserting the obturator through the percutaneous access, there is risk of injury to blood vessels, intestinal loops or the bladder. This can result in significant complications, which will require a Laparotomy.

Risk of damage to the blade of the cutting tubes!
If the jaws of the gripper is not completely closed when it is pulled out of the protective tube, the blade will be damaged (see pictures).



Damaged blades and cutting tubes must not be used!

Cutting tubes must not be resharpened!

USE

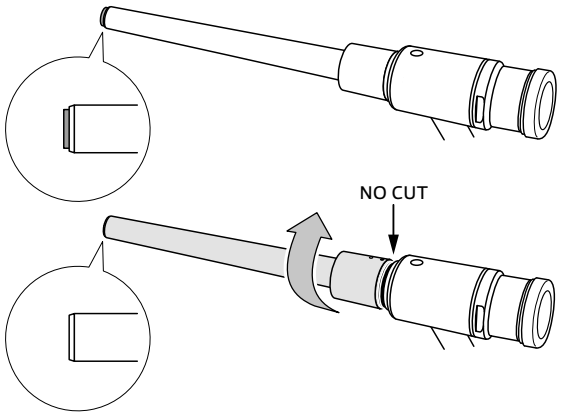
OPTION 1 – MORCELLATION WITH PROTECTION TUBE

HYSTERECTOMY

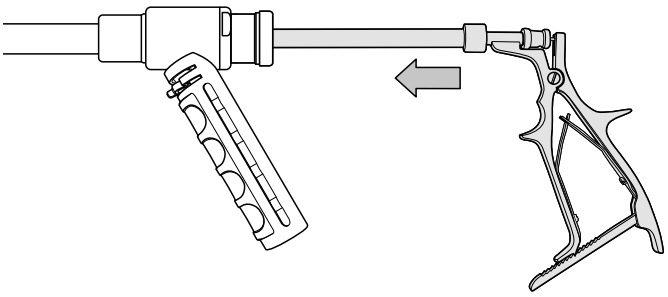
1 **Select the procedure for the hysterectomy in accordance with current medical standards.**

2 **Inserting the cutting tube**
Make sure that the obturator is inside the cutting tube.
Make sure that the protection tube covers the blade of the cutting tube (set position to **«NO CUT»**; **«PROTECTED»** is also shown on the black ring between the gear unit and protection tube).
Insert the morcellator with the obturator in the protection tube under visual control (endoscopy) into an existing percutaneous access.

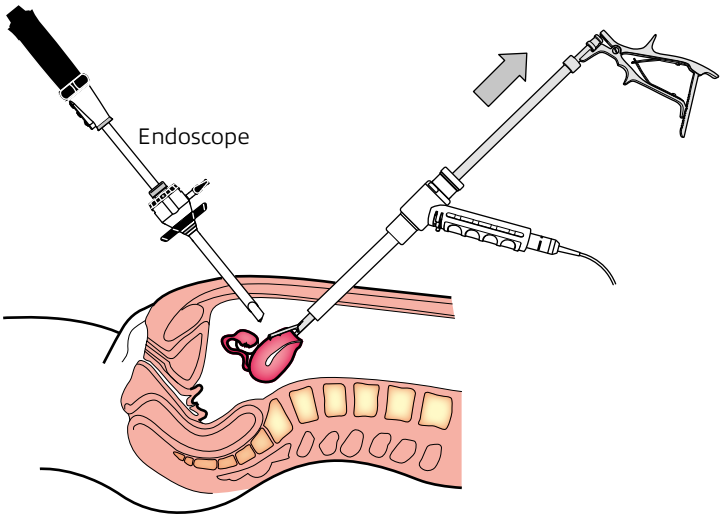
3 **Using cutting tube**
To use the cutting tube, rotate the protection tube to uncover the blade of the cutting tube (unprotected **«CUT»** position is displayed).
To cover the blade again, rotate the protection tube (protected, **«NO CUT»** position is displayed; **«PROTECTED»** is also shown on the black ring between the gear unit and protective tube).



4 **Inserting the gripper**
Pull the obturator out of the protective tube.
Close the proximal opening of the gear unit immediately with your thumb.
Insert gripper carefully under visual control (endoscopy)through the proximal opening of the gear unit.



5 **Removing tissue**
Grasp the tissue with the gripper under good visual control (endoscopy).
Activate the handle detent.
Start the motor of the morcellator by pressing the pedal.
Pull the tissue, using the gripper, towards the rotating blade of the morcellator.
As the cut progresses pull the gripper with the tissue further out of the morcellator.
Carefully pull the complete gripper with the separated tissue out of the morcellator and the patient. The retracted mouth must not touch the blade of the cutting tube.
Repeat the process until the tissue has been completely removed.
Make sure that the proximal opening of the sealing unit is closed immediately with your thumb when there is no instrument in the morcellator to prevent large quantities of gas from escaping.



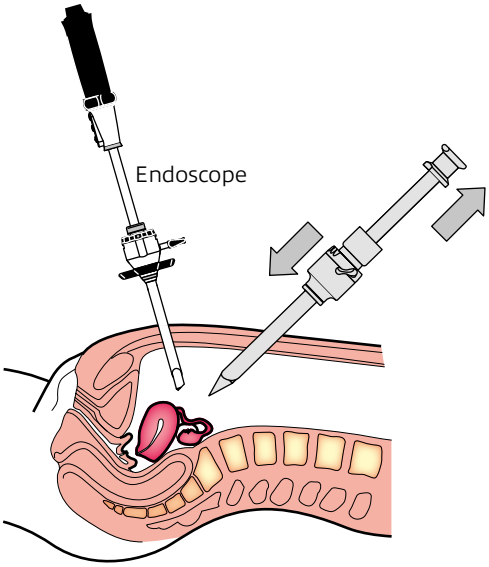
USE

OPTION 2 – MORCELLATION WITH TROCAR SLEEVE

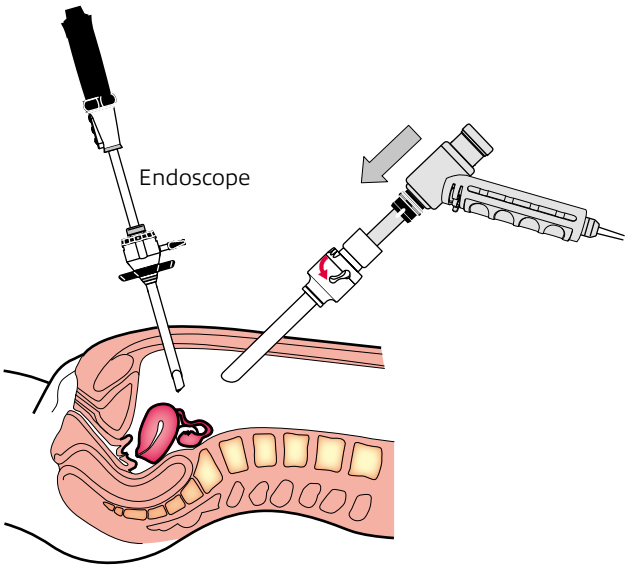
HYSTERECTOMY

1 **Select the procedure for the hysterectomy in accordance with current medical standards.**

2 **Inserting the trocar sleeve**
Insert the trocar sleeve with obturator into an existing access under visual control (endoscopy).
Remove the obturator.

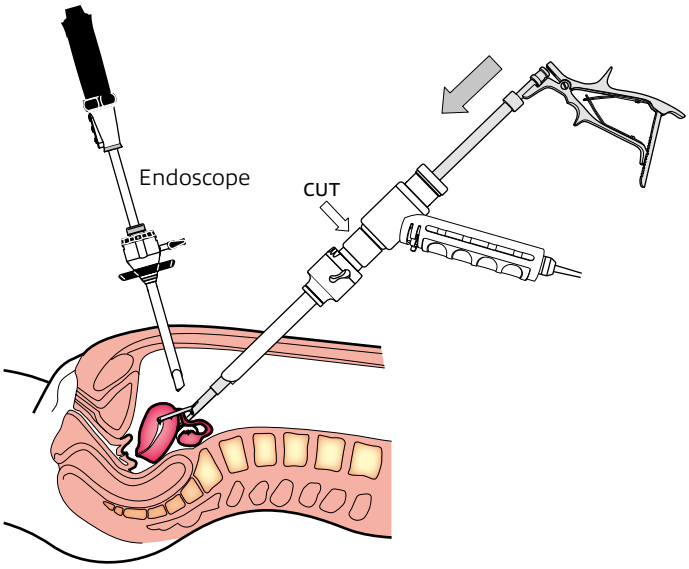


3 **Inserting the cutting tube through the trocar sleeve**
Actuate the valve flap lever of the trocar sleeve and hold in this position.
Carefully insert prepared cutting tube with gear unit and seal unit into the proximal opening of the trocar sleeve.
The cutting tube must be fully inserted.
Release the valve flap lever of the trocar sleeve.
The guide pin of the trocar sleeve must be in the distal slot of the gear unit.
Click the trocar sleeve into position.
Make sure that the cutting tube remains in the **«NO CUT»** position.



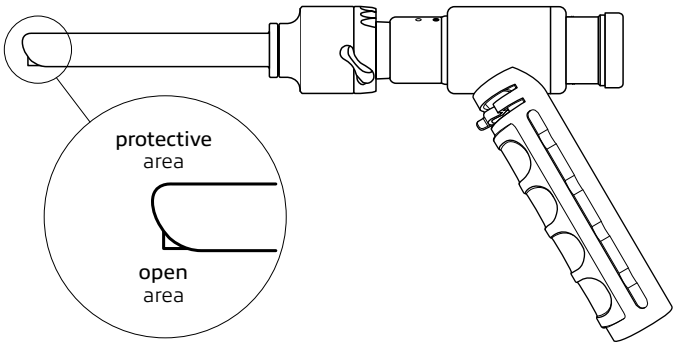
4 **Inserting the forceps**
Carefully insert forceps through the proximal opening of the gear unit and trocar sleeve.

5 **Preparing the cutting tube**
Rotate the trocar sleeve so the **«CUT»** position is visible from above.
When the cutting tube is completely inserted, the cutting edge is now only partially covered by the trocar sleeve.

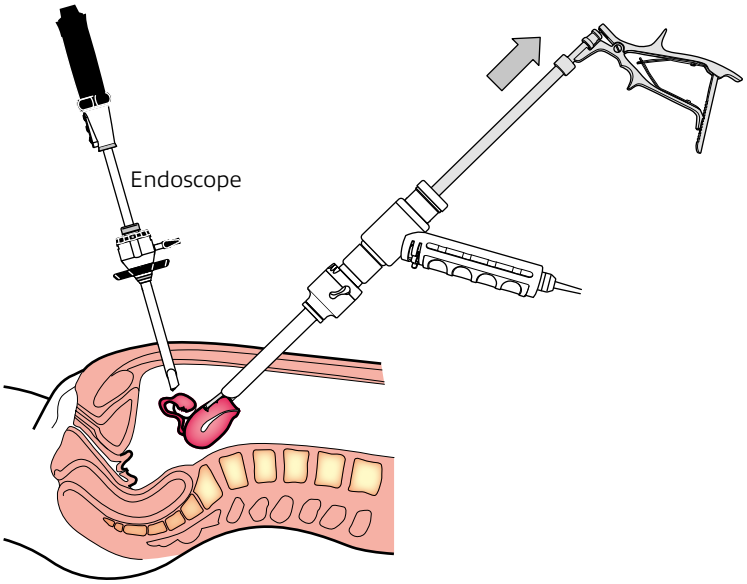


USE

6 **Protecting the tissue**
The nose on the trocar sleeve, which partially covers the sharp edge of the blade, must protect tissue that must not be damaged. To do this, turn the morcellator to the desired position.



7 **Removing the tissue**
Grab the required tissue with the forceps.
Set the handle lock.
Start the motor of the morcellator kit.
Use the forceps to pull the tissue to be removed towards the rotating blade.
Pull the forceps out of the patient through the gear unit. The retracted jaws of the forceps must not touch the blade.
Repeat the process until the tissue has been completely removed.

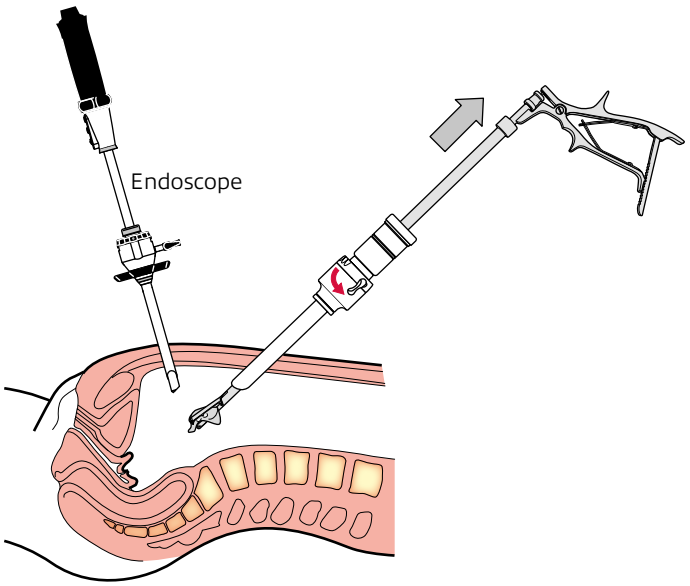


REMOVING TISSUE WITHOUT THE USE OF THE GEAR UNIT (ACCORDING TO OPTION 2)

The trocar sleeve is very well suited for removing additional tissue from the abdominal cavity through a percutaneous approach. To do this, place the sealing adapter on the trocar sleeve and screw the sealing unit onto the sealing adapter.

1 **Insert the forceps under arthroscopic observation through the sealing unit and the opened trocar sleeve into the abdominal cavity.**

2 **Grab the tissue with the forceps and pull it out through the trocar sleeve and seal unit.**



USE

OPTION 3 – MYOMECTOMY

The myoma drill has been designed exclusively for removing tissue from a myoma.

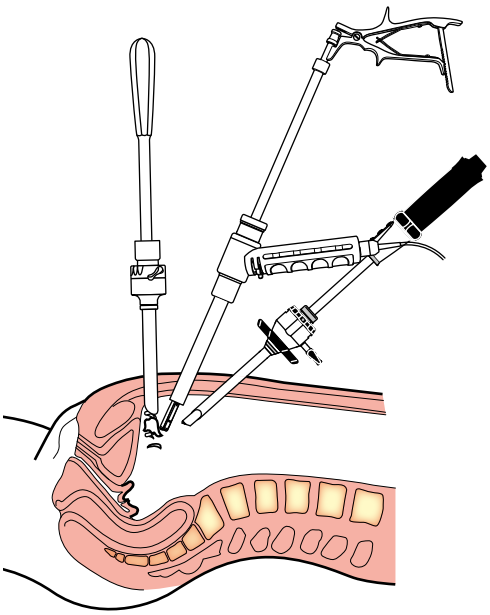
For a myomectomy, only the trocar sleeve (REF 5141nou) with a diameter of 12 mm may be used together with the myoma drill.

1 **Inserting the morcellator**
Insert the morcellator with protective tube through the percutaneous access.
Keep the forceps ready to remove the tissue from the myoma drill.

2 **Inserting the myoma drill**
Insert the trocar sleeve through an additional percutaneous access.
Open the valve flap of the trocar sleeve and insert the myoma drill.

3 **Uncovering the myoma**
Remove tissue from the myoma with the myoma drill.

4 **Inserting the forceps**
Insert the forceps through the second percutaneous access and remove the separated tissue from the myoma drill.
Remove the myoma drill.



5 **Removing separated tissue**
If the piece of tissue is larger than the diameter of the cutting tube, start the motor of the morcellator kit.
Use the forceps to pull the removed tissue towards the rotating blade. (Smaller pieces of tissue can be removed without morcellation)
Carefully pull the forceps fully out of the gear unit and out of the patient. The retracted jaws must not touch the blade of the cutting tube.

6 **Removing additional tissue**
If necessary, re-insert the myoma drill and repeat the above process.

USE

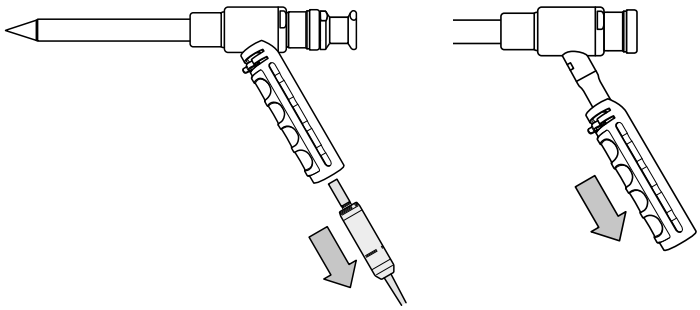
AFTER USE

1 **Switch the device off using the power switch at the back of the device (“O” position on the power switch).**

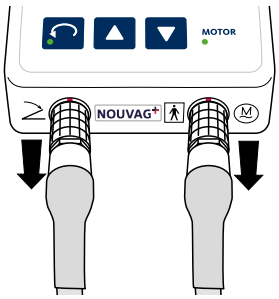
2 **Remove the protective tube (if using the morcellator with the protective tube)**
Rotate protection tube to the **«NO CUT»** position.
Close the proximal opening of the gear unit with your thumb to prevent of gas loss.
Hold the protection tube with one hand and carefully detouch the gear unit together with the cutting tube and remove it from the patient.
The protection tube can now also be removed from the percutaneous access.
If applicable, remove any other instruments.

3 **Removing the cutting tube (if using the morcellator with the trocar sleeve)**
Close the proximal opening of the seal unit with your thumb to prevent gas loss.
Hold the trocar sleeve and carefully disconnect the gear unit with cutting tube from the trocar sleeve. Remove from the patient. The valve flap closes automatically as soon as the cutting tube is pulled out.
The trocar sleeve can remain as access throughout the rest of the procedure.

4 **Disconnecting gear unit connections**
Pull the motor device connection plug from the motor connection of the control unit.
Pull the motor coupling from the gear unit’s motor connection.
Pull the motor out of the handle.
Lift and hold the locking lever of the handle.
Remove the handle from the gear unit’s motor connection.



5 **Remove connections of the pedal and the motor**
Disconnect the connection plugs of the pedal and the motor from the control unit.



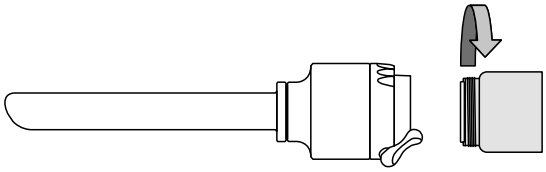
6 **Before preparation at the location of use**
Take the product to the preparation area immediately.
Prepare the product as specified in this instructions for use.

USE

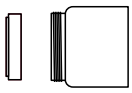
DISASSEMBLING THE TROCAR SLEEVE

Disassemble the trocar cannula before decontamination. Dismantle the trocar cannula and rinse in deionised water during disassembly.

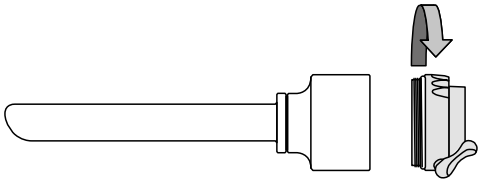
1 **Unscrew sealing cap holder from the proximal end of the trocar sleeve.**



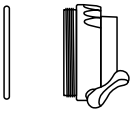
2 **Remove the internal seal from the sealing cap holder.**



3 **Unscrew the valve body from the main body.**

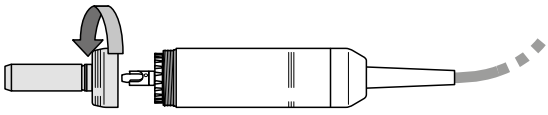


4 **Remove the red O ring from the valve body.**

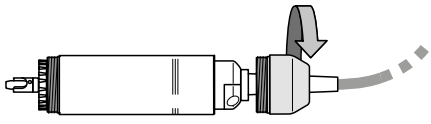


DISASSEMBLING THE MOTOR

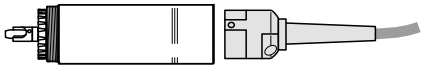
Disassemble the motor before decontamination.



1 **Unscrew handpiece holder from motor.**

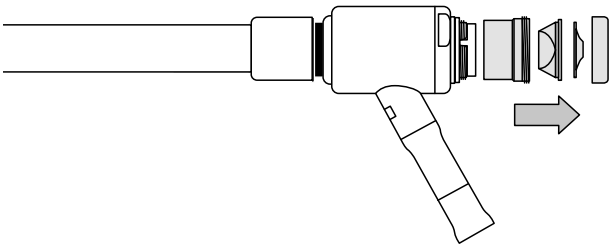


2 **Unscrew motor cap from the motor.**



USE

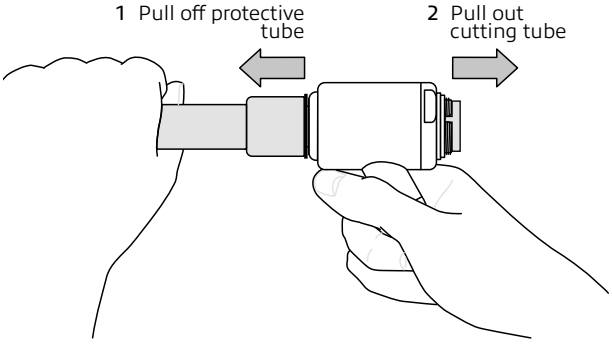
3 **Pull motor plug from motor.**



DISASSEMBLY OF THE GEAR UNIT AND MORCELLATOR WITH PROTECTION TUBE

1 **Disassembling of the sealing unit**
Remove membrane screw from the sealing unit and remove membrane seal.
Remove the seal retainer from the gear unit and remove the roof shaped seal.

> The distal end of the cutting tube is very sharp. Handle the cutting tube with particular care.



2 **Disassembling the protective tube and cutting tube**
Make sure that the lock nut of the protective tube covers the distal end of the cutting tube (protected **«NO CUT»** position is visible).
Hold the gear unit with one hand so the distal end of the cutting tube does not point to the user or any other person.
With the other hand carefully disconnect the protection tube from the gear unit and pull it off.
Hold the cutting tube with the same hand and press it slightly against the gear unit until it releases itself from the holder and slides out smoothly. It can now be pulled out of the proximal opening of the gear unit.

INSTRUMENT PREPARATION

Risk of infection!
Prepare the product before its first use and before every subsequent use as specified in this manual. Inadequate and/or incomplete preparation of the product may cause an infection of the patient. Observe the following specific instructions.

Do not clean morcellator with compressed air!
In the case of unwrapped steam sterilization, care must be taken to ensure that individual parts receive a firm fit in the sterilization basket so that they are not damaged by rolling around.
Allow the morcellator to cool down after steam sterilization!

Immersing instruments in cleaning solution.
Never exceed the maximum concentration and exposure time specified by the manufacturer of the cleaning and disinfection solution.
Air bubbles must not adhere to the instrument.
All components of the instrument must be completely immersed in the cleaning solution.
All lumina of the instrument must be completely filled with cleaning solution and must be free of bubbles.

Do not use cleaning solutions that contain solvents.
If sterilized accessories are not used immediately, a sterilization indicator must be placed in the packaging and it must be labeled with the sterilization date.

Perform cleaning, disinfection and sterilization after every treatment.
To autoclave single items, such as cutting tubes, NOUVAG recommends the use of sterilization packages to prevent of damage.
Make sure that the sterilization packaging is not more than 80 % filled.
Autoclave material for at least 5 minutes at 134°C.
If sterilized material is not used immediately, the sterilization packaging must be labeled with the sterilization date.
NOUVAG recommends including a sterility indicator.

CONTROL UNIT AND PEDAL

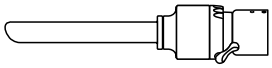
The control unit and pedal do not come into contact with the patient.
Wipe the outside using micro-biologically tested surface disinfectant or a 70 % -Isopropyl alcohol solution. The front plate of the control unit is sealed accordingly for this purpose and can be wiped clean.

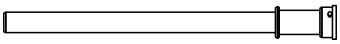
Risk of damage!
Do not use incompatible preparation methods. The product may be damaged.

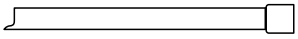
Risk of damage to the TCM 3000 BL Morcellator control unit!
Wipe away dirt or dust with a soft cloth.
Use a moist cloth for stubborn dirt.

INSTRUMENT PREPARATION

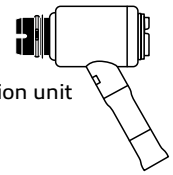
THE FOLLOWING PRODUCTS MUST BE REPROCESSED


Trocar sleeves

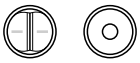

Cutting tubes

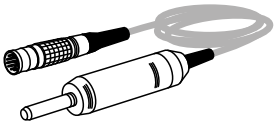

Protection sleeves

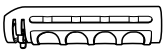

Sealing adapter


Transmission unit

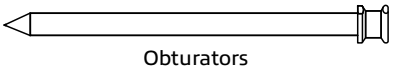

Seal unit

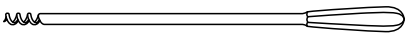

Roof shaped seal and membrane seals


Electronic motor


Handle


Spray adapter with thread


Obturators


Myoma drill

Reprocessing restrictions	Long waiting times before reprocessing are to be avoided because of the risk of drying and corrosion. Keep the products moist after use so that contamination cannot dry on. The period of time between use and preparation of the products should not exceed 2 hours. Frequent reprocessing has little effect on the products. The end of product life is usually determined by wear and tear and damage through use. In case of excessive use, the end of the product life may also be reached before the specified sterilization cycles. The product lifespan of the individual products is listed below: **250 sterilization cycles**: gear unit and the electronic motor For the handle, protection tubes, obturators, trocar sleeves, sealing unit, threaded spray adapter and cutting tubes, normal wear determines the service life. The service life of the roof seal, membrane seals, plug-in spray adapter supplied with the spray can depend on use, handling and the condition of the material.
General handling	1. Mentioned products must be thoroughly cleaned, disinfected and sterilized before they are used for the first time (brand new products) and immediately after each use. Only cleaned and disinfected products enable correct sterilization! 2. The products must always be handled with the utmost care during transport, cleaning, care, sterilization and storage. 3. We recommend the use of mildly alkaline and enzymatic cleaners with the lowest possible amount of silicate in order to avoid staining (silicate formation) on the products. 4. Only commercially available, DGHM / VAH-listed agents may be used for cleaning and disinfection. The method of use, exposure time and suitability of disinfecting and cleaning substances can be found in the information provided by the manufacturers of these agents. 5. The operating instructions for the devices and chemicals, etc. used in the reprocessing must be strictly observed. 6. The dosage of chemicals, exposure times and exposure temperatures during cleaning and disinfection must be strictly observed. 7. In the event of excessive wear and tear and damage through use, the end of the product life may be reached before the above-mentioned sterilization cycles. 8. Do not overload cleaning and disinfection device (RDG). Avoid rinsing shadows. Ensure safe storage in the machine. 9. Observe the national regulations for the reprocessing of medical devices. 10. Under no circumstances should the products be cleaned in an ultrasonic bath! This leads to the impairment of functionality. 11. NOUVAG recommends using a sieve basket with a rinsing bar from 3mach (REF 51401), a reusable container for convenient preparation and storage (including transport) of the products. The sieve basket can be used for safe storage of the products both during the washing process and during and after sterilization until the products are used. The sieve basket is suitable for use with sterilization paper or a rigid sterilization container. On its own, it does not have a barrier effect to protect sterility. ⚠ **No responsibility can be accepted for the reuse of products in patients with Creutzfeldt-Jakob disease (CJD) or its variant (vCJD). The Robert Koch Institute recommends that used products be withdrawn from circulation after use to avoid infection of other patients, users and third parties.**
Reprocessing preparation at the place of use	Remove blood, secretions, tissue and bone residues with a disposable cloth immediately after the operation. Do not allow to dry out! Dried residues cause corrosion.

INSTRUMENT PREPARATION

Storage and transportation	Contaminated products must be stored and transported to the reprocessing site in a closed container in order to avoid damage to the products and contamination of the environment.
Pre-cleaning for cleaning and disinfection	1. Wipe products with a damp disposable cloth, removing all visible contamination. 2. Dismantle the products as far as possible according to [AFTER USE >30]. 3. Brush off plastic parts and attachments under running tap water with a soft brush. 4. Only commercially available, DGHM / VAH-listed agents may be used for cleaning and disinfection. The method of use, exposure time and suitability of disinfecting and cleaning substances can be found in the information provided by the manufacturers of these agents. 5. Rinse disassembled products and their attachments for 10 seconds from the outside with a water pressure gun in the sink with a minimum pressure of 2.0 bar. 6. Flush the gear unit over the coupling housing using a water pressure gun and Luer-Lock flushing adapter (REF 19586) (preferably in a water bath, otherwise cover the pressure compensation opening with a cloth). Alternatively, the coupling housing can also be flushed with a water-based cleaning spray, e.g. AQUACARE® (REF 1600617-001) from Bien-Air (bienair.com). For this purpose, also use a water bath or cloth to cover the pressure equalization opening. **Electronic motor 21, including cable 2,9 m (REF 2090nou)** ⚠ The electronic motor must not be placed in an ultrasonic bath or cleaned with compressed air. Do not kink the motor cable because of the risk of a cable breakage. Use the lubricant spray recommended by the manufacturer. Steam sterilize the electronic motor in a sterilization bag and let it cool down. 1. Wipe the electronic motor with a dampened disposable cloth and remove all visible dirt. 2. Unscrew add-on parts such as the motor cap and remove the cable including the motor cap as described in Section [DISASSEMBLING THE MOTOR >31]. 3. Unscrew the handpiece carrier and add it to the reprocessing procedure.  4. Brush the plastic parts and add-on parts of the motor with a soft brush under running tap water. 5. Flush the motor and attachments from the outside for 10 seconds with a water pressure gun (with a minimum pressure of 2.0 bar. Local tap water is sufficient for this purpose, as the last step is always a mechanical cleaning with deionized water and hard water from pre-cleaning cannot remain. **Transmission unit including sealing unit (REF 5163nou)** 1. Wipe the transmission unit and sealing unit with a disposable cloth and remove all visible impurities. 2. Dismantle the products as far as possible according to [AFTER USE >30]. 3. Brush plastic parts and attachments with a soft brush under running tap water. 4. Rinse the disassembled sealing unit for 10 seconds from the outside with a water pressure gun (with a minimum pressure of 2.0 bar) or spray it with a water-based cleaning spray at the motor connection coupling (cover the pressure compensation opening with a cloth as shown in the picture). Carry out mechanical cleaning with deionized water. **Handle (REF 5183nou) Trocar sleeves (REF 5141nou | REF 5142nou) Cutting tubes (REF 5154nou | REF 5155nou) Obturators (REF 5151nou | REF 5152nou) Protection sleeves (REF 5137nou | REF 5138nou)** 1. Wipe products with a damp disposable cloth and remove all visible contamination. 2. Dismantle the products as far as possible according to [AFTER USE >30]. Replace damaged cutting tubes, obturators or handles with new ones. 3. Brush off plastic parts and attachments with a big, round, soft brush under running tap water. 4. Rinse dismantled products and their attachments from the outside for 10 seconds with a water pressure gun with a minimum pressure of 2.0 bar. Carry out mechanical cleaning with deionized water.

INSTRUMENT PREPARATION

<table>
<tr><td>Cleaning</td><td>Machine cleaning
1. Products and attachments are placed in the sieve basket after pre-cleaning.
2. Connect the coupling housing of the gear unit to the Luer-Lock nozzle using the flushing adapter (REF 19586).
3. Machine cleaning is only successful if the pre-cleaning described above has been complied with!
4. The cleaning is carried out with the Vario-TD program in the cleaning and disinfection device (WD). The use of fully demineralized water is recommended for the cleaning process.
5. After completing the cleaning program (including thermal disinfection), check the products and attachments, including seals and O-rings, for visible contamination in grooves and spaces. Repeat the cleaning if necessary.</td><td>Automatic cleaning process (Vario-TD program)
1. Pre-clean for 4 minutes with cold water < 40°C.
2. Empty
3. Clean for 5 minutes at 55°C with 0.5 % alkaline, or at 40°C with 0.5 % enzymatic cleaner.
4. Empty
5. Neutralize for 3 minutes with cold water < 40°C.
6. Empty
7. Rinse with cold water < 40°C for 2 minutes.
8. Empty</td></tr>
<tr><td>Disinfection</td><td>Machine disinfection
The washer/disinfector has a thermal disinfection program that follows cleaning. The mechanical, thermal disinfection must be carried out taking into account the national requirements with regard to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3000 for the electronic motor and the attachments. Disinfection must be carried out with fully demineralized water.</td><td>⚠ Insufficient rinsing or staying in the disinfectant or cleaning agent for too long can corrode the products.
Please refer to the instruction leaflet for the respective cleaning agent and disinfectant for dwell times.</td></tr>
<tr><td>Drying</td><td>Machine drying
The drying of the products and the attachments takes place through the drying cycle of the washer-disinfector. If necessary, manual drying can also be achieved using a lint-free cloth. Pay particular attention to the grooves and spaces between the products. Each WD has to provide a corresponding drying process on the part of the manufacturer (see DIN EN ISO 15883-1). Please observe the relevant information and instructions for use from the manufacturer of the washer-disinfector.</td><td>Manual drying
Set up the products vertically, separated from the attachments, in order to encourage the outflow of liquid. Let the products dry for at least 30 minutes.</td></tr>
<tr><td>Control and care of the electronic motor
 
(REF 19584)</td><td colspan="2">1. Carry out a visual inspection for damage, corrosion and wear, both outside and inside the electronic motor.
2. To maintain (lubricate) the electronic motor, use the lubricant spray from the clutch side for approx. 3 seconds. To do so, the spray adapter (REF 19584) is screwed on the motor instead of the motor cap.
3. Then wipe the electronic motor with a damp cloth.
  </td></tr>
<tr><td>Control and care of the transmission unit</td><td>1. Carry out a visual inspection for damage, corrosion and wear, both outside and inside the gear unit.
2. To maintain (lubricate) the gear unit, spray it with the lubricant spray. Spray from the clutch side for approx. 3 seconds. To do this, the blue spray attachment supplied with the lubricant spray is inserted into the coupling of the gear unit and a puff of spray is released for approx. 3 seconds. Cover the pressure compensation opening with a cloth as shown in the picture and collect any oil introduced under pressure.
3. Wipe the transmission unit with a damp cloth.</td><td>  </td></tr>
</table>

INSTRUMENT PREPARATION

Sterilization	The products are sterilized using a fractionated pre-vacuum steam sterilization process (in accordance with DIN EN 13060 or DIN EN 285), taking into account the respective national requirements. Minimum requirements: 1. Pre-vacuum phases: 3 2. Sterilization temperature: minimum 132°C to maximum 137°C 3. Holding time: At least 5 minutes (full cycle) 4. Drying time: at least 10 minutes When sterilizing several products in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see manufacturer's instructions). In the case of autoclaves without a pre-vacuum, a drying phase must take place. After the sterilization, the perfect sterilization result must be checked with the help of appropriate indications. According to the Robert Koch Institute, reprocessing ends with the documented release of the medical device for use. If the sterilized products are not used immediately after sterilization, the packaging must be labeled with the sterilization date.	
Storage	Storage of sterile packagings The sterilized product is stored protected from dust, moisture and contamination. Direct sunlight must be avoided during storage. After the expiry date, the product must be reprocessed.	Handling of sterile packaging Before unpacking the product, check the integrity of the sterile packaging. When unpacking the product, the corresponding aseptic regulations must be observed.
Information on validation of the Reprocessing	The above reprocessing process has been verified by a validated procedure. The following materials and machines were used: 1. Alkaline cleanser: Neodisher® Mediclean forte; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Lubricant spray: Bien-Air LUBRIFLUID® 3. Cleaning and disinfection device: Steelco, PWD 8626 4. MIS load carrier 5. Steam sterilizer: Webeco, A65-1 6. Sterile packaging: steriCLIN #3FVLI330114 Chemicals and machines other than those mentioned can also be used. In this case you agree with the manufacturers or suppliers whether their products provide the same performance as the products with which the process was validated. If you decide to use a different reprocessing method than the one mentioned above, it is your duty to prove suitability accordingly.	

There is no experience with the implementation of other sterilization processes, such as plasma sterilization, low-temperature sterilization processes, etc.
The user bears full responsibility when using a method other than the described, validated sterilization method!

Please also observe the legal provisions applicable in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements for effective prion inactivation.

FORCEPS

The forceps shown in the illustration are not included in the "Morcellator kit", but can be ordered as an optional extra. The detailed preparation instructions are included with the instructions for use supplied with the forceps.

MAINTENANCE

GENERAL MAINTENANCE

MOTOR CABLE

¬ Replace a damaged motor cable by a new one (REF 76052)

PROTECTION TUBES

¬ Replace a damaged protective tube by a new one.
Protection tube Ø 12 mm (REF 5137nou)
Protection tube Ø 15 mm (REF 5138nou)

OBTURATORS

¬ Replace damaged obturators.
Obturator Ø 12 mm (REF 5151nou)
Obturator Ø 15 mm (REF 5151nou)

SEALS FOR TROCAR SLEEVE

¬ Replace any damaged seals with new seals.
Seal set for trocar sleeves Ø 12/15 mm (REF 5177nou), PU 10 pcs.

¬ Replace any damaged seals with new seals.
O ring for trocar sleeves Ø 12/15 mm (REF 5180nou), PU 10 pcs.

¬ Replace damaged seal cap holders with new ones.
Seal cap holder Ø 12 mm (REF 51484nou), PU 1 pcs.
Seal cap holder Ø 15 mm (REF 51502nou), PU 1 pcs.

SEALING UNIT WITH MEMBRANE FIXING RING FOR CUTTING TUBES Ø 12/15 MM

¬ Replace damaged parts with new ones.
Sealing unit including membrane fixing ring and 1 sealing set (REF 5136nou), PU 1 pcs.

SEALS IN SEALING UNIT

¬ Replace damaged seals with new ones.
Membrane seal blue (REF 5166nou) for the use with cutting tubes Ø 12/15 mm
Roof shaped transparent seal (REF 5167nou) suitable for cutting tubes Ø 12/15 mm, PU 10 pcs.

SPRAY ADAPTER FOR LUBRICANT SPRAY

¬ Replace missing adapter by a new one.
Spray adapter (REF 19584) for the lubrication of the electronic motor 21 with lubricant spray (REF 2127).

FLUSHING ADAPTER LUER-LOCK

¬ Replace missing adapter by a new one.
Flushing adapter Luer-Lock (REF 19586) for pre- and machine cleaning of the gear unit (REF 5163nou).

(REF 19584)

(REF 19586)

MAINTENANCE

REPLACING THE CONTROL UNIT FUSE

Users can replace faulty control unit fuses by themselves. These are located at the rear of the device in the fuse slot beside the power switch:

2 **Switch the device off.**

3 **Unplug the power plug.**

4 **Open the fuse slot using a screw driver.**

5 **Replace the faulty fuse T 1 AL, 250 V AC.**

6 **Slide the fuse holder back in and close the fuse slot.**

7 **Check the mains voltage shown on the fuse slot.**

8 **Plug in the power plug again.**

1 Fuse slot locking mechanism **2** Display window for voltage setting **3** Fuse slot **4** Fuse 1 **5** Fuse 2

SAFETY INSPECTIONS

The essential requirements have been defined and assessed within the risk analysis. The approved results have been filed in the risk management file deposited with the manufacturer.

The performance of safety inspections on medical devices is required by law in several countries. The safety inspection is a regular safety check that is compulsory for those operating medical devices. The objective of this measures is to ensure that device defects and risks to patients, users and third parties are identified in time.

The STI (Safety technical inspection) for the TCM 3000 BL Morcellator shall be executed every 2 years by authorized experts. Results shall be documented. The service instructions, circuit diagrams and descriptions are available on request from the manufacturer.

NOUVAG offers a safety inspection service for its customers. Addresses can be found in the appendix of this instructions for use under [Service points >43]. For further information please contact our technical service department.

MALFUNCTION AND TROUBLESHOOTING

MALFUNCTION	CAUSE	SOLUTION	REFER TO INSTRUCTIONS FOR USE
Device is not operational (Display is not on)	Control unit is not switched on.	Set the power switch "I/O" to "I"	[ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1) >14] [ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2) >17]
	Power connection is not established.	Connect the device to the power supply.	[ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1) >14] [ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2) >17]
	Incorrect operating voltage.	Check the mains voltage.	[CONNECTION TO THE POWER SUPPLY >13]
	Faulty fuse.	Replace the fuse.	[REPLACING THE CONTROL UNIT FUSE >39]
Motor does not run	Motor is not switched on.	Switch on the motor, using the treadplate.	[USING THE CONTROL UNIT >22]
	Motor is not connected.	Connect the motor cable to the control unit.	[ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1) >14] [ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2) >17]
	Gear unit is not correctly attached to the motor.	Press the electronic motor firmly onto the gear unit coupling until it clicks into position and check that it is secure by moving it slightly in the opposite direction.	[ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1) >14] [ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2) >17]
Foot switch is not operating (Display is on)	Foot switch is not connected	Plug the foot switch cable into the foot switch socket.	[ASSEMBLING THE MORCELLATOR KIT WITH THE PROTECTIVE TUBE (OPTION 1) >14] [ASSEMBLING THE MORCELLATOR KIT WITH THE TROCAR SLEEVE (OPTION 2) >17]

If a fault cannot be rectified, please contact your supplier or an authorized service center.

FAULT MESSAGES ON THE DISPLAY

FAILURE REPORT	CAUSE	SOLUTION
	Motor failure	Switch device off and on again.
	The device detected under-voltage while the motor was running.	The pedal must be released for a short period.
	Pedal was pressed while switching the device on.	The pedal must be released for a short period.

If a fault cannot be rectified, please contact your supplier or an authorized service center.

ACCESSORIES AND SPARE PARTS

DESCRIPTION	REF
Morcellator gear unit	5163nou
Trocar sleeve Ø 12 mm	5141nou
Trocar sleeve Ø 15 mm	5142nou
Protection tube reusable Ø 12 mm	5137nou
Protection tube reusable Ø 15 mm	5138nou
Obturator Ø 12 mm	5151nou
Obturator Ø 15 mm	5152nou
Cutting tube Ø 12 mm	5154nou
Cutting tube Ø 15 mm	5155nou
Drill for myoms Ø 10 mm, Length 330 mm	5193
Handle complete	5183nou
Electronic motor 21, 40'000 rpm	2090nou
Motor cable compl., pre-assembled, 2,9 m	76052
Instrument membrane sealing Ø 12/15 mm, PU 10 pcs.	5166nou
Roof shaped seal Ø 12/15 mm, PU 10 pcs.	5167nou
Seal cap holder for trocar sleeve Ø 12 mm, PU 1 pcs.	51484nou
Seal cap holder for trocar sleeve Ø 15 mm, PU 1 pcs.	51502nou
Gasket for trocar flap Ø 12/15 mm, PU 10 pcs.	5177nou
O-ring for trocar sleeve Ø 12/15 mm, PU 10 pcs.	5180nou
Sealing unit Ø 12/15 mm	5136nou
Lubricant spray	2127
Spray adapter with thread, for lubricant spray (REF 2128)	19584
Flushing adapter Luer-Lock	19586

To order additional parts, please contact our customer service department.

INFORMATION ON DISPOSAL

Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Prevailing national and local disposal regulations apply.

When disposing of the device, device components and accessories, the requirements specified in legislation must be followed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

TECHNICAL DATA

Voltage, switchable	100 V~ / 115 V~ / 230 V~, 50/60 Hz
Fuse power supply	2 fuses T 1 A, 250 V AC
Power consumption	60 VA
Maximum motor speed	37'000 rpm
Maximum motor torque	6 Ncm
Maximum torque at transmission outlet	80 Ncm**
Motor coupling	ISO 3964 (INTRA)
Motor cable length	2,9 m
Pedal cable length	2,9 m
Morcellator speed range	50 – 1'000 rpm
Type of applied part	Type BF*
Protection class	Class I
Pedal	IPX8
Dimensions (W x D x H)	120 x 180 x 110 mm
Net weight of control unit	1,8 kg

* Applied part is the morcellator.
** Maximum torque is delivered in the speed range between 200 – 400 rpm.

WARRANTY COVERAGE

NOUVAG warrants this product to be free from defects in workmanship and materials for a period of twelve (12) months from the original date of purchase. If the warranty card is returned for registration or the warranty extension is requested on our website within 4 weeks from the date of purchase, the warranty coverage is extended for a period of 6 months, wear parts are excluded from the warranty. During this warranty period, NOUVAG agrees to either repair or replace the product at its option if the product fails to function properly under normal use and service and such failure is due solely to a defect in workmanship or materials.
This warranty is void if repair or service of the product is performed or attempted by anyone not authorized by NOUVAG to do so, or if a replacement part not authorized by NOUVAG is used in any repair or service.

POST MARKET SURVEILLANCE

In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.

To provide adequate information, please compile the incident questionnaire at the web address Nouvag.com > Contact us > Incident questionnaire.

SERVICE POINTS

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CE 0197

A complete list of NOUVAG certified service points are found on the NOUVAG website: Nouvag.com > Service

APPENDIX

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the TCM 3000 BL Morcellator.

Changes or modifications to this product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with this or other equipment. This product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING
Use of portable phones or other radio frequency (RF) emitting equipment, including accessories (antennas e.g.) in distances below 30 cm (12 inches) to the product, may cause unexpected or adverse operation.

WARNING
The product is suitable for use in hospitals other than in the vicinity of active devices of the HF surgical devices or except in HF screening rooms used for magnetic resonance imaging.

WARNING
The product shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the product shall be tested to verify normal operation in the configuration in which it is being used.

Essential Performance
The essential performance is that the drilling, milling and grinding of the bone and tissue, taking into account the speed is maintained. The maximum speed deviation is -20%, +5% at a range between 2'000 – 40'000 RPM.

Compliant Cables and Accessories

WARNING
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the product.
The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.
NOTE: Any supplied accessories that do not affect EMC compliance are not listed.

Description	Length max.
Power supply cord REF 22261 / 22262 / 22264 / 22266	3.0m
Electronic motor REF 2090nou	2.9m
Foot pedal IPX8 REF 1507nou	2.9m

Guidance and manufacturer's declaration – electromagnetic emissions

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Product is suitable for use in buildings other than residential buildings and buildings that are immediately connected to the public power supply network that also supplies buildings used for residential purposes provided the following warning is observed: **Warning:** The Product is only intended for use by specialized medical staff. This product can cause radio interference which may make it necessary to take suitable remedial measures such as new alignment, new positioning or screening of the product or a filter in the connection to the installation site.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

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Surge IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree	Mains power quality should bet hat of a typical commercial or hospital environment.
variations on power supply input lines IEC 61000-4-11	0 % U_T; for 1 cycle 70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	0 % U_T; for 1 cycle 70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80 % AM at 1 kHz	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80 % AM at 1 kHz	$d = 0{,}35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	$d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,7 GHz
			Where *P* is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.

b over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Electromagnetic immunity against high-frequency wireless communication devices						
Test frequency MHz	**Frequency band** MHz	**Communication service**	**Modulation**	**Maximum Performance** W	**distance** m	**Test level** V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
8785						

Recommended separation distances between portable and mobile RF communications equipment and the not life support equipment

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0{,}7\sqrt{P}$
0,01	0,04	0,04	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,7
10	1,1	1,1	2,2
100	3,5	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance fort the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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