VERSATOR®

Tissue Morcellation System

REFER TO INSTRUCTIONS FOR USE

www.veolmedtech.com

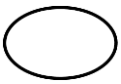
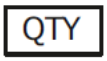
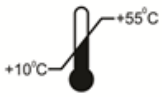
VERSATOR® Tissue Morcellation System has the following contents:

Component	Product Code
VERSATOR® Handpiece	VR-1000
VERSATOR® Rotor Cable-Sterile	VR-2000
VERSATOR® Rotor Cable-Reusable	VR-0034
VERSATOR® Drive Unit (VDU)	VR-3000

Date of Initial Issue: 17-10-2024
Date of Revision: NA

Symbols

	**Refer to instruction manual/ booklet**
	**Do not reuse**
	**Do not re-sterilize**
	**Sterilized using Irradiation**
	**Date of Manufacture**
	**Manufacturer** Veol Medical Technologies Pvt. Ltd. A-747, Near Pavan Bus Stop, MIDC Pawane, TTC Industrial Area, Koparkhairane, Navi Mumbai 400705. Maharashtra, India. Ph: +91-882-882-0407 Email: info@veolmedtech.com; Website: www.veolmedtech.com
	**Medical Device**
	**Do not use if package is damaged**

	**Keep away from direct sunlight**
	**Keep dry**
	**Caution** See instruction for use
	**Single sterile barrier system**
	**Expiry date**
	**Phthalate Information:** Versator® Handpiece (VR-1000) is phthalate free.
	VERSATOR® Rotor VR-0034 has a PVC casing containing DEHP.
	**Latex Information:** The Versator® Handpiece (VR-1000) & Versator® Rotor Cable-Sterile (VR- 2000) are latex free.
	**This device is to be sold by or on the order of a physician only**
	**Quantity**
	**Lot Number**
	**Storage Temperature Range** +10℃ to +55℃
	**Type BF Applied Part**
	Pedal
	**EC- Representative** Mars Medical, Landhausstrasse 46, 70190 Stuttgart, Germany. Contact: +49 1751938653, Email Id.: info@marsmedical.de EUDAMED SRN No. DE-AR-000006312

CE 0123	CE mark and identification number of the Notified Body TUV SUD. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC. Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany, ID No.0123

1. General Information:

1.1 Intended Use

VERSATOR® Tissue Morcellation System is intended for the morcellation and removal of dissected tissue under direct or laparoscopic visualization, during laparoscopic gynaecologic procedures.

1.2 Indications for Use

The VERSATOR® Tissue Morcellation System is indicated for cutting, coring & extracting tissues during laparoscopic gynaecologic procedures.

1.3 Contraindications

The VERSATOR® Tissue Morcellation System is contraindicated for use on vascularized tissues. It is not to be used as a dissecting tool. All target tissues and organs must be de-vascularized and dissected before morcellation.

The use is also not recommended for the following vulnerable populations:
Paediatric patients
Pregnant women

Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are: - post-menopausal or over 50 years of age, or- candidates for en bloc tissue removal through the vagina or via a mini-laparotomy incision.

There is a residual risk of dissemination of cancer cells due to Morcellation in confirmed or suspected cases of uterine sarcoma including leiomyosarcoma hence it is contraindicated.

1.4 Intended patient population

The VERSATOR® Tissue Morcellation System is intended to be used in female patients aged 18 years and older and indicated for laparoscopic myomectomy or laparoscopic hysterectomy. The patient should have appropriate medical status to undergo surgery. The indications for surgery may vary from patient to patient.

1.5 Intended user profile

The device is intended to be handled by the medical personnel and professionals qualified in the transportation, preparation, sterile processing, and use of surgical devices. This includes scrub technicians, circulating nurses, and sterile processing technicians. This product is intended for use only by medical professionals with adequate training, knowledge and experience in the use of endoscopic / laparoscopic procedures.

It highly recommended to use MORSAFE® Tissue Morcellation bag along with VERSATOR® Tissue Morcellation System for safer power morcellation.

2. TECHNICAL SPECIFICATIONS

2.1 VERSATOR® Handpiece (VR-1000) Specifications.

Physical	Weight*	190 grams
Dimension of hand-piece	Length X Height X Width X Outer Tube Diameter *	286 mm X 142 mm X 43 mm X 16 mm
	Working length *	160mm

Functional	Speed range*	180 to 1440 RPM. For details, please see IFU of VDU (VR-V-0113)
Cutting modes	3 Positions, 3 modes	Off, Cut, Cut Plus
Core guard positions	3 Positions	Left (L), Top (T) and Right(R)
Classification	Applied Part According to the standard: IEC 60601-1)	Type BF
	IP Rating According to the standard: IEC 60601-1)	IP00
	According to Directive 93/42/EEC (MDD)	Class IIa Rule 9
Sterility	Supplied sterile	Do not re-sterilize or Re-use
Shelf Life	Duration	3 Years

2.2 Obturator Specifications

Physical	Weight*	26 grams
Dimension	Length*	340.60 mm
	Effective Length*	287mm
Sterility	Supplied sterile (along with the handpiece)	Do not re-sterilize or re-use

2.3 Reducer Specifications *(applicable for both Reducer S and L)*

Physical	Weight*	2.5 grams
Dimension	Seal Opening*	3.5mm for Reducer-S
		6.5mm for Reducer- L

2.4 VERSATOR® Rotor Cable-Sterile (VR-2000) Specifications

Physical	Weight*	420 grams
Rotor	Cable Length*	2000 mm
Drive unit lock	CPC male connector	Similar to Standard type of Drive units
Shelf Life	Single Use disposable	3 years from date of manufacturing
Sterility	Supplied Sterile	Do not re-sterilize or Re-use.
Classification	Applied Part (According to the standard: IEC 60601-1)	Type BF
	IP Rating (According to the standard: IEC 60601-1)	IP00
	According to Directive 93/42/EEC (MDD)	Class IIa Rule 9

2.5 VERSATOR® Rotor Cable - Reusable (VR-0034) Specifications

Physical	Weight *	465 grams
Rotor	Cable Length*	2000 mm
Drive unit lock	CPC male connector	Similar to Standard type of Drive units
Shelf Life	Please see comment in adjacent box	To be used within 3 years from date of manufacturing or within 6 months after first use (whichever is earlier)

Reuse	Sterilize before first use and before each re-use	10 Times by Autoclave Re-sterilization.
Classification	Applied Part	Type BF
	IP Rating	IP00

2.6 VERSATOR® Drive Unit (VR-3000) Specifications

Physical	Weight*	5.5 kg Approx, 12.1 lbs (Excluding the power cord and footswitch)
	Dimensions*	352mm x 287mm x 103mm (l x w x h)
Electrical	Rated voltage, frequency	100-240 VAC, 50-60 Hz
	Maximum power drawn	350 Watts, 4.8 A
Fuse	5mm x 20mm	100V – 10A 240V – 5A Operating speed: Fast Acting
Functional	Speed range/ Operating Speed Δ Temperature of VDU during use ON Time during use OFF time use	Speed range of VDU motor is approximately 500 to 4000 rpm. Range 20^0 C to 80^0 C +/- 2^0 C Range is 20 to 60 minutes +/- 1 min Range is 30 to 20 minutes +/- 1 min
Power Cable	Length	2.5 meter to 5 meter (country specific)
	Cable Connector description	As per country of use
	Cable Description (For Canada)	NEMA 5-15P
	Cable Description (For Brazil)	NBR14136
	Cable Description (For India)	IA16A3
	Cable Description (For Malaysia)	BS1363A
	Cable Description (For Japan)	JIS 8303
	Cable Description (For Europe)	IEC 884/CEE7-VII
	Cable Description (For Denmark)	AFSNIT
	Cable Description (For Australia)	AS/NZS 4417
Foot Switch	Cable Length*	3 meters
	IP rating	IP07
	Rated Voltage	100-240 V, 50-60 Hz
	Connector Pin	5 pole connectors
Service Life	Total duration of availability of support	5 Years from the date of manufacturing.
Classification	According to Directive 93/42/EEC (MDD)	Class IIa Rule 9

3. WARNINGS & PRECAUTIONS

Do not use if sterile barrier of VERSATOR® Tissue Morcellator package is damaged. If damage is found, call the representative who supplied the product to your institution. After the use, disposal should be done in a safe manner in accordance with the sharps product disposal procedure followed in your institution or as per applicable regulations.

3.1 USFDA Black-box Warning

Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

3.2 General Precautions

3.2.1 The Instructions for Use manual should be thoroughly studied and ensured that all the instructions given in this user manual are followed while using the device.

3.2.2 The clinician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

3.2.3 Failure to carefully follow all applicable instructions may result in significant injury to the patient, surgeon or attendants and may have an adverse effect on procedural outcomes.
3.2.4 Good surgical practices should be followed for management of contamination or infected wounds.
3.2.5 Use of VERSATOR® Tissue Morcellation System should be considered for patients who the physician determines are not high-risk surgical candidates.
3.2.6 Store the VDU in a clean, dry area away from the direct sunlight and at room temperature.
3.2.7 VDU is a medical electrical equipment that must be handled with care. It is meant for use by well trained and knowledgeable professionals only.
3.2.8 Carefully inspect the device and all associated equipment, instrumentation and cabling for wear or damage prior to use. DO NOT attempt to operate this device if any damage is observed. Contact the distributor or field service technician for assistance regarding repair or replacement.
3.2.9 Observation of the touchscreen display is required during operation of the device. Status of the rotation of the handpiece cutter blade is seen on the touch screen. Similarly, cutter blade RPM in terms of Speed level, VDU temperature and load on the system are indicated on touch screen. This output indications are only approximate information of these parameters and may not be accurate.
3.2.10 Observation of the tip of the Hand-Piece is a compulsory action during operation of the device.
3.2.11 The VDU should be placed such that the circulation of air by the fan is not obstructed.
3.2.12 The VDU is designed to remain stable on the table and will not slide easily. But the user is warned that undue pulling of the handpiece and rotor cable connected to VDU can cause VDU to slide and fall from the table.
3.2.13 When the VDU is stopped at any particular speed, it is to be noted that on restart of VDU, the VDU will start its operation at previously stopped speed. The user has to take care of this as it can cause inadvertent high-speed start.
3.2.14 In the unlikely event of the handpiece not stopping its rotation when needed, the surgeon should immediately put the cutter blade in “OFF” position so that the blade does not make any unintended cuts to the tissue.
3.2.15 VDU is a non-continuous operating device. The control of its use is maintained by an automated temperature and load sensing mechanism using closed loop control.
3.2.16 Please note that the VDU, Foot Switch and power cord are shipped non-sterile.
3.2.17 Use only non-flammable materials when cleaning or disinfecting the VDU.
3.2.18  To avoid the risk of an electric shock, the VDU must only be connected to supply mains with protective earth.
3.2.19 In an emergency VDU can be isolated from the power supply by putting off the Rocker switch.
3.2.20 Use ONLY the VDU to connect the VERSATOR® products. Use of any other drive mechanisms may result in failure of the VERSATOR® devices to perform as intended.
3.2.21 The VDU contains no user-serviceable components. Repairs and maintenance must be made directly by manufacturer or its authorized representative.
3.2.22 VDU shall be connected to power source that will be supplied by a UPS or generator to enable continued usage in case of power failure. Backup time for UPS should be minimum 60 minutes or as per the application.
3.2.23 VDU has equipotential Pin, which can be used if the facility has appropriate connectors.
3.2.24 VDU is earthed via the earthing to mains cable and the equipotential pin is an additional safety feature.
3.2.25 VDU does not require any special installation except steady power.
3.2.26 VDU can be isolated in Emergency from the mains.
3.2.27 Oxygen rich environment in operating room can contribute to increased risk of fire and explosion hazards with the VDU.
3.2.28 NO MODIFICATION OF THIS EQUIPMENT (i.e., VDU) IS ALLOWED.
3.2.29 No maintenance should be carried out while VDU is in use with the patient.
3.2.30 User should not use any other power cable than that supplied by manufacturer.
3.2.31 In case of power cable failure, the manufacturer should be contacted for the replacements.
3.2.32 Versator Tissue Morcellation System should not be used without appropriate patient selection and pre-operative diagnostics. Note that certain types of cancer may not be detectable in such pre-operative diagnostics potentially leading to spreading cancer and thereby potentially decreasing the long–term survival of the patient. The trained professional performing the surgery is responsible for obtaining the patient’s written informed consent on this information.
3.2.33 VDU should not be connected to an additional multiple socket – outlet or extension cord.

3.3 Procedural Precautions

3.3.1 The blade / cutter should be kept completely covered i.e., the Rotatory Knob at the top of the VERSATOR® Handpiece should be kept at OFF position during insertion and removal of the device. Exercise care when inserting or removing the device from the body. Insertion, use and removal of the VERSATOR® Handpiece should be performed under direct visualization at all times.

3.3.2 Always use the Obturator along with the Handpiece while inserting the device through the laparoscopic port. This is essential for a smooth and easy insertion of the Handpiece through the laparoscopic port. Maintain the same procedure while using the device with MorSafe® Tissue Morcellation Bag.

3.3.3 Before inserting Obturator, ensure the following

- Rotatory Knob is at OFF position i.e., blade should be completely secure inside the outer tube of VERSATOR® Handpiece.
- That, the alignment feature is completely aligned with the corresponding alignment feature at the proximal end of the Handpiece.
- Deployer knob is pushed completely to expand the VERSATOR® Obturator.

3.3.4 To prevent accidental injuries to the abdominal wall or similar other tissues or organs, the tissue to be morcellated should be completely exposed before using the VERSATOR® Handpiece.

3.3.5 The VERSATOR® Handpiece should not be placed in contact with tissue that is not to be morcellated.

3.3.6 Sometimes it so happens those large masses of tissue move uncontrollably thus coming in contact with the device. This unintended movement of the device can cause significant injury to the patient. Hence a second pair of grasping forceps or a fixation instrument may be used to prevent large pieces of tissue from moving uncontrollably and coming in contact with the device.

3.3.7 Caution should be exercised when introducing or removing instruments to prevent inadvertent damage to the device seals. Special care should be exercised when inserting sharp or angled-edged endoscopic / laparoscopic instruments to prevent tearing of the seals.

3.3.8 VERSATOR® Handpiece has metallic components and is conductive and thus should not be used in direct contact with instrument using other energy sources such RF, electrical or Laser especially devices with BF & CF category as it may cause burn injuries to the patient.

3.3.9 Before attempting to insert a morcellator VERSATOR® Handpiece, make sure incision is increased to appropriate size to enable 15 mm diameter morcellator to get inserted through it.

3.3.10 Do not use excessive force while inserting VERSATOR® Handpiece in abdomen. This could damage the product.

3.4 Device-related Precautions

3.4.1 Careful inspection of the VERSATOR® Tissue Morcellation System and all associated equipment and instruments prior to use for its functionality is extremely essential.

3.4.2 The blade/cutter of the device should not be sharpened or modified. Bent or distorted blades can injure the patient, surgeon or the attending staff or, damage the device.

3.4.3 Non-functional instruments should not be used and should be returned to the supplier.

3.4.4 If any component or accessory of the device appears to be damaged, please DO NOT attempt to use it.

3.4.5 Do not use the VERSATOR® Handpiece & VERSATOR® Rotor Cable-Sterile if the package is opened or damaged, as sterility may have been compromised.

3.4.6 VERSATOR® Handpiece & VERSATOR® Rotor Cable-Sterile is a single use disposable device. DO NOT re-sterilize or re-use.

3.4.7 Do not use any part of the VERSATOR® Tissue Morcellation System beyond the indicated expiration date (where applicable).

3.5 Unpacking and General Instructions

3.5.1 Remove all components carefully from the shipping carton and check all components to ensure they have not been damaged during shipment.

3.5.2 All the contents of the carton have to be thoroughly checked for any signs of damage.

3.5.3 In case any damage is found, contact the shipping company or distributor or Manufacturer or Authorised Representative in respective country immediately.

4. ADVERSE EVENTS & POTENTIAL COMPLICATIONS

4.1 Caution should be exercised to prevent accidental injury to other organs due to the device coming in contact with other tissues or organs, e.g., Bowel injury.

4.2 In literature sources, complications have been reported to be caused due to remnants of the morcellated tissue in the patient. Small missed specimen can get re-vascularized and grow to form another mass of tissue thus leading to complications like pain, dysmenorrhea, adenoma etc. It is recommended to use VERSATOR® Tissue Morcellation system along with MorSafe® Tissue Morcellation Bag.

4.3 If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis.

The following complications have been reported as consequences that may be associated with the use of a tissue morcellation device:

Mildly Serious:	**Serious:**
• Laparoscopic port site pain • Scar dehiscence • Scar rupture • Abdominal Pain • Bowel Distension • Adhesions	• Excessive Blood Loss • Pelvic Pain • Hematoma • Pelvic Abscess • Tachycardia • Fever • Dissemination of un-suspected cancer • DPL

5. OPERATIONAL INSTRUCTIONS

5.1 Versator Handpiece and Rotor cable

5.1.1 Overview

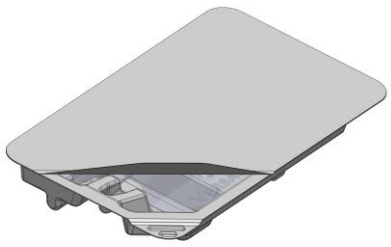
The VERSATOR® Tissue Morcellation System is engineered to provide smooth and efficient tissue morcellation. The VERSATOR® Drive Unit is used in conjunction with the VERSATOR® Handpiece & VERSATOR® Rotor Cable-Sterile.

Note: *Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and have an adverse effect on the outcome of procedures performed.*

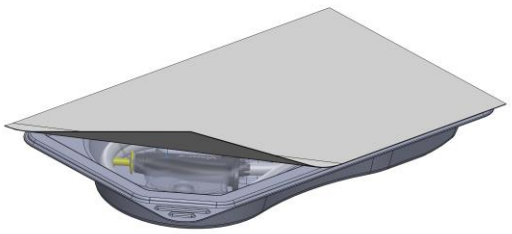
Operational Condition: The whole procedure should be carried out in ambient atmospheric condition in a hospital environment and ambulatory surgery centres.

5.1.2 Preparation of the device for use

5.1.2.1 Remove the device from the Sterile packaging by peeling the Tyvek lid. (Figure 1)



Versator Handpiece



Versator Rotor cable

Figure 1: Removing the device from packaging

		
Step 1 Align the Rotor to the Handpiece	**Step 2** Insert the Rotor completely till a "Click" sound is heard	**Step 3** Rotor is now locked to Handpiece & ready for use

Figure 2: Insertion of Rotor into the hand-piece

5.1.2.2 Unpack the sterile blister pack of VERSATOR® Rotor Cable-Sterile and place the Rotor in a sterile area. Remove the safety cap covered over both square ends of Rotor cable.

5.1.2.3 Unpack the sterile blister pack of VERSATOR® Handpiece and place the Handpiece, Obturator and two Reducers in a sterile area.

5.1.2.4 Connect the VERSATOR® Rotor Cable-Sterile to the VERSATOR® Drive Unit (VDU), as shown in Figure: 5. Ensure that an audible click is heard when the squared end of the VERSATOR® Rotor Cable-Sterile is inserted into the CPC coupling of the VERSATOR® Drive Unit (VDU) which indicates proper locking.

5.1.2.5 Attach the VERSATOR® Handpiece to the VERSATOR® Rotor Cable-Sterile by inserting it into the VERSATOR® Handpiece as shown in Figure: 2. Check the alignment of the VERSATOR® Rotor Cable-Sterile with respect to the VERSATOR® Handpiece while insertion.

5.1.2.6 An audible click is heard which indicates that the VERSATOR® Rotor Cable-Sterile has been securely locked into the VERSATOR® Handpiece.

5.1.2.7 If handpiece does not snap in easily, rotate the rotor slightly by tapping on foot switch and try again.

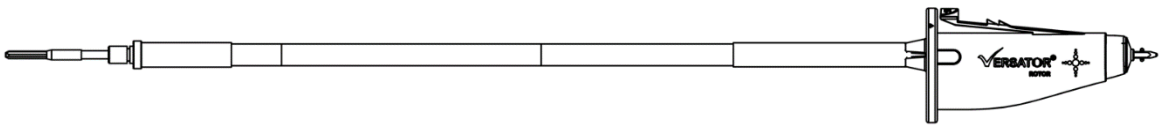


Figure 3: Straightening of Rotor Cable

Note:

- For rotor cable to function properly, it is imperative that it be straightened prior to use. To straighten, grasp the rotor at both ends and stretch it until flat as shown in figure 3. This will help remove any undesirable kinks in the rotor cable.
- Do not pull the Rotor cartridge lever excessively away from the cartridge body. This may break the lever. During storage or handling make sure the rotor cartridge lever is not damaged or deformed and if the lever is pressed onto the cartridge body, carefully pull it until it returns to its actual position.
- Do not bend the Rotor Cable (VR-2000) excessively. Do not bend below a radius of 150 mm to ensure a smooth performance.
- Do not bend the Rotor Cable (VR-0034) excessively. Do not bend below a radius of 100 mm to ensure a smooth performance.

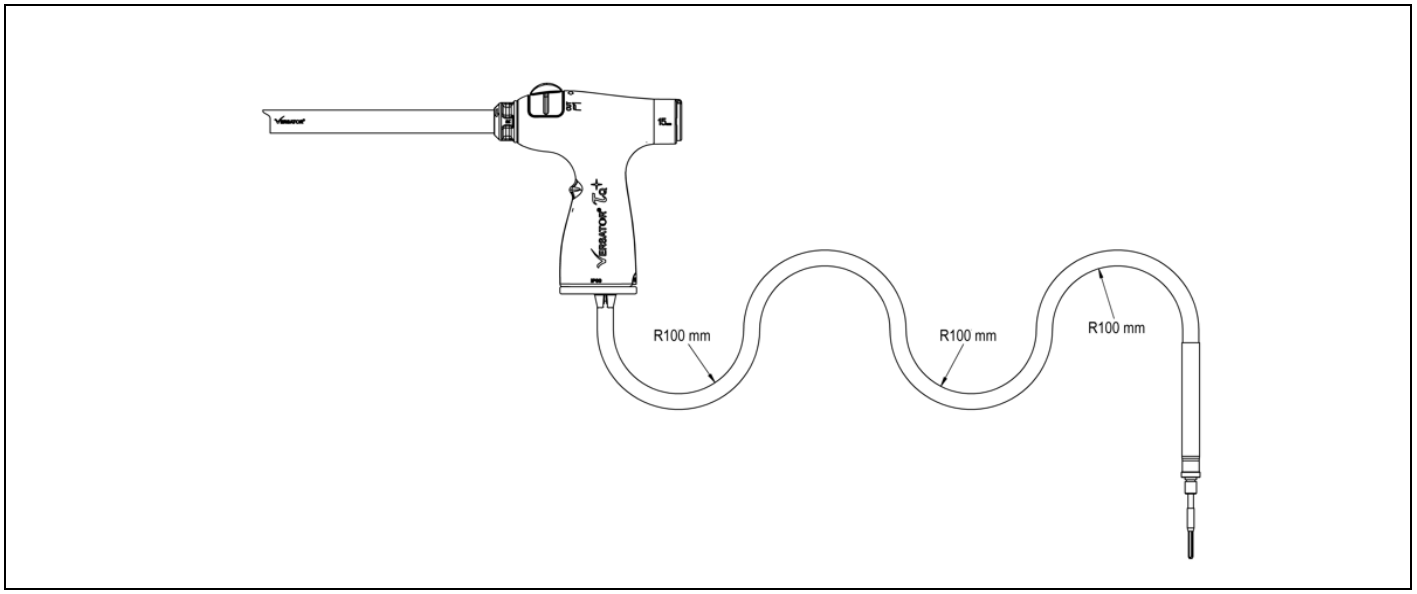


Figure 4: Bending rotor cable (VR-0034)

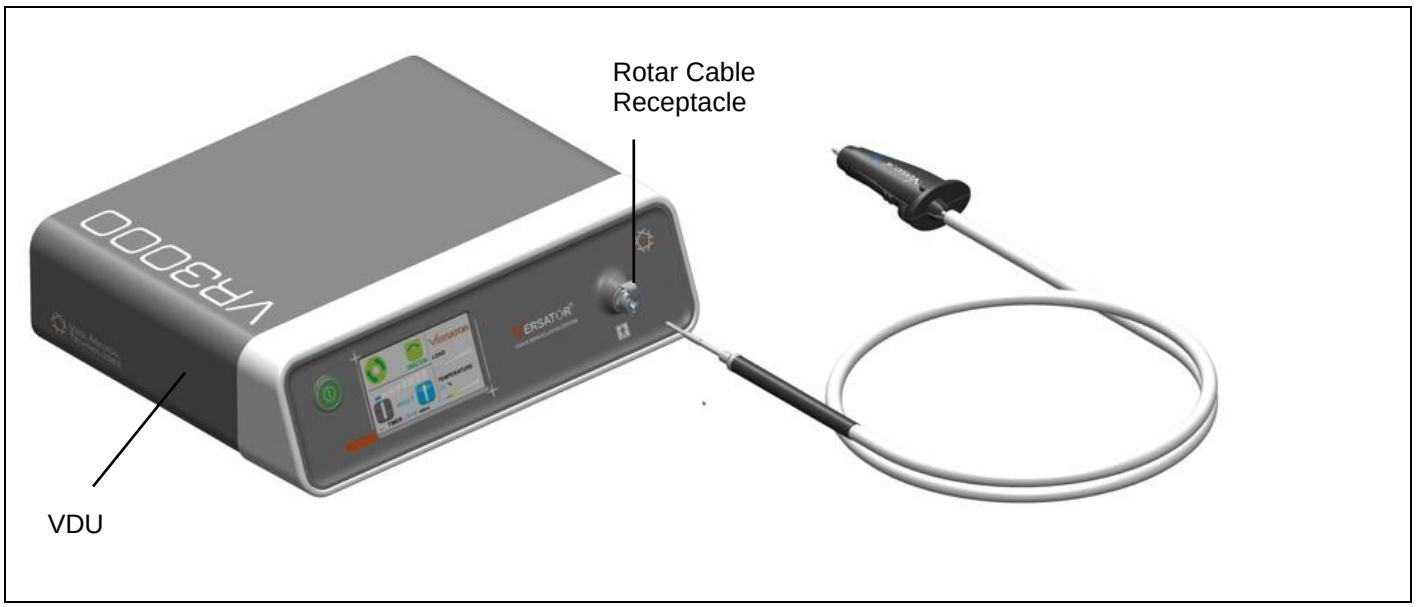


Figure 5: Connect the Rotor Cable to the VDU

IMPORTANT: Check following points before use:

- Check the VERSATOR® Handpiece activation modes, Cut, Off (•) and Cut + (Plus). Ensure that the Rotatory Knob is in OFF position before inserting into the Rotor.
- Check cutter rotation modes (Speed and direction of cutter rotation) on VDU.

Figure 6: Insertion of obturator into the handpiece

5.1.3 Insertion of the device in the body

3.1.3.1 Make sure the VERSATOR® Hand piece is set at "**OFF"** (•) mode, which is the no cut position.

3.1.3.2 Before insertion of Obturator into the VERSATOR® Hand piece, ensure that the 'Deployer' is pulled away from the 'Obturator Outer Tube' so as to expose the 'Cavity of Deployer' as shown in the picture below.

3.1.3.3 Insert the Obturator in to the VERSATOR® Handpiece through its proximal end such that the alignment feature of the Obturator gets engaged with the corresponding feature on the VERSATOR® Handpiece (Figure: 6).

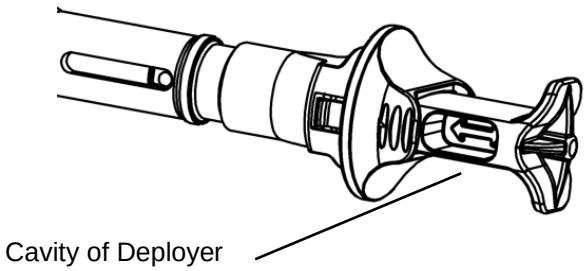


Figure 7: Deployer to be pulled to expose the cavity of deployer

3.1.3.4 Insert the above assembly through the lumen/port into the abdomen while holding Obturator such that it should not retract during insertion.

3.1.3.5 Once the VERSATOR® Handpiece is in place, the Obturator is to be removed by pulling the deployer knob of the Obturator proximally and away from the VERSATOR® Handpiece.

3.1.3.6 The laparoscope should be thoroughly cleaned prior to re-introduction into the abdominal cavity to prevent dissemination of cells / tissue on the lens.

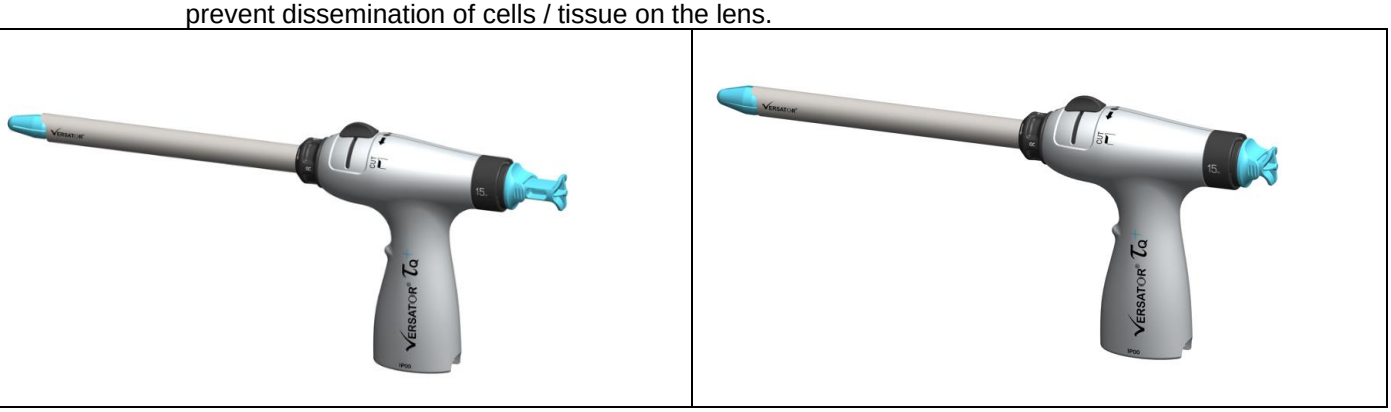


Figure 8: Obturator inserted into Handpiece

5.1.4 Tissue morcellation with VERSATOR® Handpiece

5.1.4.1 After the Obturator is removed from the hand-piece, attach suitable Reducer at proximal end of Handpiece before inserting a laparoscopic grasper or any other instrument through lumen.

5.1.4.2 A laparoscopic grasper is inserted through the lumen of the VERSATOR® Handpiece from the proximal end to grasp the tissue for morcellation at the distal end. Ensure that the jaws of the forceps are in closed position during insertion and retrieval.

5.1.4.3 Activate the VERSATOR® Hand piece by rotating the Rotatory Knob to desired cutting mode position.

5.1.4.4 The Rotatory Knob has two modes for 'Cutting'. The first mode marked as **"CUT"** wherein the blade is partially opened and the core guard provides stability to the tissue during cutting. This mode can be used for cutting the tissue with a peeling effect.

5.1.4.5 The other mode is **"CUT +"** wherein the blade is fully exposed as the core guard moves back. This mode can be used for peeling as well as coring and is more suitable for experienced users to achieve quicker morcellation rate. Thus, in all, the Rotatory Knob has three positions – two cutting modes **"CUT"** and **"CUT +"** with an **"OFF" (•)** position between them. [Shown as **(•)**]

CUT Mode

OFF Mode

CUT PLUS Mode

Figure 9: Rotatory Knob with “CUT”, “OFF” & “CUT PLUS” modes

5.1.4.6 Morcellation takes place when the tissue is pulled out by the forceps against the sharp rotating edge of the Hand piece. Amount of tissue morcellated will depend on the position of the Hand piece with respect to tissue to be cut and exposure of the Hand piece.
5.1.4.7 This tissue will be pulled out from the proximal end of the Hand piece.
5.1.4.8 A valve has been provided to prevent loss of insufflation gas when no instrument traverses the lumen.

5.1.5 Removal of the device

5.1.5.1 After morcellation is completed, the Rotor can be stopped by lifting the foot from the Foot Switch.
5.1.5.2 After the Hand piece rotation has stopped, the Rotatory Knob is brought to the “OFF” position (Figure: 9). This will ensure that the blade gets secured before removing the Handpiece from the body.
5.1.5.3 After usage of the device, please ensure the integrity of the device is maintained.

IMPORTANT:
Blade of the VERSATOR® Handpiece must not be rotating while withdrawing the same from the patient’s body otherwise it can cause serious injury to the surrounding organs and tissues. After retrieval of the device from the patient’s body, visually inspect the tip of the Handpiece by rotating the Rotatory Knob to cut-plus position to ensure that the tip is intact before ending the procedure.

5.1.6 Immediate post-operative steps

5.1.6.1 Pressing the “press” button provided at the lower end of the Hand piece will unlock the rotor (Figure: 10).

Figure 10: "Press" button provided at the lower end of the Handpiece

5.1.6.2 The rotor can then be removed by pulling it out of the VERSATOR® Hand piece.
5.1.6.3 The Handpiece and Rotor is disposed in a disposal container. Handpiece should be disposed in accordance with the sharps product disposal procedure followed at your hospital & Rotor to be disposed in accordance with the disposable medical device disposal procedure followed at your hospital.
5.1.6.4 Do Not Clean and Re-sterilize Handpiece or Rotor.

5.1.7 Use of Reducer

5.1.7.1 Align the holes and press the Reducer snaps against the proximal end of the VERSATOR® Handpiece to mount the reducer. (Figure: 11).
5.1.7.2 A gentle audible "click" is heard when the Reducer is securely placed.

Figure 11: Reducer mounted on Handpiece

5.1.7.3 Insert a laparoscopic instrument through the seal opening. The VERSATOR® Reducer can accept 5mm-10mm instruments through its self-adjusting seal without the need for manual adjustment or the loss of pneumoperitoneum pressure.
5.1.7.4 The VERSATOR® Reducer can be disengaged from the Handpiece by pulling its tongue away from the Handpiece.

5.2 Versator Drive unit:

5.2.1 Assembly:

Please note that the VDU and power cord are shipped non-sterile. The system components should be assembled as follows:

5.2.1.1 Attach the foot switch cord connector to the Foot Switch Socket at the back of the VDU. (Figure 13)

Note: '●' red dot mark on connector should be aligned with '·' red square mark on socket while inserting.

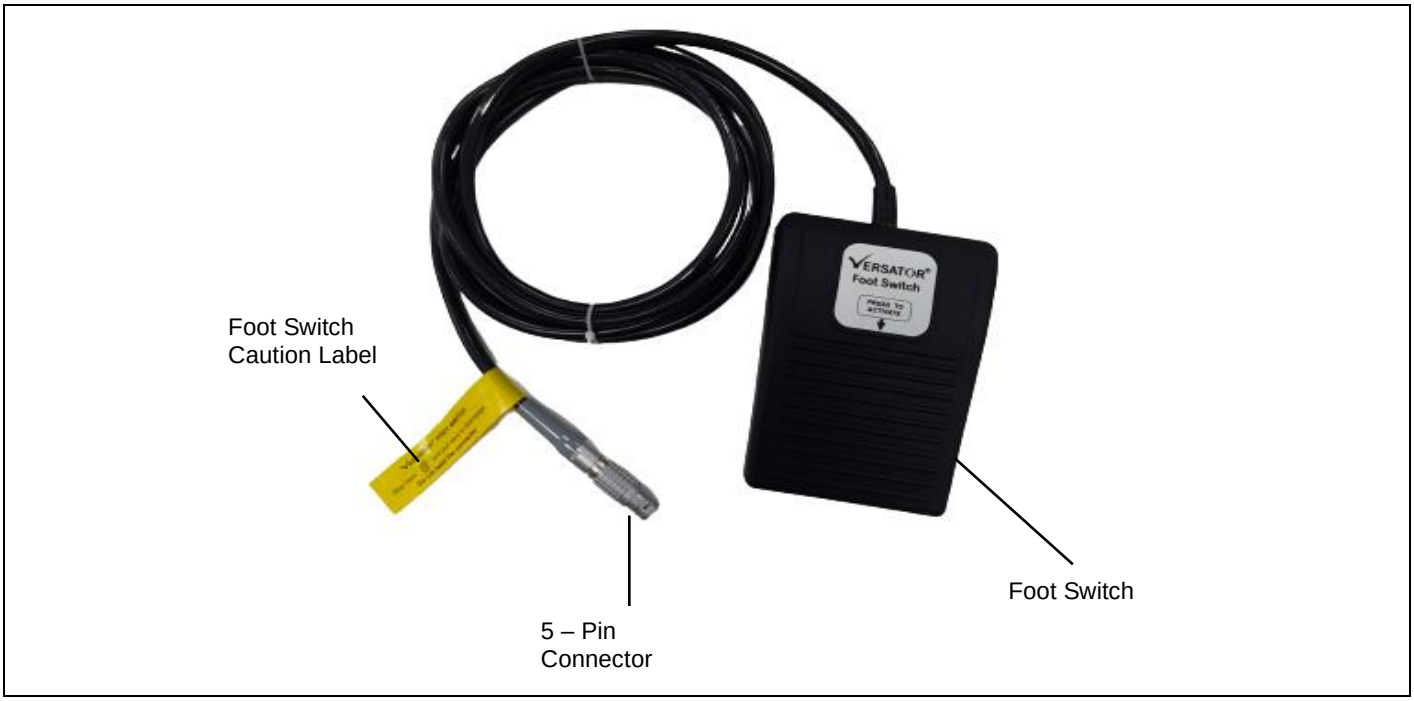


Figure 12: Foot Switch with Cord

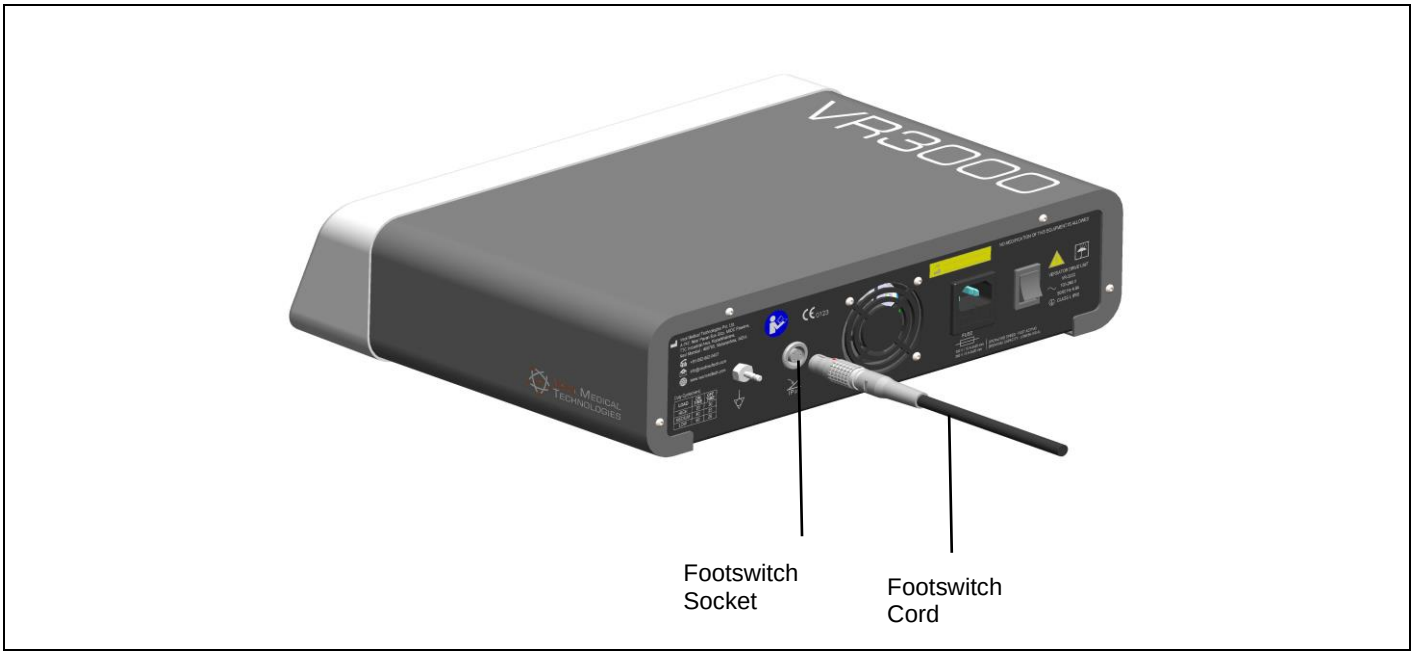


Figure 13: Connecting Foot Switch Cord to the VDU

5.2.1.2 Connect the Rotor Cable to the VDU. (Figure 14).

5.2.1.3 The Rotor Cable receptacle is located on the front of the VDU. Press down on the metal tab until it locks in place.

5.2.1.4 Carefully insert the squared end of the Rotor Cable into the receptacle till a click sound is heard confirming the locking of Rotor Cable to the VDU.

Note: Position the VDU in such a way that the Rotor Cable hangs in a large arc with no sharp bends or loops. A minimum distance of 1 metre should always be maintained between the VDU and the VERSATOR® Tissue Morcellator Handpiece. Do not attempt to sharply bend the Rotor Cable in a diameter of less than 8 inch (20cm). Sharply bent or kinked Rotor Cables may cause the VDU to overheat, overload and stop momentarily.

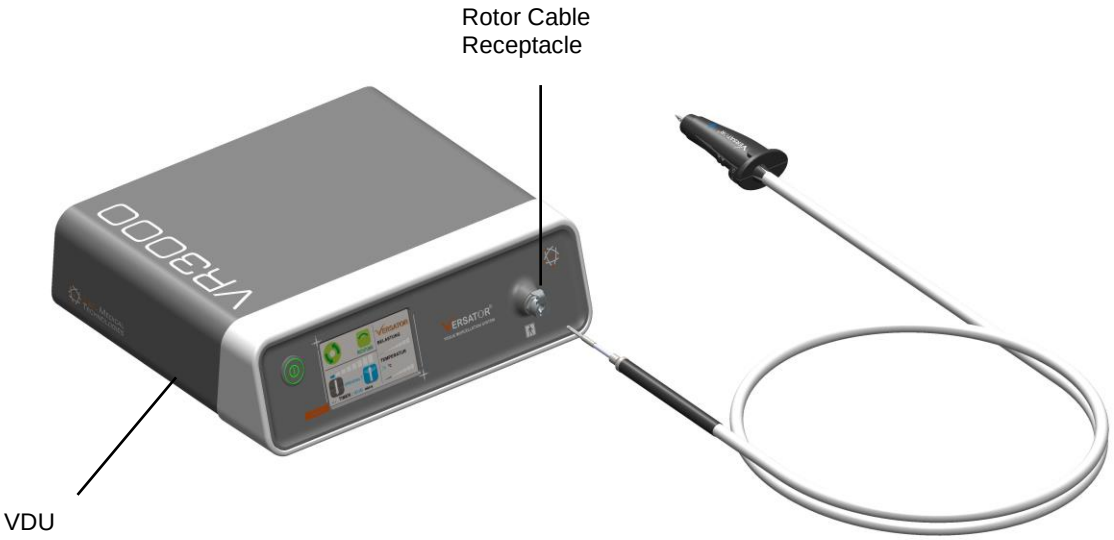


Figure 14: Connecting Rotor Cable to the VDU

5.2.1.5 Attach equipotential plug (available at the point of use) to the equipotential terminal.

Figure 15: Connecting equipotential plug to equipotential terminal

5.2.1.6 Attach the power cord to the back of VERSATOR® VDU (Figure 16)**.** Connect the power cord of VERSATOR® VDU to an AC **Earthed** receptacle.

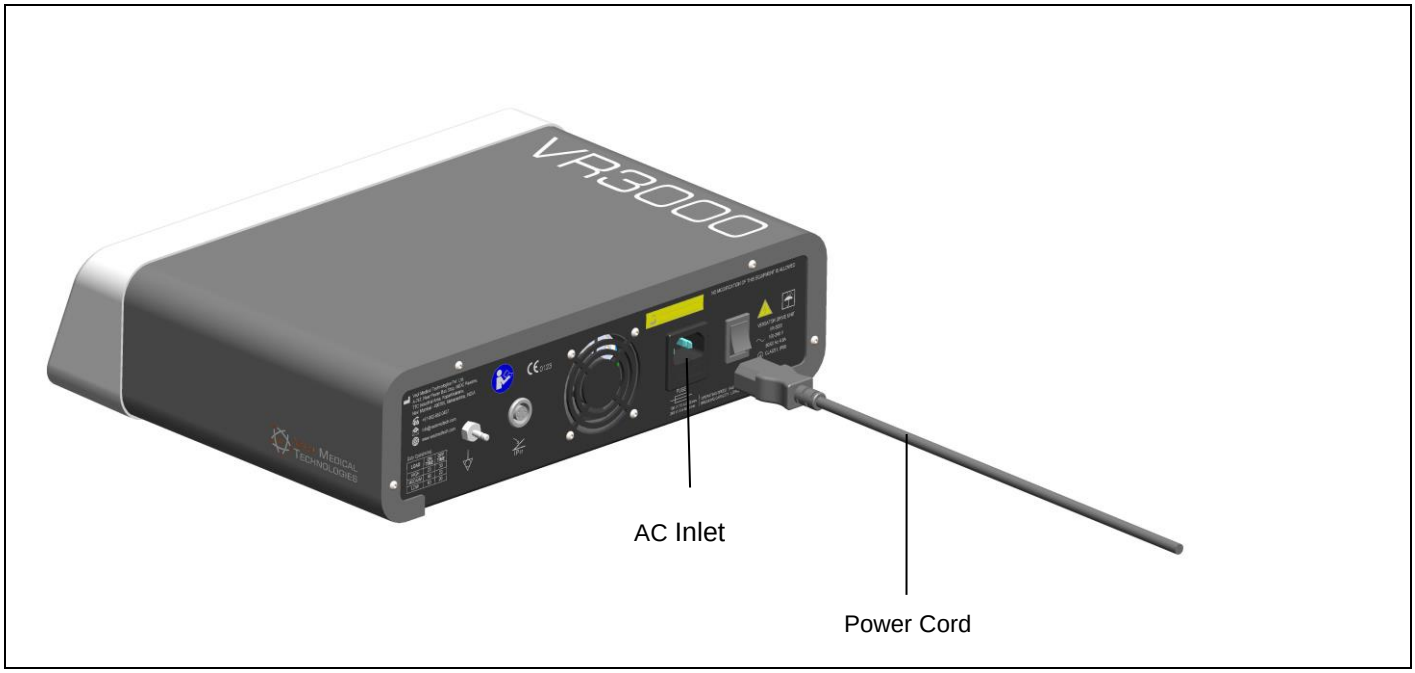


Figure 16: Connecting Power Cord to the VDU

5.2.1.7 Connect the Rotor Handle into VERSATOR® Tissue Morcellation Handpiece in the sterile area Figure 17. (This step will be performed by the surgeon or the assistant in sterile area).

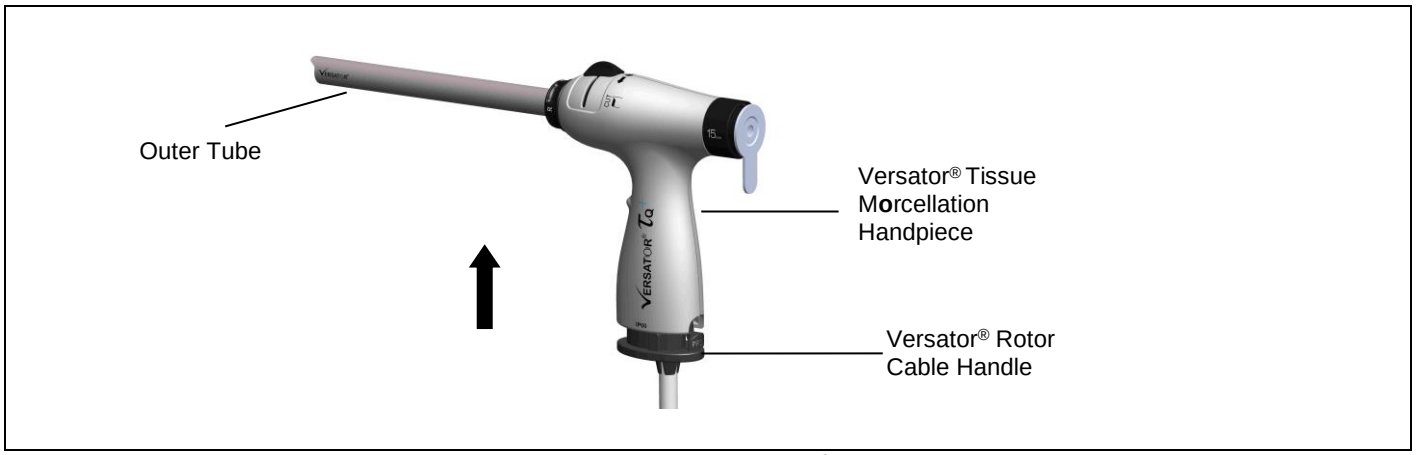


Figure 17: Connecting Rotor Handle into VERSATOR® Tissue Morcellation Handpiece

5.2.2 INSTRUCTIONS FOR USE

Positioning Instructions
In Operation theatre VDU should be positioned in such a way that it will maintain at least 1 meter of distance from patient as shown below (Figure 18).

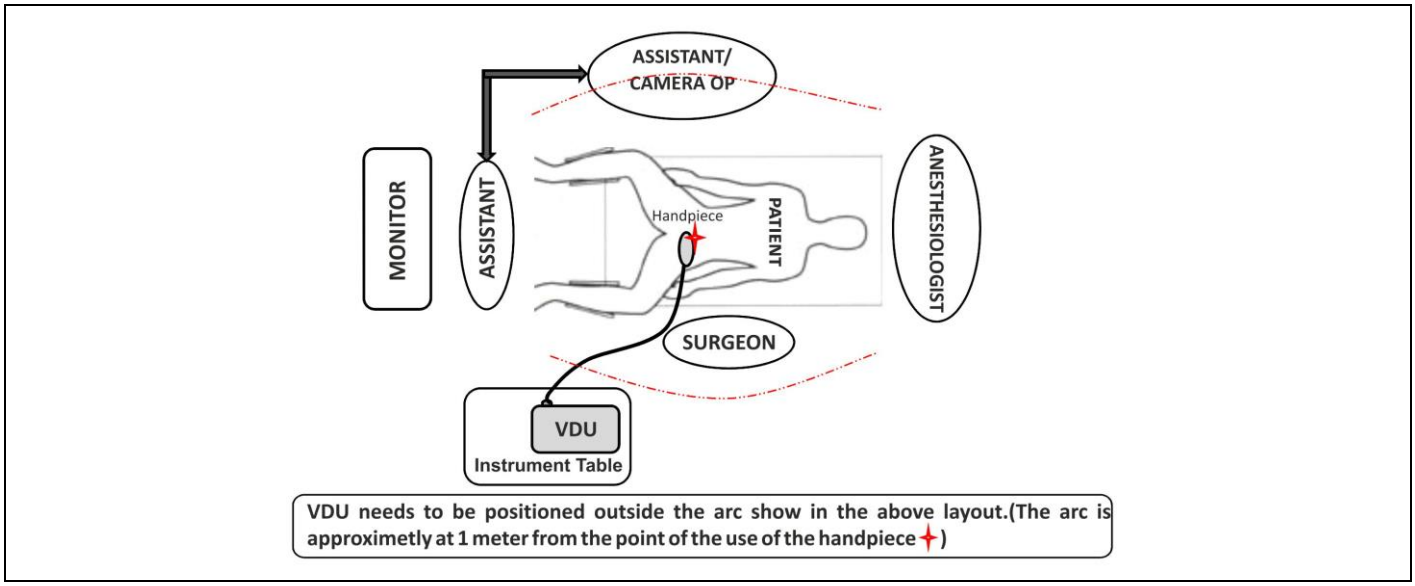


Figure 18: OT layout for positioning of VDU

5.2.3 Operational Instructions

The instructions listed below are to be followed for the optimum functioning of the VDU:

5.2.3.1 Place the VDU in a position that allows free air circulation by cooling from the vent.

5.2.3.2 Connect foot switch by inserting the footswitch connector into foot switch socket at the back of the VDU (See Figure 13).

5.2.3.3 Connect the Rotor Cable to VERSATOR® VDU (See Figure 14)

5.2.3.4 Connect the free end of the power cord into the AC inlet that is provided at the back of VERSATOR® VDU (See Figure 16). Connect the other end of the power cord to the 100V-240V AC wall socket.

5.2.3.5 After connection, switch ON the mains from the wall socket. Now TURN ON the Rocker switch (located at the back of the VDU as shown in Figure 17) which will lead the front mounted push button to glow green. The frequently used functions on the VDU are "Power On", "Power OFF", "Speed control" and "Direction Control".

5.2.3.6 The VDU is powered ON by pressing the Push Button located at the front of the VDU and the interface is displayed on the touch screen.

5.2.3.7 The VDU motor has the speed range of 500 rpm to 4000 rpm in eight steps. Tapping the icon on the touchscreen will increase the speed and the icon can decrease the speed. (The speed can also be changed while cutter is rotating.)

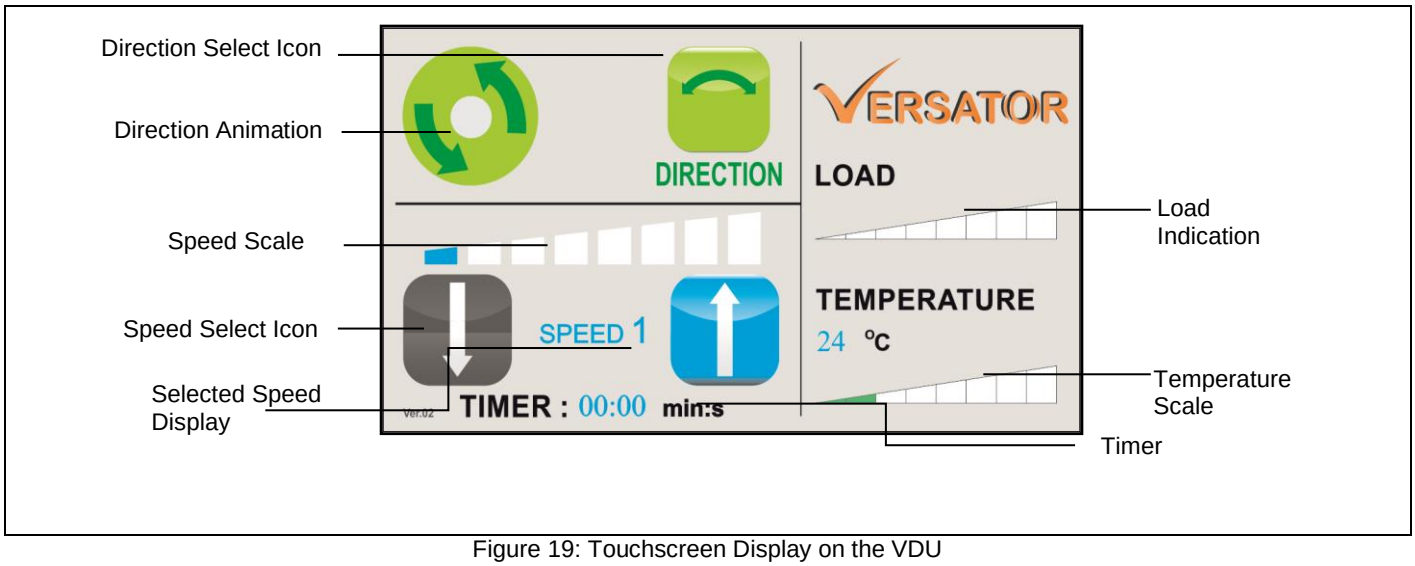


Figure 19: Touchscreen Display on the VDU

5.2.3.8 Select the direction of rotation of the cutter blade by tapping on . This is the Direction Select Icon (Figure 19). Depending on the direction selected, Direction Animation Icon will change. (The direction can also be changed while the cutter is rotating.)

5.2.3.9 Connect VERSATOR® Tissue Morcellation Handpiece to VERSATOR® VDU in the sterile area using Rotor as shown in Figure 17. For more details, please refer Section 6 of VERSATOR® IFU (VR-V-0118) Handpiece and Rotor.

5.2.3.10 To begin the cutter rotation, press the foot switch. The Timer will start counting and the Direction Animation Icon will start rotating in the selected direction.

5.2.3.11 The cutter rotation and timer can be stopped by lifting the foot from the Foot Switch. To continue the time and cutter rotation presses the Foot Switch.

5.2.3.12 After tissue morcellation is completed, the cutter rotation can be stopped by lifting the foot from the Foot Switch.

5.2.3.13 To turn off the display, the green Push Button should be pressed. To cut off the mains power supply to VERSATOR® VDU, the rocker switch should be TURNED-OFF.

5.2.3.14 (Note: After turning off the rocker switch, the Push Button may continue to glow due to residual current. However, the VDU is in non-operating mode and does not pose any risk to the operator or the patient.)

5.2.3.15 Disconnect the Power-cord, Foot Switch and the Rotor from the VDU. For disconnecting foot switch pull out connector by holding on knurl textured ' ' part. Do not twist the connector.

Note:
Timer will be reset to zero only if VERSATOR® VDU is restarted by pressing Push Button. If the load on the motor exceeds the specified limit (in case of jam), VERSATOR® VDU will emanate beep sound and LOAD scale will display Overload (as indicated in RED colour).

If the temperature of device reaches above 80^{o} Celsius, the motor will stop rotating and hence cutter will stop rotating and temperature scale will display Overload (as indicated by blinking of the temperature bar display).

6. BASIC TROUBLESHOOTING

Sr. No.	Issues	Checkpoints for rectification
1.	The Push Button does not glow.	i) Check the power cable is properly attached to the AC inlet. ii) Check whether both the rocker switch and main switch are in ON mode. iii) Check Fuse & Replace the fuse of appropriate rating in case of 100V input voltage replace fuse with 10A rating, In case of 240V input replace fuse with 5A rating fuse.
2.	No display/ fluctuating display.	i) If the green push button does not glow, follow the checkpoints for Issue 1. ii) If the green push button glows and display is still not visible, contact service personnel.
3.	The cutter tube of Handpiece does not rotate/ rotation stops abruptly.	i) Check if the footswitch is properly connected. ii) Check for connection between the rotor and the VDU. Reinsert the rotor if required.
4.	Unable to change the direction/ speed	i) Turn the Push Button OFF and restart.
5.	Overheating of the motor	i) The VDU contains an internal switch to shut the unit off upon overheating. In this event, turn the Rocker Switch OFF and allow the unit to cool for several minutes before restarting.
6.	Rotor cable twists up and stalls the motor	i) Check if the minimum distance between the VDU and the VERSATOR® Tissue Morcellator is approximately 1m. ii) If the problem still persists, reverse the direction of the rotation with the direction icon and intermittently run the motor briefly until the wire unwraps and hangs freely with no loops.

7. TRANSPORT, STORAGE AND CARE

7.1 Storage and Transportation:

The VERSATOR® Handpiece (VR-1000), VERSATOR® Rotor Cable-Sterile (VR-2000), VERSATOR® Rotor Cable – Reusable (VR-0034) and VERSATOR® Drive Unit (VR-3000) should be transported and stored in a clean and dry area away from the direct sunlight, as per the below temperature and humidity conditions:

Storage: +10℃ to +55℃
Transportation: -10℃ to +60℃

Note: Sterility of the product is not affected in case of accidental removal of polymer cap from rotor tip.

7.2 Use and Maintenance:

- The VERSATOR® Handpiece (VR-1000), VERSATOR® Rotor Cable-Sterile (VR-2000), VERSATOR® Rotor Cable – Reusable (VR-0034) and VERSATOR® Drive Unit (VR-3000) used between temperatures 15ºC to 30ºC.
- After completion of use, dispose VERSATOR® Handpiece VR-1000, VERSATOR® Rotor Cable-Sterile VR-2000 and VERSATOR® Rotor Cable – Reusable (VR-0034) in accordance with hospital, administrative and/or local government policy.
- The VERSATOR® Drive Unit should be stored in a cool and dry place. Do not spray, drop or immerse VERSATOR® VDU in liquid. The VERSATOR® Drive Unit should be used at operating temperatures, Relative Humidity, Operating Pressure and Storage pressure mentioned below:

  Temperature: 15ºC to 30ºC.
  Relative Humidity: 20% to 70%
  Operating pressure: 0.7 to 1.08 bar
  Storage pressure: 0.5 to 1.08 bar

Note: When the VDU is taken into the Operation Room from a very cold zone (below 10 deg C), it is likely to cause condensation of water on the electrical circuits of the VDU. Hence, it is advisable to wait for about 4 hrs before using the VDU to ensure evaporation of all condensed water.

After completion of use, clean the VERSATOR® Drive Unit in accordance with hospital, administrative procedure. See section 5 below.

Handling instructions of VDU with its packaging during transportation

- Use original packaging of device for any transportation if any required in Product Service Life.
- Product is fragile and should be handled with care.
- The packages during transportation should be handled with care.
- The packages should not be exposed to direct sunlight or rain.
- Transportation temperature should be maintained as mentioned above.
- The packages should be safeguarded from any contamination, such as chemical vapors, pesticides, undue dust, insets and pests.
- Packages should be transported carefully to prevent damage by stacking beyond the limits mentioned on the packaging (i.e., 6) or damage by abrasion to sharp objects.
- Packages should be handled in appropriate orientation as mentioned on the packaging.

Safe disposal:

For disposal of VDU, VR-3000 after its service life, ensure compliance with hospital/administrative policy and/or local government policy or it is recommended to avail services of Professional junk remover service provider to haul away junk in a safe and environmentally responsible manner.

8. CLEANING/ REUSE

Always keep the VDU clean and dry. The VERSATOR® VDU can be reused many times but it should be cleaned after every use. Spilled fluids may be wiped clean from the outer case with cotton swab dipped in disinfectant like surgical spirit. Ensure that no liquid penetrates the device. (Make sure that cotton swab is properly squeezed to remove excess disinfectant). **DO NOT** use a wet cloth or sponge for cleaning. After usage of the device, please ensure the integrity of the device is maintained.

Important: Disconnect VERSATOR® VDU from the power supply before cleaning.

9. RESTERILIZATION OF REUSABLE COMPONENTS

Sterilization protocol for VERSATOR® Rotor for first use and Reuse.

This document is intended to provide detailed instructions for cleaning and sterilization of the re-usable VERSATOR® Rotor (VR-0034). The healthcare facility should ensure proper selection of the equipment used, operators involved in the processing and the cleaning agents utilized as all these contribute to the efficacy of the processing.

Warnings: The VERSATOR® Rotor is supplied Non-Sterile and thus it needs to be sterilized before use. The recommended sterilization method is by Steam sterilization. Please follow the instructions for sterilization even before the first use.

Limitations: The Rotor should be used only for its intended purpose. The Rotor Cable is a limited re-use device and shall be used for not more than 10 surgical procedures (each procedure utilizing the single use disposable Versator Handpiece VR-1000).

Sterilization prior to first use and Reprocessing Limits:
VERSATOR® Rotor is supplied by Veol Medical as Non-Sterile and hence it need to be sterilized before the first use and before each subsequent uses.

General Recommendations:

- Do not re-use any devices marked for “Single use”.
- Rotor Cable should not be subjected to more than 145 deg C (3.1 bar, 45 PSI) of moist heat.
- The sterilization of the Rotor before first use and re-use is the responsibility of the user. If the Rotor Cable is used without sterilization, then the user shall take full responsibility for the use.
- The user shall ensure that all safety precautions pertaining to the personal safety of the personnel involved in sterilizing the Rotor are taken before sterilization of the Rotor Cable.
- Use only Neutral or mild alkaline detergent solutions for cleaning the Rotor Cable.
- The healthcare facility should ensure that the selected processing steps are safe and effective.

Instructions:

Operation	Operating Mode	Remarks
Point of use	Clean the Rotor Cable with disposable cloth or paper wipes	
Pre-disinfection or decontamination prior to processing.	As soon as the use of the Rotor Cable in surgery is completed, the Rotor cable should be immersed in enzymatic solution for at least 20 minutes. At the end of immersion time, thoroughly rinse the Rotor cable in running water.	Suitable Enzymatic solution recommended for medical devices may be used. Please read the instructions of the manufacturer for the concentration to be used and compliance to safety.
Manual Cleaning/ Automated cleaning	Soak the Rotor cable in neutral or mild alkaline detergent solution for 20 minutes (or Ultrasonic bath for 10 minutes) and lightly brush the Rotor Cable at both the ends with a soft brush to remove all dirt. Brush all along the length of the Rotor cable if dirt exists. If required, Automatic Disinfector may be used. Flush at 45 deg C followed by wash and rinse cycle.	Both ends are the points at which the flexible rotational shaft comes out of the Rotor cable. Neutral or mild alkaline detergent maybe used. Clean water may be used for cleaning.
Rinsing and Drying	Rinse again in with clean water at least for 1 to 2 minutes to remove traces of detergent, if any. Check that there are no remains of the detergent. Rinse till Rotor cable is free of detergents. Wipe off excess water and air-dry the same.	

	If automated disinfector is used, Rotor cable may be dried at 60 degree C.	
Inspection	Check that the Rotor cable is not damaged in any way. Gently rotate the flexible cable with hand from one end and ensure that the flexible shaft within the Rotor cable rotates well. This ensures that mechanical transmission is okay.	
Packing	Place the Rotor Cable in a pouch meant for steam sterilization (preferably with steam sterilization indicator). Handling of the Rotor Cable in any other method should follow the hospital/clinical protocol	The pouch may be a self-sealable pouch meant for steam sterilization. Alternately, a wrapping that withstands steam at 134 deg C and retains the sterility after autoclaving may be used. Ensure that the pouch will be able to accommodate a diameter of at least 30 cm. The Rotor Cable should be wound gently at a radius of about 15 cm to preventing it from kinking or breaking.
Steam Sterilization	Sterilize in steam autoclave at 134 deg C for 5 minutes (Pressure 2.07 bar) in a pouch in a Gravity type sterilizer.	
Storage	The Rotor cables sterilized in a pouch may be dried to be free of moisture if it is not planned to be used immediately.	

10. WARRANTY AND CUSTOMER SERVICE

The VERSATOR® Tissue Morcellation System is manufactured for use only by qualified medical practitioners who have been trained in its use. Any VERSATOR® product with defect will be repaired or replaced, at Veol Medical Technologies Pvt. Ltd.'s option, as the sole and exclusive remedy at no charge to the customer.

The VERSATOR® Handpiece and VERSATOR® Rotor Cable-Sterile is a single use disposable product with a shelf life of 3 years. Any defect found before the use of the product is to be reported to the distributor/manufacturer under warranty for repair or replacement at Veol Medical Technologies Pvt. Ltd.'s option.

Veol Medical Technologies Pvt. Ltd. shall not be liable, expressly or implied, for any damages which might arise or be caused, whether by the customer or by any of the users of the products, as a result of:

1. misuse, mishandling, and/or improper operation.
2. repairs or modification performed other than by a Veol Medical Technologies Pvt. Ltd authorized repair facility.
3. use in any manner or medical procedure, other than those for which it is designed.
4. any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the products.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATUATORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON VEOL MEDICAL TECHNOLOGIES PVT. LTD'S PART. VEOL MEDICAL TECHNOLOGIES PVT. LTD. neither assumes nor authorizes any person to assume for it any other liabilities in connection with the sale of said products. To ensure proper use, handling and care of products, consult the Instructions for Use.

Any serious incident that has occurred in relation to the device should be reported to the Veol Medical Technologies Pvt Ltd and Veol's authorized representative in respective country in which the user and/or patient is established.