

Velocity^{ALPHA}

Velocity Alpha™
Highspeed Surgical Drill System



US Instructions for use

Table of Contents	
General information	4
Intended use	4
System components	4
COMBINATION OF SYSTEM COMPONENTS	5
Manufacturer responsibility	6
General information	6
Warning / safety information	6
IMPROPER HANDLING	7
DANGER ZONES M AND G	7
DISPOSABLE BATTERIES (FOR WIRELESS FOOT SWITCH*)	7
INSTRUMENTS	7
CONTROL UNIT	8
POWER CABLE / SWITCH	8
POWER FAILURE	8
SYSTEM FAULTS / SYSTEM CRASH	8
IRRIGATION LIQUID	8
IRRIGATION TUBE SET STERILITY	8
ROTATION ENERGY	8
RISKS CAUSED BY ELECTROMAGNETIC FIELDS	8
ELECTROMAGNETIC COMPATIBILITY (EMC)	8
System description	10
FRONT OF CONTROL UNIT	10
BACK OF CONTROL UNIT	10
FOOT SWITCH	11
<i>Installing / removing the foot bar</i>	11
<i>Inserting / changing batteries (REF: VAFCBT*)</i>	12
<i>CAN dongle description (REF: VAFCD*)</i>	12
<i>CAN dongle activated</i>	12
<i>Coupling (pairing)</i>	12
<i>Switching off coupling (pairing)</i>	12
<i>Help with coupling problems</i>	12
<i>Plugging in / disconnecting the wired foot switch (REF: VAFCD*)</i>	13
<i>Plugging in / removing the CAN dongle (REF: VAFCD* for wireless foot switch REF: VAFCBT*)</i>	13
DESCRIPTION – MOTOR WITH CABLE	14
Installing/setting up the system	15
Setting up the system	16
SWITCHING THE CONTROL UNIT ON AND OFF	17
<i>Switching the control unit on</i>	17
<i>Switching the control unit off</i>	17
TEST RUN	17
Icons 18	
ICONS - DISPLAY	18
ICONS - INFORMATION	18
ICONS - MAIN MENU	18
ICONS - PROGRAM	18
ICONS - SETUP	19
Default settings	20
Initial commissioning – setup wizard	20
Control unit operation – main menu	21
Operating time	22
USAGE WITH DRILL ATTACHMENTS	22
USAGE WITH SAW ATTACHMENTS	22
OVERHEATING	22
System settings	22
IRRIGATION LIQUID QUANTITY	22
IRRIGATION PUMP ON/OFF	22
DIRECTION OF ROTATION	22
RESET TO DEFAULT SETTINGS	23
CHANGING PROGRAMS USING THE FOOT SWITCH	23
CHANGING THE DISPLAY MODE	23
FOOT SWITCH MODE	23
MOTOR START MODE	23
MOTOR STOP MODE	24
CUSTOM SETTINGS	24
SOFTWARE UPDATES	24
Error messages	24
Assembly and usage	25
WORKING WITH ATTACHMENTS AND ACCESSORIES	25
<i>Coupling the attachments and motor</i>	25
<i>Inserting rotating instruments / exposure function</i>	25
<i>Installation of minimally invasive attachments to the base unit for VMN-T shafts (REF: VMN-C2)</i>	26
<i>Removing minimally invasive shafts from the base for VMN-T shafts (REF: VMN-C2)</i>	27
<i>Working with attachments</i>	27
<i>Assembling the craniotome</i>	27
<i>Working with craniotomes</i>	28
<i>Removal of milling cutter from craniotome</i>	28
USING THE SPEED REDUCER	28
SAWS	29
<i>Inserting the saw blades</i>	29
<i>Working with saw attachments</i>	29
CONSUMABLES	29
Processing and care	30
GENERAL INFORMATION	30
WARNINGS	30
CLEANING AGENTS AND DISINFECTANTS TO BE USED	31
CONTROL UNIT AND FOOT SWITCH	31
<i>Manual cleaning and disinfection</i>	31
MOTOR AND ATTACHMENTS	31
<i>Pre-disinfection at the place of use</i>	31
<i>Option 1: Manual cleaning (motor and attachments)</i>	32
<i>Option 2 – recommended option: Automated cleaning (motor and attachments)</i>	32
<i>Cleaning adapter filter</i>	33
<i>Care and inspection</i>	34
<i>Visual inspection of cleaning results</i>	34
<i>Oil care</i>	34
<i>Packaging</i>	34
<i>Sterilization (motor and attachments)</i>	35
<i>Storage</i>	35

System service	35
RECURRING TESTS.....	35
Repairs and returns	35
Technical data	36
Recycling and disposal	36
Symbols used / explanation.....	37
Warranty.....	38

General information

You must make sure you have read and understood this manual before using the Velocity Alpha™ system.

The Velocity Alpha™ system may only be used by trained personnel, such as doctors and users with technical training. The development of the device was aimed at medical user groups with experience in using motor-operated surgical instruments.

The surgeon and all other personnel involved must familiarize themselves with the system and how to use it.

adeor recommends guidance and training by adeor personnel or a partner authorized by adeor.

Intended use

The Velocity Alpha™ drill system is indicated for trepanating, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone and bone replacement materials.

Medical indication:

Applications:	Cutting, removing, shaping and sawing hard and soft tissue and replacement materials
Areas of use:	Neurosurgery and spinal surgery

Medical contraindications:

The Velocity Alpha™ drill system must not be used on the central nervous or vascular system.

The safe and efficient use of components is influenced by factors which can only be controlled by the user. For this reason, this user instructions offer a base for usage. The user is responsible for observing the warnings and safety information, and for carrying out the work correctly.

System components

Article number	Description
Control unit	
VAM	Velocity Alpha™ motor with 3.5 m cable
VAC110	Control unit (110V)
VAC220	Control unit (220V)
VAFC	Foot switch (wired)
VAFCBT*	Foot switch (wireless)*
VAFCD*	Dongle for VAFCBT*

* not cleared for US market

Craniotome attachment	
VMN-C1	Craniotome base
VMCH-1	Duraguard, short
VMCH-2	Duraguard, medium
VMCH-3	Duraguard, long
VMCH-1R	Duraguard, short, rotatable
VMCH-2R	Duraguard, medium, rotatable
VMCH-3R	Duraguard, long, rotatable
VMCH-D	Craniotome head
Drill attachment, straight	
VMN-XS	Nose piece, straight, extra short
VMN-S1	Nose piece, straight, short
VMN-S2	Nose piece, straight, medium
VMN-S3	Nose piece, straight, long
Drill attachment, angled	
VMN-A1	Nose piece, angled, short
VMN-A2	Nose piece, angled, medium
VMN-A3	Nose piece, angled, long
VMN-A4	Nose piece, angled, XL
VMN-A5	Nose piece, angled, XXL
VMN-A6	Nose piece, angled, XXXL
Base attachment for minimally invasive attachment shafts	
VMN-C2	Base for VMN-T attachments
Minimally invasive attachment shafts, straight	
VMN-TS1	Minimally invasive attachment, 90 mm, straight
VMN-TS2	Minimally invasive attachment, 120 mm straight
VMN-TS3	Minimally invasive attachment, 150 mm straight
VMN-TS4	Minimally invasive attachment, 180 mm straight
Minimally invasive attachment shafts, angled	
VMN-TA1	Minimally invasive attachment, 90 mm, angled
VMN-TA2	Minimally invasive attachment, 120 mm, angled
VMN-TA3	Minimally invasive attachment, 150 mm, angled
Speed Reducer / Trepan Adapter	
VMT-102E	Trepan Hudson adapter
Saw attachments (microsawing)	
VMN-OS1	Saw attachment, oscillating
VMN-SS1	Saw attachment, sagittal
VMN-RS1	Saw attachment, reciprocating

Irrigation attachments	
VMN-IR-XS	Irrigation attachment, extra short
VMN-IR-1	Irrigation attachment 1, short
VMN-IR-2	Irrigation attachment 2, medium
VMN-IR-3	Irrigation attachment 3, long
VMN-IR-4	Irrigation attachment 4, XL
VMN-IR-5	Irrigation attachment 5, XXL
VMN-IR-6	Irrigation attachment 6, XXXL
Accessories	
OA-100	Oil spray adapter
TSC-VA	Transport & storage case
PST-200	Sterilization tray, plastic
PST-201	Sterilization tray, stainless steel
VMME-FS-H	Foot bar for foot switch
VMM-EC-S	Irrigation stand
VMM-CLIPS	Irrigation tube clip set (5 pieces)
CA100	Cleaning adapter

Consumables	
HiCUT burs and cutters	Only used in combination with relevant attachments
HiCUT saw blades	
Meridian perforators	
VMM-ITS-6	Irrigation tubing set 3.8 m (6 pieces)
64375	MELAG ceramic filter disc for cleaning adapter (10 pieces)

Combination of system components

Control unit	Motor	Attachment		Instrument	Speed	Areas of use	
VAC110 or VAC220	VAM	VMN-C1	VMCH-1 VMCH-2 VMCH-3	HiCUT craniotomy burs	Up to 80,000 rpm	Neurosurgery	
			VMCH-1R VMCH-2R VMCH-3R VMCH-D				
		VMN-C2	VMN-TS1 VMN-TS2 VMN-TS3 VMN-TS4	HiCUT burs for minimally invasive attachments		Neurosurgery and spinal surgery	
			VMN-TA1 VMN-TA2 VMN-TA3				
				VMN-XS VMN-S1 VMN-S2 VMN-S3 VMN-A1 VMN-A2 VMN-A3 VMN-A4 VMN-A5 VMN-A6		HiCUT burs	
				VMN-OS1 VMN-SS1 VMN-RS1		HiCUT saw blades	Saw mode (P4)
		VMT-102E	Meridian perforators	Perforator mode (P3)	Neurosurgery		

Manufacturer responsibility

The manufacturer can only guarantee the safety, reliability and efficiency of the system if the following points are observed:

- ▶ The system must be used in accordance with these operating instructions.
- ▶ The system does not contain any components which can be repaired by the user themselves. Repair and service must be carried out by adeor.
- ▶ The power supply in the application environment must be installed in conformity with IEC 60364-7-710 ('Installation of electrical equipment in rooms for medical use') or in accordance with the regulations in the application country.
- ▶ Unauthorized opening of system components will invalidate the warranty.

General information

The user must make all necessary preparations for a successful operation, including preparing for a possible malfunction.

The adeor Velocity Alpha™ system must be cleaned, disinfected and sterilized before and after every use according to processing instructions. Usage of the system without completely processed system components is prohibited.

Do not use any damaged, faulty or altered adeor system components.

Do not use the system in direct proximity to the patient's ear canal. The build-up of noise may cause long-term damage.

Always wear eye protection when operating the adeor Velocity Alpha™ system.

Check for damage before each use (device must be disconnected from the power supply):

- ▶ Check the motor, attachments and instruments for visual defects.
- ▶ Assemble the system in the desired configuration and check the plug connections between the motor and attachment by pulling gently.
- ▶ Check that the connection between the milling cutter/saw blade and attachment is secure by pulling gently on the milling cutter/saw blade.
- ▶ Leave the motor to run briefly (test run)
 - Does overheating occur?
 - Is lubricant leaking?
 - Are the parts moving abnormally in relation to each other?

The Velocity Alpha™ system may only be used after a successful test.

Warning / safety information



Observe the following safety information in all circumstances:

- ▶ Only use the system in accordance with its intended purpose.
- ▶ Store the system, including the foot switch, for 24 hours at room temperature before using it for the first time.
- ▶ Replace the foot switch when you notice a decrease in the resistance of the pedal.
- ▶ Never touch the patient and the foot switch connection on the control unit or the irrigation tube at the same time.
- ▶ The ESD (electrostatic discharge) spring contact on the underside of the foot switch must always touch the floor during operation.
- ▶ Only install the adapter and shafts when the motor is at a standstill.
- ▶ Never touch moving instruments.
- ▶ Never activate the quick release mechanism of the motor adapter while the motor is running.
- ▶ Check the control unit, attachments, motor cable and all other components for visible damage before each use.
- ▶ Do not use the system if there is visible damage.
- ▶ Avoid overheating the operating area.
- ▶ Disconnect the control unit from the power supply before changing fuses.
- ▶ Check the program settings before each system start.
- ▶ Observe the manufacturer's information for the attachments and instruments with regards to speed and direction of movement.
- ▶ Do not forget to oil the system components. Oil care reduces friction, reduces the noise level and prolongs the lifespan of the system components.
- ▶ Do not use too much force when milling. The best results are achieved when minimal force is used.
- ▶ Never bend the shafts/instruments and do not use them as levers.
- ▶ Never use the system in surgery until a successful function test has been carried out.
- ▶ Start cleaning the components used directly after application.
- ▶ Never clean the system in an ultrasonic bath.
- ▶ Do not use defective or blunt instruments (milling cutters, saw blades).
- ▶ Do not mill in areas that you cannot see.
- ▶ Never use the system without previous training by adeor or an authorized adeor partner.
- ▶ Never activate the foot switch while instruments are in use or attachments are being changed.

- ▶ Do not re-sterilize and reuse disposable devices.
- ▶ Do not use the system near MR systems.
- ▶ Only use instruments approved by adeor.
- ▶ Touching surrounding tissue with the instrument may lead to injury.
- ▶ Always ensure that there is a sufficient supply of irrigation liquid and make sure that it is aspirated properly.

Never work with increased pressure or force. High-speed drill systems only require minimal pressure. Increased pressure leads to major wear and tear on the system. Working with increased pressure and / or insufficient irrigation may overheat tissue and cause tissue damage.

Saws

- ▶ Only assemble parts with matching type or serial numbers.
- ▶ (Exception: It may be necessary to change parts during service and / or repair work - these may have a new serial number).
- ▶ Only screw in the clamp screw completely when a saw blade is fixed (danger of breaking).

Improper handling

Improper handling in combination with a faulty system structure or faulty service causes the manufacturer's liability for the system to expire.

Danger zones M and G

In accordance with IEC 60601-1/ANSI/AAMI ES 60601-1, the control unit - together with the foot switch and motor - is not designed for use in potentially explosive environments or with potentially explosive anaesthetics which contain oxygen or nitrogen.

The system is not suitable for use in environments with concentrated oxygen.



The foot switch meets IEC 60601-1/ANSI/AAMI ES 60601-1 for use in Zone M (AP).

Zone M is defined as and describes the part of a room where potentially explosive environments may arise as a result of the combination of various anaesthetics and / or other medical compounds. The environments in question are spatially and temporally limited.

Zone M describes a cut-off pyramid under the operating table with an angle of 30°.

- ▶ Be aware that it is difficult to recognize when the motor is running at very low speeds.
- ▶ The ESD (electrostatic discharge) spring contact on the underside of the foot switch must touch the floor during use.

Disposable batteries (for wireless foot switch*)

- ▶ Change the disposable batteries immediately when requested to do so (battery symbol in the control unit display).
- ▶ Only change the batteries outside Zone M.
- ▶ Only use high-quality AA / Mignon / LR6 / 1.5 V disposable batteries. There is a risk of explosion if you use the wrong battery type.
- ▶ Never use new, old or different kinds of disposable batteries at the same time.
- ▶ Do not use rechargeable batteries.
- ▶ When inserting disposable batteries, pay attention to the correct positioning of the plus and minus poles.
- ▶ Check the O-ring on the battery compartment cover for damage. Change faulty and / or loose O-rings immediately.
- ▶ Always keep reserve batteries handy.
- ▶ Dispose of defective or used disposable batteries immediately and properly via collection systems. Do not dispose of batteries with household waste.

Disposable batteries may cause damage by leakage or corrosion.

- ▶ Remove the disposable batteries if you are not using the foot switch for a long period.
- ▶ Observe the safety information from the battery manufacturer.

Instruments

- ▶ Only insert the instrument into the attachment when the motor is at a standstill.
- ▶ Do not use any damaged components.
- ▶ Never activate the clamping mechanism on the attachment while the device is in use or running down.
- ▶ Always ensure that there is enough irrigation liquid.
- ▶ Avoid overheating treatment areas.
- ▶ Never reach into instruments while they are running (or running down).

* not cleared for US market

Control unit

The control unit is classified as a 'conventional device (closed device without protection against water penetration)'.

Power cable / switch

- ▶ Only use the power cable provided.
- ▶ Never pull on electric cables.
- ▶ Only use the power cable with sockets with protective contacts.
- ▶ Place the device in a way that ensures that the on/off switch and socket can be reached at any time.
- ▶ The system can be disconnected in dangerous situations by switching off or pulling the plug from the power source.
- ▶ The on/off switch can also be used to stop the system safely.

Power failure

In the event of a power failure or, if the system is switched off, the last settings used are stored for a restart.

System faults / system crash

- ▶ A system crash does not mean a critical fault.
- ▶ In this instance, just restart the system.

Irrigation liquid

The system was developed to be used with physiological saline solution.

- ▶ Only use the adeor irrigation tube set and accessories approved by adeor.
- ▶ Always make sure that the operating conditions are correct.
- ▶ Always ensure that there is sufficient and suitable coolant available and that appropriate aspiration is carried out.
- ▶ Only use suitable coolants and observe the medical information and notes from the manufacturer.

Irrigation tube set sterility

The irrigation tube is a sterile disposable item. Observe the expiry date and disposal guidelines for irrigation tubes.

- ▶ Only use undamaged irrigation tubes.

Rotation energy

The rotation energy stored in the drive system can cause the torque to briefly exceed the set value, if the tool decelerates.

Risks caused by electromagnetic fields

The functionality of implanted pacemakers and implantable cardioverter defibrillators (ICDs) can be influenced by magnetic fields.

- ▶ Find out whether the patient is wearing a pacemaker or ICD and check the insert.
- ▶ Analyze the risks and benefits.
- ▶ Keep the motor as far away from the implanted device as possible.
- ▶ Do not place the motor on the patient.
- ▶ Take action if there are any signs of the patient's general health condition changing.
- ▶ Symptoms such as an increased heartbeat, irregular pulse and dizziness may be signs of problems with pacemakers or ICDs.

Electromagnetic compatibility (EMC)

EMC warnings and information:

- ▶ The power plug is a means of disconnecting the device from the power supply (disconnection from the power socket). Make sure that the socket is easy for the operator to reach. Do not place the control unit in a position where it is difficult to pull the power plug from the socket.
- ▶ Avoid using this unit in close proximity to other equipment or stacked with other equipment as this may cause malfunction. If the device must still be used in this manner, this device and the other devices should be observed to ensure that they are working properly.
- ▶ The use of accessories, transformers and leads not specified or provided by adeor may cause an increase in electromagnetic interference emitted or a reduction in electromagnetic interference immunity of the device, and lead to malfunction.
- ▶ Portable HF communication devices (wireless devices, including accessories such as antenna cables and external antennae) should not be used at a distance below 30cm (12 inches) from the designated adeor parts and leads of the Velocity Alpha™ Highspeed Surgical Drill System. Non-compliance may result in a decrease in the device's performance characteristics.
- ▶ The characteristics of this device, which are identified by transmissions, mean that it can be used in industrial areas and in hospitals (CISPR 11, Class A). When used in a living area (for which Class B is usually required, in

accordance with CISPR 11), this device may not offer appropriate protection from radio services. If applicable, the user must take remedial actions, such as converting or realigning the device.

Medical electrical devices are subject to special precautionary measures with regards to EMC, and must be installed and operated in accordance with the following guidelines.

adeor guarantees that the control unit can only meet EMC guidelines if original adeor accessories and spare parts are used. Using accessories and spare parts which are not authorized by adeor may lead to increased emission of electromagnetic disturbances or reduced resistance against electromagnetic disturbances.

The current EMC manufacturer declaration can be directly requested from adeor:

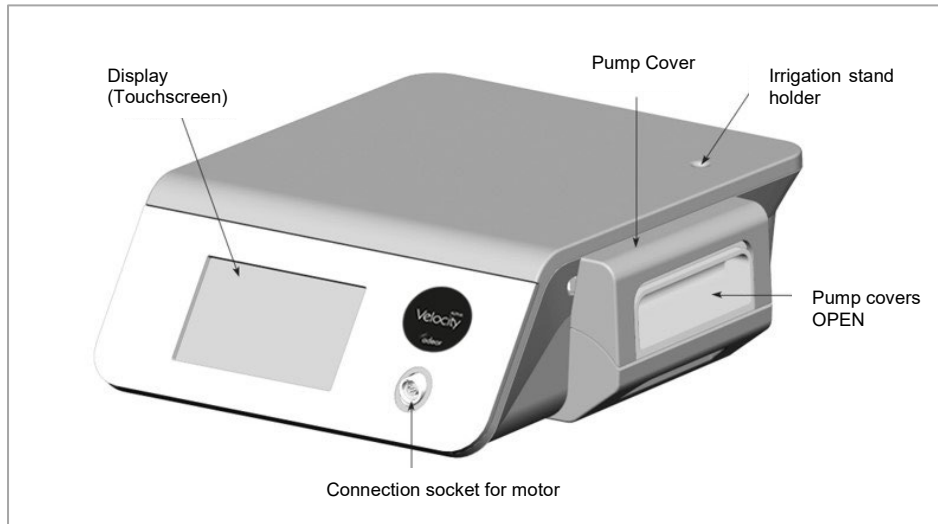
Email: office@adeor.com

HF communication equipment

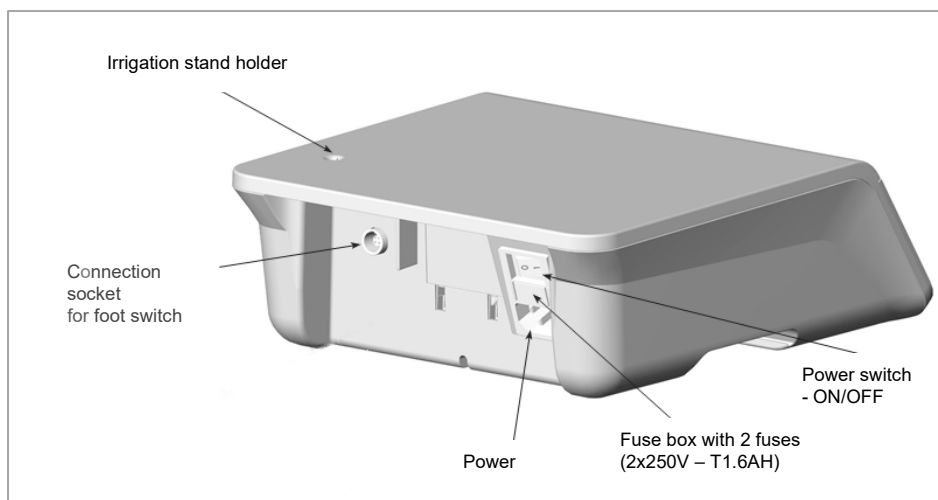
Do not use any portable or mobile HF communication devices (such as mobile telephones). These can influence medical electrical devices.

System description

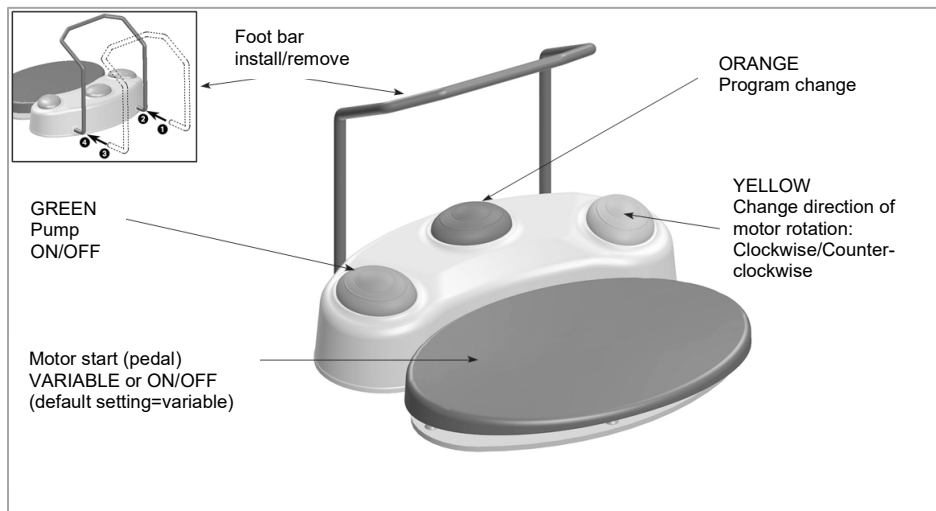
Front of control unit



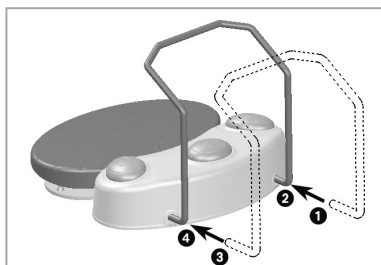
Back of control unit



Foot switch

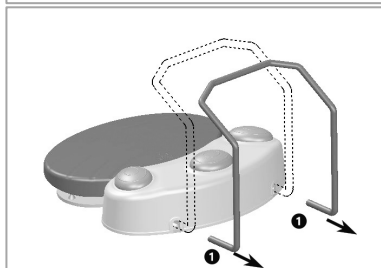


Installing / removing the foot bar



Installing the foot bar

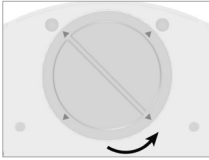
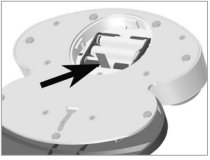

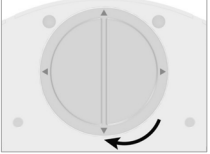
- ▶ Position one of the foot bar endings in the hole in the foot switch.
- ▶ Slide the foot bar in as far as possible.
- ▶ Position the second foot bar ending in the other hole in the foot switch.
- ▶ Slide the foot bar in as far as possible.



Removing the foot bar

- ▶ Pull the foot bar out.

Inserting / changing batteries (REF: VAFCBT*)

<p>1. Opening the battery compartment</p>  <p>Open the battery compartment ▶ Pay attention to the symbols.</p>	<p>2. Removing the batteries</p>  <p>Pull the red tab and remove the batteries.</p>
<p>3. Inserting the batteries</p>  <p>Insert the batteries. ▶ Pay attention to the positioning of the plus and minus poles.</p>	<p>4. Locking the battery compartment</p>  <p>Lock the battery compartment.</p>

CAN dongle description (REF: VAFCD*)**CAN dongle activated**

Icon visible on display

- ▶ CAN dongle plugged in
- ▶ Control unit switched on
- ▶ Foot switch activated

Coupling (pairing)

The wireless foot switch (REF: VAFCBT*) and the CAN dongle (REF: VAFCD*) are coupled on delivery. If the coupling is inactive, activate the coupling on the control unit and follow the instructions.

Switching off coupling (pairing)

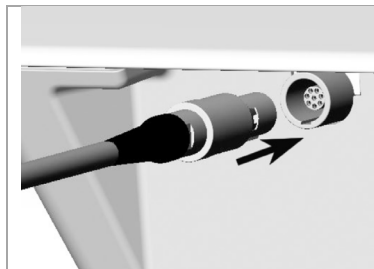
Press the green, orange and yellow buttons on the wireless foot switch together for at least three seconds (REF: VAFCBT*).

Help with coupling problems

- ▶ Check the plug connection of the dongle.
- ▶ Remove any metallic objects between the foot switch, control unit and dongle.
- ▶ Change the position of the foot switch.
- ▶ Remove any temporary sources of disturbances (e.g. brush motors, mobile telephones, wireless devices, WLAN).
- ▶ Undo the coupling (pairing) and recouple it.
- ▶ Remove and then reinsert the batteries.

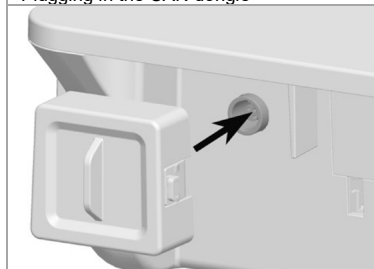
If these steps do not solve the coupling problem, an inspection by adeor will be required.

* not cleared for US market

Plugging in / disconnecting the wired foot switch (REF: VAFC)

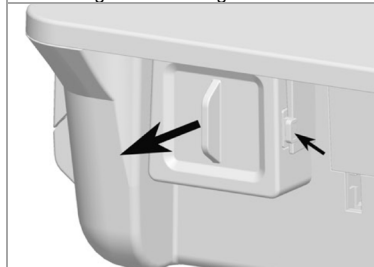
Plug the foot switch in or disconnect the foot switch from the control unit.

Pay attention to the positioning.

Plugging in / removing the CAN dongle (REF: VAFCD* for wireless foot switch REF: VAFCBT*)**Plugging in the CAN dongle**

Plug in the CAN dongle.

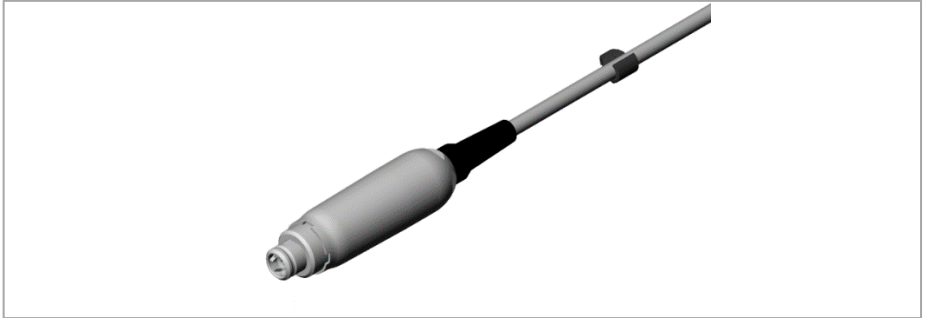
Pay attention to the positioning.

Removing the CAN dongle

Press the locking tab on the side and remove the CAN dongle.

* not cleared for US market

Description – motor with cable



The motor with cable is a Type B application part (not suitable for intracardial use).

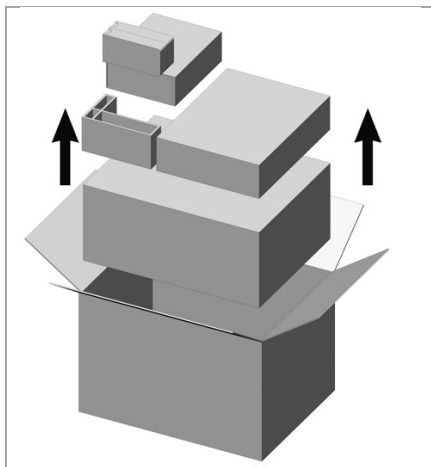
The motor with cable must not be oiled (lubricated for life).

The motor with cable must not be dismantled.

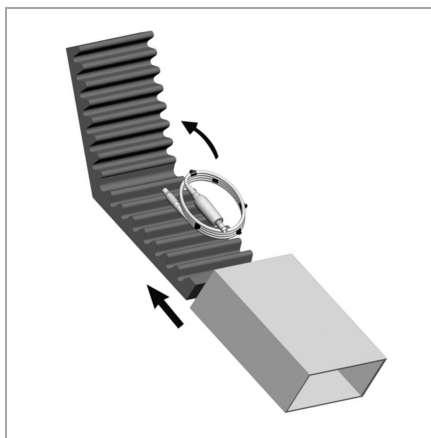
To reduce wear, do not immerse the motor with cable in liquids.

Installing/setting up the system

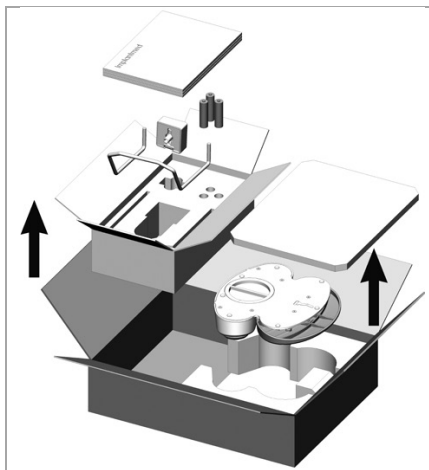
1. Take out the individual packaging pieces.



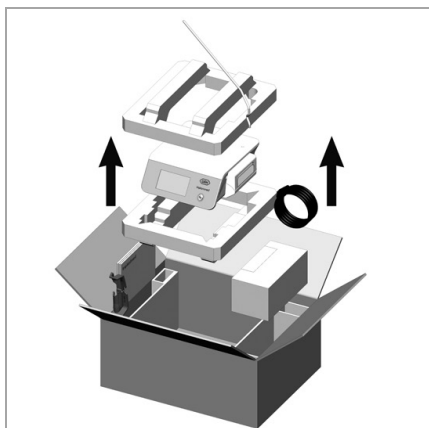
2. Take out the motor with cable.



3. Take out the foot switch, user instructions and accessories.



4. Lift out the insert with the control unit. Take the power cable, irrigation stand and user instructions out.



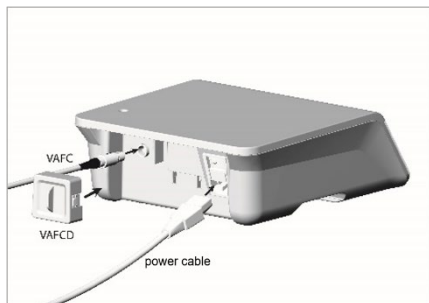
The packaging is environmentally friendly and can be disposed of by local recycling companies. adeor recommends to retain the original packaging.

Setting up the system

Place the control unit on a flat level surface.
Make sure that the control unit can be disconnected from the mains at any time.

Plug in the power cable and foot switch.

- ▶ Pay attention to the positioning.



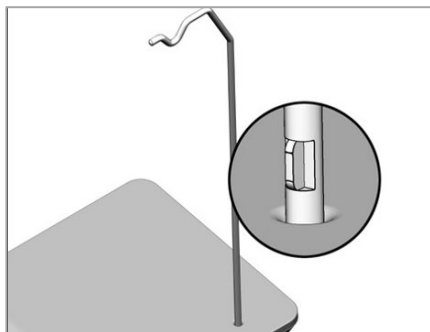
Plug in the motor cable.

- ▶ Pay attention to the positioning.



Insert the irrigation stand.

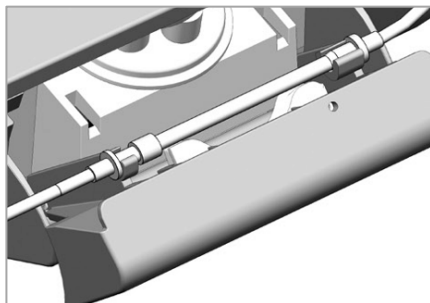
- ▶ Pay attention to the positioning (maximum load capacity 1.5 kg).



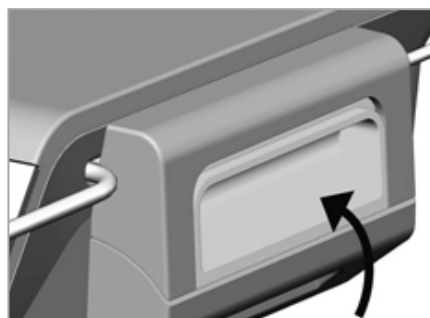
Open pump cover.

Insert/remove irrigation tube.

- ▶ Pay attention to the sequence.



Close pump cover.



Switching the control unit on and off

Switching the control unit on

Insert the power cable into a socket with protective contact. (The third conductor in the power cable is the protective conductor.)

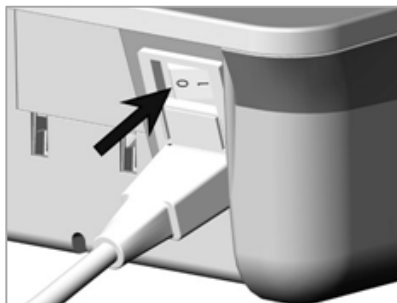


Switch the device on using the toggle switch on the back.



Switching the control unit off

Switch off the device using the power switch.



Disconnect the power connection.








Test run

Do not hold the motor at eye height with the attachment mounted.







- ▶ Mount the attachment to the motor.
- ▶ Insert the instrument.
- ▶ Align the attachment, together with the instrument, with the head facing downwards.
- ▶ Start the motor using the foot switch.
- ▶ If there are any malfunctions (e.g. vibrations, unusual noises or heating up), **stop the motor immediately** and contact adeor directly (email: office@adeor.com).

Icons









Icons - display

	Add user
	Back/Cancel
	Confirm/Save
	Change to next page
	Decrease/increase settings by pressing the plus/minus buttons or moving the slider.





Icons - information

	Setting selected
	Black = information Blue = information with possible choices
	Red = error message, work cannot be continued Orange = error message, work can be continued
	red = change batteries
	Wireless foot switch (REF: VAFCBT*)
	Foot switch (REF: VAFC)

Icons - main menu




















	Absolute
	Bars
	Percentage
	Copy
	Rename
	Activate
	Extinguish
	Rotation speed











Icons - program

	Program 1 Standard mode
	Program 2 Maximum rotation speed mode
	Program 3 Perforator mode
	Program 4 Saw mode

* not cleared for US market

Icons - setup

	Screen and motor lock
	User
	System
	Coupling (pairing)
	Manage users
	Copy
	Rename
	Extinguish
	Activate
	Foot switch settings
	Variable
	On/Off
	No foot switch connection.
	Set screen and motor lock
	Interval of screen and motor lock
	Sound
	System test
	Equipment info
	Service

	Software update
	Reset
	Licences
	Start over
	Motor control info
	User interface
	Foot switch info
	Module info
	Language
	Direction of rotation

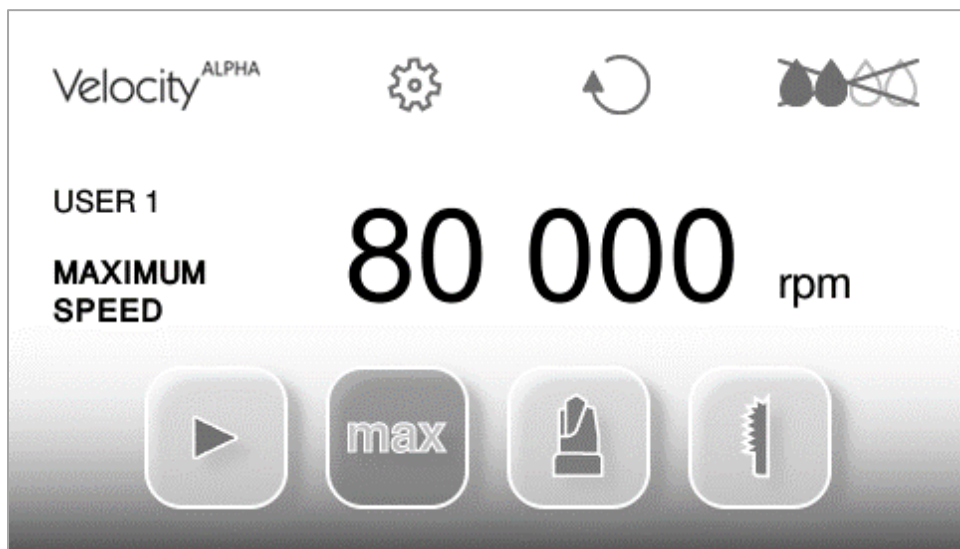
Default settings

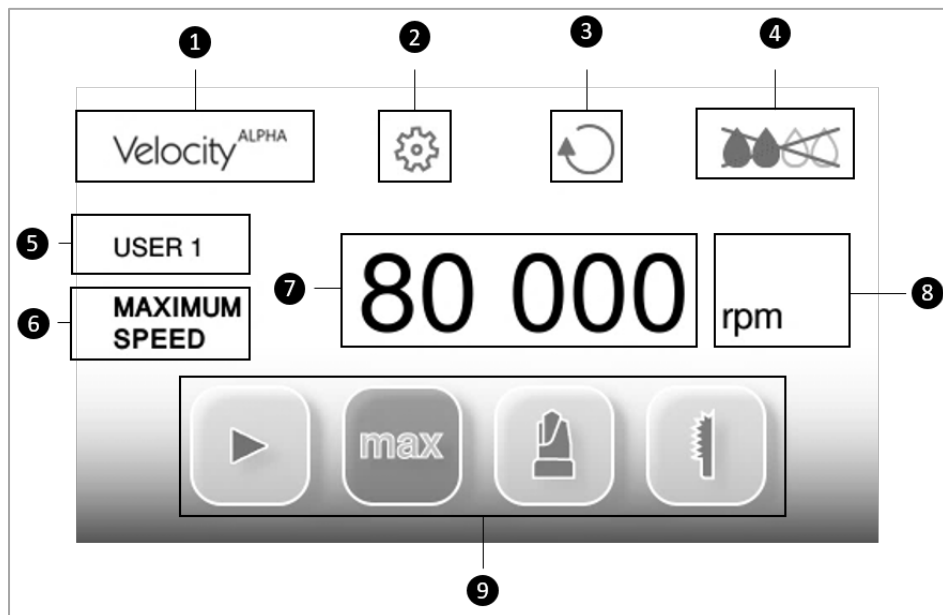
	Program 1 Standard mode	Program 2 Max. speed	Program 3 Perforator mode	Program 4 Saw mode
Gear ratio	1:1	1:1	64:1	1:1
Rotation speed (rpm)	75,000	80,000	900	40,000
Adjustment range	1000 – 80,000	rigid	800 - 1200	rigid
Motor rotation direction	clockwise	clockwise	clockwise	clockwise
Irrigation	off	off	off	off

Initial commissioning – setup wizard

▶ Only operate the touchscreen with your fingers.
Operating the touchscreen with hard objects may scratch or damage the surface.
Switch the control unit on and follow the setup wizard instructions.
The setup wizard will take you through the various setup steps to the main menu:

- ▶ Language selection
- ▶ Personalize or start
- ▶ Users can be created under 'Personalize'
- ▶ Set foot switch (variable or on/off)



Control unit operation – main menu

1	Device name	6	Name of program
2	Settings	7	Set rotation speed
3	Turn clockwise/counter-clockwise (only available in normal and maximum mode)	8	Work display rotations per minute (change work display: absolute, bars, percentage)
4	Set irrigation liquid quantity	9	Programs 1-4
5	Current user	-	-

Operating time

Usage with drill attachments

The system was developed for intermittent service. A 10-minute break should be inserted after 3 minutes of continuous work. The intermittent operation illustrated helps to prevent the system from overheating and endangering the patient and the user.

Application:	180 secs
Break:	600 secs

Usage with saw attachments

Saws may be operated for 30 seconds without interruption. This process can be repeated 10x with a break of 60 seconds in between.

Application:	30 secs
Break:	60 secs
Repetitions:	10

Overheating

Long operating periods and/or increased side loads may cause the device to overheat.

Follow the following instructions if overheating occurs

- ▶ Never place the motor or attachment on the patient.
- ▶ Stop using the device. Cooling can be achieved by means of periodic use.

System settings

Irrigation liquid quantity



Tap the four drop symbol to change the irrigation liquid quantity.

A sub-menu will open with the percentage information. A value between 0 and 100% (0/25/50/75/100%) can be set with the +/- buttons. 100% is equivalent to approx. 100ml/min.

Changes can either be confirmed and saved or canceled.


Irrigation pump ON/OFF

The pump can only be switched on or off when the motor is at a standstill. This is done by pressing the green button on the foot switch. When the irrigation pump is activated, the four drop symbol appears on the system display.

	Irrigation pump ON
	Irrigation pump OFF

Direction of rotation

You can change the direction of rotation for the system by pressing the yellow button on the foot switch or by touching the direction symbols on the touchscreen.

	clockwise rotation
--	--------------------

The standard direction of rotation is clockwise. When you have changed the direction of rotation, an acoustic warning signal (three beeps) sounds before each start and the symbol flashes.

The direction cannot be changed in perforator mode (P3) or saw mode (P4) for safety and technical reasons.

Reset to default settings

1. Select 'Settings' on the main screen.
2. Select System.
3. Select Device Info.
4. Select Reset.
5. Confirm or cancel reset.
6. After confirmation, the system is reset to default settings and restarted.

Changing programs using the foot switch

Programs can be changed / switched by pressing the orange button. This is accompanied by acoustic signals.

If you have arrived at Program 4 (saw mode) and change back to Program 1 (standard mode), a short acoustic signal will sound.


After each program change, the direction of rotation automatically returns to the standard (clockwise direction).

Changing the display mode

Symbol selection:

rpm	Rotation speed
------------	----------------

The following display variants can be selected to show the number of revolutions during usage:






100	Absolute
	Bars
%	Percentage

The relevant display mode is selected by confirmation.

Foot switch mode




The foot switch is either operated in ON/OFF or VARIABLE mode.

Follow the instructions below to change the foot switch settings:

1.	Touch the Settings symbol on the display
2.	
3.	
4.	 for variable mode
5.	 for on/off mode
6.	




Motor start mode

Follow the instructions below to change the motor start mode:

1.	Touch the Settings symbol on the display
2.	
3.	
4.	Motor start
5.	Available modes: slow, medium, fast
6.	




Motor stop mode

Follow the instructions below to change the motor stop mode:

1.	Touch the Settings symbol on the display
2.	
3.	
4.	Motor stop
5.	Available modes: slow, medium, fast
6.	

Custom settings

Follow the instructions below to set up a user:

1.	Touch the Settings symbol on the display
2.	
3.	
4.	Enter user name with max. 15 characters
5.	

Software updates

The USB ports on the back of the device are intended for carrying out software updates.







A software update may only be carried out by personnel authorized by adeor.

Error messages

Error messages can be deleted by tapping or releasing the pedal (gray) on the foot switch.

If the error in question is not resolved, an inspection by adeor will be required.

If there is a total system failure, switch the control unit off and on again.

Icon	Description	Solution
	FOOT SWITCH WARNING	Check the foot switch connection. Check the dongle* connection.
	MOTOR WARNING	Check the motor connection. Leave the motor to cool down for at least 10 minutes.
	STORAGE DEVICE WARNING: Not enough storage space available. Unknown file system. Write protection is active. Unknown storage device.	Plug in a USB flash drive with sufficient storage space. A software update may only be carried out by personnel authorized by adeor.
	OVERHEATING WARNING	Switch control unit off. Leave the control unit to cool down for at least 10 minutes. Switch control unit on.
	TIMEOUT WARNING	Release pedal (gray) of the foot switch. Leave the motor to cool down for at least 10 minutes.
	SYSTEM ERROR	Switch control unit off and on again. If the error message reappears, contact adeor directly.

* not cleared for US market

Assembly and usage

To avoid reducing the lifetime of the motor, make sure that the attachment is always mounted on the motor to prevent contamination of the coupling. Make sure the motor is only activated when the attachment is mounted and the instruments are completely inserted.

Working with attachments and accessories



General safety guidelines

- ▶ Do not switch the system on without an instrument inserted. This helps to prolong the lifespan of the attachments.
- ▶ The shortest milling cutter exposure length is recommended when milling with a head diameter over 4mm. This helps to prolong the lifespan of the attachments.
- ▶ Work with low pressure. Let the instrument carry out the cutting function.
- ▶ Never slide the motor coupling to the front during usage. Otherwise, the motor coupling will open and the attachment will come loose from the motor.
- ▶ Saw blades must be clamped as deep as possible. Loosely clamped saw blades cause high centrifugal forces and vibrations.

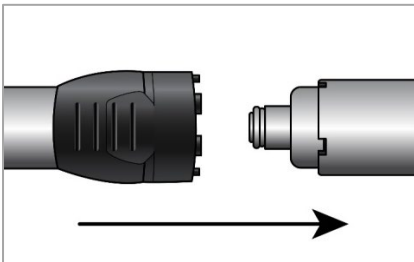
Coupling the attachments and motor



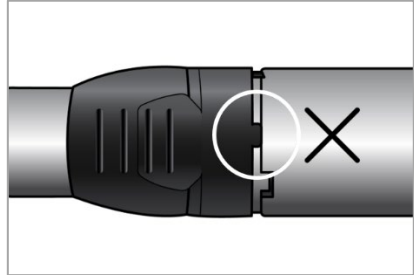
The system must be switched off while coupling the attachment and motor.

The coupling is automatic.

The attachment must only be attached to the motor. There is no need to retract the black motor coupling while it is uncoupled.

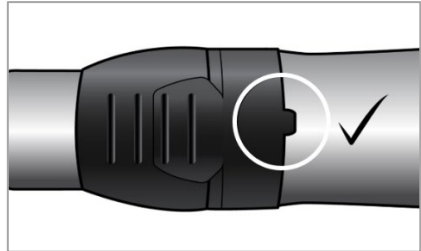


Rotate the attachment until the teeth engage with the recesses provided. The diagram below shows a position where the attachment is not coupled with the motor.



The black fastener will slide over the teeth if the motor coupling is successful. The diagram below shows the position where the fastener is completely closed.

Carry out a tensile test after coupling.



Switch the motor off after use. The black coupling can then be retracted and the attachment will come loose from the motor. To do this, hold the motor with your right hand and the attachment with your left hand. Now push the black motor coupling forward with your right index finger and thumb. The coupling will come loose.

Make sure that the attachment does not fall down while uncoupling.

Inserting rotating instruments / exposure function

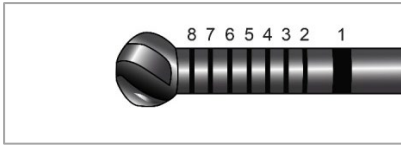


The system must be switched off while inserting instruments.

The milling cutter has 8 markings. These represent the exposure lengths. The milling cutter can be inserted directly into the attachment.

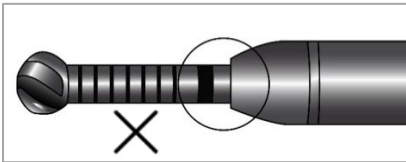
**TIP**

There is no need to activate the black fastening mechanism.

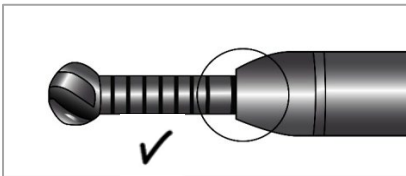


A thick bar can be found on the milling cutter (1). If the milling cutter is inserted and this mark is no longer visible, this means that the milling cutter is properly connected (position 1). You should hear a mechanical click.

The diagram below shows the milling cutter in a position in which it is not coupled.

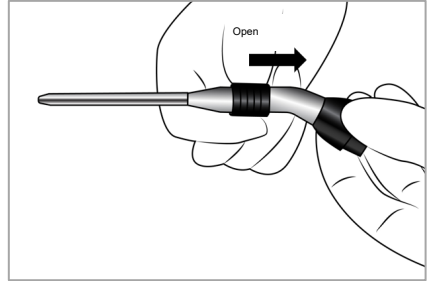


The diagram below shows the position where the milling cutter is coupled correctly.



Carry out a short tensile test on the milling cutter. If it cannot be pulled out with little force, it means the system is coupled correctly.

The milling cutter can be inserted more deeply into the attachment by opening the black milling cutter coupling.



- ▶ Inserting a milling cutter into a minimally invasive attachment and the exposure function work under the same principle. A tensile test must be carried out to check that the coupling is secure whenever the clamping length of the milling cutter is changed.
- ▶ Switch the motor off after using. The black milling cutter coupling can then be retracted and the milling cutter can be pulled out.

Installation of minimally invasive attachments to the base unit for VMN-T shafts (REF: VMN-C2)



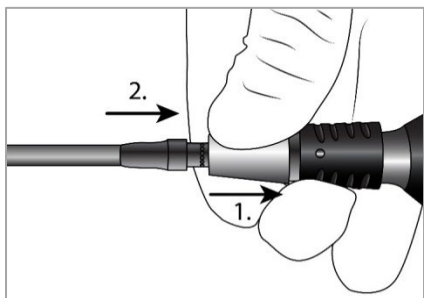
The system must be switched off while installing the minimally invasive shaft and base for VMN-T shafts.

Each minimally invasive shaft (see table 1) is compatible with the base for VMN-T shafts (REF: VMN-C2). A complete minimally invasive attachment is formed from both parts.

REF no.	Designation
VMN-TS1	Minimally invasive attachment, 90 mm, straight
VMN-TS2	Minimally invasive attachment, 120 mm straight
VMN-TS3	Minimally invasive attachment, 150 mm straight
VMN-TS4	Minimally invasive attachment, 180 mm straight
VMN-TA1	Minimally invasive attachment, 90 mm, angled
VMN-TA2	Minimally invasive attachment, 120 mm, angled
VMN-TA3	Minimally invasive attachment, 150 mm, angled

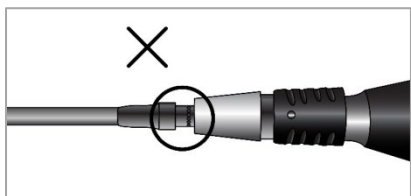
Table 1: Minimally invasive shafts

1. Retract the *metallic* coupling on the base (REF: VMN-C2) for VMN-T shafts.
2. Insert the minimally invasive shaft (see Table 1).
3. Release the coupling.

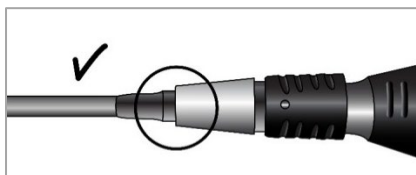


Carry out a short tensile test on the shaft. If it cannot be pulled out, the system is coupled correctly.


The minimally invasive attachment in the following diagram is **not** coupled correctly.



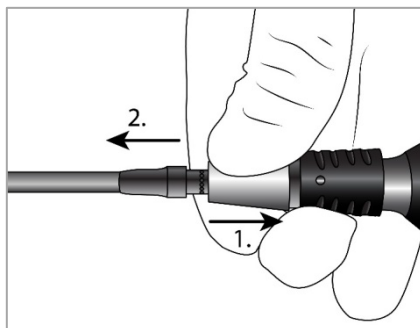
The following diagram shows a minimally invasive attachment which has been coupled correctly.



Removing minimally invasive shafts from the base for VMN-T shafts (REF: VMN-C2)

 The system must be switched off while dismantling the minimally invasive shaft and base for the shafts.

1. Retract the *metallic* coupling on the base (REF: VMN-C2) for VMN-T shafts.
2. Removing the minimally invasive shaft (see Table 1).
3. Release the coupling.




Working with attachments

The drill system should be held like a dissector in order to achieve an optimal result.

The foot switch should be activated before the milling cutter touches the area of work.

Avoid pressing down too hard. Too much pressure can cause thermal necrosis due to overheating. In extreme cases, the instrument may break.

Assembling the craniotome

 The system must not be switched on while assembling the craniotome base and Duraguard.

Select the right milling length (-S, -M or -L) for your application.

Insert the cutter into the craniotome base.

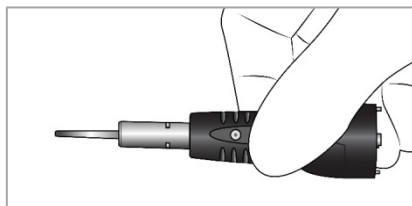
The automatic black cutter fastener must not be retracted.

The cutter will be completely coupled when you hear a mechanical click.

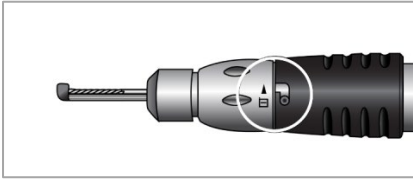
Check that the connection between the milling cutter and craniotome base is secure by performing a tensile test.

Now attach the relevant Duraguard (size 1, 2 or 3) to the craniotome base.

Slide the Duraguard down until the small pin on the side of the Duraguard enters the hole provided on the black cutter fastener.

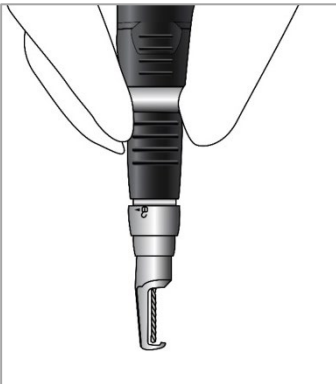


The Duraguard is fastened by rotating it in accordance with the marking. Rotate it until it cannot be rotated any further.



Working with craniotomes

The craniotome should be held as shown in the diagram below (with the thumb, index and middle fingers).



! Do not exert force. Let the craniotome cutter carry out the cutting work. If the pressure is too high, the craniotomy results will worsen and operating time will be unnecessarily prolonged. A slight negative angle is ideal for using the craniotome.

If the anatomy stops the craniotomy, this can be corrected with a minimal downward movement. It is also possible to loosen the tilted milling cutter in such a case, using the backwards mode.

Removal of milling cutter from craniotome

- ▶ First, switch off the system after use.
- ▶ Then decouple the craniotome from the motor.
- ▶ Decouple the Duraguard in accordance with the marking and remove it from the craniotome base.
- ▶ Slide the milling cutter fastener right to the back and remove the milling cutter from the craniotome base.

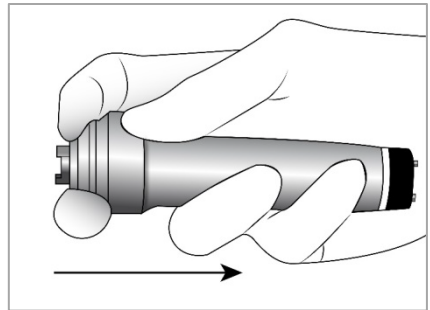
Using the speed reducer

First, change the control unit to perforator mode.

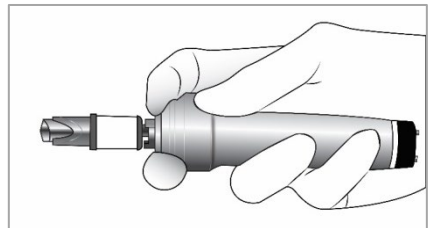
! The system must not be switched on while assembling the speed reducer and perforator.

The speed reducer is attached to the motor in the same way as the other attachments.

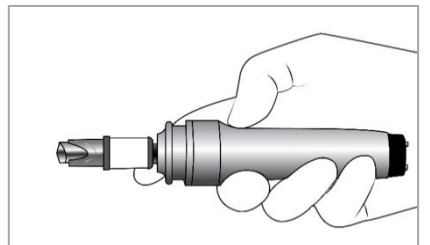
To insert a perforator, the safety protection of the speed reducer must be pulled back, as shown in the following diagrams.



The perforator can now be inserted with the Hudson shaft.



If the safety protection is loosened, the perforator is locked.



- ▶ The fastening must then be checked with a tensile test to see if it is secure .

- ▶ Use the perforator in accordance with the manufacturer's instructions. Make sure that there is continuous irrigation during the drilling process.

Saws



The system must not be switched on while assembling the saw attachment and saw blade.

Inserting the saw blades

Attachments for saw blades:

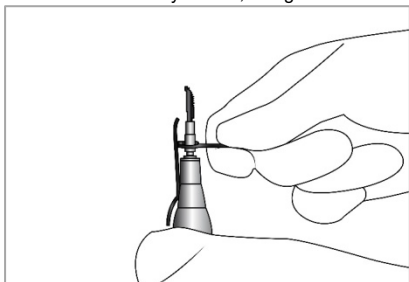
Ref no.	Designation
VMN-R1	Saw attachment, reciprocating
VMN-SS1	Saw attachment, sagittal
VMN-OS1	Saw attachment, oscillating

You will find the available saw blades in the instructions for use for HiCUT instruments.

Place the saw blade in the saw blade insert (fastener).

Saw blades must be clamped as deep as possible.

Rotate the saw blade fastener clockwise until it cannot be rotated any further, using a wrench.



To remove the saw blade after use, the saw blade fastener must be rotated counter-clockwise using a wrench.

Working with saw attachments



First, change to saw mode using the control unit. The saw blades must be moving before positioning them against the bone. Tilting, levering and bending must be avoided during the sawing process (danger of breaking).

Always avoid using too much contact pressure. Too much pressure can cause thermal necrosis due to overheating. In extreme cases, the instrument may break.

Consumables

An overview of the HiCUT™ burs and cutters, perforators and saw blades for the system is available separately.

Single-use HiCUT™ burs and cutters, Meridian perforators and saw blades must not be reprocessed.

Processing and care

General information

Follow national regulations, national and international standards and local clinical hygiene instructions for processing.

The relevant national regulations on processing devices must be observed for patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible CJD variants.

Automated processing should be prioritized over manual cleaning.

Successful processing of medical devices can only be guaranteed if the processing method has been validated beforehand. It is recommended to use a washer-disinfector according to ISO15883. The operator / technician is responsible for this. The recommended chemicals / cleaning agents have been used for validation.

Damage to the device can occur as a result of unsuitable cleaning agents / disinfectants (see 'Cleaning agents and Disinfectants to be used' chapter below). and / or overly high temperatures. Frequent processing has minor effects on the instruments (motor and attachments).

Perform visual inspections after each processing cycle with adequate lightning. Magnification is not required.

The end of the device's lifespan is normally determined by wear and tear, and damage resulting from usage.

If at least one of the following applies, the device has reached its end of useful life and must not be reprocessed for surgical use:

- ▶ Obvious damage or corrosion
- ▶ Discoloration, stains or rust
- ▶ Bending, pitting, cracks or fractures
- ▶ Illegible laser engravings, labelings and or other markings
- ▶ Rough or jammed mechanism

Return the device to dealer or dispose according to local and national regulations.

Dried or affixed surgical residues can make cleaning difficult or ineffective, and lead to corrosion. The time interval between using and processing should therefore be no longer than 6 hours. Fixed pre-cleaning temperatures >45° C or fixed disinfectants (active ingredient: aldehydes / alcohols) should not be used either.

Excessive amounts of neutralizing agents or basic cleaners may lead to chemical aggression / or discoloration, and the laser markings may become visually or mechanically illegible.

Residues containing chlorine or chlorides, e.g. in surgical residues, drugs, saline solutions and service water used for cleaning, disinfection and sterilization, cause corrosion damage (pitting or stress corrosion) and result in damage to metallic

devices. These must be removed by flushing thoroughly with demineralized water, then drying. Dry again if necessary.

For processing the device, only use processing chemicals which have been tested and authorized (e.g. FDA authorization or CE label), and which are compatible with the materials of the device in accordance with the recommendations of the chemical manufacturer. All application specifications from the chemical manufacturer must be obeyed without fail.

Otherwise, material damage such as corrosion, cracks, breakages, premature ageing or swelling may occur.

- ▶ Do not use any metal brushes or other scouring agents which may damage the device's surface and cause corrosion.
- ▶ You can find more detailed information about hygienically harmless and material-preserving / value-retaining processing at www.a-k-i.org.

Warnings

- ▶ Wear protective clothing.
- ▶ Observe national guidelines, standards and regulations for cleaning, disinfection and sterilization.
- ▶ Clean and disinfect the components immediately after each surgical procedure, in order to flush out any liquids which may have entered (such as blood, saliva or saline solution residues) and prevent the internal parts from becoming fixed.
- ▶ The control unit and foot switch must not be washed or sterilized.
- ▶ Motor drill system components must never be cleaned in an ultrasonic bath or a disinfectant solution.
- ▶ Do not place the side of the attachments where the milling cutter is inserted on pins or any other sharp objects.
- ▶ Do not flush the attachments with pressure from the side where the milling cutter is inserted.

Cleaning agents and disinfectants to be used

- ▶ Use cleaning agents and disinfectants which
 - are authorized for plastic and stainless steel, in accordance with manufacturer's instructions.
 - do not contain chlorine.
 - do not have a protein-fixing effect.
 - do not affect plasticizers (e.g. in silicone).
- ▶ Do not use any cleaning agents which contain acetone.
- ▶ Pay attention to information about concentrations, temperatures and exposure times. Follow the manufacturer's instructions for using cleaning agents and disinfectants.
- ▶ Do not exceed the maximum temperature of 60°C during chemical cleaning and / or chemical disinfection.
- ▶ Do not exceed the maximum temperature of 90°C during thermal disinfection with demineralized water.
- ▶ Dry the device for at least 10 minutes at a maximum of 120°C. The stated drying period is only a guide. This must be checked, taking specific conditions (e.g. device loading) into account, and adjusted if necessary.

Control unit and foot switch

Attention!

- ▶ The control unit and foot switch are not authorized for automated cleaning (thermal disinfectant) and sterilization.
- ▶ Do not immerse the control unit or foot switch, or clean under running water.
- ▶ Disinfect with wipe-down disinfectant certified by officially recognized institutes (e.g. FDA, CE marking), without chlorine or acetone according to the manufacturer's specifications for use of the disinfectant. E.g. Schülke+ microcide universal liquid, exposure time 2 minutes.
- ▶ Clean and inspect the ESD (electrostatic discharge) spring contact on the underside of the foot switch regularly. Check that the spring touches the floor before each use.

Manual cleaning and disinfection

The front of the control unit and the foot switch are sealed and can be wiped with a wet cloth.

Motor and attachments

The instructions described below apply to all devices in the following list:

Angled attachments	Irrigation attachments
VMN-A1	VMN-IR-XS
VMN-A2	VMN-IR-1
VMN-A3	VMN-IR-2
VMN-A4	VMN-IR-3
VMN-A5	VMN-IR-4
VMN-A6	VMN-IR-5
-	VMN-IR-6
Straight attachments	Saw attachments
VMN-XS	VMN-OS1
VMN-S1	VMN-SS1
VMN-S2	VMN-RS1
VMN-S3	-
Minimally invasive attachment shafts, including base for VMN-T shafts	
VMN-C2	
VMN-TS1	
VMN-TS2	
VMN-TS3	
VMN-TS4	
VMN-TA1	
VMN-TA2	
VMN-TA3	
Motor with cable	Speed reducer
VAM	VMT-102E
Craniotomes attachments including craniotome base	
VMCH-D	
VMN-C1	
VMCH-1	
VMCH-2	
VMCH-3	
VMCH-1R	
VMCH-2R	
VMCH-3R	

Table 2 Motor and attachments

Pre-disinfection at the place of use

If device is visibly contaminated, perform manual pre-disinfection with disinfection wipes. Therefore, only use disinfectants without chlorine or acetone certified by officially recognized institutes (e.g. FDA, CE marking).

Follow the manufacturer's specifications for use of the cleaning agent.

The validation was carried out with Schülke+ microcide wipes.

Option 1: Manual cleaning (motor and attachments)**Note:**

The cleaning and disinfection process has been validated in accordance with current standards.

Motor with cable (VAM)

Do not immerse/place the motor with cable in liquid disinfectant or in an ultrasonic bath.

Cleaning steps:

1. Clean the motor under running water (< 35°C, tap water quality).
2. Rinse off all surfaces.
3. Remove any liquid residues using compressed air.

Disinfection

adeor recommends wipe-down disinfection.

Use wipe-down disinfectant which has no protein-fixing effect, does not contain chloride or acetone and is certified by officially recognized institutes (e.g. FDA, CE marking). Follow the manufacturer's specifications for use of the cleaning agent.

The validation was carried out with Schülke mikroZid® AF wipes and Metrex CaviWipes™.

- ▶ Ensure that the motor with cable is completely dry from the inside and outside after cleaning and disinfection.
- ▶ Remove any liquid residues using compressed air.

Attachments**Cleaning steps:****1. Soaking**

Soak the instruments in a mixture of cleaning agent and water (21°C - 25°C, drinking water quality) for 2 minutes.

Cleaning agent: 1% vol. neutral soap and 99% vol. tap water.

Follow the manufacturer's specifications for use of the cleaning agent.

Validation was carried out with HAKA neutral soap.

2. Intermediate flushing and cleaning

Get rid of gross contamination using a soft, clean and disinfected brush for at least 30 seconds under running water (<38°C, drinking water quality) until visually clean. Intermediate flushing should be carried out for at least 10 seconds.

Do not use any metal brushes or other scouring agents which may damage the device's surface and cause corrosion.

3. Drying

Dry the attachments (6 bar) for at least 30 seconds.

Wipe them dry with a clean cloth.

Repeat the cleaning process if necessary.

Disinfection

Only use disinfectants with a pH value of 7.6 – 7.9 which have no protein-fixing effect, do not contain chloride or acetone and are certified by officially recognized institutes (e.g. FDA, CE marking). Follow the manufacturer's specifications for use of the cleaning agent.

The validation was carried out with 2% neodisher Septo Active (Dr. Weigert).

The disinfection should be carried out for a hold time of 15 minutes.

Rinsing

Rinse the instruments under critical water e.g. deionized, distilled or demineralized water), 21° - 25°C, for 30 seconds.

Ensure that the motor with cable is completely dry from the inside and outside after cleaning and disinfection.

**TIP**

If possible, use the adeor cleaning adapter (REF: CA100) to rinse the attachments. In order to do this, the cleaning adapter must be connected to a water tap and the individual components must be attached to the adapter. Rinsing should take approx. 30 seconds.

Option 2 – recommended option: Automated cleaning (motor and attachments)**Note:**

The cleaning and disinfection process has been validated in accordance with current standards.

Step 1: Attaching to adapter

The cleaning adapter (REF: CA100) should be used to remove soiling within the shaft guide.

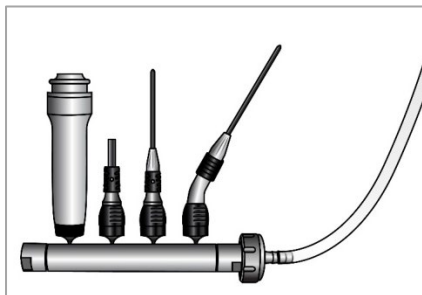
Attach the attachments to the adeor cleaning adapter so that they lock in.

When cleaning minimally invasive attachments, note that the minimally invasive attachment shafts (VMN-T) and shaft bases (REF: VMN-C2) can only be cleaned when assembled together.

This applies to all minimally invasive attachment shafts listed in Table 1.

Step 2: Connecting to device

Connect the cleaning adapter to the relevant connection on your cleaning and disinfection device, see diagram below.



Positioning in a cleaning and disinfection device should be carried out in accordance with EN 15883-1 and -2. This also applies to irrigation attachments (see Table 2).

Validation was carried out in a BHT INNOVA M3 machine in accordance with the following program.

Step 3: Cleaning and Disinfection

Only use cleaning agents with a pH value of 10.4 - 10.8 which do not contain chloride or acetone and are certified by officially recognized institutes (e.g. FDA, CE marking).

Follow the manufacturer's specifications for use of the cleaning agent.

The validation was carried out with 0.5% neodisher Mediclean Forte (Dr. Weigert).

Start program sequence:

1. Cleaning phase 1 minute at 30°C
2. Cleaning phase 6 minutes at 55°C
3. Rinsing with critical water (e.g. deionized, distilled or demineralized water) 1 minute
4. Thermal disinfection with critical water (e.g. deionized, distilled or demineralized water) for 5 minutes at 90°C

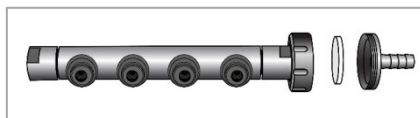
5. Drying: Drying times depend on the program of the cleaning and disinfection device.

Step 4:

Remove the attachments from the cleaning adapter. To do this, retract the coupling on the attachments. Then disconnect the cleaning adapter from the cleaning and disinfection device.

Cleaning adapter filter

The cleaning adapter has an integrated filter disc (REF: 64375). The filter disc must be changed after 20 processes / cycles or after 14 days at the latest (whichever comes first).



Before inserting a new filter disc, the disc must first be rinsed under running water for a short period and the adapter thoroughly cleaned of any dirt particles, preferably with compressed air.

Care and inspection

Visual inspection of cleaning results

Check the surfaces. If these are not sufficiently clean, the process must be repeated.

Oil care

Oil the following attachments regularly after use and before each sterilization with medical-grade maintenance oil on white-oil base, suitable for the respective sterilization process i.e. PANA Spray Plus (NSK, Order Code Z182600). If this is not done, the lifespan will be shortened.

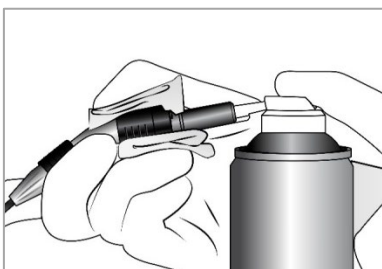
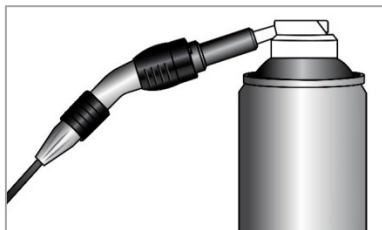
Ref no.	Description
VMN-XS	Straight attachment, extra short
VMN-S1	Straight attachment, short
VMN-S2	Straight attachment, medium
VMN-S3	Straight attachment, long
VMN-A1	Angled attachment, short
VMN-A2	Angled attachment, medium
VMN-A3	Angled attachment, long
VMN-A4	Angled attachment, XL
VMN-A5	Angled attachment, XXL
VMN-A6	Angled attachment, XXXL
VMN-TS1	Minimally invasive attachment, 90 mm, straight
VMN-TS2	Minimally invasive attachment, 120 mm, straight
VMN-TS3	Minimally invasive attachment, 150 mm straight
VMN-TS4	Minimally invasive attachment, 180 mm, straight
VMN-TA1	Minimally invasive attachment, 90 mm, angled
VMN-TA2	Minimally invasive attachment, 120 mm, angled
VMN-TA3	Minimally invasive attachment, 150 mm, angled
VMN-C2	Base unit for VMN-T shafts
VMN-C1	Craniotome base
VMT-102E	Speed reducer
VMN-OS1	Saw attachment, oscillating
VMN-RS1	Saw attachment, reciprocating
VMN-SS1	Saw attachment, sagittal

Table 3 attachments for oil care

Before oiling, check whether the attachments are visibly dry. If necessary, dry with a clean cloth. Screw the adeor oil spray adapter (REF: OA-100) onto the oil spray. Oiling should be carried out from the side of the motor coupling, which is attached to the oil adapter.

Use a germ-free, fiber-free cloth to hold the attachment in place.

Spray for a maximum of 2 seconds.



When oiling minimally invasive attachments, make sure that the minimally invasive attachment shafts (REF: VMN-T) and base unit (REF: VMN-C2) are assembled together.

This applies to all minimally invasive attachments mentioned in Table 1.

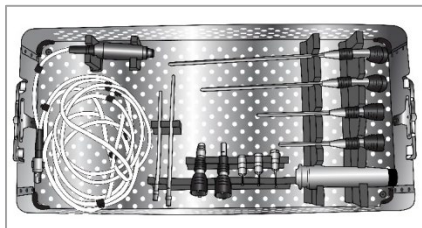


TIP

adeor recommends a function test before sterilization in autoclaves, including test runs of all components.

Packaging

The instruments can be autoclaved in the adeor trays (REF: PST-200 or REF: PST-201). Trays should be loaded as follows.



Devices are shrinkwrapped in laminate bags (e.g. paper laminate film in accordance with ISO 11607), which have been tested in accordance with EN 865-5, or in sterilization paper which has been tested in accordance with EN 865-2.

Make sure that only completely dry devices are being stored.

Sterilization (motor and attachments)

Only sterilize attachments which have been prepared, oiled, disinfected and tested.

Steam sterilization in pre-vacuum process or gravity method as follows:

Vacuum process: 4 min at 132°C
Drying: 16 min

Gravity method: 15 min at 132°C
Drying: 20min

From a microbiological point of view, longer holding times and moderately higher temperatures are possible.



TIP

When sterilizing several attachments in one sterilization cycle, the maximum load of the sterilizer must not be exceeded.

Note:
The sterilization processes have been validated in accordance with current standards.

Storage

Sterile devices must be stored in dust-proof, germ-proof packaging in a dry, dark and temperature-controlled area. It is recommended to transport individual components in a storage tray.

System service

The device components cannot undergo maintenance while being used on the patient.

Recurring tests

Regular recurring function and safety tests, including accessories, are required and should be carried out at least once every three years, unless shorter intervals are prescribed by law.

The tests must be carried out by a person authorized by adeor.

Repairs and returns

For returns, either contact adeor directly or contact the presiding service partner.

- ▶ Always return the entire system in the event of a defect, as the electronics will need to be fully tested.
- ▶ Use the original packaging for returns.
- ▶ Do not wrap the cable around the motor and do not fold the cable (risk of damage).
- ▶ Remove batteries from the foot switch.

Environmental conditions





Storage and transport temperature:	-40 to +70°C
Storage air humidity:	8% - 80% relative, non-condensing
Temperature in operating theatre:	+10 to + 35 °C
Air humidity in operating theatre:	15% - 80% relative, non-condensing
Atmospheric pressure	70 – 106 kPa

Technical data

	VAC-220	VAC-110
Supply voltage	220 – 240 V	110 – 130 V
Permitted deviation	± 10%	± 10%
Frequency	50 – 60 Hz	
Main fuse	2x 250 V – T1.6AH	
Max. power consumption	170 VA	
Max. mechanical performance	80 W	
Torque	2.2Ncm	
Motor speed	1000 – 80,000 rpm	
Irrigation flow rate	At least 90ml/min at 100%	
Dimensions (L x W x H)	100 x 262 x 291mm	
Control unit weight incl. motor	3.5 kg	

	VMN-RS1	VMN-SS1	VMN-OS1
Gear ratio	3.25 : 1	3.25 : 1	3.4 : 1
Lift	1.8mm	approx. 3°	approx. 12°
Max. rotational speed (rpm)	40,000	40,000	40,000
Sawing frequency with max. rotational speed (rpm)	12,300	12,300	11,800

Classification in accordance with section 6 of the general basic safety requirements for medical electrical equipment (ME) in accordance with § 5 IEC 60601-1 / ANSI/AAMI ES 60601-1

	Class II equipment
	Type B applied part (not suitable for intracardial application)
	Foot switch in accordance with Class AP in accordance with IEC 60601-1 / ANSI / AAMI ES 60601-1 in Danger Zone M
	Footswitch is watertight in accordance with IPX8, 1 m, 1 Std. / IEC 60529
Control unit	Waterproof in accordance with IPX0 (not waterproof)
Pollution level:	2
Overvoltage category:	II
Altitude:	3000 m (above sea level)

Recycling and disposal































adeor has developed and manufactured the Velocity Alpha™ system to be as environmentally friendly as possible.



- ▶ Waste electronic devices
- ▶ Accessories and spare parts
- ▶ Packaging

Make sure that the system and its components are not contaminated on disposal. Follow your local guidelines for disposing of electronic items. Legal regulations must be followed for disposal.

Symbols used / explanation

	Consult instructions for use		Date of manufacture
	Manufacturer		CE mark with identification number for the notified body
	Caution! Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.		Expiry date
	Electric applied part Type B		Non-sterile
	Latex-free		Connection for foot switch
	Store in a dry place		Only use if packaging is undamaged
	Reference number		Batch number
	Serial number		Temperature limits
	WARNING: Observe warnings		Do not throw away with household waste
	Zone M Anaesthetic agent inspection under Class AP		Thermo washer disinfectable
	Class II		DataMatrix code
	Can be placed in an autoclave < 135°C		Data structure in accordance with UDI
	Top		Non-ionizing electromagnetic radiation
	Fragile		Battery compartment open*
	Battery compartment closed*		Refer to instructions (blue)

* not cleared for US market

Warranty

adeor medical AG devices are developed and manufactured with the utmost care.

Tests and controls by highly qualified personnel guarantee a safe and flawless function. Please note that warranty claims are only valid if all instructions in the attached manual have been followed.

adeor is liable as a manufacturer for material or manufacturing defects from the date of purchase, within a warranty period of 24 months.

adeor medical AG is not liable for damages due to improper handling or repairs by third parties who are not authorized by adeor.

The user is responsible for the use of the instruments. adeor medical AG are excluded from any liability for damage resulting from this.

Warranty claims must be submitted to adeor or the service partner, with the purchase receipt attached. Performing a warranty service will not prolong the warranty or any other guarantee period.

Improper use and unauthorized installation, alterations or repairs to the foot switch, and non-compliance with our instructions, absolves adeor medical AG of any warranty services or other claims.



adeor medical AG
Martinshof 5
83626 Valley
Germany

Phone +49 89 74 44 23 98
Fax +49 89 74 42 48 09
Email: office@adeor.com
<http://www.adeor.de>

Version: 2021-07-US

adeor medical AG

