Velocity ALPHA

Velocity® Alpha
pneumatic high speed drill

EN Instructions for Use

adeor MEDICAL

Table of Content

General Information

You must make sure you have read and understood this manual before using the pneumatic Velocity® Alpha high speed surgical drill system.

The system is indicated for professional use (healthcare professionals) according to its intended use in surgery in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance, with the Instructions for Use.
The system may only be used by trained personnel such as doctors and users with technical training. The product development was aimed at medical user groups, experienced in operating pneumatic driven 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 pneumatic Velocity® Alpha high speed surgical drill system is indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone and biomaterials.

Medical indication:

Applications:	Separating, removing, shaping and sawing hard tissue / bone and bone replacement materials
Area of Use:	Neurosurgery, ENT surgery, spine surgery, orthopedics

Medical contraindication:

The pneumatic Velocity® Alpha drill system must not be used on the central nervous or central circulatory system.
The safe and effective use of pneumatic driven applied parts depends heavily on influences that only the user can control him- or herself. Therefore, the specifications provided represent framework conditions only. The user is responsible for observing the warnings and safety information, and for carrying out the work correctly.

System components

Article number	description
Pneumatic unit	
ZMM-100	Pneumatic high speed motor (max. 100.000 RPM, at 8 bar, < 116 psi)
ZMT-102	Trepan motor (1.200 RPM)
ZMF-150	Pneumatic foot switch
ZMW-110	Motor hose 3 m (motor - foot switch)
ZMW-110/ SA1	Motor hose 5 m (motor - foot switch)
ZMW-120/A	Wall hose 5 m with Aesculap/Dräger connector (foot switch - wall)
ZMW-120/S	Wall hose 5 m with Synthes connector (foot switch - wall)
ZMW-121	Wall hose 5 m, open end (foot switch – wall)
Craniotome attachments	
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	Attachment, straight, extra short
VMN-S1	Attachment, straight, short
VMN-S2	Attachment, straight, medium
VMN-S3	Attachment, straight, long
Drill attachment, angled	
VMN-A1	Attachment, angled, short
VMN-A2	Attachment, angled, medium
VMN-A3	Attachment, angled, long
VMN-A4	Attachment, angled, XL
VMN-A5	Attachment, angled, XXL
VMN-A6	Attachment, angled, XXXL
Irrigation canulae	
VMN-IR-XS	Irrigation attachment, extra short
VMN-IR-1	Irrigation attachment, short
VMN-IR-2	Irrigation attachment, medium
VMN-IR-3	Irrigation attachment, long
VMN-IR-4	Irrigation attachment, XL
VMN-IR-5	Irrigation attachment, XXL
VMN-IR-6	Irrigation attachment, XXXL

Accessories	
OS-100-1	Oil spray, 500ml
OA-100	Oil spray adapter
PST-200	Sterilization tray, plastic
PST-201	Sterilization tray, stainless steel
CA100	Cleaning adapter
Consumables	
HiCUT burs and cutters	Only usable in combination with relevant attachment
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

Foot switch	Motor	Attachment		Instrument	Speed	Areas of use
ZMF-150	ZMM-100	VMN-C1	VMCH-1 VMCH-2 VMCH-3 VMCH-1R VMCH-2R VMCH-3R VMCH-D	HiCUT craniotomy burs	Up to 100.000 RPM	Neurosurgery
		VMN-XS VMN-S1 VMN-S2 VMN-S3 VMN-A1 VMN-A2 VMN-A3 VMN-A4 VMN-A5 VMN-A6		HiCUT burs		Neurosurgery, spine surgery, ENT surgery and orthopedics
	ZMT-102			Meridian Perforators	Up to 1.200 RPM	Neurosurgery

Manufacturer Responsibility

The manufacturer can only ensure the safety, reliability and efficiency of the system if the following requirements are met:

- The system must be used according to this operating manual.
- The system does not contain any components which can be repaired by the user. Repair and service must be carried out by an adeor authorized service partner.
- 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 pneumatic Velocity® Alpha high speed surgical drill system must be cleaned, disinfected and sterilized before, respectively after every use according to processing instruction. Usage of the system without completely processed system components is prohibited.

Do not use the system in direct proximity to the patient's ear canal. The resulting noise emission can cause long-term damage.

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

- Check all components for visual deficiencies/defects.
- Assemble the system to your desired configuration and check all connecting elements between the motor and the attachment by pulling gently.
- Check the connection between the instrument and attachment is secure by pulling gently on instrument.
- 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 pneumatic Velocity® Alpha high speed surgical drill system may only be used after a successful test.

Warning / Safety information

⚠ Any serious incident in relation to the device should be reported by the user and/or patient to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚠ Observe the following under all circumstances:

- Only use the system according to its intended use.
- Only use components of the pneumatic Velocity® Alpha high speed surgical drill system with each other (do not combinate components of the normal pneumatic Velocity® Alpha high speed surgical drill system with the MR compatible system).
- Before using the system for the first time, store it at room temperature for 24 hours.
- Do check all system components for visible damage before each use.
- Do not use damaged, faulty or altered systems / system components.
- Do not use the system without eye protection.
- Never use the system in surgery until a successful component check and function test has been carried out.
- Never use the system without previous training by adeor or an authorized adeor partner.
- Never use oxygen as a source of compressed air for operating the system.
- Never activate the foot switch whilst inserting or changing instruments or attachments. Only attach attachments and instruments when the motor is at a standstill.
- Never touch moving instruments.
- Never activate the quick release mechanism of the motor and/or attachment while the motor is running.
- Avoid overheating the treatment site.
- Always ensure that there is a sufficient supply of irrigation liquid and make sure that it is aspirated properly.
- Never bend the shafts/instruments and do not use them as levers.
- Do not forget to oil the system components. Oil care reduces friction, reduces the noise level and prolongs the lifespan of the system components.
- Start cleaning the components used directly after application.
- Never clean the system in an ultrasonic bath.
- Do not use the system near MR systems.
- Do not use defective or blunt instruments (HiCUT).
- Do not cut in areas you cannot see.
- Touching surrounding tissue with the instrument may lead to injury.
- Do not re-sterilize and reuse disposable products.
- Only use instruments approved by adeor.

Never work with increased pressure or force. Highspeed 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.

Residual risks

Apart from the risks already mentioned, additional complications can occur due to the surgical procedure which cannot be directly attributed to the device:

- Patient harm, anesthesia damage or surgeon injury
- Intracranial or extracranial damage or infection
- Sensitization or intoxication, necrosis or unintentional bone damage

Improper handling

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

Instruments

- Do not use any damaged components.
- Never activate the tension mechanism on the attachment while the device is in use or running down.

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.
- 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.

Operating time

Usage with drill attachments

The system is developed for intermittent service. A 10-minute (600 seconds) break should be performed after 3 minutes (180 seconds) 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

Overheating

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

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.

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 instrument is completely inserted.

Foot switch/hoses

⚠ General safety guidelines

- Operate the system only with compressed air or nitrogen. The use of compressed oxygen can cause fires and explosions.
- Set operating pressure between 6 bar and 8 bar. Do not exceed operating pressure of 8 bar or motor damage will result.
- Ensure that the hose lines are not tied, kinked, crushed or otherwise blocked.

Operation with a central gas supply system in accordance with DIN 13260 and EN 737

The gas supply must provide dry, clean air. It must be set as follows:

Minimum operaration pressure	6 bar
Nominal operating pressure	8 bar
Maximum operation pressure	8 bar
Minimum gas-supply	300 l/min

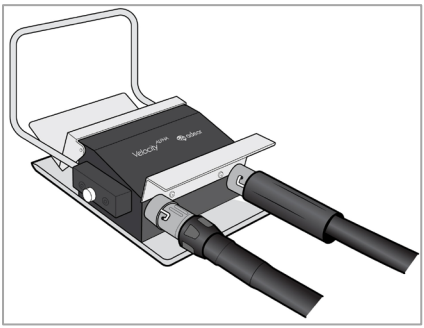
Operation with compressed gas cylinders according to DIN 4664

The following requirements must be met:

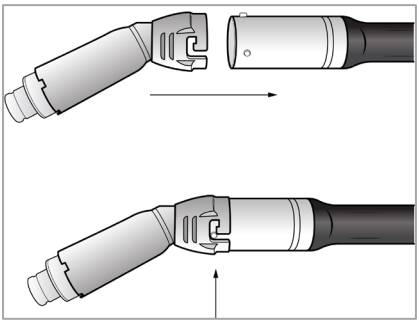
- Use of compressed air or nitrogen.
- Sufficient supply of full gas cylinders available.
- Cylinder pressure must be reduced to an operating pressure of 6 bar to 8 bar using a pressure reducer.

Set up hose connections

1. Connect the wall hose to the foot switch by aligning the bayonet mount pins on the male with the L-shaped slots on the female and pushing the two gently together. Once the pins reach the bottom of the slot, the parts are rotated clockwise until the pins reach the end of the slot and snap into place.
2. Connect the motor hose to the foot switch in the same way as in step 1.



3. Connect the motor hose to the motor/speed-reducer in the same way as in step 1.



Disconnect hoses

The bayonet mount can be opened by pressing the two connections together gently and turning them counterclockwise until the pins can slide out of the slots on the female.

⚠ Do not try to open the bayonet mount by pulling forcefully on the hose. The junction of the internal compressed air hose could be damaged and the hose could burst.

Attachments

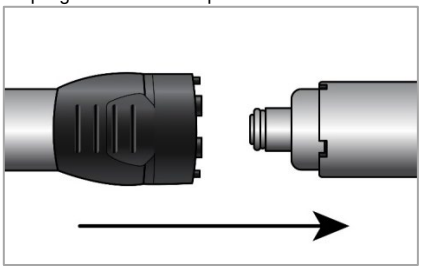
⚠ **General safety guidelines**

- Do not switch the system on without an instrument inserted. This helps to prolong the lifespan of the attachments.
- The shortest cutter exposure length is recommended. This helps to prolong the lifespan of the attachments. To avoid vibration, the cutter should be used in the shortest exposure position.
- 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.

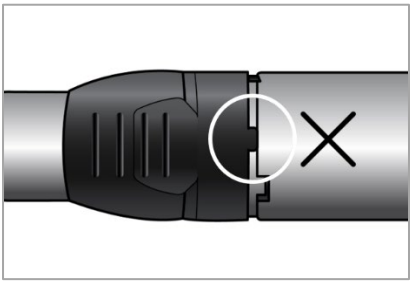
Coupling attachments to the motor

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

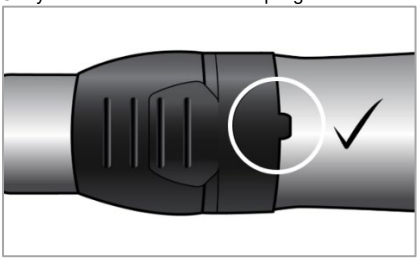
The coupling is automatic.
The attachment must only be attached to the motor. There is no need to retract the black motor coupling while it is uncoupled.



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.

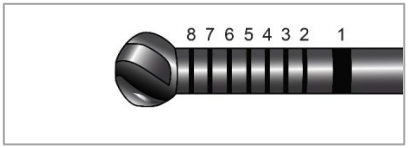


Do not activate the motor after finishing the application. The black coupling can then be retracted and the attachment will come loose from the motor. To do this, hold the motor with one hand and the attachment with the other left. Now push the black motor coupling towards the instrument-tip with your index finger and thumb. The coupling will come loose. Make sure that the attachment does not drop while uncoupling.

Inserting rotating Instruments / exposure-function

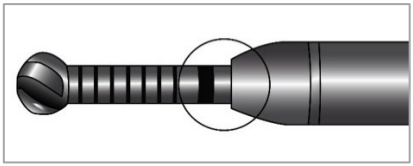
⚠ The system must not be activated while inserting instruments.

The cutter has 8 markings. These represent the exposure lengths.
The cutter can be inserted directly into the attachment. It is not necessary to pull back the black automatic cutter lock.

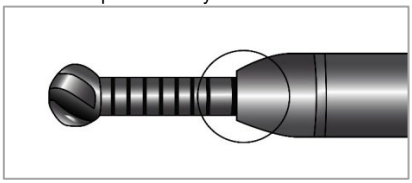


A thick bar can be found on the cutter (1). If the cutter is inserted and this mark is no longer visible, this means that the cutter is properly connected (position 1). You should hear a mechanical click.

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

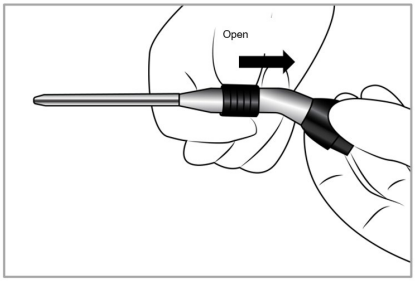


The diagram below shows the position where the cutter is coupled correctly.



To avoid vibration, the cutter should be used in the lowest exposure position as possible.
Carry out a short tensile test on the cutter. If it cannot be pulled out with little force, it means the system is coupled correctly.

The cutter can be inserted more deeply into the attachment by pulling back the black cutter coupling of the attachment.



After every change of the exposure length a new tensile test must be carried out to ensure that the secure pairing remains.

Decoupling instruments

Do not activate the motor after finishing the application. Now the black coupling mechanism can be pulled back and the cutter can be removed from the attachment. Make sure to not drop instruments while uncoupling.

Working with attachments

The drill system should be held like a dissector to achieve an optimal result. Moreover, the attachments should be guided by hand as close as possible to the attachment tip to avoid swinging.
The foot switch should be activated before the cutter touches the area of work. The rotation speed should be regulated to the application-specific speed via varying force actuation of the foot switch. Avoid applying too much force on the instrument. Too much pressure can cause necrosis due to overheating. In extreme cases, the instrument may break.

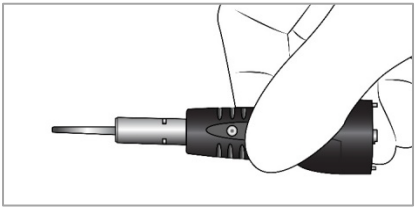
Craniotomes

Assembly of craniotome cutter

⚠ The system must not be activated while assembling the craniotome base and duraguard.

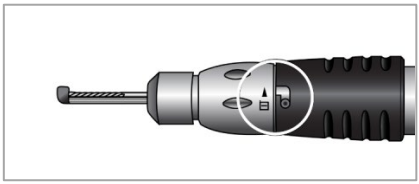
Select the correct cutter length for your task (-S, -M or –L).
Insert the cutter into the craniotome base.
It is not necessary to pull back the black automatic cutter lock.

The cutter is completely coupled when you hear a mechanical click.
Check that the connection between the 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 (make sure the duraguard is completely screwed open). 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.

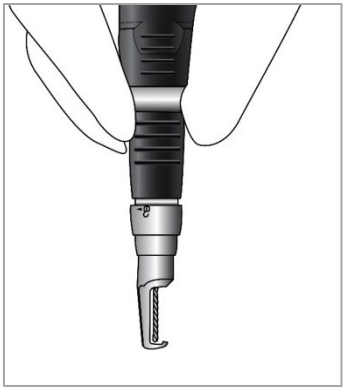


Removal of cutter from craniotome

- After the application, the system should not be activated again.
- Then decouple the craniotome from the motor.
- Decouple the duraguard in accordance with the marking and remove it from the craniotome base.
- Slide back the cutter fastener and remove the cutter from the craniotome base.

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.

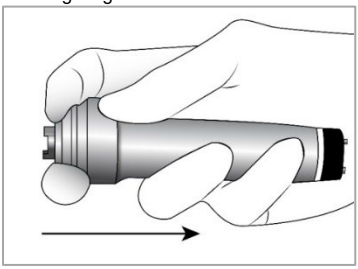
If the anatomy stops the craniotomy, this can be corrected with a minimal downward movement. It is also possible to loosen the tilted cutter in such a case, using the backwards mode.

Speed Reducers

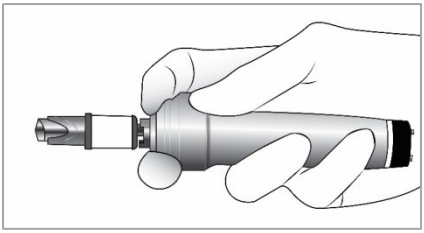
⚠ The system must be switched off while assembling the speed reducer and perforator.

The speed reducer is attached directly to the motor-hose in the same way as the motor.

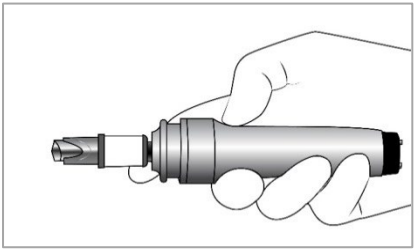
To insert a perforator, the coupling of the speed reducer must be pulled back, as shown in the following diagrams.



The perforator can now be inserted with the Hudson shaft.



When the coupling is released, 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.

Consumables

An overview of the HiCUT™ cutters and perforators for the system is available separately. Single-use HiCUT™ cutters and Meridian perforators are single-use products and must not be processed.

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.
Processing procedure described below has been validated in accordance with current standards.

Automated processing should be prioritized over manual cleaning where possible.

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 because of unsuitable cleaning agents/disinfectants (see 'Cleaning agents and Disinfectants to be used' chapter below) and/or overly high temperatures.
Frequent processing according to defined procedure has minor effects on the instruments.
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 adeor or dispose according to local and national regulations.

The device can be processed at least 500 times. This has been verified by technical and biological acceptance criteria after 500 processing cycles.

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. Fixing pre-cleaning temperatures >45° C or 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.

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, 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 foot switch and wall hose must not be 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 cutter is inserted on pins or any other sharp objects.
- Do not flush the attachments with pressure from the side where the 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.
- Follow cleaning procedure (exposure/holding times, temperatures, order of steps etc.) as described below.
- Pay attention to information about concentrations, temperatures and exposure times. Follow the manufacturer's instructions for using cleaning agents and disinfectants.

Foot switch and wall hose

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

Wall hose	Foot switch
ZMW-120/S	ZMF-150
ZMW-120/A	-
ZMW-121	

⚠ The devices are not authorized/validated for automated cleaning (thermal washer disinfector) and sterilisation.
Do not immerse or clean under running water.

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.

Manual cleaning and disinfection

Clean and disinfect the medical device immediately after each treatment.
- Wipe foot switch and wall hose with a wet cloth.
- 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. The validation was carried out with Schülke+ mikrozid universal liquid, exposure time 2 minutes.

▶ Ensure that the device is completely dry from the inside and outside after cleaning and disinfection.

Motor hose

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

Motor hose
ZMW-110
ZMW-110/SA1

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.

Manual Cleaning

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

1. Remove all detachable components (e.g. motor from motor hose)
2. Remove all gross soil from the equipment using disposable absorbent wipes or a soft, lint-free cloth wetted with a lukewarm (<50 °C) mixture of cleaning agent and water (drinking water quality).
   Cleaning agent: 1 % vol. neutral soap and 99 % vol. tap water.

Follow the manufacturer's specifications for use of the cleaning agent.
Validation (SN 35908) was carried out with HAKA neutral soap.

3. Place the equipment in a sink and rinse with fluent lukewarm water (<50 °C). Wipe the surfaces with disposable absorbent wipes or a soft, lint-free wetted cloth until no more residues are visible, at least for 1 min.
   > Ensure all external surfaces of the product are thoroughly wetted.
   > Ensure that the connectors are not submersed, and that no liquid enters the inner hose.
   > Ensure that the cleaning agent from step 2 is properly washed away.
4. Use a clean and disinfected soft brush to clean the product thoroughly. Pay particular attention to rough surfaces, crevices, and hard-to-reach areas, where soil may be shielded from the brushing, such as details around a connector.
5. Visually inspect the product for any remaining soil. If soil remains, repeat the cleaning and rinsing procedure using fresh cleaning solution, brush, and wipes.
6. Allow the equipment to drain on disposable absorbent wipes.
7. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air (<2 bars).
8. After cleaning, inspect and test the components.

Motor, trepan motor and attachments

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

Motor	Trepan motor
ZMM-100	ZMT-102
Angled attachment	Straight attachment
VMN-A1	VMN-XS
VMN-A2	VMN-S1
VMN-A3	VMN-S2
VMN-A4	VMN-S3
VMN-A5	-
VMN-A6	
Craniotome	Irrigation attachments
VMCH-D	VMN-IR-XS
VMN-C1	VMN-IR-1
VMCH-1	VMN-IR-2
VMCH-2	VMN-IR-3
VMCH-3	VMN-IR-4
VMCH-1R	VMN-IR-5
VMCH-2R	VMN-IR-6
VMCH-3R	-

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+ microzid wipes.

Option 1: Manual cleaning and disinfection

Do not immerse/place the components in an ultrasonic bath.

Step 1: Soaking
Soak the attachments 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.

Step 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.

Step 3: Drying
Dry the attachments (6 bar) for at least 30 seconds.
Wipe them dry with a clean cloth until completely dry.
Repeat the cleaning process if necessary.

Step 4: 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.

Step 5: Rinsing
Rinse the instruments under critical water (21° - 25°C, e.g. deionized, distilled or demineralized water), for 30 seconds.

Ensure that the attachments are completely dry from the inside and outside after cleaning and disinfection.

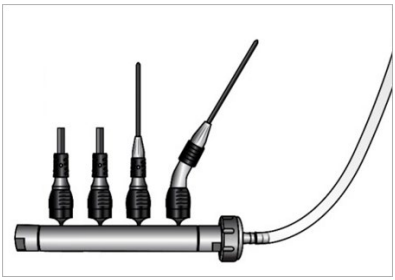
TIP

If possible, use the adeor cleaning adapter (REF: CA100) to rinse the attachments. 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 and disinfection

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.

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.

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) with the following program.

Start program sequence:

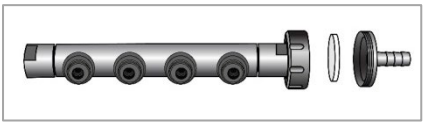
1. Cleaning phase 1 minute at 30 °C
2. Cleaning phase 6 minutes at 55 °C
3. Rinsing with critical water (e.g. deionized, distilled or demineralized water) 1 minute
4. Thermal disinfection with critical water (e.g. deionized, distilled or demineralized water) with A_0 value = 3000 (as e.g. 5 minutes at 90 °C)
5. Drying: Drying times depend on the program of the cleaning and disinfection device.

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

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. adeor Velocity Alpha oil spray (REF: OS-100-1).

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-C1	Craniotome base
ZMM-100	Motor
ZMT-102	Trepan motor

⚠ Lifetime will be significantly shortened when oil care is not performed before every sterilization cycle.

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, i.e. adeor Velocity Alpha oil spray (REF: OS-100-1).

Attachments:

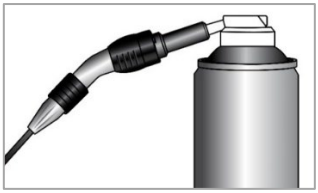
Oiling should be carried out from the side of the motor-attachment coupling, which is attached to the oil spray adapter.

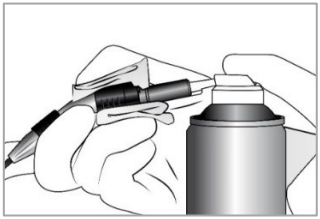
Motors:

Oiling should be carried out from the side of the motor-hose coupling by inserting the oil spray adapter into the air intake area of the motor and holding both components firmly together. The oil adapter cannot be coupled to the motor via a coupling mechanism.

Use a germ-free, fiber-free cloth to hold the device in place.
Spray for a maximum of 2 seconds.

TIP
For better oiling result: Insert a cutter into attachment.



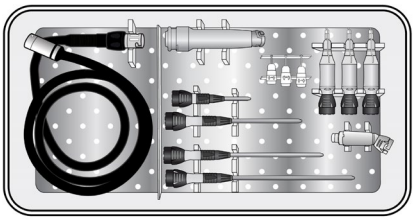


TIP
adeor recommends a function test before sterilization in autoclaves, including test runs of all components.

Sterilization and storage

Packaging

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



Devices/Tray are shrink-wrapped 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 sterilisation paper which has been tested in accordance with EN 865-2.

Make sure that only completely dry devices are being stored.
Do not wrap the hose around the motor and do not fold the motor hose (risk of damage).

Sterilisation (motor, trepan motor, attachments and motor hose)

Motor	Trepan motor
ZMM-100	ZMT-102
Angled attachment	Straight attachment
VMN-A1	VMN-XS
VMN-A2	VMN-S1
VMN-A3	VMN-S2
VMN-A4	VMN-S3
VMN-A5	-
VMN-A6	
Craniotome	Irrigation attachments
VMCH-D	VMN-IR-XS
VMN-C1	VMN-IR-1
VMCH-1	VMN-IR-2
VMCH-2	VMN-IR-3
VMCH-3	VMN-IR-4
VMCH-1R	VMN-IR-5
VMCH-2R	VMN-IR-6
VMCH-3R	-
Motor hose	
ZMW-110	ZMW-110/SA1

Only sterilize devices which have been prepared, oiled (if applicable), disinfected (if applicable) and checked or tested.

Steam sterilization in pre-vacuum process or gravity method as follows with sterilization device acc. EN 285:

Vacuum process:	3 min at 132 °C
Drying:	16 min
Gravity method:	10 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.

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

Recurring tests

We recommend a recurring function and safety test of the system components once a year.
The tests must be performed 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
- Use the original packaging for returns.
- Do not wrap the hose around the motor and do not fold the motor hose (risk of damage).

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

ZMM-100	
Speed (at 8 bar / 116 psi)	max. 100.000 rpm
Weight	99 g
Length	85 mm
Diameter	20 mm
ZMT-102	
Speed	max 1.200 rpm
Weight	460 g
Length	143 mm
Diameter	27 mm
ZMF-150	
Weight	2.1 kg
Attachments	
Shaft diameter	5.4 mm
Universal cutter system	Yes
1-click coupling	Yes
Variable exposure	Yes

Recycling and disposal

adeor has developed and manufactured the pneumatic Velocity® Alpha high speed surgical drill 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.

Used Symbols

	Consult instructions for use
	Manufacturer
	Date of manufacture
 1304	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.
	WARNING: Observe warnings
	Expiry date
	Single Use only
	Non-sterile
	Only use if packaging is undamaged
	Reference number
	Batch number
	Serial number
	Sterilized using irradiation
	Temperature limits
	Do not throw away with household waste
	Store in a dry place
	Latex-free
	Medical device

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 system components, and non-compliance with our instructions, absolves adeor medical AG of any warranty services or other claims.

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