

## OmniOS

### BATTERY-POWERED SURGICAL POWER TOOL SYSTEM HANDPIECE INSTRUCTIONS FOR USE VPD1-HP

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### 1. Precautions Before Use

#### 1.1. Warning

- This product is a medical device and shall not be used for unintended purposes.
- Read and understand the operating guidelines before handling this device. Be especially cautious about safety information.
- Only persons who were educated on the handling of reusable medical devices shall handle this device.
- Always provide personal protective equipment to persons handling this product according to instructions related to detergents and safety and health materials. Wear personal protective equipment at all times.
- Unless specified otherwise, only use instruments approved by the manufacturer.
- Do not remodel components or accessories of this product. Failure to abide by the guidelines above may lead to injuries of patients and medical staff caused by infections, cross-infections, and product troubles.

#### 1.2. Handling of Device

- The following instruments are required to handle the device according to the guidelines in this Manual.
  - Personal auxiliary equipment recommended by the detergent manufacturer
  - Warm fresh water or deionized water
  - Absorbent paper towel
  - Soft and napless cloth
  - Syringe
  - Nonabrasive, soft, and flexible synthetic bristle brush
  - Compressed air for medical use, <140 kPa
  - Dryer
  - Sterilized wrap, grade 500 or higher
  - Chemical indicator
  - Sterilizer
- Water
  - Warning: Use fresh water when diluting the detergent and rinsing the device. Mineral residues in hard water can stain the device or prevent effective cleaning and decontamination.
  - Caution: Poor water quality may have an adverse effect on the service life of this product. Always abide by the water quality requirements under AAMI TIR 34. For manual cleaning, warm water in the optimal temperature range of 27 - 44°C is recommended.
- Detergent
  - Warning: Only use the detergent of a specific form to clean the device. Read, understand, and follow the usage, instruction, and warning information provided with the detergent for proper handling and use of this product. Always prepare the detergent solution as recommended by the manufacturer. Be cautious about the concentration and total variance.
  - Caution: We recommend using a neutral detergent to clean the device. Always use a detergent appropriate for aluminum, stainless steel, plastic, and rubber surfaces.
  - Note: This product used the following cleaning agents for manual cleaning verification.

Supplier	Product	Compatibility
RUHOF	Endozime® AW Triple Plus with APA	All Materials

The detergent used for verification is recommended to clean this product, but other detergents may have equivalent or superior performance. However, it is necessary to check the information or actual test results provided by the detergent supplier when using another detergent.

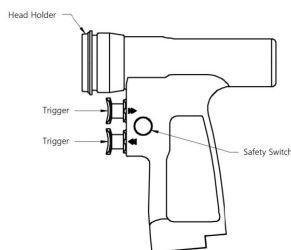
### 2. Product Overview, Parts, and Name and Structure

#### 2.1. Product Overview

This product can be rotated in forward or reverse direction using the rotational force of the motor. It is used to perforate or cut bones by attaching a medical drill, burr, or blade to the drill attachment.

#### 2.2. Name and Structure of Handpiece Parts

##### - VPD1-HP



#### 2.3. Name and Structure of Each Component

##### 2.3.1. List of Components

Product Name	Model Name
Battery pack	VPD1-BP
Battery pack case	VPD1-BPC
Battery shield	VPD1-BS

Battery charger	VPD1-BCH
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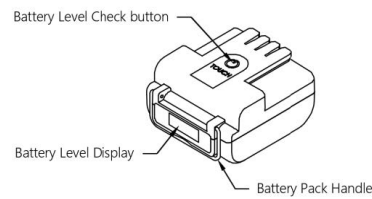
##### 2.3.1. List of Components

Product Name	Model Name
Jacobs Drill Attachment	VPD1-JDA
Universal Drill Attachment*	VPD1-UDA
Large AO Drill Attachment*	VPD1-LAODA
Small AO Drill Attachment	VPD1-SAODA
Oscillating Saw Attachment	VPD1-OSA
Universal Reamer Attachment*	VPD1-URA
Jacobs Reamer Attachment*	VPD1-JRA
Large AO Reamer Attachment*	VPD1-LAORA
Wire-Pin Driver Attachment	VPD1-WPDA
Reciprocating Saw Attachment*	VPD1-RSA
TPLO Saw Attachment	VPD1-TPLOA

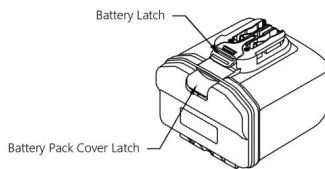
\* The Attachments above are sold separately.

##### 2.3.2. Name and Structure of Each Part

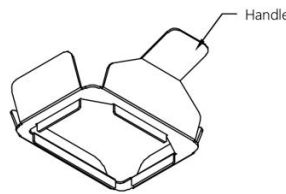
###### - Battery pack (model name: VPD1-BP)



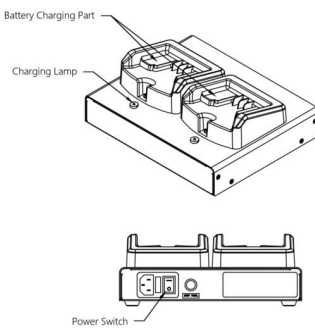
###### - Battery case (model name: VPD1-BPC)



###### - Battery shield (model name: VPD1-BS)



###### - Battery charger (model name: VPD1-BCH)



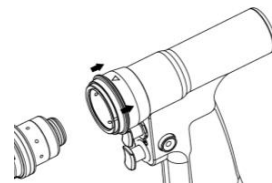
### 3. How to Use and Precautions During Use

#### 3.1. How to Use

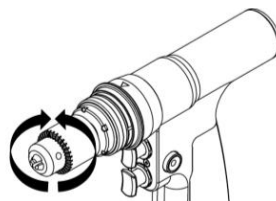
##### 3.1.1. Connection of Attachment

###### 1) Connection of Attachment, Applied part and handpiece

- ① Pull the head cover of the handpiece and insert the attachment to be used in the correct position. Align the top arrow of the handpiece with the groove on the attachment.



- ② If the head cover does not return to the original position with a clicking sound, rotate the attachment until it returns.

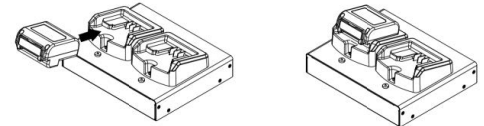


- ③ Hold the attachment with a hand and shake to check that it is fixed in place.
- ④ To change the angle of the attachment, pull the head cover of the handpiece and adjust the angle by rotating the attachment.
- ⑤ Install appropriate accessories (drill, sawblade, wire, pin, etc.) as required (these accessories are Type B applied parts).

#### 3.1.2. Charging and Connection of Battery Pack

##### 1) Charging of battery pack

- ① Mount the battery pack on the battery charger and start charging.



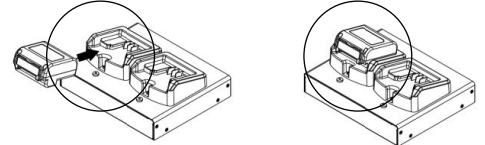
- ② Colors of the charging lamp on the battery charger indicate the following conditions.

Charging Lamp Color	Condition
Green	Power supplied (without battery pack mounted)
Orange	Charging battery pack
Green	Charging complete (with battery pack mounted)

- ③ Once charging is done, separate and store to prevent contamination.

##### 2) Charging and Battery Pack

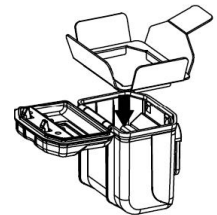
- ① Mount the battery pack on the battery charger and start charging.



- ② Once charged, the battery gauge becomes full and is indicated as 100%
- ③ After charging, separate the pack for storage to prevent contamination.

##### 3) Insertion of battery pack into battery case

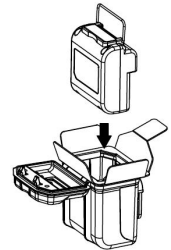
- ① A person who can contact sterilized medical devices shall set the sterilized battery shield on the sterilized battery case.



- ② A person who can contact non-sterilized medical devices shall check battery level by pressing the battery level check button on the battery pack. This battery pack automatically shuts power OFF after 3 hours pass without use.

Battery Remainder	Status
	Fully Charged
	Discharged

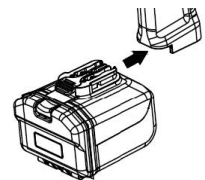
- ③ A person who can contact non-sterilized medical devices shall grab the battery pack handle and insert the battery pack into the battery case. Be careful not to contact the battery pack with the exterior of the battery case.



- ④ A person who can contact sterilized medical devices shall remove the battery shield and close the battery case cover.

##### 4) Connection of battery case and handpiece

- ① Turn the handpiece safety switch to the safety mode.
- ② Push the battery case inserted with the fully charged battery pack into the handpiece until it makes a clicking sound.

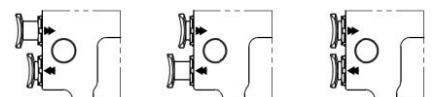


- ③ Slightly pull the battery case and check that the battery case is firmly fixed onto the handpiece.
- ④ Unlock and press the trigger to check handpiece operation.

#### 3.1.3. Handpiece Operation

##### 1) How to operate handpiece

###### VPD1-HP



Clockwise (CW) Counterclockwise (CCW) Oscillating Rotation

## 2) Recommended Cycle of Handpiece

Conditions of Use	Recommended Cycle
Drilling (When using drill/reamer/wire-pin driver)	1 minute of use, 4 minutes of rest, repeated 3 times
Oscillating (When using drill/reamer/wire-pin driver)	15 seconds of use, 15 seconds of rest, repeated 5 times
Sawing (When using oscillating/reciprocating saw)	30 seconds of use, 4 minutes and 30 seconds of rest, repeated 3 times
Rest between cycles (after using 3 times)	3 hours

### 3.1.4. After Finishing

#### 1) Separation of attachment

- ① After using the handpiece, turn the handpiece safety switch to the safety mode to lock the trigger.
- ② Remove the drill bit and blade attached to the attachment.
- ③ Pull the head cover on the handpiece and remove the attachment.

#### 2) Separation of battery case and battery pack

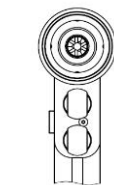
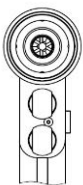
- ① Press the battery latch on the battery case and separate it from the handpiece.
- ② Press the battery pack cover latch on the separated battery case to open the cover and remove the battery pack.

### 3.2. Precautions During Use



#### 1) Warning

- When not using the handpiece or when handing it over to another person, always place the handpiece safety switch on the safety mode to lock the trigger.



Safety Mode

Safety Mode turned OFF

- Before operating the handpiece, slightly pull the cutting accessory and always check that the cutting accessory is firmly fixed onto the handpiece.
- Do not hold or touch rotating or reciprocating components while the handpiece is in operation.
- Do not change position of the safety switch while the handpiece is in operation.
- Always operate the equipment within the specified environmental conditions.
- Always abide by the recommended cycles to prevent overheating.
- Do not cut pins or screws using the blade. Cutting these items can lead to contamination of the surgical site from metal scraps and/or ejection of metal fragments at high speed.
- Always lubricate attachments in advance using saline solution. Flow through during the cutting process to prevent overheating.
- Do not bend objects attached to the attachment (drill, blade, wire pin, etc.) while using or apply excessive pressure or force by twisting. Excessive pressure and force may bend or break the objects and cause tissue damage, loss of touch control, and/or ejection of fragments at high speed.
- Oscillating attachment or objects (drill, blade, wire pin, etc.) can cause bone or tissue damage and inaccurate arrangement of the wire pin. If they oscillate, check that the attachment and objects are fixed in place and take measures.
- If oscillation continues after taking measures, stop using and contact the seller or manufacturer for further measures.
- Do not operate the head cover while the handpiece is in operation.
- Do not use the reciprocating mode if objects other than the drill attachment are attached to the handpiece.
- Do not operate the handpiece until the blade contacts the bone or tissue. The blade may break or slip out of the handpiece.
- Do not grab the operating part of the attachment (ex. blade knob of oscillating saw attachment, etc.) while operating the handpiece. Objects can slip out of the attachment.
- Do not insert the screw into the bone using the handpiece.
- Read and understand the instructions before using this product or components that are compatible with this product. Be especially cautious about safety information. Make sure to become familiar with the equipment before using.
- Only medical professionals trained to use this product shall use this equipment.
- Medical professionals who perform the operation have the responsibility to decide appropriateness of this equipment and techniques to be used on each patient. The manufacturer does not recommend any surgical process or technique.
- After receiving the equipment at first, operate the equipment before use to check for damaging of each component. If damage is found or the equipment fails to satisfy the inspection criteria, immediately stop using and contact the seller or manufacturer.
- Do not use this equipment in areas where flammable anesthetics or flammable medicines are mixed with the air, oxygen, or nitrous oxide.
- When using medical electrical equipment, pay particular attention to electromagnetic compatibility (EMC). Use this product according to EMC information. Portable and mobile radio frequency (RF) communication equipment may affect functions of this product.
- Before using, always set product temperature to be within the operating temperature range specified in this document.
- Always follow the recommended cycle of the handpiece to prevent overheating.
- Do not allow the battery contact part to touch metallic objects.
- The battery pack contains lithium ion substances. Do not short, open, crush, or burn circuits as there are risks of fire, burn, and explosion.
- When disposing of the battery pack, do not throw it into a fire.
- Do not discard the battery with general wastes.
- Since the battery disposal method differs according to the country and region, dispose of the battery using an adequate method.

#### • Precautions

- Prevent the handpiece from stalling. If compliances are not followed, the handpiece motor and battery pack can be damaged. If the handpiece is stuck and does not move, let go of the trigger immediately. Remove obstacles and reoperate the handpiece.
- If the handpiece is discharged during use, replace the battery pack with a fully charged battery pack. Failure to do so may damage the battery pack and reduce its service life.
- Do not drop the battery pack or give a shock. Doing so can cause failure or damaging of the battery pack.
- Always keep the battery pack fully charged. Neglecting the discharged battery pack can damage the battery pack and reduce its service life.

## 4. Cleaning Method

### 4.1. Initial Handling and Preparations Before Cleaning

#### 4.1.1. Precautions During Use (After Use)

- If this product is dried after being contaminated by blood, body fluids, bones, and tissues, it can be difficult to clean. Do not let the product surface to become dry after use
- After using this product, remove foreign matters on the surface using an absorbent paper towel. Before cleaning, cover with a wet cloth to prevent drying or spray cleaning foam on the parts with foreign matters as necessary.
- Do not wet or immerse this product in saline solution.
- Remove all attached objects and battery before cleaning this product.
- After using, clean the product as quickly as possible (within 2 hours).



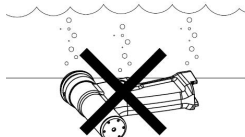
#### 4.1.2. Warning

- Be especially cautious not to get wounded by sharp edges during transportation.
- Do not damage the product mechanically during transportation (ex. loading with a heavy instrument).
- Do not immerse or soak any equipment in liquid unless otherwise specified.

### 4.2. Cleaning

#### 4.2.1. Cleaning Precautions

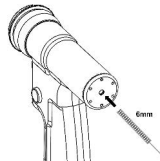
- Do not use an ultrasonic cleaner.
- Do not completely immerse this product in liquids, like water.



- When cleaning, do not drop the product or give a strong shock.
- Unless specified otherwise, do not use solvents, lubricants, rinsing aids, or other chemicals.

### 4.2.2. Manual Cleaning

- ① Remove all foreign matters remaining on this product using an absorbent paper towel wet with the detergent or a soft, napless cloth.
- ② Remove foreign matters in the deep groove or holes of this product using a soft brush of appropriate diameter.



- ③ Remove foreign matters by moving this product to clean the hidden surface.



- ④ Clean foreign matters in running water or using a syringe filled with water.
- ⑤ After removing all foreign matters, thoroughly rinse the product in running warm water to remove all detergent residues. Rinse repeatedly until water coming out of the device becomes clear.
- ⑥ Remove water on the product by leaning the product after rinsing.
- ⑦ After cleaning, visually check and inspect the product to make sure that all foreign matters and detergent have been removed. If water or detergent can be seen, repeat the cleaning procedure.
- ⑧ After rinsing, remove water on the product using an absorbent paper towel.
- ⑨ Dry the product immediately after cleaning.

### 4.2.3. Automatic Cleaning

- This device does not support automatic cleaning.

### 4.3. Drying

- 4.3.1. The product must be dried immediately after cleaning. The drying conditions are as follows.

- Dry the product using a soft, napless cloth or air.
- When using an oven, dry the product at a temperature of 110°C or lower (drying time: at least 30 minutes at 110°C).

- 4.3.2. After drying, perform inspection and maintenance on the product immediately.

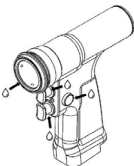
## 5. Inspection and Maintenance

### 5.1. Inspection

- Check that all moving parts can be operated freely. Inspect abnormal sound, vibrations, and surface abnormalities.
- Check for product separation and gaps, burrs, or sharp projections that can cause injuries.

### 5.2. Maintenance

- If attaching parts of the attachment, trigger, and safety switch become stiff, use a medical lubricant (product certified biologically). Wipe out remaining lubricant.



### 5.3. Precautions

- Only individuals who have been educated and have experience in the maintenance of reusable medical devices shall inspect this product.
- Only use a medical lubricant that can be used in the human body.
- Unless specified otherwise, do not disassemble, remodel, or repair this product.
- If a problem is found during inspection and maintenance, stop using and contact the seller or manufacturer to take measures.

## 6. Sterilization Method

### 6.1. Packing

- If there is no problem found during inspection and maintenance, perform airtight packing to prevent contamination before sterilizing.
- This product must be packed individually and can be loaded on a tray only if there is an exclusive tray.
- This product must use dual packing with a medical sterilized pouch or wrap appropriate for steam sterilization. The packing must be sealed.
- If there is no sterilization indicator, insert a sterilization indicator into the packing.

### 6.2. Sterilization

- This product shall only use steam sterilization. Other sterilization methods are not recommended.
- The steam sterilization conditions of this product are as follows (ISO17665-1,2).

Sterilization Method	Sterilization Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum	132°C	4 minutes	30 minutes
Gravity	132°C	15 minutes	30 minutes

- The minimum exposure time can be extended to 20 minutes but may shorten the service life of this product.
- Our company does not guarantee sterilization effects for methods and conditions not proposed.

### 6.3. Storage and Transportation

- The sterilized product shall be transported and stored while being careful not to damage the packing.
- The sterilized product shall be always kept in an environment with controlled temperature and humidity.

## 7. Product Specifications

### 7.1. Handpiece

Model Name	VPD1-HP
Dimensions (LxWxH)	44 mm x 132.7 mm x 152 mm
Weight	0.78kg
Speed	1,200 RPM (when using drill attachment)
	12,000 CPM (when using oscillating saw attachment)

Recommended Cycle	Drilling	1 minute of use, 4 minutes of rest, repeated 3 times	
	Oscillating	15 seconds of use, 15 seconds of rest, repeated 5 times	
	Sawing	30 seconds of use, 4 minutes and 30 seconds of rest, repeated 3 times	
Rest Between Cycles		3 hours	
Maximum Surface Temperature	Drilling/Oscillating	48°C or lower (when applying recommended cycle)	
	Sawing	51°C or lower (when applying recommended cycle)	
Equipment Type		Type B Applied Part	
Power Supply		Internally powered Refer to battery pack for voltage rating	
Degree of Protection Against Harmful Infiltration of Water		IPX7	
Environmental Conditions	Transportation and Storage	Temperature	-20 - 40°C
		Humidity	10% - 75 %
	Operation	Air Pressure	50 - 106 kPa
		Temperature	10 - 27°C
Warranty Period	Humidity	30 - 75 %	
	Air Pressure	70 - 106 kPa	
		1 year	
		90 days (Batteries Only)	



- Warning: Always check the cycle and method of using objects (attachment, drill bit, blade, etc.) before use.

### 7.2. Battery Charger

Model Name	VPD1-BCH
Power Input	100-240V ~, 50/60Hz, 1.0A (2Ch)
Power Output	16.8V ---, 1.0A (2Ch)
Degree of Protection Against Harmful Infiltration of Water	IPX0

### 7.3. Battery Pack

Model Name	VPD1-BP
Dimensions (LxWxH)	74 mm x 82.4 mm x 43.7 mm
Weight	0.29kg
Category	Rechargeable, lithium ion battery pack
Type	41NR19/65
Rated Voltage	14.4 V ---
Capacity	2,450 mAh
Degree of Protection Against Harmful Infiltration of Water	IPX0
Transportation and Storage Temperature	15 years: -30-25°C 3 months: -30-45°C 1 month: -30-60°C
Temperature of Use (Surface Temperature)	Charging: 0-45°C Discharging: -20-70°C

## 8. Description of Symbols

Symbol	Description
	Forward Trigger or Reverse Trigger Conditional symbol; action is in the direction of the arrow.
	Lubricant Application. Lubricate the designated location.
	Catalogue Number: Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number: Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Date of Manufacture: Indicates the date when the medical device was manufactured.
	Rx only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Warning: Warning to prevent a serious accident, of damage to property.
	Follow the User Manual
	Temperature Limit: Indicates the temperature limits to which the medical device can be safely exposed.
	Atmospheric pressure limitation: Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Humidity limitation: Indicates the range of humidity to which the medical device can be safely exposed.
	Consult instructions for use: Indicates the need for the user to consult the instructions for use.
	Manufacturer: Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Direct Current (DC)
	Alternating Current (AC)
	To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, ALWAYS collect this product separately for recycling. DO NOT dispose of this product as unsorted municipal waste. Contract your local distributor for disposal information.
	Type B applied part: To identify a type B applied part complying with, IEC 60601-1
	Caution: To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Do not immerse in any liquid: To identify that the appliance must not be immersed in any liquid.
Saw 30 sec / 4.5 min x 3	Duty Cycle – See the Specification section
Drill 1 min / 4 min x 3	

## Movora

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