


Qualität und Funktion

**Gebrauchsanweisung**  
*Instruction Manual*

**Socket Valve**  
**V09, V09-A, V10, V10-A**



Rev.0-2021-07\_V09,V09A,V10,V10A

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unique prosthetic solutions  
A company of the Bauerfeind Group

 **uniprox**<sup>®</sup>



Please read the IFU carefully before fitting. Only correct usage will warrant the function.

### 1. Intended Use

The valves control the expulsion of air between the prosthetic socket and the residual limb by this the fixation of the prosthetic limb prosthesis.

### 2. Technical data

#### 2.1 V09, V09-A Socket Valve – for check- and interim sockets

- V09: Manuel air expulsion
- V09-A: Automatic air expulsion
- Direct fitting in thermoplastic socket material
- Extra large valve opening: Inside  $\varnothing = 30$  mm, Outside  $\varnothing = 35$  mm
- Set includes: dummy with pin, 2 deep drawing socks

**REF**

Order No.	Material	Valve Opening	Article No.
V09	Plastic	$\varnothing 30$ mm	4 233 100 00 00 000
V09-A	Plastic	$\varnothing 30$ mm	4 233 040 00 00 000

#### 2.2 V10, V10-A Socket Valve – for container sockets

- V10: Manuel air expulsion
- V10-A: Automatic air expulsion
- Extra Large Valve opening like V09 (valve body exchangeable)
- Valve house from stainless steel
- Dummy set E-V44 and wrench E-V45 need to be ordered separately

**REF**

Order No.	Material	Valve Opening	Article No.
V10	Plastic, Stainless steel	$\varnothing 30$ mm	4 660 050 00 00 000
V10-A	Plastic, Stainless steel	$\varnothing 30$ mm	4 660 050 00 01 000

### 2.3 Service parts V09 and V10

Valve body for V09 and V10 with manual air expulsion

Order No.2	Material	Article No.
E-V46	Plastic	4 660 059 00 03 000

Valve body for V09-A and V10-A with automatic air expulsion

Order No.	Material	Article No.
E-V47	Plastic	4 660 059 00 04 000

Dummy-set for V10/V10-A

Order No.	Material	Article No.
E-V44	Aluminium	4 660 059 00 01 000

Special wrench for V10

Order No.	Material	Article No.
E-V45	Steel	4 660 059 00 02 000

### 3. Indication/ Contraindicationen

Indicationen:

- Prosthetic fitting of the lower extremity

Contraindicationen:

- not known

### 4. Side effects

There are no known side effects.

## 5. General safety instructions



- This medical product is designed for: single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- Improper modification or application to the product is not allowed. In case of non-observance, the function of the product may be impaired, so that product liability is excluded.

## 6. Instruction

### 6.1 Socket Valve V09, V09-A

- Socket valves is fitted exclusively in thermoplastic sockets that are produced using the vacuum forming process.
- Determine and mark the position of the valve on the model and then insert the dummy provided into the valve housing and secure it to the model with the nail provided.
- Since the valve housing must be tightly enclosed by the vacuum-forming material in order to ensure for it to function perfectly, sufficient negative pressure directly in the valve region is absolutely essential. A suction channel to the valve is therefore drilled through the model. Alternatively, the two nylon stockings provided can also be pulled over the model.
- Pull the warmed vacuum forming material over the model, remove the air by suction and use a hot-air blower to keep the valve region warm until the material is completely pressed against the housing.
- Drill open the socket material on the dummy nail and remove this nail, cut the socket and remove it from the model.
- Grind free the valve dummy used, remove it and regrind and polish the edges in the valve opening region.
- Treat the socket edges in the usual way.

### 6.2 Socket Valve V10, V10

Use dummy set E-V44 to install the valve in the socket material.

### 6.2.1 Vacuum forming

- Fix the vacuum forming dummy in place on the plaster model using a wood screw or nail. If the dummy does not fit properly on the model, the model must be reworked as appropriate.
- When vacuum forming, make sure that the vacuum force on the dummy is strong enough to suck the material all around it.
- Heat the plastic material and carry out the vacuum forming process as normal.
- Once everything has cooled down, grind carefully until the upper surface of the dummy comes free.



If the valve is to be used in a test socket, use the vacuum forming dummy with the lamination dummy on top for vacuum forming to ensure that the harder test socket material does not have to be ground down too far!

### 6.2.2 Laminating

- To laminate the vacuum-formed inner socket, screw the lamination dummy to the vacuum forming dummy in the inner socket using the enclosed countersunk head screw.
- Pull the PVA film over the model and laminate as normal.
- After curing, grind the lamination dummy carefully until it comes free.
- After removing the model, pass the valve ring with the sealing ring through the socket opening that has been created from the inside and screw on the valve nut. Use installation wrench E-V45 to do this.

## 7. Maintenance and Cleaning

As part of regular prosthesis maintenance the valves must be checked and cleaned every 6 months at the most.



Cleaning:

- Compressed Air up to 2 bar
- Soap and hand warm water
- Do not use aggressive solvents for cleaning.



### **8. CE- Conformity**

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to Uniprox and the competence European Authority.

### **9. Warranty and Guarantee**

With regular maintenance, the valve can be used for the duration of the prosthesis use (usually 5 years).

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

### **10. Storage and Disposal**

The product is disposable with standard household garbage.

#### **Please direct any questions to:**

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