

## Symbol-Legende Icon Legend

	Achtung Attention		Europäischer Bevollmächtigter European Authorized Representative
	Artikelnummer Article number		CE-Kennzeichnung CE marking
	einzelner Patient- mehrfach anwendbar single patient- multiple use		Übersetzung Translation
	Reinigung Cleaning		Vertriebspartner Distributor
	Hersteller Manufacturer		Importeur Importeur
	Nicht bleichen Do not bleach		Keine chemische Reinigung No chemical cleaning
	Nicht bügeln Do not iron		Nicht im Trockner trocknen Do not tumble-dry
	Umpacken Repackaging		

Qualität und Funktion

## Gebrauchsanweisung Instruction Manual

### Vakuum-Jet VJ1, VJ2 Vaccum-Jet VJ1, VJ2



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Rev.1-2023-04\_VJ1,VJ2



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

## 1. Intended Use

The Vacuum-Jet controls 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 Vaccum-Jet VJ

- Direct socket attachment by M36 thread
- The vacuum-jet provides temporary vacuum, thus the residual limb is not exerted to vacuum permanently and may relax in non-weight bearing phases
- Includes: VJ1, Pyramid adapter with M36 thread, Dummy set
- Lamination anchor needs to be ordered separately
- Used material:
  - Pyramid with M36 thread: steel
  - Dummy for the nozzle insert: POM
- Weight limit: 125 kg

#### REF

Order No.	Material	Promimal Adaption	Distal Adaption	Article No.
VJ1	Steel, Plastic	M36-Thread	Pyramid	4 175 000 77 00 000

### 2.2 Vaccum-Jet VJ2

- The vacuum-jet provides temporary vacuum, thus the residual limb is not exerted to vacuum permanently and may relax in non-weight bearing phases
- Freely positionable in the socket
- Can be retrofitted
- Includes: VJ2, Dummy plate with screw, sealing ring

#### REF

Order No.	Material	Size	Article No.
VJ2	Steel	Ø 12 x 16 mm	4 663 050 00 00 000

## 2.3 Service parts

Vaccum-Jet VJ2: For regular maintenance, a replacement kit contains a set of filters, a protective cap and a sealing ring

Order No.	Description	Article No.
E-VJ2	Replacement kit	4 660 010 90 55 000

## 3. Indications/ Contraindications

Indications:

- Amputation of lower extremities
- Specifically for BK-protheses combined with knee sleeve

Contraindications:

- Not known

## 4. Side effects

There are no known side effects.

## 5. General 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.
- The maximum weight loads are listed under "2. Technical Data". Additional loads must be taken into account when calculating the weight.
- Protect against dust, moisture, aggressive media, and mechanical forces so that the function of the valve insert is not affected.
- In the event of functional limitations, such as a limited vacuum or no vacuum, excessive noise, or as a result of an external impact (e.g. fall), the Vacuum Jet 2 must be checked by a specialist workshop and, if necessary, returned to Uniprox GmbH & Co. KG.
- Talc must not be used in the valve area as this may clog the nozzle and affect function.
- The product is intended to be used at temperatures from -10°C to 50°C.

## 6. Installation

The Vacuum Jets are equipped with a valve insert with nozzle. In conjunction with a knee sleeve that forms an airtight seal around the prosthetic socket, as well as a liner without a distal connection (Uniprox Softskin CL), the excess air can flow out when a load is put on the socket. The Vacuum Jet can be used in test and definitive prosthetic sockets. The appropriate processing aids (dummies) are included in the delivery.

### 6.1 Vacuum-Jet 1

- Grind the surface of the distal end of the positive plaster cast. Drill an 8 mm hole in the center and position the dummy for the nozzle insert on the positive.
- For the PVA film to get a better vacuum effect, thus ensuring a more exact impression of the dummy (no. 1), put a thin nylon liner (MG206) over the positive.
- Screw the pin dummy (no. 2) into the dummy (no. 1) and cover it with PVA film. Tie off the PVA film in the groove of the pin dummy and fasten the film with some PVC tape.
- Use several reinforcement layers, tie them off at the dummy's collar (no. 1), and then fold them back.
- After shaping the socket adapter, lubricate all threads and clamping screws with silicone grease.
- Screw the dummy (no. 3) into the adapter. Protect the clamp and dummy (no. 3) with Plastilin.
- Position the socket adapter including the dummy, and screw it in using the M5x10 countersunk screw (no. 4).
- Use several reinforcing layers on the socket adapter, according to the weight and activity of the prosthesis user. Casting can then take place as usual after the second layer of PVA film has been put on.
- After curing, the dummies can be removed and the socket can be ground.

- Screw the pyramid into the socket adapter. Then the valve body (no. 5) can be screwed into the pyramid with the O ring (no. 6) and washer (no 7) from the inside of the socket, using a screwdriver. Insert the supplied filter flush into the pyramid adapter.



### 6.2 Vacuum-Jet 2

- To place the dummy disk, drill a 3 mm hole into the positive model in the desired position. Using the dummy screw, attach the dummy to the model.
- Then, put the PVA film over the model.
- For an adequate vacuum and better shaping of the dummy, an MG206 nylon stocking should be used. Casting can then take place as usual.
- After curing, the dummy screw is freed and unscrewed.
- When the socket has been removed from the model and smoothed, the valve body is inserted from the inside through the screw hole and secured using the nut.
- If required, the valve seat can be sealed with M22-0.1 silicone adhesive.
- Shorten the protective cap depending on the projection of the valve housing.

## 7. Maintenance and Cleaning

The function of the vacuum jet must be checked at regular intervals not exceeding 6 months. The filters of the vacuum jet must be cleaned regularly by qualified personnel and replaced if necessary. They can be reordered via the E-VJ2 replacement set, which also includes a protective cap and a sealing ring.



Cleaning:

- can be cleaned with a mild detergent and a damp cloth (>30°C)
- Do not use aggressive cleaning agents.
- With the filters removed, the valve body can be blown out from the inside to the outside with compressed air up to 2 bar.



### **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 an 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. Disposal**

The product is disposable with standard household garbage.

There are no storage recommendations.

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

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