

INSTRUCTIONS FOR USE

IFU CODE: 22



Valves

VAC-300, EPS-Valve, VAC-200, VAC-200-EXT



Fig 1. Components of EPS-VALVE

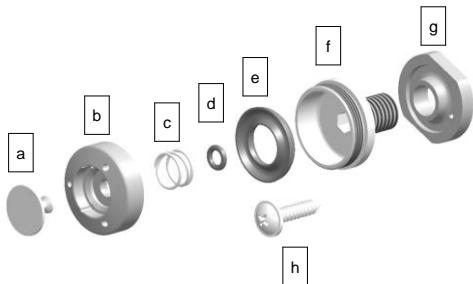


Fig 2. EPS-VALVE (V-Ring Positioning)

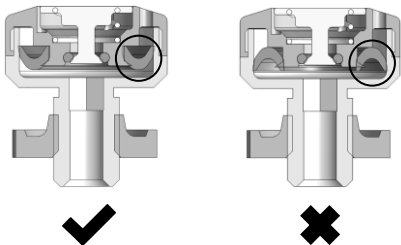


Fig 3. EPS-VALVE

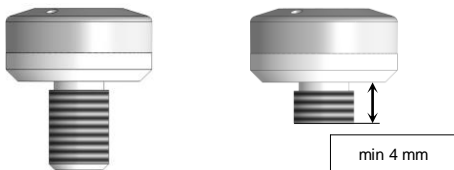
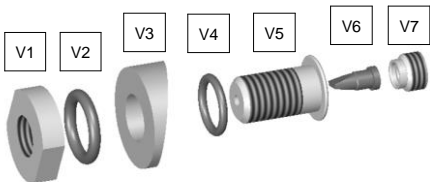


Fig 4. Components of VAC-300



INFORMATION

Last Update: 01-02-2023



- Please read this document carefully before using the product.
- Instruct the user in the appropriate and safe use of the product.
- Follow the safety instructions to abstain injuries and damage to the product.
- Please keep this document in a safe place.

Contents

1. EPS-Valve	1
2. VAC-300	4
3. VAC-200	6
4. Environmental Conditions.....	7
5. Service Life	7
6. General Safety Instructions	8
7. Maintenance	9
8. Warranty	9

1. EPS-Valve

Connection Tube with Seat Ring

Expulsion Valve with a button

One way air discharge

Aluminum anodized body



Code	Material	Outside Diameter
EPS-Valve	Aluminum body	40 mm

1.1 Components (Fig. 1)

a	Button
b	Plastic Cover
c	Spring of Button
d	O-Ring
e	V-Ring
f	Main Body
g	Plastic Nut
h	Self-Tapping Screws

1.2 Assembly - Directly to the Socket

1. Fabricate the socket as usual.
2. Mark the position of the valve on socket.
3. Drill a perpendicular hole in the socket wall with an 8.5 mm drill bit.
4. Tap the hole using M10X1.5 tap.

5. Make sure the cap and rubber membrane are removed before trimming the threads to prevent debris from accumulating in the airways.
6. Measure the socket wall thickness at the insertion point with a caliper. Shorten the threads accordingly using a hacksaw and smooth the edges.

CAUTION!



Do not shorten the threads more than 4 mm as this may affect the seal and increase the risk of cap breakage. (See fig.3)

1.3 Assembly with Plastic Nut (g)

1. The plastic nut (g) is used to fix the valve.
2. Prepare the plaster in the usual way.
3. Secure the plastic nut to the model using the self-tapping screw. Make sure the part is flush with the model.
4. It may be necessary to remove or add plaster.
5. Produce the socket as usual.
6. Loosen the self-tapping screw to remove the socket from the model.
7. Make sure the Plastic Cover (b) and V-Ring (e) are removed before shortening the threads to prevent dirt from accumulating in the airways.
8. Measure the socket wall and plastic nut (g) thickness at the insertion point with a caliper. Trim the chamfers accordingly and smooth the edges using a hacksaw.

CAUTION!



Do not shorten the threads more than 4 mm as this may affect the seal and increase the risk of cap breakage. (See fig.3)

1.4 Installation of EPS-Valve

1. Apply silicone adhesive to the threads and body that come into contact with the socket.

Note: The use of epoxy or similar materials is not recommended as this may compromise the sealing.

2. Install the valve and hand-tighten using a 5 mm hex wrench.

CAUTION!



Be careful not to tighten too much, the threads may be damaged.

NOTE!



After installation, distribute the silicone adhesive around the valve/socket contact to ensure an airtight seal.

3. Be sure airways and valve parts are free of debris before final assembly.

4. Replace the rubber V-Ring to cap. Make sure the concave surface is facing the cap cavity.

When reassembling, make sure the V-Ring is on the cap and not on the body. (See fig. 2)

5. Screw on the cap with the cap key.

2. VAC-300

One-way Valve

This valve enables the expulsion of excessive air out of the socket during stance phase and effectively prevents air from flowing in during swing phase

Easy installation on the socket wall without special tools. It also provides easy maintenance and replacement.



Code	Material	Outside Diameter
VAC-300	Aluminum	25 mm

Consisting of:

Valve body of anodized aluminum

Exchangeable sealing lip valve

Counter nut with O-ring

Foam filter insert

2.1 Components (Fig. 4)

V1	Nut of Main Body
V2	Large O-Ring
V3	Supporting Part
V4	Small O-Ring
V5	Main Body (Valve Body)
V6	Pneumatic One-Way Valve
V7	Special Set Screw

2.2 Assembly

1. Drill a 10 mm hole from the outside of the socket at an appropriate location.
2. Heat the socket in this area with hot air inside and socket the outlet.
3. Remove the Small O-Ring (V4) from the Valve Body.
4. Adopt the Valve Body with Valve inside the socket.
Danger of burn wounds!
5. Screw the Nut of Main Body (V1) with the flat side the outer socket side.
6. Fix the screw with a 4 mm allen key until the Valve Body is flush with the internal socket.
7. After the socket cools down, unscrew the Nut of Main Body (V1) and unscrew the Valve Body with Valve.
8. Put the Small O-Ring (V4) on the Valve Body and fix it in the socket.
9. For conical stump the Supporting Part (V3) can be used. Place between socket and Nut of Main Body (V1).
10. Screw fix the Nut of Main Body (V1) on the Valve Body with the Small O-Ring (V4) side towards the socket.
11. Screw the Valve Body with Valve with a 4 mm allen wrench.
12. Insert the dust filter into the allen screw of the Valve.

3. VAC-200

Automatic Flat Rubber Valve

Automatic one-way valve

With thump flap



Code	Material	Outside Diameter
VAC-200	Rubber	40 mm

3.1 VAC-200-EXT

Connection Tube with Seat Ring

For valves having an outside diameter of 40 mm.



Code	Material	Outside Diameter
VAC-200-EXT	Rubber	40 mm

4. Environmental Conditions

Acceptable Environmental Conditions
Temperature use range: -10 °C to +45°C
Humidity: Allowable relative humidity 20% to 90%, non-condensing

Unsuitable Environmental Conditions
Fresh Water, salt water, sweat, urine, acids e.g.
Sand, dust, highly hygroscopic particles (e.g., talcum)
Mechanical vibrations, impacts
Cleaning agents containing solvents

5. Service Life

Service life of the EPS-Valve and Vac-300 products are about 2 years and this duration depends on the daily activity of the user.

It's crucial that, both of the vacuum valves should be controlled regularly to provide air-flow.

6. General Safety Instructions

CAUTION!



To avoid the risk of injury and product damage, do not use for longer than the service life of the product.

The suitability of the device to the patient and the prosthesis should be evaluated by a healthcare professional.

The device must be fitted and adjusted by a healthcare professional.

Avoid using this product in unsuitable environmental conditions. If the product has been exposed to unsuitable environmental conditions, check for damage.

Avoid using powder in areas close to the valve. Powder or highly hygroscopic particles such as talcum can limit or disable the valve's functionality. Any powder on the inside of the socket or on the skin can disrupt the valve and restrict its functions.

Do not use the product that is damaged, has limited functionality or is in doubtful condition. Ensuring that appropriate measures are taken (e.g. control, cleaning, repair, replacement by the authorized workshop or manufacturer).

To prevent mechanical damage, be careful and caution when working the product.

Use the product for a single patient to avoid injuries and product damage.

Products should be used in appropriate combinations. Using the product with unsuitable combinations may result in possible injury.

7. Maintenance

1. After the first 30 days of use, the prosthesis parts should be visually inspected and function checked.
2. Inspect the entire prosthesis for wear during normal consultations.
3. This prosthesis and components should be checked for its functions at least once a year with regular intervals by a prosthesis specialist. There is no risk if suggestions are followed by properly.

8. Warranty

IB-ER company provides the warranty for the products in case of material and production flaws. Warranty duration for the above-mentioned products are individually mentioned at below.

Product	Duration After The IB-ER Invoice Date
VAC-300	6 Months
EPS-VALVE	

This warranty covers on only replacement and repair of failed products after assemblies performed by qualified individuals and competent institutions. This warranty is not applicable in case of following points:

- Improper use of the product, using with unsuitable conditions and fault assembly.
- Issues arising from replacement of our products with other products.



İB-ER Makina A.Ş
Selvitepe OSB Mah. OSB 2006. Cad. No: 13/1
45400, Turgutlu - Manisa / Turkey

Phone : +90 (236) 312 32 00

Fax : +90 (236) 312 32 06

info@ib-er.com

www.ib-er.com



Ercan Gozuacik
Reinickendorfer Str 45 13347 Berlin GERMANY
(for regulatory affairs only)