



## Package Insert

Dear customer,  
Please read the package leaflet carefully,  
because it contains important information.

**MEDI PAC**<sup>®</sup> GmbH  
ISO 9001 ■ ISO 13485 ■ ISO 15378



# Vacuum bottle



<b>Product:</b>	The vacuum flask is sterilised, evacuated and tested for endotoxins according to Ph.Eur. The vacuum flask is a collection container that does not contain any anticoagulant. The vacuum flask is intended for single use. Reuse poses a potential patient risk or risk of infection to the user. Contamination of the product can lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the vacuum flask.
<b>Materials:</b>	Pharmaceutical glass, natural rubber, polypropylene, aluminium
<b>Purpose:</b>	The intended purpose is the temporary absorption of blood, which is enriched with an ozone-ozone mixture and reinfused as part of ozone-oxygen therapy.
<b>Users:</b>	The vacuum flask can be used by doctors of all specialties. It is not intended for patients to use the vacuum flask themselves at home. Disabled persons are also excluded from the intended user profile.
<b>Patient population:</b>	The vacuum flask is intended for use on adult patients up to old age, excluding children and pregnant women.
<b>Contra-indication:</b>	There are no known contraindications to the use of the vacuum flask. Healthcare professionals using the therapies must be aware of the contraindications associated with the therapy.
<b>Safety instructions:</b>	<ol style="list-style-type: none"><li>1. The vacuum flask is sealed with a natural rubber stopper – note this if you are allergic to latex.</li><li>2. Possible coagulation disorders of the patient, impaired renal function, also under dialysis or haemofiltration, must be checked and observed before use.</li><li>3. Observe the general legal regulations and instructions of the device manufacturer. The medical rules and regulations must always be observed.</li></ol>
<b>Accessories:</b>	Transfusion set; transfer filter set, bacteria filter 0.2 µ; perfusion set (butterfly); disposable syringe 50/60 ml
<b>Instructions for use:</b>	<ol style="list-style-type: none"><li>1. Before use, check the vacuum flask for intactness and possible transport damage, e.g. by visual inspection and sound.</li><li>2. Depending on the area of application, the manufacturer's instructions for use for devices and accessories must be observed.</li><li>3. As a rule, approx. 120 ml of blood is taken from the normal patient during ozone-oxygen therapy, which is then exposed to approx. 100 ml of ozone-oxygen mixture at a maximum ozone concentration of 60 µg/Nml. After this exposure, the blood and ozone-oxygen mixture are mixed by <u>gently swivelling</u> the vacuum bottle.</li><li>4. Transfusion sets with a steel tip are recommended for better puncturing of the natural rubber stopper. Close the roller clamp on the transfusion set and puncture the bottle stopper at the point marked with the large circle.</li><li>5. Puncture the transfer filter set into the cross of the bottle stopper.</li><li>6. The vacuum flasks are stored at room temperature and protected from direct sunlight.</li><li>7. The usual local regulations must be observed when disposing of the vacuum flasks.</li></ol>
<b>Packaging sizes:</b>	Packs of 10 vacuum flasks 250 ml each Packs of 10 vacuum flasks 500 ml each
<b>Level of Information:</b>	March 2024

