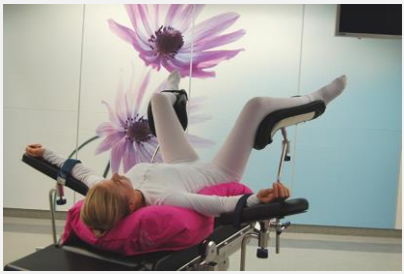
EN

THE SURGICAL BEDDING CONCEPT – A NEW GENERATION

Made of a refined and improved polyurethane foil · new color



Please read the instruction of use completely before use the Vacuform 2.0. Always store the instruction of use near the using area.

This manual will acquaint you step-by-step with the handling of the vacuum mattress for surgical purposes. The presented illustrations are deliberately limited to currently common practice techniques and do not claim to be exhaustive with regards to other doctrines or medical points of view.

Application

The **Vacuform 2.0** is a patient-vacuum-bedding-system in the OP-, X-ray-, CT- and MRI-area for the short time bedding (24 hours, definition DIN EN ISO 10993-1). The wide product line with a lot of different sizes and forms covers nearly the whole spectrum of the patient bedding in the internal clinical area.

When used in magnetic resonance imaging (MRI) the use of the 2-part CPC valve "coupling / plug" is recommend. Please contact us for further information.

Description

Vacuform 2.0 is made of an improved polyurethane foil. The new foil is non-conductive as well as biocompatible and free of phthalates (plasticizer), latex and PVC. The innovative MicroSpace filling ensures a perfect pressure release that optimized the essential microcirculation of the blood. By molding to the patient's body the contact, pressure is spread optimally and reduces the pressure per square centimeter. This is especially important in time-consuming operations, or for the elderly and cachectic (emaciated) patients. The risk of pressure ulcers is significantly reduce.

Vacuform 2.0 QuickForm is a 6-chamber system. The filling is distribute optimally and **QuickForm** is immediately ready for use with full all advantages. **QuickForm** is ideal for short-term operations and simple beddings.

Vacuform 2.0 enables secure and fixed positioning in any position. Also a positioning at extremely tilted operating table is possible (Ex. Sigma Lap). Additional **Vacuform 2.0** can use for internal clinical transports in defined position or as a plaster bed.

Kunststofferzeugnisse für das Kranken- und Rettungswesen

B.u.W. Schmidt GmbH · Porschestraße 29 · D-30827 Garbsen · Tel. +49 (0) 5131 / 6008
Fax +49 (0) 5131 / 9 63 93 · E-Mail: mail@buwschmidt.com · www.buwschmidt.com

EN

Exemplary indications

· Side position · Semi-lateral position · Supine position · Seated / half-seated position · Screw position · Lithotomy position · Laparoscopic positions · Internal clinical transport · Plaster bed

Technical data

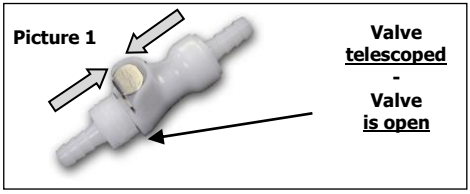
Filling: Polystyrene Micro pearls 35 g/l · Cover: Polyurethane Foil, biocompatible, magenta · Measurement and use-area of the corresponding size and form please borrow from the brochure or the price list.

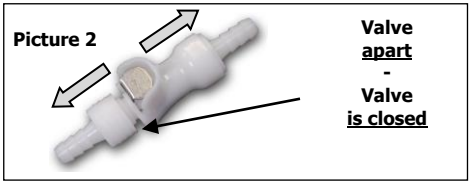
Valve function

Vacuform 2.0 is equipped with a **one-piece** valve, which can be easy handle with one hand due to its small size and it is permeable to X-rays and MRI.

In order to open the valve, it must be telescope until it snaps in audibly (**Picture 1**). It is close by pushing the silver button. The telescoped valve pops apart a bit and the airflow is shutting down (**Picture 2**).

Please inquire for the valve "coupling/plug".





Safety instructions

- **Do not use Vacuform 2.0 if there is no permanently stable vacuum.**
- **After suction, disconnect the hand pump from the valve in order to avoid tilting the valve head and damage to the valve!**
- **The hose of an existing extraction system can remain on the mattress (permanent sucking), if defects (holes) occur during the operation.**

- Avoid all contact of pointed or sharp objects with **Vacuform 2.0.**
- Before each use, check the mattress for leak tightness: Extract air and close the valve. Does the mattress lost after about 2 hours of stability, is it leaking and can no longer be used. See "Repair".
- The surfaces of both sides of **Vacuform 2.0** are different. The patient must be always lay on the upper surface. **The upper surface is sign with the vacuform label.**
- **No** cloth or similar **between operating table** and **Vacuform 2.0** mattress.
- **Always** use our non-slip products, if the operation requires a tilt of the operating table. If the VACUFORM mattress is longer than 100 cm a correspondingly large piece of Non-slip film has to be use. If non-slip mats are used, one mat per 50 cm length of the mattress have to be use.
- Use additional systems (e.g., straps) to secure the patient when needed, e.g. with strong inclination of the operating table.
- Avoid intra-operative manipulations at the patient.
- Avoid adjustments at the storage/position without renewed adaptation from **Vacuform 2.0** at the patient.


DO NOT PULL ON THE VALVE!

EN

- **Always** put a suitable cloth between patient and mattress to avoid moisture accumulation under the patient.

Please note

If **Vacuform 2.0** is use for a longer period, it is commendable to check it continuous. If the stability of the mattress should have reduced, it is necessary to suck off air afterwards.

Store the **Vacuform 2.0** in slightly exhausted state. This increases the service life considerably and the mattress can be easily carried and stow.

Preparation and patient positioning

1) Preparation of the vacuum mattress:

- Put the mattress in the right way on the table. The upper surface with the vacuform label is the patient side!
- Do not put a cloth between operation table and mattress!
- Extend the vacuum mattress so that the filling-material is equally distributed. **(Not applicable for Vacuform 2.0 QuickForm)**
- Suck the vacuum mattress a little bit, so that it is form-stable. **(Not applicable for Vacuform 2.0 QuickForm)**
- Control of the vacuum mattress on possible defects (damage of the foil / leaky valve).
- Use the VACUFORM lay-on cloth or a cloth of similar material.

2) The patients positioning:

- Put the patient on the vacuum mattress.
- Let some air into the vacuum mattress so that the patient sinks in a little bit, but the mattress is still remaining form-stable. **(Not applicable for Vacuform 2.0 QuickForm)**
- Bring the patient in the planned position.
- Adjust the vacuum mattress at the patient.
- If the patient is in the final position and the mattress is adjust, the air can be suck off from the mattress until it is solid.
- Close the valve and check the correct position of the both valve parts. (see valve function)
- Sleek-traction of the cloth under the patient.

3) Unloading of the patient:

- Let just as much air into the vacuum mattress that it is malleable but still retains its shape. Press the edge on the side of the mattress down and lighten as the use of the transfer board or similar.
- Transfer the patient into the bed or on the transportation-car.

The procedure for the handling of all sizes and shapes of Vacuform 2.0 is the same.

Cleaning / disinfection

The red dye in the blood colours intensely and penetrates deeper into the surface, the longer it stays there. Therefore, the product should be promptly clean in case of contamination before disinfection to avoid spotting as much as possible. The same procedure is also use for coloured disinfectants, e.g. Cutasept G. A material defect cannot be derive from such discoloration. Remaining discoloration will neither damage the material nor affect the performance properties of the product. Before disinfecting, always thoroughly clean the product manually. Use a mild, lukewarm soapy solution and a soft, lint-free cloth or a soft sponge. Rinse residues of the soap solution with clear water. Do not use scouring aids, e.g. a plaster sponge with a rough surface. These would irreparably damage the material and limit the function of the product.

EN

For disinfection, commercially available ready-to-use or mixable water-soluble surface disinfectants for sensitive plastic surfaces should be use in a maximum of 2% solution. In any case, observe the information given by the respective manufacturer regarding the mixing ratio, application and reaction time. Ensure complete wetting of the surface to be disinfect. If the disinfectant does not evaporate completely after the exposure time, rub dry the residual moisture with a soft, lint-free and clean cloth (eg disposable cloth).Harsh or corrosive agents (acetone, gasoline or similar) may not be used. These would also damage the film irreparably and limit the function.

ATTENTION! The product must not be disinfect mechanically or thermally (e.g. autoclave). In particular, make sure that the product will not contaminated after disinfection during transport or storage.

Repair

To ensure constant safety for patients and operators, the product must undergo regular inspections. The intervals are setting by the operator and depend on the frequency of use (specific issues).

For the repair of minor damage (pinholes, etc.) repairing kits including instructions can be obtain from us. A special briefing is not required. Repairs performed must be recheck. Further use may only allowed after passing the test. If bigger repairs are required, they may only be carry out by the manufacturer or an authorized person.

Liability for material defects

We provide free rework or free replacement for material or manufacturing defects (material defects) within 24 months from the date of delivery. Excluded from this are damage caused by mechanical (for example pointy or sharp-edged objects) or chemical (for example, sharp disinfectants) influences during use or storage, as well as normal wear and tear as they arise during use (signs of wear). This also includes any colorations that do not result in any loss of function.

We are not liable for direct or indirect damage of any kind to persons or objects resulting from improper use, disregard of the instructions for use or the inability to use due to failure to complete or not completed repairs.

Increased use and / or a frequently enhanced vacuum can reduce the volume of the filler material. Likewise, frequent disinfecting can reduce the flexibility of the film. This is normal application-related wear that is not cover by the warranty.

German Medical Device Operator Regulation (MPBetreibV)

Regarding the preparation of medical devices (cleaning / disinfection), the requirements in § 8 of the "MPBetreibV" must be observed.

According to the German "MPBetreibV", the user of a medical device must check its proper condition and flawless function before the first use or each application (see § 4, para. 6) and at regular intervals (see § 11, para. 1). The intervals are setting by the operator and depend on the frequency of use (specific issues). The test includes, if available, required accessories. If a deviation or a damage is detect, the affected parts must be promptly take out of service and replaced or repaired. If necessary, contact the manufacturer.

NOTE: At the same time, use these tests to familiarize other users with the functionality and handling of the medical devices or to refresh already existing knowledge (see § 4, paras. 2 + 3).

For disposal or recycling of the product, please contact your local disposal company. With free return to our company, the product will be environmentally friendly recycled.