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## Instructions For Use

These instructions for use apply to the medical device group

### Eckart Klobe Vacuum Bell for Non-Invasive Lifting of Funnel Chest with the basic UDI-DI ++G059EKVBDN

**To be used only on medically selected patients according to medical instructions**

#### Scope:

These instructions for use cover the following Vacuum Bell versions:

<u>Vacuum Bell version</u>	<u>Reference number</u> <b>REF</b>
Large Vacuum Bell (26 cm)	EKVB 26 AA
Small Vacuum Bell (19 cm)	EKVB 19 AA
Small Vacuum Bell Type Bodybuilder (19 cm)	EKVB 19 BA
Small Vacuum Bell Type Women (19 cm)	EKVB 19 WA
Mini Vacuum Bell (16 cm)	EKVB 16 AA

#### Manufacturer and the address of his registered place of business:



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## 1. Information on following these instructions for use


### Legend of the icons used in labeling and instructions for use


 **Medical device marking.** Identifies the Vacuum Bell as a medical device according to the EU Medical Device Regulation

 **CE marking.** Identifies the conformity of the Vacuum Bell with the EU Medical Device Regulation


 **Reference number.** Indicates the particular version of the Vacuum Bell

 **Serial number.** Identifies the individual Vacuum Bell in question

 **Date of Manufacture.** Identifies the date of manufacture of the Vacuum Bell

 **Manufacturer.** Identifies the manufacturer of the Vacuum Bell

 **Consult patient information leaflet**

 **Consult instructions for use.** Read the instructions for use before using the Vacuum Bell and retain them for its entire service life.

 **Protect device from direct sunlight.** Protect Vacuum Bell from direct sunlight.

 **Protect device from moisture.** Protect Vacuum Bell from moisture.

### Explanation of the warnings in these instructions for use

Signal word	Designation
<b>DANGER!</b>	There is an imminently hazardous situation and serious harm or death is possible
<b>WARNING!</b>	Possible hazard resulting in serious harm or death
<b>CAUTION!</b>	Possible hazard resulting in minor or moderate harm
<b>NOTE</b>	Maloperation may result in damage to the Vacuum Bell

## **2. Intended use:**

Non-invasive lifting of the funnel chest (pectus excavatum) and its fixation in the elevated position.

### **Attributed medical benefit/effect.**

Non-invasive lifting of the funnel chest (pectus excavatum) and its fixation in the elevated position.

The Eckart Klobe Vacuum Bell elevates the chest by applying negative pressure to it. In most cases, the effect of lifting can be observed directly through the polycarbonate window. The role of the applied Vacuum Bell is then to keep the lifted funnel chest in its elevated position.

In most cases, the Vacuum Bell easily overcomes the mechanical resistance of the bones, cartilages and ligaments involved in the funnel chest. Nevertheless, the internal muscles such as the diaphragm tend to keep pulling the funnel chest back into its excavated shape. Thus, another role of the Vacuum Bell is to stretch these muscles in order to weaken their traction.

Successful correction of funnel chest requires continued use of the Vacuum Bell over a long period of time. After release of the Vacuum Bell at the end of a treatment unit, partial return of the funnel chest is to be expected at first. This partial return of the funnel chest may last for a few minutes or hours. The shape of the funnel chest after stopping treatment for a few days may be taken as an indication of the lasting success already achieved.

The Vacuum Bell can be applied for most of the day without interfering with common activities. In particular, this applies to lying down; sitting; standing; walking; going to school; office work; and light housework. This allows for long daily application periods, permitting the new shape of the chest to adapt to the biomechanical challenges of everyday life.

### **Attributed medical benefits:**

- Treatment and relief of funnel chest and *possible* related sequelae, such as social withdrawal; chronic back pain; chronic bronchitis; frequent recurrent pneumonia; chronic hiccups; chronic heartburn, etc.
- Treatment, alleviation, and compensation of disabilities such as, *if applicable*, reduced lung volume, or *possibly* impaired free heartbeat due to the space-occupying mass of the funnel chest - and, *possibly* associated with this, impaired physical performance.
- Changes in anatomy or in a *possible* physiological or pathologic process or condition, such as *possible* changes in chest wall motion dysfunction characteristic of funnel chest, and *possible* changes in psychotrauma in somatically manifest dysfunction of chest wall motion.

### **Indications for Use:**

Funnel chest (pectus excavatum) and related deformities of the bones and cartilages of the chest.

**Intended patient population:** Eligible patients between the ages of 5 and 59 years as determined by a physician.

**Intended Users:** Patients as laypersons in a home setting.

### **Contraindications:**

- **DANGER! Do not use the Vacuum Bell in skeletal disorders affecting bone stability**, such as osteogenesis imperfecta (brittle bone disease) and osteoporosis (loss of solid bone tissue).
- **DANGER! Do not use the Vacuum Bell in vascular disorders** of the central cardiovascular system such as aneurysms (pathologic dilation of arteries), for instance as part of Marfan syndrome, Ehlers-Danlos syndrome, Loeys-Dietz syndrome, etc.
- **DANGER! Do not use the Vacuum Bell in blood coagulation disorders** such as thrombopathy and hemophilia (bleeding disorder) or when taking strong anticoagulants.

### **Restrictions on intended use:**

**DANGER!** Do not use the Vacuum Bell if an implant supports/reshapes the rib cage from within or if such an implant has failed to support/reshape the rib cage from within. In these cases, there is the risk of internal bleeding in the event of pulmonary contusion, especially if the chest wall recedes back to said implant once the Vacuum Bell is removed.

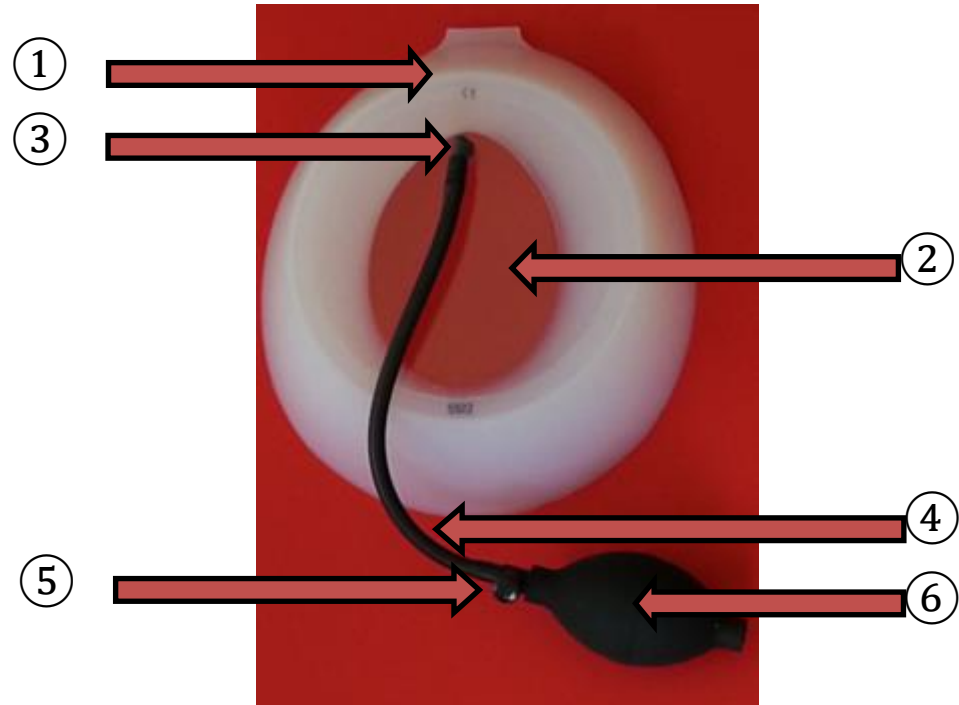
**WARNING!** Do not use the Vacuum Bell in situations where the blood may be supersaturated with dissolved gases:

- Do not use the Vacuum Bell in means of transport such as airplanes, high altitude mountain railroads, etc. which carry passengers to very high altitudes very quickly,
- Do not use the Vacuum Bell immediately after dives (wait twice the surface interval before next treatment unit).

**CAUTION!** Do not use the Vacuum Bell during thoracic surgery. The suction cup is neither sterile nor intended for sterilization.

### 3. Vacuum Bell description:

#### Components, functionalities, materials



No.	Component	Description / Functionality	Material
①	Elastic silicone body	To be placed on the chest wall	Orthopedic silicone
②	Polycarbonate Window	Permanently molded into the elastic silicone body / allows visual inspection of the treated region	Polycarbonate
③	Tubing nozzle	Screwed into the polycarbonate window / acts as air conduit	Polyamide
④	Suction tubing	Slipped over tubing nozzle / acts as air conduit	Silicone
⑤	T-valve	Plugged into the suction tubing / maintains negative pressure and allows manual repressurization.	POM, Synthetic rubber
⑥	Suction ball	Slipped over the T-valve / allows manual negative pressure generation (venting)	PVC

### **Technical notes:**

The **elastic silicone body** of the Vacuum Bell is made of orthopedic silicone. This material is comfortable and soft and very well tolerated by the skin - it has very good chemical and mechanical durability.

The **polycarbonate window** of the Vacuum Bell is made of polycarbonate and therefore susceptible to alkaline solutions; ammonia; a number of organic solutions; and steam sterilization. (The manufacturer has no information on other sterilization procedures. Therefore, no assurances can be given in this regard.)

The **tubing nozzle** is made of polyamide. The screw connection between the tubing nozzle and the polycarbonate window has limited strength. Replacements for broken or over-tightened tubing nozzles can be ordered from the manufacturer. Heat deformed threads in the polycarbonate window cannot be repaired.

The **suction tubing** is made of silicone. Even though silicone is considered gas-permeable on the molecular level, the suction tubing has very good resistance and sealing properties for the practical concerns at hand here.

The **T-valve** is made of POM and has an embedded valve insert made of synthetic rubber.

The **suction ball** is made of PVC. For safety reasons, the suction ball has limited suction power. Also for safety reasons, the Vacuum Bells may only be operated with the supplied suction balls.

The **Vacuum Bell** can be **cleaned** with a soft cloth. Moisten this cloth with

- clear water,
- soapsuds,
- ethanol (also called “ethyl alcohol” or spirit of wine)
- 1-propanol (also called propyl alcohol or propanol for short)
- 2-propanol (also called “isopropyl alcohol” or isopropanol).

Exercise caution with other disinfectants. They could cloud the polycarbonate window.

**Visually inspect** the Vacuum Bell before each use to ensure that it is properly clean and mechanically intact.

**Functional check:** Perform the following test to check for leakage:

Vent (evacuate) the Vacuum Bell on a clean, stable, smooth and airtight surface (e.g., on a table top). If the Vacuum Bell remains firmly attached there for more than one hour without additional pumping, the device can be considered airtight enough.

**Spare parts:** In the event of inadequate airtightness, the following parts, which occasionally wear out or become defective, may be ordered as replacements from the manufacturer:

- New tubing nozzle
- New suction pump (suction tubing, T-valve and suction ball already assembled)

### **Not allowed are**

- Design modifications of the Eckart Klobe Vacuum Bell not approved by the manufacturer
- Combinations of the Eckart Klobe Vacuum Bell with other devices not approved by the manufacturer.

## Available Vacuum Bell versions

The Eckart Klobe Vacuum Bell comes in five versions:

<u>Vacuum Bell version</u>	<u>Reference number</u> <span style="border: 1px solid black; padding: 2px;">REF</span>
<b>Large Vacuum Bell (26 cm)</b>	<b>EKVB 26 AA</b>
<b>Small Vacuum Bell (19 cm)</b>	<b>EKVB 19 AA</b>
<b>Small Vacuum Bell Type Bodybuilder (19 cm)</b>	<b>EKVB 19 BA</b>
<b>Small Vacuum Bell Type Women (19 cm)</b>	<b>EKVB 19 WA</b>
<b>Mini Vacuum Bell (16 cm)</b>	<b>EKVB 16 AA</b>

The **centimeters** in the designation of the Vacuum Bell version indicate its longitudinal diameter (largest diameter).

The **last two letters AA in the reference number** indicate the standard version of the Vacuum Bell with the corresponding longitudinal diameter.

### Differences in and description of the Vacuum Bell versions with 19 cm longitudinal diameter

- **Small Vacuum Bell (19 cm)**, reference number EKVB 19 AA : Standard version.
- **Small Vacuum Bell Type Bodybuilder (19 cm)**, reference number EKVB 19 BA : Has slightly thinner and softer flanks than the standard version.  
Therefore, the Small Vacuum Bell Type Bodybuilder (19 cm) will seat a little softer on large pectoral muscles and sensitive nipples. In horizontal constriction of the rib cage along the insertion of the diaphragm, it can initially elevate the rib cage along this line, thus opening an anatomically favorable path for further sculpting of the funnel chest.
- **Small Vacuum Bell Type Women (19 cm)**, reference number EKVB 19 WA : Fitted at the waist for recess and protection of the breasts. It is usually adequate for cup sizes A and B, sometimes up to C (German sizing).

#### **4. Operating mode / treatment principle**

**Physical principle (abstract/scientific):** The pressure inside the chest - largely determined by the air pressure in the lungs - pushes and bends the more or less flexible chest wall into the zone of reduced air pressure enclosed by the Vacuum Bell.

Thus, when properly selected and used, the Vacuum Bell also lifts and bends the sternum, together with the cartilaginous anterior ends of the ribs, in the middle of the anterior chest wall from their excavated posture into a more elevated position.

As a result, the Vacuum Bell also generates bending moments, the counterforces of which are applied in part by the anchoring of the ribs to the spine.

**Physical principle (practical/illustrative):** The Eckart Klobe Vacuum Bell can be used to apply negative pressure to the human chest wall.

The negative pressure in the region enclosed by the Vacuum Bell results in traction and lifting forces on the chest wall, which is more or less flexible.

To compensate for this resulting traction and lift, the inner flanks of the elastic silicone body of the Vacuum Bell rest on the chest wall, where they generate contact pressure.

Both the resulting traction and lift in the region covered by the Vacuum Bell and the contact pressure of the inner flanks of the elastic silicone body can be used therapeutically in a targeted manner by suitable selection of the Vacuum Bell.

**Using the physical principle:** If possible, the Vacuum Bell should be large enough so that the inner flanks of the Elastic Silicone Body can still brace themselves outside the funnel chest.

In addition, the Vacuum Bell should be selected and positioned such that the force it provides results in the greatest bending moments in those areas where the bones and cartilages involved should undergo the greatest local bending loads. Most often, these are the areas in the center as well as all around the edges of the funnel chest.

**Lifting of the funnel chest** may involve three types of remodeling of the bones, cartilages, and ligaments of the chest:

- a) Reversible elastic deformation - still below the trigger level for permanent physical remodeling of the chest.
- b) possible (micro-) ruptures, usually required as a trigger for permanent physical remodeling of the chest. Such (micro-) ruptures may result in a temporary loss of stability of the rib cage until they heal. Particularly at the beginning of treatment with the Vacuum Bell, a corresponding loss of stability and tenderness of the chest is to be expected.
- c) a rather gradual permanent physical remodeling of the chest. In other words, what is intended to be a permanent correction and improvement of the funnel chest.

**Partial return of the funnel chest to its excavated position** after the Vacuum Bell has been removed can be understood as a competition, not yet won, between the remaining stability of the elevated chest and the muscles pulling from within.

In many cases, the **art of the treatment** lies in lifting the funnel chest gently and with the least possible loss of stability of the chest. Even 2 or 4 weeks of treatment before the funnel chest comes close to the polycarbonate window for the first time is usually time well spent.

**In order to achieve the best possible treatment outcome**, unnecessary changes in negative pressure should be avoided - regardless of being generated deliberately under false assumptions or caused by wear-related leaks *in* the Vacuum Bell or due to leakage at the contact area between the Vacuum Bell and chest wall. (Parts with occasional wear, such as tubing nozzle, suction tubing, T-valve, and suction ball may be ordered from the manufacturer, if needed)

Lifting of the chest wall stretches the **muscles pulling from within**, such as the diaphragm and the transversus thoracis muscle. As a result, these muscles will adapt to their new position and will not pull the funnel chest inward quite as far or much once the Vacuum Bell has been removed. In some cases, this adaptation of the muscles takes the longest time in the entire treatment process.

**Concomitant physical exercises are often imperative** to straighten, stretch and tighten the upper body in support of the Vacuum Bell treatment.

The Vacuum Bell can overcome the skeletal resistance of funnel chest in most cases, but upright posture is only possible with the power of the patient's own muscles.

**The organic ramifications of funnel chest** can go far beyond the cosmetic aspect. Most striking example: Funnel chest pressing on parts of the heart can reduce the patient's cardiac output and thus also limit the performance range available up to peak physical exercise capacity.

## **5. Vacuum Bell application**

### **Application of the Eckart Klobe Vacuum Bell requires determination by a physician**

- that the patient is medically fit for the Vacuum Bell treatment
- and that the Vacuum Bell is appropriate for the patient.

Ideally, patients undertake their first application of the Eckart Klobe Vacuum Bell under the supervision of their physician.

**Selection of the appropriate Vacuum Bell version is critical.** The treatment outcome that can be achieved by the patient does depend on this selection.

Selection of the appropriate Vacuum Bell version for each patient requires a certain amount of experience. It has to take into account several different criteria such as gender; age; body size; body weight; posture; shape and depth of the funnel chest; and potential sensitivity of the nipples. In women, the size and shape of the breasts are also important, as well as whether there is enough space between the breasts to apply a Vacuum Bell.

On the one hand, the Vacuum Bell should be large enough to still brace itself outside the funnel chest. But on the other hand, it should not be so large that it pushes down painfully on the neck and abdomen, or draws air from the sides. And in women it should not bear painful pressure on the breasts.

Due to its impact on possible treatment outcome, only trained healthcare professionals should select, with due care, the Vacuum Bell appropriate for each patient.

Ideally, selection of the Vacuum Bell appropriate for the patient is carried out by a fitting in a center of excellence with proper equipment.

For patients determined suitable by a physician, the manufacturer Eckart Klobe also offers the selection of an appropriate Vacuum Bell on request. To this end, the manufacturer requires the following patient details:

- year of birth
- body height
- body weight
- approximate depth of funnel chest
- the distance from the center (tip) of the left nipple to the center (tip) of the right nipple

and one photo each (at least neck to waistline):

- centered from front (frontal)
- right semi profile (at 45° angle from right front)
- left semi profile (at 45° angle from left front)

The **Vacuum Bell is usually best placed** over the center of the funnel chest or the funnel chest-like excavation of the rib cage. This is especially true for asymmetric excavations of the rib cage.

The **orientation (direction of rotation) of the Vacuum Bell** is usually such that the tubing nozzle sits above the upper part of the sternum.

The **Vacuum Bell is applied** by spreading the flanks of its elastic silicone body and pushing them lightly against the patient body. The inner flanks of the elastic silicone body of the Vacuum

Bell should seal it against the skin. Once the negative pressure has been established, the Vacuum Bell will adhere to the body by itself.

In some cases, it may be necessary for the patients to first lie on their backs and press down the elastic silicone body of the Vacuum Bell with one finger each at those places where air can initially still creep in. Once the negative pressure has been established, the Vacuum Bell will adhere to the body under its own power in these cases as well.

To avoid falling in the event of any dizziness that may occur **while the negative pressure is being generated in the Vacuum Bell**, the patient should adopt a sitting or supine position for this.

The **suction effect** is created once the compressed suction ball is released. It is usually enough to compress the suction ball again only after it has regained its round shape.

**Patients should moderate the amount of negative pressure they apply.** They may feel the traction of the Vacuum Bell, but usually should not have to experience severe pain. Specifically: Once it starts to hurt, the patients generally do not have to continue pumping.

**Once the negative pressure has been created in the Vacuum Bell**, the patient can stand up carefully and then walk around.

The **typical length of daily application** of the Eckart Klobe Vacuum Bell is 1 to 3 hours (daily), for example, while watching TV or doing the usual household chores. If tolerated, preferably longer.

**During the first weeks of treatment** with the Eckart Klobe Vacuum Bell, the manufacturer recommends that the following upper limits be observed for the length of application:

- during the 1st week of treatment, *no more than* 1 hour a day
- during the 2nd week of treatment, *no more than* 2 hours a day
- etc.

**Repressurization** of the Vacuum Bell, e.g., at the end of a treatment unit, should be performed by turning the rotary knob on the T-valve (directly next to the suction ball) to avoid abrupt repressurization.

**Favorable periods of application for the Vacuum Bell** are those without ensuing work of the muscles. Preferably before sleep, or if tolerated, also during sleep. Better after sports than before.

**Hair on the chest** may interfere with the tight fit of the Vacuum Bell. This may require occasional trimming.

**A full or semi-full stomach** can help seal the Vacuum Bell around the upper abdomen - especially in very slim patients.

**NOTE** The Vacuum Bell should always be kept as dry as possible. Do not expose the Vacuum Bell to running water and running perspiration, and also do not clean it with running water as this may cause the valves to leak. (Replacements for leaking valves can be ordered from the manufacturer.)

## **6. Medical warnings, precautions, notes, legal information**

**DANGER!** Do not use the Vacuum Bell if an implant supports/reshapes the rib cage from within or if such an implant has failed to support/reshape the rib cage from within. In these cases, there is a risk of internal bleeding in the event of pulmonary contusion, especially if the chest wall recedes back to said implant once the Vacuum Bell is removed.

**WARNING! Do not use the Vacuum Bell** in situations where the blood may be supersaturated with dissolved gases:

- Do not use the Vacuum Bell in means of transport such as airplanes, high altitude mountain railroads, etc. carrying passengers to very high altitudes very quickly,
- Do not use the Vacuum Bell immediately after dives (wait twice the surface interval before next treatment unit).

**CAUTION! Do not use the Vacuum Bell** during thoracic surgery. The suction cup is neither sterile nor intended for sterilization.

**CAUTION! The Vacuum Bell should not be used** with subcutaneous silicone or autologous fat implants in breast or funnel chest augmentation.

**CAUTION! In Poland syndrome**, treatment with the Eckart Klobe Vacuum Bell is only recommended if it has been medically verified that the skeletal thorax is complete – i.e., if all ribs are present and in place.

**CAUTION!** Treatment with the Vacuum Bell for funnel chest may **temporarily reduce the stability of the chest**. Activities and sports that place particular strain on the thorax, e.g., boxing and wrestling, should therefore be avoided for the entire course of treatment.

**CAUTION!** Vacuum Bell treatment may result in **dizziness**. At the beginning and end of a treatment session, the patient should assume a sitting or supine position. Slow evacuation and slow repressurization of the Vacuum Bell may reduce the risk of dizziness. Once the Vacuum Bell is under full negative pressure, the patient may stand up carefully and move around the room.

**CAUTION! Bone fractures:** If the patient is at increased risk of bone fractures, appropriate studies and preventive measures are mandatory.

**CAUTION! Hematomas (bruises):** These could indicate (micro-) ruptures of bones, cartilages and ligaments. However, they can also arise from the suction effect alone without ruptures. In case of dark (black) hematomas, seek medical help.

There may be **darkening of the skin**, e.g., shades of brown. Possible cause: Metabolic by-products of hematomas. They usually resolve within a few days after resolution of the hematoma or after termination of the Vacuum Bell treatment.

**CAUTION! Gynecomastia (enlarged nipples, enlarged breasts):** In some adolescents and young men using the Vacuum Bell, enlargement of the nipples has been observed, as if female breasts were starting to develop.

Suspected cause: Breast growth induced by the repeated touch stimulus of the Vacuum Bell. Treatment: Consult the treating physician. Depending on the situation, the physician can decide whether a break of several weeks is all that is needed or if drug therapy is required.

**Irritated nipples:** May arise due to contact with the Vacuum Bell. This is especially the case if the edge of the Vacuum Bell crosses the nipples.

Prevention: Within limits, an attempt can be made to offset the Vacuum Bell slightly to one side, so that, for example, one nipple is fully covered and the other remains completely bare.

**Tenderness of the chest as in sore muscles:** May result from stretching of the muscles between the ribs when the latter change position. May require a few days off treatment.

Prevention: Shorter lengths of treatment and weaker negative pressure.

**Intermittent back pain:** May arise from bending moments, the counter forces of which are partly provided by the attachment of the ribs to the spine.

Prevention: Shorter lengths of treatment and weaker negative pressure.

**Chafed skin:** May arise from the skin chafing on the polycarbonate window, especially when the Vacuum Bell is worn during vigorous physical activity. Requires a break of several days until the chafed skin has healed, otherwise it tends to bleed under negative pressure.

Prevention: Shorter lengths of treatment, weaker negative pressure and less movement when wearing the Vacuum Bell.

**Watery skin vesicles.** May appear. Mostly clear to light yellow, less commonly slightly reddish in color. Requires a break of several days until the vesicles have resolved, otherwise they tend to bleed under negative pressure.

Prevention: Shorter lengths of treatment, weaker negative pressure and possibly less movement when wearing the Vacuum Bell.

**Flabby skin:** May arise from fluid accumulating in the tissues.

Prevention: Shorter lengths of treatment and weaker negative pressure.

**Red coloration of the skin** under the Vacuum Bell (dark red to purple): May appear.

Suspected cause: Blood temporarily pooling under the Vacuum Bell.

Treatment: Remove the Vacuum Bell after about 20 minutes, wait a few minutes and reapply the Vacuum Bell, if needed. Decrease the negative pressure.

**Blood droplets on the skin:** May appear due to the negative pressure.

Prevention: Shorter lengths of treatment and weaker negative pressure.

**Petechiae (pinpoint bleeding in the skin)** may result from the negative pressure. Typically 2 to 4 millimeters in diameter. In many cases unavoidable. Usually takes a few weeks to disappear after termination of treatment.

**Acne (clogged sebaceous glands):** May develop in the suction zone of the Vacuum Bell.

**Tingling arms:** Resembles precursor to numbness. More common in the extensor muscles of the upper arms, less common in the forearms.

Prevention: Shorter lengths of treatment and weaker negative pressure.

**Febrile bronchitis:** Observed in a single case after the very first treatment. It is unclear whether this was causally related or just a common winter cold while moving with naked upper body.

Prevention: Avoid chilling, shorter lengths of treatment and weaker negative pressure, especially at the beginning of treatment.

## **Legal information:**

***Disposal of Eckart Klobe Vacuum Bells:*** No specific requirements.

Disposal can be carried out safely in accordance with the applicable local disposal regulations.

***Suspected serious incident suspected with use of an Eckart Klobe Vacuum Bell must be reported to the following authorities:***

- Manufacturer
- Treating physician
- Regional competent authority

Definition of “**serious incident**”:

‘serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person,
- b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- c. a serious public health threat;