

1. General Information

In order to use the Roll-On Cuffs safely, the user must be familiar with these instructions for use.

The following points must be pointed out as they may cause irreversible damages to the Cuffs.

- The maximum circumference of the extremity must not be exceeded
- Inflate the cuff to 130mmHg before use. Never use a higher pressure
- Never change the pressure during use
- Immediately prior to autoclaving the air in the cuff must be pressed out completely via the valve on the manometer
- Perpendicular insertion of the needle

Roll-On Cuffs are warranted against material or manufacturing defects for 50 uses or a period of one year from the date of invoice, whichever comes first, provided that it has been used according to the Instructions for Use. Any return must include the Roll-On Cuff and the completed Record Card for evaluation of a defect.

The Roll-On Cuffs fulfill the essential requirements of MDD 93/42/EEC for medical devices and carry the CE mark with the identification number 0123.

2. Safety check

Prior to each use the cuff needs to be checked for damage.

Check whether the cuff is airtight by inflating it to a pressure of 130 mmHg to stretch the material. Afterwards release the pressure to 80 mmHg and disconnect the connecting tubing. After 10 minutes connect the cuff again to the manometer. The pressure drop must not be higher than 4 mmHg.

3. Function and use

Blood exsanguination as alternative to the Esmarch Bandage

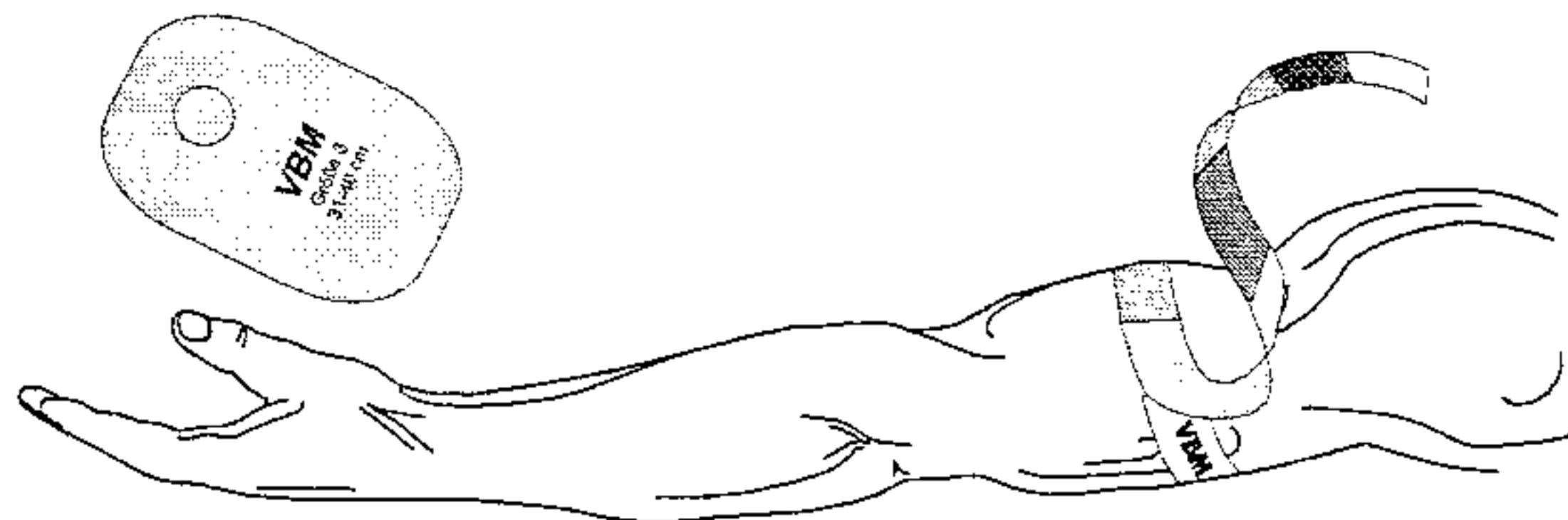
For a fast and comfortable alternative to the Esmarch Bandage use the Roll-On Cuff as described above. The Roll-On Cuff is rolled up to the Tourniquet cuff which will then be inflated. Afterwards remove the Roll-On Cuff again.

4. Roll-On Cuff sizes

Size	Color Code	Extremity Circumference [cm]	Extremity Circumference [inch]	REF
0	grey	16 - 21	6 - 8,5	21-95-710
1	white	20 - 28	8 - 11	21-95-711
2	light blue	26 - 33	10 - 13	21-95-712
3	yellow	31 - 40	12 - 15,5	21-95-719
4	red	38 - 49	15 - 19	21-95-722
5	green	47 - 60	18,5 - 23,5	21-95-727
6	dark blue	58 - 70	22,5 - 27,5	21-95-729

5. Use on the arm and leg

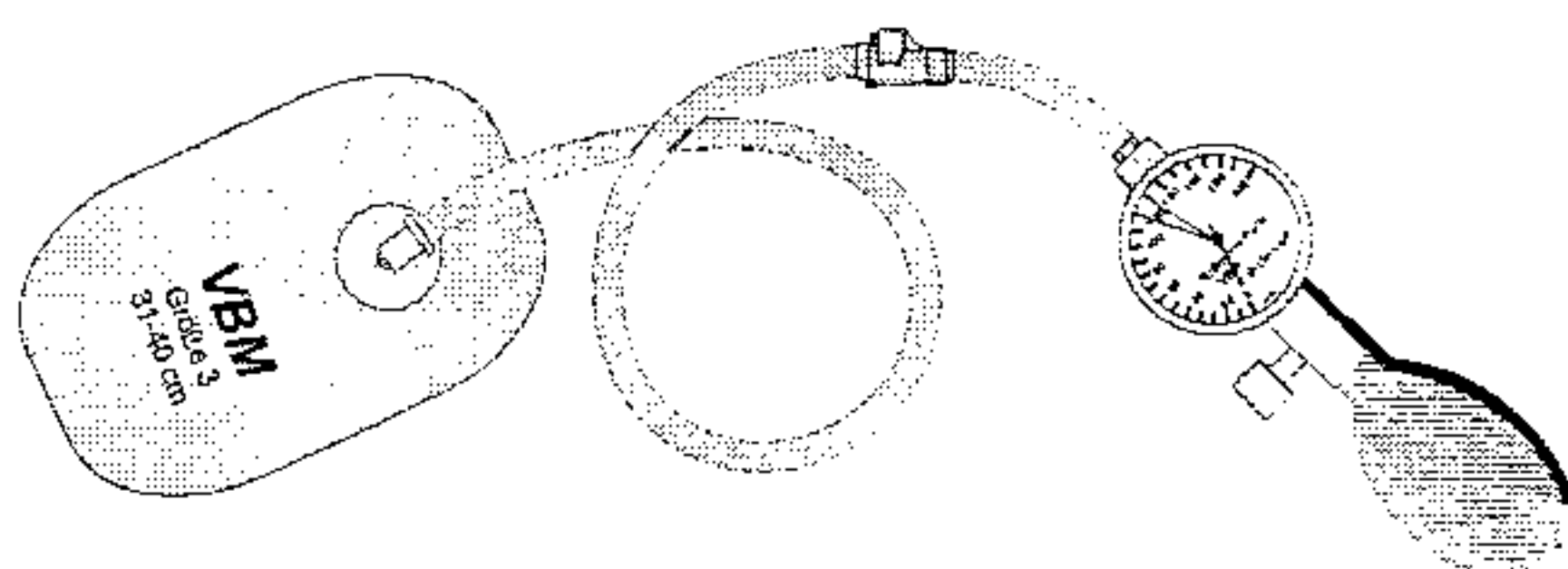
- a) Choose the suitable cuff size by measuring the circumference of the extremity with the colour-coded tape-measure. In case that a complete bloodless field is desired and if sizes overlap, always choose the smaller size.



Attention:

The maximum circumference of the cuff must not be exceeded

- b) Insert the connection tubing perpendicular with the needle into the valve (black point). Before insertion apply some water or silicone grease on the needle so that it glides more easily. Inflate the cuff to 130 mmHg (blue mark on the scale). Remove the connection tubing from the cuff.



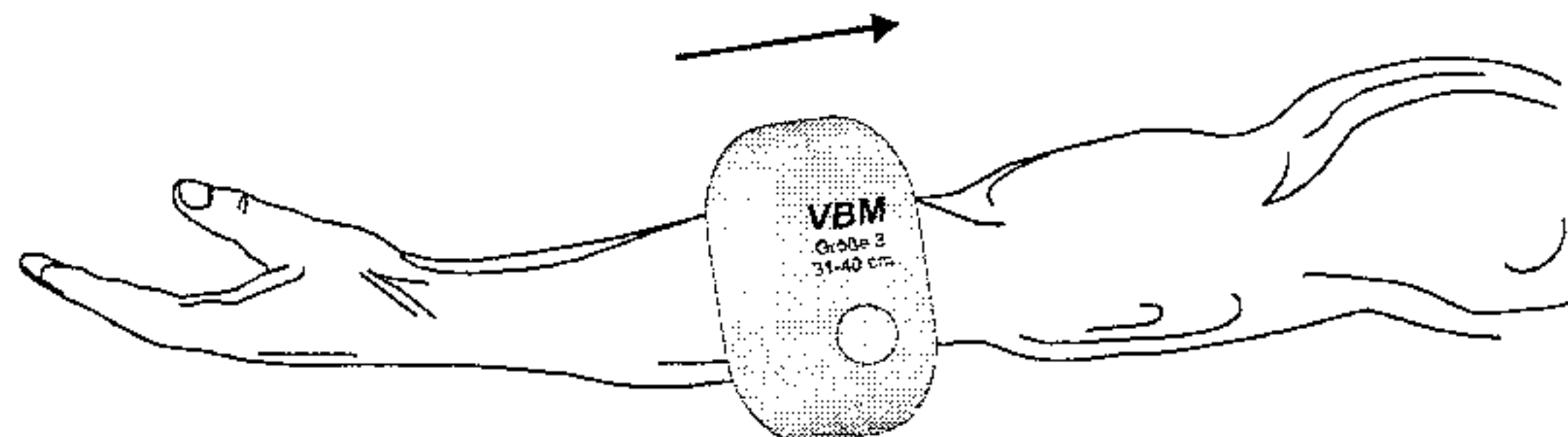
Important:

Ensure a perpendicular insertion of the needle into the valve. An insertion from the side might damage the valve with the risk of leakage.

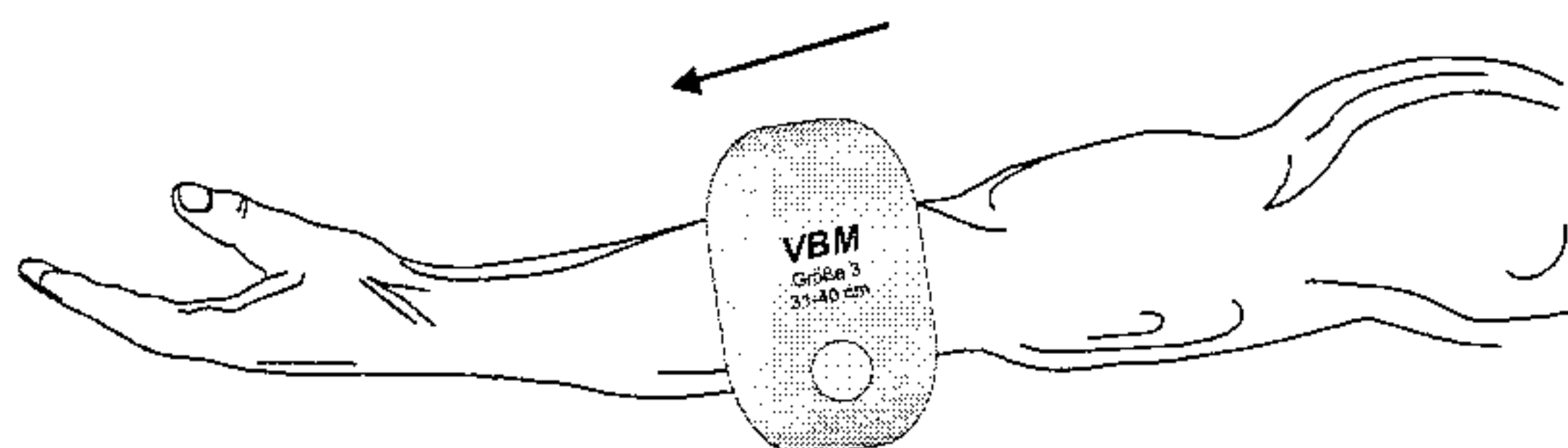
Attention: - Never change the pressure during use.

- Make sure that the cuff is never inflated to more than 130 mmHg else it will be overstretched. This might cause irreversible material damage.

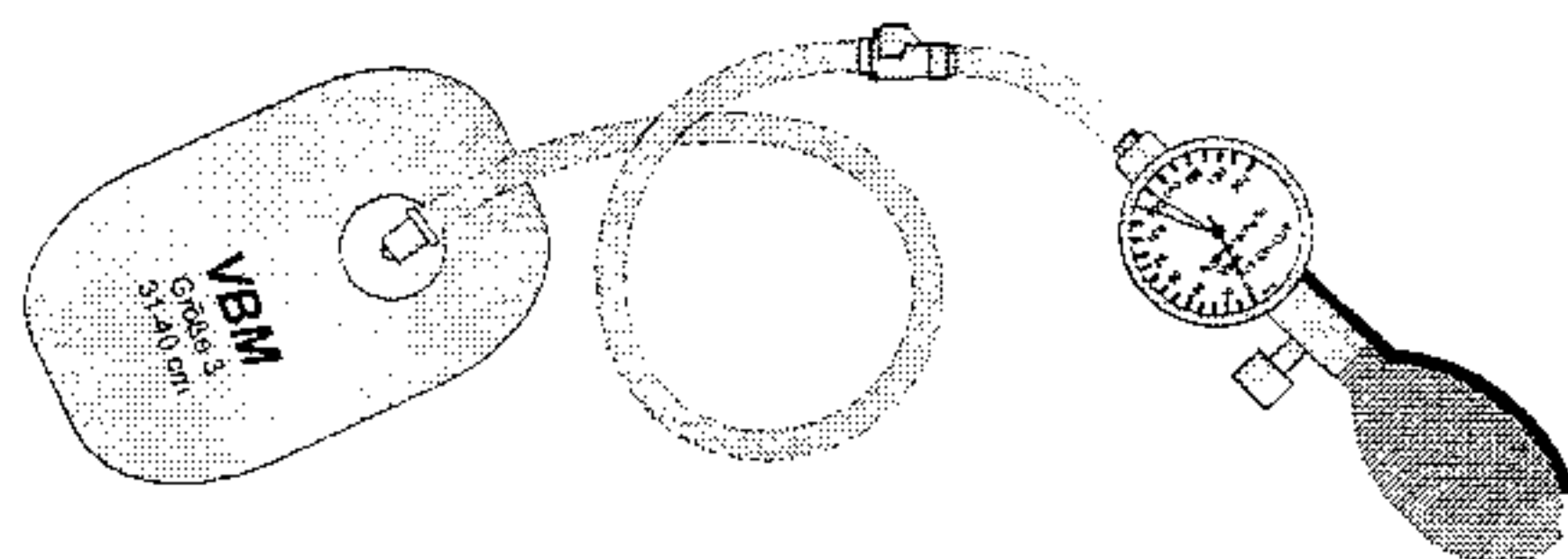
- c) Roll the cuff over the extremity to achieve a bloodless field.



- d) After the Tourniquet cuff has been inflated, roll down the Roll-On Cuff over the extremity. Never deflate the cuff before rolling it down as this makes it impossible to roll it down.



- e) After use release the pressure in the cuff with the release valve of the manometer.



6. Cleaning, disinfection and sterilization

Roll-On Cuffs, connection tubing, tape-measure and brake-block

Prior to first use as well as after each use clean or disinfect (sterilize) the products. The cuff must be completely evacuated. Therefore connect the cuff to the manometer and open the release valve. Release all air by squeezing the cuff with both hands.

Warning

After each reprocessing or before each use the products need to be checked carefully for damages (cracks, tears, etc). Damaged products must not be reused! Please note that the products must not be in contact with hard or sharp-edged objects.

Cleaning

For mechanical cleaning VBM recommends pH-neutral agents. Soap-suds or alkaline agents can also be used if a citric acid-based neutralisation agent is used afterwards. Abrasives, hard brushes or other materials which might damage the surface must not be used. Eliminate all residues of the cleaning agents by thoroughly rinsing with deionised water.

Disinfection

For disinfection use commercially available disinfectants for instruments which have been tested and approved for silicone materials. Disinfectants containing compounds similar to phenol or alkylamines (such as Glucoprotamin) are not suitable and may result in hardening of the material. Strictly adhere to the immersion time and application concentration recommended by the manufacturer. Eliminate all residues of the cleaning agents by thoroughly rinsing with deionised water. For disinfection VBM recommend thermal disinfection (93°C/10min). To prevent material-dependent ageing temperature for drying should not exceed 95°C.

For treatment of our reusable products from silicone and polysulfone, we recommend the following agents of the company ECOLAB:

1. For manual treatment:

- Sekusept® powder classic 2% concentration
- Sekusept® active 2% concentration

2. For mechanical treatment:

- Sekumatic® FR 0.5% measured out by machine (Miele Vario programme)
- Sekumatic® FRE 0.5% measured out by machine (Miele Vario programme)
- Sekumatic® FNZ 0.3% neutralisation (Miele Vario programme)

The agents mentioned above have to be used following the instructions for use of ECOLAB (ECOLAB Germany - Anwendungstechnik - Phone: +49 (211) 98 93-0 - www.ecolab.com).

Sterilisation

For sterilisation VBM recommend a validated steam sterilisation process according to DIN EN ISO 17665-1 at 132/134°C / 270/273°F (5-18min). Prior to each sterilisation process the devices must be cleaned, rinsed with water and dried. Residues of the cleaning agents and disinfectants could cause damage of the material.

Attention: The cuff needs to be completely evacuated to prevent irreversible damage of the material during autoclaving.

Manometer, handpump and tape-measure

Wipe manometer, handpump and tape-measure with a damp cloth and mild cleaning agents. They must not be autoclaved.

7. Storage

Recommendations for storage are available at www.vbm-medical.de in the download section.