

Instructions for the use of the medical product ultrasound gel.

Non-sterile ultrasound gel is, according to Regulation (EU) 2017/745, annex VII, chapter II, section 4f, rule 1, a non-invasive medical product and belongs to class I.

This is a contact gel for external use for the transmission of ultrasound waves in conjunction with ultrasound devices and is for use in therapeutic and diagnostic medicine. It can be used wherever a viscous, non-greasy, water-based, non-sterile contact gel is needed.

The ultrasound gel is applied directly to uninjured areas of skin. The quantity needed depends on the skin area. Even small amounts are sufficient to achieve the continuous transmission of ultrasound waves.

Excessive pressure on the transducer can result in low quality output. Following use, the ultrasound gel can be wiped off using paper towels.

The ultrasound gel is kind to the skin, pH balanced, free of microbubbles and allows precise transmission. It is water-based and is free of grease and formaldehyde. Only preservatives which have been approved for cosmetic use are used during production and fragrances and colourants are not used.

The ultrasound gel has high storage stability, but should be protected from sunlight and stored in frost-free conditions.

Ultrasound gel is available in the following containers, labelled and packed:

250 ml PE plastic bottle

500 ml PE plastic bottle

1000 ml PE plastic bottle

5000 ml PE plastic container (plus dispenser)

10000 ml PE plastic container (plus dispenser)

5000 ml PE flex. plastic container (cubitainer) (with separate dispensing tap)

10000 ml PE flex. plastic container (cubitainer) (with separate dispensing tap)

The products are provided with batch numbers and expiry dates.

Due to the impossibility of re-sealing the dispensers in the case of the 5 L and 10L plastic containers (a result of their design), a product life of 6 months from the time of opening is guaranteed, or the expiry date which is printed on the product, whichever is sooner. The same applies to all other containers.

As a general rule, the containers should be carefully closed following use.

Ultrasound gel that has passed its date of expiry should not be used.¹

Ultrasound gel is a self-explanatory medical product and does not require instructions.² Ultrasound gel can only be used by persons who have the necessary training (e.g. doctors) and experience. Users are responsible for their own qualifications.³ The hygiene regulations which are directed at the user are to be followed.

The transferral of ultrasound gel from 5 L or 10 L containers into small containers of up to 1000 mL should only be carried out in accordance with the hygienic specifications provided:

Having disinfected his or her hands, and wearing single-use gloves, the operator uses the small containers provided by the manufacturer. Each small container must only be filled with contents from a single larger container, so that there is clear traceability. Once emptied, the large containers and any emptied small containers are to be disposed of.

Before use, the condition of the ultrasound gel should be checked.⁴

Ultrasound gel is not to be used if there is reason to believe, on the basis of medical science, that the safety and health of the patient, the operator or third parties may be endangered during appropriate use for the product's intended purpose.⁵

Medical products must not be used if they show defects which could endanger patients, staff or third parties.⁶

¹ §4 Para. 1 No. 2 MPG (Law on Medical Products)

² §4 Para. 3 MPBetreibV (Medical Devices Operator Ordinance)

³ §4 Para. 2 MPBetreibV (Medical Devices Operator Ordinance)

⁴ §4 Para. 6 MPBetreibV (Medical Devices Operator Ordinance)

⁵ §4 Para. 1 No. 1 MPG (Law on Medical Products)

⁶ §14 Clause 2 MPG (Law on Medical Products)