



Instruction for Use EN

Medical Birthing Pool Filter



Description

The filter of the T-safe medical product family is based on hollow fiber technology and is specifically designed to remove bacteria such as, but not limited to, *Pseudomonas aeruginosa* and *Legionella pneumophila* from tap water to prevent diseases caused by infections in hospitals and healthcare facilities.

T-safe Medical Birthing Pool Filter is a complete unit equipped with a male M24 or M28 thread. The filter is supplied with a water flow regulator, which protects the filter against sudden water pressure peaks.

T-safe Medical Birthing Pool Filter is validated for use up to 31 days from installation. The filter flow rate may reduce over time depending on water quality and rate of use. The filter should therefore be replaced at the frequency required in order to maintain satisfactory fill time.

This IFU covers the following products

Item	Code
Medical Birthing Pool Filter, M28m	02-092040
Medical Birthing Pool Filter, M24m	02-092041
Replacement filter	02-000210

Installation

Install the product directly from the packaging or use gloves and ensure that the filter does not come into contact with sources of contamination before being installed.

Note: Make sure to install the filter above water level in the birthing pool to avoid retrograde contamination.



Mount the complete unit on an outlet with a female M24 or M28 thread depending on the model. Make sure to tighten so no leaking occurs.

Installation of Replacement Filter

Install the product directly from the packaging or use gloves and ensure that the replacement filter does not come into contact with sources of contamination before being installed.



Remove the used filter from the brass part by unscrewing the complete unit and mount the new complete filter unit. Make sure to tighten so no leaking occurs.

Information

Cleaning

If professional cleaning procedures are in place, the external surfaces of the filter may be cleaned using a new disposable wipe, e.g., with 1000 ppm chlorine. Extra care should be taken to prevent contamination of any outlet of the filter. Do not disconnect the filter during cleaning.

Disposal

The filter cartridge and non-metallic parts can be disposed of with ordinary waste following applicable local regulations under the waste category number 180104 in accordance with EU Directive 75/442/EEC.

The Lead-Free brass metal parts can be cleaned, descaled, and disinfected to be reused with a replacement filter cart-ridge. When disposing of the metal parts please ensure to recycle correctly, following local guidelines.

Storage – non-commissioned filter

The product must be stored at temperatures between 5 °C and 40 °C and at a humidity of max. 60 %. Expiry date: See label on the packaging or marking on the product.

Tolerance to Surface Disinfectants

T-safe water filters are compatible with common surface disinfectants and cleaning agents. This has been validated after 276 exposures (simulating three daily exposures for 92 days) under frequent intermittent use of the following disinfectants:

- ca. 70% ethanol solution
- 1% chlorine solution
- ca. 2% chlorine dioxide solution
- ca. 7.5% hydrogen peroxide solution
- ca. 15% quaternary ammonium solution

Tolerance to Water System Disinfectants

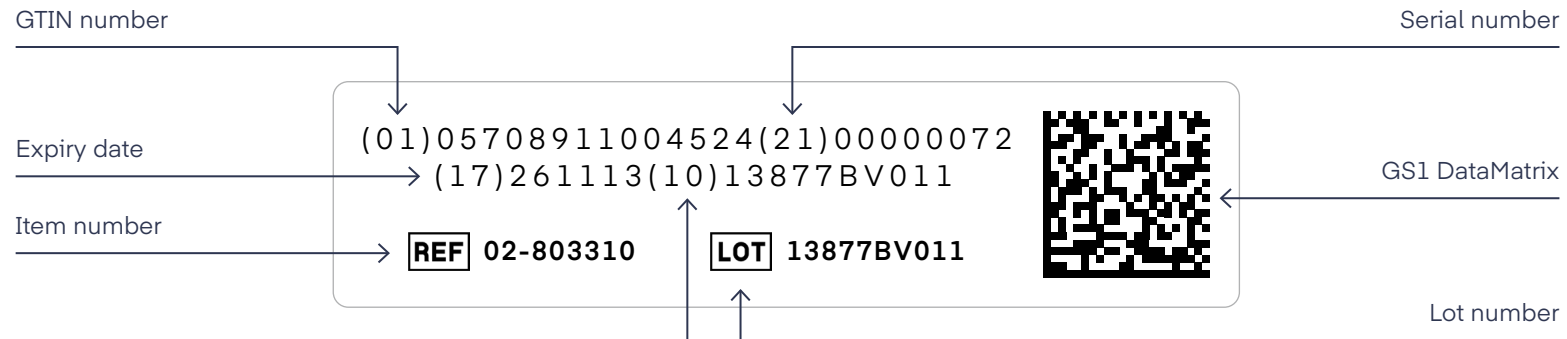
The T-safe water filters are compatible with common water system disinfectants. This has been validated by integrity testing the filters after exposure to the following disinfectants at the concentrations and contact time listed:

- 30 ppm chlorine dioxide combined with 200 mg/L suspended solids in continuous operation throughout the life cycle
- 30 ppm hydrogen peroxide in continuous operation throughout the life cycle
- 15 ppm free chlorine in continuous operation throughout the life cycle
- 10 ppm ozone in continuous operation throughout the life cycle
- 10 ppm chloramine in continuous operation throughout the life cycle
- 1000 ppm free chlorine through a 1-hour shock treatment
- 50 ppm Hypochlorous Acid (HOCL) through a 2-hour shock treatment
- 50 ppm Chlorine Dioxide through a 2-hour shock treatment
- 3500 ppm hydrogen peroxide through a 6-hour shock treatment
- 3000 ppm Silver Stabilised Hydrogen Peroxide through a 14-hour shock treatment
- An aqueous solution with pH 12 through a 1-hour shock treatment
- 1000 ppm peracetic acid at 60° C through a 2-hour shock treatment

Traceability

Each filter has a unique identification number. The filter is marked with item number, Lot number, and expiry date, both in GS1 DataMatrix and human readable text.

The filter can be marked with a permanent pen with an installation date.
The following information is laser-engraved on the filters:



Precautions

- Do not use the filter if the package is open or damaged, or filter is visually damaged
- Do not disconnect the filter during the period of use
- Avoid mechanical impact and do not strike the filter with heavy or metallic objects, as this may damage the filter
- The outlet of the filter should not come into direct contact with skin or hair
- The filter must not be used continuously with water temperatures above 60 °C. The optimal working range is 10 °C – 45 °C
- The filter cannot tolerate pressure above 5 bar
- If the filter is subjected to excessively high water pressure, this will cause the filter to collapse (sudden decrease in water flow). The filter must then be discarded
- The filter cannot be “backwashed”
- The contamination level and the amount of filter-blocking particles and substances in the water might reduce the lifetime of the filter
- The filter cannot be rinsed or cleaned in a dishwasher or autoclave
- The filter must be discarded if the expiry date has passed
- Do not modify or make changes to the filter or the adapter
- Important: The filter may not be placed in a hot water bath

Note

- Do not use the water for contact lenses
- The quality of the water is not suitable for pharmaceutical use
- The filter will neither alter the taste nor the odor nor the chemical composition in the water, and does not cause any changes in the concentration of salts, metals, lime scale, chemicals, pesticides, and dyes

No liability for misprints or typographical errors.



T-safe A/S

Gydevang 1

3450 Allerød, Denmark

+45 48 17 22 82

info@t-safe.com

t-safe.com