

Instruction for Use



Medical Birthing Pool Filter



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 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.

The filter is marked with item no., Lot no. and expiry date, both in GS1 DataMatrix and human-readable text. The filter can be marked with a permanent pen with an installation date.

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 replacement filter does not come into contact with sources of contamination before being installed.

1

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



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

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.

1

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.



Cleaning

If professional cleaning procedures are in place, the external surfaces of the filter product may be cleaned using a new disposable wipe. Extra care should be taken to not contaminate any outlet of the filter product. Do not disconnect the filter during cleaning.

Exposure to Chemical and Thermal Water Treatment

The filter can tolerate the following continuous disinfection treatments:

- 30 ppm chlorine dioxide
- 15 ppm free chlorine (hypochlorite)
- 10 ppm ozone
- 30 ppm hydrogen peroxide
- 10 ppm chloramine

Shock Treatment:

- Up to 1000 ppm free chlorine for 1 hour at room temperature
- pH 12 for 1 hour at room temperature
- 1000 ppm peracetic acid for 2 hours at 60° C

Thermal Treatment

The filter can tolerate thermal disinfection up to 6 times in the lifetime of the filter under the following conditions: 70° C for 5 minutes.

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 by EU Directive 75/442/EEC.

The Lead-Free brass metal parts can be cleaned, descaled, and disinfected to be reused with a replacement filter cartridge. 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.

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 adaptor

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 or 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.



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