



Instruction for Use EN

Medical Shower Filter

31 & 92 Day



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.

The T-safe medical product family is intended to manage the microenvironment of injured skin or mucous membrane and therefore prevention of sickness-related to bacteria.

T-safe medical products are suitable for use in wound care, burn tubs, water birth, hand washing, regular baths and bottling of drinking water.

T-safe Medical Shower Filter 31 & 92 Day are complete units equipped with a male 1/2" thread. The product is supplied with a flow regulator, which protects the filter against sudden water pressure peaks.

T-safe Medical Shower Filter 31 & 92 Day will effectively retain bacteria for a maximum period of up to 31 and 92 Days respectively, within the limitations of use as described herein.

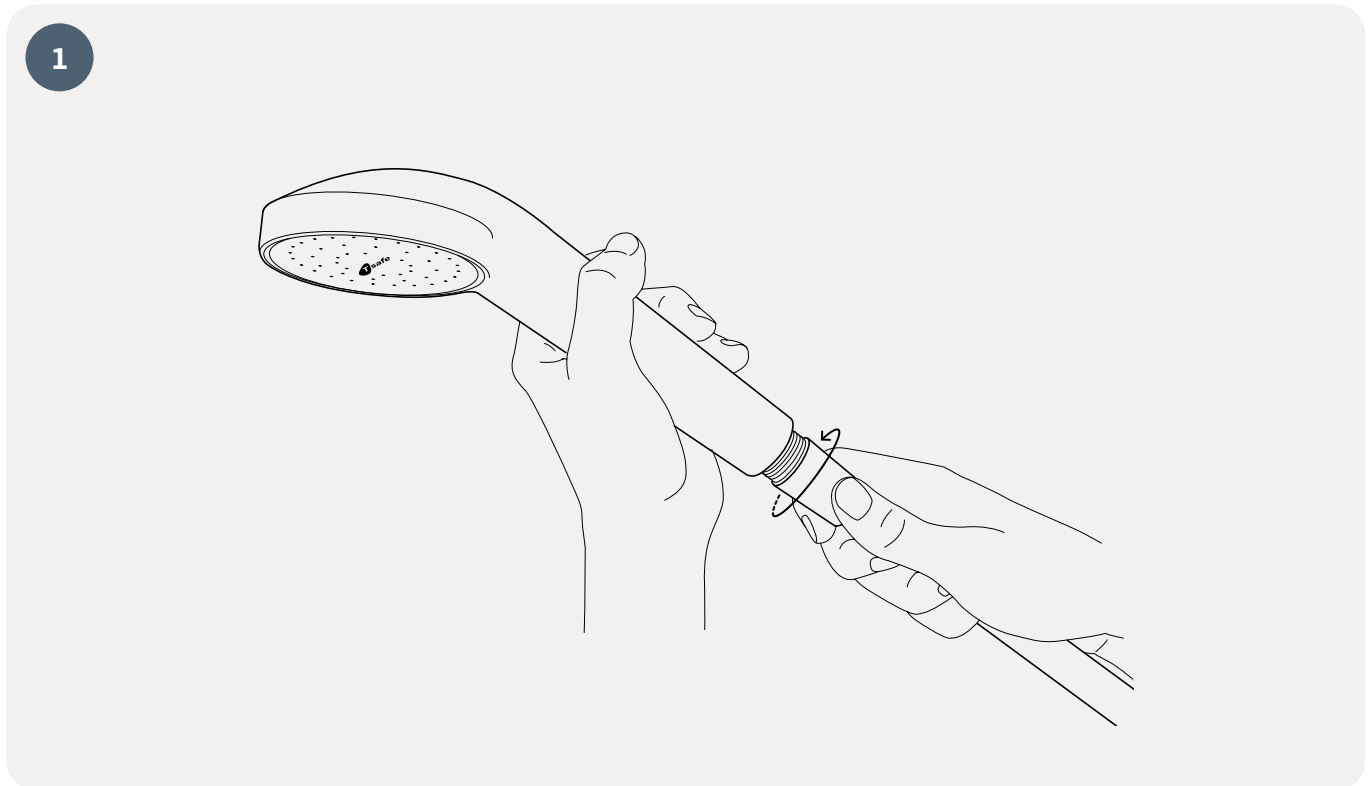
This IFU covers the following products

Item	Code
Medical Shower Filter 31 Day	02-803310
	02-803311
	02-803312
Medical Shower Filter 92 Day	02-803121
	02-803125
	02-803330
	02-803331
	02-803332
	02-803333
	02-803335

Installation

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

The gasket is integrated into the product to ensure it is replaced with each filter change so no leaking occurs.



Fasten the shower hose tightly to the shower - it is now ready for use.

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 product 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.

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

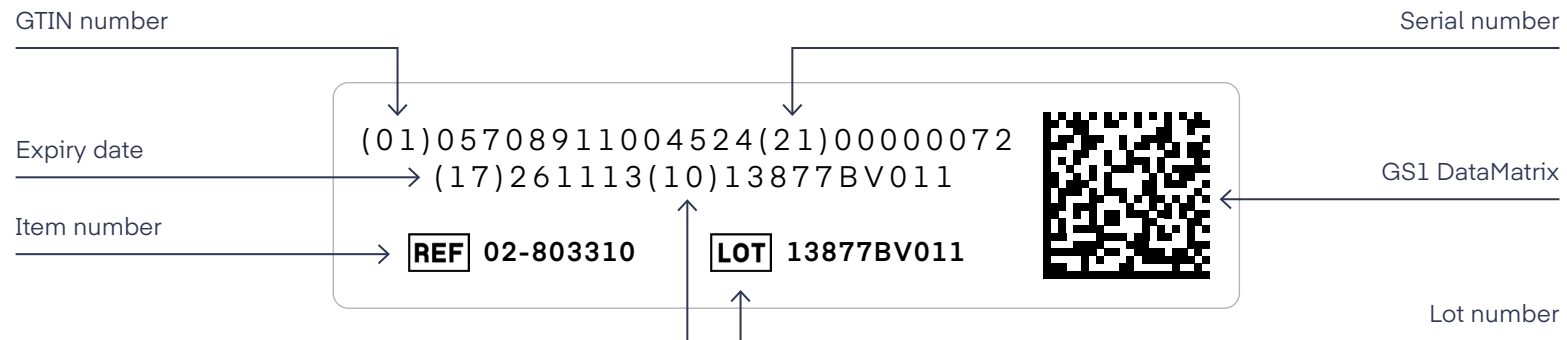
The T-safe water filters are compatible with common water system disinfectants. This has been validated by integrity testing the filters after exposure to the following disinfectants at the concentrations and contact time listed:

- 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
- 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.



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