



Instruction for Use EN

Medical Tap Filter Fixed Position

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 in order to prevent diseases caused by infections in hospitals and healthcare facilities.

The T-safe Tap Filter Fixed Position 31 and 92 Day are complete units, which connect onto a range of T-safe adapters. In order to use the tap filter a T-safe adapter must therefore be installed on the tap.

T-safe Medical Tap Filter Fixed Position 31 and 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 Tap Filter Fixed Position 31 Day	02-831401
	02-831402
	02-831411
	02-831412
Medical Tap Filter Fixed Position 92 Day	02-831405
	02-831406
	02-831415
	02-831416

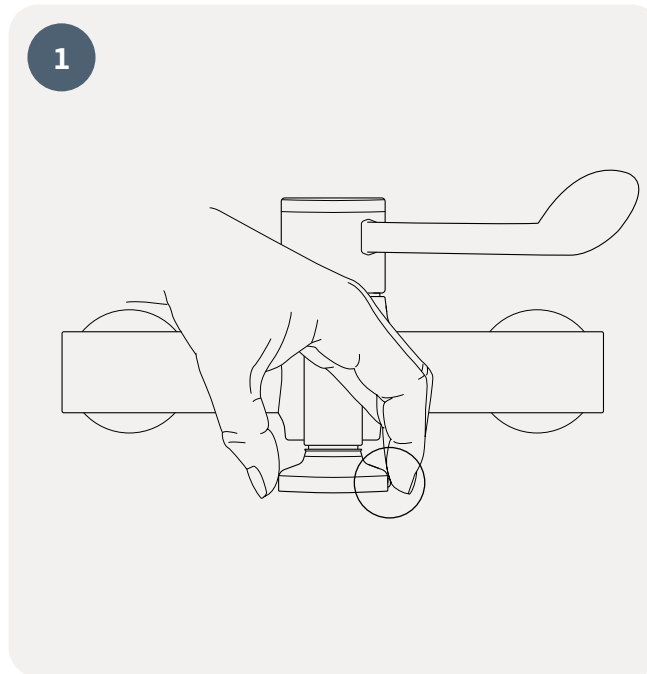
Installation

Install the product directly from the packaging and ensure that the filter does not come into contact with sources for contamination before being installed. Please note that the filter should only be used with an original T-safe Tap Adapter.

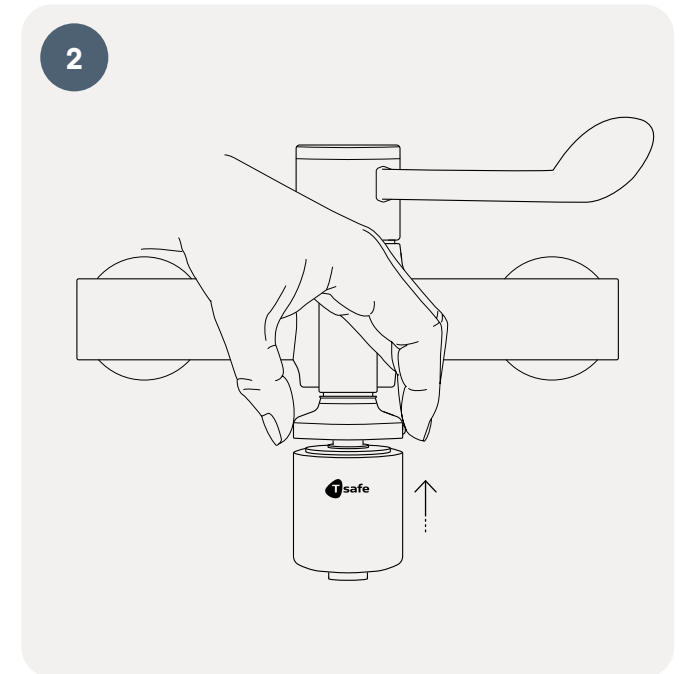
This is only applicable when exchanging the filter on an existing adapter installation:

Before installing the replacement filter, exchange the attached O-ring on the Tap Adapter, as to reduce the risk of contaminated water passing by.

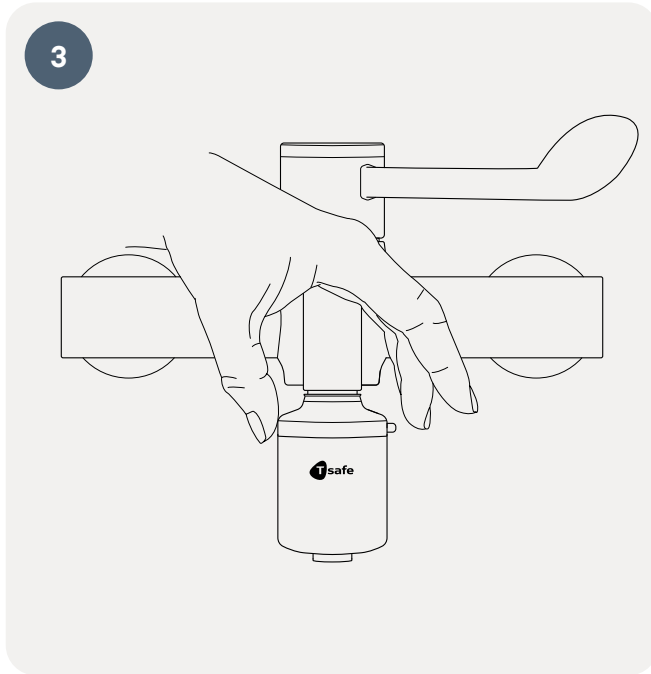
Note: Do not touch the filter outlet in order to reduce risk of retrograde contamination!



Press the grey locking pawl (located on the tap filter adapter), push fully and hold.

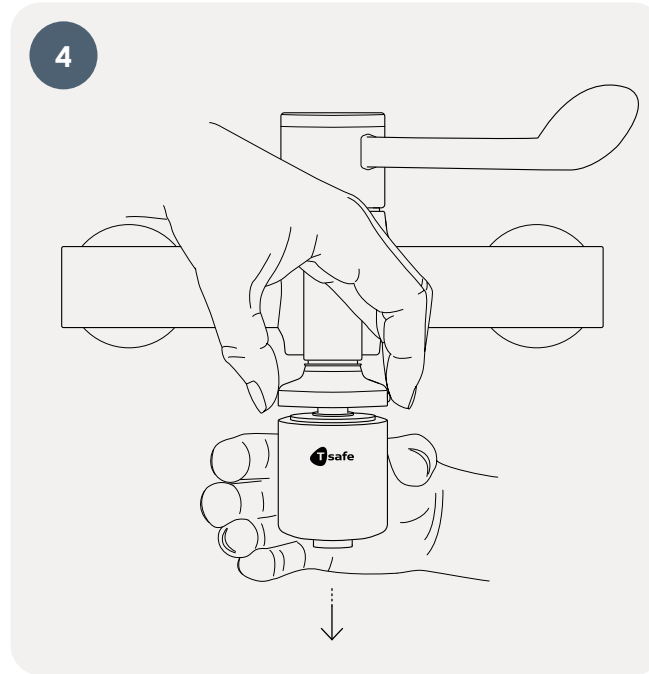


At the same time manoeuvre and push the tap filter inlet upwards fully into the adapter. Handle the filter using the packaging to avoid touching and contaminating the filter outlet.



Release the grey locking pawl to activate the locking mechanism and fix the filter in place.

The filter is installed correctly when there is no gap between the adapter and filter, and when the locking pawl has returned to its resting position.



To remove the filter during exchange, press the grey locking pawl, pushing fully to release the locking mechanism and pull the filter downwards.

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

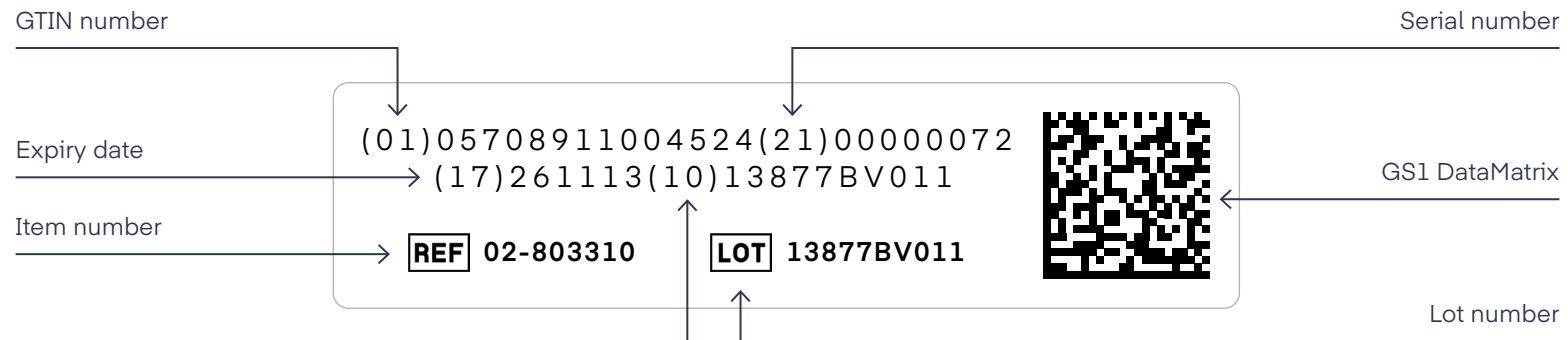
The T-safe water filters are compatible with common water system disinfectants. This has been validated by integrity testing the filters after exposure to the following disinfectants at the concentrations and contact time listed:

- 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 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.



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