



Instruction for Use EN

Medical Tap Filter Side Mount

31 & 92 Day



Description

The filter of the T-safe medical product family is based on sterilising grade membrane 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 Tap Filter Side Mount 31 & 92 Day are complete units, which connects 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 Side Mount 31 & 92 Day will effectively retain bacteria for a maximum period of up to 31 & 92 Days respectively, within the limitations of use as described herein.

This IFU covers the following products

Item	Code
Medical Tap Filter Side Mount 31 Day	02-831202
	02-831203
	02-831206
	02-831207
Medical Tap Filter Side Mount 92 Day	02-831200
	02-831201
	02-831204
	02-831205

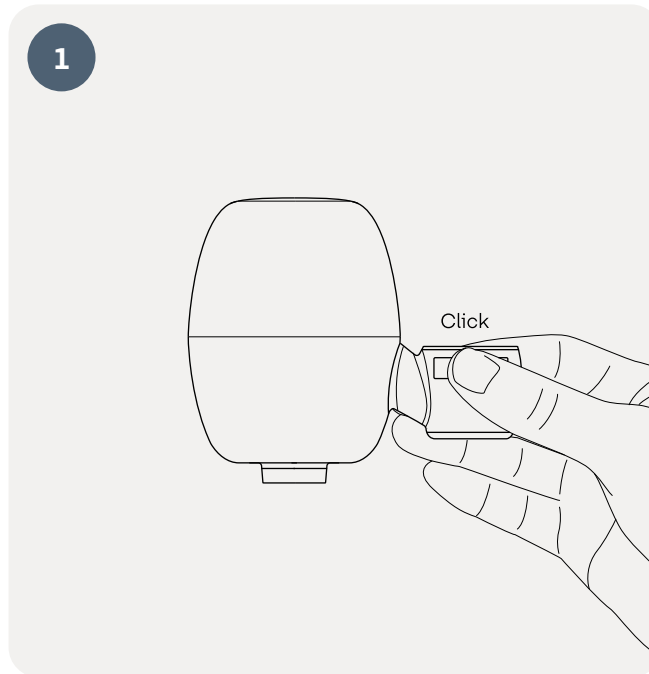
Installation

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

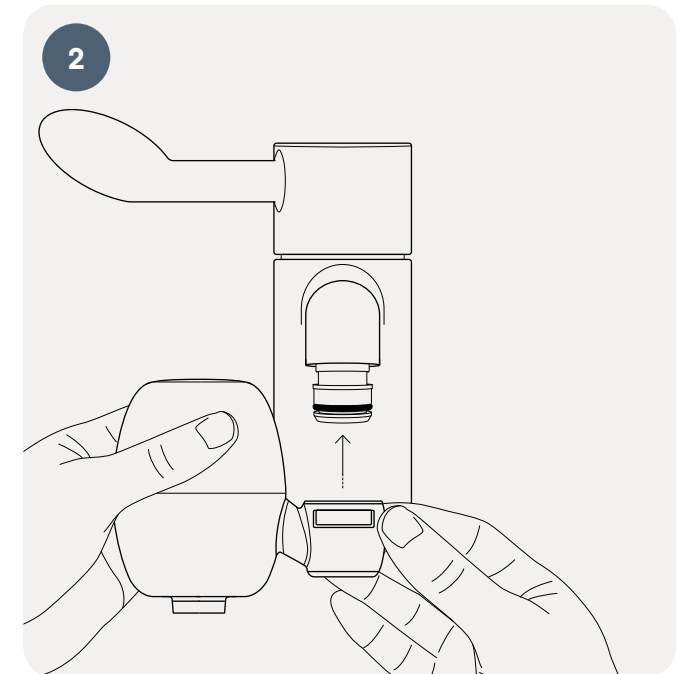
This is only applicable when exchanging the filter on an existing adapter installation:

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

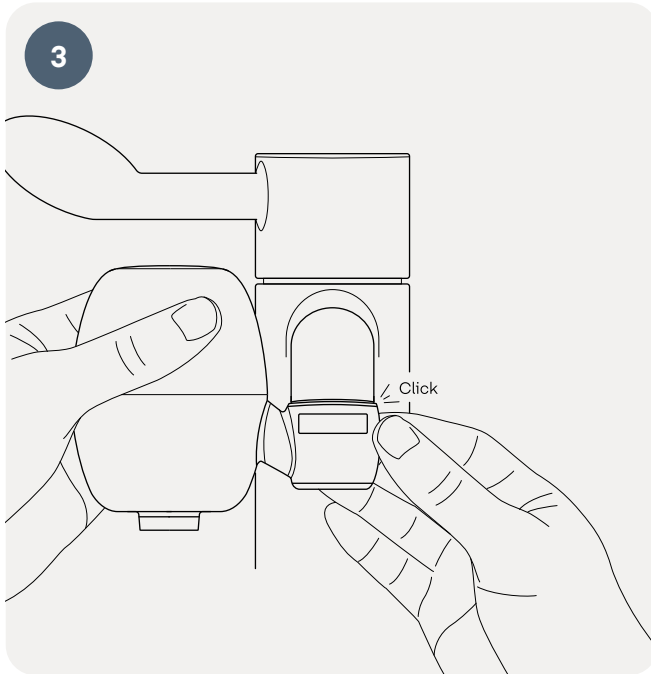
Note: Do not touch the filter outlet in order to reduce risk of retrograde contamination!



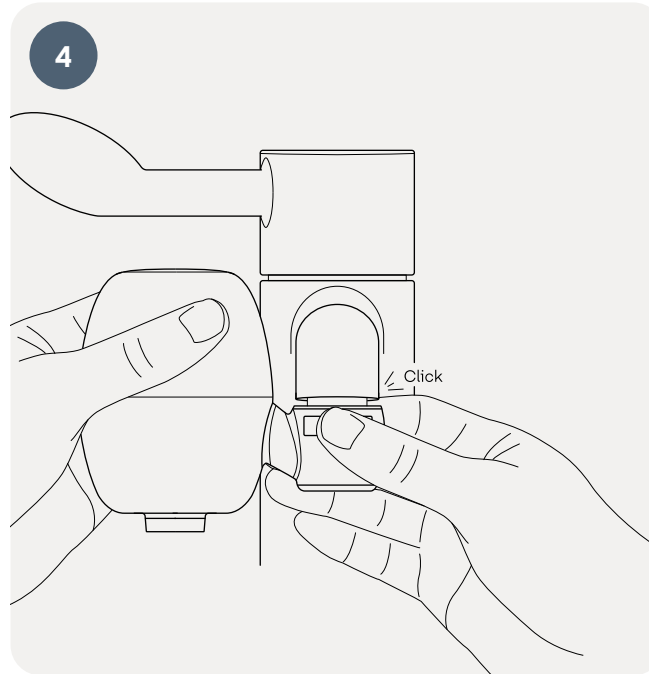
Push the locking pawl into the open position before installing the tap filter onto the already installed T-safe adapter. Make sure the grey locking pawl is in the "open" position.



Push the tap filter onto the already installed adapter. Make sure not to touch the outlet of the filter.



Lock the tap filter onto the adapter by pushing on the back of the locking pawl until the curved shape appears in the front.



When exchanging the tap filter simply push the grey locking pawl in order to release the tap filter from the adapter.

Use a disposable bag to package the filter and discard it without touching or releasing contaminated water.

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

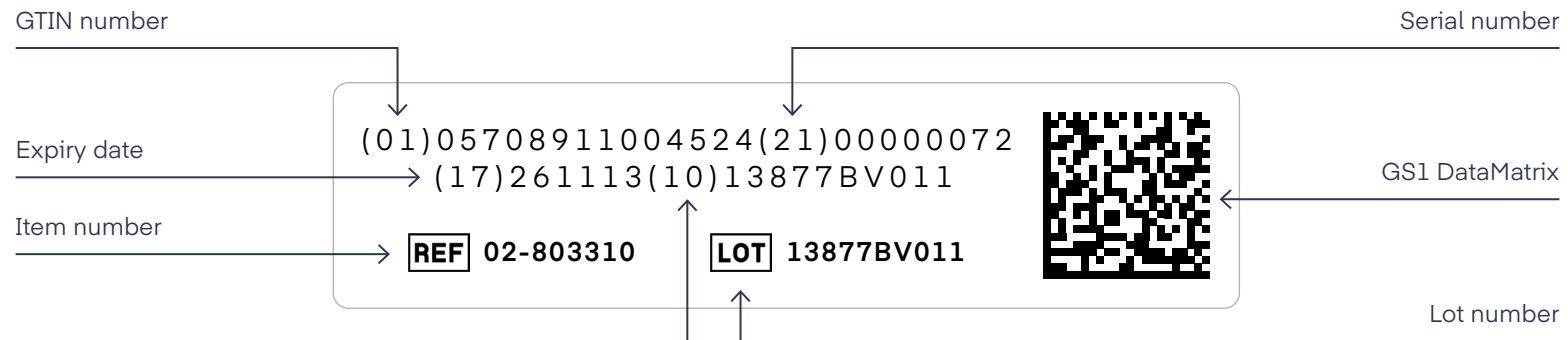
The T-safe water filters are compatible with common water system disinfectants. This has been validated by integrity testing the filters after exposure to the following disinfectants at the concentrations and contact time listed:

- 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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