

Instruction for Use



Medical Tap Filter Fixed Position 31 and 92 Day

Tsafe

Medical Tap Filter Fixed Position 31 and 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 adaptors. In order to use the tap filter a T-safe adaptor 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.

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 Tap Filter Fixed Position 31 Day	02-831401
	02-831402
Medical Tap Filter Fixed Position 92 Day	02-831405
	02-831406

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 a original T-safe Tap Adapter

This is only applicable when exchanging the filter on an existing adaptor installation: Before installing the replacement filter, exchange the attached O-ring on the Tap Adaptor, 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!

1

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



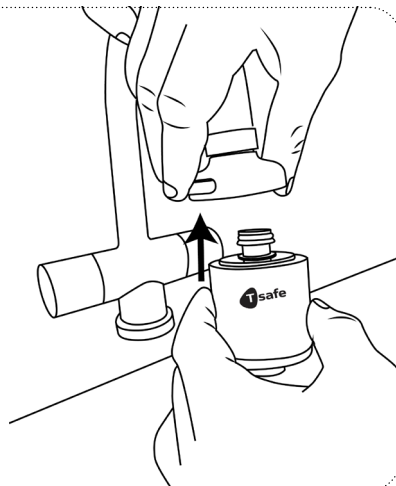
3

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.



2

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.



4

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



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 not contaminate any outlet of the filter, to avoid unintended contamination. 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

The filter can tolerate thermal disinfection up to 6 times in the lifetime of the filter under the following conditions:

- 60° C for 20 minutes
- 65° C for 10 minutes
- 70° C for 5 minutes

Important: The filter may not be placed in a hot water bath.

Disposal

The product can be disposed of with ordinary waste following with applicable local regulations under the waste category number 180104 and by 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.

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

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 concentration of salts, metals, lime scale, chemicals, pesticides, and dyes

No liability for misprints or typographical errors.



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