

FILT'RAY^{2G} Disposable Water Filters

USER MANUAL

ENGLISH VERSION

POINT-OF-USE FILTERS

14, 31 & 62 days and 3 & 4 months

Shower Water Filter, Faucet Water Filter and In-Line Water filter

REFERENCES

AT030711, AT030713, AT030715, AT030717, AT030718, AT030719, AT030720, AT030721, AT030722, AT030723, AT030724, AT030725, AT030727, AT030728, AT030729, AT030730, AT030731, AT030732, AT030733, AT030734, AT030739, AT030740, AT030741, AT030742, AT030743, AT030744, AT030767, AT030768

To guarantee the optimal performance of the **FILT'RAY^{2G} Disposable Water Filters**, please ensure that you follow the instructions for installation (see I.) and read the warnings carefully (see II.).

General specifications

- Disposable **non-sterile and sterile** filters
- Effective against **waterborne pathogens** for up to **14, 31 & 62 days and 3 & 4 months**

Indications for Use

The aqua-tools **FILT'RAY^{2G} Disposable Water Filter** is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, the filters may aid in infection control. The filters produce water that is suitable for washing and drinking, superficial wound cleansing (minor cuts, scrapes, or abrasions), cleaning of equipment used in medical procedures and washing of surgeon's hands. **The filters are not intended to provide water that can be used as a substitute for USP grade sterile water.**

Description of Device

The **FILT'RAY^{2G}** family of filters are intended to produce bacteriologically controlled, purified water for general medical uses at point of use (e.g., washing of surgeon's hands, surgical instruments, and cleansing). These devices remove microbial contaminants via a hollow fiber microfiltration technology with a corresponding pore size of 0.1µm (nominal). This microfiltration technology ensures that the purified water will be exempt from bacteria, including *Legionella* spp., *L. pneumophila*, *Pseudomonas aeruginosa* and other pathogenic bacteria. Of note, the subject **FILT'RAY^{2G}** devices do not contain latex, nor tissues or by-product animal origins, nor derived of blood or any substance considered as a medicine.

FILT'RAY^{2G} disposable water filters are designed to ensure water safety at points of use. They are recommended for managing biological risk.

14, 31 & 62 day and 3 & 4 months **FILT'RAY^{2G} Disposable Water Filters** provide a barrier against waterborne microorganisms (aerobic flora that grow at 22°C to 36°C, *Pseudomonas aeruginosa*, *Legionella pneumophila*, etc.). These filters are designed to help control environmental conditions and are used to protect users against waterborne pathogens.

Laboratory-based microbiological challenges of *Brevundimonas diminuta*, *Legionella pneumophila* and *Pseudomonas aeruginosa* guarantee a **7 log retention capacity** for all waterborne microorganisms larger than 0.2 µm (2).

I. INSTALLATION INSTRUCTIONS

Warnings

- Filters installation must conform with professional **aseptic technique**. Hands must be disinfected prior to installation. Inappropriate installation may result in a source of contamination or carry-over contamination.
- Make sure that the individual unit packaging (plastic bag) is not punctured or torn and that the filter is not damaged. If this is the case, do not use the device, as the performance can no longer be ensured.

General Information

- The shower head filter (screw-on) features a standard fitting and can therefore be connected to all flexible shower hoses.
- The faucet and wall-mounted shower filters can be connected to most plumbing fixtures using an adaptor (clip-on); contact us for a list of commercially available adaptors.
- Installation of the inline filter requires the use of rapid connectors and/or connector nozzles, contact us for a list of commercially available adaptors.

Installation

1. Turn off the water supply.
2. Remove the used filter or the original shower head (for first-time installation of a shower head filter) or fit the adaptor, if needed (for first-time installation of a faucet filter) (see removal, below).
3. Carefully open the individual unit packaging (bag), making sure that the filter portion remains inside the bag. **Do not touch the open end of the tap or the shower head with your fingers.**
4. Keeping the filter in the bag, screw it onto the end of the hose (shower head filter) or clip it on (faucet or wall-mounted shower filter) or clip the filter inlet to the adaptor in the direction of the arrow indicating water flow on the label (inline filter).
5. The bag can then be removed.
6. Turn the water on for a few seconds to check that the adaptor(s) and the filter are **perfectly watertight**. In the case of leaks, repeat the installation procedure, using a new filter, if needed.

Removal

1. Turn off the water supply.
2. Remove the used filter by unscrewing it from the end of the hose (shower head filter) or unclipping it from the adaptor (faucet, wall-mounted shower and inline filters).
3. Dispose of the used filter according to your institution's established procedures.

A non-leaching bacteriostatic agent is embedded into the housing material of the **FILT'RAY^{2G}** disposable water filters in order to minimize the risk of retrograde contamination (see IV.).

If the filters can be soiled on the surface, it is advisable to wipe the outer surface without touching the outlet. To do so, filters must not be disconnected or soaked in a cleansing / disinfectant solution.

Waste management

Used **FILT'RAY^{2G}** disposable water filters do not present any special infectious risk. They are classified as normal household waste. Nevertheless, we recommend that all non-recyclable plastic products be disposed of responsibly via ecological collection and treatment facilities (1).

Maintenance

To facilitate the tracking of maintenance procedures, a removable adhesive label (located on the filtration device) can be used to record important information for your safety records (date of installation, date of removal, filter unique identification number, etc.). This information is also in shape of UDI (Unique Device Identification) which is a data matrix with information such as (01) GTIN: Global Trade Item Number, (10) Lot number, (17) expiration date, (21) Unit Number, (240) aqua-tools Part Number.

Contraindications

● FILT'RAY^{2G} disposable water filters must not under any circumstances be used to produce water for **pharmaceutical purposes** (i.e., water that will be used in solutions intended to be administered orally, injected, or perfused).

● FILT'RAY^{2G} disposable water filters **are not intended to provide water that can be used as a substitute for USP grade sterile water.**

II. WARNINGS

● FILT'RAY^{2G} disposable water filters are single-use (disposable). They cannot be sterilized or re-installed on another point of use.

● FILT'RAY^{2G} disposable water filters have a limited time use. Once they have completed their useful life, filters should be discarded and replaced.

● FILT'RAY^{2G} disposable water filters should not be used once **expiration date** (indicated on the label) is **past due**.

● FILT'RAY^{2G} disposable water filters must not come into direct contact with germ sources (dirty skin or hands, feces...)

● FILT'RAY^{2G} disposable water filters must not be struck or dropped (fall). Filter performance is not guaranteed if the filter casing is physically damaged. Do not attempt to open the device.

● FILT'RAY^{2G} shower head filters must always be replaced in the wall-mounted bracket after use. They must not be unscrewed at any point during the period of use. The same applies for the faucet, the wall-mounted shower and the inline filters which must not be unclipped at any time during the period of use except for when the water supply network is disinfected (at which time a new filter must be installed).

III. TECHNICAL SPECIFICATIONS

Conditions for use

The performance of FILT'RAY^{2G} disposable water filters is guaranteed when the water pressure and temperature remain between 14.5 and 72.5 PSI and 41°F and 140°F, respectively. Flow rates measured under normal conditions are as follows:

Typical Flow Rate (gal/min)					
Product	Water Pressure (Psi)				
	14.5	29	43.5	58	72.5
FILT'RAY ^{2G} Shower Head Filter	1.2	2.3	3.1	3.9	4.5
FILT'RAY ^{2G} Wall-Mounted Shower Filter	1.0	2.4	3.4	4.5	5.1
FILT'RAY ^{2G} Faucet and In-Line Filter	0.6	1.2	1.7	2.0	2.3

*Flow rate measurements are determined with the filters installed on a faucet.

Typical Flow Rate (L/min)					
Product	Water Pressure (Bar)				
	1	2	3	4	5
FILT'RAY ^{2G} Shower Head Filter	4.5	8.7	11.9	14.9	16.9
FILT'RAY ^{2G} Wall-Mounted Shower Filter	3.9	8.9	13	16.9	19.4
FILT'RAY ^{2G} Faucet and In-Line Filter	2.2	4.7	6.3	7.7	8.8

*Flow rate measurements are determined with the filters installed on a faucet.

Heat and chemical resistance

FILT'RAY^{2G} disposable water filters are resistant to the thermal and chemical shocks that frequently occur during disinfection of the water supply system (2). They remain effective after treatment at **70°C (158°F) for 30 min** (cumulative maximum) or a dose of active chlorine at **100 ppm for 60 min** (cumulative monthly maximum: FILT'RAY^{2G} 31-day filters: 1 hour at 100ppm, FILT'RAY^{2G} 62-day filters: 2 hours at 100ppm, FILT'RAY^{2G} 3-month filters: 3 hours at 100ppm and FILT'RAY^{2G} 4-month filters: 4 hours at 100ppm).

After exposure to such treatments, please note that there may be a reduction in water flow due to contamination of the water supply with various types of particles. In such cases, the water filter should be replaced with a new filter should the flow rate become greatly reduced and/or unacceptable.

Blockage tolerance

FILT'RAY^{2G} disposable water filters have a certain amount of tolerance to blockage with the Bub'Air Wash™ technology, which provides a re-suspension self-cleaning mechanism. Nevertheless, the flow rate at the point of use may decrease somewhat

before the end of lifetime if there are unusually high levels of particles or suspended microorganisms in the water supply (for example, after a maintenance procedure has been performed). If the flow rate becomes too slow for user comfort, simply replace the filter.

IV. PRODUCT COMPLIANCE

The Sterile FILT'RAY^{2G} disposable water filters are sterilized by gamma irradiation in compliance with ISO 11137.

Do not re-sterilize.

For Sterile and non-sterile FILT'RAY^{2G} disposable water filters:

- A non-leaching bacteriostatic agent is embedded into the housing material of the FILT'RAY^{2G} disposable water filters in order to minimize the risk of retrograde contamination. Laboratory-based microbiological testing for *Escherichia coli*, methicillin-resistant *Staphylococcus aureus* (MRSA), *Legionella* sp., and *Pseudomonas aeruginosa* guarantees the retention of more than 98% of bacteria (2);
- They have received worldwide drinking water compliance certifications (ACS-France, KTW-Germany, WRAS-United Kingdom*);
- They meet the requirement of the Australian/New Zealand Standards AS/NZS 3497 « Drinking water treatment units » and AS/NZS 4348 « Water supply - Domestic type water treatment appliances - Performance requirements » for the class II(a): microbiological treatment - bacteria removal. Certification and WaterMark marking.
- They are class II medical devices in the USA
- They are class I medical devices for Europe that comply with directive 93/42/CEE. Marking CE 0459: year 2016;

For more information, please refer to the performance data sheet – available upon request.

V. MANUFACTURING INFORMATION

FILT'RAY^{2G} disposable water filters are manufactured in France

By : **aqua-tools** 26, rue Charles-Édouard Jeanneret | 78300 POISSY | France

and distributed by **(in the USA only):**

aqua-tools

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(1) For more information, visit our website at: www.aqua-tools.com or contact us:

Phone : 617-398-2497

E-mail: sales@aqua-tools.com

(2) For the results of the laboratory testing, see the "Scientific and Technical Validation Guide" for the relevant product. Document available upon request.

* In progress

Product label – meaning of symbols

Rx only: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."

	Compliant with the Essential Requirements
	Non-sterile
	Compliant with the Essential Requirements - Sterile
	Sterilised using irradiation
	Do not re-sterilize
	Catalogue number
	Batch code
	Use by
	Consult instructions for use
	Manufacturer
	Free of natural latex
	Do not use if package is damaged
	WaterMark marking: License number for AS/NZS 3497 compliance by CertMark