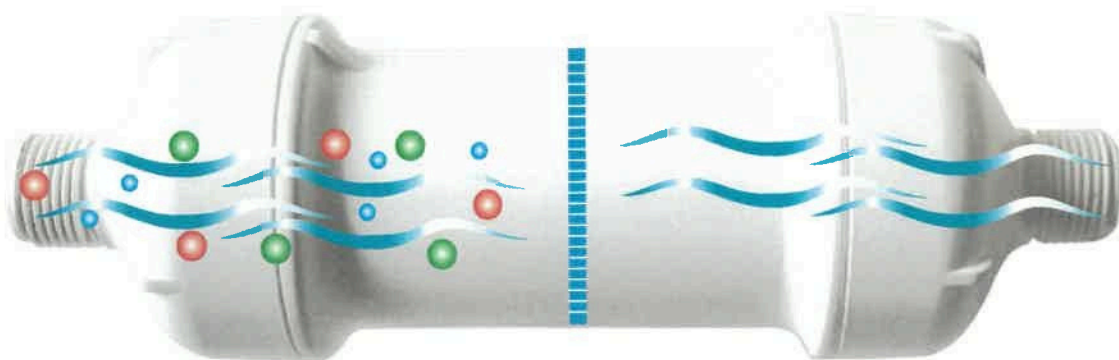


ANTIBACTERIAL ULTRAFILTER FOR
DENTAL UNITS

AMBTM

ADVANCED MEDISULFONE[®] BIOBARRIER



MICROBIOLOGICALLY **PURE**, CONTINUOUS **WATER**
FOR THE **SAFETY** OF YOUR PATIENTS

Is there a risk to your patients from contamination of your water lines?

Worldwide scientific research over many years clearly highlights the risk. It comes from penetration and growth of bacterial colonies within the water lines, generating biofilm⁽¹⁾. Without intervention harmful levels of bacteria can accumulate that are dangerous to health! These organisms are easily inhaled from fine mist that is ever present whenever intraoral spraying takes place^(2,3). In particular Legionella is a serious threat to the elderly and to immune-suppressed patients⁽⁴⁻⁶⁾.

- (1) Barbeau J et al | Biofilms, infectious agents, and dental unit waterlines: a review | Can J Microbiol. 1998 Nov;44(11):1019-28
- (2) Hambleton P et al | Survival of virulent Legionella pneumophila in aerosols | J Hyg (London)1983 Jun;90(3):451-60
- (3) Bakerville A et al | Experimental transmission of legionnaires' disease by exposure to aerosols of legionella pneumophila | The Lancet, Volume 318, Issue B260, Pages 1389 - 1390, 26 December 1981
- (4) Fraser DW et al | Legionnaires' disease: description of an epidemic of pneumonia | N Engl J Med. 1977 Dec 1;297(22):1189-97
- (5) Williams JF et al | Microbial contamination of dental unit waterlines: origins and characteristics | Compend Contin Educ Dent. 1996 Jun;17(6):538-40,
- (6) Ricci ML et al | Pneumonia associated with a dental unit waterline | Lancet 2012; 379:684



How to prevent and minimise this risk?

Dental units with mains supply have two possible sources of water contamination:

- a) The mains water supply*
- b) Water contaminated during treatments can be sucked back into the water lines thereby introducing infection. This can be termed "Suck back" or "Reverse Contamination"⁽⁷⁾

Your water supplier* is responsible for the water to the point where it enters the building. After that it is the responsibility of the consumer. Also drinking water generally does not require the high level of purity that is needed to avoid contamination of water lines in medical facilities.

- (7) Walker JT et al | Microbial biofilm formation and contamination of dental-unit water systems in general dental practice | Appl Environ Microbiol. 2000 Aug;66(8):3363-7

Risk prevention of bacterial back contamination through intra-oral instruments irrigation lines

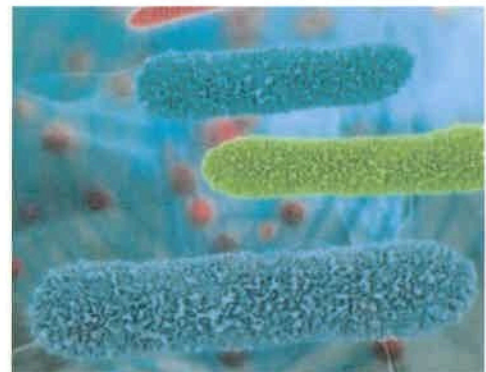
Regarding point (b) there are recommended preventive measures to control and reduce the reverse contamination risk, namely:

- b1) Use a sterilised handpiece for each patient
- b2) Use a sterile or disposable 3 in 1 syringe tip

To manage contamination risk in the water lines there are several solutions on offer. Some use soluble Sodium and Silver salts whilst others Hydrogen Peroxide with Silver Ion solutions.

The challenge with such solutions is that to be reliable and effective they rely on regular user intervention. Forget the routine and the protection is missing!

- (8) Mills SE, Karpov RI | Dental waterlines and biofilm-searching for solutions | Compend Contin Educ Dent. 2002 Mar;23(3):237-40



Micro biologically pure mains water: always!

The risk of contamination from the mains supply

Daytime, chemical solutions can take up to 40 or 50 minutes to achieve optimal effect but may not guarantee bacteriologically pure water. Our innovative and revolutionary Medisulfone^{®*} filter does"!

Advanced MediSulfone Biobarrier is a micro-porous tubular capillary fibre that prevents all microorganisms passing through it. It ensures that mains water is completely filtered and microbiologically pure for a whole year and without affecting your unit!

This extraordinary ultra-filter is a by product of state of the art research and development for dialysis applications. The technology has been adapted to provide the flow rate and pressure needed to ensure safe water in dental units.

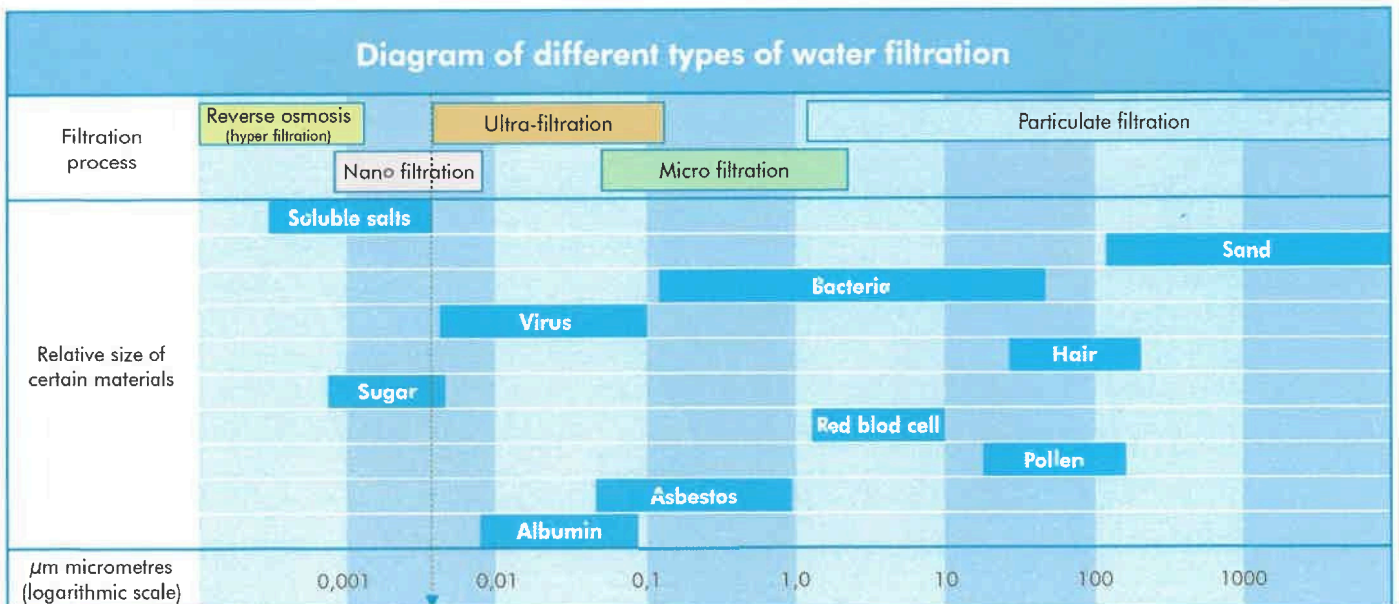
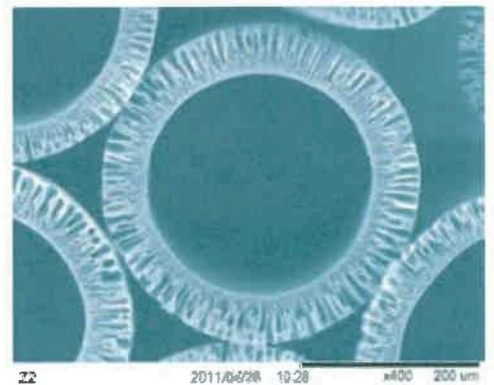
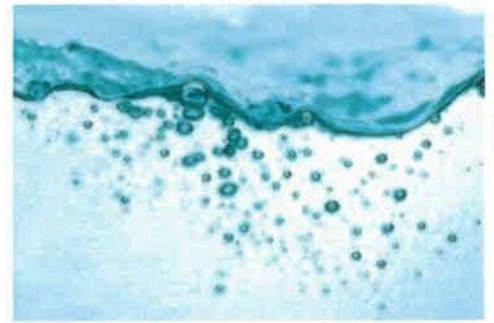
It has proven to be extremely effective in purifying the water that feeds them.

The new ultra-filter AMB[™] is a CE marked medical device: it guarantees microbiologically pure output water and when used in association with the procedures to prevent "suck back" contamination gives you optimal assurance.

This powerful combination of preventive measures enables dental professionals to provide patients the utmost protection from infection.

Moreover, since the new AMB[™] ultra-filter works in both directions and because it is installed upstream of each unit, it also acts as a microbiological barrier in reverse!

Therefore, if one unit is accidentally contaminated, even for a very short period, the AMB[™] ultra-filter prevents the spread of contamination throughout your practice.



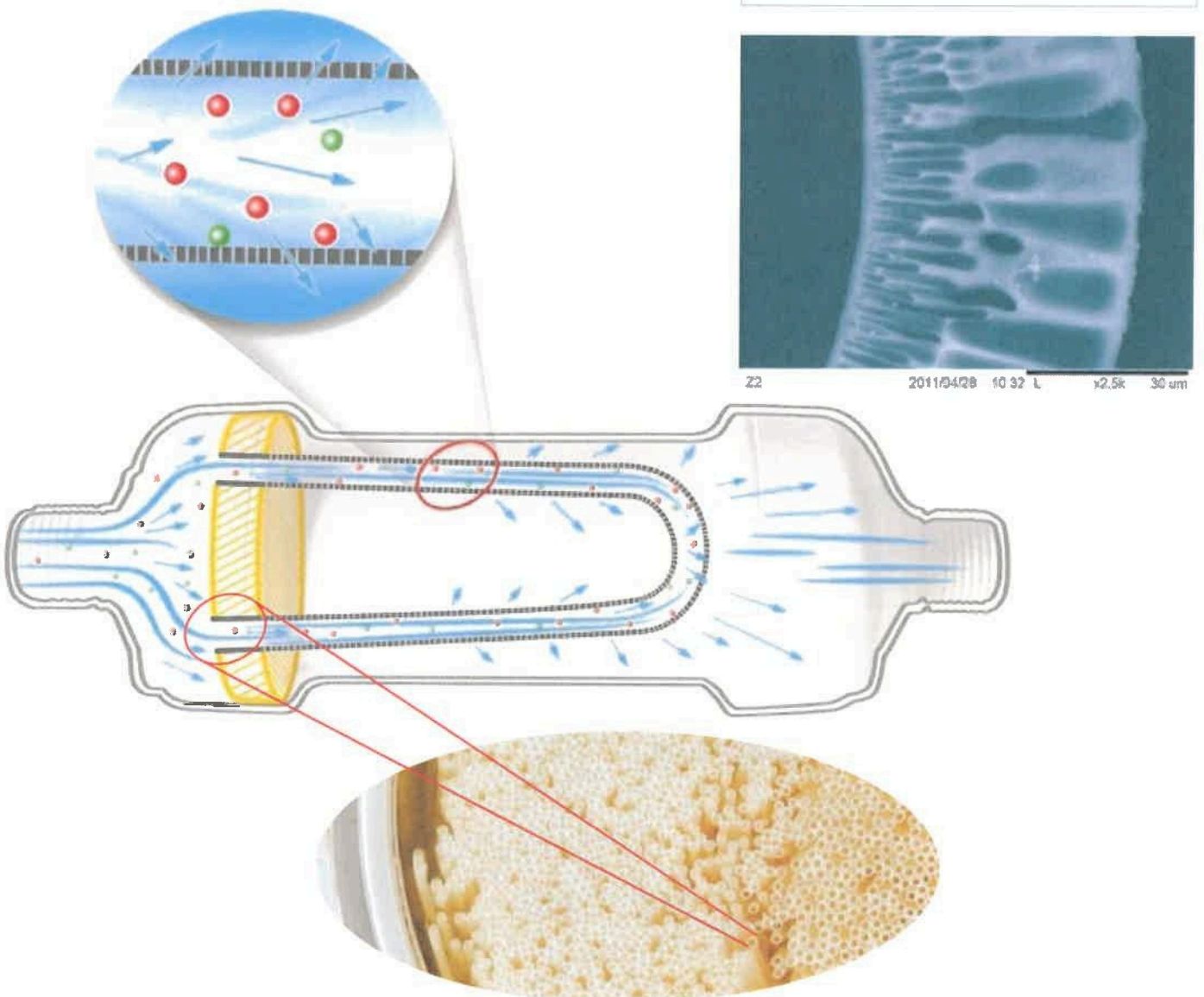
Description

The Advanced MediSulfone® Biobarrier (AMB™) is a disposable ultra-filter that produces microbiologically pure water for supplying dental units. Once installed it should not be removed until the end of its serviceable life (1 year). Do not attempt to sterilize or sanitize.

Description of the MediSulfone® membrane: the technical superiority of this membrane is because of its structure.

The inner surface of this tubular membrane has a high density of pores that determine a cut-off of only 15 kDa ($<0,005\mu\text{m}$). Medica is a leading Italian company specialized in extrusion of microbiological water purification capillary membranes, the technology was developed for the purification of aqueous solutions used in the world of dialysis.

Biological filter performance: validation was carried out according to the ASTM F 838-05 method at the University of Modena and Reggio Emilia - Department of Public Health Sciences.



Technical Specifications

Max input pressure	5 bars
Max input temperature	50° C
Filter membrane	Medisulfone® UF
Membrane material	Polisulfone
Cut-off of membrane	15 kDa (0,005µm)
Microbial Retention	Bacterial > 10 ¹⁰ (B.diminished)
	Viral > 10 ⁸ (PhiX-174)
	Endotoxins > 10 ⁵ EU/ml
Service life expectancy	12 months*
Fittings	BSPT 3/8" Male
Dimensions	Length mm 157 - Ø mm 48
Weight	110 gr.

*service life depending on the installation of a mesh pre-filterer.

Installation warnings

Open the package and mark the label on the filter with the date of installation.

Turn off the water supply and install the filter upstream of the dental unit with the arrow pointing in the direction of the flow.

Please note that the filter will only feed one dental unit and must be installed inside the pedestal of the machine.

Check that the water is flowing freely through the unit.

The installation and replacement of the filter should only be carried out by qualified technicians.

Contraindications

Health: the AMB™ ultra-filter produces microbiologically pure water. Then it was not intended and must not be used as a substitute for sterile water.

Chemical: the AMB™ filter removes microbiological contaminants. To get chemically pure water it is required to use the filter in conjunction with other devices fit for purpose (DI beds, RO systems).

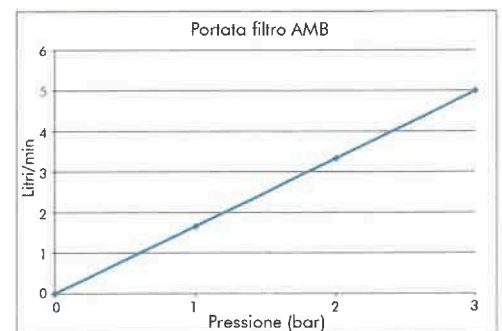
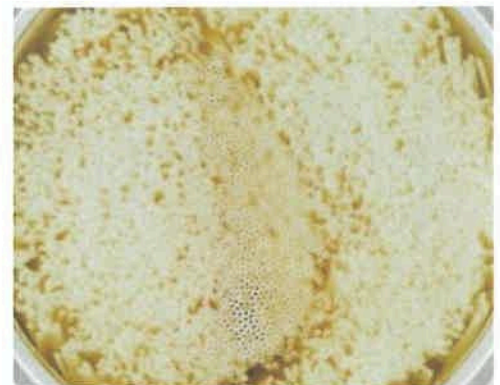
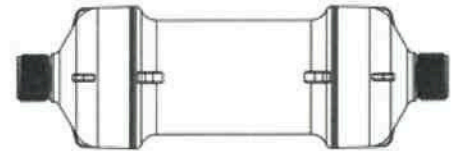
Warnings and precautions

Pressure and temperature: the AMB™ filter is designed for a water maximum input pressure of 5 bars and a maximum temperature of 50°C.

Replacement: once installed, the filter is designed to operate within the specifications detailed in the table. In relation to the characteristics and bio burden of the mains water input, the duration of the filter may vary with a minimum guaranteed of one year.

Disposal

The AMB™ filter, once used, must be disposed of as medical waste according to DPR 254/2003.





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MEDICA
SEAMLESS INNOVATION FOR LIFE QUALITY



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