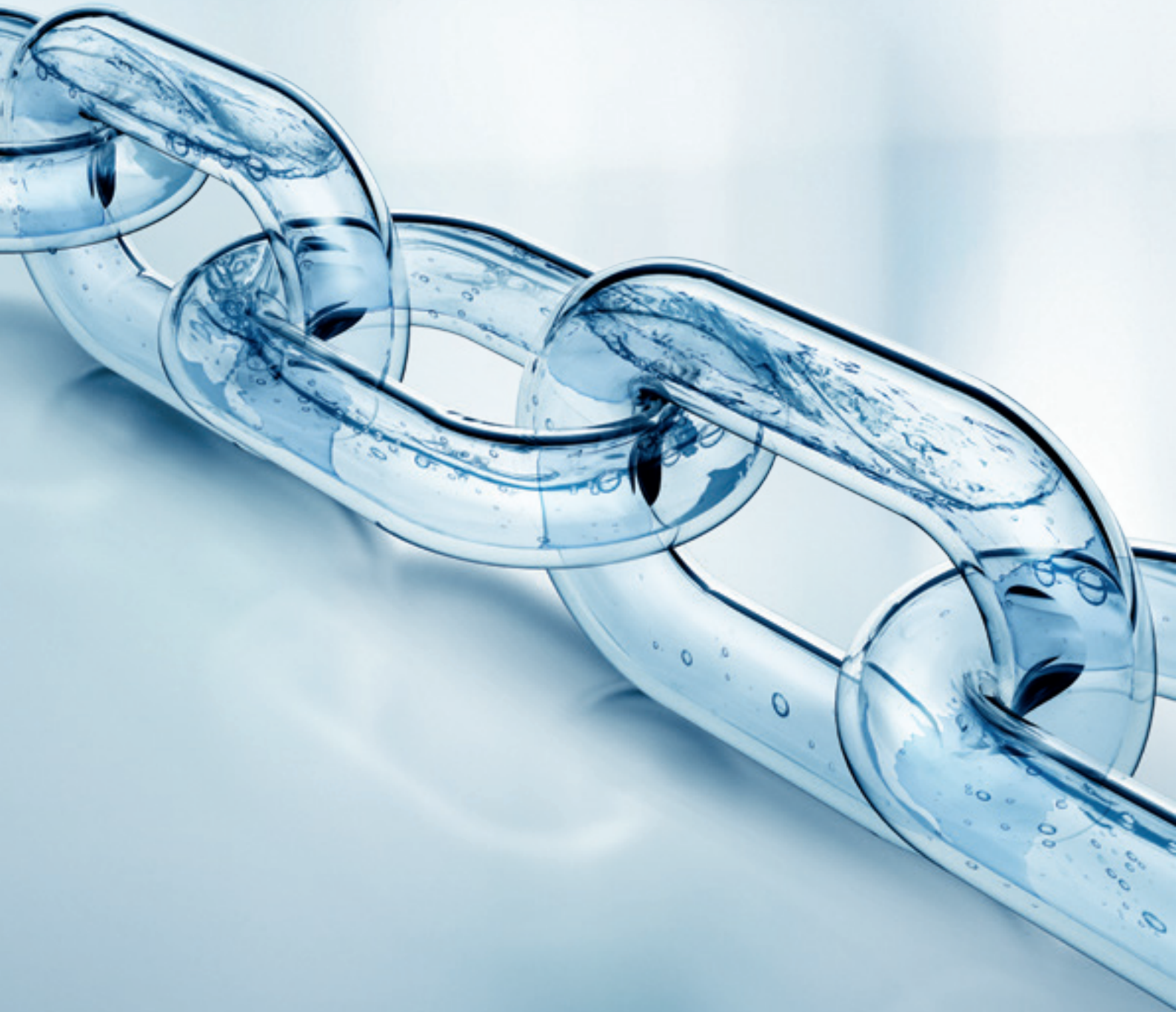


**Baxter**

Gambro

# hygienic chain<sup>®</sup>

**EVERY LINK MATTERS**



Making possible personal.



## THE HYGIENIC CHAIN CONCEPT – A HOLISTIC APPROACH TO FLUID PURITY

Consideration of every link has never been truer within dialysis; from the water treatment equipment, concentrates and consumables, fluid distribution and the HD machine, a fully integrated system offering is essential.<sup>1-3</sup>

Maintaining the fluid purity is ensured through the Hygienic Chain concept, an operational mind-set that can help provide pure fluids maximizing the dialysis treatment and patient wellbeing.<sup>2,4,5</sup> One key element is an effective proactive disinfection regime.<sup>6-8</sup> This protects system integrity while affording protection to your patients<sup>2</sup> from the hazards of biofilm throughout the entire system.<sup>8-10</sup>

## THE IMPORTANCE OF FLUID PURITY

When it comes to dialysis; purified water is recognized as a necessity for ensuring effective treatments.<sup>1</sup> Dialysis water impurities are increasingly seen as risk factors in dialysis;<sup>11</sup> affecting the patient's well-being and their quality of life.<sup>5,12-17</sup> Maintaining fluid purity means attending to the entire chain of components and processes involved in HD, we call this the Hygienic Chain concept whereby the level of purity is created link by link; where 'every link matters'.<sup>2,18</sup>



# THE DEFINITION OF WATER PURITY

For dialysis clinics, water quality is a critical factor in the overall care received by dialysis patients.<sup>1,5,12-17</sup> Over extended periods of regular dialysis therapy, contaminants can affect efficiency, the performance and maintenance of the equipment, and most importantly play a major role in the induction or modulation of patient morbidity.<sup>9,18-20</sup> Without an effective preventative disinfection regime of the dialysis system there is the risk of biofilm formation.

Biofilm is a community of microorganisms covered in protective polysaccharide slime.<sup>6,8,21</sup> Once established, biofilm can release numerous toxins into the fluid phase (endotoxins, polypeptides known as exotoxins and other substances<sup>1</sup>). Monocyte and cytokine production occur from the transfer of these bacterial by-products into the blood during the HD treatment.<sup>13,20</sup> Consequently the bacterial contamination of the dialysis fluid is a major factor in HD biocompatibility.<sup>3,4</sup>

Activation of monocytes and cytokine production can potentially lead to dialysis-associated inflammation. Aside from inflammation, they can have many secondary effects leading to poor patient wellbeing.<sup>5</sup>

## DIALYSIS FLUID PURITY

Poor dialysis fluid quality leads to adverse clinical events including inflammation and infection.

## IMPROVED PATIENT WELL-BEING

The holistic approach to fluid purity through Hygienic Chain philosophy enables the generation of high quality dialysis fluid which may provide improved clinical outcomes.

## PROACTIVE DISINFECTION REGIMES<sup>6,22</sup>

Implementation of the Hygienic chain philosophy is an effective approach to maintaining system integrity and may avoid treatment related inflammation.<sup>5,12-17</sup>

## REDUCED ADVANCED MEDICAL CARE

Improved dialysis fluid quality can decrease inflammation and co-morbidities.<sup>2-5</sup>

## DECREASED INFLAMMATION

- Mitigation of atherosclerosis and heart disease induced by chronic inflammation
- Improvement in nutritional status due to increased removal of pro-inflammatory mediators
- Erythropoietin effectiveness is enhanced.<sup>3,4,6,18</sup>

In the pages that follow, we hope to provide insight and advice on how you can strengthen every link of the Hygienic Chain concept to ensure optimal fluid quality for your patients.



# PROTECTING YOUR PATIENTS FROM TAP TO NEEDLE

Water has a unique ability to dissolve most chemical compounds and support all forms of life. This means there are many contaminants that can exist within water which have to be removed if it is to be used within the dialysis setting.<sup>23</sup> Not only this but further complications can exist as the incoming water supply can vary dramatically due to seasonal and climatic changeover.

One single technology is not sufficient to achieve the desired purification qualities for dialysis water and ultimately dialysis fluid.<sup>2,23</sup> In order to consistently maintain the high degree of fluid purity proactive disinfection regimes have to be employed coupled with system maintenance; and complete system thinking,<sup>6,21</sup> thereby ensuring the purification process and ultimately the patient's wellbeing.



## Micro-filtration:

Micro-porous filters provide protection against particulates and colloids.

## Base-exchange softening:

Ion-exchange (cation resin) technology removes calcium and magnesium; preconditioning the incoming water supply while protecting the reverse osmosis membranes from the risk of scaling.<sup>18</sup>

## Absorption techniques:

Activated carbon tanks or carbon blocks remove chlorine/chloramines and large organic compounds. Multiple units ensure the guidelines for Empty Bed Contact Time (EBCT). This ensures levels are met and patients are protected from haemolytic reactions due to chlorine.<sup>18,24</sup>

## Final filtration:

Protects the reverse osmosis membranes from any breakthrough of fine particles from the activated carbon treatment beds/filters allowing the unit to run efficiently within its operating parameters.

## Online monitoring:

This technology is employed to monitor several constituents (hardness and chlorine levels) automatically prior to the Central Water Plant. All system checks should be carried out as guided by the equipment manufacturer, manual and automated while following all calibration steps as required.

## CWP:

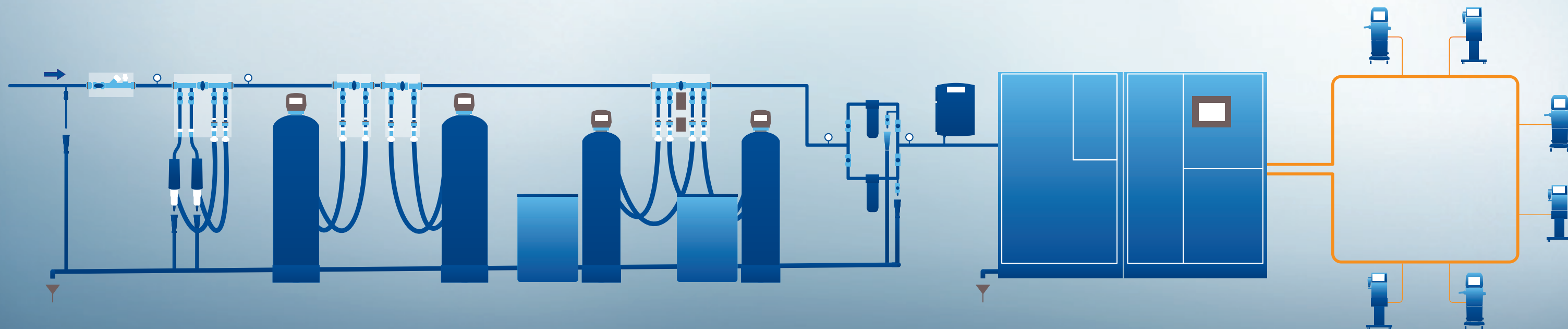
Reverse osmosis technology in a single or twin pass configuration ensure exceptional purity by removing almost all remaining contaminants (95-99%) after the pre-treatment has pre-conditioned the incoming water supply. Proactive disinfection regimes employed to minimise biofilm proliferation.

## Post RO filtration:

Additional loop filters capable of withstanding disinfection regimes can be employed to provide further protection against microbial contamination if deemed necessary.

## Distribution loop:

Disinfection of the loop, supply lines and dialysis machine are essential in limiting biofilm formation in the fluid pathways. A proactive disinfection regime is essential in maintaining a system which can provide all treatment modalities.



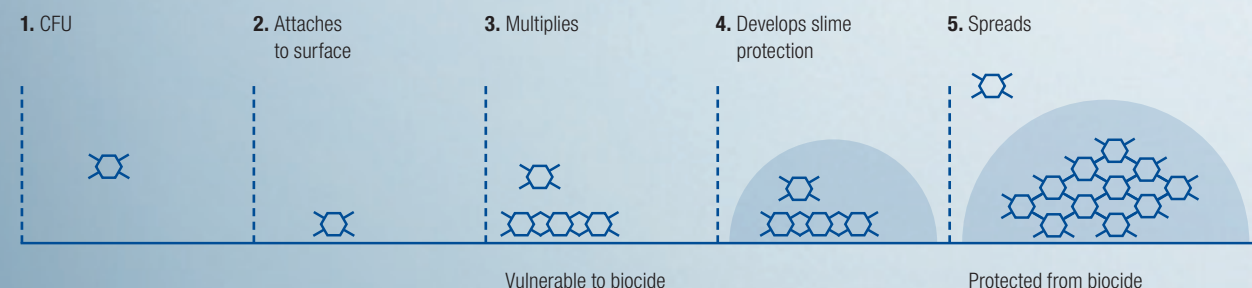


# THE DANGERS OF BIOFILM

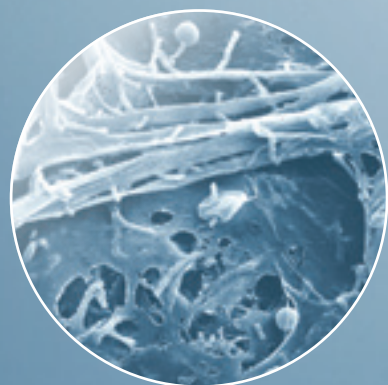
One of the most critical elements within the Hygienic Chain concept is the water purification equipment and associated distribution loop.<sup>2,6,21,25</sup> This string of technologies help condition the water and provide a sound process for the preparation of dialysis fluid. It is at this stage where you can have the greatest risk of biofilm development.<sup>7</sup>

Biofilm formation is a consequence of bacteria in any aqueous environment and once established its eradication is almost impossible. Gram negative bacteria that grow in water and dialysate produce endotoxins that are pyrogenic (the outer cell membrane contains lipopolysaccharides that are released into the surrounding fluid as the bacteria multiply and die).<sup>5,13</sup> In addition various bacterial species produce a class of polypeptides called exotoxins as well as other cell fragments and metabolic products in the fluid phase. While the biofilm itself adheres to the surfaces and is not found in the fluid phase; its toxic by-products do. At high exposure pyrogen reactions may occur. At low levels these products stimulate monocytes to release pro-inflammatory cytokines.<sup>26</sup>

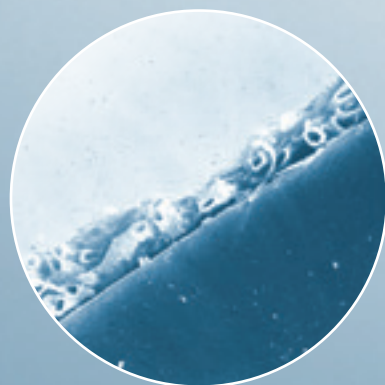
## IN-CENTER WATER PIPING – PROTECTED FROM BIOSLIME



Bacteria floating in the HD fluid encounter a hard surface and attach with a reversible bond. The bacterium multiplies and develops a protective slime layer. Once this layer is established, the bacteria form a permanent bond and are all but impossible to eradicate. From here, the colony will spread leaching toxins into the surrounding HD fluid.

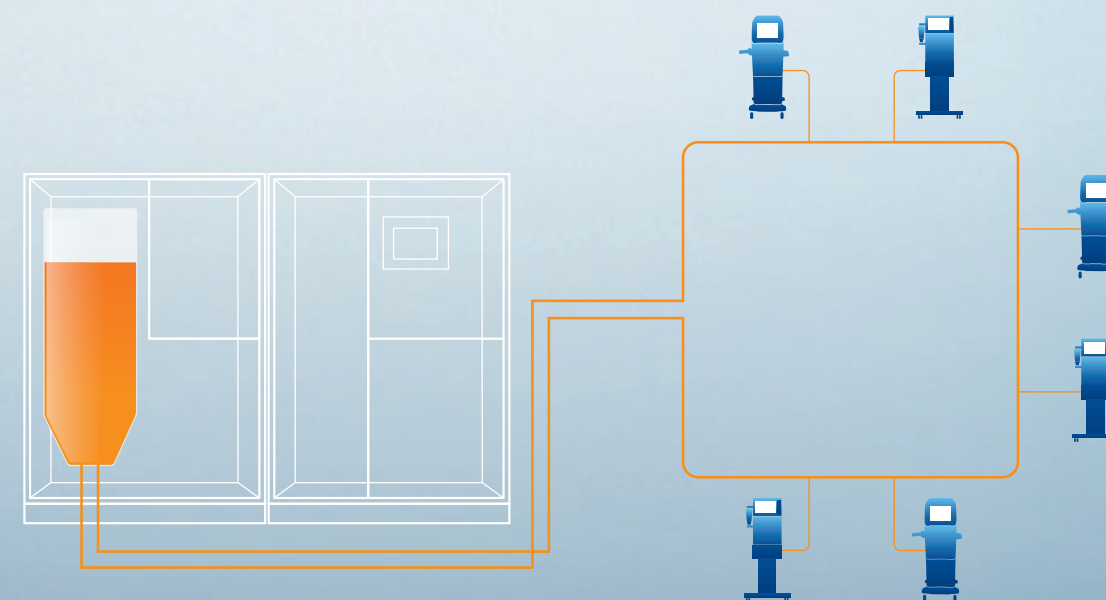


Biofilm is resistant to all standard forms of disinfection because the microbes are protected beneath a tough polysaccharide slime layer.



Cross-section of HD fluid tubing. Note the layer of biofilm. As the polysaccharide matrix spreads, it may become home to a wide range of bacteria, yeast, and fungi.

# STOP BIOFILM BEFORE IT EVEN STARTS



Automated heat disinfection of both the distribution loop and reverse osmosis membranes can help reduce biofilm growth.<sup>6,21</sup> Using heat disinfection is one of the simplest, most consistent and effective disinfection strategies that can be implemented thus, allowing the nursing teams to focus on the patients. Utilising heat disinfection gives your renal unit a more environmentally friendly option to that of Control of Substances Hazardous to Health (COSHH) regulated chemicals. It also provides a long-term consistent disinfection strategy.



# THE PATH TO PURE FLUIDS FOR PATIENTS

The next link in the Hygienic Chain concept is the HD machine and concentrates. While most major brands of HD machines would appear to perform dialysis treatments equally well, their hygienic performance may vary. The Hygienic Chain concept is the proven approach to be effective against biofilm formation<sup>6,21,27</sup> and its known impact on patient well-being as every link within the system is designed to aid reduction in microbial proliferation.



## HD MACHINES DESIGNED FOR OPTIMISING FLUID PURITY

A simplified flow path ensures an even flow rate throughout the entire fluid path. With no dead ends, complicated valves or chamber systems, our machines give microbes no chance to settle especially during heat or chemical disinfection. The design of our dialysis machines allows:

- No stagnation of water and dialysis fluid between treatments
- Disinfection for microbial control
- A systematic approach which helps reduce the chances of contaminants reaching the dialysis membranes
- Disinfection for all components and materials

(See individual dialysis system brochures)

## DRY BICARBONATE CARTRIDGES

Bicarbonate concentrates can be a challenge especially when liquid bicarbonate is utilized in the clinic environment. Liquid bicarbonate can lead to bacterial growth if continual surveillance and disinfections are not carried out.<sup>11</sup> This can be avoided altogether with the use of a dry bicarbonate powder cartridge. As the first to launch the dry bicarbonate we have been able to make numerous advances in making bicarbonate easy, safe and hygienic.

- Hermetically sealed and ready for on-line preparation as needed
- No chance for contamination to occur between preparation and use; The Gambro BICART cartridge minimizes the risk of bacterial contamination and growth versus liquid bicarbonate<sup>11</sup>
- Global leader in bicarbonate powder for dialysis over 25 years supplying over 200 million treatments and remains an essential part of the Hygienic Chain concept
- System can be extended to the Gambro BICART SELECT system which includes Dry Sodium Chloride

## AUTOMATIC CLEANING & DISINFECTION

Citric acid and sodium carbonate powders are used to decalcify and clean the HD machine's fluid paths. Since liquid citric acid can provide an excellent growth medium for microbes, it is important that fluid preparation is only done as needed, a crucial element the Gambro CLEAN CART cartridge may achieve. The CLEAN CART cartridge offers your clinics many benefits:

- Ensures that this fluid is prepared by the machine only as needed, with no time for contamination
- Just place the cartridge in the holder and press the disinfection button
- Initiates heat disinfection in combination with decalcification or cleaning
- Combines disinfection into one operation
- Optimized to maximize use of hot water with continuous downstream flow

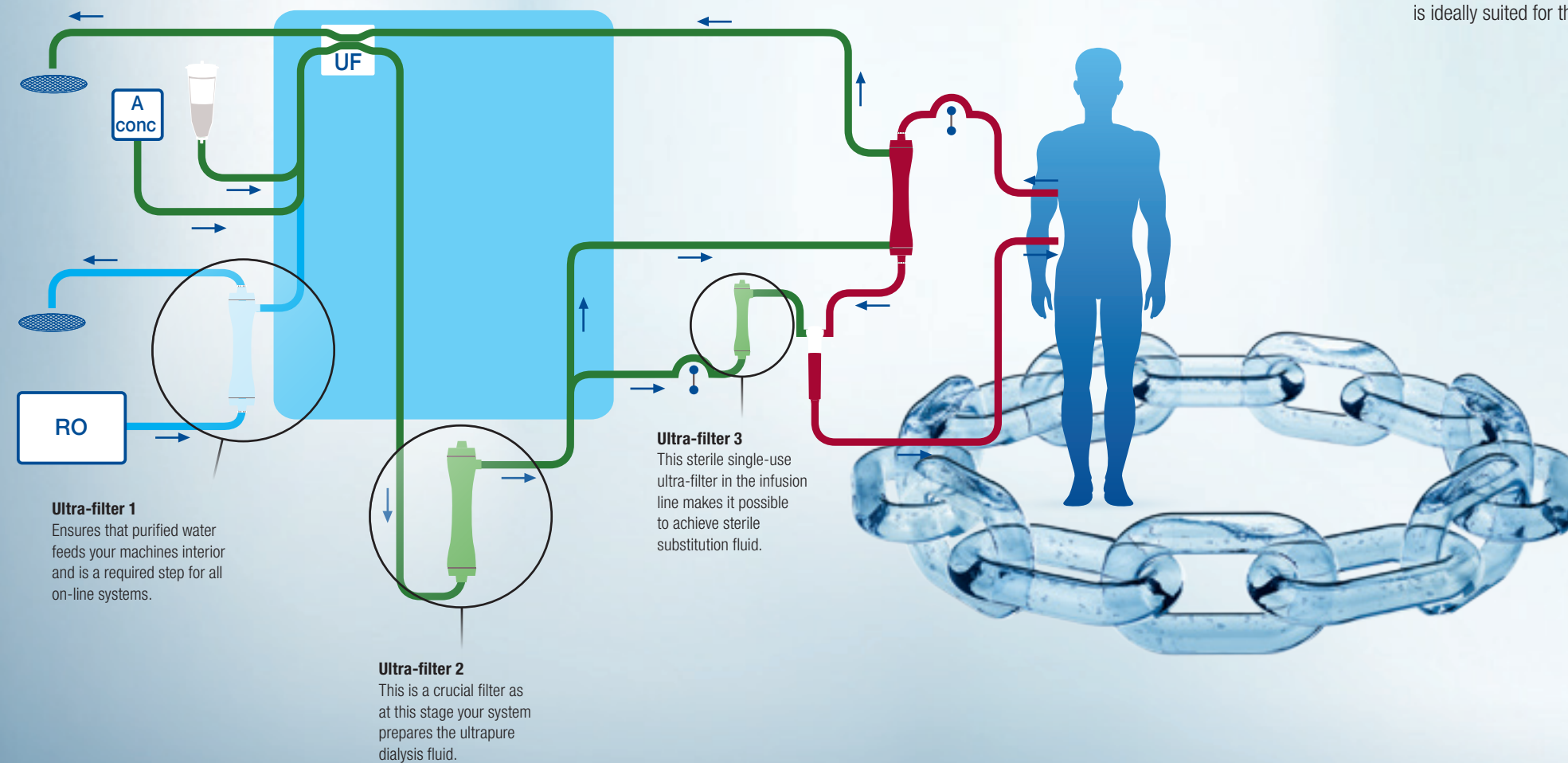
(See ARTIS PHYSIO system brochure for more details)





## ULTRA-FILTERS – REINFORCING THE STRENGTH OF YOUR FLUID PURITY

Ultra filters can help strengthen the Hygienic Chain concept by removing further contaminants from the dialysis fluid through absorption and size retention.<sup>28</sup> This has a positive result for patients as trials have shown a reduction of micro inflammation with the use of ultrafilters.<sup>1,14,17,22,28-32</sup> By inserting an ultra-filter in the dialysis fluid line you can significantly reduce the levels of microbial organisms and their by-products. More ultra-filters are required to prepare on-line substitution fluid for HDF or HF. To ensure sterility and non-pyrogenic fluid in all cases, the third filter is utilised.

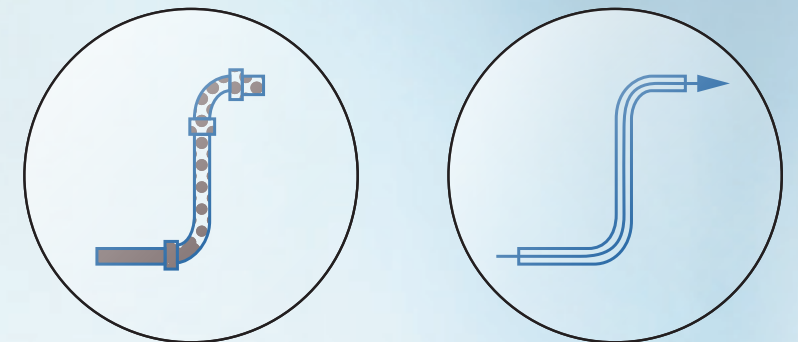


## TUBING A CRITICAL LINK IN THE HYGIENIC CHAIN CONCEPT

Tubing and inlets are the very crucial link in the Hygienic Chain concept. Tubing is a large part of the Hygienic Chain concept as it links all machines with their fluid source and it is perhaps the most important because it is so often found to be the source of contamination due to the growth of biofilm.<sup>6,21</sup> The effectiveness of all other purity precautions is seriously reduced if microbial proliferation and toxic by-products from biofilm are not removed. The problem remains that these areas are often overlooked and not addressed by many disinfection routines.

Gambro's automatic hot water flushing program stops biofilm before it starts with a proactive regime.<sup>6,21</sup> While biofilm is virtually impossible to remove, it can be prevented from establishing a presence. Prevention with daily prophylactic disinfection is our proven approach.<sup>6,21</sup> That is, daily circulation of hot water through the entire fluid circuit in your clinic. In fact, the Gambro system can perform this daily routine automatically during non-dialysis periods.<sup>8,27</sup>

There are many requirements placed on HD system tubing. It should be tough, flexible, heat resistant, chemically inert, and have a smooth inner surface. Meeting all these requirements, our cross-linked polyethylene (PEX) tubing is ideally suited for the specialized demands of the HD clinic.



- As biofilm fastens to walls it will not show up in CFU counts
- Joints may provide additional space for biofilm growth
- Inner surfaces are not suited for the special demands of HD clinics
- Gambro PEX tubing offers an advantage over any other type of tubing, including electro-polished stainless steel
- It is tough, flexible, heat resistant, chemically inert and has a smooth inner surface<sup>33</sup>
- Facilitates all disinfection processes – No low flow zones that can favour microbial deposition and ultimately biofilm formation
- Maximizes the performance of the Hygienic Chain concept



## CREATE SECURITY FOR YOUR OPERATIONS

The Hygienic Chain concept supports an efficient and effective clinic by avoiding unnecessary maintenance, downtime and system damage. Our water treatment units are reliable and can protect your system against biofilm formation which as a result can save your clinic in terms of time, additional costs and risk reduction.<sup>6,8,21,25</sup>



### **ELIMINATE BIOFILM – SAVE TIME AND COSTS**

When you eliminate biofilm you may minimize possible downtime due to maintenance. This as a result may potentially save costs and resources in your dialysis unit.<sup>6,8,21,27</sup> Thus enabling a more patient centric approach to clinic function.

The Hygienic Chain concept can also give you a reduction in preparation time prior to the dialysis session starting, freeing staff time and resources for other needs through its automation.

(See individual system brochures for details)

### **SAVING COSTS BEYOND THE CLINIC**

Providing a high standard of water and dialysis fluid purity may lead to direct and indirect clinical benefits including better correction of anemia with reduced erythropoiesis-stimulating agent (ESA) and improved patient outcomes with reduced morbidity and hospitalization rates which can result in better patient well-being reduced emergency admissions and cost advantages for providers.<sup>5,15,31,34</sup>

### **EXTRA PURITY, SECURITY AND AUTOMATION**

The complete Hygienic Chain concept ensures fluid with a limited biological load from the start and prolongs the life of the ultra-filters and reduces the need for elaborate maintenance programs.

As a result of increasing standards set by international guidelines,<sup>2,23,25</sup> automating your system and ensuring every link in your hygienic chain is strong, you can also reduce the future risk of incurring larger costs such as a replacement of the complete water treatment system and/or distribution loop due to biofilm growth.<sup>6,8,21</sup>



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