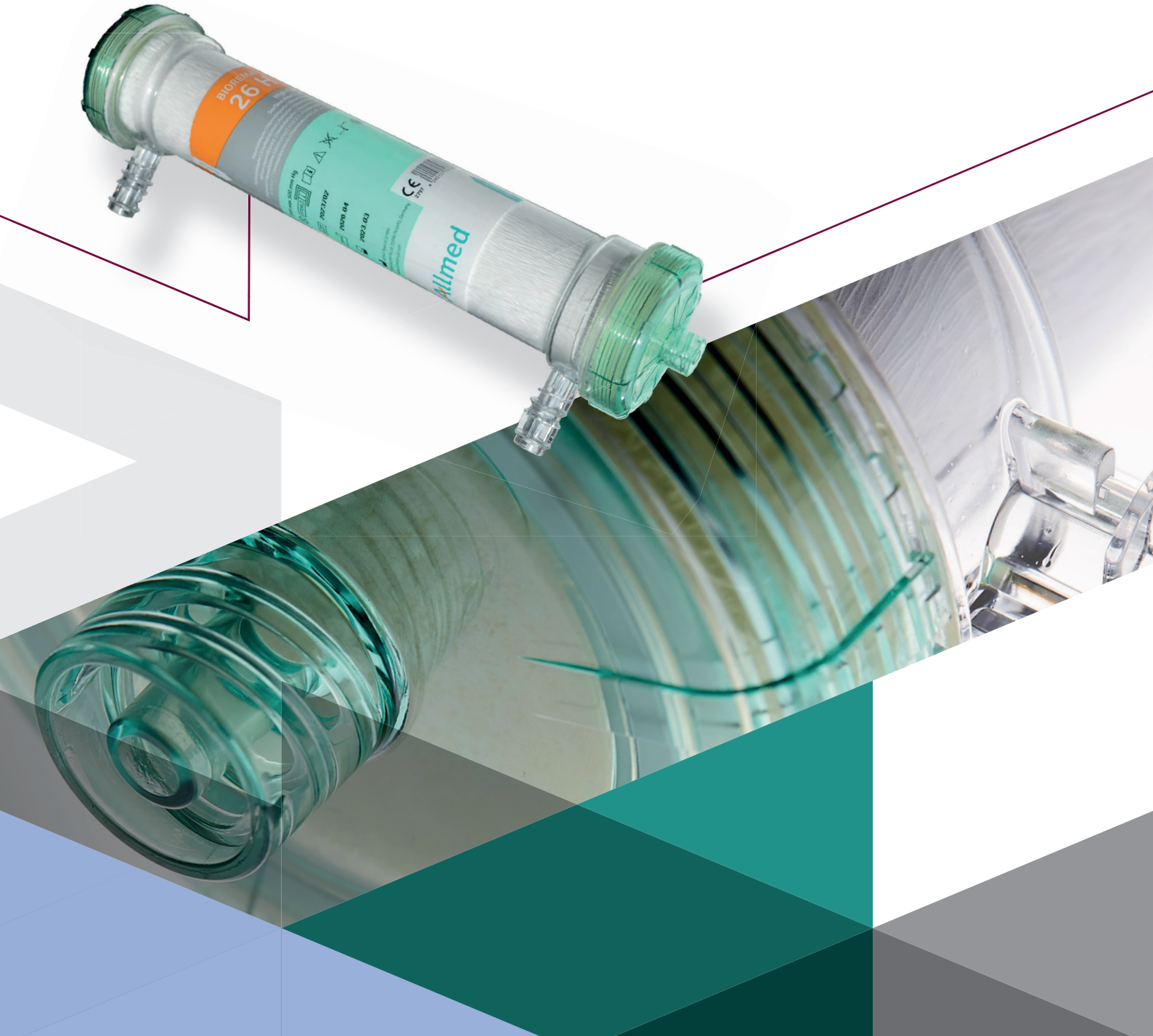
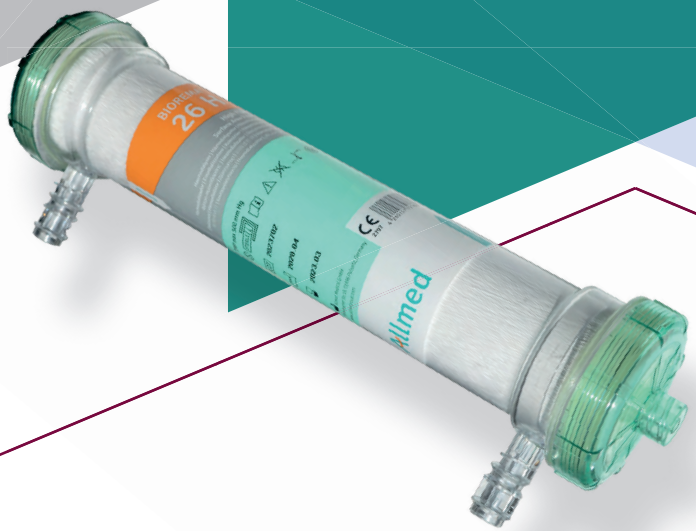
KIMAL | Allmed

Biorema® 26H

The best option for effective and quick removal of large molecules, including various cytokines





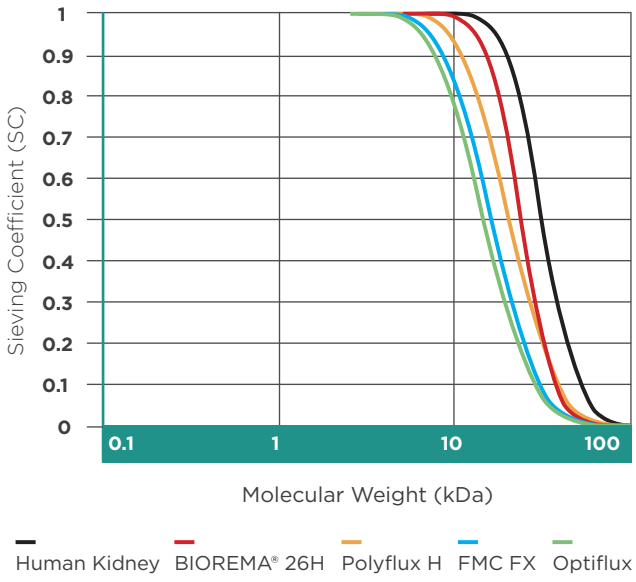
BIOREMA® 26H

Allmed's special Haemodiafilter with elevated cut-off, exceptionally high surface area (2.6 m²), and endothelial-protective sterilisation technology: the best and most biocompatible choice for removal of a wide range of molecules up to 40 kDa, including the majority of cytokines, yet with minimal albumin loss.

WET STEAM

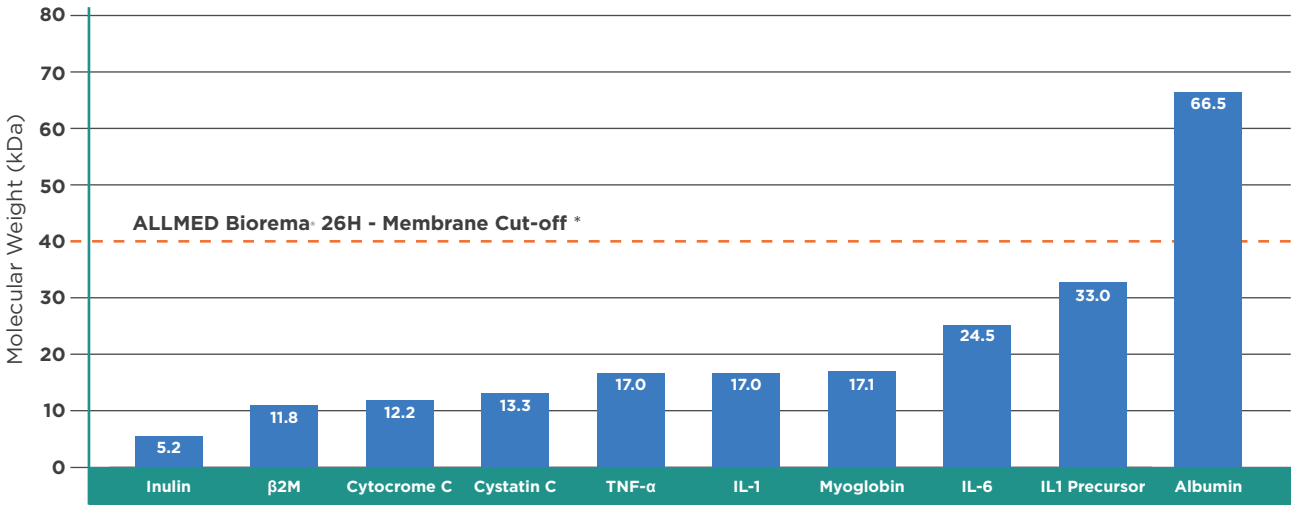
Biorema® 26H - Membrane cut-off

The removal of larger uremic toxins by conventional dialysis membranes is restricted by their molecular weight cut-offs. Recent availability of a new generation of haemodialysis membranes with molecular weight cut-offs closer to that of the native kidney has led to assesment of their potential utility across several different clinical scenarios. Initially designed for larger uremic toxins depuration, clinicians are now using these membranes for the removal of a wide range of cytokines in patients with severe inflammatory syndromes.



Allmed's Biorema® 26H

Thanks to its cut-off going up to 40 kDa, Biorema® 26H offers excellent removal of middle molecules as well as a wide group of cytokines, with minimal loss of albumin.



* 95% retention. Determined in 5% albumin solution.

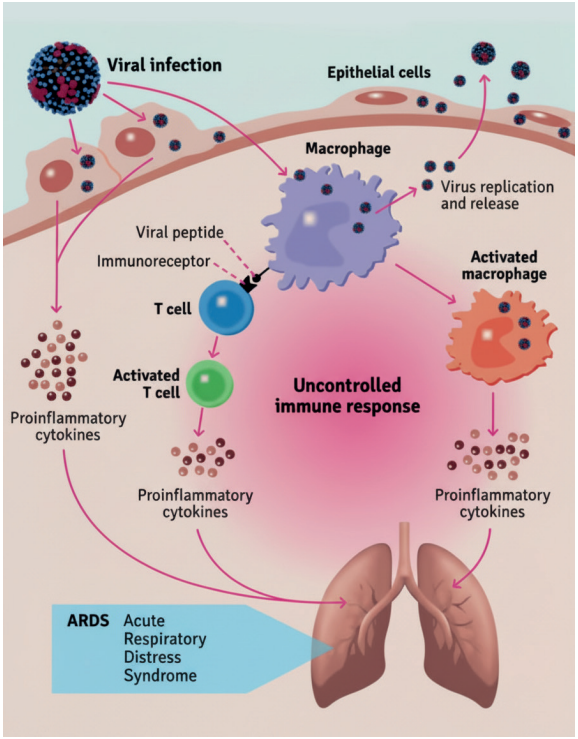
Cytokines removal in infections

Recent pandemic COVID-19 has once more evidenced the key role played by the inflammatory processes. The worldwide outbreak of COVID-19 requires intensive care for 5% of the infected population.

Among those critically ill patients, the mortality rate is 49%. [1]

Recent studies found that the patients' lungs appeared to deteriorate quickly, typically seven days into the disease Scientific community is increasingly convinced that, at least in some cases, the cause is the body's own immune system overreacting to the virus. The problem is broadly known as a "cytokine storm". [2]

Predictors of fatality from a recent retrospective, multicentre study [2,3] included elevated levels of IL-6 suggesting that mortality might be due to virally driven hyperinflammation. [4]



Such a hyperinflammatory syndrome requires treatment for a patient's increasingly desperate immune response to the virus. The approach is to reduce the level of cytokines to a level where it no longer hurts the body but still allows the body to fight the infection. [1,2,4]

Extracorporeal filtration can reach this goal [4,6] but it is mandatory to use an adequate filter summing up the following characteristics:

OPTIMAL CUT-OFF

Biorema® 26H, its optimised cut-off value of 40 kDa is designed with a capacity to remove cytokines, majority of which are in the range of 17 to 33 kDa

HIGH SIEVING & REMOVAL RATE

Our product offers unique sieving capabilities, illustrating higher sieving of Myoglobin than FX CorDiax, Polyflux and Elisio H. [8] Thanks to its unique surface area, on clinical evaluation in France (24 sessions/8 patients) Biorema® 26H achieved a remarkable Removal Rate of Myoglobin of >75.5%. Myoglobin is a key marker for removal of larger molecules, such as cytokines

HIGH PERMEABILITY

The UF coefficient of Biorema® 26H, equal to 98 ml/h*mmHg, assures efficient ultrafiltration

EXCELLENT BIOCOMPATIBILITY

Polyethersulfone synthetic membrane, sterilised by endothelial-protective steam sterilisation [7], provides excellent biocompatibility and prevents further contribution to the inflammatory process

LARGE SURFACE

Biorema® 26H, packing nearly 5 kilometres of hollow fibre membranes, is the largest dialyser of its kind available in the market today, maximising to the fullest extent the removal rate of middle molecules within the same treatment time

Allmed's Biorema® 26H possessing all the above characteristics makes it uniquely beneficial for treatments in which removal of inflammatory mediators is a key strategy in patient therapy.

Use of **Biorema® 26H** is of course not limited to the above indication, the product serves as a stable and concrete support to physicians in treating patients affected by comorbidities or other pathologies requiring removal of high molecular weight substances.

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2. Metha P, Mc Auley DF, Brown M, Sanchez E, Tattersall RS, Manson JJ, et al. COVID-19: consider Cytokine storm syndromes and immunosuppression. The Lancet vol.395 March 28,2020
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8. Data per manufacturer's brochures

Autoclaved Wet Steam sterilisation: best for patients & the environment

Dialyser sterilisation can be achieved via steam, ethylene oxide (ETO), electron beam, or gamma irradiation. The preferred method of sterilisation is steam. Steam-sterilised membranes have been found to improve endothelial cell viability when compared to gamma rays-sterilised ones. [1,2]

The use of steam instead of gamma rays for sterilisation can improve the biocompatibility of membranes [2,6,7,8]. Electron beam sterilisation has been reported to cause significant thrombocytopenia following dialysis [3].

Possible changes caused by radiation in structural and membrane transport parameters are not clearly established and may lead to the generation of toxic derivatives and the loss of biocompatibility properties. [4]

For example, Polyurethane, which is widely used as potting dialyser material, produces carcinogen 4,4'-methylenedianiline when it is submitted to gamma ray irradiation for sterilisation. This production is not present with autoclave sterilisation procedures.[2]

Autoclaved dialysers are individually sterilised by the passage of a continuous flow of steam in both compartments (blood and dialysate sides) in a temperature of 121 °C for 25 minutes. Compared with other sterilisation methods, this continuous steam flow presents the additional advantage of eliminating possible manufacturing residues.[5]

As the Biorema® 26H is wet-steamed, it requires lower priming compared to other sterilisation methods for the same product, offering an optimised rheology during clinical use. Steam sterilisation has less impact on the environment compared with irradiation and ethylene oxide. Considering its very high biocompatibility and the acquired experience, steam sterilisation is to be favoured in the choice of dialysers of equivalent performances.[5]

The combined effect of steam sterilisation (protective of endothelial cell viability) together with the removal capacity of proinflammatory substances such as cytokines (which compromise the endothelium) provides a unique feature to the **Biorema® 26H** in treatments where protecting the patient's endothelium is a key objective.

BIBLIOGRAPHY:

1. Haroon S, Davenport A, Choosing a dialyser: what clinician need to know. Hemodialysis International 2018; 22:S65-S74
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Clearance in vitro (ml/min) QD = 500 ml/min QF = 0 ml/min T = 37°C Max TMP = 500mmHg	**Q_b= 200 ml/min**	**Q_b= 300 ml/min**	**Q_b= 400 ml/min**
Urea	199	292	359
Creatinine	197	279	337
Phosphate	196	270	318
Vitamin B12	174	221	244
Inulin	137	158	169

Sieving Coefficients	**Q_b= 200 ml/min**
Vitamin B12	1
Inulin	1
Cytochrome C	> 0.90
ß2 microglobulin	> 0.90
Myoglobin	> 0.7
Albumin	< 0.002

Surface area	2.6 m^2
UF coefficient (ml/hr*mmHg)	98
Cut-off	40 kDa
Blood priming volume	153 ml
Sterilisation	Wet Steam
Packaging	12 dialysers per box

* Performance data were measured in vitro according to standard ISO 8637
* UF measurement: using bovine/human blood (Hct 32%;protein 60g/l)
* Typical values obtained with an individual batch of fibres, clinical use may illustrate a difference in results in relation to different Ultrafiltration/measuring techniques and possible variation between batches of fibres

Internal diameter
200 µm

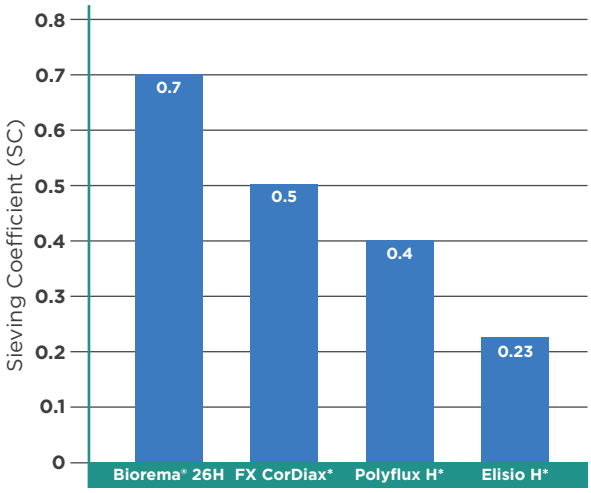
Wall thickness
30 µm

Membrane material
Polyethersulfone

High Cut-off
40kDa

High surface
2.6 m^2

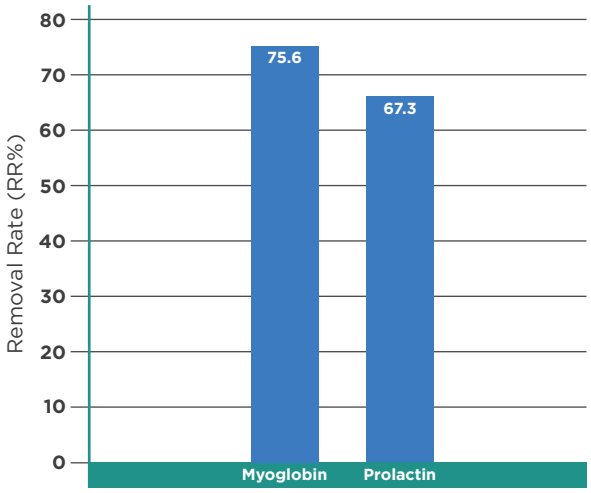
Sterilisation
Wet Steam



Myoglobin Sieving Coefficient

Excellent Sieving Coefficient (SC) characterises **Biorema® 26H** as the most adequate dialyser for the removal of middle molecules and more, counteracting cytokine production in several infections or disorders.

* Data per manufacturer's brochures



Myoglobin and Prolactin RR%

Recent clinical evaluation in France of the **Biorema® 26H** (24 sessions/8 patients) demonstrated remarkable Removal Rates for large molecules such as Myoglobin and Prolactin, supporting the use of **Biorema® 26H** for cases in which large size molecules must be removed.

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Contact us for more information:

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Email: renal@kimal.com

Scan the QR code to learn more

www.kimal.com

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