Medtronic

The membrane that matters

Clearum™ HS Dialyzer

Clearum™ HS is a high flux steam sterilized dialyzer with a biocompatible membrane that provides adequate balance between diffusion and convection in standard hemodialysis, on-line hemofiltration and on-line hemodiafiltration.[1]

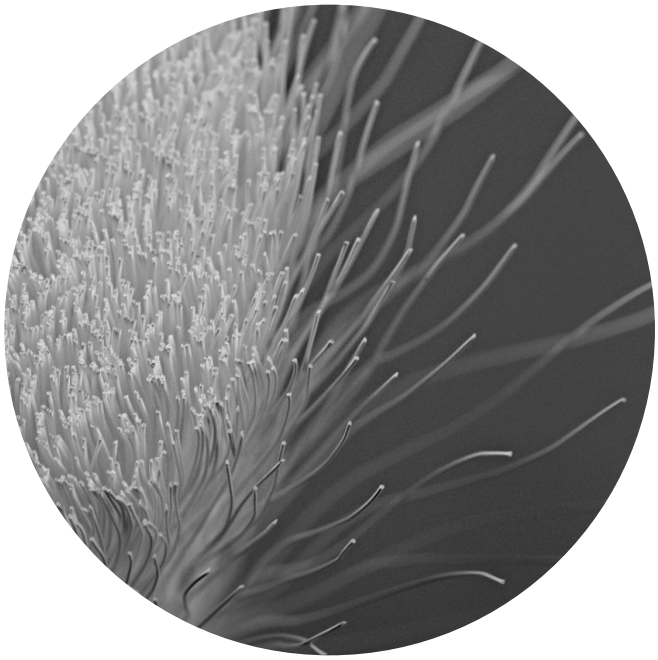
This technology is addressed to patients with moderate risk of inflammation, malnutrition, and cardiovascular disease.[2]

Clearum™ HS dialyzer promotes toxin removal and retention of critical proteins to provide safe and effective therapy.[1]

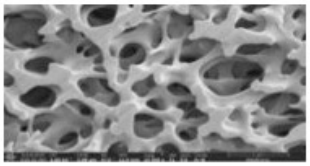
Biocompatibility and safety

The Clearum™ HS series dialyzers are well tolerated and safe.[1]

- Episodes like hemolysis, alteration of platelets and leukocytes and adverse reactions to the blood, can be limited thanks to the inner lining of the capillary and smooth potting surface, the amount of Polyvinylpyrrolidone (PVP) in the membrane and the steam sterilization.[3,4,5]
- Bisphenol A (BPA) may be considered a uremic toxin that can accumulate in End-Stage Renal Disease (ESRD) patients and because of its negative effects may be associated with diabetes and cardiovascular diseases.[6,7] Clearum™ HS dialyzers are BPA-free.[8]
- The Clearum™ HS performs as a barrier, minimizing the transfer of pyrogens into the patient's bloodstream in case of backfiltration.[9] This can prevent potential patient side effects such as inflammation and the release of cytokines.



Clearum™ HS Dialyzer 17



Magnification 25,000 x

Figure 1 – Scanning Electron Microscope (SEM) image of Clearum™ membrane

Dialyzer performance

The Clearum™ HS membrane helps ensure adequate dialyzer performance to deliver efficient patient outcomes.

- Diffusion mechanisms are fostered by the undulation of capillaries, which improves the membrane wettability and by a balanced packing density, that facilitates the dialysis solution flow.[10]
- Removal of medium molecular weight toxins is promoted by a limited variability in pore size distribution that can lead to a stable sieving coefficient and by the steam sterilization process that promotes higher surface wettability and membrane hydrophilicity.[11,12,13]
- The sharp distinction between the small and large membrane pore areas can determine a marked separation between substances we want to retain and those to be eliminated[11,12] (Figure 1).

Clinical evidences

Clearum™ HS shows adequate performance and tolerance in HD and HDF.

- The application in HD offers blood purification in line with standard expectation and with several popular dialyzers for small molecular weight toxins and for middle as well[1] (Figure 2).
- Achievable infusion volumes in HDF on-line are adequate and allow to obtain high removal rates for medium and large molecular weight toxins[1] (Figure 4).
- Safe and well tolerated treatments thanks to very limited albumin losses in both HD and HDF applications[1] (Figure 3 and 5).

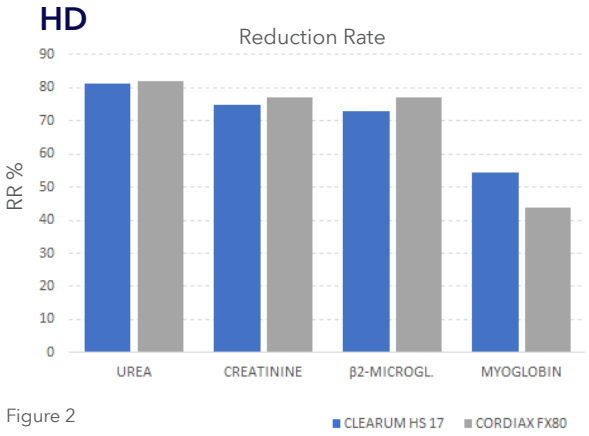


Figure 2

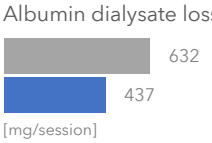


Figure 3

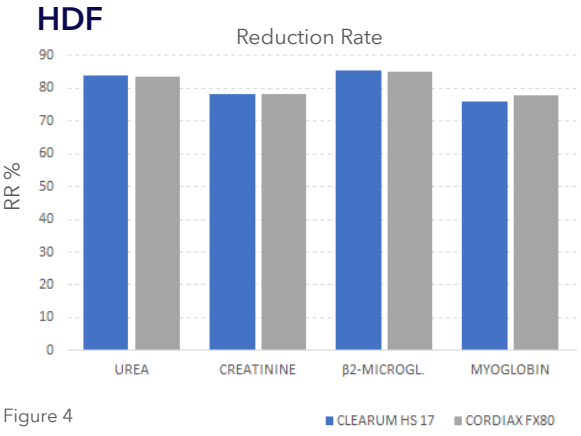


Figure 4

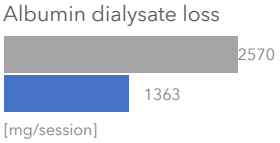


Figure 5

Usability

100%
Packaging and easy connection appreciation rate from users[14]

Clearum™ HS dialyzers are designed to deliver effective treatments.

- The dialyzer packing density and the hydrophilicity of the membrane promote an efficient priming and adequate air removal which may prevent potential clotting issues.
- Wide range of surface areas and applicability to standard HD, on-line HF and on-line HDF treatments.

Care for the environment

60%
Reduction of carbon footprint thanks to polypropylene housing[16]

Clearum™ HS dialyzers take care for the environment.

- Helps ensure ozone is not released into the atmosphere thanks to steam sterilization.[15]
- Up to 95 % of the water used during Clearum™ HS fiber manufacturing can be recovered.

Diffusive clearance optimized by capillary microwaves[10]

Considerable performance on all monitors on the market[14]

Effective for standard **HD and HDF online** treatments[1]

BPA-free and biocompatibility ensuring less patient complications[7,8,9]

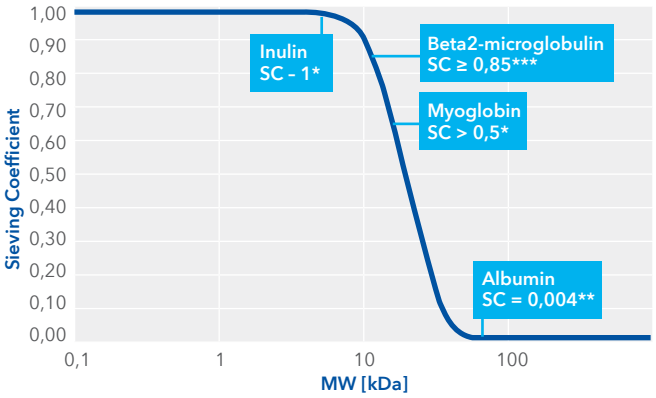
Adequate balance between **diffusion and convection**[10,11]

Steam sterilization for a more stable membrane and process[11,13]

In vitro performance

Item	Urea (ml/min)	Creatinine (ml/min)	Phosphate (ml/min)	Vitamin B12 (ml/min)
Clearum™ HS 13	246	220	205	141
Clearum™ HS 15	264	240	226	160
Clearum™ HS 17	266	243	231	167
Clearum™ HS 20	271	253	243	184
Clearum™ HS 22	275	258	248	194

In vitro clearances: Q_B = 300 ml/min; Q_F = 10 ml/min; Q_D = 500 ml/min



*Sieving Coefficient values as per IFU
**Experimental mean value within the limit of ≤0,01 as reported in the IFU
*** Experimental value >0.80 as reported in the IFU

Ordering information

Code	Item	Description	Quantity
IBP4370	Clearum™ HS 13	1,3 m² High Flux Dialyzer, steam sterilized	21 per box
IBP4371	Clearum™ HS 15	1,5 m² High Flux Dialyzer, steam sterilized	21 per box
IBP4372	Clearum™ HS 17	1,7 m² High Flux Dialyzer, steam sterilized	21 per box
IBP4373	Clearum™ HS 20	2,0 m² High Flux Dialyzer, steam sterilized	21 per box
IBP4374	Clearum™ HS 22	2,2 m² High Flux Dialyzer, steam sterilized	21 per box

1. Maduell F, Broseta JJ, Rodríguez-Espinosa D, et al. Efficacy and safety of the clearum dialyzer. *Artif Organs.* 2021;45(10):1195-1201.
2. Tattersall J, Martin-Malo A, Pedrini L, et al. EBPG guideline on dialysis strategies. *Nephrol Dial Transplant.* 2007;22(Suppl 2):ii5-21.
3. Zweigart C, Neubauer N, Storr M, et al. Progress in the Development of membranes for Kidney-Replacement Therapy. In: Diori E, Giorno L. Comprehensive Membrane Science and Engineering. *Elsevier;* 2010:369.
4. Kokubo K, Kurihara Y, Kobayashi K, Tsukao H, Kobayashi H. Evaluation of the Biocompatibility of Dialysis Membranes. *Blood Purif.* 2015;40(4):293-7.
5. Müller TF, Seitz M, Eckle I, Lange H, Kolb G. Biocompatibility differences with respect to the dialyzer sterilization method. *Nephron.* 1998;78(2):139 142.
6. Gao X, Wang HS. Impact of Bisphenol A on the Cardiovascular System Epidemiological and Experimental Evidence and Molecular Mechanisms. *Int J Environ Res Public Health.* 2014;11(8):8399–8413.
7. Rezg R, El Fazaa S, Gharbi N, Momaqui B. Bisphenol A and human chronic diseases: current evidences, possible mechanisms, and future perspectives. *Environ Int.* 2014;(64):83–90.
8. Based on internal test report # INR.086_R00 - BPA Absence evaluation.
9. Based on internal test report # TR_END_001_R00 Clearum Endotoxin Retention Test Report.
10. Based on internal test report # TR_CLE_008_R02_Clearum Clearance Test Report.
11. Based on internal test report # TR_SIE_007_R02_Clearum Sieving Coefficient Test Report.
12. Based on internal test on Scanning Electron Microscope (SEM) images.
13. De S, Roy A. Hemodialysis Membranes: For Engineers to Medical Practitioners (1st Ed.). 2017.
14. Based on Clearum™ HS Series Limited Controlled Distribution Report.
15. GIPA, IIA. A comparison of gamma, e beam, x ray and ethylene oxide technologies for the industrial sterilization of medical devices and healthcare products. 2017.
16. Keoleian, Gregory, Shelie Miller, Robb De Kleine, Andrew Fang, Janet Mosley. (2012) "Life Cycle Material Data Update for GREET Model." University of Michigan: Ann Arbor: 1-74.

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