

Clearum™ HS Dialyzers



Clearum Overview

Clearum™ high flux steam sterilized (HS) dialyzers are standard hemodialysis dialyzers with a biocompatible, high-flux membrane that provides adequate balance between diffusion and convection in both HD, HF and HDF.

Clearum™ HS Dialyzers promote toxin removal and retention of critical proteins to provide safe, effective therapy^{1,2,3}

1. TR_SIE_007_R01_Clearum Sieving Coefficient Test Report
2. 2.TR_CLE_008_R01_Clearum Clearance Report
3. 3.MaduellIF, Broseta JJ, Guillen MA, et al. Efficacy and Safety of the Clearum Dialyzer. *Artif Organs*. 2021;45(10):1195-1201.



Medtronic

Clearum™ HS dialyzer features

performance



green
aspects



Safety



usability



Medtronic

Safety

BIOCOMPATIBILITY

BPA free materials and processes

Steam sterilization ensures a **lower impact on various indices** from WBC, platelet count, level of C3a, C5a and PMN elastase¹.

HEMOCOMPATIBILITY

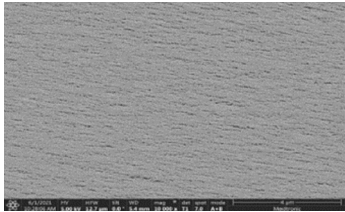
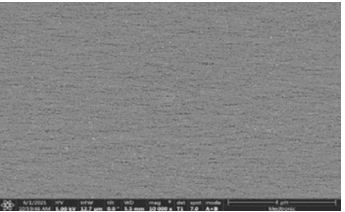
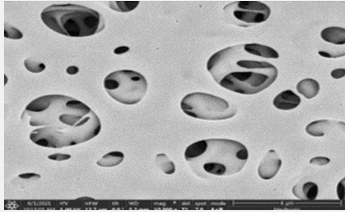
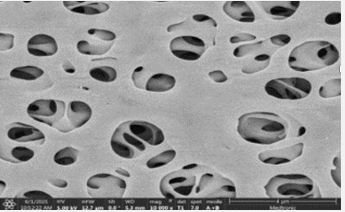
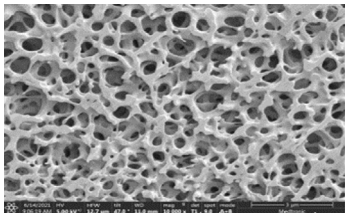
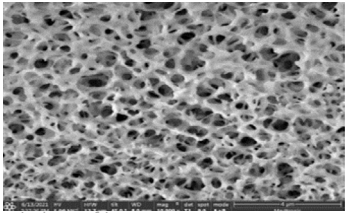
ENDOTOXIN BARRIER

The Clearum™ HS dialyzer hollow fiber performs as a barrier to pyrogen transfer decreasing the occurrence of **non infective inflammation**².



1. Müller TF, Seitz M, Eckle I, Lange H, Kolb G. Biocompatibility differences with respect to the dialyzer sterilization method. *Nephron*. 1998;78(2):139-42
2. TR_END_001_R00 (claim CE marked)

Performance

Magnification 10 000 x	Clearum™ HS 17 dialyzer (Medtronic)	Optiflux F180A (Fresenius)	Outcome
Internal Surface			Stable Sieving Coefficient of substances to retain and reduced rugosity and cell adhesion
Outer surface			Higher tolerance towards steam sterilization and Stable clearance
Cross Section			Improved clearance and marked separation between substances to retain and those to be eliminated

SEM imaging of rcs Clearum dialyzer fibers and comparison with original design and competitor dialyzer fibers
Author: Reza Jahanbekam, Date: June 16th, 2021, reviewer: Anna Belu, file name: 061621db

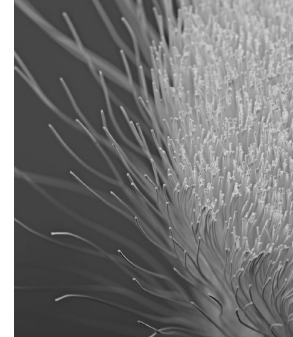


selective

consistent

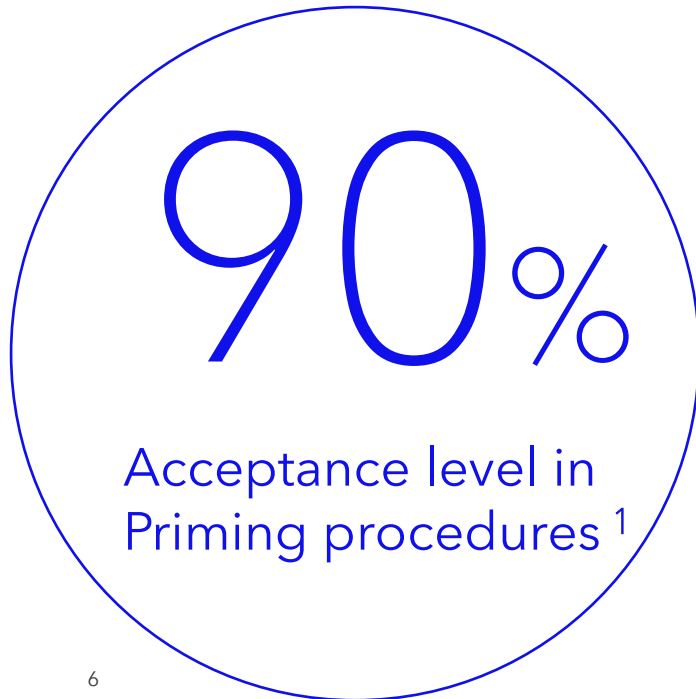
Performance

The **undulation** of the capillaries and a balanced **packing density** allows Clearum™ HS dialyzer to foster diffusion mechanisms



Users showed a strong acceptance level of Clearum™ HS dialyzer in priming procedures, **not only with Medtronic machines but also with the competitors ones:**

- Fresenius 5008
- Nikkiso DDB EXA
- Baxter Artis
- Nipro Surdial X
- Braun Dialog¹



selective

consistent

Usability



Conclusions from Limited Control Distribution Report (Western Europe):

Clearum™ HS dialyzer demonstrated strong or good acceptance with **priming, blood rest, packaging, and handling** with Medtronic and other machines on the market¹.

PRIMING

HANDLING

Polypropylene material used in Clearum™ HS dialyzer housing

is about 30% lighter than PC (polycarbonate), making it easier to manage for the operators².

1. Clearum™ HS dialyzer HS Series LCD Report_Rev00
2. TR_SUW_003_R00_Clearum Shipping Unit Weight Test Report

Green Aspects

- **Polypropylene** material reduces the carbon footprint by 60%¹
- 95% of the **water** and solvent can be **recovered and recycled**²
- **Steam Sterilization** process avoids releasing **ozone material**³

LOWER CO₂
EMISSION

WATER
RECOVERY

NO OZONE
RELEASE

1. Keoleian G, Miller S, De Kleine R, Fang A, Mosley J. Life Cycle Material Data Update for GREET Model. University of Michigan: Ann Arbor. 2012:1-74

2. The recovery system_percentage values of recovery_signed.

3. GIPA-IIA, 2017, A comparison of gamma, e-beam, x-ray and ethylene oxide technologies for the industrial sterilization of medical devices and healthcare products



Received: 20 March 2021

Revised: 19 April 2021

Accepted: 2 May 2021

DOI: 10.1111/aor.13993

MAIN TEXT ARTICLE



Efficacy and safety of the Clearum dialyzer

Francisco Maduell^{1,2} | **José Jesús Broseta¹** | **Diana Rodríguez-Espinosa¹** |
Evelyn Hermida-Lama¹ | **Elena Cuadrado-Payán¹** | **Lida María Rodas¹** |
Miquel Gómez¹ | **Marta Arias-Guillén¹** | **Néstor Fontseré¹** | **Manel Vera¹** |
Nayra Rico³

Aim of the study: efficacy and risk of hypoalbuminemia of Clearum compared with previously evaluated hemodialysis (HD), expanded hemodialysis (HDx) and postdilution hemodiafiltration (HDF) treatments.



Study design:

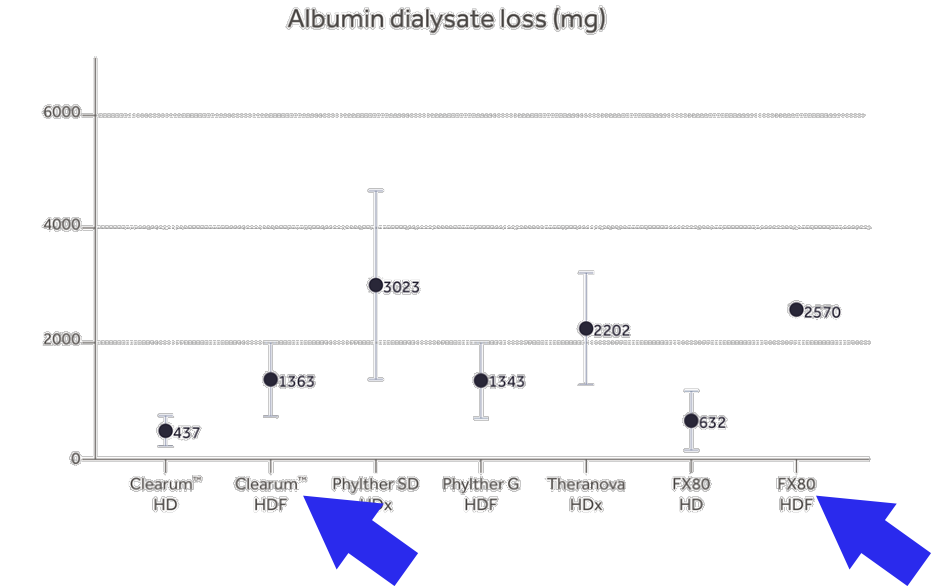
- Perspective, single center
- 15 patients, average age 68 ys (range 47-88)
- 7 dialysis sessions with «routine» hemodialysis

1. Clearum HS17 in HD
2. Clearum HS17 in HDF-post
3. Phylther HF17SD in HD (HDx)
4. Phylther 17G in HDF-post
5. Theranova 400 in HD (HDx)
6. FX80 Cordiax in HD
7. FX80 Cordiax in HDF-post

Clinical Experience



Reduction Ratio RR(%)		Clearum™ HS 17	Clearum™ HS 17	Phylther 17-SD	Phylther 17-G	Theranova 400	FX80 Cordiax	FX80 Cordiax
		HD	HDF	HDx	HDF	HDx	HD	HDF
Small Toxins	Urea (60 Da)	81.3 ± 4.2	84.0 ± 3.8	80.0 ± 5.1	84.2 ± 4.4	83.6 ± 5.1	81.9 ± 3.5	83.6 ± 4.8
	Creatinine (113 Da)	74.8 ± 4.7	78.3 ± 5.1	73.4 ± 5.4	78.5 ± 5.6	77.6 ± 5.4	77.0 ± 7.8	78.0 ± 5.9
Medium Toxins	β ₂ -microglobulin (11, 818 Da)	72.8 ± 7.7	85.2 ± 4.1	75.6 ± 4.1	83.0 ± 4.8	81.7 ± 4.9	77.2 ± 3.5	85.1 ± 3.9
	Myoglobin (17, 200 Da)	54.2 ± 7.9	75.8 ± 7.7	68.6 ± 6.8	73.4 ± 6.6	70.4 ± 7.0	43.7 ± 5.5	77.6 ± 6.9
	Prolactin (23, 000 Da)	50.4 ± 9.4	73.8 ± 9.0	65.7 ± 9.3	67.7 ± 6.6	70.4 ± 6.5	44.7 ± 8.8	75.3 ± 8.5
Large Toxins	α ₁ -micoglobulin (33, 000 Da)	12.2 ± 9.5	23.7 ± 10.5	24.0 ± 12.2	21.9 ± 15.1	22.1 ± 7.6	6.6 ± 11.4	26.4 ± 12.3
	α ₁ -acid glycoprotein (41, 000 Da)	6.8 ± 6.8	10.5 ± 6.7	11.0 ± 8.8	10.6 ± 9.8	15.6 ± 7.9	4.7 ± 8.6	18.2 ± 11.4
	Albumin (66,000 Da)	7.6 ± 5.3	8.3 ± 6.2	7.2 ± 6.6	10.7 ± 7.5	10.0 ± 7.1	7.1 ± 6.8	8.5 ± 7.6



- No differences between small molecules
- Clearum dialyzer in HDF obtained similar results to the Helixone in HDF, slightly superior to the polyphenylene dialyzer also in HDF, and statistically superior results to both dialyzers in HDx
- Albumin losses with the Clearum dialyzer were among the lowest

Q&A

Thank you

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

© 2022 Medtronic. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. ^{™*} Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic.

EMEA-RC-2200026-era-22-clearum-in-booth-presentation-en-we-6930624

Medtronic