RENAL CARE



SUREFLUX™

SYMMETRIC CELLULOSE TRIACETATE DIALYZER

NIPRO

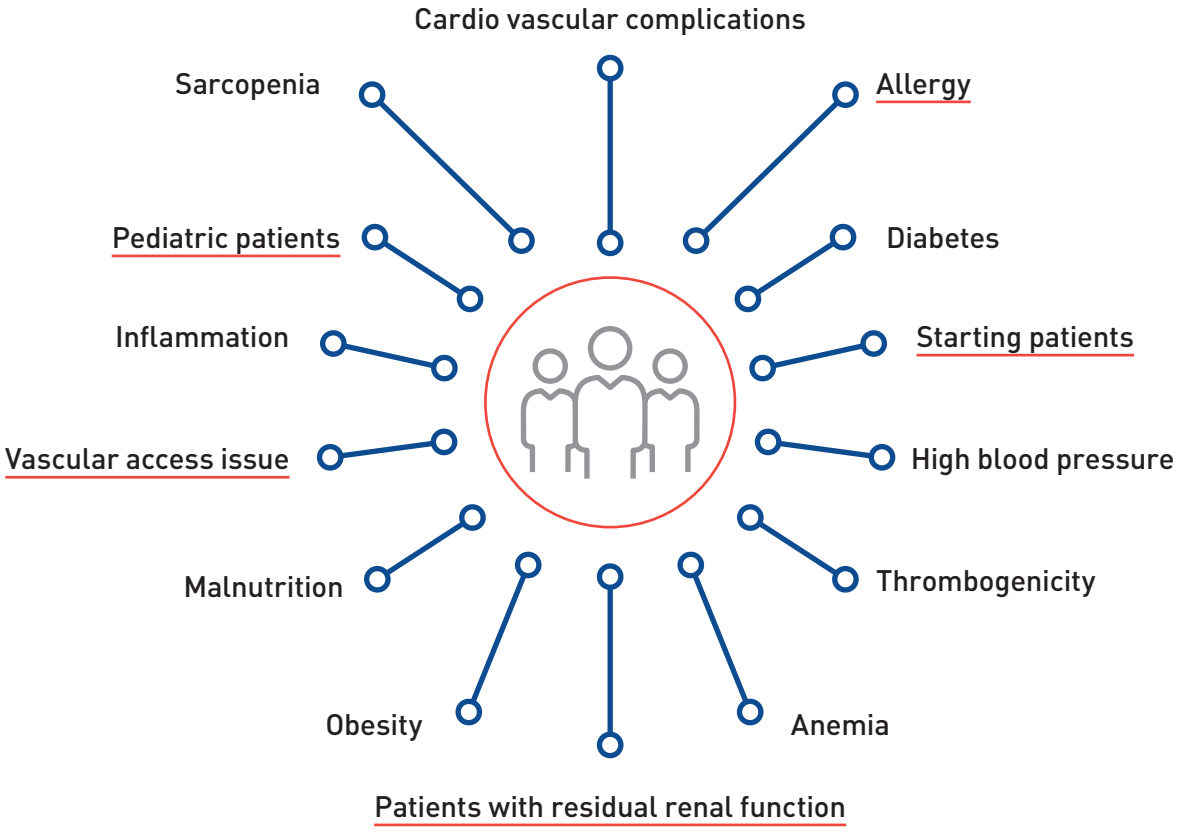
SUREFLUX™: your dialyzer of choice for safe and efficient hemodialysis (HD) treatments

Chronic kidney disease (CKD) affects more than 10% of the world's population. For end stage renal disease patients, dialysis is still the main life-sustaining treatment. However, dialysis patients have **several comorbidities and variable medical needs**.

The CKD **patient starting hemodialysis** has a **fragile and unstable** clinical condition. Initiating dialysis for these patients can be challenging since the fluid removal and clearance of uremic toxins can be poorly tolerated.[1]

Pediatric patients constitute another group of **fragile and sensitive** patients posing lots of challenges to maintain their natural growth and limit their exposure to chemicals and synthetic materials.[2]

Yet another challenge is the hypersensitivity of patients to the foreign materials in the extracorporeal circuit that can trigger unexpected events. **Allergy** to the components of the circuit, and particularly the **dialysis membrane**, can cause immediate or delayed response in patients. The extent of these responses can be variable from mild allergic symptoms to life-threating anaphylactic shocks.[3]



Next to the medical indications, technical issues add another layer of complexity to dialysis treatments. For instance, in patients with **bad vascular** access limiting the reach of efficient convective volumes, HDF treatment is impossible.[4] For these patients, the choice of the **best possible dialyzer** to increase the dialysis efficiency becomes crucial.

Not all dialysis patients are similar. For complex patients we need to offer an **individualized** treatment to meet **their specific medical needs**.

The causes of allergic reactions in hemodialysis

The reported prevalence of allergic reactions during and after dialysis treatment is estimated at **more than 1 in 50 patients**.[3] The use of synthetic membranes in dialysis patients is notoriously associated with these allergic reactions.

The most notorious allergens in the hemodialysis circuit are:

- Synthetic dialyzer fibers (membranes)
- Materials containing Bisphenol A (BPA), Di-2-ethylhexyl phthalate (DEHP), or Polyvinylpyrrolidone (PVP)

Causative membrane	% Allergic reactions
Polysulfone	69,7%
Polyethersulfone (PES)	27,0%
Polyacrylnitrile (PAN)	3,0%
Cellulose-derivates	0,0%



SUREFLUX relieves hypersensitivity reactions

Case Report : 1

One of the most striking evidence of hypersensitivity to the synthetic membranes reported in a study by Dr Martín-Navarro is the case of a dialysis patient who showed **severe anaphylactic reactions to several synthetic membranes (Polyflux, Nephral, and FX80)**. Finally, **only the use of SUREFLUX could normalize the severe symptoms of the patient** enabling the continuation of the dialysis treatment.[5]

> *" This case provides new information on the effectiveness of cellulose triacetate (CTA) membranes in intolerance to synthetic membranes."* [5]

More evidence

"A key finding in the cases in our department is that all hypersensitivity reactions disappeared after changing the dialyzer to cellulose triacetate." [8]

"Cellulose triacetate membranes appear to be a good alternative for hypersensitive patients." [3]

Pruritus is common, but does it have to be?

In general, pruritus (itchy skin) in hemodialysis patients is thought to be caused by the accumulation of uremic toxins. The percentage of patients who are at least moderately bothered by itchy skin ranged from 26% in Germany to 48% in the UK.[6]

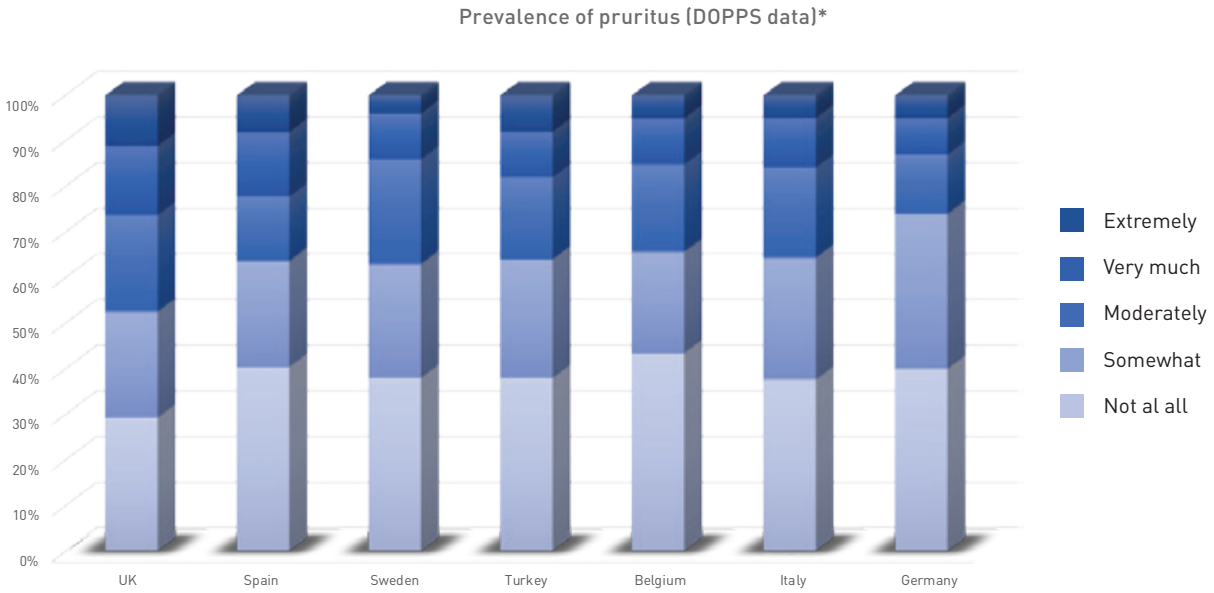


Figure adapted from Rayner HC et al 2017, Clin J Am Soc Nephrol.
*DOPPS: Dialysis Outcome and Practice Patterns Study

78% of patients with pruritus were relieved after switching dialyzers[7]

9 hemodialysis patients treated with polysulphone or polymethyl methacrylate (PMMA) dialyzer membranes were presented with persistent pruritis. **After switching to cellulose triacetate dialyzers, pruritis improved in 7 out of the 9 patients**.

Important note: additional removal of uremic toxins was not a factor in ameliorating pruritis, as there was no difference in Kt/V in between treatments with the different dialyzers.

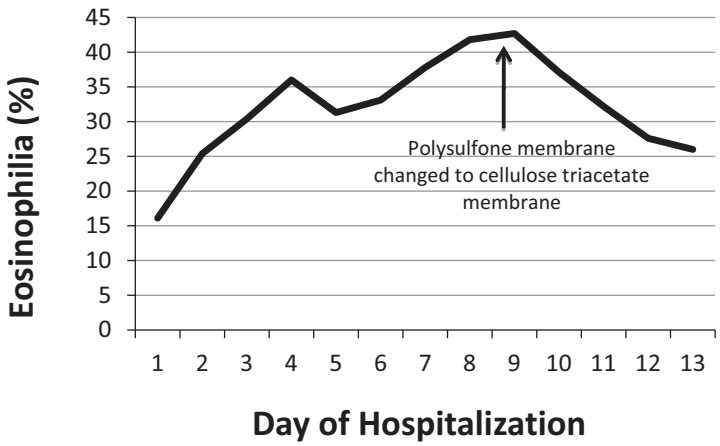


Case Report : 2

Severe anaphylaxis resolved by SUREFLUX

Hypersensitivity to membrane material can lead to a severe response as was the case for the following patient. While using a **polysulfone membrane** the patient demonstrated severe anaphylactic shock.

After ruling out hypersensitivity to ACE inhibitors and anticoagulation, **only changing the dialyzer to CTA, could resolve** the immunoglobulin E-mediated **allergic response** in the patient.[9]



Eosinophilia (increase and activation of eosinophils mediated by immunoglobulin E) was only normalized after switching from polysulfone to CTA membrane.

Less allergic reactions with SUREFLUX thanks to its high biocompatibility

SUREFLUX offers high biocompatibility due to:

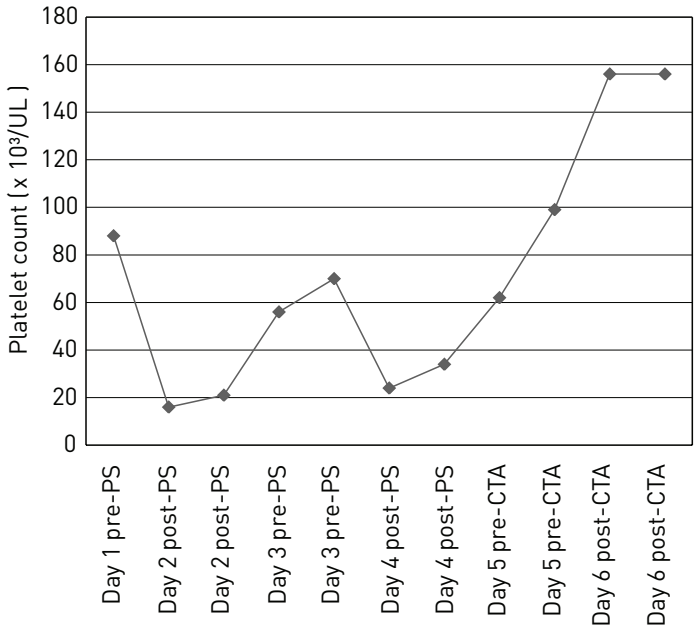
- high hydrophilicity of the semi-synthetic membrane and no need for PVP, contrary to the majority of synthetic membranes
- use of the biocompatible glycerol as a pore-forming and pore-stabilizing agent
- not containing bisphenol A (BPA) in its polymer structure



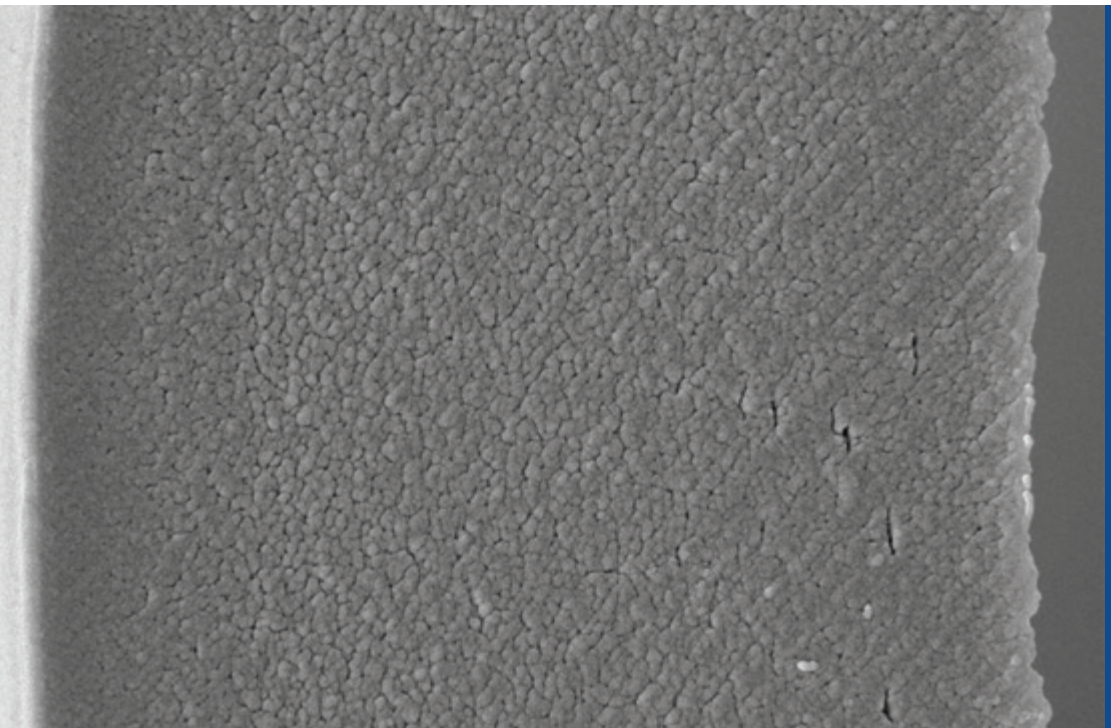
Case Report : 3

Less undesired blood-membrane interactions

For patients at risk of thrombocytopenia, the use of a biocompatible membrane is essential. This case is a proof of principle that the rise and fall in the pre- and post-dialysis platelet levels when using a synthetic polysulfone membrane can be reversed to **stable platelet levels by switching to a CTA membrane**.[14]



"In patients at high risk for thrombocytopenia during hemodialysis, the modified cellulose membranes could be a better alternative to the standard synthetic membranes in preventing dialyzer membrane-associated thrombocytopenia." [14]



Membrane cross section (x 2000)

- Symmetric cellulose triacetate membrane
- Ideal for HD treatments

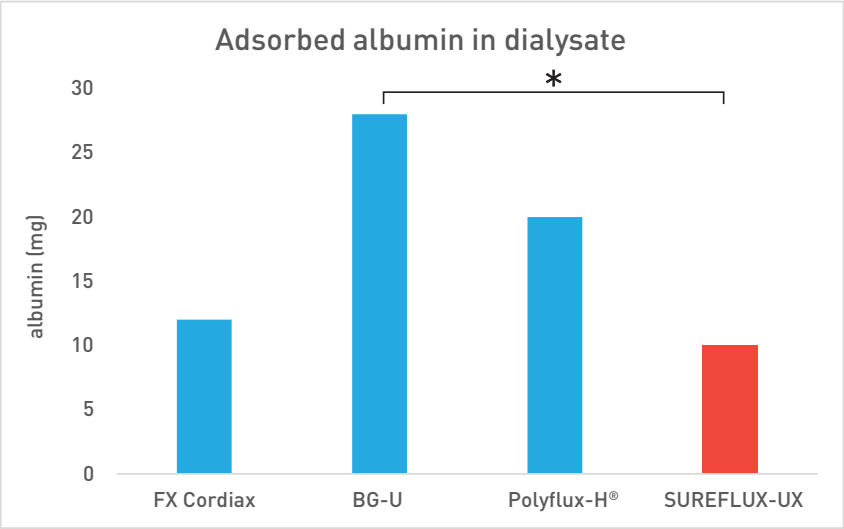
Albumin retention

Hypoalbuminemia, common among dialysis patients, is directly linked to **higher all-cause and cardiovascular mortality risks**.[20, 21]

Chronic inflammation and malnutrition limits albumin synthesis in patients - therefore it is essential for them to retain as much albumin as possible during dialysis.[22]

The choice of the dialyzer can directly affect the amount of albumin loss during a dialysis session.

SUREFLUX has shown the lowest amount of albumin loss in comparison with other dialyzers in HD while maintaining a superior removal of middle molecule uremic toxins.[19]



The lowest albumin in dialysate is seen for SUREFLUX. Prospective, randomized single center study; N=22, HD, average Qd: 403 mL/min, average Qb: 399 mL/min.

Adsorption of biocompatible molecules

In this in vitro study, it was proven that SUREFLUX has a higher adsorption of albumin and specific apolipoproteins in comparison with a polysulfone membrane.

Proteins more retained by polysulfone	Proteins more retained by SUREFLUX
Hemoglobin chains: shear stress and partial hemolysis	**Albumin:** protein's relative lack of glycosylation, which prevents platelet adhesion
Ficolin 2: activation of the complement pathway	**Apolipoprotein:** increase of biocompatibility
Fibrinogen: pro-coagulatory activity	—

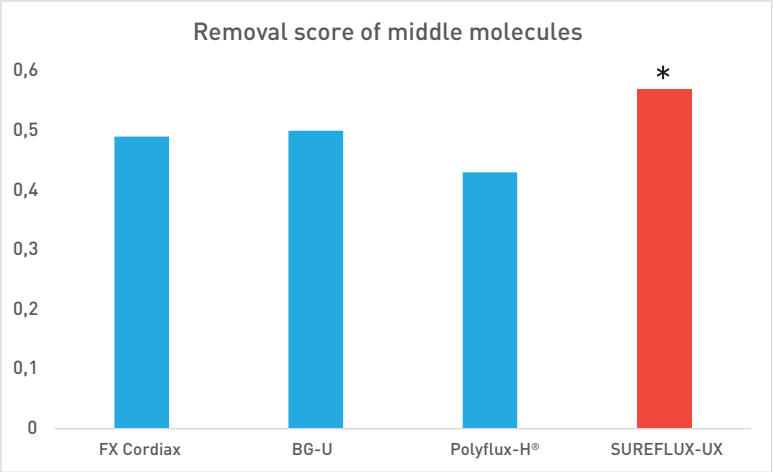
The selective adsorption of biocompatible molecules in SUREFLUX, results in a **less complement and pro-coagulation response in the blood-dialyzer interaction**.[13]

Removal of middle size molecules

In CKD, the accumulation of uremic toxins has a direct impact on the survival of patients through increasing inflammation, infections, and vascular damage.[15-16]

A surrogate marker of middle molecular uremic toxins, **Beta2 microglobulin (β2M)** is evidenced as an independent predictor of **all-cause mortality and cardiovascular events**.[17] The HEMO study has demonstrated an 11% higher mortality rate for a 10 mg/L increase in serum β2M levels.[18]

SUREFLUX shows a superior efficiency in the removal of middle molecules in comparison to other dialyzers in HD.[19]



Significantly higher mid-range global removal score in SUREFLUX vs each of the dialyzers in HD. Prospective, randomized single center study; N=22, average Qd: 403 mL/min, average Qb: 399 mL/min. The removal score includes : creatinine, β2M, myoglobin, prolactin, α-1-microglobulin), and assuming albumin removal as a negative effect.[19]

Safe and efficient use in SLED

Managing the acute kidney injury in critically ill patients is rather complicated due to several severe comorbidities in these patients. [23] **Sustained Low-Efficiency Dialysis (SLED)** is increasingly used for these patients and is shown to have a comparable 90-day survival compared to the conventional continuous veno-venous hemofiltration.[24]

Due to an increase in the amount of time, one of the biggest challenges with the SLED technique is the avoidance of clotting in the dialyzer where the choice of **the biocompatible dialyzer becomes critical**. Fiaccadori et al. have demonstrated the **successful treatment with SUREFLUX** in a total of 41 SLED sessions on 12 patients using an **HD-dedicated machine** Surdial X and regional citrate anticoagulation **reaching nearly prescribed dialysis doses**.[25]

This study is a proof of concept on the **safe and efficient use of SUREFLUX in SLED**, without major clotting issues.



Pediatric-range dialyzer

The prevalence of dialysis among children has been stably growing offering a life-sustaining solution.[26] For this vulnerable group of patients, **maintaining their residual kidney function**, natural growth, and state of well-being are extremely crucial.

Studies have suggested that **residual renal function increases the survival** of infants and have a positive effect on their growth and nutrition. [27] Currently, the majority of the pediatric patients are treated with synthetic membranes with polycarbonate housing made with **BPA**.[2] Leaching of BPA during pediatric treatment can **decrease their residual renal function and increase their propensity for allergic reactions**.[28]

Moreover, the size of the extracorporeal blood volume including the dialyzer should be kept as minimum as possible to avoid the risk of hypotension and fluid overload.[29]

SUREFLUX, which is not made with BPA and has a pediatric-tailored membrane size, provides the best solution for children in dialysis and guarantees their safety and well-being.


NIPRO HEMODIALYZER
SUREFLUX™-25UX
NIPRO HEMODIALYZER
SUREFLUX™-05L
BPA FREE
DEHP FREE
0,5m² / TMP 66kPa (500mmHg)
MADE IN JAPAN
EN HEMODIALYZER
DE HAEMODIALYSATOR
FR HÉMODIALYSEUR
ES HEMODIALIZADOR
IT EMODIALIZZATORE
NL HEMODIALYSEMACHINE
PT HEMODIALISADOR
EL ΣΥΣΚΕΥΗ ΑΙΜΟΚΑΘΑΡΣΗΣ
SV HEMODIALYSATOR
DA DIALYSEAPPARAT
NO HEMODIALYSEMASKIN
FI HEMODIALYSAATTORI
RU ДИАЛИЗАТОР
PL HEMODIALIZATOR
RO HEMODIALIZOR
BG ХЕМОДИАЛИЗАТОР
CS HEMODIALYZÁTOR
TR HEMODİYALİZÖR
HR HEMODIJALIZATOR
HU HEMODIALIZÁTOR
LT HEMODIALIZATORIUS
LV HEMODIALIZATORS
SK HEMODIALYZÁTOR
SL DIALIZATOR KRVI
ET HEMODIALÜÜSISÜSTEEM
TH เครื่องไตเทียม
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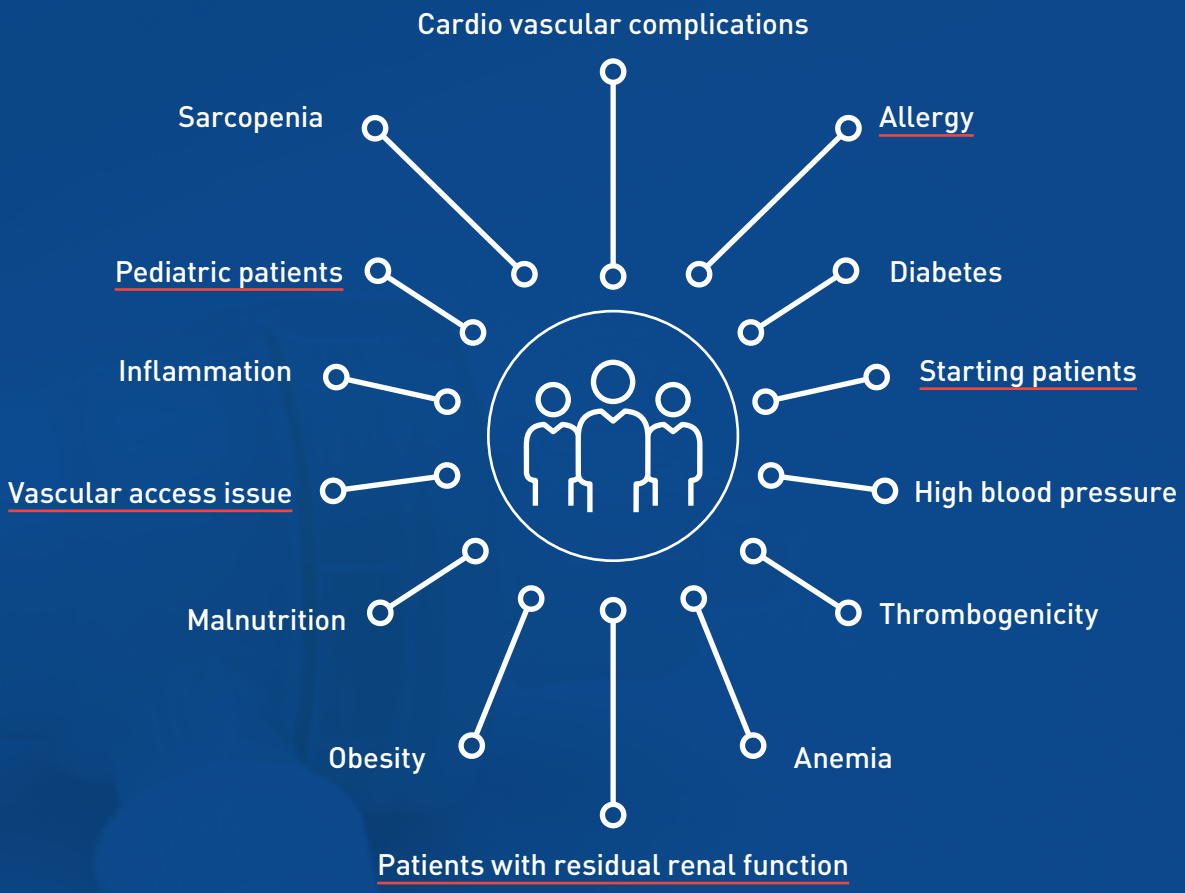
SUREFLUX, a highly biocompatible symmetric cellulose triacetate dialyzer offers:

A large portfolio for HD treatments:

- The best alternative for allergic patients
- Relieves hypersensitive reactions
- Ideal for pediatric patients
- Safe and efficient in SLED
- Gentle and efficient for starting patients



SUREFLUX™ E

NOT MADE WITH BPA

PERFORMANCE

Clearance (mL/min)*1	Qb/Qd (mL/min)	05E	07E	09E	11E	13E	15E	17E	19E	21E
Urea	200/500	151	168	177	187	191	194	196	198	199
	300/500	182	208	227	243	258	265	274	279	284
	400/500	193	227	253	270	283	297	306	313	317
Creatinine	200/500	125	146	160	173	178	183	189	191	194
	300/500	144	171	189	207	217	229	238	244	251
	400/500	152	185	213	230	247	259	271	280	286
Phosphate	200/500	102	119	132	146	155	161	169	174	177
	300/500	108	137	155	172	186	195	203	215	221
	400/500	115	149	167	191	207	218	230	244	254
Vitamin B12	200/500	55	69	81	91	101	109	118	124	130
	300/500	58	75	88	95	107	118	127	136	146
	400/500	61	80	95	104	117	127	137	149	159
KUF (mL/hr/mmHg)*2		9	11	12	14	17	18	19	22	25

*1 *In Vitro* Test Condition (EN1283/ ISO8637) : Qf 0 mL/min at Qd 500 mL/min
*2 KUF (EN1283/ ISO8637) : Bovine blood (Hct 32±2 %, Protein 60 g/L, 37 °C at Qb 300 mL/min

SPECIFICATIONS

	05E	07E	09E	11E	13E	15E	17E	19E	21E
Effective Surface (m²)	0.5	0.7	0.9	1.1	1.3	1.5	1.7	1.9	2.1
Priming Volume (mL)	35	45	56	68	78	90	101	113	122
Effective Length (mm)	165	176	191	205	216	227	236	245	254
Inner Diameter (µm)	200	200	200	200	200	200	200	200	200
Membrane Thickness (µm)	15	15	15	15	15	15	15	15	15
Maximum TMP (mmHg)	500	500	500	500	500	500	500	500	500

SUREFLUX™ L

PERFORMANCE

Clearance (mL/min)*1	Qb/Qd (mL/min)	03L	05L	07L	09L	11L	13L	15L	17L	19L	21L
Urea	200/500	92	141	160	172	182	187	191	194	196	197
	300/500	103	169	193	217	236	248	258	265	272	276
	400/500	111	183	210	241	261	278	292	302	307	312
Creatinine	200/500	70	114	134	151	166	173	179	183	187	190
	300/500	78	130	156	181	199	211	224	234	241	246
	400/500	85	139	175	201	219	234	250	265	274	281
Phosphate	200/500	50	90	100	119	131	142	150	158	163	167
	300/500	57	96	114	137	151	163	177	187	198	205
	400/500	62	110	127	145	164	180	197	211	222	227
Vitamin B12	200/500	24	44	55	67	76	84	93	102	109	116
	300/500	25	45	57	72	83	93	104	115	121	131
	400/500	26	50	63	77	87	97	110	119	130	138
KUF (mL/hr/mmHg)*2		3	5	7	8	10	12	14	17	19	22

*1 *In Vitro* Test Condition (EN1283 / ISO8637) : Qf 0 mL/min at Qd 500 mL/min
*2 KUF (EN1283/ ISO8637) : Bovine blood (Hct 32±2 %, Protein 60 g/L, 37 °C at Qb 300 mL/min

SPECIFICATIONS

	03L	05L	07L	09L	11L	13L	15L	17L	19L	21L
Effective Surface (m²)	0.3	0.5	0.7	0.9	1.1	1.3	1.5	1.7	1.9	2.1
Priming Volume (mL)	22	35	45	56	68	78	90	100	113	123
Effective Length (mm)	165	165	176	191	205	216	227	236	245	254
Inner Diameter (µm)	200	200	200	200	200	200	200	200	200	200
Membrane Thickness (µm)	15	15	15	15	15	15	15	15	15	15
Maximum TMP (mmHg)	500	500	500	500	500	500	500	500	500	500

SUREFLUX™ UX

NOT MADE WITH BPA

PERFORMANCE

Clearance (mL/min)*1	Qb/Qd (mL/min)	11UX	13UX	15UX	17UX	19UX	21UX	25UX
Urea	200/500	193	194	197	197	199	200	200
	300/500	251	262	270	276	281	285	286
	400/500	289	304	317	328	336	344	352
	400/800	325	342	354	364	371	377	381
	500/800	391	412	427	440	450	457	467
Creatinine	200/500	181	186	192	195	197	198	200
	300/500	240	245	255	265	270	274	282
	400/500	266	283	294	304	316	323	334
	400/800	290	310	325	336	347	356	364
	500/800	326	347	366	383	397	410	428
Phosphate	200/500	166	173	179	184	187	190	192
	300/500	205	219	231	245	253	260	269
	400/500	236	255	270	283	301	317	329
	400/800	257	277	294	309	321	331	343
	500/800	290	305	331	342	353	369	385
Vitamin B12	200/500	131	142	150	157	163	169	175
	300/500	149	165	178	189	199	208	219
	400/500	161	178	193	207	219	229	244
	400/800	170	190	207	223	236	249	267
	500/800	182	204	224	242	258	272	295
Inulin	200/500	83	95	104	112	119	125	133
	300/500	92	107	117	124	133	143	153
	400/500	99	112	125	137	147	157	175
	400/800	104	118	132	145	157	168	187
	500/800	118	136	152	167	181	192	211
Myoglobin	200/500	50	57	64	70	76	82	92
	300/500	56	64	72	80	87	94	108
	400/500	67	77	87	96	105	110	121
	400/800	70	80	89	99	109	118	135
	500/800	71	83	93	105	113	124	141
KUF (mL/hr/mmHg)*2		25	30	35	38	41	46	53
Sieving Coefficient*3	Vitamin B12	0.993	*1 *In Vitro* Test Condition (EN1283 / ISO8637) : Qf 0 mL/min *2 KUF (EN1283/ ISO8637) : Bovine blood (Hct 32±2 %, Protein 60 g/L, 37 °C), Qb 300 mL/min *3 SC (EN1283/ ISO8637) : Qb 300 mL/min, Qf 60 mL/min					
	Inulin	0.946						
	Myoglobin	0.652						
	Albumin	0.005						

SPECIFICATIONS

	11UX	13UX	15UX	17UX	19UX	21UX	25UX
Effective Surface (m²)	1.1	1.3	1.5	1.7	1.9	2.1	2.5
Priming Volume (mL)	66	76	88	98	109	119	142
Effective Length (mm)	205	216	227	236	245	254	280
Inner Diameter (µm)	200	200	200	200	200	200	200
Membrane Thickness (µm)	15	15	15	15	15	15	15
Maximum TMP (mmHg)	500	500	500	500	500	500	500

Very selective sieving properties.

- High removal of low molecular weight proteins.
- Minimized albumin loss.

Excellent biocompatibility:

- Triacetate, used as hollow fiber material, ensures outstanding biocompatibility and low thrombogenicity.

Materials

Membrane : Cellulose Triacetate
Housing : Polypropylene
Header : Polypropylene
Potting Compound : Polyurethane

Sterilization Method

Dry Gamma

Packaging

24 pcs/box

Clearance data obtained in Japan. Clearance data can vary slightly depending on the test setup, lot nr. and production site.

References

1. McIntyre CW, et al. Starting dialysis is dangerous: how do we balance the risk? Kidney Int. 2012
2. Benz M.R. SF. Technical Aspects of Hemodialysis in Children. Pediatric Dialysis Springer. 2012
3. Esteras R, et al. Incidence of Hypersensitivity Reactions During Hemodialysis. Kidney Blood Press Res. 2018
4. Maduell F, et al. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients. J Am Soc Nephrol. 2013
5. Martín-Navarro JA, et al. Hypersensitivity to synthetic hemodialysis membranes. Nefrologia. 2014
6. Rayner HC, et al. International Comparisons of Prevalence, Awareness, and Treatment of Pruritus in People on Hemodialysis. Clin J Am Soc Nephrol. 2017
7. Dolley-Hitze T. poster SFNDT congress. 2018
8. Sánchez-Villanueva RJ, et al. Hypersensitivity reactions to synthetic haemodialysis membranes. Nefrologia. 2014
9. Sayeed K, et al. Anaphylactic Shock at the Beginning of Hemodialysis. Semin Dial. 2016
10. Melzer D, et al. Urinary bisphenol A concentration and risk of future coronary artery disease in apparently healthy men and women. Circulation. 2012
11. Shankar A, et al. Relationship between urinary bisphenol A levels and diabetes mellitus. J Clin Endocrinol Metab. 2011
12. Konishi S, et al. Eluted substances from hemodialysis membranes elicit positive skin prick tests in bioincompatible patients. Artif Organs. 2015
13. Ronci M, et al. Proteomic Characterization of a New asymmetric Cellulose Triacetate Membrane for Hemodialysis. Proteomics Clin Appl. 2018
14. Olafiranye F, et al. Resolution of dialyzer membrane-associated thrombocytopenia with use of cellulose triacetate membrane: a case report. Case Rep Med. 2011
15. Ikizler TA. Optimal nutrition in hemodialysis patients. Adv Chronic Kidney Dis. 2013
16. Cohen G. Immune Dysfunction in Uremia 2020. Toxins (Basel). 2020
17. Foster MC, et al. Serum β-Trace Protein and β2-Microglobulin as Predictors of ESRD, Mortality, and Cardiovascular Disease in Adults With CKD in the Chronic Renal Insufficiency Cohort (CRIC) Study. Am J Kidney Dis. 2016
18. Cheung AK, et al. Serum beta-2 microglobulin levels predict mortality in dialysis patients: results of the HEMO study. J Am Soc Nephrol. 2006
19. Gomez M, et al. Distinct Solute Removal Patterns by Similar Surface High-Flux Membranes in Haemodiafiltration: The Adsorption Point of View. Blood Purif. 2021
20. Fishbane S, et al. Update on Anemia in ESRD and Earlier Stages of CKD: Core Curriculum 2018. Am J Kidney Dis. 2018
21. Iimori S, et al. Anaemia management and mortality risk in newly visiting patients with chronic kidney disease in Japan: The CKD-ROUTE study. Nephrology (Carlton). 2015
22. Kim S, et al. Hypoalbuminemia and Clinical Outcomes: What is the Mechanism behind the Relationship? Am Surg. 2017
23. Kes P, et al. Acute kidney injury in the intensive care unit. Bosn J Basic Med Sci. 2010
24. Schwenger V, et al. Sustained low efficiency dialysis using a single-pass batch system in acute kidney injury - a randomized interventional trial: the REnal Replacement Therapy Study in Intensive Care Unit PatiEnts. Crit Care. 2012
25. Di Mario F, et al. P1056 sustained low efficiency dialysis (sled) with standard hemodialysis machine and citrate as circuit anticoagulant in critically ill patients with acute kidney injury. Nephrology Dialysis Transplantation. 2020
26. Bonthuis M, et al. Ten-year trends in epidemiology and outcomes of pediatric kidney replacement therapy in Europe: data from the ESPN/ERA-EDTA Registry. Pediatric Nephrology. 2021
27. Chesnaye NC, et al. Survival in children requiring chronic renal replacement therapy. Pediatr Nephrol. 2018
28. Quiroga B. Strategies to Protect Dialysis Patients against Bisphenol A. Biomolecules. 2021
29. Fischbach M, et al. Hemodialysis in children: general practical guidelines. Pediatr Nephrol. 2005

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Nipro Renal Care is a global market leader with over 6 decades providing renal solutions for dialysis and dialysis-related treatment. We specialize in developing dialysis machines, water treatment systems, and a comprehensive portfolio of disposable medical equipment.

In order to address the needs of patients, healthcare professionals, and procurement managers alike, Nipro Renal Care is driven by innovation and patient safety to offer the highest quality products that optimize time, effort, and costs.

LIVE LONGER. LIVE BETTER.

Please contact your local representative for more information.

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