RENAL CARE

Allergic diseases are on the rise worldwide.

Is there a solution that meets the therapeutic needs of allergic patients and improves their quality of life?

ALLERGIC REACTIONS DURING HEMODIALYSIS

NIPRO MEDICAL EUROPE

Allergies are a growing public health concern[1,2]

150 million Europeans suffer from chronic allergic disease

Allergies are now one of the most common chronic diseases in Europe

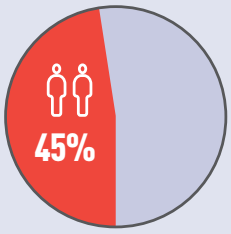
Once considered a rare disease, today more than 150 million Europeans suffer from chronic allergies. The current prediction is that half of the entire EU population will be affected by an allergy by 2025.

Growing number of lives negatively affected

Up to 20% of patients with allergies live with a severely debilitating form of their condition. Reduced quality of life goes beyond physical constraints and mental/emotional stress. Educational performance, career progression, and overall personal development may be negatively impacted.

100 million

Asthma and allergic rhinitis alone are estimated to result in more than ***100 million*** lost workdays and missed school days in Europe every year.



45% of allergy patients are likely to be misdiagnosed in the EU

Misdiagnosis is a serious problem

In addition to the negative impact on quality of life, level of care, and healthcare provider workload, there is an additional economic burden due to misdiagnoses. The avoidable indirect costs within the EU is estimated between € 55-151 billion per year.

While allergies pose general health and economic concerns...

How do they affect hemodialysis patients and treatments?

Awareness of allergic reactions during hemodialysis is warranted

The reported prevalence of allergic reactions during and after treatment is estimated at more than 1 in 50 patients.[3]

1 in 50 patients

The prevalence of allergic reactions is thought to be underestimated

- Not all patients report symptoms
  17% of patients with severe pruritus did not mention it to their healthcare provider[4]
- Symptoms are not always recognized
  In 69% of facilities, medical directors underestimated the prevalence of pruritus[4]
- Allergic reactions can be mistaken for:[5]
  - symptoms of end stage renal disease[6]
  - side effects of hemodialysis treatment[7]
  - symptoms of other pathologies[8,9]

Symptoms of allergic reactions	Symptoms of end stage renal disease	Side effects of hemodialysis treatment
Nausea and vomiting	Nausea	Nausea and vomiting
Itching	Itching	-
Dyspnea	Dyspnea	Dyspnea
Abdominal cramps	Pain, cramps, or numbness in legs or feet	Abdominal cramps
Hypotension	Hypertension	Hypotension

Non-exhaustive list of symptoms associated with allergic reactions[5], end stage renal disease[6], and side effects of hemodialysis treatment.[7]

So how can healthcare providers recognize allergic reactions in their hemodialysis patients?

The cause of allergic reactions in hemodialysis

A patient's immune system may recognize the otherwise harmless material composition of the extracorporeal circuit as a "foreign entity" and react against it. In this case, the dialyzers and/or bloodlines become allergens.

Most notorious allergens in the hemodialysis circuit

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

Membranes that caused hypersensitivity reactions[3]

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

All dialyzers that provoked allergic reactions had synthetic membranes, with polysulfone as the most common cause.[3]

Membranes that relieved hypersensitivity reactions

"Our observations suggest that the dialyzers containing modified cellulose, polyacrylonitrile (PAN) and polymethylmethacrylate (PMMA) can be used unreservedly in patients reacting to polysulfone or polyethersulfone dialysers. Most experience is available with cellulose triacetate dialyzers."

Boer WH, Liem Y, de Beus E, Abrahams AC. Acute reactions to polysulfone/ polyethersulfone dialysers: literature review and management. Neth J Med. 2017 Jan; 75(1) :4-13.

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

Esteras R, Martín-Navarro J, Ledesma G, Fernández-Prado R, Carreño G, Cintra M, Cidraque I, Sanz I, Tarragón B, Alexandru S, Milla M, Astudillo E, Sánchez E, Mas S, Tejeiro RD, Ortiz A, Sánchez R, González-Parra E. Incidence of Hypersensitivity Reactions During Hemodialysis. Kidney Blood Press Res. 2018;43(5):1472-1478:

Cellulose triacetate membranes are preferred for patients allergic to synthetic membranes. But how do you recognize the need to switch?

Know the common misinterpretations in daily practice

Allergic hypotension to polysulfone membranes misinterpreted as cardiovascular-related complications[8]

Female patient (84 years old) presented with hypotension, precordial pain, and occasional dyspnea and chest tightness during hemodialysis.

Symptoms were first attributed to her cardiovascular history.

Oxygen therapy and low ultrafiltration rate did not improve symptoms.

Solution:

When switched from polysulfone membrane to cellulose triacetate dialyzer membranes, hypotension disappeared, and hemodialysis tolerance improved.

Allergic fevers to polysulfone membranes masquerading as infection[9]

Male patient (79 years old) presented with chest pain, light headedness, dyspnea, fever, and chills – during and after hemodialysis.

Dyspnea was initially attributed to fluid overload and fever was thought to be due to recurrent pneumonia.

Cultures were negative, while respiratory, abdominal, and cardiovascular findings unremarkable.

Solution:

When switched from a polysulphone to a cellulose triacetate membrane dialyzer, the patient's symptoms resolved.

In what other ways can patients experience discomfort or treatment intolerance due to allergic reactions?

Pruritus is common, but does it have to be?

Itchy skin in HD patients

In general, pruritus (itchy skin) in hemodialysis patients is thought to be caused by the accumulation of uremic toxins. The percentage of patients at least moderately bothered by itchy skin ranged from 26% in Germany to 48% in the UK.[4]

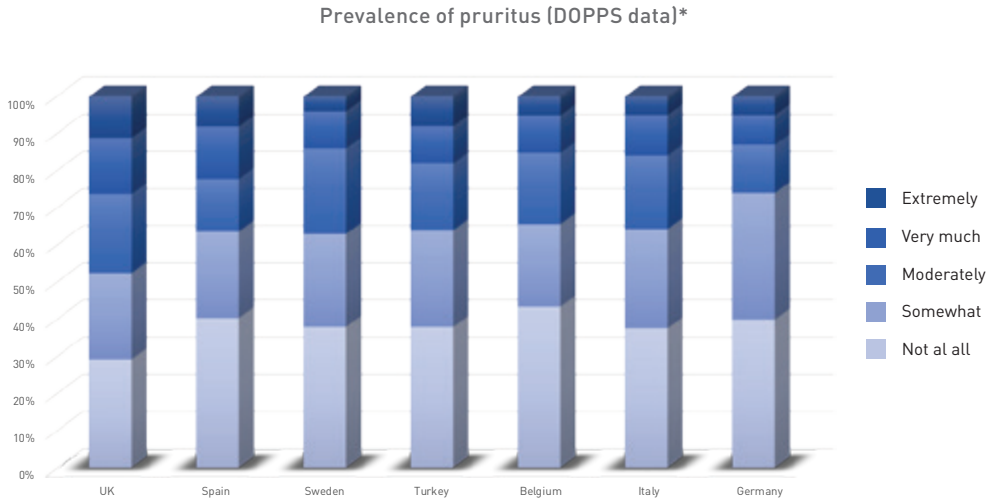


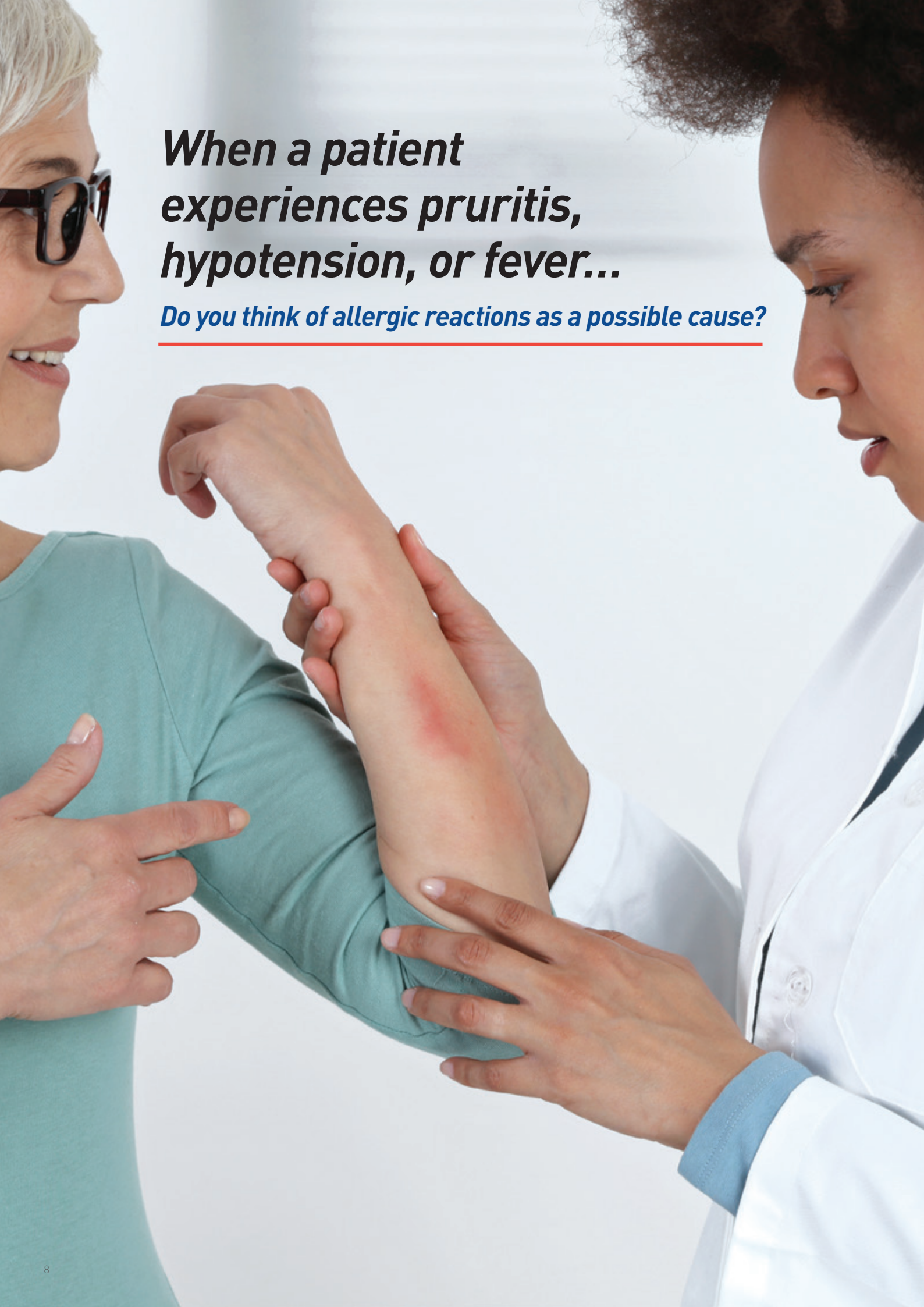
Figure adapted from Rayner HC et al 2017, Clin J Am Soc Nephrol.
*DOPPS: Dialysis Outcome and Practice Patterns Study

For patients with pruritus, 78% were relieved after switching dialyzers[11]

9 hemodialysis patients treated with polysulfone or PMMA dialyzer membranes were presented with persistent pruritis.

After switching to cellulose triacetate dialyzers, pruritis improved in 7 out of the 9 patients.

Important to 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.



When a patient experiences pruritis, hypotension, or fever...

Do you think of allergic reactions as a possible cause?

Allergic reactions in hemodialysis cannot be ignored

Allergic responses may seriously complicate treatments and initiate a negative cascade on patients, healthcare professionals, and society at large:

Patients

- Further reduction in quality of life
- Interruption of and therefore inadequate hemodialysis treatment
- Negative experience during hemodialysis sessions
- Severe allergic reactions can be life-threatening

Healthcare professionals

- Increased workload due to increased interventions by nurses
- Increased stress and pressure to perform due to possible life-threatening complications

Society

- Increased costs for testing, medications, and interventions

Recognizing allergic reactions is an integral part of daily practice

1. Know the potential allergens
2. Be alert for allergic responses masquerading as other complications
3. If allergic symptoms appear: switch to an extracorporeal circuit composed of hypoallergenic materials: cellulose triacetate membrane dialyzer or materials free of BPA, DEHP, and PVP

Nipro's solution: low allergenic dialyzers

We offer two dialyzers composed of biocompatible cellulose triacetate membrane: SUREFLUX™ and SOLACEA™.

Both dialyzers are non-synthetic and free of BPA, DEHP, and PVP - making them an ideal choice for patients with allergic reactions.

SUREFLUX™

Highly biocompatible, symmetric cellulose triacetate dialyzer.

A large portfolio for HD treatments

- Different pore sizes: low (L-series), medium (E-series), and high (UX-series) flux
- Broad surface range: 0,3 - 2,5m²

Offers several therapeutic options for your smallest to your largest allergic patient in HD.

SOLACEA™

Highly biocompatible, asymmetric cellulose triacetate dialyzer.

Unique combination for high volume HDF treatments:

- Cellulose triacetate membrane: low allergenic and optimal biocompatibility
- Asymmetric membrane structure enables online HDF with large convective volumes and clearance of middle molecular weight molecules

Offers a performance comparable to synthetic dialyzers in HDF, without the allergenic properties.

Solacea: your membrane of choice for high flux HDF

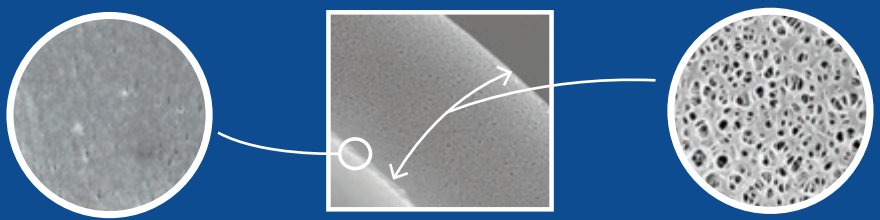
State of the art fiber spinning technology:
Asymmetric cellulose triacetate fibers

Dense layer at blood side

Filter function:
small pores, allows selective removal of uremic toxins, while ensuring low albumin loss

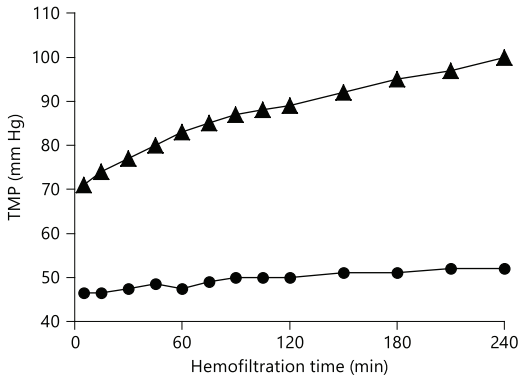
Support layer at dialysate side

Support function:
bigger pores for minimal pressure buildup with high fluxes



Keep low transmembrane pressure, even at high fluxes

Transmembrane pressure (TMP) increases during treatment with a symmetric cellulose triacetate membrane, but does not increase with an asymmetric cellulose triacetate membrane.[12]

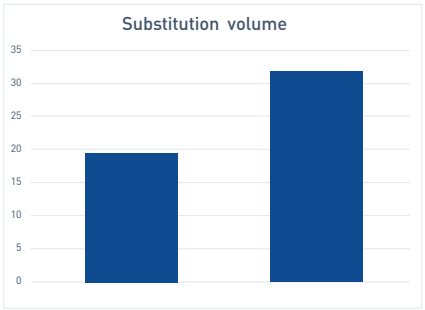


Test conditions:
Q_B = 250 ml/min
Q_F = 45 ml/min
Q_D = 500 ml/min

▲ Symmetric cellulose triacetate (Sureflux)
● Asymmetric cellulose triacetate (Solacea)

Obtain high convective volumes

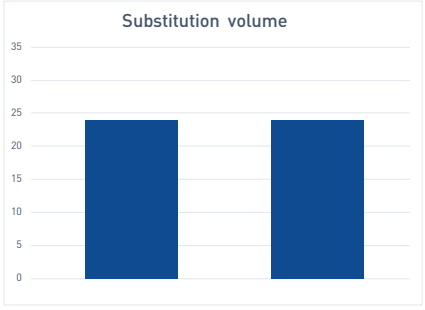
Symmetric versus asymmetric cellulose triacetate membrane[13]



Symmetric cellulose triacetate (Sureflux) | Asymmetric cellulose triacetate (Solacea)

Test conditions:
Q_B = 462 ml/min, Q_D = 500 ml/min

Synthetic versus asymmetric cellulose triacetate membrane[14]



Synthetic membrane (Elisio) | Asymmetric cellulose membrane (Solacea)

Test conditions:
Q_B = 350 ml/min, Q_D = 600 ml/min

Solacea: your membrane of choice for high flux HDF

Optimal removal of middle size molecules and minimal albumin loss

Better removal of middle size molecules than the symmetric cellulose triacetate membrane.[13]

Molecule	Symmetric cellulose triacetate SUREFLUX	Asymmetric cellulose triacetate SOLACEA	Significance
Reduction rate of middle size molecules			
β2-microglobulin	63,4%	80,4%	P<0,01
Myoglobin	64,8%	81,8%	P<0,01
Albumin loss per session			
Albumin	1,71	1,71	NS

QB: 350mL/min, QD: 600mL/min, Qs Sureflux: 68 mL/min, Qs Solacea: 111 mL/min

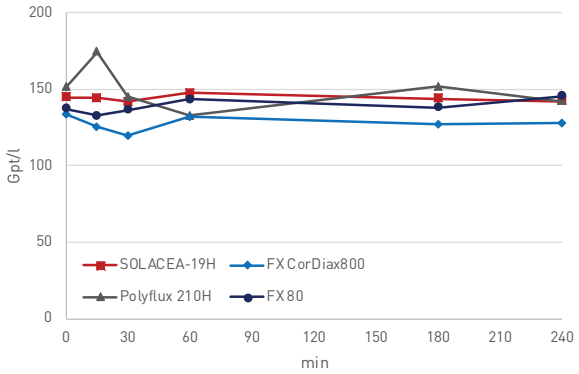
As high performing as synthetic membranes.[14]

Molecule	Polyethersulfone ELISIO	Asymmetric cellulose triacetate SOLACEA	Significance
Reduction rate of middle size molecules			
β2-microglobulin	84,8%	81,2%	NS
Myoglobin	70,2%	73,8%	NS
Phosphate	55,3%	58,4%	NS
Albumin loss per session			
Albumin	1,01	1,01	NS

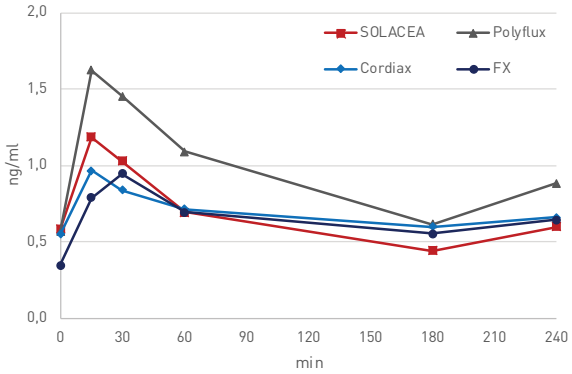
QB: 462mL/min, QD: 500mL/min, Qs Elisio: 98,8 mL/min, Qs Solacea: 98,8 mL/min

Excellent biocompatibility

Platelet count



Complement activation
Complement factor: C5a



Solacea offers a performance in HDF comparable to synthetic dialyzers, without the allergenic properties

Solacea™ H | High flux

Performance

Clearance (ml/min)*	Qb/ Qd (ml/min)	15H	17H	19H	21H	25H
Urea	200/500	196	197	198	199	199
	300/500	266	274	278	283	289
	400/500	312	323	332	340	352
Creatinine	200/500	191	193	195	198	198
	300/500	251	260	267	273	279
	400/500	289	301	311	320	331
Phosphate	200/500	185	188	190	194	196
	300/500	236	246	254	262	271
	400/500	268	282	293	301	318
Vitamin B12	200/500	150	158	164	169	176
	300/500	178	189	199	208	220
	400/500	193	208	219	230	246

Ultrafiltration Coefficient

KUF [mL/hr/mmHg]**	61	69	72	76	87

Sieving Coefficient***

Vitamin B12	1,00
Inulin	1,00
β2-microglobulin	0,85
Myoglobin	0,80
Albumin	0,013

Specifications

Effective surface area (m^2)		1,5	1,7	1,9	2,1	2,5
Priming volume (ml)		86	98	108	118	139
Effective length (mm)		227	233	245	254	280
Inner diameter (µm)		200	200	200	200	200
Membrane thickness (µm)		25	25	25	25	25
Maximum TMP (mmHg)		500	500	500	500	500
Pressure drop	Qb/Qd [mL/min]	200/500	200/500	200/500	200/500	200/500
	Blood/Dialysate [mmHg]	51/16	47/18	47/16	45/15	43/8
Material	Membrane	Assymetric cellulose triacetate (ATA)				
	Housing and header	Polypropylene				
	Potting compound	Polyurethane				
Sterilization method		Dry gamma				
Package		24 pcs/box				

In vitro testing conditions (ISO 8637)
* Clearance: Qf 0mL/min
** KUF: bovine blood (Hct 32+- 3%, Protein 60g/L, 37°C), Qb 200mL/min
*** SC: Qb 300 mL/min, Qf 60mL/min

SureFlux™ L | Low flux

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™ E | Medium flux

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™ UX | High flux

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

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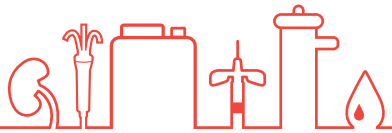
Nipro Renal Care is part of Nipro Corporation Japan, a leading global healthcare company established in 1954. With over 29.000 employees worldwide, Nipro serves the Medical Device, Pharmaceutical, and Pharmaceutical Packaging industries.

Nipro Renal Care is a global market leader with over 5 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.

BECAUSE EVERY LIFE DESERVES AFFORDABLE CARE



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