RENAL CARE

SOLACEA™

HIGH FLUX, ATA™ FIBER DIALYZER

NIPRO
MEDICAL EUROPE

SOLACEA™

HIGH FLUX, ATA™ FIBER DIALYZER

IMAGINE

Historically, the first membranes used for the hemodialysis were cellulose based. Even today, modified cellulose membranes, cellulose triacetate membranes, are remaining the fibers of choice for patients with hypersensitivity reactions against synthetic fibers.

Nowadays, however, synthetic fibers have become the preferred membrane. This switch is empowered by the demand of the new dialysis treatments. High volume hemodiafiltration (HDF), only partially possible with cellulose based membranes, is made achievable by the characteristics of a synthetic membrane, like the asymmetric fibers and chemical composition. The improvement of the dialysis treatments with synthetic fibers is however associated with an increased risk of hypersensitivity reactions.

For these reasons, healthcare providers and patients remain divided between these two different types of dialyzers, due to the unavailability of a product which combines the strengths of both membranes.

Till today.

Now imagine, a technology able to combine all the advantages typical of the synthetic membranes in terms of treatment, with the benefits of the natural fibers in terms of reduced allergic reactions.

A product able to cover the entire range of therapies from standard hemodialysis (HD) up to high volume HDF, reducing at the same time the needs for anticoagulants and limiting the risk of hypersensitivity reactions associated with a synthetic membrane.

This product finally exists: it's the new SOLACEA™, brought to you by Nipro.

UNIQUE FEATURES

ATA™ (ASYMMETRIC TRIACETATE)

SOLACEA allows outstanding performance thanks to its asymmetric structure, yet keeping all the advantages of semi-natural fibers.

SMOOTH MEMBRANE SURFACE

Reduced membrane fouling, minimizes clogging of the pores and generates a limited TMP build-up.

FULL RANGE OF APPLICATIONS

The SOLACEA can perform the 'simple' HD treatments up to the 'advanced' high volume 'convective' HDF.

BPA - FREE

SOLACEA is free of bisphenol-A, a proven endocrine disruptor and associated with the increased risk of residual kidney function loss.

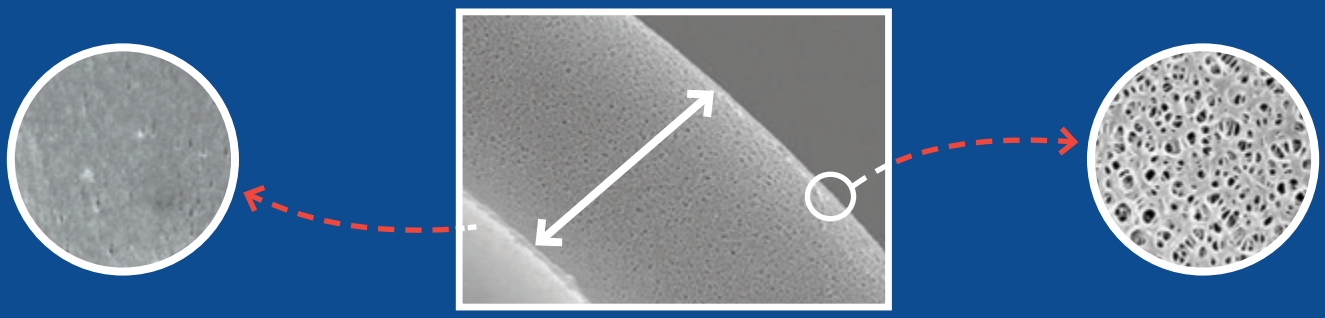
GAMMA STERILIZED

Sterilized by low dose gamma ray. This eliminates the use of ethylene oxide or inline steam with associated extra handling for packaging.

CUTTING-EDGE MEMBRANE TECHNOLOGY

SOLACEA features an ATA membrane made by a state of the art spinning technique for dialyzer fibers. This results into a thin membrane that, due to its asymmetric structure, can withstand high volume throughput. Its uniform pore distribution on the inner membrane safeguards high clearance of middle size molecules and low albumin loss.

ASYMMETRIC TRIACETATE MEMBRANE



Inner surface (x10.000)

Smooth membrane surface with optimized pore distribution

Membrane cross section (x 5000)

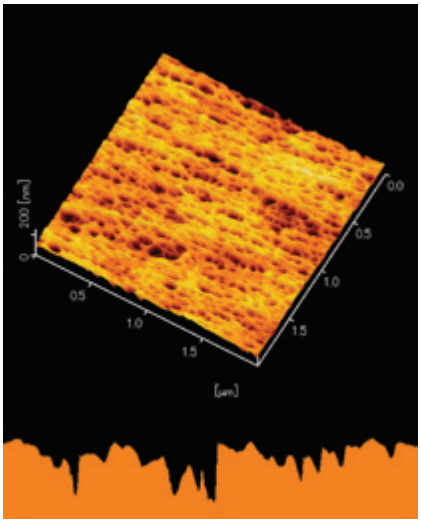
Outer surface (x10.000)

Asymmetric supporting layer reduces pressure build-up

SMOOTH MEMBRANE SURFACE

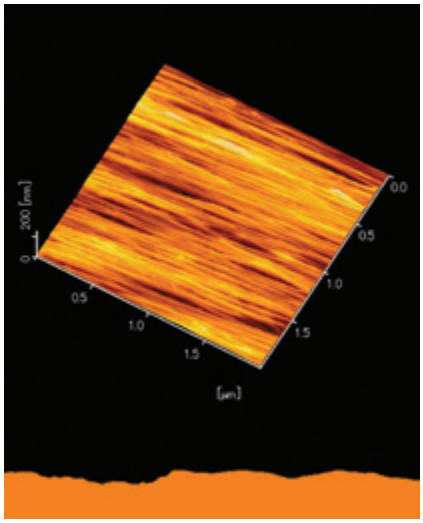
SOLACEA's smooth surface reduces membrane fouling. This decreases pore clogging and the associated performance drop at the beginning of the dialysis session.

HELIXONE™ (PS/PVP)



Ra = 11nm | RMS = 15nm

SOLACEA (ATA)



Ra = 3.8nm | RMS = 5.0nm

Atomic force microscopic (AMF) image. Ra: average roughness; RMS: square-mean roughness

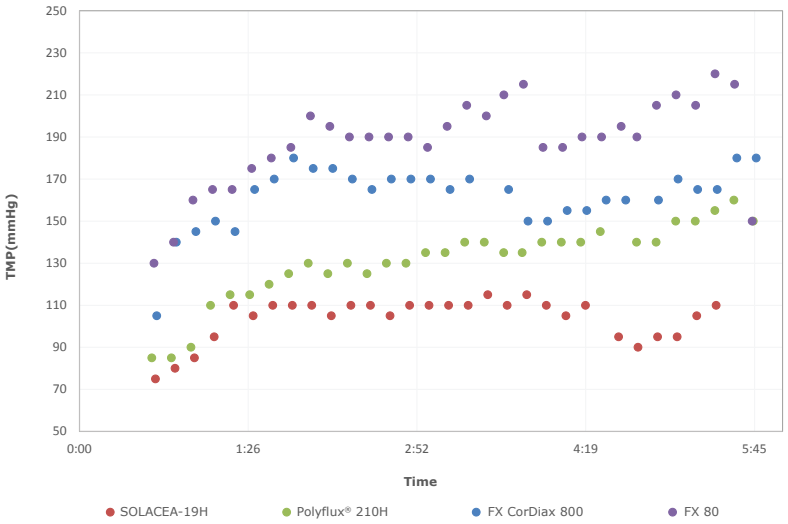
INNOVATIVE DIALYZER FOR HIGH VOLUME HDF

Effective high volume HDF treatments depend on fibers that can withstand high fluid transferal over the membrane and keeping transmembrane pressure (TMP) at a minimum. SOLACEA features an asymmetric membrane with a smooth surface, which limits TMP buildup, making the membrane ideal for treatments that require high volume fluid subtraction.

EFFECTIVE HIGH VOLUME HDF KEEPING TMP AT MINIMUM

As demonstrated in the graph, the SOLACEA has very low TMP values and the TMP buildup is very low in the first 30 min of HDF treatment.

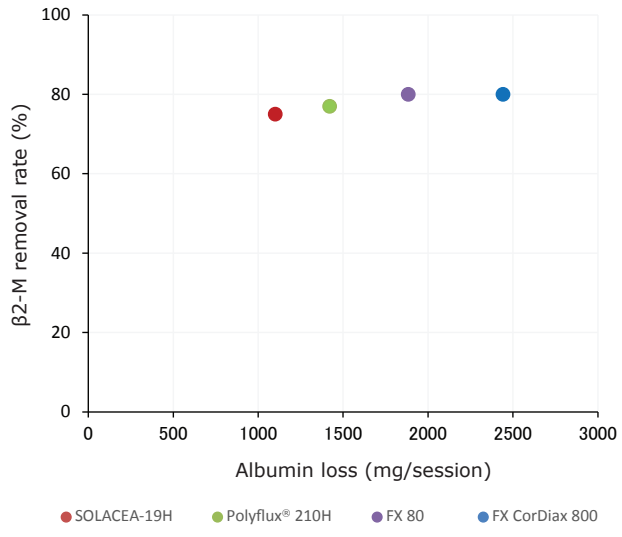
TMP*



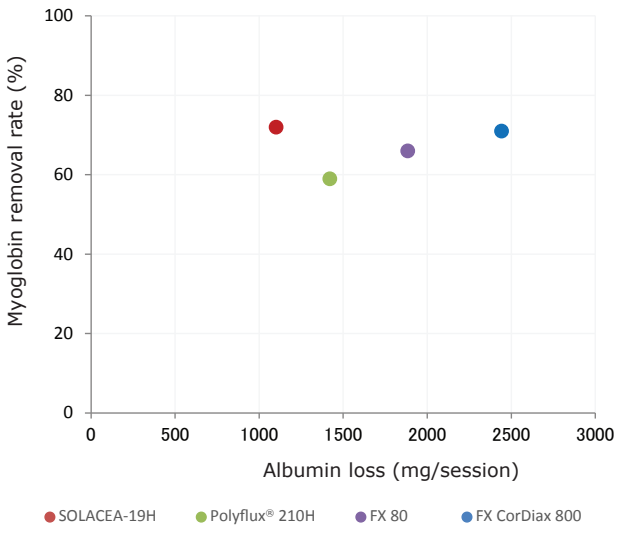
EXCELLENT PERFORMANCE WITH LIMITED ALBUMIN LOSS

As demonstrated in the graph, the SOLACEA has an excellent performance in high volume HDF, as proven by the removal rate of middle size molecules, as measured by beta-2-microglobulin (ß2-M) and myoglobin, with limited loss of albumin. In both cases, the SOLACEA shows low albumin loss, with comparable removal rate for ß2-M and high removal rate for myoglobin.

ß2-M removal and albumin loss**



Myoglobin removal and albumin loss**

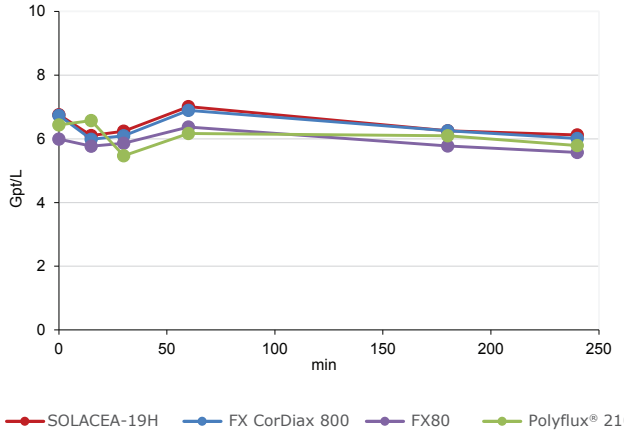


* Qb 350mL/min, Qd 600mL/min, Qs 85mL/min; ** Qb 350mL/min, Qd 600mL/min, Qs 100mL/min.
Clinical data from *in vivo* experiments performed by BioArtProducts, Rostock, Germany in 2015.

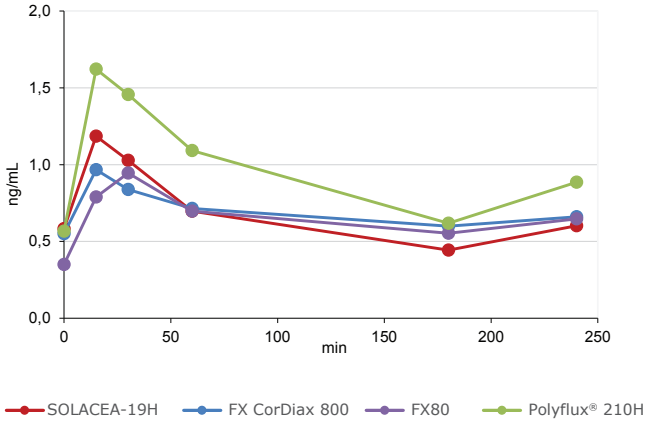
BIOCOMPATIBLE MEMBRANE

SOLACEA has excellent thrombogenicity and biocompatibility characteristics.

White blood cell count*



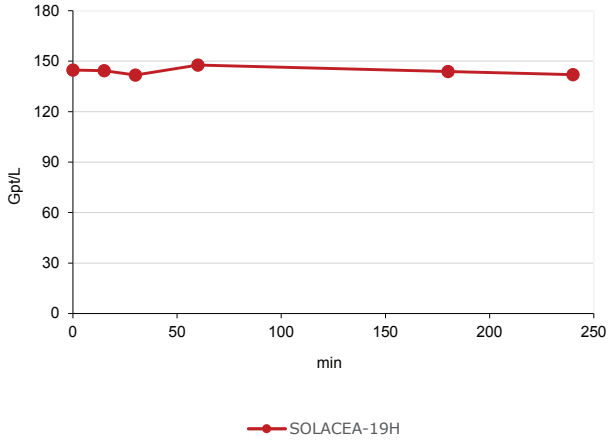
C5a generation*



In the first 30 min of the HD treatment the white blood cell count shows a small drop. The increase of complement activation, measured by C5a, is in line with synthetic membranes.

When we look at the platelet count in the first 30 min, we see that there is only a very minor drop, after which it returns to normal levels.

Platelet count*



* Qb 350ml/min, Qd 600ml/min, Qs 0mL/min. Clinical data from *in vivo* experiments performed by BioArtProducts, Rostock, Germany in 2015.

SOLACEA™ - H

HIGH FLUX

PERFORMANCE

Clearance (ml/min)[5]	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][2]	61	69	72	76	87

Sieving Coefficient[3]

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

SPECIFICATIONS

Effective surface area (m²)		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	ATA™				
	Housing and Header	Polypropylene				
	Potting compound	Polyurethane				
Sterilization method		Dry gamma				
Package		24 pcs/box				

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

Nipro Renal Care is part of Nipro Corporation Japan, a leading global healthcare company established in 1954. With over 33.000 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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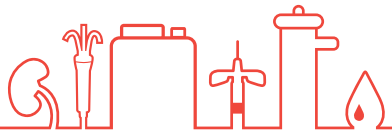
Please contact your local representative for more information.



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