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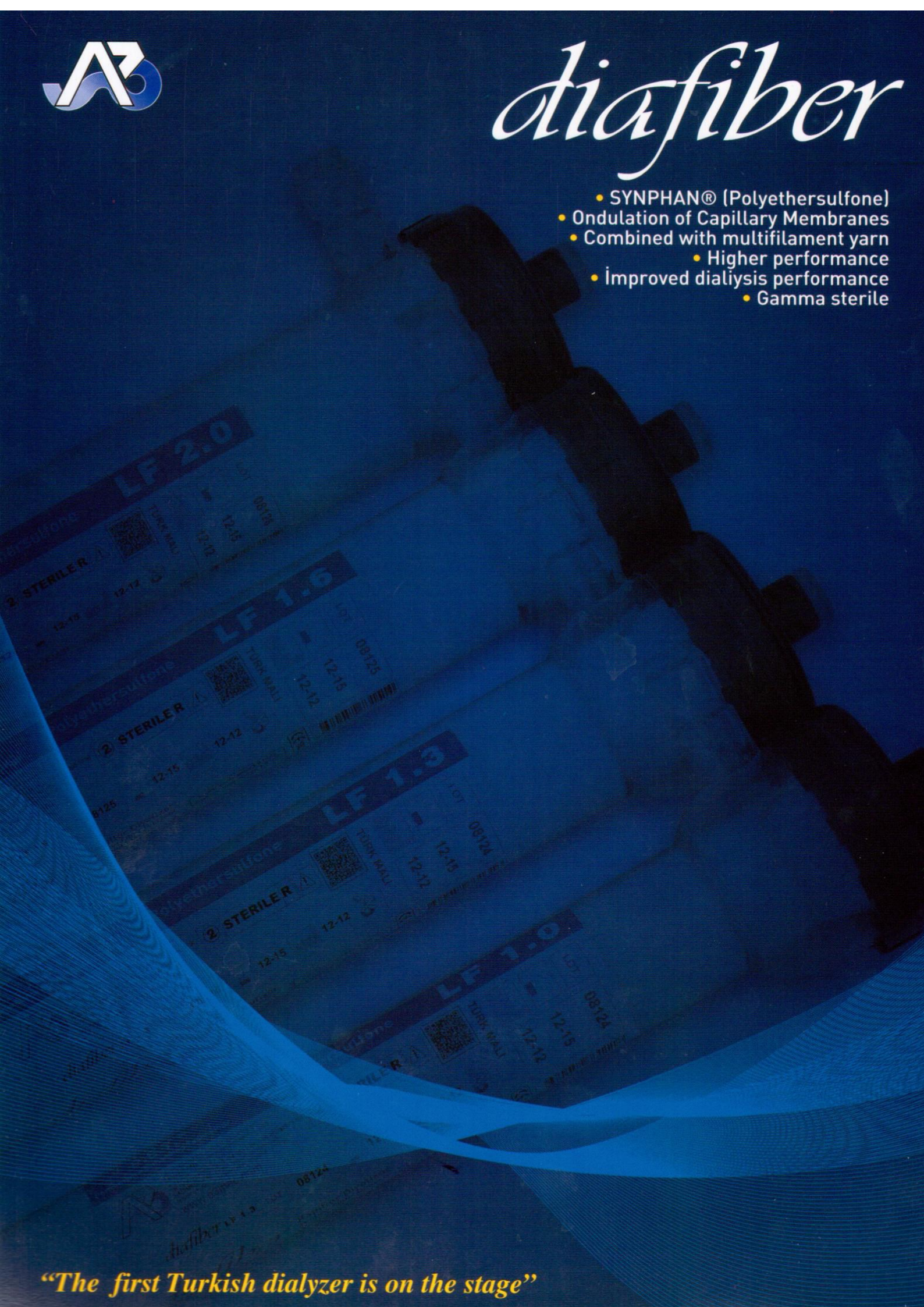
- SYNPHAN® (Polyethersulfone)
- Ondulation of Capillary Membranes
- Combined with multifilament yarn
- Higher performance
- İmproved dialiysis performance
- Gamma sterile



"The first Turkish dialyzer is on the stage"

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Diafiber membrane type; SYNPHAN®

SYNPHAN® is a new synthetic family of membranes, setting advanced standards in haemodialysis and representing the next generation of dialysis membranes.

SYNPHAN® is available in three different membrane types all made of polyethersulfone. Its unique polymer and pore structure provides excellent haemocompatibility and performance, making it probably the most sophisticated dialyser membrane type available today.

Reliability and consistency are the foundations of a powerful family. It is the same in the highly technical world of dialysis membranes. The SYNPHAN® product family was designed for consistent quality and performance. With membranes for low-flux, mid-flux and high-flux dialysis, SYNPHAN® is an innovative system-based concept, which can be used for all patients. With its improved dialysis performance in each segment, SYNPHAN® helps to ensure that end-stage renal disease patients enjoy improved quality of life. If it's a decision for life, SYNPHAN® is always the right choice.

SYNPHAN® can be used with all common sterilization methods and for all treatment modalities. SYNPHAN® is significantly better than other synthetic membranes in removal of ß2-microglobulin.

High-end performance in each flux segment provides improved removal of uraemic toxins/ SYNPHAN® provides excellent and stable performance during the entire dialysis session. SYNPHAN® benefits from Performance Enhancing Technology

FAQ

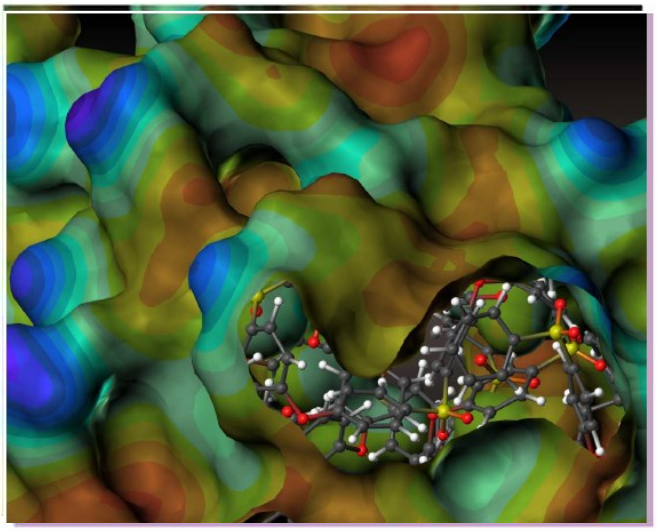
What's so different about SYNPHAN®?

SYNPHAN® is a new dialysis membrane, made from a new polymer, polyethersulfone. The high mechanical and chemical stability of the polymer makes it possible to produce a membrane with a difference: SYNPHAN® has a reduced wall thickness compared with conventional synthetic membranes, leading to increased ultrafiltration rates and higher performance, and a unique three-phase structure.

How does the three-phase structure of SYNPHAN® improve its performance?

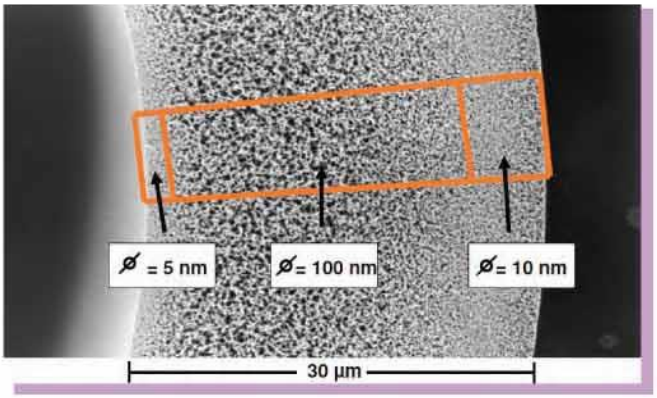
The three-layer structure guarantees controlled treatment conditions during dialysis. The separation layer defines the sieving coefficient profile, and is designed to give optimal clearance of middle molecules such as ß2-microglobulin. The support layer ensures high mechanical strength, and the flux control layer contributes to the hydraulic properties of SYNPHAN®.

SYNPHAN® - Molecular Structure

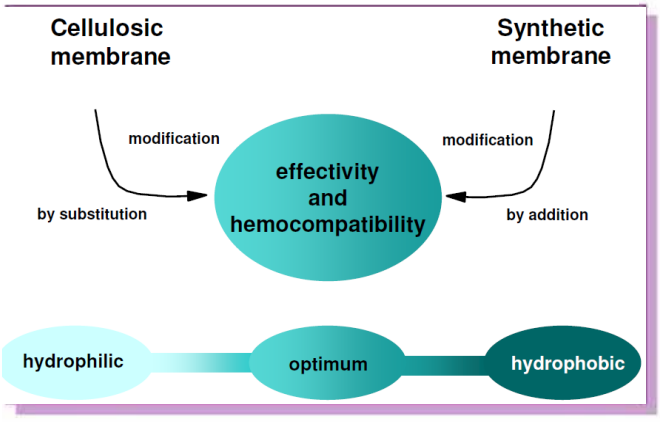


SYNPHAN® membrane structure

scanning electron microscopy



biocompatibility



High-end performance in each flux segment provides improved removal of uraemic toxins. The SYNPHAN® family of membranes have been especially developed to surpass common standards for dialysis membranes in terms of ultrafiltration and removal characteristics for uraemic toxins of all molecular sizes.

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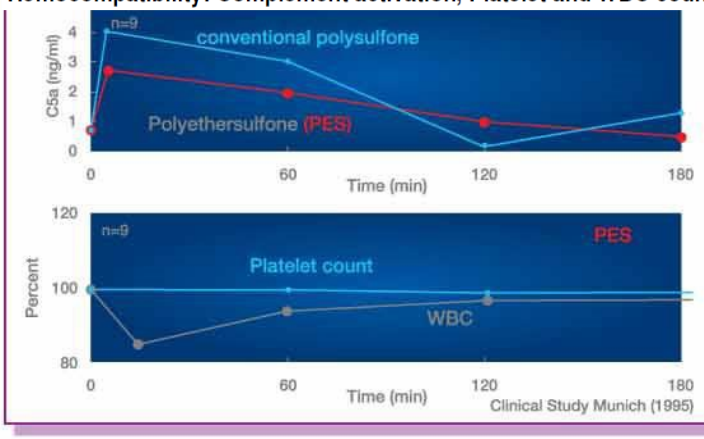
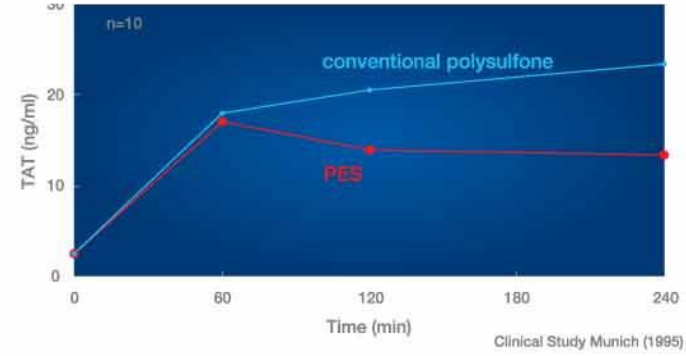
MEMBRANA
Underlining Performance

Polyethersulfone
P.E .T.®
Performance Enhancing Technology

SYNPHAN® HF600T
Hemocompatibility: Complement activation, Platelet and WBC count



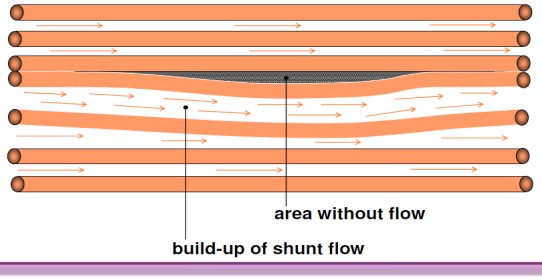
SYNPHAN® HF600T
Thrombogenicity (TAT) of PES versus PSu



P.E.T.® : Performance Enhancing Technology
- PET (Poly Ethylene Terephthalate) spacer yarns consist of multifilament threads integrated into the fiber bundles

- Improves dialysate distribution throughout the dialyzer
  - ➲ Increases clearance values
  - ➲ Maintains consistent performance
    - – throughout the entire treatment
    - – from dialyser to dialyser

Causes for Uneven Flow Distribution in the Dialysate Compartment of Dialyzers



Do we need another polysulfone membrane?

SYNPHAN® is not a polysulfone membrane – it is made from polyethersulfone, which has a higher chemical and mechanical strength. This means membrane walls can be thinner than in conventional synthetic membranes, leading to improved performance and higher ultrafiltration rates.

Why should I use SYNPHAN®?

SYNPHAN® offers the whole range of treatment modalities from low-flux haemodialysis right up to high volume haemodiafiltration. So the clinician can chose the most sophisticated membrane available for every individual patient.

What advantages does SYNPHAN® offer the doctor and the patient?

With their unsurpassed performance, all members of the SYNPHAN® family help physicians to provide optimal treatment for their patients, every day. The introduction of the P.E.T.® concept – Performance Enhancing Technology – guarantees the reliability and consistency of the performance during the whole course of every treatment

What is the P.E.T.® concept?

Performance Enhancing Technology (P.E.T.®) is a concept introduced and patented by Membrana. Membrane capillaries are combined with a multifilament yarn, to allow even flow distribution of the dialysate during the whole dialysis session. This increases the performance of the dialyser and ensures optimal, consistent clearance in every session.

Why is SYNPHAN® combined with P.E.T.®?

SYNPHAN® and P.E.T.® provide the most sophisticated synthetic dialysis membrane, combined with the best technological solution for consistent, reproducible isotropic dialysate distribution in the dialyser.

How can SYNPHAN® offer a greater margin of safety than other membranes?

Several published studies have confirmed that SYNPHAN® can retain pyrogens and material with cytokine-inducing activity, because of its characteristic physicochemical properties. The result is an added margin of safety, even if conditions are less than perfect.

What gives SYNPHAN® its high capacity to remove ß2M?

When designing SYNPHAN® the sieving coefficients for so-called middle molecules were optimized, giving enhanced removal capacity for uraemic toxins such as ß2M. For example the sieving coefficient for Cytochrome C, with a molecular weight of 13kD, is 0.63.

What makes the SYNPHAN® range a "family"?

In a family, each member plays a specific role and reliability and consistency are the foundations of the family's strength. The same is true for the SYNPHAN® family. With membranes for low-, mid- and high-flux dialysis, SYNPHAN® is probably the world's most highly developed membrane family. Using the SYNPHAN® family of membranes gives every physician access to its high levels of performance, helping to achieve increasingly ambitious goals in patient

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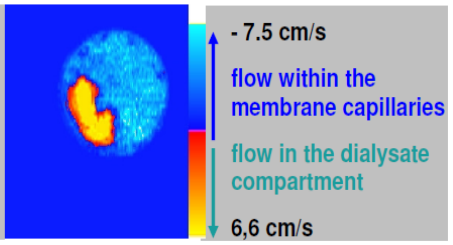
Flow Distribution in Dialyzers with / without P.E.T.®

Three-dimensional Experiments

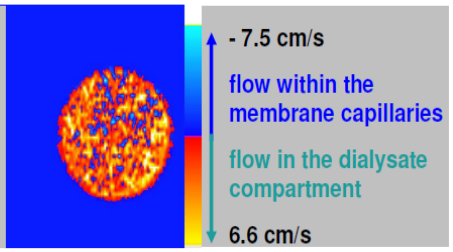
Dialyzer without P.E.T.®

build-up of shunt flow in the dialysate compartment
'low efficiency'



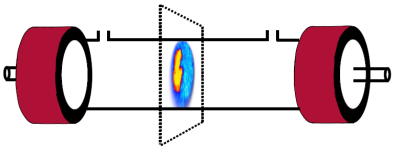
Dialyzer with P.E.T.®

even flow distribution in the dialysate compartment
'high efficiency'



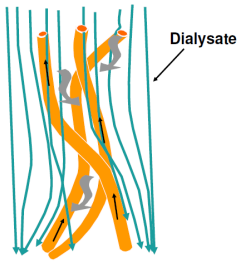
Laukemper-Ostendorf et al (1998)
J Membr Sci 138: 287-295

Flow Distribution in Dialyser measured by NMR velocity analysis



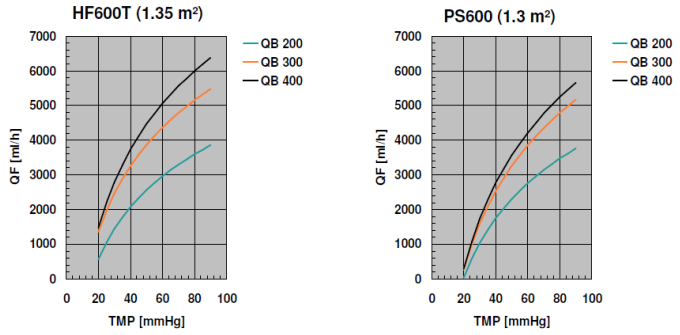
cross sectional plane for velocity analysis

Ondulation of Capillary Membranes

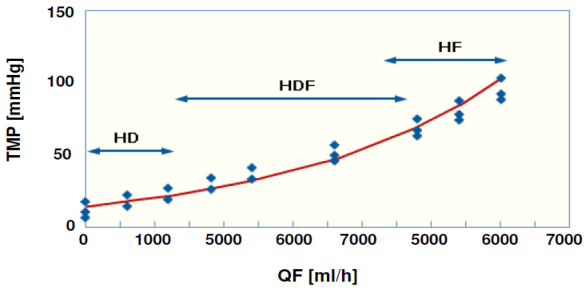


Comparison of in vitro Ultrafiltration

Human blood Hct: 32%, TP: 60 g/l

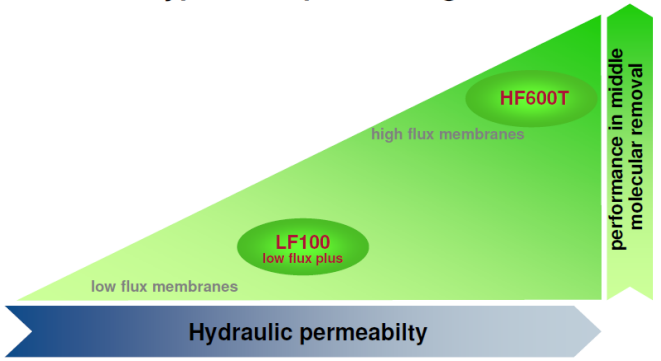


SYNPHAN® HF600T – in vitro Ultrafiltration



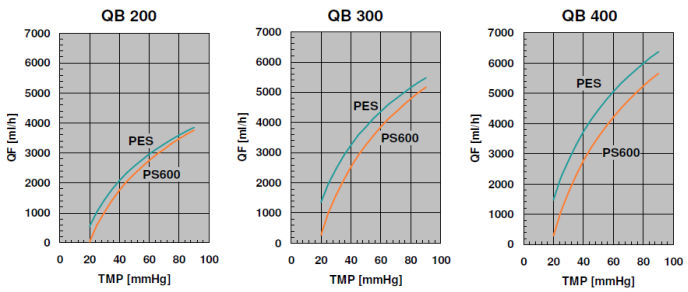
Membrana Laboratories (2001)

SYNPHAN® types and positioning



Comparison of in vitro Ultrafiltration

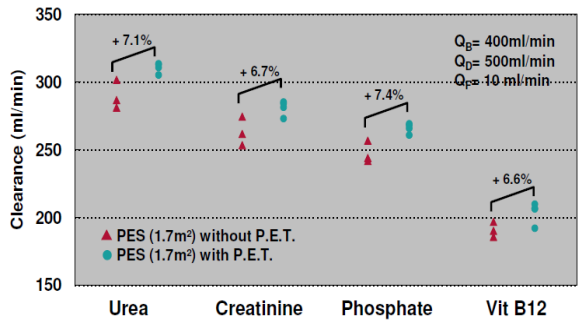
SYNPHAN® HF600T (1.35 m²) vs. PS600 (1.3 m²)
Human blood Hct: 32 %, TP: 60 g/l



Membrana Laboratories (2001)

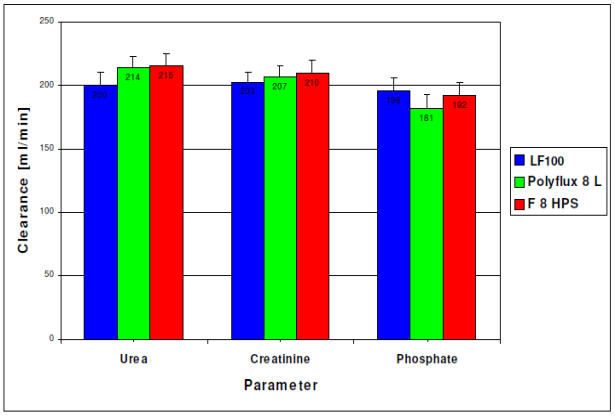
The revolutionary Performance Enhancing Technology (P.E.T.®), used in the manufacture of SYNPHAN®, incorporates a multifilament spacer yarn which helps to deliver an even flow of dialysate, providing maximum clearance and consistency.

Clearance Performance of Dialyzers using P.E.T.® and SYNPHAN®



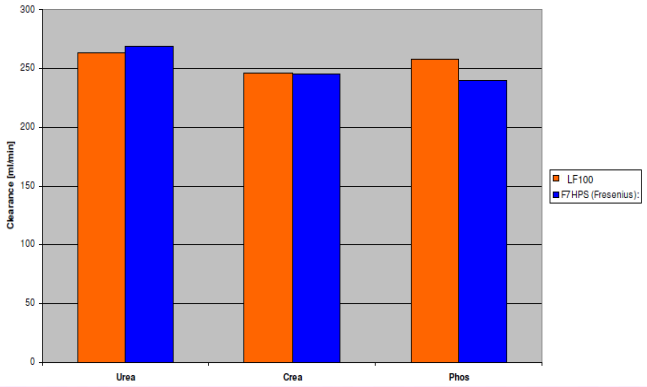
Membrana Research (1999)

SYNPHAN® LF 100: *In vivo* Performance

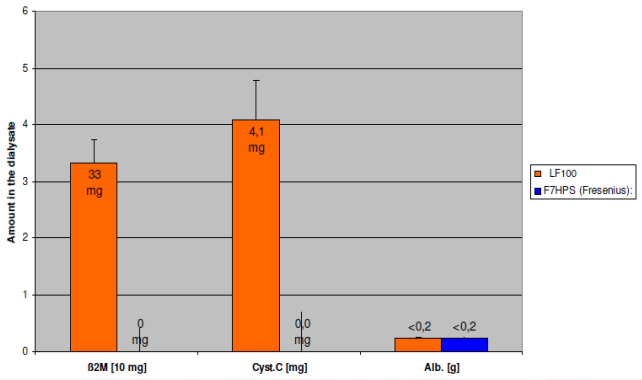


SYNPHAN® is a new synthetic family of membranes, setting advanced standards in haemodialysis and representing the next generation of dialysis membranes.

SYNPHAN® LF100: Small Solute Clearance



SYNPHAN® LF100: Removal of Middle Molecules into Dialysate



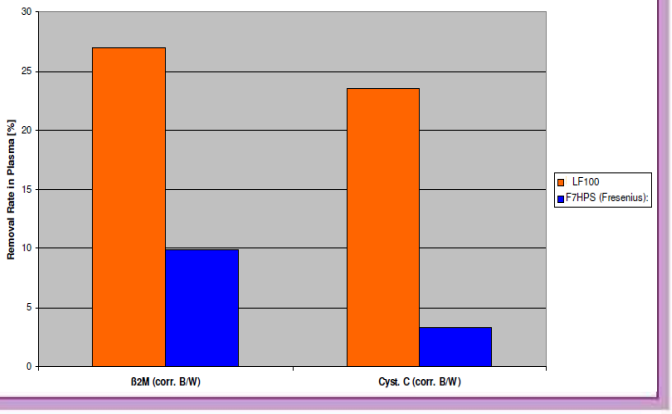
Conclusions

- → SYNPHAN® LF 100 is competitive to other synthetic low flux membranes in terms of hemocompatibilty and performance
- → In terms of middle molecular removal, SYNPHAN® LF100 is superior to conventional low-flux membranes
- → SYNPHAN® LF 100 has a higher UFR compared to other semisynthetic and synthetic low-flux membranes

Study Design

- 7 ESRD patients
- HD with 2 different dialysers
  - SYNPHAN(R) LF100, 1.7 m²
  - Fresenius F 7 HPS, 1.6 m²
- Q_B= 350 ml/min, Q_D=500 ml/min
- Performance (small solutes, ß2m, albumin)

SYNPHAN® LF100: Removal Rate of Middle Molecules



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Low Flux Dialyzer Specifications	High Flux Dialyzer Specifications

Membrane Polymer	Polyethersulfone (Synphan Membrana)
Membrane Specifications	Undulated, multifilament yarn P.E.T.®
Housing, Caps	ABS (Telrux BASF)
Potting material	Polyurethane (Elastocoat BASF)
O-rings	Silicone (Elastosil Wacker)
Sterilizing Agent	Gamma

Wall Thickness	35 micron	30 micron
Inner Diameter	200 micron	200 micron
Maximum TMP (mmHg)	600 mm Hg	500 mm Hg

Inulin		1
Albumin		<0.01
ß2-Microglobulin		0,8

Effective membrane area (m2)	1	1,2	1,3	1,5	1,6	1,8	2	1,1	1,4	1,7	2
UF Coefficient (ml/h/mmHg)	8	9	10	12	13	14	16	36	46	57	75
Priming Volume(ml)	63	75	80	91	95	107	115	65	87	102	123

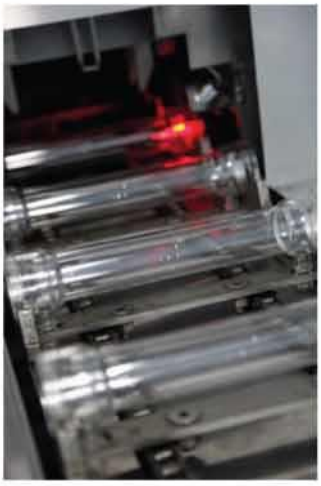
	Clearances: QB 200 ml/min										
Urea	168	191	196	213	213	218	226	189	207	211	219
Creatinine	155	177	182	197	197	202	210	182	199	203	211
Phosphate	127	144	148	161	161	165	171	175	192	196	203
Vitamin B12	68	77	79	86	86	88	91	136	149	152	158
Inulin								97	106	108	112

	Clearances: QB 300 ml/min										
Urea	217	248	254	276	276	283	293	255	279	285	296
Creatinine	192	219	225	244	244	250	259	235	257	262	272
Phosphate	148	169	174	189	189	193	200	221	241	247	256
Vitamin B12	73	83	86	93	93	95	99	159	173	177	184
Inulin								107	117	119	124

	Clearances: QB 400 ml/min										
Urea	246	280	287	312	311	319	331	304	333	340	353
Creatinine	218	249	255	277	277	284	294	272	297	303	316
Phosphate	162	185	190	206	206	211	219	257	281	287	298
Vitamin B12	79	90	92	100	100	103	107	174	190	194	202
Inulin								121	133	135	141

The in vitro performance data were obtained with QD=500 mL/min; QF=10 mL/min; T=37°C (EN1283)

The ultrafiltration coefficients (Kuf) were measured using bovine blood, Hct 32%; Protein 60g/L; T 37°C; Qb=300 mL/min



Manufacturing facility

Our manufacturing facility which is established in the structure of A3 Medical Devices which works with the brand of diafiber is one of the developed dialyzer facilities in the world.

The facility was established as manufacturing responsively and self controlled. Montage periods which go by mortal power in other similar facilities is done by machines have robotic manipulators.

With problems come across in other facilities and dialysers are examined separately, we aim to minimalize the probable problems.

Each parts of the whole manufacturing facility and machines consist of stainless steel and minimum frictional greaseless pieces which are necessary for medical usage. Most of equipments using in manufacturing facility is developed and patented for only A3 Medical Equipment facility.

A3 Medical Equipment A technology company established to produce and develop medical equipments and supplies.

Machines are produced in our facility is manufactured as being convenient to legislation for Health and Food companies have to obey and E.U. standards.

Our company prepares projects, produces and develops any kinds of machines, equipments and supplies which are used in medicine and food industry.

A3 Medical Equipment serve medical sector with substantial capital structure, high technology, flexible manufacture capability, sector experience.

A3 Medical Equipments plastic and machine manufacture facility is established to aim serving manufacture technology, provide machine and equipment,

Any kinds of machines and parts' design, development, mechanic electricity and electronic production and montage are being made in A3 Medical Devices which are essential for manufacturing food production, plastic disposable material, medicines and medical devices.

The software's for PLC, PC controlled which uses in Machines and production following and control are also produced in our facility.

Our company cooperates with many of other companies in the same sector around the whole world and manufactures at high standards with CE quality certificate which is appropriate to E.U. legislation.

A3 Medical Equipment

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