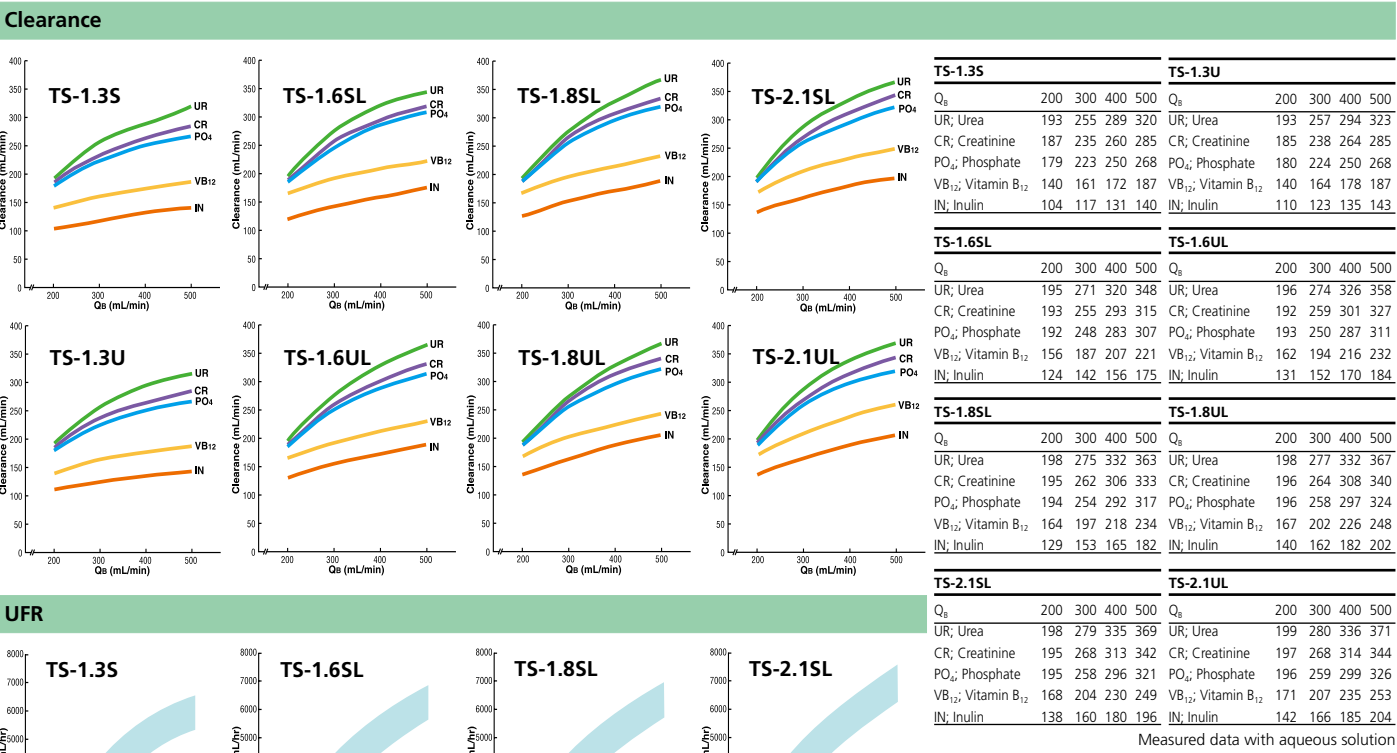


Technical Specifications and Data

Type	TS-1.3S	TS-1.6SL	TS-1.8SL	TS-2.1SL	TS-1.3U	TS-1.6UL	TS-1.8UL	TS-2.1UL
Housing	Material							
Fibers	Material							
	Inner diameter (μm)							
	Membrane thickness (μm)							
	Effective surface area (m²)							
Potting Material	Polyurethane							
Sterilization	Gamma-ray Irradiation							
Blood Volume (mL)	84	95	105	124	85	95	108	125
Clearance <i>in vitro</i> (mL/min)*								
Urea	193	195	198	198	193	196	198	199
Creatinine	187	193	195	195	185	192	196	197
Phosphate	179	192	194	195	180	193	196	196
Vitamin B ₁₂	140	156	164	168	140	162	167	171
Inulin	104	124	129	138	110	131	140	142
UFR <i>in vitro</i> (mL/hr, at 13.3kPa (100mmHg))*	4,400	4,900	5,000	5,200	4,300	4,900	5,100	5,500
Max. TMP (kPa (mmHg))	66 (500)							

* Clearances are measured with aqueous solution. Q_B: 200 ±4mL/min, Q_D: 500 ±10mL/min, Q_F: 10 ±2mL/min, Temp.: 37 ±1°C
* UFRs are measured data with bovine blood. (Ht 30 ±2%, TP 6 ±0.5g/dL) Q_B: 200 ±4mL/min, TMP: 13.3 ±1.3kPa (100 ±10mmHg), Temp.: 37 ±1°C
"Instructions for Use" should be read thoroughly prior to the use of these medical devices.
Specifications and designs are subject to change without notice for improvements.



References

1) Sakai, K., taken from the presentation made at the 48th Annual Meeting of the Japanese Society for Dialysis Therapy, Jun. 2003 (Fig.1, Table 1)

2) Hayama, M., Yamamoto, K., Kohori, F., Sakai K., et al., Biomaterials 25 (2004) 1019-1028 (Fig.1, Table 1)

3) Sakai, Y., et al., taken from the presentation made at the 22nd Annual Meeting of ISBP, Sep. 2004 (Fig. 5)

4) Miyaji, H., et al., taken from the presentation made at the 20th Annual Meeting of HPM, Mar. 2004 (Fig. 6, 7)

5) Onishi, N., et al., taken from the presentation made at the 31st Shikoku Dialysis Therapy Research Group, 1997 (Fig. 8, 9)



Hollow Fiber Dialyzer
Toraysulfone TS-S/U SERIES



EC REP
Toray International Italy S.r.l.
Via Mecenate 86, 20138 Milan, ITALY

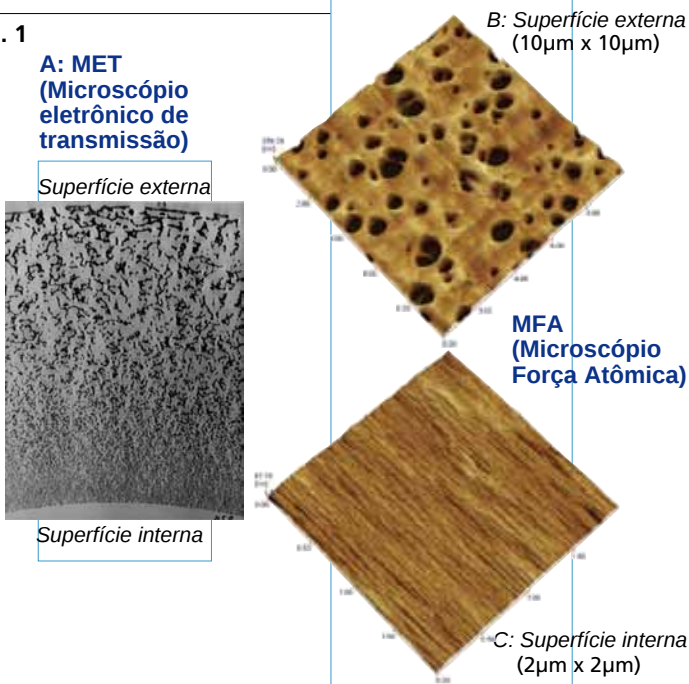
Exporter:
Toray Medical Co., Ltd.
4-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-0023, JAPAN

Manufacturer:
Toray Industries, Inc.
1-1, Nihonbashi-Muromachi 2-chome, Chuoku, Tokyo 103-8666, JAPAN

Toraysulfone Excelência em Membrana de Polisulfona

Avançada nanotecnologia Melhor coeficiente de filtragem

Fig. 1



Precisão na filtragem molecular

A membrana de polisulfona do Toraysulfone possui uma estrutura assimétrica, com uma alta capacidade de ultrafiltração e remoção de solutos.

Fig. 1 mostra, A: MET Observação da seção da membrana, B e C: MFA observação na superfície da membrana. Todos eles mostram a estrutura assimétrica dos poros da membrana.

Crosslinked Structure of PVP in Toraysulfone Membrane

Polyvinylpyrrolidone (PVP) in Toraysulfone membrane is crosslinked during γ -ray sterilization, and less PVP is eluted from membrane.

Fig. 2 is an observation of three different polysulfone membranes after soaking in DMAc (solvent for polysulfone).

PVP dissolves away together with polysulfone in A2 and A3 membrane. However crosslinked PVP in Toraysulfone remains as a transparent structure.

Crosslinked PVP in Toraysulfone remains even in the solvent.

Toraysulfone has less elution of PVP compared to other membranes.

Spacer Yarns

Toraysulfone hollow fibers are covered by "Spacer yarns" as shown in Fig. 3.

Spacer yarns facilitate the dialysate to flow uniformly around the hollow fibers and to reduce the "mass transfer resistance in dialysate side" without affecting a pressure drop in the dialysate compartment.

Spacer yarns help to enhance the efficiency of dialysis.

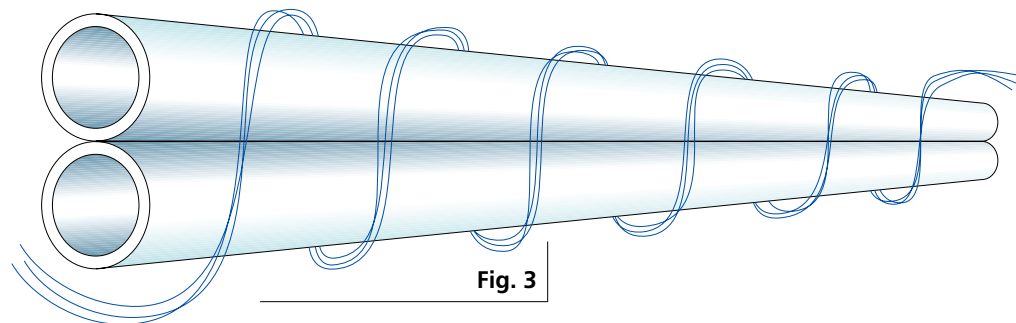


Fig. 3

New design

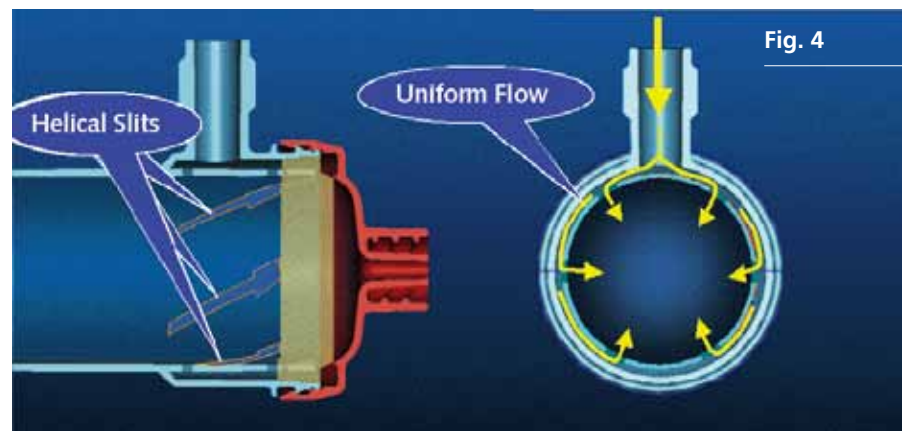


Fig. 4

Helical Slits Structure

Toraysulfone TS series has specially designed baffle structure with helical slits, in order to obtain the uniform flow of dialysate. (Fig. 4)

In this new design, the baffle was arranged so as to surround both ends of the fiber bundle. The dialysate uniformly penetrates into the fiber bundle from surrounding slits.

Uniformity of dialysate flow in the new Toraysulfone TS series can be observed by X-ray CT scan as shown in Fig. 5.

Fig. 5

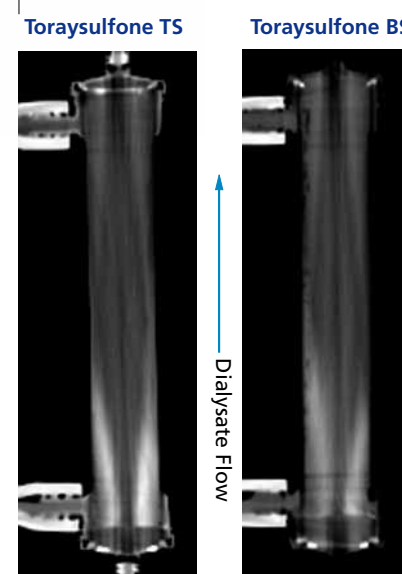
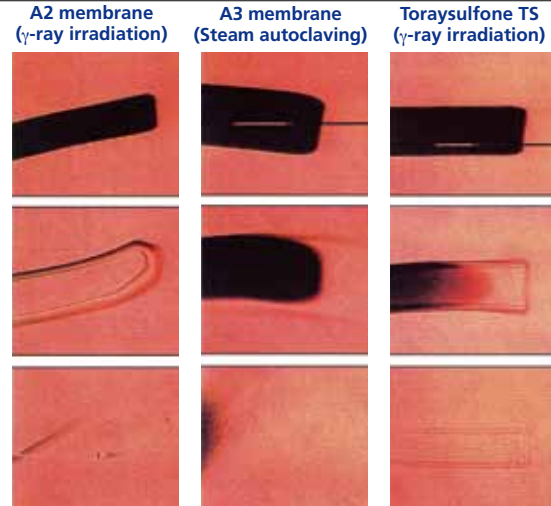


Table 1

Membrane	Water content (%)		Tortuosity		Thickness (µm)		Pore diameter (nm)		Pore length (µm)
	Skin layer	Support layer	Skin layer	Support layer	Skin layer	Support layer	Skin layer	Support layer	
Toraysulfone	27	70	1.13	1	2	38	8.8	418	40.3
A1	31	70	1.73	1	3	42	11	494	47.2
A2	42	73	1.14	1	7	38	9.5	499	46.0
A3	47	77	1.80	1	2	38	13.0	699	41.6

Fig. 2



Superior Performance and Proven Biocompatibility

Clinical Evaluation of Clearance

Clearances of new Toraysulfone TS series and BS series (current product) were compared in 8 end stage renal disease (ESRD) patients (crossover study).

Clearances of phosphate and α 1-MG in TS series were significantly higher than BS series. (Fig. 6)

In comparison of clearances in 6 ESRD patients (crossover study) between TS series and another polysulfone dialyzer (another PS), clearances in uric acid and α 1-MG were also significantly higher in Toraysulfone TS series. (Fig. 7)

Fig. 6: Comparison of Clearance in TS and BS

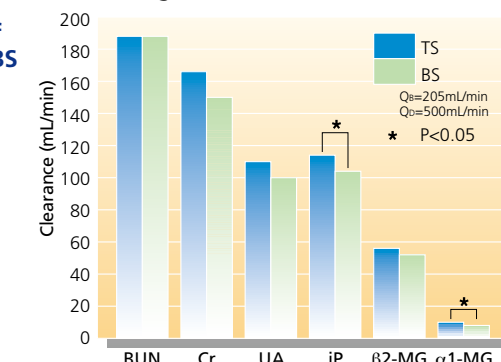
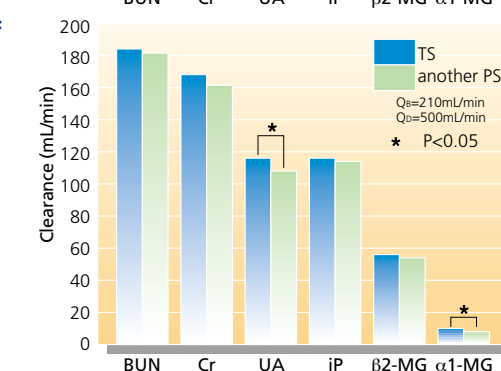


Fig. 7: Comparison of Clearance in TS and another PS



Comparison of Biocompatibility

Significant change in C3a and leukocyte counts were observed with CTA membrane (CTA). In contrast, less significant changes were observed with Toraysulfone membrane. This suggests that the Toraysulfone membrane has better biocompatibility than that of CTA. (Fig. 8, 9)

Fig. 8: Changes in C3a comparing Toraysulfone and CTA

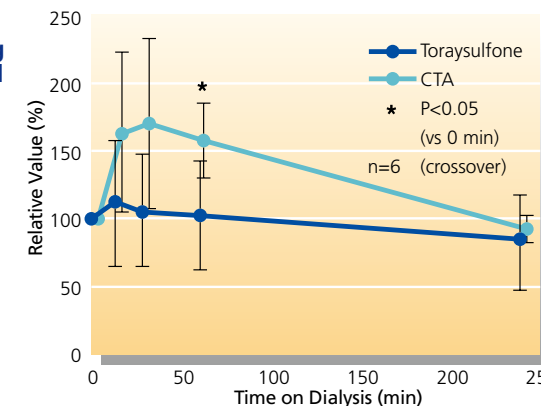


Fig. 9: Changes in leukocyte counts comparing Toraysulfone and CTA

