

Specification

Plasma Separator Evaclio		EC-4C20	EC-4C10
Hollow fiber	Material	Ethylene-vinyl alcohol co-polymer	
	Inner diameter	175 μm	
	Wall thickness	40 μm	
Housing	Material	Polycarbonate	
	Membrane surface area	2.0 m ²	1.0 m ²
	Outer dimension	57φ x 280 L mm	45φ x 280 L mm
Priming volume		Approx. 150 mL	Approx. 82 mL
Sterilization		Gamma-ray irradiation	

Note

- Please read instructions carefully before using the product.
- Evaclio™ is a trademark of SB-KAWASUMI LABORATORIES, INC.

Distributed by

CE 0123

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KLE-EC4C-2112-02-FF



Selective Plasma Exchange with Evaclio™ EC-4C

~Reduced loss of coagulation factors~

ANCA-associated Vasculitis

Myasthenia Gravis

Drug Toxication

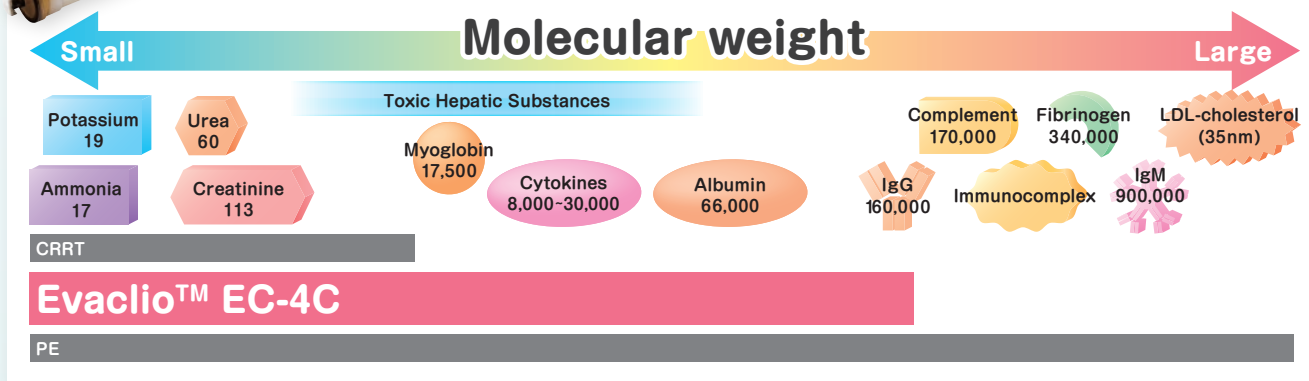
Toxic Epidermal Necrolysis



What is Evaclio? Membrane plasma separator with unique permeability

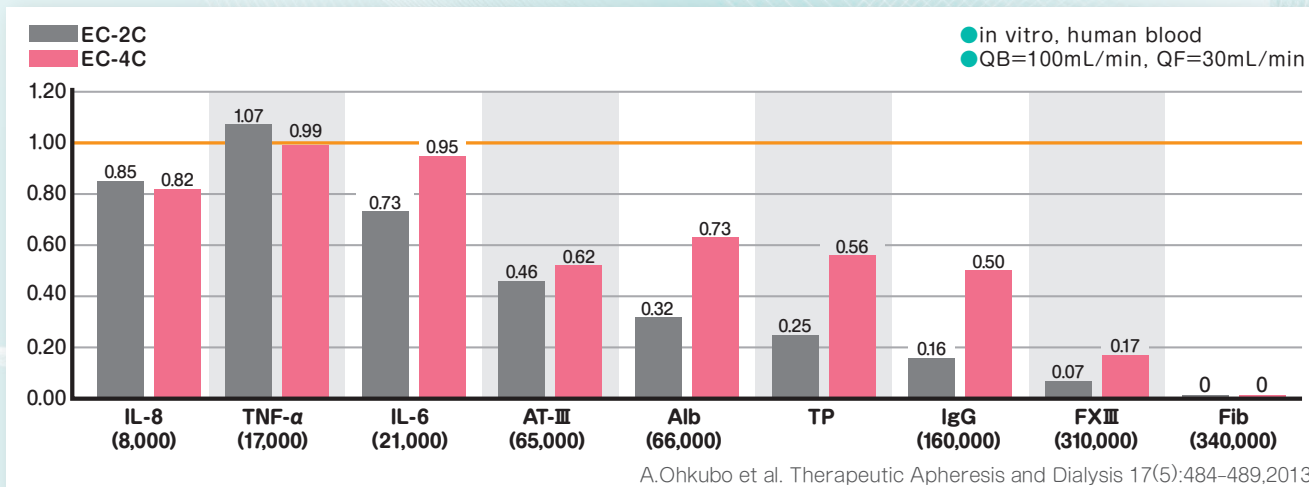


Evaclio is a membrane separator with smaller pore size than conventional plasma separators. It allows small and medium molecular weight proteins to be removed, while retaining large molecular weight proteins.



Sieving Coefficient

Evaclio EC-4C has sieving coefficient "0" for fibrinogen. It can remove IgG and lower weight molecules, while retaining fibrinogen in patients' blood.

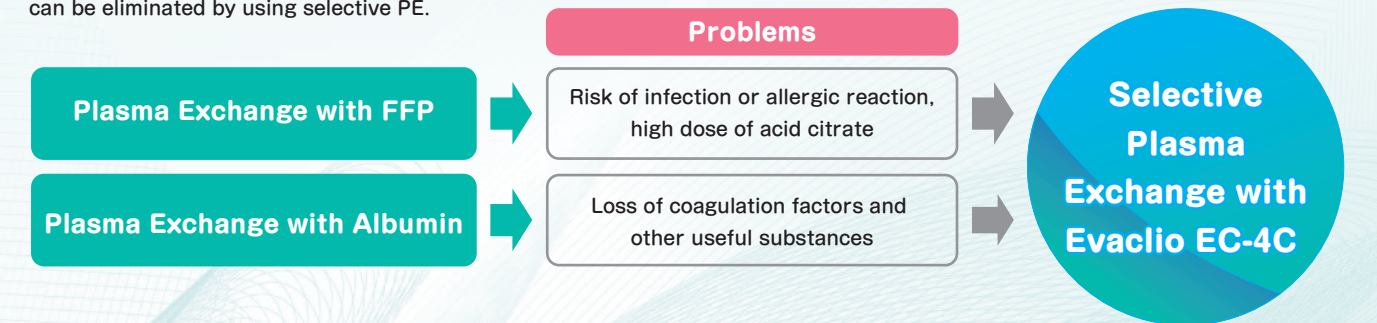


Potential indications

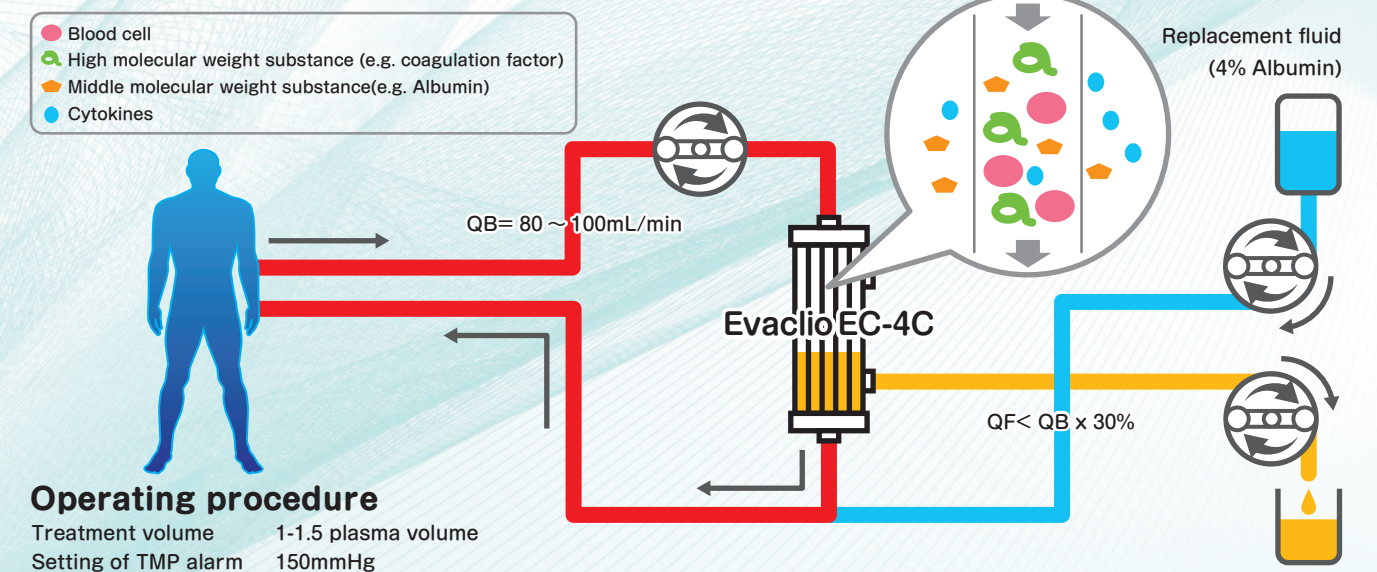
Indication	Target substance	Molecular weight
IgG antibody related autoimmune disorders (e.g. ANCA-associated Vasculitis / Myasthenia Gravis / Pemphigus Vulgaris / Bullous Pemphigoid)	IgG antibody Cytokines	160,000 8,000 ~ 30,000
Toxic Epidermal Necrolysis (Steven-Johnson syndrome)	soluble Fas-ligand Cytokines	26,000 (in trimer) 8,000 ~ 30,000
Recurrent Focal Segmental Glomerulosclerosis	Circulating Factors	30,000 ~ 50,000
Drug Toxication	Causative drug (with molecular weight smaller than albumin)	<66,000

Selective Plasma Exchange (Selective PE)

Selective Plasma Exchange using the Evaclio EC-4C retains more coagulation factors than conventional plasma exchange, therefore the use of FFP is unlikely to be required. The potential problems with conventional plasma exchange as shown below can be eliminated by using selective PE.



Flow diagram & setting (example)



Clinical effectiveness ANCA-associated Vasculitis

Selective PE was performed for 17 patients with MPO-ANCA associated vasculitis.

(2 times/week, average 3.6 times/patient)

- MPO-ANCA level decreased an average of 81% (Fig.1).
- Reduction of fibrinogen was less than DFPP or IAPP (Fig 2).
- Selective PE can be performed with albumin solution for substitution fluid.

Selective PE may be a safe and effective treatment taking into consideration of the risk of infection or bleeding tendency.

Fig 1. Change of MPO-ANCA

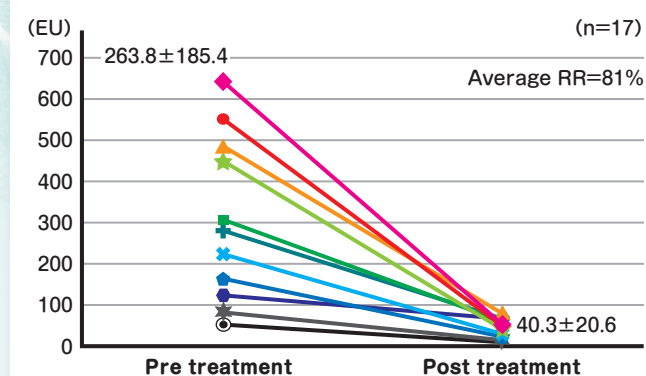


Fig 2. Fibrinogen reduction

