

Asahi**KASEI**

IMMUSORBA™ **PH-350(L)**

Immunoabsorption Column



***Treatment for
Autoimmune diseases***

ASAHI KASEI MEDICAL CO., LTD.
A Pioneer in Blood Purification

Selective immunoadsorption for autoimmune diseases with easy to handle single use column

Indication

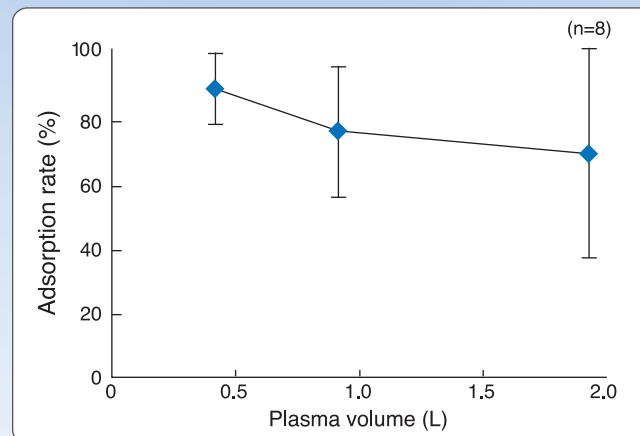
Autoimmune diseases

(e.g., Systemic lupus erythematosus (SLE), Malignant rheumatoid arthritis (MRA), Guillain-Barré syndrome (GBS), Chronic inflammatory demyelinating polyneuropathy (CIDP), Multiple sclerosis (MS))

Features of IMMUSORBA PH-350(L)

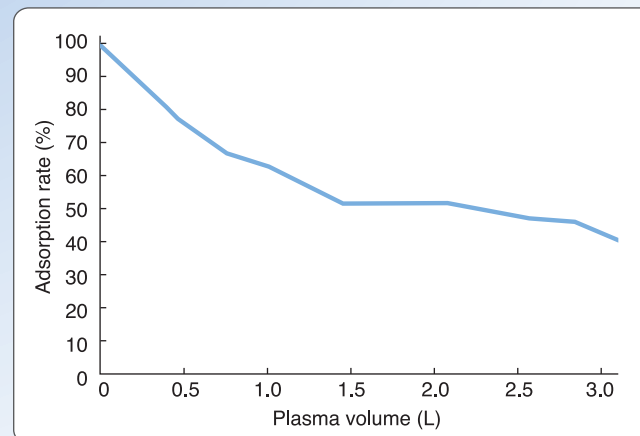
- Therapeutic plasmapheresis by removing pathogenic substances from patient's plasma by selective adsorption.
- No need for the replacement of plasma, minimizing the risk of infection with hepatitis, AIDS, etc.
- Applicable to patients with protein allergy.

Change in adsorption rate of rheumatoid factor (RF) (*in vivo*)



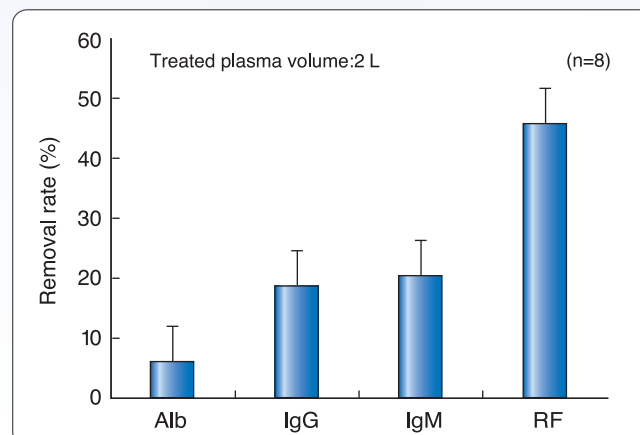
Plasma samples were collected at the inlet and outlet of the column.
(Data) Kamifukuoka Sogo Hospital, Seisui Hospital

Time course change in adsorption rate of anti-DNA antibody (*in vivo*)



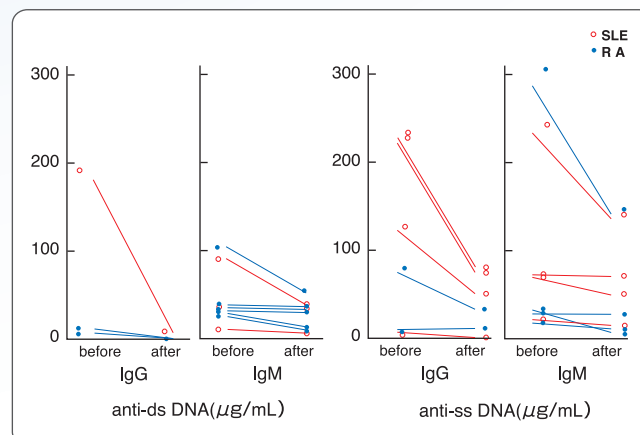
Plasma samples were collected at the inlet and outlet of the column.
Ohashi et al. Jpn J Apheresis 13(2): 201-202, 1994

Removal rate of RF and plasma components (*in vivo*)



Blood samples for removal rate were collected before and after treatment
(Data) Kamifukuoka Sogo Hospital, Seisui Hospital

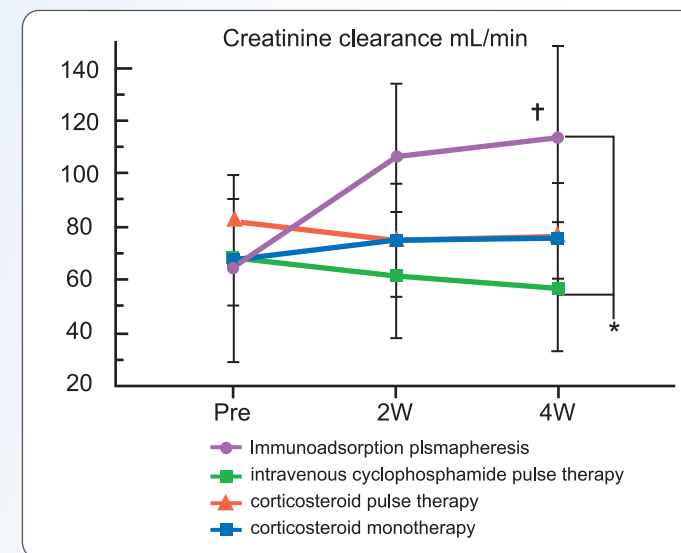
Changes in anti-DNA antibody titers (*in vivo*)



Plasma samples were collected at the inlet and outlet of the column.
Okudaira et al. Therapeutic Plasmapheresis IV, 149-152, 1984

Clinical Course

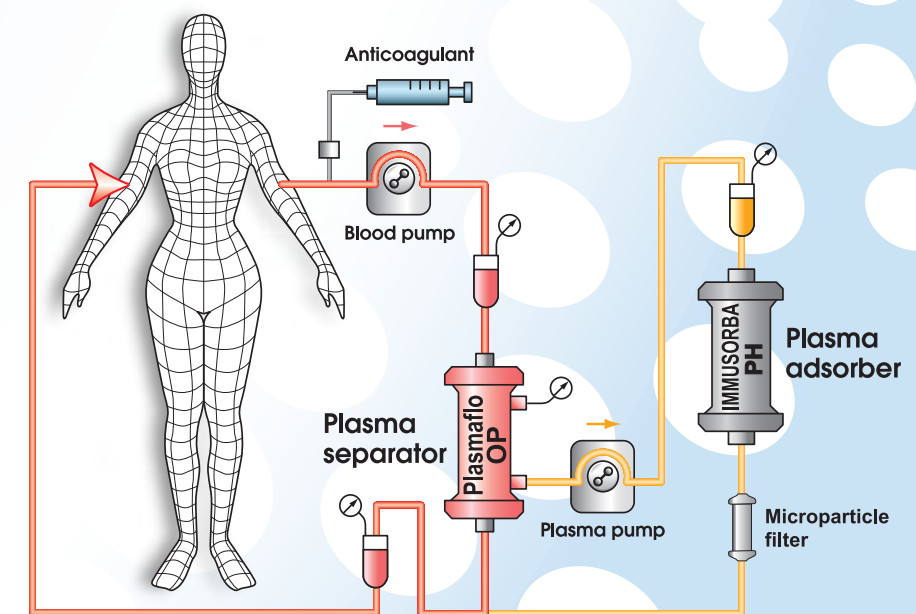
Changes in creatinine clearance. (*P<0.05 vs. baseline).



Six patients with histologically proven lupus nephritis (LN) associated with proteinuria and abnormal sedimentation on urinalysis were treated with oral corticosteroid (prednisolone 1 mg/kg/day) and IAPP (Immusorba PH-350; 2 L of plasma twice weekly for 2 weeks). The clinical efficacy of IAPP was compared with conventional pharmacotherapy regimes by conducting a retrospective review of 23 LN patients treated at our hospital using corticosteroid pulse therapy (CSPT, N = 7, intravenous methylprednisolone 500 mg/day for 3 days), intravenous cyclophosphamide pulse therapy (IVCY, N = 7), or corticosteroid monotherapy (CSMT, N = 9, oral prednisone 1 mg/kg body weight daily, for 4 weeks). The improvement in creatinine clearance was significant ($P < 0.05$) in the IAPP group only. In combination with corticosteroid therapy, IAPP appears to be an effective and safe treatment for LN.

Sugimoto et al. Ther Apher Dial. 10:187-92, 2006

Circuit Diagram



Specifications

Immunoabsorption Column	Adsorbent	Material	Phenylalanine immobilized polyvinylalcohol gel
		Volume	350mL
	Priming Volume		300mL
	Container	Material	Polypropylene
		Dimension	211mm [L] x 62mm [D]
Microparticle Filter	Weight		650g
	Sterilization		High pressure steam
	Filter	Material	Polyethylene (coated with ethylene-vinylalcohol copolymer)
		Area	0.07m ²
	Container	Material	Poly (vinyl chloride)
		Dimension	165mm [L] x 22mm [D]
	Priming Volume		30mL
	Sterilization		Ethylene oxide

Caution

For patients undergoing treatment with angiotensin-converting enzyme (ACE) inhibitor, there is a possibility that treatment with the IMMUSORBA PH-350 will lead to a drop in blood pressure. Simultaneous treatment with ACE inhibitor and the IMMUSORBA PH-350 must be avoided.

The IMMUSORBA PH-350 is intended for the treatment of plasma. Never run whole blood through the IMMUSORBA PH-350. Thrombocytes cannot pass through the IMMUSORBA PH-350 and may cause blockage. Do not use the IMMUSORBA PH-350 with plasma containing a large amount of thrombocytes.

References

【Reviews of the product】

- 1) Hirata et al. Immusorba TR and PH. Ther Apher Dial. 7:85-90, 2003
- 2) Yoshida et al. Immusorba TR and Immusorba PH: basics of design and features of functionas. Ther Apher. 4:127-134, 2000

【Reviews in clinical use】

- 1) Yang et al. Plasma adsorption in critical care. Ther Apher. 6:184-188, 2002
- 2) Tagawa et al. Ability to remove immunoglobulins and anti-ganglioside antibodies by plasma exchange, double-filtration plasmapheresis and immunoadsorption. J Neurol Sci. 157:90-95, 1998
- 3) Yamazaki. Extracorporeal immunoadsorption. Therapeutic Plasmapheresis VI 113-121, 1986

【Pre-clinical & Development】

- 1) Yamazaki et al. Extracorporeal immunoadsorption with IM-PH or IM-TR column. Biomater Artif Cells Artif Organs. 17:117-124, 1989

【Application to SLE】

- 1) Loo et al. Immunoadsorption and plasmapheresis are equally efficacious as adjunctive therapies for severe lupus nephritis. Transfus Apher Sci. 43:335-40, 2010.
- 2) Yamaji et al. Long-term clinical outcomes of synchronized therapy with plasmapheresis and intravenous cyclophosphamide pulse therapy in the treatment of steroid-resistant lupus nephritis. Ther Apher Dial. 12:298-305, 2008.
- 3) Sugimoto et al. Immunoadsorption plasmapheresis using a phenylalanine column as an effective treatment for lupus nephritis. Ther Apher Dial. 10:187-92, 2006.
- 4) Gaubitz et al. Immunoadsorption in systemic lupus erythematosus: different techniques and their current role in medical therapy. Ther Apher Dial. 7:183-188, 2003
- 5) Gaubitz et al. Prospective randomized trial of two different immunoadsorbents in severe systemic lupus erythematosus. J Autoimmun. 11:495-501, 1998
- 6) Ohashi et al. Study on the removal capacity of immunoadsorption column and its improvement. Jpn J Apheresis 13:201-202, 1994
- 7) Sagawa et al. Significance of Immunoadsorption Therapy in Patients with Systemic Lupus Erythematosus: Analysis of Serum Autoantibody and Immune Complexes by a Isoelectric Focusing Column. Therapeutic Plasmapheresis (XII) 569-571, 1993
- 8) Amasaki et al. Effect of Immunoadsorption Therapy on Lupus Nephritis Using Immunoadsorbent PH350 Columin. Therapeutic Plasmapheresis (VIII) 88-92, 1989
- 9) Yamazaki et al. Immunoadsorbent (IM-P) plasma perfusion in patients with rheumatoid arthritis or SLE. Life Support Syst. Suppl 1:98-101, 1983

【Application to RA】

- 1) Kobayashi et al. Plasma Cleaning Using Immunoadsorbent IM-P for Patients with Rheumatoid Arthritis. Therapeutic Plasmapheresis (IV) 152-157, 1984
- 2) Okudaira et al. Effect of immunoadsorbent treatment on auto-antibody levels. Therapeutic Plasmapheresis (IV) 149-152, 1984

【Other application】

- 1) Iimura et al. Plasmapheresis Therapy in Progressive Systemic Sclerosis: Short-Term and Long-Term Effects. Jpn J Apheresis 13:133-134, 1994
- 2) Koh et al. Immunoadsorption Plasmapheresis in Polymyositis/Dermatomyositis: Beneficial Effects in Four Cases. Jpn J Apheresis 13:131-132, 1994
- 3) Amemiya et al. Plasmapheresis Therapy in Progressive Systemic Sclerosis. Therapeutic Plasmapheresis (VIII) 97-100, 1989

AsahiKASEI

Manufacturer:

ASAHI KASEI MEDICAL CO., LTD.

1-105 Kanda Jinbocho, Chiyoda-ku, Tokyo 101-8101, Japan
TEL: +81-3-3296-3727 FAX: +81-3-3296-3722
URL: <http://www.asahikasei-medical.com>

Represented in Europe by:

ASAHI KASEI MEDICAL EUROPE GmbH

Herriotstrasse 1, 60528 Frankfurt am Main, Germany
TEL: +49 (0) 69 66 37 15 00 FAX: +49 (0) 69 6 66 51 93

Represented in Americas by:

ASAHI KASEI MEDICAL AMERICA INC.

3570 Winchester Road, Suite 101, Memphis, Tennessee 38118, USA
TEL: +1-901-362-6105 FAX: +1-901-362-6180

CE
0086