

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

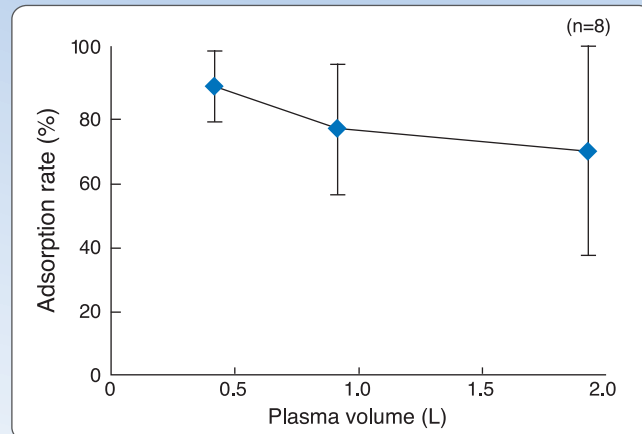
Autoimmune diseases

(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)

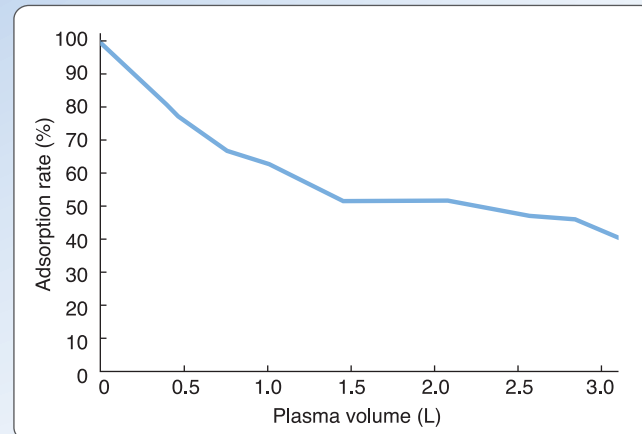
- Therapeutic plasmapheresis by removing pathogenic substances from patient's plasma by selective adsorption.
- No need for the replacement of plasma, minimizing the risk of infection with hepatitis, AIDS, etc.
- Applicable to patients with protein allergy.

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



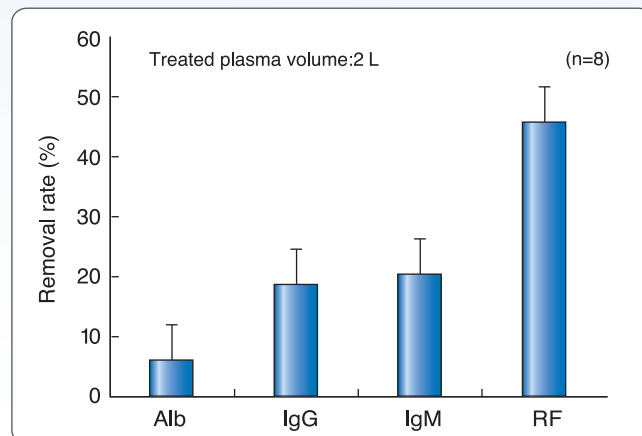
Plasma samples were collected at the inlet and outlet of the column.
(Data) Kamifukuoka Sogo Hospital, Seisui Hospital

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



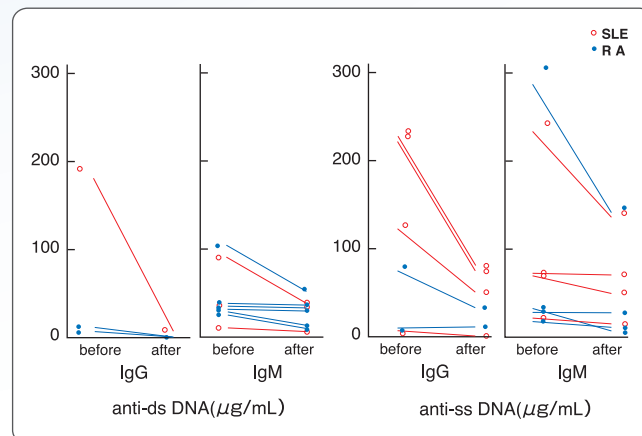
Plasma samples were collected at the inlet and outlet of the column.
Ohashi et al. Jpn J Apheresis 13(2): 201-202, 1994

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

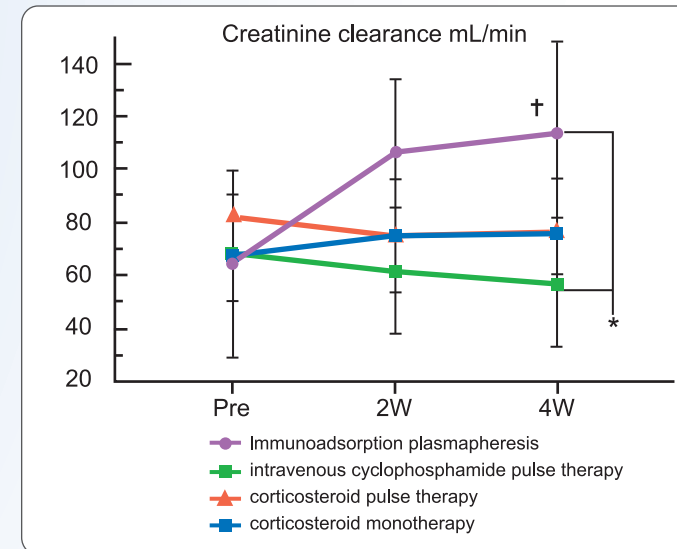
Changes in anti-DNA antibody titers (*in vivo*)



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

Clinical Course

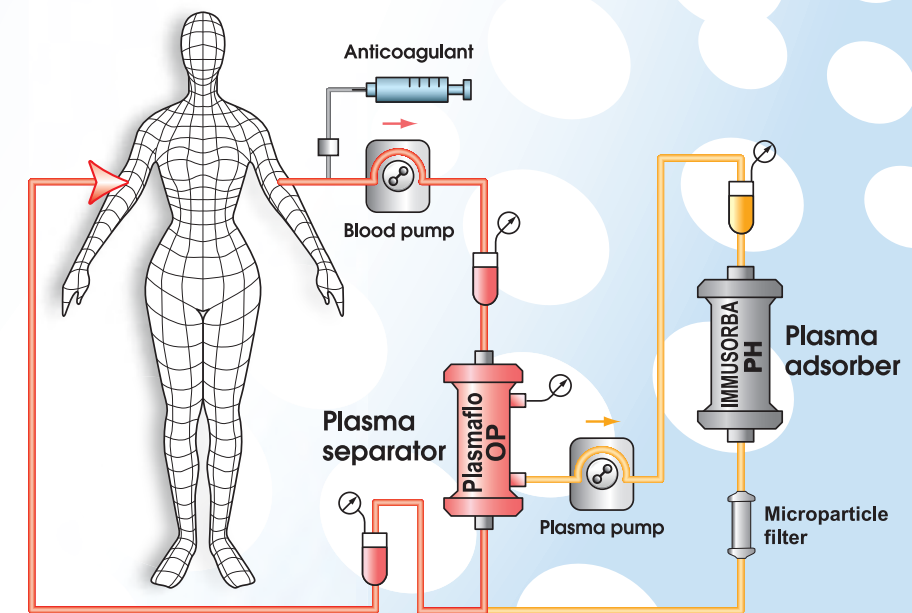
Changes in creatinine clearance. (*P<0.05 vs. baseline).



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
	Weight		650g
Microparticle Filter	Sterilization		High pressure steam
	Filter	Material	Polyethylene (coated with ethylene-vinylalcohol copolymer)
		Area	0.07m ²
	Container	Material	Poly (vinyl chloride)
	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) Hirano et al. Immunoabsorption using Immusorba TR and PH. *Transfus Apher Sci.* 56:661-5, 2017
- 2) Hirata et al. Immusorba TR and PH. *Ther Apher Dial.* 7:85-90, 2003
- 3) 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) Yamaji. Immunoabsorption for collagen and rheumatic diseases. *Transfus Apher Sci.* 56:666-70, 2017
- 2) Yang et al. Plasma adsorption in critical care. *Ther Apher.* 6:184-188, 2002
- 3) Tagawa et al. Ability to remove immunoglobulins and anti-ganglioside antibodies by plasma exchange, double-filtration plasmapheresis and immunoabsorption. *J Neurol Sci.* 157:90-95, 1998
- 4) Yamazaki. Extracorporeal immunoabsorption. *Therapeutic Plasmapheresis VI* 113-121, 1986

【Pre-clinical & Development】

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

【Application to SLE】

- 1) Huang et al. Rapid reduction of antibodies and improvement of disease activity by immunoabsorption in Chinese patients with severe systemic lupus erythematosus. *Clin Rheumatol.* 35:2211-8, 2016
- 2) Loo et al. Immunoabsorption and plasmapheresis are equally efficacious as adjunctive therapies for severe lupus nephritis. *Transfus Apher Sci.* 43:335-40, 2010.
- 3) 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.
- 4) Sugimoto et al. Immunoabsorption plasmapheresis using a phenylalanine column as an effective treatment for lupus nephritis. *Ther Apher Dial.* 10:187-92, 2006.
- 5) Gaubitz et al. Immunoabsorption in systemic lupus erythematosus: different techniques and their current role in medical therapy. *Ther Apher Dial.* 7:183-188, 2003
- 6) Gaubitz et al. Prospective randomized trial of two different immunoabsorbers in severe systemic lupus erythematosus. *J Autoimmun.* 11:495-501, 1998
- 7) Ohashi et al. Study on the removal capacity of immunoabsorption column and its improvement. *Jpn J Apheresis* 13:201-202, 1994
- 8) Sagawa et al. Significance of Immunoabsorption 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
- 9) Amasaki et al. Effect of Immunoabsorption Therapy on Lupus Nephritis Using Immunoabsorbent PH350 Column. *Therapeutic Plasmapheresis (VIII)* 88-92, 1989
- 10) Yamazaki et al. Immunoabsorbent (IM-P) plasma perfusion in patients with rheumatoid arthritis or SLE. *Life Support Syst. Suppl* 1:98-101, 1983

【Application to RA】

- 1) Cheng et al. Plasmapheresis therapy in combination with TNF- α inhibitor and DMARDs: A multitarget method for the treatment of rheumatoid arthritis. *Mod Rheumatol.* 27:576-81, 2017
- 2) Kobayashi et al. Plasma Cleaning Using Immunoabsorbent IM-P for Patients with Rheumatoid Arthritis. *Therapeutic Plasmapheresis (IV)* 152-157, 1984
- 3) Okudaira et al. Effect of immunoabsorbent treatment on auto-antibody levels. *Therapeutic Plasmapheresis (IV)* 149-152, 1984

【Other application】

- 1) Imura 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. Immunoabsorption 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

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