

TECHNICAL DATA SHEET

Adapters for acid concentrates in bags

PRODUCT DESCRIPTION

The adapters for acid concentrates in bags are Class IIa non sterile, single-use devices that are to be used with acid concentrate in bags (Lympha™ acetate free solution and ACIDFLEX) to allow the aspiration of acid solution to pass into hydraulic circuit of the dialysis machine, creating dialysis fluid in association with dilute solution of sodium bicarbonate and quality water. The adapters are intended to be used by hospital staff or suitable trained persons.

The Bellco S.r.l. adapters for acid concentrates in bags can be used with most equipment, including:

Fresenius and Baxter Adapters – BL194 adapters for acid concentrates in bags can be used with Fresenius and Baxter dialysis machine.

Nikkiso Adapters – BL 194 adapters for acid concentrates in bags are compatible with dialysis machines equipped with acid concentrate solution connectors 4mm or 5mm in diameter. The device is used in adult patients requiring extracorporeal renal replacement therapy. The performance of the device is guaranteed for a maximum of 10 hours continuous use.

INTENDED USE

The device is intended to come into contact with concentrated acid solution allowing it to be aspirated from the dedicated bag and passed to the hydraulic circuit of the machine for creation of the dialysis fluid.

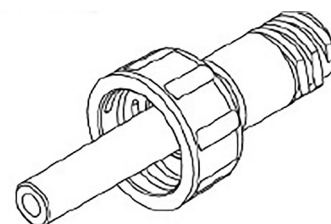


Figure 1. Fresenius Adapters — BL194 Adapters for acid concentrates in bags

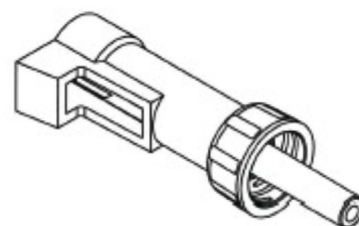


Figure 2. Baxter Adapters — BL194 Adapters for acid concentrates in bags

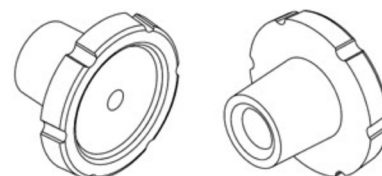


Figure 3. Nikkiso Adapters - BL194 Adapters for acid concentrates in bags

CODES AVAILABLE

CFN/REF	Description	CND	GMDN	ERP-SAP Description
IB0543001	Adapters for acid concentrates in bags	F0299	32110	BL 194 Fresenius Adapters
IB0543002	Adapters for acid concentrates in bags	F0299	32110	BL 194 Baxter Adapters
IB0543004	Adapters for acid concentrates in bags	F0299	32110	BL 194 Nikkiso Adapters

STERILIZATION METHOD AND VALIDITY

Not Sterile.

Shelf life: 3 years.

TECHNICAL CHARACTERISTICS

The technical characteristics of the adapters for acid concentrates in bags are reported below.

Components	Materials ¹
Fresenius Adapters – Adapters for acid concentrates in bags	Polypropylene
Baxter Adapters – Adapters for acid concentrates in bags	Polypropylene
Nikkiso Adapters – Adapters for acid concentrates in bags	Thermoplastic Elastomer

¹Indirect contact with blood, according to IFU.

PACKAGING

Model	Primary Packaging – Pouch	
	Material	Pouch weight (g)
Fresenius Adapters – BL194 Adapters for acid concentrates in bags	150 x 85 mm Plastic film - Polyamide/ Low Density Polyethylene Paper layer – Medical paper 60 + 11 g/m ²	3,17g
Baxter Adapters – BL194 Adapters for acid concentrates in bags	150 x 85 mm Plastic film - Polyamide/ Low Density Polyethylene Paper layer – Medical paper 60 + 11 g/m ²	3,17g
Nikkiso Adapters – BL194 Adapters for acid concentrates in bags	100 x 60 mm Plastic film – A laminated of Polypropylene/Polyethylene 100 x 60 mm Paper layer – Medical paper lackered 60 +10 g/m ²	1,19g

Model	Secondary Packaging – Box		
	Box	Weight ² [kg]	Pcs/Box
Fresenius Adapters – BL194 Adapters for acid concentrates in bags	Rippled cardboard 3 mm Box closed Dimensions: 260 x 193 x 155 mm	0,3	35
Baxter Adapters – BL194 Adapters for acid concentrates in bags	Rippled cardboard 3 mm Box closed Dimensions: 260 x 193 x 155 mm	0,4	35
Nikkiso Adapters – BL194 Adapters for acid concentrates in bags	Rippled cardboard 3mm – B Flute – KW2/US6/K2 – External White Box closed Dimensions: 290 x 250 x 165 mm	0,4	100

² Box weight filled with products

STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between +0 and +30 Celsius degrees and do not expose to direct sunlight.

Disposal: remove from the place of dialysis immediately after use. Disposal must be carried out in accordance with the regulations in force.

BIOCOMPATIBILITY

Biocompatibility tests of Adapters for acid concentrates in bags have been performed according to ISO 10993-1 and related applicable standard series.