



Total Parenteral Nutrition Bags

Dual-Chamber Bags



Features

- EC marked: Directive 93|42|EEC applicable for medical devices
- Full compliance with ISO11137: Highest sterility assurance level
- Dual-Chamber Bags: Recommended choice when longer shelf-life is necessary such as in home healthcare applications
- Multiple Manufacturing sites: High security of supply
- Each bag is air leak tested with filtered (0.2 µm) compressed air (430 mmHg)
- All connections extensively qualified: Safe and robust
- Standard design: Most designs available from stock

Specifications

Bag Chamber	EVAM®
Tubing	EVA PVC
Fittings	Female Luer® Lock, spike port, additive port
Number of ports	3 (lower chamber) + 1 (upper chamber)
Volumes	500 mL, 1 L, 2 L, 3 L
Standard capacity	Upper chamber: 1/3; Lower chamber 2/3 of total bag capacity
Sterilization	Gamma Sterilization
Shelf-Life	2 years

Description

Sartorius Stedim Biotech's range of Total Parenteral Nutrition (TPN) products offers a complete system enabling a simple, safe, patient-compliant and economical preparation, thanks to a range of Dual-Chamber Bags, whose flexibility in preparation and improved comfort in administration give patients at home improved quality of care.

Sartorius Stedim Biotech pioneered the original EVA Bags and has used its expertise to manufacture the highest quality containers for total parenteral nutrition admixtures.

The Dual-Chamber Bags are designed for separated storage of lipid emulsion until reconstitution just before administration. Complete admixtures are easily obtained by simply removing the external separation system. The separation system is a hinge system made with an aluminium profile and a santoprene joint, which avoids any contact with the TPN admixture. Particulate contamination risk is thus eliminated.

Dual-Chamber Bags are available in EVAM® in a range of 500 mL to 3 L.

Applications

- Total parenteral nutrition admixtures
- Sartorius Stedim Biotech Dual-Chamber Bag is the recommended choice when longer shelf-life is necessary e.g. in home healthcare applications. The admixture reconstitution may easily be performed by the patient at home upon training.
- The concept allows for sequential administration of the ternary mixture. It is also possible to deliver only the binary mixture if required by the patient's status.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Validation

Nutripoche® bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests provide users of Nutripoche® with data representing the widest range of process fluids in a variety of processing conditions.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single Use Products follow applicable EU directive regulations and FDA regulations for Medical Devices.

Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

EC marking in conformity with the 93|42|EEC Medical device directive.

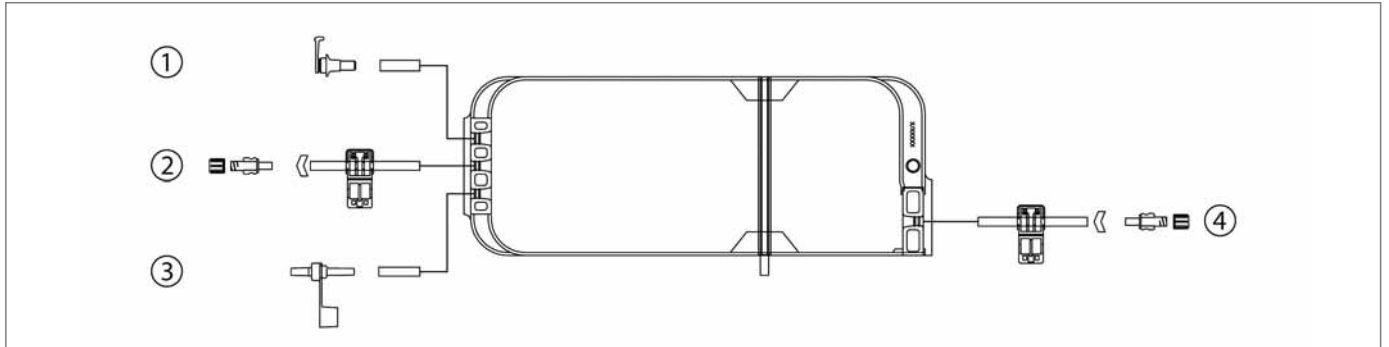
Nutripoche® Bags are tested for compliance to:

- USP <85>: Bacterial endotoxins test
- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19 : Particulate
- ISO 11737: Bioburden before sterilization
- ISO 11137: Sterilization of Medical Devices by Gamma irradiation
- E.P.3.1.7: Poly (ethylene – vinyl acetate) for containers and tubing for total parenteral nutrition preparations.

Rapid Supply

The majority of Standard Nutripoche® Bags are available from stock

Ordering information



Part Number	Description	Tubing	Bottom Port 1	Bottom Port 2	Bottom Port 3	Top Port 4	Qty/box
FNB103219	Nutripoche® EVAM® 500 mL Dual-Chamber Bag	EVA PVC	ID: 6.3 mm × OD: 8 mm (L 29 mm) + Spike port	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	ID: 4.8 mm × OD: 6.5 mm (L: 30 mm) + Additive port + closure cap	ID: 4.8 mm × OD: 6.5 mm (L 80mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	50
FNB103218	Nutripoche® EVAM® 1L Dual-Chamber Bag	EVA PVC	ID: 6.3 mm × OD: 8 mm (L 29 mm) + Spike port	ID: 4.8 mm × OD: 6.5 mm (L 80mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	ID: 4.8 mm × OD: 6.5 mm (L: 30 mm) + Additive port + closure cap	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	50
FNB102397	Nutripoche® EVAM® 2L Dual-Chamber Bag	EVA PVC	ID: 6.3 mm × OD: 8 mm (L 29 mm) + Spike port	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	ID: 4.8 mm × OD: 6.5 mm (L: 30 mm) + Additive port + closure cap	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	50
FNB103592	Nutripoche® EVAM® 3L Dual-Chamber Bag	EVA PVC	ID: 6.3 mm × OD: 8 mm (L 29 mm) + Spike port	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	ID: 4.8 mm × OD: 6.5 mm (L: 30 mm) + Additive port + closure cap	ID: 4.8 mm × OD: 6.5 mm (L 80 mm) + crimp clamp + coding ring + Female Luer® Lock connector + Luer® Lock protector	50

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by Sartorius Stedim Biotech GmbH
W · G
Publication No.: SPT2015-e09061
Order No.: 85032-535-27
Ver. 06 | 2009