

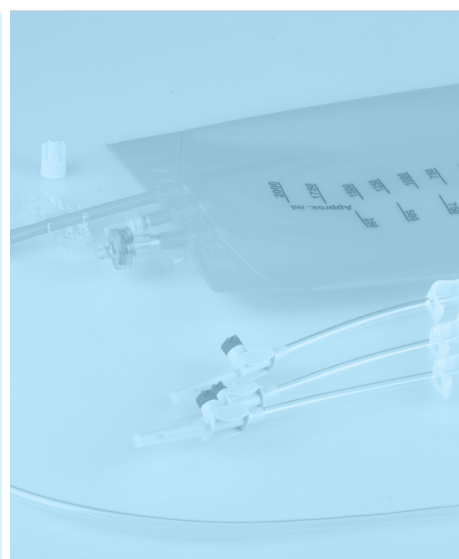
GENERAL CATALOGUE





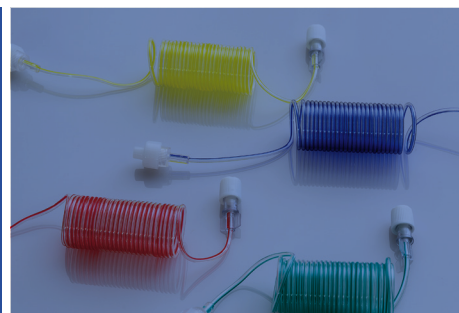
Bag

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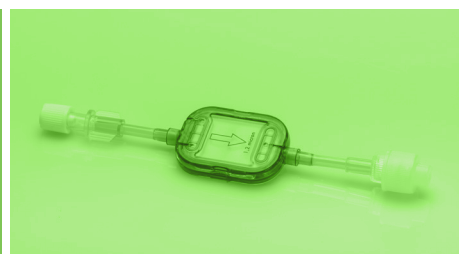
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Main business activities are designing, developing, manufacturing and commercializing medical devices, adapting them to the customers' requests. In particular:

- Disposable sterile medical devices for parenteral and enteral nutrition. Potential customization in design, capacity and material, for every feeding use with or without filling set.

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- 4
- Drainage bags: from small volumes up to 18 Liters.
 - Bags for blood, cardiac surgery or transfer.
 - Infusion and transfusion sets.

Valmed uses high frequency welding technology, applied to the production of both bags.

STRUCTURE

The new production site of 3000m², has been designed specifically for the biomedical sector, paying particular attention to the division between the various working areas and compliance with GMP.

Personal and customized badges regulate every access and the doors of the production area are characterized by the presence of traffic lights that control their opening.

Our production area is in a clean room, 1000sqm, which is certified with the ISO 8 class.

The working environment, modern and technological, in which the operators have a correct artificial and solar light, has a positive influence on the quality of the product.

The warehouse has an area of 600sqm and can hold up to 1000 pallets. An innovative storage system is adopted using the warehouse management system and the compactable warehouse.



TECHNOLOGY

Valmed's aim is to approach on the job every day with a focus on the latest technology available in the market. Led by a young and smart team, Valmed's caring about the 4.0 industry is brilliant, with all the departments fully connected in the system, interacting each other in order to not lose any information and to handle in the best way customer request.

Starting from a new project, drawings and bill of material made from our tech dept. are handled by the most recent design system which can complete interact with the ERP, software used also for commercial and administration.

Supply Chain is smartly managed with the WMS, Warehouse Management System, which can give us complete traceability of incoming materials and outgoing products.

Core of the system is MES, Manufacturing Execution System, software developed by Valmed himself with support of a local software house. Monitoring production constantly, this software can give the opportunity to improve the working process with statistical and analytics methods.

The production area and warehouse are subjected to continuous temperature, pressure and humidity monitoring and controlled by apposite system (SCADA).

Finally, Quality in process and Customer Service is controlled with an accurate system, with all the data are saved and available to handle claims and reports.

PARENTERAL NUTRITION

MAIN FEATURES

- EVA (Ethylene-vinyl acetate), EVA UV or Multilayer material
- Female or Male connector
- Medication port
- Spike port with vial-cone or twist-off
- Non-reopening or on/off clamp
- 1-way, 3-ways or 6-ways gravity filling set
- From 2000ml with internal handle
- Additional infusion set
- DEHP free- Latex free
- Sterile EtO

CAPACITY (ML)

150, 250, 500, 1000, 2000, 3000, 4000, 5000.

The EVA TPN bags are empty containers for use in compounding and storage of sterile medical solutions such as parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The empty bags are filled by connecting them to containers - generally glass bottles closed by a pierceable membrane - containing one or more solutions through standard spikes and tubes or by pump. Graduated scale printed on bag by hot method. Availability to manufacture bag in different capacity (on customer requests). Finished product OEM, CE marked or FDA 510K. Our technical department is available to research and study flexible and innovative products in collaboration with the customer.

QUALITY STANDARDS

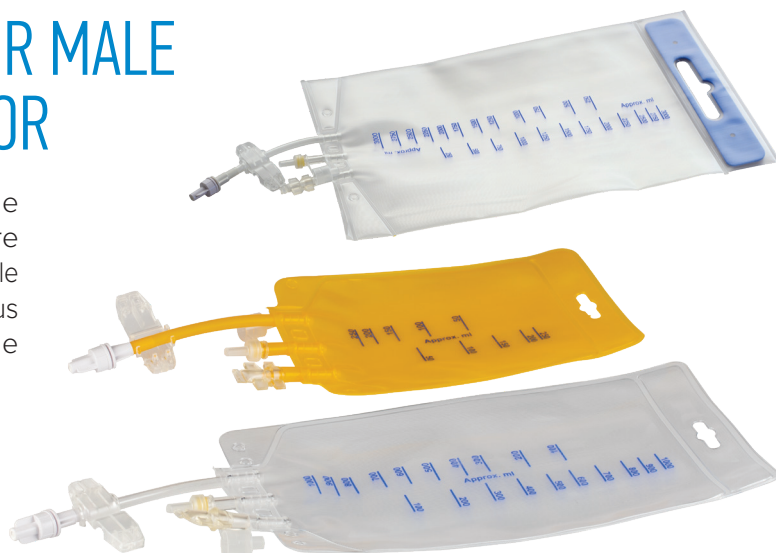
The EVA TPN bags are manufactured under a Quality Management System certified to ISO 13485 and are 100% leak tested during manufacturing. The welding process of the bags undergo stringent qualification and validation as part of the manufacturing process.

The materials of construction of the TPN bags meet:

- ISO 10993-4 - ASTM F2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
- ISO 10993-18 Leachables & Extractables
- ISO 15747 Functional Tests
- ISO 15747 Chemical evaluation

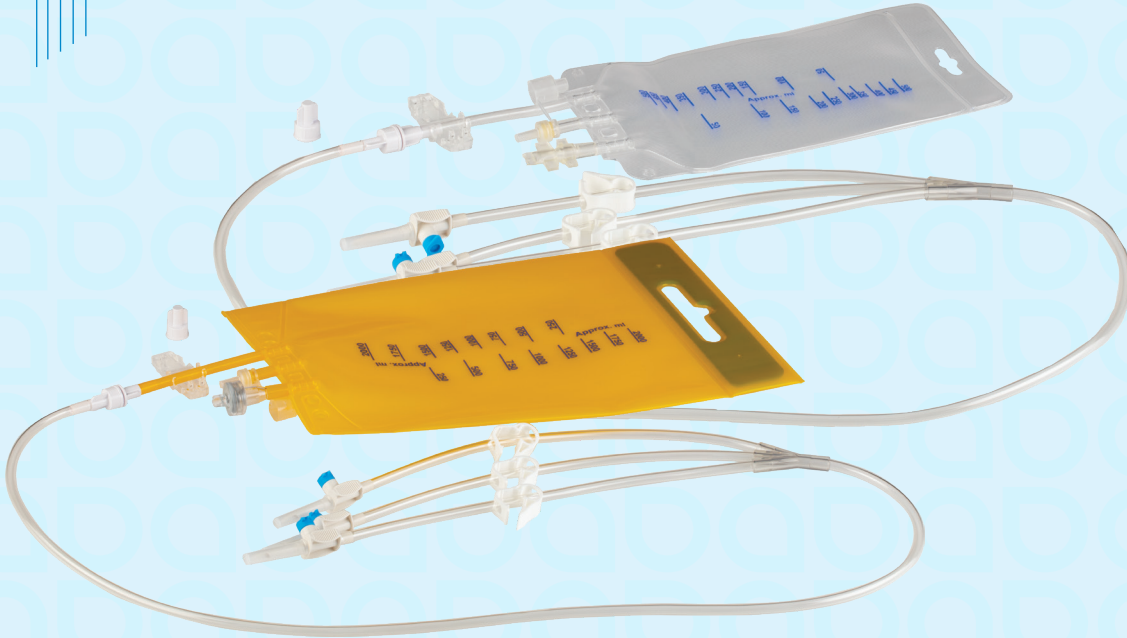
FEMALE OR MALE CONNECTOR

Bag with female or male big bore connector, compatible with the most famous compounder on the market.



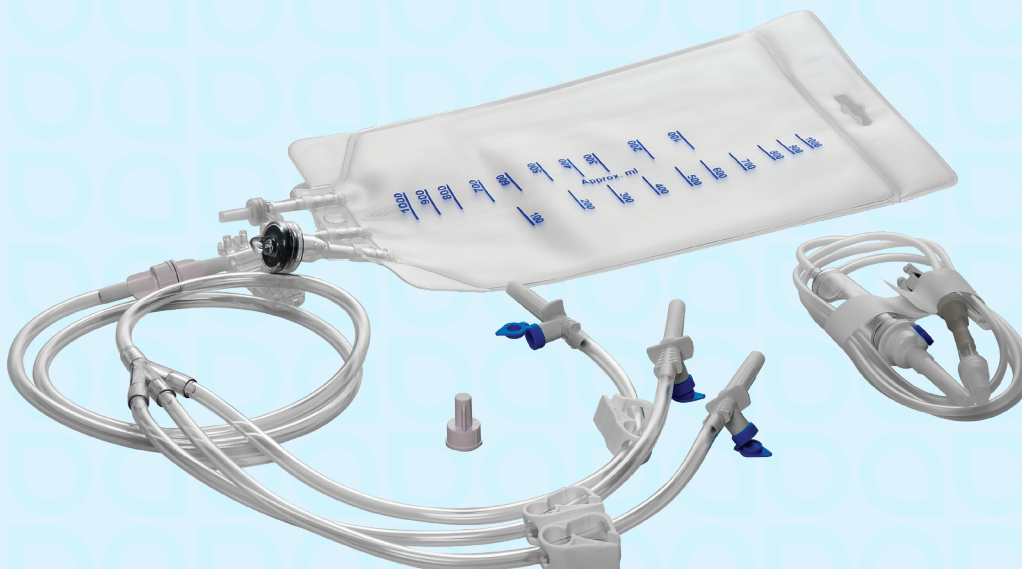
THREE WAYS GRAVITY SET

Right solution for the filling of the bag by the gravity system.
3-way set Ø4.8x6.8mm with air vented spike 3µm.



THREE WAYS SET AND INFUSION SET

Right solution for the filling of the bag by the gravity system.
3-way set Ø4.8x6.8mm with air vented spike 3µm.
In combination, infusion set with drip chamber and 15µm filter.



ONE WAY SET

Bag with just 1-way filling set Ø3x4.1mm and 1-way spike.
Suitable for use with pump.



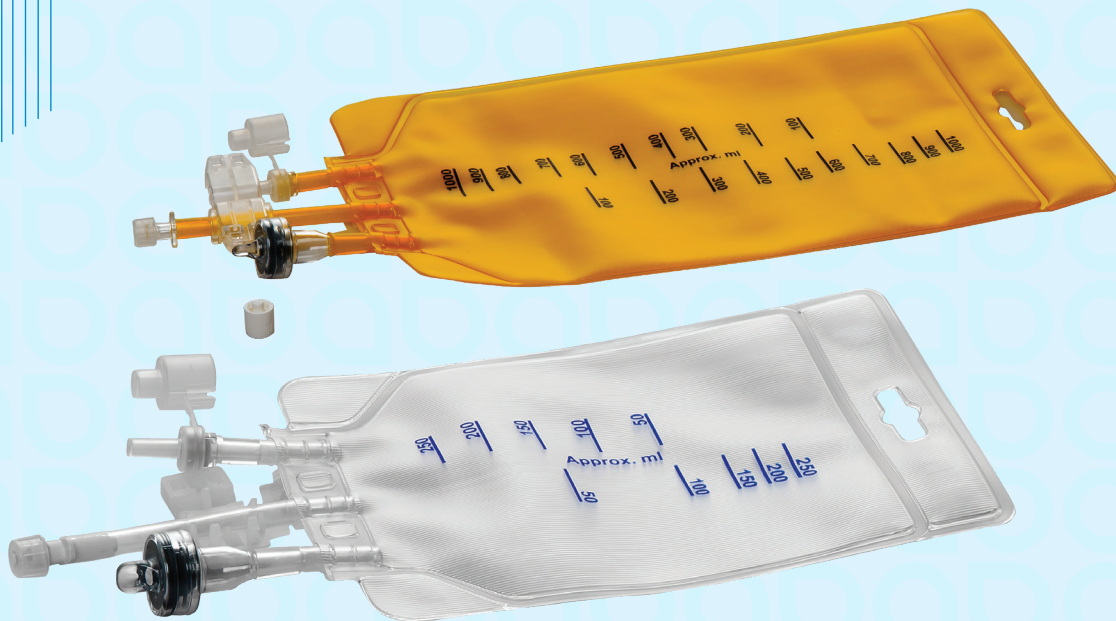
ONE WAY SET WITH INJECTION SITE

Bag with just 1-way filling set Ø3x4.1mm and 1-way spike.
Extra injection site for adding drugs during the filling step.
Suitable for use with pump.



FEMALE OR MALE LUER LOCK

Bag with FLL or MLL, connector with small diameter suitable for use with syringe set.



MULTI CHAMBERS WITH OR WITHOUT FILLING SET

The multi chambers bag is used giving the possibility to separate the lipid macronutrients from the remaining part of the hydroelectrolytic solution.

The activation of the chambers occurs by breaking the break-connector and the nutrients combine slowly to form an oil/water emulsion so that it can be infused to the patient. Filling the bag by the gravity system. 3-way set Ø4.8x6.8mm with air vented spike 3µm.

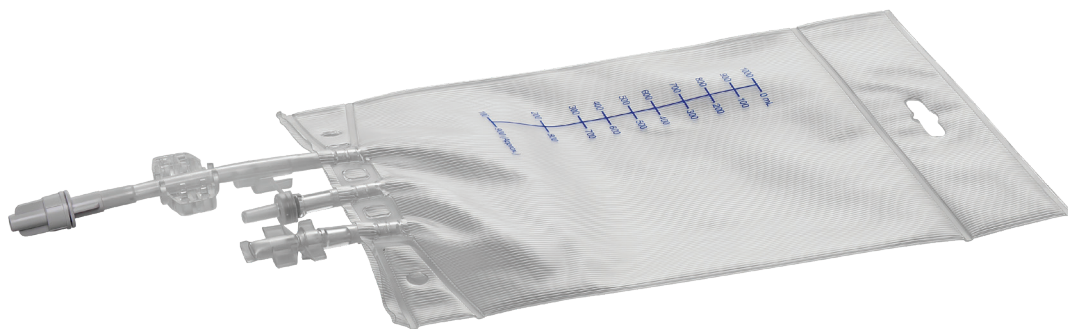
Filling with female or male big bore connector, compatible with the most famous compounder on the market.

CAPACITY (ml): 650+150, 1300+300, 2000+400, 3000+500, 5000+300.



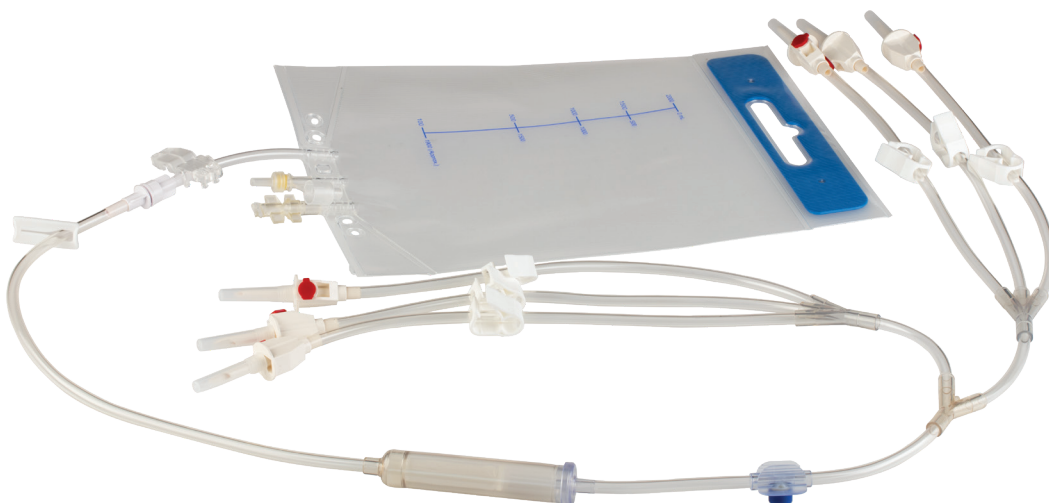
MULTILAYER BAG FEMALE OR MALE CONNECTOR

Parenteral nutrition solutions can contain amino acids and vitamins that require high barriers for oxygen, carbon dioxide and UV light. Multilayer film offer these barrier functions and it is high transparent. The coextruded material contains an EVA fluid contact layer. Bag with female or male big bore connector, compatible with the most famous compounder on the market.



MULTILAYER BAG WITH 6-WAY SET

Parenteral nutrition solutions can contain amino acids and vitamins that require high barriers for oxygen, carbon dioxide and UV light. Multilayer film offer these barrier functions and it is high transparent. The coextruded material contains an EVA fluid contact layer. 6-ways filling set with set with drip chamber and 40µm filter.



ENTERAL NUTRITION BAG

The enteral nutrition EVA bag is manufactured with the cap used during filling process and a exit tube on the bottom side. Graduated scale printed on bag by hot method. Availability to manufacture bag in different capacity (on customer requests). Finished product OEM or CE marked. Our technical department is available to research and study flexible and innovative products in collaboration with the customer.

MAIN FEATURES

- EVA (Ethylene-vinyl acetate) material.
- Transparent or violet filling cap.
- Spike port with vial-cone or twist-off
- With or without infusion set
- DEHP free- Latex free
- Sterile EtO

CAPACITY (ML)

500 - 1000
1500 - 2000

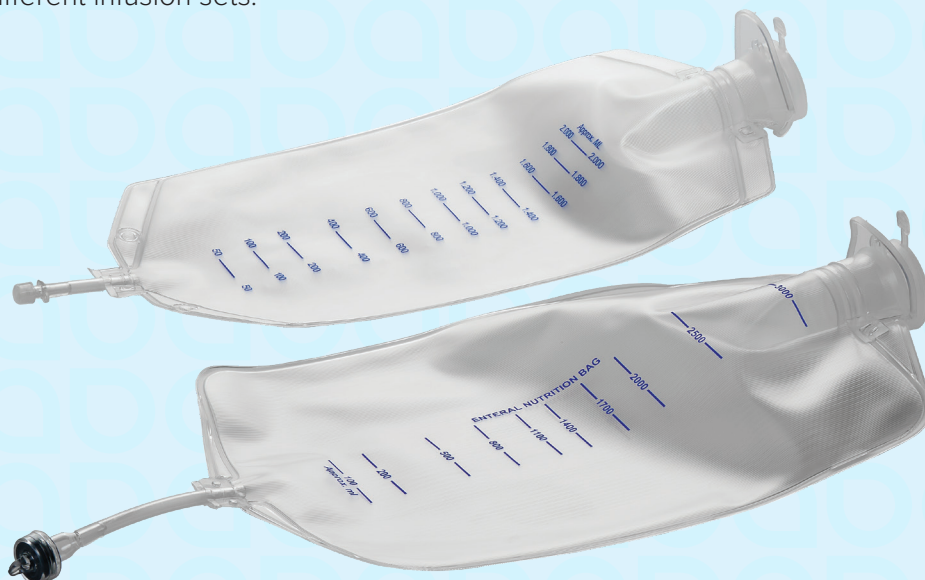
QUALITY STANDARDS

The EVA Enteral bags are manufactured under a Quality Management System certified to ISO 13485. The welding process of the bags undergo stringent qualification and validation as part of the manufacturing process. The materials of construction of the Enteral bags meet:

- ISO 10993-4 - ASTM F2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
- ISO 10993-18 Leachables & Extractables

ENTERAL NUTRITION BAG

Enteral bag with gravity infusion set, clamp, drip chamber with flow regulation roller, Y connector for eventual second administration, terminal FLL, nose-stomach tube connector. Enteral bag with pump infusion set, clamp, drip chamber whit silicone tubing, roller, Y connector for eventual second administration, terminal FLL, nose-stomach tube connector. Bag without filling set equipped only with cap with pierce able surface suitable for different infusion sets.



BLOOD

Possibility of creating all types of devices with blood contact. From the simplest plasma, transfer, cardioplegia bags to the latest ones made for cardio-surgery, as flexible reservoirs or priming for extracorporeal circulation.

Standard products are the only mentioned.

Different configuration / O.E.M. configuration available on request. Our Technical Department is always available to grant max. research and assistance, both on study flexible and innovative configuration, both on study innovative raw material (film) to use, in full cooperation with the customer.

MAIN FEATURES

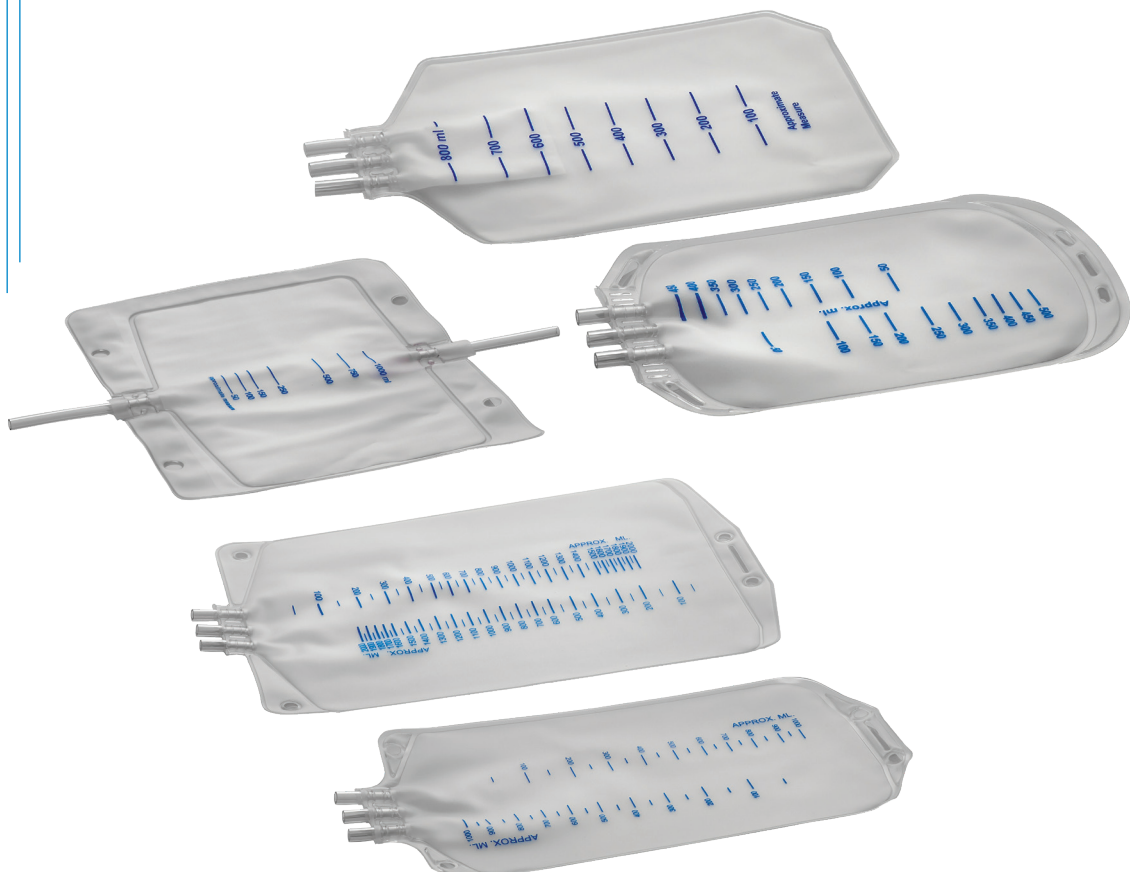
- PVC material
- Different plasticized such as DINCH - DINP - TEHTM - DEHT - CITRATE
- Different thickness up to 500µm
- Different diameters of the tubes
- Different PES filter
- DEHP - DEHP free - PHT free
- Latex free

CAPACITY (ML)

250 - 500

750 - 1300

BLOOD, CARDIAC SURGERY OR TRANSFER



CRYOCONSERVATION OR STORAGE

Blood Cryoconservation Bag is a safe way to preserve blood components when cryopreservation is indicated. This bag is indicated for freezing of blood and blood components, for cryogenic blood preservation and cord blood storage in liquid nitrogen. It is made from polyolefin film, which combines the liquid nitrogen stability with excellent flexibility and puncture resistance.

Polyolefin has low water vapor transmission and good gas barrier properties, helping to preserve the integrity of blood components.

These bags are used for 2 applications:

Storage of platelets: this is performed at 37°C.

Storage of stem cells: short term at room temperature or 37°C and Cryogenic storage at -196°C.

Polyolefin films This special material has mono layer structure and combine very high oxygen and carbon dioxide transmission rates with excellent cold storage properties down to -196°C. At this temperature the polyolefin film remains more flexible compared to EVA materials; which makes it the preferred film for such freezing application. Biocompatible according to ISO 10993. **Tubes** Monolayer or coextruded multilayer tubing with polyolefin elastomer blend outside layer. This tube is designed specifically for application like cell culturing, cold storage and blood components. Biocompatible according to ISO 10993. **Spike ports** EVA spike port is designed for main application areas including cryogenic storage. It is characterized by a perforable internal membrane and besides the spike is radio frequency welded on the top. Biocompatible according to ISO 10993.

MAIN FEATURES

- Polyolefin or PVC material
- Availability to manufacture bag in different capacities.
- Hermetically welded Spike ports.
- 1 or 2 spike-port
- 1 or 2 tubes Ø3x4.1mm
- Rated for use in liquid nitrogen.
- Different configuration are available.
- The batch and/or code can be engraved on the bag.
- The barcode can be inserted in packet of the bag.
- DEHP free - Latex free

CAPACITY (ML)

250 - 500 - 750 - 1300



DRAINAGE

Drainage bag realized with PVC material with tubes and special elbows/particular flanges. Connections are based on all standard diameter tube actually in use into hospitals/clinics. Bag configuration can be with T-tap valve, push/pull valve or turn valve, anyone with a different drainage time. Non-return valve can be added on request. Largest bag equipment includes a special handle to ensure safety fixing.

Standard products are the only mentioned. Different configuration / O.E.M. configuration available on request. Our technical department is always available to grant max. research and assistance, both on study flexible and innovative configuration, both on study innovative raw material (film) to use, in full cooperation with the customer.

MAIN FEATURES

- PVC material
- Different plasticized such as DEHP - DINCH - DINP - DEHT
- Different thickness from 200µm to 350µm
- Different diameters of the tube
- Different connector or tap
- With or without handle
- DEHP - DEHP free - PHT free
- Latex free

CAPACITY (ML)

600 - 2000 - 3000
4000 - 5000 - 6000
7000 - 8000- 10000
14000 - 18000

DRAINAGE BAG



HEATING

Bag for blood and solutions heating.

The design of the bag is configured according to the heater.

Standard products are the only mentioned. Different configuration / O.E.M. configuration available on request. Our technical department is always available to grant max. research and assistance, both on study flexible and innovative configuration, both on study innovative raw material (film) to use, in full cooperation with the customer.

MAIN FEATURES

- PVC or EVA material
- Different thickness from 200µm to 350µm
- Different diameters of the tube
- DEHP - DEHP free - PHT free
- Latex free

HEATING BAG



PUR COILED EXTENSION LINE

Coiled extension line application meaning is to skip any problems during hospital activities (obstruction during hospital activity). Valmed developed coiled extension line for infusion and suction, granting a large application field and different solutions, through the use of different raw material (soft PVC different hardness, PUR and PE) and large diameter sizes or lengths.

PUR coiled extension line are suitable with all drugs sensible at plastic material and it is in conformity with requirements of MDD 93/42 related insurance and compatibility of children and pregnant women/lactation. All coiled extension line are available in clear color, or also in amber version to ensure drug/medicine photosensitive protection; this last capacity homologated by structural tests applied by credited laboratory.

MAIN FEATURES

- Natural or UV tube
- Tube in different colors (line)
- Different lengths up to 800cm
- Different diameters of tube 1x2mm
1.5x3mm - 2.5x4.1mm - 3x4.1mm
- FLL with MLL cap
- MLL with vented cap
- Coiled version to reduce overall dimensions.
- DEHP free - Latex free
- Sterile EtO

QUALITY STANDARDS

The Extension line are manufactured under a Quality Management System certified to ISO 13485. The materials of construction of the Extension line meet:

- ISO 10993-4 - ASTM F 2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
- ISO 10993-18 Leachables & Extractables

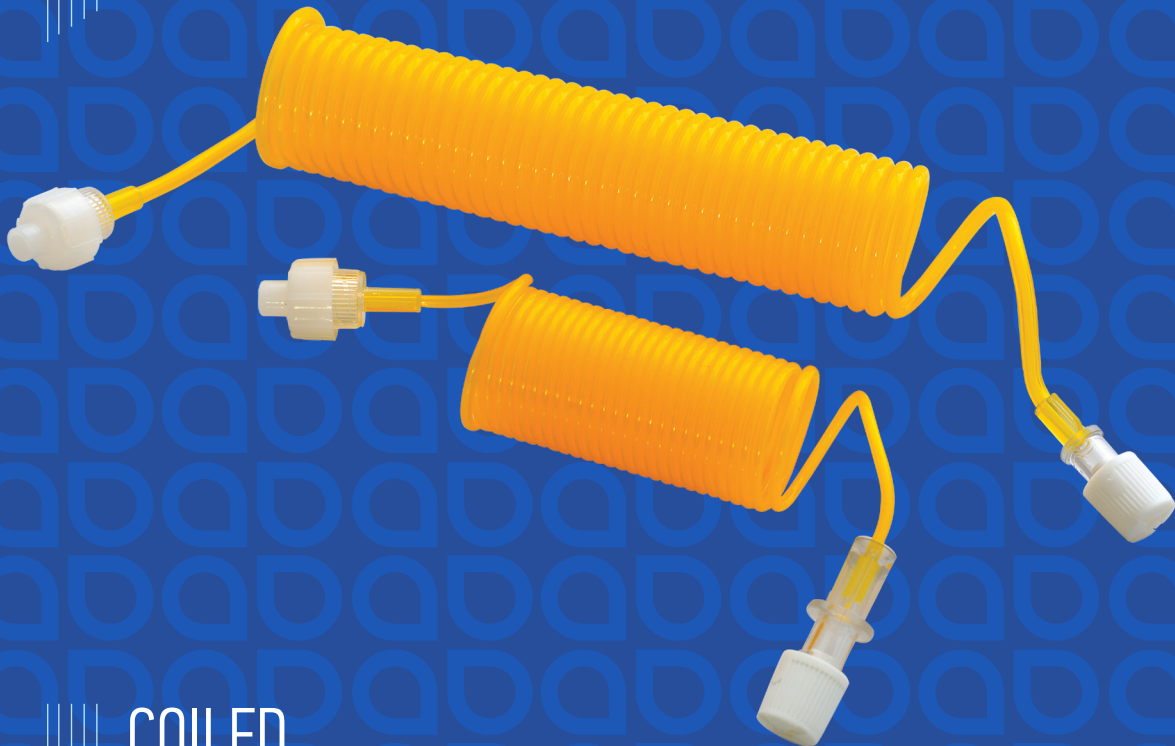
COLOR COILED EXTENSION LINE

Available with a different colored line such as red, yellow, blue or green. This is a good solution to differentiate the various infusion lines to the patient.



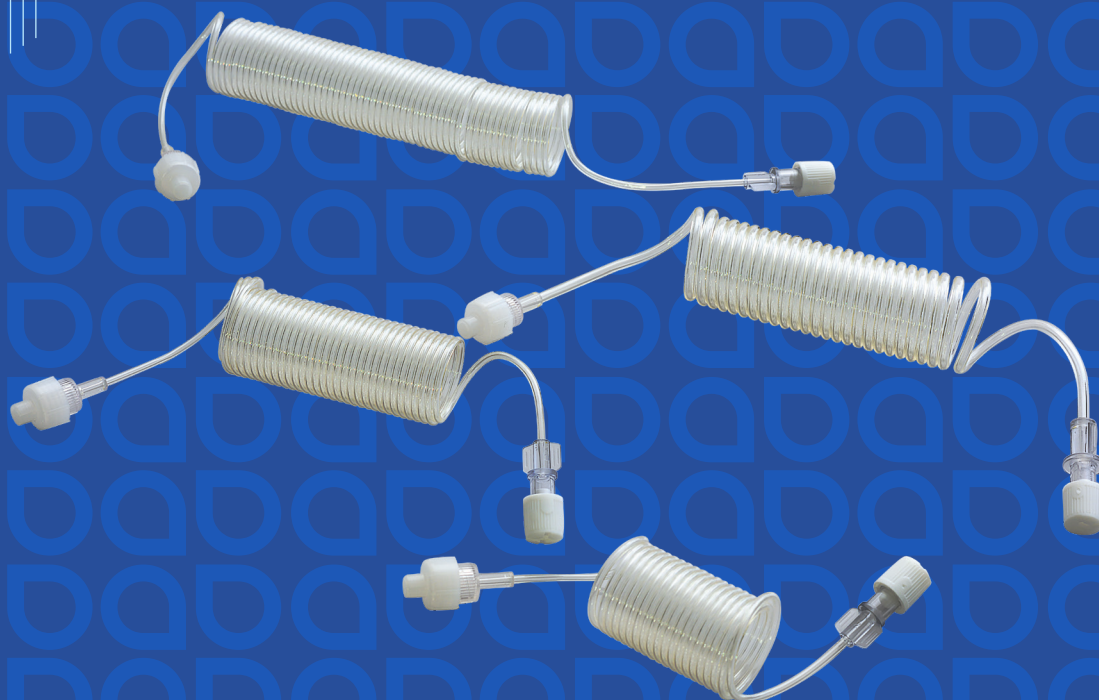
UV COILED EXTENSION LINE

Version with UV protection for all those photosensitive substances.



COILED EXTENSION LINE

Completely transparent version which guarantees excellent visibility for all standard substances



PE COILED EXTENSION LINE

Coiled and linear extension line application meaning is to skip any problems during hospital activities (obstruction during hospital activity). Valmed developed coiled extension line for infusion and suction, granting a large application field and different solutions, through the use of different raw material (soft PVC different hardness, PUR and PE) and large diameter sizes or lengths. PE extension lines have a general use appropriate at all drugs, in the meantime ensuring a suitable resistance a pressure application, in conformity with dimensional characteristics. PE extension lines in conformity with requirements of MDD 93/42 related insurance and compatibility of children and pregnant women/lactation. All extension line are available in clear color, or also in amber version to ensure drug/medicine photosensitive protection; this last capacity homologated by structural tests applied by credited laboratory.

MAIN FEATURES

- Natural or UV tube
- Different lengths up to 800cm
- Different diameters of tube 1x2mm - 1.5x3mm
- FLL with MLL cap
- MLL with vented cap
- Coiled version to reduce overall dimensions.
- DEHP free - Latex free
- Sterile EtO

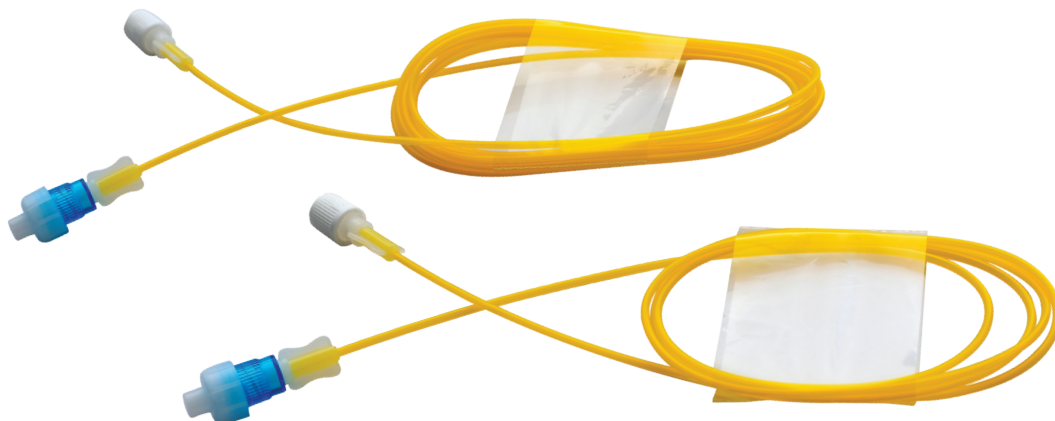
QUALITY STANDARDS

The Extension line are manufactured under a Quality Management System certified to ISO 13485. The materials of construction of the Extension line meet:

- ISO 10993-4 - ASTM F 2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
- ISO 10993-18 Leachables & Extractables

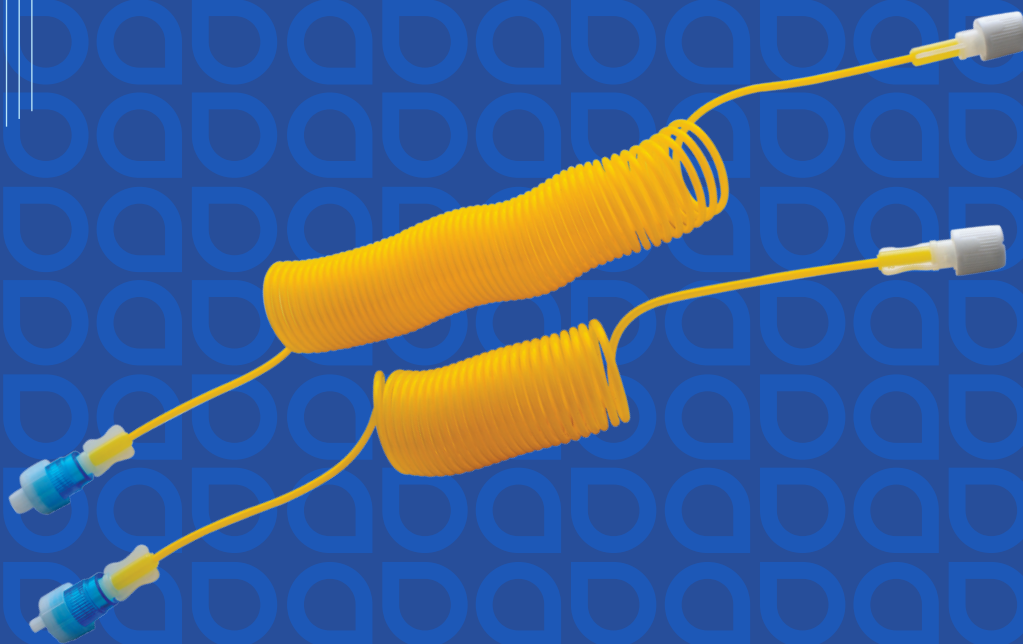
UV LINEAR EXTENSION LINE

Version with UV protection for all those photosensitive substances



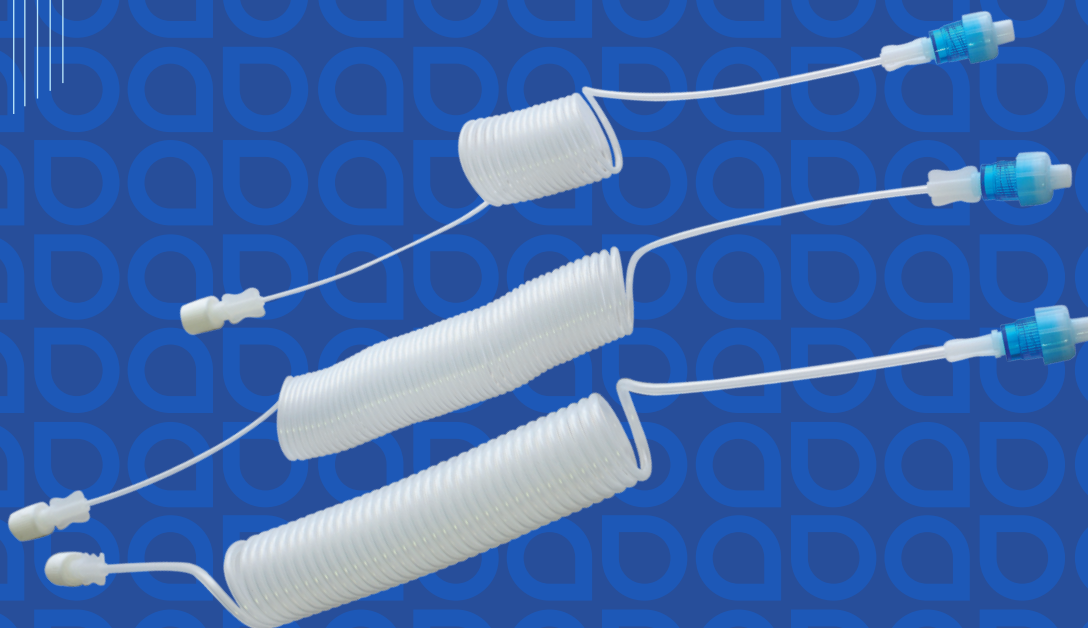
UV COILED EXTENSION LINE

Version with UV protection for all those photosensitive substances



COILED EXTENSION LINE

Completely transparent version which guarantees excellent visibility for all standard substances



INFUSION IV SET

Filtration is recommended to help prevent contamination of the blood stream. The Valmed filter sets provides a complete choice for infusion therapy.

Applications

Air bubbles removal from any liquid solutions Filters have integrated hydrophobic membranes which enable air/gas bubble removal significantly minimizing the risk of air/gas emboli for the patient. Particles, Bacteria, Fungi and Endotoxin removal Drug delivery and parenteral solution can introduce bacterial contamination or fungi to patients. These unwanted contaminants cause infections. Filter is a major safety measure to prevent contamination in an infusion system.

- Filters with PES membrane 0,2 micron prevent against bacterial contamination
- Filters with PES membrane 1,2 micron prevent against fungi contamination
- Filters with PES membrane positive charged 0,2 micron prevent against endotoxin contamination
- Filters with PES membrane 5 micron prevent against particles contamination

Filtration of photosensitive drugs (amber housing)

Filter with amber colored housing is available for drugs that are sensitive to UV light. This protects drugs against UV ray degradation.

Filtration of drugs, nutrient admixture, TPN and lipid solutions.

The filter, with pore size 0.2-1.2 micron, safety prevents the infusion of oversized lipid droplets, preventing fat emboli and minimizing particle contamination.

MAIN FEATURES

- Hydrophilic PES membrane 0.2µm - 1.2µm - 5µm
- Hydrophobic PTFE membrane
- HOUSING: clear or amber (UV protection)
- With or without Endotoxin protection
- Vents for faster air elimination
- Different diameters of the tube 1x2mm or 3x4.1mm
- Different lenght of the tube
- PUR tube clear or amber
- FLL with MLL cap
- MLL with vented cap
- Different configuration or components
- DEHP free or PHT free
- Latex free
- Sterile EtO

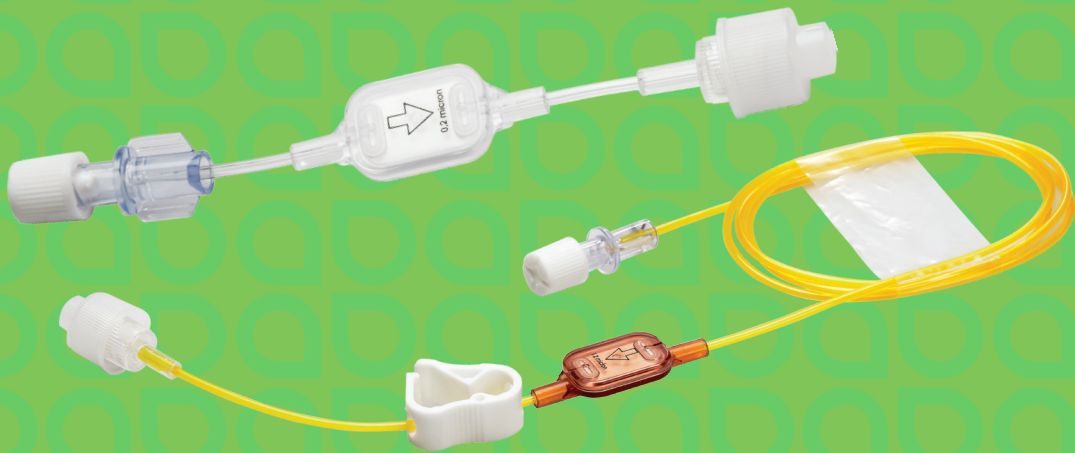
QUALITY STANDARDS

The Infusion set are manufactured under a Quality Management System certified to ISO 13485. The materials of construction of the Infusion set meet:

- ISO 10993-4 - ASTM F 2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
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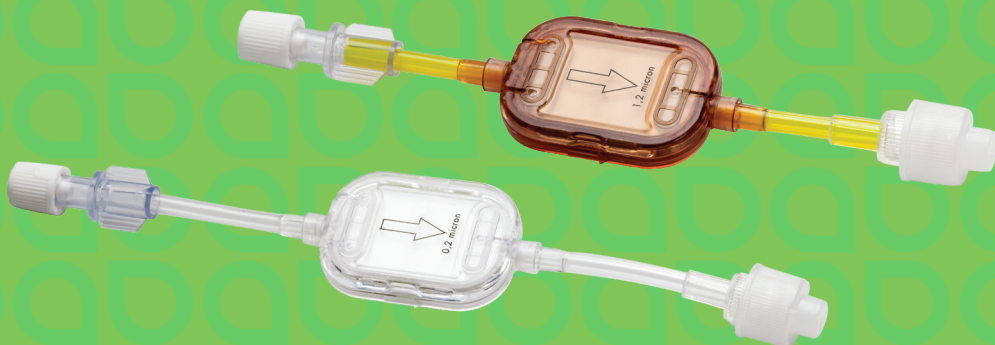
INFUSION SET WITH NEONATAL IV FILTER

Filter for use on neonatal patients with an effective filtration area of 1.45cm²



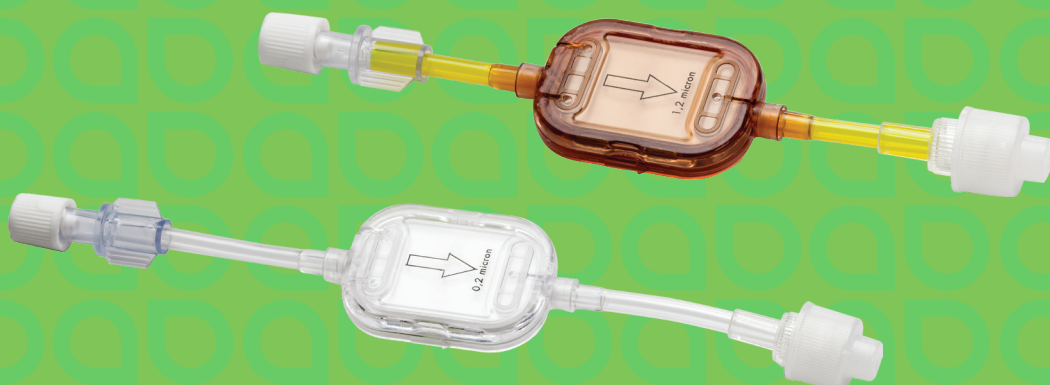
SET WITH PEDIATRIC IV FILTER

Filter for use on pediatric patients with an effective filtration area of 5cm²



SET WITH ADULT IV FILTER

Filter for use on adult patients with an effective filtration area of 10cm²



TRANSFER SET

This is an excellent medical device to fill and transfer the solutions. It is configured in different variants to meet the needs of the customer.

This category includes the gravity or pump transfer set.

All devices are LATEX FREE. Standard products are the only mentioned. Different configuration are available on specific customer requests. Our technical department is available to research and study flexible and innovative products in collaboration with the customer.

MAIN FEATURES

- Different diameters of the tube
2.5x4.1mm or 3x4.1mm
- Different length of the tube
- PUR or PVC tube
- Tube clear or amber
- Different configuration or components
- DEHP free or PHT free
- Latex free
- Sterile EtO

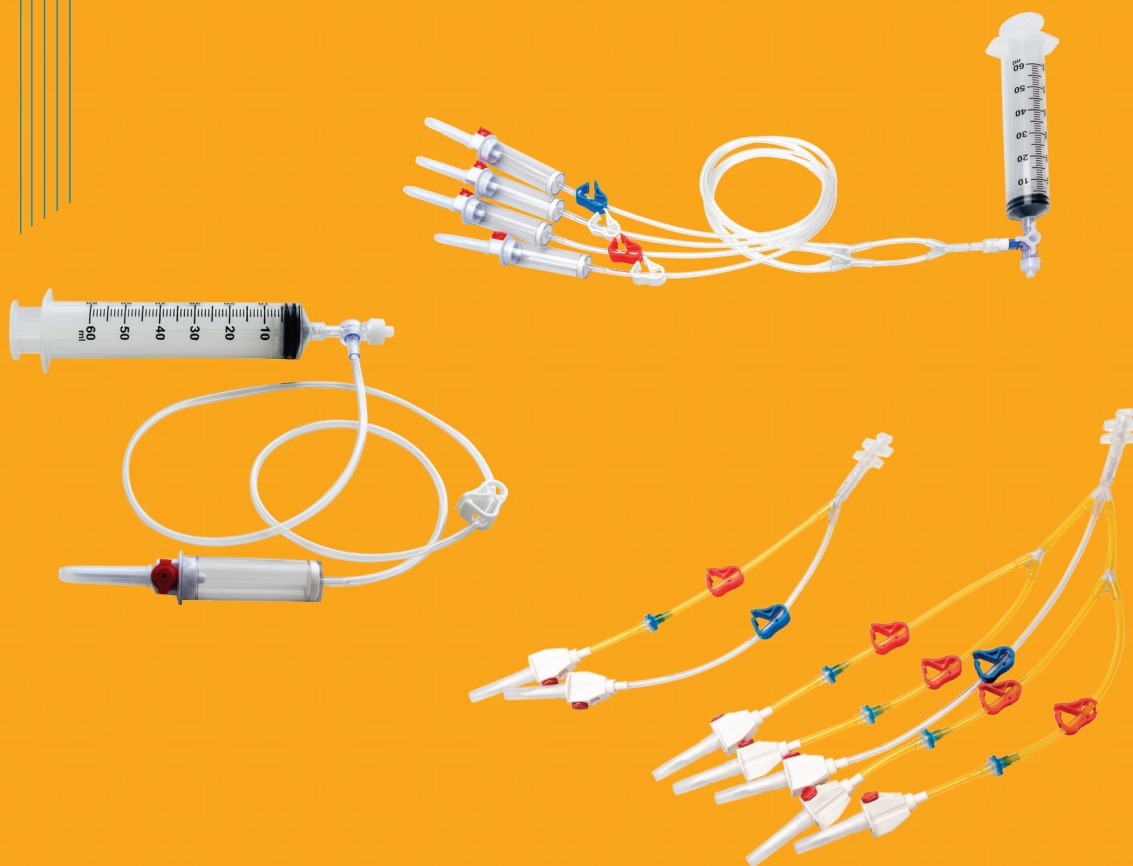
QUALITY STANDARDS

The Infusion set are manufactured under a Quality Management System certified to ISO 13485. The materials of construction of the Infusion set meet:

- ISO 10993-4 - ASTM F 2382-18: Haemocompatibility
- ISO 10993-4 - ASTM F 756: Haemocompatibility (Haemolysis)
- ISO 10993-5: In vitro cytotoxicity
- ISO 10993-10: Intracutaneous reactivity
- ISO 10993-10: Skin sensitization
- ISO 10993-11: Acute systemic toxicity
- ISO 10993-11: Pyrogen test
- ISO 10993-18 Leachables & Extractables

GRAVITY

Gravity transfer set for small solution volumes using syringes (in combination or not)

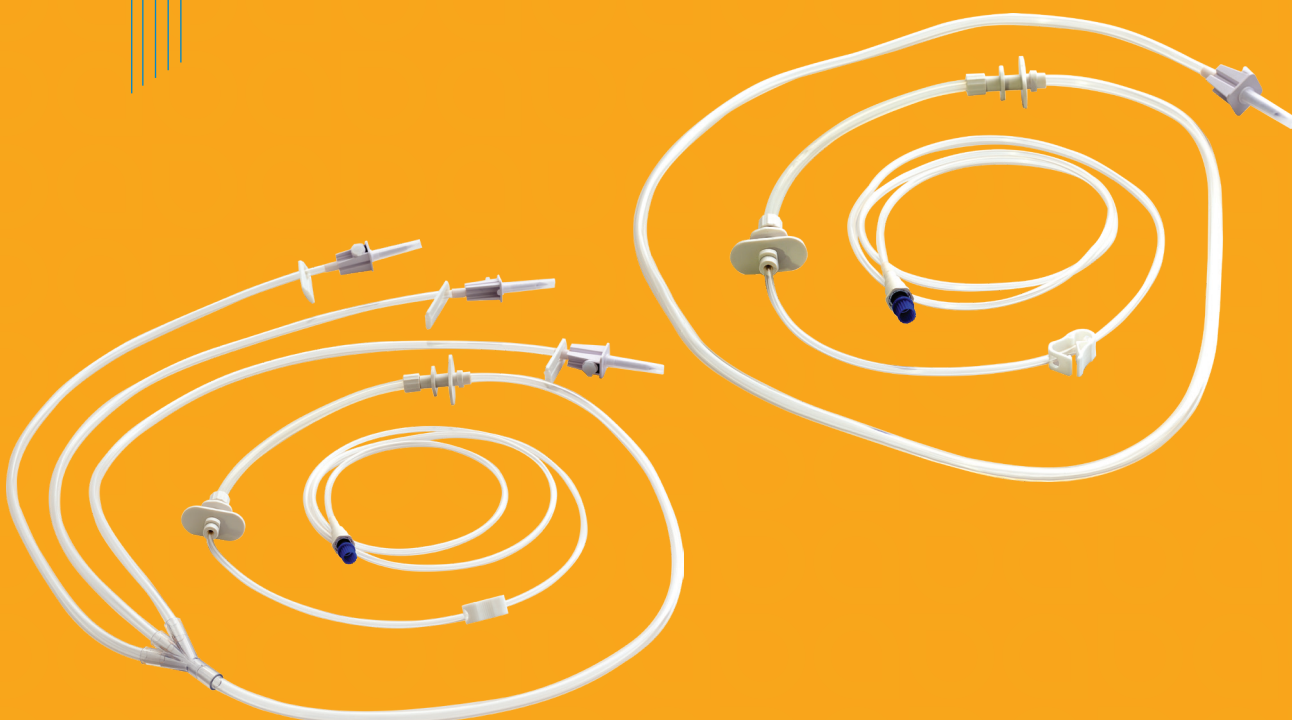


PUMP TUBE SET

Compatible with the most famous compounder on the market.

This set is available with 1 or 3 inlet way.

Correct fixing system in the peristaltic pump with calibrate silicone tube.



CERTIFICATIONS



Certificate n° 1906/MDD
Enteral and parenteral feeding bags.
I.V. infusion set and transfusion set.
Bags for enzyme replacement therapy.



Certificate n° 1907/MDD
Bags for collecting body fluids.



FDA - USA - 510K
Parenteral nutrition EVA bags (K101412)
obtained on 13/04/2011.



FDA - USA - 510K
Empty EVA Bags
(K181393) obtained on 15/02/2019.



ISO 13485 n°9124.VLM3



MDSAP n°007.22/MDSAP
(Enteral and Parenteral feeding bags. I.V. infusion and
transfusion set) US-Brazil-Canada-Australia Market





valmed®
medical devices



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medical devices

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