HELAL IRAN
Medical Devices Co.

May 2023-Ver 3nd

About us

Founded as a manufacturer of medical devices in 1991, SOHA1, now Helal Iran Medical Devices Co., launched the country's biggest, most advanced production line for single use medical syringes then, the company has taken significant steps, owing to its dedication to continuous improvement, technological development and regulatory compliance. The following achievements are some proofs of our nonstop endeavor to establish ourselves as the leading manufacturer of the industry:

- Exemplary Unit by Standard & Industrial Research Institute in 2002, 2004, 2005, 2007, 2013 and 2014.
- Quality Superior Unit in Tehran Province by Standard & Industrial Research Institute in 2008 and 2009.
- Compliance with Compulsory Standards with all products and persuasive standard for dialyzer.
- Certified Green Industry by Environment Protection Organization in 2000.
- Superior Unit in Medicine & Medical Devices Industries in the 7th National Production Festival in 2009.
- Superior Manufacturer in the 8th National Production Festival – National Honor in 2010.
- Superior Manufacturer in the 9th National Production Festival – National Honor in 2011.
- Superior Manufacturer in the 10th National Production Festival – National Honor in 2012.
- Exemplary Industrial Unit by Tehran Province Industry & Mine House & Ministry of Industries and Mines in 2009.
- Diamond Statue in the 5th National Festival of Distribution in 2012.
- Obtaining the top rank in providing after-sales services for medical equipment companies for dialysis machines in 2018

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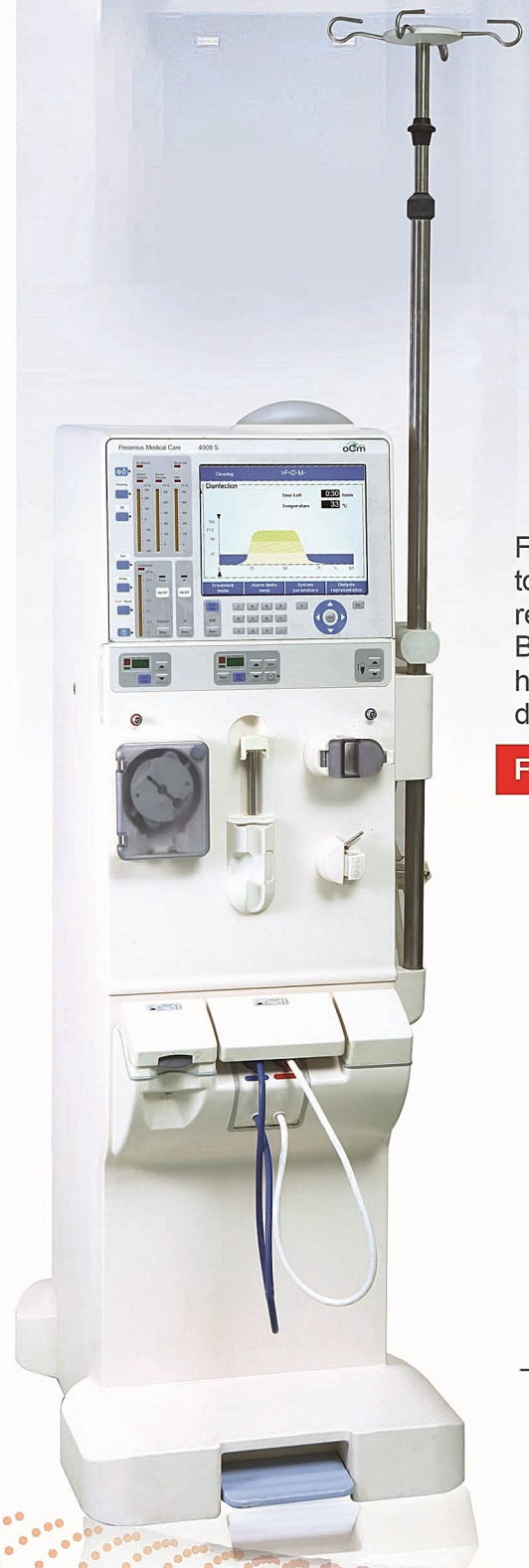
4008S Classix
Hemodialysis Machine



Fresenius Company assists all nephrologists throughout the world to decrease hospitalization and fatalities of dialysis patients resulting from cardiovascular diseases.
By keeping reliability and affordability, this machine provides hemodialysis treatment with the best quality besides technical development.

Features

- Online Clearance Monitoring (OCM)
- Ulta-Pure Dialysis Fluid (Diasafe Plus)
- Dry concentrated bicarbonate (So-bag S, or Bibag)
- Automatic self-test of all parts of the machine prior to hemodialysis
- Blood Pressure Monitoring (BPM)*
- Automatic adjusting of dialysis fluid flow with input blood flow of dialyzer for higher quality of dialysis (Adapted flow)
- Extremely precise control over patient's venous pressure (Asymmetric venous pressure)
- Detection of air in the blood circuit through ultra sound transmission, in addition to optical monitoring on the venous clamp
- Precise UF with adjustment capability from 1000 to 4000 ml/hour
- Rate of heparin pump flow from 0 to 10 ml/hour
- Rate of blood pump flow from 15 to 600 ml/min
- Single needle dialysis system with one pump (Single needle system with Click-Clack performance)

* This capability could be changed if required by the customer

5008S CorDiax
Hemodialysis Machine

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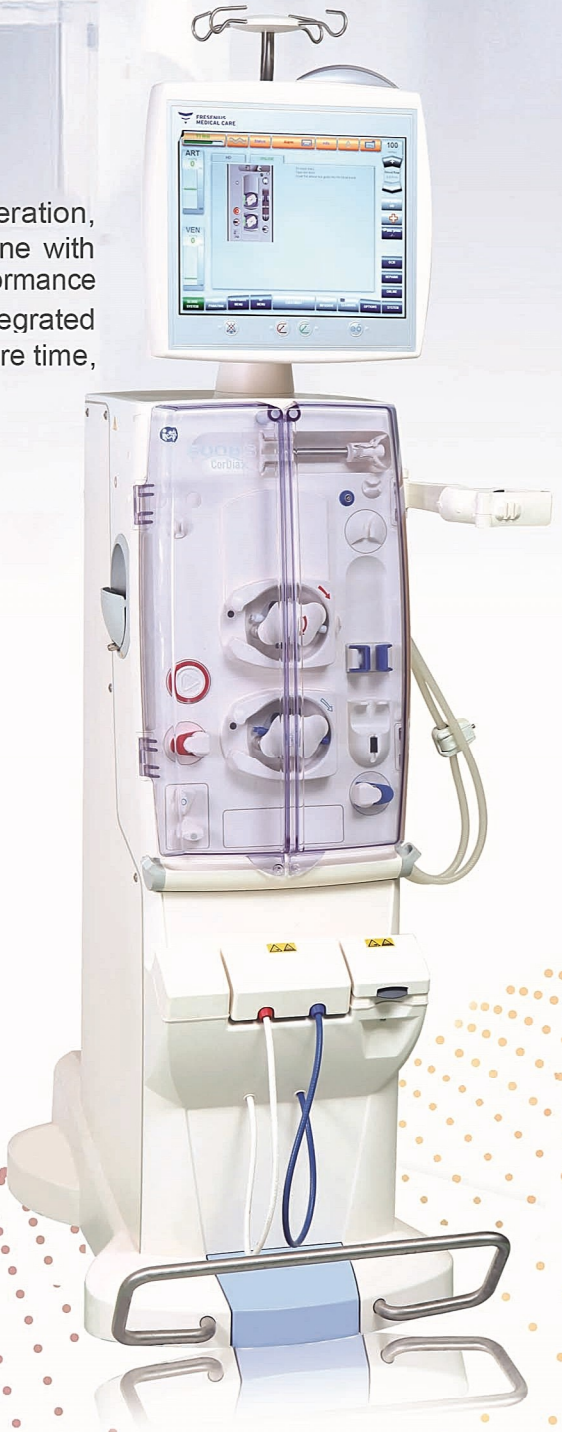
This device provides quality treatment of online hemodiafilteration, and it can supply the required physiologic alternative fluid online with high purity dialysis solution due to benefitting from advanced performance technology without any limitation. This device is a completely integrated system to support and strengthen dialysis for the present and future time, and it is made based on three principles:

1. Best treatment method for patients
2. Best performance for all users
3. Improved use of resources



Features

- Effective removal of medium molecular weight toxins
- Determining and achieving the optimized dry weight
- Easy , quick and reliable information management
- Easy application due to automatic circulation
- Integrated and compact design
- Appropriate relation between patient and user
- Online hemodiafiltration
- Optimized circulation
- Unique ease of repair and maintenance
- Blood Temperature Monitor (BTM)
- Blood Pressure Monitor (BPM)
- Online Clearance Monitor (OCM)

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Fresenius Ploysulfone High Flux Haemodialyser

- Excellent haemocompatibility
- Optimal performance
- Wide product range (1.3 – 1.8 m^2)
- Adapted treatment HD/HDF/HF
- Effective β_2-microglobulin removal
- High endotoxin retention capacity
- Compliance with ISO 8637-1, INSO-ISO 8637

In vitro performance data/technical data

Items	F60	F70	F80
Ultrafiltration coeff. (ml/h x mmHg)[1]	40	50	55
Clearance Q_B=200 ml/min			
Urea (ml /min)	185	190	192
Creatinine (ml /min)	172	177	180
Phosphate (ml /min)	170	174	177
Vitamin B_{12} (ml /min)	118	127	135
Inulin (ml /min)	88	98	110
Clearance Q_B=300 ml/min			
Urea (ml /min)	242	245	248
Creatinine (ml /min)	215	220	225
Phosphate (ml /min)	210	216	220
Vitamin B_{12} (ml /min)	134	145	155
Inulin (ml /min)	97	109	120
K_OA (ml /min)	736	767	801
In vitro performance: $Q_D = 500$ ml/min, $Q_F = 0$ ml/min, T = 37 °C (ISO 8637). (1) Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %. Use only on machines with controlled ultrafiltration!			
Sieving coefficient for β_2m	≥ 0.65		
Effective surface (m^2)	1.3	1.6	1.8
Blood flow range (ml /min)	150-400	200-500	200-600
Wall thickness / lumen (µm)		40/200	
Priming volume (ml)	82	98	110
Membrane material		Fresenius Polysulfone	
Housing material		Polycarbonate	
Potting compound		Polyurethane	
Sterilisation method		ETO	
Form of treatment	HD/HDF	HD/HDF	HD/HDF/HF
Units per box	20	18	18

Fresenius Polysulfone
Low Flux Haemodialyser

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- Excellent haemocompatibility
- Wide product range (1.3- 1.8 m^2)
- High endotoxin retention capacity
- Compliance with ISO 8637-1 and INSO-ISO 8637

In vitro performance data/technical data

Items	F6	F7	F8
Ultrafiltration coeff. (ml/h x mmHg)[1]	5.5	6.4	7.5
Clearance Q_B=200 ml/min			
Urea (ml /min)	180	184	186
Creatinine (ml /min)	164	169	172
Phosphate (ml /min)	123	132	138
Vitamin B_{12} (ml /min)	60	68	76
Clearance Q_B= 300 ml/min			
Urea (ml /min)	230	236	240
Creatinine (ml /min)	194	210	216
Phosphate (ml /min)	145	155	165
Vitamin B_{12} (ml /min)	62	72	82
K_OA (ml /min)	630	680	717
In vitro performance: Q_D = 500 ml/min, Q_F = 0 ml/min, T = 37 °C (ISO 8637). (1) Ultrafiltration coefficients: human blood, Hct 32 %, protein content 6 %.			
Effective surface (m^2)	1.3	1.6	1.8
Blood flow range (ml/min)	150-400	200-500	250-600
Wall thickness / lumen (µm)		40/200	
Priming volume (ml)	82	98	110
Membrane material		Fresenius Polysulfone	
Housing material		Polycarbonate	
Potting compound		Polyurethane	
Sterilisation method		ETO	
Form of treatment		HD	
Units per box	20	18	18

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Fresenius Ploysulfone
Capillary High Flux Haemodialyser

- Excellent haemocompatibility
- Inercased patient safety
- Minimum release of BPA (Bisphenal A)
- Adapted treatment HD
- Effective β_2-microglobulin removal
- High endotoxin retention capacity
- Compliance with ISO 8637-1 and INSO-ISO 8637
- Sterilised with inline steam method (the safest sterilisation method of haemodialyserin the world)
- Refined haemodynamics
- Simplified handling and priming
- Reduction of waste
- Improved diffusive and convective clearances

FX CorDiax

Capillary High-Flux Dialysers

FX CorDiax		40
	Q_B [mL/min]	200
Clearances [mL/min]	Cytochrome C	48
Q_D = 500 mL/min	Inulin	56
Q_F = 0	Vitamin B_{12}	96
	Phosphate	142
	Creatinine	155
	Urea	175
K_0A Urea	mL/min	547
UF-coefficient (at Q_B max)	mL/h/mmHg	21
S (sieving coefficient)	Albumin	< 0.001
	Myoglobin	0.5
	β_2-Microglobulin	0.9
Max. TMP	mmHg	600
V (blood priming volume)	mL	32
Δ P (pressure drop blood, Q_B = 300 mL/min)	mmHg	202
Max. dialysate flow	mL/min	500
Recommended blood flow range	mL/min	50–200
A (effective surface area)	m^2	0.6
Membrane		Helixone®*plus*
Sterilisation method		INLINE steam

Fresenius Polysulfone
Low Flux Haemodialyser (HPS)

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- Excellent haemocompatibility
- High endotoxin retention capacity
- Compliance with ISO 8637-1 and INSO-ISO 8637
- Sterilised with inline steam method (the safest sterilisation method of haemodialyser in the world)
- Higher clearances by a new design
- Microundulation ensures efficient dialysate flow

Invitro Performance data	F4 HPS
Ultrafiltration coefficient (ml/h·mmHg)	8
Clearance: Q_B: 200 (ml/min)	
Urea	170
Creatinine	149
Phosphate	123
Vitamin B_{12}	75
Technical Data	
Effective surface area (m^2)	0,8
Wall thickness/ inner diameter (µm)	40/200
Blood primimg volume (ml)	51
Membrane material	Fresenius Polysulfone®
Housing material	Polycarbonate
Potting compound	Polyurethane
Sterilisation method	Inline Steam
Form of treatment	HD

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Acid Fluid Concentrate

Coming in the form of acid concentrated fluid consisting of Sodium, Potassium, Magnesium, Calcium and Acetate ions, it is made by dissolution of the said ions in pure injectable water (WFI) and packing in 5-litre standard canisters. This acid concentrated fluid could be used together with bicarbonate concentrates, after being 35 times diluted in dialysis machines.

Composition

Formula	Concentrated Solution (g/l)		Diluted Solution (35 times) (g/L)		Units per box
Sodium chloride	216.812		6.194		
Potassium chloride	5.218		0.149		
Calcium chloride, $2H_2O$	6.431		0.183		
Magnesium chloride, $6H_2O$	3.557		0.101		
Acetic acid (glacial)	7.356		0.210		
Dextrose,H_2O	70.000		2.000		
Electrolytes	**mmol/l**	**mEq/l**	**mmol/l**	**mEq/l**	3
Na^+	3710	3710	106.00	106.00	
K^+	70	70	2.00	2.00	
Ca^{++}	43.75	87.50	1.25	2.50	
Mg^{++}	17.50	35	0.50	1.00	
CH_3COO^-	122.50	122.50	3.50	3.50	
Cl^-	3902.50	3902.50	111.50	111.50	

Bicarbonate Powder Concentrate (So-bag)

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Dialysis machine first mixes dry Sodium Bicarbonate in So-bag with RO pure water online, then mixes the solution with acid concentrate providing appropriate dialysis solution. Sodium Bicarbonate Concentrate, RO pure water and consumed acid concentrate fluid ratio shall be in accordance with the instructions provided for Fresenius dialysis machines.

Features

- Compliance with ISO 23600-4,5 and USP
- hemodialysis grade sodium bicarbonate
- Safe packing
- Easy transportation
- Reduced contamination during hemodialysis
- Intended for 4 hours of hemodialysis
- Input and output micro porous filters

So-bag Technical Specification

Colour Code	Weight (g)	Material		Filter (µ)		Units per box
Blue	650	Bag	Connector	80	180	16
		PA-PE	PE			

Bicarbonate powder concentrate	haemodialysis Machine
So-bag S	5008 & 4008S Fresenius Machine
So-bag B	4008B Fresenius Machine

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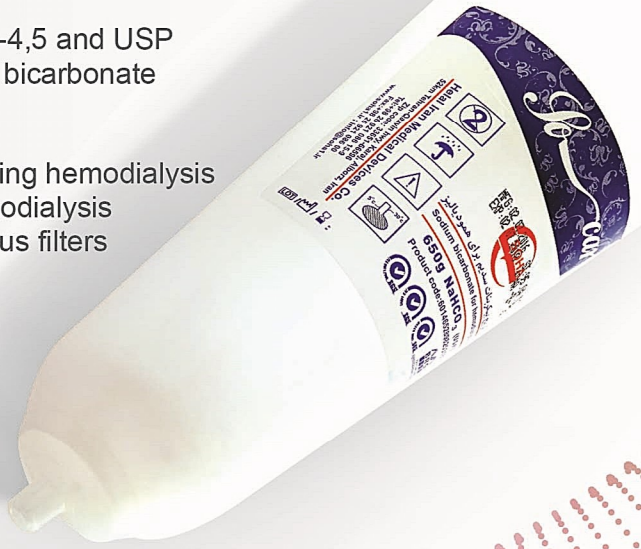
Bicarbonate Powder Concentrate (So-cart)

Dialysis machine first mixes dry Sodium Bicarbonate in So-bag with RO pure water online, then mixes the solution with acid concentrate providing appropriate dialysis solution. Sodium Bicarbonate Concentrate, RO pure water and consumed acid concentrate fluid ratio shall be in accordance with the instructions provided for Fresenius dialysis machines.

Features

- Complance with ISO 23500-4,5 and USP
- hemodialysis grade sodium bicarbonate
- Safe packing
- Easy transportation
- Reduced contamination during hemodialysis
- Intended for 4 hours of hemodialysis
- Input and output micro porous filters



So-cart Technical Specification

Label colour code	Weight (g)	Material	Filter (µ)		Units per box
Blue	650	PP	200	200	12

Bicarbonate powder concentrate	haemodialysis Machine			
So-cart	Nipro	B Braun	Gambro	Bellco

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AV Fistula Needle Set

AV fistula needle set is the interface between the patient's access and dialysis set facilitating extracorporeal circulation of blood intra dialysis.

Features

- Soft textured wings providing a secure grip
- Dry siliconized stainless steel needle extremely sharp for smooth painless cannulation
- Back-eye arterial fistula needle to provide optimal blood flow and prevent suction of the needle to the inner vessel wall thereby reducing the need for rotating the needle, which adds trauma to the AVF
- Sterile, single use, apyrogenic and biocompatible

AV Fistula Needle Set Technical Specification

Gage	Tube Length (mm)	Color Code	OD (mm)	Clamp Color Code		Connector type	Sterilization method	Units per box
				Arterial	Venous			
17G	150/300	Orange	1.47	Red	Blue	Luer Lock	ETO	40
16G		Green	1.65					
15G		Blue White	1.81					

Extracorporeal Blood Circuit for Hemodialysis (Hemodialysis set)

Including arterial and venous sets, these sets are connected to a proper fistula needle during haemodialysis operation (venous set to venous fistula set and arterial set to arterial fistula needle) and dialysis filter. The arterial set transfers the blood from patient's body to dialyzer and the venous set returns it from dialyzer back to the body.

B series & B original Haemodialysis Set

S-classix, Haemodialysis Set

Features

- Complies with ISO 8637-2 and INSO-ISO 8638
- Sterile, single use, apyrogenic and biocompatible.
- Smooth inner walls decreasing the resistance against blood flow
- Injection site facilitating frequent injection with no additional injury to the patient
- Special connector for preparation of the set for haemodialysis
- Color coding (blue) for venous and (red) for arterial, facilitating easy and error-free installation and preparation of the set
- Original model have connection with transducer protector for measuring line pressure

B series & B original Haemodialysis Set Technical Specification

Type	Blood line volume(ml)	Pump tubing			Blood chamber filter (µm)	Color coding	Units per box	Sterilization method
		ID (mm)	OD (mm)	Length (mm)				
Venous	54	-	-	-	230/270	Blue	20	ETO
	59							
Arterial	76	6.5	9.8	370	-	Red		
	82	6.3	9.5					

S-classix, Hemodialysis Set Technical Specification

Type	Blood line volume(ml)	Pump tubing			Blood chamber filter (µm)	Color coding	Units per box	Sterilization method
		ID (mm)	OD (mm)	Length (mm)				
Venous	73	-	-	-	230/270	Blue	20	ETO
Arterial	90	8	12	340	-	Red		

Transfusion Set with Leucocyte Reduction Filter

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Contrary to positive patient outcomes of transfusion of blood components, side effects, mainly posed by the leucocytes are inevitable, particularly in such patients requiring frequent blood transfusion as those suffering from thalassemia. These side effects will be effectively eliminated if leucocytes are properly removed prior to introduction of the blood component to the patient's body with the aid of Transfusion Set with Leucocyte Reduction Filter.

Features

- Compliance with ISO 1135-4 and INSO 4638-4
- Sterile, single use, apyrogenic and biocompatible
- Filter fabric material: Hemocompatible Polybutylene Terephthalate (PBT)
- Decreasing allergic reactions
- Leucocyte removal of up to 99.9%
- Optimal RBC recovery
- Removal of micro aggregates
- Air filter preventing ingress of airborne pathogens

Leucocyte filters incorporated into the sets are availabe in two sizes:

So-fil 01: For one blood unit
So-fil 02: For two blood units

Infusion Set with Leucocyte Filter Technical Specification

Product	Capacity	Leucocyte Reduction (%)	Maximum Filtration Pressure (mmHg)	Sterilisation Method	Units per box
SO – Fil 01	1 unit blood bag	99.9 % (3 log)	300	ETO	25
SO – Fil 02	2 unit blood bag	99.9 % (3 log)	300		20

Burette Infusion Set

Microset

Microset is a measured volume intravascular administration set, a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, a flash type injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Features

- Compliance with ISO 8536-5 and ISIRI 8357-5
- Sterile, single use, apyrogenic and biocompatible
- Automatic shut-off swim valve to prevent air embolism
- Transparent tubing to detect bubbles
- Piercing spike with bacteria-proof air vent
- 15 micron fluid filter
- Stopcock(roller clamp)to adjust or disconnect the fiow
- 6% tapered luer lock connector facilitating connection of the devices to IV catheter or other medical devices
- Transparent and flexible drip chamber to observe the movment of the drops
- 60 drops equal to 1± 0.1 ml.
- One Y-type injection site plus an additional injection site on the burette
- 100 ml burette with fine graduation

Burette Infusion Set Technical Specification

Burette Volume (ml)	Sterilisation Method	Units per box
100	ETO	100

Infusion Set

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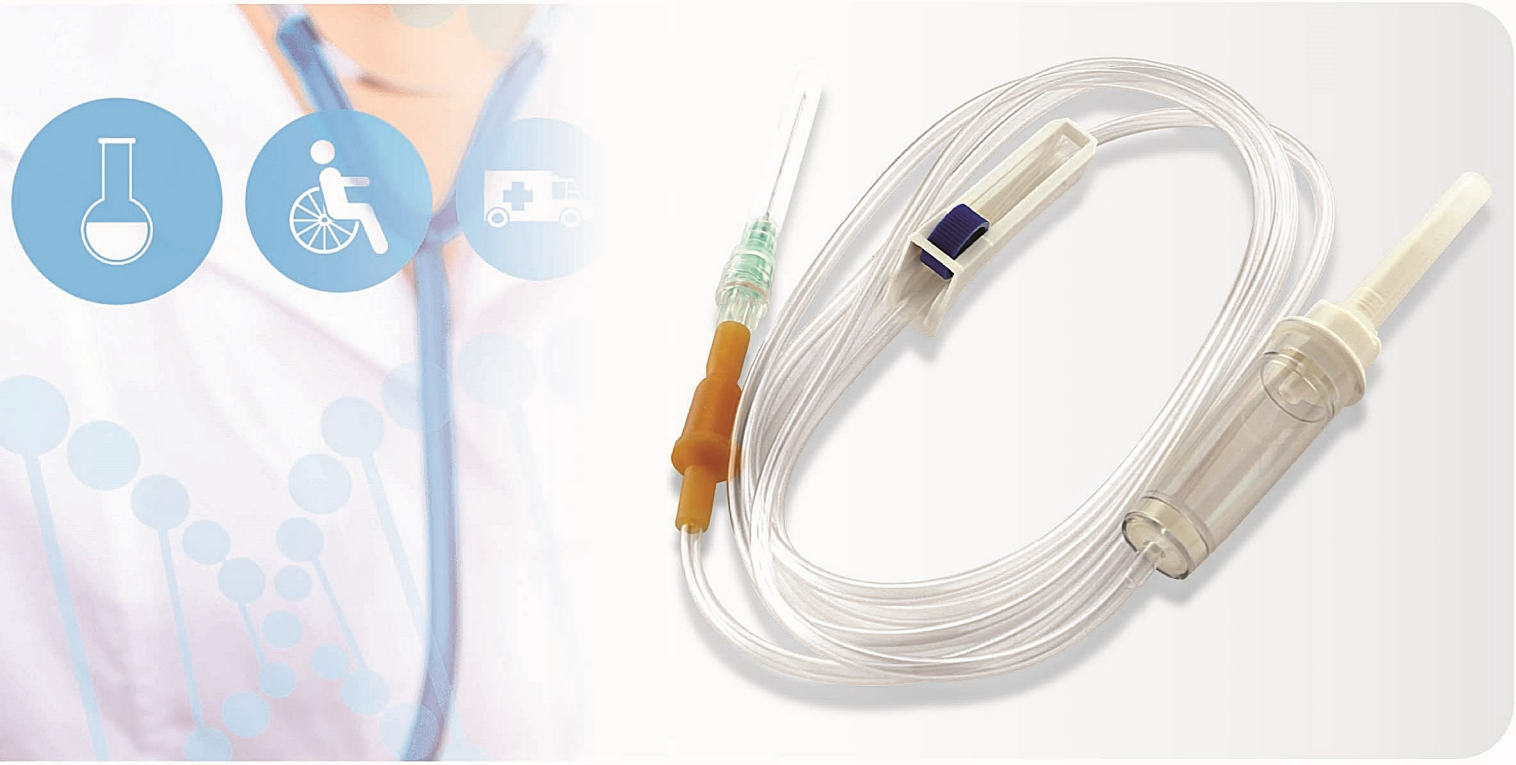
Infusion set is an intravascular administration set, a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, a flash type injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid containers.



Features

- Compliance with ISO 8536-4 and INSO 8357-4
- Sterile, single use, apyrogenic, and biocompatible
- Transparent and flexible drip chamber to observe movement of the drops
- Firm spike with special design for easy penetration into I.V. bag or other infusion fluid container
- Air filter to prevent ingress of particles and airborne pathogens into the fluid path
- 15-micron filter to prevent the particles in IV fluid reaching the fluid path
- 20 drops equal 1± 0.1 ml
- Flash-type injection site
- 6% tapered luer slip connector facilitating the connection of the set to IV catheter or other medical devices
- Stopcock (roller clamp) to adjust or disconnect the flow.

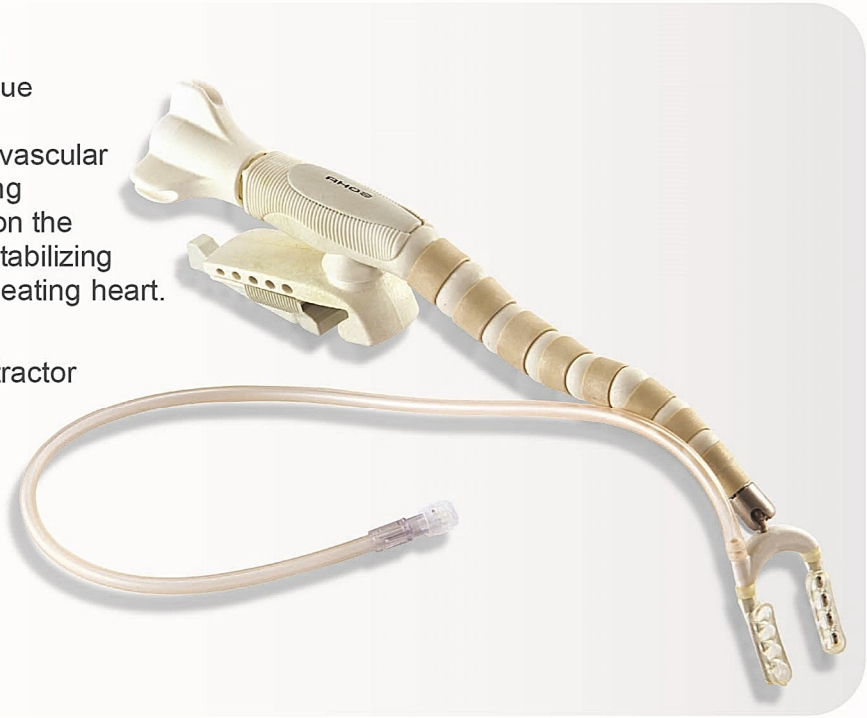
Infusion Set Technical Specification		
Length of the set (mm)	Sterilisation Method	Units per box
1500-1700	ETO	400

Tissue Stabilizer

SPAYA Heart Tissue Stabilizer

As a member of cardiac stabilization and positioning group of devices, SPAYA tissue stabilizer is intended to be used during performance of minimally invasive cardiovascular surgery for coronary artery bypass grafting through a sternotomy incision approach on the non-arrested heart. The device offers a stabilizing function to control the movement of the beating heart.

It is used in combination with sternum retractor blades and, if need be, heart positioner.



Features

- Optimal stabilization besides ease of use
- Compatibility of mount with most adult sternal spreaders
- Exceptional control and reach owing to 3D swivel
- Strong maneuverable arm
- Offering strength and stability with anastomotic site visibility and access

Intravascular Catheter

IV Catheter

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An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 7 days) to sample blood, monitor blood pressure, or administer fluids intravenously
This product has one injection site equipped with a non-return valve to prevent fluid return.

Features

- Compliance with ISO 10555-1,5 and INSO 7325-1,5
- Sterile, single use, apyrogenic and biocompatible
- Siliconized stainless steel stylet
- Radiopaque FEP polymer cannula

IV Catheter Technical Specification

Gauge	Colour Code	OD (mm)	Length (mm)	Flow Rate (ml/min)	Units per box	Sterilization Method
16 G	Gray	1.71	51	191	6000	ETO
18 G	Green	1.32	44	105		
20 G	Pink	1.10	32	79		
22 G	Blue	0.90	25	41		
24 G	yellow	0.70	19	18		
26 G	Violet	0.60	19	15		

Dental Needle

Dental needle with different longitudinal scale provides easy injection of anesthetics into the patient's gum using dentistry syringe. The product includes a cap and a protector to preserve its sterility.

Features

- Compliance with ISO 7885 and INSO 5554
- Sterile, single use apyrogenic, and biocompatible
- Dry siliconized stainless steel needle for painless smooth penetration

Dental Needle Technical Specification

Gauge	Hub Colour	OD (mm)	Effective Length (mm)	Cap	Units per box	Sterilisation Method
27 G	Gray	0.41	Short: 22 Long: 32	Blue White	5000	ETO

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Hypodermic Needle

Hypodermic needle together with a syringe is used to inject or withdraw fluids into or from the body

Features

- Compliance with ISO 7864 and ISIRI 3979
- Sterile, single use, apyrogenic and biocompatible
- Dry siliconized stainless steel needle for painless smooth penetration

Sterile Hypodermic Needles Technical Specification

Gauge	Hub Colour	OD (mm)	Length (mm)	Sterilisation Method
21 G	Green	0.82	35/37/38	ETO
22 G	Gray	0.72	31/32	
23 G	Blue	0.64	31/32	

3- Part Syringe
10 ml Hypodermic Syringe

10 ml syringe together with hypodermic needle is used to inject or withdraw fluids into or from the body. In this syringe, a siliconized rubber gasket is applied to guarantee smooth movement of the plunger inside the barrel while preventing the leakage of fluids throughout the application

Features

- Compliance with ISO 7886-1 and INSO 770-1
- Sterile, single use apyrogenic, and biocompatible
- Dry siliconized stainless steel needle for painless smooth penetration

3-part, 10 ml Syringe with needle Technical Specification

Nominal Capacity (ml)	Graduation (ml)	Needle	Nozzle type	Units per box	Sterilisation Method
10	0.5	21 G	Centric Luer Slip & Luer lock	800	ETO

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2&3-Part Syringe
2, 3 & 5 ml Hypodermic Syringe

2, 3 and 5 ml syringes together with hypodermic needle are used to inject or withdraw fluids into or from the body

Features

- Compliance with ISO 7886-1 and INSO 770-1
- Sterile, single use apyrogenic and biocompatible
- Dry siliconized stainless steel needle for painless smooth penetration

Hypodermic Syringe with needle Technical Specification

Syringe	Nominal Capacity (ml)	Graduation (ml)	Needle gage	Nozzle type	Units per box	Sterilization Method
2 ml 2&3 part	2	0.1	23 G	Centric Luer Slip	1500	ETO
3ml 3 part	3	0.1	23 G	Centric Luer lock	1500	
5ml 2&3 part	5	0.2	22 G	Eccentric Luer Slip	1000	

Insulin Syringe

The single use insulin syringe of 1 ml volume with permanently attached needle minimizes the dead space, providing precise injection with minimal waste of injectable. Originally designed for injection of 100 units of insulin, it offers one of the most economical methods for injection of any injectable such as anesthetics, compatible with the specifications of the product.

Features

- Compliance with ISO 8537 and INSO 3591
- Sterile, single use, apyrogenic and biocompatible
- Syringe graduation at one unit increments
- Dry siliconized stainless steel needle for painless smooth penetration

Insulin Syringe Technical Specification

Nominal Capacity (ml)	Colour of cap	Colour of the needle cap	Needle			Sterilisation Method	Units per box
			Gauge	OD (mm)	Effective Length (mm)		
1ml (U-100)	Orange	Orange	29 G	0.33	8-12	ETO	3000 or 1600
1ml (U-100)	White		30 G	0.30	8-12		

SOHA

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