



LEPU MEDICAL TECHNOLOGY (BEIJING) CO.,LTD.

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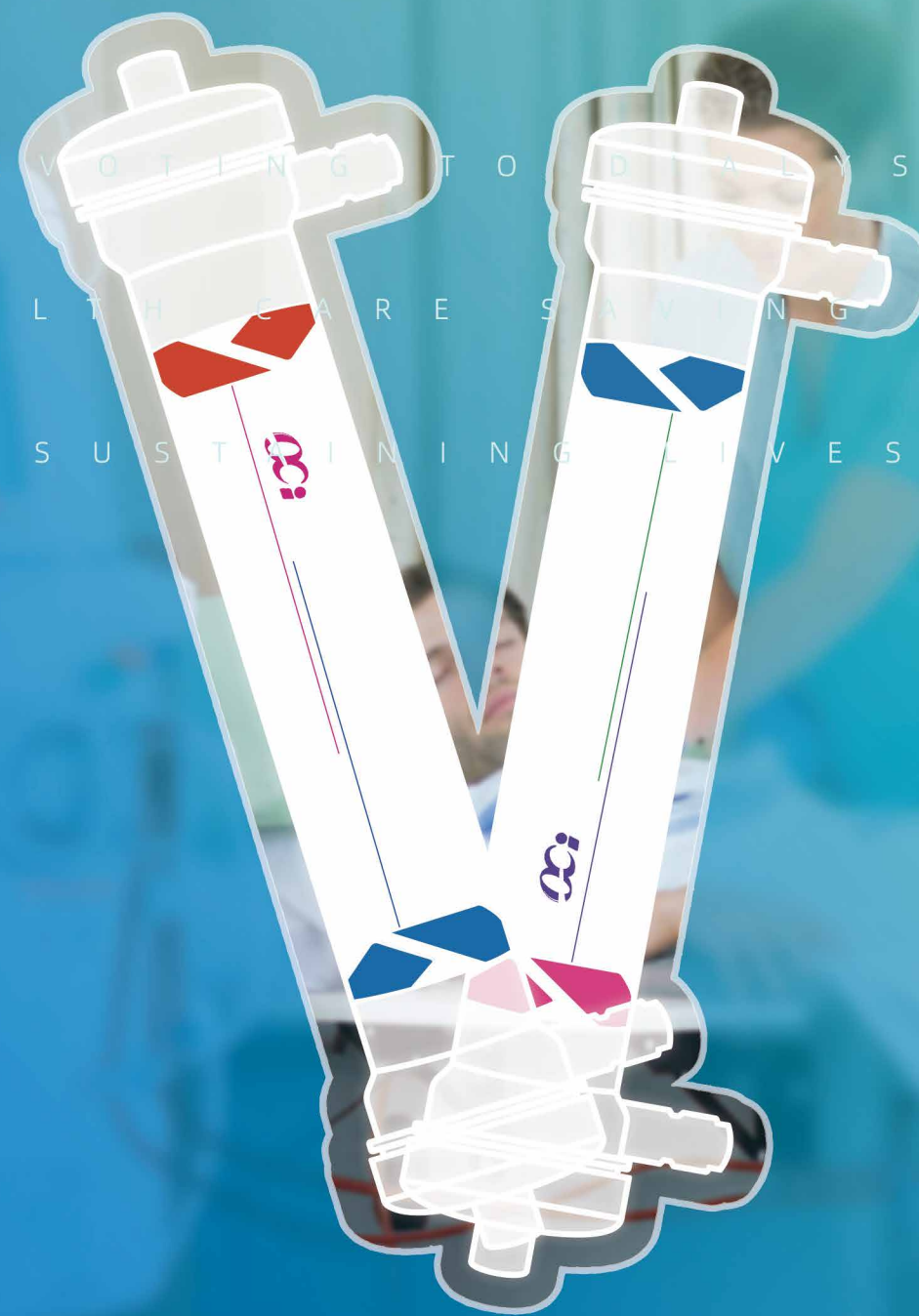
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DIALYSIS BROCHURE

DEVOTING TO DIALYSIS
HEALTH CARE SAVING AND
SUSTAINING LIVES



LEPU MEDICAL
Major Subsidiaries



The **Global Leading Group Company** in the Fields of
High-tech Medical Devices and Equipment



**COMPANY
PROFILE**

Lepu Medical Technology (Beijing) Co., Ltd. was established in 1999. Lepu Medical is specialized in developing, manufacturing and distributing the high-tech medical devices and equipment. Today, Lepu Medical has grown into a global leading group company in the fields of cardiovascular, neurovascular and peripheral vascular interventions, structural heart diseases, surgical cardiology, cardiac rhythm management, anesthesia and critical care, in vitro diagnostics and general surgery with products include coronary stents, dilatation balloon catheters, interventional accessories, occlusion devices, mechanical heart valves, electrophysiology catheters, pacemakers, in vitro diagnostic products, critical care products, angiography systems and surgical staplers. In 2009, Lepu Medical went public in ChiNext Shenzhen Stock Exchange market (stock code: 300003).

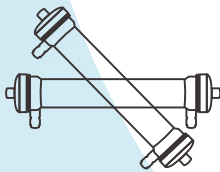
Now Lepu Medical totally has 32 primary subsidiary companies worldwide. Currently, there are 123 products have received the CE certificates, and 17 products have got the FDA approvals. As the National Interventional Cardiology Medical Instruments & Engineering Technology Research Center, Lepu Medical Group’s top strategy is to build up a 4 in 1 platform includes medical devices, medicines, health services and mobile medicals for cardiac treatments.

Lepu Medical has established three overseas subsidiary companies in Netherland, Turkey and India, obtained local registrations in 27 countries, and built the sales and distribution channels in over 80 countries and regions. Lepu Medical upholds “integrity, quality and scientific innovation” as its spirit, commitments to provide the best quality of products and services to satisfy the needs of healthcare professionals and patients.

This catalogue includes information of products available in certain countries. Availability of these products may vary with locations. Please contact Lepu Medical for more information about the approval in your region.

FACTORY PROFILE

Established in 2005, OCI Medical started entrepreneurship of developing self-spinning manufacture of PES Hollow Fiber dialyzer and PES hollow fiber membrane in China. In 2009, OCI Medical got NMPA and launch in Chinese hospitals and dialysis centers, and had been widely used in more than thousands of hospitals and dialysis centers covering most Chinese public hospitals. In 2012, the OCI company reorganized became to be one subsidiary of Lepu medical and facilitated fast development in China. Cooperate with National Key Laboratory of Polymer Materials Engineering from Sichuan University, all parts are invented and manufactured independently. 4000m2 100,000 class clean production workshop, together with high quality management system under ISO 13485 and CE certificate.



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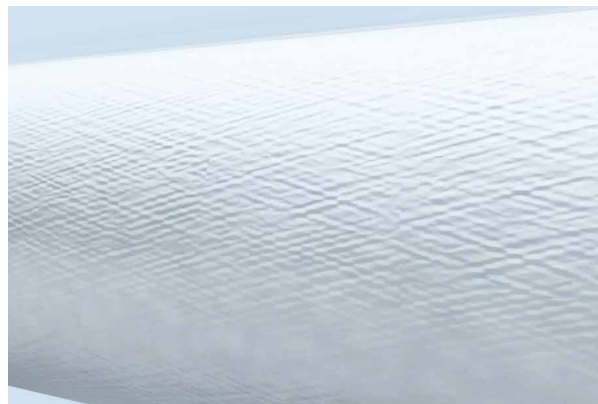
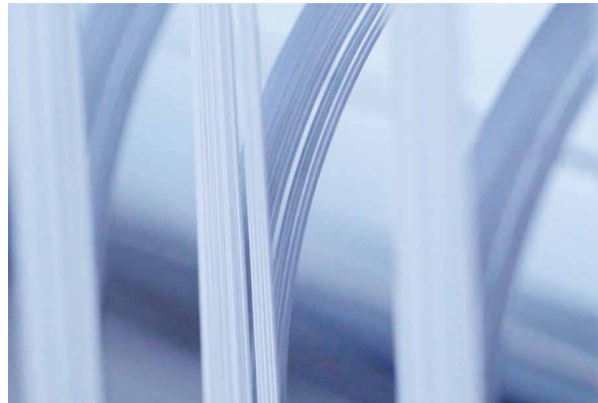
HEMODIALYSIS CATHETER | 06

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HEPL®

HepL® Polyethersulfone Hollow Fiber Membrane



 Enhanced Hydrophilicity

 Decreased Protein Adsorption

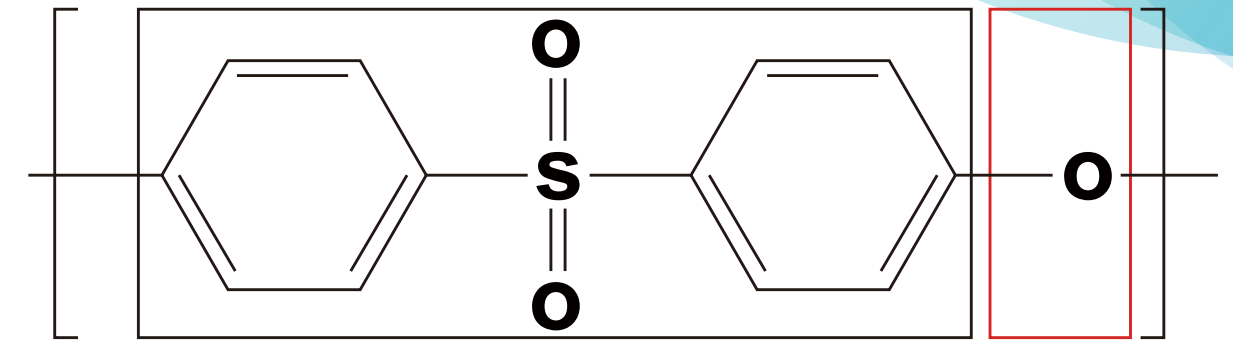
 Customized Production Service

 Anti-coagulant

MEMBRANE MATERIAL

★ Membrane material: PES


Better Choice



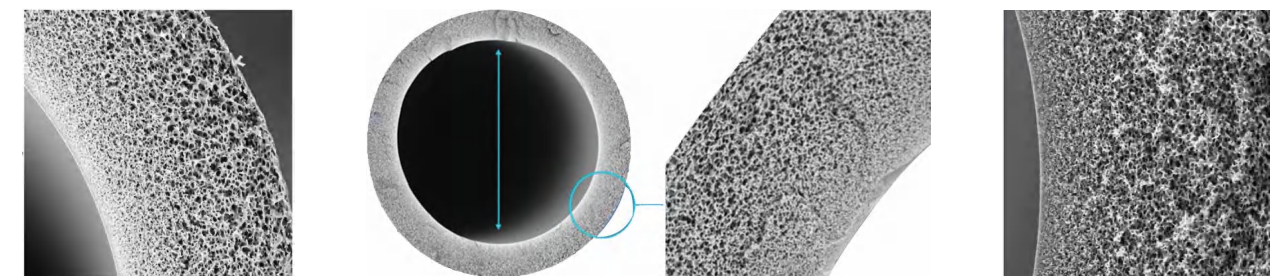
 BPA Free

 Uniform pore distribution

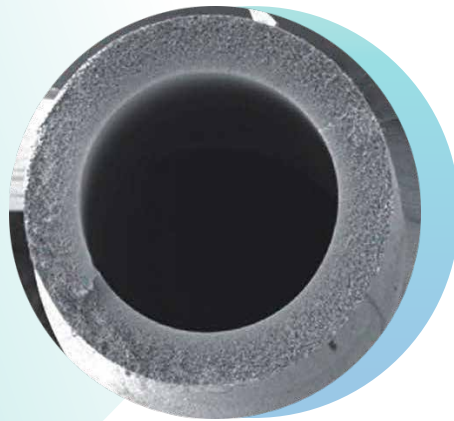
 Stable mechanical properties

 Excellent biocompatibility

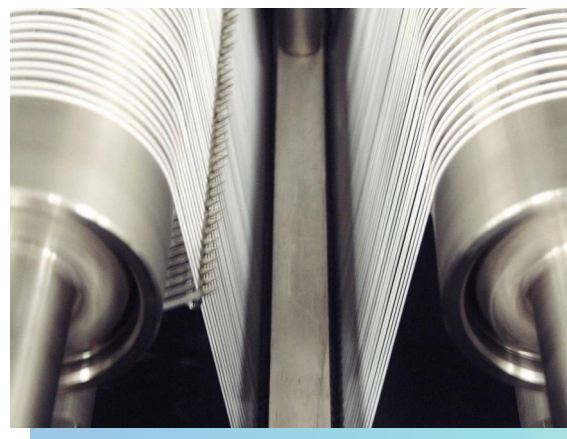
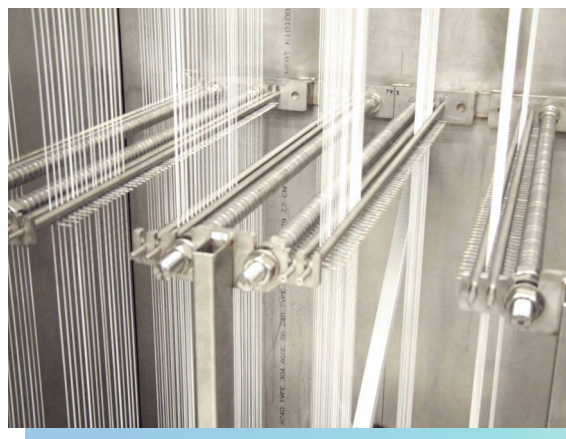
CROSS SECTION OF THE HEPL® MEMBRANE



- Smooth endothelium improves the blood compatibility and biocompatibility of the product;
- Extremely thin endothelium ensures high clearance efficiency;
- Uniform pore size enhances the clearance rate of the medium molecular substances while retaining-endotoxin.



- Specific inner diameter ensures the product's good clearance effect and reduces the probability of coagulation;
- The special design of spongy structure guarantees the maximum pressure of the membrane;
- Specific membrane thickness enabled the product with high ultrafiltration performance and clearance rate, while avoiding the reverse entry of endotoxin from dialysate into human body.



Each optimizing index is the commitment to duty, we contribute our effort and knowledge to the critical equipment, with strict standard in every manufacturing process. From raw material to clinical use, we concern every details, improve performance from the beginning, and do our best to make the right choice for each life and every moment.

HEMODIALYZER



3D Microwave Structure

Ensure uniform radial dialysate flow around each fibre within the bundle



Smooth Inlet Port

Smooth dialysate inlet port, friendly for connector of dialysis machine

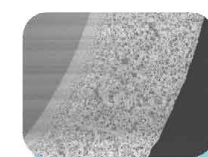


Ultrasonic Bonding

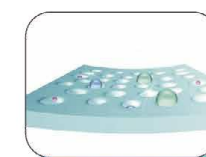
Ultrasonic bonding of the cap, avoid blood and dialysate leakage



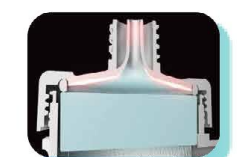
Designed Fibre
Thickness & Diameter



Smooth
Inner Surface



Specific
Pore Diameter



D-shape Ring



Transparent Cap

DIALYZER

High Flux Polyethersulfone
Hemodialyzer

NMPA CE



PC Series

PP Series



Brilliant Biocompatibility



High performance of toxins remove



Enhanced clearance of
middle-large molecules



Accurate molecular screening curve



Low albumin loss



High β_2 -microglobulin clearance rate

PC SERIES

NMPA CE

TECHNICAL SPECIFICATIONS

Model		OCI-HD150	OCI-HD180	OCI-HD200
Ultrafiltration coefficient (mL/h·mmHg)		47	49	52
Surface area (m ²)		1.5	1.8	2.0
Chamber volume (mL)		90	105	115
Maximum TMP (kPa/mmHg)		66.5/500		
Screening coefficient	β_2 -microglobulin	0.85		
	Lnulin	1		
	Myoglobin	0.35		
	Albumin	≤0.01		
Blood flow range (mL/min)		200-400		
Dialysate flow range (mL/min)		500-800		
Membrane material		HepL® Polyethersulfone (PES)		
Housing material		Polycarbonate (PC)		
Potting compound		Polyurethane (PU)		
Disinfection method		Irradiation sterilization, Valid for three years		

CLEARANCES (ML/MIN)

Test conditions: $Q_D = 500$ ml/min, In vitro simulation experiment.

Model	OCI-HD150			OCI-HD180			OCI-HD200		
QB (ml/min)	200	300	400	200	300	400	200	300	400
Urea	190	264	306	193	272	317	195	282	333
Creatinine	186	241	269	188	248	279	192	260	300
Phosphate	183	232	256	186	240	267	189	256	289
Vitamin B12	152	176	196	157	186	206	160	203	232
β_2 -MG	50	/	/	60	/	/	65	/	/

PP SERIES

NMPA CE

FEATURES:

- PP series is lighter and easier for medical staff to handle.
- Totally BPA free and ensure patient safety
- Wide range of the surface area meet different patients' needs
- Optimized structure and technological design, improve product safety and clearance rate

TECHNICAL SPECIFICATIONS

Model		OCI-HD 13M	OCI-HD 15M	OCI-HD 16M	OCI-HD 17M	OCI-HD 18M	OCI-HD 19M	OCI-HD 20M	OCI-HD 21M	OCI-HD 23M	OCI-HD 25M
Ultrafiltration coefficient (mL/h·mmHg)		39	48	57	60	63	64	67	69	73	77
Surface Area (m²) (mL)		1.3	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.5
Chamber volume		84	90	95	101	106	112	120	126	136	146
Maximum TMP (kPa/mmHg)		66.5/500									
Screening coefficient	β ₂ -microglobulin	0.85									
	Lnulin	1									
	Myoglobin	0.4									
	Albumin	≤0.01									
Membrane material		HepL® Polyethersulfone (PES)									
Housing material		Polypropylene (PP)									
Potting compound		Polyurethane (PU)									
Valid period		Irradiation sterilization, Valid for three years									

CLEARANCES (ML/MIN)

Test conditions: Q_D = 500 ml/min, In vitro simulation experiment.

Q _B	OCI-HD 13M	OCI-HD 15M	OCI-HD 16M	OCI-HD 17M	OCI-HD 18M	OCI-HD 19M	OCI-HD 20M	OCI-HD 21M	OCI-HD 23M	OCI-HD 25M
Urea / (ml/min)										
200	180	184	186	188	190	192	195	196	200	200
300	259	264	267	270	274	277	280	283	289	295
400	292	305	312	318	325	332	340	348	358	364
Creatinine / (ml/min)										
200	164	168	170	173	175	178	180	182	186	190
300	239	243	245	248	250	252	255	258	264	270
400	259	265	268	271	274	277	280	283	289	295
Phosphate / (ml/min)										
200	164	172	176	179	182	185	188	191	197	203
300	244	248	250	253	256	259	262	265	271	277
400	284	290	293	296	298	300	304	308	316	324
Vitamin B12 / (ml/min)										
200	129	135	138	140	142	144	147	150	156	162
300	159	165	168	171	173	175	178	181	187	193
400	168	176	180	185	188	192	196	200	208	216
β2-MG / (ml/min)										
200	52	60	64	67	70	73	76	78	82	86

DIALYZER

Low Flux Polyethersulfone
Hemodialyzer

NMPA CE



PC Series

PP Series



Brilliant Biocompatibility



High performance of toxins remove



Enhanced clearance of
small molecules



Good clearance rate of
the phosphate

PC SERIES

NMPA CE

TECHNICAL SPECIFICATIONS

Model	OCI-HD14L	OCI-HD16L	OCI-HD18L	OCI-HD20L
Ultrafiltration coefficient (mL/h·mmHg)	11	16	17	18
Surface area (m ²)	1.4	1.6	1.8	2.0
Chamber volume (mL)	90	105	118	130
Maximum TMP (kPa/mmHg)	66.5/500			
Blood flow range (mL/min)	200-400			
Dialysate flow range (mL/min)	500-800			
Membrane material	HepL® Polyethersulfone (PES)			
Housing material	Polycarbonate (PC)			
Potting compound	Polyurethane (PU)			
Disinfection method	Irradiation sterilization, Valid for three years			

CLEARANCES (ML/MIN)

Test conditions: Q_D = 500 ml/min, In vitro simulation experiment.

Model	OCI-HD14L			OCI-HD16L			OCI-HD18L			OCI-HD20L		
QB (ml/min)	200	300	400	200	300	400	200	300	400	200	300	400
Urea	180	216	252	183	220	256	188	226	263	192	230	268
Creatinine	170	204	221	175	210	227	180	216	234	183	219	237
Phosphate	160	176	208	163	195	253	167	200	217	172	190	223
Vitamin B12	80	88	94	91	100	105	102	112	122	113	124	129

PP SERIES

NMPA CE

FEATURES

- PP series is lighter and easier for medical staff to handle.
- Totally BPA free and ensure patient safety
- Wide range of the surface area meet different patients' needs
- Optimized structure and technological design, improve product safety and clearance rate

TECHNICAL SPECIFICATIONS

Model	OCI-HD 110L	OCI-HD 130L	OCI-HD 140L	OCI-HD 150L	OCI-HD 160L	OCI-HD 170L	OCI-HD 180L	OCI-HD 190L	OCI-HD 200L	OCI-HD 210L	OCI-HD 230L
Ultrafiltration Coefficient (mL/h·mmHg)	10	12	13	13	14	16	17	21	24	25	28
Surface Area (m²)	1.1	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3
Chamber Volume (mL)	72	80	85	90	95	101	106	112	118	123	145
Membrane Material	HepL® Polyethersulfone (PES)										
Housing Material	Polypropylene (PP)										
Potting Compound	Polyurethane (PU)										
Maximum TMP (kPa/mmHg)	66.5/500										
Valid Period	Irradiation sterilization, Valid for three years										

CLEARANCES (ML/MIN)

Test conditions: Q_D = 500 ml/min, In vitro simulation experiment.





Q _B	OCI-HD 110L	OCI-HD 130L	OCI-HD 140L	OCI-HD 150L	OCI-HD 160L	OCI-HD 170L	OCI-HD 180L	OCI-HD 190L	OCI-HD 200L	OCI-HD 210L	OCI-HD 230L
Urea / (ml/min)											
200	176	178	180	182	185	187	190	192	194	195	197
300	224	227	230	233	235	238	242	246	250	254	262
400	262	266	270	274	278	284	290	295	300	305	315
Creatinine / (ml/min)											
200	166	168	170	172	175	178	182	185	188	191	197
300	207	211	215	218	220	223	227	231	235	239	247
400	239	243	247	251	255	260	265	270	275	280	290
Phosphate / (ml/min)											
200	147	151	155	158	160	164	168	170	172	174	178
300	177	181	185	188	191	195	200	205	210	215	225
400	200	205	210	215	220	222	225	232	240	248	264
Vitamin B12 / (ml/min)											
200	97	100	103	106	108	114	120	125	130	135	145
300	105	109	113	116	118	124	130	135	140	145	155
400	119	122	125	128	130	140	150	155	160	165	175

DIALYZER

Hollow Fiber Hemodiafilter

NMPA CE



-  New PES formula, enhanced anticoagulant performance
-  High removal rate of molecules
-  Safety PP material, no BPA
-  Improved design, enhanced diffusion effect

TECHNICAL SPECIFICATIONS

Model		OCI-HF160	OCI-HF170	OCI-HF180	OCI-HF200	OCI-HF230	OCI-HF250
Ultrafiltration coefficient (mL/h·mmHg)		71	72	73	80	87	91
Surface Area (m²)		1.6	1.7	1.8	2.0	2.3	2.5
Chamber volume (mL)		100	107	112	123	133	141
Maximum TMP (kPa/mmHg)		500 mmHg / 66.5kPa					
Screening coefficient	Albumin	≤0.01					
	Inulin	1.0					
	Myoglobin	0.4					
Blood flow range (mL/min)		200-400					
Dialysate flow range (mL/min)		500-800					
Membrane material		HepL® Polyethersulfone (PES)					
Housing material		Polypropylene (PP)					
Potting compound		Polyurethane (PU)					
Disinfection method		Irradiation sterilization, Valid for three years					

CLEARANCES (ML/MIN)

Test conditions: Q_D = 500 ml/min, In vitro simulation experiment.

Model	OCI-HF160			OCI-HF170			OCI-HF180			OCI-HF200			OCI-HF230			OCI-HF250		
QB (ml/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea	197	280	330	198	282	335	198	285	340	199	288	345	199	290	348	200	292	350
Creatinine	195	262	310	195	266	316	196	269	320	197	273	330	198	280	336	200	283	340
Phosphate	185	245	281	187	250	291	189	255	296	192	260	308	194	266	315	196	272	322
Vitamin B12	152	183	201	156	189	210	159	194	215	164	202	223	169	211	232	174	220	244
β ₂ -MG	65	/	/	67	/	/	70	/	/	75	/	/	78	/	/	81	/	/

Hemoperfutor

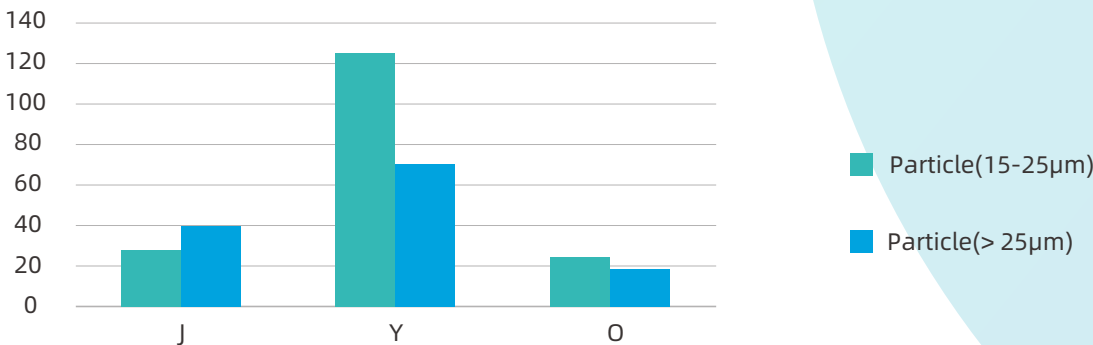
Disposable Hemoperfutor

NMPA

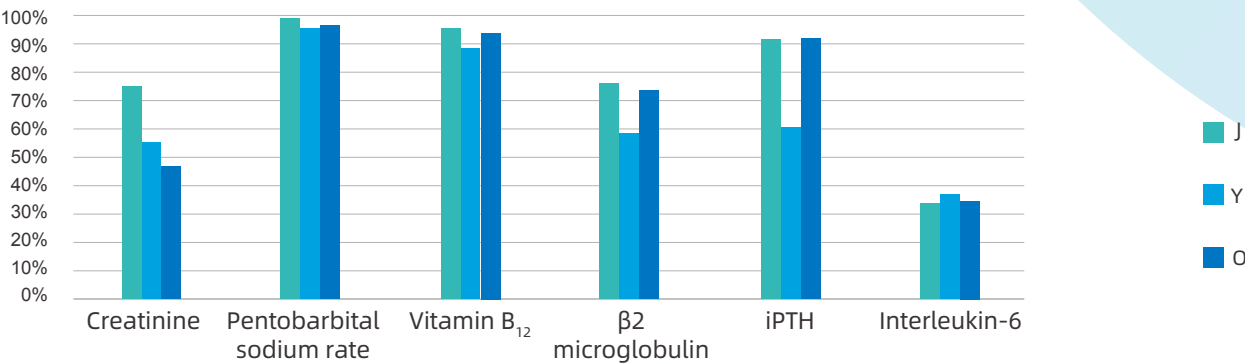


- Optimized resin synthesis technology, minimized toxic side effects and solvent residues
- Neutral preservation solution, avoid acidosis by long term use
- Safety PP shell material, no BPA
- High quality laminating technology, better biocompatibility
- Optimized pore diameter, remove both medium and large molecules
- High mechanical strength, lower particle shedding rate

PARTICLE SHEDDING RATE



ADSORPTION PERFORMANCE



TECHNICAL SPECIFICATIONS

Model	OC-100 (A)	OC-130 (A)	OC-160 (A)	OC-200 (A)	OC-230 (A)
Adsorbent volume	100	130	160	200	230
Adsorbent material	Polystyrene divinylbenzene (Resin)				
Filling fluid	Injection water				
Material for shell accesories	PP & Nylon & Silicone Rubber				
Adsorption performance	Vitamin B12			β ₂ microglobulin	
	≥90%			≥80 μg/ml	
Pressure resistance	100kpa				
Disinfection method	Irradiation sterilization, Valid for two years				

ADSORPTION PERFORMANCE

Test conditions: Q_D = 500 ml/min In vitro simulation experiment

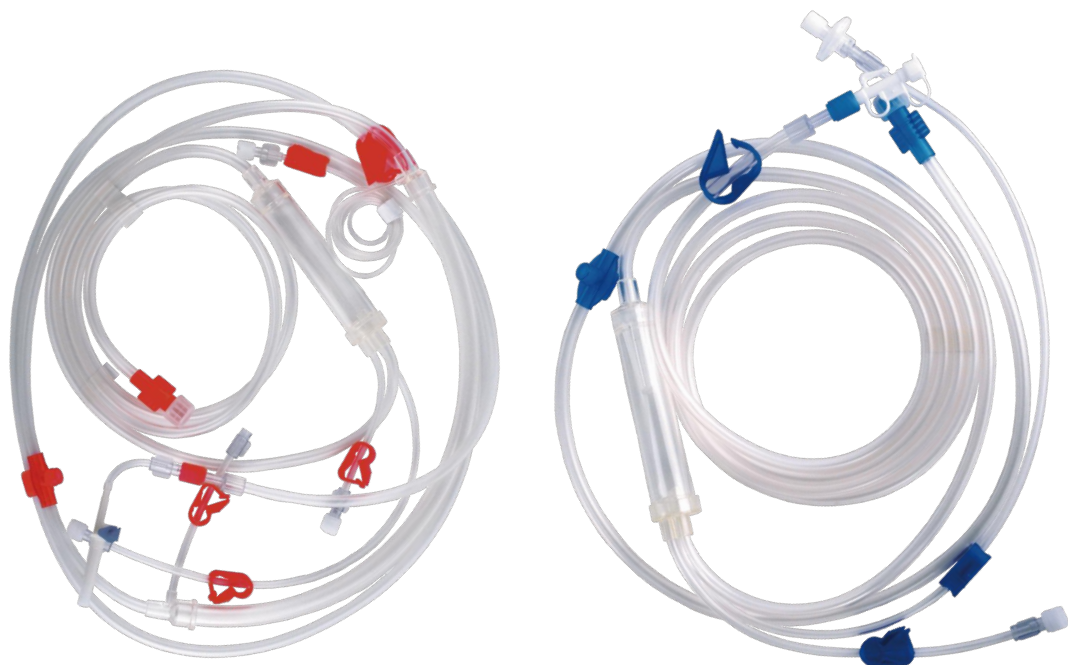
Vitamin B12 (≥90%)	OC-100 (A)
	OC-130 (A)
	OC-160 (A)
β ₂ microglobulin (≥80 µg/ml)	OC-200 (A)
	OC-230 (A)

DISPOSABLE BLOODLINES

NMPA CE

FISTULA NEEDLES

NMPA CE



Complete specifications



Suitable for most series of the blood purification equipment (TORAY, BAXTER, BELLCO, GAMBRO, NIKKISO, BRAUN, FRESenius, etc.)



Specification:OCI-14G, OCI-15G, OCI-16G, OCI-17G



Ultra thin walls of the needles permit maximum blood flow rates

TECHNICAL SPECIFICATIONS

OCI-BD-D-A	Double chambers, wide pump tube
OCI-BD-S-B	Single chamber, narrow pump tube
OCI-BD-D-B	Double chambers, narrow pump tube

HEMODIALYSIS POWDER A / B

Hemodialysis Concentrate



- Upscale Raw Material
- Suitable for all Dialyzers and Machines
- 100 Thousand-Grade Dust-free and Sterile Production Workshop

TECHNICAL SPECIFICATIONS

Sodium	Sodium is the main cation in extracellular fluid and plays an important role in maintaining plasma osmotic pressure and blood volume
Potassium	potassium regulates the appropriate osmotic pressure in cells,regulating the acid-base balance of body fluids,participate in the metabolism of sugar and protein in cells
Calcium	Calcium maintains the normal permeability of blood vessels , participate in muscle contraction, participate in the blood coagulation process
Magnesium	Participation in all energy metabolism.activation and catalysis of over 300 enzyme systems, including gulcose utilization, fat , protein and nucleic acid synthesis, adenosine triphosphate metabolism, membrane ion transport, etc
Chloroine	The chloride ion in the dialysate is essential! the same as the extracellulfar fluid, determined by the concentration of cations and sodium acetate

TECHNICAL SPECIFICATIONS




Shape and properties	White crystalline powder or particle
Indication	Product for hemodialysis in patients with renal failure
Packaging	One person/bag; Ten persons/bag
Bacterial endotoxin	After dilution with water for endotoxin test as dialysis solution, bacterial endotoxin is not more than 0.5EU/ml
Insoluble microparticles	After dilution to dialysis solution, after deducting the content of particulates after background $\geq 10\mu\text{m}$ particles not more than 25/ml $\geq 25\mu\text{m}$ particles not more than 3/ml
Microbial limit	The total number of bacteria in proportion to the proportion of the concentrated solution in this product not more than 100CFU/ml, toal number of molds and yeasts not more than 10CFU /ml, escheri chiacolicannot be selected
Term of validity	12 months from the date of production

SODIUM BICARBONATE BAG / CARTRIDGE

Hemodialysis Concentrate

NMPA CE



-  Safe and Easy to Use
-  Quality Assurance
-  100 Thousand-Grade Dust-free and Sterile Production Workshop

TECHNICAL SPECIFICATIONS

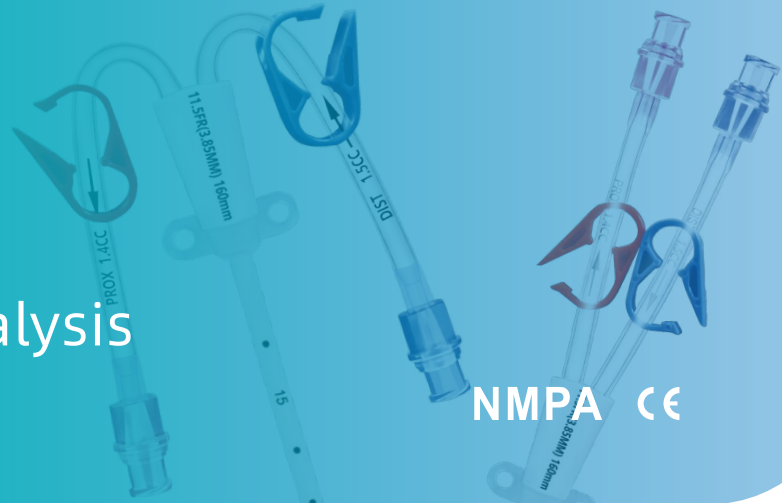
Shape and properties	White crystalline powder or particle
Indication	Product for hemodialysis in patients with renal failure
Specifications	HND-DDB01:1 one person/bag
Bacterial endotoxin	HND-DDB01:1 one person/bag bacterial endotoxin is no more than 0.5eu/m
Particulate matter	After dilution to dialysis solution, after deducting the content of particulates after background $\geq 10\mu\text{m}$ Particles not more than 25/ml $\geq 25\mu\text{m}$ Particles not more than 3/ml
Microbial limit	The total number of aerobic bacteria is not less than 100cfu/ml, and the total number of molds and yeasts is not more than 10cfu / ml. No E.coli canbedetected
Term of validity	12 months from the date of production

TECHNICAL SPECIFICATIONS

Shape and properties	White crystalline powder or particle
Indication	Product for hemodialysis in patients with renal failure
Specifications	HND-DDB01:1 one person/bag
Bacterial endotoxin	After diluted with water for endotoxin test as dialysis solution, bacterial endotoxin is no more than 0.5eu/ml
Particulate matter	After dilution to dialysis solution, after deducting the content of particulates after background $\geq 10\mu\text{m}$ Particles not more than 25/ml $\geq 25\mu\text{m}$ Particles not more than 3/ml
Microbial limit	The total number of aerobic bacteria is not less than 100cfu/ml, and the total number of molds and yeasts is not more than 10cfu / ml. No E.coli canbedetected
Term of validity	12 months from the date of production

DOLPHIN






Disposable Hemodialysis Catheter Kit








NMPA CE





FEATURES

-  Soft blue tip
-  Patented connection design
-  Flexible polyurethane material
-  Latex-free
-  Standard/full packages

BENEFITS

-  Easy entry
-  Less harm to vessel
-  Anti-kink
-  Anti-bacterial
-  Leakage-proof

RANGES

-  Single/double/triple lumen
-  5-50cm multi-catheter lengths

ORDERING INFORMATION

Catalogue No.	Lumen Type	Catheter Type	Catheter O.D.	Catheter Length (cm)	Lumen Size (G)
					A/V
TGHCBSJ(Y)2-115-13 (D)	Double-Lumen	Straight	11.5F	13cm	12/12
TGHCBCJ(Y)2-115-13 (D)	Double-Lumen	Curved	11.5F	13cm	12/12
TGHCBSJ(Y)2-115-16 (D)	Double-Lumen	Straight	11.5F	16cm	12/12
TGHCBCJ(Y)2-115-16 (D)	Double-Lumen	Curved	11.5F	16cm	12/12
TGHCBSJ(Y)2-115-20 (D)	Double-Lumen	Straight	11.5F	20cm	12/12
TGHCBCJ(Y)2-115-20 (D)	Double-Lumen	Curved	11.5F	20cm	12/12
TGHCBSJ(Y)2-12-13 (D)	Double-Lumen	Straight	12F	13cm	12/12
TGHCBCJ(Y)2-12-13 (D)	Double-Lumen	Curved	12F	13cm	12/12
TGHCBSJ(Y)2-12-16 (D)	Double-Lumen	Straight	12F	16cm	12/12
TGHCBCJ(Y)2-12-16 (D)	Double-Lumen	Curved	12F	16cm	12/12
TGHCBSJ(Y)2-12-20 (D)	Double-Lumen	Straight	12F	20cm	12/12
TGHCBCJ(Y)2-12-20 (D)	Double-Lumen	Curved	12F	20cm	12/12
					D/A/V
TGHCBSJ(Y)3-12-13 (D)	Triple-Lumen	Straight	12F	13cm	16/12/12
TGHCBCJ(Y)3-12-13 (D)	Triple-Lumen	Curved	12F	13cm	16/12/12
TGHCBSJ(Y)3-12-16 (D)	Triple-Lumen	Straight	12F	16cm	16/12/12
TGHCBCJ(Y)3-12-16 (D)	Triple-Lumen	Curved	12F	16cm	16/12/12
TGHCBSJ(Y)3-12-20 (D)	Triple-Lumen	Straight	12F	20cm	16/12/12
TGHCBCJ(Y)3-12-20 (D)	Triple-Lumen	Curved	12F	20cm	16/12/12

STANDARD PACKAGE:

- Central Venous Catheter (1)
- Guide Wire (1)
- Tissue Dilator (1)
- Scalpel (1)
- Introducer Needle / Y-Shape Needle (1)
- Blue Introducer Syringe (1/0)
- Syringe with Needle (1/2)
- Heparin Cap (1/2/3)
- Catheter Fastener (1)
- Extension Line Clamp (1/2/3)



NMPA CE

FULL PACKAGE:

- | | |
|--|------------------------------|
| Central Venous Catheter (1) | Syringe with Needle (1/2) |
| Guide Wire (1) | Heparin Cap (1/2/3) |
| Tissue Dilator (1) | Catheter Fastener (1) |
| Scalpel (1) | Extension Line Clamp (1/2/3) |
| Introducer Needle / Y-Shape Needle (1) | Gauze Pad (2) |
| Blue Introducer Syringe (1/0) | Prep Sponge Swab (3) |
| | Applicator case (2) |

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- Silk Suture with Straight and Bended Needles (2)
- Wound Closure Strip (1)
- Dressings (1)
- Fenestrated Drape (1)
- Small Drape (1)
- Middle Drape (1)
- Gloves (1)

