



HEMODIALYSIS CATHETER KIT

Technical Data Sheet

According to Medical Device Directive 93/42/EEC including amendment 2007/47/EC Annex II

Doc No.: TDS/HCT/-23

Rev No.: 00

Rev. Date: 30.10.2023

Section 1: Identification of the Device

1.1	Generic Name:	Hemodialysis Catheter Kit																																																												
1.2	Specific Type or Variation:	Short Term for Temporary Use																																																												
1.3	GMDN (global medical device nomenclature):	Double lumen hemodialysis catheter, implantable																																																												
1.4	GMDN Code:	37278																																																												
1.5	UMDNS (universal medical device nomenclature system):	Catheter, Hemodialysis																																																												
1.6	UMDNS Code:	15022																																																												
1.7	Risk Classification:	Class IIa, Rule 7 (Surgically invasive devices intended for short-term use) (According to 93/42/EEC Medical devices directive incl. Amendment 2007/47/EC, Annex IX)																																																												
1.8	Reference Code(s):	<table><tr><td>HCT10001</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 10 cm</td></tr><tr><td>HCT10002</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 13 cm</td></tr><tr><td>HCT10003</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 15 cm</td></tr><tr><td>HCT10004</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 16 cm</td></tr><tr><td>HCT10005</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 20 cm</td></tr><tr><td>HCT10006</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Straight, 30 cm</td></tr><tr><td>HCT10007</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 10 cm</td></tr><tr><td>HCT10008</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 13 cm</td></tr><tr><td>HCT10009</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 15 cm</td></tr><tr><td>HCT10010</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 16 cm</td></tr><tr><td>HCT10011</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 20 cm</td></tr><tr><td>HCT10012</td><td>Hemodialysis catheter kit</td><td>Single Lumen, 8 Fr, Curved, 30 cm</td></tr><tr><td>HCT10013</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 13 cm</td></tr><tr><td>HCT10014</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 15 cm</td></tr><tr><td>HCT10015</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 16 cm</td></tr><tr><td>HCT10016</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 20 cm</td></tr><tr><td>HCT10017</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 30 cm</td></tr><tr><td>HCT10018</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 13.5 cm</td></tr><tr><td>HCT10019</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 25 cm</td></tr><tr><td>HCT10020</td><td>Hemodialysis catheter kit</td><td>Double Lumen, 11.5 Fr, Straight, 12.5 cm</td></tr></table>	HCT10001	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 10 cm	HCT10002	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 13 cm	HCT10003	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 15 cm	HCT10004	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 16 cm	HCT10005	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 20 cm	HCT10006	Hemodialysis catheter kit	Single Lumen, 8 Fr, Straight, 30 cm	HCT10007	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 10 cm	HCT10008	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 13 cm	HCT10009	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 15 cm	HCT10010	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 16 cm	HCT10011	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 20 cm	HCT10012	Hemodialysis catheter kit	Single Lumen, 8 Fr, Curved, 30 cm	HCT10013	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 13 cm	HCT10014	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 15 cm	HCT10015	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 16 cm	HCT10016	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 20 cm	HCT10017	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 30 cm	HCT10018	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 13.5 cm	HCT10019	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 25 cm	HCT10020	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Straight, 12.5 cm
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HCT10021	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 13 cm
HCT10022	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 15 cm
HCT10023	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 16 cm
HCT10024	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 20 cm
HCT10025	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 30 cm
HCT10026	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 13.5 cm
HCT10027	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 25 cm
HCT10028	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Curved, 12.5 cm
HCT10029	Hemodialysis catheter kit	Double Lumen, 11.5 Fr, Pre-Curved, 15 cm
HCT10030	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 13 cm
HCT10031	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 15 cm
HCT10032	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 16 cm
HCT10033	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 20 cm
HCT10034	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 30 cm
HCT10035	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 13.5 cm
HCT10036	Hemodialysis catheter kit	Double Lumen, 12 Fr, Straight, 25 cm
HCT10037	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 13 cm
HCT10038	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 15 cm
HCT10039	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 16 cm
HCT10040	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 20 cm
HCT10041	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 30 cm
HCT10042	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 13.5 cm
HCT10043	Hemodialysis catheter kit	Double Lumen, 12 Fr, Curved, 25 cm
HCT10044	Hemodialysis catheter kit	Double Lumen, 12 Fr, Ön-Curved, 15 cm
HCT10045	Hemodialysis catheter kit	Double Lumen, 8 Fr, Straight, 12 cm
HCT10046	Hemodialysis catheter kit	Double Lumen, 8 Fr, Straight, 13 cm



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HCT10047	Hemodialysis catheter kit	Double Lumen, 8 Fr, Straight, 15 cm
HCT10048	Hemodialysis catheter kit	Double Lumen, 8 Fr, Curved, 12 cm
HCT10049	Hemodialysis catheter kit	Double Lumen, 8 Fr, Curved, 13 cm
HCT10050	Hemodialysis catheter kit	Double Lumen, 8 Fr, Curved, 15 cm
HCT10051	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 11 cm
HCT10052	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 12 cm
HCT10053	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 13 cm
HCT10054	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 15 cm
HCT10055	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 16 cm
HCT10056	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Straight, 20 cm
HCT10057	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 11 cm
HCT10058	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 12 cm
HCT10059	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 13 cm
HCT10060	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 15 cm
HCT10061	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 16 cm
HCT10062	Hemodialysis catheter kit	Double Lumen, 8.5 Fr, Curved, 20 cm
HCT10063	Hemodialysis catheter kit	Double Lumen, 9 Fr, Curved, 10 cm
HCT10064	Hemodialysis catheter kit	Double Lumen, 11 Fr, Straight, 13 cm
HCT10065	Hemodialysis catheter kit	Double Lumen, 11 Fr, Straight, 15 cm
HCT10066	Hemodialysis catheter kit	Double Lumen, 11 Fr, Straight, 16 cm
HCT10067	Hemodialysis catheter kit	Double Lumen, 11 Fr, Straight, 20 cm
HCT10068	Hemodialysis catheter kit	Double Lumen, 11 Fr, Curved, 12.5 cm
HCT10069	Hemodialysis catheter kit	Double Lumen, 11 Fr, Curved, 13 cm
HCT10070	Hemodialysis catheter kit	Double Lumen, 11 Fr, Curved, 15cm
HCT10071	Hemodialysis catheter kit	Double Lumen, 11 Fr, Curved, 16 cm
HCT10072	Hemodialysis catheter kit	Double Lumen, 11 Fr, Curved, 20 cm



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HCT10073	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 13 cm
HCT10074	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 13.5 cm
HCT10075	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 15 cm
HCT10076	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 16 cm
HCT10077	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 20 cm
HCT10078	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 25 cm
HCT10079	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Straight, 30 cm
HCT10080	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 13 cm
HCT10081	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 13.5 cm
HCT10082	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 15 cm
HCT10083	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 16 cm
HCT10084	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 20 cm
HCT10085	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 25 cm
HCT10086	Hemodialysis catheter kit	Triple Lumen, 11.5 Fr, Curved, 30 cm
HCT10087	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 13 cm
HCT10088	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 13.5 cm
HCT10089	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 15 cm
HCT10090	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 16 cm
HCT10091	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 20 cm
HCT10092	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 25 cm
HCT10093	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Straight, 30 cm
HCT10094	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Curved, 13 cm
HCT10095	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Curved, 13.5 cm
HCT10096	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Curved, 15 cm
HCT10097	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Curved, 16 cm
HCT10098	Hemodialysis catheter kit	Triple Lumen, 12 Fr, Curved, 20 cm



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HCT10099 Hemodialysis catheter kit Triple Lumen, 12 Fr, Curved, 25 cm

HCT10100 Hemodialysis catheter kit Triple Lumen, 12 Fr, Curved, 30 cm

Section 2: Purpose of Use

2.1	Intended Use:	Hemodialysis catheter kit is intended for use in patients for whom dialysis treatment is indicated. The kit helps to provide a temporary access for hemodialysis treatment until permanent access is provided or another treatment is substituted. Hemodialysis Catheter Kit, is offered to the market as a complete set for the hemodialysis procedure. Being positioned percutaneously, Ares hemodialysis catheter kits are biocompatible and designed with optimum care. This device is sterilized by ethylene oxide and is for single use only. Attempt to resterilize this device may cause malfunction, insufficient sterilization and harm to the patient. The device is for adult use only; in vascular accesses by physicians. It is used by physicians thoroughly trained and experienced in this procedure. The patient groups include adults of all ages and sexes, excluding pregnant women.
2.3	Level of Use:	Ares Medikal Hemodialysis Catheter Kits are presented to the end-user for intravenous and percutaneous insertion into the jugular vein, subclavian vein or femoral vein of the patient. Ares Hemodialysis Catheter Kits include a radiopaque polyurethane catheter which allows for a flow rate of 500 ml/min. The catheter varies upon lumens, French sizes and length. The catheter comes with variable length to accommodate with the anatomical differences of the patients to be compatible with different insertion techniques. Radiopaque tip of the catheter provides perfect visualization under x-ray. The kits include hemodialysis catheters with atraumatic tip, 10 fr and 12 fr dilators with robust structure to gain effective vessel widening, 18 G 7 cm puncture needle for easy and safe introduction to the vein, 0,038" 70 cm nitinol mini guidewire for effective insertion of the catheters, and accessories to facilitate the procedure. The smooth and soft shaft of the catheter as well as its thermosensitive material minimizes the risk of vessel trauma and assures secure operation. The solid body of the dilators ensure ease of use and provides optimum safety for intravenous introduction.
2.4	Contradictions:	None known
2.4	Intended User Group:	The device is for professional use only. It should be used by physicians who are thoroughly trained and experienced in intravascular procedures
2.6	Clinical Department:	Vascular Surgery

Section 3: Technical, Physical and Chemical Characteristics

3.1	Components:	1. Catheter 2. Luer Lock Injection Caps 3. Dilators 4. Guidewire 5. Scalpel 6. Syringe 7. Needle 8. Compress Pad
3.2	Dimensions:	
3.3	Drawing:	
3.4	Raw Materials:	• Catheter: Polyurethane (PU) • Injection Caps: (PC-Silicone) • Dilator: Polyethylene (PE) • Guidewire: Nitinol • Scalpel: Stainless Steel 304 • Syringe: Polyethylene (PE) • Needle: Stainless Steel 304
3.5	Biocompatibility:	• Acute Systemic Toxicity by Intravenous Test - MD455/1920/1653(ib) • Acute Systemic Toxicity by Intraperitoneal Test - MD455/1920/1653(id) • In Vitro Cytotoxicity Test - MD455/1920/1653 • Animal Intracutaneous Reactivity Test - MD455/1920/1653(ii)



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- Subacute Systemic Toxicity Test - MD455/1920/1653
- In Vitro Hemocompatibility Test - MD455/1920/1653(iii)
- Guinea Pig Maximization Test- MD455/1920/1653(iv)
- Pyrogen Test By Intravenous Injection of Rinsate Of hemodialysis catheter kits MD455/1920/1653(xiii)

Section 4: Packaging

4.1	Sterility Status on Delivery:	Sterile
4.2	Primary Packaging:	Medical grade peel pouch per 1 pc
4.3	Secondary Packaging:	Outer box (45 cm x 51 cm x 52 cm) per 100 pcs
4.4	Shelf Life	3 years
4.5	Transportation and Storage Status:	Store and transport device at room temperature in a dark and dry place. Keep the product away from places where it is exposed to direct sunlight, ionizing radiation and organic solvents.
4.6	Warning:	Ares Hemodialysis Catheter Kit are supplied in sterile form with an unopened package, which is a sterile barrier for the contents. In case of a damage on the package, do not use the device and contact with Ares representatives.
4.7	Disposal:	Once used, the device is accepted as a medical waste and should be disposed as per the protocol for disposal of contaminated materials.

Section 5: Standards and Certification

5.1	Applied Standards:	EN ISO 13485: 2016; EN ISO 14971: 2019; EN ISO 20417:2021 EN 556-1:2001; EN ISO 15223-1:2021; EN ISO 10555-1:2009; EN ISO 11070:2014 ;EN ISO 10993-1: 2020; EN ISO 10993-4:2017; EN ISO 10993-5: 2009; EN ISO 10993-7:2008; EN ISO 10993-10:2021; EN ISO 10993-11:2018; EN ISO 11135:2014; EN ISO 11737-1: 2018; EN ISO 11737-2: 2009; EN ISO 11607-1:2019; EN ISO 11607-2:2019; MEDDEV 2.7/1 rev.4
5.2	Legal Manufacturer:	Ares Medikal San. Tic. Ltd. Şti. Aşık Veysel Mah. 5821/1 Sk. No: 6 Karabağlar 35110 İzmir-Turkey
5.3	CE Marking	CE 0068
5.3	ISO	ISO 13485:2016

ARES MEDİKAL
SAHAYI TICARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gazimir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:4545336122779750