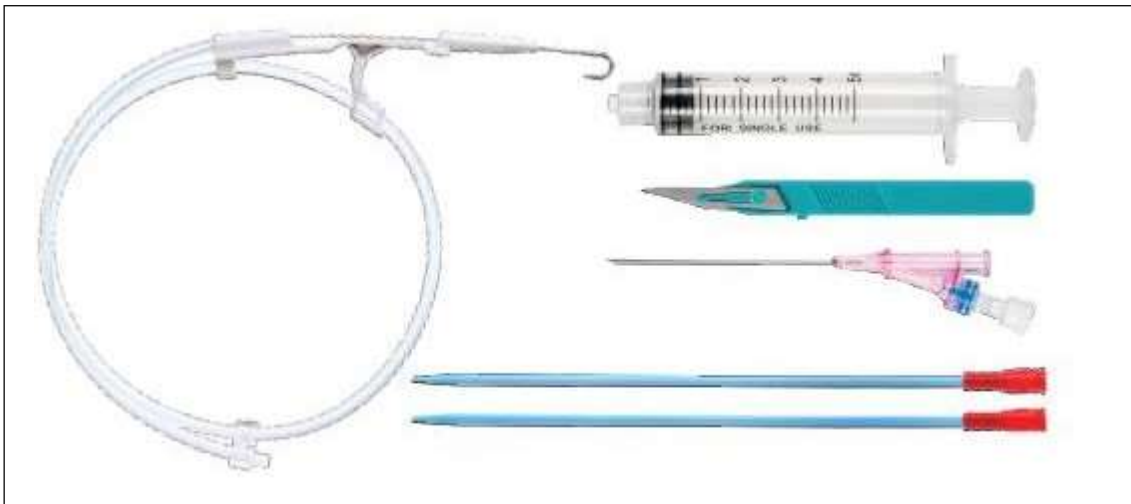


# DETAILED SPECIFICATION

	<b>HEMODIALYSIS CATHETER</b>	
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Product Code	Description
13450	POLYMED Haemodialysis catheter, 11.5 FR x 12 cm, Double Lumen, Straight Extension Tubes
13451	POLYMED Haemodialysis catheter, 11.5Fr x 13cm, Double Lumen, Straight Extension Tubes
13452	POLYMED Haemodialysis catheter, 11.5Fr x 15cm, Double Lumen, Straight Extension Tubes
13453	POLYMED Haemodialysis catheter, 11.5Fr x 20cm, Double Lumen, Straight Extension Tubes
13454	POLYMED Haemodialysis catheter, 12Fr x 13cm, Double Lumen, Straight Extension Tubes
13455	POLYMED Haemodialysis catheter, 12Fr x 15cm, Double Lumen, Straight Extension Tubes
13456	POLYMED Haemodialysis catheter, 12Fr x 20cm, Double Lumen, Straight Extension Tubes
13457	POLYMED Haemodialysis catheter, 11.5Fr x 13cm, Double Lumen, Curved Extension Tubes
13458	POLYMED Haemodialysis catheter, 11.5Fr x 15cm, Double Lumen, Curved Extension Tubes
13459	POLYMED Haemodialysis catheter, 11.5Fr x 20cm, Double Lumen, Curved Extension Tubes
13460	POLYMED Haemodialysis catheter, 12Fr x 13cm, Double Lumen, Curved Extension Tubes
13461	POLYMED Haemodialysis catheter, 12Fr x 15cm, Double Lumen, Curved Extension Tubes
13462	POLYMED Haemodialysis catheter, 12Fr x 20cm, Double Lumen, Curved Extension Tubes
13463	Hemodialysis catheter (12FrX16cm), Double lumen, Raulerson syringe 5ml, 18GX7cm Needle
13464	Hemodialysis catheter (12FrX20cm), Double lumen, Raulerson syringe-5ml, 18GX7cm Needle
13465	Hemodialysis catheter (12FrX16cm), Triple lumen, Raulerson syringe-5ml, 18GX7cm Needle
13466	Hemodialysis catheter (12FrX16cm), Triple lumen, Curved Extension tubes
13467	Hemodialysis catheter (12FrX16cm), Triple lumen, Straight Extension tubes
13468	POLYMED Haemodialysis catheter, 12Fr x 16cm, Double Lumen, Straight Extension Tubes
13469	POLYMED Haemodialysis catheter, 12Fr x 16cm, Double Lumen, Curved Extension Tubes
13470	POLYMED Haemodialysis catheter (12Fr x 13cm), Triple Lumen, Curved Extension Tubes
13471	POLYMED Haemodialysis catheter, 12Fr x 20cm, Triple Lumen, Curved Extension Tubes
13472	POLYMED Haemodialysis catheter, kink resistant guide wire (NiTi), 12 Fr x 16 cm, TripleLumen, curved extension tubes
13473	POLYMED Haemodialysis catheter, kink resistant guide wire (NiTi), 12 Fr x 16 cm, DoubleLumen, curved extension tubes
13474	POLYMED Haemodialysis catheter, kink resistant guide wire (NiTi), 11.5 Fr x 13 cm, DoubleLumen, curved extension tubes
13475	POLYMED Haemodialysis catheter, kink resistant guide wire (NiTi), 11.5 Fr x 15 cm, Double Lumen, curved extension tubes
13476	POLYMED Haemodialysis catheter, kink resistant guide wire (NiTi), 11.5 Fr x 15 cm, DoubleLumen, straight extension tubes

## Product Photographs



**FLOW RATE FOR EACH TYPE OF LUMEN**

Flow rate											
Sr. No	Product	Indwelling catheter length (±5 mm)	Distal(ml/min)			Medial(ml/min)			Proximal(ml/min)		
			Claim	Min	Max	Claim	Min	Max	Claim	Min	Max
1	2 Lumen Curved 12FR	130	310	279	357	-	-	-	310	279	357
2	2 Lumen Curved 12FR	150	280	252	322	-	-	-	280	252	322
3	2 Lumen Curved 12FR	160	300	270	345	-	-	-	300	270	345
4	2 Lumen Curved 12FR	200	295	266	339	-	-	-	295	266	339
5	2 Lumen Straight 12FR	130	320	288	368	-	-	-	320	288	368
6	2 Lumen Straight 12FR	150	280	252	322	-	-	-	280	252	322
7	2 Lumen Straight 12FR	160	300	270	345	-	-	-	300	270	345
8	2 Lumen Straight 12FR	200	295	266	339	-	-	-	295	266	339
9	2 Lumen Curved 11.5FR	130	300	270	345	-	-	-	300	270	345
10	2 Lumen Curved 11.5FR	150	295	266	339	-	-	-	295	266	339
11	2 Lumen Curved 11.5FR	200	290	261	334	-	-	-	290	261	334
12	2 Lumen Straight 11.5FR	130	305	275	351	-	-	-	305	275	351
13	2 Lumen Straight 11.5FR	150	300	270	345	-	-	-	300	270	345
14	2 Lumen Straight 11.5FR	200	295	266	339	-	-	-	295	266	339
15	3 Lumen Curved 12FR	160	215	194	247	215	194	247	75	68	86
16	3 Lumen Straight 12FR	160	215	194	247	215	194	247	75	68	86
17	3 Lumen Curved 12FR	200	215	194	247	215	194	247	75	68	86
18	3 Lumen Straight 12FR	200	215	194	247	215	194	247	75	68	86

## **GENERAL INFORMATION**

### **Intended Use:**

The device designed to remove a virulent substance in haemodialysis treatment from patients of chronic kidney failure, which are unable to use AV Fistula of acute haemodialysis.

### **Kit Contents**

- Indwelling Catheter
- Y-Introducer needle with valve
- J-Tip Nitinol guide wire
- Dilator 2
- Luer lock syringe
- Scalpel

### **Legal Manufacturer-**

POLY MEDICURE LIMITED

Plot No.: 115 -116, Sector 59, HSIIDC Industrial Area, Ballabgarh,  
Faridabad, HARYANA, INDIA - 121004

### **Production Site-**

POLY MEDICURE LIMITED

Plot No.:115 -116, Sector 59, HSIIDC Industrial Area, Ballabgarh,  
Faridabad, HARYANA, INDIA – 121004

### **European Authorized Representative- Name and address**

OBELIS S.A.  
Boulevard Général Wahis 53,  
B-1030, Brussels,  
Belgium,

**Certification:**

<b>Certification</b>	<b>Notified Body</b>
EN ISO 13485:2016/DIN-EN ISO 13485:2016 <b><u>Certificate No.: Q5 041938 0001</u></b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339, Munich, Germany

**Classification and GMDN Data:**

**Device Class**

- As per "Classification Criteria" in Annexure IX of the Council Directive 93/42/EEC Haemodialysis Catheters are normally intended for continuous use for more than 60 minutes and less than 30 days. Hence these are for short-term use as per description in the 1.1 of Annexure IX.
- Various sterile Haemodialysis Catheters penetrate inside the surface of body, hence is "Invasive device" as per 1.2 of Annexure IX. As per the Directive devices which penetrate the body through other than an establish body orifice are surgically invasive devices hence Haemodialysis Catheters are "Surgically invasive device."
- As per Rule 7 for Classification, all „surgically invasive devices“ intended for short-term use are classified in Class IIa. Hence Haemodialysis Catheters are classified as **Class IIa** Medical device.

**Device Description:**

Hemodialysis catheter is a catheter used on a temporary basis for vascular access for hemodialysis. The product is a tubular, flexible device. Hemodialysis catheters are for relatively short-term use because of an acute need for dialysis or because chronic dialysis is just starting.

- The product is designed to prevent coagulation when the blood passes the catheter tube.
- The material is designed to prevent a thrombosis which can occur by foreign substance in the blood vessel.
- The soft rounded distal tips provide the best protection for the blood vessel.
- Catheters are made from the soft polyurethane and have Double lumens in various lengths.
- 360° venous return ports decrease vessel turbulence while increasing blood flow.
- 360° arterial ports help eliminate vessel occlusion & arterial insufficiency.
- French size and length designations for ease of identification.
- Tapered soft tip of catheter is to minimize trauma of a blood vessel.
- The product is highly suitable for the patient & doctor use and disposable after single use.
- The product is sterilized by EO (Ethylene Oxide) Gas.
- The product and packaging does not contain any constituent of animal origin.

**Sterilization Method/Shelf Life:**

**Sterilization Method:** Ethylene Oxide Sterilization.

**Shelf Life:** Five years from the date of manufacturing.

**Packaging Characteristics:****Unit**

Quantity	1 No.
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**Duplex**

Quantity	10 No.
Dimensions-L x H x W (mm)	355 x 218 x 180

**Carton**

Quantity	40 No.
Dimensions-L x H x W (mm)	740 x 460 x 205

**Storage Conditions:**

Between 5°C to 35°C

**Materials of Concern:**

<b>Material</b>	<b>Present (No/Yes)</b>
DEHP free	Yes
Latex free	Yes
Free of substances of animal origin BSE/TSE	Yes