

Product Structure and Model Specifications

Aspiration Catheter

File No.: JMIC-APC-Models01

Version: A/0

Date: 2023-07-10

Editor:

Reviewer:

Approval: _____

1. Models & Variants Table

Models / Variants	Length (cm)	Distal O.D (mm)	Proximal O.D (mm)	I.D (inch)	Makers	Coating Length (cm)	Tip Shape
APC5085S	85	5F/1.73	5.3F/1.78	0.058"	1	60	Straight
APC5115S	115	5F/1.73	5.3F/1.78	0.058"	1	60	
APC5125S	125	5F/1.73	5.3F/1.78	0.058"	1	60	
APC5135S	135	5F/1.73	5.3F/1.78	0.058"	1	60	
APC5085M	85	5F/1.73	5.3F/1.78	0.058"	1	60	MP
APC5115M	115	5F/1.73	5.3F/1.78	0.058"	1	60	
APC5125M	125	5F/1.73	5.3F/1.78	0.058"	1	60	
APC5135M	135	5F/1.73	5.3F/1.78	0.058"	1	60	
APC6085S	85	6F/2.08	6F/2.08	0.071"	1	60	Straight
APC6115S	115	6F/2.08	6F/2.08	0.071"	1	60	
APC6125S	125	6F/2.08	6F/2.08	0.071"	1	60	
APC6135S	135	6F/2.08	6F/2.08	0.071"	1	60	
APC6085M	85	6F/2.08	6F/2.08	0.071"	1	60	MP
APC6115M	115	6F/2.08	6F/2.08	0.071"	1	60	
APC6125M	125	6F/2.08	6F/2.08	0.071"	1	60	
APC6135M	135	6F/2.08	6F/2.08	0.071"	1	60	
APC7085S	85	7F/2.35	7F/2.35	0.081"	1	60	Straight
APC7115S	115	7F/2.35	7F/2.35	0.081"	1	60	
APC7125S	125	7F/2.35	7F/2.35	0.081"	1	60	
APC7135S	135	7F/2.35	7F/2.35	0.081"	1	60	
APC7085M	85	7F/2.35	7F/2.35	0.081"	1	60	MP
APC7115M	115	7F/2.35	7F/2.35	0.081"	1	60	
APC7125M	125	7F/2.35	7F/2.35	0.081"	1	60	
APC7135M	135	7F/2.35	7F/2.35	0.081"	1	60	
APC8085S	85	8F/2.67	8F/2.67	0.088"	1	60	Straight
APC8115S	115	8F/2.67	8F/2.67	0.088"	1	60	
APC8125S	125	8F/2.67	8F/2.67	0.088"	1	60	
APC8135S	135	8F/2.67	8F/2.67	0.088"	1	60	
APC8085M	85	8F/2.67	8F/2.67	0.088"	1	60	MP
APC8115M	115	8F/2.67	8F/2.67	0.088"	1	60	
APC8125M	125	8F/2.67	8F/2.67	0.088"	1	60	
APC8135M	135	8F/2.67	8F/2.67	0.088"	1	60	
APC12085S	85	12F/4.0	12F/4.0	0.138"	1	60	Straight
APC12115S	115	12F/4.0	12F/4.0	0.138"	1	60	
APC12125S	125	12F/4.0	12F/4.0	0.138"	1	60	
APC12135S	135	12F/4.0	12F/4.0	0.138"	1	60	

2. Product Composition

2.1 Product Structure

The microcatheter consists of a catheter hub, catheter protective sheath, and catheter body (including radiopaque marker, metal wire, PTFE lining, outer tubing, hydrophilic coating), as detailed in Figure 1-1.

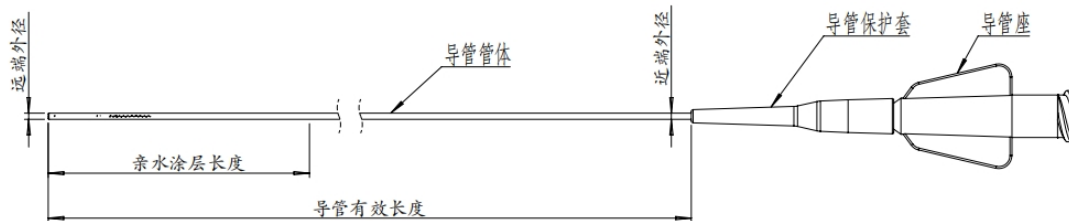


Figure 2-1: Schematic Diagram of Product Structure

The shaft is composed of radiopaque marker, metal wire, PTFE lining and outer tubing. Schematic diagrams of the two types are shown in Figure 1-2.

Braid + Coil

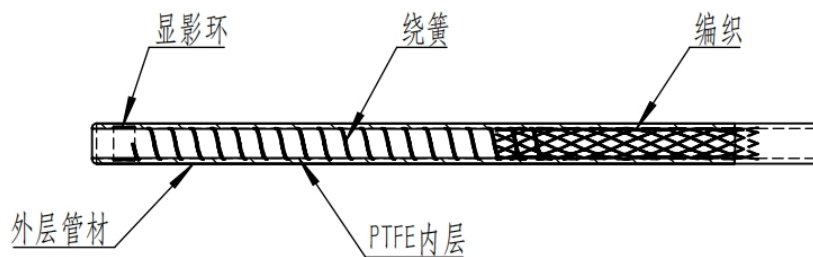


Figure 2-2 Catheter Body Structure Demonstration

Aspiration Catheter have four different distal end shapes, namely:

<p>Straight Shaped</p>	
<p>MP Shaped</p>	

2.2 Microcatheter Components

Component Name	Raw Material
Catheter Hub	Polyamide 12 (PA12)
Catheter Handle	Thermoplastic polyurethane (TPU)

Catheter Body	Inner Surface	Polytetrafluoroethylene (PTFE)
	Braiding	SUS304 Stainless Steel SUS 304
	Outer Surface	thermoplastic elastomer (PEBAX), PA12
	Marker	Platinum 90%/Iridium 10%
Hydrophilic Coating		Methyl methacrylate
		Polyvinylpyrrolidone (PVP)
Accessories		
Shaping Mandrel		Stainless Steel SUS 304
Introducer Sheath		High Density Polyethylene

Annex C Testing Procedure

Friction Testing

C.1 Mechanism

Through the axial tensile machine and longitudinal clamping device, the microcatheter in the hydrophilic state is tested based on the set tension and speed to obtain its sliding friction after hydrophilicity, and its stability is inspected.

C.2 Instrument

Tensile machine, longitudinal clamping device, silicone pad with a hardness of 60 ± 10 , water tank at $37\pm 2^\circ$ C, and supporting fixtures.

C.3 Testing Procedure

C.3.1

Immerse the microcatheter or a cut segment into the water tank, ensuring that the tested portion's surface remains lubricated.

C.3.2

Use the longitudinal clamping device to tighten the guide extension of the catheter, applying a clamping force of 5 ± 0.5 N.

C.3.3

Secure one end of the catheter on the tensile testing machine, set the testing speed to 100mm/min, and the testing displacement to 100mm.

C.3.4

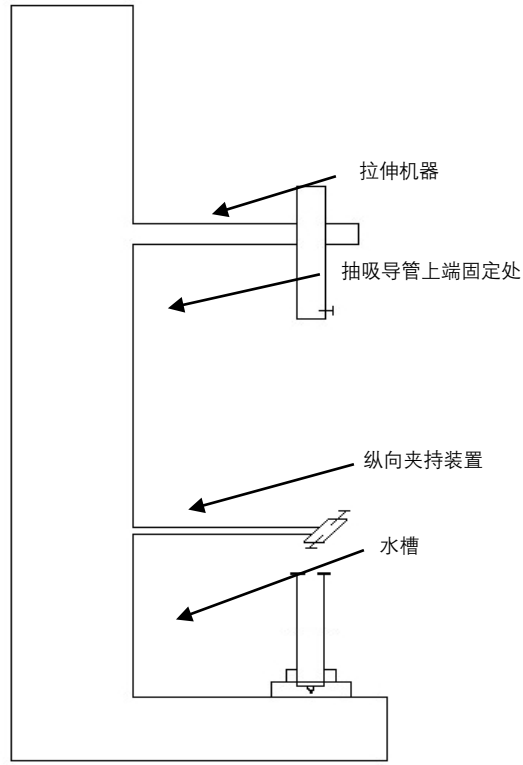
After the test is completed, return to the original position and record the maximum sliding frictional force during the microcatheter testing process.

C.3.5

Repeat steps A.3.1 to A.3.4 five times.

C.4 Testing Results

The maximum sliding friction force recorded in five consecutive tests for the microcatheter should be less than 0.5N.



Demonstration