

COMPANY STANDARD FOR FINISH PRODUCTS (SPECIFICATIONS)

CS-FP



ABDOMINAL DRAINAGE KIT(ADK)

SMD/ CS-FP/ 28

Edition No. - 04

Rev. No. - 01

Rev. Date:-03.02.2020

Product Description : A transparent PVC bag with Marking and Hanger, Attached a flexible PVC tube with Coloured connector and drainage valve. A Drainage Catheter with eyes and marking packed in a Pouch with Transparent PVC film at one side and printed medical grade paper on other side.

Product Code : SMD 1011
Intended Use : Used for abdominal Drainage.

PRODUCT SPECIFICATIONS

SIZE (FG)	O.D. Of Catheter	Length of catheter (± 10 mm)	O.D. of Tube (± 0.20 mm)	Total Length of tubing (± 10 mm)	Marking from tip on Catheter	No. of Eyes	Rated Volume
10	3.30 ± 0.15 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
12	4.00 ± 0.15 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
14	4.70 ± 0.20 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
16	5.30 ± 0.20 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
18	6.00 ± 0.20 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
20	6.70 ± 0.20 mm	500 mm	9.00 mm	1000 mm	80 to 260	04	100 to 2000 ml
22	7.30 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
24	8.00 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
26	8.70 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
28	9.30 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
30	10.00 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
32	10.70 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
34	11.30 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml
36	12.00 ± 0.20 mm	500 mm	9.00 mm	1000 mm	120 to 300	06	100 to 2000 ml

Testing Procedure: - All tests should be done as per Standard testing Procedure of Abdominal drainage Kit (Steri-ADK) (Ref. No. - SMD-STP-32)

Testing Parameters:-

Sr. No.	Test Parameters	Specifications/Limit
1.	O.D. of Catheter	As per Product Specifications
2.	Length of Catheter	As per Product Specifications
3.	O.D. of Tube	As per Product Specifications
4.	Total Length of Tube	As per Product Specifications
5.	No. of Eyes	04/06 as per size
6.	Rated Volume	Measured as per marking on bag

PREPARED BY Asst-Manager QC	APPROVED BY Sr. Manager QA	ISSUED BY Deputy General Manager QA	CONTROLLED STAMP Page 1 of 2
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7.	Marking on Catheter	As per Product Specifications
8.	Height of Bag	270 / 300 ± 10.0 mm
9.	Width of Bag	180 ± 10.0 mm
10.	Radio-opaque Line	Should be Present
11.	Leakage Test	Apply 0.5 bar air pressure through funnel & dip the whole assembly in water filled tub Should be No bubbles formed.
12.	Heavy Metal	NMT 1.0 ppm (As per USP)
13.	Non-Volatile Residue	NMT 15.0 mg (As per USP)
14.	Residue on Ignition	NMT 5.0 mg (As per USP)
15.	Buffering Capacity	Comply (As per USP)
16.	Bacterial Endotoxin Test (LAL test)	NMT 20EU/Device (As per USP)
17.	Sterility Test	Comply (As per USP)

Where, NMT=Not More Than

Labeling

Product Name, Size
Length, Batch/Lot No, Mfg. Dt.
Exp. Dt. cautions. CE Mark
Mfr. Address. etc.

Packing Parameter Individual Packing

- a) Peelability
- b) Sealing

- c) Pouch Size
- d) Box
- e) Carton

Standard

Pouch Packed
Easy to Peel without sticking.
No leakage after pushing with normal force on the sealed pouch
250mm x 110mm (± 5mm)
50 pcs. 215 x 190 x 285mm (±10mm)
08 Box 780 x 310 x 460mm (±10mm)

Review: - After 05 years from effective Date or Whenever any type of changes due to Audits/ Amendments in applicable standards.

PREPARED BY

Asst-Manager QC

APPROVED BY

Sr. Manager QA

ISSUED BY

Deputy General Manager QA

CONTROLLED STAMP