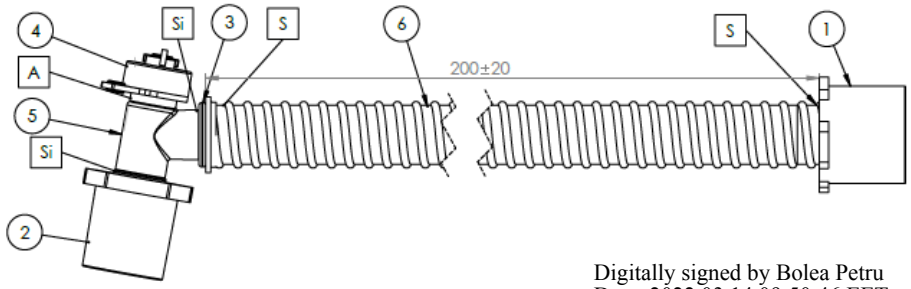
1. Product Name and Product Code:

AL-16400.V001 Double Swivel Catheter Mount Smoothbore



Digitally signed by Bolea Petru
Date: 2022.03.14 09:50:46 EET
Reason: MoldSign Signature
Location: Moldova

2. Manufacturer:

Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method:

Ethylene oxide sterilization .This product line is provided both as sterile and non-sterile.

Packaging:

Product is packed individually. This package has two layer, one side is Film which is general thermoforming packaging material for medical devices. The other side is medical paper which is designed to be used as a porous lidding material in medical packages and as a porous web in industrial, medical pouches.

4. Intended Use and Functional Description :

5. Catheter mounts are adaptors that connect the tracheal tube to the end of the anaesthetic breathing system. Various connectors fit between the distal end and the tracheal tube.

6. Time of Usage:

5 years from the date of production .

7. Product Description:

UNIT NO	PART NUMBER	DESCRIPTION	QUANTITY
1	151.03.193	15M - 22 F STRAIGHT CONNECTOR SBC	1
2	151.03.204	SWIVEL CATHETER MOUNT 22 MM CONNECTOR SBC	1
3	151.03.205	SWIVEL CATHETER MOUNT 15 MM CONNECTOR MOLD SBC	1
4	151.03.206	CATHETER MOUNT CAP MOLD TPE	1
5	151.03.207.01	SWIVEL CATHETER MOUNT BODY NEO MOLD PETKIM	1
6	151.05.03.122	15 MM SMOOTHBORE CATHETER TUBING 20 CM CUT PVC	1

7.1. Classification: Class IIa Rule 2

7.2. This product does not contain any metalic parts

7.3. Volume of the product varies according to tubing length and other parts of the product.

7.4. Pediatric, and adult versions of circuits are available.

8. Tests performed on the product :

8.1. Dimensional controls (Gauge, caliper and weight controls)

8.2. Leakage

8.3. Resistance to flow

8.4. Routine assembling process controls

8.5. Pull test

8.6. Biocompatibility

8.7. Accelerated aging test

9. Standarts:

EN ISO 13485:2016, 93/42/EEC Medical Device Directive**,** EN 556-1:2001, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 23328-1, EN ISO 23328-2

10. Waste Method:

After use product will be “contaminated medical waste” and package will be “packaging waste” so they should be handled according to relevant national and international standards and regulations.