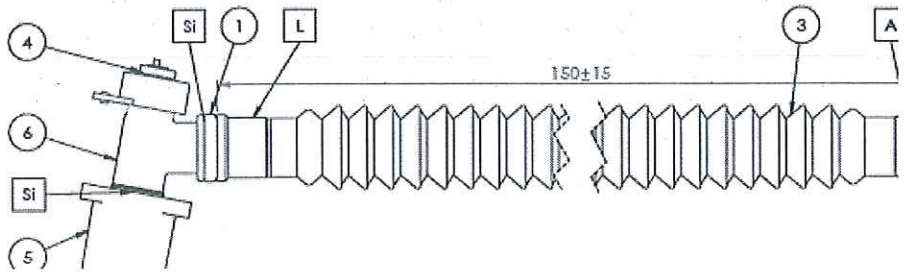
1. Product Name and Product Code:

AL-17309.V001 Double Swivel Catheter Mount Extendible (Sterile EO)



Manufacturer:

Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

2. 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.

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3. Intended Use and Functional Description :

4. 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.

5. Time of Usage:

5 years from the date of production .

6. Product Description:

6.1. Classification: Class IIa Rule 2

6.2. This product does not contain any metalic parts

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

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

6.5. 15 MM Polypropylene Extendible Tubing

6.6. 15M-22F Connector for circuit connection

6.7. Double swivel patient connection

7. Applied Standarts:

EN ISO 13485, 93/43/EEC Medical Device Directive, ISO 12342, EN 5356, ISO 11135-1, ISO 10993-7, ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2.

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.

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