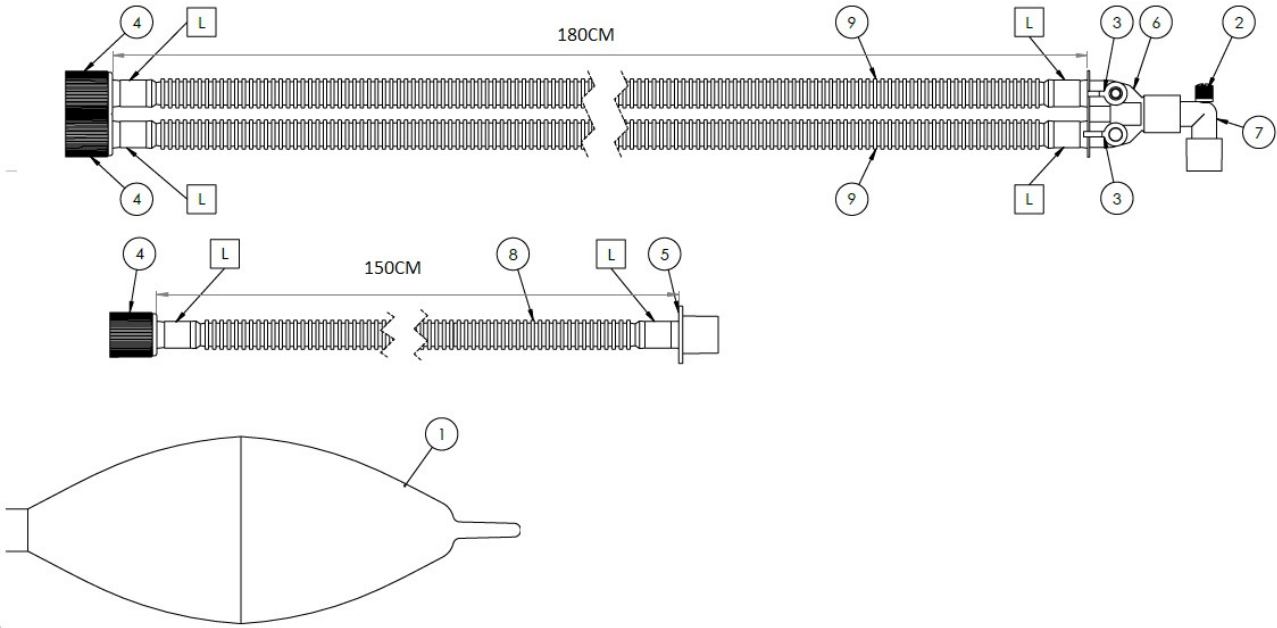


1. Product Name and Product Code:

AL-1401-060.V019- Pediatric Anesthesia Circuit Corrugated PE Tube

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

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

4. Packaging:

Nylon packaging. ISO Class 8 Clean Room Manufactured

5. Intended Use and Functional Description :

Disposable circuits used to conduct medical gases from the anaesthesia system to the patient.

Anaesthetic gas exits the anaesthesia machine (via the common gas outlet) and then enters a breathing circuit. The function of the circuit is to deliver oxygen and anaesthetic gases to the patient and to eliminate CO₂. The CO₂ may be eliminated by gas inflow or by soda lime absorption.

6. Shelf life :

5 years from the date of production .

7. Product Description:

7.1. Classification: Class IIa Rule 2

7.2. This product does not contain any metallic parts

7.3. Spesification of the product :

Item	Description	Quantity
150.07.023	1 LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER	1
150.11.036	ELBOW CONNECTOR LUER CAP	1
151.03.074	Y CONNECTOR CAP	2
151.03.084.01	15 MM STRAIGHT CONNECTOR	3
151.03.113.02	15-22 MM STRAIGHT CONNECTOR PP	1
151.03.161.01	PEDIATRIC Y CONNECTOR PP WITH PORT	1
151.03.178.01	ELBOW CONNECTOR WITH CO2 PORT PP	1
151.05.01.178	15 MM CORRUGATED TUBING PE 150 CM CUT	1
151.05.01.159	15 MM CORRUGATED TUBING PE 180 CM CUT	2

8. 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

9. 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.