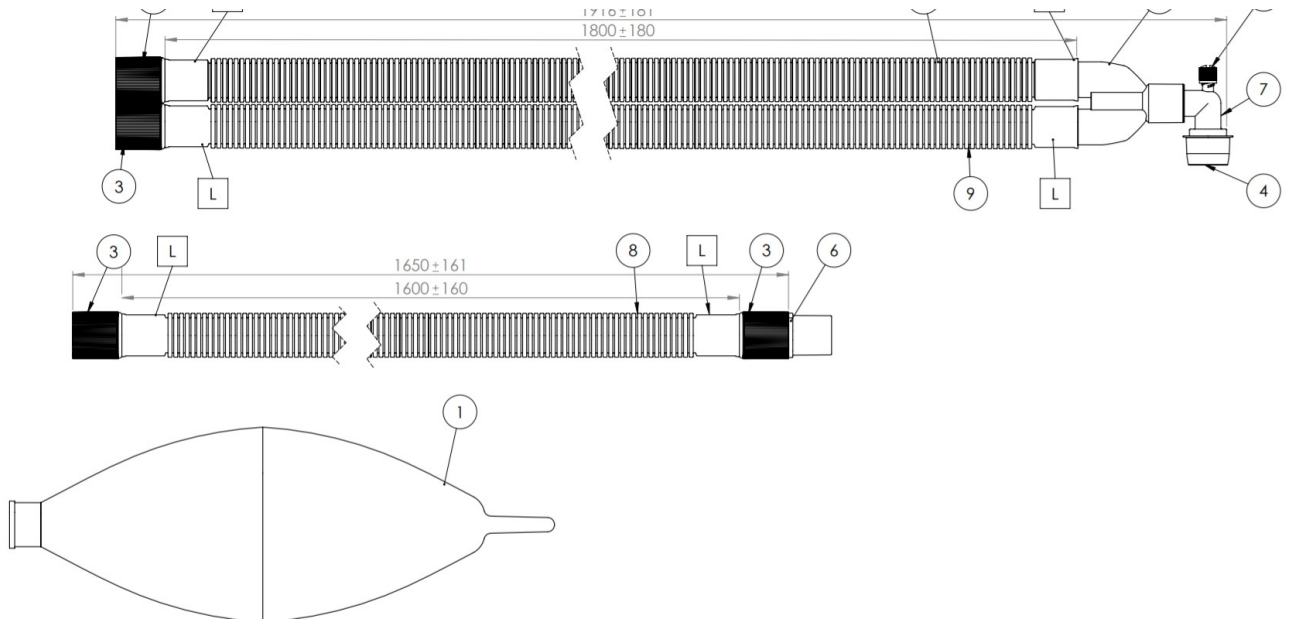


**1. Product Name and Product Code:**

AL-11019-060.V002- Adult Corrugated Circuit 180cm with limb and breathing bag (Sterile EO)

**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:**

Tyvek 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 CO<sub>2</sub>. The CO<sub>2</sub> 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. Specification of the product :**

Item	Description	Quantity
150.07.040	2 LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER(RIGID PP CONNECTOR)	1,0
150.11.036	ELBOW CONNECTOR LUER CAP	1,0
151.03.001.01	22 MM STRAIGHT CONNECTOR	4,0
151.03.021.01	LONG CONNECTOR CAP RED	1,0
151.03.087.02	22 MM PARALLEL Y CONNECTOR W/OUT PORTS PP	1,0
151.03.110	22-22MM STRAIGHT CONNECTOR	1,0
151.03.178.01	ELBOW CONNECTOR WITH CO2 PORT PP	1,0
151.05.01.055	22 MM CORRUGATED TUBING PE 160 CM CUT	1,0
151.05.01.062	22 MM CORRUGATED TUBING PE 180 CM CUT	2,0

**8. Standarts:**

EN ISO 13485:2003, 93/42/EEC Medical Device Directive, EN ISO 5367, EN ISO 5356-1, EN ISO 11607-1:2009, EN ISO 11607-2:2009, EN ISO11135-1:2007, EN ISO 23328-1, EN ISO 23328-2,EN ISO 594-1

**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.