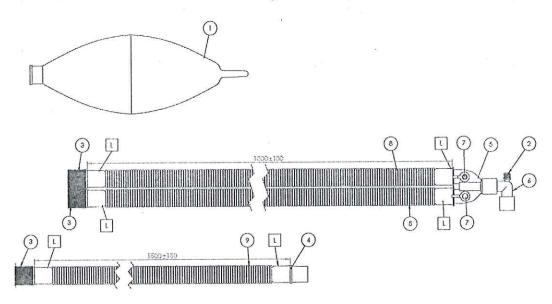


PRODUCT DESCRIPTION

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 CO2. The CO2 may be eliminated by gas inflow or by soda lime absorption.



PRODUCT DESCRIPTION

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 metalic parts

7.3. Specification of the product:

UNIT NO.	PART NUMBER	DESCRIPTION	QUANTITY
1	150.07.040	2 LT NEOPRENE SINGLE FOLDED BREATHING BAG	1
		WITH STICKER (RIGID PP CONNECTOR)	
2	150.11.036	ELBOW CONNECTOR LUER CAP	11
3	151.03.261	22 MM STRAIGHT CONNECTOR EVA (NEW)	3
4	151.03.255	22-22 MM STRAIGHT CONNECTOR (NEW)	1
5	151.03.150	22 MM PARALLEL Y CONNECTOR PP	1
6	151.03.224.01	ELBOW CONNECTOR WITH PORT PP	1
7	151.03.264	Y CONNECTOR CAP (NEW)	2
8	151.05.01.062	22 MM CORRUGATED TUBING PE 180 CM CUT	2
9	151.05.01.074	22 MM CORRUGATED TUBING PE 150 CM CUT	1

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.

MEDITERA TIBEL MALZEN

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