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1. Introduction

1.1 Device Name:

Disposable Anesthesia Breathing Circuits

1.2 Description

The Disposable Anesthesia Breathing Circuits are used to deliver oxygen or inhalational anaesthetic agents to a patient. A sterile range of single-use disposable breathing circuits mainly manufactured from medical grade PP and EVA to reduce risk of cross infection and cleaning/sterilization costs. Our disposable anesthesia breathing circuits are available in a wide range of sizes and configurations for different applications as well as for different patient groups (neo, ped, adult).

1.3 Basic UDI-DI

697317566CFZR020100ZK

697317566CFZR020101ZM

697317566CFZR020102ZP

2. Intend Use

The Disposable anesthesia breathing circuits is for conduction of medical gases between patient and anesthesia machine or ventilator.

3. Indications

The disposable anesthesia breathing circuits is intended to be used with positive pressure ventilator for spontaneously breathing system to assist lung expansion, deliver aerosol medication, or to assist ventilation. It also be used in anesthesia/oxygen sedation systems for delivering to a patient a mixture of anesthesia and oxygen gases.

4. Intended patient population

Patients who need to set up artificial airway circuit with anesthesia machine and ventilator.

5. Intended user

Professional medical staff..

6. Expected clinical benefits

Maintain air temperature and humidity
Operation time short

7. Residual risks

Failure to strictly enforce the instructions may result:
Self-extubation

Accidental extubation

Disconnection/detachment/loose connection,

Leak (not associated with disconnection)

8. Particular user qualifications

.Experienced healthcare staff

9. Risks of reusing single use devices

This product is a disposable product, Reprocessing, resterilization and/or reuse of this product is prohibited, reuse may cause infection or fail to reach the intended use.

10. Contraindication

- History of pneumothorax
- Pulmonary air leak
- Recent pneumonectomy (without functioning chest tube)
- Pulmonary hemorrhage
- Lack of patient cooperation
- Vomiting

11. Adverse Events

None

12. Residual risks

Failure to strictly enforce the instructions may result:

Cause Endoluminal bacterial contamination of lumen; Disconnection/detachment/loose connection; Leak (not associated with disconnection)

13. Caution

The user should be familiar with the following cautions when considering or attempting anesthesia breathing circuits use:

- 6.1 To be used only by a licensed and trained persons professional in the use of anesthesia gas. Patient should always be closely monitored during the usage. If patient has an adverse reaction, reduce or stop the flow of anesthesia gas as needed.
- 6.2 All persons providing mechanical ventilation must be trained in the use of ventilator. Therapists should evaluate how their patients tolerate the treatment. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective ventilation.
- 6.3 Surgical gloves should be worn during preparation and insertion to minimize contamination of the airway.
- 6.4 Use only with devices having ISO standard connectors.

14. Waring

7.1 The anesthesia breathing circuits is for SINGLE USE ONLY and has to be disposed after use. Used device shall follow a handling and elimination process for bio - hazard products, in accordance with all local and national regulations.

7.2 Reprocessing, resterilization and/or reuse of this product is prohibited.

7.3 Do not use this device if the device is damaged or the unit packaging is damaged or opened.

- 7.4 Check all system components for obstructions, damage, and foreign matter before installation. The security of all connectors should be checked when the anesthesia breathing circuit is established and frequently thereafter.
- 7.5 Make sure to install the anesthesia breathing circuits without loops and kinks as they may increase resistance.
- 7.6 In combination with oxygen or nitrous oxide, ignition sources such as electrosurgery and laser surgery devices can cause fires.
- 7.7 The breathing circuits can be used with the following gases and anesthetic agents: Nitrous oxide, sevoflurane, desflurane, isoflurane, halothane, enflurane.
- 7.8 Furthermore, failure to read and thoroughly understand the contents of this instruction manual may result in serious injury to the patient and/or user. It is essential to follow the instructions, as well as instructions found in other instruction manuals, infection control requirements and current hospital protocols for usage, cleaning and sterilization.

15. Principles Of Operation

- 7.1 Peel off the bag, take out the product.
- 7.2 Check all the connection parts of product, and tighten all the connection.
- 7.3 Fixing connector with anesthesia and breathing system, 15/22mm connector to be connected with the patient interface.
- 7.4 Test the product and ensure the product compatible with the machine, confirm that all connections are secure and free of leakages or blocked.

16. Technical And Performance Data

16.1 Connecting firmness

The adaptors, Y piece, water trap, tube shall not detach from each other at a force of less than 45 N.

16.2 Leakage

Total leakage should not exceed the leakage limit listed for the designated patient category in Table 1. For catheter mount, leakage should not exceed 25 ml/min at (60 ± 3) hPa [(60 ± 3) cmH₂O]

Table 1 Leakage limit by patient category

Patient category	Intended delivered volume	Leakage limit ml/min	At pressure hPa(cmH ₂ O)
Adult	≥ 300 ml	70	60 ± 3
Paediatric	50 ml < 300 ml	40	60 ± 3
Neonatal	≤ 50 ml	30	60 ± 3

16.3 Resistance to flow

- 16.3.1 The flow resistance of each limb should not exceed the flow resistance limit listed for the designated patient category in Table 2. For catheter mount, flow resistance should not exceed 0.06 cmH₂O/l/min/m at 30 l/min

Table 2 Flow resistance limit by patient category

Patient category	Intended delivered volume	Flow resistance limit hPa/l/min (cmH ₂ O/l/min)	At flow l/min
Adult	≥300 ml	0.06	30
Paediatric	50 ml< 300 ml	0.12	15
Neonatal	≤50ml	0.74	2.5

16.3.2 For bending flow resistance, the pressure at the flow rate stated when the limb is suspended over the metal cylinder shall not exceed 150 % of the value obtained when the limb is straight.

16.4 Compliance

The compliance of each type disposable anesthesia breathing circuits should not exceed the compliance limit listed for the designated patient category in Table 3.

Table 3 Compliance limit by patient category

Patient category	Intended delivered volume	Compliance Limit ml/hPa (ml/cmH ₂ O)	At Pressure hPa (cmH ₂ O)
Adult	≥300 ml	5	60 ± 3
Paediatric	50 ml< 300 ml	4	60 ± 3
Neonatal	≤50ml	1.5	60 ± 3

17. Operation Ambient Conditions

Temperature 10 to 40°C

Relative humidity 10 % to 80 %

Atmospheric pressure 700-1200 hPa

18. Storage

Please store the device in a dark cool, keep the temperature between 0 °C to 40 °C and a relative humidity of no more than 80% environment, avoiding direct exposure to sunlight and chemical fume.

19. Sterilization

EO sterilization

20. Shelf Life

3 Years.

21. Explanation Of Symbols Used On Labels And Instructions For Use

	Consult accompanying documents		Authorized representative in the European Community
	Do not use if package is damaged		Batch code
	Do not re-sterilize		Date of manufacture
	Do not re-use		Manufacturer
	Sterilized using ethylene oxide		Catalogue number
	Use-by date		Keep away from sunlight
	Keep dry		CE marking of conformity, and Notified Body Code
	Adult patient		Pediatric patient
	Neonatal patient		

22. Applicable types

This Instruction for Use apply to the following types

Disposable Anesthesia Breathing Circuits-double limb				
Basic UDI: 697317566CFZR020100ZK		EMDN:R02010102		
98.06.008	98.06.028	98.06.033	98.06.063	98.06.009
98.06.011	98.06.034	98.06.039	98.06.064	98.06.012
98.06.014	98.06.040	98.06.045	98.06.069	98.06.015
98.06.017	98.06.046	98.06.051	98.06.070	98.06.018
98.06.020	98.06.052	98.06.057	98.06.075	98.06.021
98.06.023	98.06.058	98.06.033	98.06.076	98.06.024
98.06.030	98.06.029	98.06.065	98.06.080	98.06.100
98.06.036	98.06.035	98.06.066	98.06.083	98.06.106
98.06.042	98.06.041	98.06.071	98.06.086	98.06.112
98.06.048	98.06.047	98.06.072	98.06.089	98.06.118
98.06.054	98.06.053	98.06.077	98.06.092	98.06.124
98.06.060	98.06.059	98.06.078	98.06.095	98.06.130
98.06.099	98.06.135	98.06.081	98.06.102	98.06.101
98.06.105	98.06.136	98.06.084	98.06.108	98.06.107
98.06.111	98.06.141	98.06.087	98.06.114	98.06.113
98.06.117	98.06.142	98.06.090	98.06.120	98.06.119
98.06.123	98.06.147	98.06.093	98.06.126	98.06.125
98.06.129	98.06.148	98.06.096	98.06.132	98.06.131
98.06.137	98.06.138	98.06.143	98.06.144	98.06.149
98.06.150				
Disposable Anesthesia Breathing Circuits-double limb				
Basic UDI: 697317566CFZR020100ZK		EMDN:R02010101		
98.06.007	98.06.026	98.06.025	98.06.061	98.06.079
98.06.010	98.06.032	98.06.031	98.06.062	98.06.082
98.06.013	98.06.038	98.06.037	98.06.067	98.06.085
98.06.006	98.06.044	98.06.043	98.06.068	98.06.088
98.06.019	98.06.050	98.06.049	98.06.073	98.06.091
98.06.022	98.06.056	98.06.055	98.06.074	98.06.094
98.06.098	98.06.097	98.06.133	98.06.116	98.06.115
98.06.104	98.06.103	98.06.134	98.06.122	98.06.121
98.06.110	98.06.109	98.06.139	98.06.128	98.06.127
98.06.140	98.06.145	98.06.146		
Disposable Anesthesia Breathing Circuits-single limb				
Basic UDI:697317566CFZR020101ZM		EMDN:R02010101		
98.06.152	98.06.183	98.06.214	98.06.245	98.06.275
98.06.153	98.06.184	98.06.215	98.06.246	98.06.276
98.06.154	98.06.185	98.06.216	98.06.247	98.06.277
98.06.155	98.06.186	98.06.217	98.06.248	98.06.278
98.06.156	98.06.187	98.06.218	98.06.249	98.06.279
98.06.157	98.06.188	98.06.219	98.06.250	98.06.280

98.06.158	98.06.189	98.06.220	98.06.251	98.06.281
98.06.159	98.06.190	98.06.221	98.06.252	98.06.282
98.06.160	98.06.191	98.06.222	98.06.253	98.06.283
98.06.161	98.06.192	98.06.223	98.06.254	98.06.284
98.06.162	98.06.193	98.06.224	98.06.255	98.06.285
98.06.163	98.06.194	98.06.225	98.06.256	98.06.286
98.06.164	98.06.195	98.06.226	98.06.257	98.06.287
98.06.165	98.06.196	98.06.227	98.06.258	98.06.288
98.06.166	98.06.197	98.06.228	98.06.259	98.06.289
98.06.167	98.06.198	98.06.229	98.06.260	98.06.290
98.06.168	98.06.199	98.06.230	98.06.261	98.06.291
98.06.169	98.06.200	98.06.231	98.06.262	98.06.292
98.06.170	98.06.201	98.06.232	98.06.263	98.06.293
98.06.171	98.06.202	98.06.233	98.06.264	98.06.695
98.06.172	98.06.203	98.06.234	98.06.265	98.06.294
98.06.173	98.06.204	98.06.235	98.06.266	98.06.295
98.06.174	98.06.205	98.06.236	98.06.267	98.06.296
98.06.175	98.06.206	98.06.237	98.06.268	98.06.297
98.06.176	98.06.207	98.06.238	98.06.269	98.06.298
98.06.177	98.06.208	98.06.239	98.06.270	98.06.299
98.06.178	98.06.209	98.06.240	98.06.694	98.06.300
98.06.179	98.06.210	98.06.241	98.06.271	98.06.301
98.06.180	98.06.211	98.06.242	98.06.272	
98.06.181	98.06.212	98.06.243	98.06.273	
98.06.182	98.06.213	98.06.244	98.06.274	
Disposable Anesthesia Breathing Circuits-catheter mount				
Basic UDI:697317566CFZR020101ZM		EMDN:R020201		
98.06.302	98.06.309	98.06.316	98.06.323	98.06.330
98.06.303	98.06.310	98.06.317	98.06.324	98.06.331
98.06.304	98.06.311	98.06.318	98.06.325	98.06.332
98.06.305	98.06.312	98.06.319	98.06.326	98.06.333
98.06.306	98.06.313	98.06.320	98.06.327	
98.06.307	98.06.314	98.06.321	98.06.328	
98.06.308	98.06.315	98.06.322	98.06.329	
Type4: Disposable Anesthesia Breathing Circuits-kit				
Basic UDI: 697317566CFZR020102ZP		EMDN:R020199		
98.06.334	98.06.406	98.06.478	98.06.550	98.06.622
98.06.335	98.06.407	98.06.479	98.06.551	98.06.623
98.06.336	98.06.408	98.06.480	98.06.552	98.06.624
98.06.337	98.06.409	98.06.481	98.06.553	98.06.625
98.06.338	98.06.410	98.06.482	98.06.554	98.06.626
98.06.339	98.06.411	98.06.483	98.06.555	98.06.627
98.06.340	98.06.412	98.06.484	98.06.556	98.06.628
98.06.341	98.06.413	98.06.485	98.06.557	98.06.629
98.06.342	98.06.414	98.06.486	98.06.558	98.06.630
98.06.343	98.06.415	98.06.487	98.06.559	98.06.631

98.06.344	98.06.416	98.06.488	98.06.560	98.06.632
98.06.345	98.06.417	98.06.489	98.06.561	98.06.633
98.06.346	98.06.418	98.06.490	98.06.562	98.06.634
98.06.347	98.06.419	98.06.491	98.06.563	98.06.635
98.06.348	98.06.420	98.06.492	98.06.564	98.06.636
98.06.349	98.06.421	98.06.493	98.06.565	98.06.637
98.06.350	98.06.422	98.06.494	98.06.566	98.06.638
98.06.351	98.06.423	98.06.495	98.06.567	98.06.639
98.06.352	98.06.424	98.06.496	98.06.568	98.06.640
98.06.353	98.06.425	98.06.497	98.06.569	98.06.641
98.06.354	98.06.426	98.06.498	98.06.570	98.06.642
98.06.355	98.06.427	98.06.499	98.06.571	98.06.643
98.06.356	98.06.428	98.06.500	98.06.572	98.06.644
98.06.357	98.06.429	98.06.501	98.06.573	98.06.645
98.06.358	98.06.430	98.06.502	98.06.574	98.06.646
98.06.359	98.06.431	98.06.503	98.06.575	98.06.647
98.06.360	98.06.432	98.06.504	98.06.576	98.06.648
98.06.361	98.06.433	98.06.505	98.06.577	98.06.649
98.06.362	98.06.434	98.06.506	98.06.578	98.06.650
98.06.363	98.06.435	98.06.507	98.06.579	98.06.651
98.06.364	98.06.436	98.06.508	98.06.580	98.06.652
98.06.365	98.06.437	98.06.509	98.06.581	98.06.653
98.06.366	98.06.438	98.06.510	98.06.582	98.06.654
98.06.367	98.06.439	98.06.511	98.06.583	98.06.655
98.06.368	98.06.440	98.06.512	98.06.584	98.06.656
98.06.369	98.06.441	98.06.513	98.06.585	98.06.657
98.06.370	98.06.442	98.06.514	98.06.586	98.06.658
98.06.371	98.06.443	98.06.515	98.06.587	98.06.659
98.06.372	98.06.444	98.06.516	98.06.588	98.06.660
98.06.373	98.06.445	98.06.517	98.06.589	98.06.661
98.06.374	98.06.446	98.06.518	98.06.590	98.06.662
98.06.375	98.06.447	98.06.519	98.06.591	98.06.663
98.06.376	98.06.448	98.06.520	98.06.592	98.06.664
98.06.377	98.06.449	98.06.521	98.06.593	98.06.665
98.06.378	98.06.450	98.06.522	98.06.594	98.06.666
98.06.379	98.06.451	98.06.523	98.06.595	98.06.667
98.06.380	98.06.452	98.06.524	98.06.596	98.06.668
98.06.381	98.06.453	98.06.525	98.06.597	98.06.669
98.06.382	98.06.454	98.06.526	98.06.598	98.06.670
98.06.383	98.06.455	98.06.527	98.06.599	98.06.671
98.06.384	98.06.456	98.06.528	98.06.600	98.06.672
98.06.385	98.06.457	98.06.529	98.06.601	98.06.673
98.06.386	98.06.458	98.06.530	98.06.602	98.06.674
98.06.387	98.06.459	98.06.531	98.06.603	98.06.675
98.06.388	98.06.460	98.06.532	98.06.604	98.06.676
98.06.389	98.06.461	98.06.533	98.06.605	98.06.677
98.06.390	98.06.462	98.06.534	98.06.606	98.06.678
98.06.391	98.06.463	98.06.535	98.06.607	98.06.679

98.06.392	98.06.464	98.06.536	98.06.608	98.06.680
98.06.393	98.06.465	98.06.537	98.06.609	98.06.681
98.06.394	98.06.466	98.06.538	98.06.610	98.06.682
98.06.395	98.06.467	98.06.539	98.06.611	98.06.683
98.06.396	98.06.468	98.06.540	98.06.612	98.06.684
98.06.397	98.06.469	98.06.541	98.06.613	98.06.685
98.06.398	98.06.470	98.06.542	98.06.614	98.06.686
98.06.399	98.06.471	98.06.543	98.06.615	98.06.687
98.06.400	98.06.472	98.06.544	98.06.616	98.06.688
98.06.401	98.06.473	98.06.545	98.06.617	98.06.689
98.06.402	98.06.474	98.06.546	98.06.618	98.06.690
98.06.403	98.06.475	98.06.547	98.06.619	98.06.691
98.06.404	98.06.476	98.06.548	98.06.620	98.06.692
98.06.405	98.06.477	98.06.549	98.06.621	98.06.693



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