

# Technical Data Sheet

## Limb-O Anesthesia Breathing Circuit

Product Codes and Product Description	AFNXXXXX Limb-O™ Single Limb Anesthesia Breathing Circuit AFPXXXXX Limb-O™ Single Limb Anesthesia Breathing Circuit
General Product Description	An anesthetic machine is the pathway by which the volatile anesthetic agent and oxygen are conveyed to the patient and carbon dioxide is removed. The two methods for removal of carbon dioxide are that of venting all expired gases to the exterior, and the method of absorbing the carbon dioxide chemically and rebreathing the expired gas. They can be rebreathing (also known as circle system) or non-rebreathing. Circuits are provided for adult, pediatric and neonatal patients.
Pack factor	AFNXXXXX - 20 AFPXXXXX - 20
EAN/GTIN	AFNXXXXX CS 50885403243156 AFNXXXXX EA 10885403243158 AFPXXXXX CS 50885403243200 AFPXXXXX EA 10885403243202
Intended Use	Intended to administer medical gases to a patient during anesthesia.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for short term at more than sixty minutes and less than thirty days as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	Anesthesia Circuits are designed to be used in combination with anesthesia machines.
Shelf Life	The Anesthesia Circuit and its components do not require a “use-by” date because they are sold non-sterile and single use, disposable. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	Anesthesia Circuits, Face Masks, Breathing Bags and Gas Sampling Lines are class IIa by rule 2, short term, non-invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents: DOC1300853: Cytotoxicity, DOC1300853, DOC1300882, DOC1300887, DOC1300890, DOC1300890: Sensitization, DOC1304936: Cytotoxicity
Materials	<b>AFNXXXXX:</b> 9% EVA, Polyisoprene, Polypropylene, HDPE, 9% EVA, 18% EVA, blue colorant, Polypropylene, blue colorant, Polypropylene, Polypropylene <b>AFPXXXXX:</b> 9% EVA, Polyisoprene, Polypropylene, Polypropylene, HDPE, 9% EVA, 18% EVA, blue colorant, Polypropylene, Polypropylene, blue colorant
Storage	There are no special storage conditions or handling requirements. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.

### GLOBAL HEADQUARTERS

Vyaire Medical, Inc.  
26125 North Riverwoods Blvd  
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USA

  Vyaire Medical  
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FI-00510 Helsinki  
Finland

Vyaire Medical Pty Ltd  
Level 5, 7 Eden Park Drive  
Macquarie Park, NSW, 2113  
Australia

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## *Limb-O Anesthesia Breathing Circuit*

GMDN Code	37704 Anesthesia Breathing Circuits, single use
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	<b>AFNXXXXXX:</b> DEHP Free, PVC Free, Latex Free, Contains BPA <b>AFPXXXXXX:</b> DEHP Free, PVC Free, Latex Free, Contains BPA
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

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