

Obelis s.a

Address: Boulevard Général Wahis 53, 1030 Brussels, Belgium

TEL: +32-2-7325954, FAX: +32-2-732-6003

FLIGHT MEDICAL INNOVATIONS Ltd.

VX-DL Adult Autoclavable F.S. Kit (1.8m)

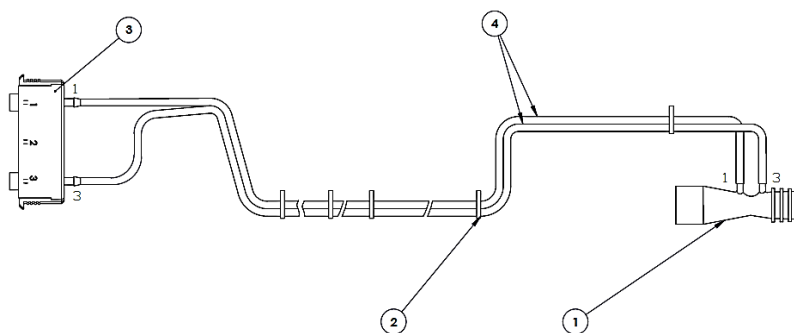
REF VX64-0004

INTENDED USE:

The breathing circuit is intended to administer gases such as oxygen, air or a combination to an **adult** patient requiring Ventilation. It is a part of the interface between a mechanical ventilator and the patient for inhalation and exhalation.

CONTENT: Ventoux - Dual Limb Adult Autoclavable Flow Sensor Kit

1. Flow Orifice
2. Tube Clamps
3. Quick Connector
4. Flow Transducer Lines



CAUTION:

1. The content of the bag is clean but not sterile.
2. Open the packaging with care. Avoid using sharp objects as they may harm the product.
3. Inspect the product prior to use to ensure that all components are intact.

INSTRUCTIONS FOR USE:

1. Attach a breathing circuit (authorized by Flight Medical) through all evenly spread Tube clamps (2). Avoid tubes kinking.
2. Connect the proximal end of the breathing circuit to the distal end of Flow Orifice (1).
3. Prior to connecting the patient, perform a circuit test according to the instructions in the Ventoux Operator's Manual.
4. Store in a cool and dry place.

CLEANING/STERILIZATION CONDITIONS:

1. Rinse the circuit components with water and air to clear flow sensor tubing and passages of soil residuals.
2. Soak the circuit components a mild detergent, for at least 10 minutes.
3. Thoroughly wipe all the external surface of the test article with a soft cloth, moistened with detergent solution to remove any visible soil residuals.
4. Rinse the circuit components thoroughly under distilled water for at least 30 seconds, to remove all traces of the detergent.
5. Shake off excess water, and place all parts on a clean towel to air dry.
6. Sterilize using this validated autoclave procedure (steam sterilization procedure) :
 - a. Temp.: 134°C (273°F)
 - b. Time: 4 Min
 - c. Drying time: 15 Min

DO NOT USE THE FOLLOWING FOR CLEANING: Phenol (>5%), Ketones, Formaldehyde, Chlorinated/Aromatic Hydrocarbons, Inorganic Acid. Do not Autoclave if medications containing Quaternary Ammonium, Chlorinated or Aromatic Hydrocarbons have been used.

WARNINGS:

Replace after 40 autoclave cycles.

This product is to be assembled only into a Dual Limb breathing circuit authorized by Flight Medical.

This product is designed to be used with Ventoux Ventilators only.

Federal (U.S.A) law restricts this device for sale by or on the order of a physician.