sedanamedical
Bringing inhaled sedation to intensive care

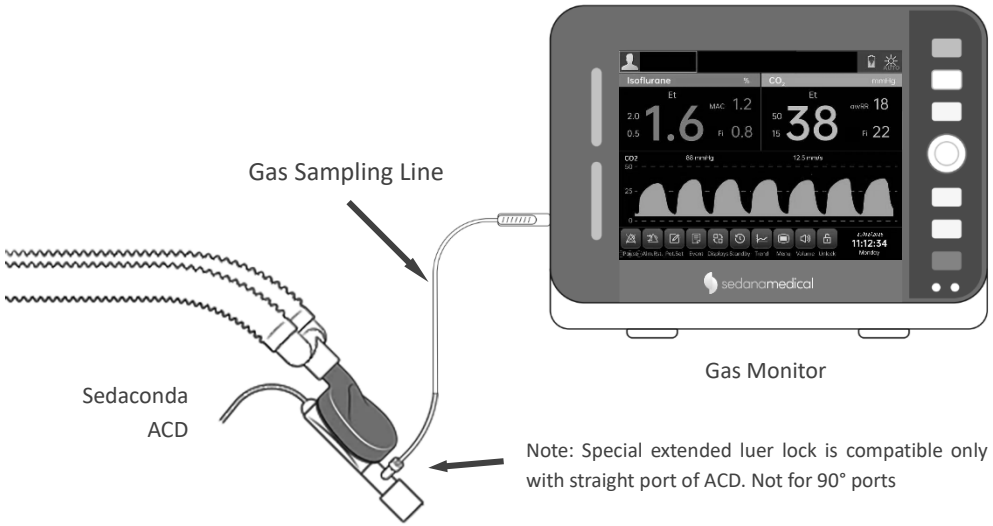
Instructions For Use

Gas Sampling Line

NOTE: These instructions contain important information for the safe use of the device. Read these instructions for use in their entirety, including warnings and cautions before using this device. Failure to properly follow warnings, cautions and instructions could result in serious injury or death to the patient.

GENERAL WARNING: A WARNING statement provides important information about a potentially hazardous situation, which, if not avoided could result in serious injury to patient.

CAUTION: A CAUTION statement provides important information about a potentially hazardous situation, which if not avoided could result in minor or moderate injury.



DEVICE DESCRIPTION: Gas Sampling Line. The medical device is non-sterile, disposable, single-use gas sampling line that enables sampling of respiratory gases. The gas sampling line is available in different end connection adapters to connect to monitors.

INDICATIONS: The gas sampling line should be connected to Sedaconda ACD sampling port luer connection, in intubated patients needing the expired gas sampling for sedation therapy. please refer to the Sedaconda ACD Instructions for Use.

CONTRAINDICATIONS: Avoid use on patients with very thick or copious secretions. Patients pulmonary secretions should be continually monitored and assessed to confirm that humidification is sufficient to meet the patients on-going clinical needs.

INTENDED USE: Sampling lines allow connection between the Sedaconda ACD and gas sampling device to allow sampling of the patients respiratory and anaesthetic gases. The device is intended for a as 'Single-Use' with Sedaconda ACD and gas sampling equipment. The sampling line system is verified for use with gases: O2, CO2; and anaesthetic agents: isoflurane, sevoflurane.

PATIENT CATEGORY: The device is suitable for use on adults and paediatric patient populations.

MICROBIAL PROTECTION: This gas sampling line is specifically designed for use with Sedaconda® therapy. It features midstream ACD gas sampling to reduce exposure to condensates, a moisture-reducing tube design to lower humidity, and an integrated hydrophobic membrane filter inside the connector. Together, with isoflurane gas, these elements help minimize the risk of microbial contamination to the gas monitor and surrounding environment.

INSTRUCTIONS:

Follow these instructions for proper care of device to prevent risk of contamination and injury.

Pre-Use Check

1. Prior to installation, check that all system components are free of obstructions and foreign bodies.
2. Insert the special connector inside the Sedana gas monitor or fix the flexible red adapter to connect to luer-lock port of other gas monitor. Ensure that the gas monitor is 'zero-calibrated' before connecting to Sedaconda ACD. Connect / disconnect the extended luer lock connection of the sampling line to the luer lock connection of ACD.
3. Following secured installation, the sampling line must be checked for leaks and occlusions.

In-Use Check

Monitor the sampling line throughout use and replace if visible aspiration of secretions, visual contamination, increased resistance, or event of sampling occlusion alarm on gas monitor.

WARNINGS:

1. This device is intended for '**Single-Use**', do not reuse once the device is removed from the system.
2. This device is disposable and is not intended for prolonged or extended use or reuse.
3. The Luer Lock port connector on sampling lines is specially designed and for the exclusive use with Sedaconda ACD, for sampling respiratory and anaesthetic gases in intubated patients.
4. This device is intended to be use for '**Maximum 72-hours**'. Extended use of sampling line beyond specified limits may compromise performance and measurement accuracy of gas monitoring.

CAUTION:

1. This sampling line is only to be used under medical supervision by appropriately qualified and trained medical personnel in hospital care usage environment.
2. To avoid contamination, the device should remain packaged until ready for use. Do not use the device if the packaging is damaged.
3. Do not place anything on supply tubing that may obstruct flow, excessive patient secretion or a build-up of liquids in the tubing may occlude the sampling and require more frequent replacement
4. The device must not be cleaned or reprocessed or re-sterilised for re-use on patients.

STORAGE CONDITIONS: Recommended storage at room temperature, for indicated device shelf-life.

DISPOSAL: Following use, the device must be disposed of in accordance with local hospital, infection control and bio-hazard waste disposal regulations.

REPORTING: In case of a serious incident involving this product, please report to the manufacturer/distributor and relevant health authority, with product details, incident date, description, and your contact information.

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