SODA LIME

CANISTERS AND CARTRIDGE
CO_2 ABSORBENT (MEDICAL GRADE)

INSTRUCTIONS FOR USE

molecular
Filtration Group

TRADE NAMES: Sodasorb and Sodasorb LF, Sofnolime and Sofnolime SoLo Cartridge devices, Aria and Alto Style Canisters

⚠ WARNINGS & PRECAUTIONS

Avoid contact of soda lime with eyes, skin and clothing.

Soda lime carbon dioxide canisters should not be used in ways not specified by these instructions for use.

Do not use soda lime carbon dioxide absorbents with chloroform or trichloroethylene as carbon monoxide will be produced.

Soda lime carbon dioxide absorbents are not an antimicrobiological filter or inhibitor. It is the responsibility of the user to take appropriate measures regarding patient cross contamination using an appropriate filter. System filters should be fitted in accordance with equipment manufacturer's instructions to protect the patient from particulates and prevent contamination of the breathing circuit and soda lime from bacterial and viral contamination.

Canister shall be changed following the use with notifiable infectious disease involving the risk of transmission via the breathing system e.g. tuberculosis, acute viral hepatitis, measles, influenza virus, infection and/or colonisation with a multi-resistant pathogen or upper or lower respiratory tract infections.

Soda lime carbon dioxide absorbent must be used within its shelf life. The expiration date is printed on device packaging.

There is potential for dust generation and migration into the breathing circuit due to poor handling, and care should be taken to minimise the risk of dust. Avoid breathing dust, which can cause irritation.

Do not flush dry gas through the canister when not in use as this can dry out the soda lime, leading to a loss of performance.

Ensure storage of the product is conducted in accordance with the instructions.

Do not use damaged canisters or those where the seal has been prematurely removed during storage permitting ingress of air.

The colour change may reverse if the device is left alone, except for Sodasorb LF, which has a permanent colour change.

The absorbent may contain traces of different soda lime grades of a different colour.

COMPATIBLE EQUIPMENT

These canisters are compatible with the following equipment.

Cartridge	• GE Healthcare (Datex Ohmeda) GMS Absorber as fitted to Aestiva® Excel® and Modulus™ • Dräger Narkomed® 2B, Narkomed® 4, Narkomed® GS, Narkomed® Mobile • Mindray® A5, A7 • Penlon® A100™, SP100™, SP200™ • Spacelabs® Focus™, Frontline™, Sirius™ • Maquet® KION®-i
Aria Canister	• GE Healthcare Aisys®, Avance®, Aespire®, ADU™
Alto Canister	• GE Carestation 600 Series, 750, 800

GENERAL DESCRIPTION

Soda lime carbon dioxide absorbents remove carbon dioxide from breathing circuits, in systems such as anaesthesia and respiratory therapy equipment.

INTENDED USE

Soda lime is intended to remove expired carbon dioxide in a closed or semi-closed breathing circuit in a clinical environment.

INTENDED USER

This device must be used by appropriately trained healthcare professionals familiar with the operation of closed or semi-closed loop breathing circuits.

INDICATION

The device is indicated for the removal of carbon dioxide from medical closed or semi-closed breathing circuits.

CONTRAINDICATIONS

Soda lime cannot be used with trichloroethylene (trilene) and chloroform.

CLINICAL BENEFIT

This device supports closed or semi-closed breathing circuits, through the regulation of patient carbon dioxide levels reducing the risk of hypercapnia.

LIMITATIONS

Soda lime carbon dioxide absorbents are for use only with oxygen, nitrous oxide, halothane, enflurane, desflurane, sevoflurane and isoflurane.

PERFORMANCE

Expected performance up to 8 hours asorption with absorption levels of 250ml per minute of CO_2.

PREPARATION

⚠ **Before conducting any preparation activities ensure that the warnings and precautions of this instructions for use have been read and understood.**

1. OPENING/UNWRAPPING

- Remove cap(s) and dispose of in a safe manner just before attempting to fit canisters.
- Do not use canisters which are damaged or caps have been prematurely removed.

2. CHANGING

- Canisters should always be handled gently to avoid fragmentation and dust formation.
- For pre-filled carbon dioxide absorbent round cartridge, completely remove any outer wrapping. Inspect the body, top and bottom grids for defects, damage or obstructions.

3. PRE-CHECK

- It is the responsibility of the user to perform any necessary equipment pre-checks in accordance with machine instructions.
- The device must be checked for damage prior to use.

USE

- Before use, check the breathing circuit for gas flow restrictions and leaks.
- The soda lime carbon dioxide absorbents contain an indicator that turns from white to purple or from pink to white in use. The absorption of carbon dioxide is indicated by a gradual colour change in the direction of air flow through the absorbent. The intensity of colour change may vary from one application to another. Colour change is only a guide, the anaesthetist should rely primarily on carbon dioxide monitors (capnograph) as well as time and volume calculations to determine remaining absorptive capacity.
- System filters are to protect the patient from contaminants and should be fitted in accordance with machine manufacturer's instructions.

COLOUR CHANGE

Depending on the product, the soda lime colour change is either white to violet or pink to white. The type of colour change will be indicated on the label, using one of the symbols indicated in the table below. The absorption of carbon dioxide is indicated by a gradual colour change in the direction of air flow through the absorbent. The intensity of colour change may vary from one application to another. Colour change is only a guide, the anaesthetist should rely primarily on carbon dioxide monitors (capnograph) as well as time and volume calculations to determine remaining absorptive capacity.

STORAGE AND DISPOSAL

1. STORAGE AND HANDLING

- Store product in an environment that minimises exposure to UV light.
- Ensure adequate ventilation of the storage area. Keep containers tightly closed, at 0-35°C (32-95°F), dry and out of direct sunlight.
- Keep from freezing, which may reduce carbon dioxide absorption performance and increase dust.
- Avoid creating airborne dust, especially when pouring or handling loose material.
- Handle with care, especially when placing product in a canister.
- Soda lime carbon dioxide absorbents are classified as Corrosive and as an Irritant.
- Consult relevant SDS for additional information.

2. DISPOSAL

- The user shall dispose of used canisters/cartridges in compliance with all applicable local laws and regulations. Disposal may vary with the chemical or biological agents used with the absorbent (e.g. anaesthetic agents, acid-base vapours, etc.).
- Soda lime carbon dioxide absorbent that has been used with flammable anaesthetic must be kept away from heat, sparks and open flames, as residue may be present.
- See relevant SDS for soda lime products for hazards and precautionary statements.

FEEDBACK AND SERIOUS INCIDENTS

If any serious incident has happened where this device is suspected to be a contributary factor, then this should be reported to Molecular Products Limited, using **complaints@molprod.com** and the competent authority in the country the device was used in.

ADDITIONAL IFUS

If additional IFU's are required please use the contact section on page 3 to request additional copies free of charge or alternatively visit Molecular Products website to download an eIFU version.

Consult instructions for use	The instructions for use must be read	Indicates that the content of the device is corrosive
Do not use if package is damaged	Caution	Indicates the contents of the device are an irritant
Expiry date	Authorized representative in the European Community/ European Union	Humidity limits
Manufacturer	Single use	UK Conformity assessment mark
Manufacture date	This way up	Fragile, handle with care
Catalogue	Unique device identifier	Temperature limit
Batch code	Indicates that the product is a medical device	Distributor
Keep away from sunlight	European CE Mark	Quantity
Indicates the unique formula number of the product	Keep dry	Period after opening

Indicating the product changes colour from pink to white after absorbing carbon dioxide

Indicating the product changes colour from white to violet after absorbing carbon dioxide

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