

Sofnolime[®] medical USP grade

Sofnolime carbon dioxide absorbent (USP grade) for use in closed circuit anaesthesia



molecular

Filling Absorbers

To ensure satisfactory performance in use, loose fill absorbers must be filled correctly and should be charged with fresh Sofnolime just before use. Open the container carefully and pour in gently and steadily about one third of the absorber depth of granules. Gently tap the sides to settle the granules and repeat for the next third, then again for the final third until the canister is full. Fill the absorber completely but do not overfill it. Remove any residual granules or dust from the sealing area of the absorber before seating fully in the absorber unit in accordance with the equipment manufacturer's instructions. Do not tap so violently as to form dust, or invert or roll containers prior to dispensing to correct any settling or segregation that may have occurred during transit. Soda lime may etch glass and certain plastics but not steel, after long term use. Apparatus should be cleaned regularly to prevent a permanent film of soda lime forming on glass surfaces. Pre-filled cartridges should only be unsealed immediately prior to use to ensure the product is fresh and the history is known.

Colour Indicator

During use, a white (pink to white grade) or violet (white to violet grade) colour will start to develop and will deepen in intensity to indicate exhaustion of the Sofnolime. The appearance of a colour change confirms the activity of the material and indicates the progress of the carbon dioxide adsorption. This allows any severe uneven gas flow (channelling) within the canister to be identified.

When using single absorbers, suitable monitoring of inspired carbon dioxide is required to assess when to replace the soda lime as it is the trailing edge of the reaction zone that changes colour not the leading edge. A slowly increasing carbon dioxide concentration at the outlet will usually begin to occur when the colour change has penetrated to around half the depth of the absorber. If a double absorber is used, the leading absorber should be removed when the colour just begins to appear in the second absorber. This second, part-used, unit is moved to the inlet (leading) and a fresh absorber becomes the new second unit. This mode of operation uses all of the available carbon dioxide removal capacity. Used or partly used material should be discarded.

Colour Regeneration

If exhausted self-indicating soda lime is left to stand its colour will slowly change back, due mainly to small quantities of unreacted sodium hydroxide in the interior of the granules migrating to the surface.

Sofnolime in this apparently regenerated condition, should never be used again as it will quickly become exhausted and its colour will usually change again almost immediately. It is therefore essential to always empty or change canisters immediately after use.

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Heat and Moisture Appearance

The reaction of soda lime with carbon dioxide typically produces a 10 – 30°C temperature increase in the absorber. Higher temperature increases are observed with lower fresh gas flow rates due to the increased carbon dioxide loading on the absorber.

Temperatures much above 50°C may indicate abnormal conditions (see Safety Aspects). The heat of reaction is often sufficient to cause some of the water in the soda lime to evaporate and condense elsewhere in the breathing circuit. The patient also contributes some humidity through respiration. A water trap is often incorporated in the absorber and circuit, to isolate excess water. Free water in the absorber is not a problem, unless it reaches excessive levels when it can locally flood the granule surface preventing gas contacting and possibly cause clumping of the granules on standing.

Duration in Use

A canister of soda lime cannot be expected to give a fixed number of hours' performance. Lifetime will depend not only on the original soda lime but also on other factors, including the gas flow rate; the patient size; respiratory and metabolic rate; the design (and packing) of the absorber and breathing circuit as well as the handling and condition of the soda lime. As a rough guide, Sofnolime will absorb approximately 110 to 140 litres of carbon dioxide per kg of Sofnolime under typical anaesthesia conditions. This equates to up to about 12 hours per kg for an average patient with a base metabolism producing 200 cm³ carbon dioxide per minute.

Safety Aspects

Being alkaline in nature, soda lime should not be allowed to come into contact with sensitive skin, particularly with the eyes or mucous membranes. This material is classified as corrosive. Persons handling soda lime e.g. filling and emptying of absorbers should wear suitable eye/face/hand protection (see Safety Data Sheet). Dust levels encountered during the use of soda lime can be minimised by:

- Correct storage (see Storage)
- Careful handling during transport, storage and use
- Regular cleaning of absorbers and breathing circuits
- Discarding the last 10mm or so of the pack, which may consist of dust or small granules
- Including an antibacterial or similar filter at the circuit or Y piece

Sofnolime is not recommended for use with trichloroethylene (Trilene) and chloroform, but can be safely used with all modern anaesthetic gases. The most commonly used gases are nitrous oxide, Halothane, Enflurane, Isoflurane, Desflurane and Sevoflurane. Sevoflurane (only) is reported to be able to degrade in contact with strong bases to produce breakdown products of unknown toxicity in humans. Desflurane can degrade to produce small amounts of carbon monoxide if it gets warm in the presence of a strong alkali. Sofnolime contains no potassium hydroxide which is known to increase the production of these compounds. Sofnolime uses a low concentration of sodium hydroxide to catalyse the reaction. This ensures a high carbon dioxide capacity whilst at the same time minimising the risk of anaesthetic agent interactions.

Neither carbon monoxide nor compound A, in other than trace clinically insignificant amounts, are formed in a properly run circuit. Extreme abnormally hot, dry conditions are required to produce significant quantities of any by-products. Sofnolime is widely used with these agents, and has been shown to exhibit a low interaction compared with other brands of soda lime. The reduction of moisture levels in soda lime should therefore be avoided and the following precautions are suggested:

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Ensure regular change-out of absorbers - use a date sticker to keep track.

- Avoid setting basal or continuous flow of oxygen or fresh gas overnight or over weekends if absorbent is still in place.
- Ensure valves on gas delivery unit & central gas supply/central gas suction are switched to “park” between cases & daily respectively.
- Avoid attempts to dry out circuits between cases (if the absorbent is in place) by: running the ventilator; setting continuous gas flows or using central suction.
- Use low or moderate gas flows to maintain moisture levels in the circuit. Some circle systems have the absorber immediately downstream of the fresh gas inlet which may dry the soda lime more rapidly.
- Bypass the absorber when using high flows for extended periods or remove absorbent when equipment is out of use or on standby for more than a day.

Should the soda lime be suspected to have dried out (e.g. to less than about 5% w/w water), or if a sharp temperature increase is observed during the washing-in phase, or an unusual delay in the increase in inspired anaesthetic concentration is observed, the soda lime absorber should be replaced immediately with a fresh unit. Water should never be added to Sofnolime to try to correct for low moisture as this will decrease the efficiency of the absorber due to local flooding. The moisture content range is factory-controlled to meet the required medical specification (USP: 12 - 19%).

Spent Sofnolime canisters may still contain some absorbed or entrained anaesthetic agent which needs to be assessed and managed during disposal e.g. by incineration or land fill (see Safety Data Sheet for guidance on disposal). Sofnolime does not contain phthalates, medicinal products or blood derivatives.

Storage

Sofnolime is supplied in plastic or foil laminated air-tight containers. The containers should be kept sealed and stored in a clean dry environment, at an even temperature between 0°C and 35°C. Storage at higher temperatures can result in reduced efficiency and service life due to moisture loss. When correctly stored, unopened packs will maintain absorption capacity for the following times:

| Pack | Size | Shelf life years |
|-----------------------------|--------|------------------|
| Plastic Twin Pack | 4.5Kg | 5 |
| Plastic kegs | 20Kg | 5 |
| Plastic pails | 16.8Kg | 5 |
| Pre-packed Cartridges | all | 2 |
| Bags, multi laminate / foil | all | 2 |

Containers must not be stored where they can become subject to the following:

- Direct strong sunlight
- Contact with or close to incompatible chemicals or acids
- Partial or total water immersion
- Atmospheres with abnormal concentrations of carbon dioxide, hydrogen sulphide or other acidic gases
- Freezing conditions (below 0°C).
- Excessive stacking loads - 2 pallets high is the maximum permissible.