



SERYNOX® / PLACYNNOX® Instructions of Use

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This manual will explain step by step the application of SERYNOX®/ PLACYNOX® and the assembling of the breathing devices for safe use.



Classification:	ATC code N01AX63
Administration form:	Gas for inhalation (Nitrous Oxide 50% / Oxygen 50%)
Indications:	SERYNOX® / PLACYNOX® is indicated in adults, adolescents and children older than 1 month for: short-term analgesia for painful procedures or conditions of mild to moderate pain intensity and sedation during acute emergency pain, anxiety, dental surgery, analgesia, obstetrics and any kind of acute pain treatment in podiatric.

SERYNOX® / PLACYNOX® Cylinder Presentation

- The SERYNOX® / PLACYNOX® cylinder is white with a white and blue shoulder.
- The cylinder is equipped with a GCE Medivital top of blue and white color.





Flow control knob

From 0 to 15 l/min

Pressure indicator

170 bars: cylinder is full
0 bar: cylinder is empty
>30 bar before treatment



Switch-off valve

When stored, the valve must be on
"OFF" position

When in use with breathing circuit or
demand-valve, the valve must be on
"ON" position





Demand-valve outlet

To be used with the demand-valve for a quick and easy-to-use connection



Filling port

The coverage should not be removed



Required Devices for SERYNOX® / PLACYNOX® Breathing Circuit

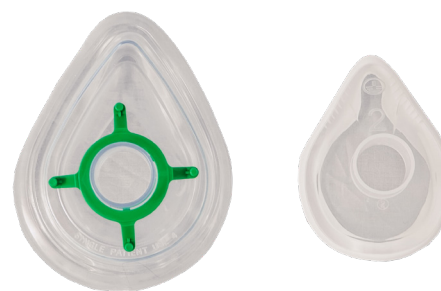
Exhausting pipe



Connecting pipe



Masks



Filter

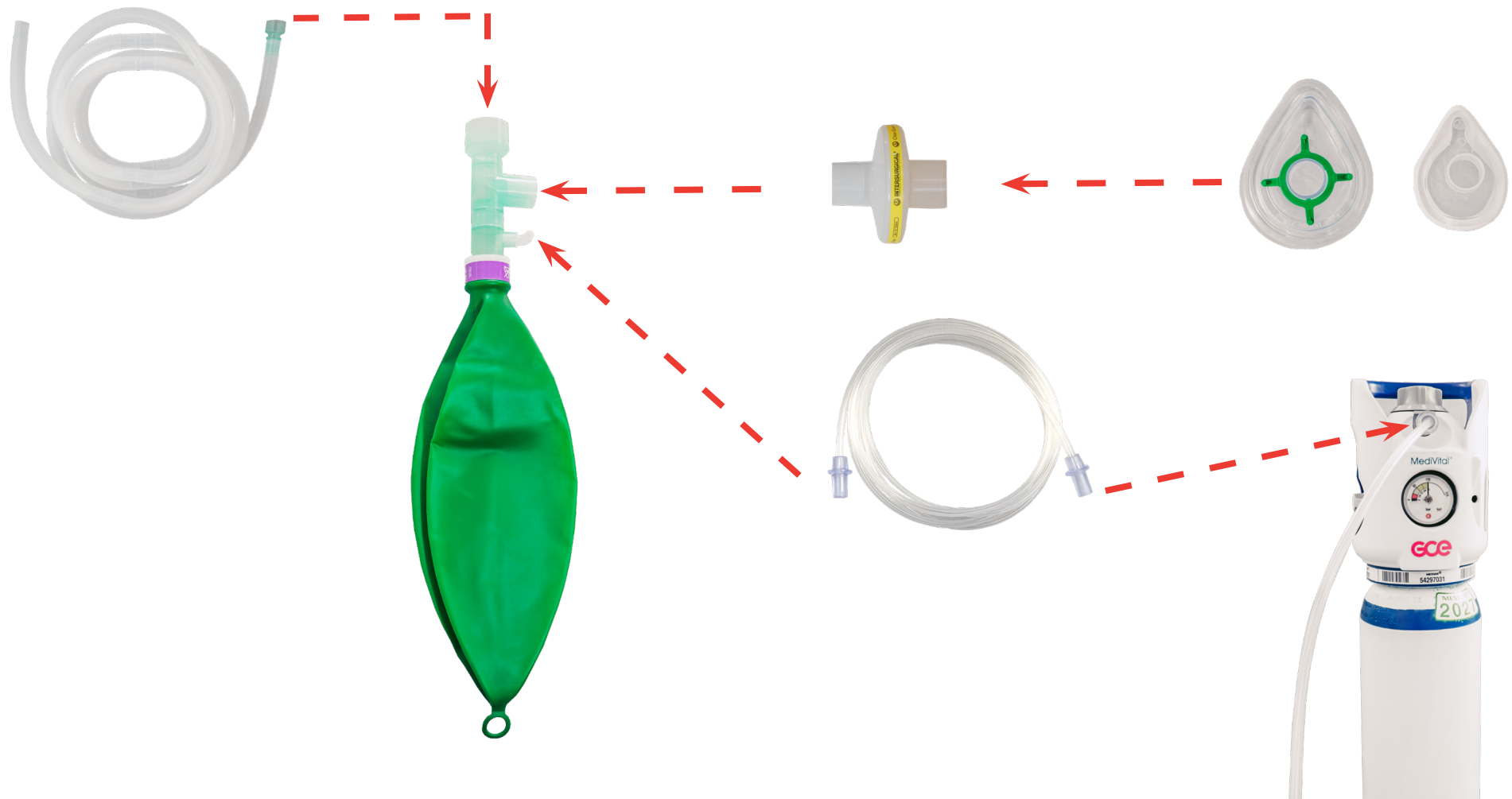


Balloon



The balloon, also called continuous flow administration, is commonly used. The gas fills the balloon at all time and the patient breathes normally. The exhaled gas does not go back to the balloon due to a one-way valve and is sent to a scavenging system.

Set-up of SERYNOX® / PLACYNOX® Breathing Circuit & Cylinder



Assembling SERYNOX® / PLACYNOX® Breathing Circuit

Balloon and pipes can be used up to 15 times. Masks and filters have to be changed after every use.

Assemble the connecting
pipe to the balloon



Connect the filter to the
“T” connector



Adjust the mask to
the filter



Plug the exhausting
pipe to the “T” connector



Application of SERYNOX® / PLACYNOX® Breathing Circuit



Plug the connecting pipe
to the outlet of the
cylinder



Put the shut-off valve in
"ON" position



Adjust the flow to the
patient breathing capacity.
The balloon should be
filled with gas at all times



The patient should hold the
mask and breath normally all
through the procedure

Disconnecting SERYNOX® / PLACYNOX® Breathing Circuit



Put the control knob on
0 L/min.



Put the shut-off valve in
"OFF" position



Disconnect the pipe



Store securely the cylinder in
an upright position at an
ambient temperature until the
next use

Required Device for Demand Valve

The demand-valve, also called discontinuous administration, enables the gas to be delivered only when the patient is inhaling. When exhaling, the flow stops and the exhaled gas is sent to a scavenging system.

Mouthpiece



Demand valve



Scavenging adaptor



Filter



Different sizes of adult masks



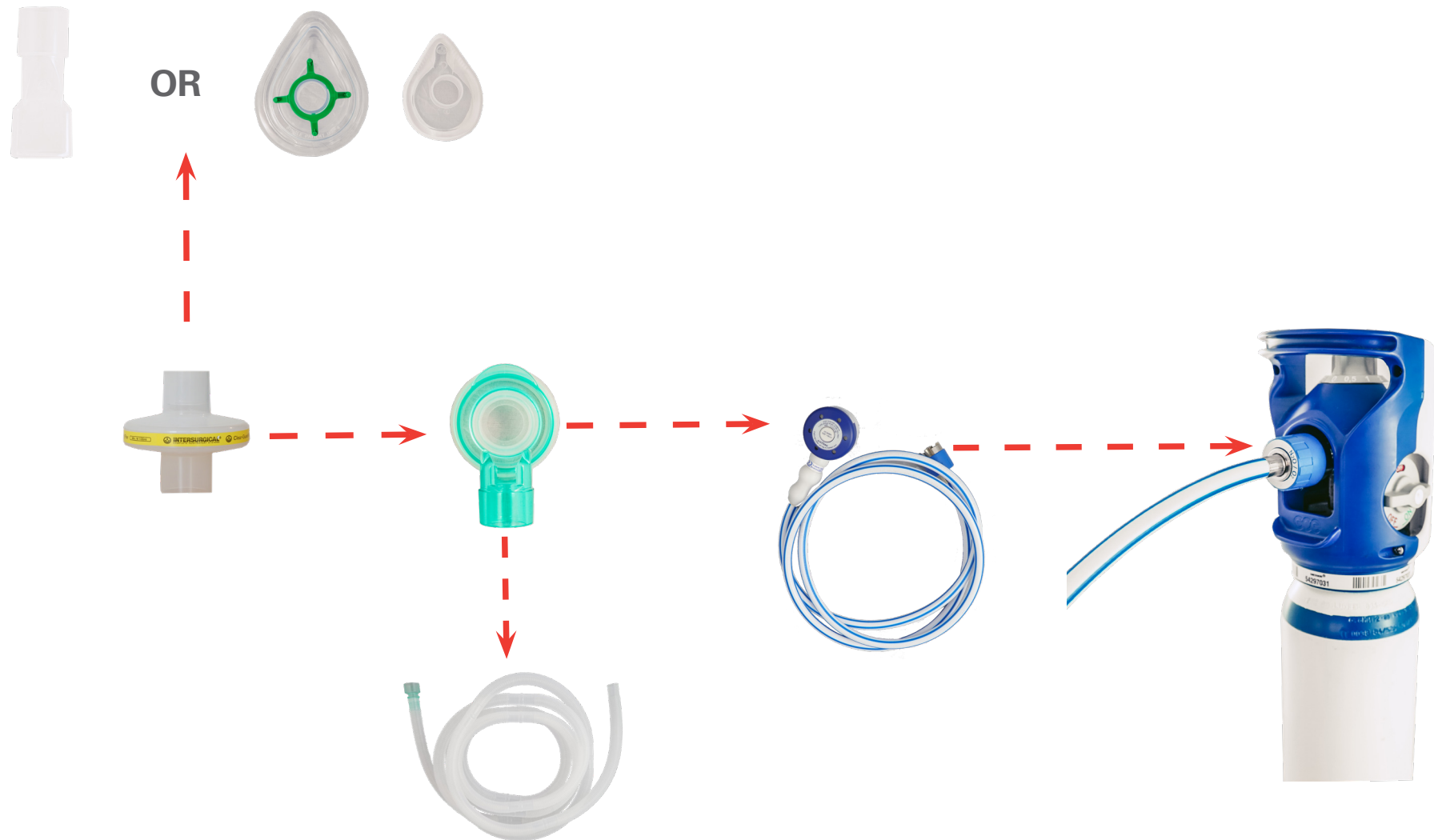
Pediatric mask with or without different smells



Exhausting pipe



Set-up of SERYNOX® / PLACYNOX® Demand Valve & Cylinder



Assembling SERYNOX® / PLACYNOX® Demand Valve

Place the scavenging adaptor on the demand valve, the filter and the exhausting pipe. Place the mask...



... or mouthpiece



Plug the hose to the demand-valve outlet.



Application of SERYNOX® / PLACYNOX® Demand Valve

Always press the flush button on the demand valve prior to use to be sure that the gas is flowing.

Put the shut-off valve
in "ON" position



Press the flush button
on the demand valve



The patient should hold the demand-valve and
breath normally all through the procedure



Disconnecting SERYNOX® / PLACYNOX® Demand Valve

Put the shut-off valve in
“OFF” position



Unplug the hose to the
demand-valve outlet



Store securely the cylinder in
an upright position at an am-
bient temperature until next
use





SERYNOX® / PLACYNOX®



Active Substance: Medicinal gas, compressed Colourless gas: Nitrous oxide 50% and Oxygen 50% **Composition:** Each gas cylinder contains: Nitrous oxide 50% and Oxygen 50% (at a pressure of 170 bar at 15°C) **Therapeutic Indication:** Serynox is indicated in adults, adolescents and children older than 1 month for: short-term analgesia for painful procedures or conditions of mild to moderate pain intensity and sedation during dental surgery, when rapid analgesic onset and offset effects are wanted. **Contraindications:** Patients, who require ventilation with 100% O₂, Intracranial hypertension, Any altered state of consciousness that prevents the patient from cooperating, In patients with untreated vitamin B12- or folic acid deficiency, Recently occurring, unexplained neurological disorders, Patients with heart failure or cardiac dysfunction (e.g. after cardiac surgery) in order to avoid the risk of further deterioration in heart function When Serynox is inhaled, gas bubbles (gas emboli) and gas-filled cavities may expand due to the increased ability of nitrous oxide to diffuse. Consequently, it is contraindicated in the following conditions: Maxillofacial- and facial injuries, Head injuries, Pneumothorax, Severe emphysema, Gas embolism, Following deep sea diving with risk of decompression sickness, Following air encephalography, During middle ear surgery and sinus surgery, Severely dilated gastrointestinal tract, If air has been injected into the epidural space to determine the placement of the needle for epidural anaesthesia, In patients recently having undergone intraocular injection of gas (e.g. SF₆, C₃F₈, C₂F₆) until the gas in question is fully absorbed, or within 3 months after the last injection of an intraocular gas. Severe postoperative complications may occur due to increased intraocular pressure. **Undesirable effects:** Nitrous oxide passes into all gas containing spaces in the body faster than nitrogen passes out. Use of nitrous oxide may result in expansion of non-vented gas containing cavities. Megaloblastic anaemia and leucopenia have been reported following prolonged or repeated exposure to Serynox. Neurological effects such as neuropathy and myeloneuropathy have been reported with exceptionally high and frequent exposure. **Description of selected adverse reactions:** Common adverse reactions (≥1/100 to <1/100) Nervous system disorders: Dizziness, Lethargy, drowsiness and Gas containing disorders: Nausea and Vomiting **Special warnings:** Reduced fertility in medical and paramedical personnel has been reported after repeated exposure to nitrous oxide in inadequately ventilated rooms. It is not currently possible to confirm or exclude the existence of any causal connection between these cases and exposure to nitrous oxide. Areas in which Serynox is used should be adequately ventilated and/or equipped with scavenging equipment in order that the concentration of nitrous oxide in ambient air is as low as possible and below occupational exposure limits. The gas mixture should be stored and used only in areas/rooms where the temperature exceeds 00c. At lower temperatures the gas mixture can separate and result in administration of a hypoxic gas mixture. **Precautions for use:** Serynox should only be administered by competent personnel. Hyperventilation should be avoided as this may lead to abnormal movements. Self-administration should be preferred to allow the assessment of the level of consciousness. Attentive monitoring is required in patients taking central nervous system depressant medicinal products and in particular opiates and benzodiazepines, because of the increased risk of deep sedation, possible drowsiness, oxygen desaturation, vomiting and hypotension. Following discontinuation of the administration of Serynox, the patient should recover under proper supervision until the potential risks resulting from use of Serynox have subsided and the patient has recovered satisfactorily. Recovery of the patient should be assessed by healthcare personnel. Repeated administration or exposure to nitrous oxide may lead to addiction. Caution should be exercised in patients with a known history of substance abuse or in healthcare professionals with occupational exposure to nitrous oxide. The neonate should be checked for possible respiratory depression when Serynox is administered to the mother during childbirth. **For further information, please see Summary of Product Characteristics (SmPC).** Only available by prescription. **Version 02.2023**

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