

General Information

THE INTAVENT BASIC® SINGLE USE

THE INTAVENT BASIC® IS A SINGLE USE, DISPOSABLE DEVICE AND SHOULD BE DISCARDED AFTER USE AS IT DOES NOT WITHSTAND STERILISATION

Contraindication

1. The device is contraindicated for use in an MRI environment as sufficient testing has not been performed to validate that it is MRI safe or MRI compatible.
2. The device is not recommended for use during laser surgery.

Caution

1. The device is designed for use by trained clinicians only.
2. The device is restricted to a short term use, not exceeding 4 hours. The device is made of PVC and prolonged use could cause irritation.
3. The device is supplied sterile for single use only and it shall not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
4. For safe use, new anaesthetic skills must be attained.
5. Laryngeal spasm may occur if the patient becomes too lightly anaesthetised during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anaesthesia. If laryngeal spasm occurs, do not remove the device, but treat the cause. Only remove the device when reflexes are fully competent.
6. The device does not prevent regurgitation or aspiration. Its use in anaesthetised patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. Do not use the device without taking appropriate precautions to ensure the stomach is empty.
7. Do not pull or use undue force when handling the inflation line or try to remove the device from patient by the inflation tube as it may detach from the cuff spigot.

Choose the Correct Size of Device

Patient Size/Weight

Size 3: 30kg - 50kg

Size 4: 50kg - 70kg Adult

Size 5: Over 70kg Adult

Keep a clearly marked syringe for inflation and deflation of the cuff.

Pre-Use Checks

It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use. These tests should be carried out as follows:

1. Examine the interior of the airway tube to ensure it is free from blockage or loose particles. Then examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. Holding at each end, flex the airway tube to increase its curvature up to but not beyond 180°. Should the tube kink during this procedure, discard the device.
3. Deflate the cuff fully. Reflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 3	45ml,	Size 4	60ml,	Size 5	75ml
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 Examine the cuff for leaks and herniations. If there is any indication of either, discard the device. A herniating mask may cause obstruction during use. Then deflate the mask again.
4. Examine the airway connector. It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
5. Should you require advice with regard to procedure, or assistance in checking safety of current stock, please do not hesitate to contact Intavent Direct Ltd.

Preparation

Deflate completely in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold away from the bowl of the mask. Lubricate the back of the cuff thoroughly just before insertion. A medical grade water-soluble lubricant, such as K-Y Jelly® should be applied. Do not lubricate the front as this may result in aspiration of lubricant.

Insertion

Note: gloves must be worn

1. Anaesthesia must be deep enough to permit insertion.

Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given. A volatile agent or Propofol preceded by an opiate provide suitable insertion conditions.

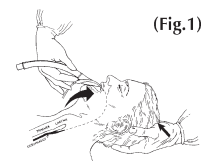
Manufactured by:

Venner Medical (Singapore) Pte Ltd
35 Joo Koon Circle, Singapore 629110

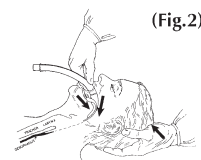
EU Authorised Representative:

Intavent Direct Ltd
14 Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU

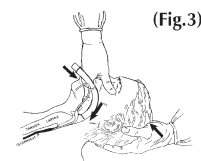
2. Position the head and neck as for normal intubation. Keep the neck flexed and the head extended by pushing on the occiput with one hand while inserting the mask into the mouth with the other hand (Fig.1).



3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube (Fig.1). Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.

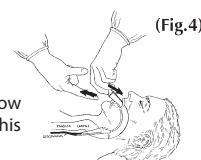


4. Using the index finger, push the mask backwards still maintaining pressure against the palate (Fig.2).
5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion (Fig.3). Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. (Fig.3).



AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.

When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth (Fig 4).



6. Check that the black line on the tube faces the upper lip. Now immediately inflate the cuff without holding the tube. Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. NEVER OVERINFLATE THE CUFF.

Maximum inflation volumes (ml)

Size 3	30ml
Size 4	45ml
Size 5	50ml

7. Connect to gas supply, holding tube, to prevent displacement. Gently inflate lungs to confirm correct placement. If a bite block is deemed clinically desirable, insert roll of gauze as bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the Intavent Basic® it is important to remember to insert a bite-block gauze at the end of the procedure.

Maintaining the airway

1. Remember that obstruction can occur if the device becomes dislodged or is incorrectly inserted. The epiglottis may be pushed down with poor insertion technique. Check by auscultation of the neck and correct by re-insertion or elevation of the epiglottis using a laryngoscope.
2. Malposition of mask tip into the glottis may mimic bronchospasm.
3. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.
4. Keep the bite-block gauze in place until the device is removed.
5. Do not deflate the cuff until reflexes have fully returned.
6. Air may be withdrawn from the cuff during anaesthesia to maintain a constant intracuff pressure (ideally about 60cm H₂O).

Removal

1. The device, together with the bite-block gauze, should be left in place until the return of consciousness. Oxygen should be administered using an appropriate oxygen enrichment device and standard monitoring should be in place. Before attempting to remove or deflate the device, it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.
2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary to perform suction because the correctly used device protects the larynx from oral secretions. Patients will swallow secretions on removal. Suction equipment should however be available at all times and used if required to remove excessive secretions.
3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.
4. After use, the device should be discarded and must not be re-used.

Manufactured from phthalates free PVC



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