Pharyvac Suction Catheter Instructions for Use

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REF **SUK**

All applicable language and symbols essential for proper use appear on the IFU and primary packaging.

1. Description

The Pharyvac Suction Catheter is a sterile, single-use, balloon-cuffed surgical suction catheter intended to remove blood, fluid, smoke, and debris from the nasal cavity during endonasal and related surgical procedures.

- Catheter Body: Semi-rigid oral-access catheter with four lumens (one suction lumen, two irrigation lumens, and one inflation lumen). Two 90° bends for proper positioning in the nasopharynx with proximal access through the oral cavity.
- Suction Tip: Domed with multiple suction ports to prevent clogging while maintaining continuous suction.
- Occlusive Balloon: Semi-compliant cuff with posterior inflation lumen to create a seal in the nasopharynx, preventing migration of blood into the oropharynx, airway, or digestive tract.
- Suction Adapter: Barbed connector compatible with standard surgical suction tubing
- Inflation Luer: Luer-activated check valve for occlusive balloon inflation with air
- Pilot Balloon: Proximal visual/tactile indicator of occlusive balloon inflation status
- Irrigation Luers: Luer-Lok adapters to connect saline-filled syringes. Two lateral channels for saline delivery on either side of the septum to clear blood, debris, and surgical instruments.

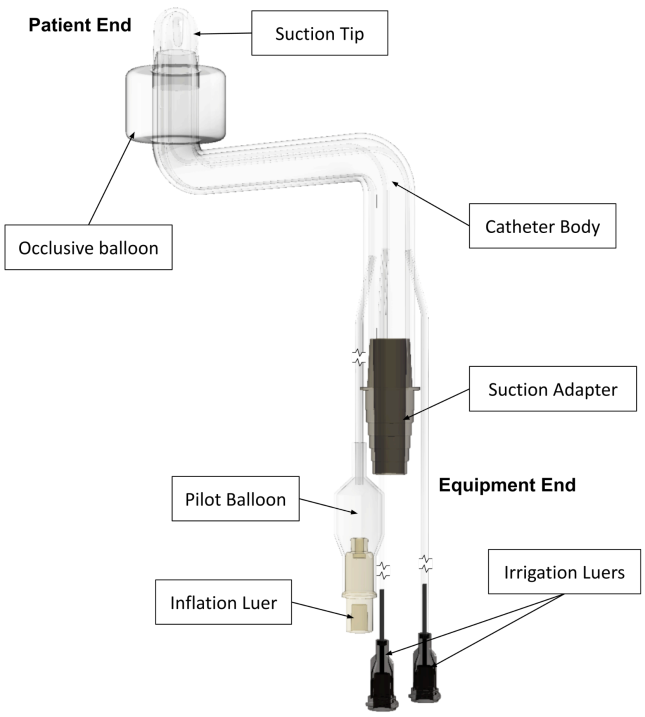


Figure 1. Pharyvac Suction Catheter

2. Intended Use

The Pharyvac Device is intended for use in endonasal surgeries performed on adults over 18 years old. It is intended to be single use, sterile, and used to reduce blood migration from the nasal cavity into the lower aerodigestive tract.

It can also suction bodily fluid, surgical smoke, and surgical debris, as well as support surgical field irrigation without the need for removal of endonasal surgical tooling.

3. Contraindications

- Patients with a communication between the intracranial space and the nose/sinus.
- Patients with aberrant vascular anatomy, prominent adenoid tissue, prior radiation to the nasopharynx, or cervical instability.
- Patients with upper airway obstruction that prevents catheter placement.
- Patients with pharyngeal trauma or lesions where balloon cuff inflation could cause harm.
- Not indicated for pediatric patients.

4. Warnings & Precautions

Preparation and Disposal

- Device is single-use only; do not resterilize or reuse.
- Inspect packaging and catheter integrity before use. Do not use if damaged or expired.
- Opening the device outside the sterile field may result in contamination. Do not introduce a non-sterile device into the sterile field.
- Dispose of used device in accordance with institutional biohazard waste protocols.

Handling During Insertion, Positioning & Removal

- Do not insert the device until adequate anesthesia has been achieved and airway control has been established. Monitor jaw activity during light anesthesia, position the device to minimize tissue entrapment if biting occurs, and maintain awareness of tongue placement when the patient may regain partial muscle control.
- Do not insert the device into the trachea or lower airway. The device is intended for placement in the nasopharynx behind the soft palate.
- Misplacement or misuse can cause mucosal injury.
- Avoid contact between the device or tubing and the upper incisors during insertion, balloon inflation, manipulation, or removal.
- Do not pull, twist, compress, or apply tension to the occlusion balloon, inflation/irrigation/suction tubing, pilot balloon assembly, check valve assembly, or any attached extrusion during positioning, repositioning, or handling, and avoid instrument contact that applies concentrated force to the balloon attachment region. This may cause disconnection, kinking, loss of balloon inflation/irrigation/suction, unintended movement, or loss of fluid control allowing blood into the oral cavity.

Operating Parameters

- Do not exceed suction pressure of 20 kPa (150 mmHg). Excessive pressure may cause tissue injury, bleeding, airway trauma, or degradation of device performance. Monitor suction performance throughout the procedure.
- Do not allow contact between the device and energy-emitting tools or sharp instruments; the device is not resistant to surgical lasers.
- Do not use in the MR environment. The device contains metallic components and must not be exposed to MRI magnetic fields.
- Do not connect to a dedicated smoke evacuation system.
- The device body is manufactured from radiolucent materials to minimize interference with fluoroscopy/X-ray; any radiopaque components are limited to intentional elements and are not expected to obscure the clinical field under normal use.

5. Storage

- Store in original packaging at room temperature.
- Keep away from moisture, heat, and direct sunlight.

6. Compatibility

The device is compatible with the following equipment:

- Sterile saline solution
- Standard suction tubing
- Wall suction systems and closed waste management systems
- Luer-slip and Luer-lok syringes

6. Patient Assessment

1. Ensure that the patient has been anaesthetized and intubated according to the standard of care at the surgery location.
2. Open the patient's mouth and examine the oral cavity and pharynx directly for signs of previous damage. Use the patient's medical history as appropriate during this step. Visualization can optimized using a tongue refraction instrumentation, cheek retraction instrument, as well as a light source. Laryngoscopic visualization may be utilized at the surgical team's discretion. If there is prior trauma, lesions, dental instability, or other damage exists, abort the procedure.

7. Device Assessment

1. Verify that the sterile barrier is intact before use. Prior to use, the device's packaging should be inspected for damage and seal integrity (e.g., punctures, tears, damaged packaging seals, etc.). If any damage is observed, discard the device, and do not use it because the sterility of the device is compromised.
2. Check the expiration date on the pouch label. DO NOT use product that is past its expiration date. The manufacturer cannot guarantee the product's performance after this date.
3. Open the device within the sterile field using aseptic technique.
4. Inspect catheter, balloon, and connectors for signs of damage such as cracks, kinks, tears, or discoloration. DO NOT use the product if it appears damaged.
5. Ensure the occlusion balloon is fully deflated before use.

8. Device Insertion

1. Communicate with anesthesia team that device insertion is taking place.
2. Grasp the device by the middle section of the main catheter body and rotate 90 degrees such that the suction tip is pointed laterally, with the suction tip toward the surgeon (Fig 2A)
3. Position the distal end of the device (with the suction tip and the occlusive balloon) in the patient's mouth such that the suction tip aligns with the oropharynx. (Fig 2A)
4. Slowly insert Pharyvac under direct guidance through the oral cavity and into the nasopharynx by using a sweeping motion to simultaneously rotate the device to point the suction tip superior while sliding the distal end behind the soft palate (Fig 2B). Maintain a clear view of the tongue and soft palate during insertion. Laryngoscopic guidance, tongue retraction using instrumentation, and/or a light source may be used at the surgical team's discretion. A tongue depressor may also be necessary for patients with macroglossia. Avoid excessive pressure on the tongue. Do not force the distal tip against resistance. Excessive insertion force may deform the distal tip and reduce suction performance.
5. Pull the device inferior such that the middle section of the catheter sits on the tongue.
6. Push the device posterior until distal end against posterior nasopharynx. Use tactile feedback and/or direct visualization to confirm. The balloon cuff should be positioned in the nasopharynx such that, when inflated, it will create a seal between the nasopharynx and soft palate.
7. Position the proximal end of the device along the midline next to the endotracheal tube. Confirm that device is not interfering with endotracheal tube. (Fig 2C)
8. Confirm under direct visualization that the uvula is in the normal anatomical position.
9. Fill an inflating luer slip or luer lock syringe with 4cc of air (Fig 3A). The nominal balloon inflation volume is 4cc.
10. Connect syringe to pilot balloon, pushing in to activate the valve.
11. Slowly, while holding the device steady with the balloon cuff positioned in the nasopharynx, inflate the balloon cuff with 4cc of air. Confirm balloon is inflating by observing the soft palate moving anterior under direct visualization (Fig 3B). Monitor tongue and uvula positioning during inflation to avoid excess pressure.
12. Remove syringe from pilot balloon.
13. Communicate to the anesthesia team that device has been placed.

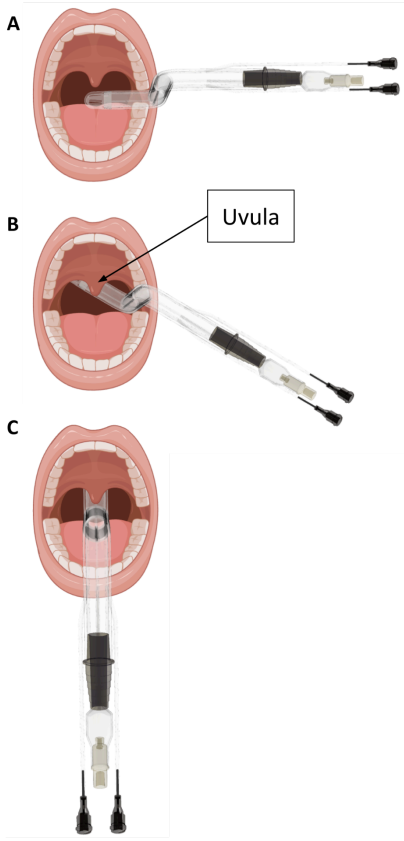


Figure 2. Device insertion

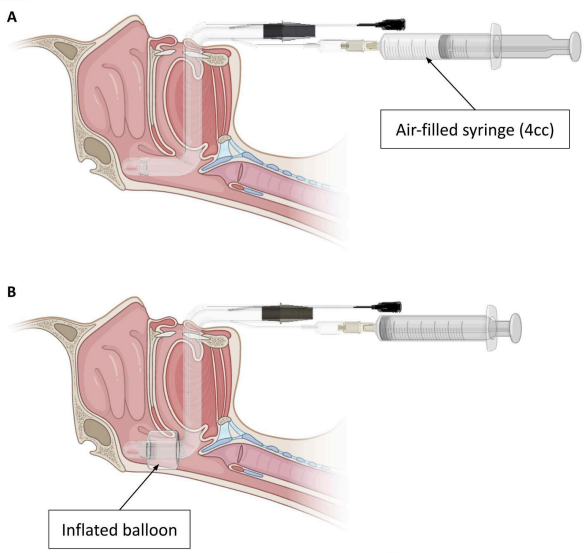


Figure 3. Device inflation

9. Drape the Patient

1. Ensure device is positioned along the midline of the patient, with the proximal end resting on the chin (Fig 4A). Ensure the device does not cross over, compress, displace, or otherwise interfere with the endotracheal tube or LMA during placement or use.
2. Confirm that ventilation remains unobstructed after positioning the device. Reposition the catheter immediately if any interference with the airway device is observed.
3. Tape the proximal end of the device to the chin to secure it into place, wrapping once around the catheter body. Tape should be proximal to the bend and distal to the exiting minor extrusions. Tape should not overlay ET tube tape. (Fig 4B)
4. Prep and drape the patient in standard fashion for nasal endoscopy clean contaminated case, draping out the nasal and oral cavities using a U-shaped head and neck drape (Fig 4C)
5. Add a clear adhesive utility non-latex drape (i.e., Steri-Drape, 3M) or other surgical adhesive drape, adhering the drape between the nose and upper lip and laying the rest of the drape over the mouth. (Fig 4D)

a. Ensure that the proximal end of the device, including suction connectors, irrigation connectors, pilot balloon, and inflation controls, remains visible and accessible after surgical draping. Draping that covers these components may prevent monitoring or adjustment of suction, irrigation, or balloon inflation during the procedure.

6. Visually confirm position of distal suction tip under endoscopic guidance through the nasal cavity. Tip should point superior and rest inferior to the roof of the nasopharynx and posterior to the septum. Superior edge of the balloon should align with the nasal floor. (Fig 5)
7. Position irrigation lumens above the draping on the torso of the patient such that they are accessible by the user.

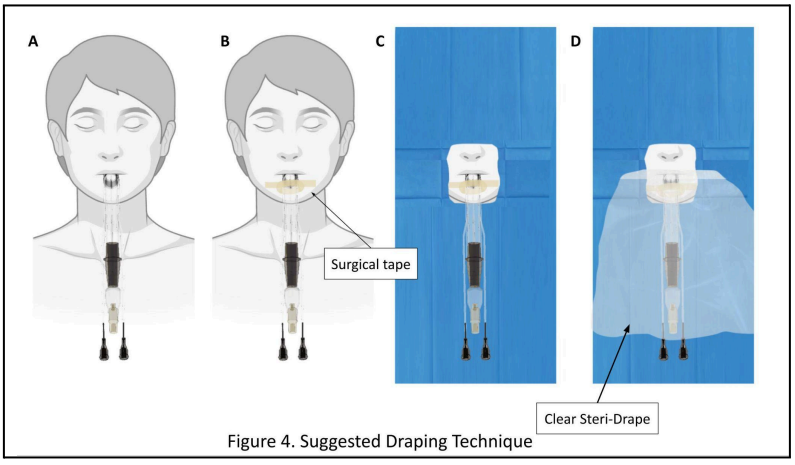


Figure 4. Suggested Draping Technique

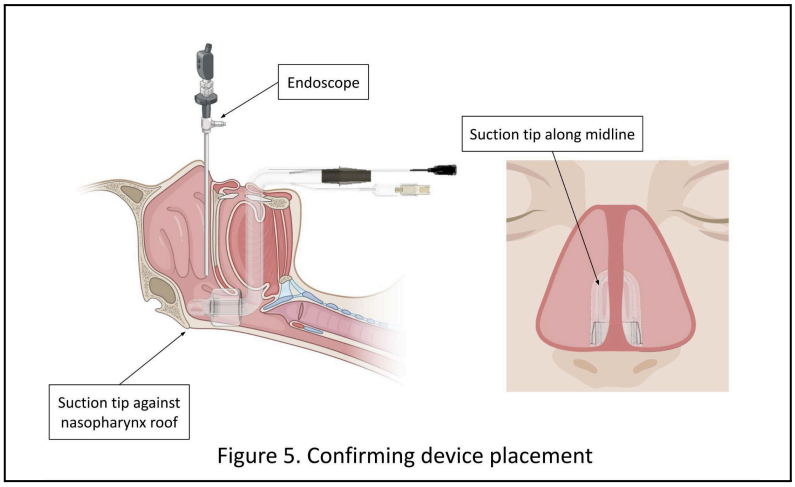


Figure 5. Confirming device placement

10. Applying Suction

1. Set pressure on the suction machine to desired pressure between 7-20 kPa (50-150mmHg), but keep suction off. Do not use device with pressures outside of this specified operating range. The Pharyvac Suction Catheter is compatible with wall suction and closed-system waste management devices.

a. Set suction pressure within the recommended operating range prior to use. Excessive suction pressure may draw surrounding tissue into the suction openings and cause tissue injury. Insufficient suction pressure may reduce removal of blood, debris, or surgical byproducts and degrade visualization.

2. Immediately before starting the procedure, connect one end of standard medical suction tubing to the suction system and the other end to the proximal suction adapter on the device, pushing such that they connect tightly. (Fig 6)

a. Connect standard suction tubing to the proximal suction adapter by pushing the tubing firmly onto the barb until fully seated. Verify that the connection is secure before beginning the procedure.

3. Turn suction on. Verify that suction flow is present before beginning the procedure.
4. Confirm device is suctioning audibly and visually under endoscopic guidance
5. Begin transnasal surgery.

a. Ensure that pledgets, tissue, or other surgical materials do not cover the suction openings during use. If suction flow decreases, inspect the tip for obstruction and reposition or clear the openings to restore suction.

b. Avoid contacting the occlusion balloon with surgical instruments during the procedure. Instrument contact may puncture or tear the balloon, resulting in loss of balloon pressure, loss of occlusion, device migration, and uncontrolled blood migration into the oral cavity.

6. Monitor suction and balloon function throughout the procedure.
7. Ensure no tools or equipment are set on top of the suction or irrigation tubing throughout the course of the procedure, as this may occlude flow or collapse the catheter.

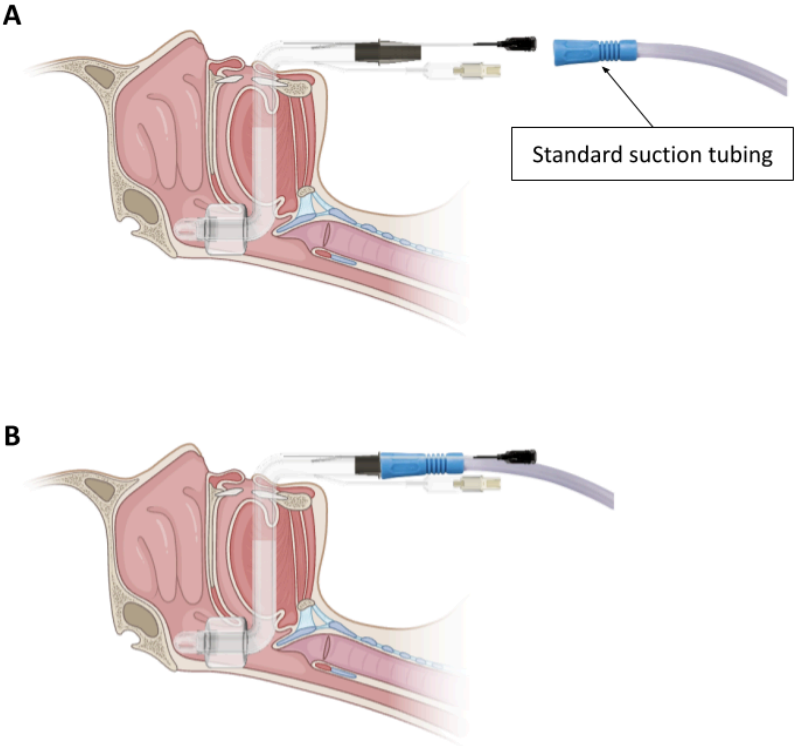


Figure 6. Connecting Suction

11. Initiating Irrigation

1. Fill 10-50cc Luer slip or Luer lock syringe with warm sterile saline or use prefilled syringe
2. Identify proximal Luer adapter on device. Connect the irrigation syringe securely to the luer adapter and confirm that the connection is fully seated before use. Avoid pulling or applying tension to the irrigation tubing or syringe during the procedure. Ensure syringe is connected to the intended side (left or right) (Fig 7C-D)
3. Push syringe to inject irrigation through the distal irrigation port into the nasal cavity (Fig 7A-B)
4. Move surgical tools or endoscope into the stream of saline in the nasal cavity to clean them or use stream of saline to flush surgical site
5. Disconnect syringe from device to prevent accidental force and displacement.

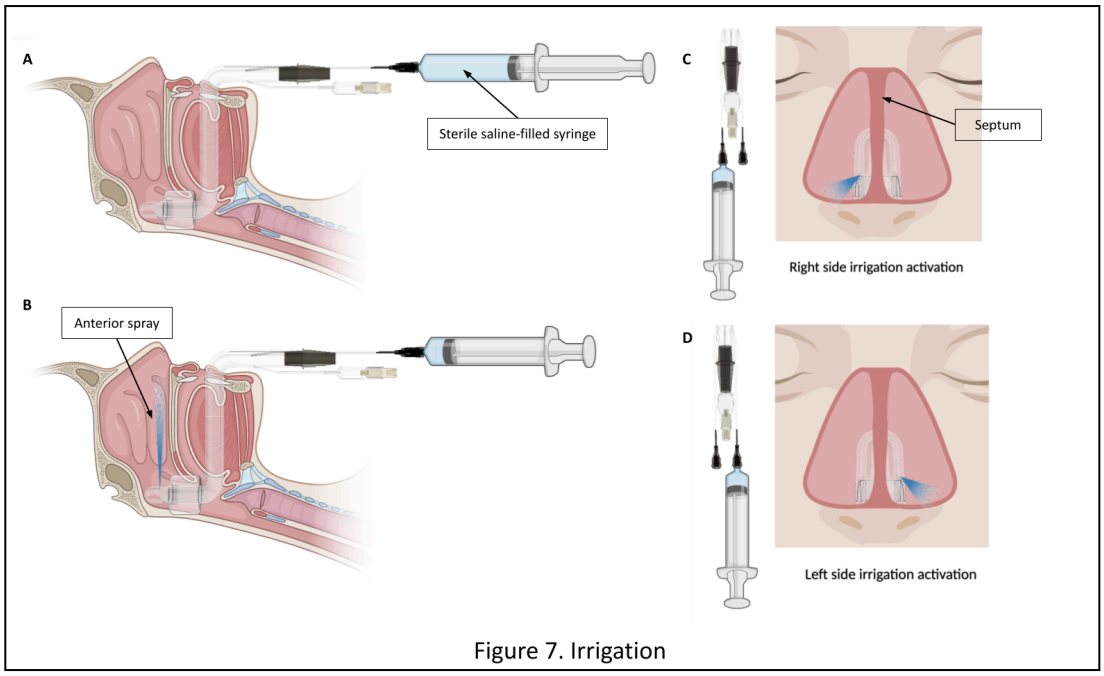


Figure 7. Irrigation

12. Repositioning the Device

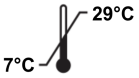
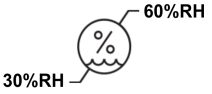
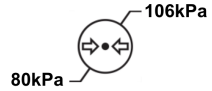
1. Communicate with anesthesia that the device is being positioned.
2. Lift the Steri-Drape to expose the proximal end of the device
3. Grasp the proximal end of the device by the main catheter body (not connected tubing or balloon components) with one hand and with the scope in the other hand visualize the distal suction tip in the nasal cavity
4. Use small movements to adjust positioning of the distal suction tip by manipulating the proximal end accordingly. Remove tape and re-tape if needed. Deflate and re-inflate the balloon as needed, never exceeding a total of 4cc in the balloon.
5. Flip Steri-Drape back over the oral cavity and resume operating

13. Device Removal

1. Communicate with anesthesia that the device will be removed.
2. Turn off powered suction device (i.e. wall suction, Neptune, etc.) and disconnect suction tubing before removing the device. Removal of the device with active suction can cause unnecessary trauma to surrounding tissue and increase resistance during withdrawal.
3. Disconnect standard medical suction tubing from proximal suction adapter on device.
4. Disconnect any syringes connected to irrigation Luers.
5. Connect a syringe filled with 0cc of air to the proximal end of the pilot balloon, pressing in to activate the valve.
6. Withdraw all air (4cc) from the balloon and ensure the balloon is completely deflated.

a. Fully deflate the occlusion balloon before removing or repositioning the device. Removing the device while the balloon remains inflated may increase resistance and require excessive force during withdrawal.

7. Disconnect the syringe from the pilot balloon.
8. Place one hand on the ET tube to secure and stabilize the airway. With the other hand, gently remove the device from the nasopharynx, using the same motion used to insert the device but in reverse, under direct visualization.
9. Inspect the device to ensure it is intact and that there are no missing pieces.
10. Inspect surgical field, nasopharynx, oropharynx, and oral cavity for injury or retained fragments. Any foreign bodies left in the cavity may cause aspiration.
11. Dispose of device per biohazard protocols. Do not reuse or resterilize the device.

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	Do not resterilize	Indicates a medical device that is not to be resterilized
	Do not use if packaging is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Single sterile barrier system	Indicates a single sterile barrier system
	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Do not re-use	Indicates a medical device that is intended for one single use only
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Unique device identifier	Indicates a carrier that contains unique device identifier information
QTY	Quantity	Indicates device count

Manufacturer:
Pharyvac Surgical Technology, Inc.
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