

## **INSTRUCTIONS FOR USE**

### **SupraVent<sup>™</sup> and IntroGard<sup>™</sup>**

#### **Limited Market Release**

#### **Device Description**

The SupraVent<sup>™</sup> and IntroGard<sup>™</sup> are medical devices designed for pre-hospital (emergency) and hospital airway management. The SupraVent<sup>™</sup> is a supraglottic airway device that facilitates temporary ventilation and serves as a conduit for endotracheal intubation. The IntroGard<sup>™</sup> is a device that assists in the precise placement of an endotracheal tube (ETT) through the SupraVent<sup>™</sup>'s Intubation Conduit. This document provides instructions for their combined use during a limited market release involving an EMS Director (ER physician) and licensed paramedics or EMTs.

#### **Intended Use**

The SupraVent<sup>™</sup> and IntroGard<sup>™</sup> combination is intended to provide temporary supraglottic airway management and facilitate endotracheal intubation in pre-hospital (emergency) and hospital settings to ensure a patient airway.

#### **Indications for Use**

Airway management in adult patients requiring supraglottic airway support and/or endotracheal intubation utilized by physicians and trained EMS personnel (e.g., licensed paramedics, EMTs) under medical oversight.

#### **Contraindications**

- Not for use in patients with known or suspected airway obstructions that prevent supraglottic airway or ETT placement.
- Not for use by untrained personnel.
- Not for use in pediatric patients (limited market release limited to adult patients).

#### **Warnings**

- Both devices are for single-use only.
- Ensure all components are intact and undamaged before use.

- Improper placement of the SupraVent™, IntroGard™, or ETT may result in inadequate ventilation or airway tissue damage.
- Only trained personnel should use these devices.
- Do not use if packaging is damaged or opened.
- Remove the IntroGard™ from the ETT after placement to avoid obstruction.
- Remove the SupraVent™ from the airway after ETT placement to avoid tissue damage.

### **Precautions**

- Verify compatibility with the selected ETT size (7.0-8.0 mm) and gastric tube (16Fr or smaller) before use.
- Ensure adequate lighting and visualization during airway management.
- Use only water-soluble lubricants.
- DO NOT USE if IntroGard™ is not well lubricated
- Follow standard emergency airway management protocols.
- Do not advance IntroGard™/ETT unit if resistance is felt
- Monitor patient oxygenation and ventilation throughout the procedure.
- Have backup airway management devices available in case of failure.

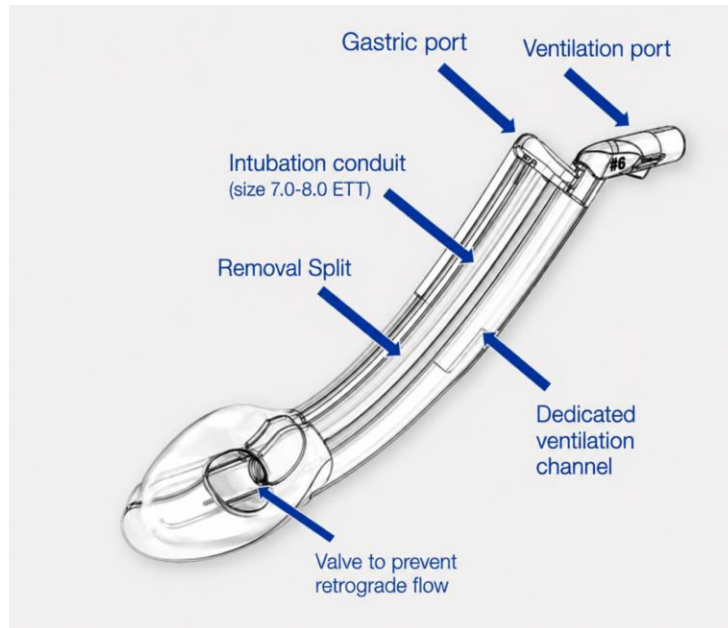
### **Potential Complications**

- Airway tissue damage or bleeding due to improper insertion of the SupraVent™, IntroGard™, or ETT.
- Misplacement of the SupraVent™ or ETT leading to inadequate ventilation.
- Obstruction of the airway if the IntroGard™ is not removed post-ETT placement.
- To avoid tissue damage the SupraVent™ must be removed from the airway in a timely fashion in accordance with standard laryngeal mask airway usage and guidelines.
- Esophageal or gastric trauma from improper gastric tube insertion.

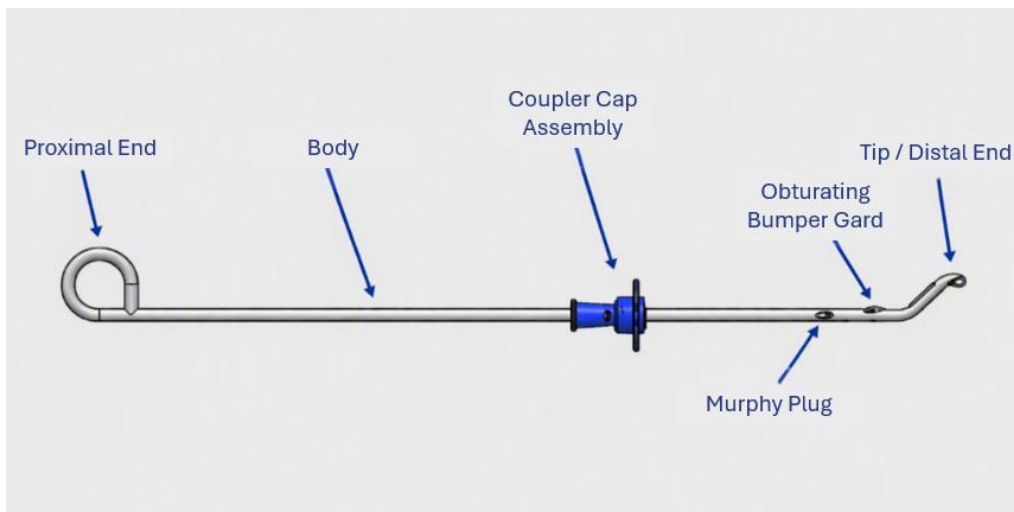
### **Study-Specific Instructions**

This device combination is under evaluation in a limited-participant study. Participants (EMS Director and licensed paramedics) must:

- Complete training on the SupraVent™ and IntroGard™ prior to use.
- Follow these instructions precisely during the study.
- Provide survey responses post-use to evaluate device performance.
- Report any adverse events or device issues to the study coordinator immediately.



**SupraVent™ Diagram**



**IntroGard™ Diagram**

## Preparation for Use

1. Inspect both the SupraVent™ and IntroGard™ for integrity. Do not use if damaged.



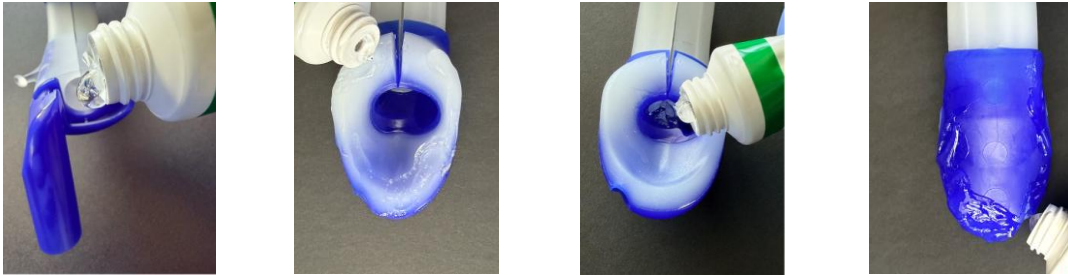
2. Verify compatibility with the selected ETT or IntroGard™ (7.0–8.0 mm) and gastric tube (16Fr or smaller).



3. Ensure all necessary equipment (e.g., laryngoscope, ETT, gastric tube, lubricant, ventilation device) is available.
4. Confirm that the user is trained in the combined use of SupraVent™, IntroGard™, and emergency airway management.

## Instructions for Use

1. **Lubricate the SupraVent™:** Generously lubricate all surfaces of the distal bowl of the SupraVent™, the proximal and distal ends of the intubation conduit as well as the valve area with a water-soluble lubricant to facilitate smooth insertion.

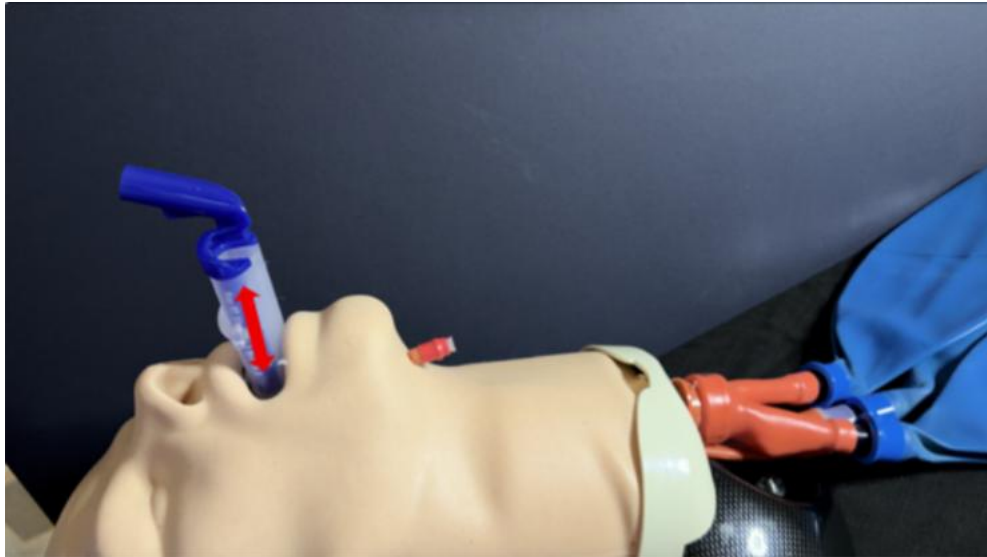


2. **Position the SupraVent™:** Open the patient's mouth and place the lubricated anterior open split bowl surface on the back of the tongue.



3. **Insert the SupraVent™:** Push the SupraVent™ into the patient's throat until resistance is met, ensuring proper supraglottic placement.

**Note:** You may advance or retract the SupraVent™ 1 to 2cm to optimize the seal and ventilation.



4. **Ventilate the Patient:** Connect a ventilation device to the SupraVent™ 15 mm connector and ventilate the patient. Ventilate through the SupraVent™ until the ETT is in place and ventilation is established through the ETT. Secure and tape the SupraVent™ onto the patient's upper lip or face using the 15 mm connector if desired.



5. **Insert Gastric Tube (if indicated):** Pass a 16Fr or smaller lubricated gastric tube into the gastric suction port as clinically indicated.



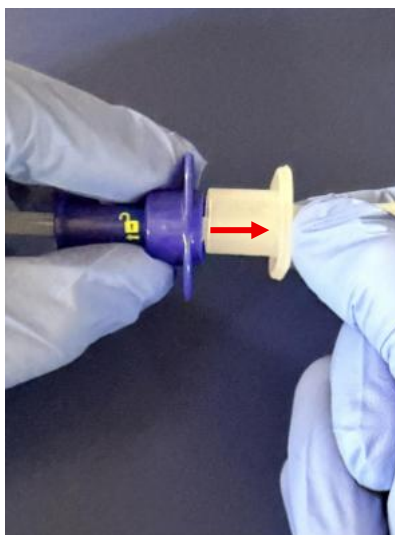
6. **Prepare the IntroGard™:** Generously lubricate the distal tip of the IntroGard™ with a water-soluble lubricant.



7. **Insert IntroGard™ into ETT:** Insert the IntroGard™ tip into the ETT (size 7.0–8.0 mm) via the 15mm connector on the proximal end of the ETT. (**Note:** Grip the distal end of the IntroGard™ upon initial insertion into the ETT to prevent unintentional bending).

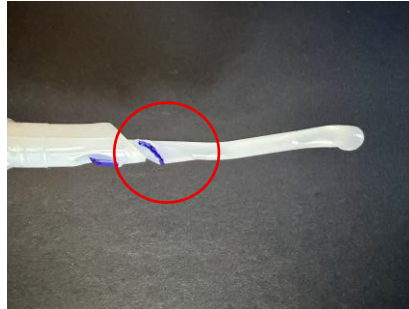


8. **Secure Coupler Cap:** Slide and secure the unlocked Coupler Cap onto the 15mm connector of the ETT.

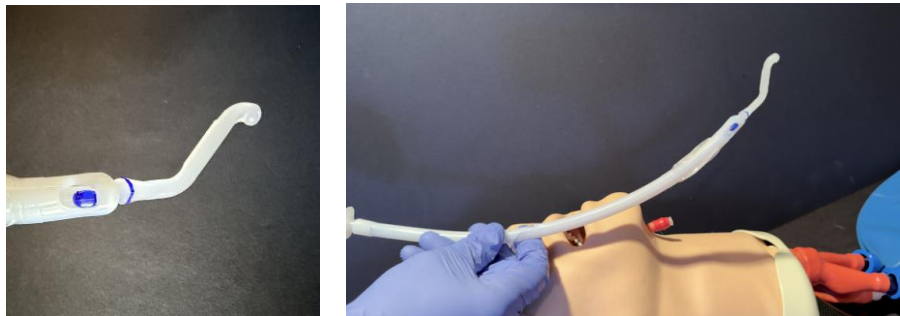


9. **Position IntroGard™ in ETT:** Adjust the IntroGard™ tip within the ETT so that:

- The proximal rim base of the Obturating Bumper Guard aligns with the distal tip of the ETT.



- The Murphy Plug is centered within the Murphy eye of the ETT.



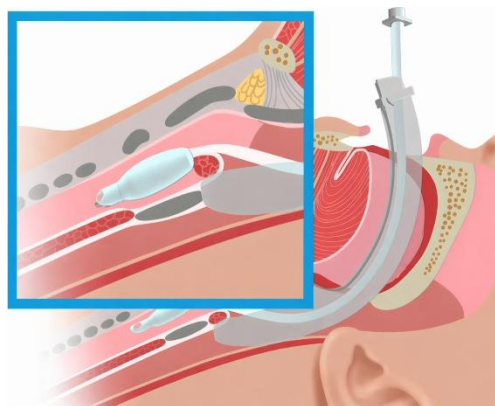
10. **Lock the IntroGard™:** Lock the IntroGard™ into position by pressing the top lock component into the Coupler Cap.



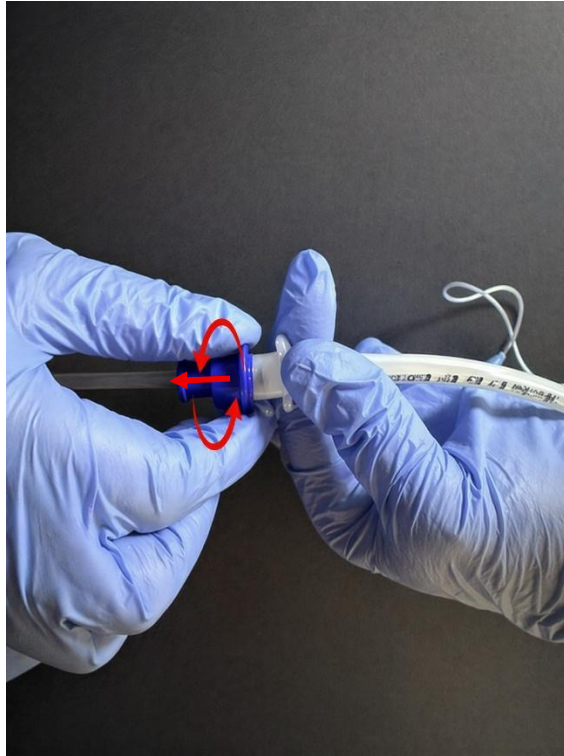
11. **Insert ETT/IntroGard™ Unit:** Pass the ETT/IntroGard™ unit into the SupraVent™'s Intubation Conduit until the ETT cuff is beneath the vocal cords, per clinician's judgment.



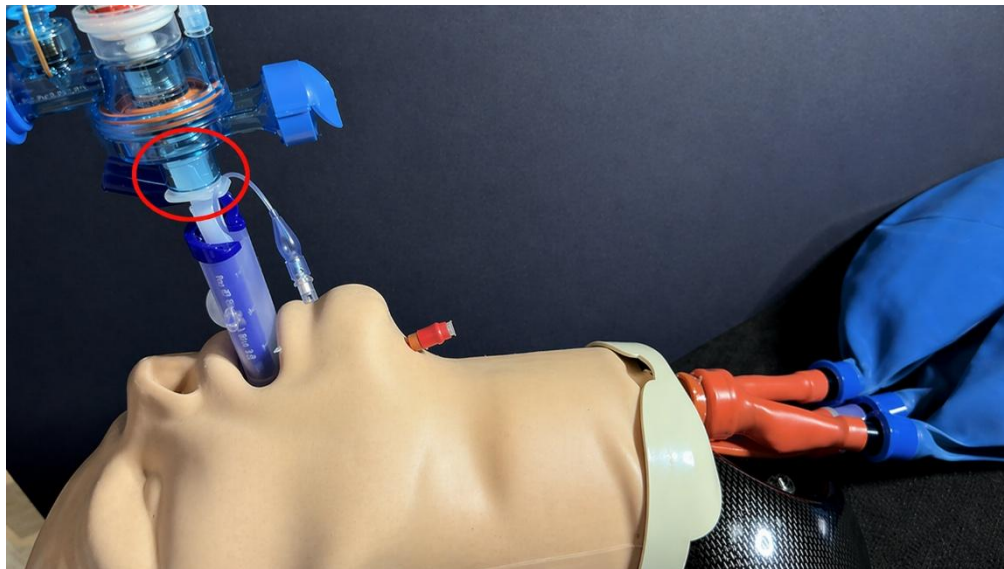
12. **ETT Cuff Inflation:** Once the ETT is in a satisfactory position, inflate its cuff.
13. **Confirm ETT Placement:** Significant resistance to ventilation through the SupraVent™ suggests proper ETT placement in the trachea.



14. **Remove IntroGard™:** Hold the ETT securely. Rotate the Coupler Cap to release and remove the IntroGard™ from the ETT.



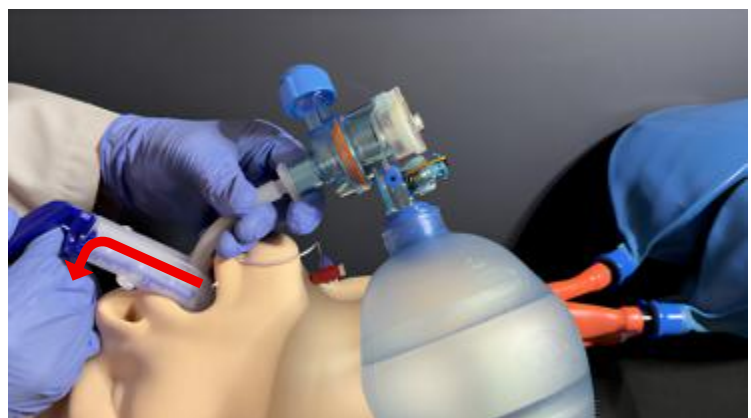
15. **Ventilate via ETT:** Begin ventilation through the ETT to confirm successful intubation.



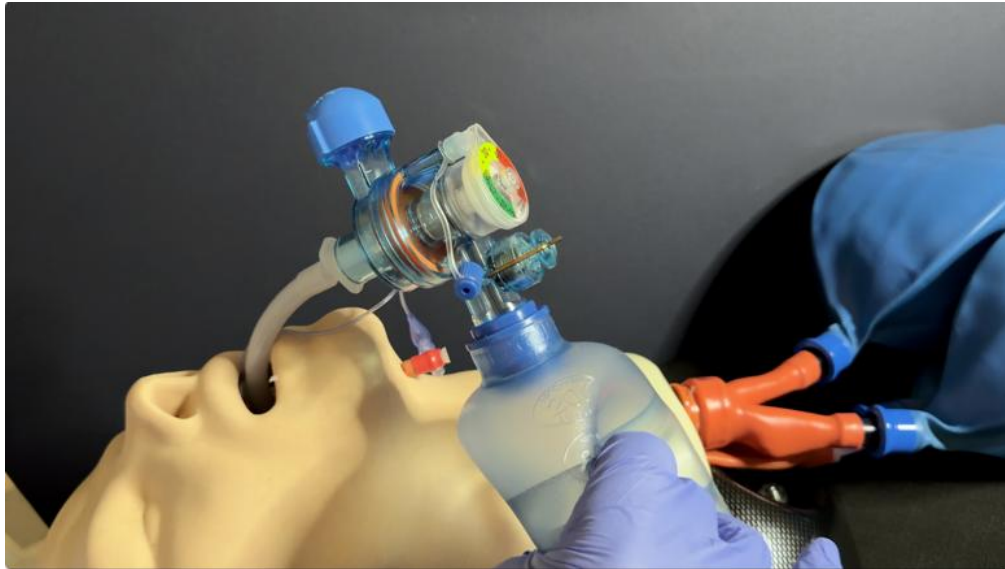
16. **Prepare for SupraVent™ Removal:** Pull the pilot cuff tubing forward through the split. Then push the ETT and its pilot cuff tubing forward through the split of the SupraVent™.



17. **Remove the SupraVent™:** Maintain a secure hold on the ETT at the patient's lower jaw. Remove the SupraVent™ by pulling upward and toward the patient's upper jaw using the device's connector, ensuring the ETT remains in place.



18. **Confirm Final Placement:** Verify ETT placement using standard clinical methods (e.g., capnography, chest rise, breath sounds).



19. **Secure ETT:** Secure the ETT to the patient to prevent dislodgement and continue ventilation.

### **Post-Procedure**

- Dispose of the SupraVent™ and IntroGard™ in accordance with local biohazard regulations.
- Monitor the patient for complications (e.g., hypoxia, airway tissue damage, gastric trauma).
- Document the procedure, including any issues or adverse events, in the patient's record and study survey.

### **Storage and Handling**

- Store both devices in a cool, dry place away from direct sunlight.
- Do not use if either device appears damaged or if the expiration date has passed.
- Handle with care to avoid damaging device components.

### **Contact Information**

For limited market release inquiries or to report adverse events, contact the coordinator provided by the medical device company, Gardner Medical Instruments. For general device information, refer to the company's limited market release documentation.

Gardner Medical Instruments  
7777 W. Lincoln Highway, Suite 1A  
Frankfort, IL 60423  
Email: [info@ventubationsystems.com](mailto:info@ventubationsystems.com)  
Website: [www.ventubationsystems.com](http://www.ventubationsystems.com)

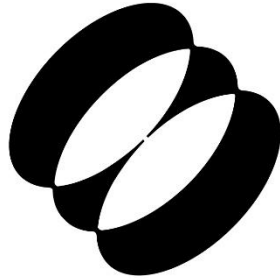
### Symbols for Packaging

Explanation of symbols on product or package labeling:

|                                                                                     |                                  |
|-------------------------------------------------------------------------------------|----------------------------------|
|    | Caution                          |
|   | Do not use if package is damaged |
|  | Single Use                       |
|  | Non-sterile                      |
|  | Temperature limit                |
|  | Humidity Limitations             |
|  | Manufacturer                     |
|  | Manufacture date                 |

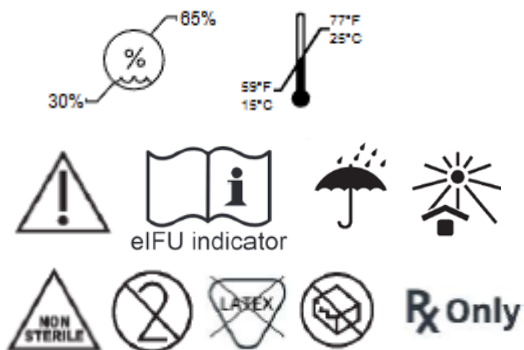
|                                                                                                      |                                                                                          |
|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|                     | Expiration Date                                                                          |
|                     | Batch Code (Lot Number)                                                                  |
|                     | Catalogue Number (Reference Number)                                                      |
|                     | Latex Free                                                                               |
|                     | Only be dispensed to or used under the supervision of a licensed healthcare practitioner |
|                     | Medical Device                                                                           |
| <br>eIFU indicator | Refer to Instructions for Use                                                            |
|                   | Keep away from sunlight                                                                  |
|                   | Keep Dry                                                                                 |





# Ventubation<sup>TM</sup>

## SYSTEMS



**Manufactured at an ISO 13485 certified facility for:**



Gardner Medical Instruments  
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Frankfort, IL 60423

Email: [info@ventubationsystems.com](mailto:info@ventubationsystems.com)  
[www.ventubationsystems.com](http://www.ventubationsystems.com)

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