

HAPIGuard

**Cap To Help Prevent
Hospital-Acquired Pressure
Injuries**

INSTRUCTIONS



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MEDICAL DEVICES

📍 3831 Turtle Creek Blvd., Unit 14F, Dallas Texas 75219. ☎ 1-800-972-8855

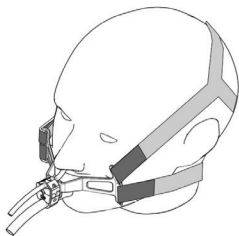
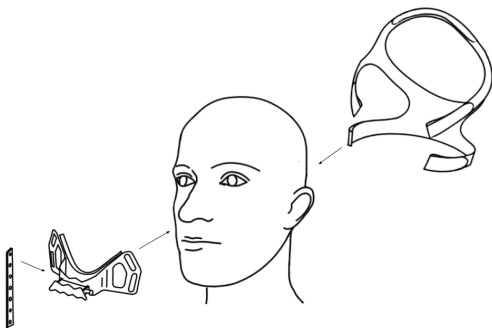
HapiGuard - Instructions

HapiGuard – Set up/Fitting Instructions

1. Remove the three separate components from the package (visual instructions below).
 - If there are any questions or concerns with setup or product quality, change HapiGuard or contact customer service.
 - Elastic Headband (A "B" will designate the back of the head.)
 - Endotracheal, Orogastric/Nasogastric Tube Harness (securement block)
 - Silicone strap
 - Attach the headband to the patient's head - use straps with Velcro to secure to the back of the neck and at the crown of the head.
2. The arrow designates the top and bottom position of the securement block.
3. Start from the back of the head and align the straps above and below the ear. Loop and secure the Velcro to the top and bottom of the securement block. Once all four straps are secured to the back of the neck, loop the strap at the crown of the head and secure the Velcro. Finally, adjust all straps for patient comfort.
4. Attach the endotracheal, orogastric/nasogastric tube harness by connecting the four openings on the harness to the four ends of the strap. The harness should be placed below the patient's nasal passage. It must sit above patient's mouth and lips.
5. Position the ETT at the bottom of the block groove and secure it with the elastic strap. Next, position the NGT in the top block groove and secure it with the rest of the elastic strap.
6. Attach the silicone strap via the silicone eye to the end attachment and wrap it around the ETT. Once wrapped, continue to connect it to the other end attachment. Wrap the strap once on top for NGT tubes and connect it again to the other end attachment.
7. Move the ETT regularly among the four inserts on the bottom grooves to prevent the ETT from staying on one part of the lips for more than 24 hours.
8. An NGT (above the harness, via the nare, nasal column) can be placed in the groove associated with the specific nare where the device is placed. This tube does not need to be moved unless it is no longer needed for the patient.
9. The OGT (below the harness, via the mouth) can be attached next to the ETT to secure both at the same time via the silicone strap to the harness.
10. If there are neuromonitoring devices attached to the head, the headband will have a separate component that allows it to go around the device.
11. Please use caution, or consult with a surgeon or physician regarding placement concerns prior to attachment.
12. Please see the detailed picture for further instructions on placement, or contact IMD or an IMD salesperson.

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If any manufacturing defect occurs with HapiGuard during its use, please contact
customer service. Regular clinical rounding must be performed to check skin
condition and integrity.

HAPIGuard - Description & Warnings

1. Description: Single-use patient care endotracheal tube and orogastric/nasogastric holder. This device comes with three separate components in the package. They are intended to work as one integrated unit which will safely and securely attach ETT and OGT/NGT tubes to minimize the risk of facial device-related Hospital Pressure related injuries.

2. Cautions: Please inspect product and package prior to use. Do not use product if packaging has been compromised.

3. Indication: To prevent Hospital Acquired Pressure device related Injuries and to securely and safely secure ETT and OG/ NG tubes to patient's face and head for those patients requiring airway support and enteral feeding.

4. Contraindications: HapiGuard should never be used for any other purpose than to attach and secure ETT and OG/NG tubes. HapiGuard strictly prohibits using the ETT or OG/NG for any other purpose than listed above.

Storage of HapiGuard should be between 60-75 degrees during storage and transport.

5. Warnings/ Precautions:

- Single use only, cleaning of devices is strictly prohibited by IMD or HapiGuard
- If there are any questions or concerns with set up or product quality, change HapiGuard or contact customer service.
- If instructions are not inside the shipping package, please contact Inventive Medical Device customer service.
- Each patient may have different lengths of time to wear HapiGuard. Do not exceed 5 days of use for any single guard/patient.
- Washing, cleaning, cutting or altering the mask with cleaning chemicals or instruments will affect HapiGuard function and will no longer be supported by IMD or HapiGuard.
- Please use caution in using external chemicals, gels, dyes or stringent hair products which will make the HapiGuard void of warranty.
- Any unauthorized use of HapiGuard will void the CAP warranty.
- HapiGuard will not be liable for any damages for defects that may be associated with ETT, OG or NG device malfunctions.
- HapiGuard will not be liable if product placed into use past indicated storage life, shown on product
- Only expert clinical judgment should be used when attaching HapiGuard to a patients face and head.
- Oil-based or petroleum lubricants should never be used with oxygen delivery devices or HapiGuard.

6. Adverse Reactions : The following Adverse reactions may occur with HapiGuard

- Skin Abrasion from moving product harshly against skin
- Overtight or incorrect sizing of HapiGuard
- Patients who are not alert or awake must be checked regularly to assess sizing and skin integrity.
- Clinical staff need to move the ETT and the OG/NG tube appropriately per IMD instructions.