Masks Manufactured By Philips Respironics - Updated Contraindications and Warnings

Philips Respironics, the manufacturer of masks used in the treatment of obstructive sleep apnea, has issued a Medical Device Recall in the form of a Field Safety Notice, to update its existing 'Contraindications' and 'Warnings' to the following:

Contraindication: *Use of the mask is contraindicated for patients and their household members, caregivers, and bed partners that may be in close vicinity to patients using the masks, that have implanted devices that may be affected by magnets, including but not limited to:*

- Pacemakers
- *Implantable cardioverter defibrillators (ICD)*
- Neurostimulators
- Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e. neck and head)
- *CSF (cerebral spinal fluid) shunts (e.g., VP (ventriculo peritoneal) shunt)*
- Aneurysm clips
- Embolic coils
- *Intracranial aneurysm intravascular flow disruption devices*
- Metallic cranial plates, screws, burr hole covers, and bone substitute devices
- Metallic splinters in the eye
- *Ocular implants (e.g., glaucoma implants, retinal implants)*
- Certain contact lenses with metal
- *Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)*
- Magnetic denture attachments
- Metallic gastrointestinal clips
- *Metallic stents (e.g., aneurysm, coronary, tracheobronchial, biliary)*
- *Implantable ports and pumps (e.g., insulin pumps)*
- Hypoglossal Nerve Stimulators
- Devices labeled as MR (magnetic resonance) unsafe
- *Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field*

1. I have been advised that the following Philips Respironics patient interface devices (face and nasal masks) - Amara View Minimal Contact Full-Face Mask, DreamWear Full Face Mask, DreamWisp Nasal Mask with Over the Nose Cushion, Wisp Nasal Masks, Wisp Youth Nasal Masks, and Therapy Mask 3100 NC/SP ("Affected Masks") - contain magnets.

2. I understand that the Affected Masks contain magnets which can potentially affect the functioning and/or induce the movement/dislocation of medical implants or medical devices that can be impacted by the magnetic fields.

3. I have been advised that if the mask magnets are placed less than 6 inches (approx. 15.24 cm) away from a metallic implant or device the magnets may cause the device to not perform as intended, which may result in a serious injury.

4. I understand that I should **STOP** using the affected mask, if the implant/medical device is contraindicated against the mask magnets. I should consult my physician or immediately to determine if another mask can be used for their therapy. In the interim, switch to a non-magnetic mask if available, for continued therapy.

5. I have been advised that household members, caregivers, and bed partners with a medical implant/device must ensure the mask is kept at least 6 inches (approx. 15.24 cm) away from the medical implant(s)/device(s).

6. I understand that I have no obligation to purchase a Philips Respironics mask and that I may select a mask other than one manufactured by Philips Respironics.

7. I have been advised that I can contact Philips Respironics customer service to learn more about non-magnetic mask options.

Patient's Signature: _____ Date signed: _____

Print name: _____

Witness: _____ Date signed: _____