

Philips Magnetic Masks Recall FAQ

1. Is Philips recalling more equipment?

The Food and Drug Administration (FDA) has declared a Class 1 recall on certain CPAP/BiPAP masks manufactured by Philips that use a specific type of magnetic connector or closure. The magnet closures can potentially affect implant devices and are contraindicated. These brand name masks are:

- Amara View Full-Face Mask
- DreamWisp Nasal Mask with Over-the-Nose Cushion
- DreamWear Full Face Mask
- Wisp and Wisp Youth Nasal Mask
- Therapy Mask 3100 NC/SP

2. Who is affected?

The patients currently using magnetic masks who are affected and considered contraindicated by this recall are identified below. The language is from the FDA-approved insert that update contraindications for the magnetic masks.

Contraindications

Use of the mask is contraindicated for patients and their household members, caregivers, and bed partners who may be in close vicinity to patients using the mask, who 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

Warning: Magnets with a magnetic field strength of 400 mT are used in the mask. With the exception

of the devices identified in the contraindication, ensure the mask is kept at least 6 inches (approx. 15.24 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This includes household members, caregivers, and bed partners that may be in close vicinity to patients that use the masks.

3. Can I continue to use my mask?

If you, a bed partner, or a caregiver do not have an implantable device identified as contraindicated, you can choose to continue using the magnetic mask. These masks are not being withdrawn from the market and are still available. Use of a magnetic 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

4. I have an implanted device and have been using my magnet mask (for whatever length of time) without any problems. Can I continue to use my mask?

Use of these magnetic masks are contraindicated for patients and their household members, caregivers, and bed partners that may be in close vicinity to patients using the masks, who have implanted devices that may be affected by magnets.

SuperCare Health follows FDA guidelines and recommendations, and will not provide a magnetic mask to patients who identify as falling within the contraindications. We will provide an alternate mask without magnets.

5. My doctor specifically prescribed this recalled mask. Or this recalled mask is the only mask that works for me. What should I do?

SuperCare Health follows FDA guidelines and recommendations, and will not provide a magnetic mask to patients who identify as falling within the contraindications. We will provide an alternate mask without magnets.

We will work with you and your physician to identify an alternate mask without magnets that best meets your needs.

6. What long-term side effects should I be aware of?

As a rule of thumb, you should ensure any magnet is kept at least 6 inches (approx. 15.24 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This includes household members, caregivers, and bed partners that may be in close vicinity to patients that use the masks.

If an implanted device is being affected by a magnet or localized magnetic field in close proximity, removing that magnet should enable the device to quickly return to normal operation.

7. How do I get a mask replacement?

If you are affected by the contraindications, you can call SuperCare Health at 877-797-5337 to get an alternate mask without magnets as a replacement.

8. Do I have to wait for my resupply eligibility to get a replacement mask?

You should contact SuperCare Health immediately for a replacement mask if you are affected by the recall. You do not need to wait for your eligibility window.

9. I just recently got a new mask through regular resupply? Do I still need to get a replacement mask?

You should contact SuperCare Health immediately for a replacement mask if you are affected by the recall and received a magnetic mask. Your resupply order was fulfilled prior to the recall notification and we apologize for any inconvenience.

10. Will early replacement affect my eligibility window for resupply? Will I have to wait extra months for new cushions or tubing?

If you receive a replacement mask for the magnetic mask, this will not affect your routine replacement schedule.

11. I need to use my CPAP to keep breathing. How long will it take to get a replacement mask?

SuperCare Health can ship your replacement for delivery within 2-3 business days.

12. What do I do with the recalled mask?

You can dispose of your mask without special precautions, as you normally would when you get resupplied with fresh items.