



URGENT Field Safety Notice

Sleepnet Corporation Masks with Magnets – Potential Magnetic Interference with Certain Medical Devices

Notification to Patients

Date: March 1, 2024
Reference: 2024-FSN-1

Dear Patient,

Please be advised that Sleepnet Corporation is updating the warnings and contraindications for our masks with magnets. It is important to read this notification carefully as it contains important safety information.

A contraindication means that you should not use the mask if the situation/condition applies to you.

Products Affected

All lot numbers of Sleepnet masks with magnets: Mojo Full Face Mask, Mojo 2 Full Face Mask, iQ 2 Nasal Mask, and Phantom 2 Nasal Mask.

Population Affected:

Patients, as well as their caregivers, bed partners, or anyone in close physical contact while using the mask, who have an active medical implant or metallic implant that can be impacted by the magnetic field.

Product Description

The masks provide an interface to deliver air between the patient and a positive airway pressure device such as a CPAP or bilevel device. The magnets in these masks provide a quick and easy method of attaching and detaching the mask from the headgear.

Description of Change

The existing contraindications and warnings are being revised as a proactive measure to provide additional safety information to patients and healthcare professionals. **Sleepnet has not received any reports of injury or adverse events related to the use of our products containing magnets.** This is a proactive step based on information obtained from post market surveillance indicating a possible risk to patients and anyone in close physical contact with the mask, having an active medical implant or metallic implant that can be impacted by the magnetic field.

New Contraindication

Do not use this mask if you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets. Implant examples include, but are not limited to, pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, aneurysm clips, metallic stents, ocular implants, insulin/infusion



pumps, cerebral spinal fluid (CSF) shunts, embolic coils, metallic splinter, implants to restore hearing or balance with implanted magnets (such as cochlear implants), flow disruption devices, contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, bone substitute device, magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher, etc. If you have any questions regarding the implant, consult your physician or the manufacturer of your implant.

Updated Warning

Magnets are used in the mask and headgear clips with a field strength of 380mT. With the exception of the devices identified in the contraindication, ensure that the mask is kept at least 6 inches (approx. 16 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 applies to you or anyone in close physical contact with the mask.

Patient Safety Information

The masks with magnets are safe to use when following the revised warning and contraindication.

When a magnet comes into close proximity to certain medical implants or metallic implants, it could interfere with the performance or the position of the implant. This could potentially lead to serious injury or death.

Sleepnet Corporation has been distributing masks with magnets since 2006 and has not received any reports of injury or potential injury relating to the magnets.

Products Affected

The images below show the affected masks and location of the magnets. The location of the magnets on the mask and on the headgear clips are circled.

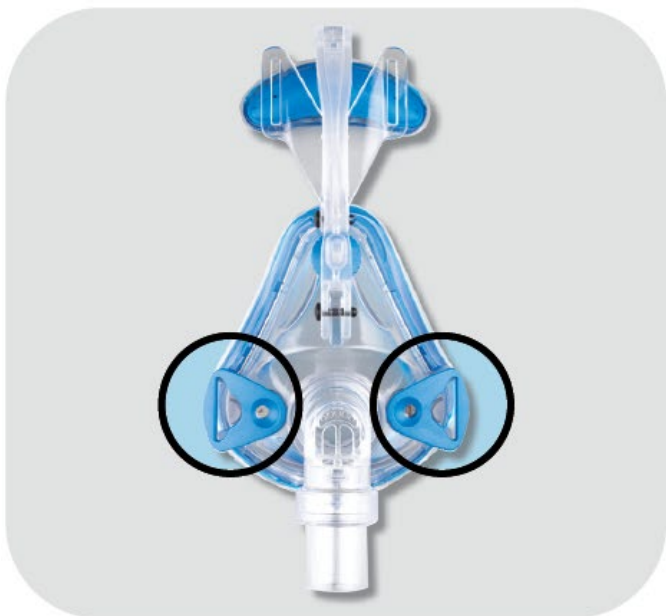
Phantom 2 Nasal Mask, part numbers 50182 and 50186 *Note: not all part numbers are available in all countries*



iQ 2 Nasal Mask, part numbers 50164 and 50169 *Note: not all part numbers are available in all countries*



Mojo Full Face Vented Mask and Mojo Full Face Non Vented Mask, part numbers 50835, 50836, 50837, 50838, 50920, 50921, 50922, 50923 *Note: not all part numbers are available in all countries*





Mojo 2 Full Face Vented Mask, Mojo 2 Full Face Non Vented Mask, and Mojo 2 Full Face AAV Non Vented Mask, part numbers 50817, 50818, 50819, 50820, 50912, 50913, 50914, 50915, 50941, 50942, 50943, 50944

Note: not all part numbers are available in all countries



All other Sleepnet Corporation masks do not contain magnets and are not affected.

Actions to be taken by Sleepnet Corporation

Sleepnet Corporation is updating the product warnings and contraindications as indicated for the affected mask products.

Actions to be taken by you

1. If you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets, contact your mask provider for a replacement mask that does not contain magnets.
2. Stop using the mask.
3. If you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask does **NOT** have an active medical implant or metallic implant that will interact with magnets, you do not need to do anything.
4. If you are unsure whether or not you should use your mask with magnets, consult your physician or the manufacturer of your implant.
5. Continue using masks according to the updated instructions and labeling if patients or people in close proximity to them do not have implanted metallic medical devices or metallic objects in the body.

Sincerely,

Jennifer Kennedy
Director of Regulatory and Quality