Another Recall Involving Philips Positive Airway Pressure Machines

Philips Respironics has recalled more than 17 million masks used with bilevel positive airway pressure and continuous positive airway pressure machines because they contain magnets that could affect a wide range of implanted metallic medical devices, resulting in injury or death, the FDA recently announced.

The Philips positive airway devices are also known as bilevel PAP, BiPAP, BPAP, or CPAP machines and are used by people with obstructive sleep apnea, respiratory insufficiency, or respiratory failure. The masks used with them feature magnetic headgear clips to keep them in place. The recall involves 5 mask types: the DreamWisp, DreamWear, Amara View, Wisp, and Wisp Youth masks.

Medical devices in patients—as well as in bed partners, caretakers, and others in close proximity to patients—that could be affected by the mask magnets include brain stents, embolic coils, aneurysm clips, pacemakers, implantable cardioverter-defibrillators, ventriculoperitoneal shunts, ocular implants, magnetic denture attachments, insulin pumps, certain neurostimulators used in and around the neck, cochlear implants, ocular implants, and any devices labeled as MR (magnetic resonance) unsafe, according to the FDA and Philips. The masks could also affect people who have metallic objects in their body, such as shrapnel, the FDA and Philips noted.

If neither patients nor the people in close proximity to them have metallic medical devices or metallic objects in their body, use can continue, a Philips statement noted.

As of early September, Philips had reported 14 serious injuries related to the use of the recalled masks, including arrhythmia, seizures, and irregular blood pressure, according to the FDA. Philips said it had received 16 reports of cases in which mask magnets might have affected medical devices, including defibrillators shutting off periodically, pacemaker interference, shunts that needed to be replaced, and cognitive issues related to the use of the recalled masks.

The FDA provided details about the mask recall in a letter to health care professionals. This was not the first recall involving the Philips positive airway pressure machines. A 2021 recall was due to the risk of polyester-based polyurethane foam, used to lessen the machines’ sounds and vibrations, breaking off and being inhaled or swallowed by users. The masks recalled because of the potentially dangerous magnets are used with some of the machines recalled because of the foam issue, the FDA said.

New Breast Implant Safety Concerns

Reports of squamous cell carcinomas and various lymphomas in scar tissue around breast implants spurred the FDA to issue a recent safety alert.

The risks appear to be rare, the agency said after conducting an initial review, noting that as of September 1, 2022, it had received 10 medical device reports about squamous cell carcinoma and 12 about various lymphomas related to breast implants that don’t necessarily represent unique cases. A preliminary review of the published literature revealed fewer than 20 cases of the former and fewer than 30 cases of the latter, the FDA said.

“Right now, we do not have enough information to say whether breast implants cause these cancers or if some implants pose higher risk than others,” according to a statement from the FDA, which is urging the reporting of any cases of squamous cell carcinomas, lymphomas, or any other cancers in the scar tissue, or capsule, around breast implants. “This is an emerging issue and our understanding is evolving,” according to the statement. Some reports involved patients presenting with swelling, pain, lumps, or skin changes who were diagnosed with cancer after years of having breast implants, the FDA said.

Still, health care professionals and people who have or are considering breast implants should be aware of these cases, according to the safety alert. People who have breast implants don’t need to change their routine medical care and, if they have no symptoms or signs of abnormal changes, shouldn’t remove the implants because of the safety alert.

The lymphomas that are the subject of the recent safety alert aren’t the same as breast implant–associated anaplastic large cell lymphoma, which the FDA began describing as a potential risk more than a decade ago.

According to one report, breast augmentation is the most common surgical procedure performed by plastic surgeons in the world, and in 2018, the US was the country in which the largest number were performed. That year, 17.3% of the nearly 1.9 million breast augmentations worldwide were performed in the US.

Partnership Focuses on Neurodegenerative Diseases

The 2 federal agencies are partnering with the Critical Path Institute (C-PATH)—an independent nonprofit, public-private partnership created in 2005 under the auspices of the FDA’s Critical Path Initiative program—on the Critical Path for Rare Neurodegenerative Diseases.

“There is a crucial need to develop new treatments that can improve and extend the lives of people diagnosed with rare neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS),” FDA Chief Medical Officer Hilary Marston, MD, MPH, noted in a statement.

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C-Path will convene experts, including patient communities and advocacy organizations, to discuss such topics as patient-focused drug development and use of the FDA-funded Rare Disease Cures Accelerator Data and Analytics Platform.

The Accelerating Access to Critical Therapies for ALS Act, signed by President Joe Biden on December 23, 2021, required the US Department of Health and Human Services, through the FDA and the NIH, to create the public-private partnership. The partnership is a key component of the FDA's Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis, which was announced in June.

ALS is a fatal disease that has no cure. In 2015, 16,583 people in the US were identified as having the disease, according to a 2018 report from the US Centers for Disease Control and Prevention.

~ Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.