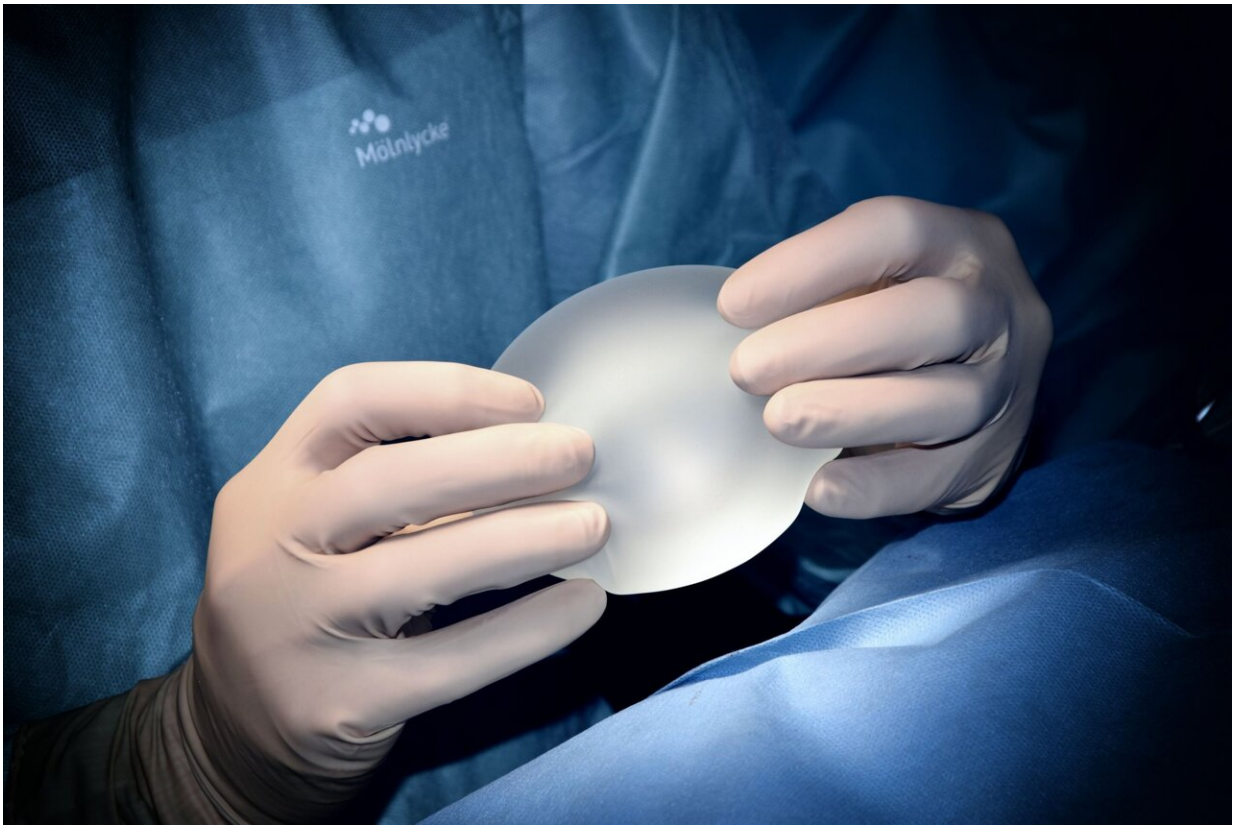


Explaining the 'black box' warning on breast implants

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Breast implants now come with a "black box" warning. What does that mean for the 300,000 patients who choose to have breast reconstruction after a mastectomy or breast augmentation for cosmetic reasons each

year?

We asked Keith Hood, MD, a plastic and reconstructive surgeon at Rush, to explain the warning and discuss the risks of [breast implants](#) based on the latest evidence.

What are black box warnings, and why do breast implant manufacturers now have to include them on their packaging?

The U.S. Food and Drug Administration requires some drugs and medical devices to carry black box warnings to alert [health care professionals](#) and consumers about serious risks associated with the products. As of last month, the FDA requires saline-filled and silicone gel-filled breast implants to include these warnings.

"The overarching goal of the guidance is to better inform patients about breast implants and breast [implant](#) surgery and improve communication between patients and their physicians," says Hood, who is also an assistant professor of plastic and [reconstructive surgery](#) at Rush University Medical Center.

Specifically, the FDA wants consumers to know the following about these devices:

- Breast implants don't last a lifetime.
- Complications can occur with breast implants, and the risks increase over time.
- Breast implants may be associated with a type of cancer and other symptoms.

To ensure that patients understand these risks, the FDA now requires all

surgeons to go over a checklist with their patients. "This is something that I've been doing for years, and I think any responsible physician goes over the risks with their patients," Hood says.

What type of cancer is associated with breast implants?

Breast implant-associated anaplastic large cell lymphoma, also known as BIA-ALCL, is a type of cancer of the immune system that occurs more often with textured implants, says Hood, who prefers using non-textured implants.

Although the [risk](#) of developing this cancer is low, it can be serious and lead to death, according to the FDA's guidance. This cancer can occur many years after surgery and may also be associated with fatigue, joint pain and other systemic symptoms that are sometimes described as "breast implant illness."

Patients who have textured implants can have them removed and replaced with non-textured implants—a surgery that Hood routinely performs for those concerned about BIA-ALCL.

Are certain patients more likely to have complications after getting breast implants?

Yes, patients with a higher risk for complications after breast implant surgery tend to be the same patients at higher risk for complications after any surgery, Hood says.

For example, you may have higher risks for complications if:

- You are a smoker or use nicotine.

- You have diabetes.
- You take medicines that weaken your immune system.
- You take blood thinners.

According to the FDA, you may also have a higher risk for poor outcomes if you are a cancer patient who requires chemotherapy or radiation therapy before or after breast surgery. Discussing these risks and your concerns with your surgeon is important to make the decision that is right for you, Hood says.

How long do breast implants last?

Many patients are surprised to learn that breast implants aren't meant to last a lifetime, Hood says. Over time, some people who have breast implants may develop painful scar tissue around their implants, a condition known as capsular contracture, Hood says. Other long-term risks include rupture of the implant.

"The longer that implants remain in the body, the greater the risk for complications, including capsular contracture or implant rupture," Hood says. He advises patients who have had implants to see their surgeon annually to screen for these complications. After five years, he recommends a magnetic resonance imaging (MRI) test to check the implants. After that, he suggests repeat MRIs every two to three years.

For many patients, implants may need to be removed and replaced after 10 or 20 years most commonly, Hood adds.

How should patients discuss these risks with their surgeon?

Patients choose to undergo [breast](#) implant surgery to improve their emotional and physical well-being, whether they are having a [breast](#)

[reconstruction](#) to help them feel whole again or pursuing [breast augmentation](#) to enhance their appearance.

Before having this procedure—or any type of [surgery](#)—Hood advises patients to seek out trusted sources of information like their surgeon.

"I always encourage [patients](#) to do their research and inform themselves as much as possible, and a big part of that involves talking to their surgeon about the risks, benefits and lifetime of implants," Hood says.

Provided by Rush University Medical Center

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