

## FDA calls for new warning labels on breast implants about scarring, pain, rupture and even a rare form of cancer

- Breast augmentations were the most popular cosmetic procedure performed in 2018 in the US, with more 313,000 operations
- The FDA has called for a boxed warning, the agency's most serious type, on breast implants
- The agency also wants a checklist for women to make sure they understand possible side effects such as scarring and even cancer
- Textured breast implants have been linked to ALCL, a rare form of cancer of the immune system, in more than 800 women, causing at least nine deaths

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Health officials want women getting breast implants to receive stronger warnings and more details about the possible risks and complications.

The Food and Drug Administration (FDA) said on Wednesday that manufacturers should add a boxed warning - the most serious type of warning - for women considering implants.

The agency is also recommending patients complete a checklist to make sure they understand all the possible side effects of the implants, including scarring, pain, rupture and even a rare form of cancer.

'We have heard from many women that they are not fully informed of the risks when considering breast implants,' the FDA said in a statement detailing the recommendations.

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On Wednesday, the US Food and Drug Administration called for breast implant manufacturers to add a boxed warning, warning women about potential risks and side effects. Pictured: A silicone gel breast implant

Dr Stuart Linder, a board-certified plastic surgeon based in Beverly Hills, California, told DailyMail.com that he thinks the warnings are beneficial.

'A patient cannot have too much information,' he said.

'The more informed patient, the better it is for the doctor ... and for the woman. This is an investment. We're investing in the body and health and cosmetic appearance.'

Breast augmentations were the most popular cosmetic procedure performed in 2018, with more 313,000 operations, according the American Society of Plastic Surgeons.

However, about one in five women who get implants for cosmetic reasons need to have them removed within eight to 10 years, according to the FDA.

The agency also wants companies to explain that breast implants often require repeat surgeries and they should not be considered lifelong devices.

'Having placed over 14,000 implants in my career, we explain pre-operatively to every patient that they will require another operation down the road,' Dr Linder said.

'The average is 10 to 12 years and it could be less. But we tell them that they will have to replaced them down the road.'

The FDA says it will take public comment on the proposed guidelines before adopting them.

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In 2017, the FDA linked textured breast implants to ALCL, a rare form of cancer of the immune system, which has killed at least nine people.

And, earlier this year, the agency said implants caused the same cancer in 457 American women, up from 414 cases in the previous report.

This led to the FDA calling on manufacturer Allergan to pull its Biocell implant in July.

The company issued a worldwide recall for the implants, which had already been restricted or removed from numerous countries, including the US.

In a separate issue, the FDA has received thousands of reports from women who blame their implants for a host of health problems including rheumatoid arthritis, chronic fatigue and muscle pain.

Currently, the FDA does not recognize so-called 'breast implant illness' as a diagnosis but, on its website, urges doctors to not dismiss patient concerns until 'much larger and longer' studies are conducted.

The FDA has stood by its longstanding position that the implants are essentially safe so long as women understand they can have complications.

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