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Breast Implants

Updated

November 2007

IT'S YOUR HEALTH

Breast Implants

The Issue

Breast implants are medical devices. Like all medical devices, they provide certain benefits, but also pose certain health risks. If you are considering breast implant surgery, it is very important to understand the nature and extent of these risks before you make a decision. The decision to choose breast implant surgery can only be made by you in consultation with your doctor.

Background

Before they can be offered for general sale in Canada, breast implants must have a medical device license from Health Canada. At present, two types of breast implants have the required license and are available for general sale in this country. They are:

- saline filled implants, and
- silicone gel-filled implants.

All makes and models of breast implants licensed for general sale in Canada have shells or envelopes that are made from silicone.

No medical device is 100% safe and effective. Health Canada's licensing of a medical device does not mean the

device is risk-free. Rather, it means the device has the potential to provide benefits, and the risks have been reduced as much as possible. The risks that remain are always explained in the labelling.

Before deciding on breast implant surgery, you should research the risks and consult a doctor so you can make an informed decision.

An Overview of Potential Risks Related to Breast Implants

Breast implants are not considered to be lifetime devices. Whether implant surgery is for the purpose of reconstruction or augmentation, you will likely need additional surgeries and visits to your surgeon over time. At some point, your implants will probably have to be removed, and you will have to decide whether or not to replace them.

In addition, most women with breast implants will experience complications of some kind. These can include pain, disfigurement and serious infections. Complications can also include a condition called capsular contracture – a tightening of the scar tissue, or capsule,

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that the body forms around breast implants.

There is also a chance that breast implants may rupture. It is easier to detect ruptures in saline-filled breast implants than in silicone gel-filled implants.

Before you decide to go forward with breast implant surgery, you should also consider the following:

- Many of the changes to the shape of the breast after implantation are irreversible.
- Removal of the implants may leave unacceptable dimpling, puckering, wrinkling or other cosmetic changes to the breast.
- Breast implants may affect your ability to produce milk for breast feeding.
- Breast implants make routine mammography screening more difficult.
- Breast implant surgery carries the same general risks as other surgical procedures. Check with your doctor for more information about the standard risks. All surgery, including breast implant surgery, has risk involved.

Some women believe breast implants cause systemic illnesses such as autoimmune disease or connective tissue disease. To date, there is no definite proof that this is the case.

Also, there have been suggestions that some of the materials in breast implants (e.g., platinum used in silicone gel-filled implants) are toxic and can dissolve out of the implant. There is no scientific evidence to support these suggestions, and all materials used in breast implants sold in Canada have been tested for toxicity.

Certain parties are trying to market test kits to measure levels of platinum or antibodies to silicone in women with breast implants. You should be aware that these kits are not licensed for sale in Canada, as there is no evidence they are effective.

Minimizing Your Risk

Before you decide to have breast implant surgery, you must consider all of the risks and weigh them against the potential benefits. At the end of this article, you will find a list of sources providing additional information about the potential risks of breast implants. Health Canada urges you to review this information and discuss any concerns in detail with your doctor before you make a decision.

In addition, all breast implants sold in Canada contain a patient labelling insert, which identifies all potential risks related to breast implant surgery. You should take the time to read it carefully before making your decision.

When you finish your research, give yourself a “cooling off” period of several weeks before you commit to surgery. If you decide to go ahead, you and your surgeon should both sign the “informed consent” form, and you should keep a copy for your records.

Health Canada’s Role

Health Canada’s role is to ensure medical devices are supported by comprehensive evidence demonstrating their safety and effectiveness before they can be marketed to Canadians. This is accomplished by a combination of pre-market review and post-market surveillance, as outlined in the

Medical Devices Regulations and the Food and Drugs Act.

The Regulations require manufacturers of all implanted medical devices to have evidence showing that the devices are safe, effective, and properly labelled before they are sold in Canada.

Need More Info?

Contact:

Medical Devices Bureau, Health Canada
150 Tunney’s Pasture Driveway,
P.L. 0301H1
Ottawa, ON K1A 0K9
email: mdb_enquiries@hc-sc.gc.ca

Health Canada has developed a series of questions you should review with your plastic surgeon. To obtain this list of questions go to:
www.hc-sc.gc.ca/iyh-vsv/med/questions_e.html

To determine if a medical device is licensed for sale in Canada, visit:
www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic_e.html



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Also, see the following scientific review articles, which discuss the potential risks associated with breast implants.

Mortality among Canadian Women with Cosmetic Breast Implants, P.J.

Villeneuve et al. *American Journal of Epidemiology* 164(4) 334-341 (2006).

Full text of this publication is available online at:

<http://aje.oxfordjournals.org/cgi/content/abstract/164/4/334>

Safety of Silicone Breast Implants, Institute of Medicine published by the National Academy Press, 2000. Full text of this publication is available online at

www.nap.edu/books/0309065321/html/

Silicone Gel-filled Breast Implants - Report of the Independent Review Group, 1998. This publication is available online at

www.silicone-review.gov.uk/

Consensus Declaration on Breast Implants June 23, 2000 by the European Committee on Quality Assurance and Medical Devices in Plastic Surgery.

www.secre.org/pdf/equam.pdf

For additional articles on health and safety issues go to the It's Your Health Web section at:

www.healthcanada.gc.ca/iyh

You can also call toll free at

1-866-225-0709

or TTY at 1-800-267-1245*

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