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.

An Overview of Potential Risks Related to Breast Implants

Research the risks before deciding on breast implant surgery so that you can make an informed decision.

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 include rupture, pain, disfigurement, serious infections, and a condition called capsular contracture. This is a tightening of the scar tissue, or capsule, that the body forms around breast 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 screening mammography 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.

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.

At the end of this document, you will find an extensive 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, prior to making a decision.

The History of the Breast Implant Controversy in Canada

Starting in the 1960s, silicone gel-filled and saline-filled breast implants were sold in Canada for both augmentation and reconstruction purposes. The first breast implants all had smooth surfaces and relatively thick shells.

A great number of changes have been made since the introduction of breast implants in 1962. Over the years manufacturers have altered the shell strength and composition, provided barrier layers to limit gel leakage,

modified valves used in saline implants and changed the thickness of the silicone gel used. These changes have been made with an aim to improve the safety and clinical performance of these devices.

In the past, scientific literature raised a number of concerns regarding possible systemic illnesses that might be associated with silicone gel-filled breast implants. On January 6, 1992, Health Canada asked manufacturers to stop the sale of these implants in Canada until further studies could be done. A similar decision was made in the United States, and silicone gel-filled breast implants were removed from general sale. Since then, a number of large studies and reviews have concluded that this was not the case. To date, there is no definite answer to this issue. The studies do, however, point out the need for women to understand the potential risks involved with breast implants. They also indicate a need for further studies to address other risks.

The Current Situation

Today, only saline-filled breast implants, with smooth or textured surfaces, are available for open sale in Canada. At this time, no manufacturer is licensed to sell silicone gel-filled breast implants in Canada. Doctors who wish to obtain silicone gel-filled implants for their patients on a case-by- case basis may apply in writing to Health Canada's Medical Devices Bureau. Each application is evaluated by Bureau staff before access is granted.

Minimizing Your Risks

Before you decide to have breast implant surgery, you must consider all of the risks, and weigh them against the potential benefits. When you finish your research, give yourself a "cooling off" period of several weeks before you commit to surgery. You and your surgeon should both sign the "informed consent" form, and you should keep a copy for your records. 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 a decision.

Health Canada's Role

Health Canada's role is to ensure that Canadians have access to medical devices that are safe and effective. 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 medical devices to have evidence showing that the devices are safe, effective, and properly labelled before they are sold in Canada. For certain categories of medical devices, the manufacturers are required to submit this evidence to Health Canada for a pre-market review.

Most implanted medical devices licensed for sale in Canada since 1983 have undergone this pre- market review for safety and effectiveness. However, provisions in the Medical Devices Regulations allowed devices sold prior to October 1982, including many breast implants, to stay on the market.

During pre-market review, Health Canada assesses the evidence submitted by manufacturers to ensure that it meets the eleven safety and effectiveness requirements contained in the Regulations. In the case of breast implants, the evidence must also meet requirements outlined in a Health Canada Guidance Document.

No medical device is 100% safe and effective. Health Canada's pre-market review and 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.

Need More Info?

Health Canada urges you to study the information contained in the resources listed here:

Considering the complexity of the above information, Health Canada hasdeveloped a series of questions you should review with your plastic-surgeon. To obtain this list of questions go to:
http://www.hc-sc.gc.ca/zenglish/iyh/medical/index.html
and click on Breast Implant Questionaire

To determine if a medical device is licensed for sale in Canada, visit:
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/meddev/mdlic_e.pdf

A number of scientific review articles have also been published, which discuss the potentials risks associated with breast implants:

- Safety of Silicone Breast Implants, Institute of Medicine published by the National Academy Press, 2000. Full text of this publication is available on-line at www.nap.edu
- Silicone Gel-filled Breast Implants - Report of the Independent Review Group, 1998. This publication is available on-line 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. http://www.secpre.org/pdf/equam.pdf