Health Canada Santé Canada

Canada

Ongoing Regulatory Actions and Activities - Breast Implants

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FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting
March 25-26, 2019

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Medical Devices Regulations

- Health Canada, under the authorities in *Food and Drugs Act* (FDA) and *Medical Devices Regulations* (*MDR*), regulates the sale and importation for sale of devices in Canada.
- Breast implants are regulated as Class IV medical devices.

Food and Drugs Act

https://laws-lois.justice.gc.ca/eng/acts/f-27/

Medical Devices Regulations

https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/

Currently Approved Breast Implants in Canada

ALLERGAN
- Textured (Biocell & Microcell)
- Smooth

MENTOR
- Textured (Siltex)
- Smooth

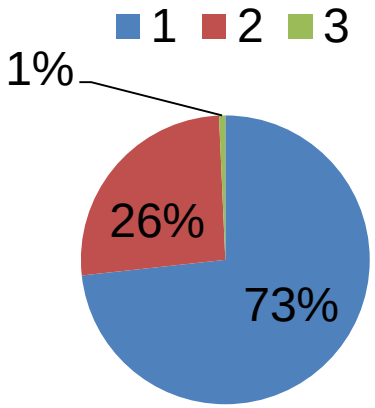
IDEAL IMPLANT
- Smooth

A detailed list of approved breast implants can be found on MDALL Database**:**
https://health-products.canada.ca/mdall-limh/

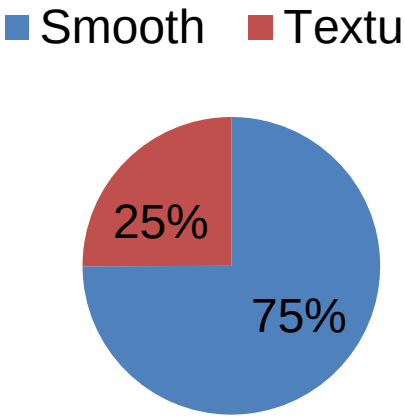
As of January 2019 a searchable online database of medical device incidents is also available:
https://hpr-rps.hres.ca/mdi_landing.php

Breast Implants
Market Profile in Canada (2007-2016)*

Breast Implant Sales - by Filler Type



Breast Implant Sales - by Surface Type



* Total sales (2007-2016): ~ 385 000

Pre-market Data Assessment

In addition to requirements laid out in "***Preparation of a Premarket Review Document for Breast Implant and Tissue Expander Device Licence Applications***" to confirm continued safety and effectiveness, conditions under Section 36 of the MDR require manufacturers to submit clinical data on an annual basis for:

- Connective Tissue Diseases and rheumatological signs and symptoms
- Diagnoses of cancers, including breast cancer
- Neurological disease among patients that had the breast implants
- Reproduction, offspring and lactation issues
- Data comparison between the breast implant patients and historical controls
- Beginning 2011, labelling updated to include Anaplastic Large Cell Lymphoma (ALCL) and to submit reports of all cases of BIA-ALCL)

Annual Clinical Safety and Effectiveness Follow-up data through 10-year for silicone gel-filled breast implants was communicated through Summary Basis of Decisions (SBDs) that are published on the Health Canada Website:

- https://hpr-rps.hres.ca/reg-content/summary-basis-decision.php

Post-market data assessment- BIA-ALCL

Safety assessment - 2016-2017

- Breast implant manufacturers provided marketing data and BIA-ALCL cases for the period 2007-2016
- 5 confirmed Canadian BIA-ALCL cases using WHO definition
- Etiologic theories and risk factors reviewed however a definite causal link could not be established
- Consulted with Canadian plastic surgery societies

Recommendations:

- Risk communication was issued to provide information on signs and symptoms, testing steps to recognise and diagnose BIA-ALCL and treatment options (consultation of clinical guidelines)
- Strengthen product labelling on risks associated with BIA-ALCL
- Conditions added to all breast implant licences regarding reporting of BIA-ALCL (including saline-filled breast implants)

FDA Panel discussion topics

- Safety concerns – BIA-ALCL
- Symptoms informally reported as “breast implant illness”
- MRI Imaging – Screening for silent rupture
- Registries
- Next steps

BIA-ALCL

Ongoing Assessment – 2018-2019

- Scope: Safety / effectiveness profile of various breast implant device types according to differential BIA-ALCL risk

- Triggers:
  - receipt of additional Canadian cases (next slide)
  - international developments (France, other)
  - newly available scientific and clinical data

- Ongoing consultation with Canadian plastic surgeon associations on the benefit-risk profile of textured breast implants

BIA-ALCL – Characteristics of Cases

		Confirmed Cases (28)	
		n	%
Age at time of diagnosis (yrs)	Mean	50.7	-
	Range	34-66	-
	Not Specified	15	54
Time from initial implant to diagnosis (yrs)	Average	9.0	-
	Median	8	-
	Range	3.6-33	-
	Not specified	3	11
Surface type	Textured	26	93
	Smooth	0	0
	Not specified	2	7
Fill type	Silicone	24	86
	Silicone with previous saline	3	11
	Saline	1	4
	Not specified	0	0
Notable outcomes	Metastasis	1	4
	Death	0	0
	Survived/ doing well	23	82

Health Canada – toxicity and systemic effects

- The potential for silicone gels found in breast implants to induce toxic effects was reviewed in the context of the silicone gel-filled breast implant applications prior to licensure and was also the subject of the Expert Advisory Panel reviews in Canada and the USA in 2005.

- The findings of these panels, literature and data reviewed determined breast implants to be safe and effective.

- Labelling and patient information was included to inform patients with regards to possible complications.

- Health Canada is currently planning:
    - Discussions regarding informed consent and communications to patients
    - A safety review of the peer-reviewed scientific data and incidents concerning “breast implant reported systemic symptoms”

MRI Imaging –Screening for Silent Rupture

- Different health care environments

- The 2005 Canadian Expert Advisory Panel on Silicone Gel-filled Breast Implants advised a six-step process for determining implant integrity should be related to clinical signs and symptoms:
  1. patient self-examination,
  2. new symptom or sign suspected,
  3. physician physical exam,
  4. ultrasound, mammogram or both,
  5. MRI if ultrasound is negative or inconclusive, and
  6. explantation of suspected implant in consultation with surgeon

- Since 2006 when the silicone gel-filled breast implants were approved, this six-step process was included in the Canadian labelling for all silicone gel-filled breast implants

Health Canada - Registries

- Previous attempts to establish a national breast implant registry federally in Canada have been unsuccessful.

- In 2006 when the silicone gel-filled breast implants were licensed, Health Canada requested the inclusion of implant registration cards in the package information to all patients receiving silicone gel-filled breast implants.

- Health Canada is currently again exploring the feasibility of a national breast implant registry with the Canadian stakeholders under the principles established by the International Collaboration of Breast Registry Activities (iCOBRA)

Next Steps

- Promotion of education among patients and within the physician and healthcare community is key to diagnosing, treating, and tracking cases of BIA-ALCL

- Reaching out to general practitioners, oncologists, radiologists, pathologists and other subspecialties

- Exploring consultation with external experts

THANK YOU