

Canada OK's silicone gel implants

23 October 2006

Canadian health officials have approved the use of silicone gel breast implants, 14 years after the government imposed a partial ban of the product.

Health Canada said it reviewed documents and British and U.S. studies before deciding silicone implants did not cause auto-immune diseases or other systemic illnesses, the Toronto Globe and Mail said. It was these concerns that initially led to the ban.

Licenses granted to Inamed Corp. and Mentor Medical Systems require them to provide data for at least 10 years from a clinical trial, the Globe and Mail said. The manufacturers also must conduct a long-term study of women for possible rare side effects when using the implants.

Plastic surgeons are wondering how much of an impact the new licenses will have, the newspaper said. During the moratorium, women could receive gel-filled implants through a Health Canada program that required doctors to certify suitable alternative procedures weren't available.

The safety of gel implants was questioned when a Canadian study reported a 73 percent higher rate of suicide among women with breast implants than the general population, the Globe and Mail said. In the United States, allegations arose that Mentor misrepresented safety data for its gel breast implants, the report said.

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