

WORLD

British Seek Data on Suspect Breast Implants



Jean-Paul Pelissier/Reuters

French officials searched Poly Implant Prothèse in La Seyne-sur-Mer as part of an inquiry into substandard breast implants.

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With the British government under increasing pressure to follow the French health authorities' recommendation to remove breast implants made with low-grade silicone, Health Secretary Andrew Lansley ordered British clinics on Wednesday to quickly report how many of the implants have ruptured or oozed.

"The question really comes down to the extent to which these implants fail relative to normal implants and the relative risks of their removal compared to the risk of having an operation." Mr. Lanslev told BBC radio.

Mr. Lansley was acknowledging that the British authorities did not have reliable statistics on ruptures or oozing of the implants, throwing into doubt the basis for their earlier recommendation that women with the implants in question not undergo "routine removal."

The French government recommended on Dec. 23 that the 30,000 Frenchwomen with the implants **have them removed**, citing a failure rate of around 5 percent, a figure they have since raised to about 5.5 percent, calling it unacceptably high. The silicone gel inside them causes inflammation.

British officials at the time cited their own finding that the failure rate among more than 40,000 British women was closer to 1 percent to support their recommendation against removal, an operation performed under general anesthesia that carries its own potential risks.

Nigel Mercer, a former president of the British Association of Aesthetic Plastic Surgeons, said the government lacked data on how many British women have implants that have ruptured. But he said the real issue was not the numbers, but the risk posed by the implants' use of industrial-grade, not surgical-grade, silicone.

"The British government is all hung up on the rupture rate, but that's missing the point," Dr. Mercer said. "It's what's inside the implants. It's not fit to be inside a human being."

The silicone gel inflames body tissues if it leaks, and the leaks also raised fears of a possible link to cancer. Health authorities around the world have issued statements saying no link has been found.

With British private clinics reportedly charging up to \$4,690 to remove the implants, the overall cost could be more than \$187 million for 40,000 patients, a burden the National Health Service is loath to bear.

The French government is paying the cost of removal for its citizens. The national health system estimated that it would cost about \$77 million to treat all 30,000 French patients.

Mr. Lansley, the British health secretary, acknowledged in a statement that "this is a worrying time" for women who have implants made by Poly Implant Prothèse - known as PIP - and he sought to place the responsibility for care on the doctors who implanted the devices.

More than 300,000 women outside **France** - mostly in Western Europe and Latin America - also received PIP implants. None are known to have been

Latin America - also received PIP implants. None are known to have been sold in the United States.

The French daily Le Monde reported on Tuesday that TÜV Rheinland, the German company responsible for assuring that PIP implants met European regulations, was being sued by distributors in Brazil, Bulgaria, Mexico, Thailand, Syria and Italy.

TÜV Rheinland said last week that it had been deliberately deceived by PIP, which used high-grade silicone when TÜV's inspectors were present and returned to the substandard product after they left. It said it filed a criminal complaint against PIP.

French officials are also turning up their scrutiny of Jean-Claude Mas, the founder of PIP. Mr. Mas, who is already the subject of a fraud investigation by Marseille prosecutors over the implants, was questioned on Monday by the French agency that deals with the safety of health products, French news media reported.