

Breast implant maker used non-approved gels: lawyer

27 December 2011

The founder of the French firm that made breast According to PIP's implants feared to be at risk of rupturing has exported 84 perce admitted using non-approved but non-toxic silicone 100,000 implants. gels, his lawyer said Tuesday.

Jean-Claude Mas's now-bankrupt company, Poly Implant Prosthese (PIP), was shut down and its products banned in April 2010 after it was revealed to have been using non-authorised silicone gel that caused abnormally high implant rupture rates.

Yves Haddad, a lawyer for the 72-year-old, said his client was at home in the south of France. Mas could not appear in public because of <u>poor health</u> and problems walking.

Haddad said Mas acknowledges using unapproved into the firm. silicon gel, but is adamant it is safe.

"PIP knew it wasn't in compliance, but it wasn't a toxic product," the lawyer said, adding it "had not been proven" the implants were any more likely to leak.

PIP used two types of silicone in its implants, Haddad said. One of them was an approved gel made by American firm Nusil, but it also used a homemade gel that was five times cheaper for the cash-strapped PIP, which filed for bankruptcy in 2010.

Haddad said the gel was chemically identical to Nusil.

In 2000, a representative from the US <u>Food and Drug Administration</u> visited PIP, Haddad said. Following the visit, PIP products were banned in the US.

Documents obtained by AFP showed tens of thousands of women in more than 65 countries, mainly in South America and western Europe, received implants produced by PIP. According to PIP's 2010 <u>bankruptcy filing</u>, it had exported 84 percent of its annual production of 100,000 implants.

France's <u>health ministry</u> has advised 30,000 women in France with PIP implants to have them removed, saying that while there is no proven <u>cancer risk</u>, the <u>prostheses</u> could rupture.

Any woman who declines the removal must have a breast scan every six months, the ministry added.

Prosecutors in Marseille, near PIP's home base of Seyne-sur-Mer, have received more than 2,000 complaints from Frenchwomen who received the implants, and have opened a criminal investigation into the firm.

Prosecutors have interviewed about 15 people in the case and a trial is expected next year for "aggravated deceit."

Mas was among the first to develop <u>breast implants</u> in France, initially producing saline-based prostheses, Haddad said.

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