

Unauthorised replacement hips fitted to 650 French patients

May 2 2013, by Elisabeth Zingg

French surgeons have fitted 650 people with replacement hips that had not been certified as meeting European standards, it emerged Thursday in a case with echoes of a scandal over faulty breast implants.

[Health officials](#) said there was no reason to believe that the non-certified [prosthetics](#) posed any health risk but the surgeons involved have been asked to carry out checks, including scans, on the patients concerned.

Pending the outcome of those, an investigation has been launched into the manufacturer, Ceraver, and around 1,000 of its artificial hips have been confiscated, the national agency for medicine safety (ANSM) said.

The safety agency is also studying claims that newly developed Ceraver metal pins that had not received official clearance were implanted into four patients without them knowing they were effectively taking part in an experiment.

Ceraver is France's second-biggest manufacturer of [artificial joints](#) with an output of around 3,000 prosthetic [ankles](#), hips, knees and shoulders a year.

In an ongoing trial, several executives of French company PIP are accused of producing breast implants with unauthorised industrial-grade [silicone gel](#) and fraudulently passing them off as having met European Union health [safety standards](#).

The implants, which were fitted to an estimated 300,000 women worldwide, were subsequently discovered to rupture twice as often as those made with medically approved gels.

The non-certified artificial [hips](#) were sold to around 60 French hospitals. None were exported and, to date, there have been no reports of problems with them, the ANSM's deputy director-general, Francois Hebert said.

The company's failure to abide by correct procedures was discovered during unannounced inspections of Ceraver's two production centres near Paris in early April following a tip-off from a whistle-blower.

The company's CEO-Chairman, Daniel Blanquaert, admitted in an interview with newspaper Le Parisien, which broke the story, that there had been irregularities in the labelling of the artificial joints.

"We are in the wrong," he told the paper. "But for us the modifications we made to the joints were minor and did not justify going through the whole certification process again, which would have taken one to two years."

Ceraver's metal pins, which are used to strengthen limbs following surgery to repair fractures, had an anti-bacterial coating which the company has spent many years developing, according to Blanquaert.

He told Le Parisien that the surgeon who had implanted the pins in four patients had been about to retire and had wanted to be the first to use them because he was confident they would come to be regarded as a breakthrough in medicine.

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