

A manufacturer promised “quality without compromise”. Instead he used industrial ingredients — and hundreds of thousands of women are at risk

THE GREAT FRENCH BREAST IMPLANTS SCANDAL



REUTERS/ERIC GAILLARD

FAULTY GOODS: A defective silicone gel breast implant manufactured by PIP after it was removed from a patient in a clinic in Nice late last year

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In March 2010, a pair of health inspectors acting on a tip paid a three-day visit to a factory in this hilly town on the Mediterranean coast.

The factory was the headquarters of Poly Implant Prothese (PIP), a leading international maker of breast implants founded by French entrepreneur Jean-Claude

Mas. The inspectors found something odd: six discarded plastic containers of Silopren, a liquid silicone designed for industrial, not medical use, lined up along the outside wall of the production site.

A week later, gendarmes descended on the plant. Mas skipped out just ahead of them, eluding interrogation for nearly eight months, but his game was up. In the nearly two years since, the cheap silicone used in PIP’s fake breasts has continued to leach into women’s bodies. In France, 1,262 of the roughly 300,000 breast implants the company sold



REUTERS/INTERPOL/HANDOUT

GAMBLER: Jean-Claude Mas as he appears on a “red notice” posted by Interpol after a driving offense in Costa Rica. His lawyer says he cut corners to save money



REUTERS/BENOIT TESSIER

RECONSTRUCTION: Paris-based plastic surgeon Isabelle Sarfati chose PIP implants for breast cancer survivors before stopping due to higher rupture rates.

worldwide have split open in the past two years. PIP has been closed down, Mas has been arrested and put under investigation for alleged bodily harm, and French and European safety regulators have been thrust into an uncomfortable spotlight.

Mas, 72, a grocer's son from the south of France, had no scientific training. Yet for the first decade of this century he was able to manufacture and sell faulty breast implants on international markets that he and some of his employees knew to be substandard, according to testimony given to French police and seen by Reuters.

The history of breast implants is littered with flawed devices, a colourful cast of intertwined players and billion-dollar lawsuits. Reuters reviewed hundreds of pages of police investigation transcripts and financial documents, and interviewed former PIP employees, the company's suppliers, customers and health experts, to piece together this latest chapter in that history.

It is a tale of a haphazardly run and cash-strapped company that allegedly took desperate and sometimes deceptive steps to shave costs and hide the true ingredients of its devices. PIP's efforts were made easier by a European regulatory regime that had been essentially outsourced to the very companies

“Maybe it’s shameful, but there you go. We live in a capitalist world.”

that are meant to be regulated.

Among the new details to emerge: PIP was able to save an estimated 1.2 million euros (\$1.6 million) in one year by using the industrial-grade silicone in its implants, according to figures cited by police investigators. And it relied on crude, unscientific tests of product quality, such as judging silicone gel by sticking a finger in it, according to one former worker. Some 75 percent of its implants used the non-approved, cheaper gel, Mas told police.

“Maybe it’s shameful, but there you go,” Yves Haddad, a lawyer who represents both Mas and his now-defunct company, told Reuters at the end of December. “We live in a capitalist world.”

Mas, who declined to comment for this story, has said his products are harmless. After the health ministry advised Frenchwomen to have the devices removed, he told French radio network RTL last month that the decision was “criminal” and the health minister “needs to be committed.”

A CAREER IN SALES

Jean-Claude Florent Mas, born in Tarbes, near the Spanish border, was a salesman by temperament. He sold everything from life insurance to wine and dental equipment. He entered health care in the mid-1960s, working for various labs, including one that was bought by Bristol-Myers in the 1970s, where he stayed until 1980 as a salesman in the south of France. Mas' attorney, Haddad, says his client was one of the firm's top salesmen, although Bristol-Myers could not confirm that or say why he left.

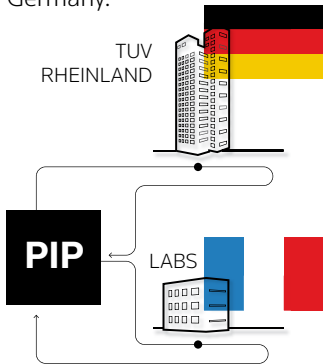
It was after Bristol-Myers that Mas got involved in breast implants. He began working with a French plastic surgeon, Henri Arion, who had made France's first breast implant in 1965, and was now selling saline implants under the name Simaplast.

It wasn't a great start. Simaplast's implants eventually were found to be prone to rupture, according to a 1999 study by U.S. non-profit Institute of Medicine. Simaplast morphed into a company named MAP - the precursor to PIP - where Mas said he performed every job from production to sweeping the floors. The small group of employees included a woman, Dominique Lucciardi, who would become Mas' companion and mother of his two children. They would take turns filling

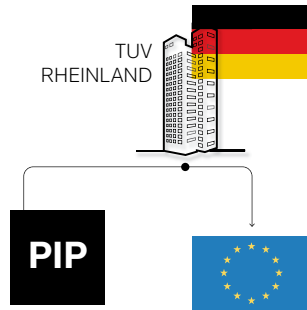
DANGEROUS LOOPHOLES

French police have arrested PIP boss Jean-Claude Mas for alleged bodily harm in a breast implant scandal. But some doctors, regulators and the medical devices industry itself say Europe's weak regulatory system is also at fault.

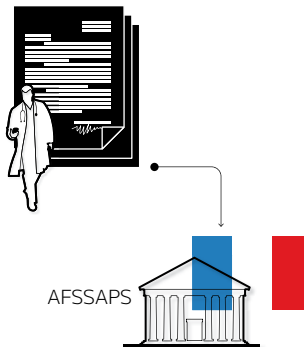
France has a medical regulator, AFSSAPS, but it doesn't vet new devices. European nations entrust that work to one of between 70 and 80 Notified Bodies in Europe. In PIP's case, it was TUV Rheinland of Germany.



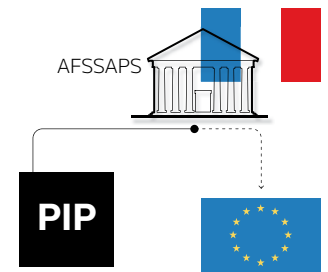
TUV Rheinland certifies the PIP breast implant for sale in the E.U. American regulators reject the device, but European sales continue for years.



Surgeons in France begin complaining to France's AFSSAPS about high rupture rates in PIP implants.



After an on-site inspection, AFSSAPS takes the product off the market in France and alerts other authorities.



AT ISSUE

TUV does minimal oversight. It merely reviews paperwork and test results submitted by the maker. PIP allegedly lied about its implant ingredients – including low-grade silicone.

the prostheses, he told police.

In 1991, aged 52, Mas launched PIP, a limited liability company and chose as its headquarters the site of the old Simaplast factory. In preparation, he had applied for a patent to sell implants containing silicone covered in polyurethane foam, he told police.

As he launched PIP, a breast implant scandal involving Dow Corning was sweeping across the United States. The American firm was found to have knowingly concealed safety concerns about its implants, and in 1992, the U.S. Food and Drug Administration called for a moratorium on the devices. Four years into PIP's life, in 1995, France also banned silicone in breast implants, a ban that ended in 2001.

Mas found that by innovating, he could still bring products to market. He switched to implants filled with saline solution and launched a pre-filled version; other brands needed to be filled while the patient was on the operating table. PIP's new product saved time, and surgeons liked it. PIP moved into the huge U.S. market in 1996, and soon the

United States made up 40 percent of its revenue, according to company records.

AN ASYMMETRIC APPROACH

Opportunities for PIP grew on its home turf in 2001, when France lifted its ban on silicone implants, and the United States slowly began to approve more versions containing silicone gel, for which Mas already had a formula. "When I started PIP I brought this formula that I had kept," he told police. "Why change it?"

Regulators had never examined nor approved that filler, but Mas insisted to his staff that it was perfectly safe, his employees told Reuters.

Building on his innovations in saline implants, in 2002 Mas brought a new twist to silicone by launching an asymmetrical product that became popular with surgeons and patients, because it gave a more natural look than the "classic" style of implant, which resembled a perfectly round orb.

PIP's approach to filling these implants was novel. On paper, the company said it used

NuSil, a silicone blend made by a California company of the same name, which can be used in medical applications, including implantable devices. NuSil was founded by PIP's former U.S. distributor, Donald McGhan, who is now in prison in Texas for an unrelated fraud conviction. The company has declined any comment on the PIP affair.

But in reality, PIP was mostly using Mas' own non-approved PIP gel, which looked and felt exactly like NuSil, but cost a seventh of the price.

A litre of NuSil cost about 35 euros, versus 5 euros for PIP's version, Thierry Brinon, PIP's former technology head in charge of research and development, told police. Each implant on average used 330 cubic centimetres of gel. That meant it cost 11.55 euros to fill an implant with NuSil and a mere 1.65 euros to use PIP's gel, a difference of 9.90 euros on each implant produced.

Claude Couty, the former chief financial officer of PIP, told police it cost an average total of 38 to 42 euros to manufacture an implant filled with PIP gel, versus 52 for an

implant filled with NuSil. Investigators in the legal case file estimated that in one year alone, 2009, using PIP gel instead of NuSil saved the company nearly 1.2 million euros.

PIP sold implants to French surgeons for about 300 euros a piece. Abroad, the asking price was about 100 euros, according to former PIP staff and surgeons.

"This formula is perfect," Mas told police. "It's better than the formula for making NuSil."

DECEIVING INSPECTORS

But because NuSil was a known quantity and his gel recipe was not, Mas concealed the implants' ingredients from the regulator. Flaws in Europe's regulatory system gave him a helping hand.

France has a government regulator, the Agence Francaise de Securite Sanitaire des Produits de Sante, or AFSSAPS, which has the power to remove products from the market but does not certify them. But the agency that certified PIP's implants was actually a private company, based in Germany. TUV Rheinland first approved PIP's saline implants in 1997. Its officials paid annual visits to the factory in La-Seyne-sur-Mer and announced them 10 days in advance, in accordance with European guidelines.

That gave PIP plenty of time to hide the truth. Ahead of TUV visits, workers would clear away evidence of the cheaper silicones PIP was using and put together a doctored version of documents that included no references to the use of unapproved silicone, Mas and ex-managers told police. All internal communications related to TUV's visits were oral, said one former worker.

"Since 1997, we automatically hid the products that allowed us to make the PIP gel," Mas told police, according to notes in the case file, "because I knew they weren't regulation." In his second police interview, Mas said he had given "the order to hide the truth from TUV" since 1993.

TUV sued PIP in February 2011, saying PIP had tarnished its reputation by using TUV's name to market sub-standard products and that it had been systematically misled.

A HELPFUL LOOPHOLE

There were other gaps in the regulations that helped PIP keep its products on the market for so long. The system does not require on-site, unannounced checks of the implants' contents. Nor does it require that the chemical composition of the implants, once approved, be re-tested.

A TUV spokesman said it would only have made an unannounced visit for checks if



RUPTURED: A PIP silicone gel implant after its removal from a patient

there were very serious indications that something was amiss. There have been no cases of unannounced checks in Germany in the past 40 years, he added.

Moreover, TUV's yearly audits are essentially audits of overall processes; they do not perform on-site lab tests. The German company believes PIP deliberately deceived it.

AFSSAPS said it tested the insides of PIP's implants in 2001 to make sure they were what PIP said they were when silicone breast implants were allowed back onto the French market.

After 2001, however, that job went to two independent French laboratories: LEMI, Laboratoire d'Evaluation des Materiels Implantables and LNE, Laboratoire National de Metrologie et d'Essais. Mas told police the laboratories performed tests in 2002 and 2008.

AFSSAPS' deputy director general, Francois Hebert, told Reuters these tests were likely ordered by PIP following requests from surgeons, who may have sent back defective implants and asked for further evaluation.

LNE said its tests were mechanical — how likely PIP's implants were to resist pressure, for instance — but declined to provide further information. LEMI said its tests related to toxicity, but also declined to provide further information.

The first random test by AFSSAPS would not come until mid-2010 by which time PIP was under investigation by police. That was when AFSSAPS issued a report which said, "this one does not reach the degree of quality of a silicone gel intended for breast implants."

This week, France's health department and



CANDID: Jean-Claude Mas' lawyer Yves Haddad says his client is worn out. "This is a businessman who has been around. I'm even surprised he's still here"

AFSSAPS submitted a report to the country's health minister acknowledging gaps in the French and European regulatory system. The report cited the lack of unannounced visits and on-site testing of implants but said that PIP's alleged fraud was so sophisticated that "it's not evident that an inspection, even an unannounced one, could have been effective."

NO QUESTIONS ASKED?

The raw silicone materials for the PIP-formula gel included different products: Silopren — which was kept in the containers that had been spotted by inspectors — and Baysilone. PIP bought these silicone oils from a German distributor, Brenntag. It turned to a French distributor, Gaches Chimie, for a third oil, Rhodorsil 47V1000.

Brenntag confirmed it sold silicone oils to PIP from 2001 to 2010, but said it stopped when it was made aware PIP was under investigation. A Brenntag spokesman,

Hubertus Spethmann, said that as far as Brenntag knew, PIP was a diversified supplier whose products included wound dressing pads and other padding products that could be filled with silicones such as the oils it produced. Brenntag would not comment on the orders PIP made or any payment problems with the French company.

Reuters could not independently confirm that these items were sold by PIP.

Representatives from Brenntag periodically asked to visit PIP's headquarters, according to one ex-PIP employee, a request that caused much worry within PIP. Brenntag would not comment on the visits.

On at least two occasions, Brenntag sales representatives paid a visit, but were welcomed by Mas in his office and did not visit the production labs, the former worker said this month.

"Mas would tell them we used the silicone oil for creams, certainly not breast implants," said the ex-worker. "We were very uncomfortable and let Mas do all the talking."

Gaches Chimie also confirmed it occasionally sold its silicone oil to PIP from the early 2000s until 2009, when the orders stopped. CEO Pierre Gaches said he did not believe his company was PIP's main supplier and never had concerns about the ultimate use of the oil, because it is used in many industrial applications.

NEW BMWs

Even as PIP used unapproved materials for its silicone implants, its innovative saline products were running into problems in the United States. Lawsuits from hundreds of patients alleged they deflated, sometimes within months of surgery. The FDA was never to approve PIP's silicone products, instead posting a warning about the firm's practices on its website.

Mas made a reverse takeover to try to open PIP to U.S. capital and prepare the way for a re-launch.

In 2003, his Luxembourg holding company Milo Finance bought a majority stake in U.S.-listed Heritage Worldwide, and handed to Heritage the control of PIP. In its first annual filing with the U.S. Securities and Exchange Commission after the merger, Heritage disclosed that for the financial year ended June 23, 2003, PIP had a loss of \$693,336. That loss grew to \$5.6 million in 2004.

PIP also turned to markets where regulation was not as stringent. It found distributors to open sales in 10 new countries "in which no regulatory problems were anticipated," Heritage said in its 2003 annual report.

Exports were less profitable - foreign sales fetched about a third of the French price - but there was volume in South America, which soon became PIP's top market with two-thirds of sales, driven by Venezuela and Colombia.

In 2005 and 2006, PIP showed a profit. One former employee said these were the "glory days" for the company, which employed about 120 workers. Operating margins reached 20 percent, the sort of level an early cellphone maker could expect.

"We'd see a smile on the face of Mr. Couty," said a former manager. One of those years, the company bought new BMWs for Couty and Mas, Couty told police. He did not respond to requests for an interview.

Mas, now at France's retirement age of 65, took on a chairman's "supervisory and advice-giving" role in 2004, for which he received 360,000 euros per year, a five-fold rise over his 2003 salary.

Finance chief Couty became CEO, but PIP's liquidator, Xavier Huertas, wrote in a March 2010 report that Mas continued to control production, R&D and sales, and "in fact, to lead the company at the side of Mr. Couty."

However, crisis was around the corner. Litigation and the financial shocks of 2008 were to send Mas back into PIP's labs, to try to improve on his "perfect" gel formula.

FRICION MOUNTS

Mas was never trained as a scientist. He was a tinkerer, an experimenter who relied on his gut. But even he was to realise that PIP gel had a problem: it leaked too much silicone oil.

Of seven former PIP staff interviewed by Reuters, only two said they had no idea that the company was using a homemade gel. Three others suggested they kept quiet because they were worried about their jobs.

After 2005, PIP staff became more vocal. That year, the heads of production, quality control and research and development together asked Mas to fill all PIP's implants with NuSil, Hannelore Font, the company's quality control director, told police. Mas replied this would be "economically impossible". Font did not return calls requesting an interview.

For 2008, PIP set aside 1.4 million euros to cover potential lawsuits, according to liquidation documents. It had underestimated. A British court ordered the company to pay 1.6 million euros to plaintiffs who alleged the envelopes covering PIP's implants were not strong enough and leaked gel. U.S. litigation cost another 160,000 euros.

"All this litigation weakened the health of the company," said Haddad, the attorney for PIP and Mas.



REUTERS/JEAN-PAUL PELISSIER

WRECKAGE: Nearly two years after PIP was shut down by regulators, squatters have defecated on the floor of its former offices, while boxes of implants strew the company's abandoned building near Toulon

Complaints rose, and PIP's customers paid more slowly. The liquidator noted that PIP's export clients on average took nearly nine months to settle.

Suppliers balked, too. NuSil held up a shipment destined for PIP due to non-payment, PIP's purchasing manager, Nadine Carrodano, told police. Couty wrote to Mas describing what he called his "fears for the future."

By June 30, 2009, PIP's debts reached 8.5 million euros. "In every area the company was crumbling," Carrodano told police. She declined to comment.

"FINGER IN THE GEL"

In 2008, PIP invested 300,000 euros on a new machine to make the implants' shells, hoping more uniformity would cut leakage, according to Couty.

Brinon, PIP's technical director, said Mas came to him in early 2008 and told him to start developing a new gel, PIP 2. Brinon refused, and the task went instead to another worker who had never worked on implants before coming to PIP. The goal, he said, was to create a gel that would not leak so much oil. This was crucial: silicone gel that seeps out may cause irritation and inflammation in women's bodies.

That worker told Reuters that Mas relied on trial and error, adding a bit of this and a bit of that in the lab: "He didn't do scientific tests," the former worker said. "He'd look and say, 'that's good, that's bad.'"

To judge whether more or less oil was seeping out of the gel, the worker said, "you would look and then put your finger in the gel

and you'd see if there was oil or not on your finger."

Finally, midway through 2008, PIP 2 was ready.

Brinon was sceptical. His own mother, who had once had cancer, had a PIP implant and he was worried, he told police. He began doing his own tests on PIP gel and NuSil. He told police that PIP 1 gel excreted more oil than PIP 2, and much more than NuSil, which leaked oil in "infinitesimal amounts."

A FINAL THUMBS-UP

Mas threw himself into export sales. His passport, a copy of which is included in police documents, shows visits to Panama, Venezuela, Colombia, Brazil, Uruguay, Ecuador, China, Singapore and the Philippines in 2008 and 2009.

Back at home, staff morale was low.

On May 4, 2009, a commerce court in the city of Toulon ordered PIP into the French equivalent of Chapter 11 proceedings.

About a dozen employees were laid off, month-to-month workers' contracts were cut and evening shifts scaled back, according to liquidation documents.

Font, the quality-control staffer, told police she delivered an ultimatum to Mas at a meeting with other managers, saying she would no longer sign off on implants ready to be shipped. Instead, Couty took that on.

TUV performed an audit in early 2010. Purchasing manager Carrodano told police she was "close to tears" after TUV gave PIP the thumbs-up. Font got a doctor to sign a medical release to keep her away from work. Unpaid suppliers stopped sending raw materials; production ground to a halt.

"FRAGILE PEOPLE"

On March 16, 2010, AFSSAPS officials came calling, a visit that had been arranged five days in advance. AFSSAPS had recently received letters from a Marseille surgeon signalling his concerns with PIP rupture rates. The regulator also received in the mail photos sent anonymously of empty containers of non-approved raw materials at PIP's plant.

On the first day of their visit, inspectors noticed nothing abnormal. The following morning, without telling PIP, they visited PIP's production facility. It was then they spotted the empty containers labeled "Silop,"



REUTERS/JEAN-PAUL PELUSSIER

VACANT LOT: The gates to PIP's former production site in La Seyne-sur-Mer have been welded shut following the factory's closure

for Silopren. The lead inspector estimated they had contained nearly 9 tonnes of the liquid silicone.

Days later, when police visited the site, Mas slipped out quickly. When French police finally managed to question him in November, they asked why he had left in such a hurry. According to a police transcript of the interview, he said he was no longer in charge of the company - he had handed the reins to his finance director years back. "I thought it wasn't me you were coming to see..."

Within two weeks of the regulators' visit, PIP was shut down and AFSSAPS pulled its implants from the market. Some 29,000 products were seized. Laid-off staff burned tyres and hurled discarded implants into the car park.

Mas went abroad again. Costa Rica, Nicaragua, Columbia, Spain and Venezuela are among visits his passport records in 2010. In Costa Rica, he was pulled over and charged with drunk driving.

On Sept. 27, 2010, Mas transferred his ownership of a real estate holding company to his partner Lucciardi and their son, according to Luxembourg filing documents. That company holds the title to a four-bedroom villa with a pool not far from PIP's headquarters.

It was here police arrested Mas in January. The

home, according to estate agents, is currently listed for sale at about 1.6 million euros.

In their questioning of Mas in October 2011, he told police that over the years, 75 percent of PIP's implants were filled with his homemade formula. The French regulator says there are so far 1,262 cases of the devices rupturing in France. Health experts say no concrete link has been shown between PIP implants and breast cancer, but the French government has advised women to have their PIP implants removed.

Mas, who is out on bail, was asked by police what he thought of the women who issued complaints about the failed devices.

"It's about fragile people, or people who are doing it for the money," he said, according to the interview transcript.

(Alexandria Sage reported from Paris, Natalie Huet from La-Seyne-sur-Mer and Jean-Francois Rosnoble from Marseille; additional reporting by Marc Joanny in La-Seyne-sur-Mer, Elena Berton in Paris, and Ludwig Burger and Maria Sheahan in Frankfurt; writing by Alexandria Sage; Editing by Sara Ledwith and Simon Robinson)

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