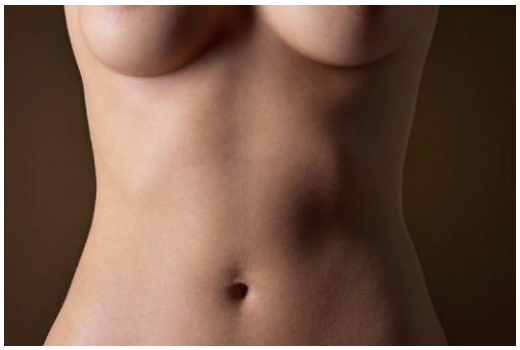
Feature Article

"Half a pound of industrial silicone, Half a pound of greed. That's the way the money goes, PIP goes the scandal!"



Breast implants have a history going back fifty years to the early 1960s when the first of their kind underwent medical trials and were pioneered by two Texan plastic surgeons. Over time, both silicone and saline filled varieties (and a brief foray into soya bean oil) have been developed, trialled and improved upon with much controversy along the way.

In 1990 silicone breast implants hit the news with reports from some women claiming that their implants were seriously affecting their health; this sparked widespread debate and media publicity at the time, both in the USA and the UK. Then, in 1991, American implant manufacturer Dow Corning lost a multi-million dollar lawsuit based on claims that its silicone implants were the cause of a plaintiff's autoimmune disease.

Shortly afterwards, in January 1992, the U.S. Food and Drug Administration (FDA) issued an outright ban on the use of silicone gel filled implants for cosmetic augmentation. At the time many claimed this to be a hasty decision, based more on political and social pressure than on scientific proof and evidential data, with many feeling eventually vindicated when the ban was subsequently lifted 14 years later in 2006. A similar ban was imposed by the French authorities between 1995 and 2001. During this time however no such ban existed for silicone breast implants in the UK.

Roll on to March 2010 and twenty years later silicone breast implants are catapulted to the top of the news headlines once again. This time it's not a blanket implant problem, but the murky story that is emerging around French made PIP or Poly Implant Prothèse implants which were found to be being manufactured using industrial grade silicone for upwards of a decade apparently unbeknown to the authorities.

So, there's the criminal who made them, the CE marking authority who approved them and failed to spot a problem in years of inspecting, the UK regulators who did no further checks of their own, the private clinics (and NHS) who used them in good faith, perhaps naively or perhaps motivated by profit and cost savings, and the consumers who 'bought' them none the wiser but now resent the 'ticking time bombs' inside their chests. Let's look at the events that have unfolded, the plans going forward and the lessons that can be learnt.

Poly Implant Prothèse – A Company History

Poly Implant Prothèse or PIP was a French company founded by businessman and former medical sales rep Jean-Claude Mas with a manufacturing base in Seyne-sur-Mer, a small town between Marseille and Nice in the South of France. They began business in 1991 and started selling hydrogel breast implants in 1994. It was in 1997 that they were authorised to then produce implants containing a medical grade silicone gel (NuSil) but had few places to sell them to due to the various bans, so focused their business very much on the saline implant market.

Attempts were made to break into the lucrative US market with sales of saline filled implants starting in 1996 (said to be worth 40% of the company's then revenue) and a distribution partnership with Donald McGhan and his then company Medicor Ltd in 1999. McGhan, although considered a pioneer within the implant industry dating back to his work with Dow Corning and McGhan Medical Corp (later merged with Inamed, eventually becoming part of Allergan), also has a history of legal troubles relating to fraud and false accounting to his credentials, along with a current prison sentence; an interesting choice of distribution partner therefore for Mr. Mas. If you want to read more about Donald McGhan and his relationship with PIP, this **story** makes an interesting read.

In March 2000 the US FDA conducted a new review of the PIP saline filled implants and refused to approve them, noting that there wasn't enough data to prove that they were safe; 3 months later the FDA also warned of 11 deviations from good manufacturing practices at the PIP manufacturing plant in France following a visit, and determined their products to be 'adulterated'.

Many surgeons at the time reported on the deflation rates of the saline filled implants being excessively high compared to other products, thought to be most likely due to a poor quality membrane surrounding the saline. Later clinical data showed this failure rate: ***A comparison of 500 prefilled textured saline breast implants versus 500 standard textured saline breast implants: is there a difference in deflation rates?,*** Stevens WG,et al.2006.

In the December of 2000, PIP withdrew its original hydrogel implants as it was also unable to prove their safety; stocks were recalled in the UK by regulators but no checks were offered to women who had received them.

With the lifting of the ban on silicone implants in their home country, France, in 2001, PIP is now known to have embarked on the fraud and started using industrial grade silicone gel in their breast implants (unbeknown to their supplier who was not aware of its planned use in products for humans) instead of their previously approved medical grade content. These were then sold around the globe.

The French Society of Plastic, Reconstructive and Aesthetic Surgery (SOFCPRE) was later able to reveal that from 2005 onwards the company also dispensed with a protective barrier which normally surrounds an implant to offer strength and reduce the migration risk of the gel.

This fact is concurred by observations from Adrian Richards, plastic surgeon and Medical Director of **Aurora Clinics** who noted that; “PIP implants are more likely to rupture and have a higher rate of gel bleed than other normal implants. We feel that this is likely to be because the silicone shell may be missing the barrier layer to silicone (i.e. they seem to have fewer layers in their shell than other implants); this allows the silicone gel to bleed through the shell.”

At the end of March 2010, the French medical regulatory authority (AFSSAPS) informed our own MHRA (Medicines and Healthcare products Regulatory Agency) that it had suspended the marketing, distribution, export and use of the silicone gel filled PIP breast implants after it found on inspection that breast implants made by the company since 2001 had been filled with a silicone gel with a composition different from that used to obtain their original European CE Mark approval, making them illegal. The French authority recalled all of these devices at that point and the company was closed down.

Further, recent tests on samples of the silicone gel have shown it to contain Baysilone, Silopren and Rhodorsil, components which are normally used as fuel additives or in the manufacture of industrial rubber tubing; a far cry from anything medical that’s for sure. Speculation has also stated that the PIP silicone was similar to that used in the production of mattresses, but a recent expert report noted that the composition of silicone used by PIP during the period of manufacture concerned is not wholly certain.

Contemporary silicone breast implants contain a cohesive gel in which the polymer is cross linked and the gel form is stable. This cohesive characteristic of the gel reduces the risks associated with rupture as the gel is “held together” and is less likely to migrate into the breast tissues or the lymphatic system; one marketing term has referred to this characteristic before as like the ‘gummy bear’ children’s jelly sweet.


A Mentor Cohesive Silicone Gel Implant Cut Open

It appears that the gel within the adulterated PIP breast implants is significantly less cohesive than other contemporary implants. The implications of this include a greater tendency to interface with the local tissue and a greater potential to generate an inflammatory response. There is also some data supporting an increased risk of in-vivo transdermal irritation from PIP implants. Anecdotal evidence has been reported by cosmetic and plastic surgeon associations that, when a PIP implant ruptures, silicone gel is more widely dispersed in surrounding tissue and the resulting explantation is more difficult and more involved.

Surgeon Adrian Richards, who has been performing explantation operations has recorded data on the implants, noting early results of approximately 30% complete rupture, a 60% significant gel bleed and 10% normal, intact implants. He concluded; “From our results we feel that due to the questionable quality of the implant shell and contents that all patients should consider having their PIP implants removed.” Adrian discusses his findings and data gathering, including gathering serial numbers from PIP explantation in the following video.

[SPACE FOR VIDEO EMBED]
http://www.aurora-clinics.co.uk/video.html?type=iv&procedure=breast_implantremoval&page_id=4085&start=0

Two other surgeons, Jan Stanek and Miles Berry performed an audit of 453 patients and concluded that PIP implants exhibited a failure rate of between 16% and 34%, compared with a failure rate of 0.9% against other implant brands used by them.

The Criminal Element

So why would a company risk endangering life by manufacturing something destined for implantation into a human being which had in no way been tested for such use? And why were they allowed to get away with it for so long?

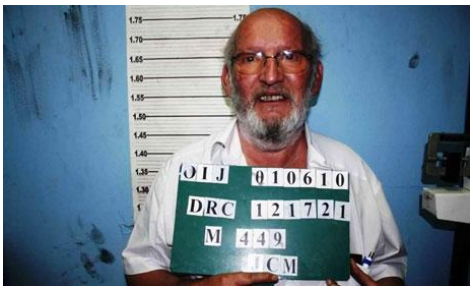
In police interviews carried out in the Autumn of 2011, PIP Technical Director, Thierry Brinon said "the sole motivation was to significantly increase the company's profitability. Thus in 2009, the price of PIP gel (industrial grade) was €5 per litre compared to €35 for the NuSil gel (medical grade), meaning the company gained €1,000,000 per 100,000 implants".

Boss, Mr. Mas admitted in the same round of police interviews that he had successfully deceived German CE Mark inspectors for well over a decade by ordering employees, as early as 1993, to hide unauthorised silicone upon the scheduled visits to the factory by said inspectors. With a 10 day advanced warning for inspections this apparently became an easy routine.

"I gave the order to hide all documents relating to uncertified PIP gel and, regarding containers (where the gel was kept), staff did what was needed to make them disappear. We did it for 13 years without any problems"; said the unashamed Frenchman. He estimated that 75% of the implants they made were with the unapproved silicone gel and approximately 25% with the approved NuSil gel. It's likely that no one will ever know which batches of implants are which.

Already facing charges of fraud in France (trial this October), it was reported that Jean-Claude Mas had been named as a 'consultant' in a business plan registered by his son and daughter in June 2011 which intended to restart the manufacture of breast implants at the original PIP factory under a new company name, France Implant Technologie, a plan which is now believed to have collapsed, thankfully.

Former PIP employees have also testified that in more recent years the company also made male implants, such as chest/pectoral, buttock and testicular implants which most likely also contain the same grade of industrial silicone; a whole new scandal waiting to blow up!



Source: Interpol

In January 2012, 72 year old Jean-Claude Mas was arrested at his home in Marseille, along with the former chief executive of the company, Claude Couty, both were bailed and now face charges (along with the fraud case) of involuntary injury, a lesser charge than the predicted involuntary manslaughter charge but one which would still carry a jail sentence. A trial date for the injury charge could however be several years away as the investigation is likely to be lengthy.

The Initial Fall Out

Globally more than 300,000 PIP breast implants are believed to have been sold to 65 countries over the last 12 years, more than half of those went to South America.

The attraction for many clinics was the cost differential in relation to other brands. PIP implants were said to cost around £50 a pair, compare that to other examples such as Nagor products coming in at between £330 - £500 and Allergan products at between £200 (CUI) and £400 (Natrelle) and it's easy to see the appeal of PIP. Although many have argued this was a warning in itself as cheap doesn't always amount to cheerful!

In the UK it is estimated to affect some 40,000 women. PIP implants were also sold to a now bankrupt Dutch company and rebranded at Rofil-Medro or Rofil-M implants (designated as batches IMGHC-TX, MX-IMGHC, and IMGHC-LS), estimated to affect a further 5,000 UK women. Additionally, many Brits who chose to go abroad for cheaper surgery to countries such as Belgium, Hungary, Poland and the Czech Republic may also have received implants by one name or another and be unaware of it.

In late January it also came to light that a former German company, GfE Medizintechnik GmbH sold breast implants that were manufactured using PIP components. From September 2003 to August 2004, 728 implants were produced and sold under the brand name TiBREEZE. Apparently these silicone implants were coated by GfE Medizintechnik GmbH with a titanium layer and subsequently filled by PIP in France with their silicone gel. Most of those implants were sold in Germany, accounting for approximately 280 patients. In addition to Germany,

TiBREEZE implants were delivered to the following countries: Belgium, Italy, Finland, South Africa, Switzerland, England, Austria and Lichtenstein. It's currently unknown how many women or who might be affected in the UK.

Other European countries who have estimated the number of women affected by PIP implants include Germany (unreported), France (30,000), Spain (8,000 – 12,000), Italy (4,300), Czech Republic (2,000), The Netherlands (1,000), Bulgaria (750), Belgium (674), Austria and Greece (50). Additionally it has been reported that approximately 5,000 Australian women have had PIP implants.

The discovery of the use of industrial grade silicone gel cast much concern over the safety of the products and the MHRA advised in the Spring of 2010 that all British women fitted with the PIP implants should consult their implanting surgeon if they had any concerns, whilst the French authorities and they investigated further and ran toxicology tests on the unknown gel.

At the same time, BAAPS, the British Association of Aesthetic Plastic Surgeons advised women to have ultrasound tests to determine the state of their implants, in terms of any rupture or weakening of the structure.

Cancer Concerns

In February 2011, the MHRA issued a safety alert on the possible, but very low risk, of a link between anaplastic large cell lymphoma (ALCL), a rare form of cancer which affects cells of the immune system and silicone gel implants in general. However, no confirmed cases have been reported to the MHRA in the UK.

According to the American Society for Aesthetic Plastic Surgery (ASAPS), ALCL in the presence of breast implants has been noted in sporadic case reports over the past 25 years. To date, ALCL has only been identified in 34 cases out of an estimated 5 to 10 million women with implants worldwide. The U.S. FDA asked all American healthcare providers via a **medical device safety notice** to report any confirmed cases of ALCL in women with breast implants.

Then at the end of 2011 we saw the PIP story hit epic proportions in the media following the report of the death of a women in France implanted with PIP implants who had died from ALCL, causing much renewed speculation about the link between these specific implants and cancer.

The MHRA noted in December 2011 that it was aware of the report from France but maintained it had no evidence of a link between breast implants and cancer.

France then recommended that all women who have PIP breast implants should have them removed as a preventative measure because of health concerns about high rates of implant rupture and cancer, despite many other countries stating that there was no evidence of any increase in incidents of cancer associated with PIP breast implants.

Much attention was then being focused on rupture rates which ranged dramatically with data from the MHRA quoting 1% (a typical rate for most implant brands), French authorities quoting 5%, the Harley Medical Group who performed the most UK PIP implantations quoting 1.8% and Transform Group quoting its own data as showing 7%; other reports have come in as high as 11%. Additionally the MHRA noted that in its discussions with other health or regulatory experts from Australia, the Netherlands, Portugal, Italy, Ireland, Hungary, Austria, Denmark and Malta, they had all agreed that there was no evidence of any disproportionate rupture rates other than in France.

Until a consensus could be established on a risk of rupture and whether this is any worse than established and valued brands of breast implants, no decision was being made by UK authorities on removal advice, despite the proven industrial grade contents of the implants and the advice then announced by France.

However, health officials in The Netherlands, Germany, the Czech Republic and Venezuela then began following suit and advising women with PIP implants to have them removed.

As more tests were performed and more evidence and data came to light debate in the UK raged over whether implants should be removed and replaced in patients as a matter of urgency or whether the risks of them remaining are equal to or less than those involved in a repeat surgical procedure or those of any other breast implant.

Add to that the cost and who pays it; France and latterly Holland (who have fewer women affected) have stuck their necks out and said the government will pay, but here many argue that private clinics who used these 'cheaper' implants should foot the bill, yet many surgeons and clinics want to charge the patients themselves, at least for the hospital costs involved, or get the government to subsidise it.

The Interim Report of The Expert Group

After the initiation of a speedy government review by the Secretary of State for Health, Andrew Lansley in conjunction with an expert group consisting of plastic surgeons and other scientists, a request was issued for clinics involved to submit data on the number of procedures and ruptures within 48 hours, pending a decision from the Department of Health which came at 5pm on Friday 6th January, (report available **here** in PDF format).

The report noted that the overriding concern of the group was the 'safety and compassionate treatment of women with PIP breast implants'. They reviewed the available data on the health risks of the implants, taking into account the anxiety of many women who received them in good faith on the assumption that they were manufactured in accordance with EC standards, yet as well as coming to various conclusions they also noted that the available evidence was subject to considerable uncertainty and therefore recommended the collection of additional information which they believed would enable the group to reach a more informed view. A further meeting was planned for 4 weeks after the report date.

One of their primary findings was that some 80,000 implants (40,000 women) were sold in the UK and that to date some 478 adverse incident reports have been received regarding the implants. The group noted that this rate of incidents was not considered to be significantly different from that for other brands of breast implant.

However, from about 2006 onwards, concerns began to emerge among cosmetic surgeons about the performance of PIP implants. The report highlighted that in 2008 the MRHA noted an increase in the number of reports of ruptures and raised concerns with the manufacturer and the notified body, but this was understood to be the result of an increase in sales and improvements in the manufacturer's reporting criteria. The MHRA raised further concerns in 2009.

On 20 December 2011, following a large increase in the number of reported ruptures and concerns over a possible cancer risk, AFSSAPS wrote to European regulatory bodies alerting them to the new data. On 23 December the French Ministry for Health announced that it was advising women, as a precautionary measure, to consider explantation. After consideration of the evidence reported within the UK and consultation with other countries known to have used PIP implants, the MHRA issued interim advice. This suggested that, on the available data, women in the UK should not be advised to seek explantation in the absence of clinical symptoms.

The expert group's remit was therefore to review this advice, given the data available to them, including further information from the French authorities, and decide if there was any need to change the MHRA advice.

They considered the issues of whether, on the balance of evidence, women with PIP implants who have no current symptoms should be advised as a precautionary measure to seek an explantation, or should be advised to wait for the possible development of symptoms that might indicate a rupture; essentially balancing the risks associated with PIP implants, including the risks resulting from possible rupture of the implant, against the risks of undertaking explantation surgery earlier than might otherwise be necessary. They noted that it was worth bearing in mind that all breast implants have finite life, something which most recipients do not seem to realise, and that data from the FDA would suggest that 1 in 5 cosmetic breast implants are explanted or replaced within 10 years of the initial implantation.

They also had to consider the cancer risk which had been raised by a case in France and concluded that on the available data, there is no evidence that PIP implants are associated with a higher risk of breast cancer than other silicone gel implants, which is in line with the advice of the French National Institute for Cancer (INCA) who state that "the number of breast cancers seen in women with PIP implants is less than the levels for the general population".

The Official Word

In a statement issued by the Department of Health after the Expert Group meeting, they said, "the group has concluded that the advice given by the MHRA still stands and that there is **not enough evidence to recommend routine explantation of these breast implants**."

In relation to those women wanting to have the implants removed and replaced it said; "the ***NHS will replace the implants if the original operation was done by the NHS. We expect the private sector to do the same*** for their patients."

The health service has therefore clearly laid down the gauntlet and asked the private sector to bear the cost for those patients that it treated; it also plans to pursue those who won't treat patients by saying; "If a clinic that implanted PIP implants no longer exists or refuses to care for their patient – where that patient is entitled to NHS services, the NHS will support the removal of PIP implants. **Any NHS service in that respect would not include**

the replacement of private cosmetic implants. The Government will pursue private clinics with all means at its disposal to avoid the taxpayer picking up the bill."

A statement by NHS Wales went further by saying that if it were to do operations on patients previously treated privately, that it would also replace the implants at the same time to avoid a need for a further operation for implantation for the patient at a later date.

As well as the Department of Health, several others health authorities and industry associations have issued statements in relation to recommendations for explantation and medical practitioners encountering patients with the adulterated implants.

The World Health Authority issued a **statement** which included links to the specific recommendations by national regulatory bodies for 28 countries worldwide. In conclusion to their statement WHO said "It is, furthermore, important to consider strengthening adverse event reporting of medical devices", an opinion which is now widespread.

The International Society of Aesthetic Plastic Surgery (ISAPS) came out as a major supporter of the French recommendation and announced that they also recommend removing or exchanging the PIP implants immediately, even if there are no clinical signs of rupture, in order to avoid further health risks. This stance was also backed by the American Society of Aesthetic Plastic Surgeons (ASAPS).

A joint surgical statement on **clinical guidance for patients, GPs and surgeons** in relation to PIP implants has been endorsed by the Association of Breast Surgery, British Association of Plastic, Reconstructive and Aesthetic Surgeons, British Association of Aesthetic Plastic Surgeons, Federation of Surgical Speciality Associations and the Royal College of Surgeons. They say that the new guidance provides patients with practical advice on what to expect and their rights, indicates to GPs where to refer different groups of patient and advises Surgeons on treatment. The guidance, available in **PDF**, goes beyond current government advice aimed at patients with symptoms to give additional practical advice for the majority of patients who do not, say the joint associations.

The Regulator

Many have pointed the finger at the regulator, in the UK the MHRA for failing to be wholly aware of the adulterated nature of a supposedly CE marked medical device, and for an apparent lack of its own monitoring of the continued safety and proper manufacture of such products, which was left to the CE marking authority's inspectors.

The Independent Healthcare Advisory Services (IHAS) which as a trade body represents its members, independent healthcare providers such as cosmetic surgery clinics agrees with the Department of Health's decision not to recommend immediate explantation of PIP implants and said in a statement that it hoped the government would now 'face up to their responsibility as regulators of PIP implants', detailing; "All public and private sector surgeons used these implants, which were not the cheapest on the market, in good faith with the knowledge that they had been approved by the Department of Health agency, the MHRA."

The MHRA issued a statement on this challenge in which it said; "The manufacturer PIP gave these products a European CE Mark indicating that it complied with the relevant EU regulations. This was overseen by TUV Rheinland, a German commercial organisation responsible for undertaking the necessary safety and regulatory checks required for a CE Mark. Once a medical device has a CE Mark it can be placed on the market in any EU member state. Under these circumstances, our responsibility here was to investigate adverse incidents as part of our post-market surveillance role. We did this and we have continually monitored the safety of these breast implants. Once we were notified of the problem by France, we swiftly issued advice that these implants should not be used in the UK and commissioned testing to evaluate the safety of the implants."

Aware that the current role and remit of the MHRA in relation to the continued monitoring of CE marked medical devices is lacking and more hands-on monitoring may have prevented this fraud from continuing for so long, they concluded by saying; "We will be working closely with other health departments and regulators in Europe to consider whether there are wider implications for the regulation of implants and other medical devices."

TUV Rheinland has said that its remit was to look into the manufacturing process but not the content of the silicone used in the implants. This would seem to be a contradictory stance as surely what is being used in the manufacture of a product forms a vital part of any analysis of said manufacturing process.

At the end of January it was reported that Italy's plastic surgeon association (Associazione dei Chirurghi Plastici dell'Italia Centrale) has filed a lawsuit in a court in Rome against the now defunct Poly Implant Prothèse and TUV Rheinland stating that its members would consider themselves injured parties. The association's Vice President, Mario Pelle Ceravolo, said; "Surgeons who used the incriminating implants were as much the objects of fraud as were the patients, Doctors who used the PIP implant cannot be blamed."

Reports have also come in from other EU countries of plans for legal action by various third party distributors against the CE Mark provider TUV Rheinland for failures in the ongoing monitoring and inspection of the manufacture of PIP implants.

MEPs are also calling on the European commission to ensure more traceability and unannounced inspections for the manufacturers of breast implants. MEPs welcomed the commission's announcement of stress tests to be carried out on the medical services directive's regulation of breast implants in light of this scandal.

The Clinics

The majority of PIP recipients in the UK were treated privately (some 95%, 5% on the NHS) and of those most were clients of the Transform Group. The Harley Medical Group, The Hospital Group and Linia.

In response to the statement from the Department of Health, some of the larger cosmetic surgery chains such as The Harley Medical Group are refusing to absorb the full cost of removal and replacement and are openly telling patients how much it will cost them, as they believe that the government is liable, through the MHRA, for regulating a medical device as fit for use which they took on good faith and implanted into patients, hence they are of the opinion that it should foot the bill and not them.

Chairman of The Harley Medical Group, Mel Braham, whose chain of clinics carried out the largest number of PIP implant operations (13,900 between September 2001 and March 2010) went as far as to say in an interview with the BBC on 11th January 2012 that it would bankrupt his company if they had to replace all PIP implants for all patients treated free of charge.

By the end of the month, they had agreed however to remove and replace PIP implants free of charge for those within 6 years of implantation, remove the implants free of charge for those within 10 years of implantation but require the replacement for those between 6 and 10 years of implantation to be at cost price, all cases must be of a confirmed rupture and accompanied by a scan, i.e. no replacement for replacement sake for free.

As you can imagine, this was not what the thousands of women with PIP implants and no symptoms of rupture wanted to hear from their implanting clinic.

The Transform Group, the UK's largest cosmetic surgery chain who noted that aside from 108 patients they have not used PIP implants in general since 2005, initially told patients on 17th January 2012 that it would charge the at cost price of £1,850 for anyone wanting removal alone or £2,650 for removal and replacement with Allergan CUI implants. However by 25th January 2012 they made a u-turn and decided to offer free removal of PIP implants to anyone who received them from Transform since 1st January 2001; a free ultrasound scan is also being offered to the same patients. Yet, replacement will still incur an 'at cost' price (whether the original PIP has ruptured or not) of £2,500. Free removal and replacement is only being offered to those whose operations were post 2006 and are thus still under warranty.

The Hospital Group has said that it will offer free removal to women it operated on with PIP implants from 2001 – 2009 irrespective of any ruptures; but will charge for removal and replacement at a subsidised cost of £1,500 or £3,500 for non-Hospital Group patients. All replacements will be with Allergan CUI implants.

The following additional private clinics have said they will replace PIP implants free of charge if clinically necessary: Holly House, Highgate Hospitals, Make Yourself Amazing, Ramsay Health Care, Spire Healthcare, BMI Healthcare, Nuffield Healthcare and HCA International.

Nagor, the only British manufacturer of breast implants, who have been in business since 1979, are the only company who provide an automatic lifetime guarantee (warranty) for their implants which covers rupture and capsular contracture is also offering free replacement implants to any women affected by PIP ruptures.

Douglas Black, National Sales Manager at Nagor said about this decision; "Nagor has pledged to help as many PIP women as possible, back in March 2010 Nagor offered to replace any ruptured PIP implants with free of charge Nagor implants. The offer was sent to all BAAPS & BAPRAS members following the discovery of a UK patient having a ruptured PIP implant. This is unconditional and I hope shows our support to surgeons and patients alike. At the end of 2011, Nagor extended its support to UK PIP patients by contacting as many clinics as possible to discuss reduced costs of implants to help with further reductions to the cost of revision."

The Patients

Hell hath no fury like a woman scorned, in this case not rejected by a lover but by the clinics with whom they placed their trust; many are not going to take this lying down. A multitude of patient campaign and support groups sprang up overnight when the scandal broke, aided by social media platforms such as Twitter and Facebook including the **PIP Ruptured Breast Implant Awareness** page, the **PIP Breast Implant** group, the **PIP Implant Forum**, along with direct campaign groups against clinics such as **PIP Implants – Boycott Harley Medical Group** , along with **Harley Medical Group must replace PIP Implants**. If ever there was doubt about the power of social media, such high profile issues played out in via this medium give the public the national voice that previously wouldn't have been possible.

Stories and experiences were shared and strength was found to fight, with a variety of protest marches planned and coordinated via Twitter in cities such as Bristol, Birmingham and London, where a march down Harley Street to the front steps of clinics involved was covered by all the national news networks; people power at its best.

Along with the fighting spirit comes the emotional turmoil that many women now find themselves grappling with. A recent online survey by **Clinical Partners**, a private clinic of psychiatrists, psychologists and psychotherapists, polled women who have, or have had, PIP breast implants. With over 120 respondents, it revealed that nearly half of the women had missed work due to stress over having PIPs, nearly 8 out of 10 felt that their self-esteem and self-worth has been affected, two thirds are feeling severely depressed and anxious and 80% feel they will need the help of a therapist or counsellor. Added to that, nearly all (92%) are suffering from insomnia, with many needing to visit their GP for anxiety medication and sleeping pills.

Women confessed to being 'in tears all the time' and being 'a complete mess', with many reporting that they were unable to be intimate with their partners, unable to look after their children, unable to do or want to do their jobs and hating their own bodies.

The Law

Where there's blame, there's a claim...or so the mantra goes. As you can imagine, the country's solicitors and personal injury law firms have been quick to jump onto this scandal. A quick Google search will reveal a myriad of companies touting for business, offering to represent women who received PIP implants.

Additional Facebook pages appeared which at first glance looked like another support group, but were in fact a front for a law firm, such as **PIP Implant Help** which has almost 3,000 likes.

According to **First Personal Injury** it is thought that a group of around 200 British women will be applying for a group litigation order. Proceedings are to be brought as consumer claims against the clinics that fitted the implants on the grounds that they did not do what they promised and were in breach of contract.

They also note that depending on the circumstances, women may also be in a position to bring a personal injury claim. They can claim not only if their implants have ruptured but also for the pain and suffering of having their implants removed as a precautionary measure, as well as the psychological problems associated with this. The limitation period for personal injury cases is 3 years from the date of knowledge therefore they advise that it is in the women's interest to act quickly, so we may start to see such cases very soon. Alison Evans, a solicitor at the firm said; "Companies who offered the PIP implants could have a duty to pay compensation to those affected under Consumer Protection legislation and we are currently investigating this possibility."

Recent reports have also been abound on Twitter stating that The Hospital Group in particular are demanding that patients sign a disclaimer preventing future legal action prior to any removal and/or replacement surgery for PIP implants, clearly anticipating the very claims that this law firm is considering.

Learning The Lessons

To add yet another proverb to the list, *there's no point crying over spilt milk*, what's done is done and the mess will have to be cleared up, but what can be learnt from this event?

The Lancet believes that lessons can be taken for the USA where regulations on medical devices such as breast implants are much tougher via the Food & Drug Administration (FDA); often criticised for being slow and bureaucratic it is argued that this is preferable in the interest of patient safety to the more lax European model.

The most voiced recommendation is for the reinstatement of a national breast implant register, a scheme that previously ran from 1993 and was shelved by the government in 2006, leading to a lack of quality and consistent data having been recorded and discovered upon investigation of this incident by authorities and the UK Expert Group. Were a register still in place it has been argued that patient identification, batch number and implant

traceability and rupture and adverse incident reporting would all have been much easier and more apparent, possibly sooner. Many associations therefore, including BAAPS, are campaigning for the reinstatement of a national register, as currently available in the USA.

Another proposal voiced is for an insurance scheme for cosmetic surgery patients. Sir Bruce Keogh, who is leading the government review into PIP implants (more details on this and a broader review of the UK cosmetic surgery industry within our Legislation section), told the BBC the scheme would protect consumers in a similar manner to the travel business, where the Association of British Travel Agents (Abta) offers financial protection for its members and their customers should something go wrong. Although a nice idea, one wonders if the cost of such insurance for an industry such as cosmetic surgery would be prohibitive to both patients and clinics, particularly when considering the current costs incurred by surgeons and clinics already for medical malpractice insurance via third parties and medical defence unions.

It's true to say that this scandal has revealed many failings in current regulatory systems for medical devices, both pre-market and post-market, in adverse incident reporting and follow-up and ongoing monitoring of manufacturers, along with back-up plans for when something goes badly wrong. Perhaps it's the wake-up call that the industry and the government needed to think seriously about the future regulation and management of an industry which clearly can put human life at risk.

Lorna Jackson

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She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Aesthetic Medicine*, *Cosmetic News* and *Aesthetic Dentistry Today.*

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