

## **A ROUGH LEGACY**

*By Giulio Valesini - Simona Peluso*

*Images by Paolo Palermo*

*Edited by Giorgio Vallati*

### **SIGFRIDO RANUCCI IN THE STUDIO**

In Italy, 50 thousand breast prostheses are implanted every year. The market leader is the multinational company Allergan; however, two of its models with a rougher silicone shell have been withdrawn from the market, and they have not been awarded European CE mark. The reason for this is not clear; a number of documents are missing, we don't know which ones. But the discussion right now among scientists is focused on rough silicone implants, the coarser ones which are also referred to as "macro-textured": it appears that these may cause a rare type of lymphoma. In recent days in France, the French health authorities have opened a debate, and currently, just as we are going on the air, the American FDA organisation is also looking into the issue. And what are we doing, meanwhile?

### **GIULIO VALESINI**

How old are you?

### **PATIENT**

Twenty one. I do body building. I do competitions, and basically all the girls have had surgery.

### **GIULIO VALESINI**

What size?

### **PATIENT**

A generous C cup, not bigger.

### **GIULIO VALESINI**

What type of implants are they using?

### **PATIENT**

Oh god, I can't remember.

### **GIULIO VALESINI**

Smooth or rough?

### **PATIENT**

Smooth, I think. I don't want to get it wrong.

### **GIULIO VALESINI**

What implants have you chosen? Smooth or rough, doctor?

### **PAOLO SANTANCHÈ – PLASTIC SURGEON**

To the naked eye, they appear smooth, but under an electronic microscope, we can see this textured surface, which is a bit like frosted glass, so essentially imperceptible.

### **GIULIO VALESINI**

In your opinion, do the laws in Italy guarantee 100 percent safety for women who undergo this type of breast surgery?

**PAOLO SANTANCHÈ – PLASTIC SURGEON**

Absolutely not!

**GIULIO VALESINI OFF SCREEN**

More than 30 million women across the world live with breast implants. Anatomical, round or teardrop-shaped implants can be used. The surface of these implants can be smooth or textured - that is, rough or macro-textured, even more rough: they say that it adheres better to the tissue and gives a better aesthetic result. But a number of recent international studies have linked these implants to a new form of cancer: ALCL, Anaplastic Large-Cell Lymphoma. The French health authorities have opened the debate on this issue.

**THIERRY THOMAS - DIRECTOR FOR MEDICAL DEVICES FOR ANSM (FRENCH NATIONAL AGENCY FOR THE SAFETY OF MEDICINES AND HEALTH PRODUCTS)**

The question that we need to answer is this: in light of this risk, are there situations in which it is essential to use a textured implant?

**GIULIO VALESINI OFF SCREEN**

For clarity, ANSM, the French national agency that monitors medical devices, has brought together plastic surgeons, patients and health officials from all over the world in Paris. Representatives from the leading manufacturers have also been convened, including German company Polytech.

**WOLFANG STEIMEL – CEO OF POLYTECH**

We are asking governments to collect more data, but we can't stop using rough implants.

**GIULIO VALESINI**

Are you not concerned about the increase in cases of anaplastic lymphoma?

**WOLFANG STEIMEL – CEO OF POLYTECH**

No, there aren't many cases.

**GIULIO VALESINI OFF SCREEN**

In Italy, it is estimated that 90 percent of the prostheses implanted are of the rough or textured type. The biggest producer of these is the multinational company Allergan. In December, the French notified body GMED did not renew the CE mark on their flagship line. The company did not provide all of the documents requested, and was obliged to withdraw the Biocell and Microcell macro-textured models from the market. And now, the recommendation from the French authorities is that rough implants should be avoided.

**ELODIE GUÉGUEN – RADIO FRANCE JOURNALIST**

It is not a health policy decision to ban them. And lots of surgeons are still using them. They aren't taking full responsibility. And with the Allergan implants, no decisions were made either: when the notified body did not renew the CE mark, the health authorities simply recalled some batches. They didn't do anything else.

**GIULIO VALESINI OFF SCREEN**

The recalled Allergan implants were also used in many Italian public hospitals; our Ministry chose not to make any specific recommendations. Marcella Marletta has been at the head of the medical device directorate for a number of years.

**GIULIO VALESINI**

What do you think of the fact that the French authorities have invited, have provided their doctors with a recommendation to prioritise smooth implants? Are the French exaggerating the issue?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

We have not yet made a decision with regard to the global scientific data; we make our decisions in line with the global task force, so with Canada, the FDA in America...

**GIULIO VALESINI**

So the French are overstating things?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

I don't want to say that they are exaggerating the matter, I'm just saying that our decisions are in line with those taken globally. These are not decisions that are made "at home", so to speak: we are part of the wider world, and it is this world that dictates the laws.

**GIULIO VALESINI OFF SCREEN**

In reality, right back in 2011 the FDA published an initial report flagging up 60 cases. In 2016, the World Health Organization officially classified the disease as anaplastic large cell lymphoma associated with breast implants. As it currently stands, the cases reported to the FDA number 457. So far 17 women have died. There have been 39 diagnoses in Italy. Around one in every 30 thousand implants, according to the Ministry of Health. Many patients have been treated at the Sant'Andrea University Hospital in Rome.

**FABIO SANTANELLI DI POMPEO - DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

In the clinical history of each of these women, we found that they had received macro-textured breast implants.

**GIULIO VALESINI**

Like those made by Allergan, which have now been suspended from the market.

**FABIO SANTANELLI DI POMPEO - DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

That's right.

**GIULIO VALESINI**

What is the link between a rough, macro-textured implant and the appearance of the lymphoma?

**FABIO SANTANELLI DI POMPEO - DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

It depends a lot on the ability of the body to defend itself against external agents, be it smoke, or environmental carcinogens, rather than a prosthesis that stimulates

continuous inflammation. So above all, it's about genetics. The other possibility is that the surface of the some types of textured implants release particles, or in other words very small fragments of the prosthesis. And each of these tiny fragments causes a chronic inflammatory reaction.

#### **GIULIO VALESINI OFF SCREEN**

The lymphoma appears on average seven years after the implant operation is performed, but can even appear 25 years after the initial breast surgery. To treat it, the implant must be removed, along with the capsule that the tissues form around it. It is therefore essential to receive a diagnosis as early as possible .

#### **FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

In 80 percent of cases, the disease presents with the onset of a seroma. This seroma has particular characteristics because it is cold. This does not happen directly after the operation, at which point it is normal, but rather after some time.

#### **GIULIO VALESINI**

What do you think of the failure to renew the CE mark for Allergan implants?

#### **FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

When you don't know something, you can either distract yourself, or think the worst.

#### **GIULIO VALESINI**

What do you do?

#### **FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME**

I usually don't get distracted. So if they haven't said anything, I fear that this failure to communicate is due to a desire not to stir up panic. And not to set off a bomb that subsequently becomes difficult to control. They declared that they had requested some documentation, I don't know what type.

#### **GIULIO VALESINI OFF SCREEN**

In 2016, the French health authorities examined the documentation of all of the manufacturers of breast prostheses on the market. They discovered that the bio-compatibility testing for rough models simply hadn't ever been done. They asked all the companies to redo the test.

#### **WOLFGANG STEIMEL – CEO OF POLYTECH**

We did the test; we submitted it to ANSM and made sure that we were in conformity. It's other manufacturers that are giving misleading information, or not giving it at all.

#### **GIULIO VALESINI OFF SCREEN**

From this document it emerges that in order to obtain the CE mark, the companies presented the tests carried out on the smooth implants, suggesting that these were equivalent.

#### **SILVIA FARÈ – PROFESSOR OF BIOMATERIALS, POLYTECHNIC UNIVERSITY OF MILAN**

I don't think this is enough. Because when the prosthesis is implanted and comes into contact with the tissue, whether it is a smooth surface or a rough surface changes the behaviour of this tissue.

**GIULIO VALESINI**

The human body reacts in a different way.

**SILVIA FARÈ – PROFESSOR OF BIOMATERIALS, POLYTECHNIC UNIVERSITY OF MILAN**

Exactly.

**GIULIO VALESINI OFF SCREEN**

Every company has its own model of textured implant, which may be more or less rough.

The effect is obtained during the manufacturing process of the silicone shell.

**SILVIA FARÈ – PROFESSOR OF BIOMATERIALS, POLYTECHNIC UNIVERSITY OF MILAN**

This is Allergan's implant, where you can see these holes. They are square in shape because they are obtained by bombarding the silicone shell with sodium chloride crystals. Afterwards the salt is washed off, because salt melts in water, and this textured effect is achieved.

**GIULIO VALESINI**

As if the implant had been covered in little holes.

**SILVIA FARÈ – PROFESSOR OF BIOMATERIALS, POLYTECHNIC UNIVERSITY OF MILAN**

Yes, that's right.

**GIULIO VALESINI OFF SCREEN**

At the Polytechnic University of Milan, prostheses that have been explanted are also analysed, in order to understand how they react within the human body years after implantation.

**GIULIO VALESINI**

So you examined these explanted prostheses and found that some were broken? The gel had come out of some of them?

**SILVIA FARÈ – PROFESSOR OF BIOMATERIALS, POLYTECHNIC UNIVERSITY OF MILAN**

It varied according to the situation. Some had ruptured. We saw that after five years, there were already problems with changes to the implants, particularly with regard to the gel.

**GIULIO VALESINI OFF SCREEN**

Implant rupture is one of the most common complications both with smooth and rough prostheses, but there is not enough data on the occurrence of lymphoma.

**MARIO PELLE CERAVOLO – ITALIAN ASSOCIATION OF AESTHETIC PLASTIC SURGERY**

The risk of a patient who chooses to have breast implants dying of cancer is three times less than a person who spends two days in New York City.

**SIMONA PELUSO**

Crusades against this or that model of prosthesis make no sense.

**MARIO PELLE CERAVOLO – ITALIAN ASSOCIATION OF AESTHETIC PLASTIC SURGERY**

It is entirely pointless. At least until we have real proof.

**SIMONA PELUSO**

There hasn't been one particular prosthesis that's got the blame...

**MARIO PELLE CERAVOLO – ITALIAN ASSOCIATION OF AESTHETIC PLASTIC SURGERY**

I didn't say that. I said that with textured prostheses, those with very marked texturisation are associated with a greater presence of this type of pathology. This has been verified.

**GIULIO VALESINI OFF SCREEN**

Officially there is no link between lymphoma and the non-renewal of the CE mark for Allergan implants, but according to a study carried out by an international task force in 2018 which looked at all cases of lymphoma in Australia and New Zealand, women with Biocell implants from Allergan had a 14 times higher chance of developing lymphoma.

**LAURENT LANTIERI – DIRECTOR OF PLASTIC SURGERY, GEORGES POMPIDOU HOSPITAL - PARIS**

I find these cases of lymphoma very worrying: this is why for years I have been calling for a ban on using macro-textured prostheses.

**GIULIO VALESINI**

Can we still refer to it as a remote risk?

**LAURENT LANTIERI – DIRECTOR OF PLASTIC SURGERY, GEORGES POMPIDOU HOSPITAL - PARIS**

It's a disease that occurs after a significant period of time; it's only being diagnosed now in patients who were operated on ten years ago. The approach taken by health authorities, though, is to wait and wait, without making any preparations for the problem, and so when disaster strikes, there will be attempts to do something but we won't have the resources. So we end up just talking, and hiding the problem.

**GIULIO VALESINI OFF SCREEN**

Laurent Lantieri is one of the most famous plastic surgeons in the world; he is one of the pioneers of the face transplant. For years, he has been part of a ministerial committee on breast implants in France.

**GIULIO VALESINI**

Should these macro-textured implants be withdrawn from the market?

**LAURENT LANTIERI – DIRECTOR OF PLASTIC SURGERY, GEORGES POMPIDOU HOSPITAL - PARIS**

There is no reason to leave them on the market. We don't need them. In plastic surgery, we can use round implants, for reconstruction there are alternative

techniques that don't use prostheses, or micro-textured versions. If they aren't necessary and they pose a risk, why use them?

### **SIGFRIDO RANUCCI IN THE STUDIO**

When a case is diagnosed, the health authorities don't know what to do. This is because they have failed to check previously when the devices were approved, and so they can't check after the fact because they don't know who, how, where and when or what type of prosthesis has been implanted. According to the head physician at the hospital of Sant'Andrea, they are either distracted from the issue or there's something worse going on, or perhaps they are looking at the rest of the world, as the Director General of our Ministry of Health Marletta says. The person who is has been in charge of medical devices for years is looking at the rest of the world. She's looking at the rest of the world and says that she has the situation under control. But how can this be true, if she doesn't know who is at risk? In 2010, hundreds of thousands of women had received silicone implants produced by a French company: PIP. It was later discovered that these prostheses had been manufactured using low-cost, industrial grade silicone. And when they tried to figure out which women had these implants, they didn't know where to start, because there was no register. And so then they said: never again.

### **FRANÇOISE CÔTE**

These are my implants. I've had five operations to remove all of the silicone residues that they left inside me.

### **GIULIO VALESINI OFF SCREEN**

During the French health authority hearing, a number of patients spoke. Françoise Côte has been diagnosed with an autoimmune condition, Asia syndrome. Her symptoms manifested after the rupture of one of her rough implants, which caused silicone to be dispersed throughout her body.

### **FRANÇOISE CÔTE**

They only talked about lymphoma, there wasn't any mention of autoimmune diseases related to breast implants. It's unbelievable. Unacceptable.

### **CLAUDIO CANNISTRÀ – PLASTIC SURGEON BICHAT HOSPITAL - PARIS**

Are these inflammatory diseases associated with the implants or are they linked to a whole series of environmental situations, such as diet, changes to the bacterial flora and food intolerances that can facilitate the development of these diseases in the presence of a foreign body? Perhaps it is time, it is an opportunity to carry out more in-depth studies and provide patients with answers too.

### **GIULIO VALESINI OFF SCREEN**

Over the last two years, at least 200 cases of autoimmune syndromes caused by silicone in breast implants have been officially diagnosed. Françoise founded an association that unites hundreds of women with problems relating to implants across Europe. According to an FDA report, 20 percent of breast implants are removed within the first eight years due to complications: rupture, contracture, inflammation.

### **JOËLLE MANIGHETTI**

When the scandal broke out, I'd had the implants for four months: they operated on me to change them, and found that one of the two implants had lost 10 percent of its volume, because it was leaking silicone.

### **GIULIO VALESINI OFF SCREEN**

Joëlle Manighetti is part of the breast prosthesis monitoring committee. In 2009, after being diagnosed with cancer, her breast was reconstructed using an implant made by PIP, a French company. The company's president Jean-Claude Mas had been selling prosthetics full of non-medical industrial silicone for years, at a low price. As he himself admitted after his arrest. Thousands of women - more than 17,000 in France alone - were forced to remove their implants. Not even TÜV Rheinland, the institution that had issued the CE mark, had noticed the scam.

### **JOËLLE MANIGHETTI**

When they went to do the inspections - and bear in mind that they always announced their visits in advance - they only looked at the paper documents. It's not like they could find out who knows what.

### **GIULIO VALESINI OFF SCREEN**

In Italy, four thousand women received non-compliant silicone implants.

### **NADIA PRADETTO**

I found out by hearing about it on television. I went to get the implant card, almost laughing, thinking: "Of course mine aren't the ones implicated". But the card had PIP written on it. I had another operation to remove and replace them, and the implant on the right had ruptured.

### **GIULIO VALESINI**

Nobody called you? Your doctor, a health facility, the Ministry, to tell you to get checked out because you had this type of implant...?

### **NADIA PRADETTO**

Absolutely not. No.

### **GIULIO VALESINI OFF SCREEN**

Jean Claude Mas had insured his company for a few million euro. To receive compensation, a class action lawsuit was launched against the notified body TÜV Rheinland.

### **LUDOVICA AMBROSIO – LAWYER, AMBROSIO E COMMODO LAW FIRM**

It is certain that this non-approved silicone has led to inflammation and pain, and in the most serious cases, these implants have also ruptured. And the silicone material has spread inside the breasts of a number of women, which again, in the most serious cases, has led to the formation of silicone nodules in the lymph nodes.

### **ALESSANDRA TORRERI – LAWYER, AMBROSIO E COMMODO LAW FIRM**

The latest medical record regarding removal of silicone nodules arrived yesterday.

### **GIULIO VALESINI OFF SCREEN**

After the scandal, the health authorities across Europe promised more checks. In Italy in 2012, the Minister for Health Renato Balduzzi, and so parliament, approved the establishment of a mandatory register of breast implants. This register called for the inclusion of the brand, model, date of surgery and the names of the surgeon and the patient.

### **PAOLO SANTANCHÈ – PLASTIC SURGEON**

This register was never rolled out.

**GIULIO VALESINI**

But what happens then if the Ministry wants to know how many Allergan textured breast implants there are in Italy?

**PAOLO SANTANCHÈ – PLASTIC SURGEON**

They'd have to do what they did with the PIP implants: send NAS, the police anti-adulteration and health unit, to all the clinics, and get them to go through all the folders from the previous ten years with a fine-tooth comb, look through all the records to see what brand of implant... So, basically something that...

**GIULIO VALESINI**

But has history not taught us anything, doctor?

**PAOLO SANTANCHÈ – PLASTIC SURGEON**

No. That's what politicians are like. They're dense.

**GIULIO VALESINI OFF SCREEN**

To make the register operational, an ad hoc decree was required from the Prime Minister, and this was only issued in 2017. Since then, more years have passed, but there's still no trace of the register.

**GIULIO VALESINI**

We passed a law in 2012, saying that we would create a register in order to ensure that this matter would be seriously monitored: fantastic, very appropriate - except for the fact that this register does not exist.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

In 2012, we passed law 179 which stipulated that the register would be introduced via a Ministerial Decree.

**GIULIO VALESINI**

I understand, but does it take five years to issue a Ministerial Decree?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

Ask the presidency of the Council of Ministers.

**GIULIO VALESINI**

But surely you have pushed them on this?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

We have made the contribution we can. But I'm not the government.

**GIULIO VALESINI**

Now, we are in 2019 and there is still no register, and the Director General herself tells me that there is an issue with under-reporting by doctors and companies.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH**

Do you really think that if I could have had a mandatory register, not today but ten years ago, I would not have wanted one, given the passion I put into what I do?

**GIULIO VALESINI**

But you don't have one though doctor.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,  
MINISTRY OF HEALTH**

I am patient. I will have the register when the laws and all the bureaucratic processes that exist for these things allow me to have it.

**GIULIO VALESINI OFF SCREEN**

In 2018 the Ministry of Health recorded 600 events. There were 270 in 2012. But the real number could be much higher.

**GIULIO VALESINI**

600 reports of ruptured implants in tens of thousands is clearly a case of under-reporting. We don't have a register, so it's under-reporting by doctors, companies...we're a bit in the dark here, doctor.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,  
MINISTRY OF HEALTH**

The whole world is in the dark, your concern is shared globally.

**GIULIO VALESINI**

You keep saying this, but it's not making me feel reassured, doctor. On the contrary, it's worrying.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,  
MINISTRY OF HEALTH**

It's not meant to reassure you; rather one should be asking how a Ministry with the means of a public administration body can achieve what we have. And be admired by the rest of the world.

**GIULIO VALESINI**

What have you done? Can you explain to me?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,  
MINISTRY OF HEALTH**

We have focused our attention on the problem of large cell lymphoma.

**GIULIO VALESINI**

Yes, but in France there has been a public debate, to which they have invited ...

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,  
MINISTRY OF HEALTH**

We have drafted a publication. The public debate will be held after our circular, our publication is issued. Anyway, the French have the notified body that certified the prostheses.

**SIGFRIDO RANUCCI IN THE STUDIO**

A problem shared is a problem halved, although this old adage is not quite as reassuring when it comes to health. Our politicians are dense, as Professor Santanchè

told us: he should know, since he was married to the Honourable Daniela. We might also start to think that he has a point. Especially given that in a number of countries, an implant register has already been established, although this is voluntary: in some of the UK, in Sweden and in Denmark. In Holland, meanwhile, a mandatory register has been instituted by law; this is a model that works and one that we should imitate. So what have we done, meanwhile? We introduced the register in 2012, but it's taken us five years to apply the decrees. Why have we wasted so much time? Director general Marletta told our colleague Giulio that she would personally ask the Presidency of the Council of Ministers. Now, it is true that Giulio Valesini gets everywhere, but as someone who has been working for the Ministry for so many years, what has she done? She has looked at the rest of the world. But finally, on Friday, what did she announce? That the implant register is going to be rolled out. Will it really happen? We will check. But she didn't say a word about all those suburban clinics where low-cost prostheses are implanted, even illegally, and where there is no requirement for medical records and therefore no traceability. And from us, a piece of advice: for those who have chosen to have implants for aesthetic reasons - because unfortunately only women who have had them for medical reasons are subject to mandatory checks - we would say, ensure you get checked annually. Ask and ensure you insist, keep the label of the prosthesis model that you had implanted, and if you experience any pain or swelling, go to your doctor immediately: if diagnosed early, lymphoma doesn't need to be frightening. Simply removing the implant and the tissues involved results in a 100% recovery.