



Motiva Implant Matrix[®]
Post-Market Vigilance Report
October 2010 - June 2015

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1. PURPOSE

To summarize the status of complaints for the Sterile Silicone Breast Implants Motiva Implant Matrix®, manufactured by Establishment Labs, as part of the Post-Market Surveillance Program.

2. SCOPE

The analysis report includes all the product complaints for the Motiva Implant Matrix® products reported to the Sales Support Department and processed by the Quality and Regulatory Department, as stated on SOP-019 "Complaint Handling" for the following product families:

- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SmoothSilk® or SilkSurface™.
- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS.
- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS with Qid™.
- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™.
- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS.
- Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS with Qid™.
- Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™.
- Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ with Qid™.

This report covers the Motiva Implant Matrix® Silicone Breast Implants listed, from the commercial launch in October 2010 to June 30th 2015, and considers all events reported, regardless of the complaint investigation results and whether these results indicate causes foreign to the implantable device. Motiva Implant Matrix® was launched in the European Union in the first quarter of 2011.

3. EXECUTIVE SUMMARY

Since the commercial launch of Motiva Implant Matrix® in October 2010, Establishment Labs has placed a total of 102498 breast implants in the international market, including Latin America, Europe, Middle East, Africa and Asia-Pacific regions.

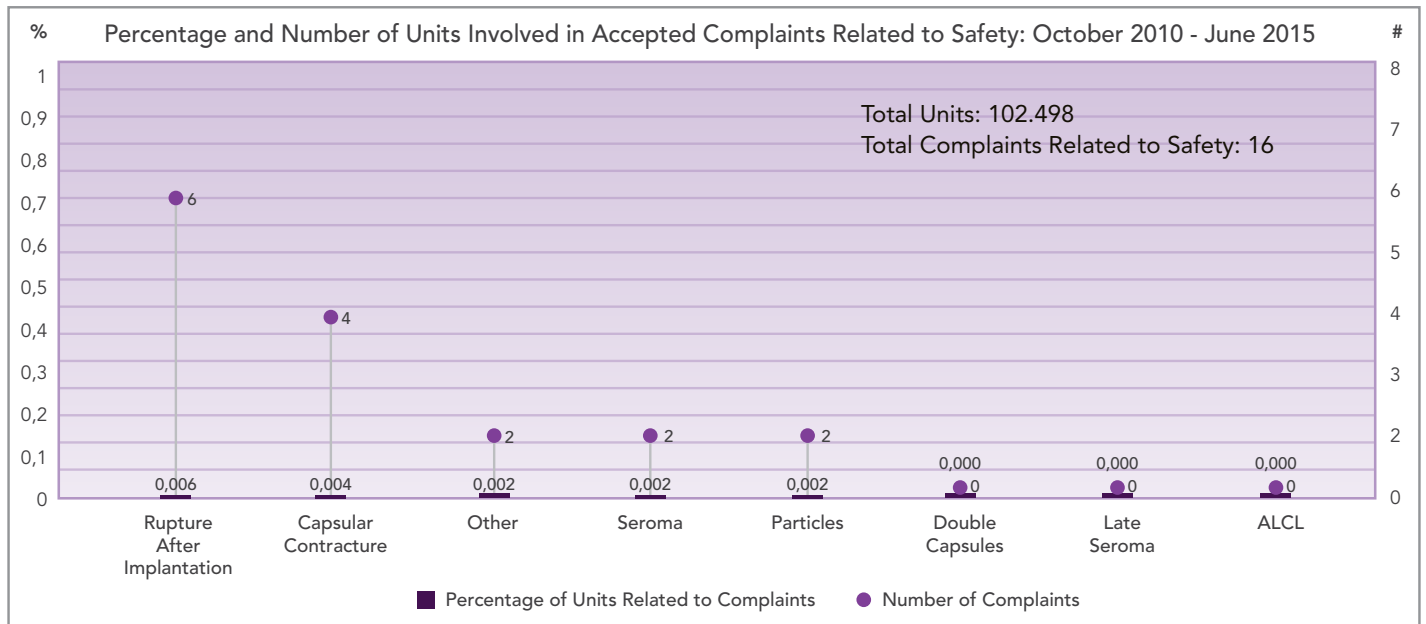
According to the Quality Management System internal control for complaints, LIS-027 "Control Log for Customer and Distributor Complaint", a total of 95 complaints have been reported, investigated and processed by our Quality Management System, which represent 0.09% of the total units placed in the market as shown in Table #1.

Table 1: Number and Percentage of Complaints from the Year 2010 to June, 2015.

Year	Number of Complaints	Percentage of Complaints (%)
2010	0	N/A
2011	6	<0.1%
2012	19	<0.1%
2013	29	<0.2%
2014	18	<0.1%
2015	23	<0.2%
Total	95	0.10%

Each complaint has been investigated separately and then analyzed in conjunction to other complaints, define any trend regarding the type of product and/or event. The most relevant information gathered from the investigation indicates that the number of complaints is extremely low when compared to similar products in the market and that the existing complaints have had no impact on the patients health.

From a total of 95 complaints reported worldwide, only 16 events have been related to safety. The other 79 complaints have been associated to events occurring during the surgical procedure. These complains have been rejected. In Chart #1, the 16 accepted complaints, all related to safety are classified by type of event. In Chart #2, the remaining events (not related to safety) are categorized. Percentages are global.



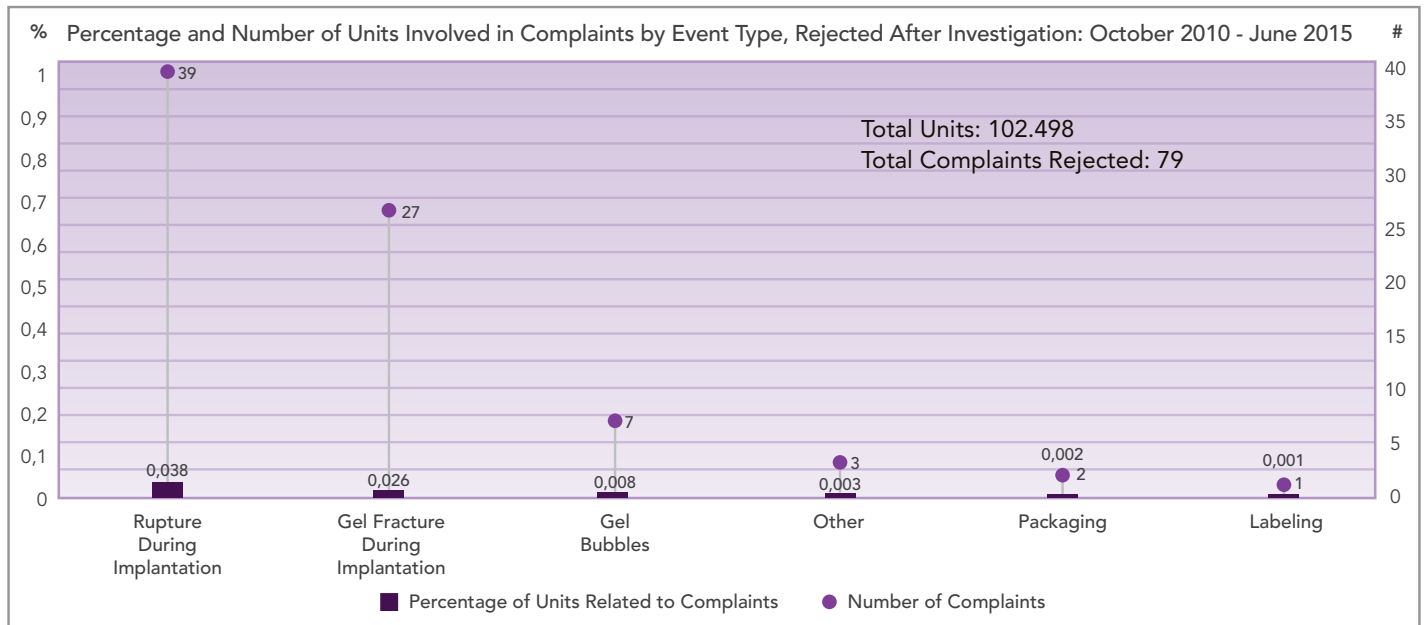
Source: LIS-027 "Control Log for Customer and Distributor Complaint, Establishment Labs, Quality Management System, released date: 29-Jun-15."

Chart #1. Motiva Implant Matrix® - Percentage of Units and Number of Complaints Related to Safety: October 2010 – June 2015, in relation to the total of units.

As depicted on Chart #1, the most frequent type of event leading to product complaint related to Safety is "Rupture After Implantation (0.006%)", followed by "Capsular Contracture (0.004%)". The frequency of each of the remaining events is below 0.002%.

Of the six (6) cases of "Rupture after Implantation", 5 are related to implants with super-high profile: CORSE. The investigation of these 6 cases of "Rupture After Implantation" reveals marks of sharp surgical instruments on the implant's surface, which suggest that the weakening of the shell leading to rupture might have occurred during the implantation process. Therefore, those events are not considered related to the device quality or performance.

The impossibility of determining the handling of the explanted products after their removal makes it impossible to determine without a doubt the precise cause of the rupture. Thus, these complaints were accepted by the Quality Department.



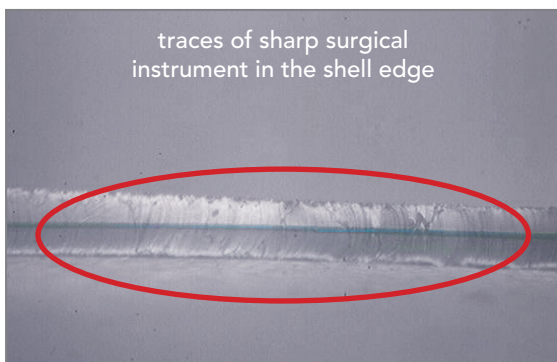
Source: LIS-027 "Control Log for Customer and Distributor Complaint, Establishment Labs, Quality Management System, released date: 29-Jun-15."

Chart #2. Motiva Implant Matrix® - Percentage of Units and Number of Complaints Rejected as a Claim.

As shown on Chart #2, the most frequent type of event leading to a rejected product complaint is "Rupture during implantation (0.038%)", followed by "Gel fracture during implantation (0.03%)". The frequency of each of the remaining event types is below 0.01%.

From all the events reported as "Rupture During Implantation", the most frequent implant profile, with 39 cases, representing 62% is CORSÉ (super-high projection). This can be due to mishandling in the efforts to introduce a high projection implant through a small incision during the surgical procedure. The second profile, with 13 cases, representing 33%, is FULL (high projection). Finally, there are 2 cases with DEMI (moderate), representing 5%, while no cases of rupture during implantation were reported with mini (low) projection, as described in Chart #3.

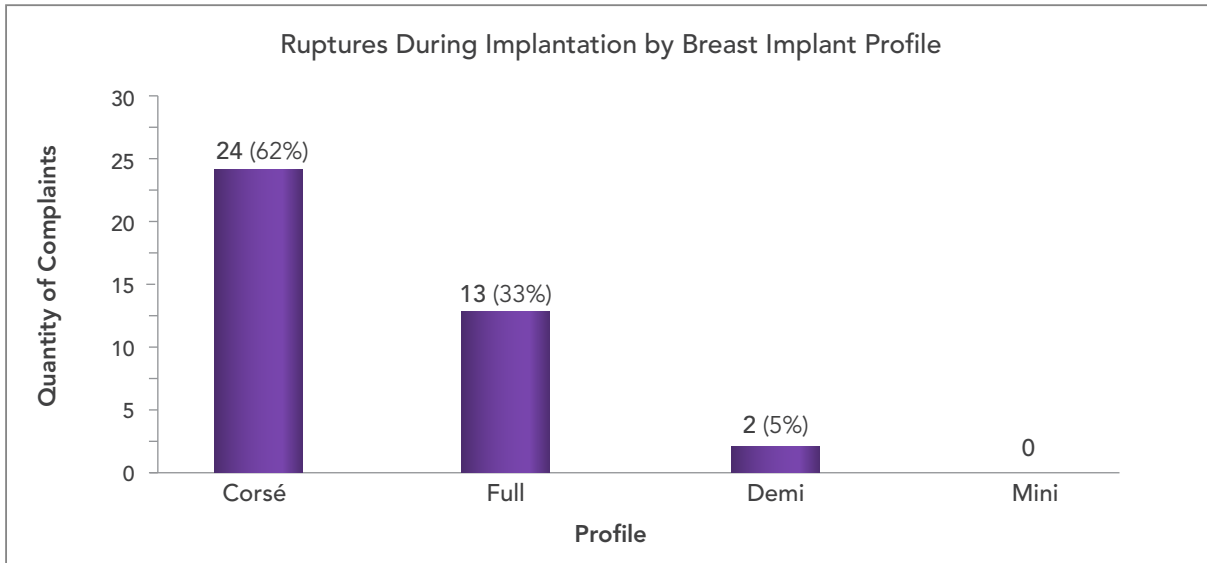
The investigation of all cases of rupture during implantation reveals traces of sharp surgical instruments on the implant surface as well. Pictures #1 and #2 show traces of a sharp instrument on the elastomer shell surface.



Picture # 1



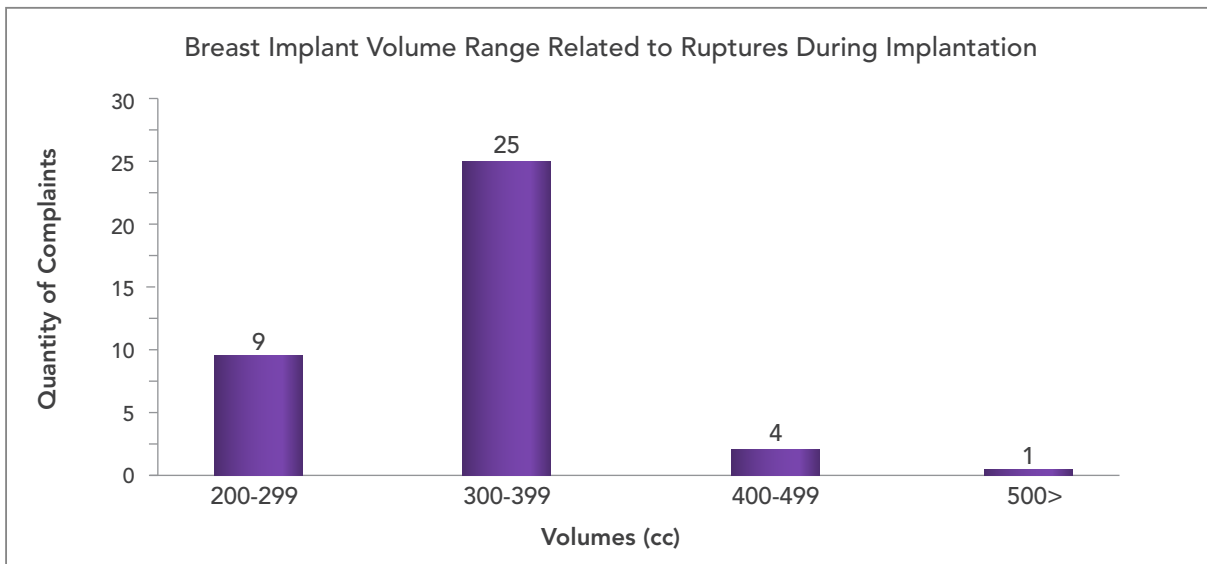
Picture # 2



Source: LIS-027 "Control Log for Customer and Distributor Complaint, Establishment Labs, Quality Management System, released date: 29-Jun-15."

Chart # 3. Motiva Implant Matrix® - Number of implant ruptures during implantation reported according to profile.

The literature suggests that the incidence of implant rupture during implantation is proportional to the volume of the breast implant. Chart #4 shows the number of ruptures during implantation in the 260cc – 625cc volume range of Sterile Silicone Breast Implants Motiva Implant Matrix®. As expected, most of the cases are in the volume range of 300cc and 400cc, which is the most frequently sold volume range.



Source: LIS-027 "Control Log for Customer and Distributor Complaint, Establishment Labs, Quality Management System, released date: 29-Jun-15."

Chart # 4. Motiva Implant Matrix® - Implant ruptures during implantation according to their volume.

4. CONCLUSION

After analyzing all the complaints reported through the Quality Management System up to this date, it can be concluded that the product complaints reported and investigated are not related to the mechanical, chemical or biocompatibility characteristics of the breast implants, which could affect their performance or the patient's health. The potential occurrence of these complications is stated in the Motiva Implant Matrix® products Directions For Use (DFU) and their rates are very low when compared to similar reports of other breast implants available in the market.

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