SILIMED
passion inspiring science

Urgent Field Safety Notice – Silimed Implants

Commercial name of the affected products:
Plastic surgery: Mammary implants, pectoral implants, gluteal implants, calf implants, implants for hand surgery, tissue expanders, facial implants, nostril retainers, suspension sheets for breast surgery.
Bariatric surgery: gastric bands and balloons.
Implants for urology: testicular implants, penile implants, vesical conformers, periurethal constrictors, tubes for hypospadias, vaginal stents.
Silicone implants for general surgery: blocks and sheets.
Silicone invasive devices: sizers for silicone implants.

FSCA-identifier : FSCA 2015-01

Type of the Action: stop commercialization and request end-users to cease use and quarantine all listed devices

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Date: 24/09/2015

Attention:
To all distributors and end-users (professionals, hospitals and healthcare facilities)

Details on affected devices:
All batch/serial numbers of the devices listed below:

- **Plastic surgery**: Mammary implants, pectoral implants, gluteal implants, calf implants, implants for hand surgery, tissue expanders, facial implants, nostril retainers, suspension sheets for breast surgery.
- **Bariatric surgery**: gastric bands and balloons.
- **Implants for urology**: testicular implants, penile implants, vesical conformers, periurethal constrictors, tubes for hypospadias, vaginal stents.
- **Silicone implants for general surgery**: blocks and sheets.
- **Silicone invasive devices**: sizers for silicone implants.

A detailed list with catalogue numbers of all products can be found attached to this letter.

Description of the problem:

During an audit on Silimed's manufacturing procedures by our Notified Body Tüv Süd particles on the surface of some breast implants have been discovered. At that moment a corrective action has been installed in the Silimed's Mammary Implant process in an attempt to eliminate the possibility to transfer particles to implants surface. However these actions did not resolve the issue in a definitive way and as such Tüv Süd has decided to suspend the CE-certificate until 17 December 2015. Although our risk assessment did not reveal any serious health risks, Silimed is in discussion with the European Competent Authorities and our Notified Body to investigate this problem into more depth to verify and provide evidence that there is no risks for the patients' health and which additional preventive or corrective actions can be taken to eliminate the transfer of particles. **As a precautionary measure**, end-users are in the meantime being requested not to proceed with the implantation of the above mentioned devices until further notice.

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Annex to FSN – Information Letter to end-users

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Advise on preventive actions to be taken by the user:

The **Distributors** of Silimed Implants shall:

- Immediately freeze the commercialization of all implants (suspend the commercialization and internal distribution of the implants until the manufacturer's recertification or further notice). **This is not a recall of the products.**
- Quarantine the devices in stock by serial/batch number.
- Send all end-users to whom the devices were sold the annexed information letter preventing them from implanting and requesting them to quarantine the listed products until further notice. Please fill in your contact details in the annexed information letter before shipment of the letter.
- Gather signed confirmation forms from end-users that the above information was well received and send these forms back to Silimed.

Please transfer this notice to other organisations on which this action has an impact.

If you have any questions please contact us at:

Contact details:

Manufacturer: SILIMED – Industria de Implantes Ltda
Rua Figueiredo Rocha 374
21240-660 Rio de Janeiro
Brazil
Contact person: Katia Guimarães – Marketing Department
E-mail: katia@silimed.com.br

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

p/ Louise Azevedo Alves

Gabriel Robert
CEO

Louise Azevedo Alves
Farmacêutica Responsável
CRF 3417

Advise on preventive actions to be taken by the user:

- Cease implantation and place the products in quarantine until further notice.
- Please pass this notice on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Sign the confirmation form attached and send it back to your distributor of Silimed products to acknowledge receipt of this Field Safety Notice. Contact details of your distributor can be found below.

If you have any questions please contact us at:

Contact details:

Country	Address	Distributor	Contact	Phone	E-mail
Portugal Spain	Avenida Santos Dumont, 50 - 1050-204. Lisboa - Portugal	Hospitex	Joana Marcelino	351 918 635 695	geral@hospitex.pt joana.marcelino@hospitex.pt jmarcelino@hospitex.pt.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

p/ Louise Azevedo Alves

Gabriel Robert
CEO

Louise Azevedo Alves
Farmacêutica Responsável
CRF 3417

SILIMED – Industria de Implantes Ltda
Rua Figueiredo Rocha 374
21240-660 Rio de Janeiro
Brazil

Acknowledgement of receipt

The undersigned confirms that he/she has well received the above information related to the Field Safety Notice with reference FSCA 2015-01 and will act accordingly.

Institution:
Name: Date and signature: