



Urgent Field Safety Notice on Solysafe Septal Occluder

Immediate action required

August 4, 2010

Dear Medical Care Provider,

this is a urgent field safety notice of Swissimplant AG for their **Solysafe Septal Occluder** implants - comprising all models - as listed on the attached pages. Swissimplant AG has received individual reports from the field on unexplained behaviour of wires of the **Solysafe Septal Occluder** implant of a diameter of 30 mm and 35 mm. Swissimplant AG implements the following voluntary safety measures and will continue to investigate the issue comprehensively.

For the sake of precaution, Swissimplant AG is initiating a comprehensive and immediate

stop of implantation, marketing, selling and distribution of the Solysafe Septal Occluder of all models.

Information available to Swissimplant AG from the reports on isolated cases regarding models of diameters 30 mm and 35 mm indicate that the wires of these implants might become deformed, fractured, detach from the implant body, migrate within and outside of the patient's heart or embolise. The implant as a whole may in the course of this also be dislodged and not function properly. Such developments may cause serious or even fatal health consequences (inter alia lung embolisms or strokes).

The number of possible incidents of implant malfunction which have been reported to Swissimplant AG is very low (0.5% of products on the market). To date only isolated cases have been reported and possible malfunctions are limited to implants with a diameter of 30 mm and 35 mm. In order to ensure maximum patient safety Swissimplant AG for the present has decided to stop distributing and ask healthcare providers to stop implanting implants of **all diameters**.

Accordingly, we kindly request you to please complete the enclosed Urgent Field Safety Notice Acknowledgement and stock status form and promptly send it via telefax to our Customer Service Department at +41 32 625 0500. This will allow us to document your receipt of this letter.

For patients who have already received a Solysafe Septal Occluder of diameters 30 mm and 35 mm we advise you to

disclose the information in this letter to your patients concerned and request them to urgently present themselves for an implant evaluation as soon as possible.

These patients should be examined for any irregularities with their implant. The existence of deformation, fracture, migration of the implant wires and any possible dislodgement of the implant should be verified through a radiologic examination (chest x-ray or fluoroscopic exam).

Furthermore, regardless of implanted diameter size, physicians should advise

all patients to seek immediate medical attention that have reported any potential signs and symptoms of an embolic event or any heart condition after the implantation of a Solysafe Septal Occluder.

Upon each examination of the concerned patients we kindly ask you to

immediately revert to Swissimplant AG Customer Service Department at +41 32 625 0505 who will redirect you to competent expert personnel.

Please forward the examination findings and reports of any irregularities to Swissimplant AG as well (via telefax to +41 32 625 05 00 or by email to support@swissimplant.com). Swissimplant AG will conduct a detailed evaluation of your patient's case in view of your and your patient's best possibly informed decision regarding the further treatment.

Please contact Swissimplant AG under our hotline +41 32 625 0505 immediately if you suspect any abnormalities of the implant.

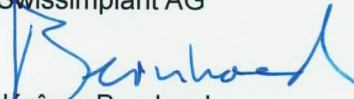
In this case immediate medical attention might be required to prevent serious health damage.

The relevant National competent authorities have been advised of these Field Safety Corrective actions.

We sincerely apologize for any inconvenience. If you require additional information or clarification regarding this, please contact Swissimplant AG's Customer Service Department at +41 32 625 0505.

Thank you and best regards

Swissimplant AG



Jérôme Bernhard