SIS MEDICAL
Swiss | Interventional | Systems

Frauenfeld, 03 Aug 2017

Urgent FIELD SAFETY NOTICE
Commercial Products: BEO NC PTCA Catheters Ø3.0, lengths 17, 20 and 22 mm, and Ø3.5, lengths 15, 17, 20 and 22 mm, specific lots
FSCA Identifier FSCA20170803
Type of Action Product Withdrawal (Corrective Action)

Dear SIS Medical Distribution Partner / Quality / Regulatory Representative

SIS Medical is performing a Field Safety Corrective Action (FSCA) to withdraw specific lots of BEO NC PTCA catheters listed in the attachment from the market. As per SIS Medical's internal records you have obtained devices of these affected lots.

In SIS Medical's internal trending we have noted an increased complaint rate with balloon deflation difficulties of device lots manufactured in a certain period. The overall complaint rate obtained for this issue is 0.06%. Potentials risks that may be associated with deflation difficulties may comprise cardiosurgical intervention and myocardial infarction.

Products from the affected lots having been successfully used with patients in a cardiac procedure are not subject to this FSCA.

Reason for this FSCA
During production of the catheter it may have occurred that the inflation / deflation lumen of the catheter has been reduced. Thus, inflation and / or deflation difficulties may occur, leading to aforementioned hazard to the patient.

Actions to be taken by SIS Medical Distribution Partner
1. Immediately acknowledge receipt of this Field Safety Notice (FSN) and the attached *Product Withdrawal Form* to SIS Medical (ra@sis-medical.com).
2. Inform responsible health care professional within your organization and your end users with this FSN.
3. Collaborate with SIS Medical should any country-specific notification to the respective National Competent Authority be necessary.
4. Identify and quarantine the affected devices in your warehouses and those of your end users.
5. Once consolidation is complete at your location
    a. contact SIS Medical Distribution AG (jacqueline.gassmann@sis-medical.com or heidi.meuli@sis-medical.com) with regards to exchange of quarantined devices and to obtain instructions for the return of goods to SIS Medical Distribution AG.

b. complete *Product Withdrawal Form* with **products used** (SIS Medical Customer and your customers) and **products returned**. Return *Product Withdrawal Form* with all unused products to SIS Medical Distribution AG.
c. Send an electronic copy of the filled in *Product Withdrawal Form* to ra@sis-medical.com

SIS Medical's Actions
SIS Medical has already initiated and implemented corrective actions to ensure product safety and performance.
The Swiss Competent Authority *Swissmedic* has been notified.
SIS Medical is striving to replace returned products with similar products, depending on availability.

Contact Point for Questions RE FSCA
Dr. Erhard Hüsler
Head QA/RA
SIS Medical AG
Hungerbüelstrasse 12A
CH-8500 Frauenfeld
E-Mail: ra@sis-medical.com

Contact Point for Returning of Goods
Jacqueline Gassmann, Heidi Meuli

SIS Medical Distribution AG
Hungerbüelstrasse 12A
CH-8500 Frauenfeld
E-Mail jacqueline.gassmann@sis-medical.com
heidi.meuli@sis-medical.com

SIS Medical regrets any inconvenience this action may cause and appreciates your understanding and collaboration. SIS Medical is committed to develop, produce and distribute innovative high quality products to the satisfaction of its customers.

Sincerely,

SIS MEDICAL AG
Hungerbüelstrasse 12a
CH-8500 Frauenfeld

Dr. Erhard Hüsler
Head QA/RA