



STSSengewald Klinikprodukte GmbH · Adlerstrasse 2 · 83101 Rohrdorf / Germany

Date 5 December 2019
Contact Uwe Gölz
Phone +49 176/17224 - 159
E-Mail ugoelz@stsmedicalgroup.com

Urgent Safety Notice and Field Safety Corrective Action CPT with “Pacemaker Drape 70+100+70 x 320cm”

Adressee

H. Dam Kærgaard A/S
Gammel Kongevej 60
1850 Frederiksberg
Danmark

Identification of the Medical Device

Drape S559119-9 „Pacemaker Drape 70+100+70x 320cm

in

CPT S66813522-08 Pacemaker Saet



Description of the problem and root cause

Dear customer,

you have reported a malfunction of one of our drapes (19-1201). During the procedure of implanting a pace maker the adhesive part of the drape, which surrounds the situs came off or came partly off. The user decided to apply additional medication (Antibiotics) to avoid post operative infection. No samples have been provided, as the contaminated drape was scrapped after the procedure.

First investigations on available products on STS stock do not show any deviation with regards to adhesiveness.

Reduced adhesiveness can also be related to the procedure itself e.g. the used disinfectant or other influences.

However as a preventive measure it was decided to recall all remaining lots and stop production. The investigation of the root cause is currently in progress.

Which actions have to be taken by you?

Please block and return all available devices and assure that a further usage of this devices is excluded.

For further proceeding and picking up of the goods if needed, please contact

Patricia Nero

Customer Service Complaint Handling

+49 (0) 8031/72 24-140

Email: PNero@stsmedicalgroup.com



Forwarding of this information:

Please make sure in your organization that all users of the above mentioned products and other persons to be informed receive this Urgent Safety Notice.

If you have given the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information at least until the action has been completed.

The Danish Medicines Agency has received a copy of this FSN.

Contact at STS Medical Group Sengewald:

Patricia Nero

Customer Service Complaint Handling

+49 (0) 8031/72 24-140

Email: PNero@stsmedicalgroup.com

Adlerstr. 2

83101 Rohrdorf/Thansau

Benedikt Staiger

Quality Management

+49 (0) 7451/55 35 - 66

Email: Bstaiger@stsmedicalgroup.com



Thank you in advance for your understanding and cooperation.

With best regards

Uwe Goelz

Corporate Director Quality Management & Regulatory Affairs
Safety Officer MPG S30

Mobile: +49 (0) 176/17224 - 159
Email: UGoelz@stsmedicalgroup.com