

B. Braun Melsungen AG
Division Aesculap

Sieversufer 8
12359 Berlin
Germany

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Date: November 23, 2016

B. Braun Singapore Pte. Ltd.
to Agnes Seah
#15-05 Parkview Square, North Bridge Road 600
188778 Singapore
SINGAPORE

Customer No. 9999900049
Field Safety Notice for SeQuent Please 2.0x20mm REF 5022220 LOT 16E02809

Dear ladies and gentlemen,

You are using the medical device SeQuent Please 2.0 x 20 mm with the article number REF 5022220 LOT 16E02809 in your interventional cardiology.

Verification of the batch history record of a complained product revealed that one product of the referenced batch contains a different SeQuent Please catheter than mentioned in the outer product label. The primary packaging inside the cardboard box may be labelled as and contains a SeQuent Please 2.5 x 15 mm REF 5022206. Labelling information in primary packaging may not comply to the information given in the secondary packaging labelling.

Vascular Systems has not received information regarding patient injury in conjunction with this product non-compliance.

After careful failure cause analysis Vascular Systems came to the conclusion that both products had been mixed within two good orders on August 17, 2016. The applied process has been adapted meanwhile to make sure that this product failure can be avoided in the future.

We hereby ask you not to use the referenced articles. Furthermore we would like to ask you to review your stock for the affected products and to prepare products for handover to our sales representative. Our sales representative will contact you within the next days to receive the affected products.

Pertained products should be returned latest by November 30, 2016, to the following address:

B. Braun Melsungen AG Vascular Systems
Dr. Dirk Schauer
Sieversufer 8
12359 Berlin

Product replacement will be arranged immediately after return of goods.

Vors. des Aufsichtsrats:
Prof. Dr. h.c. Ludwig Georg Braun

Vorstand:
Prof. Dr. Heinz-Walter Große
(Vorsitzender)
Dr. Annette Beller
Anna Maria Braun
(stellv. Vorstandsmitglied)

Otto Philipp Braun
Prof. Dr. Hanns-Peter Knaebel
Dr. Meinrad Lugan
Caroll H. Neubauer, LL.M.
Markus Strotmann

Sitz der Gesellschaft: Melsungen
Reg. Gericht: Amtsgericht Fritzlar
HRB 11 000

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B. Braun Singapore Pte. Ltd.

Please make sure that all users of above mentioned products as well as other persons who have to be informed receive knowledge of this field safety notice. In case of products have been forwarded to third parties please forward a copy of this information accordingly.

B. Braun Melsungen AG has informed the responsible competent authority Bundesinstitut für Arzneimittel und Medizinprodukte about the release of the field safety notice in written form.

In case of questions regarding this course of events as well as product replacement please contact Dr. Dirk Schauer, Head of Quality Management CoE Vascular Systems, phone: +49 30 568207-174, e-mail: dirk.schauer@bbraun.com.

We apologise for any inconveniences this process of safekeeping may cause and very much appreciate your support.

B, Braun Melsungen AG

i.V.



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Dr. Dirk Schauer
Head of Quality Management CoE VS

i.V.



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Dr. Bernhard Jänicke
Safety Officer