

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

34209 Melsungen
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Your reference:
Our reference: RECALL 2019-07-22

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Date: 2019-07-22

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE – Serofine® Recall

To whom it may concern,

We would like to inform you that the following product has to be recalled from the market in the course of a Field Safety Corrective Action:

| Article No. | Name | Batch |
|-------------|-----------|--|
| 16441MS | Serofine® | 18E28G8712 18G01G8711 18G02G8711 18G02G8712 |

Serofine® is a dedicated needle for use in combination with the easypod® Application Device. Serofine® is a single-use device.

The dedicated combination of the easypod® Application Device and the Serofine® needle is used for the application of the growth hormone SAIZEN®.

Reason for the Recall

In course of our post-market surveillance activities we found that there is the possibility that the above mentioned batches of Serofine® Needles in the dispenser box of 100 pcs. could not be used with the easypod® application device due to the bigger size of the protective cap.

Actions to be taken by the customer:

Our records have shown that your customers or patients have received the affected Serofine® product as specified above.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned products in your organization are informed about this Field Safety Corrective Action. If you are a distributor, please forward this correction notification to your customers or patients.

Chairman of the Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Anna Maria Braun, LL.M.
(Chief Executive Officer)
Dr. Annette Beller
Dr. Meinrad Lugan

Caroll H. Neubauer, LL.M.
Dr. Joachim Schulz
Markus Strotmann

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
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Carl-Braun-Straße 1
34212 Melsungen
Germany

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- Identify, quarantine and return affected goods.
- Do not use affected devices anymore.
- Confirm receipt of this information.

If more information is needed, please contact

Italy

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00176 Rome
Italy

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Northern Ireland

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Merck, S.L.U.

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Contact : Sandra Eder

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Kindly accept our apologies for any inconveniences.

Yours sincerely,



i.V.
Dr Ludwig Schütz
Safety Officer Medical Devices
B.Braun Melsungen AG



i.A.
Oleg Jochim
Director Quality Management Industrial Business
B.Braun Melsungen AG