

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

34209 Melsungen  
Germany

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

Contact:

Fon:  
Fax:  
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Internet:

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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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

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Merck, S.L.U.

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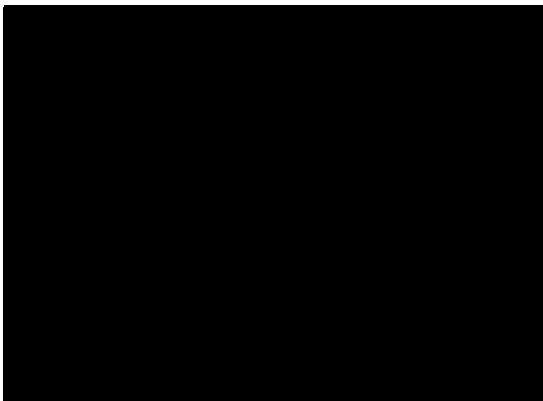
Austria

Contact : Sandra Eder

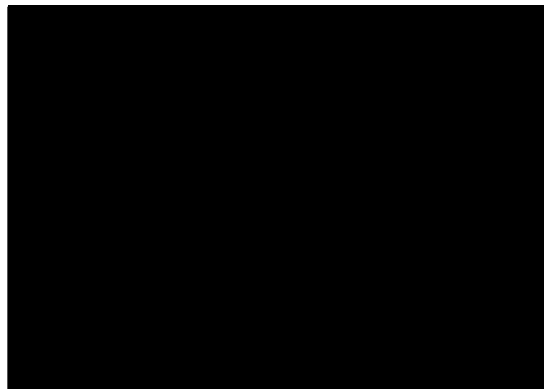
[sandra.eder@merckgroup.com](mailto:sandra.eder@merckgroup.com),

Kindly accept our apologies for any inconveniences.

Yours sincerely,



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