

**Subject: Market Inspection of Some Models of Forearm Crutches 220 and 230**  
**FSN Ref.: 2023-10-RT-FSN FSCA Ref.: 2023-10-RT**

Dear Sir/Madam,

We would like to inform you that some models of our Forearm Crutches 220 and 230 with interchangeable handles are undergoing a market inspection.

During an internal quality check, a technical defect was identified that could compromise the functionality of the product, potentially leading to a sudden breakage of the forearm crutch. This could result in severe falls and consequent serious injuries.

Potentially affected products in the colors blue, gray, black, and turquoise were sold during the following periods:

Article and Color	Sales Period
220 Blue	May 10, 2022, to August 10, 2022
220 grey	June 27, 2022, to September 14, 2022
220 black	May 6, 2022, to August 16, 2022
220 turquoise	July 14, 2022, to December 22, 2022
230 grey	July 8, 2022, to December 21, 2022

In the interest of patient safety, we are inspecting all forearm crutches with the characteristics listed in the table. Please note that this market inspection pertains solely to forearm crutches with interchangeable handles. Products with different handles during the specified periods and colors are not affected.

Kindly remove all affected forearm crutches received from us within the specified periods from sales immediately and refrain from further distribution to patients.

As the defect is not externally visible, we urgently request you to provide us with the LOT number found on the MDR label on the forearm crutch's tube. **Please submit the respective LOT numbers by December 15, 2023, via email to [qm-service@ossenberg.com](mailto:qm-service@ossenberg.com).** Upon review of the submitted LOT numbers, we will promptly get in touch with you to discuss the next steps.

**Ossenberg GmbH**

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 REG.-NR. MQI 0115318

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 Amtsgericht Steinfurt  
 HRB 6073

Geschäftsführer:  
 Martin Lisker

**Kreissparkasse Steinfurt**  
 DE14 4035 1060 0072 4888 69  
 WELADED1STF

**Deutsche Bank Rheine**  
 DE02 4037 0079 0422 2527 00  
 DEUTDE3B403

**National-Bank Essen**  
 DE54 3602 0030 0000 6786 51  
 NBAGDE3EXXX

**OLB Osnabrück**  
 DE94 2802 0050 5047 3594 00  
 OLBODEH2XXX

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Customers, patients, to whom you have handed out forearm crutches matching the above characteristics, must be immediately informed not to use them further, as there is a potential risk of severe health hazards due to possible sudden breakage of the forearm crutch leading to falls. Should you require assistance with this communication, we are available to support you. If necessary, ensure the provision of replacement products to patients.

We understand the potential inconvenience caused by this market inspection and are committed to managing the situation as smoothly as possible. Please feel free to reach out to us with any questions.

Thank you in advance for your cooperation and understanding.

Sincerely,

Martin Lisker CEO, Ossenberg GmbH

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