URGENT – MEDICAL DEVICE FIELD CORRECTION

Invacare® Homecare Series Bed and Invacare® G-Series Beds Containing Component Model Numbers: G50, G53, G54, BAR5490IVC, BAR5000IVC, 5000IVC, 5490IVC, 5490LOW

Date: January 22, 2024

URGENT: Product Recall Notice – Invacare® Homecare & G-Series Bed Components

Dear Provider:

We are writing to inform you of an important product recall impacting our Invacare® Homecare and G-Series bed components, ***within a specific serial number range produced between August 21, 2023, and November 2, 2023***, that have recently been identified with a potential weld defect. The problem was first discovered as a series of complaints received from customers reporting broken welds on bed components. Invacare investigated these complaints and determined they were related to the welding process. There has been one minor injury and no deaths or serious injuries reported related to this issue. You and your customers' safety and satisfaction are of utmost importance to us, which is why we are taking immediate action to address the issue.

According to our records, you have received one or more beds with these affected components (please see the Microsoft Excel file attached to this communication for your specific serial numbers). We sincerely apologize for the inconvenience or concern this may cause. Although the risk associated with this issue is low, we believe it is crucial to take proactive measures to ensure the safety and satisfaction of our customers. As a result, we have initiated a voluntary recall for all potentially affected units.

Potentially Affected Units

The Invacare® Homecare and G-Series bed components manufactured at the Invamex facility between August 21, 2023, and November 2, 2023, with the following model numbers are potentially affected:

Component Model Number	Description	Component of Bed Model(s)
G50	HEAD SECTION FULL ELECTRIC G-SERIES BED	G5510
G53	BED ENDS G-SERIES BED	G5510
G54	FOOT SECTION FULL ELECTRIC G-SERIES BED	G5510
BAR5490IVC	BARIATRIC BED FOOT	BAR600IVC
BAR5000IVC	BARIATRIC BED HEAD	BAR600IVC
5000IVC	HEAD SPRING SCTN-ALL MDLS	5410IVC or 5410LOW or 5310IVC
5490IVC	FULL ELECTRIC FOOT SPRING	5410IVC or 5410LOW
5490LOW	FOOTSPRING FOR 5410LOW BED	5410LOW

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Homecare bed component models 5301IVC and BAR5301IVC bed ends are <u>not</u> included in the field action.

To address the issue, we ask that you follow the procedure below:

1. **Please locate your affected stock**
   Please review your records to locate the affected components. Above is a list of model numbers to assist you with this process. To help you locate the model and serial number, an example of the product label is shown below.

   For unused bed components, still in their box, the model number and serial number is located on the carton label.

2. **If the affected bed component has already been delivered to a consumer customer:**
   Please contact your customer. As a precaution, we advise discontinuing use of the affected product, if feasible. Please use the attached 'Communication to Consumer' to help you communicate this information to your customer.

3. **For affected bed components that have not been delivered to a customer:**
   Please quarantine the inventory.

Yes, you can.

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4. **Please contact us for further guidance.**
   Please contact our dedicated Customer Support Team at 1-877-413-6008, 8:30AM -5PM EST which will guide you through the returns process and work with you to provide replacement(s) or account credit(s) for the affected unit(s) returned.

5. **Report missing or previously destroyed serial numbers.**
   If a serial number in the attached Microsoft Excel file is missing or known to have been previously destroyed, please report this back to us by marking an 'X' in the **Product Missing or Previously Destroyed** column and emailing the updated Excel file to recall@invacare.com.

6. **We finally ask that you please complete the provider acknowledgement form** and submit it to us. You can click on the link below to complete the form.

https://forms.office.com/r/a595CDPR4M

Please note that this recall is being conducted with the knowledge of the FDA and is subject to FDA effectiveness checks. As a provider, you are responsible for ensuring the above and outlined field correction is conducted with your customers. If you become aware of an adverse event associated with the use of this device, please report this to FDA's Medwatch and to Invacare as a complaint.

Once again, we thank you for your prompt attention to this important matter. We appreciate your understanding and cooperation. We are committed to working with you to resolve this matter efficiently.

Yours sincerely,

Invacare Quality & Regulatory Team

Attachments: Customer Letter
Serial Number List