

(Enter Company Name)

Field Safety Notice for (Enter Product Name and Version Number)

(Enter Date)

Keep in mind that FSN has to be written in the language of the country you are operating your device in, so you may have to translate this template text.

For your orientation: the German BfArM has also published past reports as templates to be used by other manufacturers.

(Page 1: Cover Letter) Dear Customer,

Our company's products are subject to continuous and rigorous surveillance to ensure ongoing safety and reliability while being used.

As part of our product surveillance, we identified a potential problem that could impact the performance of the device.

We would therefore like to provide you with the following information:

- description of the problem and under which circumstances it may occur
- recommended actions to avoid the problem or minimize its implications
- actions planned by (company name) to resolve the problem

If you need any further information or support concerning this, please reach out to our company representative: (Company Contact Details and Responsible Person)

We would like to apologize for any inconvenience.

Sincerely,

(Enter name of responsible Medical Device Safety Officer / Person Responsible for Regulatory Compliance)

(Page 2: FSN Report) (Product Name)

Field Safety Notice for (Version Number)

(Date)

This document contains important information for the continued safe and proper use of your medical device.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication. Please retain a copy with the Instructions for Use and confirm the receipt of this notice.

Affected Product:
Unique Device
Identification:
Version:
Problem Description:
Hazard Involved:
Recommended Actions:
Actions Planned by
(company name):
Further Information and Support: (Refer to a country contact including information on availability.)

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