Urgent Field Safety Notice

YYYY-MMM-DD | FSCA 2026-015 – OT 1555113 | Rev 01

Subject: Getinge Poladus 150 H1/H2

Products affected:

This Field Safety Notice applies to all Getinge Poladus 150 H1/H2 devices manufactured under the item numbers listed below.
Our records indicate that at least one (1) of the below listed products was delivered to your location. Please verify if you have any of the listed products and follow the information in this notification.

Item number	UDI	Item name
6034510000	04053275000226	Getinge Poladus 150 H1
6034510001	04053275000233	Getinge Poladus 150 H1
6034510002	04053275000240	Getinge Poladus 150 H2
6034510003	04053275000257	Getinge Poladus 150 H2
6034510004	04053275000264	Getinge Poladus 150 H2
6034510005	04053275000271	Getinge Poladus 150 H2

Description of the issue

During an internal review of Poladus' technical documentation, it was determined that, for three (3) specific worst-case sterilization tests on materials, the defined acceptance criteria were not met in all test cases, even though the overall result was documented as “PASS”.
For the following materials, microbicidal effectiveness could not be fully proven:

- Polypropylene
- Polystyrene
- Polytetrafluorethylene
- Polyurethane
- Stainless steel
- Ethylvinyl acetate
- Kraton
- Titanium for mated surfaces

These three tests had therefore been invalidated.

Potential hazards

A Health Hazard Evaluation has identified a risk of patient infection due to the non-detection of materials potentially not sufficiently sterilized. Due to the identified unclear test results, we cannot completely rule out the risk of patient infection at this time. Even though the probability is considered low, the potential severity could be critical.

Precautions

We are currently redoing the affected tests and will inform you as soon as results which have passed acceptance criteria are available. As noted above, the failure to detect contamination of instruments could lead to patient infection, although the likelihood of occurrence is low. For this reason, we currently do not recommend use of the device.

We are aware that you might not have an alternative for the low temperature sterilization of instruments which could pose the risk of a delay or denial of treatment. If you choose to continue to use the devices due to a lack of alternatives, please make sure to meet the requirements of EN ISO 14937, ISO 22441, and the device's instructions for use for your validation activities (such as use of chemical and biological indicators).

Getinge Actions

The affected tests will be redone to show compliance with the set acceptance criteria.
You will be informed as soon as the affected tests meet acceptance criteria and your use of the product may safely resume.

Customer Actions

1. Please ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.
2. Please complete and send the Customer Reply Form to your local Getinge representative via email at <insert local Getinge representative email>.

Attachments

- FSCA 2026-015 - OT 1555113 Reply form

We sincerely apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

Getinge is communicating this information to the appropriate regulatory agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Diana Gutekunst
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Germany

Signature: Diana Gutekunst
Electronically signed by: Diana Gutekunst
Reason: I approve this document.
Date: Jul 8, 2026 15:54:12 GMT+2

Email: diana.gutekunst@getinge.com

Contact details of your local Getinge representative

Contact Name
Contact e-mail
Contact phone
Contact office address