URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 27001

To: Risk Manager/Hospital Administrator
Director of Biomedical Engineering
Director of Clinical/Radiology

RE: **Imactis® CT-Navigation™ System – Potential for difference between simulated needle position and actual needle position**

Safety Issue

GE HealthCare has become aware of a potential issue on Imactis® CT-Navigation™ systems that can lead to discordance between the simulated needle trajectory/tip position and the actual needle trajectory/tip position. This condition can occur when needles with metal handles or metal hubs are used, and the metal handle or metal hub comes in close proximity to the needle holder. An inaccurately simulated needle trajectory, if not recognized, could result in advancement of the needle to an unintended location and potential patient harm.

Note: The existing User Manual indicates that metallic masses can cause perturbation and warns that system accuracy can be affected by large metallic objects. With this correction we are adding an explicit warning regarding the potential issues associated with metal handles or metal hubs.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer / User

You can continue to use your system if you DO NOT use needles with metal handles or metal hubs.

A User Manual addendum is included with this letter (see Appendix A) that includes specific instructions to avoid the use of needles with metal handles or metal hubs.

Please place a copy of the addendum in Appendix A with the User Manual for each Imactis® CT-Navigation™ system in your facility.

Please ensure all potential users in your facility are made aware of this safety notification and the required actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.27001@gehealthcare.com or use the QR code to submit your response electronically.

Affected Product Details

Product	HIBCC / UDI [DI]
Imactis® CT-Navigation™ System	+B681J02000

Intended Use:
The Imactis® CT-Navigation™ system is a stereotaxic accessory for Computer Tomography (CT) systems. Imactis® CT-Navigation™ displays a simulated image of an interventional instrument on a computer monitor screen that also shows images of the targeted organ(s) and the current and projected future path of the interventional instrument.

Product Correction	With this letter (see Appendix A), GE HealthCare is providing a User Manual addendum that includes specific instructions to avoid the use of needles with metal handles or metal hubs. Updated electronic User Manuals will be available by March 16, 2026, on the GE HealthCare Customer Documentation Portal.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE HealthCare or your local Service Representative.

GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact GE HealthCare per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Safety Officer
GE HealthCare

Appendix A – User Manual Addendum

This addendum is an addition to the information contained in the User Manual

⚠ WARNING

DO NOT USE NEEDLES WITH A METAL HANDLE OR METAL HUB.
A METAL HANDLE OR METAL HUB CAN CAUSE MAGNETIC INTERFERENCE THAT CAN SIGNIFICANTLY AFFECT THE ACCURACY OF THE SIMULATED NEEDLE TRAJECTORY.

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MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

To complete this form online, scan the QR code below	**To complete this form via email, scan or take a photo of the completed form and email to recall.27001@gehealthcare.com**