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Distributed to:

IMACTIS® CT-Navigation™ Clinical Users
Biomedical Engineers and Team

August 13th, 2020

IMPORTANT CUSTOMER INFORMATION

Commercial name of the affected product: IMACTIS CT-Navigation™ Workstation

Device technical reference: J02000 or J00180

Device marketing reference: MA-J02000 or MA-J00180

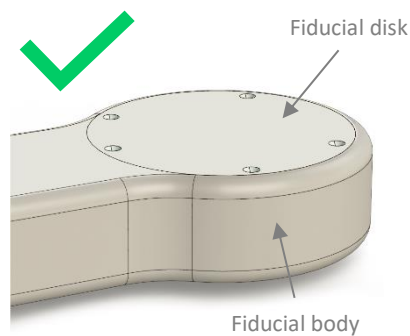
Type of action: Information

Details of affected component:

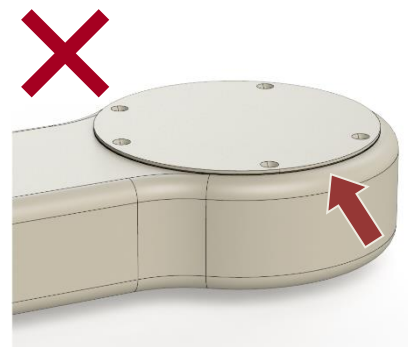
Patient fiducial (Reference IHR-YY-XXX) connected to the CT-Navigation™ workstation.

Description of the problem:

In the event of a shock or fall, the fiducial disk, normally flush with the surface, could become detached from the fiducial body.



Picture 1. Patient Fiducial Conformity



Picture 2. Patient Fiducial Non-Conformity




In the event of a separation, it has been reported that some users have tried to re-assemble the fiducial disk inside the fiducial body and attempted to use the device again.

The use of this device under these conditions is not safe. The patient fiducial must be repaired and re-calibrated or should be replaced by an Imactis Field Engineer.

The use of a re-assembled patient fiducial could lead to inaccuracies of the IMACTIS® CT-Navigation™ device.

In the event you notice the separation of the fiducial disk, please contact your IMACTIS® representative who will manage the return, repair and recalibration, or the replacement of your patient fiducial.

As a reminder, the following warnings are noted in the instructions for use supplied with the device:

	The shocks and falls must be avoided. Any shock or damage can affect the system accuracy. Make sure before each use to check the status of the components. Never use the IMACTIS® CT-NAVIGATION software after a major shock to the magnetic emitter and receiver.
	The user is responsible for checking continuously that the information displayed on the screen by the system are accurate and coherent with the reality. In case of doubt, it is necessary to redo a series of images to check the needle position and update the IMACTIS® CT-NAVIGATION software data or to continue using the conventional interventional protocol.
	If the user has any doubts about the system accuracy during the navigation, a new acquisition of images must be performed. This new acquisition will allow the needle position to be checked and will update the IMACTIS® CT-NAVIGATION software data.

Transmission of this customer important information:

This information must be shared with all required employees within your facility.

Action plan:

- An acknowledgement of receipt of the important customer information must be sent back to the manufacturer (See attached Appendix A).
- A warning label, which will be sent to your facility, must be affixed to the IMACTIS® CT-Navigation™ workstation (See attached Appendix B).

IMACTIS® confirms that the French competent authority has been notified.

If you have any questions related to this important information, please contact your IMACTIS® representative.

We apologize for any inconvenience this may cause and thank you in advance for your attention to this matter.

Sincerely,



quality@imactis.com

Signature: X

APPENDIX A - ACKNOWLEDGEMENT OF RECEIPT OF IMPORTANT CUSTOMER INFORMATION

I (Name)..... (Function).....

Site.....

CT-Navigation™ Workstation(s) **IMB**¹-.....

acknowledge receipt of the important customer information under reference SAFNT\20-004.

I confirm that:

- CT control scans of the patient were performed with the IMACTIS® CT-Navigation™ system as recommended in the user manual;
- CT scans did not reveal any inaccuracies that jeopardized patient safety;
- No adverse events related to the use of the IMACTIS CT-Navigation™ device occurred during the interventions performed since the system installation.

I hereby certify that the patient fiducial **IHR**²-..... (Check the appropriate status):

- 1) Is correctly assembled (See Picture 1) and has not been damaged in any way; or
- 2) Is slightly detached and not flush with the surface (See Picture 2); or
- 3) Has been partially or completely disassembled and then put back in place.

If you have selected box 2) or 3), do not use the CT-Navigation™ system and contact your IMACTIS® representative immediately.

Date :

Signature :

Please send this signed acknowledgement of receipt to quality@imactis.com.

¹ The reference IMB-YY-XXX is on the back of the station on the identification label.

² The reference IHR-YY-XXX is engraved on the patient fiducial.

APPENDIX B – WARNING LABEL CT-NAVIGATION™ PATIENT FIDUCIAL

This document will be attached with the label sent to your facility.
Once the label is in place, please return this signed document to quality@imactis.com.

Instruction:

Affix the warning label on the **upper edge of the cart drawer** of the IMACTIS® CT-Navigation™ workstation.



I confirm the warning label has been affixed to the workstation as described above.

Name:

Position:

Date :

Signature :