IMACTIS®
20 rue du Tour de l'eau
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Mail quality@imactis.com

«Hospital_Name»
To the attention of the Materiovigilance contact
«Customer_Address»
«Zip_Code» «City» - «Country_name»

July 30th, 2019

Urgent Field Safety Notice

Commercial name of the affected product: Navigation Kit
Device reference: I10100
Type of action: LOT RECALL

Details on affected devices:

The single-use navigation kit under reference I10100 contains components used during interventional radiology procedures navigated with the IMACTIS® CT-Navigation system.
One of the components of this kit, the sensor cover under reference PC3688, is being recalled by its manufacturer ECOLAB.
Therefore, we must recall the following kit batches:

REFERENCE IMACTIS® → I10100 NAVIGATION KIT			
LOT	**Expiry date**	**LOT**	**Expiry date**
17110001	2019-08	**18120001**	2020-04-01
18010001	2019-09	**19010002**	2020-04-01
18010002	2019-09	**19020001**	2020-11-26
18040001	2019-12	**19020002**	2021-01-26
18060001	2020-02	**19030001**	2021-01-22
18070001	2020-02	**19040001**	2021-01-22
18110001	2020-02	**19060001**	2021-04-09
18110002	2020-02	**19060002**	2021-04-09

We are doing all we can to ensure that you may continue to effectively treat your patients with IMACTIS® CT-navigation system. This letter explains the situation and presents the action plan implemented.

Description of the problem:

The manufacturer of the cover under reference PC3688 informed us as follows:

A source of microbial contamination has been identified in a raw product used to manufacture the tip of the cover.
There is a very low risk of bacterial contamination, induced by some batches of covers. The hazard resulting from the defect is direct exposure of the intra-cardiovascular, intra-lymphatic or neurological system to a level of endotoxin sufficient to produce a pyrogenic response. Endotoxins that enter the bloodstream or cerebrospinal fluid can cause an inflammatory response causing fever, leukopenia or leukocytosis or fatal shock. The assessment of the occurrence probability of a potentially dangerous event resulted in a result of less than 1%.
In general, the evaluations concluded that the potential health risk associated with the use of covers was low for both the patient and the user.
The warning on the product is also recalled in the manufacturer's safety notice: "must not come into contact with the central nervous system"

IMACTIS® has not been informed to date of any adverse events related to the hazard described above.

Advise on action to be taken by the user:

⌋ the identification and quarantine of the concerned devices,
⌋ the acknowledgement of receipt of the safety information provided in **Annex 1** to be returned to the manufacturer.

Transmission of this Field Safety Notice:
This safety information must be transmitted to all persons in your facility who may be concerned by the implementation of safety corrective actions or to any department to which the recalled products could have been transferred.

We recommend that you pay particular attention to the corrective actions in order to ensure compliance.

Action plan:
A new sensor cover reference, used under the same conditions with the IMACTIS® CT-Navigation system, has been identified. This is reference 610-797 from the manufacturer CIVCO. Therefore, the following actions will be implemented:

- ✓ As of today, recall of the batches of navigation kits.
  Complete **Annex 1** and send to quality@imactis.com before August 9, 2019.
  Complete **Annex 2** referencing the recalled lot numbers and return to the address provided.

- ✓ Until 16 August 2019 inclusive, in order to enable you to carry out the planned interventional radiology procedures that are navigated with the IMACTIS® CT-Navigation system solution, covers under reference 610-797 can be sent to replace the PC3688 covers contained in the kits. PC3688 covers must be destroyed by you (certificate of destruction in **Annex 3**).

- ✓ IMACTIS® send back the new I10100 navigation kits containing the cover under reference 610-797.

We apologize for the inconvenience. If you have any questions regarding this safety notice or the identification of the systems concerned, do not hesitate to contact your IMACTIS® representative immediately.

IMACTIS® confirms that your national competent authority has been informed of this safety advisory.

We thank you for your attention to this matter and look forward to resolving this quickly and with as little impact as possible.

……
……

Signature:

Signature:

ANNEXE 1 – AKNOWLEDGEMENT OF RECEIPT OF THE SAFETY NOTICE

I undersign (Name)…… (Function)……..

Site ……..

acknowledge receipt of the safety information letter under reference SAFNT\19-001 and confirm that I have read it and distributed it to the IMACTIS® CT-Navigation system users' staff.
I also confirm that no adverse events related to the above hazards have occurred after the use of the navigation kits.

Finally,

☐ I do not have any navigation kit in stock,

or

☐ I do not keep any navigation kit and I will return all the kits in stock

or

☐ In order to ensure the planned interventional radiology procedures, and until new navigation kits are returned to me, I keep ……. (*detail how many*) Navigation kit(s) and wish to receive the same number of covers under reference 610-797. Other in stocks kits will be returned to IMACTIS. Replacement covers shall be sent for my attention, at the following address:

……

……

……

……

✓ I undertake to use these covers as a replacement for the PC3688 covers contained in the I10100 navigation kits. I also provide the certificate of destruction of these PC3688 covers (**annex 3**).

Date : Signature :

Please send this form **before August 9th**, 2019 to quality@imactis.com

ANNEXE 2 – FORM TO COMPLETE AND TO JOIN TO THE NAVIGATION KITS RETURNED

Return Material Authorization **RMA #_____** *(A remplir par IMACTIS® à reception)*			
SITE:			
Contact name:			
Adress:			
mail		**phone**	
Date			

REFERENCE IMACTIS® → I10100 NAVIGATION KIT					
Check the lots returned	LOT	Nbre of kits	*Check the lots returned*	LOT	Nbre of kits
☐	17110001		☐	18120001	
☐	18010001		☐	19010002	
☐	18010002		☐	19020001	
☐	18040001		☐	19020002	
☐	18060001		☐	19030001	
☐	18070001		☐	19040001	
☐	18110001		☐	19060001	
☐	18110002		☐	19060002	

To be returned completed with the NAVIGATION KITS returned to the following address:

IMACTIS
20 rue du Tour de l'eau
38400 Saint-Martin d'Hères
FRANCE

ANNEXE 3 – CERTIFICATE OF DESTRUCTION OF COVERS PC3688

I undersign (Name)…… (Function)……..…..

Site ……..

confirm I have destroyed ……. (*detail how many*) covers PC3688.

Date : Signature :

Please send this form **before August 9th**, 2019 to quality@imactis.com