Rev 1: 06 OCT 2020
Manufacturer's Ref Number: CT-20-00324

Date: XX OCT 2020

Urgent Field Safety Notice
Niobe ES

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
Niobe ES
Potential Fire Hazard

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	An assembly of electromechanical devices designed to be used during computer assisted surgery
1.	2. Commercial name(s)
	Niobe ES
1.	3. Primary clinical purpose of device(s)*
	The Niobe ES system is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart, pericardial space, coronary vasculature, and peripheral vasculature by orienting the device tip in a desired direction.
1.	4. Device Model/Catalogue/part number(s)*
	001-006000-1 (Niobe with Siemens); 001-006100-1 (Niobe with Philips)
1.	5. Software version
	All
1.	6. Affected serial or lot number range
	0105, 0108, 0113, 0116, 0124, 0125, 0126, 0128, 0130, 0131, 0134, 0135, 0138, 0139, 0140-0142, 0144, 0147, 0149, 0154, 0158, 0162, 0163, 0169, 0170, 0172-0174, 0177-0179, 0181-0183, 0185, 0187, 0189, 0190, 0192-0202, 0205, 0206, 0208-0210, 0212, 0214-0222, 0224-0229, 0231, 0232, 0235-0242, 0244, 0245, 0249, 0251-0256, 0251-0278, 0280-0284, 0286-0288, 0290, 0297
1.	7. Associated devices
	Navigant

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A SATA cable in the Niobe computer cabinet was designed in a way that could lead to electrical arcing.
2.	2. Hazard giving rise to the FSCA*
	Electrical arcing can cause a fire in the Niobe cabinet.
2.	3. Probability of problem arising
	Based upon information from the manufacturer of the cable there is a 0.02% chance that electrical arcing can occur during the lifetime of these cables
2.	4. Predicted risk to patient/users
	It is anticipated that if this event to recur, damage to personnel could include burns and smoke inhalation.
2.	5. Background on Issue
	A fire in the Magnet Controller Computer was reported on 12 AUG 2020. The fire was contained within the computer cabinet and was extinguished with no injuries. It was discovered that the SATA cable inside the computer had arced, resulting in the fire.

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

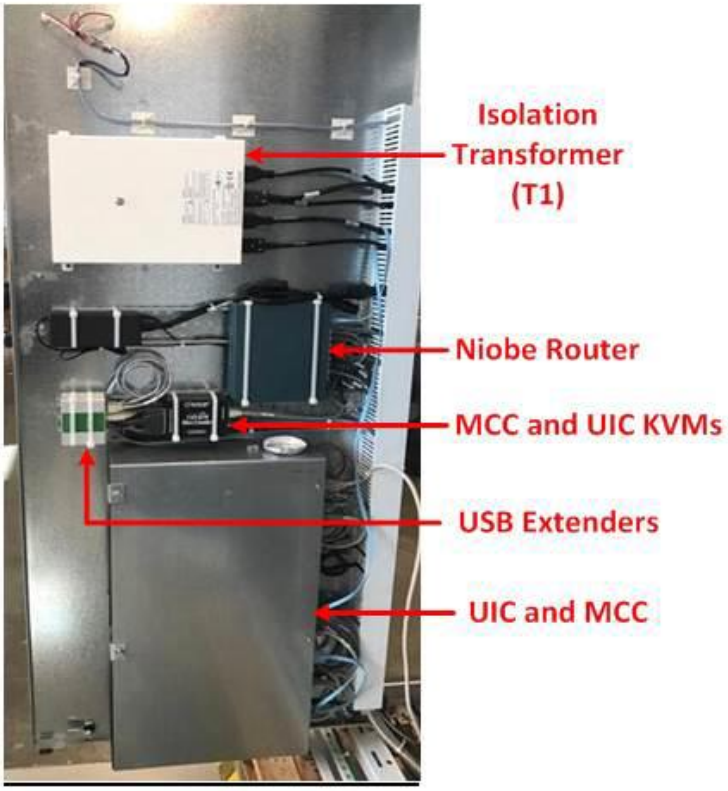
☐ Other ☐ None

Please respond to this FSN with the Serial Number of the MCC and UIC in the Niobe computer cabinet. Please follow these steps in order to identify the Serial Numbers. Please contact Stereotaxis personnel if assistance is required.

1. Locate the Niobe Computer Cabinet

2. Open Niobe Computer Cabinet
3. Locate the Swing Door inside of the Niobe Computer Cabinet

4. Open the swing door and you will see the following components



5. Record UIC and MCC Serial Numbers on FSN Customer Response Form

6. Return completed FSN Customer Response Form to Stereotaxis personnel

3.	2. By when should the action be completed?	Within 30 days of receipt

3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No This issue has not created any known harm to any patients and the issue would not impact the results of a completed procedure	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None For systems with computers that are affected, the SATA cable will be replaced by Stereotaxis Field Service Personnel	
3	6. By when should the action be completed?	Within the next 6 months
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Stereotaxis, Inc.**
	b. Address	**4320 Forest Park Ave Suite 100 St. Louis, MO 63108**
	c. Website address	**www.stereotaxis.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. Name/Signature	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.