Rev 1: September 2018
Manufacturer's Ref Number: CT-19-00613

Date: 04 MAY 2020

Urgent Field Safety Notice
Niobe ES

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*

Rev 1: September 2018

Manufacturer's Ref Number: CT-19-00613

Urgent Field Safety Notice (FSN)
Niobe ES
Object Placed on Keyboard

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	An assembly of electromechanical devices designed to be used during computer assisted surgery (CAS) as a functional
1.	2. Commercial name(s)
	Niobe ES
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. 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.	5. Device Model/Catalogue/part number(s)*
	001-006000-1 (Niobe with Siemens); 001-006100-1 (Niobe with Philips)
1.	6. Software version
	All
1.	7. Affected serial or lot number range
	All
1.	8. Associated devices
	Navigant

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Pressing down one of the keys on the keyboard continuously can cause the vector to continually rotate, thus rotating the catheter inside the ventricular chamber.
2.	2. Hazard giving rise to the FSCA*
	This unintended motion could potentially cause injury to the patient.
2.	3. Probability of problem arising
	Based upon review of complaint and procedure data, the problem is expected to occur in less than 0.01% of procedures.
2.	4. Predicted risk to patient/users
	It is anticipated that if this event to recur, the catheter could potentially cause injury to the endocardiam and valve structures within the heart
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	It was reported that during a VT ablation procedure done on 8/30/2019, something was set on the keypad, pressing down one of the keys causing the vector to continually rotate
2.	7. Other information relevant to FSCA
	N/A

	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	
3.	2. By when should the action be completed?	Within 30 days of receipt
3.	3. Particular considerations for: 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	
3	6. By when should the action be completed?	Action has been completed
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. 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.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	

	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.