Rev 2: February 2020
FSN Ref: NEODOC-18-23 FSCA Ref: NEODOC-18-27

Date: 2023-05-03

Field Safety Notice
NeoNavia CorePulse probe

For Attention of*: XXX

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Field Safety Notice (FSN)
NeoNavia CorePulse probe –
Tissue sample chamber does not open

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The CorePulse™ probe is intended to provide tissue samples from breast lesions and axillary lymph nodes for histologic examination.
1.	2. Commercial name(s)*
	NeoNavia CorePulse probe
1.	3. Unique Device Identifier(s) (UDI-DI)
	17350081940062
1.	4. Primary clinical purpose of device(s)*
	The CorePulse™ probe, when used as a part of the NeoNavia® biopsy system, is intended for obtaining tissue samples from both breast lesions and axillary lymph nodes for diagnostic analysis of breast abnormalities. 
1.	5. Device Model/Catalogue/part number(s)*
	REF # 2103
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	LOT # K23C065
1.	8. Associated devices
	The CorePulse™ is one of three probes that are used as a part of the NeoNavia® biopsy system (base unit + driver + probe)

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Through NeoDynamics' processes for product complaints, it has come to our attention that in some cases the tissue chamber will not open and therefore the sample cannot be retrieved from the probe. No patient injuries have been reported. Based on the mentioned complaints and our initial investigations, we as the legal manufacturer send out this Field Safety Notice. We have initiated corrective and preventive actions to address the non-conformities.
2.	2. Hazard giving rise to the FSCA*
	The highest risk associated with not being able to retrieve a sample from the CorePulse™ probe is that another sample must be taken with a second probe. Performing multiple biopsy procedures until the number and quality of samples are satisfactory for the

	physician is part of the standard clinical method for biopsies and acceptable from a risk/benefit point of view, as documented in the risk management file for the NeoNavia® Biopsy System.

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

NeoDynamics needs your help to locate all affected CorePulse™ probes and take actions. Follow the instructions:

1. If you never opened the outer box that CorePulse™ probes from LOT # K23C065 arrived in go to 6. The outer box that CorePulse™ probes from LOT # K23C065 arrived in looks like this:

2. Any CorePulse™ probes from LOT # K23C065 taken out of their sterile individual packaging must be discarded as biohazardous waste.
3. Identify all CorePulse™ probes from LOT # K23C065 still in their sterile individual packaging or still in their white 5 pack box.
4. Put all CorePulse™ probes from LOT # K23C065 that are still in their sterile individual packaging or still in their 5 pack box back in the outer box that they arrived in.
5. If the box that the CorePulse™ probes from LOT # K23C065 arrived in is no longer available, any shipping box will do.
6. Ensure the outer box that the CorePulse™ probes from LOT # K23C065 arrived in (or the shipping box you selected) is securely sealed with tape.
7. Print the attached label using colour print.
8. Use tape to securely fasten the label to the box as shown in these pictures:

Before:

After:

9. With a marker (any colour) write the number of CorePulse™ probes from LOT # K23C065 that is in the box, for example “8”:

10. Segregate (quarantine) the labelled boxes containing CorePulse™ probes from LOT # K23C065 from all other probes, ensuring that no mix ups can occur.

	11. Await a NeoDynamics representative to come to pick up the labelled boxes containing CorePulse™ probes from LOT # K23C065. We deeply regret the inconvenience this procedure causes you. Our goal is to make this process as uncomplicated as possible for you. NeoDynamics aims to be a responsible legal manufacturer providing safe and effective medical devices to the market. Retrieving all CorePulse™ probes from LOT # K23C065 is important to us.	
3.	2. By when should the action be completed?	ASAP, but no later than 2023-05-18.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, through email saying "I have received your email and the FSN". (The Delivery receipt function and the Reading receipt function will be used for the emails sent from NeoDynamics.)
3.	**4. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None NeoDynamics has stopped all delivery of CorePulse™ probes availalbe in stock. All CorePulse™ probes delivered to the market will be retrieved from the clinics according to this Field Safety Notice.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes.	

	Transmission of this Field Safety Notice
	This notice needs to be passed on to 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.