

Date: 26/7/2021

Urgent Field Safety Notice
RevoWavePX

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
Distributor Olympus Europe Email: FSCA@olympus-europa.com

Urgent Field Safety Notice (FSN)
RevoWavePX

1. Information on Affected Devices			
1. Device Type(s)			
GMDN:46691 Gastro-urological guidewire, single-use GMDN: 64109 Tracheobronchial guidewire			
2. Commercial name(s)			
RevoWavePX			
3. Unique Device Identifier(s) (UDI-DI)			
RWHA-3526ID : (04545428038694) RWHS-3526ID : (04545428038687)			
4. Primary clinical purpose of device(s)			
This guidewire is designed for temporary use in guiding a catheter, tube, etc. and in adjusting their positions inside the body. This guidewire should not be used for inserting into blood vessels.			
5. Device Model/Catalogue/part number(s)			
RWSS-3545I	RWSS-3526I	RWHA-2545I	RWHS-3526ID
RWSA-3545I	RWSA-3526I	RWHJ-3545SJ	RWHA-3526ID
RWHS-3545I	RWSA-3555I	RWHJ-2545SJ	RWHA-2526ID
RWHA-3545I	RWUA-2555I	RWSS-3555I	RWHS-2526ID
RWUA-3545P	RWHS-2545I	RWUS-2555I	
6. Affected serial or lot number range			
RWHA-3526ID (Lot.No.10608) RWHS-3526ID (Lot.No.10608)			

2. Reason for Field Safety Corrective Action (FSCA)
1. Description of the product problem
The Ti-Ni alloy wire used for the guide wire has a tapered tip to give it flexibility. The length of this taper processing and the outer diameter of the Ti-Ni alloy wire are different from the original specifications.
2. Hazard giving rise to the FSCA
Originally, a member with a taper length of 150 mm and an outer diameter of the core wire of 0.60 mm is used. The mixed one has a taper length of 200 mm and an outer diameter of 0.58 mm. Since the taper length is longer and the outer diameter is smaller than conventional products, the flexibility of the guide wire tip is softened. Therefore, the risk of perforation to the patient is considered to be lower than that of the original product.
3. Probability of problem arising
We understand that about 300 of the two specifications of the products targeted this time are mixed. Since the total number of target products is 950, about 32% of the products are mixed.
4. Predicted risk to patient/users
As explained in Section 2.2, it is judged that there is no risk to users and patients.

<p>5. Background on Issue</p> <p>The two types of taper lengths (1500m and 2000mm) were inadvertently mixed during cleaning. The usage history of the member was confirmed, and it was confirmed that it was included in one lot (Lot.No.10608).</p>

3. Type of Action to mitigate the risk	
1. Action To Be Taken by the User	
<input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None <p>All inventory in the Distributor's warehouse will be returned. Disposers are responsible for disposing of products shipped to the market. Make sure that the disposal record is provided to the manufacturer.</p>	
2. By when should the action be completed?	It is expected that it will take about one month to complete the handling of returned products and waste products.
3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
4. Action Being Taken by the Manufacturer	
<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
5. By when should the action be completed?	It is expected that it will take about one month to complete the handling of returned products and waste products.
6. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information	
1. FSN Type	New
2. Further advice or information already expected in follow-up FSN?	No
3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
a. Company Name	PIOLAX MEDICAL DEVICES, INC.
b. Address	2265-3 Kamiyabe-cho, Totsuka-ku, Yokohama-shi, Kanagawa 2220033, Japan
c. Website address	https://www.piolax-md.co.jp/en/
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
5. Name/Signature	Insert Name and Title here and signature below

Transmission of this Field Safety Notice
<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..</p>