

Date: 04/08/2021

## **Urgent Field Safety Notice** **Device Commercial Name**

**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

**Urgent Field Safety Notice (FSN)**  
**Device Commercial Name**  
**Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	1. Device Type(s)*
.	<u>Ilizarov Wire Tensioner</u>
1	2. Commercial name(s)
.	<u>Ilizarov Wire Tensioner</u>
1	3. Unique Device Identifier(s) (UDI-DI)
.	<u>08033201842072</u>
1	4. Primary clinical purpose of device(s)*
.	<u>The wire tensioner is used to tension the wires of the Ilizarov circular fixator</u>
1	5. Device Model/Catalogue/part number(s)*
.	<u>71070341</u>
1	6. Software version
.	<u>NA</u>
1	7. Affected serial or lot number range
.	<u>See Appendix</u>
1	8. Associated devices
.	<u>Within context of the FSCA eg for IVD reagents and platforms.NA</u>

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	1. Description of the product problem*
.	<u>An internal Washer of the Ilizarov Wire Tensioner has been made in a wrong plastic material that could wear and break during the sterilization process in autoclave. Consequently this could cause malfunctioning of the tensioner.</u>
2	2. Hazard giving rise to the FSCA*
.	A possible malfunctioning of the wire tensioner could cause an increase of operating time without any risk to the patient.
2	3. Probability of problem arising
.	Occasional probability
2	4. Predicted risk to patient/users
.	Negligible severity . Occasional x negligible = acceptable
2	5. Further information to help characterise the problem
.	
2	6. Background on Issue
.	Manufacturer became aware because supplier communicated the use of wrong plastic material for the production of internal washer. As corrective/preventive action: the level of incoming controls has been increased.
2	7. Other information relevant to FSCA
.	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device    <input type="checkbox"/> Quarantine Device    <input checked="" type="checkbox"/> Return Device    <input type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other                      <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: right;">No critical impact on patient and/or user</p>
<b>3.</b>	<p><b>3. Particular considerations for:</b>                      Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended? Choose an item.</p> <p>Provide further details of patient-level follow-up if required or a justification why none is required</p>
<b>3.</b>	<p><b>4. Is customer Reply Required? *</b> (If yes, form attached specifying deadline for return)</p> <p style="text-align: right;">Yes. Deadline: 31/10/21</p>
<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input checked="" type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Software upgrade                      <input checked="" type="checkbox"/> IFU or labelling change  <input type="checkbox"/> Other    <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
<b>3</b>	<p><b>6. By when should the action be completed?</b></p> <p style="text-align: right;">Specify where critical to patient/end user safety</p>
<b>3.</b>	<p><b>7. Is the FSN required to be communicated to the patient /lay user?</b></p> <p style="text-align: right;">No</p>
<b>3</b>	<p><b>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?</b></p> <p>Choose an item.                      Choose an item.</p>

<b>4. General Information*</b>		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.	
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: Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	<b>www.medicalplastic.it</b>
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	<b>LIST OF LOT NUMBERS, SERIAL NUMBERS, MANUFACTURING DATE AND EXPIRY DATE</b>
4.	10. Name/Signature	

<b>Transmission of this Field Safety Notice</b>	
	<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>

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