Rev 1: September 2018

FSN Ref: 200-23-030-001 FSCA Ref: 200-23-030-002

Date: 13.11.2023

Urgent Field Safety Notice
Comfort marker 2.0 Safety Needle

For Attention of*:End users of the Comfort Marker 2.0 Safety Needle with batch numbers 20220525001

Contact details of local representative (name, e-mail, telephone, address etc.)*
Roland Kortenhorst, kortenhorst@medicalprecision.nl, +31(6)51606402, Medical Precision B.V., Telfordstraat 9-30, 8013RL, Zwolle, Netherlands

Medical Precision B.V.

Rev 1: September 2018

FSN Ref: 200-23-030-001 FSCA Ref: 200-23-030-002

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

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Comfort Marker 2.0 Safety Needle, that is used together with Comfort Marker 2.0 to place reference marks on the patients undergoing radiotherapy treatments. Safety Needles as provided in the marking set, in a white box that includes 25 Safety Needles.   
1.	2. Commercial name(s)
	Comfort Marker 2.0 Safety Needle
1.	3. Unique Device Identifier(s) (UDI-DI)
	8720165025MP CM2022LV
1.	4. Primary clinical purpose of device(s)*
	Needles to be used with Comfort Marker 2.0 system for placement of markings on human skin for radiotherapy treatments.
1.	5. Device Model/Catalogue/part number(s)*
	2022
1.	6. Software version
	N.A.
1.	7. Affected serial or lot number range
	20220525001
1.	8. Associated devices
	N.A.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Comfort Marker 2.0 Safety Needle, that is used together with device Comfort Marker 2.0 for placement of markings on human skin for radiotherapy treatments was CE certified by ECM for a shelf life of 1 year. All the tests, including real time aging that were performed to support 1 year shelf life initially claimed and were successful. Furthermore, same shelf life confirmatory tests were also performed on a 2-year real-time aged Safety Needle with the goal to collect evidence for extension of the originally claimed shelf life of the Safety Needle to two years. All the performed tests were successfully passed by two year real aged samples.

	Consequently, it was deemed sufficient proof by the regulatory expert involved during that period with the Medical Precision B.V. to support the safe performance of the Safety Needle after increased storage time and extension of the shelf life of 2 years was implemented. However, Medical Precision did not officially submit this change to the overseeing Notified Body ECM for review and approval. During the surveillance audit by the ECM the unsupervised shelf life extension became known to the auditor and actions deemed passing for the nonconformity were taken. It should be stated that there is no risks for end users or patients in using Safety Needle with two year shelf life, since all the proof of it safe performance after two years was collected and was reviewed by the auditor. Nevertheless, as the prescribed change process was not followed, the extension of the shelf life was not accepted by the auditor and remediating actions to return the claimed for the Safety Needle to the approved by the ECM during CE certification one year was mandated. Present FSCA is initiated to communicate corrected one year shelf life to the customers in possession of the Safety Needle with the claimed two year shelf life.
2.	2. Hazard giving rise to the FSCA*
	Regulatory noncompliance with the overseeing Notified Body ECM. Shelf life extension for the Safety Needle was not duly submitted and reviewed by the overseeing Notified Body ECM. However, there is no risks for end users or patients in using Safety Needle with two year shelf life, since all the proof of its safe performance after two years was collected and was reviewed by the ECM auditor.
2.	3. Probability of problem arising
	Using of the Safety Needle past its officially cleared by ECM one year shelf life. The label states two year shelf life which is not approved by ECM
2.	4. Predicted risk to patient/users
	No risk for end users and patients. It is regulatory noncompliance.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Regulatory expert involved with the Medical Precision deemed sufficient obtained via tests evidence of safe performance of the Safety Needle after two years storage. Shelf life increase to two years was implemented without notification of the overseeing Notified Body ECM.
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 1. User shall identify the batch number of the Safety Needles that they have in stock 2. User shall fill in the form attached to the document 200-23-030-003_20231114 Statement for end users & form 3. User shall decide on the following action: use the Safety Needle as is with taking into account 1 year shelf life or ship the Safety Needle back to be exchanged

3.	2. By when should the action be completed?	Form that is part of the document 200-23-030-003_20231114 Statement for end users & form shall be filled in and share with Medical Precision by 30-Nov-2023.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3. 5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☒ Other ☐ None

1. All available stock with two year shelf life was put in quarantine. This will ensure that the stock will not be shipped to the distributor/end user (Performed on 9-Nov-2023)
2. Relabelling of the quarantined Safety Needles will be performed so that 1 year shelf life is stated on the labels. This will ensure that the shelf life that was approved by the overseeing Notified Body shall be communicated to the customer (30-Nov-2023)
3. Submission of the change request for the shelf life extension to the overseeing Notified Body ECM for approval shall be carried out on the shortest notice (Performed on 10-Nov-2023)
4. Field Safety Notice shall be provided to the distributor and end customers to notify them of the approved 1 year shelf life instead of stated in labelling 2 years. It is the intent by the Medical Precision to reassure the customers/end user that there were no risks for patients in using Safety Needles with 2 year shelf life as all the tests were perform to confirm safe performance after two years of storage. Nevertheless, as the shelf life extension was not officially submitted and approved by the overseeing Notified Body, using the Safety Needle once its shelf life of 1 year has passed is no more acceptable. Sharing of the document shall be performed by distributor of Medical Precision CQ Medical (upon approval of CA, draft version will be shared on 17-Nov-2023)
5. Sharing document 200-23-030-003_20231114 Statement for end users & form with local distributors and end users, Sharing of the document shall be performed by distributor of Medical Precision CQ Medical. ((upon approval of CA, draft version will be shared on 17-Nov-2023)

3	6. By when should the action be completed?	Date added to the above identified actions in order to specify completion date per action.
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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?	
	Choose an item. Choose an item.	

	4. General Information*	
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? *	Not planned yet
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	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *Yes, Medical Precision is located in Netherlands and Health and Youth Care Inspectorate is informed.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Roland Kortenhorst, CEO**

	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.