Rev 1: September 2018

Canyon medical Inc.

FSN Ref: 20260325001 FSCA Ref: 20260325001

Date: 2.4.2026

Urgent Field Safety Notice
Microwave Ablation Antennas

For Attention of*:
Company Name:Mermaid Medical
1)Correspondence of the FSN: Recall@mermaidmedical.com
2)General Recall Contact information: Matthew Genzman
E-mail:Mge@mermaidmedical.com Tel: +1 941 867 2129
Address: Mermaid Medical A/S Frydensbergvej 25 3660 Stenløse Denmark

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name: Liang Jin E-mail:shholding@hotmail.com Tel:+49-40-2513175 Address:Eiffestrasse 80,20537,Hamburg, Germany

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Urgent Field Safety Notice (FSN)
Microwave Ablation Antennas
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Supplied in sterile.
1.	2. Commercial name(s)
	Microwave Ablation Antennas
1.	3. Unique Device Identifier(s) (UDI-DI)
	KY-2450B-0T30: 06954414684735 KY-2450B-0T31: 06954414684742 KY-2450B-0T32: 06954414684759
1.	4. Primary clinical purpose of device(s)*
	Microwave Ablation Antennas, in conjunction with the compatible Microwave Ablation Generator, is intended for coagulation (ablation) of soft tissue.
1.	5. Device Model/Catalogue/part number(s)*
	KY-2450B-QT30, KY-2450B-QT31, KY-2450B-QT32
1.	6. Software version
	NA, The device does not contain software.
1.	7. Affected serial or lot number range
	KY-2450B-0T30: Lot/number: 2511104/39, 2511137/40, 2511141/39, total 118; KY-2450B-0T31: Lot/number: 2511106/39, 2511138/36, total 75; KY-2450B-0T32: Lot/number: 2511102/10, total 10.
1.	8. Associated devices
	NA

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	During the routine sample inspection, it is discovered that there is a risk of IFU fading. IFU fading may cause the users to fail to understand and read the content of IFU.
2.	2. Hazard giving rise to the FSCA*
	IFU fading may cause the users to fail to understand and read the content of IFU, but it will not cause safety risks.
2.	3. Probability of problem arising
	Low probability.
2.	4. Predicted risk to patient/users
	The users to fail to understand and read the content of IFU.
2.	5. Further information to help characterise the problem
	No.
2.	6. Background on Issue
	During the routine sample inspection, it is discovered that there is a risk of IFU fading. IFU fading may cause the users to fail to understand and read the content of IFU. Although the analysis indicates no risk, for the safety of the users, our company has decided to exchange and destroy the above-mentioned devices.
2.	7. Other information relevant to FSCA
	No.

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	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 Assist in the exchange of Microwave Ablation Antennas
3.	2. By when should the action be completed? — Within 3 months: before the end of June, 2026
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. 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) — Choose an item.
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Exchange the device
3	6. By when should the action be completed? — Within 3 months: before the end of June, 2026
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? No Not appended to this FSN

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
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:	
	NA	
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	**Canyon Medical Inc.**
	b. Address	Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue, Jiangbei New Area, 210032 Nanjing, Jiangsu Province, P.R. China
	c. Website address	www.canyonmedical.com.cn/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**NA**
4.	10. Name/Signature	**Tony Long General Manager** 

	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.