FSN Ref: FSN-210526 FSCA Ref: FSCA-210526

FSN-300725 Field Safety Notice rev00Date: 20.07.2026

Urgent Field Safety Notice (FSN)
Potential Risk of Needle Guide and/or RF Electrode Damage and Thermal Injury During Use with Radiofrequency Ablation Systems

For Attention of

Contact details of local representative	
Company name	e-mail
KEBOMED	Ingo Hachmeister <ih@kebomed.at Christian Jagsch <chja@kebomed.at

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Disposable Needle Guide, NG140, Sterile, single-use
1.	2. Commercial name(s)
	Disposable Needle Guide
1.	3. Unique Device Identifier(s) (UDI-DI)
	4260649243046
1.	4. Primary clinical purpose of device(s)*
	Intended purpose is to be a guide for biopsy needles during TRUS biopsy or transvaginal biopsy procedures. Intended use is to help diagnosis of disease by guiding biopsy needle in biopsy operation.
1.	5. Device Model/Catalogue/part number(s)*
	NG140
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	All
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	None. The product itself is not defective. This FSN is issued due to off-label use. Missing/inadequate caution in the Instructions for Use (IFU), which will be updated accordingly.
2.	2. Hazard giving rise to the FSCA*
	The hazard is potential injury to the patient due to off-label use. Residual risk after FSCA implementation is considered low.
2.	3. Probability of problem arising
	Possible if off-label use of the product in patients.
2.	4. Predicted risk to patient/users
	- Use of the needle guide together with an RF ablation electrode may result in degradation, deformation, or damage to the needle guide and/or damage to the electrode insulation during the procedure, potentially leading to: •Local thermal injury or burns. •Unintended ablation of adjacent tissue or organs due to loss of guidance accuracy. •Retention of degraded plastic fragments or other foreign material requiring medical intervention. The device is safe and performs as intended. Residual risk after IFU update is negligible.
2.	5. Further information to help characterise the problem
	Reported case occurred due to use of the device in conjunction with RF (radiofrequency)

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	or energy-based ablation electrodes outside the device intended use.
2.	6. Background on Issue
	Manufacturer became aware through a vigilance report from AGES - Österreichische Agentur für Gesundheit und Ernährungssicherheit. One of the identified factors was that although the device description and intended use were clearly stated in the User Manual (IFU), there was no warning against using the device with RF ablation systems; this did not prevent the user from making foreseeable misuse. Consequently, the User Manual did not contain clear warnings about this potential off-label use: burns occurred to the patient's vaginal tissue due to off-label use.
2.	7. Other information relevant to FSCA
	None

	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 **Required Action for Users** - Users are requested to replace the current IFU with the updated version provided by the manufacturer, and to ensure all relevant staff are informed of the changes. No product quarantine, return, or destruction is required. - Avoid use the device for RF ablation, do not use with energy-based ablation systems. - Review IFU updates: The Instructions for Use (IFU) have been updated to include explicit warnings regarding off-label use. - Report any suspected disposable needle guide complications to WELLGO Medical Products GmbH Vigilance Department and/or your National Competent Authority. **Training Reminder for Surgeons** - Disposable Needle Guides intended purpose is to be a guide for biopsy needles during TRUS biopsy or transvaginal biopsy procedures, not suitable for RF ablation systems.	
3.	2. By when should the action be completed?	Immediately upon receipt of the updated IFU. Q3 2026
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No "No patient follow-up is required as the device performance is not affected and there is no risk from previously used products."	

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3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, please confirm receipt of this FSN and implementation of the updated IFU.
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None The manufacturer has updated the IFU to include the missing/inadequate warning. Updated IFUs will be distributed to all customers.	
3	6. By when should the action be completed?	Distribution of updated IFUs will be completed within 60 days.
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	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable.
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable. This FSN is not an update of a previous FSN.	
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:	
	Not applicable.	
4	6. Anticipated timescale for follow-up FSN	Not applicable.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	WELLGO MEDICAL PRODUCTS GMBH
	b. Address	Buchenhofener Straße 2142329 Wuppertal
	c. Website address	www.wellgomedical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes, German BfArM has been informed of this FSN communication	
4.	9. List of attachments/appendices:	Updated Instructions for Use
4.	10. Name/Signature	Latif Iba PRRC

	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

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	feedback..*

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