FSN Ref: FSCA_20210426_Peristeen Plus_FSN
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Date: May 11th 2021

Urgent Field Safety Notice
Peristeen Plus

For Attention of: end-users

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

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Urgent Field Safety Notice (FSN)

Peristeen Plus

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	
1.	2. Commercial name(s)
	Peristeen Plus water bag
1.	3. Unique Device Identifier(s) (UDI-DI)
	Peristeen Plus Transanal Irrigation with balloon catheters – system and accessories Peristeen Plus Transanal Irrigation with cone catheters – system and accessories
1.	4. Primary clinical purpose of device(s)*
	Peristeen Plus TAI system is intended to promote evacuation of the contents in the lower and the descending colon. The Peristeen Plus accessories are intended to be used as part of the TAI systems.
1.	5. Device Model/Catalogue/part number(s)*
	291400, 291410, 291420, 291440, 291470, 291480, 291490, 291510, 291520, 291600, 291610, 291620
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range CH: 7889760, 7889761, 7889765 DE: 7889735, 7889736, 7889742, 7889748, 7889759 ES: 7889767, 7889768, 7889769, 7889773, 7889774 FIN: 7838870, 7838871, 7838872, 7838876, 7838878, 7838880, 7838882, 7838885 NL: 7838833, 7838834, 7838837, 7838838, 7838841, 7838842, 7838843, 7838844, 7838845, 7838846, 7960980, 7960981, 7951008, 7951010, 7932846 NO: 7838860, 7838861, 7838865, 7838867, 7838868, 7838869 SE: 7838846, 7838847, 7838853, 7838854, 7838855, 7838857, 7838859, 7889780, 7889782, 7889784 UK: 7889730, 7916177

1.	8. Associated devices
	The FSN concerns the waterbag, which is provided together with other accessories required to perform the trans anal irrigation procedure.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Peristeen Plus presents a temperature indicator on the water bag that is intended to serve as supplemental visual aid use. During a routine stability test of the Peristeen Plus temperature indicator, inconsistencies were observed. As a result further investigation was initiated. The issue has only been observed in a laboratory setting. No complaints have been reported by end users/users. While users are already instructed by labelling to also check the temperature by other means, a faulty temperature indicator may lead to a potential risk for users mis-evaluating the water temperature when preparing the device for use, and therefore using temperatures outside of recommended range.
2.	2. Hazard giving rise to the FSCA*
	The water for irrigation should be lukewarm (34–40°C). The user can check the water temperature by running the water over your wrist to feel if it is lukewarm. If the water is too hot, it may harm the delicate lining of the bowel and if it is too cold, stomach cramps may occur.
2.	3. Probability of problem arising
	So far, the issue has only been observed in a laboratory setting. No complaints have been reported by users/end users.
2.	4. Predicted risk to patient/users
	Under the assumption that the users will follow the advice given in this Field Safety Notice, no risk will arise. Furthermore, most of the patients already receiving the product are experienced Peristeen users and are previously trained in the use of products without the temperature indicator.
2.	5. Further information to help characterise the problem
	When the advice is followed the risk is not increased.
2.	6. Background on Issue
	During a routine stability test, inconsistencies were observed. As a consequence, further investigation was initiated.
2.	7. Other information relevant to FSCA
	Not applicable.

	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 Follow the additional information provided in the letter to Peristeen Plus end user.		
3.	2. By when should the action be completed?	Immediately upon receipt of this notice the letter for the Peristeen Plus end user should be sent to all users that already have received Peristeen Plus. Additionally, the letter must be attached to all distributed products until Peristeen Plus with the updated IFU is delivered.	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None IFU will be updated accordingly for all products not yet on the market.		
3	5. By when should the action be completed?	June 1st 2021	
3.	6. Is the FSN required to be communicated to the patient /lay user?		Yes, by end-user-letter
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?		
	Yes		

	4. General Information*	
4.	1. FSN Type*	New
4.	2. 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.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	End-user-letter
4.	5. Name/Signature	Insert Name and Title here and signature below

	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. Please transfer this notice to other organisations on which this action has an impact. 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.

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