Rev 1: September 2018
FSN Ref: NCI26-060 FSCA Ref: NCI26-060

Date: 22/09/2026

Urgent Field Safety Notice
TRANSONIC - Sterile ultrasound gel

For Attention of*:Customers and distributors responsible for the receipt, storage, distribution and/or use of the affected medical devices

Contact details of local representative (name, e-mail, telephone, address etc.)*
N.A

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Urgent Field Safety Notice (FSN)
TRANSONIC - Sterile ultrasound gel
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	TRANSONIC - Sterile ultrasound gel 
1.	2. Commercial name(s)
	TRANSONIC - Sterile ultrasound gel
1.	3. Unique Device Identifier(s) (UDI-DI)
	8427734006610
1.	4. Primary clinical purpose of device(s)*
	The sterile ultrasound gel is intended to be used as an acoustic coupling medium between the ultrasound transducer and the patient's body during examination procedures. Its purpose is to facilitate the transmission of ultrasound waves by eliminating the air interface between the transducer and the patient's body. The gel is applied to intact skin, intact mucous membranes and natural body orifices, as applicable to the intended ultrasound procedure. The sterile product is recommended for diagnostic and therapeutic ultrasound applications when sterility is indicated.
1.	5. Device Model/Catalogue/part number(s)*
	TOG26
1.	6. Software version
	N.A
1.	7. Affected serial or lot number range
	Bach: 354/06-26
1.	8. Associated devices
	N.A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The affected Sterile ultrasound gel are packaged in a sterile barrier pouch. The packaging material used for the affected lots has been found to have an adhesive homogeneity issue, which results in a progressive decrease in seal strength over time. As a consequence, the integrity of the sterile barrier cannot be guaranteed throughout the product shelf life, which may result in a potential loss of sterility of the affected devices.
2.	2. Hazard giving rise to the FSCA*
	The hazard is the potential loss of sterility of the affected batches due to a potential loss of sealing strength and effectiveness of the sterile barrier during the product shelf life. Up

	to date all samples tested preserve package integrity. The FSCA is intended to mitigate this risk by preventing the use of affected devices for which the sealing cannot be guaranteed throughout their shelf life. Following implementation of the FSCA and withdrawal of the affected devices from the market, the residual risk associated with the identified packaging defect is considered controlled..
2.	3. Probability of problem arising
	Based on the investigation and testing performed on retained samples from the affected lots, a progressive decrease in seal strength has been confirmed over time. Therefore, there is a potential for loss of sterile barrier integrity during the product shelf life.The exact probability of sterile barrier failure cannot be quantified based on the available data, as up to date integrity of the package is preserved. However, as the integrity of the sterile barrier cannot be guaranteed throughout the product shelf life, the affected lots are subject to the FSCA.
2.	4. Predicted risk to patient/users
	The potential risk to the patient is the occurrence of infection and/or contamination resulting from the use of a medical device whose sterile barrier integrity has been compromised during its shelf life.
2.	5. Further information to help characterise the problem
	The issue cannot be identified by product inspection. Affected products can be identified by means o the production batches specified in this document
2.	6. Background on Issue
	The issue was initially identified during standard quality inspection of a different sterile product. During testing, a significant and unusual decrease in the seal strength of the packaging pouch was observed after the sterilization process.The manufacturing parameters, production records and in-process controls for the affected devices were reviewed and confirmed to be compliant with the established specifications at the time of manufacture. The packaging seals had also been found to be compliant during the routine controls performed prior to product release. However, additional testing performed on retained samples demonstrated a progressive decrease in seal strength over time. Further investigation identified that tis behaviour was related to an specific batch of the PA/PP film conforming the sterile package of the affected devices. The packaging material supplier conducted an investigation and confirmed that the adhesive used in the affected material was not homogeneous, resulting in inadequate sealing performance and a progressive decrease in seal strength over time.The issue is limited to the devices manufactured using the affected packaging material lots. Products manufactured using other packaging material lots were not affected, as confirmed by the corresponding testing
2.	7. Other information relevant to FSCA
	No additional information is considered necessary at this stage. Further information will be provided to the relevant authorities and affected customers as required during the implementation of the FSCA.

	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 Users and distributors are requested to identify and immediately quarantine any affected devices in their possession. The affected devices must not be used. Users and distributors are requested to contact the manufacturer or the relevant distributor and return the affected devices in accordance with the applicable recall/withdrawal instructions. No specific patient management actions are required, as no patient injuries, infections or other adverse health effects related to the affected lots have been reported to date.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: N.A 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)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	Immediately
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 Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N.A
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	**Telic, S.A.U.**
	b. Address	**Polígono Industrial Can Barri. C/ Molí d'en Barri 7, 08415 Bigues i Riells (Barcelona), Spain**
	c. Website address	www.telic.group
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**N.A**
4.	10. Name/Signature	**Laura Delgado** **Technical Director**
		

	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.