Rev 1: September 2018

FSN Ref: 26-0xx FSCA Ref: 26-0xx

Date: 20:APR:2026

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:Poland - Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL); Romania - National Agency for Medicines and Medical Devices of Romania (NAMMDR); Germany - Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) (BfArM)

Contact details of local representative (name, e-mail, telephone, address etc.)*
Kembli-Med SRL De Mijloc No. 173, 500064-Brasov, Romania; Consultronix sp. z o.o.Ul. Przemyslowa 17 32-083 Balice Poland; Polytech Domilens GmbHArheilger Weg 664380 RobdorfGermany

SURGICAL SPECIALTIES CORPORATION™

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

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Microsurgical Knife indicated for use by surgeons and qualified medical personnel for general use, ophthalmic, and minimally invasive surgical procedures.
1.	2. Commercial name(s)
	Sharpoint
1.	3. Unique Device Identifier(s) (UDI-DI)
	00848782027514
1.	4. Primary clinical purpose of device(s)*
	Indicated for use by surgeons and qualified medical personnel for general use, ophthalmic, and minimally invasive surgical procedures
1.	5. Device Model/Catalogue/part number(s)*
	72-2231 2.2MM, ANGLED, DOUBLE- BEVEL
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot# FA22CHQ
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Product shipped was 3.0mm angled, double-bevel knife, incorrectly packaged in a 2.2mm angled, double-bevel knife package.
2.	2. Hazard giving rise to the FSCA*
	The substitution of a 3.0 mm blade for 2.2mm blade may cause a temporary injury to the patient. For instance, if this is used to create an entry incision in cataract surgery, the incision may be too wide for the procedure and require a suture to decrease its width.
2.	3. Probability of problem arising
	Three complaints have been received out of 1,818 distributed units. Available inventory from the affected lot was inspection, resulting in nine (9) failures out of 846 total units. 12/2664 = 0.45% probability that the mix problem will occur. Detectability is high, because the knives are clearly marked as 3.0mm, and to a trained clinician, the larger blade is readily apparent. No patient harm has been reported to date. Therefore the probability of the hazard arising is considered low.
2.	4. Predicted risk to patient/users
	The Health Hazard Evaluation indicates a severity of low x probability low, ending in a low risk of patient harm, as detailed in question #2.3.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Customer complaint alerted the manufacturer to the issue. The root cause has been traced to a line clearance failure at final packaging, isolated to one manufacturing lot. A

	CAPA has been initiated to document the investigation and implement a corrective action.
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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Non-critical; estimate by 17-JUL-2026
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No N/A	
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?	Non-critical; estimate by 17-JUL-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? 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? *	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	**Surgical Specialties**
	b. Address	Corredor Tijuana Rosarito 2000, #24702 B, Ejido Franscisco Villa, Tijuana Baja California, Mexico
	c. Website address	**www.corza.com**
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	**Alex Castillo, VP QA/RA** Signed by: Alejandra Castillo A987C5388D334418... 4/21/2026 | 18:27 CEST

	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.