

Date: 23 July 2026

Field Safety Notice
Spike

For Attention of*: Distributors and health professionals

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

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Field Safety Notice (FSN)

Spike

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)* Product code 4038 is a sterile spike intended for preparation of cytotoxic drugs.
1.	2. Commercial name(s)* Spike
1.	3. Unique Device Identifier(s) (UDI-DI) 08051414960512 18051414960519
1.	4. Primary clinical purpose of device(s)* The spikes are designed to allow antineoplastic drugs to be diluted safely. They are non-invasive devices for the preparation, mixing and infusion of chemotherapy medications.
1.	5. Device Model/Catalogue/part number(s)* 4038
1.	6. Software version Not applicable
1.	7. Affected serial or lot number range Lot FG00641, 15000 units Lot FG01492, 50050 units Lot FG00642, 20100 units Lot FG01078, 7500 units Lot FH00208, 8100 units Lot FG01493, 48300 units
1.	8. Associated devices Not applicable

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* The purple luer lock connector appears to unscrew and detach in some cases.
2.	2. Hazard giving rise to the FSCA* The use of a defective unit may cause risk of exposure to cytotoxic drugs by nurses or patients.
2.	3. Probability of problem arising Sidam has received 1 single complaint from an hospital in Ireland that declared the case happened several times related to lot FG00641; Sidam has received 4 complaints from a second hospital in Ireland; 2 related to lot FG01492, 1 related to lot FH00208 and 1 related to lot FG01493.
2.	4. Predicted risk to patient/users Detachment of component may rise a leakage of chemotherapy solution with consequent reduced administered dose or contamination of the operator with toxic drugs. The severity associated (S) is 4 (critical – potential permanent injury, potential major impact on patient safety, requiring professional medical intervention. Quality not achieved); Occurrence (O) indicated in our risk analysis is 2 (< 10 ⁻⁵ to > 10 ⁻⁶). Occurrence is calculated as P1xP2. Currently and according to the available data, the probability P1 that hazardous situation occurs on the involved lots, is 2,4x10 ⁻⁵ . The probability (P2) that the hazardous situation

could led to a harm is not easily predictable, but experience collected on similar cases happened in the past on other preparation devices, give us evidence that patient is never involved and user (health professional) have never reported serious harms. However, considering that the hospital has found several units with loose connection, but no other complaints have been received, the Occurrence may be calculated as following:

Probability 1	Frequent	P1-5	5(O2)	10(O3)	15(O4)	20(O5)	25(O5)
	Medium	P1-4	4 (O2)	8(O3)	12(O3)	16(O4)	20(O5)
	Rare	P1-3	3 (O1)	6(O2)	9(O3)	12(O3)	15(O4)
	Extremely Rare	P1-2	2(O1)	4(O2)	6(O2)	8(O3)	10(O3)
	Improbable	P1-1	1(O1)	2(O1)	3(O1)	4(O2)	5(O2)
			P2-1	P2-2	P2-3	P2-4	P2-5
			Remote	Low	Medium	High	Very High
Probability 2							

The risk acceptability matrix calculated based on severity and occurrence estimation is
4 (severity) x 2 (occurrence) = 8:

SEVERITY	S5	Catastrophic						
	S4	Critical		8				
	S3	Major						
	S2	Minor						
	S1	Marginal						
			O1	O2	O3	O4	O5	
OCCURRENCE								

2. **5. Further information to help characterise the problem**

The involved lots have been completely distributed.

2. **6. Background on Issue**

Sidam received a complaint from local distributor in Ireland for 1 issue related to batch FG00641, 1 issue related to batch FH00208, 1 issue related to batch FG01493 and 2 issues related to batch FG01492, showing the purple connector of the spike is easily disconnected from the spike. This defect may cause risk of exposure to cytotoxic drugs above all for healthcare professional.

The units pertaining to the lot FG00641 (produced in May 2025), for the lot FG01492 (produced in December 2025), for the lot FH00208 (produced in February 2026) and for the lot FG01493 (produced in March 2026) have been completely distributed on the market. No further complaints have been received up to date regarding this lots.

2.	7. Other information relevant to FSCA
	We decide to include in this FSN also the batches FG00642 and FG01078 despite up to date are not involved on complaints because they are produced and distribute before the implementation of FSCA applied starting from batch reported on Attachment 1 to this FSN, in order to hollow the verification before the use, if the detachment issue is present.

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 instructions indicated in the communication here attached before use of the device. After having performed the test and found defective units, the user may require substitution of the non-compliant boxes.	
3.	2. By when should the action be completed?	Before use of the units pertaining to the lots indicated
3.	3. Particular considerations for: 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)	No
3.	5. Action Being Taken by the Manufacturer* ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None As immediate action a declaration has been issued for health professional to give information of checking the device before use. In case the user is not confidential, after having performed the check described in the letter and found defective units, he can require the substitution of the affected boxes.	
3.	6. By when should the action be completed?	Starting from the batch FG01494 the immediate corrective action was implemented
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?
	Not applicable

4. General Information*	
4.	1. FSN Type* Update
4.	2. For updated FSN, reference number and date of previous FSN FSN 001-2026 rev.00, rev.01 and rev.02
4.	3. For Updated FSN, key new information as follows: Identified six possible lots impacted
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 Starting from the batch FG01494 the immediate corrective action was implemented
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Sidam srl
	b. Address Via Statale Sud 169, Mirandola (MO) – Italy - 41037
	c. Website address https://sidamgroup.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: Attachment 01_Declaration for users
4.	10. Name/Signature Marco Pelati  QA Engineer Giulio Camurri  QA/RA - PRRC 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.

Decl. 31/2026 Rev.02

Mirandola, 23/07/2026

Object - Statement updates regarding product Sidam code 4038 "Spike per sacca/flacone con valvola".

To whom it may concern

We, SIDAM Srl, a company organized under the Italian Laws of Italy with registered office at Via Statale Sud 169, Mirandola (MO), Italy

Hereby declare that:

due to a defect notified by Caragen Ltd and stating that for **batches FG00641, FG01492, FH00208 and FG01493 - Product Code 4038 "the purple luer lock connection has been unscrewing and detaching from a number of bag spikes."**, Sidam as the legal manufacturer registered internally the complaints (ref. ID R156/2026, R173/2026, R174/2026, R218/2026 and R222/2026) and is currently conducting an investigation to establish Root Cause.

At the same time, **as immediate mitigation action, for the already distributed batch the following procedure is recommended to identify defective pieces before usage.**

Sidam suggests that all users should twist strength test the injection site, within the primary packaging, before opening it for use, to ensure the device is suitable for its intended use and avoid possible incident. The piece must be considered defective if the device is rotating (totally or partially) applying a twisting strength. Please see attached picture for twist testing unit inside packaging.

Please notify Caragen any unwanted boxes of Ref 4038 Lot FG00641, Lot FG01492, Lot FH00208, Lot FG01493, Lot FG01078 and FOC replacements will be organised.

Batch FG00642 reported on FSN rev.3 as batch produced before the implementation of FSCA, wasn't distributed in Ireland.

Short footage is available from Caragen Ltd or directly from Sidam to better explain the procedure, if necessary.

SIDAM s.r.l.

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