Rev 2: February 2020
FSN Ref: FSN 001-2026 rev.04 FSCA Ref: FSCA 001-2026

Date: 24th Sept 2026

Update Urgent Field Safety Notice
Spike

For Attention of*:Distributors and health professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Caragen LTD Serving Health. Suite 304, Q House, 76 Furze Road, Sandyford Business Park, Dublin 18, Ireland, D18PO23. Email: RP@caragen.com. T: +35315688960

Update Urgent 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 Lot FG01492 Lot FG00642 Lot FG01078 Lot FH00208 Lot FG01493 Lot FG01494
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 complaints from a second hospital in Ireland; 2 related to lot FG01492, 1 related to lot FH00208, 1 related to lot FG01493, 4 related to FG01494.
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 $1.6x10^{-5}$. 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(02)
			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, 2 issues related to batch FG01492 and 4 issues related to FG01494, 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. Lot FG01494 has been produced in May and has undergone to a 100% visual check before

	release. No further complaints have been received up to date regarding this lots outside Ireland.
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. **Lot FG01495 is not involved in complaints but it has been produced performing a double visual inspection and pre use checks should be performed as per the instructions contained in the FSN, to verify the correct tightness of the connection.**

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.

	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.

3.	6. By when should the action be completed?	Sidam is producing a new lot where corrective action is 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 rev.02, rev.03
4.	3. For Updated FSN, key new information as follows:	
	Identified seven 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	The batch FG01495 has been produced applying the immediate corrective action (double check before release)
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 n. 31/2026 rev.3
4.	10. Name/Signature	Daniela Malavasi RA Supervisor
		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)

Sidam
BIOMEDICAL SOLUTIONS

Decl. 31/2026 Rev.03

Mirandola, 24/09/2026

FSN 001-2026 rev. 04

FSCA 001-2026

Updated Urgent Field Safety Notice

Field Safety Corrective Action for code 4038 – spike for Bag

Code Ref.	4038	
Description	Bag for Spike	
UDI-DI	Primary packaging: 08051414960512 Secondary Packaging: 18051414960519	
Device type	Product code 4038 is a sterile spike intended for preparation of cytotoxic drugs	
Commercial name	Spike	
Intended purpose	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.	
Affected batches	Lot FG00641 Lot FG01492 Lot FG00642 Lot FG01078 Lot FH00208 Lot FG01493 Lot FG01494 Lot FG01495 **(*see note at point 4)**	
Action to be taken by the user	Lot FG00641 Lot FG01492 Lot FG00642 Lot FG01078 Lot FH00208 Lot FG01493 Lot FG01494	Sidam will replace any unwanted boxes of the following lots and FOC replacements will be organized.
	Lot FG01495	This lot has been produced after performing double visual inspection and **pre use checks should be performed** as per instructions contained in this FSN.

SIDAM s.r.l.
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Decl. 31/2026 Rev.03

Dear Customer,

SIDAM Srl, a company organized under the Italian Laws of Italy with registered office at Via Statale Sud 169, Mirandola (MO), Italy would like to inform you of an update regarding FSN 001-2026.

REASON FOR THE SAFETY NOTICE

Due to a defect notified for **batches FG00641, FG01492, FH00208, 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 and is currently conducting a technical evaluation to identify productive corrective action to solve the problem.

POTENTIAL RISK

Detachment of component may rise a leakage of chemotherapy solution with consequent reduced administered dose or contamination of the operator with toxic drugs.

Experience collected on similar cases or similar devices as well as incidents registered till now on this medical device, give us evidence that patient is never involved and user (health professional) have never reported serious harms since the use of the device is under isolator. Accordingly, no harms to the patients or users has been identified, even if risks of contamination could arise.

ACTION TO BE TAKEN BY THE USER/MEDICAL STAFF

1. Read this Field Safety Notice and ensure that all relevant departments are informed about its content.
2. 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.

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

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3. Sidam will replace any unwanted boxes of the following lots and FOC replacements will be organized:

Lot FG00641
Lot FG01492
Lot FG00642
Lot FG01078
Lot FH00208
Lot FG01493
Lot FG01494

4. Lot **FG01495** have been produced after FSCA was issued and for this reason it has been checked by Sidam at 100%. This check is a short term action to limit the problem and avoid shortage of the product, waiting for the implementation of the technical action. For this reason, we recommend to pay attention before use and verify correct tightness of the connection as described in point 1.

We regret any inconvenience caused by this action and value your cooperation and commitment to patient/user safety.

This field safety notice was submitted to your local authority within the FSCA.

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Decl. 31/2026 Rev.03

Please do not hesitate to contact us if you should have any question on this matters, using the contact details: quality@sidamit.it

Your sincerely

Prepared by	Approved by
Daniela Malavasi – RA Supervisor	Giulio Camurri - QA & RA Manager- PRRC , QP

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