



Miltenyi Biotec B.V. & Co. KG

Rev 1: September 2018

FSN Ref: EU-Complaint-002716

FSCA Ref: EU-Complaint-002716

Date: 11FEB2021

Urgent Field Safety Notice
CryoMACS Freezing Bag 750 (200-074-403)

For Attention of*:User

Contact details of local representative (name, e-mail, telephone, address etc.)*
Miltenyi Biotec B.V. & Co. KG Friedrich-Ebert-Straße 68, 51429 Bergisch Gladbach, Germany Phone: +49 2204 8306-0 Fax: +49 2204 85197



Urgent Field Safety Notice (FSN)
CryoMACS Freezing Bag 750 (200-074-403)

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	CryoMACS Freezing Bag 750
1	2. Commercial name(s)
.	CryoMACS Freezing Bag 750
1	3. Unique Device Identifier(s) (UDI-DI)
.	4049934000300
1	4. Primary clinical purpose of device(s)*
.	The CryoMACS Freezing Bags are intended for a single cycle of freezing, storage (down to -196 °C [-321 °F]), and subsequent thawing (at +37 °C [+99 °F]) of hematopoietic progenitor cells.
1	5. Device Model/Catalogue/part number(s)*
.	200-074-403
1	6. Software version
.	n/a
1	7. Affected serial or lot number range
.	7200700537


2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	It can not be fully excluded, that for a bag of this lot the formation of a channel at the upper left side occurs. In such a case the seal is not fully closed leaving a small opening to the outside.
2	2. Hazard giving rise to the FSCA*
.	Due to the small opening to the outside a small amount of cellular material filled in might leak out. A contamination of the cellular material can not be excluded.
2	3. Probability of problem arising
.	The problem was reported for one bag of 11.952 pieces sold with an incident rate of 0.01% and it occurred first time.
2	4. Predicted risk to patient/users
.	The risk for the patient due to the loss of a small amount of material is low. The risk of contamination is considered unlikely and there is the possibility to perform a sterility testing prior to use. The failure is immediately determined, so measures can be taken. No risk for the user, as long as the general precautions when working with patient material are observed.
2	5. Further information to help characterise the problem
.	The MACS logo imprinted into the bag has to be completely visible and the seals near the Twist-off-Ports have to reach completely to the edge of the Freezing Bag. Such a bag is safe to use. If you notice that the logo is incomplete and that the seal does not reach the edge completely, a channel may form at this edge which can cause a leakage.
	6. Background on Issue



2	A Rapid Alert was initiated by the FIMEA based on the customers information. For one single bag a customer described the formation of a channel at the upper left side. A 100% control of more than 1.500 bags on stock (representing 10% of the lot) has shown, that no equal case was found. No relevant deviation concerning the manufacturing process occurred. For this product no similar case was reported in the last years.
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3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Please see attachment	
3.	2. By when should the action be completed?	Prior to using the Freezing Bag.
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No The issue is observed prior to use or during filling. Frozen bags are safe to use when following the instructions for use.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> None Provide further details of the action(s) identified. A 100% control of 10% of the boxes was performed and no other affected bag found A CAPA process has been initiated to define measure to avoid a reoccurrence of this case.	
3	6. By when should the action be completed?	The 100% control is completed. Timelines for further measures are defined during the CAPA process.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No



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 Miltenyi Biotec B.V. & Co. KG
	b. Address Friedrich-Ebert-Straße 68, 51429 Bergisch Gladbach
	c. Website address https://www.miltenyibiotec.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	4. List of attachments/appendices: Recommended Action
4.	5. 

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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

Recommended Action

Aim: Detection of Bags possibly showing a failure leading to a leakage.

Miltenyi Biotec was informed about the occurrence of a leakage through a small channel at the upper left side of a **CryoMACS Freezing Bag 750** (part no. 200-074-403) , **lot no. 7200700537**.

For this product, the formation of a small triangular pocket at the edge of the Freezing Bags is described. In one singular case, an extreme form of this pocket formation has resulted in a channel on the outer edge of the bag which led to a leakage. The described issue is caused by an incorrect sealing during the production of the Freezing Bag.

The formation of a channel at the edge of the Freezing Bag is a singular event with an estimated probability of occurrence of 1-2 ppm. The formation of the triangular pocket may occur occasionally, but there is no risk of leakage, because the integrity of the bag is guaranteed.

To check that your Freezing Bags are properly sealed, please inspect them visually prior to use and pay special attention to the following features:

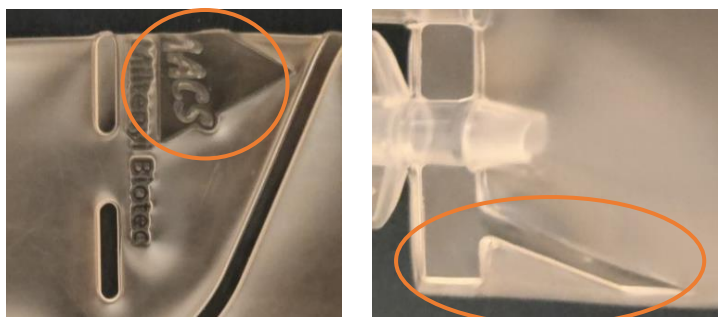
CORRECTLY SEALED FREEZING BAG



The MACS logo should be completely visible and the seals near the Twist-off-Ports should reach completely to the edge of the Freezing Bag. This is safe to use.

If you notice that the logo is incomplete and that the seal does not reach the edge completely, a channel may form at this edge which can cause a leakage.

INCORRECTLY SEALED FREEZING BAG



As a precautionary measure, we advise you not to use a Freezing Bag that shows this appearance and to contact Miltenyi Biotec.

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	EU-Complaint-002716
FSN Date*	02-Feb-2020
Product/ Device name*	<u>CryoMACS Freezing Bag 750</u>
Product Code(s)	200-074-403
Batch/Serial Number (s)	7200700537

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		



4. Return acknowledgement to sender	
Email	GlobalComplaints_MDR@miltenyi.com
Customer Helpline	Please refer to your local office as indicated on the FSN
Postal Address	Miltenyi Biotec B.V. & Co. KG Global Complaints/MDR Friedrich-Ebert-Str. 68 51429 Bergisch Gladbach, Germany
Web Portal	www.miltenyibiotec.com
Fax	0049-(0)3996-158 280
Deadline for returning the customer reply form*	23-Feb-2021

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.