Rev 1: September 2018
FSN Ref: 01_2022

FSCA Ref: 01_2022

Date: 11.11.2022

Urgent Field Safety Notice
PeriStem 650 DB

For Attention of*:all the users, health care providers, medical doctors and private and public hospital clinics using the medical devices addressed above.

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

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Urgent Field Safety Notice (FSN)
PeriStem PS 650 DB
Breaking of the bags during thawing

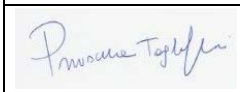
	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Medical Devices (bags) for cryopreservation of hemocomponents and mechanically digested lipoaspirate. Single use - disposable devices - supplied sterile, sterilized by means of Gamma Rays.
1.	2. Commercial name(s)
	PS 650 DB
1.	3. Unique Device Identifier(s) (UDI-DI)
	18055277210507
1.	4. Primary clinical purpose of device(s)*
	Medical Devices intended for cryopreservation in liquid nitrogen of hemocomponents (stem cells).
1.	5. Device Model/Catalogue/part number(s)*
	PS 650 - PeriStem packed in double pouch - REF. code PS 650 DB
1.	6. Software version
	//
1.	7. Affected serial or lot number range
	FA01538 - SC00816
1.	8. Associated devices
	Not Applicable.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Breaking of cryopreserved bags during thawing from the liquid Nitrogen
2.	2. Hazard giving rise to the FSCA*
	Breakage of the cryopreserved bags during thawing leading to loss of the biological material contained with impossibility to proceed to transplant in patients waiting for therapies. immediate low risks foreseen in particular for the users and third party providing for thawing of bags - patients indirectly involved - risks posed for patients are commensurated to the urgency of therapies.
2.	3. Probability of problem arising
	The use of relevant cover bag provided with the devices should reduce the risk of breakage.
2.	4. Predicted risk to patient/users
	As above mentioned the risks identify for patients are directly dependant on the urgency of therapies and on the previous health conditions of single patient to be evaluated case by case.
2.	5. Further information to help characterise the problem
	At the moment, the number of issues arisen is not statistically significant. divulgation a safety warning has been considered the best solution in order to avoid recurrence of the problem.
2	6. Background on Issue

.	Customer's complaints and report to the Italian Health Ministry regarding breakage and other defective events (e.g. swelling of the cryopreserved bags during thawing) Manufacturer Incident Report has been already filled - in and submitted to the Italian Ministry of Health as consequence of incidents relevant to breaking of bags during thawing with inability to perform stem cells transplantation. Traceability surveys on semi-finished products to identify other possible defective finished medical devices.
2	7. Other information relevant to FSCA
.	Recall of remaining pieces of the defective batches in order to avoid the use of products supposed to be defective.

	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?	30.11.2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No As consequence of breakage, patients are not able to receive the planned stem cells transplantation.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) to be provided within the returning products.	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Removal from the market of the identified defective or supposed to be defective batches.	
3	6. By when should the action be completed?	30.11.2022
3.	7. Is the FSN required to be communicated to the patient /	No

	lay user?	
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	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	//
4.	**3.** For Updated FSN, key new information as follows:	
	//	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	the use of the dedicated cover bag will be strongly recommended before starting with cryopreservation protocol. if the outcome of testing activities implemented (simulating of entire cryopreservation procedure) will be positive (no breakage nor swelling of the tested bags), will be possible reasonably conclude that the medical devices placed on the market, not pertaining to the defective batches, are compliant to the intended use and fit with their claimed intended purpose	
4	6. Anticipated timescale for follow-up FSN	15/12/2022
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Biomed Device S.r.l.**
	b. Address	**Via Vittorio Bottego, 239 - 41126 Modena (MO) - Italy**
	c. Website address	**http://www.biomeddevice.it/index.php/it/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Priscilla Tagliaferri** **QA & RA 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.