Rev 2: February 2020
FSN Ref: 001.01.2023

FSCA Ref: 001.01.2023

Date: 2023.01.22; update: 2023.02.13; update: 2023.02.23; update: 2023.04.27

Field Safety Notice
Belzer UW® Cold Storage Solution; Belzer MPS® & StoreProtect®

For Attention of*:Distributors, Importers, Hospitals, Health Care Professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Legal Manufacturer: Carnamedica Sp. z o.o. 21/U6 Olszynki Grochowskiej St. 04-281 Warsaw Poland e-mail: vigilance@carnamedica.com
Distributors of Belzer UW® Cold Storage Solution, Belzer MPS®: Bridge to Life Europe Ltd. LU 311 The Light Bulb 1 Filament Walk London SW18 4GQ Phone: +44(0)20 3411 8326 Fax: +44 (0)20 3004 1103 https://bridgetolife.eu/contact-bridge-to-life-ltd/ Bridge to Life Ltd. Logistics & Ordering: 128 Suber Rd. Suite A Columbia, SC 29210; USA **Distributor of StoreProtect®, Belzer MPS® (Poland):** Infusion 21/U6 Olszynki Grochowskiej St. 04-281 Warsaw Poland e-mail: vigilance@carnamedica.com

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FSN Ref: 001.01.2023

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Field Safety Notice (FSN)
Belzer UW® Cold Storage Solution; Belzer MPS® & StoreProtect®

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	• **Belzer UW® Cold Storage Solution (University of Wisconsin Solution)** *Container with perfusion and preservation solution for organs intended for transplantation* • **Belzer MPS® (UW Machine Perfusion Solution)** *Container with perfusion and preservation solution for organs intended for transplantation* • **StoreProtect®** *Container with perfusion and preservation solution for organs intended for transplantation*
1.	2. Commercial name(s)*
	• Belzer UW® • Belzer MPS® • StoreProtect®
1.	3. Unique Device Identifier(s) (UDI-DI)
	See Appendix A to this FSN.
1.	4. Primary clinical purpose of device(s)*
	• **Belzer UW®** Belzer UW® Cold Storage Solution (University of Wisconsin Solution) is a clear to light yellow, sterile, non-pyrogenic solution intended for the flushing and the hypothermic storage of organs (kidney, liver, pancreas) or other organs at the time of organ removal from the donor, in preparation for storage, transportation and eventual transplantation into the recipient. • **Belzer MPS®** Belzer MPS® (UW Machine Perfusion Solution) perfusion solution is a clear to slightly yellow, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous hypothermic machine perfusion of organs during their storage, transportation, until transplantation into a recipient. • **StoreProtect®** StoreProtect® is a clear to light yellow, sterile, non-pyrogenic solution intended for the flushing and the hypothermic storage of organs (kidney, liver, pancreas) or other organs at the time of organ removal from the donor, in preparation for storage, transportation and eventual transplantation into the recipient.
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix A to this FSN.
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	See Appendix A to this FSN.
1.	8. Associated devices
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)*

2. 1. Description of the product problem*

Carnamedica Sp. z o.o., with this Field Safety Notice is initiating a voluntary suspension to supply for the sterile **Belzer UW®**, **Belzer MPS®** and **StoreProtect®** (the list of reference codes and LOT numbers is included in the Appendix A), effective immediately.
Carnamedica has determined the following issues related to these devices:

- leaking within the solution bag overwrap,
- turbidity and discoloration;
- visible particulates.

The defects are immediately identifiable upon product acceptance prior to the use of the solution.
The affected devices were shipped during the time frame of 12.2021 – 11.2022.

2. 2. Hazard giving rise to the FSCA*

A damaged or leaking bag could result in microbial contamination of the sterile solution path due to lose of the sterile barrier. The turbidity and obvious intense discoloration is an indication of microbial contamination. This may predispose patients to peritonitis, infection, sepsis and failure to graft. Additional potential hazards that may result include delay in therapy.

If the visible particles are isolated in the device, local post-reperfusion ischemia may occur and there may be a potential risk of delayed graft function due to obliteration of some small vessels.

The risk is mitigated by the end user during the organs' preparation procedure according to the Instructions for Use (IFU), section PREPARATION. It is an obligatory standard for the end user to check each container that is used for presence of leakage/ discoloration or foreign particles, before the solution is administrated into the organ. In case that the solution contains any visible particles/ discoloration/ leakage, the product must be discarded and cannot be used for the patient.

2. 3. Probability of problem arising

There have been no serious injuries associated with leakage/ discoloration or particles that were reported in the accessible literature.
There are a handful of reports that cite near-miss situations, without actual injury, and the majority are discussing theoretical adverse events based on common medical knowledge but without real life proof of occurrence. It implies that the probability that the devices create hazardous situation leading to an injury is very low/ unlikely. The devices are used by the Health Care Professional user.

2. 4. Predicted risk to patient/users

Based on the internal and external investigations, the Medical Assessment part of the Health Hazard Evaluation (HHE) where the risk involved is theoretical and given that no identifiable studies relating to leakage/ discoloration or particles incidents leading to an adverse event are evident, and the lack any reports to Carnamedica of injury related to that.
The risk is mitigated by the end user during the organs' preparation procedure and should not to cause adverse health consequences. All risks were identified by the manufacturer within the risk analysis and the information about such remaining risks is incorporated into the Instruction for Use (IFU).

2. 5. Further information to help characterise the problem

Leakages and turbidity/ discoloration occur when the sterile barrier of the product is lost. Several factors can cause these defects: the EVA bag micro-sealing issue, the EVA bag injection port issue, the aseptic process issue. These issues affect only the individual affected bags, not the entire batch (LOT). The original issue is related to the individual EVA bags and can contribute to the aseptic process and result in microbiological contamination.

The presence of visible particles in the solution is the result of overheating caused by failure to meet the manufacturer's specified transport/ storage temperature in the supply chain.

	This issue is limited to Belzer UW® and Belzer MPS® solutions caused by improper product's handling and distribution.
2.	6. Background on Issue
	Customers reported an increase number of defects related to the leakages, discoloration and particles in the solutions before the use. None of the complaints report any patient adverse events.
2.	7. Other information relevant to FSCA
	Stop any further use of the affected devices.

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

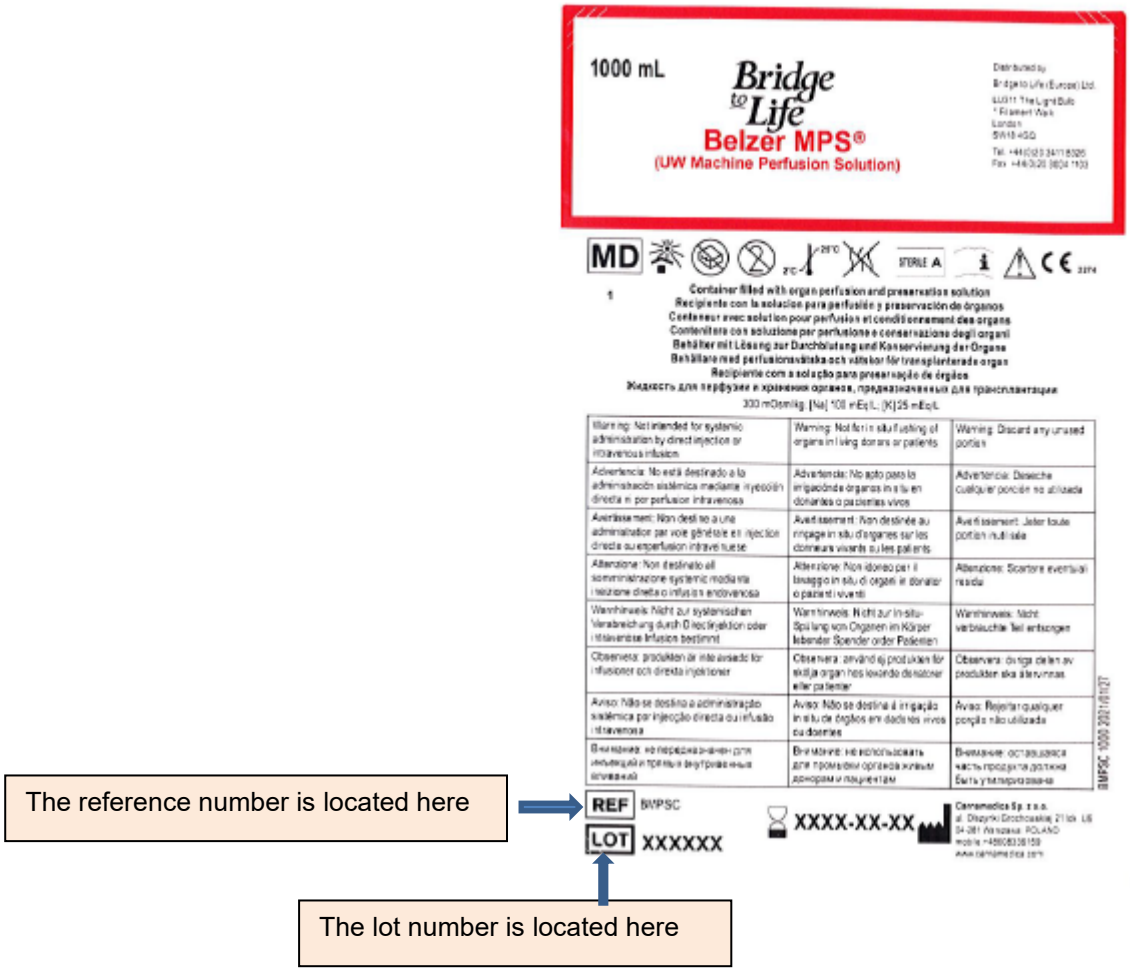
We would appreciate your assistance in the following actions:

1. **Read** the "2.1. Description of the product problem" section carefully to fully understand the issue involved.
2. Please immediately **examine** your inventory stock to determine if you have any remaining product in your possession.
3. **Stop** any further sale and distribution/ usage of the affected product.
4. The following illustrations are provided to help you identify the products and lots. Affected lots are identified by the reference number and lot number on the bag and case labels.

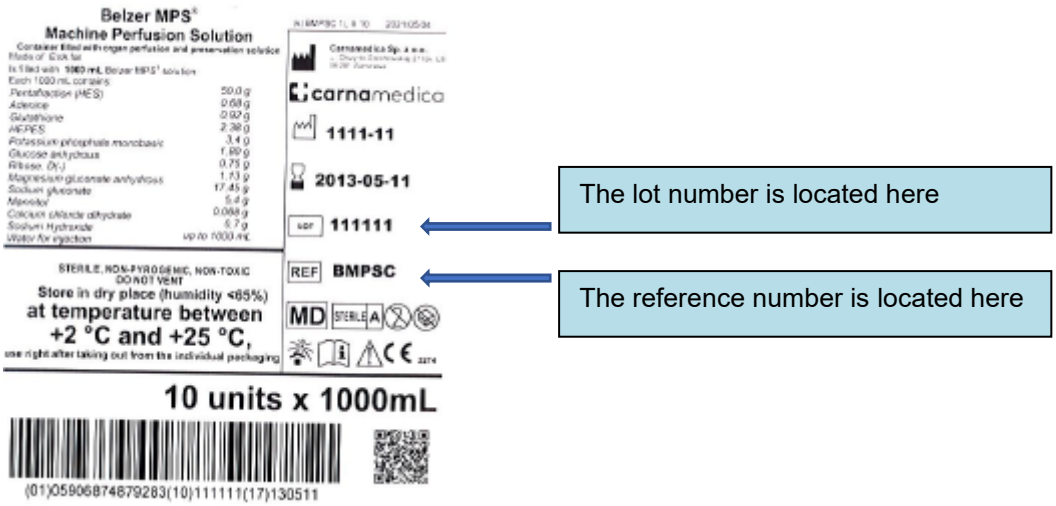
Bag labels

The reference number is located here

The lot number is located here


1000 mL
Bridge to Life
Belzer MPS®
(UW Machine Perfusion Solution)
MD
STERILE A
Container filled with organ perfusion and preservation solution
The reference number is located here
REF BMPSC
LOT XXXXXX
XXXX-XX-XX
The lot number is located here

Case label


Belzer MPS®
Machine Perfusion Solution
carnamedica
1111-11
2013-05-11
111111
REF BMPSC
STERILE, NON-PYROGENIC, NON-TOXIC
DO NOT VENT
Store in dry place (humidity <65%)
at temperature between
+2 °C and +25 °C,
10 units x 1000mL
(01)05906874879283(10)111111(17)130511
The lot number is located here
The reference number is located here

Actions related to the distributors/ importers:

1. **Conduct** a physical count and **record** the data on the Distributor/Importer Reply Form (in case of the distributors/ importers) attached to this Notice.
2. **Place** reviewed product into quarantine and **return** to the manufacturer.
3. **Return** the Distributor/Importer Reply Form to:
   - your local representative/ distributor (in country BTL representative: f.harvey@b2ll.com and m.harper@b2ll.com);
   - or via e-mail to vigilance@carnamedica.com.

   This is important to complete even, if you have no affected product on hand. Please ensure the form contains a contact name and signature.
4. **Contact** your local representative/ distributor (in country BTL representative or https://bridgetolife.eu/contact-bridge-to-life-ltd/) or Carnamedica's Service on office@carnamedica.com to understand how to obtain a credit note against affected product and organize the product's return.
5. **Maintain** awareness of this Notice until all affected product has been inspected/ destroyed.
6. **Share** this Notice with anyone who needs to be informed in your facility, or in any facility where potentially affected devices may have been transferred.
7. For any questions about the recall process, please **contact** your local representative/ distributor (in country BTL representative Mr. Mark Harper – Bridge to Life QA Director – m.harper@B2LL.com) or Carnamedica at vigilance@carnamedica.com.

Actions related to the Health Care Professionals:

1. **Conduct** a physical count and **record** the data on the Customer Reply Form (in case of the hospitals/ clinics/ etc.) attached to this Notice.
2. **Perform** and additional visual inspections according to the **Appendix B** to identify bags of solution that may represent leaking, discoloration, and contamination with particles prior to use of product. Before any use of the product, check their condition according to the IFU (Instructions for Use), section **PREPARATION**.
3. **Dispose** of the affected products through waste system, recycle packaging and **document** that on the Customer Reply Form attached to this Notice. If there is no possibility to dispose of the product in this way, you may return the product to local Customer representative through your normal means.
4. **Return** the Customer Reply Form to:
   - your local representative/ distributor (in country BTL representative: f.harvey@b2ll.com and m.harper@b2ll.com);
   - or via e-mail to vigilance@carnamedica.com.

   This is important to complete even, if you have no affected product on hand. Please ensure the form contains a contact name and signature.
5. **Contact** your local representative/ distributor (in country BTL representative or https://bridgetolife.eu/contact-bridge-to-life-ltd/) or Carnamedica's Customer Service on office@carnamedica.com to understand how to obtain a credit note against affected product.
6. **Maintain** awareness of this Notice until all affected product has been inspected/ destroyed.
7. **Share** this Notice with anyone who needs to be informed in your facility, or in any facility where potentially affected devices may have been transferred.
8. For any questions about this process, please **contact** your local representative/ distributor (in country BTL representative Mr. Mark Harper – Bridge to Life QA Director – m.harper@B2LL.com) or Carnamedica at vigilance@carnamedica.com.

2. By when should the action be completed?	The action should be completed within 90 days from delivery of this Field Safety Notice.

3.	3. Particular considerations for: Not applicable Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes The Distributor/Importer Reply Form or Customer Reply Form should be completed and returned within 90 days from delivery of this Field Safety Notice.
3.	**5. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ Software upgrade ☐ Other ☒ On-site device modification/inspection ☐ IFU or labelling change ☐ None Carnamedica has performed a root cause investigation and taken immediate corrective action. There are no other lots involved in that. Other lots were already inspected for the condition after manufacture. Carnamedica is voluntary taking this action.	
3.	6. By when should the action be completed?	The action should be completed within 90 days from delivery of this Notice.
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?	
	No	

4. General Information*		
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	This is an update to the original FSN # 001.01.2023 issued on 22 Jan 2023. [2023.02.23] – a second update of this FSN. [2023.04.27] – a third update of this FSN.
4.	3. For Updated FSN, key new information as follows:	
	This update was decided based the result of a 100% inspection of the remaining stocks of the products. This FSN has been extended with the new LOTs: 112122; 082222; 082322. The visible growing infection at the injection port was preliminary identified as a microbiological infection caused by sealing issue with the EVA bag. [2023.02.23] A second update of this FSN based on the results of the 100% inspection of the additional stocks of products. The FSN has been extended with the new LOTs: 061022 (BWUC2000); 022522; 101822; 031122; 022822. [2023.04.27] The third update of this FSN is the result of additional data from the supply chain. The FSN has been extended with the new LOTs: 111822; 111522; 080922; 082322 (BUWC). The timeline for closing this FSN needs to be extended to May 30, 2023.	

4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to: Not planned yet.	
4.	6. Anticipated timescale for follow-up FSN	Not planned yet.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Carnamedica Sp. z o.o.
	b. Address	21/U6 Olszynki Grochowskiej St.; 04-281 Warsaw; Poland
	c. Website address	www.carnamedica.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	• Appendix A – list of product references, lots and UDI codes • Appendix B – Instructions for the visual inspection • Distributor/Importer Reply Form • Customer Reply Form
4.	10. Name/Signature	Paweł Szczudło *CEO* **Signature**  Signed by / Podpisano przez: Paweł Marek Szczudło Date / Data: 2023-04-27 23:14

	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. 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 (vigilance@carnamedica.com), 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.

Appendix A – list of product references, batches and UDI codes

Reference number	LOT number	Product's name	UDI-DI code
BUWC	010722	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 010722 (17) 230707
BUWC	061022	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 061022 (17) 231210
BUWC	081222	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 081222 (17) 240212
BUWC	022422	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 022422 (17) 230824
BUWC	030222	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 030222 (17) 230902
BUWC	090122	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 090122 (17) 240301
BUWC	030322	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 030322 (17) 230903
BUWC	110922	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 110922 (17) 240509
BUWC	021822	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	(01) 5906874879221 (10) 021822 (17) 230818
BUWC	112122	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	101822	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	031122	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	022822	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	111822	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	111522	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	080922	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC	082322	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 1L	N/A
BUWC2000	030722	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 030722 (17) 230907
BUWC2000	010322	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 010322 (17) 230703
BUWC2000	030422	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 030422 (17) 230904
BUWC2000	030822	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 030822 (17) 230908
BUWC2000	123021	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 20211230 (17) 20230630
BUWC2000	030922	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879221 (10) 030922 (17) 230909
BUWC2000	030122	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	(01) 5906874879238 (10) 030122 (17) 230901
BUWC2000	082222	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	N/A
BUWC2000	082322	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	N/A
BUWC2000	061022	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	N/A
BUWC2000	022522	Belzer UW® Cold Storage Solutionl (University of Wisconsin Solution) 2L	N/A
BMPSC	110822	Belzer MPS® (UW Machine Perfusion Solution) 1L	(01) 5906874879245 (10) 110822 (17) 240508

Reference number	LOT number	Product's name	UDI-DI code
BMPSC	121721	Belzer MPS® (UW Machine Perfusion Solution) 1L	(01) 5906874879245 (10) 20211217 (17) 20230617
BMPSC	121621	Belzer MPS® (UW Machine Perfusion Solution) 1L	(01) 5906874879245 (10) 20211216 (17) 20230616
SPRT	120822	StoreProtect® 1L	(01) 5906874879009 (10) 120822 (17) 240212

Appendix B – Visual inspection for the Health Care Professionals

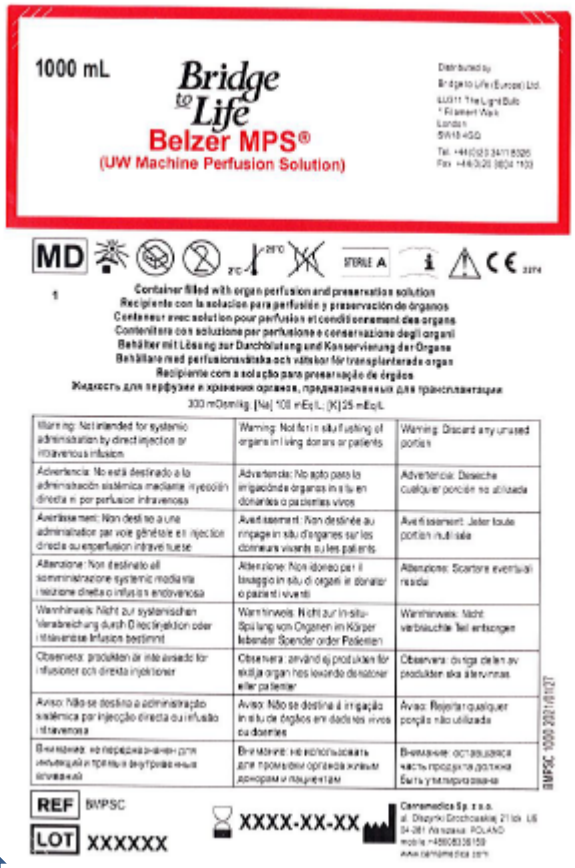
We would appreciate your assistance in the following actions:

5. **Read** the "2.1. Description of the product problem" section of the attached FSN carefully to fully understand the issue involved.
6. Please immediately **examine** your inventory stock to determine if you have any remaining product in your possession (**see Appendix A to the FSN**).
7. **Stop** any further usage of the affected product.
8. The following illustrations are provided to help you identify the products and lots. Affected lots are identified by the reference number and lot number on the bag and case labels.

Bag labels

The reference number is located

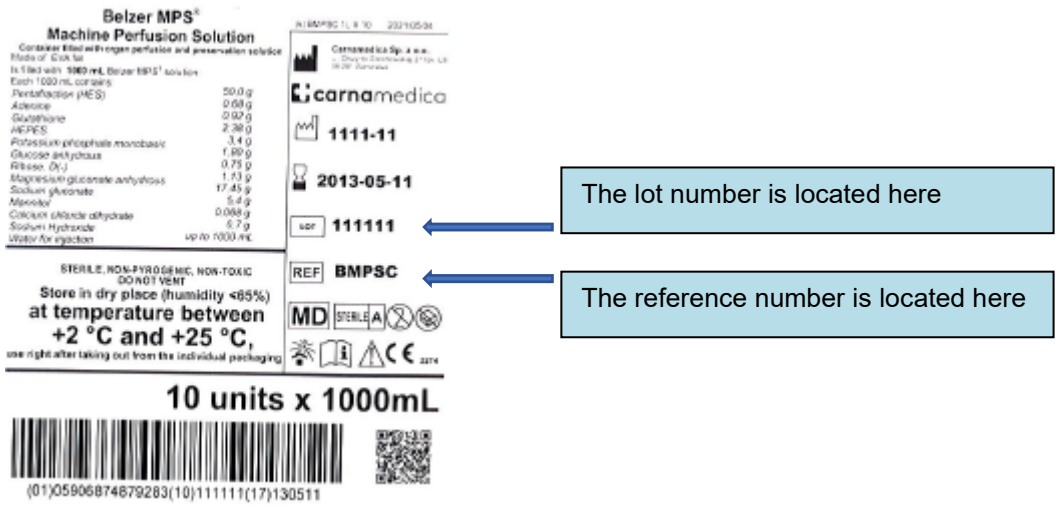
The lot number is located here



The reference number is located here

The lot number is located here

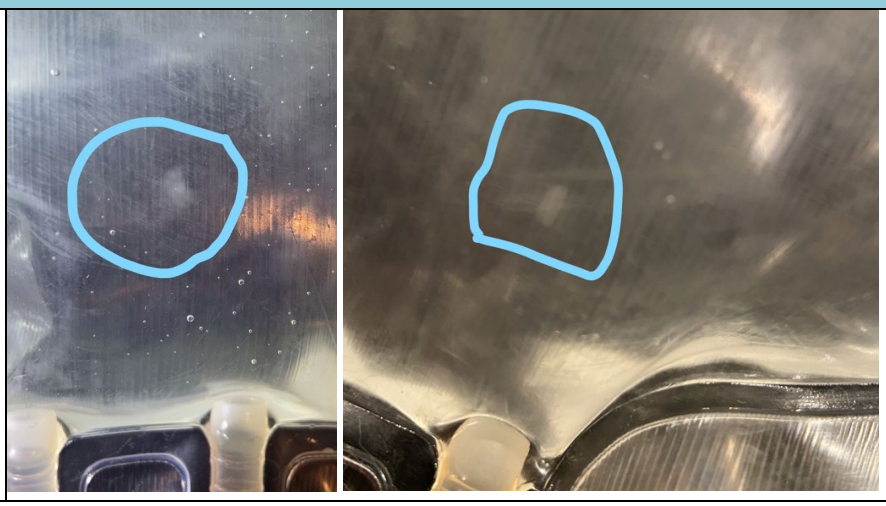
Case label



5. **Conduct** a physical count and **record** the data on the Customer Reply Form (in case of the hospitals/ clinics/ etc.) attached to the FSN.
6. **Perform** and additional visual inspections according to this Appendix to identify bags of solution that may represent leaking, discoloration, and contamination with particles prior to use of product.
   Should you have any existing product from the lots above or identify any units of solution containing leakage, discoloration or signs of contamination take immediate action to quarantine and report this information.
   Only fluid presenting a colourless appearance should be considered uncontaminated. Before any use of the product, check their condition according to the IFU (Instructions for Use), section **PREPARATION**.

UNCONTAMINATED BAG	
Description: The solution is a clear to slightly yellow, sterile. No leakages from the bag. The bag is properly labeled, clear and dry and free from moisture.	 

CONTAMINATED BAG	
LEAKAGE	
Description: Picture of Leaking Bag	  
TURBICIDY/ DISCOLORATION	
Description: Picture of the turbid/ discolored solution	 

PARTICLES	
Description: Particulate Matter in Solution	

7. **Dispose** of the affected products through waste system, recycle packaging and **document** that on the Customer Reply Form attached to this Notice. If there is no possibility to dispose of the product in this way, you may return the product to local Customer representative through your normal means.
8. **Return** the Customer Reply Form to:
   - your local representative/ distributor (in country BTL representative: f.harvey@b2ll.com and m.harper@b2ll.com);
   - or via e-mail to vigilance@carnamedica.com.

   This is important to complete even, if you have no affected product on hand. Please ensure the form contains a contact name and signature.
9. **Contact** your local representative/ distributor (in country BTL representative or https://bridgetolife.eu/contact-bridge-to-life-ltd/) or Carnamedica's Customer Service on office@carnamedica.com to understand how to obtain a credit note against affected product.
10. **Maintain** awareness of this Notice until all affected product has been inspected/ destroyed.
11. **Share** this Notice with anyone who needs to be informed in your facility, or in any facility where potentially affected devices may have been transferred.
12. For any questions about this process, please **contact** your local representative/ distributor (in country BTL representative Mr. Mark Harper – Bridge to Life QA Director – m.harper@B2LL.com) or Carnamedica at vigilance@carnamedica.com.

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