

Legal Manufacturer:

Carnamedica Sp. z o.o.
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Field Safety Notice (FSN)

Applies for the following products:

**PlegiStore[®], LungProtect[®], CelProtect[®], StoreProtect Plus[®], StoreProtect[®], PumpProtect[®],
Belzer UW[®] Cold Storage Solution (University of Wisconsin Solution),
Belzer MPS[®] (UW Machine Perfusion Solution).**

In connection with the update aimed at providing more detailed instructions for use (IFU) for the following products: PlegiStore[®], LungProtect[®], CelProtect[®], StoreProtect Plus[®], StoreProtect[®]/ Belzer UW[®] Cold Storage Solution (University of Wisconsin Solution), PumpProtect[®]/ Belzer MPS[®] (UW Machine Perfusion Solution), Carnamedica Sp. z o.o. hereby voluntarily publishes this Field Safety Notice (FSN) to ensure that all users of the above medical devices have been informed of changes to the IFU for its continued safe use.

Date of issue: 21.03.2025

For the attention of: Distributors, Importers, Hospitals, Healthcare Professionals

This Field Safety Notice relates to changes made to the Instructions for Use of containers filled with solution for perfusion or preservation of organs intended for transplantation. A detailed list of products covered by this notification can be found in the table below:

Information about the products involved in the notice
<ul style="list-style-type: none">• Belzer UW[®] Cold Storage Solution (University of Wisconsin Solution) <i>Container filled with solution for perfusion or preservation of organs intended for transplantation.</i>• Belzer MPS[®] (UW Machine Perfusion Solution) <i>Container filled with solution for perfusion or preservation of organs intended for transplantation.</i>• StoreProtect[®] <i>Container filled with solution for perfusion or preservation of organs intended for transplantation.</i>

- **PumpProtect®**
Container filled with solution for perfusion or preservation of organs intended for transplantation.
- **StoreProtect Plus®**
Container filled with solution for perfusion or preservation of organs intended for transplantation.
- **LungProtect®**
Container filled with solution for perfusion or preservation of organs intended for transplantation.
- **CelProtect®**
Container filled with solution for perfusion or preservation of organs intended for transplantation.
- **PlegiStore®**
Container filled with solution for perfusion or preservation of organs intended for transplantation.

Trade name	REF number
StoreProtect® 1l	SPRT
StoreProtect® 2l	SPRT2000
StoreProtect Plus® 1l	SPRT-P
StoreProtect Plus® 2l	SPRT-P2000
PumpProtect® 1l	PPRT
PumpProtect® 2l	PPRT2000
LungProtect® 1l	LPRT
LungProtect® 2l	LPRT2000
PlegiStore® 1l	PLST
PlegiStore® 2l	PLST2000
CelProtect® 1l	CPRT
CelProtect® 2l	CPRT2000
Belzer UW® Cold Storage Solution (University of Wisconsin Solution) 1l	BUWC
Belzer UW® Cold Storage Solution (University of Wisconsin Solution) 2l	BUWC2000
Belzer MPS® (UW Machine Perfusion Solution) 1l	BMPSC
Belzer MPS® (UW Machine Perfusion Solution) 2l	BMPSC2000

Carnamedica Sp. z o.o. has not identified any product problems. This Notice has been issued voluntarily and is intended to inform all users of the changes made to the Instructions for Use. The changes made are explained below. Please read the information provided in this Field Safety Notice and, in parallel, the full content of the instructions for use attached to the notification.

Instructions for Use	Changes made
StoreProtect®	<ol style="list-style-type: none"> The intended use of the product has been added above the description of the composition. The following has been added to the PREPARATION section: <i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i> The word “controlled” has been added to the section PACKAGING AND STORAGE and the sentence has been changed to: <i>Store StoreProtect® at a temperature controlled between +2°C and +25°C</i>
Belzer UW® Cold Storage Solution (University of Wisconsin Solution)	<ol style="list-style-type: none"> The intended use of the product has been added above the description of the composition. The following has been added to the PREPARATION section: <i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i> The word “controlled” has been added to the section PACKAGING AND STORAGE and the sentence has been changed to: <i>Store Belzer UW® Cold Storage Solution (University of Wisconsin Solution) at a temperature controlled between +2°C and +25°C</i>
PumpProtect®	<ol style="list-style-type: none"> The intended use of the product has been added above the description of the composition. The ACTIONS section was amended as follows <i>PumpProtect® machine perfusion solution is to be cooled to approximately 5° C (2° C to 8° C) prior to use in a perfusion machine capable of maintaining hypothermic conditions.</i> The following text has been added to the ADVERSE REACTIONS section: <i>No adverse reactions are known to be associated with the use of PumpProtect® in liver transplantation.</i> The following text has been added to the PREPARATION section: <i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i> <i>After pre-cooling the organ with vascular flush out using PumpProtect® or other suitable cooled solution for organ perfusion, the graft can be placed on an organ perfusion device and perfused using a suitable volume of PumpProtect® according to the manufacturer's (or perfusion center's) protocol. Donor organs must be flushed free of PumpProtect® prior to transplantation, according to transplantation centers' protocols.</i> The word “controlled” has been added to the section PACKAGING AND STORAGE and the sentence has been changed to: <i>Store PumpProtect® at a temperature controlled between +2°C and +25°C</i> The following sentence has been added to the section ATTENTION:

	<p><i>Before using PumpProtect® read these instructions for use carefully and verify that solution PumpProtect® is approved for use by the manufacturer of the machine perfusion device.</i></p>
Belzer MPS® (UW Machine Perfusion Solution)	<ol style="list-style-type: none"> The intended use of the product has been added above the description of the composition. The ACTIONS section was amended as follows <i>Belzer MPS® (UW Machine Perfusion Solution) machine perfusion solution is to be cooled to approximately 5° C (2° C to 8° C) prior to use in a perfusion machine capable of maintaining hypothermic conditions.</i> The following text has been added to the ADVERSE REACTIONS section: <i>No adverse reactions are known to be associated with the use of Belzer MPS® (UW Machine Perfusion Solution) in liver transplantation.</i> The following text has been added to the PREPARATION section: <i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i> <i>After pre-cooling the organ with vascular flush out using Belzer MPS® (UW Machine Perfusion Solution) or other suitable cooled solution for organ perfusion, the graft can be placed on an organ perfusion device and perfused using a suitable volume of Belzer MPS® (UW Machine Perfusion Solution) according to the manufacturer's (or perfusion center's) protocol. Donor organs must be flushed free of Belzer MPS® (UW Machine Perfusion Solution) prior to transplantation, according to transplantation centers' protocols.</i> The word "controlled" has been added to the section PACKAGING AND STORAGE and the sentence has been changed to: <i>Store Belzer MPS® (UW Machine Perfusion Solution) at a temperature controlled between +2°C and +25°C</i> The following sentence has been added to the section ATTENTION: <i>Before using Belzer MPS® solution (UW Machine Perfusion Solution), read these instructions for use carefully and verify that solution Belzer MPS® (UW Machine Perfusion Solution) is approved for use by the manufacturer of the machine perfusion device.</i>
CelProtect®	<ol style="list-style-type: none"> The following sentence has been added to the section POSOLOGY AND METHOD OF ADMINISTRATION: <i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i> The word "controlled" has been added to the section SPECIAL PRECAUTIONS FOR STORAGE and the sentence has been changed to: <i>Store CelProtect® at a temperature controlled between +2° C and +8°C.</i>
PlegiStore®	<ol style="list-style-type: none"> The following sentence has been added to the section WARNINGS AND PRECAUTIONS REGARDING PRODUCT SHELF LIFE:

	<p><i>Remove overwrap prior to use. Check each bag for leaks by squeezing the container. If a leak is found, discard solution bag. With the overwrap removed, perform a visual inspection of the solution for visible particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution.</i></p> <p>2. The word “controlled” has been added to the section STORAGE CONDITIONS and the sentence has been changed to:</p> <p><i>Store PlegiStore® at a temperature controlled between +2°C and +15°C</i></p>
LungProtect®	<p>1. The following has been added to the PREPARATION section:</p> <p><i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i></p> <p>2. The word “controlled” has been added to the section PACKAGING AND STORAGE and the sentence has been changed to:</p> <p><i>Store LungProtect® at a temperature controlled between +2°C and +25°C</i></p>
StoreProtect Plus®	<p>1. The following has been added to the PREPARATION section:</p> <p><i>The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.</i></p> <p>2. The word “controlled” has been added to the section PACKAGING AND STORAGE and the sentence has been changed to:</p> <p><i>Store StoreProtect Plus® at a temperature controlled between +2°C and +25°C</i></p>

Recommendations regarding actions to be taken by the distributor/user:

Actions required for the Distributor:

1. Send this Field Safety Notice to all users of the product.
2. Inform the end user that they must fill out Form FSN 1 and send it to the email address you provided by 13.04.2025 at the latest.
3. Complete Form No. 2 to FSN and send back to vigilance@carnamedica.com.
4. Send back Form No. 2 no later than **27.04.2025**.

Actions required for the end user:

1. Carefully read this Field Safety Notice and the updated Instructions for Use of the products you are using.
2. Fill out FSN Form No. 1, and send it back to the email address of your local distributor or to vigilance@carnamedica.com
3. Form No. 1 must be returned no later than **13.04.2025**.

Distribution of the safety note:

This notice must be passed on to all persons in the institution who should be informed and to any institution to which container filled with solution for perfusion or preservation of organs intended for transplantation manufactured by Carnamedica Sp. z o.o. are delivered.

Although Carnamedica Sp. z o.o. is not recalling any product, and this notice is for information purposes only, the relevant local authorities will be notified of this notice.

If you have any questions regarding this FSN notification, the product or the Instructions for Use, please contact us via email at vigilance@carnamedica.com or contact your local sales representative.

Paweł Szczudło

CEO