

2022-10-28

URGENT FIELD SAFETY NOTICE

FSCA Reference: 713001: PLS-Set – sterile barrier of components may be compromised

Field Safety Notice (FSN) Type: New

Affected Product: PLS Set

REF	Product Description	Article number	UDI-DI
BE-PLS 2050	PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068386	04058863006635
BE-PLS 2051	PLS Set Plus for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068389	04058863006666
BO-PLS 2051	HIT Set PLS Plus for extracorporeal cardiac and/or pulmonary support. SOFTLINE Coating	701068390	04058863006673
BE-PLS 2050	China PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701076706	04058863304533

Unique Device Identifier(s) (UDI-DI): See UDI-Di in the table above

Affected Serial No.: See attached Annex I List of affected batches

For Attention of: Distributors, customers and users of the PLS Set

Dear valued customer,

At Getinge we always put patient safety first.

Maquet Cardiopulmonary GmbH has therefore decided to carry out the following FSCA measures for the PLS Set, PLS Set Plus and HIT Set PLS Plus, further named PLS Set.

Product description:

The PLS Set is intended for use in an extracorporeal circulation for cardiac support and/or pulmonary support. Both veno-venous and veno-arterial blood circulation are possible:

- Veno-venous blood circulation: Exclusive support/takeover of lung function
- Veno-arterial blood circulation: Support/takeover of cardiac function and support/takeover of lung function as required

The PLS Set contains following components, see figure 1.

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1. Priming bag with 2 inlets
2. Yellow protective cap
3. 3-way stopcock
4. Tube for gas supply
5. Recirculation line
6. PLS-i Oxygenator
7. Arterial line (red marking)
8. Venous line (blue marking)
9. "Priming" 3-way stopcock
10. Priming lines with Roberts clamps
11. ROTAFLOW Centrifugal Pump RF-32
12. Sampling line (2 pieces)
13. Blue clamp
14. Scissors
15. Spike
16. Hemofiltration/Dialysis connectors (2 pieces) (only PLS Set Plus, HIT Set PLS Plus)
17. Marking for the attaching of the venous bubble sensor
18. Marking for the attaching of the arterial flow/bubble sensor

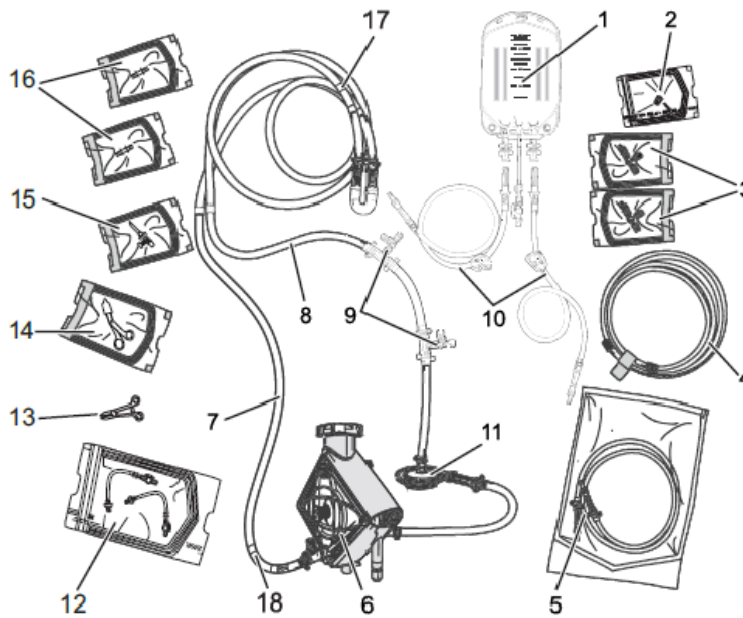


Figure 1 Components of PLS Set

Problem description

During internal investigation Maquet Cardiopulmonary GmbH (MCP) has identified that the packaging material (medical paper) of the PLS Set components recirculation line (5) and scissors (14) (see **Fehler! Verweisquelle konnte nicht gefunden werden.**) is inadequate to maintain the sterile barrier after removal from the primary sterile packaging (open Tyvek on the tray) if not consumed immediately during the priming process.

The affected packaging material of accessories might get damaged during the transportation and the damages might remain undetected as they are too small to identify them with naked eye.

The recirculation line (5) is used to wean the patient from the extracorporeal circulation (ECMO application) and is required at the end of application after 6 hours / 5 days / 14 days depending on product configuration.

The scissors (14) are used in different stages of the application 6h / 5d / 14d depending on product configuration if not consumed immediately after priming.

PLS Set itself is delivered sterile and compliant, this non-conformity relates to maintaining sterility after opening the PLS Set and removal of components (5) and (14) from the PLS Set tray for use in a later stage of extracorporeal circulation application.

Hazard giving rise to the Field Safety Corrective Action (FSCA)

Taking into consideration the packaging design of PLS Set the following immediate and long-term health consequences (harms) to patient may be potentially possible:

1. Hazardous Situation: Exposure of scissors and recirculation line to pathogenic agents
Harm (direct): Inflammation, Infection, Sepsis
2. Hazardous Situation: Component exchange/replacement
Harm (direct): User Inconvenience

Population most at risk- Immunocompromised/immunosuppressed patients

Immunocompromised or immunosuppressed patients are susceptible to a broad range and variety of infection due to a suppressed (e.g. organ transplantation, chemotherapy) or a compromised (e.g. congenital syndromes, HIV) immune system.

Patients who have undergone splenectomy, such as those with Hodgkin disease, are at greater risk of developing infections than are patients with intact spleens because the spleen performs several important host defense functions, including antibody production and the removal pathogens. This cohort of patients may be considered as a sub-category of immunocompromised patients.

Despite the lack of a complete understanding into its mechanisms and associations, diabetic patients have been demonstrated, through multiple studies, to be a risk factor for infection in general and/or surgical site infections (SSIs) in particular; therefore, diabetic patients may also be considered as a sub-category of immunocompromised patients.

Last, many authors state that there appears to be a direct link to the susceptibility of infection and increasing age which may relate to impaired/again immune function, as well as anatomical and functional changes that correspond with the aging process.

Maquet Cardiopulmonary GmbH has not received any complaints of serious injuries, deaths related to the issue described above. Although there are no complaints, MCP GmbH sees an unacceptable risk resulting from this nonconformity.

Risk Mitigating Clinical Factors

There are no clinical factors inherent to the PLS Set, per se, which may serve to mitigate the risk described the problem above. However, the PLS Set Instruction for Use (IFU) makes the following statements regarding product sterility and use:

The use of non-sterile or defective devices can result in infection of the patient, user and third parties.

- *Only use the device if it is sterile.*
- *Do not use the device if it or the sterile packaging is damaged.*
- *Observe the use-by date on the packaging.*

Always observe strict asepsis when handling the device.

It is assumed that a healthcare practitioner will 1) visually inspect the product for signs of damage or lack of sterility, and 2) not use any product that is suspected to be non-sterile or displays visible package damage that may affect sterility. A thorough examination of all products to confirm sterility is standard practice and customary behavior among healthcare practitioners. However, depending on the size, character, and location of the holes in the packaging, the product user may not recognize or perceive packaging damage and, inadvertently, deploy the product. Further, recognition of a compromised product depends greatly on the size, character, and location of the holes (or, damage) in the packaging. Very small holes, imperceptible damage, or unrecognized breaches may not be detectable by the product user upon initial inspection, especially in an emergent situation.

Type of Action to mitigate the risk

Action to be taken by the user:

- Identify Device
- Other: Details see further actions below.

Description for a safe application of the product until implementation of corrective actions:

- Please be aware that the components supplied with a PLS Set must be consumed immediately after opening the Tyvek lid of the PLS Set tray, including the supplied scissors to cut the main line. All remaining

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components that are not consumed during the priming process, must be disposed.

- For the use of the recirculation line to wean the patient from the extracorporeal circulation (ECMO application), you must take a new recirculation line from a new PLS Set, which MCP will provide you as a backup. The remaining components of the PLS set must be disposed after extraction of the recirculation line.
- All newly delivered PLS Set will contain a corresponding safety notice explaining the temporary FSCA measures again.
- If you have an affected PLS Set, please duly complete and sign the enclosed customer response form and send it back to your local Getinge representative, at the latest by November 18, 2022. Based on your response, you will receive PLS Sets, which can be used as a backup during application.
- Please report any adverse events in regard to the affected products to your Getinge Representative.
- With every new order of a PLS Set, the customer/ distributor will automatically receive an additional PLS Set (depending on the variant ordered), which can be used as a backup during application as long as the new packaging material is implemented in production.

Action to be taken by the Manufacturer:

Due Date: 18.11.2022

- Application of the instruction, described in the FSN to new delivered products. Action remains until new packaging material is implemented.

Due Date: 18.11.2022

- Packaging redesign for the affected components.

Due Date: 23.12.2022

Enclosed documents:

- Customer response form
- Distributor response form
- Annex I List of affected batches

Advice for patients or the treatment/follow-up of patients treated with potentially affected devices

N/A

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

Managing Director

Person Responsible for Regulatory Compliance (PRRC)

Contact details of manufacturer

Timur Güvercinci
Maquet Cardiopulmonary GmbH
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Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference: 713001: PLS-Set – sterile barrier of components may be compromised

Affected Product: PLS Set

REF	Product Description	Article number
BE-PLS 2050	PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068386
BE-PLS 2051	PLS Set Plus for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068389
BO-PLS 2051	HIT Set PLS Plus for extracorporeal cardiac and/or pulmonary support. SOFTLINE Coating	701068390
BE-PLS 2050	China PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701076706

Affected Serial No.: See Annex I list of affected batches

Please send this form to your local Getinge representative at the latest by November 18, 2022.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for products PLS Set. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

- I do not have any PLS Set in my inventory.
- I have following lots of PLS Set in my inventory and will use them according to given instructions.
- I have following lots of PLS Set in my inventory and will send them back to you for credit.

Following affected PLS Set/s are in our inventory:

REF	Article Number	Batch Number	Quantity

Your Comments:

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Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX.

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DISTRIBUTOR RESPONSE FORM

FSCA Reference: 713001: PLS-Set – sterile barrier of components may be compromised

Affected Product: PLS Set

REF	Product Description	Article number
BE-PLS 2050	PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068386
BE-PLS 2051	PLS Set Plus for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068389
BO-PLS 2051	HIT Set PLS Plus for extracorporeal cardiac and/or pulmonary support. SOFTLINE Coating	701068390
BE-PLS 2050	China PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701076706

Affected Serial No.: See Annex I list of affected batches

Please send this form to your local Getinge representative at the latest by November 18, 2022.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for products PLS Set. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected customers.

- I do not have any PLS Set in my inventory.
- I have following lots of PLS Set in my inventory and will use them according to given instructions.
- I have following lots of PLS Set in my inventory and will send them back to you for credit.

Following affected PLS Set/s are in our inventory:

REF	Article Number	Batch Number	Quantity

Your Comments:

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Country

Distributor (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX.

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Annex I List of affected batches

This Annex I List of affected batches is considered as a supplementary attachment to the 713001 Field Safety Notice.

Below are listed all batches of products which are affected and have been distributed.

REF	Product Description	Article	Batch range
BE-PLS 2050	PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068386	from 3000204268 to 3000272105
BE-PLS 2051	PLS Set Plus for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701068389	from 3000212851 to 3000270727
BO-PLS 2051	HIT Set PLS Plus for extracorporeal cardiac and/or pulmonary support. SOFTLINE Coating	701068390	from 3000208694 to 3000227579
BE-PLS 2050 China	China PLS Set for extracorporeal cardiac and/or pulmonary support. BIOLINE Coating	701076706	from 3000190149 to 3000252498

Country	Article No.	REF	Batch range
Argentina	701068386	BE-PLS 2050	from 3000215240 to 3000238293
Australia	701068389	BE-PLS 2051	from 3000217589 to 3000254983
Australia	701068390	BO-PLS 2051	3000227579
Austria	701068386	BE-PLS 2050	from 3000207509 to 3000208672
Belgium	701068386	BE-PLS 2050	from 3000205883 to 3000210639
Belgium	701068389	BE-PLS 2051	from 3000212851 to 3000228857
Belgium	701068390	BO-PLS 2051	3000208694
Brazil	701068386	BE-PLS 2050	3000217602
Brazil	701076706	BE-PLS 2050 China	3000221775
Canada	701068389	BE-PLS 2051	3000221769
Chile	701068386	BE-PLS 2050	from 3000205881 to 3000218623
China	701076706	BE-PLS 2050 China	from 3000190149 to 3000252498
Colombia	701068386	BE-PLS 2050	3000207494
Croatia	701068386	BE-PLS 2050	from 3000205884 to 3000217606
Croatia	701068389	BE-PLS 2051	3000221769
Cyprus	701068386	BE-PLS 2050	from 3000207494 to 3000216183
Czech Republic	701068386	BE-PLS 2050	from 3000205882 to 3000218628
Czech Republic	701068389	BE-PLS 2051	from 3000212853

Country	Article No.	REF	Batch range
			to 3000236094
Denmark	701068389	BE-PLS 2051	from 3000212853 to 3000220056
Estonia	701068389	BE-PLS 2051	from 3000212851 to 3000218618
Finland	701068389	BE-PLS 2051	from 3000212853 To 3000228857
France	701068386	BE-PLS 2050	from 3000205882 to 3000217606
France	701068389	BE-PLS 2051	from 3000212851 to 3000236094
France	701068390	BO-PLS 2051	from 3000208694 to 3000227579
French Polynesia	701068389	BE-PLS 2051	from 3000217604 to 3000228857
Germany	701068386	BE-PLS 2050	from 3000204268 to 3000218628
Germany	701068389	BE-PLS 2051	from 3000212851 to 3000236094
Germany	701068390	BO-PLS 2051	from 3000208694 to 3000227579
Greece	701068386	BE-PLS 2050	from 3000207500 to 3000217602
Hong Kong	701068386	BE-PLS 2050	from 3000207495 to 3000254703
Hungary	701068386	BE-PLS 2050	3000216175
India	701068386	BE-PLS 2050	from 3000204268 to 3000254979
Ireland	701068386	BE-PLS 2050	3000205884
Israel	701068386	BE-PLS 2050	from 3000204268 to 3000218623
Italy	701068386	BE-PLS 2050	from 3000204268 to 3000218627
Italy	701068389	BE-PLS 2051	from 3000217605 to 3000220056
Italy	701068390	BO-PLS 2051	3000208694
South Korea	701068386	BE-PLS 2050	from 3000205881 to 3000254704
Kuwait	701068389	BE-PLS 2051	3000212851
Luxembourg	701068386	BE-PLS 2050	from 3000208685 to 3000217595
Macedonia	701068386	BE-PLS 2050	from 3000205884 to 3000217601
Malaysia	701068386	BE-PLS 2050	from 3000210639 to 3000218627
Martinique	701068386	BE-PLS 2050	from 3000207495 to 3000207509
Mexico	701068386	BE-PLS 2050	from 3000206011 to 3000206018
Mexico	701076706	BE-PLS 2050 China	3000224128
Morocco	701068389	BE-PLS 2051	3000225891

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Country	Article No.	REF	Batch range
Netherlands	701068386	BE-PLS 2050	from 3000204268 to 3000218623
New Zealand	701068389	BE-PLS 2051	from 3000217588 to 3000254983
Norway	701068386	BE-PLS 2050	3000216187
Pakistan	701068386	BE-PLS 2050	from 3000208680 to 3000210631
Paraguay	701068386	BE-PLS 2050	3000217601
Poland	701068386	BE-PLS 2050	from 3000204268 to 3000225896
Poland	701068389	BE-PLS 2051	from 3000212851 to 3000228857
Portugal	701068386	BE-PLS 2050	from 3000207511 to 3000218628
Réunion	701068386	BE-PLS 2050	from 3000207513 to 3000217602
Romania	701068389	BE-PLS 2051	3000217604
Russia	701076706	BE-PLS 2050 China	from 3000190149 to 3000222468
Saudi Arabia	701068389	BE-PLS 2051	from 3000221769 to 3000254981
Slovenia	701068386	BE-PLS 2050	from 3000208672 to 3000218627
Spain	701068386	BE-PLS 2050	from 3000205881 to 3000218627
Sweden	701068386	BE-PLS 2050	3000208680
Switzerland	701068386	BE-PLS 2050	from 3000207490 to 3000218623
Taiwan	701076706	BE-PLS 2050 China	from 3000190149 to 3000192097
Thailand	701068389	BE-PLS 2051	From 3000212851 to 3000228855
Turkey	701068386	BE-PLS 2050	from 3000207490 to 3000254979
Turkey	701068390	BO-PLS 2051	3000227579
United Arab Emirates	701068389	BE-PLS 2051	from 3000221769 to 3000254981
United Kingdom	701068386	BE-PLS 2050	from 3000207490 to 3000254706
Vietnam	701068386	BE-PLS 2050	from 3000207500 to 3000207509
Vietnam	701068389	BE-PLS 2051	from 3000217588 to 3000228857