January 14, 2025

Cardiohelp System and HLS Set Advanced – Modified Indications for Use

This letter only applies to the United States

Dear Valued Customer:

Maquet Cardiopulmonary GmbH, a subsidiary of Getinge, is making additional modifications to the Indications for Use for the Cardiohelp System (hardware) and the HLS Set Advanced (disposable) beyond the changes that were previously communicated in July 2024. The new Indications for Use, as of January 2025, are shown in the table below.

The United States Food and Drug Administration (FDA) issued a final order [Federal Register Volume 80, Number 109] to reclassify nonroller-type cardiopulmonary bypass pump (NRP) devices for cardiopulmonary and circulatory bypass. This reclassification order affects the Cardiohelp System and HLS Set Advanced and requires that Maquet Cardiopulmonary modify the Indications for Use of the products. The indications for use are further modified as follows:

	Indications for Use (Pre-July 2024)	Indications for Use (Communicated July 2024)	New Indications for Use (January 2025)
	For Historical Reference Only		
Cardiohelp System	The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours). The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.	The CARDIOHELP System are devices that use a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: • Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or • Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.	The CARDIOHELP System are devices that use a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: • Partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or • Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

	Indications for Use (Pre-July 2024)	Indications for Use (Communicated July 2024)	New Indications for Use (January 2025)
	For Historical Reference Only		
HLS Set Advanced	The HLS Set Advanced / HIT Set Advanced is part of the CARDIOHELP System. For the indication for use, refer to the CARDIOHELP System Instructions for Use.	The HLS Set Advanced is a device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: • Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or • Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.	The HLS Set Advanced is a set of disposable devices (used with the Cardiohelp System) that includes an oxygenator that provides physiologic gas exchange, a heat exchanger that allows regulation of blood temperature, and a centrifugal pump that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: • Partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or • Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

This modification to the Indications for Use is a result of an FDA reclassification order and is not related to open Field Safety Corrective Actions (FSCAs) or the May 08, 2024 FDA Letter to Health Care Providers regarding Safety and Quality Concerns with Getinge Cardiovascular Devices.

For more information on the FDA's Letter to Health Care Providers or the FDA reclassification order please refer to the following website links:

- https://www.getinge.com/us/insights/safety-notifications/
- https://www.govinfo.gov/content/pkg/FR-2015-06-08/html/2015-13889.htm

A copy of the revised Cardiohelp System and HLS Set Advanced Instructions for Use are included with this mailing:

1. Cardiohelp System (Version 2.3, issue date 2025-01)
2. Intra-hospital Patient Transport (Version 2.2, issue date 2025-01)
3. HLS Set Advanced 5.0 and 7.0 (Version 6.0, issue date 2025-01)

An electronic version of these Instructions for Use are also available online at:
https://www.getinge.com/us/products/cardiohelp-system/

Actions to be taken by the customer:

Our records indicate that you have previously received the Cardiohelp System.

1. Users should be made aware of the modified Indications for Use for the Cardiohelp System and the HLS Set Advanced.
2. Please forward this information to all current and potential Cardiohelp System users within your facility.
3. Your facility can use the devices in accordance with the new Indications for Use, the revised IFUs, and the May 08, 2024, FDA Letter to Health Care Providers regarding Safety and Quality Concerns with Getinge Cardiovascular Devices. **No devices need to be returned.**

4. If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Actions to be taken by Getinge:

1. Getinge is notifying each facility using the Cardiohelp System of the modified Indications for Use as specified by the FDA reclassification order.
2. The Cardiohelp System and HLS Set Advanced Instructions for Use (IFU) have been revised to reflect the new Indications for Use statement, including new restrictions on some of the current Therapy Applications (thApp) available on the Cardiohelp System.
3. The revised IFUs are included in this communication and are available online for existing users at https://www.getinge.com/us/products/cardiohelp-system/.
4. The revised IFUs will be packaged with new production units within the next 3 months.

If you have any questions, please contact your sales representative.

This communication is being made with the knowledge of the U.S. Food and Drug Administration.

Best Regards,

Dieter Engel

Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Jan 14, 2025 17:45 GMT+1

Dieter Engel

Vice President, Maquet Cardiopulmonary GmbH

Emily Valerio

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Emily Valerio

Vice President, Regulatory Affairs