July 10, 2024

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 modifying the Indications for Use for the Cardiohelp System (hardware) and the HLS Set Advanced (disposable).

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 as follows:

	Previous Indications for Use	New Indications for Use
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.

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1 Geoffrey Way
Wayne, NJ 07450
USA

	Previous Indications for Use	New Indications for Use
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.

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 recent 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

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 that will be available soon, and the recent 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.

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2. The current Cardiohelp System and HLS Set Advanced Instructions for Use (IFU) will be updated 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 IFU will be packaged with new production upon implementation and will soon be available online for existing users.

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

Dieter Engel

Vice President, Maquet Cardiopulmonary GmbH

Emily Valerio

Emily Valerio

Vice President, Regulatory Affairs

Getinge
1 Geoffrey Way
Wayne, NJ 07450
USA