Healthcare Setting Enrollment Form

HEPZATO KIT™
(melphalan) for Injection/
Hepatic Delivery System (HDS)

PHONE: 1-833-632-0457
EMAIL: coordinator@HEPZATOKITREMS.com
WEB: www.HEPZATOKITREMS.com

INSTRUCTIONS

Due to the risks of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events, HEPZATO KIT is available only through a restricted program called the HEPZATO KIT REMS (Risk Evaluation and Mitigation Strategy). In order to dispense the HEPZATO KIT, healthcare settings must be certified in the HEPZATO KIT REMS.

Healthcare settings must designate an Authorized Representative to:

- Complete the certification process by completing the **Healthcare Setting Enrollment Form** on behalf of the healthcare setting.
- Oversee implementation and compliance with the HEPZATO KIT REMS requirements as outlined below.

Complete all required fields below and submit this enrollment form to the REMS Coordinating Center to via e-mail at coordinator@HEPZATOKITREMS.com or complete it online at www.HEPZATOKITREMS.com.

- Product orders cannot be placed until the healthcare setting certification is complete.
- Completion of this form does not guarantee your healthcare setting will be certified to dispense the HEPZATO KIT.
- The HEPZATO KIT REMS will provide confirmation of certification via e-mail after processing this form.

For additional information, or more copies of any of the HEPZATO KIT REMS materials, please visit the REMS Website at www.HEPZATOKITREMS.com or call the HEPZATO KIT REMS Coordinating Center at 1-833-632-0457.

HEALTHCARE SETTING INFORMATION (all fields are required)		
☐ New Certification ☐ Change in Authorized Representative		
Healthcare Setting Name:		
Address Line 1:		
Address Line 2 (optional):		
City:	State:	Zip Code:

AUTHORIZED REPRESENTATIVE RESPONSIBILITIES

On behalf of my healthcare setting, I am the Authorized Representative, designated by my healthcare setting, to carry out the certification process and oversee implementation and compliance with the HEPZATO KIT REMS on behalf of the healthcare setting.

To become certified to dispense, the healthcare setting must:

- Have percutaneous hepatic perfusion procedure team(s) that must include healthcare providers with expertise in interventional radiology, anesthesiology, and perfusion as described in the Instructions For Use.
- Have the following on-site: interventional radiology suite or operating room with fluoroscopy and with resuscitation personnel, equipment, and medications.

As the Authorized Representative, I must:

- Review the product's Prescribing Information, Instructions for Use, Program Overview, and Didactic Modules.
- Enroll in the REMS by completing and submitting the Healthcare Setting Enrollment Form to the REMS.
- Have the percutaneous hepatic perfusion procedure team members that perform procedures with HEPZATO KIT review the product's Prescribing Information and Instructions for Use.

REMS USE ONLY
Tracking Number _____ Date _____

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- Have the percutaneous hepatic perfusion procedure team members that perform procedures with HEPZATO KIT take the **Program Overview, Didactic Modules**, and Preceptorship training provided by Delcath Systems, Inc.
- Have the percutaneous hepatic perfusion procedure team members that perform procedures with HEPZATO KIT successfully complete the Proctorship training and successfully complete and submit the **Criteria for Procedural Competency Checklist** to the REMS.
- Establish processes and procedures to ensure relevant new staff who will perform percutaneous hepatic perfusion procedures with HEPZATO KIT are trained.

Before administering, I and/or the healthcare setting staff must:

- Obtain authorization to dispense each HEPZATO KIT by contacting the REMS to verify the percutaneous hepatic perfusion procedure team is qualified using the **Procedure Team Qualification Status Form**.

During and after administering, for at least 72 hours, I and/or the healthcare setting staff must:

- Assess the patient for severe peri-procedural complications associated with HEPZATO KIT.
- Document and submit severe peri-procedural complications using the **Severe Peri-Procedure-related Complications Adverse Events Documentation Form** to the REMS.

To maintain certification to dispense, annually, I must:

- Have a percutaneous hepatic perfusion procedure team(s) that must include healthcare providers with expertise in interventional radiology, anesthesiology, and perfusion as described in the Instructions For Use.
- Have percutaneous hepatic perfusion procedure team members who have each performed one procedure in the first six months following completion of training, a second procedure in the next six months, and at least two procedures annually thereafter.
- Have the following on-site: interventional radiology suite or operating room with fluoroscopy and with resuscitation personnel, equipment, and medications.
- If there is a change in Authorized Representative, have a new Authorized Representative enroll in the REMS by completing the **Healthcare Setting Enrollment Form**.

At all times, I must:

- Maintain records of each percutaneous hepatic perfusion procedure team member's training.
- Maintain records of the percutaneous hepatic perfusion procedures performed with HEPZATO KIT and the associated percutaneous hepatic perfusion procedure team members' participation.
- Maintain records that processes and procedures are in place and are being followed.
- Comply with audits carried out by Delcath Systems, Inc., or a third party acting on behalf of Delcath Systems, Inc., to ensure that all training, processes, and procedures are in place and are being followed.

By signing this form, I agree, on behalf of myself and my healthcare setting(s), to comply with all REMS Requirements.

AUTHORIZED REPRESENTATIVE INFORMATION (all fields are required)	
First Name:	Last Name:
Credentials: ☐ MD ☐ DO ☐ RN ☐ PharmD/RPh ☐ NP/PA ☐ Other (please specify)	
Department:	
Phone:	Email:
Authorized Representative Signature:	**Date (MM/DD/YYYY):**

Authorized Representatives are encouraged to report any other serious adverse events to Delcath Systems, Inc. at 1-833-632-0458 or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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