Criteria for Procedural Competency Checklist

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

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

INSTRUCTIONS

HEPZATO KIT is only available through the HEPZATO KIT Risk Evaluation and Mitigation Strategy (REMS) to mitigate the risks of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events associated with HEPZATO KIT.

Percutaneous Hepatic Perfusion Procedural Team members that perform procedures with HEPZATO KIT must review the product's Prescribing Information, Instructions for Use, **Program Overview, Didactic Modules**, undergo the Preceptorship training, and must also successfully complete the Proctorship training provided by Delcath Systems, Inc.

To document completion of training requirements, complete and submit this form online at www.HEPZATOKITREMS.com or email to coordinator@HEPZATOKITREMS.com.

New Form		Updated Form Date su			bmitted to REMS:			
Authorized Representative (all fields are required)								
First Name:	irst Name:					Last Name:		
Email:	mail:					Phone:		
Healthcare Setting Information (all fields are required)								
Healthcare Setting Name:								
Address Line 1:								
Address Line 2:								
City:					State:		Zip Code:	
Specialist Role: (all fields are required)								
Specialist Role:	Interventional Radiology Anesthesiology Per					Perfusion		
First Name:	e:				Last Name:			
National Provider Identifier (NPI) #:								
Healthcare Setting Name:								
Credentials:	dentials: MD DO Other, please specify:							
Title:								
Address Line 1:								
Address Line 2:								
City:					State:		Zip Code:	
Email:					Phone:			
Date Prescribing Information, Instructions for Use, Program Overview, and Didactic Modules Reviewed:					Date:		Trainer Name:	
Date of Preceptorship Training Provided by Delcath:					Date:		Trainer Name:	
Date of Proctorship Training Provided by Delcath:					Date:		Trainer Name:	



REMS USE ONLY Tracking Number

DOCUMENT NO.: MED-007
REVISION: A
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EFFECTIVITY DATE: 08-Jan-2024

Date