# Urgent Field Safety Notice

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**Commercial Name:** Delcath Systems - CHEMOSAT HDS
**Field Safety Notice:** Delcath Complaint 002-2021
**Type of action:** Field Safety Notice as per 4.7 of MEDDEV 2.12-1 Rev 8

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**Date:** 19-Mar-2021

**Attention:** Delcath Systems - CHEMOSAT HDS Customers

**Details on affected devices:**
A sterile 18F Sheath component is supplied as part of Chemosat HDS Kit. The 18F Sheath is contained in the Femoral Accessory Pack.

| Femoral Accessory Pack (contains 18F Sheath) | Lot Numbers |
|---|---|
| Part number 420025 | L006825, L007228, L006585, L007428, |
| Part number 420008 | L007226 |

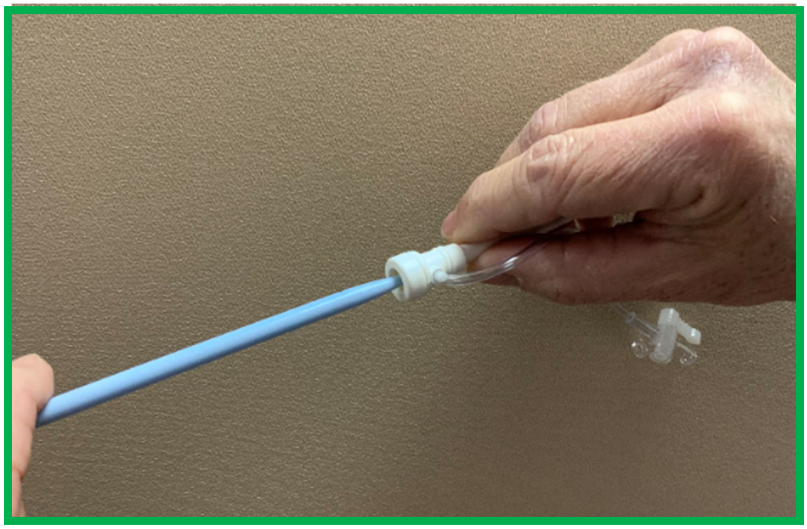
**Description of the problem:**
Delcath Systems is providing this Field Safety Notice after reports were received of the silicone valve in the 18F Sheath potentially becoming unseated during the preparation of the dilator and sheath.

**Advise on action to be taken by the user:**
The dilator, catheter and obturator should be carefully and slowly inserted into the centre of the sheath's valve. Off-centre placement or a rapid removal may damage the valve components, resulting in blood flow through the valve, as well as cause a vacuum, which may allow air to enter the sheath.

If unusual resistance is met during the dilator insertion, please slowly remove the dilator, and inspect the valve to ensure it has not been damaged or displaced. Replace the sheath, if valve damage, or valve displacement is observed.

After placement of the 18F Sheath in the femoral vein, observe for excessive blood leakage out of the sheath where the guidewire, catheter, or obturator interface, and continue to monitor throughout the treatment.

**CORRECT DILATOR INSERTION:**



**INCORRECT DILATOR INSERTION:**

**Transmission of this Field Safety Notice**:
Sent to Delcath CHEMOSAT HDS Customers.

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**Contact reference person:**
Ray Treacy – Associated Director Quality Assurance EMEA – rtreacy@delcath.com
00 353 91 746200 ext 216

| 1. **Information on Affected Devices*** | |
|---|---|
| 1. | 1. Device Type(s)* |
| | 18F Sheath component part of Chemosat HDS Kit. This product is supplied sterile. |
| 1. | 2. Commercial name(s) |
| | Delcath Chemosat Hepatic Delivery System (HDS) |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 00850014023003, 00850014023010, 00850014023034, 00850014023027, 00850014023041, 00850014023058 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | The Delcath CHEMOSAT® Hepatic Delivery System is used for percutaneous local intra-arterial administration of high doses of chemotherapeutic agent to the liver. The purpose of the device is to allow administration of high dose chemotherapy to the liver, and subsequently to remove a high percentage of the administered drug before it reaches systemic venous circulation. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | 602001-01, 602001-02, 602001-03, 602001-04 and 602002-01, 602002-02, 602002-03, 602002-04, 602016, 602017 |
| 1. | 6. Software version |
| | Not applicable |
| 1. | 7. Affected serial or lot number range |
| | Femoral Accessory Pack (contains 18F Sheath)<br>Part number 420025 – lot numbers - L006825, L007228, L006585, L007428,<br>Part number 420008 – lot number - L007226 |
| 1. | 8. Associated devices |
| | Not applicable |

| 2 **Reason for Field Safety Corrective Action (FSCA)*** | |
|---|---|
| 2. | 1. Description of the product problem* |
| | Delcath Systems is providing this Field Safety Notice after reports were received of the silicone valve in the 18F Sheath becoming unseated during the preparation of the dilator and sheath. This issue occurred during an Investigator Trial in the EU and in two cases outside of the EU. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | The 18F sheath can potentially be damaged while preparing for a procedure or during the procedure. As this sheath is typically closely observed during preparation and during the procedure, damage to the valve will be noticed. During the procedure if any bleeding occurs through the damaged valve, it typically will be observed by the team conducting the procedure. Thus the result that is reasonably expected to occur in cases in which this may happen is a delay of the procedure while the sheath is replaced. |
| 2. | 3. Probability of problem arising |
| | Per Health Hazard Evaluation – Probability of occurring is 1.6% (Based on 3 issues/188 shipped). |
| 2. | 4. Predicted risk to patient/users |
| | Health Hazard Evaluation indicates the anticipated risk – severity = Minor, Probability = Remote. The probability of injury to the patient is remote. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | Delcath Systems received complaint reports of the silicone valve in the 18F Sheath potentially becoming unseated during the preparation of the dilator and sheath. This issue occurred during three treatments – 1 case in Turkey, 1 case in a clinical trial in the USA and 1 case in an investigator-initiated trial in the EU. |
| 2. | 7. Other information relevant to FSCA |
| | Not Applicable |

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| | **3. Type of Action to mitigate the risk*** | |
| 3. | **1. Action To Be Taken by the User*** | |
| | ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☒ Other ☐ None<br><br>**Advise on action to be taken by the user:**<br>The dilator, catheter and obturator should be carefully and slowly inserted into the centre of the sheath's valve. Off-centre placement or a rapid removal may damage the valve components, resulting in blood flow through the valve, as well as cause a vacuum, which may allow air to enter the sheath.<br><br>If unusual resistance is met during the dilator insertion, please slowly remove the dilator, and inspect the valve to ensure it has not been damaged or displaced. Replace the sheath, if valve damage, or valve displacement is observed.<br><br>After placement of the 18F Sheath in the femoral vein, observe for excessive blood leakage out of the sheath where the guidewire, catheter, or obturator interface, and continue to monitor throughout the treatment.<br><br>See images above on page 2 for additional clarity. | |
| 3. | 2. By when should the action be completed? | Specify where critical to patient/end user safety<br>During the preparation of the 18F Sheath component, prior to insertion into the patient. Continued monitoring of the sheath during treatment. |
| 3. | 3. Particular considerations for: Choose an item.<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>Choose an item.<br><br>Not applicable | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes - Receipt Acknowledgement Form attached. |

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| 3. | **5. Action Being Taken by the Manufacturer**<br><br>☐ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☒ Other ☐ None<br><br>Field Safety Notice will be provided to customer sites. | |
| 3 | 6. By when should the action be completed? | 31-Mar-2021 |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |
| | Not Applicable | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Not Applicable |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Not applicable | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Not planned yet |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | No follow-up FSN expected | |
| 4 | 6. Anticipated timescale for follow-up FSN | Not Applicable |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 2 of this FSN*)* | |
| | a. Company Name | Delcath Systems |
| | b. Address | 566 Queensbury Ave, Queensbury, NY 12804 |
| | c. Website address | Chemosat.com |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *<br>Inspectie Gezondheidszorg en Jeugd (IGJ) | |
| 4. | 9. List of attachments/appendices: | **None** |
| 4. | 10. Name/Signature | .....<br>Associated Director Quality Assurance EMEA |
| | | |

| | Transmission of this Field Safety Notice |
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| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..* |

# RECEIPT AND ACKNOWLEDGEMENT FORM
# RESPONSE IS REQUIRED

**Field Safety Notice:** Delcath Complaint 002-2021

I have received, read, and understand the instructions provided in the Delcath Field Safety Notice dated 19-Mar-2021 regarding reports received of the silicone valve in the 18F Sheath becoming potentially unseated during the preparation of the dilator and sheath.

| Contact Information Name | |
|---|---|
| Name | |
| Title | |
| Telephone | |
| E-mail Address | |

| Signature of Receipt and Acknowledgement | Date |
|---|---|
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Upon completion of this form and signing, please return the form by e-mailing a pdf copy of the form to rtreacy@delcath.com.