Galt Medical Corp.
Rev 1: September 2018

FSN Ref: 1649395-11-16-2020-001 FSCA Ref: 1649395-11-16-2020-001

Date: 11/16/2020

# Urgent Field Safety Notice
# Centeze Centesis Catheter

For Attention of*:Quality/Regulatory Affairs Department:

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| Emergo Europe; EmergoVigilance@ul.com, Prinsessegracht 20 2514 AP The Hague |

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# Urgent Field Safety Notice (FSN)
# Centeze ® Centesis Catheter
# Centeze catheters associate with the lots referenced in this FSN may have a tip geometry with a thicker wall, resulting in a more obtuse tip angle.

| 1. Information on Affected Devices* | |
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| 1 | 1. Device Type(s)* |
| | The Centeze is intended for use in percutaneous fluid aspirations and small volume drainage procedures. For both adult and adolescent groups. |
| | 2. Commercial name(s) |
| | Centeze Centesis Catheter |
| | 3. Unique Device Identifier(s) (UDI-DI) |
| | N/A |
| | 4. Primary clinical purpose of device(s)* |
| | The Centeze is intended for use in percutaneous fluid aspirations and small volume drainage procedures. For both adult and adolescent groups. |
| | 5. Device Model/Catalogue/part number(s)* |
| | DRC-002-06 |
| | 6. Software version |
| | N/A |
| | 7. Affected serial or lot number range |
| | 20160253, 20160253, 20148911, 20189100, 20108509 |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
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| 2 | 1. Description of the product problem* |
| | *Centeze catheters associate with the lots referenced in this FSN may have a tip geometry with a thicker wall, resulting in a more obtuse tip angle. This obtuse tip angle if present in the catheter tip can cause increased insertion resistance through the epidermis layer of the skin. This increased resistance in cases where the target anatomy might encounter thick or elastic skin could be sufficient enough to cause the catheter wall to fold/buckle along the length of the catheter. Once the catheter wall has folded/buckled, the device is rendered unusable.* |
| | 2. Hazard giving rise to the FSCA* |
| | *The potential for an obtuse tip in the drainage catheter set is due to a manufacturing error during the tipping process of the catheter and has occurred in only a small percentage of the Centeze® product. Use of a Centeze® centesis catheter with a thicker wall does not present a risk of patient injury but catheter wall failure (buckling) can result and require use of a replacement device. Therefore, to minimize end-user dissatisfaction and to ensure full reconciliation of affective product, a field correction (removal) of product is recommended.* |
| | 3. Probability of problem arising |
| | *CAPA 1210 investigation findings indicate that the buckling of the catheter is the result of using an incorrect tipping die during the tipping process. The use of the incorrect tipping* |

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| | *die produces a tip geometry with a thicker wall, resulting in a more obtuse tip angle, for the product covered under this FSN.* |
| | 4. Predicted risk to patient/users |
| | *The use of a Centeze® centesis catheter with a thicker wall does not present a risk of patient injury but catheter wall failure (buckling) can result and require use of a replacement device. Therefore, to minimize end-user dissatisfaction and to ensure full reconciliation of affective product, a field correction (removal) of product is recommended.* |
| | 5. Further information to help characterise the problem |
| | N/A |
| | 6. Background on Issue |
| | *Galt Medical received negative feedback from a customer regarding 6Fr Centeze. Lot 20160253. The end-user said it 'felt dull', i.e. it did not puncture the skin easily. As a result of his pushing hard the catheter accordion-ed back on the introducer. This was reported to happen a couple of times.* |
| | 7. Other information relevant to FSCA |
| | N/A |

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| | **3. Type of Action to mitigate the risk*** | |
| 3. | 1. Action To Be Taken by the User*<br><br>☐ 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>Provide further details of the action(s) identified. | |
| | 2. By when should the action be completed? | |
| | 3. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| | 4. 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>Provide further details of the action(s) identified. | |
| | 5. By when should the action be completed? | March 2021 |

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| | 6. Is the FSN required to be communicated to the patient /lay user? | No |
| | 7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |
| | No Appended to this FSN | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| | 2. For Updated FSN, key new information as follows: | |
| | N/A | |
| | 3. Further advice or information already expected in follow-up FSN? * | YES |
| | 4. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | *Monitoring of the Field Safety Corrective Action Communication forms and the Returned Goods Authorization process will be on-going. If necessary, follow-up letters, phone calls or visits by the Galt Medical Corp. sales representatives may be used to complete the effectiveness checks. Level A (100% of consignees to be contacted) Effectiveness Checks will be conducted.* | |
| | 5. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Galt Medical Corp. |
| | b. Address | 2220 Merritt Drive Garland, TX 75041 Phone: 972-271-5177 Fax: 972-2714706 |
| | c. Website address | www.galtmedical.com |
| | 6. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes | |
| | 7. List of attachments/appendices: | Attachment A- Health Hazard Evaluation Summary, Attachment B-Distribution List, Attachment C-Field Safety Corrective Action Communication Forms, Attachment D-Examples of Product Labels |
| | 8. Name/Signature | .....<br>.....<br>[redacted] |

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| | **Transmission of this Field Safety Notice** |
| | 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. |

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| | 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..* |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.