FSN Ref: Dale 850-20230320 FSCA Ref: CAP-20230302-1

Date: 2023/03/21

Urgent Field Safety Notice
Dale 850 Sterile Catheter Securement Device

For Attention of*:Dale Medical Products, Inc. Customers

Contact details of local representative (name, e-mail, telephone, address etc.)*
Dale Medical Products, Inc., 40 Kenwood Circle, Suite 7, Franklin, MA 02038, USA Raymond Gruneberg, 508-316-4608, r.gruneberg@dalemed.net

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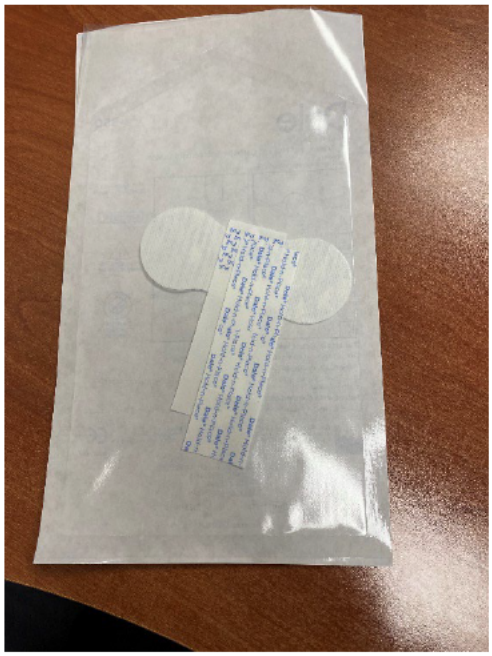
Urgent Field Safety Notice (FSN)
Dale 850 Sterile Catheter Securement Device
Potential to be Not Sterile

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	  Adhesive backed sterile catheter securement device
1.	2. Commercial name(s)*
	Dale IV, Arterial and Mid-Line Catheter Securement Device
1.	3. Unique Device Identifier(s) (UDI-DI)
	0080020200124
1.	4. Primary clinical purpose of device(s)*
	Used to hold IV Catheters in place with a skin friendly adhesive
1.	5. Device Model/Catalogue/part number(s)*
	Dale 850
1.	6. Affected serial or lot number range
	LOT Number 216545

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Sterility of the product cannot be stated by our Notified Body, MedCert in Germany due to a change to the sterilizing facility location.
2.	2. Hazard giving rise to the FSCA*
	As noted, although the devices were sterilized, it cannot be stated and in the worst case the devices may not be sterile.

2.	3. Probability of problem arising
	The probability of the device not being sterile is extremely low, as the lot went through the prescribed sterilization cycle with the Gamma Dosimetry Record for the lot provided with no excursions noted. Further, samples from the lot were also used for a sterilization dose audit which substantiated the stated dose for this production lot.
2.	4. Predicted risk to patient/users
	Dale Medical predicts no risk to patients because the devices were sterilized to the prescribed dose of 25-40 kyg by our contracted sterilization company. Our normal location was closed for preventive maintenance, so the devices were sent to a different location that was not documented in our sterilization validation; therefore TECHNICALLY, sterility cannot be stated.
2.	5. Background on Issue
	The device history records for this lot 216545 was being reviewed by our Notified Body during our annual ISO 13485 surveillance audit and the change of the sterilization location was noted and documented.

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 ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None The devices are being recalled so they may be returned to Dale Medical or destroyed in the field as documented through correspondence with Dale Medical	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety. 28 April, 2023
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Recall letters were provided to the two affected customers in Italy and Slovenia with details of the quantity of devices and date the devices were shipped to them by Dale Medical.	
3.	5. By when should the action be completed?	28 April, 2023

3.	6. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Dale Medical Products, Inc.
	b. Address	40 Kenwood Circle, Franklin, MA, USA
	c. Website address	www.dalemed.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	
4.	6. Name/Signature	[redacted]

	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.