FSN & FSCA Ref: 2021-01

02 JUN 2021

Urgent Field Safety Notice
Bulkamid® Urethral Bulking System

For Attention of: Chief Executive / Risk Management / Purchasing/ Recall Coordinator

Contact details of local representative (name, e-mail, telephone, address etc.)
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Urgent Field Safety Notice (FSN)
Bulkamid® Urethral Bulking System

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	Bulkamid Urethral Bulking System is a urological product supplied with sterile, single use component devices (Bulkamid® Hydrogel, Bulkamid® Needle and Bulkamid® Rotatable Sheath)
1.	2. Commercial name(s)
	Bulkamid® Urethral Bulking System
1.	3. Unique Device Identifier(s) (UDI-DI)
	05704101500128
1.	4. Primary clinical purpose of device(s)
	Bulkamid Urethral Bulking System is intended for treatment of female urinary incontinence
1.	5. Device Model/Catalogue/part number(s)
	50012
1.	6. Affected serial or lot number range
	See attached list of Lot Nos.

2. **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	Lack of sterility assurance of Bulkamid® Needles included in the product.
2.	2. Hazard giving rise to the FSCA
	The use of non-sterile devices may lead to an increased risk of patient urinary tract infections.
2.	3. Probability of problem arising
	Based on incident data the likelihood the problem will arise is low.
2.	4. Predicted risk to patient/users
	For most patients, the severity would be experienced as a temporary inconvenience. However, if left untreated urinary tract infections (UTIs) can lead to more serious health consequences. It is not likely that the use of Bulkamid Urethral Bulking System with the affected needles will cause serious health consequences (death, permanent impairment, or life-threatening injury). Due to the nature of the treatment with Bulkamid Urethral Bulking System, prophylactic antibiotics are recommended in the Instructions for use. Post Market Surveillance data for Bulkamid system have been reviewed and no increase in frequency of incidents, e.g., elevated frequency of UTIs or other safety concerns have been identified which require further actions related to patients already treated with potentially affected devices.
2.	5. Background on Issue
	Contura International A/S has been informed of suspected falsification of records and validation documentation by a third-party sterilization facility related to the sterilization process of Bulkamid® Needles manufactured by Adria S.r.l. and Gallini S.r.l.
2.	6. Other information relevant to FSCA
	Bulkamid® Needles manufactured by Contura International A/S since November 2020 are not impacted.

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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 ☒ Destroy Device ☒ Other Please complete and return the enclosed Customer Reply Form within 10 days of receipt.		
3.	2. By when should the action be completed?	As soon as possible, but no later than 10 days after receipt of this FSN.	
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		
3.	5. By when should the action be completed?	2021-10-31 worldwide	
3.	6. Is the FSN required to be communicated to the patient /lay user?		No

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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	Contura International A/S
	b. Address	Sydmarken 23, DK-2860 Soeborg
	c. Website address	www.contura.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	List of Lot Nos. and Customer Reply Form
4.	6. Name/Signature	 Carina Moldow RA Director Contura International A/S

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. Please transfer this notice to other organisations on which this action has an impact. 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.

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