HOBBS MEDICAL, INC.

FSN Ref: FSN-22-XXX

FSCA Ref: FSCA-22-001

Date: 23-AUG-2022

Urgent Field Safety Notice
Devices with Lot Number ending "R"

For Attention of*: Recall Coordinator; Inventory Manager

Contact details of local representative (name, e-mail, telephone, address etc.)*

(Hobbs will add Distributor address here)

Urgent Field Safety Notice (FSN)
Devices with Lot Number ending "R"

1. Information on Affected Devices	
1.1	**Device Type(s)**
	The issue affects specific lots of multiple devices. Affected lots were manufactured by Hobbs Medical with Lot numbers ending in suffix "R," distributed by Hobbs between March 2018 and September 2020.
1.2	**Commercial name(s)**
	Refer to appendix I for list of product names.
1.3	**Unique Device Identifier(s) (UDI-DI)**
	Refer to appendix I for list of product UDI information.
1.4	**Primary clinical purpose of device(s)**
	Refer to appendix I for clinical purpose of each device.
1.5	**Device Model/Catalogue/part number(s)**
	Refer to appendix I for list of Model/Catalog numbers.
1.6	**Affected lot number range**
	Refer to appendix II for list of affected lot numbers. The reported problem only affects these specific lot numbers of each device.

2. Reason for Field Safety Corrective Action (FSCA)	
2.1.	**Description of the product problem**
	Labels of affected devices display an incorrect expiration date which incorrectly extends the shelf life of the product.
2.2	**Hazard giving rise to the FSCA**
	There have been no reports of injury from the use of affected products, however malfunction of an expired device could result in patient injury. This FSCA is being undertaken as a precaution.
2.3	**Probability of problem arising**
	The probability of malfunction is estimated to be remote. No complaints have been reported related to the affected devices.
2.4	**Predicted risk to patient/users**
	The estimated risk to patients and users is low. There have been no reports of malfunctions or injuries related to the affected lots.
2.5	**Background on Issue**
	The labeling error was found during an internal review: Labels subjected to second sterilization cycle were assigned new expiration dates (based on the date of the second sterilization cycle) rather than retaining the original expiration date as intended (based on the original date of sterilization and original date of manufacture). There have been no reports of complaints or incidents related to the identified problem or involving affected lots. Only the specific lots identified in this notice are affected by the labeling issue.

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 Please contact CustomerService@hobbsmedical.com to coordinate the return.	
3.2	**By when should the action be completed?**	Quarantine affected lots immediately upon receipt of this notification to prevent use.
3.3	**Particular considerations:** None **Is follow-up of patients or review of patients' previous results recommended?** None is required because the risk to patient is very low.	
3.4	**Is customer Reply Required?**	Yes. Please use attached form and return as soon as possible.
3.5	**Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3.6	**By when should the action be completed?**	Immediately upon receipt of this notification.
3.7	**Is the FSN required to be communicated to the patient?**	No

HOBBS MEDICAL, INC.

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	Hobbs Medical, Inc.
	b. Address	8 Spring Street Stafford Springs, CT 06076 USA
	c. Website address	www.hobbsmedical.com
4.4	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.5	List of attachments/appendices:	Appendix I: Product List Appendix II: Lot List Appendix III: Sample Labeling
4.6	Name/Signature	Jennifer Hodge Quality Assurance/Compliance Administrator

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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..

HOBBS MEDICAL, INC.

8 Spring Street
Stafford Springs, CT 06076 USA

TEL +1 (860) 684-5875
FAX +1 (860) 684-7574
www.hobbsmedical.com

PRECISION INTRUMENTS FOR ENDOSCOPY *ISO 13485 REGISTERED*

ACKNOWLEDGEMENT FORM

URGENT FIELD SAFETY NOTICE # FSN-22-XXX

Incorrect Expiration Date on Products with Select Lot Numbers Ending in "R"

Our records indicate your facility received product subject to the above recall described in Field Safety Notice# FSN-22-XXX. Please use this form to report how many units of the affected lots remain on-hand at your facility. Please sign on page 2 and submit completed forms to CustomerService@HobbsMedical.com

a) Quantity of affected units remaining in inventory at time of Recall:

Lot#	Model/ Catalog #	UDI #	Brand Name	Displayed EXP Date	Qty Remaining On-Hand (to be returned)
H10-18-155R	3304	M84933040	Achalasia Balloon Dilators (OTW)	2025-01-01	
H03-18-004R	3306	M84933060	Achalasia Balloon Dilators (OTW)	2024-05-01	
H04-19-012R	3900	M84939000	Vacu-lok Aspirating Syringe	2024-12-01	
H01-20-138R	4204	M84942040	Cytology Brushes: Pulmonary	2025-03-01	
H12-19-050R	4204	M84942040	Cytology Brushes: Pulmonary	2025-03-01	
H12-19-051R	4204	M84942040	Cytology Brushes: Pulmonary	2025-03-01	
H01-20-179R	4206	M84942060	Cytology Brushes: Pulmonary	2025-03-01	
H01-20-181R	4206	M84942060	Cytology Brushes: Pulmonary	2025-03-01	
H01-20-182R	4206	M84942060	Cytology Brushes: Pulmonary	2025-03-01	
H10-19-117R	4620	M84946200	Transbronchial Aspiration Needle and Vacu-lok Aspirating Syringe	2024-12-01	
H11-17-020R	6104	M84961040	Biliary Pigtail Stents	2023-07-01	
O08-15-142R	BE-2	04042761076913	Flex-Ez Over the Wire (OTW) Balloon Dilators: Esophageal	2025-09-01	
O10-15-019R	BE-5	04042761076944	Flex-Ez Stylet Balloon Dilators: Esophageal	2025-09-01	
O07-15-123R	BE-6	04042761076951	Flex-Ez Stylet Balloon Dilators: Esophageal	2025-07-01	
O07-15-217R	BE-6	04042761076951	Flex-Ez Stylet Balloon Dilators: Esophageal	2025-07-01	
O10-15-020R	BE-6	04042761076951	Flex-Ez Stylet Balloon Dilators: Esophageal	2025-07-01	

b) Scope (Check only one): The count of the affected product is for (___ALL /___NOT ALL) usage and storage locations at this facility. If "All" is checked, proceed to "Signature" below.

c) If NOT for entire facility, quantities listed above is ONLY FOR following location(s) in facility:

_____

d) List Area(s) of facility where additional product may be located (Please copy those areas):

By signing below, I acknowledge that we have received notification and are aware of the above Field Safety Notice and have set aside any remaining units to preclude use of the product. Product set aside will not be used and will be returned to Hobbs Medical.

Signature:	**Date:**
Printed Name:	**Contact Phone:**
Position:	**Best Contact Email*:**

* Email requested but optional – contact email of preferred contact person for restocking/product credit follow-up, if needed.

For assistance in returning product or for any questions relating to the scope of this recall please contact Hobbs Customer Service at **1-800-344-6227** or CustomerService@hobbsmedical.com

Part 3: Return of affected lots

Please return all Product and copy of this completed Form to:

Hobbs Medical
ATTN: Customer Service
8 Spring St.
Stafford Springs, CT 06076

Please contact Customer Service to request a Return Authorization (RA) number to include on each unit and each shipping container.

Appendix I Product List

Model/ Catalog #	UDI	Brand Name	Nomenclature System	GMDN Code	GMDN Text	MDD Class	Intended Use
3304	M84933040	Hobbs Achalasia Dilation Balloon	GMDN	45712	Gastrointestinal/biliary dilation balloon catheter	Class I	To be utilized by a trained physician for dilatation of the lower esophageal sphincter (LES) when a stricture is present.
3306	M84933060						
3900	M84939000	Vacu-lok Aspirating Syringe	GMDN	35886	Body aspiration needle, single-use	Class I	To be utilized by a trained physician and/or trained personnel during an endoscopic procedure when maintaining maximum negative pressure is required.
4204	M84942040	Hobbs Medical Cytology Brush	GMDN	38834	Flexible endoscopic cytology brush, single-use	Class I	Bronchial Pulmonary Brush to be utilized through a flexible endoscope by physicians and/or personnel who are trained in endoscopic techniques to allow blind, non-directed, protected specimen brush sampling of tissue or cells from the upper or lower respiratory tract and/or to perform surveillance cultures.
4206	M84942060						
4620	M84946200	Transbronchial Aspiration Needle and Vacu-lok Aspirating Syringe	GMDN	35886	Body aspiration needle, single-use	Class IIa	To be utilized during flexible bronchoscopy by a trained physician to obtain a cell aspirate in the bronchial tree.
6104	M84961040	Hobbs Biliary Pigtail Stent	GMDN	42701	Polymeric pancreatic stent, non-bioabsorbable	Class IIb	The stent family products are intended to be used by a physician/trained personnel for endoscopic bile duct/pancreatic duct stent drainage, providing effective relief
BE-2	04042761076913	Flex-Ez Over the Wire (OTW) Balloon Dilators: Esophageal	GMDN	45712	Gastrointestinal/biliary dilation balloon catheter	Class I	Balloon dilator to be used with an Olympus endoscope under direct vision by a trained physician for the dilation of strictures in the oesophagus.
BE-5	04042761076944	Flex-Ez Stylet Balloon Dilators: Esophageal					
BE-6	04042761076951	Flex-Ez Stylet Balloon Dilators: Esophageal					

Appendix II Lot List

Lot#	Model/ Catalog #	UDI #	Total Qty Manufactured	Manufacture Date	Actual EXP Date	Displayed EXP Date (Post Resertilization)	Qty Distributed in EU
H10-18-155R	3304	M84933040	1	2018-11-01	2023-11-01	2025-01-01	1
H03-18-004R	3306	M84933060	1	2018-03-01	2023-03-01	2024-05-01	1
H04-19-012R	3900	M84939000	40	2019-05-01	2024-05-01	2024-12-01	25
H01-20-138R	4204	M84942040	100	2020-02-01	2025-02-01	2025-03-01	40
H12-19-050R	4204	M84942040	100	2020-01-01	2025-01-01	2025-03-01	10
H12-19-051R	4204	M84942040	100	2020-01-01	2025-01-01	2025-03-01	40
H01-20-179R	4206	M84942060	100	2020-02-01	2025-02-01	2025-03-01	50
H01-20-181R	4206	M84942060	100	2020-02-01	2025-02-01	2025-03-01	30
H01-20-182R	4206	M84942060	100	2020-02-01	2025-02-01	2025-03-01	10
H10-19-117R	4620	M84946200	20	2019-11-01	2024-11-01	2024-12-01	7
H11-17-020R	6104	M84961040	15	2017-11-01	2022-11-01	2023-07-01	2
O08-15-142R	BE-2	04042761076913	10	2015-10-01	2020-10-01	2025-09-01	10
O10-15-019R	BE-5	04042761076944	10	2015-10-01	2020-10-01	2025-09-01	10
O07-15-123R	BE-6	04042761076951	8	2015-09-01	2020-09-01	2025-07-01	8
O07-15-217R	BE-6	04042761076951	10	2015-09-01	2020-09-01	2025-07-01	10
O10-15-020R	BE-6	04042761076951	2	2015-11-01	2020-11-01	2025-07-01	2
			Total MFR'd: 717			**Total Distributed in EU:**	**256**

Attachment III – Sample Labeling