Rev 1: September 2018
FSN Ref: FSN-1833132-12/13/23-001-R FSCA Ref: 1833132-12/13/23-001-R

Date: 21DEC2023

Urgent Field Safety Notice
FLEXSelect Elastic Bands

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*
G&H Europe BV 3 Edisonstraat 3861 Nijkerk, Netherlands email:bdiouf@sabfa28.com

Flexmedics

Rev 1: September 2018
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Urgent Field Safety Notice (FSN)
FLEXSelect Elastic Bands
Potential distribution of latex products to patients with a latex allergy

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Amber 5/16" Latex Elastic Bands
1.	2. Commercial name(s)
	FLEXSelect Elastic Bands
1.	3. Unique Device Identifier(s) (UDI-DI)
	10195291042642
1.	4. Primary clinical purpose of device(s)*
	Exert a force to move teeth
1.	5. Device Model/Catalogue/part number(s)*
	AMD56
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	1120035
1.	8. Associated devices
	n/a

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Latex elastic band patient packs were labelled as containing non-latex elastic bands. Flexmedics latex elastic bands are initially packaged in patient packs with the product information on one side and the latex warning preprinted on the other side. Then, a quantity of 100 patient packs are placed in a bulk package with an additional bulk outer label. To summarize, the patient packs contained latex elastic bands but the label's description incorrectly stated non-latex instead of latex, the outer label's description was correctly printed, and the latex warning was on both forms of packaging.
2.	2. Hazard giving rise to the FSCA*
	Flexmedics does not expect any device failures instead there is an opportunity for misuse of the device due to the labelling. Due to this error, there is a potential for a patient with a latex allergy to use the patient packs containing latex elastic bands during their orthodontic treatment. This recall only involved one batch of Flexmedics elastic products.
2.	3. Probability of problem arising
	First time occurrence, probability of problem arising is remote (error percentage of 0.5% since 2021).
2.	4. Predicted risk to patient/users
	Potential patient consequences involve a patient experiencing problems ranging from mild dermatitis to anaphylactic shock due to a latex allergy.
2.	5. Further information to help characterise the problem
2.	6. Background on Issue
	Flexmedics became aware of the mislabelling issue on December 13th through a customer complaint (23-12-035). To date, we have received two complaints from two different distributors: one in Europe and one in New Zealand. The complaints described

	the discrepancy between the patient pack's product description and the bulk label's product description. No injuries or adverse events were reported.
2.	7. Other information relevant to FSCA
	n/a

	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 If 'Destroy Device' is you selected option, provide proof of destruction (e.g. pictures or videos)	
3.	2. By when should the action be completed?	As soon as possible, within the next 30 days.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Update SQL statement in template to restrict non-applicable parts from option list.	
3	6. By when should the action be completed?	December 20, 2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
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?	
	No	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	January 31, 2024
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Flexmedics
	b. Address	40 Linville Way, Franklin, IN, 46131 United States
	c. Website address	https://www.ghorthodontics.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.* Yes	
4.	9. List of attachments/appendices:	Field Safety Notice Reply Form
4.	10. Name/Signature	[redacted] / Regulatory Affairs Manager
		[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.