Rev 2: February 2020
FSN Ref: FSN 24-001 FSCA Ref: 24-001

Date: 2024-07-22

Field Safety Notice

PEDIATRIC LABIAL INTERCEPTOR WITH STOP

For Attention of*:Orthodontists, Speech Therapists, and other relevant healthcare professionals.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Field Safety Notice (FSN)
Pediatric Labial Interceptor with Stop
Risk of device tearing due to chewing, leading to potential choking hazard

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Pediatric Labial Interceptor with Stop **Brief description:** A device used in orthodontic treatment to control the ventilation in pediatric orthodontic treatments, supplied non-sterile.
1.	2. Commercial name(s)*
	Pediatric Labial Interceptor with Stop
1.	3. Unique Device Identifier(s) (UDI-DI)
	3665614595044
1.	4. Primary clinical purpose of device(s)*
	The device is used to control ventilation in pediatric orthodontic treatments.
1.	5. Device Model/Catalogue/part number(s)*
	Model Number: D595 010P
1.	6. Software version
	Not applicable.
1.	7. Affected serial or lot number range
	All batches of this reference.
1.	8. Associated devices
	Not applicable within the context of the FSCA.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The stop of the Pediatric Labial Interceptor detached due to excessive chewing and shearing forces applied by the patient's teeth, creating a potential choking hazard.
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard is the risk of choking for the patient. This advice/action is intended to mitigate this risk. The residual risk, if the FSN advice/action is taken, is significantly reduced.
2.	3. Probability of problem arising
	Based on historical data, the probability of occurrence is very low, as this is the first incident in 10 years. However, it is significant enough to warrant corrective actions due to potential misuse.
2.	4. Predicted risk to patient/users
	The anticipated risk includes potential choking and minor injury to the oral cavity.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	The manufacturer became aware of the issue through incident reports. Root cause analysis identified the mechanical stress on the stop as the primary cause. This is not a defect in the device but rather a misuse by the patient.
2.	7. Other information relevant to FSCA
	The Risk Management File has been updated accordingly.

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 Users should inspect devices regularly for wear or damage, and follow the updated IFU that includes contraindications for patients with bruxism and hypertonia.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety. Actions should be completed immediately upon receipt of this notice to ensure patient safety.
3.	3. Particular considerations for: Not applicable Is follow-up of patients or review of patients' previous results recommended? No Not required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Corrective actions were immediately put in place. We temporarily halted the commercialization of this reference for more than a week while implementing corrective actions and sensitizing our commercial and logistics teams. The updated IFU will be printed and distributed in September. In the interim, a sticker modifying the IFU and highlighting contraindications and recommendations is being applied to the affected devices.	
3.	6. By when should the action be completed?	The updated IFU and corrective actions are expected to be fully implemented by 2024-09.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	
	Choose an item. Choose an item.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
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:	
	Not applicable	
4.	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	ORTHOPLUS SAS
	b. Address	28 rue Ampère, BP 28, 91430 IGNY, France
	c. Website address	https://orthoplus.fr/content/nos-certifications/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Updated IFU / IFU with stickers
4.	10. Name/Signature	SAMMOUD Youssef, Quality & Compliance Manager

	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.