Rev 1: September 2018
FSN Ref: FSN_2020_001 FSCA Ref: FSCA_2020_001

Date: 14-12-2020

Urgent Field Safety Notice
Cristal Tips Air/Water Syringe Tips

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mary O' Keeffe General Manager – Young Microbrush Ireland Direct: +353 58 45966 Fax: +353 58 45969 Clogherane, Dungarvan, Co. Waterford, X35 VE02, Ireland mary@younginnovations.com **Jose A. Espino** VP, QA/RA Young Innovations Inc. Phone: (224) 622-7191 2260 Wendt St, Algonquin, IL 60102 JEspino@younginnovations.com

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Urgent Field Safety Notice (FSN)
Cristal Tips Air/Water Syringe Tips

Exception with Legal Manufacturer and European Representative on Label

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Air/Water Syringe Tips ("Tips") and Adapters for Air/Water Syringe Tips ("Adapters")
1.	2. Commercial name(s)
	See attached
1.	3. Unique Device Identifier(s) (UDI-DI)
	See attached
1.	4. Primary clinical purpose of device(s)*
	The Tips are intended for single-use by a dental professional as a device for blowing air and water into the patient's mouth for dental procedures. The adapters are accessories intended to connect the Tips to an air/water syringe.
1.	5. Device Model/Catalogue/part number(s)*
	See attached
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	See attached
1.	8. Associated devices
	Not applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	There is no product safety problem. Between October 30 2019 and May 27 2020 products were supplied with incorrect details of the Legal Manufacturer and Authorised Representative on the labels". Further details can be provided in 2.5 and 2.6 below.
2.	2. Hazard giving rise to the FSCA*
	N/A
2.	3. Probability of problem arising
	N/A
2.	4. Predicted risk to patient/users
	N/A
2.	5. Further information to help characterise the problem
	As of May 28 2020, products are labelled with Young Innovations, Inc. as the Legal Manufacturer and with Young Microbrush Ireland Ltd as the European Authorised Representative. The products are registered in Ireland with the Health Products Regulatory Authority.
2.	6. Background on Issue
	Young Innovations INC acquired Westside Resources and had a signed agreement that allowed for the use of Westside Resources name on the labelling of product until October 30, 2019. Young Innovations continue to use the Westside Resources name on product until May 27, 2020. On June 12, 2019, Crystal Tips Holdings, now part of Young

	Innovations Inc., signed a 12 month agreement with Emergo Europe B.V., for Emergo to remain as the European Authorised Representative for the products in the scope. Although the agreements was signed and paid for, Emergo has indicated that it did not go into effect. As of May 28 2020, products are labelled with Young Innovations, Inc. as the Legal Manufacturer and with Young Microbrush Ireland Ltd as the European Authorised Representative. The products are registered in Ireland with the Health Products Regulatory Authority.
2.	7. Other information relevant to FSCA
	Not applicable

	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 *Contact Young Innovations, INC., for further information on the disposition of product. It is feasible for the Distributor to overlabel the product with the updated information.*	
3.	2. By when should the action be completed?	Not critical to patient and/or end user. Action can be completed within the next 30 days.
3.	3. Particular considerations for:	None 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 Condition has been addressed. As of May 28 2020, products are labelled with Young Innovations, Inc. as the Legal Manufacturer and with Young Microbrush Ireland Ltd as the European Authorised Representative. The products are registered in Ireland with the Health Products Regulatory Authority	
3	6. By when should the action be completed?	Not critical to patient and/or end user. Action can be completed within the next 30 days.
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	New
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	No follow-up FSN will be delivered	
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	Young Innovations, Inc.
	b. Address	2260 Wendt St., Algonquin, IL 60102 USA
	c. Website address	**https://crystaltip.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1. Sample of updated label **2.** Current Declaration of Conformity
4.	10. Name/Signature	**Jose A. Espino** **VP, QRA** 

	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.