ANTEIS SA
Chemin des Aulx, 18
1228 Plan-Les-Ouates
Geneva, Switzerland

FSN ref.: FSN-ANTEIS-2021-09

FSCA ref.: FSCA-ANTEIS-2021-09

Date: 30.09.2021

URGENT FIELD SAFETY NOTICE
BELOTERO® SOFT – BELOTERO® BALANCE – BELOTERO® INTENSE

Missing contra-indications in local language of the Instructions For Use

For Attention of: **Distributors of Belotero® Products**

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	Belotero® Soft, Belotero® Balance and Belotero® Intense are sterile, non-pyrogenic, viscoelastic, colourless, transparent crosslinked sodium hyaluronate (NaHA) gels of non-animal origin in a physiological phosphate buffer. Please see below product pictures of the packaging: 
	2. Commercial name(s)
	Belotero® Soft Belotero® Balance Belotero® Intense
	3. Unique Device Identifier(s) (UDI-DI)
	Not applicable.
	4. Primary clinical purpose of device(s)
	Belotero® Soft is an injectable biodegradable implant intended for filling of perioral fine lines. Belotero® Balance is an injectable biodegradable implant intended for filling of moderate facial wrinkles and folds as well as for lip enhancement. Belotero® Intense is an injectable biodegradable implant intended for filling of deep facial wrinkles and folds as well as to restore and enhance soft tissue volume.

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	5. Device Model/Catalogue/part number(s)
	SAP Numbers : 11684 – Belotero® Soft 11686 – Belotero® Balance 11685 – Belotero® Intense
	6. Affected serial or lot number range
	Belotero® Soft, Belotero® Balance and Belotero® Intense products, distributed since June-2020.

	2. Reason for Field Safety Corrective Action (FSCA)
2.	**1. Description of the product problem**
	This Field Safety Notice aims to inform end users that a contra indication is missing in the local translation of the Instructions for Use for Belotero® Soft, Belotero® Balance and Belotero® Intense for the products distributed in Norway, Sweden, Denmark, Greece, Czech Republic and Slovakia since June 2020. The missing contra indication is: - **In patients presenting an active auto-immune disease.** Of note, the instructions for use in English provided inside the box is correct.
	2. Hazard giving rise to the FSCA
	The hazard linked to this incorrect Instructions for Use is the injection of the product into a patient presenting an active auto-immune disease.
	3. Probability of problem arising
	There are no instances of known exposure to the deficient Instruction for Use from the post-marketing safety database. No probability can be established from post market data, but the estimation is remote.
	4. Predicted risk to patient/users
	Specific injuries related to use of dermal fillers in patients with active, auto-immune disease are speculated as being inflammatory in nature. This contraindication was added as a potential class-related, precautionary measure only. No specific events associated with any specific active, auto-immune disease nor with Belotero are known.
	5. Further information to help characterize the problem
	Not applicable.
	6. Background on Issue
	The erroneous local translation was identified in September 2021 by the manufacturer. The international IFUs inside product boxes are correct, only the local translation provided together is incorrect. Corrected IFU in the local language are provided with this Field Safety Notice.

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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 * ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) * **Please destroy the incorrect Instruction For Use if identified, and use the one provided with this Field Safety Notice.**
	2. By when should the action be completed? 20-OCTOBER-2021
	3. Is follow-up of patients or review of patients' previous results recommended? Please report without undue delay any adverse event or side effect of inflammatory nature suspected to be related to auto-immune disease.
	4. Is customer Reply Required? Yes
	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Corrected Local translation of the Instruction For Use is provided. The root cause was identified internally and is corrected.
	6. By when should the action be completed? 01-OCTOBER-2021
	7. 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
	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	Company Name	ANTEIS SA
	Single Registration Number	CH-MF-000012867
	Address	Chemin des Aulx 18 1228 Plan-les-Ouates Switzerland
	Phone number	0041 22 308 92 63
	Website address	www.anteis.com
	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. YES	
	4. List of attachments	Correct translations of IFUs Belotero Soft, Belotero Balance and Belotero Intense for the following countries: Norway, Sweden, Denmark, Greece, Czech Republic and Slovakia.
	5. Name/Signature	Max LOK Senior Director Quality & Compliance – ANTEIS SA (PRRC)
		

	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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DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-ANTEIS-2021-09
FSN Date	29.09.2021
Product/ Device name	– Belotero® Soft – Belotero® Balance – Belotero® Intense
Product Code(s)	11684 – Belotero® Soft 11686 – Belotero® Balance 11685 – Belotero® Intense
Batch/Serial Number (s)	NA

2. Distributor/Importer Details	
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	Barbara.humbert@merz.com
Postal Address	Chemin des Aulx 18, 1228 Plan les Ouates, Switzerland
Web Portal	www.anteis.com
Deadline for returning the Distributor/Importer reply form	NA

4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected devices –	Add quantity, Lot/Serial Number/Date Returned

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	(IFUs) enter number destroyed and date complete.	(same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name		Distributor/Importer print name here
Signature		Distributor/Importer sign Here
Date		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.