Rev 1: September 2018

FSN Ref: AC-FSN-03 FSCA Ref: AC-FSCA-03

Date: 15-02-2021

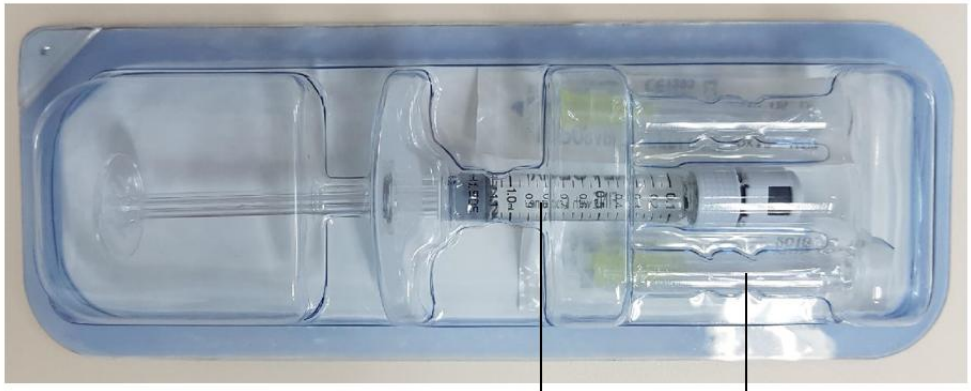
Urgent Field Safety Notice
Cross Linked Hyaluronic Acid Soft Tissue Filling Gel

For Attention of*: Distributors

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

No	Country	Company	Address	E-mail	Phone Number	The person in Charge (Position)
1	Confidential					
2						

Urgent Field Safety Notice (FSN)
Cross Linked Hyaluronic Acid Soft Tissue Filling Gel
Risk addressed by FSN

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	The product is a colourless, transparent, viscoelastic, biodegradable, non-pyrogenic and sterile gel, supplied in a disposable plastic syringe. The product consists of cross-linked sodium hyaluronate from bio-fermentation, suspended in a physiological buffer pH 6.8 ~ 7.5. The product is supplied in a disposable plastic syringe with a luer-lock fitting. The syringe is equipped with a plunger stopper, finger grip and plunger rod and packed in a blister. It is cross-linked HA filler including Lidocaine. The addition of lidocaine provides a pain relieving effect during treatment. 
1.	2. Commercial name(s)
	Cross Linked Hyaluronic Acid Soft Tissue Filling Gel , Revolax
1.	3. Unique Device Identifier(s) (UDI-DI)
	N
1.	4. Primary clinical purpose of device(s)*
	Implantation of volume loss for facial morphological asymmetry
1.	5. Device Model/Catalogue/part number(s)*
	Revolax Fine with lidocaine, Revolax Deep with lidocaine, Revolax Sub-Q with lidocaine.
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	* Detail information of these LOTs are attached. (File name: Attachment_Detail information of LOTs) Above products bear the CE Mark “CE1023” from ITC (Notifed Body) which was withdrawn on 29 November, 2018.
1.	8. Associated devices
	N/A

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The products released in EU market while CE Certification was not valid after 29/11/2018 to 20/10/2020.
2.	2. Hazard giving rise to the FSCA*
	Error of post market surveillance system
	Additional explanation: Some products were released in EU markets(UK and Denmark) while our CE Certification was not valid (after CE Certification was withdrawn, and before we approved new CE Certification) We, Across, are certificated on ISO13485:2016 for our quality management system, and all products are manufactured in approved quality system so that the products have appropriate performance, but the recall has been performed because sales in EU markets is not appropriate without CE certification. Our products are sold in Europe, South Korea and other countries, and the specification for product performance is not different from the countries. Also, manufacturing process, tests, materials and specifications are identical for products manufacture for EU and non-Europe markets. There is not any additional risks or hazards, if a user was to use product that was not supported by a valid CE Certificate. As a result, this problem is along with the process and system failure.
2.	3. Probability of problem arising
	Number of Recall target products: 324,932 syringes.
2.	4. Predicted risk to patient/users
	Predicted risk to patient/ users is classified as improbably.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	This FSCA is written in order to take recall process on the products that were sold in EU territories with CE certification which was withdrawn in November 2018.
2.	7. Other information relevant to FSCA
	The related products performance does not affect safety but we keep the notice close to the distributors.

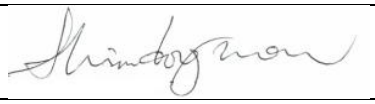
	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations

	☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified. **[Distributor role]** 1. FSN will be notified to distributors by the manufacturer using 'Distributor Reply Form' and 'Customer Reply Form' attached. 2. Distributor should check the inventory of the affected products and LOTs and check the quantities that has been released to the customers. 3. Distributor should notify all affected customers (hospital and/or clinic) this FSN using the 'Customer Reply Form' 4. All affected products must be recalled from customers and documented using the 'Customer Reply Form'. All such recalled products should be reconciled with distributor own inventory. 5. Distributor must return all affected products to manufacturer. (* All distributors who are noticed of this FSN should return the 'Distributor Reply Form'.) (** This procedure should be done within 2 months from FSN received date.) **[Customer (hospital and/or clinic) role]** 1. FSN will be notified to customers by the distributors using the 'Customer Reply Form' attached. 2. Customers should check the inventory of the affected products and LOTs and check the quantities. (If the products were already used, the quantities used should be also be documented in 'Customer Reply Form'.) 3. All affected products to must be return to the distributor. (* All customers who are noticed of this FSN should return the 'Customer Reply Form'.) (** This procedure should be done within 1 months from FSN received date.)	
3.	2. By when should the action be completed?	Within 3 months
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? N/A 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, ('Distributor Reply Form' and 'Customer Reply Form' are required within 3 months)

<table>
<tr><td>3.</td><td colspan="3">5. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

‘Distributor Reply Form’ and ‘Customer Reply Form’ will be analysed as a result of this process.</td></tr>
<tr><td>3</td><td>6. By when should the action be completed?</td><td colspan="2">Tracked products were returned already and other products in process will be completed within 3 months.</td></tr>
<tr><td>3.</td><td colspan="2">7. Is the FSN required to be communicated to the patient /lay user?</td><td>No</td></tr>
<tr><td rowspan="2">3</td><td colspan="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?</td></tr>
<tr><td colspan="3">No Not appended to this FSN</td></tr>
</table>

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Yes
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	Within 3 months
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Across Co.,Ltd
	b. Address	4F R&D center 23, Geodudanji 1-gil, Dongnae-myeon, chuncheon-si, Gangwon-do, 24398 Republic of Korea
	c. Website address	www.across.kr
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes, We, Across Co.,Ltd, are located outside of EU, so we noticed and discussed with our Authorised Representative which is located in Germany.	
4.	9. List of attachments/appendices:	FSCA (no. AC-FSCA-03), Detail information of LOTs
4.	10. Name/Signature	QMR / Dongwon, Shin
		

	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.

[Attachment] Detail information of LOTs

LOT No.	Trade Name	Market	Qty.	Mfg. date	Exp. date
CLA19002	REVOLAX FINE WITH LIDOCAINE	UK	5,200	2019.02.08	2021.02.07
		Denmark	1,071		
CLA19004	REVOLAX FINE WITH LIDOCAINE	UK	3,100	2019.05.03	2021.05.02
		Denmark	329		
CLA19005	REVOLAX FINE WITH LIDOCAINE	UK	3,747	2019.07.04	2021.07.03
		Denmark	700		
CLA19006	REVOLAX FINE WITH LIDOCAINE	UK	5,053	2019.10.22	2021.10.21
		Denmark	533		
CLA19008	REVOLAX FINE WITH LIDOCAINE	Denmark	355	2019.12.17	2021.12.16
CLC19001	REVOLAX DEEP WITH LIDOCAINE	UK	13,827	2019.01.16	2021.01.15
		Denmark	1,100		
CLC19003	REVOLAX DEEP WITH LIDOCAINE	UK	2,731	2019.02.14	2021.02.13
CLC19005	REVOLAX DEEP WITH LIDOCAINE	UK	9,500	2019.02.28	2021.02.27
		Denmark	1,500		
CLC19007	REVOLAX DEEP WITH LIDOCAINE	UK	13,309	2019.03.20	2021.03.19
CLC19008	REVOLAX DEEP WITH LIDOCAINE	UK	8,391	2019.03.22	2021.03.21
		Denmark	1,250		
CLC19010	REVOLAX DEEP WITH LIDOCAINE	UK	12,000	2019.04.23	2021.04.22
		Denmark	950		
CLC19011	REVOLAX DEEP WITH LIDOCAINE	UK	10,000	2019.04.24	2021.04.23
CLC19013	REVOLAX DEEP WITH LIDOCAINE	UK	10,000	2019.05.02	2021.05.01
		Denmark	4,300		
CLC19018	REVOLAX DEEP WITH LIDOCAINE	UK	16,539	2019.05.21	2021.05.20
CLC19019	REVOLAX DEEP WITH LIDOCAINE	UK	11,061	2019.06.14	2021.06.13
		Denmark	2,000		
CLC19020	REVOLAX DEEP WITH LIDOCAINE	UK	15,200	2019.06.27	2021.06.26
CLC19021	REVOLAX DEEP WITH LIDOCAINE	UK	9,882	2019.07.10	2021.07.09
		Denmark	2,700		
CLC19023	REVOLAX DEEP WITH LIDOCAINE	UK	9,718	2019.07.17	2021.07.16
		Denmark	3,000		
CLC19027	REVOLAX DEEP WITH LIDOCAINE	UK	12,648	2019.09.09	2021.09.08
CLC19028	REVOLAX DEEP WITH LIDOCAINE	UK	16,552	2019.09.17	2021.09.16
CLC19030	REVOLAX DEEP WITH LIDOCAINE	UK	9,600	2019.10.23	2021.10.22
		Denmark	3,350		
CLC19031	REVOLAX DEEP WITH LIDOCAINE	UK	9,600	2019.11.06	2021.11.05
		Denmark	3,348		
CLC19034	REVOLAX DEEP WITH LIDOCAINE	UK	9,596	2019.11.18	2021.11.17
		Denmark	202		
CLC19036	REVOLAX DEEP WITH LIDOCAINE	UK	6,599	2019.12.13	2021.12.12
		Denmark	3,550		
CLC19038	REVOLAX DEEP WITH LIDOCAINE	UK	3,592	2019.12.27	2021.12.26
CLD19004	REVOLAX SUB-Q WITH LIDOCAINE	UK	583	2019.03.21	2021.03.20
CLD19006	REVOLAX SUB-Q WITH LIDOCAINE	UK	7,917	2019.04.15	2021.04.14
		Denmark	600		
CLD19007	REVOLAX SUB-Q WITH LIDOCAINE	UK	4,000	2019.04.25	2021.04.24
		Denmark	2,589		
CLD19009	REVOLAX SUB-Q WITH LIDOCAINE	UK	10,073	2019.05.22	2021.05.21
		Denmark	261		
		Denmark	2,000		
CLD19011	REVOLAX SUB-Q WITH LIDOCAINE	UK	11,427	2019.06.18	2021.06.17
		Denmark	1,600		
CLD19015	REVOLAX SUB-Q WITH LIDOCAINE	UK	11,077	2019.08.06	2021.08.05
CLD19019	REVOLAX SUB-Q WITH LIDOCAINE	UK	8,123	2019.09.19	2021.09.18
		Denmark	2,049		
CLD19023	REVOLAX SUB-Q WITH LIDOCAINE	UK	3,400	2019.11.14	2021.11.13
		Denmark	1,550		
Total			**324,932**		