



**To the attention of Medical Device
Vigilance responsible / Central Pharmacy**

Saint Priest, 22 May 2025

URGENT - FIELD SAFETY NOTICE – RECALL
Extended Tip Applicator (XTA) (ref. 205108 and 205115)

Legal manufacturer:

INTEGRA LIFESCIENCES CORPORATION - 1100 Campus Road - Princeton, NJ 08540 USA - SRN:
US-MF-000007196

EC Representative :

INTEGRA LIFESCIENCES SERVICES (France) SAS - Immeuble Séquoia 2 - 97 Allée Alexandre
Borodine - 69800 SAINT PRIEST, France - SRN : FR-AR-000002474

Medical device:

The Extended Tip Applicator (XTA) is a sterile single-use device consisting of a malleable shaft and a permanently attached spray tip.
It is used for the controlled application of two liquids.

Primary clinical purpose of device:

The Extended Tip Applicator is intended for use in the simultaneous delivery of the two non-homogenous
DuraSeal® precursor solutions onto a surgical site.

Concerned references:

205108 - All unexpired lots
205115 - All unexpired lots



Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of **Extended Tip Applicator (XTA)** listed in Table 1.

The decision to conduct a voluntary recall of the product was based on an internal Integra investigation that identified products could potentially contain out-of-specification levels of endotoxin. Additionally, the full investigation demonstrated an incomplete bioburden assessment and an incomplete sterilization location transfer documentation to ensure the effectiveness of the sterilization process.

Changes have been made to the manufacturing process and a verification of the effectiveness is being conducted to remediate the out-of-specification endotoxin. Comprehensive bioburden monitoring and further validation of the applicator sterilization process will also be performed prior to the release of this product back to the market.

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number (DD-MM-YY)
205108	Extended Tip Applicator, 8CM, Box of 5	10381780000143	All unexpired lots
205115	Extended Tip Applicator, 15 CM, Box of 5	10381780000150	All unexpired lots

Risk to health

Per the Health Hazard Evaluation conducted for this issue, the potential harm due to potential out of specification endotoxin results for XTA may include inflammation. The potential harm due to potential non-sterile products is infection. Per the conclusion of this evaluation, the possibility of these adverse health consequences occurring is remote. However, out of an abundance of caution, Integra has made the decision to conduct a voluntary recall of these products. Furthermore, based on the HHE, there is no long-term risk of harm to the patient.

If you have already used these products and standard operative care was followed, **there is no additional patient follow-up required.**

Over the past five (5) years, there have been four (4) complaints reported in Europe and the UK (2 complaints in Europe and 2 complaints in the UK) due to infection for products that are used with these applicators. In addition, there have been no adverse events reported directly due to these issues for the XTA.

Our records indicate that you may have received products from these lots.

Actions to be taken by Customers:

1. Please **review and understand** the information provided in this letter.
2. Determine if the product you have is subject to the recall:
 - a. Identify the impacted reference and lot number.



- b. See Appendix 2 below for a sample of product label for where to locate the reference and lot number.
3. If you **do have** affected product(s):
 - a. Quarantine the units immediately.
 - b. Check the box “I do have affected units.” on the acknowledgement form.
 - c. Record on the form the total quantity of affected products and lot number(s) that you have.
4. If you **do not have** affected product(s), check the box, “I do not have affected units.”
5. Please **return the completed reply form by email to emea-fsca@integralife.com**,
By filling in this form, you confirm that you have received this Safety Notice, and you intend to fully comply with this notification. **We expect a response within 3 weeks.** You also confirm that this notification has been forwarded to every person concerned in your organization.
6. At receipt of your form, and if it is noted that you have affected units available for return, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product(s). A credit note will be processed upon receipt and verification of returned goods. Note: credit will only be given for the impacted lot(s) that are returned.
7. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCTS TO RETURN OR NOT – **A COMPLETED ACKNOWLEDGEMENT IS REQUIRED**

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Please feel free to contact our Post Market Surveillance Department at emea-fsca@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Post Marketing Surveillance Department

Appendix 1: Field Safety Notice Reply Form (2 pages)

Appendix 2: Sample of a product label Product Label for Part # 205108 (1 page). Use Red Circle below to Identify Lot Number

Customer Reply Form

1. Field Safety Notice (FSN) information		
FSN Reference number	2025-HHE-004 - XTA	
FSN Date	22 May 2025	
Product/ Device name	Extended Tip Applicator	
Product Code(s)	205108 / 205115	
Lots	All unexpired lots	

2. Customer Details		
Account Number		
Healthcare Organisation Name*		
Organisation Address*		
Department/Unit		
Shipping address if different to above		
Contact Name*		
Title or Function		
Telephone number*		
Email*		

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I <u>have</u> affected units available for return - enter number of products and lot number (s)	
☐	or I have affected units, and I can destroy them ⁽¹⁾ – enter number of products and lot number (s) <i>⁽¹⁾ If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form</i>	
☐	I <u>do not</u> have any affected units.	
☐	I have a query please contact me	<i>Customer to enter contact details if different from above and brief description of query</i>
Print Name*		<i>Customer print name here</i>
Signature*		<i>Customer sign here</i>
Date*		

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Customer Helpline	+33 (0) 6 30 20 69 66
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://www.integralife.com/
Deadline for returning the customer reply form*	12/06/2025

Mandatory fields are marked with *

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 action.

Appendix 2: Product Label sample

Reference 205108. Use Red Circle below to Identify Lot Number

