**To the attention of Quality Assurance Dpt or Regulatory Affairs Dpt or**

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 Distributor,

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 Distributors:**

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) in your warehouse:
    a. Quarantine them immediately.
    b. Check the box “I do have affected unit(s)” in the enclosed reply form.
    c. Record on the form the total quantity of affected unit(s) and lot number(s) that you have.
4. If **you do not have** affected product(s) in your warehouse**,** check the box, “I do not have affected unit(s)”.
5. Please check **your customer traceability records** for shipments of affected products.
6. **If you have shipped impacted products to your customers, please complete below:**
    a. Create a customer reply form with your contact details.
    b. Forward a copy of the Field Safety Notice to any of your customers that have purchased the affected products and lot numbers.
    c. Collect completed response forms and affected product(s) from your customers and indicate the total quantities and lot(s) in the distributor reply form (Appendix 1).
7. 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.
8. At receipt of the reply form, and if it is noted that you or your customers have affected products available for return, Customer Service will contact you and provide an RMA number and directions to return the product(s). The credit will be processed upon receipt and verification of returned goods.
9. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCT 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

INTEGRA

# DISTRIBUTOR/IMPORTER REPLY FORM

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

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

| **3. Distributors/Importers (Tick all that apply)** | | |
|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content.* | |
| ☐ | I have checked my inventory and I have affected units - enter number of devices and lot number | |
| ☐ | I have affected units, and I can destroy them(1) – enter number of products and lot number (s)<br><br>(1) *If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form* | |
| ☐ | I have checked my inventory and I do not have affected products | |
| ☐ | I have identified customers that received affected products and informed them of this Field Safety Notice * | *Date of communication:* |
| ☐ | I have attached customer list | |
| ☐ | I have received confirmation of reply for all identified customers | |
| ☐ | My customers have affected products | |

| | | |
|---|---|---|
| ☐ | My customers <u>have not</u> received any affected products | |
| Print Name* | | *Distributor print name here* |
| Signature* | | *Distributor sign Here* |
| Date * | | |

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

## Appendix 2: Product Label sample

### Reference 205108. Use Red Circle below to Identify Lot Number