

06 Aug 2026

URGENT FIELD SAFETY NOTICE

Manufacturer: TRX Orthopaedics (Tissue Regenix Group) (SRN: GB-MF-000018091)

FSCA Reference: CAPA 012/26-FSCA01 – OrthoPure XT - Potentially compromised sterile barrier

FSN Type: New

Affected Product: OrthoPure XT Ligament Reconstruction Implant (Size 5), Catalogue Number 2405XTS
OrthoPure XT Ligament Reconstruction Implant (Size 6), Catalogue Number 2406XTS
OrthoPure XT Ligament Reconstruction Implant (Size 8), Catalogue Number 2408XTD
OrthoPure XT Ligament Reconstruction Implant (Size 10), Catalogue Number 2410XTT

Unique Device Identifier (UDI-DI): 5060260020175
5060260020182
5060260020199
5060260020205

Affected Batch No: A01/21022025
A01/29082025

For Attention of: Users and distributors of the medical device listed above

Dear valued customer,

The purpose of this letter is to advise you that TRX Orthopaedics (TRXO), a subsidiary of Tissue Regenix Group, is voluntarily recalling batches of the OrthoPure XT Ligament Reconstruction Implant detailed herein due to a potentially compromised sterile barrier.

The OrthoPure XT is used for reconstruction of knee ligaments to restore knee function and stability. The device is available in a range of sizes (Size 5, Size 6, Size 8 and Size 10). It is supplied hydrated in 0.9% saline, packaged in a sterile double-blister barrier system (primary and secondary blister), and terminally sterilised.

An image of the device is included below.

**Problem Description:**

The manufacturer identified this issue following return of an unreleased batch of OrthoPure XT from a contract packaging manufacturer. During inspection, it was observed that some blister packs had lost their integrity. Upon investigation it was identified that some blister packs may have been formed incorrectly, resulting in a weak or compromised seal. As there is a possibility that the integrity of the blister pack may have been compromised, there is a potential risk to the product's sterile barrier.

Further investigation has indicated that the forming issue may also have affected products in the field. As a precautionary measure, corrective action will be taken to detect and prevent the use of any potentially affected products that remain in the field and are still within their shelf life.

As the OrthoPure XT device is supplied hydrated in saline, and excess saline is included within the primary blister pack, failure of the primary blister pack would result in leakage of saline into the secondary blister pack. Failure of both the primary and secondary blister packs would likely result in leakage of saline into the tertiary carton. As such, should the primary blister pack be compromised, this would likely be evident prior to use. Failure of the secondary blister pack could be characterised by a weak or abnormally easy to open seal, which is less likely to be detected prior to use.

Hazardous Situation:

TRXO determined the following hazardous situations may arise from a compromised sterile barrier:

- Contaminated product used. Compromised product safety
- Contaminated primary blister pack. Compromised sterile field.

Potential Harm:

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following:

- Infection – superficial
- Infection – systemic

TRXO have received no customer feedback or complaints to date regarding this issue and therefore no patient harm, serious injury or death has occurred as a result.

Corrective Action:

Users – Return the affected products to your local OrthoPure XT distributor.

Distributors – Quarantine affected products. Products to be subject to on-site inspection by TRXO or returned.

Action to be taken by user:

- | | |
|---|---|
| ☒ Identify device | ☒ Quarantine device |
| ☒ Return device | ☐ Destroy device |
| ☒ Follow patient management recommendations | |

Details on further action(s) for users:

- Please quarantine and return immediately all affected products in your stock to your local OrthoPure XT representative.
- Upon return of the affected products, please contact your local OrthoPure XT representative for credit or replacement.
- Patients in which potentially affected products have already been implanted should be monitored in line with the care standards at your facility.
- Please **always** report any adverse events, e.g. infections, compromised packaging, potentially related to the affected products, to the manufacturer (customerservices@tissueregenix.com), local OrthoPure XT representative, and the national Competent Authority if appropriate, as this provides important feedback.

- Regardless of whether you have affected product(s) or not, duly fill out the enclosed Letter of Acknowledgement and return it to customerservices@tissueregenix.com **as soon as possible, but no later than 31 August 2026**, mentioning **FSCA reference: CAPA 012/26-FSCA01** in the subject line of your email.

Action to be taken by the distributor:

- | | |
|---|---|
| ☒ Identify device | ☒ Quarantine device |
| ☐ Return device | ☐ Destroy device |

Details on further action(s) for distributors:

- Please quarantine all affected products in your stock and await further instruction from a TRXO representative.
- Please forward this notice to organisations on which this Field Safety Notice has had an impact.
- Upon return of the affected products from users, please quarantine and contact TRXO for credit or further instruction.
- Please always report any adverse events, e.g. infections, potentially related to the affected products, to the manufacturer (customerservices@tissueregenix.com), and the national Competent Authority if appropriate, as this provides important feedback.
- Regardless of whether you have affected product(s) or not, duly fill out the enclosed Letter of Acknowledgement and return it to customerservices@tissueregenix.com **as soon as possible, but no later than 31 August 2026**, mentioning **FSCA reference: CAPA 012/26-FSCA01** in the subject line of your email.

Action to be taken by manufacturer:

- | | |
|---|--|
| ☒ Product removal | ☒ On-site device modification/inspection |
| ☐ IFU or labelling change | ☐ Other |
| ☐ None | |

Details on further action(s) by manufacturer:

- Inform all customers possessing the affected products **promptly** about this field action by sending this field safety notice to customers.
- Upon return of affected products from users, provide the distributor with credit or replacement.
- Perform on-site inspection of distributor held devices to determine if packs are affected by this issue where appropriate.

Enclosed documents:

- Letter of Acknowledgement

Transmission of the Field Safety Notice:

- Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organisations on which the action has had an impact.
- If you have transferred the product to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness of the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologise for any inconvenience this may cause, and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have any questions or require additional information, please contact customerservices@tissueregenix.com.

Sincerely,

Technical & Operations Director

Signature:



Email:

c.rowley@tissueregenix.com

Person Responsible for Regulatory Compliance (PRRC)

Signature:



[Rebekah Taylor \(Aug 6, 2026 14:17:11 GMT+1\)](#)

Email:

r.taylor@tissueregenix.com

Contact details of manufacturer:

TRX Orthopaedics
Unit 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom
Phone: +44 330 4303056
Email:
customerservices@tissueregenix.com

Contact details of local OrthoPure XT representative:

[Enter local OrthoPure XT representative contact details](#)

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

Your organisations reply is the evidence the manufacturer needs to monitor the progress of the corrective actions to ensure patient safety

LETTER OF ACKNOWLEDGEMENT (2 PAGES)

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Affected Batch A01/21022025

No(s): A01/29082025

Please send this form at the latest by **31 August 2026**, to customerservices@tissueregenix.com.

By completing this document and signing it, I acknowledge that I have read and understood the following points:

- I have read and understood this Field Safety Notice. I/We will act as soon as possible according to given instructions.
- In confirm I have distributed this Field Safety Notice to the affected person(s).
- The following apply:

☐ All affected products have been consumed

☐ I am a **USER**. The following affected products will be returned to the local OrthoPure XT distributor for credit or replacement:

Catalogue Number	Description	Lot/Batch Number	Quantity

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- ☐ I am a **DISTRIBUTOR**. The following affected products will be quarantined until further instruction is received from TRXO:

Catalogue Number	Description	Lot/Batch Number	Quantity

Your comments:

Country

Hospital/Clinic/Distributor (full address)

Date

Name (Function)

Signature

Please return the completed form to by email to customerservices@tissueregenix.com.