

13-02-2023

URGENT MEDICAL DEVICE RECALL

TGA Recall Reference Number: RC-2023-RN-00132-1

Products: injeTAK Adjustable Tip Needle (REF: LAB DIS199 and LAB DIS201)

ARTG No. 376691

A list of affected LOT numbers is available on the following page.

Endotherapeutics Pty Ltd, after consultation with the Therapeutic Goods Administration (TGA), is conducting a hospital level recall of the Laborie Medical Technologies Inc. injeTAK Adjustable Tip Needles. The specific reference codes affected are the **LAB DIS199** and **LAB DIS201**. The injeTAK Adjustable Needle is a single-use sterile needle intended to deliver a variety of medicines into tissues during cystoscopic procedures. We are contacting you as the potentially affected product has been supplied to your organization.

Problem

There is the potential for a small hole in the film of the sterile barrier of the injeTAK Adjustable Tip Needle packaging.

Risk

The issue could impact the sterility of the device, resulting in contamination of the device.

Action

Inspect your stock **immediately** and quarantine any affected stock on hand to prevent further use. The following affected LOT numbers have been supplied in Australia:

Product Code	LOT NUMBER	Product Code	LOT NUMBER
LAB DIS199	D19B105	LAB DIS201	D19C788
LAB DIS199	D203779	LAB DIS201	D203783
LAB DIS199	D204597	LAB DIS201	D204101
LAB DIS199	D201620	LAB DIS201	D207082

LAB DIS199	D207081	LAB DIS201	D208580
LAB DIS199	D205441	LAB DIS201	D205446
LAB DIS199	D20C092	LAB DIS201	D20C093
LAB DIS199	D208579	LAB DIS201	D211095
LAB DIS199	D20C094	LAB DIS201	D211826
LAB DIS199	D20B085	LAB DIS201	D213100
LAB DIS199	D211094	LAB DIS201	D214447
LAB DIS199	D211825	LAB DIS201	D216689
LAB DIS199	D217602	LAB DIS201	D219083
LAB DIS199	D21A632	LAB DIS201	D218089
LAB DIS199	D219650	LAB DIS201	D21B081
LAB DIS199	D223087	LAB DIS201	D21C156
LAB DIS199	D224083	LAB DIS201	D223088
LAB DIS199	D224386	LAB DIS201	D224387
LAB DIS199	D225596	LAB DIS201	D226107
LAB DIS199	D225589	LAB DIS201	D229088
		LAB DIS201	D22A099
		LAB DIS201	D21B407

Complete the attached acknowledgement form **immediately even if you do not have any affected stock** and return to E: info@endotherapeutics.com.au or F: (02) 9869 7723 to reconcile this process.

Return affected stock on hand to the below address with the completed inventory form.

Attn: Recall Coordinator

Suite, 301, 2 Banfield Rd,

Macquarie Park, NSW, 2113.

Please ensure relevant staff members are informed of this recall including locums, inwards goods staff, credit returns staff, relevant clinicians, nursing staff, as applicable.

If you have supplied or transferred any potentially affected product to another facility or organization, let that facility know of the recall **immediately** by providing a copy of this letter.

Place this letter in a prominent position for at least one month.

Replacement Stock

Please be aware that there is currently no alternative stock available. Please contact Endotherapeutics Pty Ltd for updates on when stock is expected to be available.

For further information please call Customer Service at (02) 9869 2868.

Thank you for your assistance in helping us manage this recall.

Kind regards,



Court Richardson

Regulatory Affairs Manager

Endotherapeutics Pty Ltd

Customer Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

RC-2023-RN-00132-1

Please complete this form and return it via email to info@endotherapeutics.com.au or

via fax to (02) 9869 7723, ATTN: Recall Coordinator.

Organisation:		
Address:		
Contact Name:	Phone Number:	Email Address:

injeTAK Adjustable Tip Needle (product codes: LAB DIS199 and LAB DIS201, list of affected LOTs can be found on pages 1 and 2).

Please check the appropriate box below and complete the table if applicable.

- We have no inventory within the scope of this action.
- We have the following affected product at our facility and will cease use and quarantine the affected product for return to Endotherapeutics Pty Ltd:

Product Code	Lot Numbers	Quantity of Product to be Returned (Unit of Measure is box of 2 eaches)
LAB DIS199		

Have any adverse events been associated with affected product(s)? Yes: No:

If yes, please explain: _____

Product Code	Lot Numbers	Quantity of Product to be Returned (Unit of Measure is box of 2 eaches)
LAB DIS201		

Have any adverse events been associated with affected product(s)? Yes: No:

If yes, please explain: _____

If you have any additional questions, please contact Endotherapeutics Customer Service at (02) 9869 2868 or email us at info@endotherapeutics.com.au.