

10 July 2026

CRITICAL RECALL

TGA Reference Number: RC-2026-RN-00495-1

ARTG: 354371, 324222

Product Code	Product Name
IV050030	Microbore Extension Set with Female Luer Lock to Male Luer Lock
IV050140	Microbore Extension Set with Female Luer Lock to Male Luer Lock
IV050180	Microbore Extension Set with Female Luer Lock to Male Luer Lock
IV110002	Stop Cock Lipid Resistant with 15cm Extension Set
IV110003	Stop Cock Lipid Resistant with 25cm DEHP Free Extension Set
IV110011	Stopcock - 3 Way Lipid Resistant (Yellow)
Affected lot/batch	All Batches

Dear Customer,

This letter contains information that requires your urgent attention.

Multigate Medical Device Pty Ltd, following agreement with the Therapeutic Goods Administration (TGA), is conducting a **Recall** for the "Microbore Extension Set with Female Luer Lock to Male Luer Lock" with the item codes list above.

Our records show that you have received the product listed in the table above.

What is the problem:

The product is cracking or leaking when being used with propofol. Our investigation showed that product might not be suitable for use with propofol. This might result in the following problems:

- Cracks and leaks in the stopcock can cause a sudden, unmonitored drop in the infusion rate and unintended dosage drops. This can lead to unexpected patient awareness under anaesthesia or inadequate sedation.



- Cracks can create a breach in the closed sterile system increasing the risk of catheter-related bloodstream infections or sepsis.

What do you need to do:

1. Inspect your stock **immediately** and quarantine the affected stock on hand to prevent further use.
2. Complete the attached "Customer Response form" immediately and return the form to jesstie.wong@mdevices.com.au even if you do not have any affected stock so we can reconcile this recall.
3. Ensure relevant staff members are informed of this Recall.
4. If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter immediately and advise us on the attached response form.
5. Place this letter in a prominent position for at least one month.

Product return

Return affected stock on hand with the completed response form to the following address:

Attn: Quality Team (RC-2026-RN-00495-1)
Multigate Medical Device
27 Llewellyn Ave; Villawood NSW 2163; Australia

Replacement stock

There will be no replacement of the products until further investigation is completed. Please contact your sale representative to arrange for credit.

Yours sincerely

A handwritten signature in black ink, appearing to read 'JPigott'.

Jeremy Pigott
Head of Quality
jeremy.pigott@multigate.com.au