

aPotential risk of Laerdal Suction Unit (LSU) with low or reduced suction due to canister leakage

This Urgent Safety Notice applies to Laerdal (LSU) manufactured in the period of 17 April 2021 to 2 July 2021.



Affected Item: LSU Reusable Canister

LSU with Reusable Canister version

Description of the problem:

The LSU units with reusable canister manufactured in the period of 17 April 2021 and 2 July 2021 may have air leakage in the canister or canister lid, this could potentially lead to reduced or low suction function.

What Laerdal Medical will do to address the problem:

Laerdal Medical will replace affected canister lids with new Laerdal Suction Unit Reusable Canisters (784000), free of charge.

Actions to be taken by LSU users:

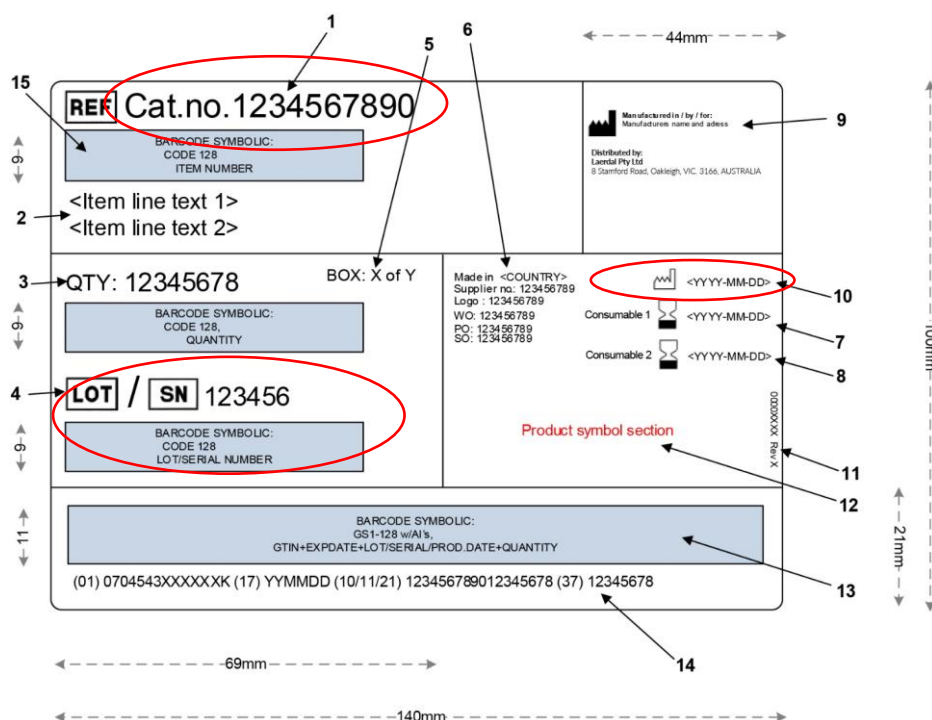
1. Identify affected Laerdal Suction Unit Reusable Canister or Laerdal Suction Units with Affected Canister using the packaging label provided below:

This Urgent Field Safety Notice covers LSU with Reusable Units with Catalogue Numbers (see *Item 1*) listed below:

- 78000000 - Laerdal Suction Unit w/Reusable Canister
- 78000003 - Laerdal Suction Unit w/Reusable Canister
- 78000033 - Laerdal Suction Unit w/Reusable Canister
- 784000 - Laerdal Suction Unit Reusable Canister

Units affected by this Urgent Field Safety Notice are labelled with:

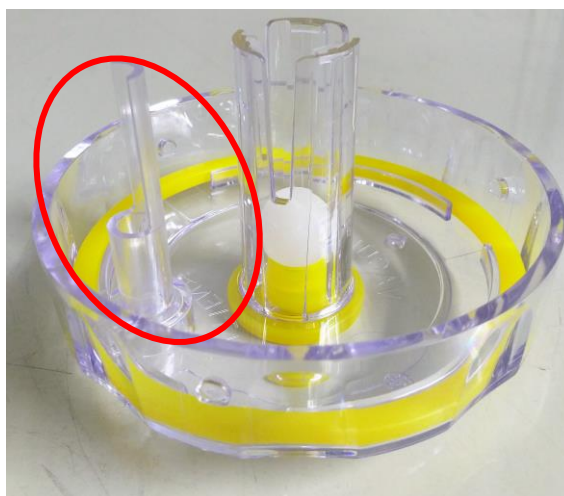
- **Manufacturing Dates** in the range 20210417 – 20210702 (see *item 10*)
- **Serial Numbers** in the range S/N 78172152534 - 78262155318 (see *item 4*)
- **Lot Number Canister** in the range 1721-2621 (*Format: Week, Year*) (see *item 4*)



2. Identify affected Laerdal Suction Unit Reusable Canister (784000) by visual inspection



1 Defective Canister Lid



2 Correct Canister Lid

When defective LSU reusable canister units are identified (see left picture), remove immediately from use and discard according to local waste management procedures.

Replacement of units

Laerdal will ship replacement units, free of charge to all customers and distributors who have purchased an affected Reusable Canister (784000) or an LSU Reusable Configurations (catalogue number no. 780000xx). Customers do not need to take any actions. Distributors must ensure that replacement canisters are shipped to affected end users.

Any faulty canisters should immediately be removed from use and disposed of. You are not required to inform Laerdal Medical of any canisters that have been disposed of.

Transmission of this Urgent Field Safety Notice:

Please transfer this Urgent Field Safety Notice to other organisations on which this action has an impact, i.e. all staff involved in the reprocessing, and use of the LSU with Reusable Canister.

Please maintain awareness of this Urgent Field Safety Notice and the required action for an appropriate period.

Contact reference person:

Add local contact

Name

Organization

Email