

27 July 2016

TGA Ref: RC-2016-RN-00996-1

ARTG: 123603

Chief Executive Officer  
Attn: Manager Central Sterilising Unit

**RECALL FOR PRODUCT CORRECTION****STERRAD® 100NX® System****CTick Labelling****Part Numbers: 10104, 10104002, 10104003 and 10104004****Please note that this Notification DOES NOT require the product to be returned.**

Dear Sir/Madam,

This letter is to advise that your STERRAD® 100NX® system requires a CTick label (RFID) be applied to comply with the Australian Communications and Media Authority (ACMA) spectrum licensing and C-Tick requirements. This labelling will be performed by a Johnson & Johnson Pty Ltd (JJM) representative, who is an authorised representative of Advanced Sterilization Products (ASP).

**This action is NOT a product removal, and you may continue to use the STERRAD® 100NX® system in accordance with the updated labelling information.**

**Facility Action:**

Our records indicate that your facility has received the above product(s) subject to this Recall for Product Correction. Please follow the instructions below:

- Evaluate your current inventory and determine if your facility has STERRAD® 100NX® system.
- Ensure anyone in your facility impacted by this notification reads this letter.
- Place a copy of this communication where a STERRAD® 100NX® system is located in your facility until a CTick label (RFID) is applied onto your system by a JJM ASP Representative.
- Complete the attached acknowledgement form for your acknowledgement of this notification and documentation of the receipt of the CTick label (RFID) on your system. Return the form by fax to 1800 241 101 or email to ra-jnjau-recallsanz@its.jnj.com
- In the event your STERRAD® 100NX® system does not have the CTick label (RFID), please contact your ASP Product Manager, Sylvia Victor-Quinn, on +61 4 2986 8616.

**JJM ASP representative Action:-**

- Make on-site visits to facilities that have a STERRAD® 100NX® system/s.
- Check inventory, by serial number, of the STERRAD® 100NX® system/s.
- If the system requires cleaning of the surfaces to be labelled, a 70% isopropyl alcohol wipe should be utilised
- Place CTick sticker on side panel of the machine (a placement diagram will be provided to you)
- Obtain Facility sign off on the acknowledgement form

This notification is being undertaken following consultation with the Therapeutic Goods Administration. Your cooperation is appreciated in providing access to your location for the JJM ASP representative. If you have any questions regarding this action, please contact your ASP Product Manager, Sylvia Victor-Quinn, on +61 4 2986 8616. We apologise for any inconvenience this action may cause and thank you for your cooperation.

Yours sincerely,



Anita Derks  
Director of Quality

