

## Urgent: Device Correction

**Date:** May 23, 2014

**Attention:** Risk Managers, Sterile Processing Department

<Customer Name>

<Customer Address>

<Customer City, State, Zip>

**Product:** Shaver Handpiece Sterilization Tray. Part Number 272-700-000



**Product Issue:** STERRAD 100S parameters provided in the Shaver Handpiece reprocessing guide (P10299 Revision A) did not fully consider all worst-case scenarios during validation testing.

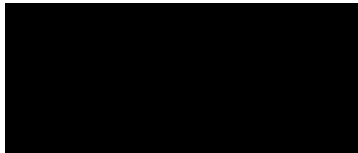
**Potential Hazards:** Although, to date there have been no reported events of infection to Stryker as a result of the use of the sterilization parameters previously provided with these trays, there is a remote possibility for infection.

**Action Required:** The STERRAD 100S sterilization method has been removed from the reprocessing guide (P10299 Revision B) as a sterilization option for the TPS Small Joint Shaver. Recipients of this letter are confirmed to have received shipments of at least one Shaver Handpiece Sterilization Tray. Please:

1. Discard any old Instructions for Use for your Shaver Handpiece Sterilization Tray(s).
2. Download the new Reprocessing Guide Part Number P10299 Revision B from the URL link below:  
[www.stryker.com/shavertray](http://www.stryker.com/shavertray)
3. **Complete and sign the enclosed "Acknowledgement of Receipt" form** and scan and email to [endorecall@stryker.com](mailto:endorecall@stryker.com).

We apologize for any inconvenience this action may cause. As we strive to deliver products that meet your expectations for quality and reliability, please do not hesitate to contact us, in case you have any further questions at 408-855-6238 or via email at [endorecall@stryker.com](mailto:endorecall@stryker.com).

Sincerely,



Regulatory Affairs Director  
Stryker Endoscopy

**Shaver Handpiece Sterilization Tray Acknowledgement of Receipt**



Part Number: 272-700-000

Shaver Handpiece Sterilization Tray

The acknowledgement card below serves as a record of your receipt of the updated Reprocessing Guide Part Number P10299 Revision B from the URL link below:

[www.stryker.com/shavertray](http://www.stryker.com/shavertray)

**Please complete the required information below.** Approval of the form below indicates that either you have read and understand the Reprocessing Parameters per Reprocessing Guide P10299 Revision B for the Shaver Handpiece Sterilization Tray or the Shaver Handpiece Sterilization Tray is no longer in service at your facility.

Please update customer address information below if necessary.

Shaver Handpiece Sterilization Tray Acknowledgement Receipt From: <Customer Name> <Customer Address> <Customer City, State, Zip> Account: <Customer Account Number>	
<b>CUSTOMER TO COMPLETE INFORMATION BELOW:</b>	
<b>Printed Name:</b>	
<b>Title Of Responsible Person:</b>	
<b>Signature:</b>	
<b>Date:</b>	

**Complete and sign** and scan and email to [endorecall@stryker.com](mailto:endorecall@stryker.com).