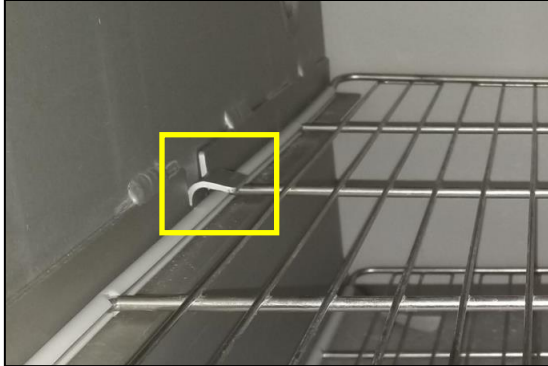


Field Safety Notice

Urgent Medical Device Correction – ISIFA2019-10-C

Stainless steel da Vinci Xi Endoscope Trays and Handheld Camera Trays Small Holes in Sterile Wrap

<p>1- Introduction and Reason for Field Action</p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>The purpose of this letter is to inform you that Intuitive has received some complaints regarding small but detectable holes in the sterilization wrap used with <i>da Vinci Xi</i> 8 mm Endoscope Sterilization Trays (PN 400498-02) and Handheld Camera Sterilization Trays (PN 400499-03). These holes could lead to a potential breach of sterility.</p> <p>Certain features on the trays with the following combination of handling and storage may cause these small holes:</p> <ol style="list-style-type: none"> 1. Loading and unloading of wrapped trays into sterilizers 2. Stacking and unstacking of wrapped trays during handling and storage
<p>2- Risk to Health</p>	<p>There have been no reported adverse events related to this issue.</p> <p>When small holes are observed in the sterilization wrap, there is a potential for delay to the beginning of the procedure while another endoscope is retrieved.</p> <p>Small holes in the sterilization wrap may lead to a potential breach in sterility which includes risk of infection. Specifically, patients who are severely immunocompromised would be most at risk for infections that would require medical treatment. Patients with normal immune systems would have a remote possibility of a superficial skin and soft tissue wound infection.</p>
<p>3- Affected Products</p>	<p>All lots of the stainless steel <i>da Vinci Xi</i> 8 mm Endoscope Sterilization Trays (PN 400498-02) and Handheld Camera Sterilization Trays (PN 400499-03)</p>
<p>4- Actions to be taken by the Customer/User</p>	<p>To mitigate the potential for small holes, in conjunction with industry practice*, observe the following recommendations:</p> <ol style="list-style-type: none"> 1. Avoid dragging a wrapped tray when loading and unloading the sterilizer 2. Lift trays instead of sliding or dragging on and off workbenches, shelves, and other horizontal surfaces <p>Continue to inspect wrapped trays prior to use per hospital policy.</p>

<p>4- Cont'd Actions to be taken by the Customer/User</p>	<p>Note: Sites using sterilizers with interior brackets should avoid dragging trays across interior brackets (See example image of STERIS V-Pro series sterilizer below).</p>  <p>Continue to follow instructions located in the da Vinci Xi Endoscope Reprocessing Instructions and da Vinci Xi Handheld Camera Reprocessing Instructions Addendum regarding stainless steel trays.</p> <p><i>* Such as AAMI/ANSI ST79:2017, AORN (Guidelines for Perioperative Practice 2019), and IAHCSCMM (Central Service Technical Manual 8th Edition)</i></p> <hr/> <p>As part of the standard field action process, please take the following actions.</p> <ol style="list-style-type: none"> 1. Inform necessary hospital personnel about this issue 2. Complete the attached Acknowledgement Form and return to Intuitive as instructed on the form 3. Please retain a copy of this letter and Acknowledgement Form for your reference
<p>5- Actions to be taken by Intuitive</p>	<p>Intuitive will follow up when replacement trays are available.</p>
<p>6- Further Information & Support</p>	<p>If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the number(s) listed below:</p> <ul style="list-style-type: none"> • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com

Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Notice.

Sincerely,

Intuitive Surgical, Sàrl
 Chemin des Mûriers 1
 CH-1170 Aubonne, Switzerland
 +41 21 821 20 20

ACKNOWLEDGMENT FORM
Field Safety Notice

Urgent Medical Device Correction – ISIFA2019-10-C

Stainless steel da Vinci Xi Endoscope Trays and Handheld Camera Trays Small Holes in Sterile Wrap

Ship-to:

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive if I have any questions.

Hospital name: _____

Position:

Name (print): _____

- Robotics Coordinator
- Operating Room Director
- Risk Manager
- Surgeon
- Other: _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: ISIFA2019-10-C
Scan and email to: EU.FSCA@intusurg.com or Fax +41.21.821.2021

Customer Service:

- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)