

Follow-up Field Safety Notice regarding Product Availability Urgent Medical Device Correction – ISIFA2019-10-C

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

Dear da Vinci Customer,

This letter is a follow-up to the Field Safety Notice related to the *Stainless Steel da Vinci Xi 8mm Endoscope Sterilization Trays (PN 400498-02) and da Vinci Xi Handheld Camera Sterilization Trays (PN 400499-03) Small Holes in Sterile Wrap* notification. The purpose of this letter is to inform you that an updated da Vinci Xi 8 mm Endoscope Sterilization Tray (PN 400498-04) product is now available to order. Upon receiving it, you may cease the use of the da Vinci Xi 8 mm Endoscope Sterilization Tray (PN 400498-02). All current requirements for handling and storage of trays should be used regardless of the tray type.

As a reminder for varied tray options: 1) plastic trays (PN 400490) can still be used safely with the appropriate handling and storage instructions for the cleaning and sterilization process as outlined in the da Vinci Xi Endoscope Reprocessing Instructions and 2) sites who use automated reprocessing (i.e. washer-disinfector) should use stainless steel trays.

Please note that the updated product version/part number is **400498-04** and you can locate it on the product label as demonstrated below:



Figure 1. Label Example for da Vinci Xi 8 mm Endoscope Sterilization Tray 400498-04

If you need further information or support regarding this Product Availability Notice, please contact your Sterile Reprocessing Support Team or contact Intuitive Surgical Customer Service at the number listed below:

- EMEA Customer Service: +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com.

Sincerely,

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