

Field Safety Notice**Urgent Medical Device Notification – ISIFA2018-11-C***EndoWrist® Monopolar Curved Scissors Tube Extension Breakage***1- Introduction
and Reason for
Field Action**

Dear *da Vinci* Customer,

Cc: Chairman Medical Board and relevant Head of Departments

This field safety notice is to inform you that Intuitive Surgical has become aware of specific *da Vinci S/Si* and *da Vinci X/Xi* Monopolar Curved Scissor (MCS) instruments that may be more susceptible to breakage of the plastic surrounding the instrument shaft (extension tube) which could potentially lead to fragments of the extension tube falling into the patient. This issue only affects the -16 version of the S/Si MCS instruments and the -14 version of the X/Xi MCS instruments.

In some instances, the potential for breakage may be preceded by the appearance of cracks near the proximal edge of the extension tube, potentially attributed to mishandling and misuse as defined by the Instrument and Accessories User Manual.



Figure 1. *da Vinci S/Si EndoWrist MCS* with proximal edge of extension tube highlighted.



Figure 2. Example of crack found on damaged MCS instruments

	<p>The Instruments & Accessory User Manuals include the following instructions, specifically found in the <i>EndoWrist Monopolar Curved Scissors Instrument</i> section:</p> <ol style="list-style-type: none"> 1. Always inspect the instruments prior to use for any damage (i.e. cracks, breakage). 2. Use of an instrument for a task other than the instrument's designed use may result in breakage or damage. The MCS is intended to be used with the <i>da Vinci Si</i> and <i>da Vinci Xi</i> systems for endoscopic manipulation of tissue, including: cutting, blunt and sharp dissection, and electrocautery. Using the MCS to retract anatomy or using an instrument to grasp hard objects may contribute to breakage, as could instrument collisions. 3. During reprocessing, make certain that the MCS has been adequately rinsed and flushed, and all cleaning chemicals have been removed. (Inadequate flushing may contribute to cracks after multiple reprocessing cycles.) <p>Please note that these User Manual handling recommendations should be observed for ALL <i>EndoWrist</i> Instruments.</p> <p>The return of undamaged product is not required. In more than 450,000 procedures, Intuitive Surgical has found a 0.024% likelihood of breakage based on instruments returned with damage. Due to the low likelihood of breakage, this advisory serves as a notification of the issue and to reiterate the guidelines for proper inspection and use of the MCS instrument.</p>						
2 - Risk to Health	<p>The following are potential risks identified for this issue:</p> <ol style="list-style-type: none"> 1) In the event an instrument fragment falls into a patient: <ul style="list-style-type: none"> • The typical fragments generated as a result of this issue could be large enough for detection by the surgeon. There may be a minor delay while the surgeon looks for and retrieves the fragment. • In the case of a fragment that is not detected and remains in the patient, our toxicology evaluation shows a low risk of long-term adverse health effects from exposure to the fragment material, and it is unlikely to pose an unacceptable incremental risk. 2) An MCS instrument with a broken extension tube may be bent and therefore not able to be removed from the cannula without creating an enlarged body wall incision. The additional length of the incision would be minimal and would allow for the minimally invasive procedure to continue. 						
3- Affected Products	<table border="1"> <thead> <tr> <th>Product Name</th><th>Part Number</th></tr> </thead> <tbody> <tr> <td><i>da Vinci S/Si</i> 8 mm Monopolar Curved Scissors</td><td>420179-16</td></tr> <tr> <td><i>da Vinci X/Xi</i> 8 mm Monopolar Curved Scissors</td><td>470179-14</td></tr> </tbody> </table>	Product Name	Part Number	<i>da Vinci S/Si</i> 8 mm Monopolar Curved Scissors	420179-16	<i>da Vinci X/Xi</i> 8 mm Monopolar Curved Scissors	470179-14
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4- Actions to be taken by the Customer/User	<ol style="list-style-type: none"> 1. Always inspect the instruments prior to use for any damage (i.e. cracks, breakage). If any cracks or breakage are visible, do not use the instrument and return the damaged instrument to Intuitive Surgical using the standard RMA process. (Note: The return of <u>undamaged product</u> is not required.) 2. Make certain that relevant personnel clearly understand the handling recommendations in Section 1 above to prevent instrument breakage. 3. Please log onto the da Vinci Online Community Field Action resource to read or complete actions related to this issue, at this link: https://www.davincisurgerycommunity.com/ 4. In the case where the da Vinci online resource cannot be used, complete the attached Acknowledgement Form and return it via fax or email to Intuitive Surgical as instructed on the form. 5. Please retain a copy of this letter and the acknowledgement form for your files.
5- Actions to be taken by Intuitive Surgical	<ol style="list-style-type: none"> 1. A copy of this Field Safety Notice will be provided to customers with the affected Monopolar Curved Scissor instruments. 2. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.
6.- Further Information & Support	<p>If you need further information or support concerning this Medical Device Notification , please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@intusurg.com. • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) • Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)

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

Sincerely,

Intuitive Surgical, Inc.

950 Kifer Road
Sunnyvale, CA 94086-5304 USA
800-876-1310

ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Device Notification – ISIFA2018-11-C

EndoWrist® Monopolar Curved Scissors Tube Extension Breakage

Ship-to:

Hospital Name:

Address:

City, State, Zip:

SFID:

ATTENTION:

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 Surgical if I have any questions.

Hospital name: _____

Position:

Name (print): _____

☐ Robotics Coordinator

☐ Operating Room Director

Signature: _____

☐ Risk Manager

☐ Surgeon

Phone Number: _____

☐ Other: _____

E-mail: _____

Date: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.

ATTN: REGULATORY POST MARKET FIELD ACTIONS

Subject line for e-mail: MCS TUBE BREAKAGE

US: U.S. Fax +1(408) 523-0619, or Scan and E-mail to Recalls@intusurg.com

Customer Service:

- North and South America: 800-876-1310 Option 3 (4 am to 5 pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)