INTUITIVE

<Month Day, Year>

Field Safety Notice

Urgent Medical Device Notification – ISIFA2018-14-C

EndoWrist® Monopolar Curved Scissors Tube Extension Distortion

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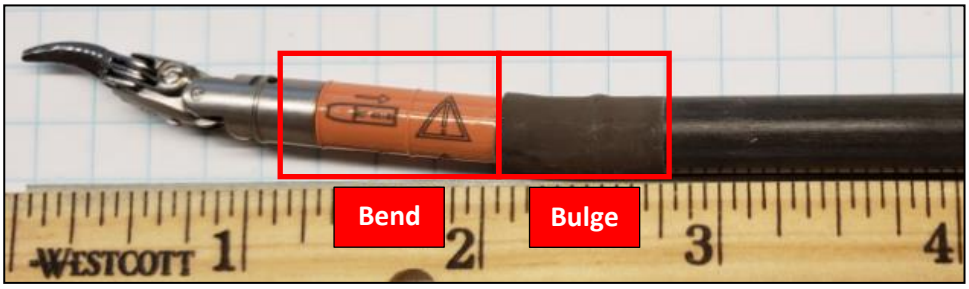
1- Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this letter is to advise you that Intuitive Surgical has identified an issue with specific *da Vinci* S/Si (PN 420179-20) and *da Vinci X/Xi* (PN 470179-18 and PN 470179-17) Monopolar Curved Scissor (MCS) instruments. Intuitive Surgical has become aware that some of these units have experienced distortion due to exposure to the high temperatures found during the standard reprocessing process. As outlined in the Instrument and Accessories User Manual, please inspect instruments for damage prior to use, and do not use an instrument if it is damaged. In addition, if an instrument cannot be manipulated in a precise manner, carefully remove the instrument and return the instrument to Intuitive Surgical. **If an instrument is damaged, please return it to Intuitive Surgical via the standard RMA process for replacement.**  **Figure 1.** Examples of instrument damage related to this field action on an affected MCS instrument
2 - Risk to Health	There have been no reported adverse events related to this issue. If detection of the distortion is not observed prior to the use of the instrument, two scenarios may be encountered. Scenario 1: The distortion to the extension tube creates interference with the cannula. This may cause increased resistance felt on instrument insertion or removal. If instrument cannot be removed, the cannula and instrument can be removed together from the patient. Scenario 2: The distortion of the tube can create imprecise articulation of the instrument, predominantly described by users as 'lagging' of the tips during opening and closing. In this case the instrument should be replaced with a new instrument. Risk to health in all scenarios is limited to minor delay for troubleshooting this issue and switching to a back-up instrument.

3- Affected Products

Part Number	Product Name	Affected Lot Number
420179-20	*da Vinci S/Si* 8 mm Monopolar Curved Scissors	All Lots
470179-18	*da Vinci X/Xi* 8 mm Monopolar Curved Scissors	All Lots
470179-17	*da Vinci X/Xi* 8 mm Monopolar Curved Scissors	All Lots

4- Actions to be taken by the Customer/User

Please take the following Actions:

1. Always inspect the instruments prior to use for any damage and do not use an instrument if it is damaged. Return the damaged instrument to Intuitive Surgical using the standard RMA process. **(Note: The return of undamaged product is not required.)**
2. Inform all da Vinci personnel who are involved with da Vinci Surgery at your site.
3. Complete the attached Acknowledgement Form and return it via email to Intuitive Surgical as instructed on the form.
4. Please retain a copy of this letter and the acknowledgement form for your files.

5- Actions to be taken by Intuitive Surgical

1. A copy of this letter 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 Medical Device Correction.

6- Further Information & Support

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:

- 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

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ACKNOWLEDGMENT FORM
Field Safety Notice
Urgent Medical Device Notification – ISIFA2018-14-C

EndoWrist® Monopolar Curved Scissors Tube Extension Distortion

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 returned all Monopolar Curved Scissor Instrument(s) that exhibit a bent or bulging tube extension within the affected part numbers and lots to Intuitive Surgical.
3. I have ensured all appropriate personnel are fully informed of the contents of this notice.
4. I will contact Intuitive Surgical if I have any questions.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

☐ **Robotics Coordinator**
☐ **Operating Room Director**
☐ **Risk Manager**
☐ **Surgeon**
☐ **Other:** _____

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: ISIFA2018-14-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)