

Urgent Medical Device Notification – 2955842-05-07-2013-005
Intuitive Surgical *EndoWrist*® Instrument Hot Shears™ Monopolar Curved Scissors

AFFECTED PRODUCT:

<u>PART NUMBERS</u>	<u>DESCRIPTION</u>
420179-09 and -10	8 mm Monopolar Curved Scissors (a.k.a. Hot Shears)
400179-09 and -10	8 mm Monopolar Curved Scissors (a.k.a. Hot Shears)

Dear da Vinci Customer,

This notification is to inform you that Intuitive Surgical has identified a potential issue with certain versions of its **Hot Shears™ Monopolar Curved Scissors (MCS)** Instrument and to inform you of precautionary steps you should take to ensure the safety of patients, while using your current inventory of MCS instruments.

Certain -09 and -10 versions of the MCS instruments may develop micro-cracks near the distal (scissor) end of the shaft following reprocessing. Intuitive Surgical identified these micro-cracks during internal testing of an unrelated design modification. The affected area is shown in **Figure 1** below and is confined to an approximately 1 cm section of the shaft, as indicated. **These micro-cracks may not be visible to the user.**



Figure 1: Location of micro-cracks

These micro-cracks may create a pathway for electrosurgical energy to leak to patient tissue during use and potentially cause thermal injury. Our analysis shows only one complaint of an injury associated with use of an MCS instrument that was later found to have micro-cracks; however, laboratory testing did not detect any energy leakage from this instrument. A 5-year retrospective analysis of complaints potentially related to cautery determined that 26 complaints could not be excluded from an association with micro-cracks, leading to an overall potential incident rate of 0.0024%.

Please follow the instructions for use supplied with the product as well as observe each of the attached precautions noted in Attachment A.

The version number of the MCS instrument can be found printed on the box label or the printed side of the blue instrument housing as indicated in **Figure 2** below.



Figure 2: Location of version number on MCS Instrument and box label

Important Note: No other Intuitive Surgical instruments are subject to this Notification.

Please Take the Following Actions:

1. **Forward this letter** to other managers within your facility (e.g., Risk Management, OR Director) who should be informed of this medical device notification.
2. **Review Attachment A for precautionary recommendations** and labeling reminders for usage of the MCS during surgery and the proper usage of electrosurgical units.
3. **Complete the attached Acknowledgement Form**, and return to Intuitive Surgical using the instructions provided.

Your local Competent Authority has been informed of this Notification.

We apologize for the inconvenience associated with this issue. We will immediately inform you when EndoWrist Hot Shears Monopolar Cautery Scissors without the potential for micro-cracks are available for replacement.

If you have questions or require additional assistance, please contact Customer Service:

- Europe, Middle East, Africa, India: **+ 800 0821 2020 or +41 21 821 2020** (8 am to 6 pm CET)
- North and South America: **800-876-1310 Option 3** (6 am to 5pm PST)

Sincerely,

Richard Reeves
Vice President, Regulatory Affairs
Intuitive Surgical, Inc.
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304

European Office
Intuitive Surgical, Sàrl
1 Chemin des Mûriers
1170 Aubonne, Switzerland

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Attachment A

Precautions and Warnings for Usage of the *EndoWrist* Monopolar Curved Scissors

- **Do not apply energy when scissor tips not in contact with tissue:** Energy should *not* be applied to an instrument when it is not in direct contact with tissue (referred to as “air-firing”). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.
- **Be aware of critical anatomy in contact with the instrument during energy activation:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
- **Survey the surgical field:** During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas “below” or “behind” the cannula and endoscope that are normally outside the field of view.
- **Consider patient condition:** Before using monopolar cautery in a procedure, consider factors that may make a patient’s anatomy and tissue more susceptible to injury from the application of cautery (e.g. patients that have received radiation therapy prior to surgery).
- **Only use a validated ESU:** The ESUs that have been validated for use with the *EndoWrist* monopolar instruments, including the MCS, are provided in the Instruments and Accessories User Manual.
- **Do not exceed maximum monopolar cautery settings:** Guidelines on the maximum cautery settings are listed in section Electrosurgical Unit (ESU) Settings and Energy Activation Cables, in the Instruments and Accessories User Manual. Exceeding the maximum cautery settings will exceed the 3kV limit for an instrument, which may result in electrical arcs and alternate site thermal injuries. The user manual also instructs users to set the power as low as possible to achieve adequate hemostasis. Refer to the general precautions and warnings in the Instruments and Accessories User Manual.
- **Refer to the general precautions and warnings in the Instruments and Accessories User Manual.**

ACKNOWLEDGEMENT FORM

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Intuitive Surgical EndoWrist® Instrument Hot Shears™ Monopolar Curved Scissors

Ship-to

Hospital Name:

Address:

City, State, Zip:

ATTENTION Robotics Coordinator.

**PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN
IMMEDIATELY**

Check option below:

I acknowledge that I have received and understood this Notification concerning the *Hot Shears Monopolar Curved Scissors* and have informed all necessary parties at my facility.

Name (print): _____

Signature: _____

Phone Number: _____

Date: _____

If you have questions or require additional assistance, please contact Customer Service:

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- North and South America: **800-876-1310 Option 3** (6 am to 5pm PST)

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical Inc.
ATTN: REGULATORY AFFAIRS
U.S. (408) 716-2704, or Scan and Email: MCS.compliance@intusurg.com