

Urgent Medical Device Notification - 2955842-05-07-2013-005

Intuitive Surgical *EndoWrist*® Instrument Hot Shears™ Monopolar Curved Scissors

AFFECTED PRODUCT:

PART NUMBERS DESCRIPTION

| | |
|-------------------|--|
| 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. This may create a pathway for electrosurgical energy to leak to tissue during use and potentially cause thermal injury. 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

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. The U.S. Food and Drug Administration (FDA) has been notified of this action. 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.

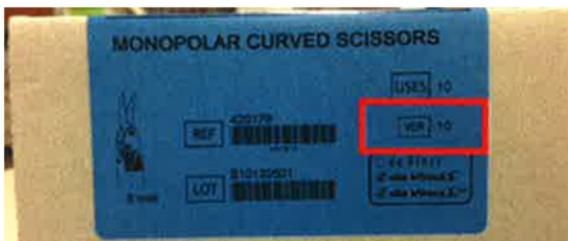


Figure 2: Location of version number on MCS Instrument and box label

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

We will follow this email communication with a hard copy letter and an Acknowledgement Form, sent via express mail to your site.

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.

Should you have any further questions or require additional assistance, please contact Customer Service:

- North and South America: **800-876-1310** Option 3 (6 am to 5pm PST)
- Japan: **0120-56-5635** or **003-5575-1362** (9am to 6pm JST)
- Korea: **02-3271-3200** (9am to 6pm KSTJ)
- Europe, Middle East, Asia and Africa: **+800 0821 2020** or **+41 21 821 2020** (8 am to 6 pm CET)

Sincerely,

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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 section 3.1 in the Instruments and Accessories User Manual.
- **Do not exceed maximum monopolar cautery settings:** Guidelines on the maximum cautery settings are listed in section 3.3, 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 section 3.3 in the Instruments and Accessories User Manual.
- **Refer to the general precautions and warnings in sections 2.1, 2.2, 4.1, and 4.2 in the Instruments and Accessories User Manual.**