

## Field Safety Notice

### Urgent Medical Device Recall – 2955842-05-07-2015-005-R

*5mm Thoracic Grasper, Main Tube Damage*

<p><b>Introduction and Reason for Field Action</b></p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary recall of older versions of the 5mm Thoracic Grasper (PN 420343 Version -01 and -02). The 5mm Thoracic Graspers are manufactured by Intuitive Surgical and used with the <i>da Vinci</i>® S™ and <i>da Vinci Si</i>™ Surgical Systems.</p> <p>Intuitive Surgical has determined that the coating of the 5mm Thoracic Grasper (version -01 and -02) main tube may experience damage. The source of the damage to the instrument main tube has been determined to be contact/abrasive forces applied to the 5mm main tube coating in excess of the material capability. The force being applied can come from a damaged cannula (bent, abraded, or notched) or by contacting an adjacent instrument.</p> <div data-bbox="683 835 1091 1142" data-label="Image"> </div> <p>Figure 1: Example of Main Tube Damage Under Magnification</p> <p>This action does not affect the newest version of the Thoracic Grasper (PN 420343 Version -03).</p>
<p><b>Risk to Health</b></p>	<p>The material that may fragment from the main tube of the Thoracic Grasper (PN 420343-01 and 420343-02) meets the ISO-10993 bio-compatibility and implantability testing requirements and manifests no signs of toxicity. To date, there have been no reports of patient injuries as a result of this issue.</p> <p>If damage is caused to the main tube during a procedure, fragments of the main tube coating may fall into the patient; however the user may visually detect instrument failure either through the Surgeon Console viewer or at the patient side during instrument exchanges.</p> <p>If damage is observed, the user would be required to replace the instruments, resulting in a minor delay in the procedure. Material observed to have fallen into the patient must be retrieved or removed through suction-irrigation.</p> <p>For Thoracic and Extra-Cardiac Surgeries, main tube damage with fragments of coating material falling into the surgeon's view will have a minor immediate health effect. A temporary delay in the procedure would occur while the fragment is retrieved and the instrument replaced.</p> <p>For Intra-Cardiac Surgery, if a fragment falls into the patient during the procedure, it is</p>

very likely to be seen due to the smaller operating space and the high contrast between the dark coating material and the light intra-cardiac tissue. Thus, the fragment would be easily retrieved and the instrument replaced with only a brief delay in the procedure. Should a particle become enclosed within the heart, the patient is at risk for an embolic event such as a stroke. This high risk is mitigated by the Cardiac Surgical Standard Operating Procedure of inspecting the atrium and valve prior to closing to ensure no material of any kind is left behind.

**Affected Countries and Products**

**Affected Countries:**  
Belgium, Brazil, Canada, Chile, Colombia, Denmark, France, Germany, India, Netherlands, Panama, Singapore, South Korea, Switzerland, Taiwan, Turkey, United Kingdom, United States.

**Affected Product:**

ISI Part Number	Product Name
420343-01	THORACIC GRASPER,5MM,IS2000, IS3000
420343-02	THORACIC GRASPER,5MM,IS2000, IS3000

Note: This field action does not affect the Thoracic Grasper PN 420343-03.

**Actions to be taken by the Customer/ User**

**Please Take the Following Actions:**

1. Ensure that all affected personnel are fully informed of this notice. Forward this notice to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform da Vinci Surgery procedures.
2. Identify affected product in your possession. Only part number 420343, versions -01 and -02, are affected (see figure 2 below for location of part and version number on instrument):

Figure 2: Example Part Number and Version Number Location

3. If you have any affected product, please contact Customer Service to arrange for Return Material Authorizations (RMAs) to return your Thoracic Grasper.
4. Complete and return the attached Acknowledgment Form to Intuitive Surgical using the instructions provided.
5. Please retain a copy of this Notice.

<p><b>Actions to be taken by Intuitive Surgical</b></p>	<p>Intuitive will provide new replacement 5mm Thoracic Grasper (version -03) instruments for those that are returned.</p> <p>Intuitive Surgical representatives will be available by phone to:</p> <ol style="list-style-type: none"> <li>1. Create any Return Material Authorizations (RMAs) for affected product.</li> <li>2. Answer any questions related to this Medical Device Recall.</li> </ol> <p>Once Intuitive Surgical receives the 5mm Thoracic Grasper instruments, Intuitive Surgical will determine the total combined number of remaining lives of all instruments returned and round up the number of lives to the nearest increment of 20 to determine the number of instruments to ship as replacements.</p> <p>For example, if a customer returned three instruments with 15 lives each, the total number of remaining lives is 45. The 45 remaining lives will be rounded up to 60 lives, and 3 Thoracic Grasper instruments will be shipped as replacement instruments (each instrument has 20 lives).</p>
<p><b>Further Information &amp; Support</b></p>	<p>If you need further information or support concerning this Medical Device Recall, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> <li>• North and South America: (800) 876-1310, Option 3 (6 AM to 5 PM PST) or mail: <a href="mailto:customersupport-servicesupport@intusurg.com">customersupport-servicesupport@intusurg.com</a></li> <li>• Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or <a href="mailto:ics@intusurg.com">ics@intusurg.com</a></li> <li>• South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ)</li> <li>• Japan: 0120-56-5635 or 003-5575-1362 (9 AM to 6 PM JST)</li> </ul>

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

Sincerely,

**Intuitive Surgical Sàrl**  
 Chemin des Mûriers 1  
 1170 Aubonne, Switzerland  
 +41 21 821 2020

## ACKNOWLEDGEMENT FORM

### Field Safety Notice

### **Urgent Medical Device Recall – 2955842-05-07-2015-005-R**

*5mm Thoracic Grasper, Main Tube Damage*

Hospital Name:

Address:

City, Postal Code:

NSID :

ATTENTION:

1. I have received and read this Recall Notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this Notice.
3. I have returned all affected 5mm Thoracic Graspers P/N 420343-01 and P/N 420343-02 in my possession to Intuitive Surgical
4. I will contact Intuitive Surgical if I have any questions.

Name (print): \_\_\_\_\_

Signature: \_\_\_\_\_

Hospital Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

Date: \_\_\_\_\_

**Position:**

- Robotics Coordinator
- Operating Room Director
- Risk Manager
- Recall Coordinator
- Other: \_\_\_\_\_

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

**ATTN: REGULATORY COMPLIANCE**

**Subject line for email: Thoracic Grasper Main Tube Damage**

**U.S. Fax +1 (408) 716-3040, or Scan and Email: [EU.FSCA@intusurg.com](mailto:EU.FSCA@intusurg.com)**

**Customer Service:**

- North America and South America: 800-876-1310 Option 3 (6 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) or [ics@intusurg.com](mailto:ics@intusurg.com)