May 19, 2015

Field Safety Notice – 2nd Notice

Urgent Medical Device Correction – 2955842-03-13-2015-003-C

Cloudy Appearance and Potential Tears on System Drapes

Introduction and Reason for Field Action	Dear *da Vinci* Customer, This is a follow-up communication to our original notification to Customers: 2955842-03-13-2015-003-C issued March 24, 2015. This Field Safety Notice is to update you regarding the *da Vinci® Standard, S™ and Si™ Surgical Systems* drapes that are affected by the potential tear-away labels and cloudy/waxy appearance issues. As documented in the initial notification, the availability of drapes unaffected by the tear-away label issue and the cloudy/waxy appearance issue was expected for lots manufactured after March 6, 2015; Nothing has changed with regard to the cloudy/waxy appearance issue. Drapes shipped with lot numbers manufactured after March 6, 2015 will not be affected by the issue of cloudy appearance. This correlates to lot numbers greater than 066 as seen in the following format: D15066xx or DA15066xx. Additional details regarding affected product described in the *Affected Countries and Products* section below. However, detailed root cause analysis and corrections for the tear away label issue are taking longer than initially expected. As such, drape product unaffected by the tear away label issue will not be available until approximately October/November 2015. Intuitive Surgical is working with both Microtek Medical and their supplier to ensure comprehensive root cause investigation and corrective/ preventive actions are implemented to prevent future occurrence of this issue. When unaffected product becomes available, a follow up notification will be provided with additional details. There have been no reported patient injuries or adverse health consequences as a result of either issue.
Risk to Health	**Tear-Away Labels:** The tear(s) may lead to possible contamination of the surgical field as a result of contamination of the sterile personnel's gloves while interacting with robotic arms. The contaminated gloves could then come into contact with the patient, instruments or operative supplies. This glove contamination would be similar to a member of the operating team inadvertently touching something non sterile and not recognizing the break in aseptic technique and continuing to operate with the same gloves. There is a slight increased risk for infection, primarily with surface contaminants, that could increase the chance of post-operative wound infection. Severely immunocompromised patients may be at higher risk of infection. This is an infrequent failure mode and tearing of drapes due to this issue has been observed in 0.8% of manufactured drapes. Of the more than 500,000 drapes shipped, there have been two complaints from the field potentially related to tears in the drapes. Additionally, since the initial notification was sent, no affected product has been returned as a result of this issue.

Affected Countries and Products

Affected Countries:

Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China (including Hong Kong), Colombia, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Finland, France, Germany, Greece, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Kuwait, Lebanon, Luxembourg, Malaysia, Mauritius, Mexico, Monaco, Netherlands, New Zealand, Norway, Pakistan, Panama, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela, Vietnam

Product affected by Cloudy/Waxy Appearance issue only:

The following part numbers are impacted by the cloudy/waxy appearance issue only:

ISI Part Number	Product Name
400015-03	*da Vinci (Standard System)* Inst. Arm Drape, 20 Pack
400016-04	*da Vinci (Standard System)* Camera Arm Drape, 20 Pack
400027-04	*da Vinci (Standard System)* Camera Drape, 20 Pack
420017-03	*da Vinci S* Patient-Cart Monitor Drape, 20 Pack
420026-01	*da Vinci S* Vision-Cart Monitor Drape, 20 Pack
420273-02	*da Vinci Si* Camera Head Drape, 20 Pack
420281-02	*da Vinci Si* Monitor Drape, 20 Pack

Table 1: Part Numbers affected by the cloudy/waxy appearance only

Affected Product for Tear-Away Labels:

Products manufactured after March 6, 2015 are potentially affected by the tear-away label issue only. The following part numbers are impacted:

ISI Part Number	Product Name
420015-03	*da Vinci Si/S* Instrument Arm Drape , 20 Pack
420022-02	*da Vinci S* Camera Arm Drape, 20 Pack
420256-01	*da Vinci S* Disposable Accessory Kit, 3 ARM, 5 Pack
420258-01	*da Vinci S* Disposable Accessory Kit, 4 ARM, 5 Pack
420279-03	*da Vinci Si* Camera Arm Drape, 20 Pack
420291-03	*da Vinci Si* Disposable Accessory Kit, 4 ARM, 5 Pack
420290-03	*da Vinci Si* Disposable Accessory Kit, 3 ARM, 5 Pack

Table 2: Part Numbers affected by the tear-away labels only

Affected Product for Tear-Away Labels and Cloudy/Waxy Appearance:

Both the tear-away labels and cloudy/waxy appearance issues potentially affect the following part numbers:

ISI Part Number	Product Name
420015-03	*da Vinci Si/S* Instrument Arm Drape , 20 Pack
420022-02	*da Vinci S* Camera Arm Drape, 20 Pack
420256-01	*da Vinci S* Disposable Accessory Kit, 3 ARM, 5 Pack
420258-01	*da Vinci S* Disposable Accessory Kit, 4 ARM, 5 Pack
420279-03	*da Vinci Si* Camera Arm Drape, 20 Pack
420291-03	*da Vinci Si* Disposable Accessory Kit, 4 ARM, 5 Pack
420290-03	*da Vinci Si* Disposable Accessory Kit, 3 ARM, 5 Pack

Table 3: Part Numbers affected by both the tear-away label and cloudy appearance issues

	Lots manufactured after March 6, 2015 are not affected by the cloudy/waxy appearance issue. This correlates to lot numbers greater than 066 as seen in the following format: D15066xx or DA15066xx.
Actions to be taken by the Customer/ User	**Please Take the Following Actions:** 1. Ensure all 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 support *da Vinci* Surgery procedures. 2. Prior to use, assess drapes per the attached inspection instructions. This inspection is required for all *da Vinci*® *Standard, S*™ and *Si*™ Surgical System drapes identified in the Affected Countries and Product section of this notification. 3. If your assessment identifies affected product, please contact Customer Service (contact information provided below) to arrange for Return Material Authorizations (RMAs) to return your affected drapes. 4. Please note that new orders or replacement drapes shipped will require inspection per the instructions attached prior to use until unaffected drapes become available. 5. Please retain a copy of this notice.
Actions to be taken by Intuitive Surgical	Intuitive Surgical representatives will be available by phone to: 1. Create any Return Material Authorizations (RMAs) for affected product. 2. Answer any questions related to this Medical Device Correction.
Further Information & Support	If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below: • North and South America: (800) 876-1310, Option 3 (6 AM to 5 PM PST) or mail: customersupport-servicesupport@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 003-5575-1362 (9 AM to 6 PM JST)

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

Sincerely,

Intuitive Surgical
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304 USA
800-876-1310

May 19, 2015

ACKNOWLEDGEMENT FORM

Field Safety Notice – 2nd Notice

Urgent Medical Device Correction – 2955842-03-13-2015-003-C

Cloudy Appearance and Potential Tears on System Drapes

Hospital Name: <mail merge>
Address: <mail merge>
City, Postal Code: <mail merge>
NSID : <mail merge>
ATTENTION: <mail merge>

1. I have received and read this Correction 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.

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: Cloudy Appearance and Potential Tears on System Drapes
U.S. Fax +1 (408) 716-3040, or Scan and Email: 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