INTUITIVE SURGICAL®

Field Safety 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 Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction related to the system drapes manufactured by Microtek Medical used with the *da Vinci® Standard™, S™,* and *Si™* Surgical Systems. To make the *da Vinci* Surgical System suitable for surgery, some components are sterile draped using clear, custom fitted plastic drapes that provide a sterile barrier to protect equipment from contamination and to maintain a sterile field. This letter outlines the specific issues as well as provides inspection instructions for continued safe use of the *da Vinci* surgical system drapes. There have been two issues identified with the *da Vinci* surgical system drapes: **Tear-Away Labels:** Through standard product quality testing, it was noted that the adhesive labels intended to keep the drape folded were found, in some instances, unintentionally overlapping multiple folds of the drape. This issue has the potential to cause small tears when the drape unfolds during the draping process. 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. **Cloudy/Waxy Appearance:** Additionally, through customer feedback Intuitive Surgical found that some of the drapes used with the da Vinci Systems may exhibit a cloudy/waxy appearance (reported in less than 0.5% of procedures). The cloudy appearance is due to increased presence of anti-static additive in the drape film. The anti-static additive does not create particles that separate from the film. However, there is potential for the waxy substance to transfer to the patient through indirect contact. The functional performance characteristics of the drapes are not affected by this issue. There have been no 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. **Cloudy/Waxy Appearance**: Direct exposure to the waxy substance may cause skin irritation and sensitization. The reaction is minor and limited to immediate contact area with no long-term health consequences.

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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

Affected Product for Tear-Away Labels:

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

See **Attachment A** for affected lot numbers.

Affected Product for Cloudy/Waxy Appearance:

ISI Part Number	Product Name
400015-03	*da Vinci (Standard System)* Instrument 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
420015-03	*da Vinci Si/S* Instrument Arm Drape , 20 Pack
420017-03	*da Vinci S* Patient-Cart Monitor Drape, 20 Pack
420022-02	*da Vinci S* Camera Arm Drape, 20 Pack
420026-01	*da Vinci S* Vision-Cart Monitor 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
420273-02	*da Vinci Si* Camera Head Drape, 20 Pack
420279-03	*da Vinci Si* Camera Arm Drape, 20 Pack
420281-02	*da Vinci Si* Monitor Drape, 20 Pack
420290-03	*da Vinci Si* Disposable Accessory Kit, 3 ARM, 5 Pack
420291-03	*da Vinci Si* Disposable Accessory Kit, 4 ARM, 5 Pack

Actions to be taken by the Customer/ User	**Please Take the Following Actions:** 1. Ensure 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. Prior to use, assess drapes per the attached inspection instructions (**Attachment B**). This inspection is not required for drapes manufactured after 06 March 2015. This correlates to lot numbers greater than 066 as seen in the following format: D15066xx or DA15066xx. See attachment A for location lot information on the label. 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. Replacement drapes will be provided. 4. 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

ACKNOWLEDGEMENT FORM

Field Safety 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: isi.compliance@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