Date : May 23, 2016

Field Safety Notice

Urgent Medical Device Correction – 2955842-05/09/16-007-C

WARNING on use of the da Vinci Xi 5 mm-8 mm Universal Cannula Seal (PN 470361) and da Vinci Xi 12 mm & Stapler Universal Cannula Seal (PN 470380) in intra-cardiac procedures on the da Vinci Xi Surgical System

Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this letter is to advise you that Intuitive Surgical is initiating a voluntary correction of the use of *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal (PN 470361) and *da Vinci Xi* 12mm & Stapler Universal Cannula Seal (PN 470380) in intra-cardiac procedures. During internal inspections, Intuitive Surgical has identified particulate in the insufflation stopcocks on the *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal. The particulate generated from the seal material has the potential to be introduced into the cannula lumen when insufflation is connected.
Risk to Health	There have been no injuries identified related to this issue. However, for intra-cardiac procedures only, there is a risk of foreign body embolism should particulates remain undetected and unintentionally left inside the heart. Do NOT use the *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal or the *da Vinci Xi* 12 mm & Stapler Universal Cannula Seal for insufflation, or open the stopcock during the procedure until this issue is resolved. It is recommended to use an angio-catheter, or Veress needle, through the chest wall for initial access and to maintain insufflation throughout the procedure. For non-cardiac procedures, including thoracic or abdominal/pelvic procedures, it has been determined that the *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal and *da Vinci Xi* 12 mm & Stapler Universal Cannula Seal have minimal risk to patients. The potential particulate is likely no larger than approximately 3mm in length, of a benign geometry with no sharp edges. It is composed of HDPE, a bio-inert material with a longstanding history of use in implantable medical devices.
Affected Countries and Products	Affected Countries: Australia, Austria, Belgium, Chile, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, India, Ireland, Israel, Italy, Japan, Monaco, Netherlands, Norway, Puerto Rico, Portugal, Qatar, Romania, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, and United States. Affected Product: Part Number: 470361 — Product Name: SEAL,IS4000 PORTS,5MM-8MM,BOX OF 10 Part Number: 470380 — Product Name: SEAL,IS4000 PORTS,12MM&STAPLER,BOX OF 10

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Actions to be taken by the Customer/ User	**Please take the following Actions:** Actions Specific to Intra-Cardiac Procedures 1. Do NOT use the *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal or the *da Vinci Xi* 12 mm & Stapler Universal Cannula Seal for insufflation, or open the stopcock during intra-cardiac procedures. 2. Until this issue is resolved, use an angio-catheter, or Veress needle, through the chest wall for initial access and to maintain insufflation throughout all intra-cardiac procedures as an alternative to insufflation through the *da Vinci Xi* 5 mm-8 mm Universal Cannula Seal (PN 470361) or the *da Vinci Xi* 12 mm & Stapler Universal Cannula Seal (PN 470380). Actions Applicable to All Affected Personnel 1. Ensure that all affected personnel are aware of the Risk to Health as stated in the above section, for both intra-cardiac and non-cardiac procedures. Forward this notice to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff, and members of your medical staff who perform *da Vinci Xi* surgery. 2. Complete the attached Acknowledgment Form and return it to Intuitive Surgical as instructed. 3. Please retain a copy of this letter and the acknowledgment form for your files.
Actions to be taken by Intuitive Surgical	Intuitive Surgical representatives will be available by phone to 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 contact 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
950 Kifer Road
Sunnyvale, CA 94086-5304 USA
800-876-1310

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ACKNOWLEDGEMENT FORM
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Hospital Name:
Address:
City, State, Zip:
NSID:
ATTENTION:

1. I have received and read this 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
☐ Surgeon
☐ Other: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: Post Market Field Actions
Subject line for email: Xi Seal
U.S. Fax +1(408) 523-0619, or Scan and Email: isi.compliance@intusurg.com or eu.fsca@intusurg.com

Customer Service:
- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Japan: 0120-56-5635 or 003-5575-1362 (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)

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