Date : 14 Apr 2016

Field Safety Notice

Urgent Medical Device Correction - 2955842-03/16/16-005-C

Proper use of da Vinci® S™, Si™, and Xi™ Instruments for Manipulation of Cryoablation Probes in Cardiac Procedures

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 regarding the use of certain *da Vinci EndoWrist* instruments with a cardiac cryoablation probe. Through bench top testing and literature assessment, Intuitive Surgical has determined that microscopic metallic particulate can be generated during both robotic and non-robotic intra-cardiac surgery. The use of *da Vinci* instruments other than the Cardiac Probe Grasper (e.g. Large Needle Driver) to manipulate a cardiac cryoablation probe during *da Vinci* cardiac surgery has been shown to increase the amount of microscopic metallic particulate. The purpose of this communication is to advise users that **only the Cardiac Probe Grasper should be used to manipulate a cryoablation probe in cardiac procedures.**
Risk to Health	To date, Intuitive Surgical has received reports of five (5) post-*da Vinci* Mitral Valve Repair patients whose MRIs of the head may show artifacts consistent with the presence of metallic microemboli. However, it has not been confirmed whether the source of these artifacts is related to *da Vinci* surgery or the *da Vinci* system or instruments. While two (2) of these patients originally presented with temporary minor neurological symptoms (e.g., headaches; dizziness), it is unclear whether these symptoms are related to the artifacts. Similar information for the other patients has not been provided to Intuitive Surgical. Due to the potential for microscopic particulate in all intra-cardiac surgery, flushing of the heart prior to closure is common clinical practice. Metallic particulate not removed by flushing procedures could potentially travel to the brain which may contribute to microemboli, pose a possible toxicological risk, or pose a risk to the patient during future MRIs. However, it is not likely that a patient would suffer permanent neurological impairment due to metallic microemboli originating from a *da Vinci* intra-cardiac procedure, and the possible risk of harm due to toxicological exposure or future MRI is very low. For reference, per the United States Pharmacopeia (USP) standard for injectable drugs, there is an allowable limit of 600 nonvisible particles over 25 µm in size in a 100mL sample. The Parenteral Drug Association defines the reliable “visible” limit for particulate size at 150 µm. Internal testing has shown that the number and size of particulate from cryoablation probe manipulation with the Cardiac Probe Grasper are well below these levels.

Affected Countries and Products

All instruments are performing as intended, therefore product is not being recalled.

Affected Countries:

Australia, Belgium, Brazil, Canada, Chile, China, Finland, France, Germany, Greece, Iceland, India, Israel, Italy, Japan, Netherlands, Qatar, Russia, Singapore, South Korea, Sweden, Switzerland, Taiwan, Turkey, United Arab Emirates, United Kingdom, and United States

Impacted Systems (specific to cardiac use)

da Vinci S Surgical System
da Vinci Si Surgical System
da Vinci Xi Surgical System

Affected Product:

*All latest released versions, in the field, as of this letter, are impacted.

Part Name(s)	Part Number(s)
User Manual, Instrument & Accessory, English (IS1200/IS2000/IS3000) (and all other languages)	550675-XX
User Manual, Instrument-Accessory, IS4000, English	551457-XX
User Manual, Instrument-Accessory, IS4000, OUS English (and all other languages)	551706-XX
User Manual, Instrument-Accessory, IS3000, Japanese	550972-XX

Actions to be taken by the Customer/ User

1. In addition to existing instructions for use, observe the following warning when manipulating the cardiac ablation probe:

Use only the Cardiac Probe Grasper to manipulate a cardiac ablation probe. While microscopic metallic particulate may be generated in any surgery, use of other da Vinci instruments (e.g. the Large Needle Driver) to manipulate a cardiac ablation probe has been shown to increase metallic particulate.

2. Distribute a copy of this letter to all *da Vinci* S, Si, and Xi users at your facility.
3. Place a copy of this letter with your user manual.
4. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed.
5. Retain a copy of this letter and the Acknowledgement Form for your files.

Actions to be taken by Intuitive Surgical	Intuitive Surgical will provide a user manual addendum to incorporate the warning related to this risk.
Further Information & Support	If you need further information or support concerning this Medical Device Notification, 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)

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

Sincerely,

Intuitive Surgical
<Insert Regional Contact Information>

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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: REGULATORY COMPLIANCE
Subject line for email: Particulate
U.S. Fax +1(408) 716-3040, or Scan and Email: <Insert Regional Contact Information>

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)