

Product Availability Notification

Important Follow-up to Urgent Medical Device Correction – 2955842-05/09/16-007-C

WARNING on use of the *da Vinci Xi* 5-8 mm Cannula Seal and *da Vinci Xi* 12 mm & Stapler Cannula Seal in intra-cardiac procedures on the *da Vinci Xi* Surgical System

Introduction

Dear *da Vinci* Customer,

This letter is a follow-up to Field Safety Communications sent on May 23, 2016 regarding the use of *da Vinci Xi* 5-8 mm Cannula Seal (PN 470361) and *da Vinci Xi* 12 mm & Stapler Cannula Seal (PN 470380) in intra-cardiac procedures.

This product availability notification is to inform you that the issue noted in the Field Safety Notice Urgent Medical Device Correction – 2955842-05/09/16-007-C regarding potential for particulates being introduced into the *da Vinci Xi* 5-8 mm and 12 mm Cannula Seals when insufflation is connected to the valve has been resolved. All products currently shipping have been corrected.

Please note that affected *da Vinci Xi* 5 - 8 mm Cannula Seals and *da Vinci Xi* 12 mm & Stapler Cannula Seals do not need to be returned. You may continue to use the affected seals per the instructions provided in the initial notification.

Starting with the Xi Seal lot numbers below, subsequent lots are unaffected by this issue causing the potential for particulates.

Part Number	Part Description	Unaffected Lots
470361	<i>da Vinci Xi</i> 5-8 mm Cannula Seal, Box of 10	Any lots starting from 73G1600703
470380	<i>da Vinci Xi</i> 12 mm & Stapler Cannula Seal, Box of 10	Any lots starting from 73H1600002

See **Appendix A** for guidance on the lot number format and **Figure 1** for the lot number location on the instrument box.



Figure 1. Lot numbers on *da Vinci Xi* 5 - 8 mm (left) and 12 mm (right) Cannula Seal boxes

Affected Countries and Product	<p>Affected Countries:</p> <p>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.</p>
Actions to be taken by the Customer/ User	<p>Please Take the Following Actions:</p> <ol style="list-style-type: none"> 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 <i>da Vinci</i> Surgery procedures. 2. New <i>da Vinci</i> Xi Cannula Seals can be ordered via the standard ordering process. 3. Please retain a copy of this notice for your records.
Actions to be taken by Intuitive Surgical	<p>Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Correction.</p>
Further Information & Support	<p>If you need further information or support concerning this Medical Device Notice, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (6 AM to 5 PM PST) or email 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 email ics@intusurg.com. • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) • Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)

Sincerely,
Intuitive Surgical
 950 Kifer Road
 Sunnyvale, CA 94086-5304 USA
 800-876-1310

Appendix A - 2955842-05/09/16-007-C

This Appendix is intended to provide instructions on how to read the batch/lot numbers related to the affected product.

- 1) Lot numbers can be broken down into four sections.

EXAMPLE:

Build Location	Month	Year	Sequence
73	G	16	00703

- 2) The Build Location number is the location ID where the part was manufactured and will not change.

EXAMPLE: 73G1600703

- 3) The next section refers to the month the unit was built. Each month is associated with a letter.

EXAMPLE: 73G1600703

Month	January	February	March	April	May	June
Letter	A	B	C	D	E	F
Month (cont.)	July	August	September	October	November	December
Letter (cont.)	G	H	I	J	K	L

- 4) The next section contains two numbers which refer to the last two digits of the year the unit was made. In our example lot, the number "16" corresponds with the year 2016.

EXAMPLE: 73G1600703

- 5) Finally, the last section refers to the sequence or unique batch/lot identification number.

EXAMPLE: 73G1600703