02-08-2016

Medical Device Recall - 2955842-07/14/16-010-R

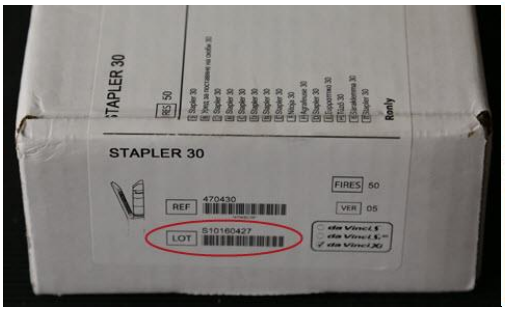
Important Follow-up to, Urgent Stop-Use Roll Bearing Product Notice

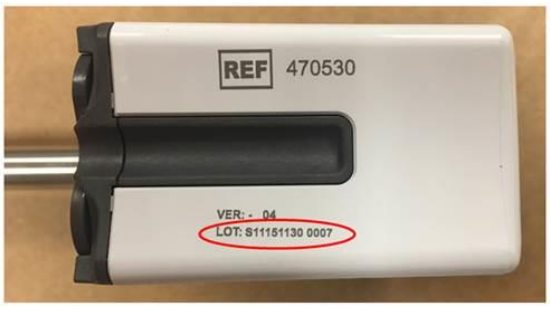
For specific *EndoWrist*® Stapler 45 and 30 instruments for the *da Vinci*® *Xi*™ Surgical System

Introduction and Reason for Medical Device Recall	Dear *da Vinci* Customer, This is a follow-up communication to the following notifications: • U.S. Customers: *Urgent Product Notice - STOP USE* issued July 14th, 2016 • International Customers: *Urgent Product Notice – STOP USE* issued July 14th, 2016 This recall notification is to inform you that Intuitive Surgical is **voluntarily initiating a Medical Device Recall related to specific *EndoWrist*® Stapler 45 and 30 instruments for the *da Vinci*® *Xi*™ Surgical System as identified in Attachment A**. Intuitive Surgical issued an *EndoWrist Xi* Stapler Stop-Use Product Notice on July 14th, 2016 in response to a field failure where the stapler remained clamped on tissue, even when the Stapler Release Kit was used. Intuitive Surgical has determined that this issue is the result of a bearing failure within the housing of the instrument. The bearing failure is associated with components from a specific bearing supplier and, as such, is found only in certain manufacturing lots of instruments as identified in Attachment A. The purpose of this Medical Device Recall notification is to advise customers of the return and replacement process for specific Xi Stapler 45 and 30 instruments with the identified bearing issue. Only the *EndoWrist Xi* Stapler 45 and 30 instrument lot numbers listed in Attachment A are affected by this Medical Device Recall. This recall does not affect or relate to *EndoWrist* Si Staplers, any other *EndoWrist* instruments, accessories or *EndoWrist* Stapler 45 and 30 components.
Risk to Health	In two clinical cases, this failure resulted in the instrument being clamped on tissue and could not be opened using the Stapler Release Kit. If the *EndoWrist* Stapler instrument cannot be released from tissue during a procedure, then the stapler and the tissue it is grasping may need to be excised using an alternative stapling device or other surgical intervention. These two clinical cases that prompted this action were completed minimally invasively with an alternative stapling device. Failure of the bearing may also cause an interruption in shaft rotation, resulting in minimal delay while the instrument is examined and replaced with a new one. The risks stated above related to this failed bearings issue have been contained based on the Stop-Use Product Notice on July 14th, 2016.
Affected Countries and Products	**Affected Countries:** Australia, Belgium, Denmark, France, Germany, Italy, Japan, Spain, Sweden, Switzerland, Taiwan, Turkey, and United States **Affected Product**: **Model Number** / **Product Name** 470298 — *da Vinci Xi* Stapler 45 470430 — *da Vinci Xi* Stapler 30 470530 — *da Vinci Xi* Stapler 30 Curved Tip **The scope of this recall only applies to the manufacturing lot numbers found in Attachment A.**
Actions to be taken by the Customer/ User	Please take the following actions: 1) Return quarantined *Xi EndoWrist* Stapler instruments with the specific lot numbers in Attachment A, whether used or unused. Please follow the instructions listed below and return these Staplers to Intuitive Surgical by 19 August 2016

To return the *Xi EndoWrist* Stapler 45 and 30 instruments with specified numbers to Intuitive Surgical:

- **Identify your entire quarantined inventory of the *EndoWrist* Stapler 45 and 30 instruments with the specified lot numbers.**
  NOTE: The lot number of the *Xi EndoWrist* Stapler 45 and 30 instruments can be found in two locations, circled in the pictures below: It is printed on the box label (left) and on the side of the instrument housing (right). If the box is unopened, do not break the seal and return the package as is.





Important: Only return the *EndoWrist Xi* Stapler 45 and 30 instruments identified in Attachment A. This Medical Device Recall does not affect or relate to *EndoWrist Si* Staplers, any other EndoWrist instruments, accessories or EndoWrist Stapler 45 and 30 components

- [redacted]
- **Note:** Please clean and sterilize all *EndoWrist* Stapler instruments before returning.
- Please return *EndoWrist* Staplers by **19 August 2016**

2) Complete the attached *Xi EndoWrist* Stapler 45 and 30 Instrument Return Acknowledgement Form and submit via email to Regulatory Compliance at isi.compliance@intusurg.com or by U.S. fax +1 (408) 523-0619

3) Please retain a copy of this Recall notice for your records with your *da Vinci* user manual.

Actions to be taken by Intuitive Surgical	1) Once Intuitive Surgical receives the specified, identified *Xi EndoWrist* Stapler 45 and 30 instruments, Intuitive Surgical will determine the total combined number of remaining fires of *like* instruments returned and will round up the number of fires to the nearest increment of 50 to determine the number of instruments to ship as replacement instruments. *For example, if a customer returns three Xi Stapler 45 instruments with 25 fires each, the total number of remaining fires is 75. The 75 remaining fires will be rounded up to 100 fires and two EndoWrist Xi Stapler 45 instruments will be shipped as replacement instruments (each instrument has 50 fires). In addition, if a customer also returns two Xi Stapler 30 instruments with 20 lives each, the total number of remaining fires is 40. The 40 remaining fires will be rounded up to 50 fires and one EndoWrist Xi Stapler 30 instrument will be shipped as replacement instruments (each instrument has 50 fires). In this example, the customer will receive replacements of like instruments: two EndoWrist Xi Stapler 45 instruments and one EndoWrist Xi Stapler 30 instrument.* 2) Intuitive Surgical will begin shipping replacement *EndoWrist Xi* Stapler 45 and 30 instruments at no charge once recalled *EndoWrist* Xi Stapler instruments are received from the customer. A purchase order is not required. The shipment will be to the attention of the contact person the hospital identifies when initiating the RMA (indicated on the Acknowledgment Form). **Important:** If receiving instruments without a purchase order presents a problem at your hospital, please contact Intuitive Surgical Customer Service. 3) Replacement Staplers will be distributed once recalled *EndoWrist* Xi Stapler instruments are received from the customer and as inventory becomes available. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Recall.
Further Information & Support	If you need further information or support concerning this Recall notification, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at • 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 03-5575-1362 (9 AM to 6 PM JST)

Sincerely,

Intuitive Surgical, Inc.
Chemin des Mûriers 1
CH-1170 Aubonne, Suisse
+41 21 821 202

02-08-2016

ACKNOWLEDGMENT FORM

Medical Device Recall - 2955842-07/14/16-010-R

Important Follow-up to, Urgent Stop-Use Roll Bearing Product Notice

For specific *EndoWrist*® Stapler 45 and 30 instruments for the *da Vinci*® *Xi*™ Surgical System

1. **CONTACT CUSTOMER SERVICE TO INITIATE AN RMA**
2. **COMPLETE FORM AND RETURN TO INTUITIVE SURGICAL** (also keep a copy of this form for your records)

Hospital Name: <mail merge field>
Address: <mail merge field>
City, State, Zip: <mail merge field>
SFID: <mail merge field>
ATTENTION: <mail merge field>

1. I have received and read this Recall Notification.
2. I have ensured all appropriate personnel are fully informed of the contents of this Recall Notification.
3. I have reviewed my site's inventory of affected instruments and identified the following quantities of affected product.
4. I will contact Intuitive Surgical if I have any questions.

Name (Print): _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

City, State, Zip: _____

Phone Number: _____

PLEASE FAX THIS RETURN ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
Subject line for fax and email: *da Vinci Xi* Stapler 45 and 30 Recall
U.S. Fax +1 (408) 523-0619, or scan and email to isi.compliance@intusurg.com
For EMEIA: eu.fsca@intusurg.com

Customer Service:

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)

ATTACHMENT A

Only the *EndoWrist* Xi Stapler 45 and 30 instrument lot numbers listed below are affected by this Medical Device Recall. This Recall does not affect or relate to *EndoWrist* Si Staplers, any other EndoWrist instruments, accessories or EndoWrist Stapler 45 and 30 components.

da Vinci Xi EndoWrist® Stapler 45 (P/N 470298)		
S10160307	S10160415	S10160519
S10160310	S10160418	S10160520
S10160311	S10160420	S10160523
S10160314	S10160421	S10160524
S10160317	S10160422	S10160525
S10160321	S10160426	S10160526
S10160325	S10160427	S10160531
S10160328	S10160504	S10160601
S10160401	S10160506	S10160607
S10160408	S10160510	S11160304
S10160411	S10160511	S11160325
S10160412	S10160513	S11160606
S10160413	S10160517	

da Vinci Xi EndoWrist® Stapler 30 (P/N 470430)		
S10160324	S10160427	
S10160418	S10160516	

da Vinci Xi EndoWrist® Stapler 30 Curved-Tip (P/N 470530)		
S10160314	S10160414	S10160523
S10160318	S10160425	S10160603
S10160325	S10160506	S10160613
S10160401	S10160513	S10160614
S10160406	S10160518	S11160413