

Field Safety Notice
Urgent Medical Device Correction – ISIFA2018-09-C
Intra-Cardiac STOP-Use of the da Vinci® Xi EndoWrist® Suction Irrigator

1- Introduction and Reason for Field Action	<p>Dear <i>da Vinci</i> Customer,</p> <p>The purpose of this letter is to inform you that Intuitive Surgical is initiating a voluntary correction specific to the use of <i>da Vinci Xi® EndoWrist</i> Suction Irrigator (PN 480299-04) in intra-cardiac procedures. Do NOT use the <i>da Vinci Xi EndoWrist</i> Suction Irrigator for intra-cardiac procedures until you receive further communication from Intuitive Surgical that the issue is resolved.</p> <p>During internal inspections, Intuitive Surgical identified the potential for a silicone particle to be generated within the <i>da Vinci Xi EndoWrist</i> Suction Irrigator. If generated, a particle may be introduced into the patient with irrigation.</p>						
2 - Risk to Health	<p>There have been no reported injuries identified related to this issue.</p> <p>The patient risk for potential silicone particles is specific to intra-cardiac procedures only. There is a potential risk of foreign body embolism if a particle is not detected and therefore unintentionally left inside the heart. Do NOT use the <i>da Vinci Xi EndoWrist</i> Suction Irrigator for intra-cardiac procedures until you receive further communication from Intuitive Surgical that the issue is resolved.</p> <p>For non-intra-cardiac procedures, including thoracic or abdominal/pelvic procedures, it has been determined that the <i>da Vinci Xi EndoWrist</i> Suction Irrigator has minimal risk to patients. The potential particle is likely no larger than approximately 3.5mm in length, and of a benign geometry with no sharp edges. It is composed of silicone, a bio-inert material with a longstanding implantable history.</p>						
3- Affected Products	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #D9E1F2;"> <th style="text-align: left;">Part Name</th> <th style="text-align: left;">Product Number</th> <th style="text-align: left;">Lot Number</th> </tr> </thead> <tbody> <tr> <td><i>EndoWrist Suction Irrigator, Single-Use Instrument</i></td> <td>480299-04</td> <td>T10180226 and onward</td> </tr> </tbody> </table>	Part Name	Product Number	Lot Number	<i>EndoWrist Suction Irrigator, Single-Use Instrument</i>	480299-04	T10180226 and onward
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<i>EndoWrist Suction Irrigator, Single-Use Instrument</i>	480299-04	T10180226 and onward					

<p>4- Actions to be taken by the Customer/User</p>	<p>Please take the following actions to ensure all personnel are fully informed of this Field Safety Notice. Forward this letter to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff, and other members of your medical staff who perform <i>da Vinci</i> procedures.</p> <ol style="list-style-type: none"> 1. Stop-use of the <i>da Vinci Xi EndoWrist</i> Suction Irrigator PN 480299-04 for intra-cardiac procedures until further notice from Intuitive Surgical. <p>Note: The return of the affected <i>da Vinci Xi EndoWrist</i> Suction Irrigators is not required as this only impacts intra-cardiac procedures.</p> <ol style="list-style-type: none"> 2. Ensure surgeons and patient side assistants using the <i>da Vinci Xi</i> and <i>X Surgical</i> Systems read and understand the contents of this letter. 3. Complete the attached Acknowledgement Form and return it via fax or email to Intuitive Surgical per the instructions contained in the Acknowledgement Form. 4. Please retain a copy of this letter and the Acknowledgement Form for your files.
<p>5- Actions to be taken by Intuitive Surgical</p>	<ol style="list-style-type: none"> 1. A copy of this Field Safety Notice will be provided to affected customers. 2. Intuitive Surgical will provide a follow up communication once this issue is resolved. 3. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.
<p>6- Further Information & Support</p>	<p>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:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@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

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

Sincerely,

Intuitive Surgical, Sàrl

Chemin des Mûriers 1

CH-1170 Aubonne, Switzerland

+41.21.821.20.20

ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Device Correction – ISIFA2018-09-C

Intra-Cardiac STOP-Use of the da Vinci® Xi EndoWrist® Suction Irrigator

Ship-to:

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

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.

Hospital name: _____

Position:

Name (print): _____

Robotics Coordinator

Operating Room Director

Signature: _____

Risk Manager

Surgeon

Phone Number: _____

Other: _____

Email: _____

Date: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.

ATTN: REGULATORY POST MARKET FIELD ACTIONS

Subject line for email: ISIFA2018-09-C

Scan and Email to: EU.fsca@intusurg.com or Fax +41.21.821.2021

Customer Service:

- North and South America: 800-876-1310 Option 3 (4 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)