INTUITIVE

September 17, 2018

Field Safety Notice

Urgent Medical Device Recall – ISIFA2018-12-R

Da Vinci Si® Drape and Disposable Accessory Kits Pouch Seal

1- Introduction and Reason for Field Action

Dear *da Vinci* Customer,

cc: Chairman Medical Board and relevant Head of Departments

This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction for specific lots of *da Vinci Si* Instrument arm drapes, Camera arm drapes and Disposable Accessory Kits with *da Vinci Si* drapes. During internal inspection, it was found that the *da Vinci Si* drape pouches may have been distributed with wrinkles along the pouch seal that could result in a channel within the seal at a very low frequency (<1%). The pouch seal is intended to maintain sterility of the drape and a pouch seal with a channel may result in breach in the sterility of the product.

To avoid inadvertently using a *da Vinci Si* drape where a breach may be present, please locate and return all affected products in your inventory. Replacement drapes will be provided up to the nearest full box for the return of affected product.

GOOD POUCH SEAL

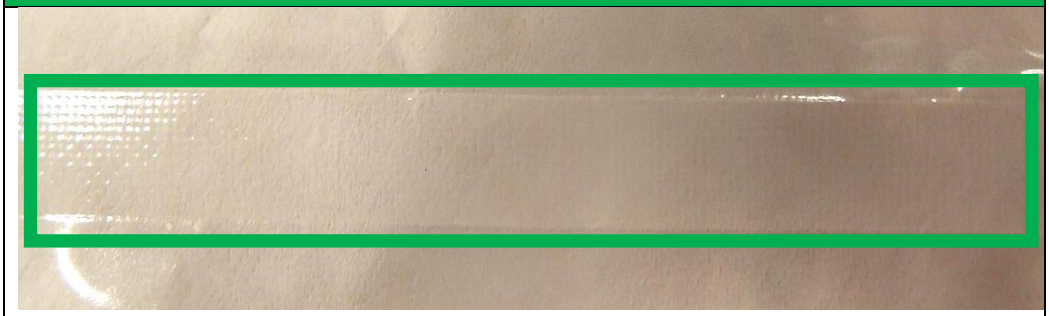

Figure 1 - Good Pouch Seal. Seal <u>is not</u> interrupted (close up view)

AFFECTED POUCH SEAL WITH STERILE BREACH PRESENT

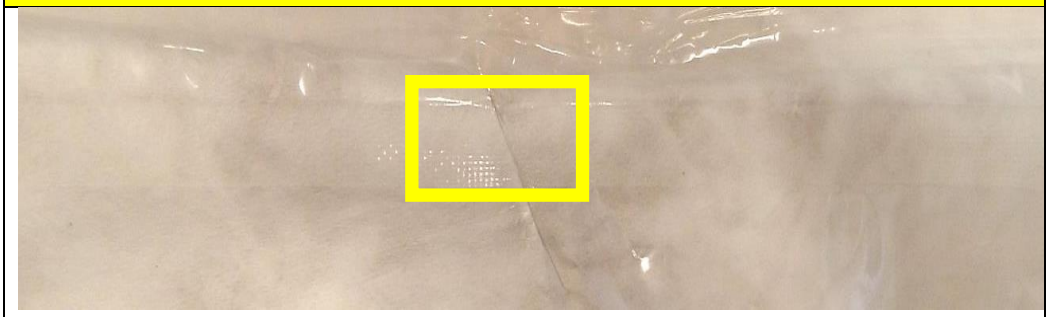

Figure 2 – Pouch Seal with a potential breach. Seal <u>is</u> interrupted. (Close up view)

<table>
<tr><td>2 - Risk to Health</td><td>The risk to patients is very low since the drapes maintain their barrier properties and are not intended to come in direct contact with the patient.

The likelihood of unintentional direct contact between the drapes and the patient is very remote. Since drapes are single-use disposable products that are not re-sterilized for multiple uses, there is no risk of infections originating from previous patients or procedures.

There have been no reported adverse events related to this issue.</td></tr>
<tr><td>3- Affected Products</td><td>
<table>
<tr><th>Part Number</th><th>Product Name/Unique Device Identifier</th><th>Affected Lot Number</th></tr>
<tr><td>420015-03</td><td>Instrument Arm Drape (Box of 20)</td><td>See Appendix A for full lot numbers</td></tr>
<tr><td>420279-03</td><td>Camera Arm Drape (Box of 20)</td><td>See Appendix A for full lot numbers</td></tr>
<tr><td>420290-03</td><td>Disposable Accessory Kit, 3-Arm (Box of 5)</td><td>See Appendix A for full lot numbers</td></tr>
<tr><td>420291-03</td><td>Disposable Accessory Kit, 4-Arm (Box of 5)</td><td>See Appendix A for full lot numbers</td></tr>
</table>
</td></tr>
<tr><td>4- Actions to be taken by the Customer/User</td><td><u>Please take the following Actions:</u>
1. Locate and return all drapes with the affected part numbers and lots to Intuitive Surgical
2. Inform affected personnel when the correction has been completed.
3. Please log into the da Vinci Online Community Field Action resource to read or complete any requested actions related to this issue, at this link: https://www.davincisurgerycommunity.com/
4. In the case where the da Vinci online resource cannot be used, complete the attached Acknowledgement Form and return it via fax to Intuitive Surgical as instructed on the form.
5. Please retain a copy of this letter and the acknowledgement form for your files.</td></tr>
<tr><td>5- Actions to be taken by Intuitive Surgical</td><td>1. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Correction.
2. Replacements up to the nearest full box will be provided for the return of affected product.</td></tr>
<tr><td>6- Further Information & Support</td><td>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 (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</td></tr>
</table>

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

Sincerely,

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

ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Device Recall – ISIFA2018-12-R

Da Vinci Si® Drape and Disposable Accessory Kits Pouch Seal

Ship-to:
Hospital Name:
Address:
City, State, Zip:
SFID:
ATTENTION:

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have returned all drapes with the affected part numbers and lots to Intuitive Surgical.
3. I have ensured all appropriate personnel are fully informed of the contents of this notice.
4. I will contact Intuitive Surgical if I have any questions.

Hospital name:_____

Name (print): _____

Signature: _____

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 POST MARKET FIELD ACTIONS
Subject line for email: ISIFA2018-12-R
U.S. Fax +1(408) 523-0619, or Scan and Email: ISI.compliance@intusurg.com

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)

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Appendix A

420015-03 Instrument Arm Drape (Box of 20)

D173357	D173337A	D180047A	D180207	D180057	D180127A	D180277

420279-03 Camera Arm Drape (Box of 20)

D180437A	D180567

420290-03 Disposable Accessory Kit, 3-Arm (Box of 5)

D173047	D173557	D173017	D180127	D172917	D180137	D172827	D172897	D180197A	D172757
D173037	D173557A	D180297	D172907	D180127A	D173207	D172847	D180397	D180037	D180287
D180267	D180197	D180277	D180417	D172787	D180047	D173057	D180407	D172797	D173567
D180477	D180607								

420291-03 Disposable Accessory Kit, 4-Arm (Box of 5)

D173147	D173177	D173517	D173437	D173487	D172937	D173407	D173417	D173317	D180117
D180177	D173477	D180087	D173187	D173137	D172987	D173217	D173067	D173497	D173447
D173427	D173287	D180167	D180027	D173577	D173077	D180097	D180157	D173627	D173607
D173467	D173567	D180197	D173257	D173637	D173457	D180267	D180257	D172997	D173547
D180317	D180237	D173227	D173537	D173507	D180107	D173617	D173267	D180247	D173197
D180057	D180187	D180347	D180337	D180377	D180037	D180307	D180437	D173017	D180507