INTUITIVE

Insert Date of Mailer

New Field Safety Notice

Urgent Medical Device Recall – ISIFA2021-08-R

Metal Tip Dislodged on da Vinci Xi and X 12-8 mm Conductive Cannula Reducer

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1- Introduction and Reason for Field Action

Dear Intuitive Customer,

The purpose of this letter is to inform you that Intuitive has become aware of the potential for the metal tip on the da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11) to get dislodged from the Cannula Reducer plastic shaft. See Figure 1 for picture of da Vinci Xi and X 12-8 mm Cannula Reducer and the location of the metal tip.

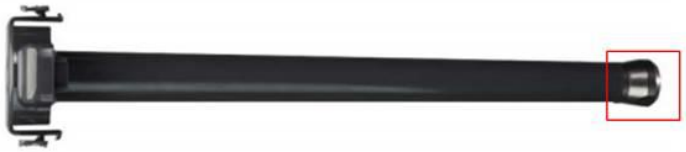

Figure 1: X/Xi 12-8 mm Reducer, 470381-11. Conductive metal tip shown in the red box.

2 - Risk to Health

If a da Vinci Xi and X 12-8mm Cannula Reducer metal tip dislodges during a procedure, the risk to health to remove a separated tip may include a minor delay in procedure while the tip is retrieved through an existing port or an additional incision. In the unlikely situation where the metal is retained in the patient, additional surgery may be required to remove the metal tip from the patient. The metal tip has a diameter of 0.560" and length of 0.440".

Since the metal tip is not sharp and non-ferromagnetic, if it is retained, it will not puncture or lacerate anatomic structures and cause harm to the patient if exposed to MRI. If the metal tip is not retrieved, the risk to health is the formation of adhesions, which may lead to a variety of symptoms including bowel obstruction and chronic abdominal pain. The most severe cases may require reoperation.

If the procedure proceeds with a Reducer without the metal tip, there is the potential for unanticipated energy leakage from an isolated endoscope inserted through the Reducer which could cause tissue damage.

3- Affected Products

Affected Product:

Part Number	Product Name	Lot Number	UDI Number
470381-11	da Vinci Xi and X 12-8 mm Cannula Reducer	See Attachment 1	0886874112588

4- Actions to be taken by the Customer/User

Locate all affected da Vinci Xi and X 12-8 mm Cannula Reducers at your site and return to Intuitive via the standard RMA process.

To help you identify the lot, the image below shows where to find the lot number on the da Vinci Xi and X 12-8 mm Cannula Reducer carton package labeling (shipper box and inner carton label).

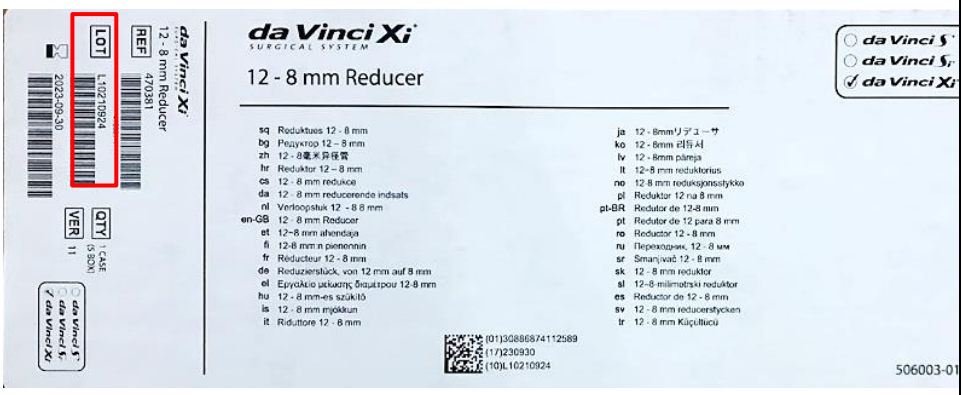

Figure 2: Example of lot number location on shipper box

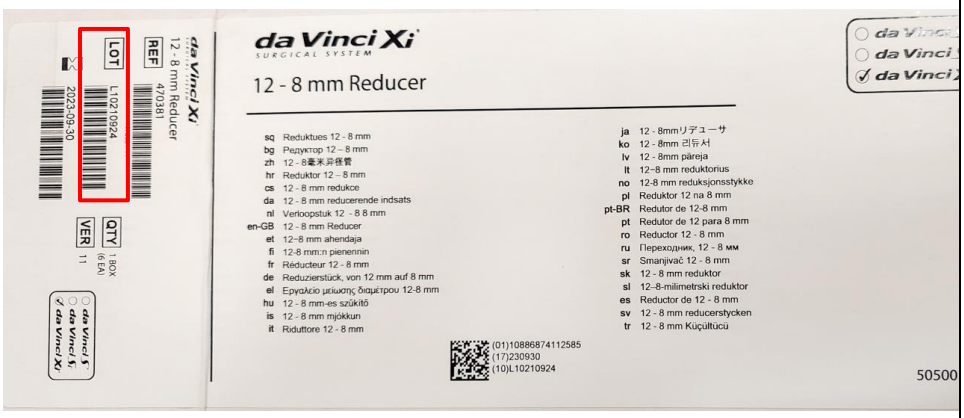

Figure 3: Example of lot number location on inner carton label

Please take the following Actions:

1. Inform necessary hospital personnel about this issue.
2. Locate all affected da Vinci Xi and X 12-8 mm Cannula Reducers at your site and return to Intuitive via the standard RMA process. To initiate the RMA process please call the applicable Customer Service Number listed in Section 6 below. Alternatively, you can also contact your Clinical Sales Representative for support with RMA initiation process.
3. Inform affected personnel when the requested actions have been completed.
4. Complete the attached Acknowledgement Form with all requested information immediately and return it via fax or email to Intuitive as instructed on the form.
5. Please retain a copy of this letter and the acknowledgement form for your files.

5- Actions to be taken by Intuitive Surgical	Credit will be provided against each returned affected product.
6- Further Information & Support	If you need further information or support concerning this Medical Device Recall, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below: • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com

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

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac, France
+800 0821 20 20

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Attachment 1

470381-11 Cannula Reducer (Box of 6)

L10210114	L10210215	L10210305	L10210514	L10210718	L10210807
L10210115	L10210216	L10210308	L10210520	L10210719	L10210808
L10210122	L10210217	L10210309	L10210521	L10210720	L10210809
L10210125	L10210218	L10210316	L10210527	L10210722	L10210812
L10210128	L10210219	L10210317	L10210528	L10210731	L10210813
L10210204	L10210225	L10210318	L10210529	L10210801	L10210819
L10210205	L10210226	L10210321	L10210715	L10210803	L10210924
L10210211	L10210301	L10210322	L10210716	L10210805	L11210111
L10210212	L10210304	L10210513	L10210717	L10210806	L11210316

M10210330	M10210408	M10210415	M10210423
M10210331	M10210409	M10210416	M10210429
M10210405	M10210412	M10210422	M10210430

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ACKNOWLEDGMENT FORM

New Field Safety Notice

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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 if I have any questions.

☐ I have reviewed my current inventory and have located _____ **Units** AND/OR _____ **Boxes** of affected lots and will be contacting Intuitive to return the affected products.

☐ I confirmed that I **do not have** any remaining affected Cannula Reducers (470381-11) at my site.

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
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2021-08-R Conductive Reducer Tip
Scan and Email: EU.FSCA@intusurg.com or Fax: +800 0821 2021 / +41 21 821 2021

Customer Service:

- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)