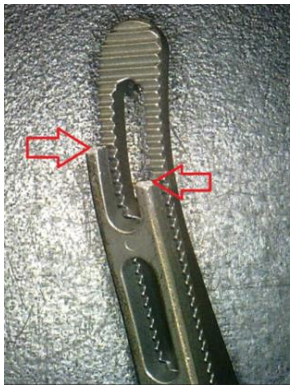
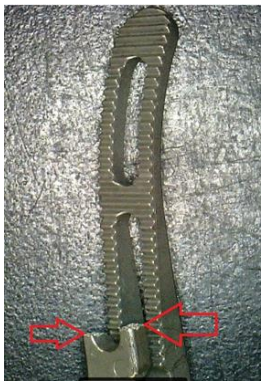
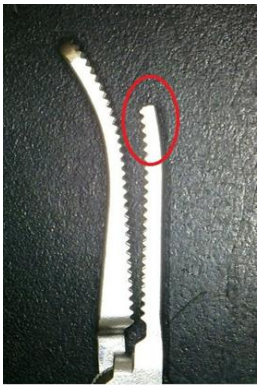
<Month Day, Year>

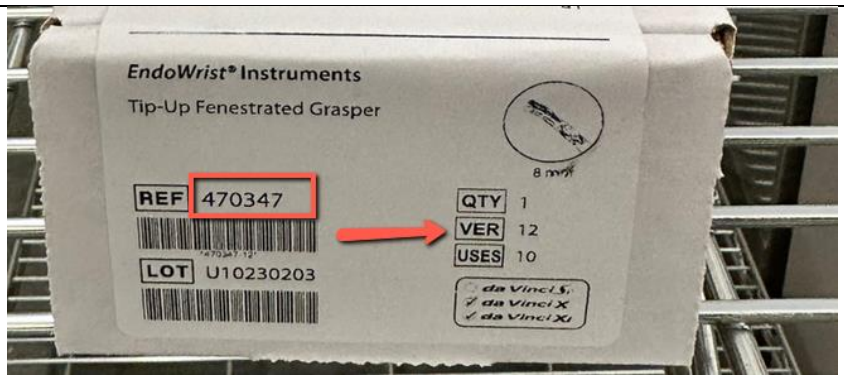
New Field Safety Notice

Urgent Medical Device - Recall of the da Vinci Xi/X Tip-Up Fenestrated Grasper (470347-12)

(ISIFA2023-02-R)

1- Introduction and Reason for Field Action	Dear Intuitive Customer, This Field Safety Notice is to notify you that Intuitive has become aware of an issue related to the manufacturing process of the grips on the da Vinci Xi/X Tip-Up Fenestrated Grasper. This issue **only pertains** to **version -12** of this instrument, no other version is impacted. This manufacturing issue has the potential to cause breakage on both upper and/or lower grips (Figures 1, 2, and 3.) Figure 3 provides a visual of the upper and lower grips, for your reference. The upper grip is shown on the left and the lower grip is shown on the right. If these breaks occur during use, it may result in fragments falling inside the patient.  Figure 1. Mid breakage  Figure 2. Base Breakage  Figure 3. Tip Breakage As a result, all affected product in your inventory should be returned to Intuitive as described in the Section 4 of this Field Safety Notice.
2 - Risk to Health	To date, 9 Adverse Events*/Serious Incidents** associated with this issue have been reported worldwide. The hazard of fragment generation exists if the instrument grip breaks during use in a procedure. Fragments that fall into the patient may be either detected or undetected. If the grip fragment is not immediately detected, it may be retained in the patient. The clinical impact of fragment retention depends upon the type of surgery performed. An unretrieved fragment within the abdominal and pelvic cavity could result in harms ranging from small bowel obstruction able to be managed non-surgically to the formation of adhesions causing female infertility or reoperation to remove the retained fragment. During intra-cardiac surgery, retained particulate

	may pose the risk of foreign body embolism, resulting in stroke. For transoral procedures, retained fragment or particulate could be expelled via cough upon extubation, or if a fragment migrates into the gastrointestinal tract, it will be eliminated from the body with no harm to the patient. If the fragment falls within the surgical field of view, the surgeon should immediately attempt to retrieve the component and withdraw it from the operative field through an existing cannula port. If a fragment falls outside of the surgical view, an extensive search to retrieve the fragment could result in a procedure delay of more than 30 minutes, the need for imaging techniques to locate the fragment, or a conversion to laparoscopic or open surgery. Detection of a broken instrument grip prior to procedure can be achieved by adhering to the recommended instrument inspection process prior to each case (per User Manual instruction). This detection may also happen during reprocessing. If detected prior to procedure, impact to patient health would be limited to a negligible delay to the start of the procedures. The Tip-Up Fenestrated Instrument grips are made of stainless steel material and not likely to pose any toxicological concerns.
3- Affected Products	Part Number 470347-12 (Tip-Up Fenestrated Grasper) UDI: 00886874112496 Note: This issue is exclusively limited to part number 470347-**12** of this instrument. Please see photos below of where the version number is located on the instrument casing (Figure 4) as well as the instrument box (Figure 5).  Figure 4. Location of Part Number and Version on instrument casing

	 Figure 5. Location of Part Number and Version on Instrument Box
4- Actions to be taken by the Customer/User	**Locate and return all 470347-12 in your inventory by requesting RMA number via email to EU Customer Service:** <mail merge local CS email address>. If you have shared these products with other sites, please make sure appropriate staff at the site receive and understand this notification so they locate and return their affected product. Please ensure to include the field action number "**ISIFA2023-02-R**" in your return notes. **Please take the following Actions:** 1. Read and understand the contents of the letter 2. Locate and return all 470347-12 in your inventory by sending an email with quantities and lot numbers to EU customer service: <mail merge local CS email address>. 3. Notify all surgeons and personnel using da Vinci Xi/X Tip-Up Fenestrated Graspers PN 470347-12 that they should review and understand the contents of this letter. 4. Complete the attached Acknowledgement Form 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. 6. Inform Intuitive of any Adverse Events*/Serious Incidents** or quality problems concerning the use of the subject device via the standard complaint process.
5- Actions to be taken by Intuitive	Credit for remaining uses will be issued, for the return of affected products. Intuitive has ceased production of version **-12** of the Tip-Up Fenestrated Grasper and this version will no longer be available. Version **-11** of the Tip Up Fenestrated Grasper i.e. PN 470347-**11** is unaffected by this issue and is available for customers to use.
6- Further Information & Support	If you need further information or support concerning this Medical Device Notification, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below: • Europe: +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 may be notified as per local regulation requirement of this Medical Device Notification.

Sincerely,

Intuitive
<mail merge local office address>

Definitions:
* Adverse Event is defined as “an event or incident that led to a death, serious injury, or serious deterioration in the state of health of a patient, user, or other person; if the event or incident was wholly or partially caused by the device or by shortcomings in the information supplied with the device.“
**Serious Incident (EUMDR 2017/745) is defined as “any incident that directly or indirectly led, might have led or might lead to any of the following:

a. the death of a patient, user or other person
b. the temporary or permanent serious deterioration of a patient’s, user’s, or other person’s state of health,
c. a serious public health threat”

INTUITIVE

ACKNOWLEDGMENT FORM

New Field Safety Notice

Urgent Medical Device - Recall of the da Vinci Xi/X Tip-Up Fenestrated Grasper (470347-12)

(ISIFA2023-02-R)

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 product and will be contacting Intuitive to return the affected products.

☐ I confirmed that I **do not have** any remaining affected Tip-Up Fenestrated Graspers (470347-12) 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: ISIFA2023-02-R
Scan and Email: EU.FSCA@intusurg.com or Fax: +800 0821 2021 / +41 21 821 2021

Customer Service:

Europe: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com