Date :_____

New Field Safety Notice

Urgent Medical Device Correction – Pitch Cable Failures on da Vinci X and Xi Tenaculum Forceps and Small Graptor™ (ISIFA2024-10-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice is to notify you that Intuitive has observed an increase in complaints regarding pitch cable failure on the Tenaculum Forceps (PN 470207) and Small Graptor (PN 470318).

The images below, Figure A, shows an intact pitch cable in the Tenaculum Forceps and Figure B shows an intact pitch cable in the Small Graptor.

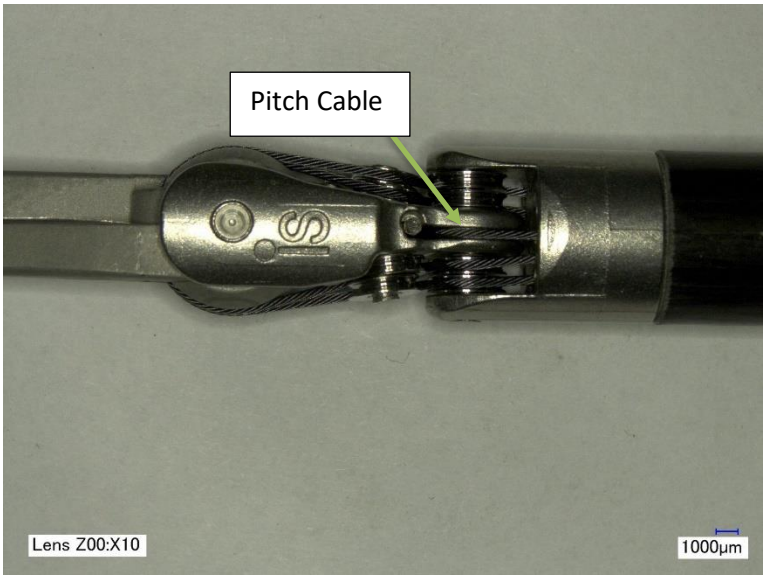


Figure A: 10x Magnified example of an intact pitch cable on an da Vinci Xi Tenaculum Forceps instrument.

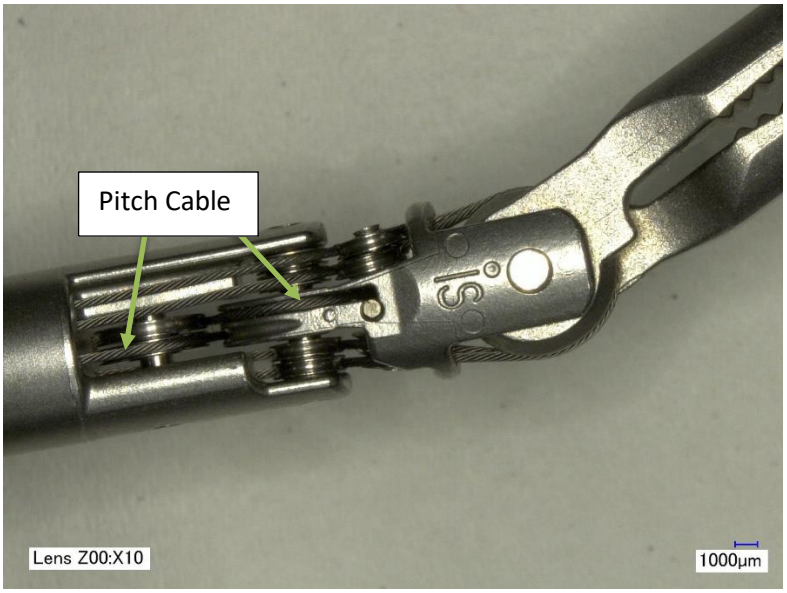
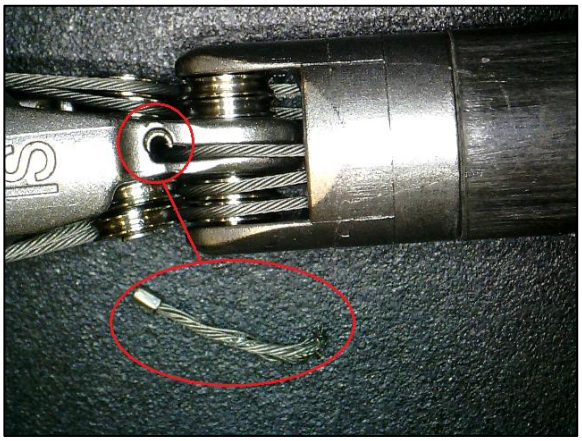


Figure B: 10x Magnified example of an intact pitch cable on an da Vinci Xi Small Graptor instrument.

	A pitch cable can fail partially (i.e., frayed) or completely (i.e., broken). A broken pitch cable can lead to loss of pitch functionality, exposure to frayed cables, or the potential for tungsten cable particulate to fall into the patient. Pitch cable failure may also result in a fragment of the pitch cable and its end-crimp becoming dislodged from the instrument (See Figure C).  **Figure C: Example of a pitch cable fragment.** Both the Tenaculum Forceps and Small Graptor use an end crimp design at the distal end, where if the pitch cable breaks it is possible for a segment of the crimp side of the cable to fall out as a fragment and into the patient. As with all our instruments, we urge adherence to the warnings and cautions as described in your user manuals. If you experience a cable failure, please be sure to inspect for any fragments before completing the procedure.
2 - Risk to Health	The failure may be detected prior to the procedure or intraoperatively. **<u>Intraoperatively:</u>** <u>*Potential for Fragment*</u>: If the instrument fails during surgery, there is potential for a fragment to separate from the pitch cable as shown in Figure C. Visible fragments can be extracted by the surgeon with surgical instruments or irrigated and suctioned out of the patient. Such attempts to retrieve material could lead to a prolonged surgery. Retrieval of fallen particulate by the user may incur a minor procedure delay (< 30 minutes). <u>*Exposure to frayed cables*</u>: If a frayed cable occurs, there can be unintended interaction between tissue and the cable. This interaction could result in tissue injury requiring intervention like physical pressure, cauterization, or suturing. <u>*Cable Particulates*</u>: It is possible that tungsten cable particulate could fall into the patient if cable failure occurs. Retrieval of fallen particulate by the user may incur a minor procedure delay (< 30 minutes). Tungsten has a safe biocompatibility profile and is MRI-compatible, so any retained cable material is unlikely to cause adverse biological reaction.

INTUITIVE

<table>
<tr><td></td><td><u>Identified Prior to Procedure:</u>
A damaged pitch cable may be observed prior to the procedure, during initialization or during reprocessing. If a pitch cable failure is detected prior to use, the affected instrument could be replaced with a backup potentially resulting in a minor delay (< 30 minutes) at the start of the procedure.

From October 1, 2022, through August 31, 2024, one adverse event was reported due to pitch cable failures in the European Region.</td></tr>
<tr><td>3- Affected Products</td><td>
<table>
<tr><th>Part Number*</th><th>Product Name</th><th>Unique Device Identifier</th><th>Affected Version Number</th></tr>
<tr><td>470207</td><td>Tenaculum Forceps</td><td>00886874112366</td><td>Version 12 and Below</td></tr>
<tr><td>470318</td><td>Small Graptor</td><td>00886874112441</td><td>Version 14 and Below</td></tr>
</table>
*See Appendix A to determine the version number of the instruments.

The pitch cable failure rate for the period of October 2022 through August 2024 is 0.62% for Tenaculum Forceps and 0.41% for Small Graptor worldwide. This rate is calculated by dividing number of complaints received for pitch cable failure by total number of procedures performed.
</td></tr>
<tr><td>4- Actions to be taken by the Customer/User</td><td>As a reminder, when using the Tenaculum Forceps and the Small Graptor instruments, please refer to and follow the instructions, warnings and cautions provided in the General Overview and EndoWrist Instrument chapters of the da Vinci X/Xi Instruments and Accessories User Manual and Reprocessing Instructions User Manual.

• In addition, please reference section titled “General Precautions for Intraoperative Use of Instruments” in the da Vinci X/Xi Instruments & Accessories User Manual and the section titled “General Cautions and Warnings” in the da Vinci X/Xi Reprocessing Instructions User Manual.
• Please refer to Appendix B for additional images for detection of pitch cable failures.

If you observe any failed (frayed or broken) pitch cables prior to use, during procedure, or during reprocessing, please stop use of instrument, remove from use and inform Intuitive via the standard complaint process.

<u>Please take the following standard actions related to Field Safety Notifications:</u>

• Complete the attached Acknowledgement Form immediately and return it via email to Intuitive as instructed on the form
• Ensure that the content of this notification is passed on to all those who need to be aware within your organization or functions where the affected instruments have been transferred.
• Retain a copy of this notification, place a copy with your affected system ensuring it is placed likely to be seen/viewed by the operators, and keep the acknowledgement form for your files.
• Inform Intuitive of any Serious Incidents* or quality problems concerning the use of the subject instruments via the standard complaint process.
• Additionally, if Serious Incidents* or quality problems are experienced, please follow your standard reporting process to your health authority, as applicable.</td></tr>
</table>

5- Actions to be taken by Intuitive	Intuitive is providing this notice to request continued adherence to the warnings and cautions as described in the User Manuals. Intuitive is committed to patient safety and is constantly evaluating opportunities to improve product performance. For both instruments, an improvement project has been initiated to increase pitch cable robustness as well as reduce the potential for a fragment. ➢ A follow up will be provided to affected customers once updated product is available.
6- Further Information & Support	If you need further information or support concerning this Field Safety Notice, 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 has been notified of this Field Safety Correction Action.

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
Pessac FRANCE

Definitions:
*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

ACKNOWLEDGEMENT FORM
New Field Safety Notice
Urgent Medical Device Correction - Pitch Cable Failures on da Vinci X and Xi Tenaculum Forceps and Small Graptor™
(ISIFA2024-10-C)

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 ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive 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 EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2024-10-C
Scan and Email to: EU.FSCA@intusurg.com

Customer Service:

- Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or eucs@intusurg.com

Appendix A: Determining Version Number of Instrument

Affected products include all da Vinci X and Xi Tenaculum Forceps Version 12 and below and all da Vinci X and Xi Small Graptors Version 14 and below.

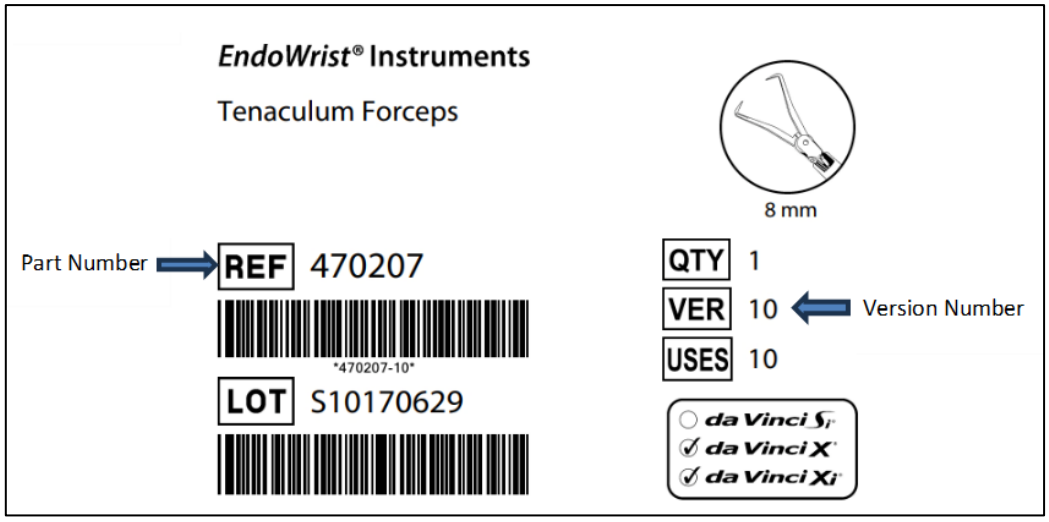


Figure D: Location of Part Number and Version on Instrument Box

Appendix B: Additional Images to Identify Pitch Cable Failure

In addition to instructions provided in da Vinci X and Xi Instruments and Accessories User Manual, the following section provides additional images to help with identification of a pitch cable failure (broken and frayed).

Pitch Cable breaks may be detected visually prior to use or through the loss of instrument function during use. Frayed and broken pitch cables may also be identified through endoscopic view.

The inspection is limited to the instrument wrist and does not require magnification as shown in the pictures below. Articulation of the instrument wrist is not required but inspection of cables on both sides of the wrist is required.

1. Inspection prior to use

Prior to use, visually inspect all instruments for broken or frayed cable per Figure E, F and G below

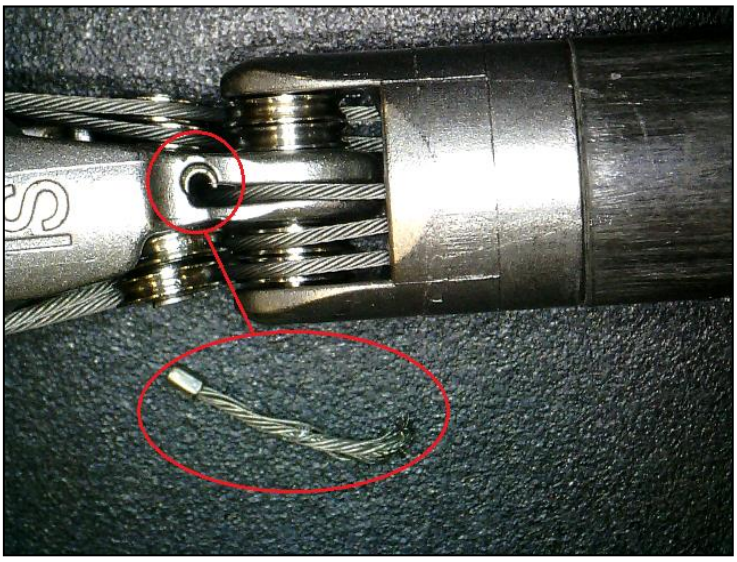


Figure E: Example of a pitch cable fragment.

Figure F: Broken Pitch Cable

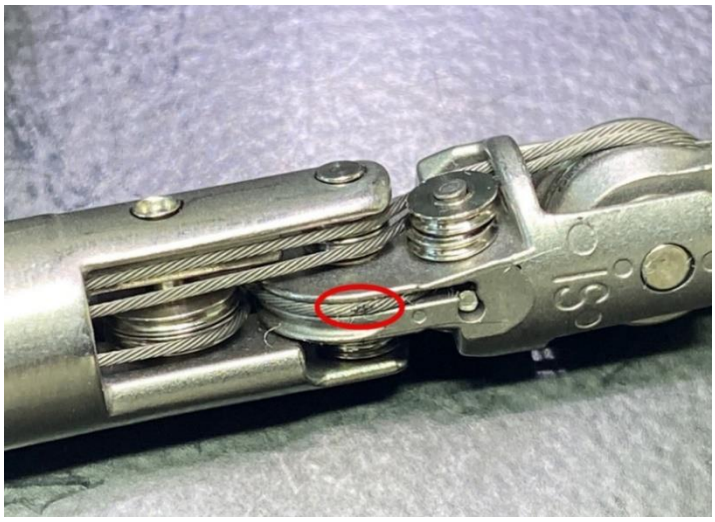


Figure G: Frayed Pitch Cable

2. Detection during use

A. Broken Cable

- If an instrument with a broken pitch cable is installed on the system, it could result in engagement failure which will be immediately detected by the surgeon.
- If a pitch cable breaks intraoperatively on an installed instrument, the failure would be immediately detected by the surgeon as it would result in imprecise motion. For example, the surgeon could command a motion at the hand controls, but the instrument may not respond as expected. Imprecise motion may manifest as reduced ability to retract tissue. If the affected instrument was grasping tissue at the time of cable breakage, the position of the grasped tissue may change due to gravity.

B. Frayed Cable

- Frayed pitch cables may be identified through endoscopic view. Existing frayed pitch cable failure will not result in affected pitch motion as the pitch cable will remain connected.
- Frayed cables that are not visually identified would be unlikely to cause any unintended tissue interactions.