

Field Safety Notice

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

Dear Intuitive Customer,

We are writing to inform 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.

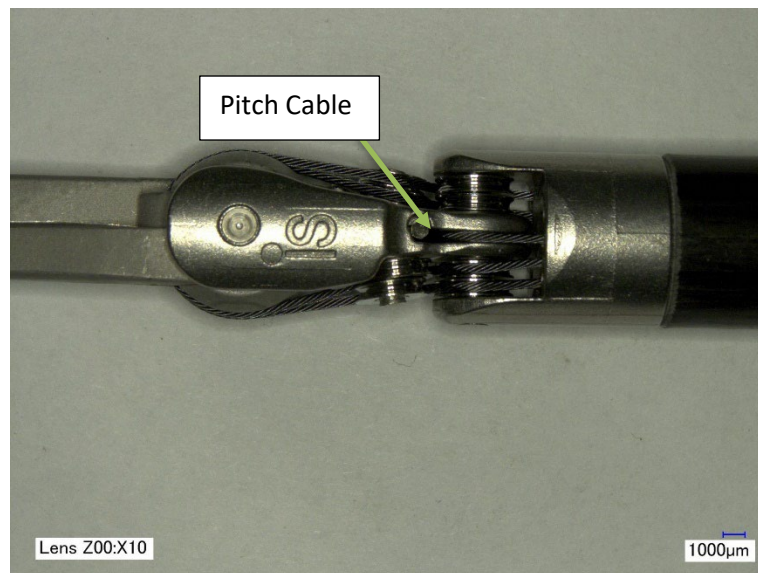


Figure A: 10x Magnified example of an intact pitch cable on an da Vinci Xi Tenaculum Forceps instrument.

1- Introduction
and Reason for
Field Action

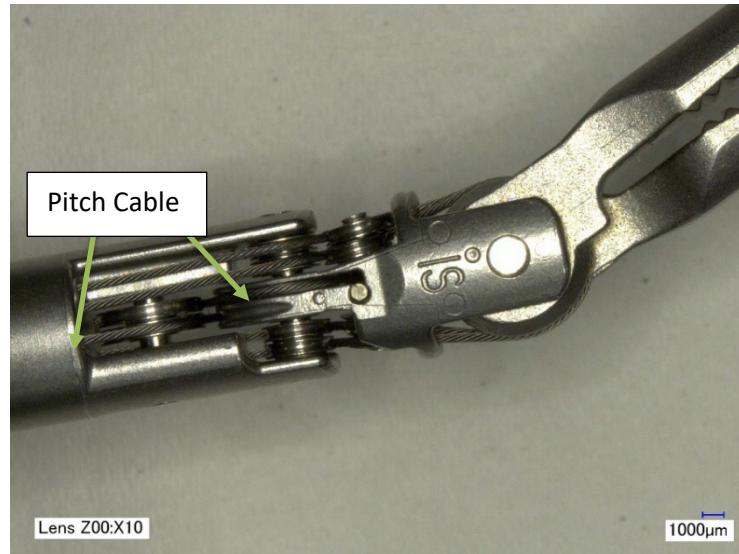


Figure B: 10x Magnified example of an intact pitch cable on an da Vinci Xi Small Graptor instrument.

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).

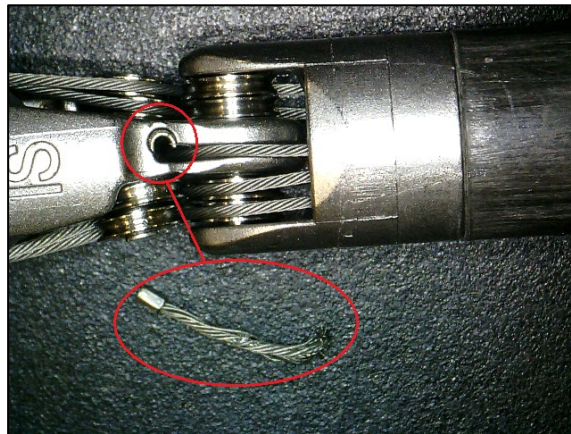


Figure C: Example of a pitch cable fragment.

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.

<p>2 - Risk to Health</p>	<p>The failure may be detected prior to the procedure or intraoperatively.</p> <p><u>Intraoperatively:</u></p> <p><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.</p> <p><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.</p> <p><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. Tungsten has a safe biocompatibility profile and is MRI-compatible, so any retained cable material is unlikely to cause adverse biological reaction.</p> <p><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 delay to the start of the procedure.</p>												
<p>3- Affected Products</p>	<table border="1" data-bbox="420 1089 1365 1278"> <thead> <tr> <th>Part Number*</th> <th>Product Name</th> <th>Unique Device Identifier</th> <th>Affected Version Number</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>These instruments can be used with the da Vinci X, da Vinci Xi, and da Vinci 5 systems.</p> <p>*See Appendix A to determine the version number of the instruments.</p>	Part Number*	Product Name	Unique Device Identifier	Affected Version Number	470207	Tenaculum Forceps	00886874112366	Version 12 and Below	470318	Small Graptor	00886874112441	Version 14 and Below
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470318	Small Graptor	00886874112441	Version 14 and Below										
<p>4- Actions to be taken by the Customer/ User</p>	<p><u>Please take the following Actions:</u></p> <ol style="list-style-type: none"> 1. 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. <ol style="list-style-type: none"> a. 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. b. Please refer to Appendix B for additional images for detection of pitch cable failures. 												

	<ol style="list-style-type: none"> 2. 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 DTG Medical Sdn. Bhd. via the standard complaint process. 3. Please display this communication with your systems; ensure it is in a place likely to be seen/viewed by operators. 4. Complete the attached Acknowledgement Form immediately and return it via fax or email to DTG Medical Sdn. Bhd. as instructed on the form. 5. Please retain a copy of this letter and the acknowledgement form for your files. 6. Inform DTG Medical Sdn. Bhd. of any Adverse Events*/Serious Incidents** or quality problems concerning the use of the subject devices via the standard complaint process.
5- Actions to be taken by Intuitive	<ol style="list-style-type: none"> A. Intuitive is providing this notice to request continued adherence to the warnings and cautions as described in the User Manuals. B. 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. <ul style="list-style-type: none"> ○ A follow up will be provided to affected customers once updated product is available.
6- Further Information & Support	<p>If you need further information or support concerning this Field Safety Notice, please contact your Clinical Sales Representative or contact DTG Medical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • 1800 812 011 or mail: customers.my@devicetechnologies.asia

Please be informed that the Medical Device Authority (MDA) will be notified of this Field Safety Notice.

Sincerely,

DTG Medical Sdn. Bhd.

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



ACKNOWLEDGEMENT FORM

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: <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.

Hospital name: _____

Position:

Name (print): _____

Robotics Coordinator

Operating Room Director

Signature: _____
and stamp

Risk Manager

Surgeon

Phone Number: _____

Other: _____

Email: _____

Date: _____

**PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO DTG Medical Sdn. Bhd.
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2024-10-C**

Scan and Email: <regulatory@dtgmedical.com.sg> Customer Service:

- 1800 812 011 or mail customers.my@devicetechnologies.asia

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.

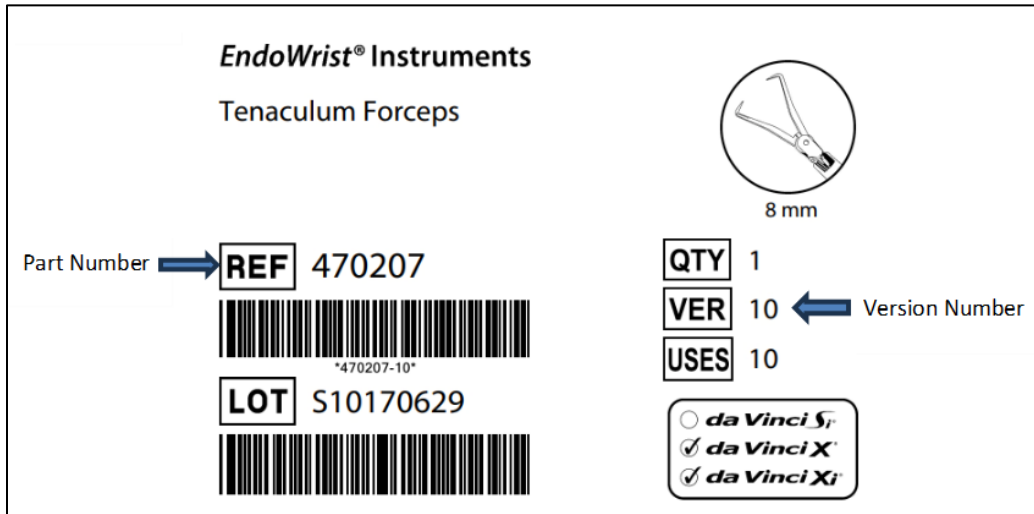


Figure D: Location of Part Number and Version on Instrument Box

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

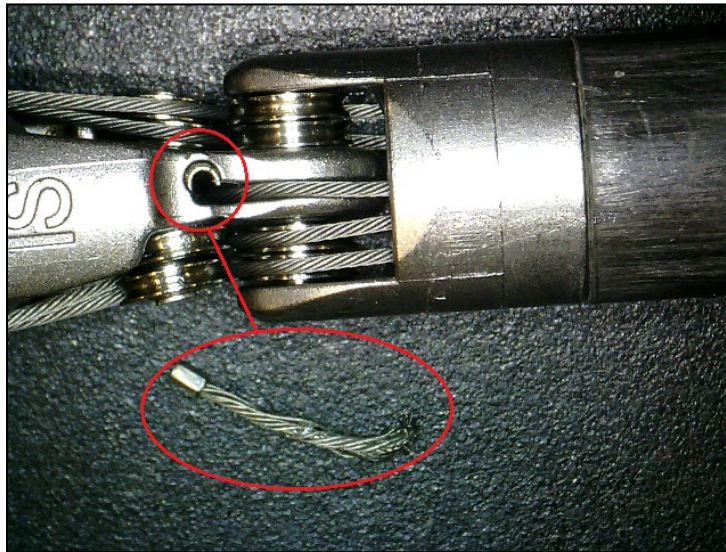


Figure E: Example of a pitch cable fragment.



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.