INTUITIVE

Fecha: 10 de febrero de 2026

Urgente: Retiro de dispositivos médicos (actualización)

Fallos en cables de agarre en instrumentos reutilizables da Vinci X, da Vinci Xi y dV5 con mordazas (ISIFA2024-09-C)

1- Introducción y motivo de la acción en el campo	Estimado cliente intuitive, Le escribimos para informarle de una actualización a la Retirada Urgente de Dispositivos Médicos (RES 95938) enviada el 19 de diciembre de 2024 respecto a la falla del cable de agarre en los instrumentos reutilizables de da Vinci X, da Vinci Xi y dV5 con mordazas (véase la comunicación original en el Apéndice A). Esta retirada se inició originalmente debido al aumento de quejas sobre cables de agarre deshilachados o rotos en instrumentos reutilizables con mordazas. Ya están disponibles versiones actualizadas de los ocho instrumentos afectados que se enumeran a continuación y son las únicas versiones que se están enviando. Las nuevas versiones incluyen un cable de agarre mejorado que reduce la posibilidad de que el cable se deshilache o se rompa.
2 - Riesgo para la salud	Según lo especificado en la comunicación original, los riesgos asociados a este problema son los siguientes: **<u>Pérdida de funcionalidad de agarre:</u>** En la mayoría de los casos, la falla total de un cable de agarre se detectaría inmediatamente debido a la pérdida de funcionalidad del agarre. La pérdida de funcionalidad de agarre podría provocar un retraso en el procedimiento para reemplazar un instrumento, restablecer la retracción del tejido agarrado o recuperar una aguja de sutura caída. Es posible que la pérdida total de la funcionalidad del agarre pueda provocar lesiones o sangrado tisular si el tejido agarrado se desprende de las empuñaduras e interactúa con otro instrumento, o si una posición inesperada del agarre provoca una interacción no intencionada con el tejido. En los instrumentos de energía bipolar, la falla total del cable de agarre puede causar una incapacidad para cerrar suficientemente las mordazas para la entrega de energía bipolar. Si el sangrado ocurre en ese momento, puede ser necesario otro método de intervención para recuperar la hemostasis. **<u>Exposición a cables deshilachados:</u>** Si se produce un cable deshilachado, puede haber una interacción no intencionada entre el tejido y el cable. Esta interacción podría resultar en lesiones tisulares que requieran intervención como presión física, cauterización o suturas. **<u>Partículas de cable:</u>** La rotura o deshilachado del cable no provocará la fragmentación de todo el cable (por ejemplo, la separación de una parte significativa del cable), ya que queda retenido en ambos extremos dentro del eje del instrumento. Es posible que partículas de cable de tungsteno caigan en el paciente si se produce un fallo del cable. La recogida de partículas caídas por parte del usuario puede suponer un retraso en el procedimiento. El tungsteno

tiene un perfil de biocompatibilidad seguro y es compatible con resonancia magnética, por lo que cualquier material de cable retenido es poco probable que cause una reacción biológica adversa.

Por favor, consulte el Apéndice A para más detalles.

3-Productos afectados

Los productos asociados a esta actualización se enumeran a continuación. Se ha identificado que estos instrumentos tienen una tasa de fallo del cable de agarre superior a lo previsto y superior al umbral de aceptabilidad de Intuitive.

Part Number	Product Name	Unique Device Identifier	Affected Version Number
470205	Fenestrated Bipolar Forceps	00886874112359	17 and below
471172	Maryland Bipolar Forceps	00886874119792	17 and below
471309	Mega Suturecut Needle Driver	00886874119815	16 and below
471205	Fenestrated Bipolar Forceps (EUP)	00886874119808	18 and below
471296	Large Suturecut Needle Driver	00886874121504	08 and below
470179	Monopolar Curved Scissors	00886874112298	19 and below and 22*
471400	Long Bipolar Grasper	00886874121528	10 and below
471093	Prograsp	00886874119785	11 and below

*470179 versión 22 está disponible solo en China. Las versiones 21, 23 y todas las futuras contendrán el diseño actualizado y no se verán afectadas por esta retirada.

Estos instrumentos pueden usarse con los sistemas da Vinci X, da Vinci Xi y dV5.

Utilice la tabla anterior para determinar qué versiones de los productos afectados están incluidas. Consulta las dos imágenes de abajo para determinar qué versión de instrumento tienes.
Las figuras A y B a continuación ofrecen orientación para localizar el número de pieza y la versión en el empaquetado y la carcasa del instrumento.

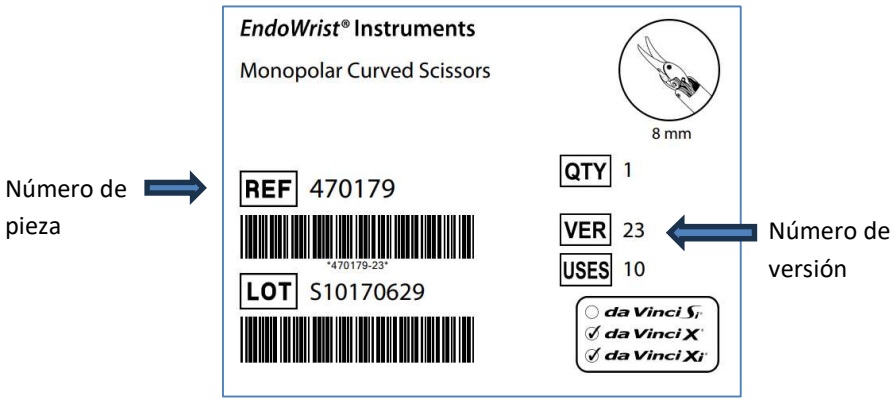
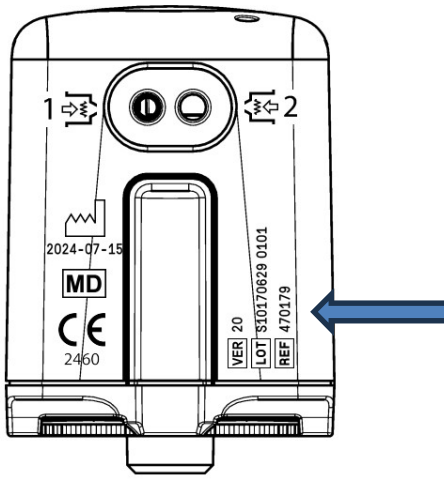


Figura A: Ubicación del número de pieza y la versión en la caja de instrumentos

	 Figura B: Ubicación de la pieza, lote y número de versión en la carcasa del instrumento
4-Acciones que debe realizar el Cliente/Usuario	**Por favor, tome las siguientes acciones:** 1. Rellene el Formulario de Acuse de Recibo adjunto y devuélvalo inmediatamente por fax o correo electrónico a Intuitive, tal y como indica el formulario. 2. Por favor, identifique y ponga en cuarentena cualquier producto afectado. 3. Los productos afectados mencionados anteriormente pueden ser devueltos enviando un correo electrónico con cantidades y números de lote al servicio de atención al cliente de tu zona. 4. Por favor, asegúrese de incluir el número FSCA “ISIFA2024-09-C” en sus notas de declaración. 5. Se proporcionarán reemplazos según el número de vidas restantes sin ningún coste adicional. 6. Si has compartido o distribuido estos productos con otros sitios, por favor asegúrate de que el personal correspondiente reciba y entienda esta notificación para localizar y devolver el producto afectado. 7. Por favor, conserve una copia de esta carta y el formulario de acuse de recibo para sus archivos. 8. Informa a Intuitive sobre cualquier Evento Adverso/Incidente Grave** o problema de calidad relacionado con el uso de los dispositivos en cuestión a través del proceso estándar de reclamación. 9. Para clientes en EE. UU.: a) Las reacciones adversas o problemas de calidad experimentados con el uso de este producto pueden ser comunicados al programa de Notificación de Eventos Adversos MedWatch de la FDA, ya sea en línea, por correo ordinario o por fax. b) Complete y envíe el informe en línea por correo o fax: Descargue el formulario o llame al 1-800-332-1088 para solicitar un formulario de notificación, luego complete y devuelva a la dirección indicada en el formulario previamente dirigido o envíe por fax al 1-800-FDA-0178.

5 - Acciones que debe realizar Intuitivo	1. Una vez que el(los) instrumento(s) devuelto(s) se reciban mediante el proceso estándar de RMA, se verificará el número de vidas restantes. 2. Se determinará el total de vidas restantes para el lugar y se enviarán los instrumentos de reemplazo en función de las vidas totales restantes por instrumento, redondeando al alza cuando corresponda. Por ejemplo: si un instrumento tiene 3 vidas restantes y un segundo instrumento tiene 5 vidas restantes, se enviará un instrumento de reemplazo
6-Información y Soporte Adicional	Si necesita más información o apoyo sobre la Retirada Urgente de Dispositivos Médicos (Actualización), por favor contacte con su Representante de Ventas Clínicas o contacte con Intuitive Customer Service en los números que se indican a continuación: 1. Norteamérica y Sudamérica: (800) 876-1310, Opción 3 (de 4 a 17:00 PST) o por correo: customerservice@intusurg.com. 2. Europa, Oriente Medio, Asia y África: +800 0821 2020 o +41 21 821 2020 (8 a.m. a 6 p.m. CET) o eucs@intusurg.com 3. Corea del Sur: 02-3271-3200 (9:00 a 18:00 KSTJ) o support.korea@intusurg.com 4. Japón: 0120-56-5635 o 03-5575-1362 (9 am a 6 pm JST) o csjapan@intusurg.com 5. India: +1-800-103-6952 (9 am a 6 pm IT) 6. Taiwán: +0800-86-8181 (9 am a 6 pm CT)

Para su conocimiento, la Autoridad Reguladora correspondiente para su región ha sido notificada sobre la Urgencia de este Dispositivo Médico (Actualización).

Atentamente,

Intuitive
<mail merge local office address>

Definiciones:
* Evento adverso se define como "un evento o incidente que ha provocado una muerte, lesión grave o deterioro grave del estado de salud de un paciente, usuario u otra persona; si el evento o incidente fue causado total o parcialmente por el dispositivo o por deficiencias en la información proporcionada con el dispositivo."
**Incidente Grave (EUMDR 2017/745) se define como "cualquier incidente que directa o indirectamente haya llevado, pudo haber conducido o podría conducir a cualquiera de lo siguiente:

1. la muerte de un paciente, usuario u otra persona
2. el deterioro grave temporal o permanente del estado de salud de un paciente, usuario u otra persona,
3. una grave amenaza para la salud pública

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FORMULARIO DE ACUSE DE RECIBO

Urgente: Retiro de dispositivos médicos (Actualización)

Fallos en cables de agarre en instrumentos reutilizables da Vinci X, da Vinci Xi y dV5 con mordazas (ISIFA2024-09-C)

Ship-to:
Hospital Name: <mail merge>
Address: <mail merge>
City, State, Zip: <mail merge>
SFID: <mail merge>
ATTENTION: <mail merge>

COMPLETE TODA LA INFORMACIÓN REQUERIDA Y ENVÍELA DE INMEDIATO

1. He recibido y leído este aviso.
2. Me he asegurado de que todo el personal apropiado esté plenamente informado del contenido de este aviso.
3. Me comunicaré con Intuitive si tengo alguna pregunta.

Nombre del hospital: _____

Nombre (en letra de imprenta): _____

Firma: _____

Número de teléfono: _____

Correo electrónico: _____

Fecha: _____

Puesto:

- ☐ **Coordinador de Robótica**
- ☐ **Director de quirófano**
- ☐ **Gerente de riesgos**
- ☐ **Cirujano**
- ☐ **Otro:** _____
- ☐

POR FAVOR, ENVÍA POR FAX O CORREO ELECTRÓNICO ESTE FORMULARIO DE ACUSE DE RECIBO A Intuitive
ATENCIÓN: ACCIONES DE CAMPO DE CUMPLIMIENTO NORMATIVO
Asunto del correo electrónico: ISIFA2024-09-C
Fax de EE. UU. +1(408) 523-0619, o escanear y enviar correo electrónico: Recalls@intusurg.com

Atención al cliente:

- 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 eucs@intusurg.com
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ) or support.korea@intusurg.com
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST) or csjapan@intusurg.com
- India: +1-800-103-6952 (9 am to 6 pm IT)
- Taiwan: +0800-86-8181 (9 am to 6 pm CT)

Apéndice A: Aviso de seguridad en el campo relacionado con la falla del cable de agarre en la Da Vinci X, Xi Instrumentos Reutilizables con Mordazas

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Date: December 19, 2024

Urgent: Medical Device Correction

Grip Cable Failures on da Vinci X and Xi Reusable Instruments with Jaws (ISIFA2024-09-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

We are writing to inform you that Intuitive has become aware of an increase in complaints regarding frayed or broken cables on some da Vinci X and Xi reusable instruments. These instruments can be used with da Vinci X, da Vinci Xi, and da Vinci 5 systems. We refer to these frayed or broken cables as "failures". There are two grip cables in the instruments which control the opening and closing of the jaws of the instrument (as shown in Figure A). The grip cable is the same across all da Vinci X and Xi reusable instruments with jaws.

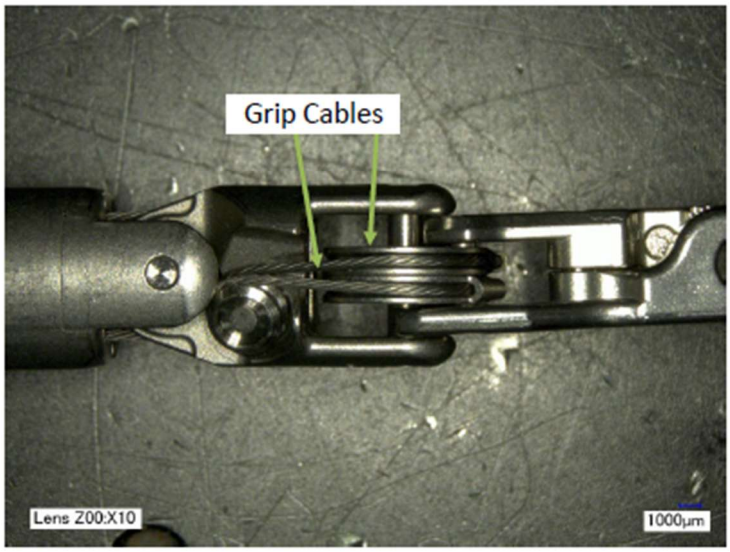

Figure A: 10x magnification of an example of an intact grip cable of a da Vinci Xi instrument.

5556045-01 Rev A ISIFA2024-09-C Page **1** of **14**
Document Template 1004273 Rev H ECO C306971
Form Template: *1010682 Rev C ECO C236769*

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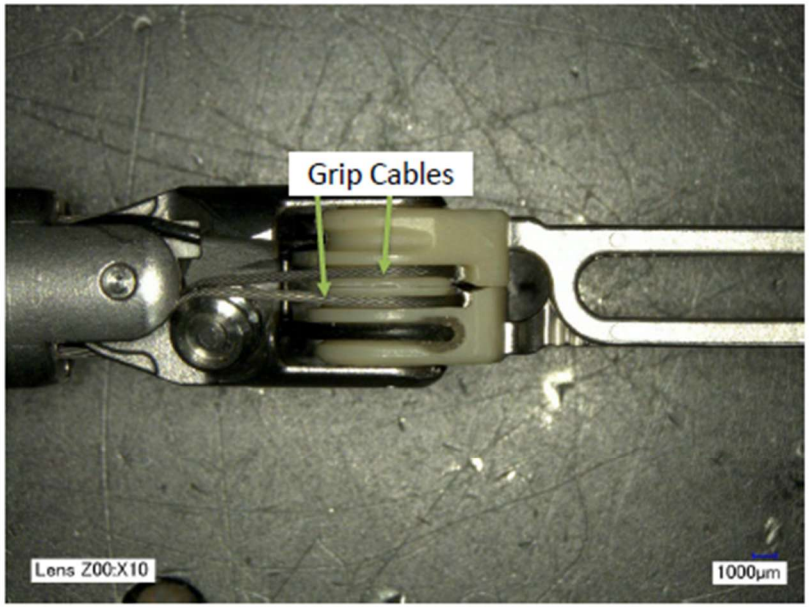

Figure B: 10x magnification of an example of an intact grip cable of a Bipolar da Vinci Xi instrument.

A grip cable can fail partially (i.e., frayed) or completely (i.e., broken). A broken grip cable can lead to loss of grip functionality, exposure to frayed cables, or the potential for tungsten cable particulate to fall into the patient. If a cable were to fail, it would be retained within the shaft of the instrument. As a result, fragments would not fall into the patient, though particulate may be generated. A partial failure might not affect grip functionality but may lead to exposure to frayed cables.

Figures C and D below show examples of broken and frayed grip cables.

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Figure C: 20x magnification of a broken grip cable on a da Vinci Xi instrument.

Figure D: 20x magnification of a frayed grip cable a da Vinci Xi instrument

Intuitive completed an investigation that reviewed grip cable failure complaints and while rates are elevated, did not identify any new or increased risks to health. Therefore, you may continue to use these instrumentsin accordance with the user manual.

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2 - Risk to Health	Complete or partial failure of a grip cable can lead to loss of grip functionality, exposure to frayed cables, and/or tungsten cable particulate. **Loss of grip functionality:** Complete failure of a grip cable would be immediately detected in most cases due to the loss of grip functionality. The loss of grip functionality could result in a minor procedure delay to replace an instrument, re-establish retraction of grasped tissue, or retrieve a dropped suture needle. It is possible that complete loss of grip functionality could result in tissue injury or bleeding if grasped tissue falls out of the grips and interacts with another instrument, or if unexpected grip positioning causes unintended interaction with tissue. For bipolar energy instruments, complete failure of grip cable may cause an inability to sufficiently close the jaws for bipolar energy delivery. If bleeding is occurring at this time, it may require alternate means of intervention to regain hemostasis. **Exposure to frayed cables:** 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. **Cable Particulates:** Cable breakage or fraying will not result in fragmentation of the entire cable, (e.g., separation of significant portion of cable) as it is retained on both ends within the shaft of the instrument. 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.
3- Affected Products	All da Vinci X and Xi reusable instruments with jaws are affected by this communication. These instruments can be used with da Vinci X, da Vinci Xi, and da Vinci 5 systems. The grip cable failure rate for the period of October 2022 through August 2024 across all da Vinci X and Xi reusable instruments with jaws is 0.82%. This rate is calculated by dividing number of complaints received for grip cable failure by total number of procedures performed using the affected reusable instruments with jaws. Refer to Appendix A for a list of affected Part Numbers. Appendix A also includes information on instrument part numbers that contributed to the increasing failure rate.
4- Actions to be taken by the Customer/User	**Please take the following Actions:** 1. Customers can continue using the products in accordance with the user manual. 2. As a reminder, when using da Vinci X and Xi reusable instruments, follow the Inspection Before Use and Warnings listed in the manual provided with your system to inspect for any broken cables. Refer to Figures C and D for examples. In

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	addition, please refer to **Appendix B** for additional images for detection of grip cable failures. 3. If you observe any failed (frayed or broken) grip 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. 4. Inform Intuitive of any Adverse Events*/Serious Incidents** or quality problems concerning the use of the subject device via the standard complaint process. 5. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. 6. Complete and submit the report Online Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.
5- Actions to be taken by Intuitive	Intuitive takes customer complaints very seriously and completed a detailed investigation on grip cable failures. This investigation concluded that the da Vinci X and Xi reusable instruments remain safe to use. Intuitive is committed to patient safety and has already started implementing updated product. The cables used in the updated product have been built using an improved process with the intent to reduce cable failure rates. Any instruments returned to Intuitive for failed cable(s) and confirmed per the RMA process, will be provided credit for remaining uses.
6- Further Information & Support	If you need further information or support concerning this Customer Communication, please contact your Clinical Sales Representative or contact Intuitive 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 eucs@intusurg.com • South Korea: 02-3271-3200 (9 am to 6 pm KSTJ) or support.korea@intusurg.com • Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST) or csjapan@intusurg.com • India: +1-800-103-6952 (9 am to 6 pm IT) • Taiwan: +0800-86-8181 (9 am to 6 pm CT)

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

Sincerely,

Intuitive

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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

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Appendix A: Affected product and updated product information

Note: Product numbers in bold in Table A1 have shown increase in grip cable failure complaints.

Table A1: Affected Product Information

Affected Product	Product Name	UDI Number
470179	Monopolar Curved Scissors (Hot Shears)	00886874112298
470205	Fenestrated Bipolar Forceps	00886874112359
471205	Fenestrated Bipolar Forceps (EUP)	00886874119808
471093	Prograsp Forceps (EUP)	00886874119785
470049	Cadiere Forceps	00886874112250
471049	Cadiere Forceps (EUP)	00886874119778
470172	Maryland Bipolar Forceps	00886874112281
471172	Maryland Bipolar Forceps (EUP)	00886874119792
470405	Force Bipolar	00886874115930
471405	Force Bipolar (EUP)	00886874120767
470400	Long Bipolar Grasper	00886874113530
471400	Long Bipolar Grasper (EUP)	00886874121528
470006	Large Needle Driver	00886874112151
471309	Mega SutureCut Needle Driver (EUP)	00886874119815
470296	Large SutureCut Needle Driver	00886874112410
471296	Large SutureCut Needle Driver (EUP)	00886874121504
470093	Prograsp Forceps	00886874112267
470309	Mega SutureCut Needle Driver	00886874112434
471006	Large Needle Driver (EUP)	00886874119754
470194	Mega Needle Driver	00886874112342
470347	Tip-Up Fenestrated Grasper	00886874112496
470401	Small Clip Appler	00886874112670
470327	Medium-Large Clip Applier	00886874112465
470230	Large Clip Applier	00886874112380
470207	Tenaculum Forceps	00886874112366
470048	Long Tip Forceps	00886874112243
471048	Long Tip Forceps (EUP)	00886874121467

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Affected Product	Product Name	UDI Number
470036	DeBakey Forceps	00886874112236
470181	Resano Forceps	00886874112304
470171	Micro Bipolar Forceps	00886874112274
471171	Micro Bipolar Forceps (EUP)	00886874121474
470033	Black Diamond Micro Forceps	00886874112229
470318	Small Graptor (grasping retractor)	00886874112441
470344	Curved Bipolar Dissector	00886874112489
471344	Curved Bipolar Dissector (EUP)	00886874121511
470001	Potts Scissors	00886874112120
470007	Round Tip Scissors	00886874112168
470190	Cobra Grasper	00886874112335
471190	Cobra Grasper (EUP)	00886874121481
470246	Atrial Retractor Short Right	00886874112397
470249	Dual Blade Retractor	00886874112403

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Intuitive is implementing updated product with an intent to reduce cable failure rates. Our ability to implement product updates across our entire portfolio is currently constrained due to manufacturing capacity and regulatory approvals. We have begun shipping updated product on *some* instruments (identified in Table A2) and are actively working on getting the updates implemented on the remainder of the products (identified in Table A3).

As noted above, availability of updated product may vary depending on region. Please contact your local Clinical Sales Representative or Customer Service to understand availability and timing for when updated product will become available for your region(s).

Table A2: Updated Product Information – Below table provides information on part numbers where updated product have been implemented. Refer to 'Updated Product Version' column for information on the version of product that has the update.

Note: All future versions will also include the updated product.

Affected Product	Updated Product Version	Product Name
470179	21*	Monopolar Curved Scissors (Hot Shears)
470205	19	Fenestrated Bipolar Forceps
471205	19	Fenestrated Bipolar Forceps (EUP)
471093	14	Prograsp Forceps (EUP)
470172	19	Maryland Bipolar Forceps
471172	19	Maryland Bipolar Forceps (EUP)
470400	12	Long Bipolar Grasper
471400	12	Long Bipolar Grasper (EUP)
470006	14	Large Needle Driver
471309	Version** 16: Starting from Lot# K11231218	Mega SutureCut Needle Driver (EUP)
470296	10	Large SutureCut Needle Driver
471296	Version 8**: Starting from K10231218	Large SutureCut Needle Driver (EUP)
470093	14	Prograsp Forceps
470309	18	Mega SutureCut Needle Driver
471006	13	Large Needle Driver (EUP)
470194	9	Mega Needle Driver
470401	12	Small Clip Appler
470327	15	Medium-Large Clip Applier
470230	15	Large Clip Applier
470207	13	Tenaculum Forceps

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Affected Product	Updated Product Version	Product Name
470036	7	DeBakey Forceps
470181	11	Resano Forceps
470318	15	Small Graptor (grasping retractor)
470344	19	Curved Bipolar Dissector
471344	19	Curved Bipolar Dissector (EUP)
470001	12	Potts Scissors
470007	8	Round Tip Scissors

***470179-22, Monopolar Curved Scissors which is only available in China, does not contain the updated product. However, 470179-21 and 470179-23 & future versions will contain the updated product**

**** For PN471309 & PN471296 the updates to reduce grip cable failures were implemented on a prior version which can be identified via the lot number mentioned in Table A2. The last 6 numbers of the lot number imply the manufacturing date of the instruments. The date format is modeled based on "YYMMDD". Refer to Figure E for an example. Any lots built beyond the date for the affected product identified in Table A2 contain the updated product.**

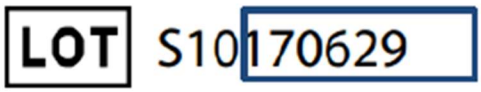

Figure E: An example of lot that was manufactured on 29th June 2017

Please see photos below of where the version number is located on the instrument box (Figure F) as well as the instrument casing (Figure G).

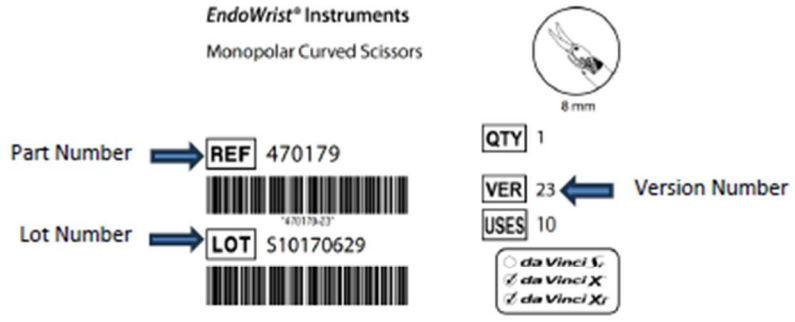

Figure F: Location of Part Number and Version on Instrument Box

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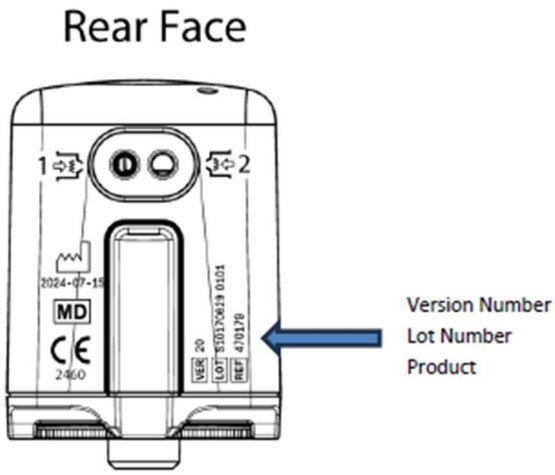

Figure G: Location of Part, Lot and Version Number on Instrument Casing

Table A3: Part Numbers Pending Implementation of Updated Product – Below table provides information on part numbers where Intuitive is still in process getting the updated product implemented. However, we have included 'Updated Product Version' column to help identify unaffected product versions when they become available.

Note: All future versions will also include the updated product.

Affected Product	Updated Product Version	Product Name
470049	11	Cadiere Forceps
471049	11	Cadiere Forceps (EUP)
470405	9	Force Bipolar
471405	9	Force Bipolar (EUP)
470347	17	Tip-Up Fenestrated Grasper
470048	11	Long Tip Forceps
471048	12	Long Tip Forceps (EUP)
470171	17	Micro Bipolar Forceps
471171	17	Micro Bipolar Forceps (EUP)
470033	12	Black Diamond Micro Forceps
470190	6	Cobra Grasper
471190	6	Cobra Grasper (EUP)
470246	11	Atrial Retractor Short Right
470249	12	Dual Blade Retractor

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Appendix B: Additional Images for Detection of Grip Cable Failures

In addition to instructions provided in da Vinci Xi and da Vinci X Instruments and Accessories User Manual, the following section provides additional images and detailed steps on how to inspect for broken or frayed grip cable which may be detected visually prior to or during use.

The inspection is limited to the instrument wrist and does not require magnification as shown in the pictures within this letter. 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 Figures H & I below

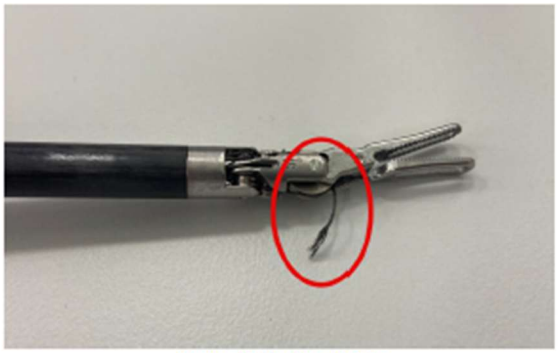

Figure H: Broken Cable

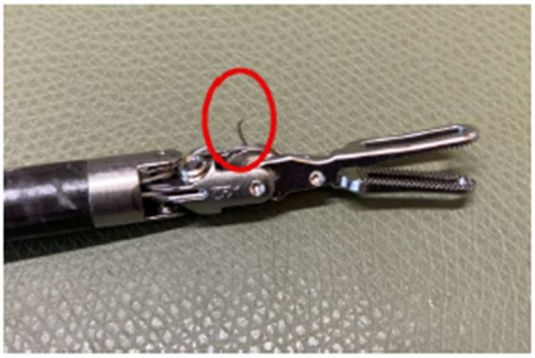

Figure I: Frayed Cable

INTUITIVE

2. Detection during use
   A. Broken Cable
      - If an instrument with a broken grip cable is installed on the system, it could result in engagement failure which will prevent completion of installation and will be immediately detected by the surgeon.
      - If a grip cable breaks intraoperatively on an installed instrument, the failure would be immediately detected by the surgeon as they would lose grip function (i.e. loss of grasp on any object within the instrument jaws).

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