

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Control de Instrumentos Endoscópicos DA VINCI
NO. IDENTIFICACIÓN RISARH	I1407-307
REFERENCIAS DEL DISPOSITIVO MEDICO	DA VINCI
REGISTRO SANITARIO	2009DM-0003498
INDICACIONES Y USO ESTABLECIDOS	<p>La finalidad del sistema de control de instrumentos endoscópicos de INTUITIVE SURGICAL es ayudar a controlar con precisión instrumentos endoscópicos de INTUITIVE, como endoscopios rígidos, disectores endoscópicos romos e incisivos, tijeras, bisturís, fórceps/pinzas, herramientas para manejar agujas, retractores endoscópicos, estabilizadores, accesorios para electrocauterización y para la manipulación endoscópica de tejidos, por ejemplo para sujetarlos, cortarlos, practicar una disección roma o incisiva, acercarlos, ligarlos, electrocauterizarlos y suturarlos durante intervenciones quirúrgicas laparoscópicas generales, intervenciones quirúrgicas toracoscópicas no cardiovasculares generales e intervenciones de cardiología con ayuda toracoscópica. El sistema puede emplearse también con mediastinotomía adjuntiva para realizar anastomosis coronaria durante la revascularización cardíaca. El sistema está indicado para su uso en adultos y en pediatría. Está diseñado para ser utilizado por médicos calificados en entornos quirúrgicos, empleando los procedimientos representativos y específicos descritos en las instrucciones de uso. El sistema de control de instrumentos endoscópicos de INTUITIVE SURGICAL se ha utilizado satisfactoriamente, entre otros, en los siguientes procedimientos;</p> <ul style="list-style-type: none"> • prostatectomía radical, pieloplastia, cistectomía, nefrotomía, reimplantación uretral • colecistectomía, funduplicatura de Nissen, miotomía de Heller, desviación gástrica, nefrotomía de donante, adrenalectomía, esplenectomía y resección intestinal. • histerectomía, miomectomía, sacrocopexia • movilización de la arteria mamaria interna, ablación del tejido cardíaco • reparación de la válvula mitral, cierre endoscópico de defectos septales auriculares, • anastomosis mamaria de la arteria coronaria descendente anterior izquierda para revascularización cardíaca con mediastinotomía adjuntiva - <p>usos representativos pediátricos: el sistema de control de instrumentos endoscópicos de INTUITIVE SURGICAL se ha utilizado satisfactoriamente, entre otros, en los siguientes procedimientos quirúrgicos pediátricos;</p> <ul style="list-style-type: none"> • pieloplastia,

reimplantación uretral • colecistectomía, funduplicadura de Nissen • ligadura del anillo aórtico, ligadura patente del conducto arterioso • cierre de defectos septales.

NOMBRE DEL FABRICANTE Intuitive Surgical, Inc

DESCRIPCION DEL PROBLEMA El fabricante informa sobre cambios a manuales de usuario, instrucciones de uso y guías de referencia rápida, para números de parte específicas, lo que puede conllevar a que se presenten potencialmente confusiones en los usuarios.

FUENTE ANEXO 1

FECHA DE NOTIFICACION 30 de Julio de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

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A22657 - Normal Priority Medical Device Alert

Medical Device Ongoing Action

Updated: July 24, 2014

UMDNS Terms:

- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Suggested Distribution:

- Clinical/Biomedical Engineering
- OR/Surgery
- Risk Management/Continuous Quality Improvement

Geographic Regions:

- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

Intuitive—Various Manuals for da Vinci Surgical Systems and Components: Manufacturer Informs Customers of Updates and Removal of Emergency Grip Release Wrench

Product Identifier:

	Part Nos.:
User Manuals, Instructions for Use (IFU), Quick Reference Guides (QRGs), and Instrument Release Kits (IRKs) for da Vinci Surgical Systems and Components:	
Cautery QRGs for da Vinci S, Si, and Standard	551992
Connection QRGs for da Vinci S, Si, and Standard	551993
Endowrist Instrument and Accessory Manuals for da Vinci S, Si, and Standard	550675
IRK Inserts for da Vinci S, Si, and Standard	550973
IRK QRGs for da Vinci S, Si, and Si-e	551979
IRK QRGs for da Vinci Standard	551980
Natural Rubber Latex QRGs for da Vinci S, Si, and Standard	551997
Stapler Addendums for da Vinci S, Si, and Standard	550986
Single Site Manuals (U.S.) for da Vinci S, Si, and Standard	551184
Single Site Manuals (Outside U.S.) for da Vinci S, Si, and Standard	550965
System Manuals for da Vinci S Surgical Systems	550516
System Manuals for da Vinci Si Surgical Systems	550650

System Manuals for da Vinci Standard Surgical Systems	550120
Vessel Sealer Addendums for da Vinci S, Si, and Standard	551027
Vessel Sealer QRGs for da Vinci S, Si, and Standard	551182
Vision Troubleshooting Guides for da Vinci S, Si, and Standard	550866

[Consumable; Capital Equipment]
Units distributed before June 2014

Manufacturer:

- Intuitive Surgical Inc 1266 Kifer Rd Bldg 101, Sunnyvale, CA 94086-5304, United States

Problem:

FDA's Center for Devices and Radiological Health (CDRH) states that Intuitive has made multiple updates to the above user manuals, IFU, QRGs, IRKs, and labeling for the above systems and components, including the removal of the Emergency Grip Release Wrench (part number 710142). FDA's CDRH also states that the manufacturer notified its customers of these updates by Field Safety Notice letter dated June 16, 2014. The manufacturer has not confirmed the information provided in the source material.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the June 16, 2014, Field Safety Notice letter, Acknowledgment Form, and updated labeling, user manuals, IFU, QRGs, and IRKs from Intuitive. Notify all relevant personnel at your facility of the information in the Field Safety Notice letter, and forward a copy of the letter to any facility to which you have further distributed affected product. Use Attachment C in the Field Safety Notice letter to identify the labeling that has been updated. Discard old versions of the above user manuals, IFU, QRGs, and IRKs, and replace them with the updated versions. Discard all versions of the Emergency Grip Release Wrench (part number 710142). Complete the Acknowledgment Form, and return it to Intuitive using the instructions on the form. Retain a copy of the Field Safety Notice letter and Acknowledgment Form with your records.

For Further Information:

Intuitive local representative or Intuitive customer service department
Tel.: (800) 876-1310 (select option 3), 6 a.m. to 5 p.m. Pacific time (North America) or (408) 523-2602
Website: [Click here](#)

References:

United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall cautery QRG for the da Vinci Standard surgical system; da Vinci S system and da Vinci Si system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall connection QRG for the da Vinci Standard surgical system; da Vinci S system and da Vinci Si system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Endowrist instrument and accessory manual for the da Vinci Standard surgical system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall insert for IRK for the da Vinci Standard surgical system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall IRK QRG for the da Vinci Standard surgical system; da Vinci S system and da Vinci Si system and Si [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall natural rubber latex QRG for the da Vinci Standard surgical system; da Vinci S system and da Vinci [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Single Site US manuals and Single Site OUS manuals for the da Vinci Standard surgical system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall stapler addendum for the da Vinci Standard surgical system; [sic] [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall system manual for the da Vinci Standard surgical system [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall vision troubleshooting guide for the da Vinci Standard surgical system; [sic] [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall vessel sealer addendum for the da Vinci Standard surgical system; [sic] [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall vessel sealer QRG for the da Vinci Standard surgical system; [sic] [online]. 2014 Jul 2 [cited 2014 Jul 14]. Available from Internet: [Click here](#).

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2014 Jul 14. FDA CDRH Database. Class II. Z-1964/1975-2014