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 – Grapadoras INTUITIVE
NO. IDENTIFICACIÓN RISARH	I1407-277
REFERENCIAS DEL DISPOSITIVO MEDICO	420230-04 y 420230-06, lotes manufacturados después del 16 de mayo de 2012 iniciando con el lote Nº M10120516
REGISTRO SANITARIO	2009DM-0003498
INDICACIONES Y USO ESTABLECIDOS	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 cardiotomía con ayuda toracoscópica. El sistema puede emplearse también con mediastinotomía adjuntiva para realizar anastomosis coronaria durante la revascularización cardiaca. 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; • 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, sacrocopopexia• movilización de la arteria mamaria interna, ablación del tejido cardiaco• reparación de la válvula mitral, cierre endoscópico de defectos septales auriculares,• anastomosis mamaria de la arteria coronaria descendente anterior izquierda para revascularización cardiaca con mediastinotomía adjuntiva - 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;• 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 un posible atascamiento de las grapadoras que se puede generar durante su inserción con cánulas de 8 mm o con reductores de cánula, lo que puede conllevar a que se presenten potencialmente retrasos en la realización de los procedimientos.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	07 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

A22617 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 1, 2014
UMDNS Terms:
- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Suggested Distribution:
- Clinical/Biomedical Engineering
- OR/Surgery

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Australia
- Belgium
- Brazil
- Bulgaria
- Canada
- Chile
- China
- Colombia
- Czech Republic
- Denmark
- Dominican Republic
- France
- Germany
- Greece
- India
- Israel
- Italy
- Japan
- Kuwait
- The Netherlands
- New Zealand
- Norway
- Panama
- Portugal
- Puerto Rico
- Romania
- Russia
- Saudi Arabia
- Slovakia
- Slovenia
- South Korea
- Spain
- Sweden
- Switzerland
- Taiwan
- Turkey
- U.K.
- U.S.

Intuitive—Large Clip Applier Instruments Used with da Vinci S and Si Surgical Systems: May Jam during Insertion

Product Identifier:
8 mm Large Clip Applier Instruments used with the following da Vinci Surgical Systems: (1) S, (2) Si [Consumable, Capital Equipment]
Instrument Part Nos.: 420230-04, 420230-06; Lot Nos.: M10120516 and higher
Instruments manufactured May 16, 2012, through May 15, 2014

Manufacturer:
- Intuitive Surgical Inc1266 Kifer Rd Bldg 101, Sunnyvale, CA 94086-5304, United States

Problem:
In a June 19, 2014, Field Safety Notice Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Intuitive states that the above clip applier instruments, used with the above systems, may jam during insertion when used with the 8 mm cannula or with certain cannula reducer accessories, potentially preventing or delaying use of the instrument. Intuitive also states that because the type of clip is used to occlude controlled vessels rather than to control episodes of active bleeding, a delay in clip application will have no immediate or long-term health consequences for the patient. Intuitive further states that this problem is caused by a manufacturing variation in the grip assembly of the instrument. Intuitive states that it has received 26 reports of instrument jamming or friction felt during insertion into the 8 mm cannula or into certain cannula reducer accessories; however, the firm has received no reports of death or injuries associated with this problem. Intuitive also states that the 26 reports represents an occurrence rate of 0.7% (26/28,938 procedures performed using the affected large clip appliers). The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. For instructions on how to identify affected product, see the instructions in Attachment A of the Field Safety Notice Urgent Medical Device Correction letter. If you have affected product, verify that you have received the June 19, 2014, Field Safety Notice Urgent Medical Device Correction letter and Acknowledgment Form. from Intuitive. An Intuitive representative will contact your facility to schedule an on-site visit to upgrade the system software, which will reduce the degree to which the jaws on affected clip applier instruments open during insertion and eliminate the occurrence of jamming. Intuitive states that you may continue to use affected product while these field corrections are being implemented and that sites not experiencing this problem will receive the software update as a preventative measure during their next scheduled preventative maintenance (PM) site visit. Complete the Acknowledgment Form, and return it to Intuitive using the instructions on the form. Retain a copy of the Field Safety Notice Urgent Medical Device Correction letter and Acknowledgment Form with your records.

For Further Information:
Intuitive local representative or Intuitive Surgical customer service department
North America and South America:
Tel.: (800) 876-1310 (select option 3), 6 a.m. to 5 p.m. Pacific time
Japan:
Tel.: (0120) 565635 or (03) 55751362, 9 a.m. to 6 p.m. Japan time
South Korea:
Tel.: (02) 32713200, 9 a.m. to 6 p.m. Korea time
Europe, Middle East, Africa, and Asia:
Tel.: (800) 08212020 or 41 (21) 8212020, 8 a.m. to 6 p.m. Central European time
E-mail: ics@intusurg.com
Website: 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 Jun 27. Member Hospital. Intuitive letter submitted by an ECRI Institute member hospital (includes reply form)