El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Control de Instrumentos Endoscópicos DA VINCI
NO. IDENTIFICACIÓN RISARH	R1506-232
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a los Graspers Torácicos de 5 mm referencias 420343-01 y 420343-02
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 el posible desprendimiento de partículas pequeñas provenientes del recubrimiento del tubo, derivado de la fuerza aplicada sobre el instrumento que puede ocasionar su desgaste y doblado, lo cual puede conllevar a que se presenten potencialmente retrasos en los tiempos quirúrgicos y eventos adversos para el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	01 de Junio de 2015

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

[High Priority] - A24431 : Intuitive—5 mm Thoracic Graspers Used with da Vinci S and da Vinci Si Surgical Systems: Contact/Abrasive Forces May Cause Damage to Main Tube Coating

Medical Device Ongoing Action

Published: Thursday, May 28, 2015

UMDNS Terms:

- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Product Identifier:
5 mm Thoracic Graspers used with the following da Vinci Surgical Systems: (1) S, (2), Si *[Capital Equipment]*
Thoracic Grasper Part Nos.: 420343-01, 420343-02

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Belgium, Brazil, Canada, Chile, Colombia, Denmark, France, Germany, India, The Netherlands, Panama, Singapore, South Korea, Switzerland, Taiwan, Turkey, U.K., U.S.

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

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, OR/Surgery, Risk Management/Continuous Quality Improvement, Materials Management

Problem:
In a May 21, 2015, Field Safety Notice Urgent Medical Device Recall letter submitted by ECRI Institute member hospitals, Intuitive states that contact/abrasive forces applied to the main tube coating of the above thoracic graspers may cause the damage to the main tube (for an image of damage to the main tube see Figure 1 in the Field Safety notice Urgent Medical Device Recall letter). Intuitive also states that the force being applied can come from a damaged (e.g., bent, abraded, notched) cannula or from contact with an adjacent instrument. Intuitive further states that if the main tube is damaged during a procedure, fragments of the main tube coating may fall into the patient; however, the user may visually detect instrument failure either through the surgeon console or at the patient side during instrument exchanges. If damage is observed, the user would need to replace the instruments, resulting in a minor delay in the procedure, and material that fell into the patient would need to be retrieved or removed through suction-irrigation. Intuitive states that the material that may fragment from the main tube of the above thoracic graspers meets the ISO-10993 biocompatibility and implantability testing requirements and manifests no signs of toxicity. Intuitive also states that for thoracic and extracardiac surgeries, main tube damage with fragments of coating material falling into the surgeon's view could have a minor immediate health effect and a temporary delay in the procedure could occur while the fragment is retrieved and the instrument replaced. For intracardiac surgery, if a fragment falls into the patient during the procedure, it is likely to be seen because of the smaller operating space and the high contrast between the dark coating material and the light intracardiac tissue and would be easily retrieved and the instrument replaced with only a brief delay in the procedure. If a particle becomes enclosed within the heart, the patient could be at risk for an embolic event such as a stroke. Intuitive further states that this high risk is mitigated by the Cardiac Surgical Standard Operating Procedure of inspecting the atrium and valve before closing to ensure that no material of any kind is left behind. Intuitive states that it has received no reports of patient injuries as a result of this problem. Intuitive also states that this problem affects only the above thoracic graspers; thoracic graspers with part number 420343-03 are not affected. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. For the location of the part and version number on the instrument, see Figure 2 in the Field Safety Notice Urgent Medical Device Recall letter . If you have affected product, verify that you have received the May 21, 2015, Field Safety Notice Urgent Medical Device Recall letter and Acknowledgment Form from Intuitive. Notify all relevant personnel at your facility of the information in the letter. To arrange for product return and to obtain return material authorizations (RMAs) contact the Intuitive customer service department using the information below. Upon receipx of affected product, Intuitive will provide your facility with new replacement thoracic graspers (part number 420343-03). To determine the number of replacement instruments to ship to your facility, Intuitive will determine the total combined number of remaining lives of all instruments returned and round the number of lives up to the nearest increment of 20 (i.e., if a customer returned 3 instruments with 15 lives each, the total number of remaining lives is 45. The 45 remaining lives would be rounded up to 60 lives, and 3 thoracic instruments, each with 20 lives, would be shipped as replacement instruments). Complete the Acknowledgment Form, and return it to Intuitive using the instructions on the form. Retain a copy of the letter 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

Comments:

- 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):

- 2015 May 27. Member Hospital. Intuitive letter submitted by ECRI Institute member hospitals: 2955842-05-07-2015-005-R (includes reply form) Download