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	I1610-440
REFERENCIAS DEL DISPOSITIVO MEDICO	IS4000 y p5X, versión de software P5
REGISTRO SANITARIO	2016EBC-0014795
INDICACIONES Y USO ESTABLECIDOS	El sistema de control de instrumentos endoscópicos de INTUITIVE SURGICAL está diseñado para ayudarle en el control preciso de instrumentos endoscópicos de INTUITIVE SURGICAL durante procedimientos quirúrgicos de urología, procedimientos quirúrgicos generales de laparoscopia, procedimientos quirúrgicos ginecológicos de laparoscopia, procedimientos quirúrgicos generales toracoscópicos y procedimientos 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 cualificados en un quirófano. Presentación comercial: el sistema DA VINCI incluye una consola del cirujano, un carro del paciente y un carro de visión, incluye además los endoscopios e instrumentos endowrist.
NOMBRE DEL FABRICANTE	Intuitive Surgical, Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa sobre la posibilidad de movimientos inesperados de la punta del instrumento bajo condiciones específicas, lo que puede conllevar a que se presenten potencialmente retrasos en los tiempos quirúrgicos y eventos adversos para el paciente.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	25 de Octubre de 2016

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] - A27412 : Intuitive—da Vinci Xi Surgical Systems with P5 Software: Software Anomaly May Result in Unexpected Master Movement and Instrument Tip Movement

Medical Device Ongoing Action

Published: Monday, October 17, 2016

UMDNS Terms:

- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Product Identifier:
da Vinci Xi Surgical Systems *[Capital Equipment]*
Model No. IS4000, P5x; Software Version P5

Geographic Regions: Australia, Austria, Belgium, Colombia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, India, Ireland, Israel, Italy, Japan, Monaco, The Netherlands, Norway, Portugal, Puerto Rico, Qatar, Romania, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, U.K., U.S.

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

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Risk Management/Continuous Quality Improvement, Information Technology

Problem:
In an October 12, 2016, Field Safety Notice Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, Intuitive states that an anomaly in the above systems' software may result in unexpected master movement and instrument tip movement under certain circumstances. Intuitive also states that certain interactions with the patient cart (during patient cart docking or during multi-port procedures, repositioning the instrument arm) can trigger this behavior upon entering following mode, when the surgeon is controlling the instruments at the surgeon console. Intuitive further states that if this behavior occurs, the surgeon may receive a recoverable error and experience movement of the master controller and/or movement of the associated cannula/instrument in any direction, including potential lateral movement; however, the instrument does not insert further beyond the tip of the cannula than it was previously inserted. Intuitive states that in all cases, cannula movement is about the remote center. Intuitive also states that it has received reports of this type of event occurring; however, all clinical cases involving these reports were completed using the da Vinci Xi surgical system and without patient injury. Intuitive states that during an internal test, the left hand control (master) on the surgeon console moved unexpectedly upon the first entry into following mode.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the October 12, 2016, Field Safety Notice Urgent Medical Device Correction letter from Intuitive. An Intuitive representative will contact your facility to schedule a software upgrade for affected systems to remedy this problem. Until you have received the software upgrade, do the following during every da Vinci Xi procedure to prevent this problem from occurring:

1. During single-site surgery, after installing each instrument on the sterile adapter, ensure that the instrument clutch is not activated and press the port clutch button for that arm. This is only necessary at the beginning of the procedure, directly after docking.
2. During multiport surgery:
    1. Immediately after docking to a cannula, press the corresponding port clutch button for that arm, and
    2. If adjusting patient clearance mid-procedure, ensure that the instrument clutch is not activated and press the corresponding port clutch button for that arm after the adjustment

Refer to the following caution related to port clutch from the da Vinci Xi system user manual (part number 551400-09 Rev B):

- "CAUTION: Hold the port clutch button with one hand and support the cannula with the other."

For the locations of the instrument clutch, patient clearance, and port clutch, see the image in the letter . Once you have received the software update, you can resume standard workflow according to the da Vinci Xi system user manual. Notify all relevant personnel at your facility of the information in the letter and retain a copy of the letter and Acknowledgment Form with your records. Complete the Acknowledgment Form, and return it to Intuitive using the instructions on the form.

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
Europe, Middle East, Africa, and Asia:
Tel.: (800) 08212020 or 41 (21) 8212020, 8 a.m. to 6 p.m. Central European time
South Korea:
Tel.: (02) 32713200, 9 a.m. to 6 p.m., Korea time
Japan:
Tel.: (0120) 565635 or (03) 55751362, 9 a.m. to 6 p.m., Japan timeWebsite: 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):

- 2016 Oct 14. Member Hospital. Intuitive letter submitted by an ECRI Institute member hospital: 2955842-10/05/16-011-C (includes reply form) Download