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	I1611-522
REFERENCIAS DEL DISPOSITIVO MEDICO	IS4000-XI, IS3000-SI y SI-E, concerniente al sellador EndoWrist, referencias 410322 y 480322.
REGISTRO SANITARIO	2016EBC-0014795 2009DM0003498
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 que el uso incorrecto del instrumento y problemas de funcionamiento puedan causar sellados insuficientes, desprendimiento de la cuchillas y la no retracción del sistema, 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	21 de Noviembre 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

[Normal Priority] - H0348 : Intuitive—da Vinci EndoWrist Vessel Sealers: Keys to Preventing Malfunctions and Patient Harm [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

Published: Thursday, November 17, 2016

UMDNS Terms:

- Telemanipulation Systems, Surgical, Minimally Invasive [18600]

Product Identifier:
da Vinci EndoWrist Vessel Sealers used with the following da Vinci Surgical Systems: (1) Si, (2) Si-e, (3) Xi *[Consumable, Capital Equipment]*
Vessel Sealer Part Nos.: 410322, 480322

Geographic Regions: Worldwide

Manufacturer(s): Intuitive Surgical Inc 1020 Kifer Rd, Sunnyvale, CA 94086-5304, United States

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

Problem:

1. Incorrect use of the da Vinci EndoWrist Vessel Sealer instrument can cause the following:
   - Incomplete cutting or sealing of tissue
   - Damage to vessel sealer jaws
   - Detachment of the knife cable from knife blade
2. These problems can cause the following device malfunctions:
   - The vessel sealer may not fully seal tissue, despite audible tones indicating the end of the sealing cycle.
   - The vessel sealer blades may not fully transect tissue or the blade may not fully retract and the system may display a blade exposure error.
   - The blades may detach from the instrument.
3. Some complications may not be immediately detectable and can cause patient harm, such as the following:
   - Insufficient vessel sealing may lead to unexpected bleeding that may not be readily apparent.
   - The exposed blades may cause inadvertent patient injury if the user continues to use the device with the blade exposed and the blade contacts tissue.

Manufacturer's Recommendations:

1. Only use the da Vinci EndoWrist Vessel Sealer instrument to cut vessels up to 7 mm and tissue bundles that fit within the jaws. Skeletonize large tissue bundles whenever possible.
2. Before activating the knife blade, ensure that the vessel sealer jaws are no more than 4 mm apart.
3. Do not use the vessel sealer on hard objects such as bone, calcified tissue, staples, or clips.
4. Do not cut sealed tissue unless the desired tissue effect is observed. Blanching, smoke, and/or bubbling are all indications of energy delivery.
5. Follow on-screen prompts for resolving blade exposure: if prompted, remove and re-install the vessel sealer. If the blade exposure resolves upon insertion, use may be continued.
6. See Intuitive's Updated Customer Letter .

ECRI Institute Recommendations:

While ECRI Institute concurs with all of the above recommendations, we have not examined any affected instruments. In addition to following the manufacturer's recommendations listed above, ECRI Institute recommends the following:

1. Monitor any changes in sealing time as this may indicate device failure.

2. Inspect tissue for adequate sealing.
3. Do not continue to use an instrument if malfunction is suspected.

Background:

- da Vinci EndoWrist Vessel Sealer instruments are used with da Vinci Si, da Vinci Si-e, and da Vinci Xi systems to cut and cauterize tissue.
- The instruments include independent cut and seal functions.
- Cutting is achieved using a cable-driven knife blade that extends upon activation and retracts once cutting is complete.

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 Nov 10. ECRI Institute
- 2016 Nov 11. Manufacturer Letter. Document submitted by the manufacturer Download