

**From:** [Intuitive Surgical](#)  
**To:** [k.attia@gulfmedical.com](mailto:k.attia@gulfmedical.com)  
**Subject:** Urgent Product Safety Notice - da Vinci Xi Universal Seal  
**Date:** Tuesday, 10 May, 2016 02:04:11

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## Urgent Product Safety Notice

***WARNING on use of the da Vinci Xi 5 mm-8 mm Universal Seal (PN 470361) and da Vinci Xi 12mm & Stapler Universal Seal (PN 470380) in intra-cardiac procedures on your da Vinci Xi Surgical System***

Dear *da Vinci* Customer,

The purpose of this communication is to advise you that Intuitive Surgical is initiating a warning regarding use of the da Vinci Xi 5 mm-8 mm Universal Seal (PN 470361-05 and 470361-06) and da Vinci Xi 12 mm & Stapler Universal Seal (PN 470380-05 and 470380-06) in intra-cardiac procedures. This message is being sent to all customers with *da Vinci Xi* Surgical Systems whether or not intra-cardiac procedures are performed on the *da Vinci Xi* Surgical System.

Intuitive Surgical identified particulate during quality inspections of the insufflation stopcock on the *da Vinci Xi* 5 mm-8 mm Universal Seal. The particulate has the potential to be introduced into the cannula lumen when insufflation is connected. Although there have been no injuries identified related to this issue, we are initiating this warning for use in intra-cardiac procedures due to risk of foreign body embolism should particulates remain undetected and unintentionally left inside the heart. During abdominopelvic and thoracic surgery, if the potential particulate is undetected and unintentionally left behind, health risk is minimal due to the bio-inert properties of the high density polyethylene (HDPE) particulate, its small size and the benign particulate geometry.

Until this issue is resolved, as an alternative to insufflation through the *da Vinci Xi* 5 mm-8 mm Universal Seal (PN 470361) or the 12 mm & Stapler Universal Seal (PN 470380) during intra-cardiac procedures, use an angio-catheter, or Veress needle, through the chest wall for initial access and to maintain insufflation throughout the procedure. Do NOT use the *da Vinci Xi* 5 mm-8 mm Universal Seal or the 12 mm & Stapler Universal Seal for insufflation, or open the stopcock during the procedure.

The potential particulate is no larger than 1/8" in length with no sharp edges. It is composed of HDPE, a bio-inert material. HDPE has been used as bone and cartilage implants since the 1940s with more than 30 years of follow-up results showing favorable response to HDPE implants. HDPE is non-ferromagnetic and, as such, an unrecovered particulate will not cause the patient harm if exposed to MRI.

While Intuitive Surgical will be following up with a formal letter shortly, please forward this communication to surgeons using the *da Vinci Xi* Surgical System, Risk Managers, OR Directors, and Biomedical Engineering staff and any other medical staff who perform *da Vinci* procedures. Please note, supply may be limited while we resolve the issue. We will notify you when corrected product begins to ship.

If you need further information or support concerning this issue, please contact your Clinical Sales Representative directly.

Intuitive Surgical takes patient safety very seriously and appreciates your immediate action and support.

Sincerely,

Intuitive Surgical Inc.

PN 552214-01 Rev A

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