

Urgent Product Safety Notice

***STOP USE of the da Vinci Harmonic ACE Insert (PN 400272)
for use with your da Vinci S and Si systems***

Dear *da Vinci* Customer,

Cc: Chairman Medical Board and relevant Head of Departments

The purpose of this communication is to advise you that Intuitive Surgical is initiating a voluntary **STOP USE on the *da Vinci Harmonic ACE insert*** for use with *da Vinci S and Si* Surgical Systems. Intuitive Surgical identified that the sterile package for the insert can become damaged during transit. This damage can lead to a breach of the sterile barrier and potential for patient infection. There have been no adverse events reported related to this issue.

Per our records, your site has received shipments of the Harmonic ACE insert (PN 400272). **Immediately stop using all *da Vinci Harmonic ACE inserts***. Further investigation is underway but at this time the issue has not been associated with other EndoWrist instruments, accessories or Xi Harmonic instruments.

Please forward this communication to surgeons using the Harmonic ACE instrument, Risk Managers, OR Directors, and any other medical staff who perform *da Vinci* procedures. Intuitive will be following up shortly with a formal letter. Harmonic ACE inserts can be returned for credit through the standard RMA process. We will follow up with information on when corrected product will be available.

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

Sincerely,

Intuitive Surgical Inc.

Customer Service:

- North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@intusurg.com.
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com