

Date: July 1st, 2014

IMPORTANT QUALITY COMMUNICATION

FIELD SAFETY NOTICE: Intuitive Surgical Large Clip Applier for use with the da Vinci® S™ and da Vinci® Si™ - 2955842-06022014-003-C

Dear Distributor,

The purpose of this Field Safety Notice is to inform you that Intuitive Surgical (ISI) is initiating a voluntary correction of two ISI Large Clip Applier Instruments (part numbers: 420230-06 and 420230-04). These instruments are used with the da Vinci S and da Vinci Si Surgical Systems. The voluntary correction is due to a manufacturing variation in the grip assembly of the instrument which can lead to the instrument feeling resistance or jamming during insertion when used with the 8 mm cannula or with certain cannula reducer accessories. The product is still safe to use. **No products need to be returned.**

The correction will include a customer notification and a software correction reducing the opening angle of the jaws during insertion of the instrument, eliminating the occurrence of jamming or friction.

We request that you take the following actions in **Steps A** to **C** below in response to this Notice. We apologize for any inconvenience that this issue causes you.

Intuitive Surgical is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Sincerely,

Intuitive Surgical Compliance

STEP A: Actions required of you

1. Carefully read the attached Field Safety Notice (FSN)
2. Identify customers that have received the affected Large Clip Appliers (Part Numbers: 420230-06 and 420230-04).
3. You will be shipped from, Intuitive, an updated Large Clip Applier (420230-07) to perform the software upgrade on your da Vinci S and Si Surgical systems at your customer's next site visit. The software upgrade will reduce the degree to which the jaws on the Large Clip Applier Instrument open during insertion and will eliminate the occurrence of jamming. Customers will not need to order new instruments.
4. Ensure the execution of the required actions for yourself and your customers. Your customers are to communicate and manage all activities directly with you and not with Intuitive Surgical.
5. Complete the attached Distributor Confirmation form. (**Step B**).
6. Send your completed Distributor Confirmation form to Intuitive Surgical by FAX or SCAN (**Step C**)



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IMPORTANT – DISTRIBUTOR CONFIRMATION

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

Step B: Complete the following information

I acknowledge that I have received and understood the contents of Intuitive Surgical Inc.'s Field Safety Notice (2955842-06022014-003-C). I also confirm that I have executed all required actions for my organization as well as with all of my affected da Vinci® customers.

Distributor Name: _____

Contact Person (print): _____

Contact Person (signature) _____

Date: _____

Phone Number: _____

STEP C: Return this page to the following contact:

PLEASE SCAN/EMAIL or FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical Inc.
ATTN: REGULATORY COMPLIANCE
U.S. +1 (408) 716-3040, or Scan and Email: jsi.compliance@intusurg.com
Subject line for email: Large Clip Applier