

ENDOCONTROL

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La Tronche, May 18th, 2017

Purpose: Advisory Notice

Dear Customer,

The purpose of this letter is to inform you on a change of the directions for use of the device: [JAIMY motorized surgical instrument](#).

Device concerned:

JAIMY Needle-holder, [commercial code: IN0806 or IN0806/R](#)

Modified directions for use:

1/ Use a lubricant to lubricate the distal extremity of the instrument before each sterilization of the device, once cleaning is completed. The process to be followed to lubricate is described in the user manual (revision V3.7 – Cleaning & Sterilization section).

Lubricant to be used: oil Aesculap® Sterilit®, commercial code JG598

2/ When tying a knot, do not hold the needle directly with the straight instrument (held in the opposite hand to JAIMY) but hold the suture a few millimeters from the needle. Otherwise, the JAIMY instrument sheath may be damaged.

Reasons for the modified directions for use:

1/ The use of the lubricant was provided in the user manual (revisions V3.5 and V3.6) as a preventive maintenance to improve jaws opening and to avoid stick-slip of the jaws.

After further studies conducted by ENDOCONTROL, we recommend the use of the lubricant systematically after each use of the device to avoid early impairment of the product performance and improve its duration life.

2/ The user manual is providing recommendations on how to handle the needle during its insertion through the trocar cannula with JAIMY. Further analysis and studies revealed that damage to the JAIMY sheath could also be caused by intra-corporeal needle management with the straight instrument held in the opposite hand to JAIMY, during the knot tying phase. Holding the suture rather than the needle will avoid this risk while being safer for the surrounding tissues.

Actions done by ENDOCONTROL:

- Provide an new revision of the user manual (revision V3.7).
- Provide sample of the lubricant.



Actions to be taken by the CUSTOMER:

- Ensure following the 2 modified directions for use.
- Send back to ENDOCONTROL an acknowledgment of this letter either by:
 - signing and sending back the “acknowledgment section” of this letter,
 - acknowledging by e-mail the reception of this letter: qualite@endocontrol-medical.com.

Yours sincerely,
Clement VIDAL
President

ACKNOWLEDGMENT SECTION

I have read and understood the advisory notice provided by ENDOCONTROL and dated on May 18th, 2017.

Name:

Position:

Date:

Signature:

