

ENDOCONTROL

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La Tronche, February 21st, 2018

Purpose: Urgent FIELD SAFETY NOTICE – JAIMY device

Dear Madam, Dear Sir,

The purpose of this Field Safety Notice 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](#)

Reasons for modified directions for use:

Due to their mechanical complexity, articulated instruments have proven to be difficult to be properly cleaned even when equipped with a flush (<https://spinalnewsinternational.com/complete-decontamination-of-robotic-instruments-virtually-impossible/>). In the development of JAIMY, ENDOCONTROL designed a fully sealed distal shaft to overcome this issue.

Nevertheless, feedback from the market has revealed that the sheath of the JAIMY distal shaft can be damaged during its use.

The damage of the sheath can lead to a loss of the integrity of the sterile barrier. The risk to the patient can be an exposure to non-sterile environment.

Corrective action taken by Endocontrol:

Development of a Tester specifically designed to allow verifying integrity (airtightness) of the device distal shaft before each use.

Actions to be taken by the user:

- 1- Use of the Tester to verify the JAIMY device before each use.
- 2- Refer to the revised User Manual of JAIMY (document "UserManual_JAIMY_V3.8") and to the Tester User Manual (document "UserManual_JAIMY_Tester_V1.0") to know how to proceed.
- 3- Communicate and ensure the reception of the Field Safety Notice to any customer using the device.
- 4- Send back to ENDOCONTROL an acknowledgment of this Field Safety Notice 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.

A tester is being sent to you in few days.

Please notice that relevant Competent Authorities in Europe have been advised.

Yours sincerely,
Clement VIDAL
President



ACKNOWLEDGMENT SECTION

I have read and understood the Field Safety Notice provided by ENDOCONTROL on February 26th, 2018.

I endorse the responsibility of transmitting this Field Safety Notice to all my customers using the device.

Company:

Name:

Position:

Date:

Signature:

Please send this acknowledgment to: qualite@endocontrol-medical.com

