

Our Ref.: MNE/19-191

Bobigny, January 8th, 2020

REGISTERED LETTER WITH ACKNOWLEDGMENT OF RECEIPT – This mail follows a previous mail.

IMPORTANT – URGENT FIELD SAFETY NOTICE (FSN)

We inform you of this urgent product safety information concerning the modification of the maximum assigned voltage of the products mentioned below:

Concerned devices list:

Legal manufacturer (*)	Product name	Reference	Batch number
Péters SURGICAL 42 rue Benoît Frachon 93013 Bobigny Cedex FRANCE	Monopolar scissors IN CUT	C5330, T5150, C5250, T5330, IC5330, IK5330, C5470, CB5330	All
	Monopolar forceps ENDOGRIP	A5330, F5330, G5330, MD5330, D5330, FS5330, FS5470, MD5470	All
	Monopolar hooks ENDHOOK	H5330, H5330L	All

(*) For the products manufactured, before the May 1st, 2018, the legal manufacturer is VECTEC SA - Bioparc - 03270 HAUTERIVE – FRANCE

To the attention of:

All the customers who received at least one of the products listed above over the last 5 years.

Description of the defect:

The assigned voltage currently claimed for the products listed above is 5,000 V peak.

Recent tests carried out on our monopolar instruments according to the standard IEC60601-1 (2005 + AMD: 2012) and IEC60601-2-2 (2017) have demonstrated a resistance of the insulator up to a voltage of 5,400 V peak for 30s. However, the applied safety factor requires revising the assigned voltage specification to 4500 V, reduced to **4,000 V** peak as a precaution, and to update our instructions for use accordingly.

Information of the current IFU (IN121 V06-2018):	Information modified in the IFU:
<p style="text-align: center;">INDICATIONS OF USE</p> <p>PETERS SURGICAL instruments are solely designed for laparoscopic surgery. Depending on each instrument and its model, they may be employed for:</p> <ul style="list-style-type: none"> - mechanical freeze incision, - monopolar incision via high-frequency (HF) current, - monopolar coagulation via high-frequency (HF) current, - mechanical dissection, - atraumatic or traumatic prehension of tissues <p>Maximum assigned voltage: 5,000 at peak voltage (the generator should be set at a lower voltage).</p> <p>Such instruments should only be handled by qualified practitioners having gained due experience thereof.</p> <p>Make sure that the voltage assigned to any accessory used in combination with a HF generator is superior to that of the generator itself (power setting, mode); please refer to IEC 60601-2-2 requirement. Please also refer to the Instructions' Manual of the HF generator.</p>	<p style="text-align: center;">Information modified in the IFU:</p> <p>PETERS SURGICAL instruments are solely designed for laparoscopic surgery. Depending on each instrument and its model, they may be employed for:</p> <ul style="list-style-type: none"> - mechanical freeze incision, - monopolar incision via high-frequency (HF) current, - monopolar coagulation via high-frequency (HF) current, - mechanical dissection, - atraumatic or traumatic prehension of tissues <p>Maximum assigned voltage: 4,000 at peak voltage (the generator should be set at a lower voltage).</p> <p>Such instruments should only be handled by qualified practitioners having gained due experience thereof.</p> <p>Ensure compatibility with all other associated instruments; <u>in particular, the connections and voltage supplied by the HF generator should be lower than the assigned voltages of the accessories being used in combination (see IEC 60601-2-2).</u> Check the instruction for use of the cable and of the HF generator regarding its operating, as well as its power and mode settings.</p> <p>NB: Only surgical monopolar cables may be connected to PETERS SURGICAL monopolar instruments</p>

Risks:

The risk of breakage of the insulation of instruments at an assigned voltage above **4,000 V peak** could cause burns, to the patient or to any person handling the device.

This risk is very low and no incident involving an electrical insulation fault has been communicated to us since the marketing of these devices.

However, as a precaution, Péters Surgical initiates this safety information in order to inform you of the new assigned voltage values.

Measures to be taken:

Do not use monopolar instruments at a voltage above 4,000 V peak

Users of monopolar instruments are reminded to follow the precautions indicated in the instructions for use, in particular: "*Always make sure that the instruments are not placed directly on the patient, or in a manner to create direct or indirect contact.*"

In addition, in compliance with good laparoscopic surgery practices, it is recalled setting the HF generator to the minimum power required to obtain the desired effect.

Transmission of this Urgent Field Safety Notice:

We kindly ask you to respect transfer this Urgent Field Safety Notice to those who need to be aware within your organization and beyond.

The National Competent Authority has been informed about this notification of this « Urgent Field Safety Notice ».

Update of the Instructions for Use:

The new Instruction for Use will be sent to you as soon as possible

Please accept our apologies for any inconvenience.

Sincerely yours,

Marie-Noelle EROUT
Quality & Regulatory Affairs Director