

Our Ref.: MNE/19-194

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 product mentioned below:

Concerned device list:

Legal manufacturer (*)	Product name	Reference	Batch number
Péters SURGICAL 42 rue Benoît Frachon 93013 Bobigny Cedex FRANCE	Monopolar cable	CAB3000	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) lead us to redefine the assigned voltage to **2,000 V** peak and to update our instructions for use.

Information of the current IFU (CA002 V06-2018):

INFORMATION REGARDING THE CABLE

The PETERS SURGICAL monopolar connection cable is exclusively designed for monopolar laparoscopic surgical instruments. The cable should only be used by qualified practitioners having gained due experience thereof.

- Maximum assigned voltage: 5000 volts at peak value.

↓ Make sure that the voltage assigned to any accessory used in conjunction with a high-frequency (HF) generator is superior to that of the generator itself (power setting, mode) (see IEC 60601-2-2 Standard). Please refer to the HF generator Instructions' Manual.



Information modified in the IFU:

INDICATIONS OF USE

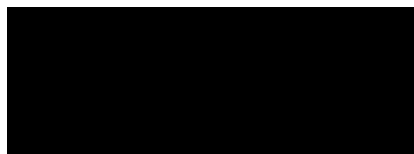
The PETERS SURGICAL monopolar connection cable is exclusively designed for monopolar laparoscopic surgical instruments. The cable should only be used by qualified practitioners having gained due experience thereof.

- Maximum assigned voltage: 2000 volts at peak value.

↓ Ensure compatibility with all other associated instruments; 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). Check the instruction for use of the cable and of the HF generator regarding its operating, as well as its power and mode settings.

NE: Only surgical monopolar cables may be connected to PETERS SURGICAL monopolar instruments





Risks:

The risk of breaking the insulation of monopolar cables at an assigned voltage above **2,000 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 cables at a voltage above 2,000 V peak

Users of monopolar cables in combination with 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 transfer this 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,

