



March 6, 2012

With clearance from our Notified Body i.e., TÜV SÜD, Kirwan Surgical Products LLC undertook testing of our forceps and cables in order to establish common electrical parameters by which one could determine compatibility with generators in the field. This approach was taken because it complies with MDD, Annex I, Essential Requirement 9.1 and relieves Kirwan Surgical Products LLC of the burden of testing our accessories with every generator in the field and every version of those generators that come on-line.

The parameters we arrived at are defined in the following statement on our reusable forceps Instructions For Use (IFU-KRF-5, Rev. F).

CAUTION: "BECAUSE OF THE VARIABILITY OF OUTPUT VOLTAGES AND MODES FROM GENERATOR TO GENERATOR, DO NOT USE THE FORCEPS WITH GENERATORS HAVING BIPOLAR OUTPUT VOLTAGES THAT EXCEED 1200 VOLTS PEAK TO PEAK. REFER TO THE APPROPRIATE ELECTROSURGICAL GENERATOR MANUAL FOR INDICATIONS AND INSTRUCTIONS ON BIPOLAR OUTPUT CHARACTERISTICS TO ENSURE THAT ALL SAFETY PRECAUTIONS ARE FOLLOWED."

Twelve hundred (1200) volts was targeted because we believe it to meet or exceed parameters of most, if not all, generators in the field that currently offer bipolar modes. In-house testing was conducted at 120% of the 1200V voltage as specified in International Standard IEC 60601-2-2:2009, clause 201.8.8.3.103.

In addition to the electrical parameters, Kirwan Surgical Products LLC builds the instrument connectors on each cable to comparable parameters set forth by each manufacturer (i.e. Erbe, Martin, Codman, Valleylab, Alcon); thereby, making Kirwan Surgical's forceps, pencils and cables fully compatible with each generator that meets the above specifications.



John Ariola, Director of Engineering

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