KOGENT™ SURGICAL

June 25, 2021

To whom it may concern,

This letter is to notify you that, in the interest of pending regulatory matters within the European Union medical device market, effective today the KoAG Bipolar Forceps, Illuminated Bipolar Forceps, and Focused Bipolar Forceps will no longer be available on the European market.

Under the European Union Medical Device Regulation, some classes of medical devices (such as the KoAG Bipolar Forceps, Illuminated Bipolar Forceps, and Focused Bipolar Forceps) require a Notified Body to be involved in the conformity assessment and CE marking process. Such Notified Bodies also undertake routine audits of medical device manufacturers.

Kogent Surgical has recently undergone a routine external audit by our EU Notified Body, The National Standards Authority of Ireland (NSAI). It was determined that a change made to the devices should have been reviewed by NSAI prior to the devices being placed on the market. Following that audit, NSAI has requested for us to discontinue the distribution of these products until the change can be approved.

As part of the effort to identify product already placed on the market, we request a list of all KoAG Bipolar Forceps, Focused Bipolar Forceps, and Illuminated Bipolar Forceps product currently on your shelf with the following information:

Part Number	Number of Boxes	Lot Number
DNLX-XXS		
DNIX-XXS		
DNNX-XXS		
DNSX-XXS		
DKFX-XXS		

Please provide this information before the close of business on July 2, 2021 to allow adequate time for us to take action. Once this product has been identified, Kogent Surgical will send you an RMA number for reimbursement and a shipping label to send the product back to our facility.

Please note that we have also notified the appropriate Competent Authority of this matter. Feel free to contact me at m.koch@katalystsurgical.com or 1-636-536-5950 if you have questions.

Thank you,

.....
Director of Regulatory Affairs