



Dear ECMO Community,

17 Dec 2019

It is with the deepest regret that I have to inform you that the OriGen Reinforced Dual Lumen Catheter and other OriGen ECMO products will not be returning to the market.

As we have discussed, the EU has designated ECMO catheters as Class III – Life support – devices, equating the risk equivalent to an implantable heart valve. Our recent regulatory difficulties along with other perceived risk factors have caused our product liability insurance carrier to decide that the risk is too great and they have declined to continue coverage of the device. We have been unable to secure alternative insurance. Without insurance coverage, we have recalled all existing products in the market, and will no longer be able to supply these.

Having said this, we are working to sell this product line to a different manufacturer, with the intention of bringing it back to the market. We cannot make any predictions, but we are pursuing several options. If any of you have a suggestion here, please let me know. We will keep everyone informed of any changes in availability.

Sincerely,

A handwritten signature in black ink that reads "Dick Martin".

Richard Martin
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