



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 following Retinal Membrane Removal Instruments will no longer be available on the European market.

Under the European Union Medical Device Regulation, some classes of medical devices (such as the DEX™ Forceps, DEX™ Scissors, DEX™ TIPS, Drip Droppers™, Backflush Handpieces, and Disposable Cannulas) 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.

Katalyst 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 Retinal Membrane Removal Instruments product currently on your shelf with the following information:

Part Number	RMR Instruments	Number of Boxes	Lot Number
CVF4032-XX	20, 23, 25, 27 ga DEX TIPS™ Yamane IOL Fixation Forceps		
CVF4033-XX	20, 23, 25, 27 ga DEX TIPS™ Morris ILM Forceps		
CVF4035-XX	20, 23, 25, 27 ga DEX TIPS™ Hassan Forceps		
CVO-HANDLE	DEX TIPS™ Slim Handle		
DV1030-XX	20, 23, 25, 27 ga Maeno-Awh Super Manipulator		
DVC1300-XX	20, 23, 25, 27 ga Disposable Cannula, Soft Tip		
DVC1314-XX	20, 23, 25, 27 ga Disposable Cannula, Diamond Dusted Tip		

DVC1325-XX	20, 23, 25, 27 ga Disposable Cannula, Brush Tip		
DVC1350-XX	20, 23, 25, 27 ga Disposable Cannula, Blunt Tip		
DVC1360-XX	20, 23, 25, 27 ga Mason Cannula		
DVC1370-XX	23, 25, 27 ga Disposable Awh MVP™ Cannula		
DVC1470-XX	23, 25, 27 ga Disposable Awh MVP™		
DVC1510-XX	20, 23, 25, 27 ga Disposable Subretinal Cannula		
DVC1815-XX	20, 23, 25, 27 ga Disposable Dual Bore Cannula		
DVF4014-27	27ga (0.41mm) Dex™ Stiff Asymmetrical ILM Forceps		
DVF4016-27	27ga (0.41mm) Dex™ Stiff Serrated Jaw Forceps		
DVF4032-25-S	25ga (0.50mm) DEX™ Stiff Yamane IOL Fixation Forceps		
DVF4032-XX	20, 23, 25, 27 ga DEX™ Yamane IOL Fixation Forceps		
DVF4033-25-S	25ga (0.50mm) DEX™ Stiff Morris ILM Forceps		
DVF4033-XX	20, 23, 25, 27 ga DEX™ Morris ILM Forceps		
DVF4035-XX	20, 23, 25, 27 ga DEX™ Hassan Forceps		
DVF4036-25-S	25ga (0.50mm) DEX™ Stiff Yoneda Super Grip Forceps		
DVF4036-XX	20, 23, 25, 27 ga DEX™ Yoneda Super Grip Forceps		
DVFO4033-XX	20, 23, 25, 27 ga Slim DEX™ Morris ILM Forceps		
DVFO4035-XX	20, 23, 25, 27 ga Slim DEX™ Hassan Forceps		
DVS5101-27	27ga (0.41mm) Dex™ Stiff Vertical Scissors		



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, Katalyst 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 or 1-636-536-5950 if you have questions.

Thank you,



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Director of Regulatory Affairs