

TO: Distributors and Blood Center/Hospital Transfusion Service Management

FROM: Jessica Hughes, Quality Assurance/Regulatory Affairs Manager

CC: Lisa Krallis-Nixon, Jo McKelvey

DATE: November 10, 2005

RE: Recall of 03-960-57

Charter Medical recently announced a recall of one lot of the 03-960-57 transfer set with 150 micron filter. This recall has been posted on CBER's website and in the newsletters and websites of other organizations within the blood banking community. Due to the volume of inquiries we have received, we would like to provide the following information.

Charter Medical's most recent recall (03-960-57) was isolated to two cases of products and impacted one hospital. All recall activities have been completed with the impacted hospital. The recall was initiated because the two cases in question had not been subjected to the gamma sterilization process.

The recall did not impact any other gamma sterilized products, including other neonatal syringe sets.

This recall is in no way related to the recall Charter Medical initiated in January 2005 for ethylene oxide sterilized products.

If you have additional questions, please feel free to contact Jessica Hughes (336) 714-4248.