NuMED, Inc.

[redacted]

October 25, 2024

[redacted]

URGENT: MEDICAL DEVICE RECALL – Z-MED II-X CATHETERS

Dear Distributor,

The purpose of this letter is to advise you that NuMED, Inc. is voluntarily recalling the following Z-MED II-X catheters:

Affected Units:

Catheter Product Code	Model Number	Lot Number	Qty	UDI	Distribution Date	Expiration Date
PDZ733	305X	JZX-5322	11	10887714019705	August 2024	2029-07-31

These units are being recalled due to them being manufactured with the incorrect balloon. The balloon that was placed on this catheter has a lower rated burst pressure than what the PDZ733 is labeled for. Size and length are correct, but the labeled rated burst pressure is different.

Balloon used – labeled rated burst pressure of 4 ATM
PDZ733 balloon – nominal pressure of 4 ATM, labeled rated burst pressure of 7 ATM.

There is a risk of balloon rupture when taken beyond 4 ATM of pressure. There have not been any associated complaints and/or adverse events associated with this issue.

All these devices should be returned to NuMED as soon as possible. The devices will be destroyed upon return.

NuMED will be initiating a Corrective Action to address this issue and to take steps to make sure that this issue does not happen again.

If you have any questions or concerns, please contact me at (315) 328-4491, or via email at nlaflesh@numedusa.com.

Sincerely,

[redacted]