Northgate Technologies, Inc.

1591 Scottsdale Court
Elgin, IL 60123
847.608.8900 Main
847.608.9405 Fax
www.ntisurgical.com

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URGENT: MEDICAL DEVICE RECALL NOTIFICATION

9 FRENCH Probe Recall

Northgate Technologies Inc. is voluntarily recalling Northgate manufactured 9 Fr probes which are a single patient disposable accessory for an IEHL Lithotripter.

The Northgate Technologies' part numbers subject to this recall are 9-203-0543, 9-900-54, and 72-00198-0. This recall impacts all lot numbers manufactured after January 1, 2015 and the products would have an expiration date after January 1, 2018.

The devices are being recalled as part of an investigation into a biocompatibility test discrepancy where a lot failed biocompatibility testing.

Actions to be Taken:
Please take the following actions immediately:

- Examine your records and ascertain the location of affected device accessories.
- Cease distribution or use and destroy those products appropriately. *
- Complete a Recall Acknowledgment Form and email it to ***tgatto@ntisurgical.com.*** This will allow us to document the device accessories you have destroyed. *

In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

*If you have affected Product, please contact Northgate Technologies Customer Service at CustomerService@NTISurgical.com, or call us at (800) 348-0424 for a Recall Acknowledgement Form.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by phone: 800-FDA-1088.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Northgate Technologies Inc. is committed to providing high quality, safe and effective devices. We sincerely apologize for any inconvenience this action may cause.