



## Brief Summary Document

### Overview

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#### Product

The AUTOLITH® TOUCH Series, Bipolar Electrohydraulic Lithotripsy Probes – IFU NOR-SPEC-6100-4860 Revision A

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### Rx Statement

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

### Content

#### INDICATIONS FOR USE

The AUTOLITH® TOUCH unit is designed to be used with Northgate Technologies, Inc. bipolar disposable EHL probes for the fragmentation of biliary calculi.

#### CONTRAINDICATIONS

The AUTOLITH TOUCH unit is not to be used on patients who have an externally connected intra-cardiac catheter or pacemaker.

**WARNINGS**

This product is for Single Use Only, DO NOT attempt to re-use or re-package this device due to risk of cross-contamination. DO NOT re-sterilize this device due to possibility of deterioration of the component materials.

**CAUTIONS**

THIS AUTOLITH<sup>®</sup> UNIT IS DESIGNED TO FUNCTION WITH SINGLE USE ELECTROHYDRAULIC PROBES MADE SPECIFICALLY FOR THE AUTOLITH<sup>®</sup> UNIT. THE PROBES SHOULD NOT BE RE-USED OR RE-STERILIZED.

The extender cable must not be soaked in a disinfecting or sterilizing solution. Damage could result.

**POTENTIAL ADVERSE EVENTS**

None.