



Brief Summary Document

Overview

Product

The AUTOLITH® TOUCH Bipolar (EHL) Electrohydraulic Lithotripter
for Biliary Calculi Fragmentation – IFU NOR-SPEC-6100-1230 Revision C

Rx Statement

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

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

INTENDED USE/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 DEVICE SHOULD BE OPERATED ONLY BY OR UNDER THE DIRECT SUPERVISION OF A PHYSICIAN EXPERIENCED IN ELECTROHYDRAULIC LITHOTRIPTER PROCEDURES. THE USER SHOULD BE THOROUGHLY FAMILIAR WITH THE OPERATION OF THIS DEVICE PRIOR TO USE.

ELECTROHYDRAULIC LITHOTRIPTER PROBES ARE PACKAGED STERILE DO NOT USE IF PACKAGING IS OPENED OR DAMAGED OR BEYOND THE DATE OF EXPIRATION.

ELECTROHYDRAULIC LITHOTRIPTER PROBES ARE LIMITED LIFE, SINGLE USE DEVICES. IF ANY OF THE FOLLOWING CONDITIONS ARE NOTED, REGARDLESS OF THE “REPLACE PROBE” MESSAGE, STOP USING IMMEDIATELY AND USE A NEW PROBE: FIRING (OR ARCING) BEHIND THE TIP, EJECTION OF TIP OR INSULATION MATERIAL, ARCING ALONG THE WIRES OR INSIDE / OUTSIDE OF THE CONNECTOR.

PRIOR TO USE AND DURING USE, BE SURE TO INSPECT THE LITHOTRIPTER PROBE TIP FOR DAMAGE THAT COULD POTENTIALLY CAUSE INJURY TO THE PATIENT SUCH AS PHYSICAL LOOSENESS AND / OR SHARP EDGES.

DO NOT PRESS THE DISTAL TIP OF THE PROBE AGAINST TISSUE. TISSUE DAMAGE, INCLUDING PERFORATION OR THERMAL INJURY CAN RESULT.

THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXED WITH AIR, OXYGEN OR NITROUS OXIDE.

NEVER ATTEMPT TO SERVICE OR CLEAN THE DEVICE WHEN IT IS CONNECTED TO A POWER SOURCE. HAZARDOUS VOLTAGES INSIDE THE DEVICE CAN CAUSE SEVERE ELECTRICAL SHOCK. DISCONNECT THE POWER CORD BEFORE SERVICING.

AFTER THE LITHOTRIPSY PROCEDURE, ALL PARTICLES RESULTING FROM THE PROCEDURE AND OBSERVED WITHIN THE OPERATIVE ENVIRONMENT SHOULD BE REMOVED IN ACCORDANCE TO GENERALLY ACCEPTED STANDARDS OF SURGICAL INTERVENTION AND CARE.

IMPROPER USE OF THE EHL PROBE COULD RESULT IN VESSEL PERFORATION FOLLOWED BY BLEEDING AND POSSIBLE INFECTION. OTHER COMPLICATIONS SUCH AS VESSEL STRICTURES RESULTING FROM EDEMA AND OCCLUSIONS CREATED BY STONE DEBRIS ARE ALSO POTENTIAL COMPLICATIONS OF EHL.

ANY PRODUCTS USED WITH THIS DEVICE THAT ARE MARKED “SINGLE USE ONLY”, ARE NOT TO BE RE-USED OR RE-PACKAGED DUE TO RISK OF CROSSCONTAMINATION. DO NOT ATTEMPT TO RE-STERILIZE THESE PRODUCTS DUE TO THE POSSIBILITY OF DETERIORATION OF COMPONENT MATERIALS.

TO AVOID PROCEDURAL DELAYS AND POSSIBLE INCOMPLETE STONE FRAGMENTATION, PLEASE HAVE TWO (2) OR MORE EHL PROBES AVAILABLE FOR EACH LITHOTRIPSY PROCEDURE.

DO NOT ATTEMPT TO REUSE A PROBE ONCE IT HAS BEEN USED PAST 100% OF ITS USEFUL LIFE.

TO AVOID THE RISK OF ELECTRIC SHOCK, THE EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

CAUTIONS

DO NOT ALLOW FLUIDS TO ENTER THE UNIT. DAMAGE CAN RESULT.

THE “REPLACE PROBE” MESSAGE IS A GENERAL INDICATOR OF EXPECTED PROBE LIFE. IT IS NOT TO BE INTERPRETED THAT PROBES CANNOT FAIL BEFORE THIS MESSAGE APPEARS. USE OF ANY PROBE SHOULD BE STOPPED IMMEDIATELY IF A MALFUNCTION OCCURS, OR IF ANY OF THE CONDITIONS STATED IN THE WARNINGS ARE OBSERVED. DO NOT DISCONNECT AND ATTEMPT TO RE-USE THE EHL PROBE. DISCONNECTING THE PROBE OR POWERING DOWN THE UNIT ERASES ALL OF THE INTERNAL STORED DATA REGARDING THE USEFUL LIFE OF THE PROBE, MAKING THE “REPLACE PROBE” MESSAGE INVALID.

THE UNIT SHOULD NOT BE OPENED EXCEPT BY A QUALIFIED SERVICE PERSON. TAMPERING BY UNQUALIFIED PERSONS CAN DAMAGE THE UNIT AND VOID THE WARRANTY.

BE SURE TO INSPECT THE **AUTOLITH® TOUCH** UNIT AND ANY ACCESSORIES FOR PROPER OPERATION BEFORE EACH USE. IF THE UNIT IS FOUND TO BE DEFECTIVE OR DAMAGED, IT SHOULD BE RETURNED TO THE MANUFACTURER OR QUALIFIED SERVICE PERSONNEL FOR INSPECTION AND REPAIR.

USE ONLY NORTHGATE APPROVED ACCESSORIES THAT HAVE BEEN DESIGNED AND TESTED WITH THE **AUTOLITH® TOUCH** UNIT TO PROVIDE MAXIMUM PATIENT SAFETY AND PRODUCT PERFORMANCE.

DO NOT ALLOW THE PROBE TIP TO DISCHARGE A SHOT INSIDE THE ENDOSCOPE. DAMAGE TO THE ENDOSCOPE CAN RESULT.

SUSTAINED USE OF THE PROBES AT HIGHER POWER SETTINGS WILL SIGNIFICANTLY SHORTEN THE USEFUL LIFE OF THE PROBE.

THIS DEVICE IS DESIGNED TO FUNCTION WITH SINGLE USE ELECTROHYDRAULIC PROBES DESIGNED SPECIFICALLY FOR THE **AUTOLITH® TOUCH** UNIT. THE PROBES SHOULD NOT BE RE-USED OR RE-STERILIZED.

DEVICE IS NOT INTENDED FOR USE WITH OR IN THE ENVIRONMENT OF MRI EQUIPMENT.

THE EXTENDER CABLE MUST NOT BE SOAKED IN A DISINFECTING OR STERILIZING SOLUTION. DAMAGE COULD RESULT.

TO ENSURE PROPER OPERATION OF THE EHL UNIT DURING THE SURGICAL PROCEDURE, BE SURE TO USE .9% NORMAL PHYSIOLOGICAL SALINE TO IRRIGATE THE ENDOSCOPIC VIEWING FIELD. NO OTHER IRRIGATING SOLUTION SHOULD BE USED.

FIRING THE EHL PROBE OUTSIDE OF A SALINE FILLED ENVIRONMENT COULD REDUCE PROBE LIFE.

THE AUTOLITH® TOUCH UNIT CANNOT BE USED IF THE EXTENDER CABLE IS MISPLACED OR LOST.

IF IT BECOMES NECESSARY TO REPLACE THE FUSES, BE SURE TO USE A 2A 250V TIME DELAY FUSE AS MARKED ON THE REAR PANEL OF THE DEVICE.

A potential shock hazard exists when the AUTOLITH® TOUCH unit cover is opened. Do not open the cover. Refer all repairs to qualified service personnel at Northgate Technologies, Inc.

Carefully check all electrical cables. Do not use a cable if it shows evidence of deterioration.

Connect the power cord to a properly wired, grounded receptacle.

Carefully check the probe. If damage or misuse is found, perform the Operational Test as described in SECTION 6 - OPERATION. See full instructions for use for details.

Use probes properly:

Turning off the AUTOLITH® TOUCH unit or reconnecting used probes will void the REPLACE PROBE data, making the REPLACE PROBE calculation invalid.

DO NOT RE-USE PROBES.

Do not allow the probe tip to discharge a pulse while inside the endoscope. Damage to the endoscope can result. The tip of the probe should be at least 5mm from the distal lens of the endoscope when firing.

Maintain the extender cable:

Sterilize the Extender Cable with autoclave after each use. Some liquid disinfectants or excessive heat may damage the cable.

Always have an extra Extender Cable available. It is NOT possible to use the AUTOLITH® TOUCH unit without the Extender Cable. The disposable EHL probes must be connected to the Extender Cable. They cannot be connected directly to the AUTOLITH® TOUCH front panel.

Always check the touch screen to verify the power level and number of pulses programmed before delivering treatment to the patient.

POTENTIAL ADVERSE EVENTS

None.