Autolith™ Touch
Biliary EHL System

A Bipolar Electrohydraulic Lithotripsy System
Single-Use, Bipolar Electrohydraulic Lithotripsy Device

The Autolith Touch 1.9 Fr., 375cm EHL Probe is a single-use device and is to be used with the Autolith Touch EHL Generator. The EHL probe was optimized for use with the SpyGlass™ DS Direct Visualization System to help manage large biliary stones.

Enhanced Configuration

The 1.9 Fr., 375cm Probe provides ample length to pass through the SpyScope™ DS Access and Delivery Catheter. The tip of the probe is chamfered or rounded to help assist the physician when passing and positioning the probe. The proximal portion of the probe is reinforced and designed to prevent probe kinking.

The Autolith Touch EHL Generator

The computer controlled Autolith Touch generator was designed to provide improved patient safety, increased stone treatment effectiveness and ease of operation. It is indicated for biliary stone treatments and has the following features:

Automatic Power Range Regulation

Designed to provide a precise balance of energy to prevent power overload to the probe.

Smart Sensing Element

The Autolith Touch system automatically monitors the probe operation to alert the user when to consider replacing the probe.

Uncomplicated Operation

The Autolith Touch color, touch screen controls make it easy to use and understand.

Ordering information

Biliary EHL Probe

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>M00546620</td>
<td>1.9 Fr., 375cm Biliary EHL Probe</td>
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Autolith Touch System

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<th>Order Number</th>
<th>Description</th>
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<tr>
<td>M005466800</td>
<td>Autolith Touch EHL Generator</td>
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Autolith Touch System Accessories

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<th>Order Number</th>
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<tr>
<td>M00546750</td>
<td>Autolith Touch Extender Cable</td>
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<tr>
<td>M00546760</td>
<td>Autolith Touch Foot Pedal</td>
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Tips for New Users

- You must use saline to irrigate. The conductive properties of saline allow the electrohydraulic lithotripsy to function properly. Sterile water will not work.
- Position the tip of the probe 1-2mm from the surface of the stone for optimal fragmentation pressure.
- Start with 3-5 pulses per foot pedal activation. Typically, the stone will move after the first few pulses and it is difficult to maintain the optimal 1-2mm distance. If you set the number of pulses to a larger number, the later pulses become less effective and essentially a waste of probe life. If you have a relatively stable stone, it may be an opportunity to increase the number of pulses.
- Start at low power and work your way up through medium and high, only if you need to. The EHL process is destructive to the probe tip. If you can start with and use low power, it will extend the life of the probe. If you are not seeing progress, increase the power.
- Depending on the makeup of the stone, it is possible it will take more than one probe to achieve the necessary fragmentation. While this is not common, it can happen with particularly large or hard stones.

Based on test results and engineering analysis, it has been shown that the Autolith™ Touch 1.9 Fr. Biliary Probe (9-202-3751) and the Autolith™ Touch Generator (9-202-00) are compatible with the SpyGlass™ DS Direct Visualization System and the SpyGlass Direct Visualization System.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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

CAUTION: The law restricts these devices to sale by or on the order of a physician. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.