

PRESENTING THE NEW

CONMED Biliary Assurance Program

We are so confident in our new Short Wire Exchange Biliary devices that we are introducing and offering the CONMED Biliary Assurance Program for our FIT™ Biliary Stone Balloons, TruPass™ Papillotome and the GORE® VIABIL® Biliary Endoprosthesis.

FIT

Biliary Stone Balloon

CONMED stands behind the FIT™ Biliary Stone Balloon and it's ability to make it through even the toughest cases without breakage. Reduction in balloon breakage during the procedure can help with shortened procedures and less cost by using only one balloon per procedure.

CONMED is offering a device replacement for *FIT™ Biliary Stone Balloon* under the Biliary Assurance Program.*

TruPass™

Triple Lumen Papillotome

With each TruPass™ tested on the line, CONMED guarantees the orientation of the TruPass™ Papillotome to be between "11:00 and 1:00 o'clock position" to assist with cannulations.

The CONMED Biliary Assurance Program will provide a replacement for each *TruPass™ Triple Lumen Papillotome* that fails to orient.*

GORE® VIABIL®

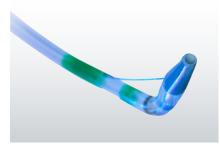
Biliary Endoprosthesis

With a 0.2% average reported migration rate, GORE® VIABIL® Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention.

Gore is so confident in these outcomes, we are offering a device replacement for *GORE® VIABIL® Biliary Endoprosthesis* if a migration occurs.*



FIT'''
BILIARY STONE BALLOON



TRUPASS™ PAPILLOTOME



GORE® VIABIL®
BILIARY ENDOPROSTHESIS

To learn more about these and other innovative products, call **800-448-6506** or visit **CONMED.com.**



BILIARY ASSURANCE PROGRAM

Program Details

Program Terms and Conditions for CONMED Corporation

FIT™ Biliary Stone Balloon

CONMED will provide a replacement device for each balloon which breaks during a procedure if the device is used in accordance with the device Instructions for Use and all other terms of the Program are met. A FIT Biliary Stone Balloon will only be replaced once and replacement devices are not eligible for this Program. In order to participate, the customer must file a complaint within five (5) days of the balloon breakage using CONMED's on-line Complaint system. In the Notes section Customer must indicate that it is requesting a replacement device pursuant to the Biliary Assurance Program. CONMED promptly will supply at no cost to customer a kit for return of the device. Within ten (10) business days of the receipt of the return kit, CONMED will ship a replacement unit to customer accompanied by a no-charge invoice. Customer is responsible for reporting the no-charge replacement device as a discount on the customer's cost report. Claims under this Program are limited to replacement of the device. Balloon breakage is a known risk of any Biliary Stone Balloon device and the provision of a replacement does not constitute an admission that there was a device malfunction or defect, or that the CONMED device, CONMED or its employees or agents, or the device itself, caused or contributed to any complications or injuries. Please see the device *Instructions for Use* for further information on the device contraindications, warnings, precautions, and potential adverse events. This Program is only applicable for CONMED FIT Biliary Stone Balloon devices purchased and used in the United States and is subject to modification or termination by CONMED at any time and without prior notification.

TruPass™ Papillotome

CONMED will provide a replacement device for each papillotome which fails to orient within an 11:00 and 1:00 position during a procedure if the device is used in accordance with the device Instructions for Use and all other terms of the Program are met. A TruPass Papillotome will only be replaced once and replacement devices are not eligible for this Program. In order to participate, the customer must file a complaint within five (5) days of the failure to orient using CONMED's on-line Complaint system. In the Notes section Customer must indicate that it is requesting a replacement device pursuant to the Biliary Assurance Program. CONMED promptly will supply at no cost to customer a kit for return of the device. Within ten (10) business days of the receipt of the return kit, CONMED will ship a replacement unit to customer accompanied by a no-charge invoice. Customer is responsible for reporting the no-charge replacement device as a discount on the customer's cost report. Claims under this Program are limited to replacement of the device. Failure to orient is a known risk of any papillotome device and the provision of a replacement does not constitute an admission that there was a device malfunction or defect, or that the CONMED device, CONMED or its employees or agents, or the device itself, caused or contributed to any complications or injuries. Please see the device *Instructions for Use* for further information on the device contraindications, warnings, precautions, and potential adverse events. This Program is only applicable for CONMED TruPass Papillotome devices purchased and used in the United States and is subject to modification or termination by CONMED at any time and without prior notification.

GORE® VIABIL® BILIARY ENDOPROSTHESIS

Gore will provide a replacement device of identical dimensions for use with the patient whose device migrates within one year post implantation. The replacement device is only available if GORE® VIABIL® Biliary Endoprosthesis is implanted in accordance with the device *Instructions for Use* (The GORE® VIABIL® Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree) and the other terms of the program are satisfied. Replacement devices provided under this program are not eligible for the program. Claims under the program are limited to the replacement device. Upon receipt of the appropriate documentation, a replacement device will be provided pursuant to the program accompanied by a no-charge invoice shipped directly to the hospital. The hospital is responsible for reporting the no-charge replacement stent as a discount on the hospital's cost report. All reports of migration will be documented appropriately within the Gore internal product surveillance process and additional information may be requested. Migrations are a known risk of any biliary endoprosthesis. The provision of a replacement device as part of the program does not constitute an admission that there was a device malfunction or defect or that Gore, its employees or agents, or the Gore device caused or contributed to any complications or injuries. Please see the device *Instructions for Use* for further information on the device contraindications, warnings, precautions, and potential adverse events. The program is subject to modification or termination by W. L. Gore & Associates without prior notification and this program is only applicable for the United States.*