URGENT FIELD SAFETY NOTICE (FSN)
URGENT MEDICAL DEVICE CORRECTION

August 13, 2012

Attention: ***GI / ENDOSCOPY Director, Materials Management***

Please forward this communication to the O.R. Director, all surgeons and surgical personnel any other potential users of the product.

Dear Customer,

BÂRRX Medical, Inc. is conducting a Voluntary Correction which affects ***all*** serial numbers of the HALO^{FLEX} Energy Generators model numbers 1190A-115A and 1190A-230A.

BÂRRX has received several complaints in the United States related to a generator malfunction where the HALO^{FLEX} Energy Generator fails to enter "standby mode" when initially powered-on. During normal operating conditions when powered-on, the generator automatically sequences through a "power-on self-test" to check for proper function. If the generator passes the self-test, it enters standby mode, displays "Ready, Connect Catheter" and is ready for use. In the complaints received, the generator became stuck in the self-test mode upon initial power-on, did not enter standby mode, and therefore could not be used for patient care. In no case has there been any patient adverse event or injury.

Required Actions:
Customers are instructed to take the following steps prior to initiating patient treatment and specifically, prior to administering conscious sedation and performing upper endoscopy:

1. Power-on the HALO^{FLEX} Energy Generator and confirm that the generator passes self-test, enters standby mode and displays "Ready, Connect Catheter".

2. Confirm that the HALO^{FLEX} Energy Generator is functioning properly at power-up and enters the standby mode then the procedure can begin.

3. Do not use the HALO^{FLEX} Energy Generator if the generator does not pass the power on self-test. In this situation, please contact your local sales representative or distributor [insert contact information] so that we can provide you with a replacement generator.

4. We ask that you reply to BÂRRX by signing and returning the attached Product Correction Form via fax to the number provided on the form. Your response is vital to our monitoring the effectiveness of this correction.

BÂRRX is developing a software revision that will prevent this malfunction from recurring. We anticipate the software revision will become available in September at which time your local sales representative or distributor will be contacting you to schedule a software upgrade for your HALO^{FLEX} Energy Generator.

We apologize for any inconvenience this may cause and thank you for your business and continued support. By following the steps detailed in the "Required Actions" section prior to administering conscious sedation and prior to administering conscious sedation and performing upper endoscopy we trust you will avoid any interruption in procedures.

If you have any questions concerning this Voluntary Correction for the HALO^{FLEX} Energy Generator you can contact a United States customer service representative at (888) 662-2779, your local sales representative, or distributor.

This Voluntary Correction is being conducted with the knowledge of your Competent Authority.

Sincerely,

Michael W. Doran
Vice President, Regulatory Affairs & Quality Assurance
BÂRRX Medical, Inc.

URGENT FIELD SAFETY NOTICE (FSN)
URGENT MEDICAL DEVICE CORRECTION

HALO^{FLEX} Energy Generators model numbers: 1190A-115A and 1190A-230A

Product REF #'s:

All serial numbers of HALO^{FLEX} Energy Generators model numbers:
1190A-115A and 1190A-230A

Date: _____

Name of Person Completing this form:_____

Title:_____

Direct Phone
#:_____Email:_____

Account Name: _____ BÂRRX Account Number:_____

Account
Address:_____

City:_____ State: _____ Zip Code:_____
Country:_____

How did the account purchase this product? (Please circle)

Direct Distributor

Distributor Name:_____

Address:_____

City:_____ State: _____Zip Code:_____
Country:_____

_____ **(please sign). I ACKNOWLEDGE RECEIPT OF THE HALO^{FLEX} ENERGY GENERATORS CORRECTION NOTIFICATION DATED AUGUST 13, 2012 AND HAVE NOTIFIED OUR SURGICAL STAFF.**

PLEASE FAX THIS ACKNOWLEDGEMENT TO THE UNITED STATES FAX # (408) 738-1741.