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Subject: Recommendations for use of FiberOptix™ (FOS) IAB

On behalf of the Cardiac Care Division of Teleflex (Formerly Arrow International)

Attention: Pharmacists and Biomedical Engineers

To our Valued Customers,

Teleflex has become aware, through customer input, of issues associated with the Fiber-Optic system (FOS or LWS) on the following Intra-Aortic Balloon (IAB) products:

Commercial name	Product code
FiberOptix Intra-Aortic Balloon – 30 CC	IAB-05830-LWS
FiberOptix Intra-Aortic Balloon – 40 CC	IAB-05840-LWS

The issues reported were:

1. Inability to establish the FOS (Fiber Optic Sensor) signal. This includes Failure to automatically or manually zero the sensor after the FOS sensor and Cal key are connected or to display an FOS Arterial pressure waveform after IAB insertion.

2. Loss of the FOS AP signal during use.

Investigation of returned product showed two primary causes:

1. Damage to or a break in the fiber.

2. A recessed connector in the IAB (Blue) slide connector.

Either of these causes would not allow the FOS system to zero and/or produce and display an AP waveform. These causes accounted for 80% of the issues reported. Our experience indicates that these causes are often related to product handling.

When the FOS signal is not available to the IABP, AutoPilot will automatically select an alternative AP signal and continues IABP support. The timing method will change from WAVE (Intra-beat timing of inflation) to Conventional timing of inflation (Predictive Inflation Method). This may result in less optimal timing during arrhythmia. Conventional timing is the current standard of care for IABP systems and is automatically selected when the FOS AP signal is not available.

Therefore, the loss of the FOS signal poses a Minor risk patients, as IABP therapy will continue based on the current standard of practice and will be equivalent to other on-market IABP systems.
The information provided below is a summary of the recommended steps for Preparing and Handling the FiberOptix™ IAB catheters from the current IAB Instructions for Use (IFU) and the AutoCat 2 Wave IABP Operation manual (IAM-9007).

The following sections will review the key steps for preparing the IAB (FOS or non-FOS), FOS sensor connection and zeroing procedure, with emphasis on those steps which may improve the ability to acquire the FOS AP signal or reduce the risk losing the FOS AP signal during use. The final section will review insertion of the IAB into the patient and the start of IABP support.

FOS IAB catheters have the same design features as standard IAB catheters with the added FOS pressure sensor in the tip of the IAB. Therefore, all steps for preparing and handling the FOS IAB are the same as the standard IAB, with one exception, zeroing the FOS sensor prior to IAB insertion.

Step 1: IAB Preparation

1. Select the IAB size based on patient characteristics and Manufacturer recommendations.
2. Select the insertion site by assessing both patient legs for pulse strength and quality. Select the leg which has the strongest pulse if possible.
3. Open the IAB package and remove the insertion kit and IAB kit. All trays are double packaged.
4. Access the femoral artery selected for IAB insertion using standard Seldinger technique.
    a. Insert the guidewire into the aorta arch, and then insert the selected sheath over the guidewire (Sheath with sideport or Sheath with no sideport). The sheath has a hemostasis valve to reduce bleeding prior to IAB insertion.
5. Prepare the IAB catheter for insertion.
    a. Place the one-way valve on the end of the IAB. It is tethered to the IAB catheter just below the end of the driveline tubing.
    b. Draw a full syringe (60cc) of air from the IAB to create a vacuum to maintain the IAB wrap.
    c. Leave the one-way valve on the IAB until it is correctly positioned in the patient.
    NOTE: This step is very important. *Pulling and maintaining* vacuum on the IAB will reduce stress on the IAB catheter and FOS cable. It improves insertability by maintaining the smallest IAB wrap diameter for insertion into the sheath and reduces the risk of damaging the fiber in the IAB during removal from the tray.
    d. Flush the central lumen of the IAB with heparinized saline or the flush solution used for arterial lines at your institution.
    e. DO NOT REMOVE the IAB from the tray until the FOS zero is complete (if the FOS sensor will be zeroed prior to insertion). This will maintain a tight wrap and allow easy passage through the sheath.

Step 2: FOS Zeroing

1. Hand the FOS IAB (Blue) connector, which is attached to a Yellow cable to the IABP operator.
    NOTE: Handle the FOS cable carefully as the fiber can be damaged by kinking, cutting or extreme bending of the cable. Do not touch the internal connections of the FOS sensor! Dirt, oils or other contaminants deposited on the connection can affect the light transmission. This may affect the ability to produce and display the AP waveform or the accuracy of hemodynamic values.

2. Connect the FOS sensor (Blue Slide connector to the IAB). A two beep tone will be heard when the sensor is fully connected and recognized by the IABP.
    NOTE: When connecting the Blue slider of the IAB into the FOS Slider (Silver) on the IABP, do not use excessive force during the connection as this may recess the FOS connector, resulting in an inability to establish the FOS AP signal. If resistance is met during the connection, pull the IAB slider back, ensuring it is straight within the slide connector. Then re-try the connection.

3. Connect the CAL key to the IABP.

CAUTION: Use only the CAL key attached to the IAB. The CAL key is unique to each FOS sensor. Use of another CAL key may result in no FOS signal or inaccurate arterial pressure readings.

4. The FOS sensor will Zero automatically once both connections are made. This process takes about 10 to 15 seconds. A 4 beep tone will be issued when the zero is complete. The FOS Icon (light bulb) will change to Green when the Zero is done.

NOTE: If the FOS sensor is NOT zeroed prior to use, the FOS Icon will remain Blue. Use an alternative AP source for treatment decisions.
While this step is ***highly*** recommended for accuracy of the hemodynamic readings, it is not required for accurate Wave timing.

5. Once the FOS sensor is zeroed, remove the IAB from the package; maintain the IAB catheter in a straight configuration.

NOTE: Do not use excessive force during IAB removal from the package and do not allow excessive bending of the IAB Catheter as it is removed from the tray. Keep the IAB as straight as possible and parallel to the tray during removal. This will reduce stress on the IAB and FOS cable.
If the IAB is difficult to remove, verify the one-way valve is still on the Driveline tubing. It may be necessary to pull additional vacuum to tighten the IAB wrap.

Step 3: Insert IAB and begin IABP support

1. Insert the IAB into the patient under Fluoroscopy or TEE guidance whenever possible. Position the IAB 1 to 2 cm below the Left Subclavian Artery.

NOTE: Do not use excessive force during IAB insertion.

a. The FOS AP signal will appear on the IABP display when the FOS sensor clears the sheath and has entered the femoral artery.

2. Remove the one-way valve, attach the driveline tubing and connect to the IABP.
3. Start IABP assist by Pressing PUMP ON.
4. Connect the central lumen of the IAB to a continuous flush set-up. This set-up can include a transducer to monitor the arterial pressure from the central lumen.

The FOS source is automatically selected in AutoPilot mode and Wave Inflation timing, using the Aortic Flow wave calculated by the Windkessel model, is automatically implemented by the AutoCat 2 Wave IABP. This unique algorithm provides intra-beat inflation timing, which may improve timing accuracy and IAB support, especially during arrhythmias.

NOTE: All FOS IAB catheters have a fully functional central lumen and maintaining patency of the lumen is ***highly*** recommended to reduce the risk of clot formation at the IAB tip and to have a back-up AP source if needed.
If the FOS AP signal is not available, connect the central lumen to a transducer and Zero the transducer. Connect the transducer to the IABP. AutoPilot mode will automatically select this waveform when it is available. In Operator mode, you can select it using the AP SELECT key on the keypad.

If the FOS sensor was NOT zeroed prior to insertion, the FOS signal should appear on the display and can be used for Wave timing. If the hemodynamic values for arterial pressure are not accurate, as compared to another accurate AP source, the FOS sensor Mean Arterial Pressure (MAP) value may be calibrated to a known accurate MAP value. This procedure is described in Chapter 7 of the AutoCat 2 IABP operation manual.

The AutoCat 2 Wave IABP requires periodic replacement of the FOS Slider (Silver connection point on the front panel of the IABP). This connector should be replaced every 200 connections to ensure optimal transmission of the FOS signal from the IABP to the FOS sensor in the IAB. This part is subject to wear

and/or contamination with oils, dirt or dust from the user or the environment. These contaminants may alter the ability to acquire and display the AP waveform.

Under average use conditions (25 IAB uses/pump/year), this part should be replaced at least every 2 years. If usage at your facility is higher, we recommend yearly replacement. If the IABP cannot produce an FOS signal consistently, especially if the FOS works on other pumps, you should consider replacing this part. As the IABP ages the ability to produce the FOS signal will degrade if this part is not maintained per Chapter 10 of the AutoCat 2 Wave Operation manual (IAM-9007).

When these steps are followed, the FOS sensor has been successfully used by many hospitals worldwide and has provided improved IABP support in the most challenging patients.

If you have any questions, please do not hesitate to contact our local Product Manager:

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Or contact your local sales representative for further support and information.

Signed,

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