T400-Series Technical Note

Use of PAU-Series COnfidence Flowprobes® with Ultrafit Liners

Protocol courtesy of J.A. Sala-Mercado CVRI, Wayne State Univ., Detroit, MI and R.L. Hammond, William Beaumont Hospital, Royal Oak, MI.

Transonic® COnfidence Flowprobes® with Ultrafit Liners are designed for easy application and fast signal acquisition on the ascending aorta and pulmonary artery in large animal species. These Flowprobes require minimal or no coupling gel for acute use and are ultra-safe for long-term chronic instrumentation.

The COnfidence Flowprobe® consists of a reusable transducer shell and disposable plastic liners that fit around the vessel. The Flowprobes are available in incremental sizes: 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 20 mm, 24 mm, 28 mm, 32 mm and 36 mm. Ultrafit Liners are supplied in a full-circle configuration for chronic implantation and with one open side for protocols that require only momentary placement. The lumen of Ultrafit Liners for Probes 8 mm to 16 mm matches the Flowprobe size. Larger size Probes (20 mm to 36 mm) are supplied with 2 liner sizes for a quick fit on the vessel without a lot of gel.

Acute Use

Ultrafit Liners are made of a special plastic that is acoustically transparent to the ultrasound signal that Transonic® Flowprobes use to measure blood flow. The liner fills in the space between the vessel and the transducers to transmit the ultrasound. The Ultrafit Liner should be sized to fit the vessel diameter to within 2 mm. A thin smear of Surgilube gel on the Flowprobe shell and inside of the Ultrafit Liner will provide effective contact to immediately receive and maintain a signal during an acute experiment.

Use of the full-circle liner is suggested for extended acute protocols as the liner will keep the vessel most securely in place. The full-circle liner can be inserted into the Flowprobe shell in either direction (liner opening against the inside of the Probe

or facing toward the opening). The liner opening edge is keyed so that the edges should not overlap. Open-ended liners are for acute use only. This configuration is suggested for short experiments. The installation is quicker since the liner does not have to pass under and around the vessel, but care should be taken to make sure the vessel

is completely within the liner lumen. The Flowprobe shell has retaining detents on either side of the shell to lock the liner in place.



COnfidence Flowprobe® with acute Ultrafit liner.

Chronic Use

The Ultrafit Liner is an inert plastic that may be implanted long-term without degradation. The smooth, soft edges of the liner keep the hard Flowprobe shell surface edges away from the vessel and protect it from abrasion and potential rupture. Since there are no air pockets to fill with gel, the COnfidence Flowprobe® with an Ultrafit Liner generates a flow signal immediately following surgical implantation. Experimental flow measurement can proceed and data can be collected without waiting for fibrotic tissue to grow into the Probe for acoustic coupling. Probe sizes 32 mm and 36 mm do not have chronic liners and may require modification for chronic use.

Ultrafit Liners are intended for single use. The COnfidence Flowprobe® and Ultrafit Liners can be sterilized by ethylene oxide gas. Reuse of the liner in chronic application is not advised. Additional liners are available from Transonic® at a minimal cost.



Use of PAU-Series COnfidence Flowprobes® with Ultrafit Liners Cont.

Chronic Placement Procedure

Ultrafit liners are supplied in a spread position for easy application (Fig. 1). The finger of a latex surgical glove is used as a "leader" to guide the liner around the vessel. The elasticity and smoothness of surgical glove latex provides the perfect applicator material to allow the surgeon to apply controlled pressure on the leading edge while the liner slips between the tissues.

- 1. Prepare the Liner
 - a) Using surgical scissors, trim the corners of the flange to a bevel on both sides of the opening of the liner.
 - b) Pass 2 (0 silk recommended) sutures through each suture hole on the ends of the liner (Fig. 2).
 - c) Cut the small finger from any size surgical glove (6, 7, 8) and place it over one end of the liner as a "leader" to draw the liner around vessel (Fig. 2).
 - d) Tie a suture laterally around the latex "leader" to secure it on the liner (Fig. 3).
- 2. Isolate a sufficient length of the vessel using blunt dissection to pass the liner around the vessel.
- 3. Using curved right angle forceps under the vessel, grasp the elastic tubing leader and gently guide the liner around the vessel (Fig. 4). Use the elasticity of the tube to draw the liner and allow the tissues to ease over the larger corners of the liner.
- 4. Once both ends of the liner are around the vessel, remove the elastic tube and tie one pair of the pre-placed sutures together (Fig. 5) to close the liner taking care that the ends of the liner do not overlap. The liner edge is keyed so that two ends will meet smoothly.
- 5. Use a smear of SurgiLube gel on the inside of the shell body for immediate acoustic coupling. This also provides lubrication to slide the Probe shell easily over the liner.
- 6. Place the Probe shell over the open end of the liner and slide it down over the parallel surfaces of the liner. Apply a slight pressure on the top of the Probe shell to pass the liner over the retaining detents and to ensure that the vessel is positioned fully within the Probe.
- 7. Tie the second pair of sutures over the top of the Flowprobe shell (Fig. 6). The sutures keep the liner from sliding out of position during beating of the heart. This is recommended for both acute and chronic protocols as significant displacement in liner/shell alignment can affect accuracy.
- 8. Tunnel the Flowprobe cable and close as protocol requires.



Fig. 1: Ultrafit Liner in spread position.



Fig. 2: Latex surgical glove is used to assist in leading the liner around the vessel.

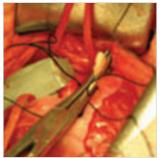


Fig. 3: Positioning the liner around the vessel.

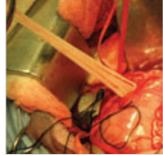


Fig. 4: Forceps grasping the elastic leader to guide the liner around the vessel.



Fig. 5: Tying the pre-placed sutures together to close the liner.



Fig. 6: Flowprobe shell in position over the liner.



Use of PAU-Series COnfidence Flowprobes® with Ultrafit Liners Cont.

Frequently Asked Questions

CAN THE ULTRAFIT LINER BE REUSED?

The Ultrafit Liners are specified for single use. We do not recommend the liners be reused for either acute or chronic applications for the following reasons:

- The performance of the liners has not been tested after multiple cleaning and sterilization cycles to ensure that the properties of the plastic material will not change with multiple use.
- Some alcohol-based cleaning agents swell the plastic so that it does not fit properly within the transducer shell. This would affect the performance of the Flowprobe.
- Scratches or other degradations in the plastic after several uses would affect the performance of the Flowprobe.
- The reuse of liners is particularly unacceptable for chronic use where "soft plastics" may harbor residues from one animal to another that might cause an allergic reaction.

CAN CONFIDENCE FLOWPROBES® BE USED ON GRAFTS?

COnfidence Flowprobes® have been tested for use on some prosthetic graft materials. Commonly used Dacron grafts have been tested with excellent results. As always, it is imperative to pretreat the graft for air removal before a signal can be obtained. It may also be possible to achieve signal in some ePTFE grafts with COnfidence Flowprobes®. Calibration and signal normalization on the graft at the factory is required to confirm that the Probe will work on the graft.



Chronic COnfidence Flowprobes® on Dacron grafts.

CAN CONFIDENCE FLOWPROBES® BE USED WITHOUT AN ULTRAFIT LINER?

COnfidence Flowprobes® are designed and calibrated for use with Ultrafit Liners. Using the shell without the liner creates the following concerns:

- Probe calibration may be affected. There may be significant error in the flow measurement if the Probe shell is used without the liner.
- The liner provides a form-fit that contains the vessel within the proper degree of alignment for accurate measurement (as long as the vessel is not much smaller than what the Probe is specified for).
- The vessel cannot be fully contained and stabilized within the Flowprobe without the liner. This may cause incomplete flow illumination of the vessel and underestimation of flow if part of the vessel is outside the Flowprobe.
- Use of acoustic coupling gel in place of the liner can significantly diminish the signal quality from the Flowprobe and may even result in an acoustic error (no signal) condition. Acoustic gel is water based and melts to become free flowing at body temperature. When placing a Flowprobe without the liner in close proximity to the heart, copious amounts of gel may be required to transmit the ultrasound signal through the space between the vessel and Probe shell. The movement of the heart and vessel causes the gel to be dispersed and rapidly leads to loss of signal. This problem was associated with PAX-series Flowprobes which had large air pockets to fill. Measurements with COnfidence Flowprobes® and Ultrafit liners do not suffer from this problem as the liner remains in place and little gel is required to couple and maintain a good quality ultrasound signal. Measurements are thereby easier to make and maintain.

(FAQ continued on next page.)



Use of PAU-Series COnfidence Flowprobes® with Ultrafit Liners Cont.

Frequently Asked Questions Cont.

CAN CONFIDENCE FLOWPROBES® BE USED AROUND LABORATORY TUBING TO MEASURE FLOW IN BENCH TUBING CIRCUITS?

COnfidence Flowprobes® are designed for measuring blood flow in vessels. The Ultrafit Liner plastic does not attenuate the ultrasound signal at body temperature as many plastics may. Instead, the liner material matches the acoustic signal in blood during in vivo use and so transmits the signal through it to measure blood flow in a vessel without error.

- By contrast, typical plastic tubing (such as pvc) usually blocks the ultrasound signal because the acoustic properties of the plastic are so different than the water based solutions. Transonic® manufactures Clamp-on and Inline Flowsensors for use on standard laboratory tubing.
- COnfidence Flowprobes® can be used on thin walled latex tubing that is used in some bench flow apparatus, but special conditions apply. Like other Transonic® Perivascular Flowprobes, the Probe may be submerged in a water bath for acoustic coupling transmission. However, the acoustic properties of the Ultrafit liner plastic are affected by temperature. The effects of temperature on acoustic signal and calibration can be corrected by heating the bath to body temperature.

WHY DO I GET LOW RECEIVED SIGNAL QUALITY WHEN I TEST CONFIDENCE FLOWPROBES® IN WATER?

- A standard test for Transonic® Perivascular Flowprobes is to check received signal in de-gassed water or saline prior to use. This simple test can identify a problem or failing Probe prior to implantation to avert costly mistakes by implanting a Probe with marginal signal. However, COnfidence Flowprobes® with Ultrafit Liners have lower signal quality in a room temperature water bath than PS-Series and PR-series Perivascular Flowprobes that do not have plastic liners.
- COnfidence Flowprobes® with Ultrafit Liners should be tested in a water bath at body temperature (35 40°C) to achieve full signal quality. At room temperature, the plastic liner attenuates the ultrasound signal transmission through the liner up to 30 40% (2 3 signal bars). At body temperature, the liner is "transparent" and the ultrasound signal transmits at full signal quality (4-5 signal bars).
- The COnfidence Flowprobe® shell can also be tested in room temperature water without the liner as a quick check if a heated water bath is not available.



Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound Flowmeters and monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. In addition, Transonic provides pressure and pressure volume systems, laser Doppler Flowmeters and telemetry systems.

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