

Guidelines for the Re-gel of the PhysioTel and PhysioTel Digital Large Animal Devices

The design of the pressure implant provides optimum performance when monitoring physiologic pressures in laboratory animals. The sensitivity of the device is largely dependent upon the terminal end of the pressure-sensing catheter. Normal catheter manipulations can result in the inclusion of air bubbles, blood components, or foreign materials into the biocompatible gel. This document will provide guidelines for the maintenance of the pressure-sensing region of the catheter, specifically replacing lost gel and displacing gel inclusions. The sensitive nature of this catheter design necessitates caution while performing these procedures. **Application of excessive force to the fluids inside the catheter will cause permanent damage to the implant and render it inoperable.**

There are two components of the pressure-sensing region of the terminal end of the catheter. The sensing region contains a viscous plug of biocompatible gel and a reservoir of non-compressible fluid. At the interface between these two components is a meniscus that is visible to the naked eye. The gel plug measures 6.5 mm in length for standard catheters and 5.25 mm for left ventricular pressure catheters; the proximal portion of the catheter contains fluid. **Use caution to avoid disturbing the fluid filled portion of the catheter as this will compromise pressure readings and cause inaccurate results.** The recommended needle choice for re-gelling a large animal catheter is the blunt-edge, lavender hub, 30-gauge needle provided with the re-gel syringe. The blunt-edging will help prevent damage to the catheter.

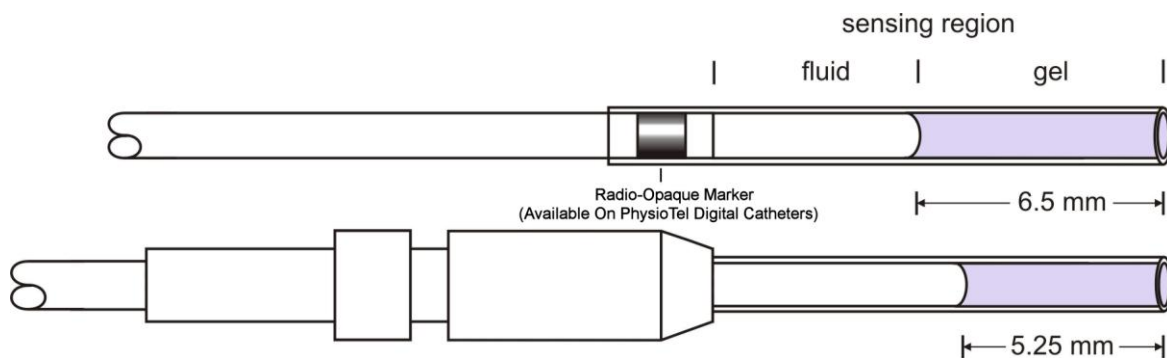


Figure 1: Systemic Blood Pressure Catheter (Top), Left Ventricular Pressure Catheter (Bottom)

After verifying the implant is on, keep an AM radio turned on and place it next to the implant to audibly monitor the amount of pressure applied to the implant. **This procedure should not significantly alter the tone of the implant. If the tone starts to change, adjust the pressure on the catheter to avoid damaging the sensor. Please note that you will not be able to hear the tone of the device with a radio when using a PhysioTel Digital implant.** With clean, gloved hands, make sure air is not present in the re-gel syringe by pressing the plunger on the syringe and expelling a small amount of gel out the tip of the needle. Making certain not to touch the catheter edges with

the needle, very carefully and slowly insert the tip of the needle into the catheter. Advance the tip of the needle until it rests just below the surface of the remaining gel (or below the surface of any blood, foreign material, or air bubbles remaining in the tip). Use gentle pressure to begin expressing gel into the catheter. Continue to inject the gel while gently withdrawing the needle from the catheter. Once the catheter tip is full of gel and air bubbles or foreign material are no longer present, gently remove any excess gel on the outside of the catheter tip. The device is now ready for implantation or re-sterilization if the device is being re-used. **Do not attempt this procedure without an AM radio when using a PhysioTel device to monitor the applied pressure on the catheter as damage can occur to the implant! Because no audible tone is monitored while re-gelling the PhysioTel Digital implant, an offset should always be taken afterwards to ensure the device is accurately measuring pressure.**