PhysioTel®Digital Device
Surgical Manual

Surgical Implantation of the PhysioTel®Digital Blood Pressure and Biopotential Telemetry Devices

Acknowledgments

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PhysioTel®Digital Device Surgical Manual

Printed in U.S.A.

Part Number

Rev. 01

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Introduction

PhysioTel®Digital telemetry devices are surgically implanted into large laboratory animals to acquire multiple types of physiologic measurements, process the information and transmit the data via radio-frequency signals. The PhysioTel®Digital device can measure pressure (such as systemic blood pressure or intra-ventricular pressure), a biopotential (such as ECG) temperature and physical activity. This manual contains detailed procedures for implantation of the ~~TS-~~L11 and ~~TS-~~L21 PhysioTel®Digital telemetry devices. The techniques described are designed for large laboratory animals including dogs, primates and swine but may be applicable to other, similar sized animals.

The PhysioTel®Digital Device Surgical Manual is intended for use by laboratory personnel who will perform or assist in surgical procedures to implant PhysioTel®Digital devices. The surgical procedures written in this manual are at a level of detail appropriate for persons who have previous experience with surgical procedures. These devices should only be implanted by a person who has previous surgical experience.

WARNING: The PhysioTel®Digital implantable device is not intended for use in humans. It is a misuse of this device, and a possible violation of law, to use these devices in humans.

This Manual Contains the Following Sections:

- Required Supplies for the ~~TS-~~L11 and ~~TS-~~L21 Surgery
- Anesthesia and Analgesia Guidelines
- Peri-operative Antibiotics
- Device Description
- Surgical Preparation
- Device Handling
- Device Placement
    - Intra-abdominal placement
        - Intraperitoneal
        - Subperitoneal
    - Extra-abdominal placement
        - Intramuscular
        - Subcutaneous
- Systemic Blood Pressure Catheter Placement
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- Solid Tip ECG Lead Placement
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- ~~Appendix A: Additional Device Information~~
- ~~Appendix B: Functional Specifications~~
- ~~Appendix C: Care and Use~~
- ~~Appendix D: Equipment and Supplies~~
- ~~Appendix E: Checking the Offset of a Pressure Device~~

Required Supplies for the PhysioTel®Digital Surgery

EQUIPMENT

- Clippers
- Supplemental heating
- PhysioTel®Digital device
- Ponemah 5.1 data collection system
- Mechanical ventilator

~~INSTRUMENTS~~

- ~~Details contained in Appendix D~~

SUPPLIES

- Surgical scrub (Chlorhexidine or Providine-Iodine scrub)
- Sterile drapes
- Sterile gloves, hair bonnet and face mask
- Sterile surgical gown
- Sterile gauze sponges-4 inches x 4 inches (10 cm x 10 cm)
- Sterile saline
- Sterile basin
- 2% Lidocaine
- Elastic vessel loops
- 2-0 * to 4-0 (Smaller or larger suture may be needed depending on size and species used) non-absorbable, non swaged suture[MES1]
- 2-0 to 4-0 (Smaller or larger suture may be needed depending on size and species used) non-absorbable suture swaged on a tapered needle[MES2]
- 2-0 or 4-0 (Smaller suture may be needed depending on size and species used) absorbable suture material swaged on a tapered needle[MES3]
- 2-0 to 4-0 (Smaller suture may be needed depending on size and species used) absorbable surgical suture swaged on a cutting needle[MES4]
- 14-gauge hypodermic needle *
- 20-gauge hypodermic needle *
- Catheter introducer (i.e. vein pick)*

- Magnet *
- Re-gel syringe
- Vetbond®Tissue adhesive (if placing systemic blood pressure catheter in iliac artery)
- Gel loading micropipette tip or insulin syringe (if placing systemic blood pressure catheter in iliac artery)

* Contained in starter kit

Anesthesia and Analgesia Guidelines

Proper peri-operative pain control and anesthesia are critical to humane treatment of laboratory animals. Each institution's staff veterinarian should be contacted for proper analgesic and anesthetic protocols and training before survival surgery is attempted.

The use of pre- and post-surgical analgesics is strongly encouraged for all surgical manipulations performed on laboratory animals. "The proper use of anesthetics and analgesics in research animals is an ethical imperative…The selection of the most appropriate analgesic or anesthetic should reflect professional judgment as to which best meets clinical and humane requirements without compromising the scientific aspects of the research protocol."[1] Questions regarding the use of analgesics should be directed to your staff veterinarian.

Typically, the surgical procedure for the ~~TS-~~L11 will require 60 minutes of surgical anesthesia, and the surgical procedure for the ~~TS-~~L21 device will require approximately 120 minutes of surgical anesthesia. Intermittent positive pressure mechanical ventilation is required any time the thoracic cavity is opened, such as during placement of a left ventricular pressure catheter. Appropriate use of this technique is essential, and should be directed by the staff veterinarian. The surgical procedures described in this manual were developed using inhalational anesthesia consisting of Isoflurane delivered in 100% Oxygen. These recommendations are intended as a guide only and should be modified to the individual animal and institution's protocol.

Anesthetized animals are predisposed to hypothermia. The use of supplemental heat sources such as warm water re-circulating heating pads or Bair Huggers® are important to maintain baseline body temperature. Hypothermia will prolong the recovery period and may result in animal loss.

For additional help in determining an appropriate anesthetic protocol, the staff veterinarian should be contacted. DSI has also prepared an Anesthesia Reference Manual as a guide to assist in choosing an appropriate anesthetic agent for a wide variety of common laboratory species.

[1] Guide for the Care and Use of Laboratory Animals, NRC, *National Academy Press*, 1996 [MES5]

Peri-operative Antibiotics and Antiarrhythmic Medications

The use of antibiotics may be elected at the discretion of the investigator. The combination of sterile device packaging and proper aseptic technique help increase the potential for successful surgical outcomes. Investigators should follow the guidelines of their own institution. Questions regarding the use of antibiotics should be directed to the institution's staff veterinarian.

Due to the manipulation of the heart, there is a potential to induce an arrhythmia, and the anesthetist may wish to be prepared to deliver antiarrhythmic agents as appropriate. The choice and dose of agents should be determined through consultation with the institution's veterinarian.

Device Description

It is important that you are familiar with the device and its function before you attempt implantation (see Figure 1).

Figure 1. PhysioTel®Digital Device[MES6]

The PhysioTel®Digital device measures pressure, a biopotential signal, temperature, and physical activity in primates, dogs and swine and is a rectangular shaped device.

The devices consist of the following major components:

Device Body - The titanium housing containing:

- Pressure sensor: receives pressure fluctuations from the fluid-filled catheter and sends the signals to the electronics module.
- Reusable electronics module: translates the pressure fluctuations, biopotential signal and temperature into digitized signals and transmits them to a receiver. It also interprets signals received from the laboratory software and contains a magnetically activated switch that allows the device to be switched on or off.
- Battery: provides the power supply for the electronics module.
- Suture aid: allows the surgeon to suture the device securely in place at the implant site.

Pressure Catheter(s) - Polyurethane tubing that extends (25, 35 or 40 cm) out of the device body and contains:

- Non-compressible fluid: relays pressure fluctuations to the sensor in the device body.

- Thin-walled section: tip of the catheter farthest from the device body that senses the dynamic portion of the pressure wave. It is designed to be completely inserted into the vessel or space where the desired pressure can be sensed. It contains biocompatible gel at the very tip, which prevents the non-compressible fluid from leaving the catheter and blood from clotting in the catheter tip (see Figure2).
- Tip cover: removable section of silicone tubing that protects the catheter tip until it is actually inserted into the desired vessel. Must be removed prior to catheter insertion.
- Systemic blood pressure catheter: containing a radio-opaque ring encircling the distal end of the systemic blood pressure catheter (This is the channel 2 catheter on the ~~TS~~ L21 PhysioTel®Digital Device.)
- Left ventricular pressure catheter: containing a plastic suture collar near the tip, with only the thin-walled section protruding beyond. The white suture collar will be inserted until the suture groove is flush with the heart wall (see Figure 3).

It is important to be familiar with the catheter and its features. See the figure below for a detailed diagram of each catheter.

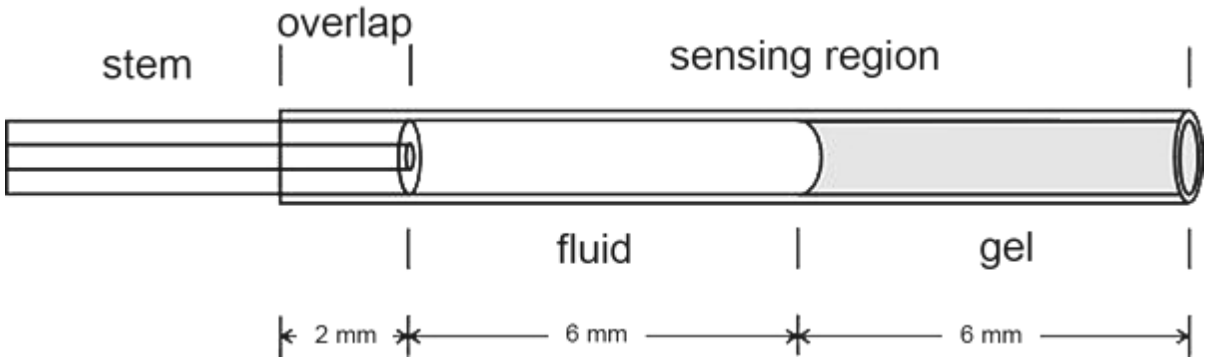


Figure 2. The PhysioTel®Digital catheter

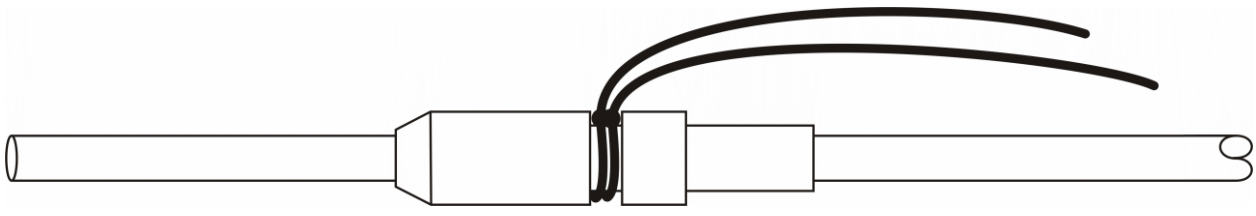


Figure 3. The Left Ventricular Catheter Tip With Collar[MES7]

Biopotential Leads - Two silicon coated helices of medical grade stainless steel wire extending out of the device body. The positive (red) lead is designed to be cut to a length suitable for the biopotential signal to be monitored. The negative (clear) lead has a solid tip and is NOT meant to be cut (unless you require traditional lead placement). It is designed to be introduced into the right jugular vein and fed into the cranial vena cava to collect the ECG signal.

- Silicone tubing: provides insulation from external electrical activity.
- Solid tip on the negative lead: senses ECG signal within the vena cava, near the base of the heart.

Figure 4. [MES8]**Solid Tip Biopotential Lead**

Device Handling

ALWAYS handle the device with care supporting both the device body and catheters from underneath when moving or placing the device. Allowing the catheters to hit a solid surface can damage the pressure sensor.

Before removing the device from its sterile package

Turn the device to the ON mode with a magnet and ~~audibly~~ verify proper device operation with a DSI receiver.

1. Record the serial number of the device and ensure that the device has been identified with the animal into which it will be implanted.

2. Measure and record the pressure offset. ~~Refer to Appendix E for further information on this process.~~

To Hydrate the Catheter

1. Open the sterile package by peeling back the white package cover from the clear plastic tray. ~~Do not discard the white package cover as it contains important device calibration information. Also do~~Do not discard the sterile package as it can be used for eventual return of the device to DSI.

2. Place the device and catheter into a sterile basin with sterile saline warmed to body temperature. ***Do not heat the sterile saline higher than body temperature as this can result in clotting at the catheter tip once it is placed in the animal.***

3. The catheter should be hydrated for approximately 30 minutes before implantation. ***Note: The catheter is very hydrophilic and, if not hydrated, will absorb water from the blood. This can cause the gel to recede due to catheter expansion and leave a void at the tip of the catheter, which could increase the risk of blood clot formation.***

WARNING: Do NOT use surgical electrocautery on the animal once the device is ~~on the surgical table~~implanted into the animal. Use of electrocautery once the ECG leads are implanted will cause failure of the device!

Preoperative Patient Preparation

1. Administer the appropriate surgical anesthesia.

2. Apply Artificial Tears eye ointment to each eye.

3. Remove the body hair liberally from all intended incision sites.

4. Surgically scrub the incision sites with Chlorhexidine or Providine-iodine scrub.

    a. A series of at least three scrubs after all gross debris has been removed is recommended.

    b. Begin each scrub in the center of the scrubbed area, over the planned incision site, and scrub in a 'bulls eye' pattern toward the periphery, never going back to the center with the same gauze sponge. The skin preparation should be thorough but gentle to avoid unnecessary skin trauma.

    c. The final application of scrub may be allowed to remain on the skin.

5. Once the animal and the surgeon have been prepped for surgery and a sterile field has been established, the surgery is ready to begin.

For intra-thoracic procedures, the animal must be placed on a ventilator to maintain respiration.

Device Implantation

Site Selection

The PhysioTel®Digital device can be implanted ~~either~~ intramuscularly, subcutaneously, intraperitoneally or subperitoneally in animals weighing at least 2.5 kilograms. Possible locations for placement of the device body vary with the species and size of animal that is implanted and the physiologic parameters that will be measured.

If core body temperature measurements are desired, the device must be placed in the peritoneal cavity or subperitoneally (between the peritoneum and the abdominal muscle). Direct placement of the device body in the abdomen of swine is not recommended due to rare cases of engulfment and ingestion of the device by the swine's gastrointestinal tract~~,~~. T~~t~~herefore subperitoneal placement is recommended in this species.

Other possible locations for placement of the device body include intramuscularly along the animal's flank or subcutaneously along the dorsum or the flank. Subcutaneous placement is not generally recommended in pigs and NHPs since they are prone to picking and rubbing the device when it is placed in this location.

For subcutaneous and intramuscular locations, the animal must be large enough to allow the antennae to lie perpendicular to the device body to preserve signal quality and in location that is not directly over bone since this can lead to skin necrosis and irritation. The device must lie flat under the skin in a pocket that is large enough to accommodate the device comfortably. However excessive pocket size predisposes to seroma formation.

Device Body Location	Dog	NHPs	Swine
Peritoneal cavity; sutured to the inner abdominal wall	Acceptable location	Acceptable location (NHP must be > 2.5 kg)	Not recommended
Peritoneal cavity; sutured between the peritoneum and the abdominal wall muscles	Acceptable location	Acceptable location (NHP must be > 2.5 kg)	Acceptable location
Intramuscularly along the animal's flank	Acceptable location	Acceptable location	Acceptable location
Subcutaneously along the dorsum or flank	Acceptable location	Not recommended	Not recommended

Intra-abdominal Placement: Intraperitoneal/Subperitoneal

Intraperitoneal/subperitoneal placement is appropriate for canines and non-human primates weighing ≥ 2.5 kg. Due to potential device engulfment by the intestines, intraperitoneal placement is not recommended in swine; instead a modified subperitoneal approach is favored. The intraperitoneal/subperitoneal placement is particularly useful when the trans-diaphragmatic approach is used to access the heart for left ventricular pressure catheter placement, since access to the peritoneal cavity will have already been established.

1. Make an incision through the skin and subcutaneous tissues between the xyphoid process cranially and the umbilicus caudally (length will vary according to procedure, and can be extended as needed).

2. Make a small incision in the body wall through the linea alba (tenting can prevent trauma to underlying viscera), then insert a forceps or grooved director and use a scalpel with the sharp edge facing externally to extend the incision. ~~Keep~~ The length of the incision in the body wall should be less~~smaller~~ than the skin incision to allow for closure (see figure 4).

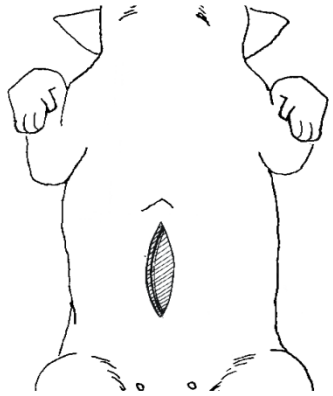


Figure 5. Midline Abdominal Incision[MES9]

Subperitoneal placement	Intraperitoneal placement
3a. Make an incision into the peritoneal lining of the abdominal wall approximately 2-3 cm to the left ~~animal's left~~ of the midline incision (the surgeon's right) large enough to place the device portion of the device.	3b. Gently retract the left side of the abdominal wall slightly to expose the internal surface approximately 2-3 cm away from the incision.
4a. Use a mayo scissors to create an appropriately sized pocket using blunt dissection. Place the device inside the pocket with the catheters and biopotential leads oriented cranially and the antennae perpendicular to the device body, towards the opposite side of the abdomen. (i.e. with	4b. Place the device inside the abdomen to animal's left of the midline incision (the surgeon's right). Orient~~ate~~ the catheters and biopotential leads cranially and the antennae perpendicular to the device body, towards the opposite side of the abdomen. (i.e. with device is placed on the left side of the linea

the device is placed on the left side of the linea alba the antennae will run along the abdominal wall, across the abdominal incision, towards the right side of the abdomen.)	alba the antennae will run along the abdominal wall, across the abdominal incision, towards the right side of the abdomen.)
5a. Secure the device body to the inside of the abdominal wall by suturing the suture aids to the inner abdominal muscle using non-absorbable suture, it may not be possible to place a suture through the deepest suture tab.	5b. Secure the device body to the inside of the abdominal wall by suturing the suture aids to the inner abdominal muscle using non-absorbable suture. Be sure the device body is secured away from the incision site so that it will not interfere with healing once the incision is closed.
6a. Close the subperitoneal pocket using absorbable suture material in a simple continuous pattern.	6b. N/A

7. Do NOT secure the antennae; the antennae will be secured just prior to closing the abdomen (see below).

8. The negative (± positive) biopotential lead(s) will now need to be exteriorized from the peritoneal cavity by passing a 14 gauge needle from outside of the abdomen to inside, next to the incision. The lead can then be passed into the needle which is then withdrawn.

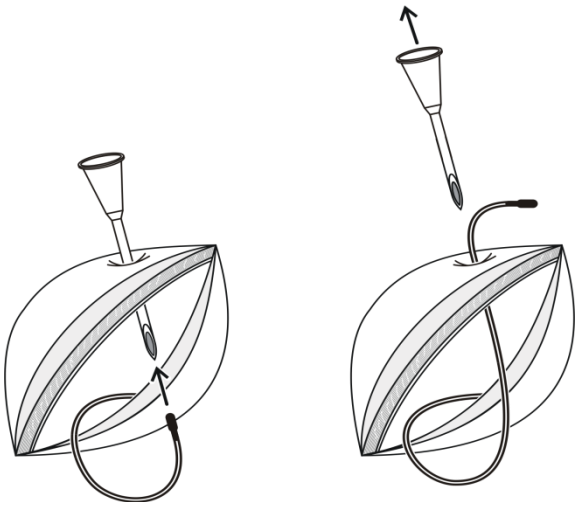


Figure 6. Cather and Biopotential Lead Exteriorization[MES10]

9. As soon as access to the abdominal cavity is no longer needed (after catheter(s) and biopotential leads have all been exteriorized/placed) the abdominal incision should be closed.

10. Before closing the abdominal wall, the antenna of the device must be secured. A small incision (~1cm) should be made in the peritoneum just ~~next~~ to the right of the midline incision (surgeon's left), across from the body of the device.

Figure 7. PhysioTel®Digital Device Placed Intraperitoneally[MES11]

11. Next a small pocket should be tunneled in the subperitioneal space using blunt dissection with a mayo scissors or a straight hemostat to provide a secure location for the antenna to sit.

12. The body wall can be temporarily apposed near the antenna (without including the antenna itself) using an interrupted suture or a towel clamp.

13. The body wall should be closed in 2-3 layers. The first layer is the muscular body wall itself which should be closed in a simple interrupted pattern with an ~~monofilament~~ absorbable suture of the appropriate size.

14. Next, the subcutaneous tissue should be closed in a simple continuous pattern using an absorbable material, burying the knots.

15. Finally, skin should be closed in an intradermal/subcuticular pattern using an absorbable suture material. This pattern is recommended to prevent post-operative irritation. Tissue glue may be used to seal the incision if the surgeon chooses.

Extraperitoneal Placement: Intramuscular/Subcutaneous

Intramuscular or subcutaneous device placement is appropriate in laboratory animals where the anatomy allows for a sufficiently sized pocket in the flank ~~(paralumbar fossa area)~~ in which the device and antenna can lie flat and at 90 degrees to one another. The device and antenna must also lie in a location that does not place either portion of the device over bone. No implants should be placed directly underneath an incision, as this can interfere with proper healing, but rather the overlying tissue should be undermined to create a pocket that lies slightly distant from the incision. The intramuscular placement provides additional soft tissue between the device body and the skin and has been noted to reduce the incidence of rubbing or scratching in swine and non-human primates.

Figure 8. PhysioTel®Digital Device in SQ/IM Pocket with Antenna at 90 Degrees

Lateral Recumbency

1. Place a straight to curvilinear incision, slightly longer than the device body, in the paralumbar fossa area, between the tuber ischii and the last rib. A second smaller stab skin incision should be made at the point to which the antenna is expected to extend (as determined by estimating approximate device location prior to surgery) at a 90 degree angle to the device body.

~~**Figure 9. Subcutaneous/Intramuscular Placement in Lateral Recumbency**~~

~~**Figure 10. Abdominal Wall Muscle Layers**~~

Subcutaneous	Intramuscular
2a. Using a mayo scissors bluntly dissect under the skin to form a pocket approximately the size of the device body.	2b. Using a gridding technique, bluntly separate the superficial external abdominal oblique muscle along the fibers running craniodorsal to caudoventrally. Be cautious not to dissect too deeply and enter the abdominal cavity.
4a. Pass a trochar and cannula can between the small stab incision for antenna placement and the larger incision for device placement.	4b. See 4a.
3a. The device body should be placed in the pocket created using blunt dissection, and sutured to the underlying muscle using non-absorbable suture material through the suture aids. The antenna should be passed through the cannula so it lies at a 90 degree angle to the device body.	3b. The device body should be placed in this space created between the external and internal abdominal oblique muscles, with their fibers running in opposite directions. The device should be secured to the underlying muscle using non-absorbable sutures through the suture aids. The antenna should be passed through the cannula so it lies at a 90 degree angle to the device body.

4. The catheters and biopotential leads now need to be routed to their implantation sites. The first step to do this requires a skin incision be made over the planned implantation site (i.e. left jugular furrow for negative solid tip lead, medial thigh for medial saphenous artery etc.).

5. A cannula and trochar can then be passed between the two incisions, the trochar removed, the catheter(s) and biopotential leads passed through the cannula and the cannula removed. If necessary to navigate difficult anatomy, an incision can be made partway between the origin and the planned implantation site, allowing for easier navigation of corners, angles etc. The surgeon is likely to pass the cannual and trochar multiple times to route the catheter(s) and biopotential leads to multiple different implantation locations.

6. AFTER the catheter(s), biopotential leads and antenna have been directed to their appropriate locations, the incision can be closed in layers.

Subcutaneous	Intramuscular
a. First the muscle can be gently approximated in a simple continuous suture pattern using an absorbable suture material on a tapered point needle. Subcutaneous tissue can also be approximated similarly. The skin can be closed using an intradermal/subcuticular suture pattern with a cutting needle. The stab incision for	b. Subcutaneous tissue can also be approximated similarly. The skin can be closed using an intradermal/subcuticular suture pattern with a cutting needle. The stab incision for placement of the antenna should also be closed using an intradermal/subcuticular pattern.

placement of the antenna should also be closed using an intradermal/subcuticular pattern.	

~~Dorsal Recumbency~~

~~Figure 11. Subcutaneous/Intramuscular Placement in Dorsal Recumbency~~

Intramuscular	Subcutaneous
1a. Place a longitudinal incision just axial (to the inside of) the fold of the flank. Make the incision long enough to allow for insertion of the device in whichever positioning will allow the antenna to sit at 90 degrees to the device body (with neither device body nor antenna placed over any bony structure). The incision is made through the skin and superficial muscle layer (external abdominal oblique), providing a natural separation between muscle layers of the lateral body wall.	1b. Place a longitudinal incision just abaxial (to the outside of) the fold of the flank. Make the incision long enough to allow for insertion of the device in whichever positioning will allow the antenna to sit at 90 degrees to the device body (with neither device body nor antenna placed over any bony structure). The incision is made through skin only.
2a. Place a small stab incision through the skin and external muscle layer at the level that the antenna will extend to.	2a. Place a small stab incision through the skin at the level that the antenna will extend to.
3a. Blunt dissection between muscles is used to create a pocket for the device. The pocket should be large enough to accommodate the device comfortably, but not too large, as this can cause seroma formation.	3b. Blunt dissection underneath the skin is used to create a pocket for the device. The pocket should be large enough to accommodate the device comfortably, but not too large, as this can cause seroma formation.

Left Ventricular Pressure Catheter Placement

Trans-diaphragmatic Approach	Thoracotomy Approach*
1a. After the abdominal wall incision has been made (see 1 and 2 in intrabdominal and subperitoneal device placement). Retract the abdomen wall with an appropriately sized Belfour retractor and elevate the xiphoid process with an army-navy or malleable retractor to allow access to the diaphragm.	1b. Counting backwards from the first or last rib, locate the 5th intercostal space. Make an incision through the skin, subcutaneous tissue, and cutaneous trunci muscle midway between the ribs, being careful to follow the contour of the ribs closely from the costovertebral junction to the sternum. Incise the latissimus dorsi and pectinius muscles parallel with the skin and then incise the external abdominal oblique.
2a. Incise the diaphragm over the left apex	2b. During exhalation, cautiously make a

of the heart. ***Remembering that during dorsal recumbency the animal's heart shifts from its natural position so the incision should be placed slightly ventrally.***	small nick in the intercostals muscles, being very careful to center the incision midway between the cranial and caudal rib; this prevents trauma to the intercostals nerve and blood vessels running along the caudal aspect of the cranial rib and provides adequate tissue for closure. Then extend the incision using a push-cut method dorsally to the tubercle of the rib and ventrally past the costochondral arch to the internal thoracic vessels (avoid cutting these vessels).
3a. The diaphragm may be kept open by placing stay sutures in the diaphragm on each side of the incision using 3-0 or 4-0 suture with a taper needle. Secure the ends of the stay suture with a hemostatic clamp which can then be held by an assistant.	3b. Place wet laparotomy sponges or gauze squares under the blades of a finochietto retractor which can be used to expose the heart and vessels.

***A rib resection may provide additional access to the thoracic cavity, especially in swine, due to the anatomical difference of a wider rib.**

Figure 12. Trans-diaphragmatic Approach to Left Ventricle [MES12]
~~**Figure 13. Thoracotomy Approach to Left Ventricle** [MES13]~~

1. Incise the pericardium to allow for access to the apex of the heart. Begin the incision by tenting the pericardium over the apex and extend the incision cranially, stopping before reaching the phrenic nerve that runs through the pericardium horizontally along the base of the heart. Next, extend the incision to the right and left below the phrenic nerve, exceess pericardial tissue can be excised.

2. Stay sutures using 3-0 or 4-0 suture on a tapered needle may be placed in the pericardium on either side of the incision to improve access to the apex of the heart. Secure the ends of the stay sutures with clamps which can be manipulated by an assistant. ***Minimize cardiac retraction as it can cause poor flow into and out of the heart, severe hypotension and arrhythmias. Monitor blood pressure and ECG closely when manipulating the heart.***

3. Identify the target area at the apex of the heart and install a purse-string suture usinig 3-4 partial-thickness bites (***avoid entering the lumen***) in the myocardium (see Figure 13). This should be done using 3-0 or 4-0 non-absorbable suture with a taper needle.

Figure 13: Placement of the purse-string suture

4. Carefully remove the tip cover from the LV catheter (Channel 1, see description above). Removal of the tip cover should be done by alternating gentle traction and release. ***Take care to prevent gel loss due to compression of the catheter or sudden release of the tip cover. Always examine the catheter prior to implantation for gel loss or bubbles. If there is gel loss or bubbles, the catheter will need to be re-gelled. For help with this process, refer to the Guidelines for the Re-gel of the PA-C40 Device on our website: www.datasci.com. A video clip of this procedure is also available on our website.***

5. Tie a piece of non-absorbable suture around the suture aid on the catheter (see Figure 14). The size of the suture should be similar to that used for the purse string suture in the heart, and using a different may be helpful.

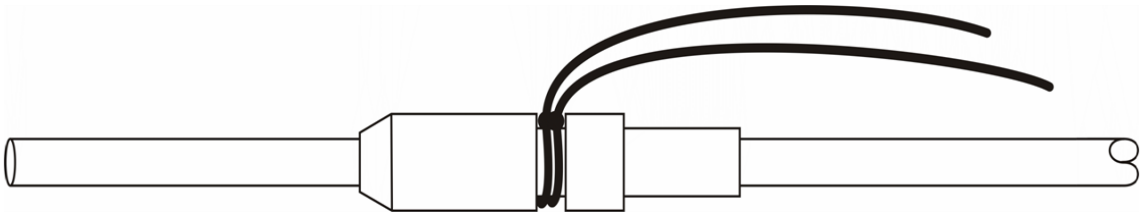


Figure 14: Suture around the suture aid

The process of inserting the catheter into the left ventricle is an intricate maneuver and needs to be performed quickly and efficiently in order to prevent damage to the heart.

6. Using a hemostat or clamp, grasp the hub of a 14-gauge needle.

7. Puncture the heart in the center of the purse-string suture and verify perforation into the left ventricle by the presence of blood in the needle (see Figure 15).

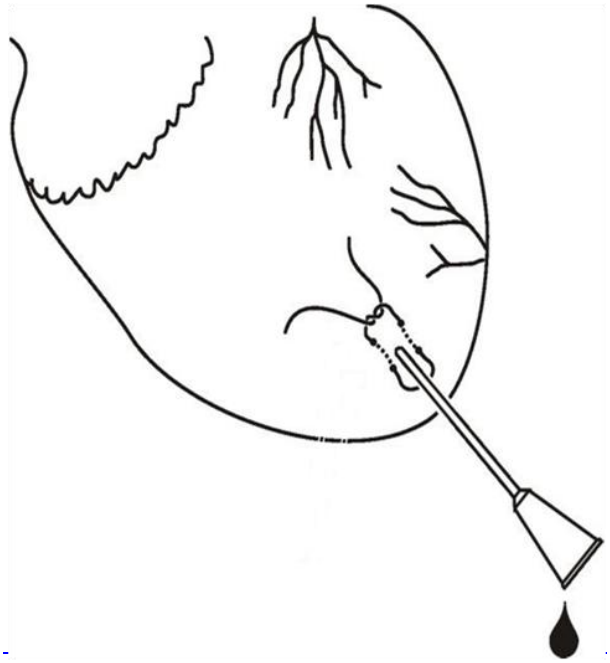


Figure 15: Puncture the heart wall

8. Withdraw the needle and insert a micro-mosquito hemostat into the hole. Open the hemostat slightly to expand the hole.

9. Grasp the overlap section of the catheter using a Ddebakey forceps, vessel cannulation forceps or gently using the hand.

10. Insert the tip of the catheter into the perforation in the heart wall. Advance the catheter until the suture aid suture on the catheter is in direct contact with the heart wall (see Figure 16). ***Releasing the catheter at this point may cause the catheter to withdraw from the heart. Keep grasping the catheter until the purse-string suture is tightened.***

Figure 16. Catheter Inserted into Heart

11. Monitor the left ventricular pressure signal to verify proper placement (see Figure 17).

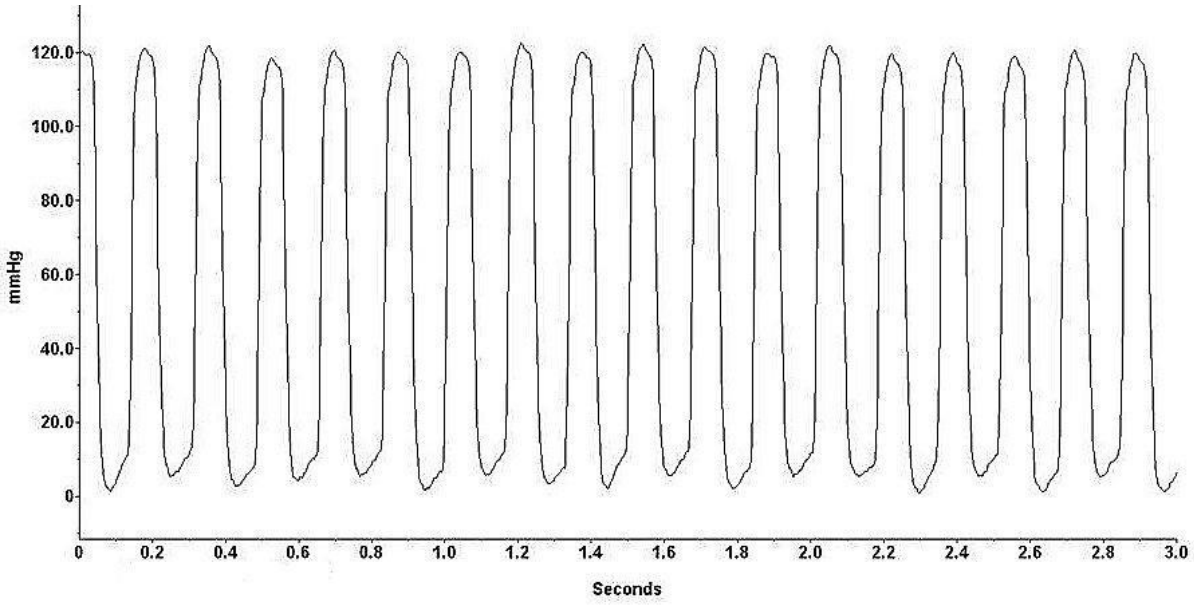


Figure 17: Left ventricular pressure signal

12. Once proper positioning is verified, draw the purse-string suture closed around the catheter. ***Ensure this suture is tight and multiple square knots are tied to prevent the catheter from withdrawing from the heart*** (see Figure 18)***.***

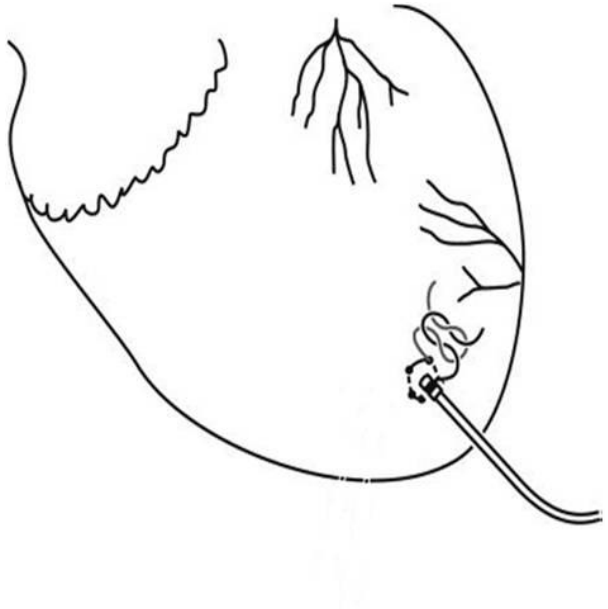


Figure 18. Tying the purse-string suture

13. Tie one tail of each of the purse-string sutures to one tail of each of the suture aid sutures (***this is why using different colored sutures can be helpful***) to further secure the catheter in place.

14. Ensure that the catheter is placed securely in the heart wall and that all bleeding has stopped, and cut the stay suture aid suture and purse string suture tails. If necessary, an additional purse-string suture can be placed.

15. Optimize the orientation of the catheter so that the catheter is perpendicular to the heart wall.

Closure of Thoracic Access

Trans-diaphragmatic Approach	Thoracotomy
16a. Prior to closing the diaphragm, any blood should be gently removed from the chest cavity. Stay sutures in the pericardium and diaphragm itself should also be removed.	16b. First gently remove any blood from the chest cavity. Pericardial stay sutures should also be removed if they were used.
17a. Begin at the dorsal-most aspect of the incision and begin closing in a simple continuous pattern using an absorbable suture on a tapered needle. The catheter should exit the thoracic cavity near the ventral aspect of the incision to allow for neutral positioning when the animal is awake or in sternal recumbency. (***Keep in mind that the heart has shifted dorsally during surgical recumbency***).	17b. Prior to closing the thorax, a 12-20 French catheter should be placed through a stab incision caudodorasl to the main incision and then tunneled under the skin to enter the thorax through the intercostal space caudal to the one through which the thoracotomy was performed.
18a. Just prior to completing the closure of the diaphragm, place a 8 to 10 french sterile urinary catheter through the incision to allow for negative pressure to be restored in the thoracic cavity. Attach a 3-way stopcock and 20 ml syringe to the end to withdraw the air until you begin to feel resistance. Remove all retraction devices from the abdomen and check again to be sure no additional air can be removed from the thoracic cavity (***if air is not completely removed the animal will have difficulty breathing after manual ventilation is discontinued***). If this should occur, thoracocentesis should be performed to remove the air as needed. Once you are satisfied all air has been removed, the catheter can be removed, and the remainder	18b. Multiple pieces of large absorbable suture (~0) should be passed around the rib in front of and behind the thoracotomy to approximate the ribs for closure of the thoracotomy. The assistant will pull the ribs together to allow the surgeon to tie each suture individually if needed.

of the diaphragm closed.	
19a. Make sure there are no leaks in the diaphragmatic closure, and that the diaphragm maintains its concave appearance following catheter removal. Place additional sutures as needed to completely seal the diaphragm, and perform repeat thoracocentesis if additional air withdrawal is needed to correct pneumothorax.	19b. Next the muscle layers of the incision should be closed in multiple discrete layers using 2-0 to 4-0 absorbable suture material in a simple continuous suture pattern (first the intercostals separately, next the serratus ventralis and scalenus together, then the latissimus dorsi separately, and finally the cutaneous trunci separately).
	20b. Finally, the skin should be closed using 2-0 to 4-0 absorbable material using an intradermal/subcuticular pattern.
	21b. Prior to discontinuation of intermittent positive pressure manual ventilation and discontinuation of anesthesia, The air should be withdrawn from the chest until negative pressure is achieved. Be sure to monitor the animal carefully as it is weaned from ventilator support and begins breathing on its own. If it experiences difficulty breathing, additional air may need to be removed from the chest.

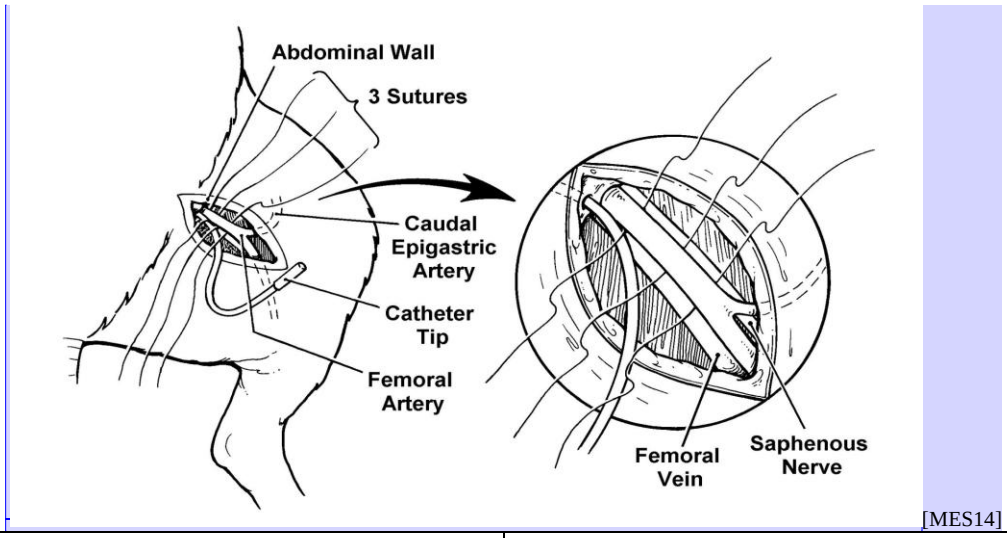
Systemic Blood Pressure Catheter Placement

There are multiple arteries where systemic blood pressure catheter (Channel 2 of an ~~TS-~~ L21) can be placed. Selection of an artery dependends on animal size, conformation, and surgeon preference. The mesenteric arteries are a good option in canines and non-human primates where these vessels are large enough for placement of the catheter (animals ≥ 6 kg). In animals ≤ 6 kg direct cannulation of the iliac artery may be preferable due to its larger size. Other arteries that can be cannulated for systemic blood pressure measurement include the thoracic descending aorta, the medial saphenous artery or the femoral artery. Use of the meseneteric, medial saphenous and femoral arteries requires permanent vessel ligation, while use of the iliac and descending aorta require only temporary occlusion.

Mesenteric or Medial Saphenous/Femoral Artery Systemic Pressure Catheter Placement

Figure 19. Mesenteric Artery Exposure

Figure 20. Medial Saphenous Artery Exposure



[MES14]

Mesenteric Artery	Medial Saphenous/Femoral Artery
1a. Locate an intestinal artery running through the mesentery closely associated with the vein and lymphatic vessel. Choose an artery that has nearby collateral blood supply to avoid compromise to the intestine. Using a fine tipped, curved forceps carefully isolate at least 2.5 cm of the artery.	1b. The pulse of the medial saphenous artery can be palpated on the inside of the thigh with the hindlimb extended straight out behind the animal and rotated externally so the inside of the thigh is easily accessable. A skin incision should be made over the palpable pulse, pulling the skin to the side to avoid damaging the underlying vessel. 1c. The femoral artery originates deeper between muscle bellies. To find it, follow the medial saphenous artery proximally and sharply transect the fascia between muscle bellies (***avoid cutting or dissecting through the muscle itself)***. Continue the dissection proximally and deep to the femoral artery. Once the fascia is cut, blunt dissection can be used to isolate the vessel and a Weitlaner retractor can be used to provide better visualization.

2. Once the appropriate vessel is located, apply a few drops of 2% Lidocaine ***without epinephrine*** on the artery to prevent vasospasm.

3. Pass three pieces of non-absorbable suture under the isolated section of artery. Tie the distal-most suture to permanently occlude the blood vessel. The two more proximal

sutures can be tied in loose knots to allow the suture to pass as it is inserted into the abdominal aorta. The proximal-most suture will be used to temporarily occlude blood flow when the artery is punctured (see Figure 21).

Figure 21. Preparing Artery for Catheter Placement

4. Prepare a 20-gauge needle by bending the beveled tip (while holding the bevel up) to a 90 degree angle (see Figure 22). This will be used to puncture the vessel and can be used to introduce the catheter.

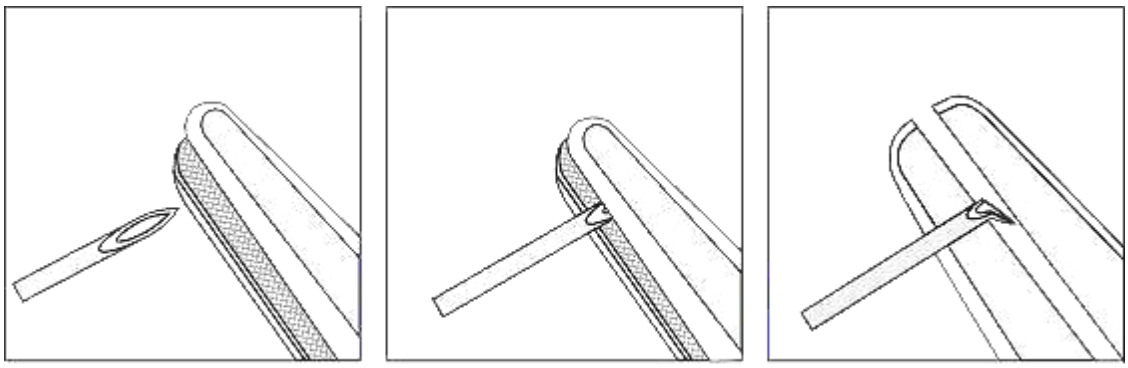


Figure 22. Bending Needle for Catheter Placement

5. Place a length marking suture around the catheter body at the approximate site that you wish to insert the catheter to; this is determined by estimating the distance needed for the pressure-sensing tip to be placed in free flowing blood within the abdominal aorta. When placing the length-marking suture use multiple passes of suture around the catheter to more evenly distribute the pressure and avoid compromising the pressure catheter or sensor (see Figure 23).

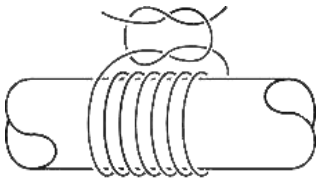


Figure 23. Length-marking Suture

6. Gently and slowly remove the tip cover using gentle traction and release, without touching the distal thin-walled sensing portion of the catheter. ***Take care to prevent gel loss due to compression of the catheter or sudden release of the tip cover. Always examine the catheter prior to implantation for gel loss or bubbles. If there is gel loss or bubbles, the catheter will need to be re-gelled. For help with this process, refer to the Guidelines for the Re-gel of the PA-C40 Device on our website: www.datasci.com. A video clip of this procedure is also available on our website.***

6. Apply gentle tension to the distal ligation suture and proximal temporary occlusion suture. Grasp the catheter at the overlap section in your dominant hand and the pre-bent 20-gauge needle in the other hand. Pierce the artery using the needle and insert the catheter under the tip of the needle as it is withdrawn. Alternatively, a vessel pick may be used to dilate the vessel slightly before placing the catheter (see Figure 24).

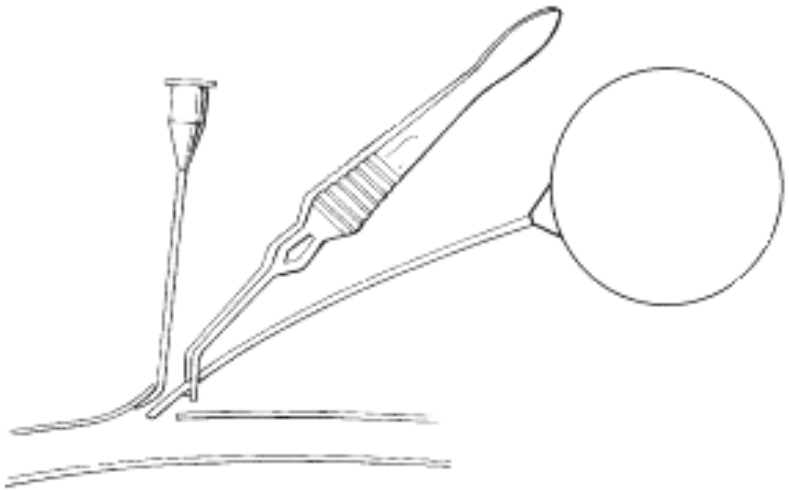


Figure 24. Systemic Pressure Catheter Placement

7. Advance the catheter into the artery until it reaches the proximal occlusion suture and then stop. Now gently tighten the middle suture around the artery containing the catheter to secure the catheter in the vessel. Next release tension on the proximal occlusion suture and continue passing the catheter until the length marking suture is at the level of the artery. Now release tension on the distal ligation suture, and tighten both the proximal temporary occlusion suture and middle sutures around the artery containing the catheter.

8. Each tail of the middle suture can now be tied to one of the length-marking suture tails to further lock the catheter into place. Next the tails of the distal occlusion sutures can be brought around the catheter and tied.

Iliac Artery Systemic Blood Pressure Catheter Placement

1. Carefully locate and isolate the iliac artery. The paired iliac arteries are located in the caudal abdomen and branch directly off of the caudal abdominal aorta and can be palpated by first detecting the aortic pulse and moving caudally (see Figure 25).

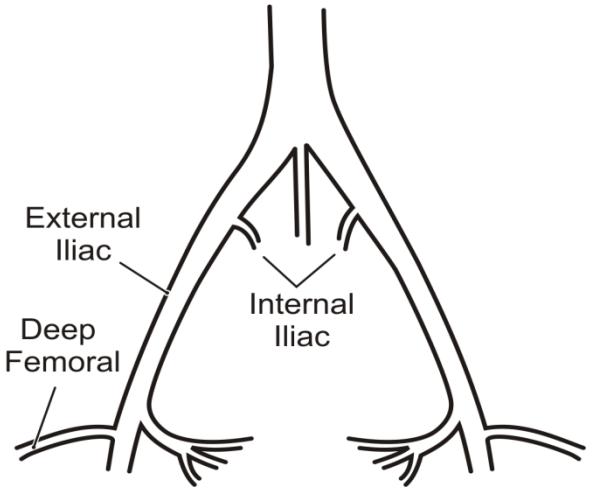
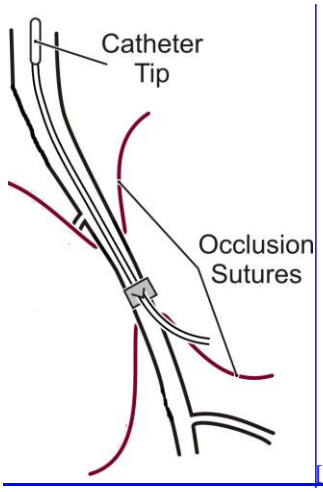


Figure 25. Iliac Artery

2. Using fine tipped, curved forceps, carefully isolate at least 2.5 cm of the iliac artery from the surrounding tissue and the iliac vein.

3. Pass two elastic vessel loops or two pieces of non-absorbable suture underneath the isolated artery section. Both sutures will be used to temporarily occlude blood flow to allow for placement of the catheter (see Figure 26). Place the loops/sutures as far apart as possible and secure with a hemostatic clamp. ***Do NOT occlude the vessel until everything is prepared for vessel cannulation.***



[MES15]

Figure 26. Temporary Occlusion of Iliac Artery

4. Fill four gel-loading micropipette tips with Vetbond^{R} tissue adhesive using capillary action and set aside. They will be used to dispense a very small amount of adhesive to seal the vessel. Using micropipettes to dispense the Vetbond will help control the amount of Vetbond applied to the artery. ***Excessive Vetbond can encircle the artery and compromise blood flow. This can result in hind limb paresis.***

5. Prepare a 20-gauge needle to puncture the vessel, place a length-marking suture and carefully remove the tip cover as described above (4-6).

6. Identify the catheter insertion site just proximal to the distal occlusion loops/suture. Apply one drop of 2% Lidocaine to the iliac artery to fully dilate it, if necessary. Grasp the catheter at the overlap section in your dominant hand and the pre-bent 20-gauge needle in the other hand. Pierce the artery using the needle and insert the catheter under the tip of the needle as it is withdrawn. Alternatively, a vessel pick may be used to dilate the vessel slightly before placing the catheter.

7. Advance the catheter into the artery until it reaches the proximal occlusion suture and then stop. Now release tension on the proximal occlusion suture temporarily to pass the catheter beyond this point and then replace gentle tension. Continue passing the catheter until the length marking suture is at the level of the artery.

8. Verify appropriate blood pressure signal has been achieved. Then thoroughly dry the artery at the catheter entry site with cotton tip applicators and apply a very small amount of Vetbond tissue adhesive using the gel-loading micropipette tips. ***If the area is not dried effectively, there will be poor bonding of the tissue adhesive, resulting in leakage.***

9. Once the Vetbond has visibly set, slowly release the tension on both of the occlusion sutures and observe the catheter entry site for leakage. If leakage is observed, re-occlude the vessel, clear the site of blood and apply only enough additional Vetbond to seal the leak.

10. Anchor the catheter in place with a small fiber patch. The patch can be prepared by cutting out a small 5 millimeter x 7 millimeter rectangle. Cut a wedge in the patch halfway across the width of the patch. (see Figure 26). Place the fiber patch across the catheter entry site with the catheter passing through the wedge. Secure the patch to the catheter, vessel, and surrounding tissues by applying a few drops of Vetbond tissue adhesive using the gel-loading micropipette tips.

Figure 26: Fiber Patch to Seal Venipuncture Site

11. Secure the catheter that is outside the vessel near the entry site to the lumbar muscles in at least two locations using non-absorbable suture. ***If the catheter is not secured to nearby muscles there is a high risk that the catheter will back out of the vessel post-operatively, which would result in internal bleeding and loss of the blood pressure signal.***

Thoracic Aorta Systemic Blood Pressure Catheter Placement

1. The descending thoracic aorta should be identified, and the thin layer of serosal covering carefully dissected away from approximately 1 cm of the vessel's surface.

2. Next a small purse-string suture should be placed and a knot loosely tied on the surface of the vessel using 3-0 to 5-0 suture material on a tapered needle. Be careful not to take full thickness bites of vessel wall or bleeding will occur. Should this occur apply gentle pressure until bleeding stops. Leave the ends of the purse-string suture long (see Figure 27).

Figure 27. Preparation of Thoracic Aorta for Catheterization

3. Complete needle preparation, length marking suture placement and tip cover removal as described above.

4. When you are fully prepared for catheter insertion, apply a Satinsky clamp to the area around the purse string to temporarily occlude blood flow. ***This clamp should remain in place for the minimum amount of time possible, so be sure everything is fully prepared prior to placement.***

5. Once the Statinsky clamp is in place, grasp the catheter at the overlap section in your dominant hand and the pre-bent 20-gauge needle in the other hand. Pierce the artery using the needle and insert the catheter under the tip of the needle as it is withdrawn. Alternatively, a vessel pick may be used to dilate the vessel slightly before placing the catheter.

6. Advance the catheter into the artery, the clamp may have to be temporarily released or adjusted to allow passage of the catheter. Continue advancing the catheter until the length marking suture is at the level of the artery. Now tighten the purse-string suture and ensure no blood leaks around the catheter, if needed, you can place an additional purse string suture around the outside of the first for hemostasis.

[MES16]

7. Each tail of the purse string suture can now be tied to one of the length-marking suture tails to further lock the catheter into place and all sutures cut short[MES17](see Figure 28).

Figure 28. Purse-string Tightening

8. Secure the catheter that is outside the vessel near the entry site to the lumbar muscles in at least two locations using non-absorbable suture. ***If the catheter is not secured to***

nearby muscles there is a high risk that the catheter will back out of the vessel post-operatively, which would result in internal bleeding and loss of the blood pressure signal.

Electrocardiogram (ECG) Lead Placement

Positive Lead Placement

The positive lead must be placed first so you can detect an ECG signal to guide placement of the negative solid tip lead. The positive lead can be placed in a variety of different locations including the abdominal side of the diaphragm, the epicardium, or subcutaneously over the middle of the left ribcage approximately level with the xyphoid process for a lead II ECG or on midline for a base-apex ECG. The choice of location for the positive lead is often dictated by the other surgical approaches being used (i.e. diaphragmatic ECG lead placement with intra-abdominal device placement etc.). Regardless of the site chosen for implantation, the basic technique is the same and will be described below.

1a. If the positive ECG lead will be placed on the diaphragm, it can be placed following closure of the diaphragm following trans-diaphragmatic placement of the left ventricular catheter. It should be placed over the apex of the heart (see Figure 29[MES18]).

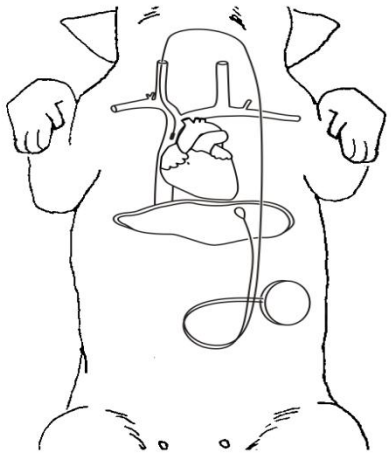


Figure 29. Diaphragmatic Positive ECG Lead Placement

1b. If the positive ECG lead will be placed subcutaneously there are two different options including a lead II configuration and a base-apex configuration. For the lead II configuration, a small skin incision should be made over the middle of the left ribcage, approximately level with the xyphoid process (see Figure 30). For the base-apex configuration, a small skin incision should be made over the ventral midline at approximately the level of the xyphoid process (see Figure 31). The lead will be exteriorized as needed and passed through a cannula to the site of implantation (as described above in the device body placement description).

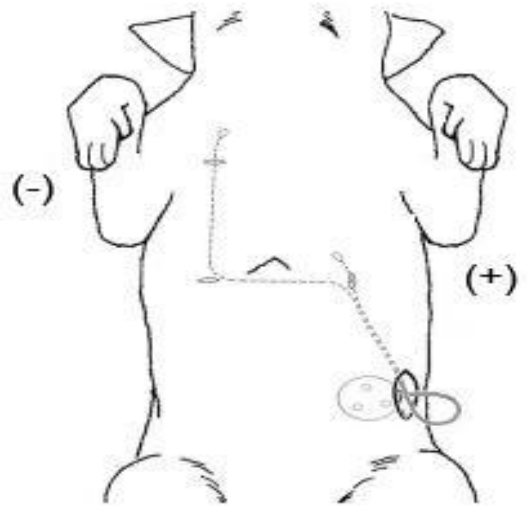


Figure 30. Lead II ECG Placement

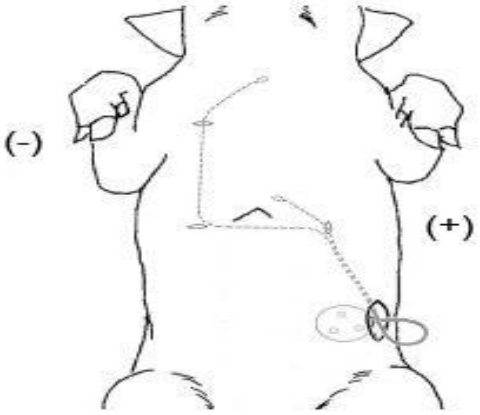


Figure 31. Base-apex ECG Lead Placement

1c. If the positive ECG lead will be placed epicardially, it will need to be directed to the thoracic cavity and placed prior to closure of the chest following left ventricular pressure catheter ± thoracic aorta systemic blood pressure catheter placement.

2. Cut the lead to the appropriate length to reach the incision, allowing for growth if needed. Next make a circumferential cut around the silicone covering from the last few centimeters of ECG lead, leaving the exposed wire. Form this wire into a loop with a diameter of approximately 1 cm and secure the loop with a non-absorbable suture. Finally, place another suture a few millimeters from the end of the silicone covering, just before the loop of exposed wire in order to prevent fluid migration (see Figure 32). Cut the tail, but leave the suture attached onto the ECG lead[MES19].

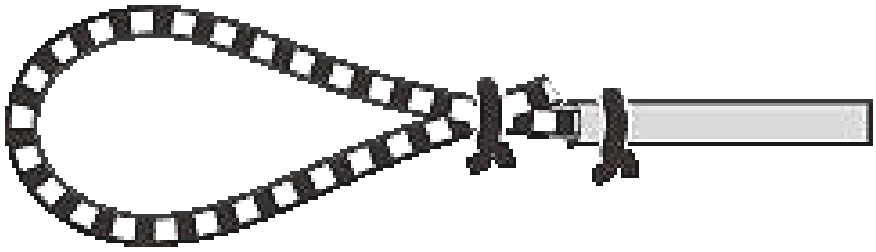


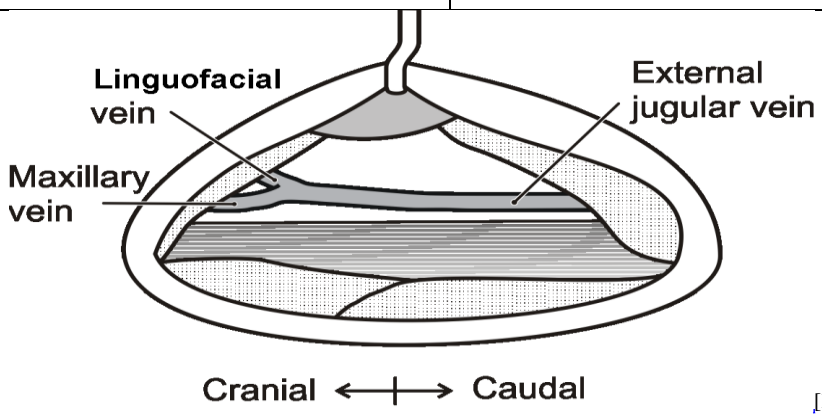
Figure 32. ECG Lead Modification

3. Take the suture still attached to the ECG lead and use this to tack the loop to the underlying muscle/tissue. Anchor the exposed portion of the lead to the underlying muscle using at least 3 simple interrupted knots using 2-0 to 0 3-0 non-absorbable suture. You can also tack the lead along its course if you are concerned about tension.

Negative Solid Tip Lead Placement

The PhysioTel®Digital device will come with a solid tip negative lead. This has been shown to provide accurate ECG signals in animals ≥ 2.5 kg while virtually eliminating muscle noise and artifact. The right external jugular vein has been used in the canine and swine. Due to differing anatomy, the internal juglar vein is recommended in non-human primates.

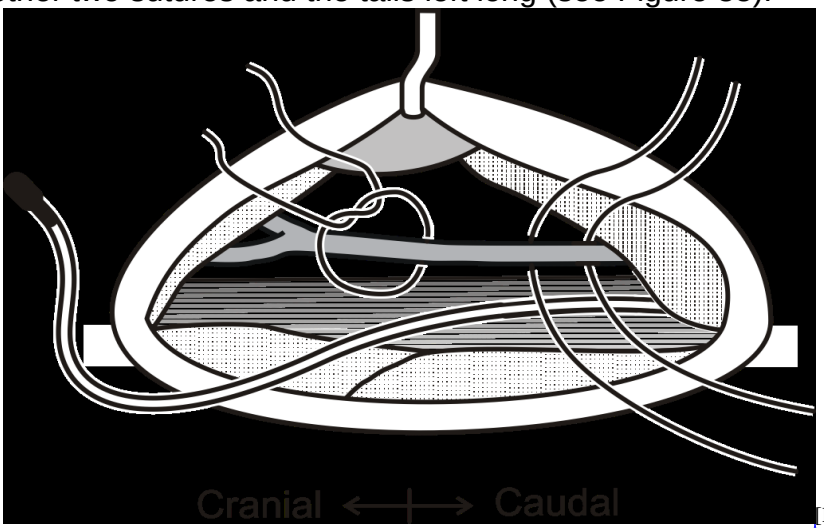
External Jugular Vein	Internal Jugular Vein
1a. A skin incision should be made in the jugular furrow to expose the external jugular vein, approximately 4 cm caudal to the confluence of the maxillary and lingofacial veins. The skin can be pulled to the side of the vein so the surgeon isn't cutting directly over the vessel. The external jugular vein can be used in the canine and swine, but the internal jugular provides a more direct route to the intended location of the solid tip in the cranial vena cava. The external jugular vein tends to be larger and located more superficially (see Figure 33).	1b. The internal jugular vein can be exposed through an incision next to the trachea approximately 1/3 of the distance between the sternum and the corner of the mandible. Blunt dissection should be used and the sternal and clavicular heads of the sternocleidomastoid muscle can be separated to expose the external jugular vein and carotid artery (see Figure 34).



[MES20]

Figure 33. External Jugular Vein
Figure 34. Internal Jugular Vein in Non-human Primate

2. Once the solid-tipped lead is exteriorized at the jugular incision via passing it through a cannula (as described above in device placement description), it's time to prepare the vessel for cannulation. Pass 3 pieces of non-absorbable suture around the vessel. The cranial-most suture will be used to permanently ligate the vessel. Loose knots can be placed in the other two sutures and the tails left long (see Figure 35).



[MES21]

Figure 35. Sutures Placed for Solid Tip Negative ECG Lead Placement

3. Tension should then be placed on the caudal suture to temporarily occlude blood flow and on the cranial ligation suture to hold the vessel in place during lead placement. Then pierce the vessel cranial to the middle tie using the bent needle technique (described above). You can then choose to use a vein pick to dilate the opening slightly and gently lift upwards.

5. The solid tipped lead can then be inserted into the vein in a direction toward the heart. Stop passing once the lead is near the caudal occlusion suture. At this point, the middle tie can be gently tightened around the lead to secure it in the vessel and then continue passing the lead into the vein (see Figure 36).

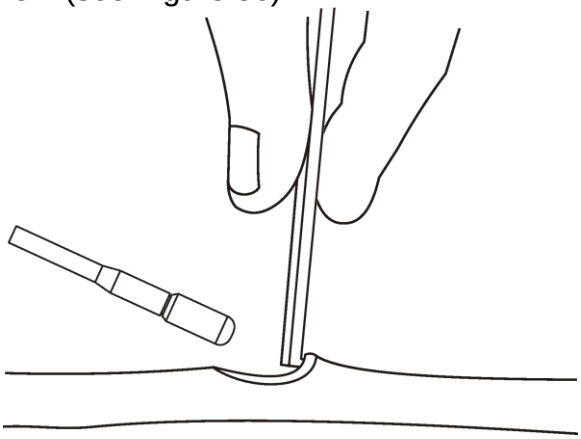


Figure 36. Placing Solid Tip Negative ECG Lead

6. ***It is imperative to monitor the ECG signal while passing the negative lead***. The appropriate location of the solid tip is dictated by the size of the P wave. The P wave will start out small and grow increasingly larger as it approaches the heart and may become negative when it is passed too far. The solid tip is in its optimal position when the P wave is approximately 1/3 the height of the QRS complex. Also ensure the head and forelimbs are in a relatively neutral position to ensure the ECG signal will remain consistent once the animal is awake. Once you are satisfied with the signal you can tighten the two caudal sutures around the vessel containing the lead and tie the tails of the cranial suture around the lead to further secure it in place.

7. The lead should also be tacked to the surrounding tissue once or twice to minimize tension and prevent it from being pulled out of the vessel (see Figure 37).

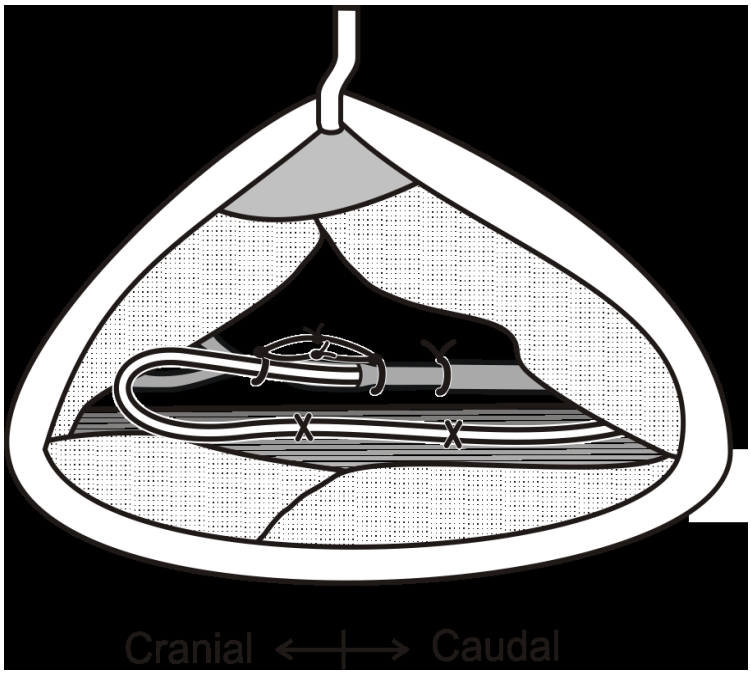


Figure 37. Solid Tip Negative ECG Lead in Place

Surgical Recovery

1. Discontinue surgical anesthesia.
2. Maintain supplemental warmth throughout the anesthetic recovery.
3. Administer post-surgical analgesia.
4. Monitor animal closely for the return of normal postures and behaviors.

This completes the surgery.

Appendix A: Additional Device Information

Device Explantation

When explanting DSI devices implanted intraperitoneally, intramuscularly or subcutaneously, consider the following:

Carefully remove the device body.

Be careful not to drop the device.

If cutting the catheter is necessary, use only a new scalpel blade to cut the catheter at a 45-degree angle away from the device body and approximately 3 cm from the device body. **Do not use any instrument other than a scalpel blade to cut the catheter. Cutting the catheter with a pair of scissors or any other instrument could cause damage to the pressure sensor and void the warranty. If the catheter must be cut, the device cannot be reused.**

Clean and sterilize the device with an approved enzyme detergent and sterilant before returning the device to DSI. For complete information on products and techniques approved for use with DSI devices, visit www.datasci.com.

Product Return Information

A detailed procedure for properly returning telemetry devices to DSI for exchange is provided on our website, www.datasci.com. The following additional considerations should be made:

- To be covered under the manufacturer's warranty, the devices must be returned for exchange within the warranty period.

- Contact DSI Technical Services with any concerns or comments regarding the performance of the devices.

- Ensure that the devices are well packed, preferably in their original packaging and boxes.

- Return the devices via a traceable shipping method to prevent losses in transit.

Complete product return information can also be found online at www.datasci.com.

~~Appendix B: Functional Specifications~~

~~Specifications~~	~~PhysioTel®Digital Device~~
~~Weight~~	
~~Volume~~	
~~Height~~	
~~Width~~	
~~Length~~	
~~Usable Catheter Length~~	~~35 cm***~~
~~Catheter Diameter~~	
~~Temperature Range~~	
~~Pressure Range~~	
~~Initial Accuracy~~	
~~Battery Life~~	
~~Intended Cage Size~~	

~~* Standard catheter length. Also available in 10 cm and 15 cm lengths.~~
~~** The diameter is 5.5 cm and the thickness is 1.5 cm.~~
~~*** Standard catheter length. Also available in 25 cm and 40 cm lengths.~~

Appendix C: Device Care and Use

Operational Modes

TL implantable devices are equipped with two operational modes: ON and OFF. Devices are shipped to you in the OFF mode. The battery in the device is not activated. When switched to ON, the devices begin to sense and transmit data. The switch to change between these two modes is in the interior of each device and is therefore not visible. The switch is magnetically activated.

To switch operational modes:

1. Power on a PhysioTel®Digital reader

2. Bring the reader close to the packaged device.

It is important the devices remain in the sterile packages!

3. Momentarily bring a strong magnet within approximately one inch of the package.

A magnetically activated internal switch is moved. The order of modes is:

- Off (You should hear no tone)
- On (You should hear a tone)

On-Site Cleaning and Re-sterilization

All new and exchanged devices shipped to an investigator are sterile and ready for implantation.

Prior to returning TL devices for refurbishment we ask that they are cleaned and sterilized. For complete and current information on products and techniques approved for use with DSI devices, visit www.datasci.com

Storage

Storage of New Devices

Carefully examine all devices when they arrive at your facility. Remove the packages containing the devices from the shipping boxes. Save the shipping boxes to use when returning used devices for the Device Exchange Program. Inspect each device package for signs of damage. Using your AM radio on the low frequency setting, turn each device on and off by scanning a magnet across the device to ensure that none of the devices were damaged during shipping. Confirm that each device is turned off before storing. Although each unit is checked just before shipping, the device may have been exposed to stray magnetic fields during shipment. This can cause the unit to be turned on unintentionally. New and exchanged units are sterile upon arrival. If the package remains undamaged, this sterility is warranted according to the information on the package label. Devices in the OFF mode may lose up to 10% of the battery life within 12 months after the manufacture date. The devices should be stored in a cool (between 10 and 25 degrees Celsius), dry area away from exposure to static discharge and magnetic fields. Never expose them to temperatures above 60 degrees Celsius, as this will void all warranties. It is also important to store them in an area where they will not be accidentally dropped or have items placed on top of them. Storage in a refrigerator does not provide significant benefit in terms of battery life.

Storage of On-Site Sterilized Devices

Occasionally there may be a delay between the device removal from the animal and return to DSI for refurbishment. Proper storage of the on-site sterilized device is necessary to ensure that the unit will not be damaged.

Thoroughly clean and sterilize each device according to DSI's On-Site Re-sterilization procedure. If the original device sterile package was saved, place the device into the plastic packaging. This will help to identify the device and the calibration values associated with it.

Do not store devices in saline or other liquid. Sterilization before storage is necessary to prevent the spread of bacteria during handling.

The devices should be stored in a cool (between 10 and 25 degrees Celsius), dry area away from exposure to static discharge and magnetic fields. Never expose them to temperatures above 60 degrees Celsius, as this will void all warranties. It is also important to store them in an area where they will not be accidentally dropped or have items placed on top of them. Storage in a refrigerator does not provide significant benefit in terms of battery life.

Using your PhysioTel®Digital reader, check each device to ensure that it is properly turned off.

For complete and current information on products and techniques approved for use with DSI devices, visit www.datasci.com.

Appendix D: Equipment and Supplies

The surgical instruments, along with their part numbers from Fine Science Tools, are listed below.

Part Number	**Description**
11006-12	Adson Forceps-straight, serrated
11027-12	Adson-Brown Tissue Forceps-straight, with teeth
13019-14	Kelly Hemostat Forceps, curved
13018-14	Kelly Hemostat Forceps, straight
13009-12	Halsted Mosquito Forceps, curved
13008-12	Halsted Mosquito Forceps, straight
11617-12	Debakey Forceps
14010-17	Mayo Scissors-straight, 15 cm
14019-14	Metzenbaum Scissors-curved, 14.5 cm
12002-14	Olsen-Hegar Needle Holder
11095-09	Backhaus Towel Clamps
	Sterile permanent marker

A hollow cannula and trocar or skin tunneling needle is also helpful to tunnel the intravenous lead subcutaneously from the device site. An excellent large animal trocar is available through Chiron Bioscience Limited.

Chiron Bioscience Limited
Email: info@chironbioscience.com
Telephone: +44(7775-517302
Fax: 44-1233-221580
PO Box 979
Canterbury
Kent
CT1 9DW
United Kingdom

Fine Science Tools, Inc.
Telephone: (1-800) 521-2109 or (1-650) 349-1636
Fax: (1-800) 523-2109 or (1-650) 349-3729
Website: www.finescience.com (A list of offices in other countries can also be found here.)
A wound clip applier can be purchased from Fisher Scientific.

- For large animals:
  - Wound clip applier with wound clips-Part Number NC9154268

~~Gel-loading micropipette tips (Part Number 02-707-83) can also be purchased from Fisher Scientific.~~
~~Fisher Scientific:~~
~~Telephone: (1-800) 766-7000~~
~~Fax: (1-800) 926-1166~~
~~Website: www.fishersci.com~~

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Appendix E: Checking the Offset of a Pressure Device

The following protocol will allow you to verify that the pressure device is functioning normally prior to surgical placement in an animal.

NOTE: Turn the device on approximately 1-4 hours before taking the pressure offset measurement. This will allow the electronics time to warm up and stabilize. Pressure offsets can be affected by temperature and intense light.

ASSUMPTION: The user is familiar with Dataquest ART configuration setup or Ponemah protocol setup for configuring and assigning devices to receivers and also for using appropriate acquisition settings. For more information please refer to the Dataquest ART User Guide or Ponemah Physiology Platform User Guide.

Dataquest ART Users

1. In the Configuration module, assign each device to a receiver, enter the calibration information, and assign an animal ID for each device.

2. After the device has been on for 1-4 hours, place the device in the packaging tray onto its assigned receiver.

3. From the Acquistion window, select the animal icon, right-click and choose **Start Sampling – Continuous…** to display the Start Continuous Sampling window.

4. Select **Trace** to display a waveform trace in the graph window. It will not save the displayed graphs.

5. From the Real-Time graph window, select **Data - Pause** once a steady waveform trace appears.

6. Click on the zoom icon depicted as a magnifying glass. This will change the display of the pressure waveform in a Static Graphs window.

7. Righ-click on the pressure waveform and select **Tracking.** This option displays the X and Y values on the Static Graphs window's status bar. By moving the mouse on the waveform, you will be able to see where the offset lies.

8. Click and drag the mouse to create a box around the portion of the waveform you would like to magnify. Repeat as necessary.

9. Record the offset value on the Lab Sheet. If desired, a hard copy of a trace can be made by right-clicking the mouse and selecting Print. This should be kept with the lab data for the project as verification of initial accuracy.

Ponemah Physiology Platform Users

1. Assign each device to a receiver, enter the calibration information, and assign an animal ID for each device through the **Edit DSI Setup** from the **Hardware** menu.

2. Select the appropriate animal ID from the **Select DSI Sources** from the **Hardware** menu.

3. After the device has been on for 1-4 hours, place the device in the packaging tray onto its assigned receiver.

4. From the **Setup** menu, choose **PD Setup**... and change the analysis module to BP for the pressure channel in the Channel Input Setup screen.

5. Close the **Setup** window and start an acquisition from **Acquisition – Start Acquistion.**

6. In the **Status** window, double-click on the blood pressure channel to open the Blood Pressure Analysis Attributes window. Select the **Offsets** tab.

7. Under “Implant Pressure Offset”, click the **Measure** button to see an instantaneous reading of the offset from 0. Clicking this again will give you an updated instantaneous offset. Click **Cancel** to close this window without readjusting the pressure trace.

8. Record the offset value on the Lab Sheet. If desired, a hard copy of a trace can be made by clicking on the print button in the graph page menu bar. This should be kept with the lab data for the project as verification of initial accuracy.