Lead Coupler Kit Manual

Lead Coupler Kit Manual

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Introduction

The Lead Coupler Kits are used to quickly and conveniently join two segments of leads (ECG, EMG, EEG, or Respiratory Impedance) and can be used with any DSI transmitter that contains leads.

Typical uses for the kits are as follows:

- Attaching existing, implanted leads to a new transmitter
- Attaching new leads to a re-used transmitter
- Repairing damaged leads while in-vivo

There are five different lead coupler kits which vary depending on transmitter model:

- Use the **Small Gauge Lead Coupler Kit** (Part Number 276-0065-001) only with the ETA-F10 or HD-X11 transmitters.
- Use the **Small Gauge Multi-Color Lead Coupler Kit** (Part Number 276-0042-001) with the F20-EET and F40-EET transmitters.
- Use the **Standard Multi-Color Lead Coupler Kit** (Part Number 276-0146-001) with the 4ET, D70-EEE, F50-EEE, and D70-CCTP transmitters. Please note that there may be more leads (colors) in the kit than are included on your transmitter model. The yellow lead can be used for the common wire, if applicable.
- Use the **Respiratory Impedance Lead Coupler Kit** (Part Number 276-0164-001) with the D70-PCTR transmitter.
- Use the **Standard Lead Coupler Kit** (Part Number 276-0031-001) with all other DSI transmitters that include biopotential leads.

A crimp tool is required for coupling the leads and is used to connect the coupler assemblies to two pieces of lead wire. Without the tool, the procedure cannot be performed appropriately. This part is not included with the coupler kits and must be purchased separately. The crimp is intended to be reused and can be sterilized if necessary. There are two different crimp tools which vary depending on the lead diameter of the transmitter model:

- Use the **Small Gauge Crimp Tool** (Part Number 276-0019-002) only with the F20-EET, F40-EET, ETA-F10, and HD-X11 transmitters.
- Use the **Standard Lead Crimp Tool** (Part Number 276-0019-001) with all other DSI transmitters that contains leads.

General Information

The lead coupler kits are provided sterile and ready to use. It is possible to use the kit during surgery or with explanted transmitters prior to resterilization. Coupling the leads can be a tedious process; it is recommended that the steps are followed carefully to ensure a solid connection. The kits may include more components than are needed for your application which can be stored for future use. Additionally, some kit components are sold separately if more are required.

In summary, two pieces of biopotential or respiratory leads are joined mechanically and electrically by a coupler assembly. Each lead is inserted onto one end of the coupler assembly and the crimp tool is used to secure the leads to the assembly. The crimp tool mechanically bends the metal tube of the coupler assembly causing the coil to be squeezed tightly against the metal pin, which provides support for the coil. After the leads are joined, a coupler sheath (clear silicone tubing) is placed over the junction to cover and insulate the metal from the surrounding tissue. Non-absorbable suture (not included in kit) should be used to hold the clear coupler sheaths in place and to seal both ends to prevent moisture entry. Non-absorbable suture should also be placed around the silicone tubing just proximal to the exposed portion of the wire to prevent moisture and contamination from entering into the lead.

After the lead is assembled, it can be used for sensing the intended biopotential or respiratory signal. Additional tip covers are provided in the standard gauge coupler kits. These are placed on the end of the sensing region of the biopotential leads for some applications. Please see the appropriate surgical manual for specific information on placing the leads and using the tip covers.

How to Use the Crimp Tool

To use the crimp tool, place the metal tube portion of the coupler assembly in the notched hole of the tool (See Figure 1). If the metal tube is not in the machine-notched hole, the tool could cut the metal tube in half, thus destroying the coupler assembly. Squeeze the handles using moderate force to make a crimp. Excess force could weaken the coupler assembly, while not enough force could allow the coil to separate from the coupler assembly. **The crimp should resemble the center crimp on the metal pin. The force will not be as extreme as with the center crimp.**

Note: The Small Gauge Crimp Tool has a very small diameter notched hole and may be difficult to see. In order to locate this hole better, there is an etched line across the flat surface of the tool that is in line with the hole. (See Figure 2)

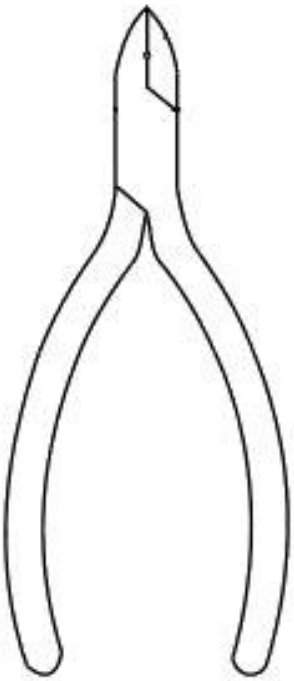

Figure 1: Standard Lead Crimp Tool

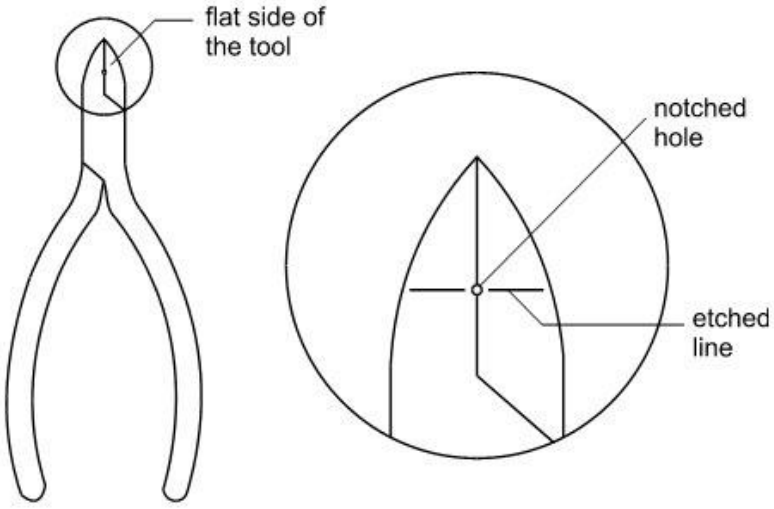

Figure 2: Small Gauge Crimp Tool

Kit Contents

Each Coupler Kit contains different amounts of lead material and crimp components based on the intended transmitter model(s). The kit contents for each part number are described below.

Note: Some kits may include more leads (color options) than are needed for your transmitter model. If desired, the lead material can still be used for non-respiratory leads even if the colors do not match. Biopotential leads should not be used as respiratory impedance leads.

Standard Lead Coupler Kit:

Item	Purpose
1 package of coupler assemblies • 5 per package	A metal tube with a metal pin crimped in place to join 2 pieces of lead together (See Figure 3)
1 package of clear coupler sheaths • 5 per package	To cover and protect the coupler assemblies
1 clear lead, 60 cm in length • 1 clear coupler sheath on the lead • 1 coupler assembly attached to an end of the lead	To extend or repair the current leads on the transmitter
1 red lead, 60 cm in length • 1 clear coupler sheath on the lead • 1 coupler assembly attached to an end of the lead	To extend or repair the current leads on the transmitter
2 packages of red tip covers • 3 per package	To protect the animal from the exposed coil when the lead is placed for sensing

Small Gauge Lead Coupler Kit:

Item	Purpose
1 package of coupler assemblies • 5 per package	A metal tube with a metal pin crimped in place to join 2 pieces of lead together (See Figure 3)
1 package of clear coupler sheaths • 5 per package	To cover and protect the coupler assemblies
1 clear lead, 20 cm in length • 1 clear coupler sheath on the lead • 1 coupler assembly attached to an end of the lead	To extend or repair the current leads on the transmitter
1 red lead, 20 cm in length • 1 clear coupler sheath on the lead • 1 coupler assembly attached to an end of the lead	To extend or repair the current leads on the transmitter

Standard Multi-Color Lead Coupler Kit:

Item	Purpose
2 packages of coupler assemblies • 5 per package	A metal tube with a metal pin crimped in place to join 2 pieces of lead together (See Figure 3)
2 packages of clear coupler sheaths • 5 per package	To cover and protect coupler assemblies
4 solid leads (blue, orange, green, yellow), 60 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current leads on the transmitter
4 striped leads (white stripe on blue, orange, green, yellow), 60 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current leads on the transmitter
3 packages of red tip covers • 3 per package	To protect the animal from the exposed coil when the lead is placed for sensing
1 Channel Indicator Card	Designates colors and channels

Small Gauge Multi-Color Lead Coupler Kit:

Item	Purpose
1 package of coupler assemblies • 5 per package	A metal tube with a metal pin crimped in place to join 2 pieces of lead together (See Figure 3)
1 package of clear coupler sheaths • 5 per package	To cover and protect coupler assemblies
2 solid leads (blue, orange), 20 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current on the transmitter
2 striped leads (white stripe on blue, orange), 20 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current leads on the transmitter
1 Channel Indicator Card	Designates colors and channels

Respiratory Impedance Lead Coupler Kit:

Item	Purpose
2 packages of coupler assemblies • 5 per package	A metal tube with a metal pin crimped in place to join 2 pieces of lead together (See Figure 3)
2 packages of clear coupler sheaths • 5 per package	To cover and protect coupler assemblies
5 solid leads (clear, red, violet, turquoise, green), 60 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current leads on the transmitter
2 striped leads (white stripe on violet, turquoise), 60 cm in length • 1 clear coupler sheath on each lead • 1 coupler assembly attached to an end of each lead	To extend or repair the current leads on the transmitter
3 packages of red tip covers • 3 per package	To protect the animal from the exposed coil when the lead is placed for sensing
1 Channel Indicator Card	Designates colors and channels

The turquoise and violet leads are intended for respiratory impedance measurements. Other colored leads are not equivalent and should not be substituted.

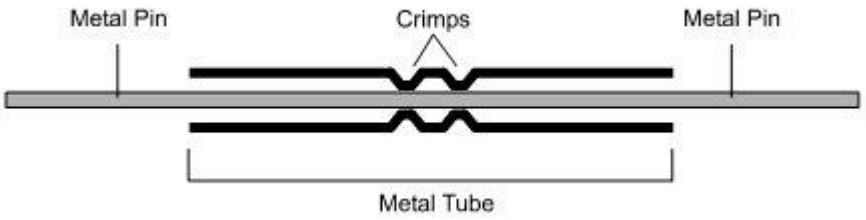

Figure 3: Coupler Assembly

Directions for Coupling the Leads

Note: When placing the leads in the animal, position the coupled area at a site that avoids undue stress and allows the coupled area to lay flat in the body to minimize pressure on the skin.

1. Trim all leads that are to be coupled to the desired length.
    a. Strip approximately 5 mm of insulation from all of the ends of each lead that will be coupled. This will expose the proper length of coil. To remove the insulation from the coil, score the insulation with a scalpel blade. Be careful not to damage the coil. Note: The respiratory impedance leads include bands of silicone every 4 cm that need to be avoided during this process.
2. Using the same color of biopotential lead that is pre-coupled, insert the other end of the coupler assembly into the coil. **Caution: The metal pin is sharp. For operator safety, do not push the metal pin into the coil using fingertips.** (See Figure 4)

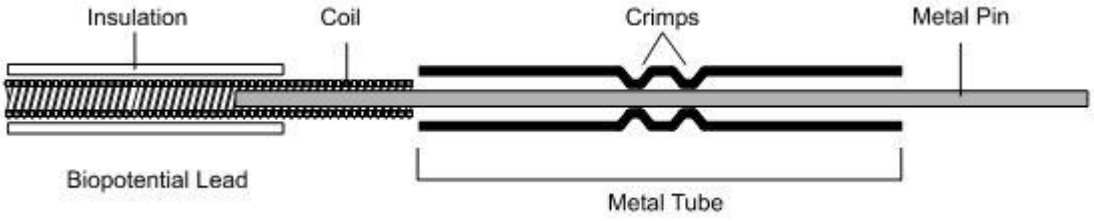

Figure 4: Coupler Assembly with Lead

3. Slide the coil over the metal pin and fully insert it into the metal tube until it stops.
4. Verify that the coil is fully inserted into the metal tube.
5. Crimp the metal tube twice on this end. (See Figure 5)

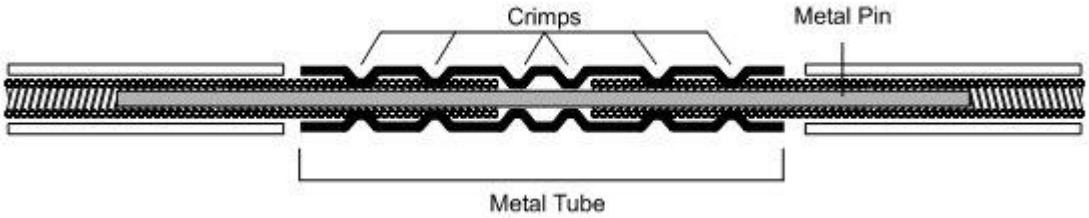

Figure 5: Coupler Assembly Showing Areas to Crimp with Crimp Tool

6. Slide a clear coupler sheath over the metal tube. This sheath should cover all exposed metals. (See Figure 6)

7. Tie a piece of non-absorbable suture around each end of the clear coupler sheath to seal it and hold it in place.
8. Repeat steps 2-7 for all other leads that need to be coupled.

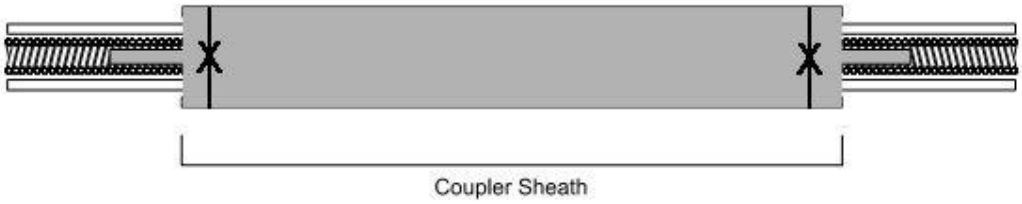

Figure 6: Coupler Sheath over Completed Coupler Assembly