

# Electrode Inserter System

## *User's Manual*



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# Warnings and Cautions

## *Warnings*

- Ensure that the appropriate spacer is used for the given electrode. Failure to do so can cause CNS injury to the subject or physical damage to the electrodes.
- Failure to depressurize the inserter between uses can cause early failure of the device.
- Completion of a Blackrock Microsystems user training program is suggested prior to the use of this system.
- Cleaning and Sterilization instructions provided have been validated by Blackrock Microsystems as capable of preparing the identified medical devices for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials, and personnel in the processing facility, achieves the desired result. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Blackrock Microsystems is not responsible for the consequences of reprocessing devices by any conditions other than those specified, and cannot attest to, or be held responsible for the functionality, cleanliness, or sterility of any devices so processed.
- Leaving the unit powered on for more than 40 minutes may cause the device to overheat, which can permanently damage the device.
- Ensure that the wand is rigidly held during insertion or the impact during insertion. Failure to do so can cause skewed electrode insertion.

# What This Manual Covers

This manual is intended as an informational tool for use of the Blackrock Electrode Inserter System. This pneumatically-actuated impulse inserter is designed to deliver a repeatable momentum and travel to the electrode array to allow insertion into neural tissue.

This manual is not intended to teach general surgical skills, techniques or principles. It is expected that those making use of this manual are trained in the surgical techniques they will be performing. It is recommended that they have also completed the Blackrock Utah Array surgical training program. While this manual provides a detailed description of the implantation device, it is not intended to be an instructional tool for implantation.

This manual covers the use of the inserter system and can be used to identify pieces of parts of the device and their respective function. This manual does not cover surgical procedure.

# Specifications

The Inserter System is comprised of the Inserter Control Box and an attached wand and trigger. These specifications provide a section to easily see useful details about specifics of the inserter system.

	<b>Inserter 110V</b>	<b>Inserter 220 V</b>
<b>Inserter Wand Tube Length</b>	8 Feet	8 Feet
<b>Max PSI</b>	30 PSI	30 PSI
<b>Implantable Electrode Length</b>	0.5, 1.0, or 1.5 mm	0.5, 1.0, or 1.5 mm
<b>Maximum Running Time</b>	40 minutes	40 minutes

# Overview of the Hardware

The Blackrock Clinical Electrode Inserter System is comprised of the inserter control box, a pneumatic piston (called wand) and tubing, a push-button trigger cable, and the power supply.

## *Inserter Control Box*

The inserter control box contains a pneumatic compressor, vacuum pump, and solenoids that control the delivery of air to the wand for pneumatic insertion. The box has controls for adjusting air pressure, duration of applied pressure, and switches for both power and enabling of the device in preparation for triggering a pneumatic impulse.



# Wand and Trigger

The inserter wand is a pneumatically actuated piston for inserting the Blackrock Utah Array. Compressed air and vacuum from the inserter control box is used to control the movement of the piston mass. The wand has a spacer piece that determines whether it is used to insert electrodes with lengths of 0.5 mm, 1.0 mm or 1.5 mm.

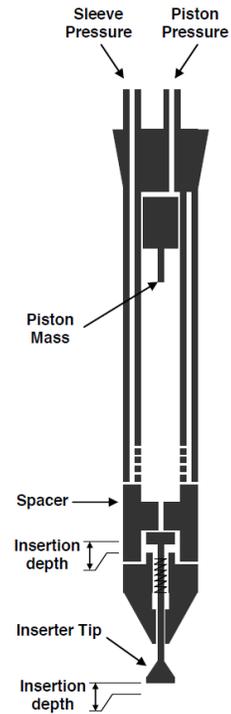
The wand is connected to a dual lumen inserter tube labeled sleeve and piston that communicate the compressed air and vacuum from the inserter control box.

A combination of compressed air and vacuum is used to control the movement of a piston mass in the shaft of the wand. The vacuum holds the mass at the top during standby. When the implantation is triggered, a pressure pulse is delivered to the piston line to propel the piston down to the inserter tip. When the piston mass strikes the tip, it quickly transfers its momentum to the tip, which pushes the array into the neural tissue in less than 1 ms.

The insertion depth is mechanically limited by the spacer positioned between the tip assembly and barrel. After the insertion, a vacuum is applied to return the piston mass to the top of the inserter wand, and the tip is retracted by a weak spring.

The outer sleeve is under constant vacuum to prevent the wand from expelling air pressure pulses out onto the surgical field.

The trigger is a push button trigger that connects to the inserter control box. When the inserter is enabled, pressing this button will cause the insertion sequence to begin.



# Assembling the Inserter System

The inserter system is comprised of the Inserter Control Box, the wand and holder, and the trigger. These parts should be connected before connecting power to the inserter control box. The wand ships fully assembled, but may be taken apart for repair or maintenance.

## *Connect the Trigger to the Control Box*

Align the keyed connector of the trigger with the connector labeled 'Trigger' on the Inserter Control Box. Push the trigger connector straight into the box and then twist the collar on the trigger cord to the right (clockwise) to engage the threads and secure the cable to the box.

## *Connect the Wand to the Control Box*

The color-coded tubes on the inserter control box (light blue and clear/white) match the colors of the dual lumen tubing. Remove the vinyl protector tubes from the ends of the inserter wand tubing, if present. Push the blue and clear tubes into the blue and white plastic connectors respectively on the front of the inserter control box. Be sure to press on the tubes until they will not go in any further. Gently pull on each tube to ensure that it is seated firmly in the box.

When properly connected, the longer of the two metal tubes on the wand are connected to the socket marked 'Piston' on the control box via the blue tube and the shorter metal tube on the wand is connected to the socket marked 'Sleeve' on the control box via the clear tube.

To remove the tubes, press the colored connector towards the control box while simultaneously gently pulling on the tube.

## *Preparing the Wand Holder*

Connect the inserter wand holder to the patient's head holder using an adapter or use another method that provides stability for the inserter wand.

After the wand holder is secured to the frame, place the inserter wand into the clamp portion of the wand holder, ensuring that the inserter wand size matches the size of the electrode.

## *Connect Power*

Check that the power switch at the back of the inserter control box is in the off (0) position. Attach the power cord to the control unit.

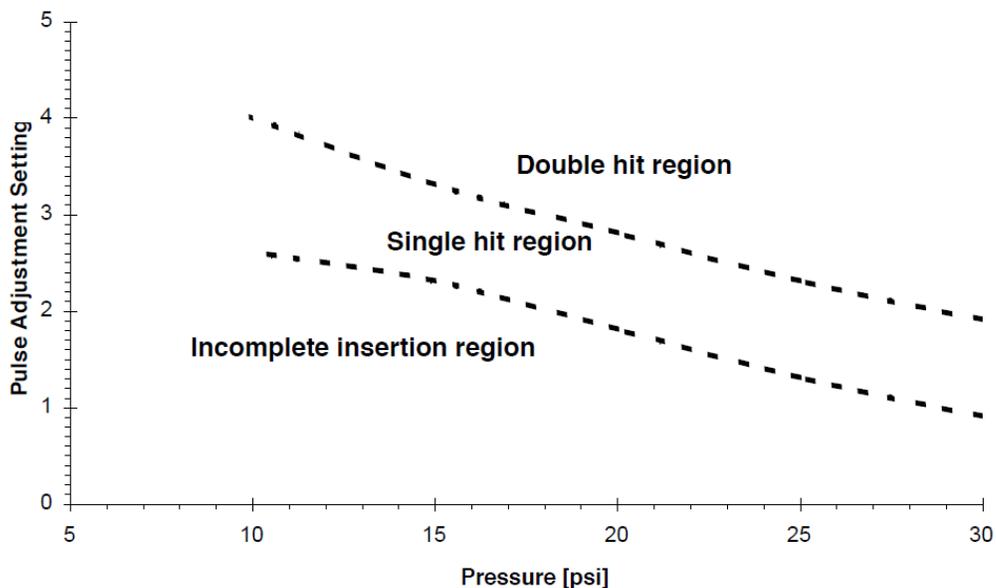
# Testing the Assembled System

Before turning on the pressure to the inserter control box, unlock the pressure control knob by pulling it away from the control box, then turn the pressure control knob to the left (counter-clockwise) until resistance is met; this will ensure that the compressor starts with low load. Ensure that the pressure reading on the dial is zero before powering the device on.

Power the device on and then slowly turn the pressure control knob clockwise until a pressure of around 20 psi is reached on the insertion pressure gauge. Let go of the control knob and let the inserter run for 10-20 seconds to ensure that pressure remains stable. Adjust the pressure until it remains stable at 20 psi. If the inserter cannot maintain a pressure that does not jitter by more than 1 psi, then it may have a leak in the internal pneumatics. Check the troubleshooting section for more detail. Set the pulse adjustment to 3.

Hold the wand vertically with the wand tip facing downward. Place a gloved finger lightly underneath the tip of the wand. Press the Enable/Disable button to enable the trigger, the button should light up.

Press the button on the end of the trigger cable to activate the inserter trigger and feel if the inserter tip moves. If it does not move, then the insertion pressure or pulse duration may be too low and the vacuum is being activated before the piston can strike the insertion tip. If the piston hits your finger twice during the pulse, then it is possible that the insertion pressure or pulse duration is too high and the piston is bouncing against the spacer. Consult the graph below for more information. These values are typical, but there may be minor variations from one inserter to another, thus testing this is recommended.



To find the single hit region, it is recommended to start at a pressure of 20, and a duration of 0, then slowly increment the duration by 0.5 each test until you sense a hit, then turn the dial an additional half turn.

If the test succeeds, repeat the test without changing the position of the wand. If the test is successful again, the inserter is ready for use. Lock the dial by toggling the small black lever away from the top of the dial.

# Disassembling the Inserter

After use, turn the pressure control knob counterclockwise until the insertion pressure gauge reaches zero. After the pressure reaches zero, turn off the inserter control box. Failure to reduce the pressure after use can cause stress on the inserter that can it to fail.

Before storing the inserter unplug and the dual lumen tubing and trigger cable.

In general, the inserter wand should never need to be disassembled.

# Changing the Insertion Depth

The inserter wand can have the spacer changed to allow it to insert electrodes of different lengths. To change the spacer, use the pair of wrenches on the tip assembly and spacer to loosen them. Finish removing the tip assembly by hand. Hold the outer tube/sleeve by hand and use the included wrench to loosen the spacer from the inner tube. Finish removing the spacer by hand. To reassemble, change the spacer and reverse the above steps.

# Cleaning and Maintenance

Each component of the system has instructions for cleaning and sterilization. The specifics of each are detailed below.

## *Inserter Control Box*

The inserter control box may be cleaned with standard cleaning solutions such as alcohol and bleach based cleansers used on non-sterile devices. Store the control box with the power cord, wand, tubes, and trigger detached. Ensure that the inserter pressure control knob is turned completely counterclockwise so that the pressure gauge reads zero.

The inserter control box does contain parts that can wear out after use. It is recommended to have the inserter control box serviced by the manufacturer, Blackrock Microsystems, once a year. To request service for the control box contact Blackrock Support using the information found at the end of this manual or at [www.blackrockmicro.com](http://www.blackrockmicro.com).

## *Wand and Tube*

The wand and tube can be cleaned with mild bleach, enzymatic cleaners, or any other non-corrosive cleaning agents.

The wand and tube can be sterilized using ethylene oxide sterilization methods.

## *Trigger Assembly*

The trigger can be wiped with mild bleach or mild soap solutions, but should not be immersed.

The trigger assembly can be sterilized using ethylene oxide sterilization methods.

# Troubleshooting

The Blackrock Electrode Inserter System is a critical device to any array surgery. Many researchers choose to have a second device on hand to mitigate cost and risk in case of a failure. Whenever possible, the inserter system should be tested before surgery and periodically.

*Inserter will not reach 30 psi.*

Insertions should not, generally, occur at pressures greater than 25 psi. If the inserter will not reach over 20 psi, there may be an issue with the compressor or there may be a loose pneumatic tube inside the inserter control box. It is possible to increase the pulse adjustment up to 7.0 to account for a slightly low insertion pressure. Insertion should never be done below 15 psi. If your inserter cannot reach a pressure of 25 psi, contact Blackrock support to arrange for service of the device.

*The enable button will not light up when pressed.*

It is possible that the connections on the button have disengaged. Contact Blackrock support to arrange for service of the device.

*The piston does not return to starting position after the inserter is used once with the wand vertically pointed down.*

This indicates a weak vacuum. Check that the tubes are connected to the inserter control box properly. Reseat the tubes in the inserter control box Sleeve and Piston connectors. If the problem persists, contact Blackrock Support to arrange for service of the device. As a temporary workaround, the wand can be turned upside down to re-seat the piston on the vacuum. This would need to be repeated for each insertion.

*The pulse adjustment dial will not turn.*

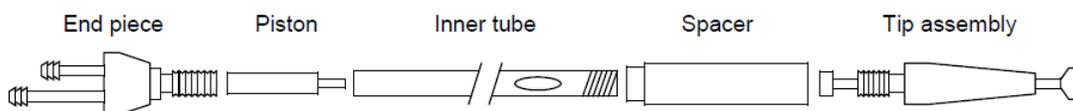
Ensure that the sliding lock on the upper right of the dial is disengaged. The lock should be engaged after choosing the proper duration and disengaged when setting the duration. If the dial will still not turn, clean the dial with a warm, mild detergent and try again. If the problem persists, please contact Blackrock Support to arrange for service of the device.

*The pressure control knob will not turn.*

Disengage the lock by pulling the knob away from the inserter control box before turning. The pressure control knob should always be locked after setting the pressure by pushing the knob into the inserter control box.

*I have tried the above calibration technique, but the wand will still not perform a single hit insertion.*

*Likely, the wand must be replaced, but occasionally, temperature changes or impacts can cause the piston to get stuck in the wand due to the tight specifications. Disassembly and reassembly of the wand can occasionally correct this.*



Exploded diagram of the wand (outer tube or sleeve omitted).

# Warranty

Blackrock Microsystems (“Blackrock”) warrants its products are free from defects in materials and manufacturing for a period of one year from the date of shipment. At its option, Blackrock will repair or replace any product that does not comply with this warranty. This warranty is voided by: (1) any modification or attempted modification to the product done by anyone other than an authorized Blackrock employee; (2) any abuse, negligent handling or misapplication of the product; or (3) any sale or other transfer of the product by the original purchaser.

Except for the warranty set forth in the preceding paragraph, Blackrock provides no warranties of any kind, either express or implied, by fact or law, and hereby disclaims all other warranties, including without limitation the implied warranties of merchantability, fitness for a particular purpose, and non-infringement of third-party patent or other intellectual property rights.

Blackrock shall not be liable for special, indirect, incidental, punitive, exemplary or consequential damages (including without limitation, damages resulting from loss of use, loss of profits, interruption or loss of business or other economic loss) arising out of non-compliance with any warranty. Blackrock’s entire liability shall be limited to providing the remedy set forth in the previous paragraph.

# Support

Blackrock prides itself in its customer support. For additional information on this product or any of our products, you can contact our Support team through the contact information below:

Manuals, Software Downloads, and Application Notes

[www.blackrockmicro.com](http://www.blackrockmicro.com)

Issues or Questions

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