

Intended Use

The Vacuum Coupler connects 3D platform neural implants to the Actuator using vacuum pressure.

Instructions

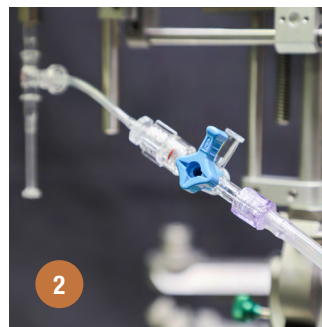
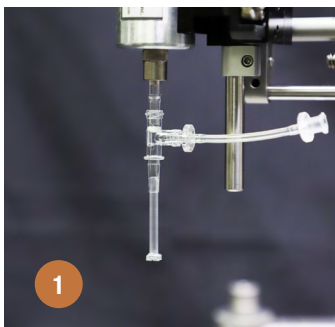
1. Sterilize Vacuum Coupler and neural implant according to institution protocol.
2. Secure the neural implant connector to the subject's skull.
3. Remove sterilized Vacuum Coupler from sterilization pouch.
4. Attach Vacuum Coupler to the Male to Female Luer attached to the Actuator (see Figure 1).
5. Attach the Connection Tubing purple male Luer to one of the female Luers on the 3-way valve (see Figure 2).

Note: The "OFF" lever should be aligned with the unused female Luer to allow air flow from the Vacuum Coupler to the Connection Tubing.

6. Attach the other end of the Connection Tubing to the outlet on the top of the vacuum pump collection bottle (see Figure 3, pictured: John Bunn Vacutec 800)

Materials Needed

- + Neural Implant
- + Vacuum Coupler
- + Vacuum Coupler Connection Tubing
- + Tweezers
- + Vacuum Pump

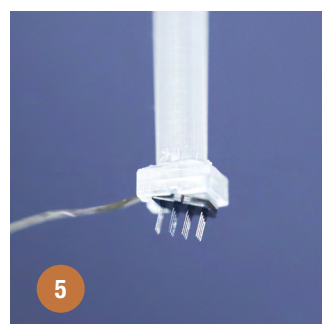
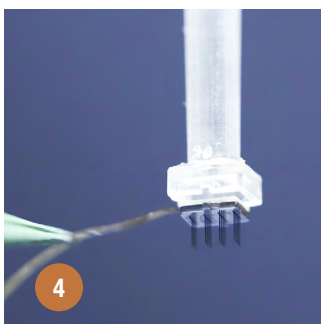


7. Use tweezers to grab onto the ribbon of the neural implant. Bring the platform of the neural implant close to the seat of the Vacuum Coupler (see Figure 4).

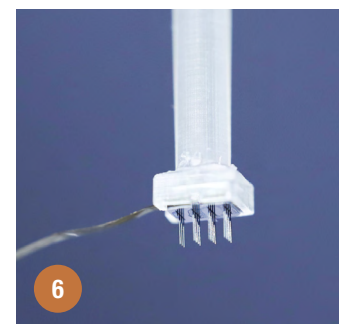
Note: The seat is a cutout that matches the outline of the neural implant platform.

8. When ready to place the neural implant in the seat, turn on vacuum pump and adjust to a vacuum pressure of 5-10 inHg.
9. Ensure the neural implant is placed well within the Vacuum Coupler seat.

Note: Figure 5 demonstrates a neural implant seated incorrectly in the seat, Figure 6 demonstrates a proper placement.



INCORRECT



CORRECT

10. Perform insertion of the neural implant using recommended parameters.

Note: A velocity of 0.050 mm/s is recommended. The range of permitted power levels is 0.50 - 1.50 Watts.

11. Turn off vacuum pump.

12. Align the “OFF” lever on the 3-way valve with the Connection Tubing purple male Luer (see Figure 7).

13. Use the NeuralGlider Software to slowly lift the Vacuum Coupler 2-3 mm from the surgical site.

Note: You may need to place the tweezers on top of the ribbon to prevent the neural implant from lifting from the brain surface. Suggestion: add a drop of saline to add some tension between the neural implant and the brain surface.

14. Lift the Vacuum Coupler manually until it can be removed from the Actuator without interference.



Operator Assistance Information

If you have questions regarding our product, please contact:
Actuated Medical, Inc. Customer Service Department
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 **Learn more at NeuralGlider.com**

These works were supported by the Brain Initiative at the NIH/NINDS SBIR Grant No. NS105500, NIH/NIDA SBIR Grant No. DA051265 and DARPA BTO Electrical Prescriptions Contract No. HR0011-16-C-0094. The content is solely the responsibility of the authors and does not represent the official views of the government.



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