



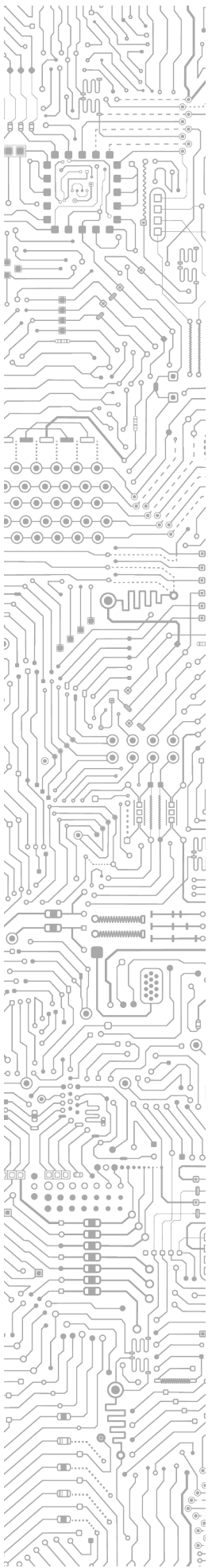
COAPT GEN 2

Dome Electrode Handbook

v6.0

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Coapt, LLC
222 W Ontario St., Suite 300
Chicago, IL 60654
844.262.7800 (toll free)
www.coaptengineering.com



Caution: Federal law restricts this device to sale by or on the order of a physician.

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USER ASSISTANCE & SAFETY





USER ASSISTANCE


If you are experiencing trouble, contact Coapt for support (toll free) at 844-262-7800.


Additional information, including technical specifications, and instructions for connecting and using the Dome Electrodes can be found online at <https://www.coaptengineering.com/resources.html>.


GENERAL WARNINGS AND PRECAUTIONS

For your safety and to prevent damage to the Dome Electrode and connected compatible device, please read and adhere to all safety precautions found in this handbook. In addition, please follow the safety guidelines found in the user manual(s) for any connected compatible device(s). Failure to heed all warnings and precautions could cause injury to the user or damage to the Dome Electrodes. The following symbol definitions pertain to warnings in this handbook and on all product labels.


SYMBOL DEFINITIONS	
 WARNING	Warning regarding possible risk of severe accidents or injury.
 CAUTION	Warning regarding possible risks of accident or injury.
	Refer to Operating Instructions prior to use.
	Type BF Applied Part

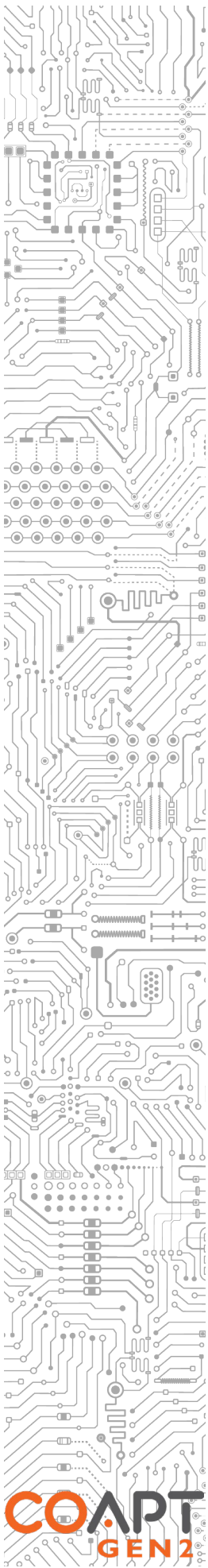
 **CAUTION** **Read and follow safety instructions.** Read this entire manual before setting up and operating the Dome Electrodes. Failure to do so could result in suboptimal system performance or injury to you, the electrodes, or the connected device.

 **CAUTION** **Consult trained specialist.** Before using the Dome Electrodes consult a trained specialist. Failure to do so could result in suboptimal system performance or injury to you, the electrodes, or the connected device.

 **WARNING** **Only Use With Approved Devices.** Only use the Dome Electrodes with equipment that has been approved as being compatible. A list of compatible devices that have passed all testing for safety and effectiveness can be requested via email and found at www.coaptengineering.com. Use of the Dome Electrodes with unapproved devices may lead to serious injury to you, the electrodes, or the connected device.

 **WARNING** **CHOKING HAZARD.** Keep away from Children.

 **WARNING** **Do Not Ingest.** Ingestion of the Dome Electrodes and its components may lead to serious injury.



⚠ WARNING **Do Not Apply to Eyes, in the Mouth, or Internally.** Application of the Dome Electrodes to the eyes, in the mouth or internally may lead to serious injury.

⚠ WARNING **Only the Dome Should Make Contact with User.** Only the Dome side of the Dome Electrode should make physical contact with the user. Contact of the threaded side or other components with the user may cause serious injury.

⚠ WARNING **Do Not Apply to Medically Compromised Skin.** Application of the Dome Electrodes to medically compromised or broken skin may lead to serious injury.

⚠ WARNING **Do Not Modify.** Modification of the Dome Electrode may only occur with express authorization from Coapt. Unauthorized modification of the Dome Electrode may lead to serious injury.

⚠ CAUTION **Do Not Use Near Open Flame.** Use care when operating Dome Electrodes near an open flame, and do not allow device to remain directly over an open flame. Direct exposure to an open flame may cause the device to exceed safe temperature limits.

⚠ CAUTION **Use in a corrosive environment.** Do not expose the device to excessive amounts of corrosive substances such as acetone, benzene or similar solution.

⚠ CAUTION **Not for Resale.** This device is intended only for the purchaser for use with approved compatible devices.

ADVERSE REACTIONS

⚠ WARNING **Not for Stimulation.** Do not use the Dome Electrodes for stimulation. Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.

⚠ CAUTION Patients should stop using the device and should consult with a physician if they experience adverse reactions from the device.

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA



Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
- Call FDA at 1-800-FDA-1088 to report by telephone
- Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf



SYSTEM OVERVIEW

PURPOSE OF THE DEVICE

The Dome Electrode is an accessory designed for passive sensing of biopotential signals. Muscle contractions produce small electrical biopotentials (voltages). These electrical signals are dispersed to the surface of the skin where the Dome Electrode provides a conduction pathway to an electrical conductor of compatible devices.

The Dome Electrode is designed to work seamlessly with biopotential recording devices as an accessory. It has a standard mating thread that enables connection to electrical conductors of compatible devices.

INDICATIONS FOR USE

The Dome Electrodes are intended for non-invasive use with recording and monitoring equipment of Electromyography (EMG).

CONTRAINDICATIONS

None known.

LIMITATIONS

Consult a trained specialist before use of the Dome Electrodes.

INTENDED USE

The Dome Electrodes are to be used for transferring surface biopotential signals from a cutaneous location to a recording system conductor for use with compatible devices.

DESCRIPTION OF THE DEVICE

The Dome Electrode is an accessory designed for enhanced detection of biopotential signals. It is a non-invasive electrode that conducts biopotential signals from the surface of the skin. The shape of the electrode simplifies placement and allows users to receive more accurate recording of biopotential signals. The material used allows for an electrode with safety and longevity. The Dome Electrode is designed to work seamlessly with biopotential recording devices as an accessory. It has a standard mating thread that enables connection to electrical conductors of compatible devices.

The Dome Electrodes function in the same method as other traditionally used electrode contacts. Muscle contractions produce small electrical potentials (voltages). These electrical signals are dispersed to the surface of the skin where they can be detected. Electrodes can detect this electrical signal on the surface of the skin because the electrodes create an equipotential area since they are more conductive than skin. The Dome Electrode provides a conduction pathway because the electrical potentials at the surface of the skin following a muscle contraction are attracted to the equipotential surface of the electrode. From there the signal can be sent to electrical conductors of compatible devices.

The Dome Electrode contains the following components:

- 316L Stainless Steel Dome Electrode
- Stainless Steel Size 4-40 Nut
- Stainless Steel Flat Washer
- Stainless Steel Split (“Lock”) Washer

COMPATIBLE DEVICES

The Dome Electrode is designed to work seamlessly with biopotential recording devices as an accessory. It has a standard mating thread that enables connection to electrical conductors of compatible devices. It can be used for many devices that require the detection or recording of biopotential signals. As more uses of the Dome Electrode become apparent new devices will undergo the same performance testing as the Dome Electrodes with the COMPLETE CONTROL System. Coapt will maintain a list of approved compatible devices that have passed all testing for safety and effectiveness. This list can be requested via email and found at www.coaptengineering.com/.

COMPLETE CONTROL System

A specific example of an approved compatible device is the Coapt COMPLETE CONTROL System. The Dome Electrodes can be used as an accessory to this device and facilitate the recording of EMG signals that will be analyzed by the COMPLETE CONTROL System to output as control signals to a prosthesis.

COMPATIBLE DEVICE	MANUFACTURER INFORMATION	USE	TESTING PERFORMED
COMPLETE CONTROL System	Coapt, LLC 222 W. Ontario St. Suite 300 Chicago, IL 60654	Dome Electrodes provide input of EMG signals from surface of the skin to the COMPLETE CONTROL System	Compatible Device Connection – Pass Signal Detection – Pass

CONDITIONS FOR USE

The Dome Electrodes are suitable for use in clinical activities, educational/research purposes, prosthetic applications, and for use in most activities of daily living, including home, social, and occupational use. The Dome Electrodes are not to be used for purposes other than those stated in the labeling.

See General Warnings and Precautions section for more information regarding acceptable conditions for using your device.

INSTRUCTIONS FOR USE

ELECTRODE PLACEMENT

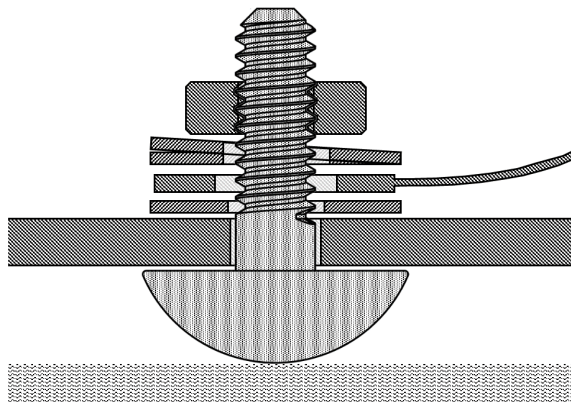
The Dome Electrodes should be placed to contact the skin surface of a user per the suggested placement guidelines of the compatible recording device being connected. For example, if the compatible device is a control system for prosthetic arms, follow the locating/placement guideless provided for optimal skin-site placement.

Typical application of the Dome Electrodes will have more than one being placed in relative proximity. For typical bi-polar EMG recordings, the Dome Electrode contacts should be placed in pairs about 30-60mm apart from each other. For the best EMG detection, it is recommended to avoid placing electrode contacts on areas that will lose electrode-to-skin contact during use.

No conductive gel is required for Dome Electrode use. However, for significantly dry skin areas, addition of moisture can ensure good signal detection.

It is recommended that Dome Electrodes are placed in a prosthetic housing material (socket), a cuff enclosure, or similar to limit movement of the Dome Electrode away from the intended skin placement site.

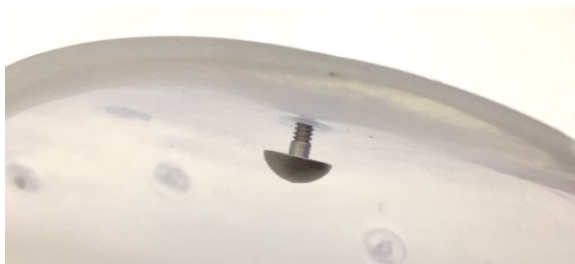
ELECTRODE CONNECTION



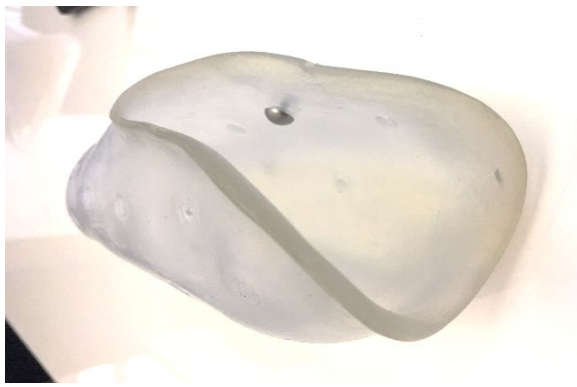
The Dome Electrodes have been designed to be compatible with industry standard biopotential processing devices. The Dome Electrodes are placed so that the dome side will contact the skin surface and the threaded stud on the other side will be placed through a small hole in prosthetic socket wall, or similar enclosure. The biopotential detection devices' conductor cable is connected to the stud on the outside of the prosthetic socket wall and the whole assembly is secured in place using the flat washer, lock washer, and tightening nut.

When assembling the Dome Electrode with compatible device:

Attach Dome Electrode to Socket / Enclosure



Place the Dome Electrode through the hole in a prosthesis' socket wall or enclosure of compatible device. Place it so the dome will make contact with the skin of the user, and the thread is on the other side of the socket or enclosure. The socket/enclosure also provides a way to keep the other hardware components of the electrode and connected device from contacting the user.



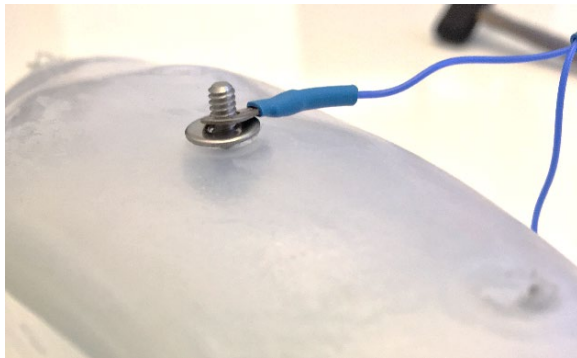
The threaded side of the Dome Electrode should not make direct contact with the user

Attach Flat Washer



Next, the flat washer is placed on the threaded side of the dome electrode.

Attach Conductor Cable



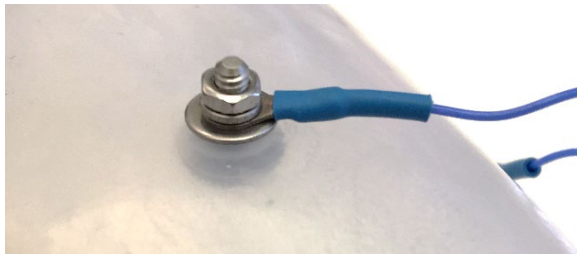
The conductor cable of the compatible device is placed on top of the flat washer. The Dome Electrode is not supplied with an electrode lead cable.

Attach Lock Washer

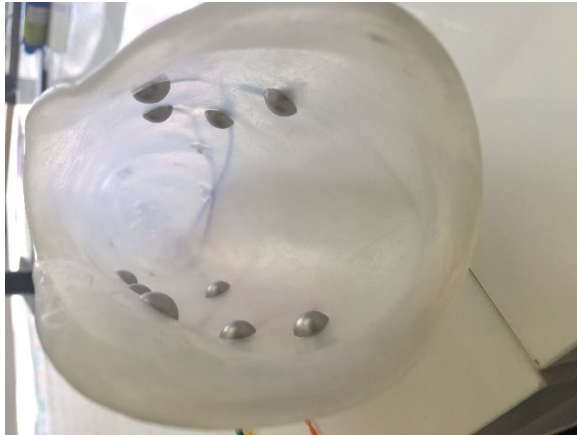


Next, a split “lock” washer is added on top of the conductor cable.

Attach 4-40 Threaded Nut



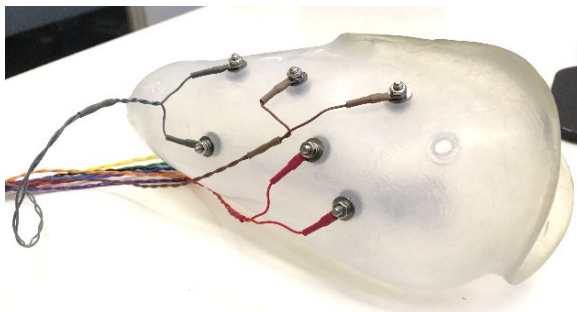
The 4-40 nut is fastened onto the threaded side of the Dome Electrode, securing all components and conductor cable to the compatible device.



Tighten the 4-40 nut, making sure the dome side of the Dome Electrode is flush with the interior surface of the socket or enclosure. No portion of the threaded side of the Dome Electrode should be visible or able to make contact with the skin or the interior of the socket or enclosure.

Caution: Do not cause cross-threading of 4-40. Do not force the nut to tighten. First use fingers to tighten until you cannot anymore. If the nut will not tighten easily with fingers, remove and adjust orientation.

Repeat for Each Electrode



Repeat steps 1-6 for each Dome Electrode that needs to be connected to a conductor.

Assembly Problems

Please contact Coapt if you are having problems assembling the Dome Electrodes.

GENERAL INSTALLATION PRECAUTIONS

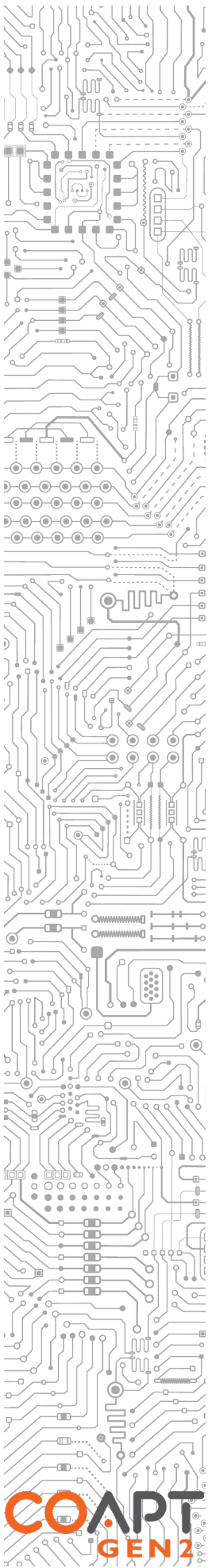
The following safety precautions should be read and followed by the qualified specialist responsible for assembling the Dome Electrode and configuring the compatible device prior to use.



Configuration by a qualified professional. The Dome Electrode must be assembled by a qualified specialist.



Do not cross-thread. Do not try to force 4-40 nut to tighten on thread. Cross threading can cause permanent damage to electrode. Tighten with fingers first, if it is not easy to tighten, remove and adjust orientation of nut.

- 
- ⚠ CAUTION** **Use of excessive force.** Do not try to force components/product into socket or cutout holes. Use of excessive force or impact force tools (e.g., hammer) could permanently damage the Dome Electrodes and result in malfunction and minor injury to the user.
 - ⚠ CAUTION** **Use with unapproved device.** Make sure that the Dome Electrodes are only connected to approved compatible devices. Use with an unapproved device that is incompatible with the system, or was not indicated during product order, may cause damage to and/or malfunction of the Dome Electrodes and device and could result in minor injury to the user.
 - ⚠ CAUTION** **Contact with threaded side and components.** Ensure that only the dome side of the Dome Electrode makes contact with the user. The threaded side and other components should be secured behind a mounting wall or enclosure. Contact with the threaded side and other components could cause minor injury to the user.
 - ⚠ CAUTION** **Compression of compatible conductor cables.** Ensure that conductor cables of the compatible device are not compressed between the components of the Dome Electrode. Compression of the conductor cables could cause the cables to fail resulting in device damage, device malfunction, and minor injury to the user.
 - ⚠ CAUTION** **Installation in material prone to static buildup.** Do not install Dome Electrode in material that is prone to experiencing a buildup of static electricity (e.g., leather, wool, nylon, and lead). Increased amounts of electrostatic discharge events could cause damage to the compatible device, resulting in device malfunction and minor injury to the user.

Duration of Use

The Dome Electrodes can safely be used for up to 24 hours a day. The Dome Electrodes underwent and received passing results for biocompatibility testing under ISO 10993 as a prolonged skin contact surface device for cytotoxicity, skin sensitization, and irritation.

ELECTRODE MAINTENANCE & CLEANING

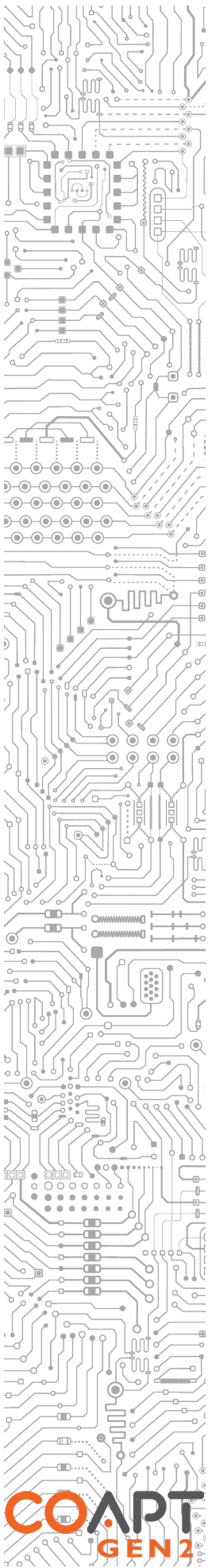
Sterilization and Cleaning

The Dome Electrodes are provided non-sterile. The user can sterilize and clean them according to the procedure below before use and at any time. The Dome Electrodes are reusable and should also be sterilized and cleaned before re-using on another user. To clean the Dome Electrodes use at least 97% isopropyl alcohol. Follow this procedure to properly clean and sterilize the Dome Electrodes:

1. Prepare by soaking a clean cloth or paper towel with at least 97% isopropyl alcohol.
2. Wipe each Dome Electrode face with a rag soaked in the isopropyl alcohol solution. Ensure that you wipe the entire surface of the dome that will make cutaneous contact with the user.
3. Allow the Dome Electrodes to dry before making cutaneous contact.

Maintenance

The Dome Electrodes should be cleaned and installed properly.



The Dome Electrodes should be inspected regularly for appearance of any corrosion and/or oxidization on the dome surface. While this is not expected, it could result in minor degradation of Dome Electrode conductivity and performance. Proper cleaning and installation will prevent surface corrosion and/or oxidization.



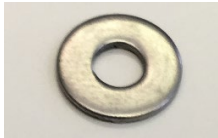

If the Dome Electrodes appear to be rusted they should no longer be used. Exposure to rust can increase the risk of tetanus if the Dome Electrodes are in close proximity to broken skin.

COMPONENT SPECIFICATIONS


COMPONENTS IN PACKAGE:

The Dome Electrode kit comes packaged in quantities of 18 for each of the following components.

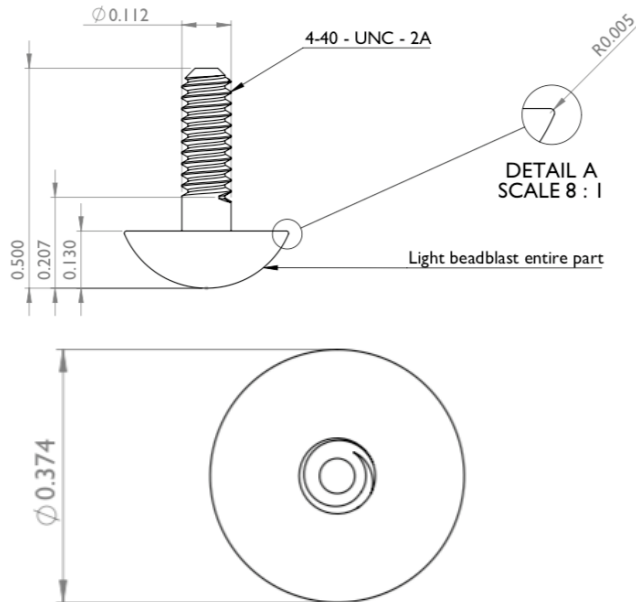
1. 316L Stainless Steel Dome Electrodes (D37C13T4L50)
2. Stainless Steel Size 4-40 Nut (#90730A005)
3. Stainless Steel Flat Washer (#92141A005)
4. Stainless Steel Split "Lock" Washer (#92146A005)

IMAGE	COMPONENT NAME	MODEL NUMBER	QUANTITY
	Dome Electrode	D37C13T4L50	18
	4-40 Threaded Nut	#90730A005	18
	Flat Washer	#92141A005	18
	Split Lock Washer	#92146A005	18

316L STAINLESS STEEL DOME ELECTRODE

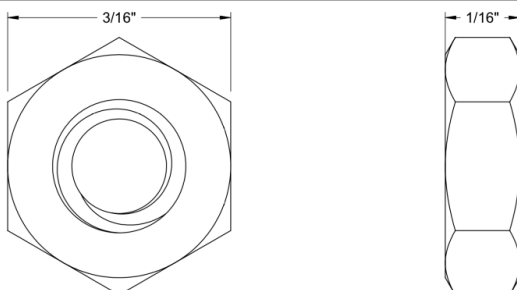
DOME ELECTRODE	
MODEL NUMBER	D37C13T4L50
MANUFACTURER INFORMATION	Pioneer Service, Inc. 542 W Factory Road Addison, IL 60101
DIMENSIONS OF DOME	Diameter: 0.375 in (9.525 mm) Height: 0.130 in (3.302 mm)
DIMENSIONS OF THREAD	Diameter: 0.112 in (2.845 mm) Height: 0.37 in (9.398 mm)

TOTAL SURFACE AREA	0.43 in ² (2.80 cm ²)
CONNECTION	4-40 sized thread
MATERIAL	316L Stainless Steel
RECORDING BANDWIDTH/FREQUENCY	0-1000Hz




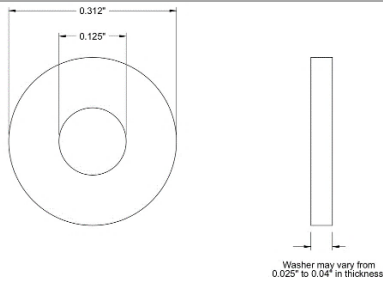
STAINLESS STEEL THREADED NUT

STAINLESS STEEL 4-40 THREADED NUT	
MODEL NUMBER	#90730A005
MANUFACTURER INFORMATION	McMaster-Carr 600 N. County Line Rd. Elmhurst, IL 60680
DIMENSIONS	Width: 0.1875 in (4.7526 mm) Height: 0.0625 in (1.5875 mm)
CONNECTION	4-40 sized thread
MATERIAL	18-8 Stainless Steel



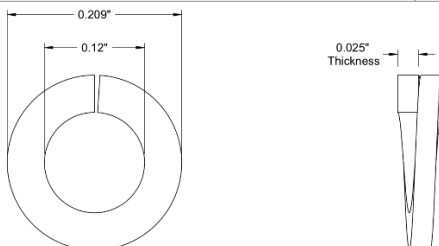
STAINLESS STEEL FLAT WASHER

STAINLESS STEEL FLAT WASHER	
MODEL NUMBER	#92141A005
MANUFACTURER INFORMATION	McMaster-Carr 600 N. County Line Rd. Elmhurst, IL 60680
DIMENSIONS	Internal Diameter: 0.125 in (3.175 mm) External Diameter: 0.312 in (7.925 mm) Thickness: 0.025-0.040 in (0.635–1.016 mm)
CONNECTION	No. 4 screw size
MATERIAL	18-8 Stainless Steel



STAINLESS STEEL SPLIT “LOCK” WASHER

STAINLESS STEEL SPLIT “FLAT” WASHER	
MODEL NUMBER	#92146A005
MANUFACTURER INFORMATION	McMaster-Carr 600 N. County Line Rd. Elmhurst, IL 60680
DIMENSIONS	Internal Diameter: 0.120 in (3.048 mm) External Diameter: 0.209 in (5.3086 mm) Thickness: 0.025 in (0.635 mm)
CONNECTION	No. 4 screw size
MATERIAL	18-8 Stainless Steel





ADDITIONAL INFORMATION

WARRANTY

Limited US Warranty:

For purposes of warranty, the “Customer” is defined as the entity that Coapt, LLC (“Coapt”) has invoiced for the custom ordered component(s) (“Items”). The 1 Year Limited Warranty only applies to Items sold to the Customer by Coapt or an authorized distributor. For an integrated system consisting of products or components purchased from both Coapt and other suppliers/manufacturers, in the event that such a system is sent into Coapt for warranty review, if it is found during evaluation that the reported problem(s) is actually associated with a product or component that was not supplied by Coapt, a “Non-Warranty Evaluation Charge” may be invoiced to the Customer.

Coapt warrants that its Items will be free from defects in material and/or workmanship for a period up to one (1) year. In the absence of a prompt notice from the clinician regarding a delay in fitting the patient, Coapt will set the Limited Warranty start date at 30 days after the shipping date. The Limited Warranty becomes null and void if complete payment is not made within the terms specified under Payment Terms.

This Limited Warranty covers all defects incurred in the clinically-prescribed use of the Items and does not cover: a) loss or damage due to abuse, mishandling, accident, or failure to follow operating instructions; b) damage by water, perspiration, sand or abrasive materials, or leaking batteries; c) use in a way not recommended by the manufacturer/distributor; d) Items serviced or modified by an entity other than Coapt (if the service or modifications are in any way related to the problem or defect); e) damage by improper installation; f) substitution of parts not approved by Coapt; g) any alteration or repair that, in Coapt's judgment, materially or adversely affects the Items. Damage as the result of normal wear and tear is not covered.

Any warranty claim shall be reported to Coapt immediately upon discovering the defect. The defective Items must be returned to Coapt or any other Coapt authorized representative. In returning the Items for repair, the Items must be delivered in packaging offering a sufficient degree of protection. The Items must be accompanied by written evidence of the date of purchase, such as invoice. Coapt will not be responsible for any loss or damage in connection with the return of the Items.

The warranty on repaired or replaced Items will be ninety (90) days or until the end of the original warranty, whichever is longer. Coapt will, at its option, repair, replace, or upgrade defective Items that are returned within this Limited Warranty Period. It is the Customer's responsibility to adhere to all Federal and State mandated shipping policies. Items covered by this Limited Warranty will be repaired, replaced, or upgraded in the United States by Coapt representatives, without charge. Coapt will return the Items to the Customer via UPS ground service, or using any comparable carrier. Requests for expedited returns of warranty repairs will be at the expense of the customer or covered by Coapt.

THE FOREGOING LIMITED WARRANTY IS COAPT'S ONLY WARRANTY WITH RESPECT TO THE ITEMS AND COAPT MAKES NO OTHER WARRANTY WHATSOEVER, WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE ITEMS, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

This Limited Warranty gives the consumer specific legal rights. The consumer may also have other legal rights which vary from state to state in the U.S., if so some of the above limitations may not apply. If it is determined by a court of competent jurisdiction that a certain provision of this Limited Warranty does not apply, such determination shall not affect any other provision of this Limited Warranty and



all other provisions shall remain in effect. This Limited Warranty is given by Coapt, with respect to Items purchased from Coapt in the United States.

Extended Warranty:

An additional two-year extended warranty and a five-year warranty are both available for purchase. Please contact your Coapt representative for pricing and terms.

RETURNS

Users should return all malfunctioning, damaged, or undesired Dome Electrodes and components directly to Coapt, LLC at:

Coapt LLC
ATTN: Returns
222 W Ontario St., Suite 300
Chicago, IL 60654

REGULATORY INFORMATION

FDA:

Coapt, LLC is registered with the Food and Drug Administration of the United States Government (Registration Number: 3010605876; Owner Operator Number: 10045459) for the manufacture and supply of prosthetics and orthotics products.



IEEE:

The Dome Electrodes were designed in conformance with the FDA recognized consensus standard IEEE 2010-2012: Recommended Practice for Neurofeedback Systems (FDA Recognition #17-13).



ISO:

The biological safety of the Dome Electrode was evaluated in accordance with ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process. The Dome Electrodes passed biocompatibility testing for ISO 10993-5: Tests for In Vitro Cytotoxicity, and ISO 10993-10: Tests for Irritation and Skin Sensitivity.

