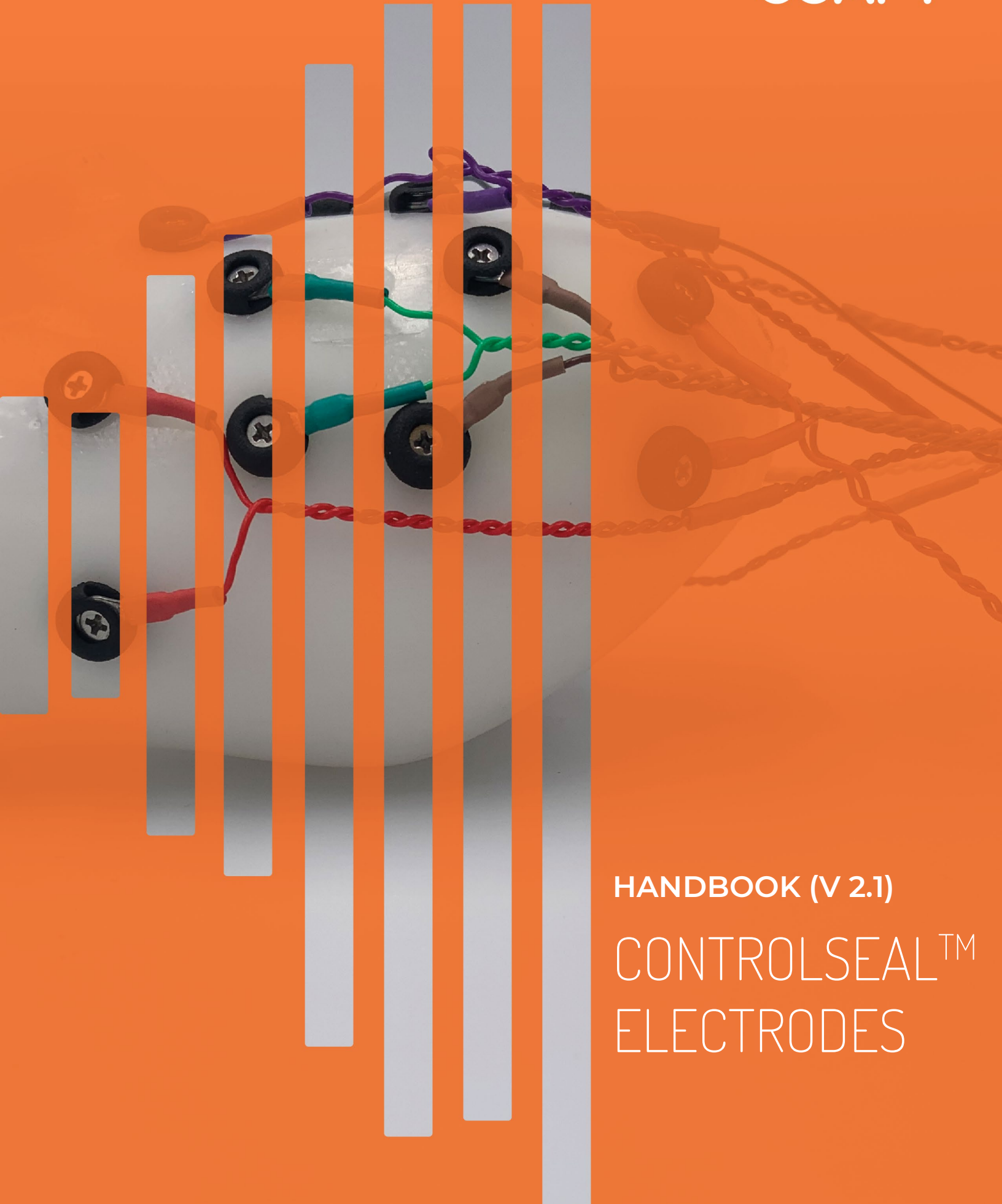


COAPT



HANDBOOK (V 2.1)

CONTROLSEAL™  
ELECTRODES

# CONTENTS

<b>CONTENTS</b> .....	<b>1</b>
<b>USER ASSISTANCE &amp; SAFETY</b> .....	<b>2</b>
USER ASSISTANCE .....	2
GENERAL WARNINGS AND PRECAUTIONS .....	2
ADVERSE REACTIONS.....	3
LABEL SYMBOL DESCRIPTIONS.....	5
<b>OVERVIEW</b> .....	<b>6</b>
PURPOSE OF THE DEVICE.....	6
INDICATIONS FOR USE.....	6
CONTRAINDICATIONS .....	6
LIMITATIONS.....	6
DESCRIPTION OF THE DEVICE.....	6
COMPATIBLE DEVICES.....	7
CONDITIONS FOR USE .....	8
<b>INSTRUCTIONS FOR USE</b> .....	<b>9</b>
ELECTRODE LOCATIONS.....	9
ELECTRODE CONNECTIONS.....	9
<b>ControlSeal™</b> Electrodes for a Range of Socket Interface Thicknesses.....	10
Triple Sealing Features of the <b>ControlSeal™</b> Electrode .....	11
<b>ASSEMBLY INSTRUCTIONS</b> .....	11
Assembly Problems.....	11
Using the Dome Assembly Aid .....	11
Installing <b>ControlSeal™</b> Electrodes with Hardware Pre-Situated in Protective Caps .....	12
Removing <b>ControlSeal™</b> Electrodes.....	13
(As Necessary): Installing Multiple Ring Terminals at an Electrode Location .....	14
(As Necessary): Installing Longer or Shorter Screws for Socket Materials Outside the 1.9-5.5 mm Range ....	15
<b>GENERAL INSTALLATION PRECAUTIONS</b> .....	16
<b>ELECTRODE CLEANING &amp; MAINTENANCE</b> .....	17
Duration of Use .....	17
Sterilization and Cleaning .....	17
Maintenance.....	17
<b>COMPONENT SPECIFICATIONS</b> .....	<b>18</b>
COMPONENTS IN PACKAGE.....	18
<b>ADDITIONAL INFORMATION</b> .....	<b>27</b>
LIMITED US WARRANTY .....	27
EXTENDED WARRANTY .....	28
RETURNS.....	28
PRODUCT RETURN POLICY .....	28
INTELLECTUAL PROPERTY DISCLAIMER .....	28
REGULATORY INFORMATION .....	29

# 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 **ControlSeal™** Electrodes can be found online at [www.coaptengineering.com](http://www.coaptengineering.com)

## GENERAL WARNINGS AND PRECAUTIONS

For your safety and to prevent damage to the **ControlSeal™** Electrodes 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 **ControlSeal™** Electrodes. The following symbol definitions pertain to warnings in this handbook and on all product labels.

### SYMBOL DEFINITIONS



**Warning regarding possible risk of severe accidents or injury.**



**Warning regarding possible risks of accident or injury.**

**NOTICE**

**Warning regarding possible damage to product or equipment.**



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



**Consult a trained specialist.** Before using the **ControlSeal™** 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.



**Only Use With Certified Compatible Biopotential Recording Devices.** Only use the **ControlSeal™** Electrodes with biopotential recording equipment that has been certified as being compatible. A list of certified, compatible devices that have passed all testing for safety and effectiveness can be requested via email and found at [coaptengineering.com/compatibledevices](http://coaptengineering.com/compatibledevices). Use of the **ControlSeal™** Electrodes with uncertified devices may lead to serious injury to you, the electrodes, or the connected device.



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

- ⚠ WARNING** **Do Not Ingest.** Ingestion of the **ControlSeal™** Electrodes and its components may lead to serious injury.
- ⚠ WARNING** **Do Not Apply to Eyes, in the Mouth, or Internally.** Application of the **ControlSeal™** 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 **ControlSeal™** Electrode should make physical contact with the user. Contact of the other components with the user may cause serious injury.
- ⚠ WARNING** **Do Not Apply to Medically Compromised Skin.** Application of the **ControlSeal™** Electrodes to medically compromised or broken skin may lead to serious injury.
- ⚠ WARNING** **Do Not Modify.** Modification of the **ControlSeal™** Electrode may only occur with express authorization from Coapt. Unauthorized modification of the **ControlSeal™** Electrode may lead to serious injury.
- ⚠ CAUTION** **Do Not Use Near Open Flame.** Use care when operating **ControlSeal™** 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** **Thermal Conductivity.** Use caution with dark-colored prosthesis sockets that are exposed to direct heat from the sun for extended periods of time. Excessive exposure can elevate the overall prosthesis temperature and the **ControlSeal™** Electrodes may transfer heat to the surface of the skin. Consider UV-blocking prosthesis coverings where significant sun exposure is expected.
- ⚠ CAUTION** **Not for Resale.** This device is intended only for the purchaser for use with certified compatible biopotential recording devices. The list of certified compatible devices is maintained at [coaptengineering.com/compatibledevices](http://coaptengineering.com/compatibledevices).

## ADVERSE REACTIONS

- ⚠ WARNING** **Not for Stimulation.** Do not use the **ControlSeal™** 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](http://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](http://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 <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

### **SUBMITTING ADVERSE EVENT REPORTS IN THE EU**

If you or someone in your family has experienced a serious adverse event, you are encouraged to report this event to Coapt and/or the national competent authority of the country in which the event occurred. Serious adverse events are defined as: any incident that led to or may lead to a death, serious deterioration of health, or public health threat. You must report the event as soon as possible. Please contact Coapt if you have any questions or need assistance.

## LABEL SYMBOL DESCRIPTIONS

SYMBOL	INFORMATION	EXPLANATION
	Consult Accompanying Documents Symbol	Please read the entire instruction manual before using the device.
	CE Mark	The device is certified with the European Union under the Medical Device Directives (93/42/EEC).
	Serial Number	Signifies the identification information for the device.
	Manufacturer	Manufacturer Name and Address
	Date of Manufacture	Date the device was assembled at Coapt.
	European Representative	Signifies the European Representative for Coapt.
	Type BF Applied Part	The device has conductive contact with the patient.

# OVERVIEW

## PURPOSE OF THE DEVICE

The **ControlSeal™** 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 **ControlSeal™** Electrode provides a conduction pathway to an electrical conductor of compatible devices.

The **ControlSeal™** 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 **ControlSeal™** 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 **ControlSeal™** Electrodes.

## DESCRIPTION OF THE DEVICE

The **ControlSeal™** 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 accurate recording of biopotential signals. The material used allows for an electrode with safety and longevity. The **ControlSeal™** 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 **ControlSeal™** 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 **ControlSeal™** 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 conducted to electrical conductors of compatible devices.

The **ControlSeal™** Electrode contains the following components:

- Passivated 316L Stainless Steel **ControlSeal™** Electrode Dome
- Passivated 18-8 Stainless Steel Phillips Flat Head 2-56 Screw
- Stainless Steel Tooth Lock Washer
- Protective Cap
- Conducting Ring-Terminal
- Buna-N Rubber O-Ring

## COMPATIBLE DEVICES

The **ControlSeal™** 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 devices that require the detection or recording of biopotential signals. As more uses of the **ControlSeal™** Electrode become apparent, new devices will undergo the same performance testing as the **ControlSeal™** Electrodes with the Coapt **Complete Control** System Gen2. Coapt will maintain a list of certified compatible biopotential recording devices that have passed all testing for safety and effectiveness. This list can be requested via contacting Coapt and at [coaptengineering.com/compatibledevices](http://coaptengineering.com/compatibledevices).

COMPATIBLE DEVICE	MANUFACTURER INFORMATION	USE	TESTING PERFORMED
<b>Complete Control</b> System Gen2	Coapt, LLC 303 W Institute Pl., Suite 200 Chicago, IL 60610	<b>ControlSeal™</b> Electrodes provide input of EMG signals from surface of the skin to the <b>Complete Control</b> System Gen2 for controlling a prosthetic device	Compatible Device Validation – Pass Signal Detection – Pass
<b>Evaluation Kit</b>	Coapt, LLC 303 W Institute Pl., Suite 200 Chicago, IL 60610	<b>ControlSeal™</b> Electrodes provide input of EMG signals from surface of the skin to the <b>Evaluation Kit</b> for evaluation and controlling a virtual device	Compatible Device Validation – Pass Signal Detection – Pass
<b>Myo/One</b>	Fillauer Motion Control 115 N. Wright Bros. Drive Salt Lake City, UT 84116	<b>ControlSeal™</b> Electrodes provide input of EMG signals from surface of the skin to the <b>Myo/One</b> for controlling a prosthetic device	Compatible Device Validation – Pass Signal Detection – Pass



## CONDITIONS FOR USE

The **ControlSeal™** 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 **ControlSeal™** 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 LOCATIONS

The **ControlSeal™** Electrodes should be located 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 guidelines provided for optimal skin-site placement.

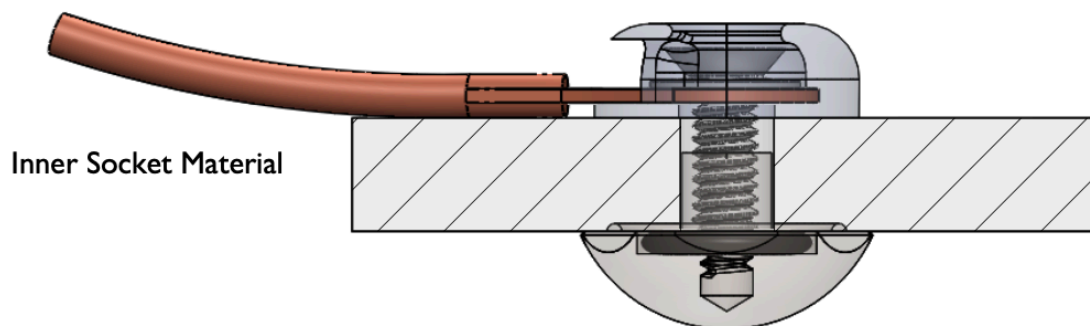
Typical application of the **ControlSeal™** Electrodes will have more than one being placed in relative proximity. For typical bi-polar EMG recordings, the **ControlSeal™** Electrode contacts should be placed in pairs about 30-60mm apart from each other. For the best EMG detection, it is recommended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

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

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

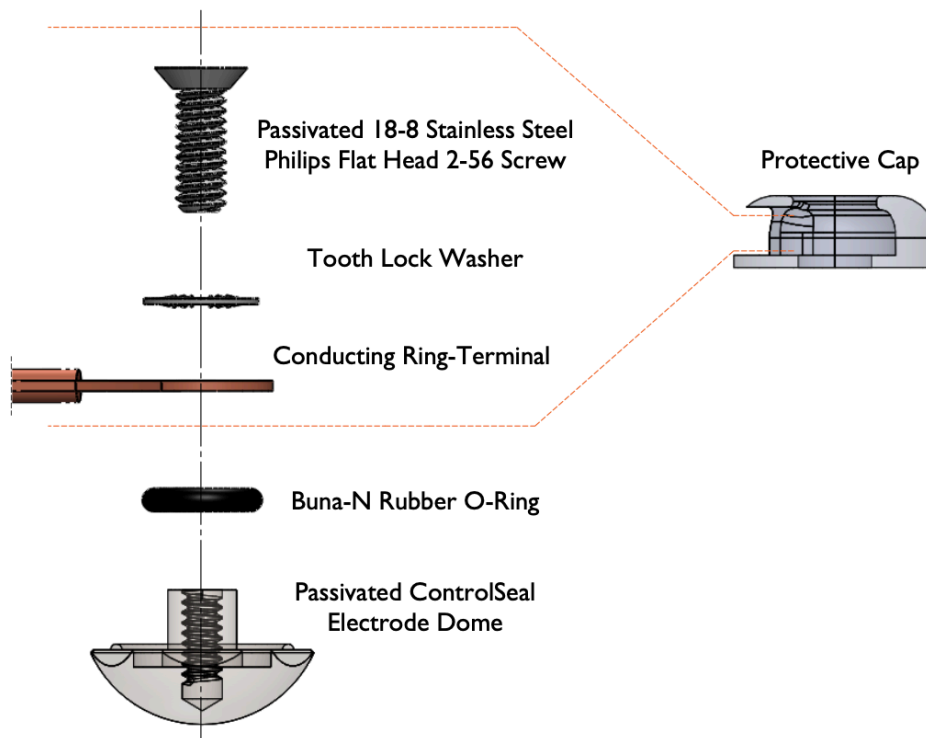
## ELECTRODE CONNECTIONS

The **ControlSeal™** Electrodes have been designed to be compatible with industry standard biopotential processing devices. The **ControlSeal™** Electrodes are placed so that the dome side will contact the skin surface and the other components placed on the other side of the prosthetic socket wall, or similar enclosure. The biopotential detection devices' conductor cable is connected to a conductive ring terminal on the outside of the prosthetic socket wall and the whole assembly is secured in place using a threaded screw passing through the lock washer and ring terminal into the threaded bore post of the **ControlSeal™** Electrode Dome. The screw head, lock washer, and ring terminal are housed within an optional protective cap.



Fully assembled **ControlSeal™** Electrode on inner prosthesis socket material

Exploded Assembly



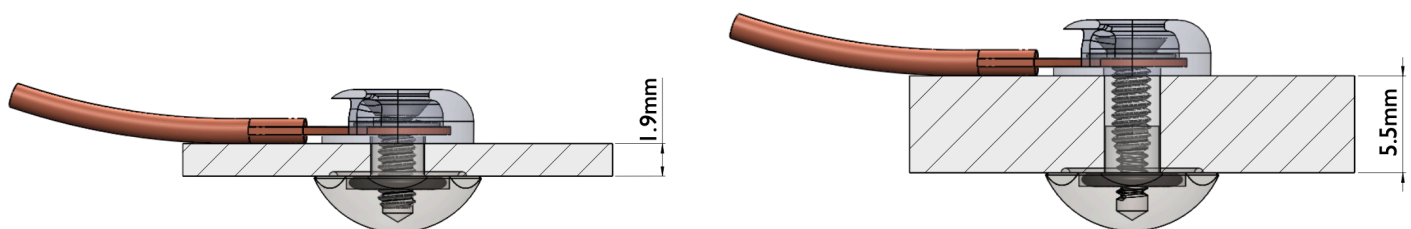
Exploded view of ControlSeal™ Electrode assembly components

ControlSeal™ Electrodes for a Range of Socket Interface Thicknesses

The **ControlSeal™** Electrodes are designed to be assembled into socket interfaces ranging in thickness from **1.9mm to 5.5mm**.

For thinner socket interface locations, the threaded screw will turn deep into the Electrode Dome threaded bore. For thicker socket interface locations, the threaded screw only needs to catch a few turns of the threaded bore.

It is acceptable to place **ControlSeal™** Electrode Domes where the height of the dome post is less than the thickness of the socket interface material.



Fully assembled ControlSeal™ Electrode on minimum (left) and maximum (right) thickness inner prosthesis socket material

## Triple Sealing Features of the **ControlSeal™** Electrode

The **ControlSeal™** Electrodes are designed with patent pending features to assist in sealing the electrode to the socket interface for maintaining socket suction and preventing fluid ingress/egress.

1. A smooth attachment post profile to maximize surface area contact in the through-hole medium
2. An annular ridge profile on the back plane of the Electrode Dome to provide a rigid ring seal
3. An O-ring groove and pre-installed O-ring to provide a secondary ring seal

For additional or alternative sealing, the O-ring can be removed and a non-corrosive sealant can be applied in the annular O-ring groove on the back plane of the Electrode Dome.

## ASSEMBLY INSTRUCTIONS

### Assembly Problems

Please contact Coapt if you encounter problems assembling the **ControlSeal™** Electrodes.

### Using the Dome Assembly Aid

The provided Dome Assembly Aid is designed to be held in space-constrained sockets by a variety of options:



**Fingers**



**Awl**



**Coin**



**Screwdriver**



**1/4" drive**



**7/16" wrench**



**1/2" socket**



**Pliers**

Installing **ControlSeal™** Electrodes with Hardware Pre-Situated in Protective Caps

1

**MAKE 1/8" DIAMETER HOLES**

Using a 1/8" drill bit or similar, make 1/8" diameter holes in the socket interface material at each planned **ControlSeal™** Electrode Dome location.



2

**PLACE THE CONTROLSEAL ELECTRODE DOME**

From the inside of the socket interface, use the provided Dome Assembly Aid to hold a **ControlSeal™** Electrode Dome and push its post through one of the 1/8" holes.

Ensure the sealing features of the back side dome sit flush with the inner face of the socket material. The curved head of the dome should be positioned to contact the skin.



3

**POSITION THE ATTACHMENT HARDWARE/ PROTECTIVE CAP**

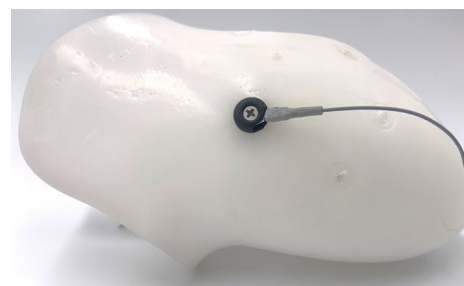
From the outside of the socket interface, align the Electrode Protective Cap (containing the lock washer, ring terminal(s) and screw) with the hole housing the **ControlSeal™** Electrode Dome.



## 4 ATTACH AND TIGHTEN

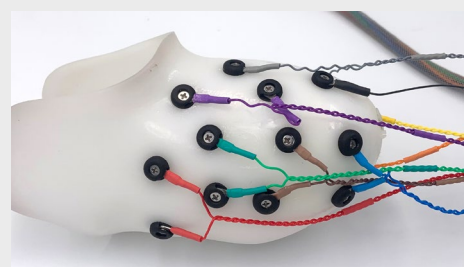
While using the Dome Assembly Aid to hold the **ControlSeal™** Electrode Dome from turning on the inside, use a small Phillips screwdriver to turn the 2-56 threaded screw into the post of the dome.

Make sure to tighten enough so the conductor cable wire cannot be moved side-to-side with finger force. Do **NOT** use thread locker.



## 5 REPEAT FOR EACH CONTROLSEAL ELECTRODE

Repeat these steps for each **ControlSeal™** Electrode.



## Removing **ControlSeal™** Electrodes

### 1 LOOSEN

While using the Dome Assembly Aid to hold the **ControlSeal™** Electrode Dome from turning, use a small Phillips screwdriver to loosen and extract the 2-56 threaded screw out from the dome.

### 2 REPEAT FOR EACH CONTROLSEAL ELECTRODE

Repeat these steps for each **ControlSeal™** Electrode as needed.

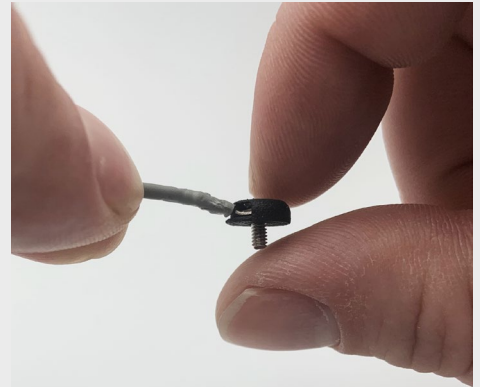
(As Necessary): Installing Multiple Ring Terminals at an Electrode Location

1

**PUSH EXISTING SCREW OUT AND EXTRACT HARDWARE**

Apply a small amount of force to the bottom of the threaded screw to “pop” the head of the screw through the top hole of the Protective Cap.

The screw then can be freely extracted. The lock washer and ring terminal can also then slide out of the side opening of the Protective Cap, if required.



2

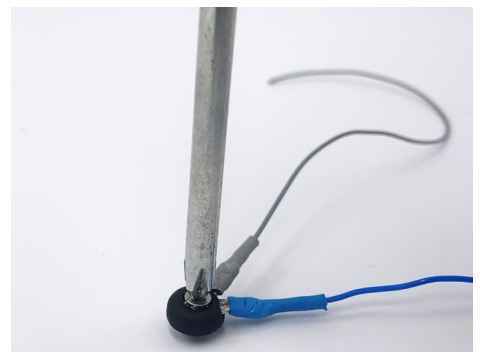
**POSITION MULTIPLE RING TERMINALS**

Insert multiple ring terminals into the side opening of the Protective Cap ensuring they exit at a slight angle from each other. Ensure the holes of the ring terminals are aligned for the threaded screw to pass through.

Slide the lock washer into the side opening of the Protective Cap ensuring the lock washer is above the ring terminals.

Push the threaded screw down through the top hole of the Protective Cap, making sure the screw goes through the lock washer and ring terminals.

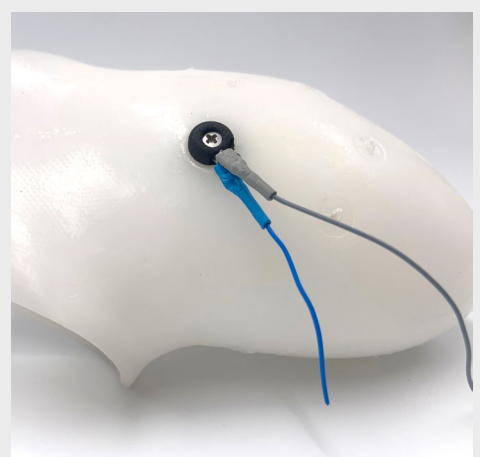
Using a little force from a screwdriver, the head of the screw will “pop” through the hole and remain captured in the Protective Cap.



3

**INSTALL**

Follow the general assembly instructions above to attach and secure to a **ControlSeal™** Electrode Dome. Do **NOT** use thread locker.



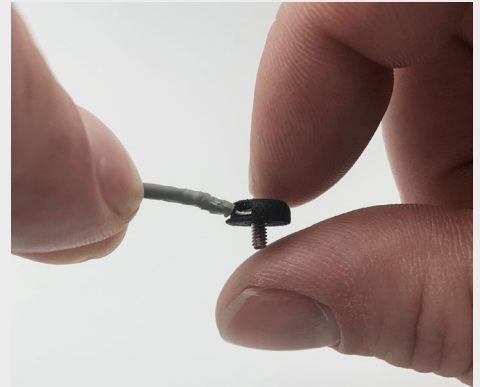
(As Necessary): Installing Longer or Shorter Screws for Socket Materials Outside the 1.9-5.5 mm Range

1

**PUSH EXISTING SCREW OUT AND EXTRACT HARDWARE**

Apply a small amount of force to the bottom of the threaded screw to “pop” the head of the screw through the top hole of the Protective Cap.

The screw then can be freely extracted. The lock washer and ring terminal can also then slide out of the side opening of the Protective Cap.



2

**POSITION REPLACEMENT SCREW**

If they were removed or fell out, insert the ring terminal and lock washer into the side opening of the Protective Cap. Ensure the lock washer and ring is above the ring terminal(s).

Push the replacement threaded screw down through the top hole of the Protective Cap, making sure the screw goes through the lock washer and ring terminal.

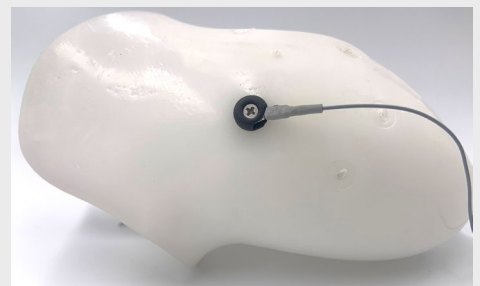
Using a little force from a screwdriver, the head of the screw will “pop” through the hole and remain captured in the Protective Cap.



3

**INSTALL**

Follow the general assembly instructions above to attach and secure to a **ControlSeal™** Electrode Dome. Do **NOT** use thread locker.





## GENERAL INSTALLATION PRECAUTIONS

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

**CAUTION**

**Configuration by a qualified professional.** The **ControlSeal™** Electrode must be assembled by a qualified specialist.

**CAUTION**

**Do not cross-thread.** Do not try to force 2-56 threaded screw to tighten in **ControlSeal™** Electrode Dome. Cross threading can cause permanent damage to electrode.

**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 **ControlSeal™** Electrodes and result in malfunction and minor injury to the user.

**CAUTION**

**Use with uncertified device.** Make sure that the **ControlSeal™** Electrodes are only connected to certified compatible biopotential recording devices. The list of certified compatible devices is maintained at [coaptengineering.com/compatibledevices](http://coaptengineering.com/compatibledevices). Use with an uncertified device that is incompatible with the system, or was not indicated during product order, may cause damage to and/or malfunction of the **ControlSeal™** 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 **ControlSeal™** 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 **ControlSeal™** 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 **ControlSeal™** 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.

**NOTICE**

**Conductive socket material.** It is important to consider electrode interference when using of electrically conductive socket materials, such as carbon fiber laminate. Conductive socket material that comes in contact with **ControlSeal™** Electrode Dome can negatively affect prosthesis performance by reducing the detected EMG signal quality. Use the provided Protective Caps and/or take care to electrically isolate the Electrode Dome and/or EMG Interface Cable ring-terminals from contact with any conductive socket materials.

## ELECTRODE CLEANING & MAINTENANCE

### Duration of Use

The **ControlSeal™** Electrodes can safely be used for up to 24 hours a day. The **ControlSeal™** Electrodes were evaluated for biocompatibility under ISO 10993 as a prolonged skin contact surface device for cytotoxicity, skin sensitization, and irritation.

### Sterilization and Cleaning

The **ControlSeal™** Electrodes are provided non-sterile. The user can sterilize and clean them according to the procedure below before use and at any time. The **ControlSeal™** Electrodes are suitable for single-patient use only but can be sterilized and cleaned between applications on that user. Follow this procedure to properly clean and sterilize the **ControlSeal™** Electrodes:

1. Prepare by soaking a clean cloth or paper towel with at least 97% isopropyl alcohol. Avoid using anything abrasive like sandpaper or steel wool.
2. Use this prepared cloth to wipe the dome surface that will make cutaneous contact with the user.
3. Allow the **ControlSeal™** Electrodes to air dry before making cutaneous contact.

### Maintenance

The **ControlSeal™** Electrodes should be cleaned and installed properly.

The **ControlSeal™** 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 **ControlSeal™** Electrode conductivity and performance. Proper cleaning and installation will prevent surface corrosion and/or oxidization.

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

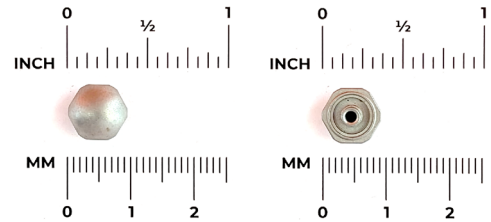
# COMPONENT SPECIFICATIONS

## COMPONENTS IN PACKAGE

A **ControlSeal™** Electrode kit contains a subset of the following components. Contact Coapt for more information.

### PASSIVATED 316L STAINLESS STEEL CONTROLSEAL™ ELECTRODES (STANDARD SIZE)

#### CONTROLSEAL™ ELECTRODE DOME (STANDARD SIZE)

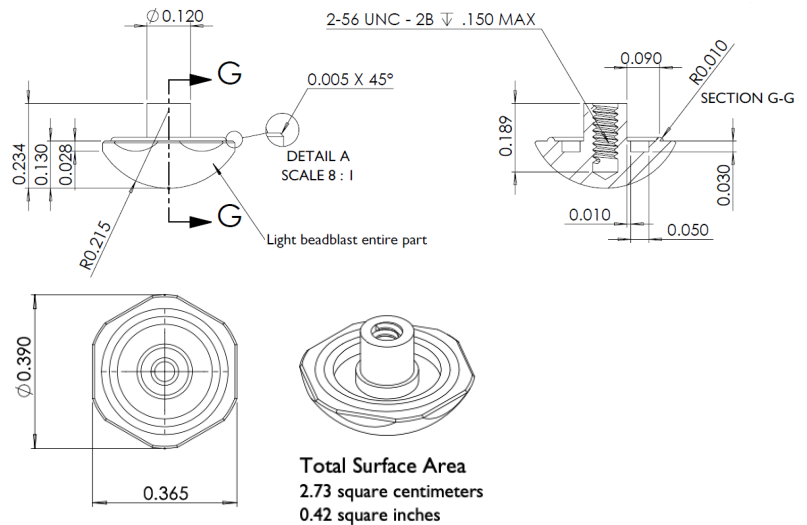


QUANTITY IN PACKAGE

Up to 18

Diameter: 0.390 in (9.906 mm)  
Height: 0.130 in (3.302 mm)

DIMENSIONS OF DOME



DIMENSION OF THREAD BORE

Diameter: 0.086 in (2.184 mm)  
Height: 0.189 in (3.801 mm)

TOTAL DOME SURFACE AREA

0.42 in<sup>2</sup> (2.73 cm<sup>2</sup>)

CONNECTION

2-56 thread

MATERIAL

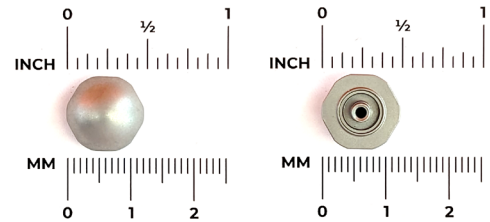
Passivated 316L Stainless Steel

RECORDING FREQUENCY BAND

0-1000Hz

PASSIVATED 316L STAINLESS STEEL CONTROLSEAL™ ELECTRODES (LARGE SIZE)

**CONTROLSEAL™** ELECTRODE DOME  
(LARGE SIZE)



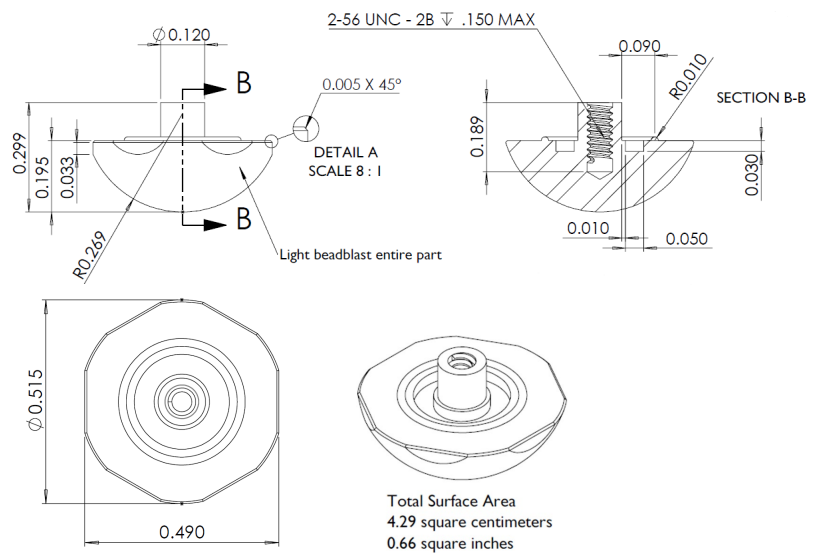
QUANTITY IN PACKAGE

Up to 18

Diameter: 0.49 in (12.446 mm)

Height: 0.299 in (7.5946 mm)

DIMENSIONS OF DOME



DIMENSION OF THREAD BORE

Diameter: 0.086 in (2.184 mm)

Height: 0.189 in (3.801 mm)

TOTAL DOME SURFACE AREA

0.66 in<sup>2</sup> (4.29 cm<sup>2</sup>)

CONNECTION

2-56 thread

MATERIAL

Passivated 316L Stainless Steel

RECORDING FREQUENCY BAND

0-1000Hz

PASSIVATED 18-8 STAINLESS STEEL PHILLIPS FLAT HEAD 2-56 SCREW

PASSIVATED 18-8 STAINLESS STEEL PHILLIPS  
FLAT HEAD 2-56 SCREW

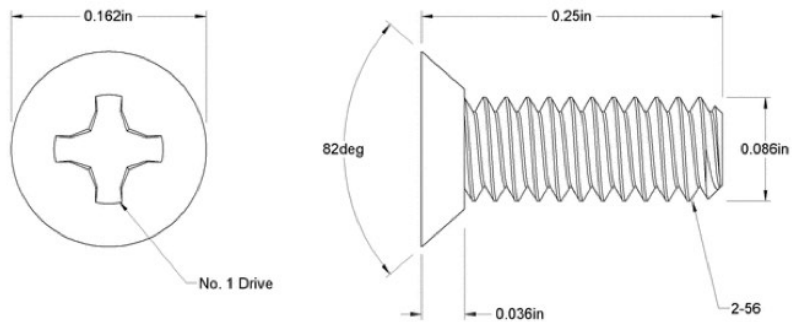


QUANTITY IN PACKAGE

Up to 18

Width: 0.162 in (4.115 mm)  
Height: 0.25 in (6.35 mm)

DIMENSIONS



CONNECTION

2-56 thread

MATERIAL

Passivated 18-8 Stainless Steel

TOOTH LOCK WASHER

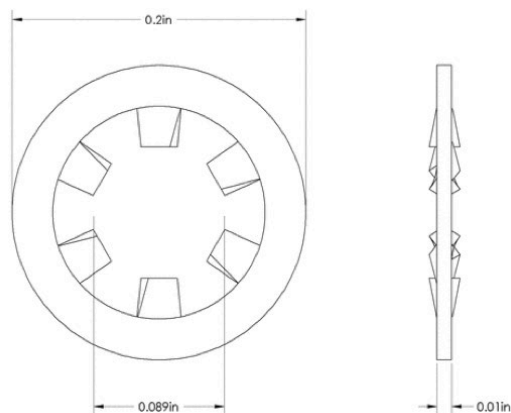
TOOTH LOCK WASHER



QUANTITY IN PACKAGE Up to 18

Internal Diameter: 0.089 in (2.261 mm)  
 External Diameter: 0.2 in (5.08 mm)  
 Thickness: 0.01 in (0.254 mm)

DIMENSIONS



CONNECTION No. 2 screw size

MATERIAL 400 series stainless steel

ELECTRODE ASSEMBLY CAP

ELECTRODE ASSEMBLY CAP

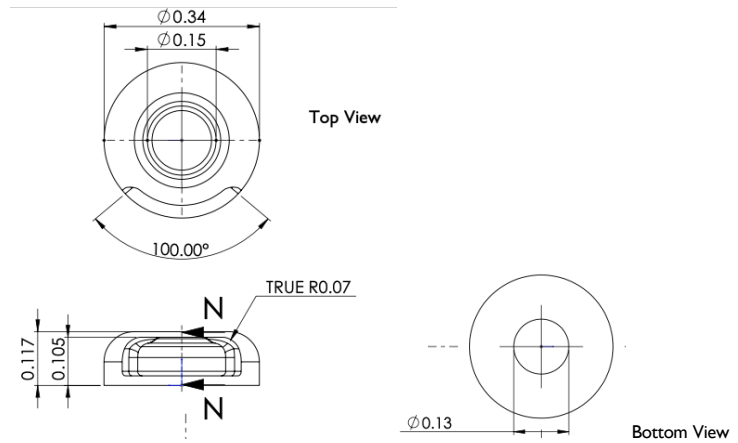


QUANTITY IN PACKAGE

Up to 18

Diameter: 0.340 in (8.636 mm)  
 Opening Diameter: 0.150 in (3.81 mm)  
 Opening Height: 0.105 in (2.667 mm)

DIMENSIONS



CONNECTION

No. 2 screw size

MATERIAL

HP PA12

CONDUCTING RING TERMINAL

CONDUCTING RING TERMINAL

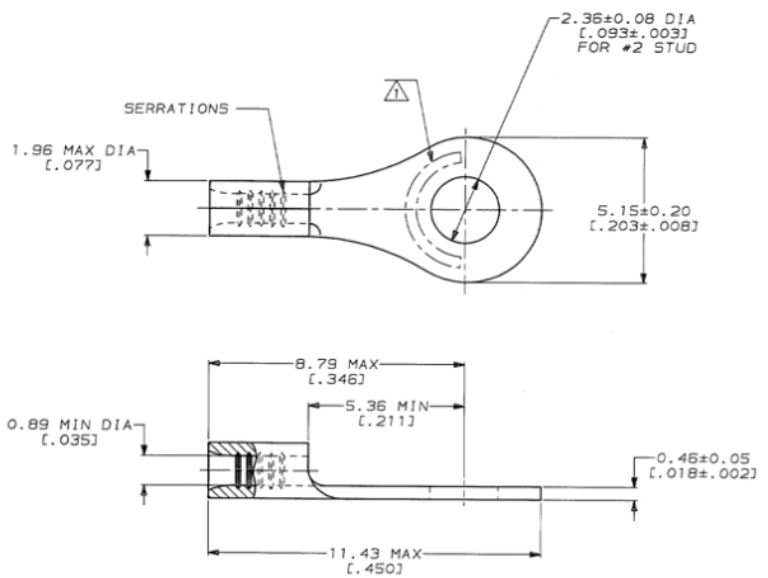


QUANTITY IN PACKAGE

Up to 18

Hole Diameter: 0.093 in (2.36 mm)  
 Ring External Diameter: 0.203 in (5.15 mm)  
 Ring Thickness: 0.035 in (0.89 mm)

DIMENSIONS



CONNECTION

No. 2 screw size

MATERIAL

Copper finished with Tin



BUNA-N RUBBER O-RING

BUNA-N RUBBER O-RING

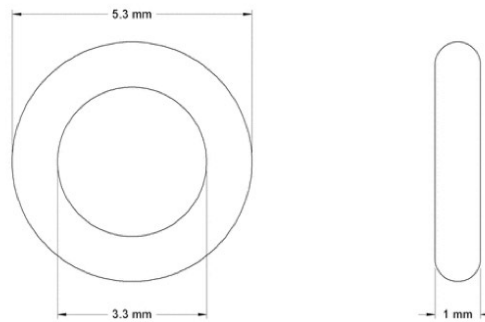


QUANTITY IN PACKAGE

Up to 18

Internal Diameter: 0.130 in (3.3 mm)  
 External Diameter: 0.209 in (5.3 mm)  
 Thickness: 0.004 in (0.1 mm)

DIMENSIONS



CONNECTION

N/A

MATERIAL

Buna-N Rubber, Durometer 70A

**DOME ASSEMBLY AID (FOR STANDARD SIZE DOME)**

DOME ASSEMBLY AID  
(FOR STANDARD SIZE DOME)

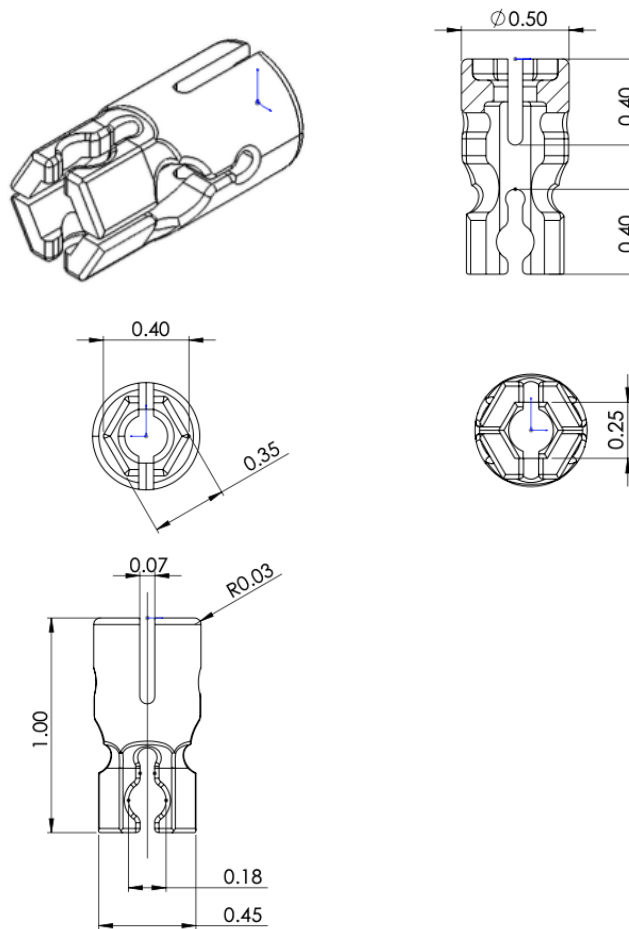


QUANTITY IN PACKAGE

Up to 1

Top Circular Diameter: 0.40 in (10.16 mm)  
Bottom Width: 0.250 in (6.350 mm)  
Tool Height: 1.0 in (25.40 mm)

DIMENSIONS



TOOL USE

(see sections within)

MATERIAL

HP PA12

DOME ASSEMBLY AID (FOR LARGE SIZE DOME)

DOME ASSEMBLY AID  
(FOR LARGE SIZE DOME)

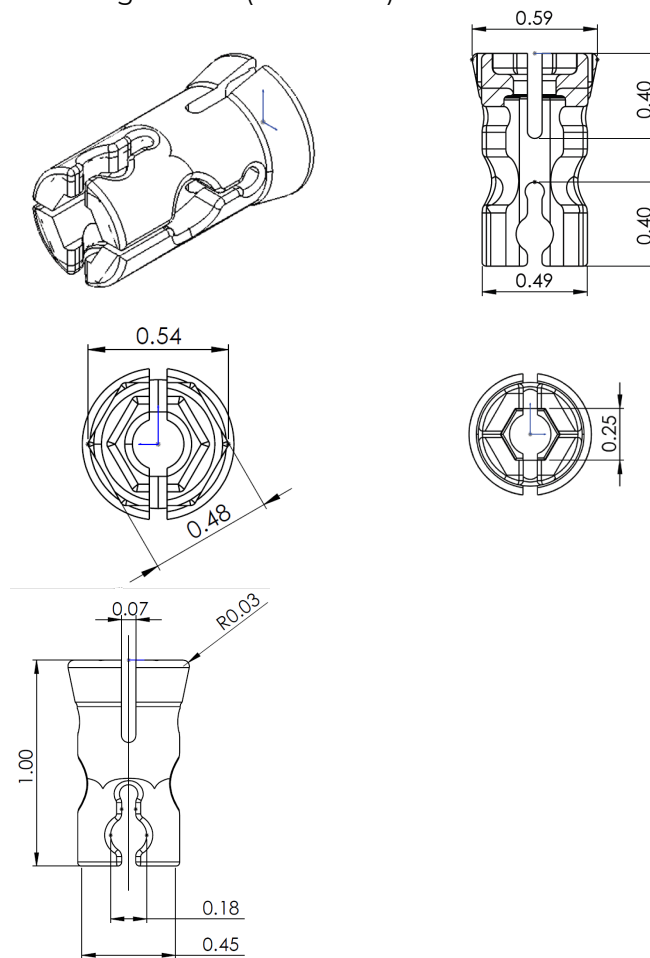


QUANTITY IN PACKAGE

Up to 1

Top Circular Diameter: 0.54 in (13.72 mm)  
 Bottom Width: 0.250 in (6.350 mm)  
 Tool Height: 1.0 in (25.40 mm)

DIMENSIONS



TOOL USE

(see sections within)

MATERIAL

HP PA12

# ADDITIONAL INFORMATION

## LIMITED US WARRANTY

For purposes of warranty, the “Customer” is defined as the entity that Coapt, LLC (“Coapt”) has invoiced for the Coapt component(s) (“Items”). The 2 Year Limited Warranty only applies to Items sold to the Customer by Coapt or an authorized distributor. For an integrated prosthetic 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 the reported problem(s) is associated with a product or component not supplied by Coapt, a non-warranty evaluation charge may be invoiced to the Customer.

Coapt warrants its Items will be free from defects in material and/or workmanship for a period up to two (2) years. 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 Items’ 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 theft, exposure of Items to fire, water, perspiration, corrosive materials such as salt water and extremely basic or acidic solutions, acts of nature or damage otherwise deemed intentional or abusive; b) damage due to failure to follow operating and installation instructions; c) damage incurred by malfunction or improper use of 3rd party components including leaking, damaged or malfunctioning batteries and cabling; d) use in a way not recommended by the manufacturer/distributor; e) 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); 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 which does not materially affect the function of the system is not covered.

Any warranty claim shall be reported to Coapt, in writing, 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. 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 returned within this Limited Warranty Period. It is the Customer's responsibility to adhere to all origin and destination shipping regulations, especially regarding shipments including Lithium-Ion Batteries. 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.

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 by country, state, province, territory, or other. 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

Additional year(s) warranty extensions are available for purchase at the time of original system purchase.

## RETURNS

Users should return all malfunctioning, damaged, or undesired product components directly to their clinician.

Clinicians should return all unserviceable product components directly to their regional distributor or Coapt.

## PRODUCT RETURN POLICY

- Item(s) returned in resaleable condition within 30 days of receipt are refunded or credited at full value without a restocking fee.
- Item(s) returned in resaleable condition between 30-120 days of receipt will be subject to a 15% restocking fee.
- Item(s) returned after 120 days of receipt are not accepted and no refund or credit is available.
- Applicable refunds will be processed within 30 days of receipt of return.
- Service/refurbishment costs for returning Item(s) to resaleable condition will be deducted from any refund and/or charged separately.

## INTELLECTUAL PROPERTY DISCLAIMER

The Coapt name, Coapt logo, products, and other Coapt trademarks and graphics are all property of Coapt, LLC. The aforementioned intellectual properties are protected by United States and international copyright, trademark, patent, trade secret, and other intellectual property laws where appropriate.

## REGULATORY INFORMATION



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.

The **ControlSeal™** Electrodes have been cleared as substantially equivalent to a legally marketed predicate device as a Class II device via Section 510(k) premarket notification; K223605



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



This device is fully compliant with the CE Marking Requirements under the European Medical Device Directive (MDD) and 2017/745 Medical Device Regulation (MDR). Coapt, LLC's European Union Authorized Representative (EC REP) is Fillauer Europe AB. **EC REP** Fillauer Europe AB, Kung Hans väg 2, 19268, Sollentuna, Sweden

# COAPT

---

303 W Institute Pl., Suite 200 | Chicago, IL 60610 | USA | 844.262.7800  
[www.coaptengineering.com](http://www.coaptengineering.com) | © 2023