

# BRIDGE ELECTRODES & SILICONE CAP



**BIONEN S.A.S.**

Via P. Petrocchi, 42/1  
50127 Firenze – Italia

**BIONEN**  
medical devices

[www.bionen.it](http://www.bionen.it)

# BRIDGE ELECTRODES & SILICONE CUP

## GENERAL INFORMATION

**Cleaning instructions:** Clean with cold water and Ph 5,5 detergent.

**Disinfection:** Disinfect with validated processes using either Amocid, Lysoformin, Alhyndex, IndicinGG or equivalent products, at high concentration too, without immersing the device into the liquids. Use products according to directives and regulations of the country in which the device is used

**Sterilization:** NO STERILE. The device doesn't need to be sterilized before use. If sterilization is necessary, sterilize with validated processes for ETO or Gamma Ray sterilization.

Do not AUTOCLAVE

**Packaging:** Plastic pouch.

**Handling and storing the device:** No special precautions for storage but it is good practice to place the device in its pouch after washing.

**Contraindications and interactions:** none.

**Declared toxicity:** none. LATEX FREE

### Warnings and Precautions:

- For professional use.
- Sold only on / per order of a physician.
- Use only in conjunction with a certificate registration system
- Only use on healthy skin.

Do not use if sensor shows signs of wear, damage, or if the metal is exposed

**Transport and Waste disposal:** Any particular transport condition and waste disposal is expected.

**Contraindications and interactions:** none.

**Declared toxicity:** none. LATEX FREE

**Warranty:** BIONEN ensures that the sensor is free from defects in material and workmanship for a period of twelve months from date of purchase. The sole responsibility BIONEN and our dealers is limited to replacement or repair of the product, in the opinion BIONEN, with no charge for parts or labor, if it is established that one of the parts is defective in workmanship, performance, or materials during the warranty period. be liable for any loss of revenues or damage, direct, indirect or incidental, including loss of profit, property damage, or personal injury arising from use, or inability to use BIONEN In no case or its dealers the product.

This warranty applies only to the original purchaser and supersedes all other warranties or previous agreements, expressed or implied. This warranty is void if the product is used for purposes other than those for which it is intended, or is subject to abuse, misuse, tampering, neglect, or unauthorized modifications. Use of this product constitutes the warranty agreement in full.

**Regulation:** Class I device.

Comply with the MDD 93/42/CEE (D.L. 46/97) and manufactured according to the procedures of BIONEN Quality System certified ISO 13485.



# BRIDGE ELECTRODES & SILICONE CUP

## BRIDGE ELECTRODE

**Intended use:** Electroencephalogram (EEG) on integral skin

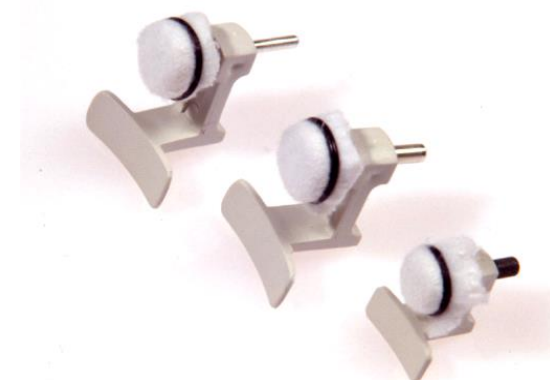
**Instructions for use:** Wet the electrode's cover with conductive solution to get the electric contact with the patient, carefully clean the electrode after each use, dry and put the electrode in a packaging as the one it is sold with, together with the instructions. The electrode is foreseen for a repetitive use and therefore can be wasted. Before use carefully check the integrity of the electrode. N.B. the silver chloride electrode is not allowed to get in contact with any other metal either in storage or use.

**WARNING:** Do not use on injured skin.

**Lifetime:** Product can be reused between 100 and 300 times. After 5 years from sale, the top shape is not guaranteed.

### AVAILABLE CONFIGURATION:

REF.	UM	N°	MATERIAL	SIZE
0001.001	NR	1	Ag/AgCl SINTERIZZATO	ADULT
0001.002	NR	1	Ag/AgCl SINTERIZZATO	PEDIATRIC
0001.003	NR	1	Ag/AgCl SINTERIZZATO A VITE DORATA	PEDIATRIC
0001.004	NR	1	Ag/AgCl SINTERIZZATO A VITE DORATA	ADULT
0001.005	NR	1	Ag/AgCl SINTERIZZATO A VITE DORATA	ADULT
0002.001	NR	1	Ag/AgCl	ADULT
0002.001-23	CF	23	Ag/AgCl	ADULT
0002.002	NR	1	Ag/AgCl	PEDIATRIC
0002.002-23	CF	23	Ag/AgCl	PEDIATRIC
0002.003	NR	1	Ag/AgCl CON ATTACCO MCH	ADULT
0002.004	NR	1	Ag/AgCl A COPPETTA	ADULT
0002.006	NR	1	Ag con presa per banana 3mm	ADULT
0002.006-23	CF	23	Ag con presa per banana 3mm	ADULT
0002.007	NR	1	Ag con presa per banana 3mm	PEDIATRIC
0002.007-23	CF	23	Ag con presa per banana 3mm	PEDIATRIC



# BRIDGE ELECTRODES & SILICONE CUP

## SILICONE CAP

**Intended use:** Correct and permanent positioning of bridge electrodes for EEG registrations.

**Instructions for use:** Choose the cap of a suitable size for the head of the patient. Fix the cap to the patient using the chin straps and verify its permanent position. Accurately clean the skin on the International System 10/20 points with solutions to take the grease out or with abrasive creams. Position the bridge electrodes under the silicone cap and verify its permanent position. Apply electro conductive cream using a syringe with blunted needle. Use the tape measure to determine the nasion-inion distance directly along the midline of the scalp. Wear the cap placing the two frontal electrodes on the subject's forehead 10% of the nasion-inion distance above the nasion (e.g., if the nasion-inion distance is 36 cm, place the electrodes at 3,6 cm above the nasion). If the cap's measure is right, all the other electrodes' placement is given right away. Connect every electrodes to the system through the connectors and measure the electrode impedance. If some electrodes turn out with too high impedance, apply the electro conductive cream again and delicately move the needle on the skin.

The application of the cap and the electrodes is painless and it does not have to harm the patient.

**Lifetime:** Product can be reused until 500 times. After 5 years from sale, the top shape is not guaranteed

### AVAILABLE CONFIGURATION:

REF	UM	N°	N° WIRE	Ø SILICONE	CHIN	SIZE
0005.000	NR	1	6x4	4mm	RIBLENE	ADULT
0005.001	NR	1	6x2	4mm	RIBLENE	ADULT
0005.002	NR	1	4x2	4mm	RIBLENE	PEDIATRIC
0005.003	NR	1	6x2	4mm	VELCRO/FOD ERA	ADULT
0005.004	NR	1	4x2	4mm	VELCRO/FOD ERA	PEDIATRIC
0005.005	NR	1	4x2	3mm	VELCRO BIANCO	PEDIATRIC
0005.006	NR	1	6x4	4mm	VELCRO/FOD ERA	ADULT
0005.007	NR	1	5x4	4mm	VELCRO/FOD ERA	ADULT

### ACCESSORIES:

REF	UM	N°	TYPE	MATERIAL	SIZE
0003.001	CF.	1	25 ORING - 25 COVER	GOMMA - COTONE	ADULT



# BRIDGE ELECTRODES & SILICONE CUP

0003.001-100	CF.	1	100 ORING - 100 COVER	GOMMA - COTONE	ADULT
0003.002	CF.	1	25 ORING - 25 COVER	GOMMA - COTONE	PEDIATRIC
0003.002-100	CF.	1	100 ORING - 100 COVER	GOMMA - COTONE	PEDIATRIC
0003.011	CF.	25	ORING	GOMMA	ADULT Ø 0.9MM
0003.021	CF.	50	COVER	COTONE	ADULT - PEDIATRICO