DIRECTIONS FOR USE
SUBDURAL ELECTRODE
"G" STYLE CONTACT
3 MM LONG CONTACT WITH
3 x 0.5 MM EXPOSURE

AD-TECH®

STERILE EO

USA
Rx ONLY

CE 2797

EC REP

E.C. REP Ltd
5 Fitzwilliam Square East
Dublin 2, D02 R744, Ireland
Tel: +353 1 2 544 944

DIRECTIONS FOR USE
SUBDURAL ELECTRODE
"G" STYLE CONTACT
3 MM LONG CONTACT WITH
3 x 0.5 MM EXPOSURE

Purpose of Electrodes: The AD-TECH Subdural Electrodes are intended for temporary (<30 days) use with recording, monitoring and stimulation equipment, for the recording, monitoring and stimulation of electrical signals on the surface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

Contraindications: The subdural electrodes should not be used on any patient whom the physician/surgeon considers at risk for infection. The subdural electrodes are not intended for continuous stimulation. Stimulation should only be applied to support the brain mapping purpose of the electrodes.

Use: The Subdural Electrode is supplied STERILE. Sterility is guaranteed unless package is damaged or seal is broken.

The Subdural Electrode has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Subdural Electrode in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

This product should only be used by a physician/surgeon trained in the use of subdural electrodes. The selection of the style of electrode is made by the physician/surgeon.

The subdural electrodes should be handled with extreme care to prevent damage (a direct pull or stress on the electrode may cause a loss of contact recordings).

The subdural electrodes can be placed through a standard burr hole site or craniotomy site. Before surgical placement confirm exposed contact side of electrode and place exposed contact side onto cortical surface. The subdural electrode should slide easily onto the cortical surface and SHOULD NOT BE FORCED.

Method for securing the electrode is selected by the physician/surgeon.

Upon completion of placement and/or tunneling, the electrode contacts outside the body need to be immediately connected to the Electrode Cable. At no time should the electrode contacts outside the body be exposed or unprotected. Connection to an Electrode Cable protects the electrode contacts outside the body. If the patient becomes mobile, the electrode contacts need to remain connected to the Electrode Cable. To connect to EEG cable, see CABRIO® / TECH-ATTACH® Connection instructions for use. Also, consult electrode code chart.

Charge density is the most useful and accurate measure of the intensity of stimulation of tissue by an electrode, because it takes into account not only current strength and pulse duration, but also electrode contact size. Charge density increases as current and/or pulse duration increase and/or contact size decreases. In order to take pulse duration and current strength into consideration for the charge density delivered by the electrode contact supplied, the Stimulation Parameters Table is provided as a guide to their safe use. Contact Ad-Tech if you have any questions.

Remove the electrodes surgically. Remove any sutures that secure electrode if that method is used.

DO NOT WITHDRAW WIRE CARRIER (TAIL) INTO THE INCISION AS THIS WILL CONTAMINATE THE WOUND.

WARNING: Percutaneous removal may result in separation of materials, requiring surgical intervention to retrieve the electrode and contacts.

For Single Use Only. Do Not Re-Sterilize or Reuse. Not Intended for Implantation

(21 CFR 860.3(d): > 30 days). For Surgical Use Only. Do not use if packaging is damaged.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

CAUTION: Reuse of this device is prohibited as it may malfunction and cause contamination and risk to the patient.

CAUTION: Disconnect from monitoring equipment during cardiac defibrillation.

STORAGE: Subdural electrodes need to be stored and used within typical hospital/office room ambient temperature and humidity conditions.

Please refer to Ad-Tech's Symbols Glossary @ www.adtechmedical.com

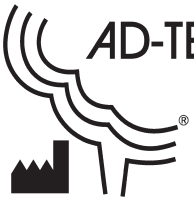
STIMULATION PARAMETERS

"G" style contact with 3 x 0.5 mm contact exposure

Charge Density (µC/cm^2)		Current (mA)								
		0.2	0.4	0.6	0.8	1	1.5	2	3	4
Pulse Duration (ms)	0.1	1.33	2.67	4.00	5.33	6.67	10.00	13.33	20.00	26.67
	0.2	2.67	5.33	8.00	10.67	13.33	20.00	26.67		
	0.3	4.00	8.00	12.00	16.00	20.00	30.00			
	0.4	5.33	10.67	16.00	21.33	26.67				
	0.5	6.67	13.33	20.00	26.67					
	0.75	10.00	20.00	30.00						
	1	13.33	26.67							
	1.25	16.67								
	1.5	20.00								
	1.75	23.33								
	2	26.67								

$$\textit{Charge Density}\ \frac{\mu C}{cm^2} = \frac{\textbf{Stimulation Intensity (mA)} * \textbf{Pulse Duration (ms)}}{\textbf{Electrode Surface Area } (cm^2)}$$

The electrode surface area is 0.015 cm^2. The maximum charge density limit for safe tissue stimulation is 30 $\mu C/cm^2$.



MEDICAL INSTRUMENT CORPORATION
400 WEST OAKVIEW PARKWAY, OAK CREEK, WISCONSIN, 53154 U.S.A
Phone: 262.634.1555 Email: sales@adtechmedical.com
Fax: 262.634.5668 Website: www.adtechmedical.com
Toll Free (U.S.A): 800.776.1555

AT10018-7-A, Rev. E