

# CLARION Components and Features

The CLARION Cochlear Implant System consists of an **Implantable Cochlear Stimulator (ICS)** with an intracochlear **electrode array**, a **Speech Processor with Headpiece**, the **Clinician's Fitting System** and the **Portable Cochlear Implant Tester (PCIT)**. In addition, various accessories and tools have been developed to assist the surgeon in the implantation of CLARION, such as the **Electrode Insertion Tool** which is included in the Surgeon's Kit.

This section describes the components of the system that are related to the surgical implantation of CLARION, including the ICS receiver and electrode array, the PCIT and the electrode insertion tool.

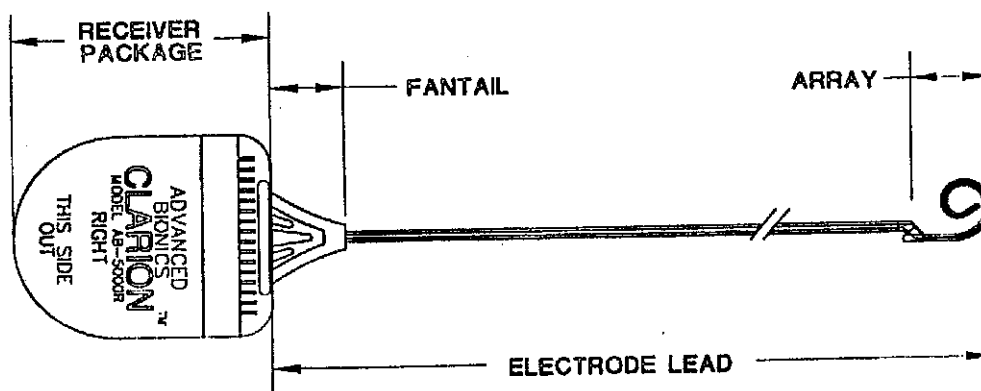
## *Implantable Cochlear Stimulator (ICS)*

The implantable component of the CLARION system is referred to as the Implantable Cochlear Stimulator or ICS. The ICS includes a magnet, electronic receiver/stimulator package and spiral electrode array (Figure 1). It is composed of materials that have been thoroughly tested for biocompatibility and is designed specifically for either the right or left ear.

The ICS electronic receiver package and magnet are contained within a hermetically sealed ceramic case, measuring 30 mm x 25 mm x 6 mm and weighing 7.5 grams. Ceramic was specifically selected so that the radio frequency transmission coils could be placed inside the package for protection. The ceramic package has an indifferent electrode band which is used as a return electrode during monopolar stimulation. CLARION incorporates eight independent stimulus output circuits, allowing stimulation of the auditory nerve fibers with a variety of signals. Each output circuit is capacitively coupled to prevent the leakage of damaging direct current and has a current regulated output from 0.5 to 2500  $\mu$ A. When all eight independent channels are operating simultaneously, the receiver has an update rate of 13,000 samples per second per channel. With sequential stimulation, biphasic pulses are delivered at a rate of 813 pulses per second per channel. CLARION has been designed to provide a broad spectrum of fitting parameters. The

stimulating waveform can be analog or pulsatile, the stimulation mode can be bipolar or monopolar and the temporal distribution of the signal can be simultaneous or non-simultaneous. All of these parameters are controlled by the external speech processor which provides power and data to the internal receiver. The receiver accepts and decodes signals from the external components of the system and conveys these signals to the electrode array in the cochlea.

An additional feature of the ICS is its bi-directional telemetry which allows the clinician to verify the integrity of the implanted electronics before, during and any time after surgery. Information is sent from the ICS back to the external components through the same inductive coupling that allows the sound signal to be transmitted from the external components to the ICS.



*Figure 1: ICS with Spiral Electrode Array for Right Ear*

Extending from the ICS is the CLARION electrode. The electrode consists of a fantail portion, electrode lead and spiral electrode array. The electrodes, composed of platinum-iridium (90:10) alloy, are housed in a silicone rubber carrier and extend from the ceramic case of the ICS receiver package. The spiral intracochlear electrode array is designed to be inserted approximately 25 mm into a normally patent cochlea. The principal feature of the array is its spiral configuration that matches the curvature of the human cochlea. Molded in a tight spiral curve, the electrode array is designed to lie on or near the medial wall of the scala tympani. It consists of 16 spherical contacts arranged in 8 near-radial bipolar pairs for stimulation of discrete segments of the cochlea. The electrode contacts are numbered 1 through 8 from apex to base and are designated as being either the medial or lateral electrode

contact within a pair. For example, M5 refers to the 5th medial contact along the array (Figure 2).

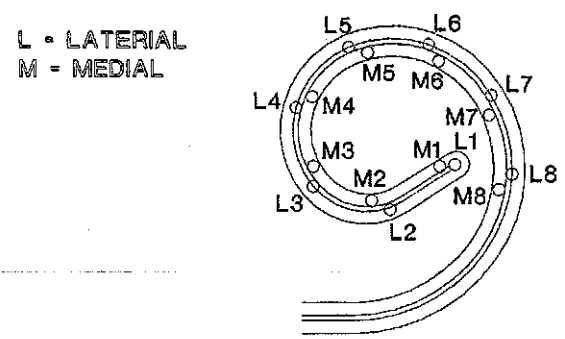


Figure 2: Electrode Labeling

The electrode array includes both a spiral portion with stimulus contacts and a straight portion without contacts (Figure 3). The neck refers to the “notch” or “knuckle” at the proximal end of the array that connects the array to the lead. The fantail is directly connected to the electronic receiver package. The lead, which extends from the fantail, refers to the silicone carrier in which the electrode wires are enclosed.

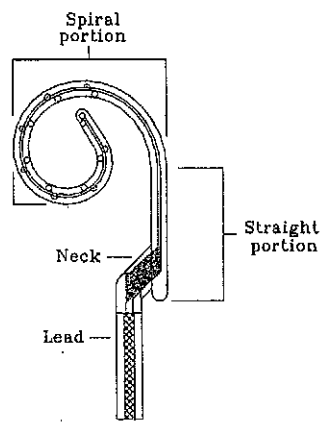


Figure 3: Electrode Array