# *A HIGH-CURRENT IrOx THIN-FILM NEUROMUSCULAR MICROSTIMULATOR*

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## *ABSTRACT*

This paper reports the development of a high-current stimulating electrode and a versatile fabrication technology required for the eventual realization of an implantable microstimulator for neuromuscular applications. The stimulating electrode is based on thin films of activated iridium oxide (AIROF), and is formed by combining more than 450, 20μmx20μm, small AIROF sites. It occupies a total active area of ≈180,000μm$^2$, and has been subjected to more than 350 million charge-balanced constant current pulses of 10mA amplitude and 200μsec duration without showing any sign of degradation. A novel and versatile fabrication technology has also been developed which offers high-performance CMOS and bipolar devices, together with Zener diodes, on-chip poly-Si/poly-Si capacitors, and high-value resistors. Isolated vertical npn transistors with current gains of 140-150, and lateral pnp transistors with current gains of 10-20, and 7V voltage references are available and have been used to implement an integrated circuit chip for an implantable neuromuscular microstimulator. The chip includes 3.5V and 8V regulators, RC low-pass and high-pass filters, and regulated current sources and sinks, and measures 1.9x1.2mm$^2$.

## *INTRODUCTION*

Functional electrical stimulation (FES) has been widely used for restoration of function in a number of applications, including auditory prosthesis and muscular stimulation. In particular, FES of paralyzed muscle in paraplegic and quadriplegic individuals has been successfully demonstrated in many different clinical settings. The majority of stimulators that have been developed incorporate stimulating electrodes and electronic circuitry to deliver controlled amounts of electrical charge into the muscle in the form of current pulses. The stimulating electrodes have typically been fabricated using long stainless steel wires, and the control circuitry has been implemented using a mix of thick-film and IC technologies. Consequently, most of the present implantable stimulators are physically large devices [1]. Although these systems have successfully demonstrated the capabilities of neuromuscular stimulation, it is believed that in order to fully realize the benefits of FES, miniature microstimulators that can pack both the electrodes and a functionally versatile circuit into a small injectable device are needed. The implementation of such microstimulators depends on the development of an array of technologies ranging from techniques for transfer of power and data, to technologies for fabrication of miniature stimulating electrodes and control electronics. We have previously developed techniques for transcutaneous transfer of power and data through radio-frequency telemetry using millimeter-sized receiving coils, and have shown that sufficient power and voltage levels can be transferred for proper stimulation of the muscular tissue [2]. This paper reports the development of a high-current miniature stimulating electrode for neuromuscular applications, and the development of a combined bipolar-CMOS technology that can be used for the implementation of a variety of circuit functions in a small area. These technologies have paved the way for the eventual realization of a single-channel, implantable microstimulator.

## *MICROSTIMULATOR STRUCTURE*

Figure 1 shows the overall structure of a single-channel implantable microstimulator for neuromuscular stimulation under development at the University of Michigan. It consists of a silicon substrate which supports two stimulating electrodes that act as the cathode and the anode of a bipolar stimulating electrode pair; a hybrid integrated circuit chip that incorporates CMOS and bipolar circuitry for power regulation and control of the microstimulator; a hybrid tantalum chip capacitor that is used for power storage; and a solenoid receiver coil that is used for power and data reception from an external transmitter. The entire power and data circuitry and its associated hybrid components are sealed in a custom-made glass capsule which is electrostatically bonded to the silicon substrate, providing a hermetic package. The stimulating electrode pair is outside of the package area and feedthroughs are provided to interconnect the electronics with these electrodes [2]. The microstimulator is to be implanted into muscle by expulsion from a hypodermic needle. In order to achieve this, the overall dimensions of the microstimulator should be less than 1.8x1.8x9mm$^3$. This is the most challenging requirement for the microstimulator. In addition, the microstimulator should be powered and controlled using RF telemetry, and it should be capable of delivering constant current pulses of 10mA amplitude for durations as long as 200μsec into loads of <800Ω.

## *IrOx STIMULATING ELECTRODES*

One of the most important criteria for any stimulating electrode is the selection of a site material that is biocompatible and is capable of delivering high charge densities to the tissue. Furthermore, the charge must be delivered without inducing gas evolution, gross pH changes, or metal corrosion at the site. For

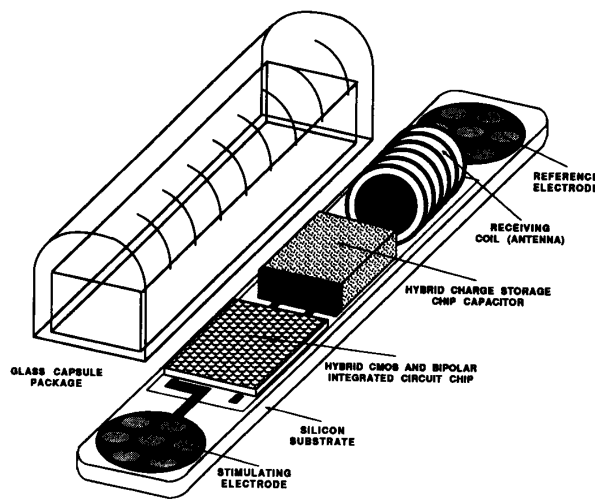


Figure 1: Overall structure of a single-channel implantable microstimulator for neuromuscular stimulation.

proper stimulation of muscle, it has been shown that high current and charge levels of ≈1-20mA and several μCoulombs are typically required [3]. Most present neuromuscular stimulating electrodes are fabricated using long coiled wires of stainless steel [4]. Because of the relatively small charge injection capacity (i.e. a few tens of $\mu C/cm^2$) of stainless steel and other materials such as platinum and gold used for stimulating electrodes, these electrodes have been fabricated with large exposed surface areas in order to maximize the charge delivery capacities and to reduce damage to the electrode and the surrounding tissue. Consequently, their large sizes, together with other disadvantages such as corrosion, metal dissolution, and lack of biocompatibility prohibit their use in the implantable microstimulator described above, and improved stimulating materials and electrodes are required.

Iridium oxide has been found to be an excellent stimulating site material [5]. It has very high charge delivery capacities (>4 $mC/cm^2$), can be deposited using various thin-film deposition techniques, and is extremely inert and biocompatible. Planar thin-film microelectrodes using anodized iridium oxide have been successfully fabricated for the stimulation of the central auditory system [5]. They incorporate stimulating sites that are typically 1000-4000$\mu m^2$ and can pass up to a few hundred microamperes of current. In order to deliver higher levels of current and charge, the total surface area of the electrode can be increased. However, it has been shown that in planar electrode structures, the current density profile within the area of the electrode surface is not uniform, and it drastically increases around the site perimeter [6]. This very high current density causes long-term non-reversible electrochemical changes to occur in the film, and the iridium oxide will peel off in these areas. Therefore, merely increasing the total surface area of the site in order to increase its current carrying capability is not sufficient and will not produce high-current planar electrodes.

In order to overcome these problems, we have developed a new thin-film stimulating electrode structure for use in neuromuscular microstimulators, as shown in Figure 2. It consists of a polysilicon or refractory metal conductor that is insulated between LPCVD silicon oxide and silicon nitride films. Multiple openings to the conductor are created in the top dielectric and are inlayed with iridium. Because of the large number of sites and because of the large total edge length, the current density profile through each small site can be made more uniform, and the current density around the perimeter of each site can be significantly reduced. When connected in parallel, these sites make up a high-current stimulating electrode that has large surface area and a large perimeter-to-area ratio. We have called these new electrodes waffle electrodes. The fabrication process for the waffle electrodes is similiar to our multichannel neural stimulating electrodes and has been described elsewhere [5].

Figure 3 shows photographs of a fabricated bipolar stimulating electrode measuring 1.5mmx9mm, and a magnified view of one of the waffle electrodes. The waffle electrode consists of a total of 450, 20μmx20μm, small sites all connected in parallel to the underlying conductor, resulting in a total active area of ≈180,000$\mu m^2$. After mounting and bonding, the iridium surfaces are activated using cyclic voltammetry to create anodized iridium oxide (AIROF) sites that possess high charge injection capacities. Electrode activation is performed by cycling the iridium sites between potential levels of -1 and 1.1 volts with respect to a saturated calomel reference electrode using a triangular voltage ramp at 2.1V/sec until a total charge storage capacity of $50mC/cm^2$ is obtained. After activation, AIROF electrodes are subjected to long-term constant current pulse tests using a cathodic-first (or anodic-first), 10mA amplitude (as required for the microstimulator), 200μsec long, constant current pulse, followed by an anodic (cathodic) charge balance pulse. The pulse test is continued until either the electrode fails or it is removed from the test for observation. We have performed a number of long-term pulse tests on different electrodes *in-vitro*. The electrode impedances before and after activation have been measured to be ≈1-2kΩ and ≈400-500Ω @1kHz respectively. A major portion of this impedance is the access resistance of the activated iridium oxide film. A number of electrodes have been subjected to more than 350 million 10mA current pulses without showing any degradation in the site properties or appearance. Figure 4 shows an SEM view of a single small site (20μmx20μm) after long-term pulse testing. Based on these results, we believe that these electrodes can be successfully used in our implantable microstimulator for periods of at least one year. The electrodes require a very small geometric area (typically 300μmx1mm), which is orders of magnitude smaller than other muscular stimulating electrodes.

The above design for these electrodes is simple, does not require any additional processing steps, and can be tailored to satisfy the needs of many biomedical applications. These are the only known planar thin film stimulating electrodes capable of delivering such large currents into tissue.

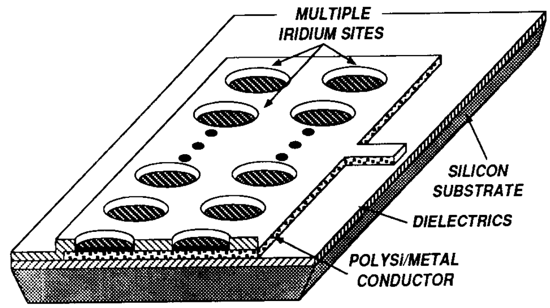


Figure 2: Structure of a waffle electrode for high-current stimulation applications.

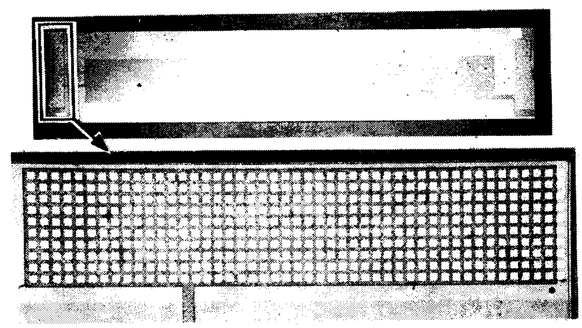

Figure 3: Photographs of a bipolar microstimulating electrode measuring 1.5mmx9mm, and a magnified view of a waffle stimulating electrode. Each small site is 20μmx20μm, and the total active area of the electrode in ≈180,000$\mu m^2$.

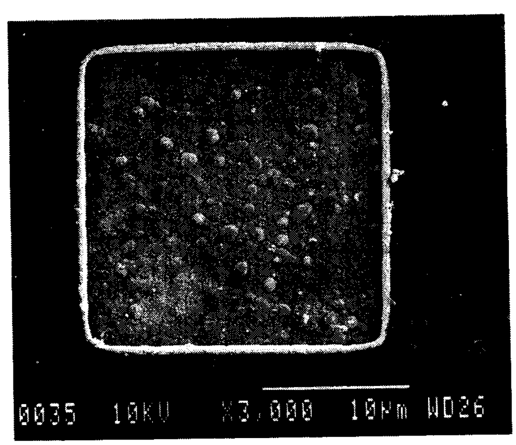


Figure 4: SEM view of a single small site (20μmx20μm) from a waffle electrode after 350 million 10mA current pulses.

## *CIRCUIT FABRICATION TECHNOLOGY*

Figure 5 shows the block diagram of the system electronics required for the microstimulator. The circuit receives an amplitude modulated RF carrier from an external transmitter and from this it should generate regulated supply voltages of 3.5V and 8V, decode the modulated control data, and regenerate the carrier clock. Figure 6 shows the circuit diagram for power regulation and data and clock recovery. As evident, a variety of active and passive devices are required for the implementation of this circuit, including Zener diodes, bipolar transistors, capacitors, and MOS transistors. Previous electronic packages for implantable stimulators have used hybrids of the above components to implement the required functions forcing them to occupy rather large areas. This cannot be tolerated in our implantable microstimulator. Since the receiver coil for the microstimulator will occupy about 40% of the total volume of the implant, the rest of the system, including the electrodes, the package, and the entire control electronics and its associated elements should be made very small and the use of hybrid components minimized in order to satisfy the dimensional requirements of the implant.

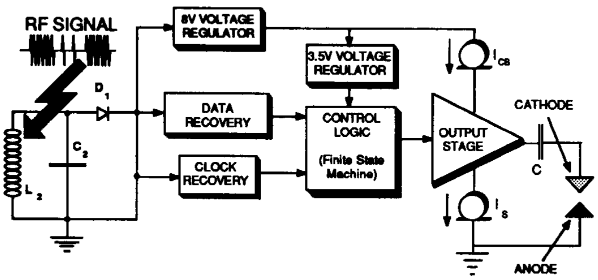


Figure 5: Overall system electronics required for a single-channel microstimulator.

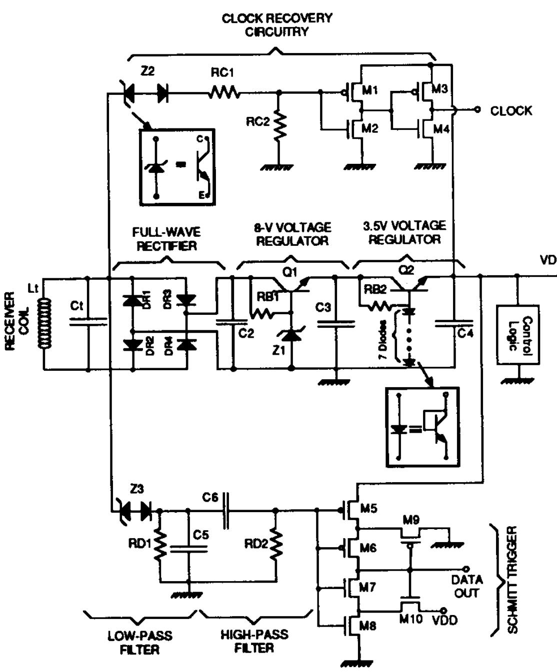


Figure 6: Circuit diagram of the power regulation and data and clock recovery circuitry for the implantable microstimulator.

We have developed a versatile fabrication technology that can be used to implement the required circuits in a small area. Figure 7 shows a cross sectional view of the device structures that can be implemented using this technology. The fabrication process combines deep-boron diffusion and a standard 3μm p-well CMOS technology to implement a variety of active devices and components. The deep boron diffusion penetrates through the n-epi layer and connects to the underlying p-substrate, thus creating junction-isolated n-epi regions. The $p^{++}$ diffused regions protect against lateral etching during silicon micromachining, and can be used for microstructure formation using boron etch-stop. In addition to standard CMOS circuitry, the lightly-doped n-epi regions can house a number of different bipolar device structures. Lateral npn and pnp bipolar transistors are fabricated in p-well and n-epi regions respectively, while vertical npn transistors are fabricated in isolated n-epi regions using an $n^+$ emitter, p-well base, and n-epi collector. The process provides a number of junction diodes and Zener-based references, including $n^+$-$p^+$ or $n^+$-$p^{++}$ with different breakdown voltages. The open-circuit collector-emitter breakdown voltage of lateral npn transistors can also be easily used as a voltage reference. It can be tailored to any specific application since it is dependent on the transistor base width. In addition to active devices, the fabrication process provides two layers of polysilicon for fabrication of on-chip capacitors, and a variety of diffused regions for forming large resistances similar to those typically available in junction-isolated bipolar technologies.

The p-well drive-in and deep boron diffusions are performed simultaneously, as discussed by Ji [7]. The fabrication process requires a total of 9 masking steps. Figure 8 shows photographs of a number of CMOS and bipolar circuits and devices fabricated using the above technology. Figure 9 shows the I-V characteristics of a vertical npn bipolar junction transistor with a current gain in the range ≈140-150. Lateral npn transistors provide a current gain of ≈50, while lateral pnp transistors provide a current gain of ≈15. The characteristics of bipolar and MOS transistors, pn junction diodes, and polysilicon capacitors are summarized in Table 1. These devices have been used to design the circuitry shown in Figure 6 for the microstimulator without the use of any hybrid components. The circuit chip for this portion occupies an area of 1.9mmx1.2mm using 3μm feature sizes.

## *CONCLUSION*

We have successfully developed a high-current thin-film electrode with activated iridium oxide surfaces for neuromuscular stimulation. The electrode consists of more than 450 small sites, each having an area of $400\mu m^2$, all connected in parallel to a single polysilicon or tantalum conductor. The large number of sites provides a high area-to-perimeter ratio, thus reducing the current density around the perimeters of the sites. The electrode occupies a total active area of $\approx 180{,}000\mu m^2$ and has been demonstrated to withstand more than 350 million charge-balanced constant current pulses of 10mA amplitude and 200μsec duration with no sign of degradation. These electrodes are the first planar electrodes that are developed for muscular stimulation.

We have also developed a versatile device and circuit fabrication technology that provides bipolar and MOS transistors and is compatible with silicon micromachining techniques. CMOS circuits fabricated in an n-epi on p-substrate using the above technology provide performance characteristics similar to our standard 3μm p-well CMOS process. Isolated vertical npn transistors with current gains of 140-150, lateral pnp transistors with current gains of 10-20, and Zener-based references with breakdown voltages of ≈7V have been fabricated and can be used to implement a variety of circuit functions, including voltage regulators, filters, and current sources and regulators. Furthermore, the process supports integrated poly-Si/poly-Si capacitors as well as high-value resistors, thereby reducing our dependence on hybrid components. An integrated circuit chip for use with an implantable microstimulator has been designed using the above process. The circuit includes 3.5V and 8V voltage regulators, RC low-pass and high-pass filters, and regulated current-sources and current mirrors.

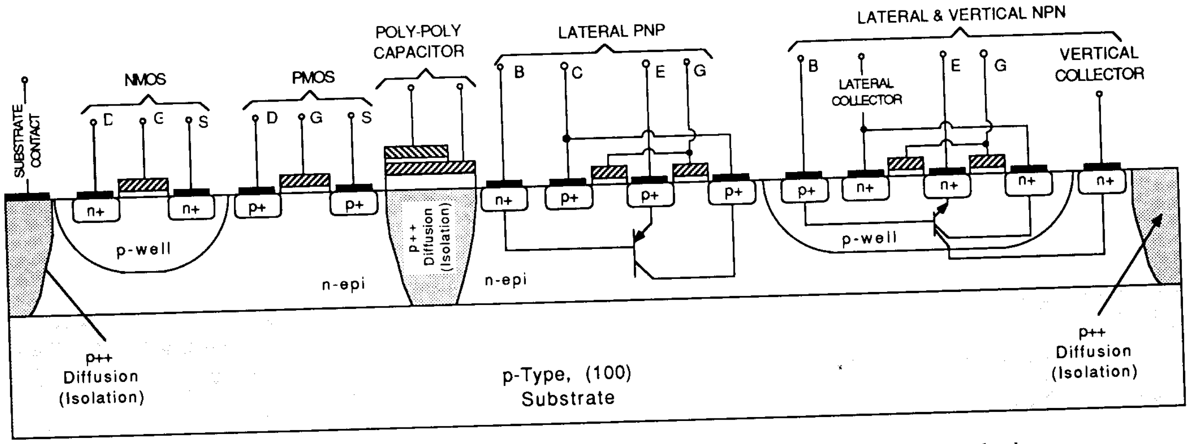


Figure 7: Cross-sectional view of the modified CMOS-Bipolar-silicon micromachining technology required for the microstimulator.


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Table 1: Summary of Bipolar-CMOS Device Characteristics.

| *Bipolar Transistors:* | Vertical npn | Lateral npn | Lateral pnp |
|---|---|---|---|
| $\beta$ | 140-150 | 50 | 10-20 |
| Breakdown ($BV_{CEO}$) | >40V | ≈7V | ≈20V |
| *CMOS Transistors:* | nMOS | pMOS | |
| $V_T$ | 0.8V | -0.8V | |
| KP | 30 $\mu A/V^2$ | 15 $\mu A/V^2$ | |
| *Junction Diodes:* | n+/p-Well | p+/n-Epi | p-Well/n-Epi |
| Breakdown | ≈20V | ≈40V | ≈85V |
| *Poly-Si/Poly-Si Capacitors* | | | |
| Capacitance/Area | | 345pF/mm$^2$ | |
| Oxide Breakdown | | >60V | |

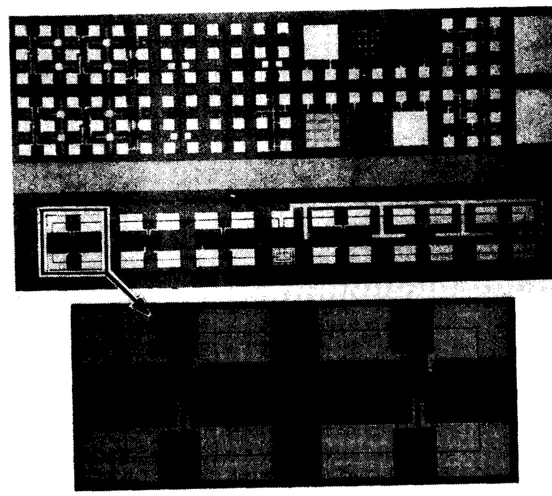

Figure 8: Photographs of a number of fabricated CMOS and bipolar circuits and devices.

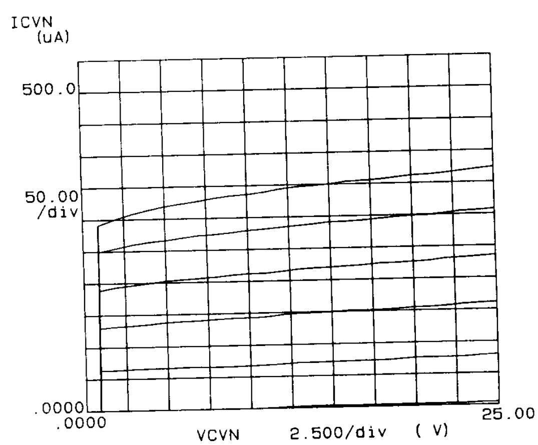


Figure 9: I-V characteristics of a vertical npn bipolar junction transistor with a current gain in the range ≈140-150.