



June 15, 2005

Food and Drug Administration  
Center for Veterinary Medicine  
Director of Compliance  
7519 Standish Place, HFV-230  
Rockville, MD 20855

Dear Director of Compliance,

Indiana-based ABC Life Science, Inc. was formed in 2005 to accelerate research and development and commercialize a platform of promising therapeutic devices and drugs for the treatment of central nervous system injury and disease.

We are currently conducting human clinical trials (under IDE G000195/S6) for a patented medical device known as an oscillating field stimulator (“OFS” device). This device has shown significant promise for acute, sub-acute and long-term (chronic) patients in the stabilization, repair, regeneration and re-construction of central nervous system tissue. Our current focus is its use in the treatment of acute spinal cord injury.

We hope to market the device to the veterinary field in January 2006 and would like to submit the attached labeling and promotional material for your review. Please refer to the Table of Contents on the next page for an outline of information covered.

We look forward to working with you to ensure that our literature complies with CVM labeling regulations and standards.

Please do not hesitate to contact me with any issues, concerns or questions.

Sincerely,

Mark Allen Carney  
President and Chief Executive Officer  
ABC Life Science, Inc.



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## 1. Brand and Generic Name

Extraspinal Oscillating Field Stimulator (OFS)

## 2. Manufacturer

Center for Paralysis Research Bioengineering Facility C/OM

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West Lafayette, IN 46907

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## 3. Indications and Usage

The Extraspinal Oscillating Field Stimulator (OFS) is indicated for the treatment of spinal cord injuries (SCI). It is designed to prevent the formation of scar forming cells at the injury site and to produce behavioral recovery from the SCI.

## 4. Device Description

The OFS, when implanted within the musculature of the patient's back (external to the spinal cord), produces a weak electrical field (ca. 300-500  $\mu\text{V}/\text{mm}^2$ ) within the damaged region of the cord, whose polarity is reversed every 15 minutes. This therapy is known to produce nerve regeneration for limited distances across and through the spinal injury, to reduce the density of scar forming cells at the injury site, and to produce a behavioral recovery from both standardized transection injuries and compression injuries to the spinal cord.

Four components of the OFS device come into contact with body tissues and blood during the 15 weeks of implantation:

1. The "jacket" or "casing" which encloses and seals the electronic components. This material is a 0.02 inch thick sheet of fluorinated ethylene propylene (FEP, otherwise known as Teflon®) extruded as a cylinder into which the electronics assembly is inserted.
2. The surface (insulation) of the insulated electrode leads. These lead wires or cables are commercially available pacemaker cable insulated with polytetrafluoroethylene (PTFE, hereinafter, the insulated cables will be referred to as cables, "pacer cables or leads," whereas the uninsulated end that delivers current to tissues will be referred to as the "electrode").
3. The Nusil MED-1137 RTV silicone based medical grade elastomer, pressure injected into the ends of the FEP cylinder to seal it at its ends. This pressure injected silicone prevents moisture from penetrating into the OFS unit's internal components.
4. The uninsulated Platinum Iridium electrodes (medical grade 90% Pt, 10% Ir annealed alloy wire). This medical grade PtIr is free of mercury contaminants, with other trace metals in the alloy occurring in concentrations of less than 100 ppm.



## 5. Guidelines for Use

The OFS Unit was designed to be used for all cases of paralysis (paraplegia) in dogs resulting from spinal cord injury. There is no restriction as to the insult, including but not limited to a) paraplegia secondary to fracture dislocation of the vertebral column (such as occurs with vehicle impact) and b) intervertebral disc herniation (common in certain breeds such as the Dauschand).

### a) Unit

The OFS implant consists of a main body (the battery and electronic circuitry) – contained within an a) sealed, b) clear, c) inert, d) medical grade Teflon, and three pairs of Teflon insulated electrodes (leads; Fig. 1). The unit is designed to be placed subcutaneously or within deeper muscle mass of the animal's back, and the electrodes fastened to paravertebral musculature above and below (rostral and caudal of) the injury site. OFS units are to be surgically implanted within 3 weeks of the spinal cord injury, and removed 14 to 16 weeks subsequent.

### b) Patient safety

There are no safety considerations whatsoever particular to the OFS unit itself – only those commonly associated with surgery under general anesthesia and with the overall state of health of the animal prior to and after spinal trauma. For example the animal must be able to undergo surgery to manage the injury by conventional means. Preexisting medical conditions (such as heart problems) should be considered by the surgeon, but do not themselves contraindicate OFS therapy.

Animals should not undergo Magnetic Resonance Imaging (MRI) while the unit is inside the patient. Conventional radiology, including CAT, will not affect the functioning of the unit and can be safely carried out after implantation. The unit is packaged in inert medical grade Teflon and the leads are insulated with Teflon – thus the OFS is inert to the body and there is no “rejection” or infection considerations other than those associated with any surgery. The uninsulated tips of the electrodes are of coiled, medical grade platinum/iridium of the type used in pacemakers and other implantable medical devices. There are no safety considerations associated with this component of the OFS unit as well.

## 6. Directions for Use: Guide for Surgeons

The OFS Unit is designed to be implanted at the time of ACUTE –usually emergency - conventional surgical management (Decompressive Surgery/ Discectomy) of the spinal cord injury. In cases where this cannot, or is not, performed the unit and electrodes can be surgically implanted within 3 weeks of the injury.

### a) Body of the OFS Unit

The cylindrical body of the OFS unit can be placed subcutaneously in larger dogs or can be inserted into a “pocket” fashioned with a finger or blunt probe beneath the fat pad or between the fascial connections of muscle layers of the back beneath the back skin. The only considerations are a) if the more superficial (subcutaneous) placement “stretches” skin tightly across/over the unit in some (usually small) breeds – contact necrosis may occur over the 14 weeks implant time. The surgeon can, if concerned, then opt for a

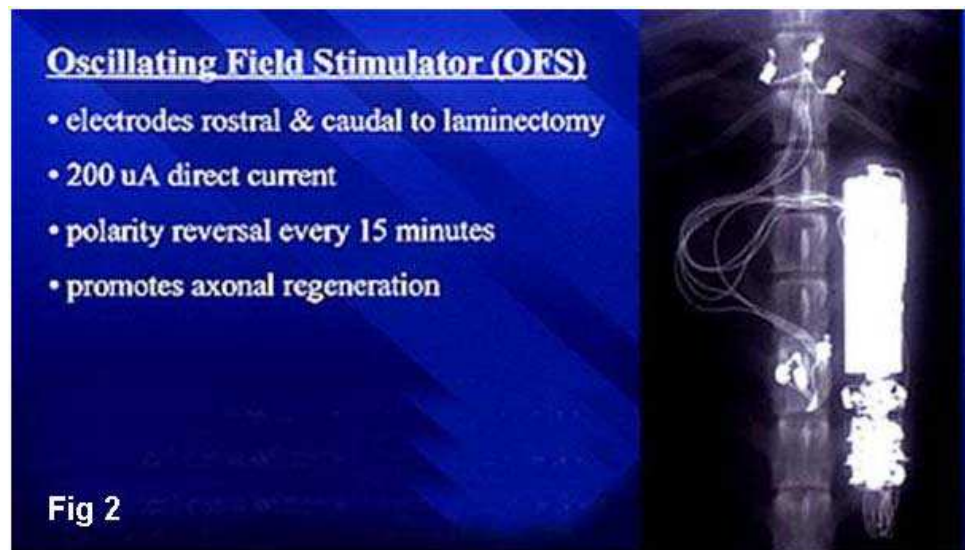
deeper placement of the body of the OFS unit at the time of implantation. This can also be done after the original implantation if superficial problems with skin stretched over the unit becomes apparent.

## b) Electrodes

The terminal of each electrode has a tab (black) proximal to the uninsulated metal providing a site for suture to muscle. All six of the electrode's terminals are fastened to superficial paravertebral musculature of the spine by tethering with suture. The electrodes are not placed within the bony spinal column, or the parenchyma of the cord. The former would interfere with the orthopedic management of the injury or spinal fusion, perhaps destabilizing the column in some cases. The latter would produce more, and unacceptable, injury to the spinal cord soft tissue.

## c) Electrode Placement

The six OFS electrodes are coded at the factory: three pairs of them with black Teflon insulation and three pairs with white insulation. Three of one set (all black or all white) is sutured to a vertebral segment rostral (head side) of the spinal cord injury, and the other three electrodes to the "tail side" (caudal) to the injury. Since the polarity of the current reverses in direction every 15 minutes, it does not matter whether black or white pairs are placed rostral or caudal of the injury, only that three electrodes of the same type (black or white) are so placed, as pictured in the diagram below.



At each "rostral" or "caudal" position, two of the three electrodes are sutured to the sides of the spine at the exposed vertebral segment: one on the left and one on the right and onto the musculature of the left and right lateral facets. The remaining electrode is sutured to the musculature of the dorsal (posterior) facet.

There are two suggested ways to determine which vertebra, rostra or caudal, of the injury site to locate these electrodes. It is assumed that the vertebral level of injury to the spinal cord has been accurately determined by radiology and/or myelography.

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If the surgeon chooses to perform a durotomy at the site of injury subsequent to a lateral or dorsal hemilaminectomy, than the electrodes should be fastened at the rostral and caudal vertebral level nearest the lesion where healthy and undamaged spinal cord tissue is revealed.

If a Durotomy is not performed, then the electrodes should be fastened approximately 1 1/2 to 2 vertebral segments rostral and caudal to the injury site.

Removal of the OFS requires general anesthesia and is straightforward: the body of the OFS unit is exposed and loosened from the implantation site, the electrodes followed to their respective suture sites, and the complete OFS Unit (body and electrodes) withdrawn; the surgical wounds closed in conventional manner, and aftercare post-surgery is conventional.

These procedures should only be performed by a veterinary small animal surgeon trained in the conventional, standard- of - care, surgical management of spinal injuries in dogs. For this reason, conventional discussion of typical surgical procedures involved in closing the surgical site and aftercare are not described here.

There are no known drug interactions with OFS. Thus pain medications, antibiotics, etc., can be given as deemed necessary. Methylprednisilone Sodium Succinate can be administered prior to, or at the time of surgery, if deemed necessary.

## 7. Storage conditions

Shelf life is approximately 1 year. Units are “activated” by the removal of a small magnet held to the outside of the unit with a plastic fastener. This magnet is removed at the time of surgical implantation by the surgeon after the unit is removed from the sterile packaging.

The magnet holds a magnetic reed switch in the “open circuit” condition so there is no power consumption by the unit.

When the magnet is removed, the OFS electrical circuit is functional.

## 8. Calibration

Not applicable. Functional character set at factory and is not alterable. Unit functioning is “all or none”.

## 9. FDA Approved Process for Sterilization

Ethylene Oxide Gas Sterilization was approved for human use. OFS Units are sterilized by an FDA approved second party company: Steris (Address: 5960 Heisley Road, Mentor, OH 44060). Sterility Testing is carried out by: NAMSA, INC. (Address: 6750 Wales Road, Northwood, OH 43619). The manufacturing facility also has the capability to perform sterility testing with state of the art equipment and has done so for over 10 years (> 300 dog implantations) without any problems if a second party company is not required. The sterile packaging is conventional medical grade with a clear covering so the units can be plainly seen inside along with an indicator strip inside to reveal “breaking of sterility”.

## 10. Serial Number and Labeling

The serial number is readable through the clear Teflon covering of the implant as pictured below. Other information contained on this label, placed within the implant at manufacture, are the business address and the admonition “Not for Human Use”.

