

**Durango
Orthopedic
Associates, P.C.**

One Mercado Street
Suite 202
Durango, CO 81301

Voice: 970-247-5362
800-524-9821
Fax: 970-259-6045

SpineColorado

One Mercado Street
Suite 200
Durango, CO 81301

Voice: 970-382-9500
Fax: 970-375-0007

Gary A. Scott, M.D.
Board Certified
Orthopedic Surgery

Jim A. Youssef, M.D.
Board Certified
Orthopedic Surgery
Fellowship Trained
Spine Surgeon

Kim L. Furry, M.D.
Board Certified
Orthopedic Surgery

Cyril A. Bohachevsky, M.D.
Board Certified
Physical Medicine & Rehabilitation
Level II Accredited

Richard L. Lawton, M.D., Ph.D.
Board Certified
Orthopedic Surgery
Fellowship Trained
Sports Medicine

Mara Isser-Sax, D.O.
Board Certified
Physical Medicine & Rehabilitation
Fellowship Trained
Spine & Musculoskeletal Medicine

Gwendolyn Grant, MD
Board Certified
Rheumatology

Robert F. Goodman, MD
Board Certified
Orthopedic Surgery

Wendy A. Jacoby, PA-C
Physician Assistant

Ann Theine, PA-C
Physician Assistant

Douglas J. Phelps, PA-C
Physician Assistant

Lance F. Hamlin, PA-C
Physician Assistant

**DURANGO
ORTHOPEDICS**

SPINE COLORADO

June 18, 2008

Ronald P. Jean
Center for Devices and Radiologic Health
(HFZ-410)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

Dear Mr. Jean:

I am currently a practicing orthopedic spinal surgeon and member of many societies, namely the North American Spine Society, American Orthopedic Association, American Academy of Orthopedic Surgeons, and an editor for Peer Review Journals, including Spine and SpineLine. I have no vested financial interest in the product being discussed before the panel. I have developed products for the cervical spine, as well as for the lumbar spine in the past, but I have no direct conflict of interest for Fiziomed or the Oxiplex Gel.

I was one of the original selected study site participants in the FDA randomized prospective trial looking at the efficacy of Oxiplex in patients who underwent microdiscectomy for back pain and leg pain. In review of the preliminary data and the latest followup data, it is clear that the Oxiplex Gel had excellent benefits for patients who received the gel in the study.

Patients who presented with both leg pain and back pain can be particularly challenging in a surgical practice, more so than other patients. This is a valid subgroup that can require extra attention, particularly if they return after surgery with recurrent symptoms. The fact that the Oxiplex Gel is shown to reduce both back and leg pain in this challenging group in comparison to the control group at 6 months postoperatively is an important clinical finding. The ability to reduce recurrent postoperative surgical pain in these patients obviously decreases the need for injection therapy, further imaging, and the need for the use of medications, as well as chronic narcotics.

Currently there are no other products or modalities designed to improve outcomes in these patients, and therefore the use of this gel in this patient population may indeed prove beneficial; however, long-term followup is obviously necessary. I do not have any examples of any problem cases that occurred or any complications that occurred in the use of this gel in my practice. I have found that most of the patients who did receive the gel went on to have good results and to my knowledge there were no recurrent disc herniations in this subgroup in my practice.

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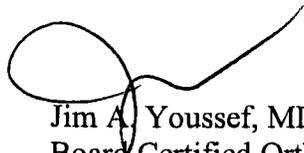
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The goal of the Oxiplex Gel is to coat and protect the nerve roots and the proposed indications to improve outcomes by reducing leg pain, back pain and neurologic symptoms. Currently there are no FDA approved products or modalities for this purpose. Surgeons often understand the importance of reducing nerve root irritation postoperatively and they often times use off-label products to decrease these postoperative complaints, including sealants, dural regenerative sheets, as well as epidural steroid application. As such, given the safety and efficacy of this product and the fact that a recent paper authored by Drs. Blumenthal and others demonstrated the decreased incidence of back pain and leg pain and associated symptoms six months following single level lower lumbar surgery for removal of herniated disc material, this would support the fact that this is a safe and beneficial product that can be utilized in this patient population to reduce their symptoms.

For this reason I would encourage you to consider approval of this device in this clinical setting. I think this would provide spinal surgeons with a more well-supported, documented product to decrease postoperative back and leg pain in patients who undergo such surgical intervention.

I thank you for your consideration. If you have any questions, please do not hesitate to contact me.

Sincerely,



Jim A. Youssef, MD
Board Certified Orthopedic Surgeon
Fellowship Trained Spine Surgeon
Fellow of American Academy of Orthopedic Surgeons