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**OSPEDALE
FATEBENEFRAPELLI E
OFTALMICO**
Azienda Ospedaliera di
Rilievo Nazionale
C.so di Porta Nuova 23
20121 Milano

**Struttura Complessa di:
NEUROCHIRURGIA
DIRETTORE
Dr. Mario Morosi**



**Unità Semplice
Day-Surgery
Responsabile
Dr. R. Assietti**

Dirigenti Medici

**Assietti Roberto
Biasini Alfredo
Gelsomino Anna
Meani Luigi
Migliaccio Giovanni
Montemezzo Francesco
Pieri Antonio
Tito Patrizia**

**☎ reparto:
02.6363.2370**

neurochirurgia@fbf.milano.it

**☎ prenotazione visite:
CUP 800638638**

Mr. Ronald Jean
Center for Devices and Radiological Health(HFZ - 410)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Jean:

I am Chief of the Day Surgery Section of the Division of Neurosurgery of Fatebenefratelli Hospital in Milan. I am writing today to report my experience with Oxiplex (also known as "MediShield" in Italy).

I have been using Oxiplex for 3 years. I conducted a prospective study to assess the safety of this product and its effectiveness in reducing pain and symptoms in my patients. I received no financial support from the manufacturer for this study and I am not a consultant to them.

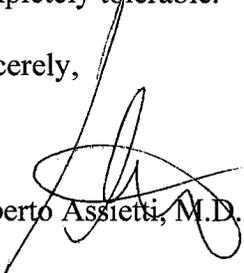
My study involved a consecutive series of 70 patients with lumbar disc herniation undergoing microdiscectomy with inter-laminectomy. 35 patients were treated at the end of surgery with Oxiplex and 35 with no gel. We assessed all patients pre-surgery and then at regular intervals using the Oswestry Disability Index and the Visual Analog Scale.

I have followed these patients for three years and at each year there was a significantly greater decrease in Oswestry and VAS leg pain scores with Oxiplex versus controls ($p < 0.05$).

I observed no safety issues in using Oxiplex and there were no differences in complications between patients using Oxiplex versus controls.

In my experience, the major advantage of using Oxiplex is the fact that the material acts as a chemical/mechanical barrier with no side effects and is completely tolerable.

Sincerely,


Roberto Assietti, M.D.