*The* **DIVISION of RADIOLOGICAL PHYSICS**

January 12, 2007

*Stanley Benedict, Ph.D.  
Professor and Director**Suresh K. Agarwal, Ph.D.  
Alan Aqualino, Ph.D.  
Gulkan Isin, MSc.  
Robert Mulder, Ph.D.  
Ke Sheng, Ph.D.  
Ray VanAusdal, Ph.D.*

Penny Lanzisera  
Nuclear Material Safety Branch  
U.S. Nuclear Regulatory Commission – Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415  
Fax: 610-337-5269

MS 16

P-6

Re: License No. 45-00034-30  
Mail Control 139589

03030672

Dear Ms. Lanzisera;

On October 11, 2006, the University of Virginia requested that License No. 45-00034-30 be amended to list Stanley Benedict, PhD, as an authorized medical physicist for the University of Virginia Gamma Knife Unit.

Our application noted that Dr. Benedict has extensive experience in various forms of stereotactic radiotherapy, and was licensed for HDR and radioactive material use at Virginia Commonwealth University (Richmond, Virginia) for many years before accepting his new position as the Director of Radiological Physics at the University of Virginia.

Attached to the application was Dr. Benedict's CV, which noted that he was one of the 5 members of AAPM Task Group 68, which investigated the repositional accuracy of stereotactic headframes (Medical Physics 32(7): 2380-2398, Jul 2005). He also is the Chairperson of AAPM Task Group 101, on Stereotactic Radiotherapy.

He recalls having received hands-on training in the operation, safety, and treatment planning aspects of the old "Model U" Gamma Knife Unit when he was beginning his career at UCLA. While there, he served as Radiation Safety Officer, overseeing the first decommissioning of a GKU.

During his later tenure at VCU, he performed stereotactic treatments only via linear accelerators (since VCU has no GKU). However, as noted in my 15 November 2006 e-mail to Dr. Gabriel, during that time period Dr. Benedict did continue to observe clinical treatments at other modern Gamma Knife Centers.

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NMCC/RGN MATERIALS-002

On December 18, 2007, I received an e-mail requesting further documentation of Dr. Benedict's abilities in areas sometimes covered by "vendor training", and requesting examples of his clinical involvement in the treatment planning, setup, and administration of patient treatments on the Model C Gamma Unit currently used at the University of Virginia. In response to this request, Dr. Benedict has supplied the following data;

1. As part of his training, Dr. Benedict participated in an overview of the Advanced Gamma Knife Courses held at the University of Virginia on Sept 20-22, 2006 and Sept. 28-30, 2005. This course is held at UVa every year (the next Advanced Gamma Knife course at UVa being scheduled for October 3-5, 2007). The best preceptor for Dr. Benedict's participation in this overview is David Schlesinger, PhD, who was one of the speakers and has been the U.Va. Gamma Knife's treatment planning guru for at least the past 2 years. Dr. Schlesinger's sessions were focused primarily toward "Hands-on Dose Planning", and far exceeded what one receives in the vendor's typical introductory training. (Agenda is attached.)
2. Dr. Benedict participated as Medical Physicist in patient clinical treatments under the supervision of Dr. Aqualino (RSO & AMP), Dr. Schlesinger (Dosimetrist), Dr. Jason Sheehan (Neurosurgeon), Dr. Ladislau Steiner (Neurosurgeon), Dr. James Lamer (Radiation Oncologist), and Dr. Tyvin Rich (Radiation Oncologist) on at least the following dates:

10/13/06: Patient 1: AVM

Patient 2: Left parietal metastasis

Patient 3: Left trigeminal neuralgia

10/16/06: Patient 1: Multiple mets (vermis, right cerebellar, right occipital, left parietal, right frontal)

Patient 2: Multiple mets (left frontal, right frontal, left occipital, right occipital)

11/10/06: Patient 1: Right trigeminal neuralgia

Patient 2: Left parietal mets (a resection cavity and a biopsy site)

Patient 3: Right trigeminal neuralgia

01/09/07: Left trigeminal schwannoma and left vestibular schwannoma

3. Dr. Benedict assisted Dr. Aqualino in the performance of every step involved in the Monthly QA of U.Va.'s Gamma Knife on both of the following 2 dates:

10/11/06 (October 2006 monthly QA)

01/09/07: (January 2007 monthly QA)

We believe the above demonstrate that Dr. Benedict's orientation has been at least as comprehensive as any programs offered at the Cleveland Clinic and UPMC. His background, training, and preceptor statements seem complete, and in accordance with the NRC regulations.

If you have any additional questions pertaining to this matter, please do not hesitate to contact us.

Respectfully submitted by

*Ralph Allen* 1/12/7

Ralph O. Allen, Ph.D.  
Radiation Safety Officer, University  
Chairman, Radiation Safety Committee  
Professor, Chemistry

*Alan Aqualino* 1/12/07

Alan Aqualino, Ph.D.  
Radiation Safety Officer, Gamma Knife Unit  
Associate Professor, Radiation Oncology

## 2006 Advanced Gamma Knife Course

**Wednesday, September 20, 2006**

- 7:15-8:00 a.m. Breakfast
- 8:00-8:15 a.m. Dr. John A. Jane, Sr. – Opening Remarks
- 8:15-8:25 a.m. Dr. Edward Nemergut – The Advantages of Placement of the Gamma Frame in the OR under Monitored Anesthesia
- 8:45-10:00 a.m. Hands on in the OR for Frame Placement
- 10:10-10:30 a.m. Dr. C. Douglas Phillips – Imaging for Pituitary Adenomas
- 10:30-11:00 a.m. Dr. Mary Lee Vance – Endocrinological Considerations of Pituitary Adenomas
- 11:00-12:00 p.m. Lunch
- 12:00-1:00 p.m. Dr. Abdul Rashid, Dr. David Schlesinger and Dr. John Snell – Working with Gamma Planning
- 1:00-1:30 p.m. Dr. Edward Laws – Surgical Resection of Pituitary Adenomas
- 1:30-1:55 p.m. Dr. Vinko V. Dolenc – Transcranial Approaches to the Pituitary and Cavernous Sinus
- 1:55-2:25 p.m. Dr. Jason Sheehan Gamma Knife Surgery for Pituitary Adenomas - Methods to Avoid Damage to the Optic Apparatus
- 2:25-2:40 p.m. Roundtable Discussion on PITS with Dr. Vinko V. Dolenc, Dr. Edward Laws, Dr. Jason Sheehan, Dr. Ladislau Steiner, and Dr. Mary Lee Vance
- 2:40-4:25 p.m. Dr. Abdul Rashid, Dr. David Schlesinger and Dr. John Snell – Hands-on Dose Planning
- 6:30 p.m. Due to a Puritanical Work Ethic, Dinner at Fuel Co. preceded by Panel Discussion, "The Gamma Knife and I" with Dr. Vinko V. Dolenc, Dr. Neal Kassell, Dr. Edward Laws, Dr. Tyvin Rich, and Dr. Mary Lee Vance

**Thursday, September 21, 2006**

- 6:30-8:30 a.m. Breakfast
- 7:15-8:00 a.m. Hands on in the OR for Frame Placement
- 8:00-8:20 a.m. Dr. C. Douglas Phillips – Neuroimaging of AVMs
- 8:20-8:40 a.m. Dr. Mary Jensen – Embolization of AVMs
- 8:40-9:10 a.m. Dr. Neal Kassell – Surgical Resection of AVMs and Cavernous Malformations
- 9:10-9:40 a.m. Dr. Vinko V. Dolenc – Anatomical Considerations for Intracranial Microsurgery and Radiosurgery
- 9:40-9:50 a.m. Break
- 9:50-10:40 a.m. Dr. Ladislau Steiner – Arteriovenous and Cavernous Malformation Residuals After Microsurgery and Gamma Surgery – Value of Embolization before Gamma Surgery – Treatment of Large AVMs – Adverse Effects
- 10:40-11:00 a.m. Roundtable Discussion on Gamma Knife for Vascular Lesions with Dr. Vinko V. Dolenc, Dr. Neal Kassell, and Dr. Ladislau Steiner
- 11:00-11:25 a.m. Dr. Mark Quigg – Epilepsy & Gamma Knife
- 11:25-12:15 p.m. Gamma Planning
- 12:15-1:00 p.m. Lunch and Discussion on Publication Philosophy
- 1:00-1:45 p.m. Dr. Dan Leksell – The History of Radiosurgery and Stereotactic Radiotherapy and their Future Role in the Management of Brain Lesions
- 1:45-3:00 p.m. Gamma Planning and Discussion of Participant's Cases
- 3:00 p.m. Historical Tour of the Lawn
- 6:30 p.m. Dinner at Fleurie preceded by Historical Vignettes on Dr. Lars Leksell with Dr. Dan Leksell

**Friday, September 22, 2006**

- 6:30-8:30 a.m. Breakfast
- 7:15-8:00 a.m. Hands-on in the OR for Frame Placement
- 8:00-8:45 a.m. Dr. Vinko V. Dolenc – Skull-Based Meningioma Surgery
- 8:45-9:30 a.m. Dr. Ladislau Steiner – Meningiomas – Small and Moderate Sized Meningiomas – Treatment of Large Meningiomas by Targeting only the Nutritive Vessel
- 9:30-9:45 a.m. Break
- 9:45-10:15 a.m. Dr. Vinko V. Dolenc – Microsurgery in vestibular schwannomas
- 10:15-10:50 a.m. Dr. Ladislau Steiner – Vestibular Schwannomas – Treatment of Small Vestibular Schwannomas – Treatment of Large Vestibular Schwannomas
- 10:50-11:00 a.m. Discussion interesting case
- 11:00-11:20 a.m. Round Table Discussion on Gamma Knife for Skull based Tumors with Dr. Vinko V. Dolenc and Dr. Ladislau Steiner
- 11:20-11:40 a.m. Dr. Steven Newman – Neuro-ophthalmological Concerns Related to Gamma Surgery
- 11:40-12:45 p.m. Dr. Abdul Rashid, Dr. David Schlesinger and Dr. John Snell – Hands-on Dose Planning
- 12:45-1:45pm Lunch and Discussion on Ethics
- 1:45-2:05 p.m. Dr. Jason Sheehan – Brain Metastases
- 2:05-2:25 p.m. Dr. Tyvin Rich – An Update on Neurotoxicity and Neurocognitive Function after Irradiation and Emerging Radiation Therapy Technologies
- 2:25-2:40 p.m. Dr. Ladislau Steiner – Concluding Remarks
- 2:40-4:15 p.m. Dr. Abdul Rashid, Dr. David Schlesinger and Dr. John Snell – Hands-on Dose Planning
- 4:15-5:15 p.m. Discussion of Participant's Cases
- 6:30 p.m. Dinner at Farmington Dr. Steiner – My Version of the Future of Stereotactic Management of Brain Lesions

Transportation is provided from the Boars Head Inn to the classrooms, as well as to the dinners.

## Advanced Gamma Knife Course at the University of Virginia

### Course Information

#### Date and Time

Participants will arrive on the evening of September 19th. Classes will begin Wednesday, September 20th at 8:00am. Participants will depart on Saturday, September 23rd.

#### Topics

AVM's and skull based tumors (i.e. pituitary adenomas, acoustic neuromas, and meningiomas).

#### Size and Participation

Individual participation in discussion and hands-on exercises is expected. The course is limited to 20 participants to foster an effective learning environment.

#### Course Overview

In this advanced course, all participants are expected to have a fundamental knowledge of radiosurgical principles. We will focus upon the nuances of Gamma Knife surgery for the treatment of AVM's, pituitary adenomas, acoustic neuromas, and meningiomas. For AVM's, we will detail our protocol and outcomes for large AVM's, the role of embolization, retreatment of AVM's, a definition of subtotal obliteration and its prognosis, and the delayed changes (e.g. cyst formation and neoplasia) that may follow radiosurgery.

For pituitary adenomas, we will highlight the challenges of retreatment and treatment when there is no discernible lesion on MRI. We will outline the timing for endocrinological remission and the small chance of recurrence despite an initial remission. The potential complications (e.g. delayed hypopituitarism, visual dysfunction, secondary tumors, and stroke) associated with Gamma Knife surgery for pituitary adenomas will also be detailed. The importance of creating an appropriate distance between the tumor and optic pathways prior to Gamma surgery and methods for achieving this will be discussed.

With regard to meningiomas, we will go beyond the standard cases to discuss treatment of large meningiomas by targeting the tumor's nutritive vessels. For acoustic neuromas, particular emphasis will be placed upon the differences in planning and outcomes of large and small lesions. Also, we will discuss the notion of hearing preservation in Gamma Knife surgery.

The course will also offer much "hands on"

training. We will schedule cases relevant to the particular topics being covered on each day. Each day will begin with stereotactic frame placement performed in the operating room. The advantages of frame placement under monitored anesthesia will be discussed. Participants will observe frame placement in the operating room.

In order to offer a diverse and well rounded course, we have invited others to speak about the history and future of radiosurgery and the complimentary roles of radiosurgery and microsurgery.

In sum, we believe the course outlined below will represent a course unlike that offered by other institutions. It will hopefully help allow us to share a different philosophy and a set of techniques not covered in other courses or written about in the literature.

#### Accreditation

The University of Virginia School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

The University of Virginia School of Medicine designates this continuing medical education activity for up to 26 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

The University of Virginia School of Medicine awards 0.1 CEU (Continuing Education Unit) per contact hour to each non-physician participant who successfully completes this educational activity. The CEU is a nationally recognized unit of measure for continuing education and training activities that meet specific educational training requirements. The University of Virginia School of Medicine maintains a permanent record of participants who have been awarded CEUs.

#### Faculty Lecturers

Vinko V. Dolenc, MD, PhD  
Department of Neurosurgery  
University of Ljubljana

John A. Jane, MD, PhD, FRCS (C)  
Chair, Department of Neurological Surgery  
University of Virginia

Mary E. Jensen, MD  
Department of Radiology  
University of Virginia

Neal F. Kassell, MD  
Department of Neurosurgery  
University of Virginia

Edward R. Laws, MD  
Department of Neurosurgery  
University of Virginia

Dan Leksell, MD  
Vice President of Medical Affairs  
Elekta

Edward Nemergut, MD  
Department of Anesthesiology  
University of Virginia

Steven A. Newman, MD  
Director of the Division of Neuro-ophthalmology  
Department of Ophthalmology  
University of Virginia

C. Douglass Phillips, MD  
Director of the Division of Neuro-radiology  
University of Virginia

Mark Quigg, MD  
Department of Neurology  
University of Virginia

Abdul Rashid, MD  
Department of Radiation Oncology  
University of Virginia

Tyvin A. Rich, MD  
Department of Radiation Oncology  
University of Virginia

David Schlesinger, PhD  
Lars Leksell Gamma Knife Center  
University of Virginia

Jason P. Sheehan MD, PhD  
Associate Director of the Lars Leksell Gamma Knife Center  
University of Virginia

John Snell, PhD  
Lars Leksell Gamma Knife Center  
University of Virginia

Ladislau Steiner MD  
Director of the Lars Leksell Gamma Knife Center  
University of Virginia

Mary L. Vance, MD  
Division of Endocrinology and Metabolism  
University of Virginia

## Area Information

### Meals and Lodging

All meals and lodging are included with the advanced course. Transportation is provided to and from the inn, course location and social events. Breakfast, lunch, dinner and a variety of refreshments will be provided through catered meals. Lodging will be provided at the Boar's Head Inn. For more information about the inn, see the contact information below.

The Boar's Head Inn & Sports Club  
Route 250 West  
Phone: (800) 476-1988 or (434) 296-2181  
Fax: (434) 972-6019  
[www.boarshheadinn.com](http://www.boarshheadinn.com)

### Charlottesville

Charlottesville is home to the University of Virginia, the birthplace of Thomas Jefferson, and a true representative of the heartland of historic Virginia. Located in central Virginia in the foothills of the Blue Ridge Mountains, Charlottesville has a population of 42,000 in a rural/metropolitan area of about 88,400. Washington, D.C. is less than two hours away, but there are many things to see and do here in town.

### Jefferson's Academical Village- University of Virginia

The University of Virginia is famed for the beauty of its buildings. Designed by Thomas Jefferson, they are considered among the finest examples of classic American architecture. The University is also noted for its scholarly achievements and historical associations. It began with Jefferson's concept and design for a community of scholars, and "academical village." The Rotunda, modeled after the Roman Pantheon, served as focal point, library and classroom. Two ranges extended from the Rotunda; professors lived and taught in the large Pavilions, and students lived in the smaller rooms in between. This tradition is carried on today - the Department of Neurological Surgery holds its teaching conferences in Pavilion V regularly.

### University of Virginia Health System

The University of Virginia Health System can trace its beginnings directly to Thomas Jefferson, under whose leadership as Rector, eight schools including a School of Anatomy and Medicine opened on March 7, 1825. Jefferson chose the school's original faculty, a single professor, Robley Dunglison, whose first class of 20 students met in his home on the Grounds. Walter Reed is among the alumni of the Medical School. The teaching hospital, which opened in 1901 as a 25-bed facility, is today housed in a new eight-

story building with 597 beds and 30 bassinets. It has nearly 100 intensive care beds. A recent report by *U.S. News and World Report* listed the Neurosciences clinical program at UVA as among the best in the nation.

### Monticello

Thomas Jefferson began construction on this architectural masterpiece in 1769 and continued for more than 40 years. He also designed the grounds of his "little mountain home." The roundabout walks, oval flowerbeds, vegetable gardens, vineyards, grove, and graveyard have been fully restored. Hours 8-5. Fee. (434) 984-9800.

### Michie Tavern Museum

This famous tavern of the 1700's still serves meals in the "Ordinary", a converted log cabin used 200 years ago. Guests enjoy food of the colonial times and can tour the Tavern, outbuildings, general store, and Meadow Run Grist Mill. The general store sells handcrafts and antiques of Virginia. Open year-round. Fee. (434) 977-1234.

### Ash Lawn

Home of President James Monroe, Ash Lawn is a 550-acre historic estate and has been almost fully restored as a working plantation. Special events at Ash Lawn include operas, concerts, and festivals. Hours: 9-6. Fee. (434) 293-9539.

### Wineries

There are many local wineries that offer tours, wine tastings and sales. Ask us for further information.

### Skyline Drive/Blue Ridge Parkway

Enjoy the beauty of the Blue Ridge Mountains, scenic overlooks, exhibits, and hiking trails. Located 25 miles west of Charlottesville with easy access via I-64.

For more information about Charlottesville and its surrounding area, visit: <http://www.charlottesville.org/> and <http://www.charlottesville-tourism.org/>

## Other Information

### Disclosure of faculty financial affiliations

As a provider accredited by the Accreditation Council for Continuing Medical Education, the Office of Continuing Medical Education of the University of Virginia School of Medicine must insure balance, independence, objectivity and scientific rigor in all its individually sponsored or jointly sponsored educational activities. All faculty participating in a sponsored activity are expected to disclose to the activity audience any significant financial interest or other relationship

(1) with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and (2) with any commercial supporters of the activity (significant financial interest or other relationship can include such things as grants or research support, employee, consultant, major stock holder, member of speakers bureau, etc.). The intent of this disclosure is not to prevent a speaker with a significant financial or other relationship from making a presentation, but rather to provide listeners with information on which they can make their own judgments. It remains for the audience to determine whether the speaker's interests or relationships may influence the presentation with regard to exposition or conclusion.

### Disclosure of discussion of non-FDA approved uses for pharmaceutical products and/or medical devices

The University of Virginia School of Medicine, as an ACCME provider, requires that all faculty presenters identify and disclose any "off label" uses for pharmaceutical and medical devices/products. The University of Virginia School of Medicine recommends that each physician fully review all the available data on new products or procedures to instituting them with patients.

### Disclosure for attendance records and certificate distribution

The University of Virginia Office of Continuing Medical Education requires that all participants sign attendance sheets daily to confirm participation in the CME activity for that day. Certificates of attendance, designating the maximum number of hours of participation, are distributed to each participant at the CME activity. Replacement certificates can be obtained from the Office of Continuing Medical Education by submitting a request for a replacement certificate accompanied by the \$10 fee.

### Special Needs

The Americans with Disabilities Act of 1992 requires that all individuals, regardless of their disabilities, have equal access. The Office of Continuing Medical Education of the University of Virginia School of Medicine is pleased to assist participants with special needs. Requests need to be made in writing and sent to the Office of Continuing Medical Education, Box 800711, 6202 Hospital West, University of Virginia School of Medicine, Charlottesville, VA 22908-0711.

**Registration Form: Advanced Gamma Course at the University of Virginia, September 2006**

Last Name	First Name	Initial	Degrees
Department and Institution			
Mailing Address			
Work Phone	Fax	E-mail	
Date of Birth (required for tracking CME credits/CEU)			
Special needs (sight impaired, wheelchair, etc.):			

Registration fee includes program, lodging, breakfast, lunch, and dinner as described in the program. Make checks payable (U.S. banks only) to the UVA Dept. of Neurosurgery. Registration will not be accepted without full tuition payment. Cancellations must be made two weeks prior to the start of the course; otherwise the tuition will count towards a future training course.

Check all that apply:

☐ Physicians Course \$ 3,500 ☐ Nurse - \$2,500

☐ Spouse / Guest (for all social events) \$200

Attending social functions on ☐ Wed ☐ Thurs ☐ Fri

Please indicate to us your background:

Neurosurgeon ☐

Radiation Oncologist ☐

Medical Physicist ☐

Other (Please describe) \_\_\_\_\_

Please mail this registration form and payment to:

UVA Dept. of Neurosurgery  
PO Box 800212

Attn: Sophie Lee Yu, Conference Coordinator  
Charlottesville, VA 22908 USA

Phone: 434-924-2336

Fax: 434-977-6279

E-mail: [sly9p@virginia.edu](mailto:sly9p@virginia.edu)

☐ Check Enclosed

☐ Dept. check to follow

Credit Card registration:

☐ VISA

☐ Master card

Account no. \_\_\_\_\_

Expiration Date \_\_\_\_\_

Signature \_\_\_\_\_

Please Register online at:

[www.healthsystem.virginia.edu/internet/neurosurgery/GKcourse](http://www.healthsystem.virginia.edu/internet/neurosurgery/GKcourse)

Registrations will not be processed unless full payment is received.

Please Describe your Experience with Gamma Knife:

None ☐

Rare (Less than 4 times a Year) ☐

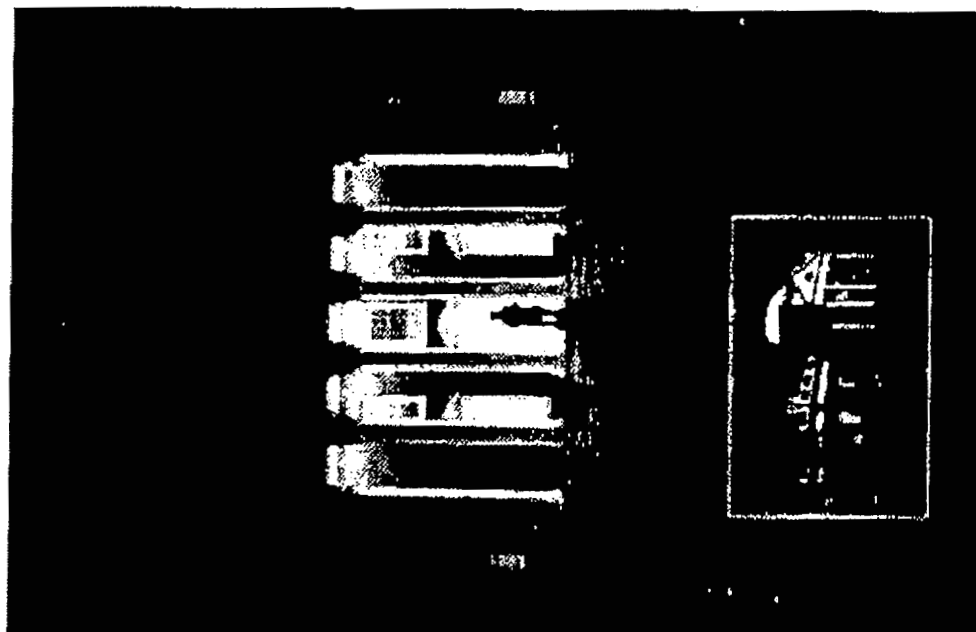
Quarterly ☐

Monthly ☐

Weekly ☐

Advanced Gamma Knife Course  
at the University of Virginia

September 20-22, 2006



Department of Neurological Surgery  
University of Virginia, Charlottesville, Virginia

Sponsored by The Office of Continuing Medical Education  
University of Virginia, Charlottesville, Virginia