

# CAS Training Programs

Guidant and Cordis recently introduced their carotid stenting training programs, which seek to balance the demand for carotid training with the experience required to perform this procedure.

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**T**raining and accreditation for carotid artery stenting (CAS) has become one of the most controversial subjects in endovascular care. Although many endovascular specialists have expressed an interest in performing this procedure, the potential for catastrophic results to patients demands that only the most highly skilled endovascular specialists perform this procedure. Now that the FDA has approved the first CAS system, attention has been focused on who will be trained to perform these procedures.

On August 30, 2004, Guidant Corporation (Indianapolis, IN) received the first FDA approval of a CAS system (the Acculink carotid artery stent and Accunet embolic protection device). On September 2, 2004, Guidant treated its first patient under the new approval.

One of the requirements of the FDA approval was the implementation of Guidant's training program. In addition, the FDA has mandated a postmarket surveillance study (PMSS) of at least 1,500 patients (1,000 new patients and 500 previously enrolled patients) for each approved device. On September 24, 2004, Cordis (a Johnson & Johnson company, Miami, FL) enrolled their first patient in their PMSS, and has implemented their training program to support their PMSS. The training programs of both manufacturers are examined in Table 1.

## GUIDANT CAROTID TRAINING: LEVEL III TRAINING PROGRAM

### Physician Selection

The Guidant Level III CAS training program is designed for those physicians who do not qualify as Level I or II physicians who are subject to different training requirements. (Guidant has defined Level I as those clinical trial investigators with at least five CAS cases using the RX Acculink/RX Accunet device systems as primary operator;

Level II is for physicians who either (1) have attended another manufacturer's CAS training program and performed at least five successful carotid stent cases as primary operator, or (2) have performed at least 10 CAS cases as primary operator.) To qualify for Guidant's Level III training program, physicians must meet the following eligibility criteria: 25 selective carotid angiograms, 10 peripheral self-expanding stent cases, and 10 procedures using .014-inch monorail systems—all as primary operator.

### Training Components

The Guidant training program comprises a 2-day regional training course, in-hospital proctoring, and staff training. The regional training course includes (1) nine hours of didactic training, (2) three hours of patient case review presented by physicians, and (3) four hours of simulation and product training presented by Guidant trainers (Figure 1). The case review includes one complete taped carotid patient case and interactive case study review sessions. The



Figure 1. Medical simulation at the Guidant training facility.

**TABLE 1. GUIDANT AND CORDIS TRAINING OVERVIEW**

Training Activity	Guidant	Cordis
Didactic/didactic review	9 hours	10 hours
Carotid stent cases review	3 hours	4 hours
Simulation and product training	4 hours	6 hours
Proctoring	8 hours (upon request)	8 hours
Staff in-service	4 hours	6 hours
Sales support	First three cases	First three cases
Total	28 hours	34 hours

simulation training includes instructions for use and hands-on product training of the RX Acculink and RX Accunet devices, with 2 hours of simulation training per physician and 2 hours of product training using a tabletop model per physician.

After completing the regional training, a 1-day proctoring session is available to the physician completing the Level III program, provided by Guidant. The hospital staff also receives 4 hours of training by Guidant field personnel, featuring an Instructions-for-Use video review, device presentations (product features, benefits, and step-by-step procedures), and device training using a tabletop model. Finally, Guidant field personnel are present to provide sales support on the first three cases after completion of the training program.

### **CORDIS CAROTID TRAINING: THE CASES PROGRAM**

#### **Physician Selection**

In the Cordis CASES training program, physicians are categorized by their experience in performing CAS and their experience with the Cordis Precise nitinol stent and the AngioGuard XP emboli capture guidewire. Physicians meeting a minimum level of experience with both CAS and use of Cordis products (such as those who participated in their SAPPHIRE clinical study) are exempt from training. Those with experience in CAS but not with Cordis devices will receive an abbreviated training program. The remaining physicians will undergo the full CASES training program (Table 2).

#### **Training Program**

The Cordis CAS training program is composed of online didactic training, a regional training course, in-hospital proctoring, and staff training. The online training consists of 6 hours of interactive computer training on a variety of diagnostic and procedural subjects.

The CASES program requires that physicians achieve a proficiency level before moving to the next phase of the training program. For example, the on-line didactic has a

series of interactive Level I simulation modules and test questions; participant scores are tracked and compared to a baseline established by expert faculty. Proficiency achievement is also required at the regional education center 2-day course and the physician proctoring event.

The regional educational center (REC) training will provide 14 hours of training in three areas: didactic review, case observation, and medical simulation training. The REC training will be provided to small groups of four trainees during a 2-day course. During the didactic review, the trainer will have access to the results of the trainee's online testing and can focus on any subject matter from that previous testing. For the Case Observation, the trainee will observe a minimum of eight cases (both taped and live) using the Cordis Carotid System within its labeled indication. Finally, at the REC, the trainees will undergo a 6-hour rotation through the simulation lab.

After successfully completing the REC course, physicians are required to be proctored for their first three carotid artery stenting procedures, which are performed in the trainee's lab. The role of the proctor is to validate that the trainee can successfully use the Cordis Carotid System consistent with the instructions for use. The proctor's role is also to assist in the instruction of the staff regarding device preparation, deployment, and assessment.

#### **Accreditation**

The various endovascular specialties and their respective professional societies have engaged in an intense debate regarding the level of experience that should be required to perform CAS. The specialties have placed varying levels of importance on such prerequisites as the number of diagnostic cerebral angiograms, the number of cerebral interventions, as well as knowledge of the carotid and cerebral anatomy. So far, those issues have not been resolved, but with the recent FDA approval of the Guidant carotid system, this issue will now need to be resolved at every institution performing this procedure.

**TABLE 2. CORDIS TRAINING REQUIREMENTS FOR PMSS INVESTIGATORS**

	Level 1	Level 2	Level 3
<b>Criteria</b>	<ul style="list-style-type: none"> <li>•Has performed at least 25 CAS procedures as primary operator</li> <li>•Has performed at least 10 CAS procedures as primary operator using the Angioguard device</li> <li>•MAE complication rates must be at or below SAPHIRE randomized data rates</li> </ul>	<ul style="list-style-type: none"> <li>•Has performed at least 25 CAS procedures as primary or secondary operator</li> <li>•Must have been primary operator in at least 13 CAS procedures</li> <li>•MAE complication rates must be at or below SAPHIRE randomized data rates</li> </ul>	<ul style="list-style-type: none"> <li>•Has performed less than 25 CAS procedures</li> </ul>
<b>Status</b>	•Exempt from CASES training program	•Partial exemption from CASES training program	•No exemption: must enroll in CASES training program
<b>Requirements</b>	<ul style="list-style-type: none"> <li>•Must complete: Staff training in in-service training*</li> <li>•Optional: CASES on-line didactic REC center Physician proctoring</li> </ul>	<ul style="list-style-type: none"> <li>•Must complete: CASES on-line didactic Staff training in in-service training Sales/clinical rep proctoring</li> <li>•Optional: REC center Physician proctoring</li> </ul>	<ul style="list-style-type: none"> <li>•Must complete CASES training: CASES on-line didactic REC center Proctoring Staff training in in-service training</li> </ul>
*Unless previously performed as part of SAPHIRE or IDE participation.			

## SUMMARY

Both companies stress that their training programs are not substitutes for hospital accreditation to perform CAS. Prior to starting one of three levels of the Guidant training program, the company requires a document signed by the physician and his department head. Once Cordis receives FDA approval of its carotid stent and concludes its PMSS, they will seek only to verify that a given hospital has CAS guidelines in place and that the specialist proves that he or she can meet them. This verification will need to be cosigned by the head of the individual's respective department. Neither Guidant nor Cordis will get involved in determining who should be accredited at a given hospital to perform carotid interventions.

Several thought leaders have expressed concern, however, that these training programs (and their accompanying qualifying criteria) may become the de facto accreditation process at most hospitals. "Credentialing is the responsibility of medical staffs and hospital administration, not medical device companies," says Barry T. Katzen, MD, of the Baptist Cardiac & Vascular Institute in Miami, Florida. "Particularly with respect to carotid artery stenting, credentialing must

entail more than device training and certification. The medical societies have a number of documents pertaining to carotid artery stenting credentialing in the works right now, but what is missing is a unified statement on carotid accreditation that applies to all specialties. This is unfortunate because it will become a source of confusion for hospitals attempting to resolve this issue." ■

*The information in this article has been provided by the respective companies.*

## CAROTID STENT TRAINING AT ISET 2005

**Dates:** January 14-15, 2005  
**Location:** Fontainebleau Hilton Resort  
 Miami Beach, Florida  
**Presented by:** Baptist Cardiac & Vascular Institute  
**Information:** (888)334-7495 or (305)279-2263  
**Online registration:** [www.ISET.org](http://www.ISET.org)  
**Registration is limited to 100 physicians.**

This seminar will take place prior to ISET 2005. Physicians attending both meetings will receive discounted registration fees.