Intravascular brachytherapy for coronary arteries

Background

Intravascular brachytherapy (IVB) for coronary arteries is a treatment that uses radiation to prevent restenosis, the reclogging of arteries, which can occur after balloon angioplasty and the implantation of a stent. Redloged arteries can leave patients struggling with chest pain, shortness of breath, and at greater risk of a fatal heart attack.

Each year, there are some 700,000 balloon angioplasty procedures performed in the United States to open narrowed coronary arteries. As a part of many of these procedures, a stent, which is a cagelike mesh device, is implanted to keep the artery propped open. But for 30% to 40% of the patients, scar tissue begins to proliferate around the stent within six months, and patients have to undergo repeated stenting on the same blood vessel.

IVB treatment prevents the proliferation of scar tissue in the coronary artery by delivering radiation to the affected tissue. During the procedure, a flexible nylon ribbon with radioactive pellets embedded in its tip is threaded through a catheter until it reaches the blockage. The ribbon is left in place for a period of time and then it is withdrawn. Typically patients are up and walking in a few hours and are able to go home the next day.

The U.S. Food and Drug Administration (FDA) has approved two systems for IVB for coronary arteries. They are the CHECKMATE™ System, developed by Cordis Corporation, a Miami-based company, and the Beta-Plus™ System, developed by Novoste Corporation, a Norcross, GA-based company. The CHECKMATE System uses a gamma-radiating source, and the Beta-Plus System uses a beta-radiating source.

Both systems require the involvement of the following three medical professionals:

- The interventional cardiologist determines that the procedure is needed and delivers the catheter to the lesion site
- The medical physicist does the mathematical calculation as to how much and how long the hot source has to sit at the lesion site to ensure proper dose absorption
- The radiation oncologist advances the hot source to the lesion site and basically administers the radiation dose

According to a Cordis spokesperson, these medical professionals have already learned most of what they need to know to perform IVB for coronary arteries in their specialty training programs. What is new for them is learning to work as a team.
### Involved specialties
Interventional cardiologists and radiation oncologists

### Positions of societies and academies

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<th>Society/Academy</th>
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<td><strong>SCAI</strong></td>
<td>The Society for Cardiac Angiography and Interventions (SCAI) promotes excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care.</td>
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To become a fellow of the SCAI, physicians must satisfy the following requirements:

- Completion of appropriate training for subspecialty board eligibility
- Completion of at least one full year or its equivalent in training exclusively in the performance of cardiac catheterization and angiographic techniques
- Spent a significant percentage of working time for at least five years after training in cardiac catheterization and angiography
- Must have been independently responsible for the performance of at least 1,000 procedures (375 for pediatric cardiologists) after basic training

The SCAI does not publish credentialing or privileging criteria for IVB for coronary arteries.

| **ACR** | The American College of Radiology (ACR) publishes the ACR Standard for Radiation Oncology. In this standard the ACR states that a radiation oncologist should have one of the following qualifications:

- Satisfactory completion of radiation oncology residency in an American Council for Graduate Medical Education (ACGME)-accredited program
- Certification in radiology by the American Board of Radiology (ABR) of a physician who confines his or her professional practice to radiation oncology
- Certification in radiation oncology or therapeutic radiology by the ABR, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada (RCPSC) |
In addition to the primary certificate in internal medicine, the American Board of Internal Medicine (ABIM) offers a subspecialty certificate in cardiovascular disease. Physicians who are awarded this certificate must have been previously certified in internal medicine by the ABIM, completed the requisite subspecialty training, demonstrated clinical competence in the care of patients, and passed the subspecialty examination.

The ABIM also offers a certificate of added qualifications in interventional cardiology for diplomates in cardiovascular disease. The certification program includes the following admission requirements:

- Current certification by the ABIM in cardiovascular disease
- A valid and unrestricted license to practice medicine

There are two pathways, the practice experience pathway and the training pathway, that are available to certification candidates.

The practice experience pathway is available only to candidates who complete the required accredited fellowship training in cardiovascular disease prior to July 1, 2000. This pathway is available only through 2003 and requires post-training performance as the primary operator of at least 150 therapeutic interventional cardiac procedures in the two years prior to application for certification or 500 therapeutic interventional cardiac procedures during the candidate's post-training career.

The training pathway is available only to candidates who completed acceptable interventional cardiology fellowship training in 1997 or later. This pathway requires 12 months of satisfactory fellowship training in interventional cardiology in addition to the required three years of cardiovascular disease training.

Interventional cardiology training taken July 1, 2002, and thereafter must be accredited by the ACGME. Interventional cardiology training taken prior to July 1, 2002, must be undertaken within accredited cardiovascular disease training programs.

During training in interventional cardiology, the fellow must have performed at least 250 therapeutic interventional cardiac procedures, documented in a case list and attested to by the training program director. In addition, the training program
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The director must judge the clinical skill, judgment, and technical expertise of the candidate as satisfactory.

Beginning with the November 2000 examination, candidates who have been out of formal training three or more years as of June 30 of the year of examination must document post-training performance as primary operator of at least 150 therapeutic interventional cardiac procedures in the two years prior to application for certification.

The ABIM notes that certification is not required of practitioners in interventional cardiology, and the Board’s certificate does not confer privilege to practice.

ABR

The ABR offers certification in radiation oncology. The ABR requires the following training for certification:

- Candidates must have five years of approved training with a minimum of four years in radiation oncology. These four years must be spent in a department approved for training in radiation oncology by the Residency Review Committee (RRC) for Radiation Oncology for the ACGME or by the RCPSC.

- The four-year residency training period must include 36 months of clinical radiation oncology with exposure to pathology and medical oncology.

- The other year, which must precede the radiation oncology training, must be ACGME, American Osteopathic Association (AOA), or RCPSC-accredited clinical training in internal medicine, pediatrics, surgery or surgical specialties, obstetrics and gynecology, family practice, transitional or categorical radiation oncology, or any combination of these.

Specialties other than those listed, including pathology and psychiatry, do not satisfy ABR requirements.

Novoste Corporation, Norcross, Georgia

“The FDA requires clinicians who use the Beta-Cath device for declogging coronary arteries to attend a Novoste training program,” says Kelly Elliott, the system’s U.S. market development manager. The training program may be given either regionally or on-site by a company clinical trainer or by a company sales representative.

The training program, which is mandatory for the interven-
tional cardiologist, the radiation oncologist, and the medical physicist, includes the following three parts:

- Didactic
- A hands-on mock procedure
- Proctored initial cases

“After the didactic session,” says Elliott, “the IVB team convenes in the cardiac cath lab and goes through the procedure step by step.” In this session, the radiation oncologist and the medical physicist learn about the cath lab environment and are trained to work in conjunction with the cardiologist so that the isotope can be delivered successfully to the treatment zone and to the lesion. Once the team is comfortable with the mock procedure, patients can then be scheduled for treatment.

During the first three to five cases, the Novoste representative is required by the FDA to be present in the cath lab to proctor the IVB team. “Once the clinicians are cleared by our representative,” says Elliott, “we certify that they have completed their three-part training.” But, she adds, if the team has problems with the Novoste device or the team is not comfortable with the procedure after the initial three to five cases, the company representative will remain at the hospital and proctor additional cases.

Novoste does not recommend any specific number of cases per year an IVB team should do to maintain competence. “We leave that up to the hospital,” says Elliott.

According to Richard R. Heuser, MD, an interventional cardiologist at the Phoenix Heart Center, Phoenix, AZ, IVB for coronary arteries is used for patients with in-stent restenosis. Occasionally it may also be used for patients who have coronary artery renarrowing without an implanted stent.

“Interventional cardiologists are the physicians who actually perform the IVB for coronary arteries procedure,” says Heuser. They are responsible for the following:

- Determining who can benefit from the technique
- Performing balloon angioplasty on the patients who’ve had renarrowing inside the implanted stent
• Assisting the radiation oncologist in advancing the radiation dose to the lesion site

• Performing any further work that has to be done to the artery

Heuser considers that the five cases, which are part of the IVB team’s training, should be enough to allow the team to become competent to perform the procedure. In these training sessions, the radiation oncologist becomes familiar with the cardiac cath lab and is instructed in coronary anatomy. Each member of the team becomes familiar with the technology, and there is in addition a review of basic radiation safety training.

“If an IVB team continues to work together,” says Heuser, “there should be no problems with maintaining competence.”

**CRC draft criteria**

**Minimum threshold criteria for requesting core privileges for IVB for coronary arteries**

- Basic education: MD or DO
- Minimum formal training: Applicants must complete an accredited training program in interventional cardiology or radiation oncology. In addition, applicants must complete a training course given by the company that developed the device used in the IVB for coronary arteries procedure. The training should include proctored initial cases.
- Required previous experience: Applicants must demonstrate that they performed five IVB for coronary arteries procedures in the past 12 months.

Note: A letter of reference should come from the director of the applicant’s interventional cardiology or radiation oncology training program as well as a letter of reference from the proctor of the applicant’s initial IVB for coronary arteries procedures. Alternatively, a letter of reference should come from the chief of interventional cardiology at the institution where the applicant most recently practiced.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate their maintained competence with evidence that they performed 10 IVB for coronary arteries procedures in the past 24 months.
In addition, continuing education related to IVB for coronary arteries should be required.

**For more information**

For more information regarding this procedure, contact:

American Board of Internal Medicine  
510 Walnut Street, Suite 1700  
Philadelphia, PA 19106-3699  
Telephone: 215/446-3500  
Fax: 215/446-3470  
Web site: www.abim.org

American Board of Radiology  
5255 East Williams Circle, Suite 3200  
Tucson, AZ 85711  
Telephone: 520/790-2900  
Fax: 520/790-3200  
Web site: www.theabr.org

American College of Radiology  
1891 Preston White Drive  
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Web site: www.acr.org

Cordis Corporation  
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PO Box 025700  
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Telephone: 305/824-2545  
Fax: 305/512-6964  
Web site: www.cordis.com

Novoste Corporation  
Beta-Cath System  
3890 Steve Reynolds Boulevard  
Norcross, GA 30093  
Telephone: 770/717-0904  
Fax: 770/717-1283  
Web site: www.novoste.com

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525 North Eighteenth Street  
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Intravascular brachytherapy for coronary arteries

Procedure 12

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9111 Old Georgetown Road
Bethesda, MD 20814
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Fax: 301/581-3408
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In order to be eligible to request clinical privileges for intravascular brachytherapy (IVB) for coronary arteries, an applicant must meet the following minimum threshold criteria:

- **Education:** MD or DO

- **Minimum formal training:** Applicants must complete an accredited training program in interventional cardiology or radiation oncology. In addition, applicants must complete a training course given by the company that developed the device used in the IVB for coronary arteries procedure. The training should include proctored initial cases.

- **Required previous experience:** Applicants must demonstrate that they performed five IVB for coronary arteries procedures in the past 12 months.

- **References:** A letter of reference should come from the director of the applicant’s interventional cardiology or radiation oncology training program as well as a letter of reference from the proctor of the applicant’s initial IVB for coronary arteries procedures. Alternatively, a letter of reference should come from the chief of interventional cardiology at the institution where the applicant most recently practiced.

- **Reappointment:** Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms. Applicants must demonstrate their maintained competence with evidence that they have performed ten IVB for coronary arteries procedures in the past 24 months.

In addition, continuing education related to IVB for coronary arteries should be required.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: 

Typed or printed name: 

Date: 

Privilege request form
Intravascular brachytherapy for coronary arteries