

NEVADA STATE BOARD OF NURSING

Practice Decision

Opinion Question:

Can a Registered Nurse, with the appropriate training and working in a cardiac catheterization lab, insert a collagen plug to achieve vascular hemostasis after intravascular catheterization and/or intervention?

Recommendation:

Allow the qualified cardiac catheterization lab Registered Nurse, who has completed appropriate competency to deploy collagen plug vascular procedures as defined by the policy and procedures of the institution and with a direct physician order.

Consumer Safety:

The collagen plug is relatively new device created to achieve vascular hemostasis following intravascular catheterization and/or intervention. The FDA has approved the catheter from a public safety standpoint. Consumer safety demands that the practitioners responsible for insertion of the collagen plug be sufficiently trained in the procedure and perform the procedure safely.

Currently, the device is deployed by a physician or a tech in the cardiovascular catheterization lab, and the results of successful deployment have varied widely. Although the physician is directly responsible for compromising intravascular integrity to perform the invasive procedure, the Registered Nurse inherits the responsibility for vascular hemostasis when the patient is transferred to the post-procedure care area.

One issue of concern for consumer safety would be whether or not the rates of successful deployment and resulting hemostasis would be improved should the Registered Nurse be authorized to deploy the collagen plug.

Consumer safety must be monitored through quality reports from care reports by each facility. Negative outcomes would include increased rates of groin hematomas, A-V fistulas, or pseudoaneurysms.

Best Interest of the Public:

The public interest would be well served by having an appropriately and adequately trained practitioner to deploy the device. Based on the standards of the Board of Nursing criteria for expanded scope of practice, the registered nurse may well be the most appropriate practitioner to deploy the device.

Safety for the practitioners:

If the Registered Nurse is authorized to deploy the collagen plug, the nurse must receive the appropriate training and demonstrate competency prior to performing the procedure. The training must consist of a comprehensive program that includes the anatomy and physiology, emergency response and return demonstrations of deployment.

With a comprehensive training program and annual competency skill validation, the Registered Nurse would be able to insert a collagen plug to achieve hemostasis.

Nursing Process:

Deployment of a collagen plug must be specified as expanded scope of nursing practice for Registered Nurses, and be performed only after competency training. The facility must develop a policy and procedure specifically for the deployment of collagen plugs by the Registered Nurse.

Current trends and national standards:

The volume of intravascular procedures requiring hemostasis is on the rise. Because the collagen plug can allow the patient more comfortable post-procedure positions and earlier mobilizations, use of the device is also increasing. However, the collagen plug is relatively new technology, and optimal benefits and outcome have yet to be standardized.

Presently, Kentucky and Arkansas have allowed Registered Nurses to deploy collagen plugs.

Literature Review:

Arkansas State Board of Nursing Position Statement #399-1: Registered Nurse Deployment of Extravascular Collagen Plugs. Kentucky Board of Nursing Advisory Opinion, April 6-7, 1998, it is within the scope of practice for a qualified registered nurse to deploy VASOSEAL, a collagen based extravascular hemostasis device. USFDA letter of confirmation allowing Datascope's request for the deployment of VasoSeal® VHD by health care professionals other than physicians, April 16, 1998. *American Journal of Cardiology*, 10th Annual TCT-329, Vascular Technicians Perform Collagen Sealing Equally as Well as Cardiologists, October 8-10, 1998. Femoral Accessed Site Closure Devices-VasoSeal® VHD, presented by Jerrold Glassman, MD, FACC, Physician Executive Leader, Scripps System of Excellence, Division of Critical Care and Cardiovascular Services. The Benefit of Nurse Deployment of the VasoSeal® Vascular Sealing Device, *Cath-Lab Digest*, November/December 1998. Comparison of Nurse vs. Physician VasoSeal® VHD Deployment, *Cath-Lab Digest*, September 1999.

Procedure Standardization:

Because the use of collagen plugs is a new procedure, few policies and procedures for use of the device by the Registered Nurse are in place.

Mechanisms to maintain competence:

Annual competency and skill validation must be demonstrated as part of each facility's competency program. Each Registered Nurse must know the facility policy and procedure regarding employment of collagen plugs.

Consistent with previous decisions:

Currently, qualified registered nurses in the State of Nevada may remove femoral sheath and insert a PICC line.

Impact: Fiscal/Manpower:

Registered Nurse deployment of collagen plugs could maximize turn around time in the procedure area. With successful deployment and hemostasis comes expected reduction in length of stay, so the patient may be discharged to home much sooner after an intravascular procedures.

Type of function:

Interdependent – with the Registered Nurse working in conjunction with the attending intravascular physician.

Approved by the Nursing Practice Advisory Committee on November 10, 1999

Adopted by the Nevada State Board of Nursing on November 19, 1999