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JUL 24 2000

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850**WARNING LETTER****VIA FEDERAL EXPRESS****VIA FACSIMILE**Mr. Lawrence Sapir
Chairman & CEO
Datascope Corporation
14 Philips Parkway
Montvale, New Jersey 07645

Re: VasoSeal ES (Extravascular Security), P920004

Dear Mr. Sapir:

The Food and Drug Administration (FDA) has reviewed at least four Datascope letters dated June 2, 2000 and signed by Jeff Voigt, Director of Marketing, Collagen Products Division (Datascope), for the VasoSeal ES Vascular Hemostasis Device (VasoSeal). We have also reviewed your web site at the Internet address: <http://www.vasoseal.com>.

VasoSeal is manufactured by Datascope Corporation (Datascope) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The VasoSeal device was approved through the Premarket Approval Process (PMA) pursuant to section 515(d)(1)(B)(ii) of the Act. FDA also determined that, to ensure the safe and effective use of the device, it is further restricted within the meaning of section 520(e) of the Act in that the sale and distribution must not violate sections 502(q) and 502(r) of the Act.

The VasoSeal ES is indicated for use in reducing time to hemostasis at the femoral arterial puncture site and in reducing time to ambulation in patients who have undergone diagnostic angiography or interventional procedures using a 5-8 French procedural sheath and using a retrograde approach. The VasoSeal ES is also indicated for use in reducing time to hemostasis and ambulation in interventional patients when immediate sheath removal is desired.

All of Mr. Voigt's letters contain the claim that VasoSeal ES devices have a major complication rate of 0.1%: *In Short, they chose VasoSeal because VasoSeal products historically demonstrate a very low reported major complication rate, 0.1%. Similar claims are made on your web site i.e., Our experience demonstrates reported major complication rates with the original VasoSeal device which have historically remained low (0.1%) while allowing certain patients to ambulate in as little as an hour.* Finally, there is also a testimonial by one of the physicians on your web

site, Jerry Glassman, M.D., Mercy Hospital, San Diego, states, *Our overall complication rates (major and minor) with VasoSeal have been extremely low – 1.25%.*

These statements essentially contradict the complication rates identified in the approved labeling and approved instructions for use (IFU). The approved labeling and IFU for VasoSeal ES lists the following major complication rates:

-Vascular Repair Surgery	1.2%
-Vascular Repair USGC (Ultrasound Guided Compression)	2.9%
-Transfusion	2.4%
-Infection Extending Hospitalization	0.6%

As you can see, the actual major complication rates are substantially higher than what is claimed in Mr. Voigt's letters and on your web site.

Presenting the VasoSeal ES device in promotional materials in a manner which suggests that the device is safer than what is actually listed in the approved labeling changes the safety of the device. According to the provisions of 21 CFR 814.39, any labeling change that affects the safety or effectiveness of a device requires the submission, and prior approval of, a PMA supplement. Additionally, section 502(a) of the Act prohibits the use of any statements in the labeling of a device that are false or misleading in any particular.

Promoting the VasoSeal ES device for major complication rates of 0.1% causes the VasoSeal ES device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The VasoSeal ES device is also misbranded within the meaning of section 502(a) of the Act, in that its labeling is false or misleading.

Additionally, we note that one section of your web site titled, VasoSeal Benefits includes both U.S. and European indications for use with the disclaimer, "Not applicable to the U.S. market." The agency believes it is inappropriate for a web site essentially targeted to the American consumer to include indications for the device that may be approved in foreign markets but not in the United States. We believe it is necessary to have a separate web site for those indications approved in the United States and one web site for those indications approved overseas.

This letter is not intended to be an all-inclusive list of deficiencies associated with your VasoSeal ES or other similar VasoSeal devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are

responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

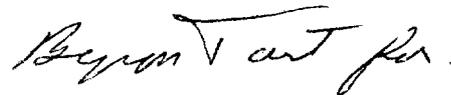
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Please indicate how many of Mr. Voigt's letters were distributed. Your response should also include all steps being taken by Datascope to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New Jersey District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New Jersey District Office (HFR-MA300), Waterview Corporate Center, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health