



September 11, 2020

Food and Drug Administration
Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852
Submitted electronically: <http://www.regulations.gov>

Re: Docket No. FDA-2018-D-2494 – Select Updates for Peripheral Vascular Atherectomy Devices-Premarket Notification Submissions; Comments of the Society of Interventional Radiology.

Dear FDA Management Staff (HFA-305):

The Society of Interventional Radiology (SIR), a professional medical society representing more than 8,000 members and the American College of Radiology, a medical professional organization representing more than 40,000 members including most US physicians who are practicing in the specialty of vascular and interventional radiology. Their combined membership possesses considerable experience with atherectomy devices in the management of patients with atherosclerotic peripheral arterial disease. The SIR and ACR are dedicated to improving public health through their focus on minimally invasive, and image-guided therapies and have come together to provide a unified comment on the Food and Drug Administration's recently publicized Select Updates for Peripheral Vascular Atherectomy Devices-Premarket Notification Submissions. The ACR and SIR appreciate this singular opportunity to provide these comments together.

The capabilities, performance characteristics and appropriate role of atherectomy devices in current treatment algorithms of peripheral arterial disease are a matter of ongoing evolution and professional consensus debate. We support the FDA in its efforts to create a greater degree of clinical safety and device operational predictability by incorporating into the current Premarket Notification Update the empirical knowledge and experience gleaned from atherectomy device use over the last three decades. Our comments and suggestions are below:

Software

The guidance regarding the role of software in atherectomy devices, and issues associated with its malfunction, interoperability, networking, and cyber security represent a realistic and appropriate level of concern. The potential future rewards of data collection and analysis, and the possible risks associated with malware and software virus infection represent both opportunities and vulnerabilities. Acknowledging these topics will help guide future device designs.

Non-Clinical Performance Testing

The Draft Guidance addresses Non-Clinical Performance Testing with attention to simulated use testing, device coating testing, debris removal, and particulate generation. We support the FDA in its efforts to further the predictability of device performance in varied endovascular environments. Furthermore, we agree with the agency's interest in developing a greater understanding around the creation and subsequent management of particulate debris during atherectomy. From a clinical perspective, the liberated particulate debris can result in

distal embolization which has the potential to negate any beneficial device performance and create significant short and long-term harm to the patient. Experience with this adverse event has evolved over the last three decades, and the FDA is appropriately focused on strategies to mitigate this risk.

Additional SIR and ACR Recommendations:

The guidance document would benefit from a glossary of terms, such that there is an agreed nomenclature to distinguish particulate debris which is organic and originates from the luminal contents or surface of the artery, from that which may be liberated from the device, itself, such as the coating on the device. This issue is discussed in Subsection r, page 5-6. In clinical practice, there is a lack of consensus on the incidence and significance of distal embolization, but when distal embolization occurs, it can be very clinically significant. Creating a uniform terminology around this adverse event may be beneficial in fostering further research and innovation.

The SIR and ACR appreciate the opportunity to provide comments on the proposed draft guidance. If additional information is required, please contact Erica Holland, Interim Executive Director at eholland@sirweb.org or ACR Government Relations Staff, Gloria Romanelli at gromanelli@acr.org.

Sincerely:



Michal M. Dake, MD, FSIR
President, Society of Interventional Radiology



Alan H. Matsumoto, MD, FACR, FSIR
ACR Chair, Commission on Interventional Radiology and Cardiovascular Imaging

CC: Erica Holland, SIR Interim Executive Director
William Thorwarth, MD, FACR, ACR Executive Director