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EXPERT CONSENSUS DOCUMENT

SCAI/ACC/HRS Institutional and Operator Requirements for Left Atrial Appendage Occlusion

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PREAMBLE

Ischemic stroke remains a significant risk for patients with atrial fibrillation (AF). The Food and Drug Administration (FDA) approval of the WATCHMAN device for percutaneous closure of the left atrial appendage (LAA) represents an important addition to the physician's armamentarium to help mitigate this problem. The evolution of LAA occlusion technology has spanned nearly two decades and three FDA panel hearings, leading to FDA approval in 2015. As this technology becomes clinically available to a broader population of patients, it is essential that physician stakeholders establish criteria for the performance of these procedures that will be used in granting initial and ongoing privileges. These criteria are offered to support The Joint Commission mandate that medical staff privileges be granted on the basis of professional criteria specified in the medical staff bylaws to ensure safe and effective patient-centered care. The emergence of transcatheter valve therapies has provided a model whereby multiple societies collaborate to provide recommendations to institutions and operators to assess their potential to establish and maintain programs for these therapies (1-3). As an extension of this concept, the Society of Cardiovascular Angiography and Interventions (SCAI), the Heart Rhythm Society (HRS), and the American College of Cardiology (ACC) agreed to provide recommendations to institutions and interested physicians for the establishment and maintenance of LAA occlusion programs. An initial multisociety overview of the field of LAA occlusion has recently been published, highlighting the critical issues surrounding LAA occlusion therapies (4). This document states that the questions of who should perform these procedures and the

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Conflict of interest: Nothing to report.

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institutional support required need further delineation. It is these issues that are the subject of this, the second multisociety document. As LAA occlusion is in its early developmental stages, the recommendations must initially rely on expert consensus. As experience with LAA occlusion grows, these recommendations will be revised and updated based on expanded expertise and published data. However, the recent FDA approval of the first percutaneous LAA occlusion device underscores the need to make initial recommendations now; this will provide a starting point for future modifications. The recommendations that follow were reviewed by the entire writing committee, with at least 70% concurrence required in order to be incorporated.

In accordance with the partnering societies' policies on relationships with industry and other entities (RWI), relevant author disclosures are included in Appendix A. In addition, authors' comprehensive RWI information, which includes RWI not relevant to this document, is available online as supplemental material. To avoid actual, potential, or perceived conflicts of interest as a result of industry relationships or other personal conflicts, members of the writing committee and the peer reviewers of this document were asked to disclose all present or prior (within 12 months before the initiation of this clinical document) potential conflicts. The writing committee includes a majority of members without relevant RWI and is chaired by an interventional cardiologist, with an additional interventional cardiologist and an electrophysiologist serving as Co-chairs. Authors with relevant RWI were not permitted to draft or vote on content or recommendations pertaining to their RWI. RWI were reviewed during conference calls and updated as changes occurred. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices A and B, respectively. The work of the writing committee was supported exclusively by the partnering societies without commercial support. Writing committee members donated their time for the preparation of this document. Conference calls of the writing committee were closed and attended only by committee members and society staff. The respective executive boards of the three professional societies provided final review and approval of the document.

SCAI, HRS, and ACC hope that adherence to the recommendations in this document will ensure safe and effective LAA occlusion technology dissemination for stroke prevention in patients with AF in the United States.

INTRODUCTION

Multiple large, prospective randomized clinical trials have demonstrated that oral anticoagulants such as warfarin, factor Xa inhibitors, and direct thrombin inhibitors are highly effective in reducing the risk of stroke and are the standard of care for many patients with AF at increased risk of thromboembolic events as assessed by CHA_2DS_2-VASc score (5–7). These agents, while effective, are associated with an increased risk of bleeding. Some patients with AF whose stroke risk profile would normally warrant anticoagulation have absolute or relative contraindications to anticoagulants. As a result, there is agreement that non-pharmacologic treatment for stroke prevention has been an unmet need, which has stimulated the development of alternatives to pharmacologic therapies. Several approaches to LAA occlusion have evolved simultaneously, including endovascular occlusion, surgical suturing, stapling, and amputation (8). These methods have been shown to vary in their efficacy and safety. The WATCHMAN device has been evaluated in two randomized clinical trials and two continued access registries encompassing greater than 2,400 patients and 6,000 patient-years (9–12). On the basis of the clinical trials data, the FDA approved the WATCHMAN device recently for patients with non-valvular AF who are at risk for stroke, suitable for anticoagulation, and for whom there is a rationale for seeking a non-pharmacologic alternative (http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf). Given the enrollment criteria, many patients who may achieve the greatest clinical benefit from this technology have never been studied in randomized trials of LAA occlusion. SCAI, HRS, and ACC support expanded clinical trials of LAA occlusion that include such patients with the hope that this will lead to refinements in eligibility criteria.

Percutaneous LAA occlusion has the potential to a have major, positive clinical impact on our treatment of certain subsets of patients with AF that are at risk for stroke. LAA occlusion techniques are technically challenging. This expert consensus statement outlines our proposed institutional and operator requirements in order to assist with the implementation of credentialing standards and help providers to participate responsibly, safely, and effectively in this new and important field. The safe application of LAA occlusion requires specific cognitive and technical skillsets and respect for the high-risk nature of these interventions. Procedural specialists† performing LAA occlusion will come from a variety of backgrounds, including interventional cardiology (adult or pediatric), electrophysiology, and cardiac surgery. It is expected that physicians will operate within the context of a multidisciplinary team (MDT) to optimize patient selection and clinical benefit. The defining principle is that LAA occlusion is an institutionally based therapy provided across multiple disciplines. Patient-centered care is defined by the Institute of Medicine as "health care that establishes a

†This document will use the term "procedural specialist" to apply to members of any subspecialty who implant LAA occlusion devices.