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Boston Scientific has received FDA and CE Mark approval for the EMBLEM Subcutaneous Implantable Defibrillator (S-ICD) System. The EMBLEM S-ICD System is a treatment option that provides protection for patients at risk of sudden cardiac arrest (SCA), yet leaves the heart and vasculature untouched, minimizing the risk of complications associated with conventional transvenous implantable cardioverter-defibrillators (TV-ICDs).

"We are excited to offer the second generation S-ICD System to physicians as a compelling treatment option for the majority of ICD-indicated patients. With the already established robust safety and efficacy clinical data, the EMBLEM S-ICD System is designed to enhance patient comfort, while still providing a less invasive treatment for patients at risk of cardiac arrest," said Dr Kenneth Stein, chief medical officer, rhythm management, Boston Scientific.

Unlike traditional ICDs that require placement of at least one lead in or on the heart, the S-ICD System is implanted just under the skin and provides the patient the same protection from cardiac arrest without invading the heart and blood vessels.

The new generation EMBLEM S-ICD System is 19 percent thinner and is projected to last 40 percent longer than the previous S-ICD System. These improvements will further improve patient comfort and cosmetic outcomes while reducing the number of times the device will require replacement. The EMBLEM S-ICD System is also enabled for remote patient management through the LATITUDE NXT Patient Management System for increased patient convenience.