

EBR launches the WiSE Coupler accessory for U.S. commercial use

Key highlights:

- EBR announces the commercial launch of the WiSE® Coupler.
- The Coupler is an accessory designed to support the implant of the WiSE Electrode.
- The Coupler is listed with the U.S. FDA as a Class I, 510(k)-exempt device (21 CFR 870.3955, product code QWA).
- The device has been evaluated in 10 U.S. WiSE implant procedures with both experienced and first-time users as part of a limited, pilot release.
- Q2 2026 Quarterly Activity Report and Form 10-Q to be released on 12 August 2026 AEST.

Sunnyvale, California; 24 July 2026: EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing device for heart failure, has listed its WiSE Coupler device with the U.S. Food and Drug Administration (FDA) as a Class I, 510(k)-exempt cardiovascular delivery catheter system positioning and stabilisation device.

The Coupler is an optional, single-use procedural accessory for use with the WiSE Delivery Sheath and Electrode Catheter during implantation of the WiSE Electrode.

It provides mechanical support, coupling the Delivery Sheath and Electrode Catheter handles as a single unit to aid positioning and stabilisation of the delivery catheter system during the procedure.

John McCutcheon, EBR Systems’ President & Chief Executive Officer said:

“The development of the WiSE Coupler reflects EBR’s comprehensive focus on execution as we scale the commercial rollout of WiSE. The availability of this new tool complements our existing program of physician training, site activation, purchasing access, and procedural support as we continue to expand the commercial rollout of the WiSE System in the United States.”

Pilot phase

The Coupler was used in 10 U.S. WiSE implant procedures by both experienced and first-time users during a pilot phase. The pilot was designed to gather physician input to support the development of training and field support materials. It was not a clinical investigation and was not designed or powered to evaluate device performance, safety or effectiveness.

Dr Anne Kroman, Specialist in Electrophysiology Cardiology at the Medical University of South Carolina, said:

“The Coupler is a procedural aid used during the WiSE implant. By keeping the delivery components together and supporting slow, steady electrode advancement, it helps maintain stability and control during a technically important part of the procedure.”

Q2 2026 Results

EBR will lodge its Q2 2026 Quarterly Activity Report and Form 10-Q with the ASX on 12 August 2026 AEST.

For more information about EBR, please visit <https://www.ebrsystemsinc.com/>.

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This announcement has been authorised for release by the EBR Systems Routine Disclosure Committee, a Committee of the Board of Directors.

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About EBR Systems

Silicon Valley-based EBR Systems (ASX:EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device in most markets and is currently only available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment in or

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completion of our clinical trials and our associated regulatory applications and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. These forward-looking statements are based on EBR Systems' current expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's ASX-traded (ASX: EBR) CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.