# IMRICOR RECIEVES FDA CLEARANCE FOR NORTHSTAR®

**Highlights:**

- **NorthStar® is the first and only MRI-native 3D mapping and guidance system to receive FDA clearance**
- **NorthStar is Imricor's first capital equipment and first software-centric product approval in the United States**
- **Foundation for future growth: NorthStar is considered the foundational software guidance system for a broad pipeline of existing and future MRI-guided procedures**



**29 January 2026** – Melbourne, Australia (**28 January 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that the United States Food and Drug Administration (FDA) has granted 510(k) clearance for the Company's **NorthStar® Mapping System** under the premarket notification process.

This marks the Company's second FDA clearance, after receiving 510(k) clearance for the Vision-MR® Diagnostic Catheter earlier this month, and it significantly strengthens Imricor's position as the market leader in MRI-guided interventional procedures.

NorthStar's clearance by the U.S. FDA marks the culmination of years of research, development, 3rd party partnerships, and regulatory work. The system is designed and intended to be the central hub of every interventional cardiac MRI lab (iCMR).

FDA clearance enables Imricor to commercially market NorthStar in the United States, the world's largest electrophysiology market. This clearance is the second of what the Company expects will be multiple regulatory clearances and approvals this calendar year, as Imricor's full MRI-guided electrophysiology platform is progressively introduced to the market.

**Imricor's Chair and CEO, Steve Wedan, added:** "At Imricor, we have been building a comprehensive suite of uniquely MRI-compatible devices for two decades. These devices, which include both consumable products and capital equipment, enable doctors to harness the superior soft tissue imaging of MRI to precisely guide minimally invasive procedures in a 100% radiation-free setting. Our goal is to enable better, faster, safer and less expensive treatments for patients worldwide; and as the world's largest market, the United States is critical to our goal.

"When it comes to iCMR procedures, NorthStar is the central hub that brings everything together. It's designed to not only facilitate diagnostic cardiac electrophysiology and ablations procedures, but also to provide MRI guidance capabilities for other procedures.

"And since NorthStar is primarily a software product, it ushers in Imricor's software era in which AI will play a big role in the future. NorthStar's platform provides a path for capability expansion that is virtually unlimited, and we will continue to invest in and expand its capabilities for years to come."

**ENDS**

Authorised for release by Steve Wedan, Executive Chair, President, and CEO

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## About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is striving to make interventional medical procedures better, safer, and more cost effective by making it possible for these procedures to be performed under real-time magnetic resonance imaging (MRI) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MRI's superior imaging capabilities.

## Imricor's Products

Imricor is a pioneer and world leader in developing MRI-compatible products for cardiac catheter ablation procedures. The Company's products include capital equipment, such as the NorthStar® Mapping System and the Advantage-MR® EP Recorder/Stimulator. Single-use devices include a variety of ablation catheters, diagnostic catheters, steerable sheaths, and other tools used for cardiac ablations.

Imricor's products are approved in the European Union, the Kingdom of Saudi Arabia, and New Zealand. US FDA approval is in process, and further approvals in other geographies such as Australia are being planned.

## Foreign Ownership Restrictions

Imricor's 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 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. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

## Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU. sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor 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. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.