



IMRICOR RECEIVES FDA CLEARANCES FOR NORTHSTAR AND DIAGNOSTIC CATHETER FOR PEDIATRIC USE

Highlights

- Imricor received FDA 510(k) clearance for NorthStar's labeling expansion to include pediatric use
- Imricor concurrently received FDA 510(k) clearance for the Vision-MR Diagnostic Catheter's labeling expansion to include pediatric use
- Clearances open the door for iMR-guided pediatric applications such as cardiac catheterisations, eliminating radiation exposure for vulnerable pediatric patient population
- Over 250k diagnostic right and left heart catheterisations are performed annually in the U.S. across both adult and children's hospitals
- Diagnostic interventions are a new market for Imricor built off NorthStar®, the world's first and only MR-native 3D iMR mapping and guidance system
- What has typically involved an MRI scan followed by an X-ray lab intervention can now be done in the iMR delivering significant time and cost savings to hospitals

2 July 2026 – Melbourne, Australia (**1 July 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to announce that it has received 510(k) clearance for its **NorthStar®** system from the U.S. Food and Drug Administration (FDA) for **pediatric label expansion**.

At the same time, Imricor also received 510(k) clearance from the FDA for its **Vision-MR® Diagnostic Catheter** for **pediatric label expansion**.

The clearances follow Imricor's announcements in January 2026 that NorthStar had received FDA clearance for use in adult patients, and in April 2026 that NorthStar had been submitted for pediatric labeling expansion. In discussions with the FDA during the review process, Imricor decided to also submit the Vision-MR Diagnostic Catheter for pediatric labeling expansion, thereby providing a more complete set of pediatric interventional magnetic resonance (iMR) devices.

The clearances allow Imricor to market NorthStar and the Vision-MR Diagnostic Catheter for use with patients of any age, including children and young adults treated at the over 250 children's hospitals across the US. Pediatric patients who may benefit from iMR procedures include those born with congenital heart defects who require several cardiac catheterizations at a young age. Young people are more sensitive to ionizing x-ray radiation exposure, and iMR procedures eliminate all procedure-related x-rays for these children.

The clearances to expand NorthStar and the Vision-MR Diagnostic Catheter to include use with pediatric patients represents another important step in the Company's U.S. commercialization strategy.



The Company believes the pediatric market represents an attractive early commercial channel for NorthStar and the Vision-MR Diagnostic Catheter in advance of broader U.S. adoption of Imricor's full EP platform in adult hospitals. Children's hospitals often have a strong interest in reducing radiation exposure and the use of contrast dyes for their patients, and as a navigation system for use in iMR procedures, NorthStar may be well suited to adapt and improve iMR procedure workflows currently performed with only stock magnetic resonance imaging system interfaces. In addition, the Vision-MR Diagnostic Catheter provides an actively-tracked tool in the iMR lab for diagnostic electrophysiological applications, once the Advantage-MR EP Recorder/Stimulator is cleared by the FDA.

Imricor's Chair and CEO, Steve Wedan, commented: "We care about children, and we don't shy away from delivering our products to all patient segments who can benefit from radiation-free iMR procedures.

"Having experienced first-hand, the pediatric use of products I personally developed throughout my career, I can say there is something particularly rewarding about providing technology to help infants and young children. Changing the world of interventional medicine for doctors and patients means changing it for *all* doctors and *all* patients."

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 (MR) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MR's superior imaging capabilities.

Imricor's Products

Imricor is a pioneer and world leader in developing MR-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. NorthStar is approved in the US.

Foreign Ownership Restrictions

Imricor's CHES 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 excluding qualified institutional buyers (QIBs, as defined in Rule 144A under the Securities Act). 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.