



## IMRICOR SUBMITS ALL REMAINING 510(K) DEVICES FOR FDA CLEARANCE

**20 July 2026** – Melbourne, Australia (**19 July 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** today announces that it has submitted its NavTrac and NavTrac-MR® Steerable Introducers for market clearance under the U.S. Food and Drug Administration's (FDA's) 510(k) premarket notification pathway.

The submission follows a series of recent FDA clearances, with NorthStar and the Vision-MR Diagnostic Catheter cleared for use in adult patients in January 2026 and for use in pediatric patients earlier this month.

The NavTrac and NavTrac-MR are steerable introducer sets, each comprising a bi-directionally-steerable sheath and an associated vascular dilator. These products are used to introduce and guide a range of cardiovascular catheters into the heart. The NavTrac version is supplied with a standard dilator for use in x-ray cath lab environments, while the NavTrac-MR version comes with a dilator containing MR active tracking coils for use in iMR lab environments.

With these submissions, every Imricor device following the 510(k) pathway has now been either cleared by, or submitted for clearance to, the FDA. In total, Imricor has completed 14 of the 15 FDA submissions required to establish its full product platform for commercialisation in the U.S., the world's largest electrophysiology market. These latest submissions continue the strong regulatory momentum the Company has built over the past six months.

### U.S. platform – regulatory momentum continues

8 of 8

European products approved — full platform commercial under EU MDR

11 of 11

US 510(k) devices including pediatric use cleared or under FDA review — final three submissions filed today

3 of 4

PMA modules submitted — only module 4 remains before full PMA filing

| Geography                  | Imricor Product Suite                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Pathway     | Status                                                                                                                                                                                                      | Details                                                                                                                                                                     |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Europe<br>EU MDR · CE Mark | Full technology platform — all 8 products CE-marked                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Med Dev Reg | APPROVED × 8                                                                                                                                                                                                | Real-time iMR-guided atrial flutter procedures approved for commercialization across Europe.                                                                                |
| United States<br>FDA       | <ul style="list-style-type: none"> <li>NorthStar</li> <li>Vision-MR Diagnostic Catheter</li> <li>Vision-MR Diagnostic Cable</li> <li>NorthStar Pediatric Label Expansion</li> <li>Vision-MR Diagnostic Catheter Pediatric Label Expansion</li> <li>Vision-MR Diagnostic Cable Pediatric Label Expansion</li> <li>Vision-MR Dispersive Electrode</li> <li>Advantage-MR EP Recorder/Stimulator</li> <li>NavTrac-MR Steerable Introducer and Dilator — <i>submitted today</i></li> <li>NavTrac Steerable Introducer and Dilator (x-ray use) — <i>submitted today</i></li> <li>NavTrac-MR Cable — <i>submitted today</i></li> </ul> | 510(k)      | <div>APPROVED</div> <div>APPROVED</div> <div>APPROVED</div> <div>APPROVED</div> <div>APPROVED</div> <div>APPROVED</div> <div>SUBMITTED</div> <div>SUBMITTED</div> <div>SUBMITTED</div> <div>SUBMITTED</div> | 6 clearances granted; 5 submissions under FDA review, including three NavTrac-MR devices submitted today.<br><br>Full 510(k) suite now filed — clearance decisions pending. |
|                            | <ul style="list-style-type: none"> <li>Vision-MR Ablation Catheter 2.0</li> <li>Vision-MR Ablation Cable Set 2.0</li> <li>RF5000 Ablation Generator, Pump, and Remote</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                | PMA         | <div>M1 SUBMITTED</div> <div>M2 SUBMITTED</div> <div>M3 SUBMITTED</div> <div>M4 PENDING</div>                                                                                                               | PMA modules 1, 2 and 3 now submitted — only module 4 remains before the full PMA filing is complete.<br><br>Clinical trial site expansion complete.                         |

**Imricor's Chair and CEO, Steve Wedan, commented:** “Just weeks after receiving pediatric clearance for NorthStar, we are already well advanced in our sales process with several U.S. pediatric sites. We expect these pediatric sites to set the stage for a broader rollout across both pediatric and adult hospitals in the United States.



"In addition to the advantages of eliminating x-ray exposure for children, the economics of performing cardiac catheterisations with NorthStar in an iMR lab are very compelling for hospitals. And while we progress our full ablation portfolio through the U.S. regulatory process, this application of NorthStar provides a path for us to establish an installed base of iMR labs in the U.S. today, many of which we also expect to become ablation sites as the portfolio gains approval.

"Submitting the NavTrac family of steerable introducers completes our 510(k) filings and brings us another step closer to delivering our *full platform* to the U.S. market. It is a significant milestone for the entire Imricor family, which includes you, our investors.

"The scale of what we are doing is extremely unusual and frankly, pretty impressive. With 14 out of the 15 required submissions now with the FDA, we have filed more than 50,000 pages of product and regulatory documentation with the agency. As many know, enabling a transition from x-ray cath labs to iMR labs required all the tools and systems needed in the lab to be re-invented and developed for use with MRI, and it's not often that such a multi-product portfolio is driven through approvals and to market all at the same time. In my 36 years of developing medical devices, I don't recall ever seeing something as ambitious as this."

## **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 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 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.

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