

Implantation of Next-Generation AngelMed Guardian® commences in US

Key Highlights:

- AngelMed announces first US implant of next-generation AngelMed Guardian device
- FDA approved AngelMed to re-implant 260 clinical trial patients under continued access study
- Follows recent announcement that first implants in Asia Pacific were completed in Singapore
- Implant performed by Kelly Tucker, M.D., Director, Electrophysiology, Orange County Heart Institute and Research Center at Pavilion Surgery Center in Orange, California

Hydrix Limited (ASX: HYD, 'Hydrix' or the 'Company') is pleased to announce that Angel Medical Systems (AngelMed) released a [statement](#) overnight that a former ALERTS Study patient in the United States has received the first implant of the next-generation AngelMed Guardian® System as part of the ALERTS-Continued Access Study. The FDA granted AngelMed approval to re-implant 260 clinical trial patients under its continued access study.

The implant of the newly refined AngelMed Guardian was performed by Kelly Tucker, M.D., Director, Electrophysiology, Orange County Heart Institute and Research Center at Pavilion Surgery Center in Orange, California.

The implanting surgeon, Kelly Tucker, M.D. stated "The AngelMed Guardian represents a real game changer in the management of coronary artery disease. This is the first ever surveillance tool for patients with a prior coronary event and has the potential to save countless lives and bring peace of mind to thousands of families. It is a great honour to be involved in this amazing technology".

The AngelMed Guardian system is designed to track significant changes in the heart's electrical signal and then alert patients to seek medical attention – this includes detection of silent heart attacks. The objective of AngelMed's ALERTS-Continued Access Study is to provide their former ALERTS clinical trial patients access to the next generation device and its life-saving features.

AngelMed CEO Gordie Nye commented, "We are thankful to the FDA for allowing us to perform this study so that our previous ALERTS patients may get the AngelMed Guardian back. These pioneers still to this day remain pivotal to our success and we as a company are excited for the road ahead as we move closer to commercialization."

Paul Kelly, Hydrix Medical General Manager commented "This is a significant step forward in the progress of the AngelMed Guardian's commercialisation. We congratulate the team involved and look forward to ongoing positive news".

The AngelMed Guardian is an implantable cardiac monitor with patient alerting for patients who have had prior Acute Coronary Syndromes (ACS), including myocardial infarctions (heart attacks) or unstable angina and who remain at high risk for recurrent ACS events. Hydrix Medical is the exclusive distributor of the AngelMed Guardian in eight Asia Pacific countries including Australia, Japan, and Singapore where four patient implants of the device were completed in August 2020. Hydrix Medical is not entitled to any revenue generated from implants in the US or any other jurisdiction outside its distribution agreement.

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This announcement is authorised for release by the Board of Directors of Hydrix Limited.

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Contact Details: For more information, please contact:

Media Enquiries:

Rod North
Managing Director, Bourse Communications
rod@boursecommunications.com.au
+61 3 9510 8309

About Hydrix Limited

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