

Aussie's CardioCel gets US approval

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Singapore: Australia based Admedus has received FDA clearance to market CardioCel in the US.

CardioCel is the group's lead regenerative tissue product to repair and treat a range of cardiovascular and vascular defects. The Company will now look to complement its existing product launch in Europe with preparation for initial sales in the US.

The intended use of CardioCel in the US is in pericardial closure and for the repair of cardiac and vascular defects in both adults and paediatrics.

"This is a significant milestone for the Company as we expand into global markets and further develop our range of regenerative tissue products for commercialisation and sale." said Mr. Lee Rodne, CEO, Admedus.

"CardioCel is an important addition to the surgeon's armoury in the treatment of congenital heart disease, as well as for the repair of heart valves and other cardiac defects" he said.

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"Admedus is looking forward to an exciting 2014/15 as we launch CardioCel globally and continue to grow our sales revenue and cardiovascular teams in these regions," said Mr. Rodne.

CardioCel is engineered by the group's ADAPT tissue engineering process to be a durable, pure collagen scaffold that avoids calcification, supports native cell infiltration, growth and differentiation and which promotes a regenerative healing process.

CardioCel has shown benefits over existing products in that it does not calcify like other tissue products and has shown to facilitate autologous tissue regeneration once surgically implanted, while retaining strength and natural elasticity. CardioCel is a ready to use, off the shelf product that has the potential to prevent follow up surgeries for patients because of its anti-calcification and regenerative properties.