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ASIA EDITION

Osprey enrolls first patient for Cincor study

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Singapore: Australia's Osprey Medical has enrolled the first patient in Cincor IDE clinical study at the Leipzig Heart Centre in Germany. Dye is routinely used for x-ray of heart tissue during coronary angiography and stenting procedures, but it can cause serious and irreversible damage to the kidneys.

Cincor System is designed to provide cardiologists with an advanced level of protection against this damage known as contrast induced nephropathy (CIN) in high-risk patients undergoing coronary angiography and stenting procedures. The Cincor System is a dye reduction and removal system that both reduces the amount of dye injected and removes a significant quantity of any dye used as it leaves the coronary sinus (the heart's main drainage vein) before reaching the kidney. At present, there is no effective way for cardiologists to prevent the dye from reaching the kidneys.

The registration-directed IDE pivotal trial will enroll 600 patients in 30 centres around the world. The trial results will support a US FDA 510(k) regulatory submission, which is expected in late 2014.

The first patient was enrolled by Dr Steffen Desch at the Leipzig Heart Center in Leipzig, Germany. Dr Desch commented, "Osprey's Cincor system, with its ability to reduce and remove contrast dye, has the potential to offer chronic kidney disease patients undergoing a coronary angiogram a lower risk of CIN."

Approximately 25 percent of all patients undergoing coronary angiography and stenting procedures are at high risk of acquiring CIN due to their pre-existing kidney disease. CIN can have a significant impact on patients' lives, which can result in longer hospitalisation, reduced kidney function, increased risk of heart disease, total kidney shut down and significant increase in likelihood of death.

As part of the trial in the US, Osprey Medical will also be collecting health economic data on patients for 12 months after the procedure. This data is not required for US regulatory approval, but will be useful for marketing Cincor by demonstrating longer-term economic outcomes to hospitals and payers.