Covidien Revascularization Device Receives FDA Clearance

**Solitaire™ FR device mechanically removes blood clots from blocked vessels after a stroke**

MANSFIELD, Mass.--(BUSINESS WIRE)--Mar. 5, 2012-- Covidien (NYSE: COV), a leading global provider of healthcare products, today announced that the Solitaire™ FR revascularization device has been cleared by the U.S. Food and Drug Administration. The Solitaire FR device is intended to restore blood flow to the brain in patients suffering acute ischemic stroke by mechanically removing blood clots from blocked vessels.

The Solitaire FR device 510(k) application was based on the results of the Solitaire With the Intention for Thrombectomy (SWIFT) clinical study. In this clinical study comparing two devices, the Solitaire FR device demonstrated superior performance to the Concentric Medical Merci Retriever™ device, a commercially available mechanical clot retriever.

The SWIFT clinical study was the first randomized clinical trial ever conducted on mechanical intervention for acute ischemic stroke. The study randomly assigned 113 stroke patients at 18 hospitals to a procedure to restore blood flow to the brain with either the Solitaire FR device or the Merci Retriever device within eight hours of stroke onset. The Solitaire FR device showed a 2.5x benefit in restoring blood flow to the brain, as determined by a blinded core lab, a 1.7x improvement in post-stroke neurological function and a 55% reduction in mortality at 90 days.

"This new device heralds a new era in acute stroke care," said Dr. Jeffrey L. Saver, the SWIFT study's principal investigator and a professor of neurology at the David Geffen School of Medicine at UCLA. "We are going from our first generation of clot-removing procedures, which were only moderately good in reopening target arteries, to now having a highly effective tool. This really is a game-changing result."

Stroke is a disease that affects the arteries leading to and within the brain. Ischemic stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is blocked by a clot. According to the American Heart Association, stroke is the fourth leading cause of death in the U.S. and a leading cause of long-term disability.

"This is good news for the approximately 700,000 people each year in the U.S. who suffer an acute ischemic stroke," said Stacy Enxing Seng, President, Vascular Therapies, Covidien. “Solitaire FR provides physicians with another important tool for treating this potentially fatal and often debilitating condition.”

The Solitaire FR device received CE Mark approval in Europe and has been commercialized internationally by Covidien since November 2009. The Solitaire FR device will be available in the U.S. next month.

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2011 revenue of $11.6 billion,
Covidien has 41,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com to learn more about our business.

Photos/Multimedia Gallery Available:
http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50191469&lang=en

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