

ISCUS Clinical Microdialysis Analyzer receives FDA clearance

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CMA Microdialysis AB (CMA) today announced that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) to market ISCUS, a portable Microdialysis analyzer, as part of the CMA Cerebral Tissue Monitoring System.

According to the CDC, stroke is the no. 3 cause of death in the US affecting more than 700,000 individuals annually. Subarachnoid Hemorrhage (SAH) represents only about 7 percent of all strokes, but has a fatality rate of more than 50 percent. Of the survivors, approximately half will suffer permanent disability.

One of the most common complications after a stroke is vasospasm. Approximately one third of spontaneous SAH's and 30-60% of traumatic bleeds are followed by vasospasm, or blood vessel constriction. Early signs of vasospasm and secondary ischemia following severe head injuries are key indicators for guiding therapy and ultimately saving lives.

The ISCUS Clinical Microdialysis Analyzer allows for continuous monitoring of changes in the brain's biochemistry by providing early evidence of ischemia or hypoxia. ISCUS is a unique and user-friendly tissue chemistry analyzer targeted for bedside use in neurocritical care.

"This is a major milestone for CMA and breakthrough for Microdialysis as a neuro-monitoring tool. I am confident that ISCUS and CMA's Cerebral Tissue Monitoring System will greatly help physicians to treat brain injured patients by providing a unique bedside tool to monitor changes in brain chemistry." says Philip Siberg, Chief Executive Officer of CMA Microdialysis AB.

The ISCUS analyser conveniently displays levels of glucose, lactate, and pyruvate retrieved from a Microdialysis catheter placed in potentially vulnerable brain tissue. ISCUS achieved the CE-mark in 2004 and has successfully been marketed and sold outside the US.

"Surgeons and intensivists now have a unique tool to diagnose ischemia after surgery or traumas earlier than before. In addition, continuous monitoring of tissue metabolism with the ISCUS can help to guide therapy and potentially improve patient outcomes," says Philip Siberg.

For more information, product notes, and pictures please contact:

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About CMA Microdialysis AB

CMA Microdialysis is the leading company devoted to the development, manufacturing and marketing of the Microdialysis technique. The company was formed in 1984 and was the first company in the world to market Microdialysis products and know-how. Consumables, instruments and computer software are sold to universities, hospitals and pharmaceutical companies as unique tools for *in vivo* sampling and diagnostics of organs and tissues. CMA has offices in Sweden, USA and Germany and distributors in 28 countries. For more information see www.microdialysis.com