

Smiths Medical Receives FDA Clearance for Epidural Administration Safety System

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Sep 21, 2012--Smiths Medical, a leading global medical device manufacturer, today announced that its Portex® CorrectInject™ Safety System for administering neuraxial (spinal and epidural) medication received 510(k) clearance from the U.S. Food and Drug Administration (FDA).

The CorrectInject™ Safety System is intended to enhance patient safety by helping to reduce the risk of tubing misconnections, while minimizing changes to clinical technique. Tubing misconnections often occur, as epidural, intravenous, enteral and other infusion lines look alike. The connectors of the CorrectInject™ Safety System are uniquely tapered and threaded to be intentionally incompatible with standard Luer connectors. The CorrectInject™ Safety System's yellow components visually signify a neuraxial delivery route and are intended to prompt clinicians to check that the medication to be delivered is appropriate for the treatment location.

Professional associations and government agencies, including the National Patient Safety Agency (NPSA) in the UK, the World Health Organization and the Joint Commission on Accreditation of Healthcare Organizations in the U.S. support the use of strategies and best practices to reduce this risk of medication administration errors, calling on product developers and manufacturers to produce connector systems dedicated for neuraxial (spinal and epidural) applications. The National Health Service (NHS) of the UK was the first government agency to adopt practices requiring the clinical use of dedicated neuraxial medication delivery systems. By April 1, 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and boluses are to be performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes.

Smiths Medical President Sрни Seshadri commented: "We are pleased to be able to offer a solution that help to reduce medication delivery errors during spinal and epidural anaesthesia administration. As a global leader of safety medical devices, it is our obligation to develop innovative medical products that not only help protect patients when they are most vulnerable but help to raise clinical standards of care." Care providers and providers of medical technologies recognize the potential of the CorrectInject™ Safety System. Earlier this year, the CorrectInject™ Safety System was showcased at the Premier Innovation Celebration, an annual conference highlighting breakthroughs in patient care where it received a Premier Innovation Award. Premier, a visionary group purchasing organization serving 2,500 U.S. hospitals and 80,000 healthcare sites, is dedicated to helping healthcare providers improve clinical and operational performance. One way that Premier does this is by collecting and analyzing clinical and financial data of its members to identify best practices and products that advance patient care by reducing costs, improving quality, and elevating safety to better manage risk. Premier provides a channel for

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suppliers of medical technology, products, and services to have their latest innovations reviewed and evaluated by committees of clinical and operational experts.

The Portex® CorrectInject™ Safety System for Epidural Anaesthesia Injection is the first of the line to be cleared for market release in the U.S. The CorrectInject™ Safety System for Spinal Anaesthesia Administration has been available in the United Kingdom, Ireland, Australia and countries in Asia since September 2011. Regionalized introductions of the CorrectInject™ Safety System, including a system for epidural infusion, will expand as country registrations and approvals are granted.

Product(s) described may not be licensed or available for sale in all countries.

About Smiths Medical Smiths Medical www.smiths-medical.com is a leading supplier of specialist medical devices and equipment for global markets, focusing on the medication delivery, vital care and safety devices market segments. It is part of Smiths Group www.smiths.com, a global leader in applying advanced technologies for markets in threat and contraband detection, energy, medical devices, communications and engineered components. Smiths Group employs around 22,000 people in more than 50 countries.

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