## ULTRADRAPE<sup>™</sup> BARRIER & SECUREMENT DRESSING FROM PARKER LABORATORIES OBTAINS CE MARK

## Innovative technology for ultrasound-guided IV insertions improves patient safety and lowers costs

FAIRFIELD, New Jersey — Parker Laboratories, a worldwide leader in ultrasound products for more than 60 years, announced it has obtained the CE mark for UltraDrape<sup>™</sup>, the first combination sterile barrier and securement dressing for ultrasound-guided peripheral intravenous (UGPIV) insertions.

<u>UltraDrape</u> was developed to address the challenges that clinicians face with UGPIV insertions. These include extended procedure time, increased risk of infection and cross contamination and securement failure resulting from inadequate gel removal.

"In addition to the existing FDA Class 1 registration, gaining the CE mark is a significant achievement that clearly speaks to the strength of our technology. Earning this mark requires a rigorous approval process and a demonstration of the effectiveness of our quality system" said Neal Buchalter, president of Parker Laboratories. "As a widely respected designation in the global market, the CE mark is a critical step in making this first-of-its-kind product available throughout the world."

The CE mark gives Parker Laboratories the opportunity to commercialize UltraDrape in the European Union. CE marking demonstrates that UltraDrape meets the essential requirements of the European Medical Devices Directive.

When using UltraDrape, ultrasound gel is applied to a removable film layer to enable target vessel identification and still keep the sterile puncture area dry and free from gel. The top layer where the gel is applied is discarded after use, minimizing the prospect of securement failure. UltraDrape also lowers the cost of performing aseptic UGPIV insertions, by removing the need for additional securement dressings, sterile gels and probe covers.

A <u>Danish study</u> showed the use of UltraDrape enabled ultrasound-guided vein identification and blood sampling with a 100 percent success rate. Researchers noted that the dressing restricted the gel and transducer to the adhesive non-sterile part of the drape, ensuring a gel-free venipuncture area.<sup>1</sup>

"This combination sterile barrier and securement approach makes it easier and faster to achieve success with ultrasound-guided PIV insertions, and it helps me do a better job as a clinician," said Nancy Moureau, RN, PhD, CRNI, CPUI, VA-BC. "By not applying gel directly to the patient's skin, I can maintain a better no-touch aseptic technique, which lowers the risk of infection and eliminates time-consuming post-procedure clean up." Dr. Moureau is an internationally recognized expert and consultant in vascular access.

Parker Laboratories' CE marking of UltraDrape coincides with the recently released <u>Association for</u> <u>Vascular Access (AVA) guidelines</u> to standardize disinfection practices for ultrasound transducers used during peripheral and central catheter insertion procedures. Previously conflicting guidelines had led to confusion and inconsistent infection-control practices.

The authors of the guidance document encourage the development of clinical products incorporating infection prevention and control, as well as patient safety, as key elements of product design.

UltraDrape is one of the first vascular access tools to enable clinicians to address the patient safety and cost-of-care needs during UGPIV procedures, as outlined by the AVA guidelines. The document is titled *Transducer Disinfection for Assessment and Insertion of Peripheral and Central Catheters for Vascular Access Teams and Clinicians*.

"These new guidelines will help clarify contradicting policies and reduce inconsistent practices, both of which have been significant obstacles in performing safe and effective UGPIV procedures," said Buchalter. "UltraDrape addresses many of the patient safety risks outlined by AVA and enables clinicians to be in compliance with the recommendations at a significantly reduced cost."

## **About Parker Laboratories**

Parker Laboratories is a leading global medical products company that develops, manufactures and sells ultrasound and electromedical contact media, as well as leading lines of institutional cleaner and disinfectants. A worldwide leader in ultrasound medical products for the past 60 years, Parker Laboratories has been consistently at the forefront of technological advances in the industry. Its flagship product, Aquasonic<sup>®</sup> 100 Ultrasound Transmission Gel, is the world standard for medical ultrasound. UltraDrape<sup>™</sup> UGPIV Barrier and Securement is available through medical supply distributors or by contacting Parker Laboratories, Inc. at (973) 276-9500 or visiting <u>parkerlabs.com</u>.

<sup>1</sup> Thorn S, et al. A technique for ultrasound-guided blood sampling from a dry and gel-free puncture area. J Vasc Access. 2016. DOI: 10.5301/jva.5000540.

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