Teleflex Announces Expanded Indications for the Arrow® EZ-IO® Intraosseous Vascular Access System

October 1, 2020

Now Cleared for up to 48-Hour Dwell

WAYNE, Pa., Oct. 01, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX), a leading global provider of medical devices for critical care and surgery, has announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand the Indications for Use of the Arrow® EZ-IO® Intraosseous Vascular Access System. This device can be used when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases.

The Arrow® EZ-IO® System is now available with the expanded indication stating use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established in adults, and in pediatric patients 12 years and older.

"Vascular access is one of the most basic, yet critical, components of patient care," said Michelle Fox, Corporate Vice President and Chief Medical Officer, Teleflex. "The ability to use the EZ-IO® System for a longer dwell time provides clinicians the option to utilize intraosseous (IO) access for the entire duration of therapy in patients with difficult vascular access where therapy is required for up to 48 hours."

In patients who require longer-term access, the expanded indication gives clinicians additional time to establish vascular access safely, choosing the appropriate device and optimal site of insertion to meet the patient's clinical needs. "These benefits are of particular importance in a time of constrained resources and patient surge," said Ms. Fox.

Expanded Indications for Use of the Arrow® EZ-IO® System are now as follows:
For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases for up to 24 hours.

Adults	Pediatrics (≤21 years old)
• Proximal humerus • Proximal tibia • Distal tibia	• Distal femur • Proximal humerus • Proximal tibia • Distal tibia

Use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

Adults	Pediatrics (≥12 years through 21 years old):
• Proximal humerus • Proximal tibia • Distal tibia	• Distal femur • Proximal humerus • Proximal tibia • Distal tibia

"We pursued this indication expansion with the FDA based on input from clinicians, who were seeking a longer dwell time," said Kevin Robinson, Vice President and General Manager, Anesthesia and Emergency Medicine Division, Teleflex. "We are pleased to make this announcement now, allowing clinicians expanded options for managing patients with difficult vascular access."

About Teleflex Incorporated
Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rüsch® and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

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