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Medtronic plc has announced the US Food and Drug Administration (FDA) 510(k) clearance of the CD Horizon Fenestrated Screw Set, which can be used for patients diagnosed with advanced stage tumors involving the thoracic and lumbar spine. This marks the first US clearance for cement-augmented pedicle screws. The CD Horizon Fenestrated Screws are used with Medtronic's HV-R Fenestrated Screw Cement, a polymethylmethacrylate (PMMA) cement, and are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

Medtronic's CD Horizon Fenestrated Screw Set features cannulated pedicle screws designed with six holes (fenestrations) located near the end of the screw, allowing controlled cement injection into the targeted vertebral body after having placed all of the screws. This self-curing PMMA cement provides immediate screw fixation in the patient's spine and significantly increases the screw pull-out strength compared to standard screws.

The cement is injected through a continuous tract in the adapter and into the screw cannula. This continuous tract delivery system is designed to have a completely secure channel that can be visually verified outside the patient to help reduce the likelihood of cement leakage at the adapter/screw interface while being compatible for minimally invasive surgery (MIS) and open procedures.

"Palliative care is important for people with cancer, and Medtronic's cement-augmented screws are a meaningful innovation that are designed to restore the integrity of the spinal column in patients with debilitating spinal tumors," said Doug King,

senior vice president and president of Medtronic's Spinal division, which is part of the Restorative Therapies Group at Medtronic. "The availability of our CD Horizon Fenestrated Screw Set represents an important advance for surgeons and provides them with another option for a complex procedure."

The CD Horizon Fenestrated Screw Set will be available this fall.