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Civco's ultrasound-guided brachytherapy gets FDA nod

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Singapore: Civco Medical Solutions has advanced the standard in real-time planning by obtaining FDA 510(k) clearance of its EX3 Stepper for Low Dose Rate (LDR) and High Dose Rate (HDR) ultrasound-guided brachytherapy for prostate cancer detection and treatment.

LDR prostate brachytherapy involves internal radiotherapy where tiny radioactive 'seeds' are delivered through a needle and are permanently placed into or near the tumor for treatment. HDR prostate brachytherapy is a similar internal treatment that involves the temporary placement of a tiny radioactive source directly into the tumor or near the targeted treatment area.

The EX3 Stepper's modular design reports angular and linear position directly to the manufacturer's treatment planning software intraoperatively. Through direct communication, the stepper offers rapid connection for data analysis and reduces clutter in the surgical suite. The unique design of the EX3 also features a removable electronic unit which mitigates the risk of damaging transmission components and reduces cleaning time after the procedure.

Civco's EX3 Stepper, like its predecessor the EXII, offers compatibility for BK Medical, GE Healthcare, Hitachi Aloka and Siemens transrectal ultrasound probes and it is currently validated for use with Varian Vitesse and VariSeed treatment planning software.

In addition to receiving FDA 510(k) clearance, CIVCO has also CE Marked the EX3 for sale in the European Union and other countries where the CE Mark is recognized.