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Relievant Seeks FDA Clearance Of AF Ablation For Back Pain

Relievant Medsystems plans to start a multi-center clinical trial later this year to support FDA clearance of its *Intracept* radiofrequency ablation system to treat back pain.

Privately-held Relievant recently completed a \$20 million financing, led by Morgenthaler Ventures, to fund the clinical trial and Intracept's U.S. market launch. The Redwood City, Calif., firm has raised \$29 million in total, with no plans for another round.

Intracept was originally 510(k)-cleared in 2007 to ablate soft tissues, without mention of any specific procedures. The company is meeting with FDA over the next few months and putting together the trial protocol to gain a specific back-pain indication, Relievant President and CEO Paul Goeld said.

During the Intracept procedure, a small probe is guided by x-ray fluoroscopy to a targeted location in the vertebral body. It then ablates the pain-emitting nerve using radiofrequency energy. The treatment takes about an hour to complete.

"We essentially ablate that nerve in much the same way that a dentist would kill the nerve when he or she performs a root canal," Goeld explained in an interview.

Goeld say he views Intracept as a quicker and less invasive alternative to major surgical remedies for back pain, such as spinal fusion.

In a 16-patient feasibility study, conducted primarily in Europe, "patients went from severely disabled to minimally disabled," the CEO said, and the positive effect lasted for a year or more.

The clinical trial will involve about 15 sites in the U.S., and will likely enroll more than 100 patients.

Every year, 12 million new patients seek treatment for back pain, Relievant estimates. Back pain is caused by a variety of factors, including spine problems, injuries or infections, and treatment options vary widely.

The firm's founders acquired the technology from Johnson & Johnson/DePuy Spine in 2006 and subsequently formed Relievant. Intracept is the company's only product.

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