

Halyard Health Announces New Data Supporting COOLIEF* Cooled RF for the Treatment of Chronic Osteoarthritis Knee Pain



Study finds COOLIEF* Cooled RF provides significantly greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections (1)

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ALPHARETTA, Ga., Sept. 18, 2017 /PRNewswire/ -- **Halyard Health** (NYSE: HYH), a medical technology company focused on eliminating pain, speeding recovery and preventing infection, today announced clinical data supporting the use of COOLIEF* Cooled Radiofrequency (RF) for the treatment of chronic osteoarthritis (OA) knee pain. The study finds that at six and 12 months, COOLIEF* Cooled RF provided significantly greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections (IAS)¹. The 12 month data was presented last week at the European Society of Regional Anaesthesia & Pain Therapy Annual Congress in Lugano, Switzerland by Professor Dr. Leonardo Kapural, Carolinas Pain Institute and Center for Clinical Research, Wake Forest University School of Medicine.

In April 2017, Halyard received **clearance** from the U.S. Food and Drug Administration (FDA) for marketing COOLIEF* Cooled RF as the first and only treatment for the relief of chronic moderate to severe knee pain caused by osteoarthritis (OA). COOLIEF* Cooled RF is a minimally-invasive and non-surgical outpatient procedure to target and treat the nerves causing chronic pain. This advanced thermal radiofrequency pain management system uses water-cooled technology to safely deactivate pain-causing sensory nerves.

Authored by Dr. Timothy Davis, founder and medical director of Orthopedic Pain Specialists in Santa Monica, California, the randomized multi-center study looked at 151-patients over 12 months with primary effectiveness at six months and 12 months. The study found:

- In 74.1 percent of the cooled RF patient group, pain was reduced by at least 50 percent at six months and maintained in over 65.4 percent of those patients for a full 12 months post procedure^{1,2}.
- At baseline, 67.1 percent of the cooled RF group and 62.7 percent of the steroid injection group reported symptoms of severe arthritis^{1,2}.
- Six months post-procedure, only 5.2 percent of the cooled RF group reported the same severity level versus 37.3 percent of patients treated with steroid injections, as measured by the Oxford Knee Score¹. The Oxford Knee Score is a validated outcomes instrument designed to assess function and pain associated with the knee¹.
- In addition, the cooled RF patient group's Oxford Knee Score remained low for 12 months with only 11.5 percent reporting severe symptoms at that point¹.

"This study proves that COOLIEF* Cooled RF provides more lasting relief than steroid injections for patients suffering from chronic osteoarthritis knee pain," said Dr. Davis. "Many patients are not immediate candidates for knee replacement surgery and other patients choose to delay surgery. It's important that these patients know they have other options for treating their chronic pain so they can get back to their normal lives faster."

"Healthcare providers wrote 259 million prescriptions for opioids in 2012—that's enough for every American adult to have their own bottle of painkillers³," said Lisa Kudlacz, vice president and general manager, Global Interventional Pain, Halyard Health. "Halyard is committed to providing patients with treatments like COOLIEF* Cooled RF that provide physicians and patients with safer and highly-effective alternatives to prescription opioids for the treatment of chronic pain."

To learn more about COOLIEF* Cooled RF, please visit <http://www.halyardhealth.com/chronicpain>.