

March 20, 2017



Kevin Friedman DO
Medical Director
Halyard Health
Submitted electronically: Kevin.Friedman@hyh.com

Re: Cooled Radiofrequency Neurotomy

Dear Dr. Friedman:

The Spine Intervention Society (SIS), a multi-specialty association of more than 2,600 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to thank Halyard Health for reaching out to seek SIS' support for the capability of cooled radiofrequency neurotomy to achieve tissue temperatures at or above 80° C/176° F.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

We would specifically like to support any efforts to appropriately classify cooled radiofrequency neurotomy procedures as thermal ablative procedures. Cooled RF should not be confused with cryoablation. While the name may be misleading, the procedure achieves thermal denervation or ablation of nerve tissue. (1) Studies have validated that cooled radiofrequency reaches ablative temperatures at or above 80° C/176° F in tissues adjacent to the probe tip similar to ablative temperatures with conventional radiofrequency procedures. (2-9) For this reason, payers should correctly classify the procedure as thermal radiofrequency neurotomy.

We invite you to share this letter with payers who currently classify cooled radiofrequency neurotomy as investigational. We hope that our comments will assist in establishing reasonable coverage policies for cooled radiofrequency neurotomy. We offer our ongoing input and expertise in this matter. If we may answer any questions or

provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@spineintervention.org.

Sincerely,



John MacVicar, MB ChB
President
Spine Intervention Society

References:

1. Principles of Thermal Radiofrequency Neurotomy. In: Bogduk N, editor. Practice Guidelines for Spinal Diagnostic and Treatment Procedures. 2nd edn ed. San Francisco: International Spine Intervention Society; 2013. p. 19-32.
2. Ball RD. The science of conventional and water-cooled monopolar lumbar radiofrequency rhizotomy: an electrical engineering point of view. *Pain Physician*. 2014;17(2):E175-211.
3. Biswas BK, Dey S, Biswas S, Mohan VK. Water-cooled radiofrequency neuroablation for sacroiliac joint dysfunctional pain. *J Anaesthesiol Clin Pharmacol*. 2016;32(4):525-7.
4. Cheng J, Chen SL, Zimmerman N, Dalton JE, LaSalle G, Rosenquist R. A New Radiofrequency Ablation Procedure to Treat Sacroiliac Joint Pain. *Pain Physician*. 2016;19(8):603-15.
5. Cosman ER, Jr., Dolensky JR, Hoffman RA. Factors that affect radiofrequency heat lesion size. *Pain Med*. 2014;15(12):2020-36.
6. Goldberg SN, Gazelle GS, Solbiati L, Rittman WJ, Mueller PR. Radiofrequency tissue ablation: increased lesion diameter with a perfusion electrode. *Academic radiology*. 1996;3(8):636-44.
7. Lorentzen T. A cooled needle electrode for radiofrequency tissue ablation: thermodynamic aspects of improved performance compared with conventional needle design. *Academic radiology*. 1996;3(7):556-63.
8. Lorentzen T, Christensen NE, Nolsle CP, Torp-Pedersen ST. Radiofrequency tissue ablation with a cooled needle in vitro: ultrasonography, dose response, and lesion temperature. *Academic radiology*. 1997;4(4):292-7.
9. Stelzer W, Stelzer V, Stelzer D, Braune M, Duller C. Influence of BMI, gender, and sports on pain decrease and medication usage after facet-medial branch neurotomy or SI joint lateral branch cooled RF-neurotomy in case of low back pain: original research in the Austrian population. *J Pain Res*. 2017;10:183-90.