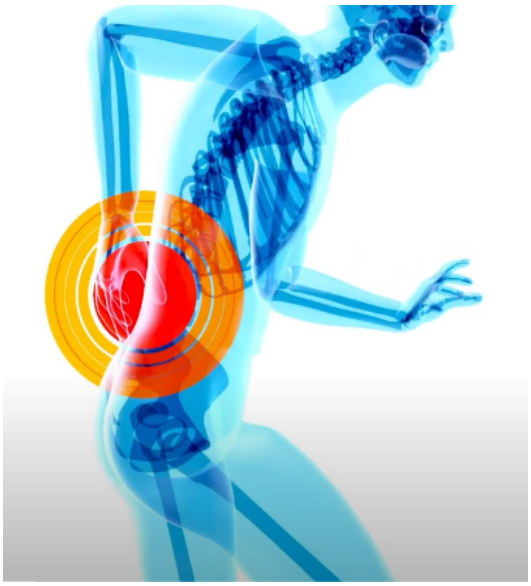


The Science & Art of Radiofrequency Ablation (RFA) for Chronic Pain

"I have a master's degree in clinical social work. I have a well-documented illness that explains the cause of my pain. But when my pain flares up and I go to the ER, I'll put on the hospital gown and lose my social status and my identity. I'll become a blank slate for the doctors to project their own biases and prejudices onto. That is the worst part of being a pain patient. It strips you of your dignity and self-worth." *—A patient with chronic pain*[1]

Sad, sleepless, and suffering is no way to go through life; yet patients living with chronic pain find themselves caught in this "terrible triad," and may resort to seeking relief with repetitive surgeries, questionable treatments, and potentially addictive drugs (e.g., opioids).[2] The multidimensional nature of chronic pain can pervade all aspects of patients' personal and professional lives. Nevertheless, advancements such as chemical neurolysis, cryoablation, and radiofrequency ablation (RFA) continue to improve the outlook for patients with chronic pain.[2-5] Clinicians have found that RFA offers the highest precision treatment for chronic pain.[5] But there is an art to RFA in the technique and the tools. From the patient perspective, how well (and how kindly) the procedure is performed can either keep them coming back or keep them away.

Your patients rely on your pain management expertise. Since 1995, Spectra Medical Devices has been supporting clinicians' expertise to help treat patients' pain. Spectra uses pain management specialists' feedback in design and development to create and improve its products. In turn, Spectra provides clinicians with top quality pain management tools. Although you may not realize it, Spectra's pain management products are used worldwide and utilized by leading original equipment manufacturers (OEMs).[6] In fact, many leading clinicians in interventional pain management prefer Spectra needles.[6,7] To learn more and hear from one of them, download this white paper.

The Burden of Chronic Pain

Globally, between 10% and 25% of adults have chronic pain.[8,9] Among the 20% of adults living with chronic pain in the United States (US), the highest prevalence is among white, non-Hispanic women aged 65 and older.[10] Chronic pain decreases physical and mental functioning, quality of life, and work productivity, and is one of the most frequent reasons for physician visits, pain medication prescriptions, and work disability claims.[1,2] Sedentary lifestyles, increasing obesity, and aging populations further contribute to the burden of chronic pain and its management.[1,2] Patients who are not candidates for or not amenable to surgery, lack health insurance, or are fear-avoidant may find it especially difficult to seek care, and delaying treatment may exacerbate their condition. Moreover, pain is strongly associated with poor clinical outcomes and exorbitant health care costs.[1,2] In fact, pain is such a staggering public health problem that the International Pain Society and Global Health Community stated in 2004 that "failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right," after which international laws began mandating that health care providers manage their patients' pain.[8]

Low back pain (LBP) and arthritic joint pain are the two most common types of chronic pain, of which the former is the most debilitating.[2] Globally, between 21% and 75% of adults suffer from LBP,[11] and 242 million people have symptomatic osteoarthritis (OA) of the knee or hip limiting their activity.[12] In the US, estimates from the Centers for Disease Control (CDC) place the prevalence of OA at 32.5 million adults.[12]

LBP experiences are unique to each person and influenced by a variety of factors, including biological, psychological, and societal.[9] Since 1990, LBP has remained the leading cause of years lived with disability.[8,9] Persons facing pain as a disability tend to be older, have poorer mental or physical health, worsened baseline function, higher stress, and increased presence of compensation.[9] Additionally, socioeconomic factors such as low income, employment or insurance status, health care access, and physically demanding occupations (e.g., long hours, lack of supporting staff, and repetitive or manual lifting) greatly influence the patient's pain management experience.[9]

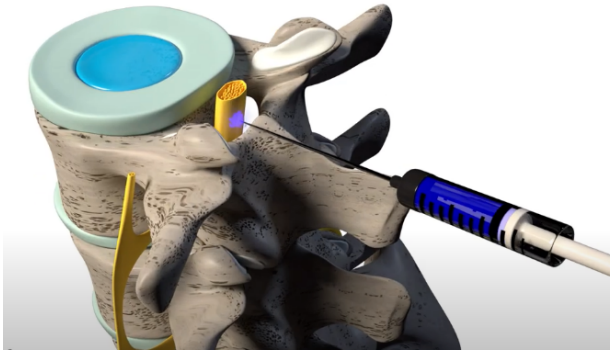
Managing Chronic Pain

The use of needles to manage pain is not a new concept; acupuncture has been practiced for more than 2,000 years.[2] Although acupuncture has relied on indirect modulation of the nervous system to manage pain, modern approaches have had a stronger effect by directly targeting the nervous system. RF needles were first used in 1931 to treat trigeminal neuralgia.[5] Widespread usage of RFA has followed due to advantages of precision, effectiveness, considerable safety margin, and reproducibility.[5] A study has shown that advancements in needle size, thermal energy application, patient selection, and patient safety have greatly improved the effectiveness of RFA in reducing pain long-term (at least 6 months) and improving function/range of motion, decreasing use of pain medication, and delaying or avoiding surgery.[13]

Interventional pain management specialists strive to alleviate their patients' pain long-term using minimally invasive, nonsurgical modalities that effectively ablate nervous system elements.[5] Several clinical practice guidelines recommended acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) as first-line treatment for OA or LBP.[14] In advanced disease, steroids and opioids are also used pharmacologically. Nonpharmacologic therapies such as stretching, heat application, and massage may be beneficial, but are generally

not considered long-term solutions.[4] Additionally, RFA is a promising alternative to opioids. Given opioids' enormous potential for harm (e.g., opioid use disorder, overdose, motor vehicle injury), many clinicians believe that the risks associated with them tend to outweigh the benefits.[15-17] Although they are commonly prescribed after surgery, opioids do not target the inflammation causing low back or arthritic joint pain. A systematic review of randomized clinical trials assessing pain and function among opioid users versus non-users showed no long-term benefit at 1-year follow-up, and patients prescribed opioids for LBP were more likely to use them long-term.[14,18] This further emphasizes the need for alternative pain management solutions.

Typically, RFA follows steroidal or other injections that are administered to control pain in the facet or sacroiliac joint nerves. Facet joint nerves are targeted in medial branch RFA, whereas sacroiliac joint nerves in the posterior sacrum are targeted in lateral branch RFA.[13]



RFA can be performed in-office as an out-patient procedure under local anesthesia, and most patients can return to their daily activities within 24 hours.[3] Prior to the procedure, the target nerve is located using lateral or medial branch diagnostic nerve blocks.[13] RFA is then performed on the confirmed nerve that responds to the block.[13] During the procedure, a high-frequency alternating current is passed through a needle and produces a focal and precise thermal lesion in the target nerve to interrupt nociceptive afferent pathways (e.g., cordotomy, rhizotomy, ganglionotomy, or neurotomy).[13,19] Imaging techniques such as fluoroscopy or ultrasound are used to visualize the target nerve location during placement of the radiofrequency (RF) needle.[3,13] Following correct needle placement, an active electrode is inserted through the hollow needle shaft, and a small amount of stimulating current is used to confirm the target nerve and ensure safe distance from other nerves.[13] Once the target nerve is verified, a local anesthetic is applied to numb it so that a heat lesion can be comfortably created using continuous (conventional), pulsed, or cooled RFA.[13] The probe sends RF waves into surrounding tissue, causing nearby nerve cells to degenerate, which can be removed by the patient's own immune system.[3] The resulting localized inflammation can be controlled with NSAIDs.

Medicare generally covers RFA after step therapy with medial branch anesthetization and repeat procedures every 6 months.[20,21] Private insurance step therapy requirements and coverage may vary, but generally follow Medicare's example.

RFA for Low Back Pain (LBP)

LBP stemming from vertebral facet joints or the posterior sacroiliac joint complex may be successfully treated using RFA.[13,22,23] RFA of the medial branch nerves for facet-mediated LBP has demonstrated durable pain relief.[22,23] A study measuring improvement in pain, function, and analgesic use in lumbar facet syndrome has shown clinical benefit for 6 to 12 months, with some patients experiencing relief up to 2 years later.[22,23] More than half of patients (58%) had at least 50% improvement in function and 53% pain reduction, with no treatment-related complications.[23] Additionally, a study of patients with LBP due to sacroiliac joint dysfunction for whom conventional medical management and/or rehabilitation had failed to

provide relief has demonstrated that subsequent RFA treatment provides analgesic benefit as well as reduces the use of pain medication.[24]

RFA for Joint Pain

Osteoarthritic joint pain may be treated with RFA under ultrasonographic or fluoroscopic visualization with newly emerging interventional techniques by applying pulsed RF,[25] thermal coagulation,[24] or multi-tined needles.[26] RFA for OA-associated knee pain is typically performed fluoroscopically, but a patient case report has shown satisfactory results using ultrasound.[27] A case series on OA-associated knee pain has also shown pain relief after ultrasound-guided RFA of genicular nerves, which lasted 6 months or longer.[28] A systematic review and meta-analysis of ultrasound-guided RFA for OA-associated knee pain reports pain relief and functional improvement.[29] Moreover, a case report on chronic post-arthroplasty hip pain has demonstrated that ultrasound-guided RFA targeting the articular branches of the femoral nerve is an effective and minimally invasive therapeutic option.[30]

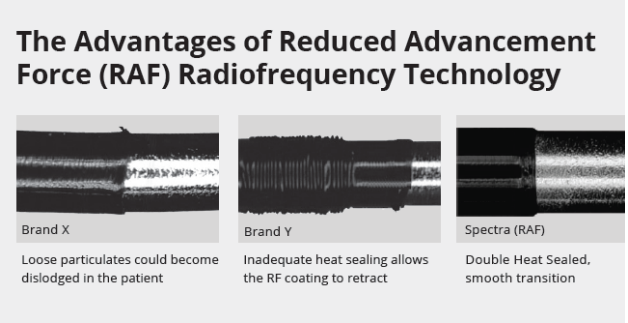
Safety of RFA

The use of lumbar facet blocks and RFA has increased considerably over the past 20 years. The procedure is generally less risky than open surgery, and complications such as bleeding, infection, or numbness/tingling at the injection site are rare.[3,31] Additionally, the American Society of Regional Anesthesia and Pain Medicine updated its clinical practice guidelines for RFA in 2020, concluding that well-selected patients may benefit from lumbar medial branch RFA.[32]

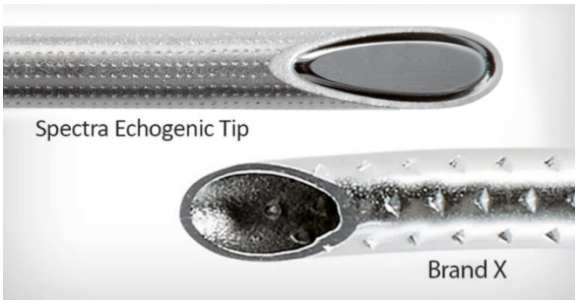
The Spectra Medical Devices RF Needle

Established in 1995, Spectra Medical Devices, is one of the largest procedural needle manufacturers in the world.[6,33] Spectra's products are sold in nearly 50 countries, and the company is a leader in procedural needle growth and innovation.[33] Spectra produces top-quality products and applies state-of-the-art technology in compliance with the US Food and Drug Administration (FDA) Quality System Regulation (QSR)/Current Good Manufacturing Practice (CGMP) rules.[33-35] Spectra's production facilities adhere to high regulatory standards, exceeding industry standards to continually produce top-quality medical equipment under strict quality control.[33] Importantly, supply chain issues that have affected so many businesses during the COVID-19 pandemic have not had major impacts on Spectra's inventory or order delivery time.

Certain aspects of Spectra's RF needles have been awarded several US patents.[33] Spectra offers the largest variety of RF needle gauge sizes (16-22GA), shaft lengths (5-20 cm), active tip lengths (4-20 mm), echogenicity (for ultrasound-guided clarity), and lubrication in the industry.[33] The needles are made from the highest tensile strength 304 stainless steel using state-of-the-art technology.[33] Spectra's reduced advancement force (RAF) technology is aimed at offering smoother insertion, less trauma to the patient, and more accurate placement.[7,33]



Additionally, the double-heat seal on the insulation significantly reduces the chance of coating retraction or peel-back. The double-heat seal also reduces the transition point between the RF coating and the active tip, with a goal of improving patient comfort during needle insertion.[7] The proprietary dimpling on the echogenic needle reduces acoustic shadowing to create a clear, defined image under ultrasound.[6,33]



Since 2020, Spectra Medical Devices has sold more than 3.5 million RF needles. Needles are available individually packaged, and as either sterile or non-sterile. Spectra's new dedicated packaging facility has fully validated processes available for contract-packaged sterile needles and for contracted packaging solutions to market products as quickly and easily as possible. Spectra offers an array of packaging options to meet customer needs and provides private labeling and appropriate studies establishing FDA sterility assurance level (SAL), bioburden, non-pyrogenicity, nontoxicity, residual ethylene oxide (EtO), package integrity, and bacteriostasis/fungistasis for its standard products.[33]

Perspectives from a Leading Interventional Pain Management Specialist

Attesting to its strong customer-centric focus, Spectra Medical works with leading clinicians to develop and continuously improve its products. Dr. Thomas Simopoulos,* an anesthesiologist and associate professor of pain medicine at Harvard Medical School, is a leader in pain management and prefers the Spectra RF needle over competitors' brands. Dr. Simopoulos cites the high product quality, the quick order turnaround time, and the patient experience as the most important qualities of Spectra's RF needles.[7] These advantages also facilitate easier training of current and future pain management specialists to provide the best care and procedure experience to their patients. Further insights from Dr. Simopoulos can be found in this video: https://www.youtube.com/watch?v=nlk2tlnQOMs[7]

*Dr. Simopoulos is a paid consultant for Spectra Medical Devices.

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