

COOLIEF* COOLED RF: A proud history of firsts

2001 FDA Clearance of Pain Management Generator

2013 Hip and Knee Modalities Launched

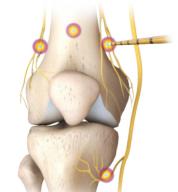
2014 Multi-Cooled Radiofrequency Launched

2017 FDA cleared to treat OA Knee pain

2018 Cooled RF of the Knee Technique Utilizing Ultrasound Guidance

2019 Shoulder Modality Launched

GET YOUR PΔTIENTS BΔCK TO THE THINGS THΔT ΜΔTTER.



COOLIEF* Cooled RF - the first cooled RF treatment for chronic OA knee pain - is now the first to bring ultrasound guided cooled RF to the knee

COOLIEF* Cooled RF for Knee Pain

Benefits include:

- No radiation
- Real-time guidance
- Soft tissue visualization (including effusions)
- Doppler (genicular nerve visualization)

The COOLIEF* Cooled RF ULTRASOUND guided technique targets the genicular nerves <u>outside</u> the <u>articular capsule</u> and <u>reduces amount and time of fluoroscopic exposure</u>.

OA knee pain patients experiencing **sub-optimal outcomes with alternatives therapies** such as arthroscopic debridement or injections are **not always candidates for more invasive procedures** due to **age, BMI, or other comorbidities**.

COOLIEF* Cooled RF technology is designed to treat the **complex** anatomy of variable nerve courses through the creation of large volume spherical lesions.

Ask about our other COOLIEF* Cooled RF Modalities:

Clinical studies of COOLIEF* Cooled RF addressing other sources of pain have demonstrated up to 24 months pain relief with improved physical function and a reduction in pain medication usage.³, ⁴

COOLIEF* Cooled RF for Hip Pain:



Designed to treat complicated and variable nerve courses such as the articular innervation of the hip through the creation of large volume, spherical lesions.

COOLIEF* Cooled RF for Shoulder Pain:



Treats chronic shoulder pain through the creation of large volume, spherical lesions.

Learn more about how COOLIEF* Cooled RF can fit into your treatment algorithm for chronic OA knee patients.

CooliefForOrthos.com

References: 1. Davis T. Study: Cooled RF Ablation Superior to Corticosteroids in Knee Osteoarthritis. Pain Medicine News 2017 Feb.

2. Halyard Health Inc. sponsored study: A Prospective, Multi-Center, Randomized, Clinical Trial Evaluating the Safety and Effectiveness of Using COOLIEF™ Cooled Radiofrequency Probe to Create Lesions of the Genicular Nerves and Comparing Corticosteroid Injection in the Management of Knee Pain. Final results 03Apr2017. Study available upon request from Avanos.

3. Stelzer W. MD, Use of Radiofrequency Lateral Branch Neurotomy for the Treatment of Sacroilliac Joint-Mediated Low Back Pain: A Large Case Series. Pain Medicine, 2013 Jan (1)29-35.

4. Malik, A. et al. Percutaneous Radiofrequency Lesioning of Sensory Branches of the Obturator and Femoral Nerves for the Treatment of Non-Operable Hip Pain. Pain Physician. 2003;6:499-502



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Treatment Options for Osteoarthritis Knee Pain Have Expanded, Providing Patients Long-Term Relief.

Orthopedic and Sports Medicine Physicians now have a long-lasting solution to fill the gap in the treatment algorithm.

THE TREATMENT CHALLENGE

Total knee replacement isn't always an option for up to 60% of patients with osteoarthritis (OA) knee pain due to BMI, age, invasiveness and other factors, including the amount of time needed for rehabilitation and recovery. Because of this, patients often will endure pain for 9 years, or longer, until surgery becomes the only option remaining.

Managing patient OA knee pain can be a challenge with today's limited treatment algorithm, as injections and medications only provide short-term relief.



Intra-articular steroid injections have been shown to decrease in effectiveness after 3-4 weeks, and after multiple injections.

According to the AAOS Treatment of Osteoarthritis of the Knee Guidelines, 2nd Edition, 2013:



Unable to recommend for or against the use of intra-articular (IA) corticosteroids for patients with symptomatic osteoarthritis of the knee.*



Cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.*

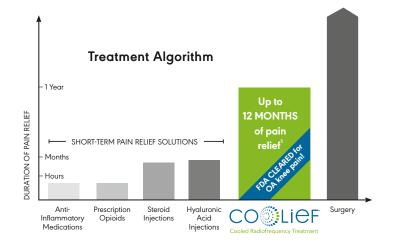
COOLIEF* COOLED RF-FDA CLEARED FOR OA KNEE PAIN

New **ULTRASOUND** guided procedure for the relief of Osteoarthritis knee pain

COOLIEF* Cooled RF is the **first and only** radiofrequency treatment **FDA-cleared** for the relief of **Osteoarthritis knee pain**.

COOLIEF* Cooled RF is a non-surgical, **non-narcotic,** thermal radiofrequency pain management system that uses water cooled technology to **safely deactivate pain-causing sensory nerves**.

Clinically proven to provide up **12 months of** pain relief.¹



HOW COOLIEF* Cooled Radiofrequency (RF) WORKS



The COOLIEF* Cooled Radiofrequency Generator transmits a small current of RF energy through an insulated electrode placed within the knee's tissue



The electrode delivers water-cooled energy through RF electrodes



This RF energy creates a targeted lesion that ablates and deactivates the sensory nerves responsible for sending pain signals to the brain, while leaving motor nerves intact to preserve function.

CLINICAL DATA SUPPORTS COOLIEF* COOLED RF FOR TREATMENT OF OA KNEE PAIN

Provides patients with longer lasting and more effective pain relief than intra-articular steroid injections²

6 months post-procedure, patients reported ≥ 50% pain relief:

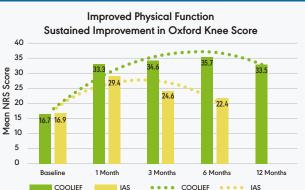
- 74% of COOLIEF* group
- 16% of IAS group

12 months post-procedure, 65% of COOLIEF* Cooled RF patients reported ≥ 50% pain relief.

• 85% of the IAS group switched to COOLIEF* Cooled RF at 6 months

The 11-point NRS consists of a scale from "0" to "10" points, with "0" indicating "no pain" and "10" being "worst pain imaginable". A treatment "responder" experienced a clinically-significant change in pain indicated by an NRS score decrease $\geq 50\%$ relative to the respective baseline.





At baseline, patients reporting severe OA:

- 67% of the COOLIEF* Cooled RF group
- 63% of the IAS group

6 months post-procedure, patients reporting severe OA:

- 5% of the COOLIEF* Cooled RF group
- 37% of the IAS group

OKS measured study subjects' knee function based on a scale from 0 to 48 points, with knee arthritis becoming less severe as score values increase.

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