Health Technology Review	
Technology Ref.:	HTA24050
Technology Name/Version/Model:	Cooled Radiofrequency Ablation
Approvals by International Bodies:	FDA (May 2023), CE Mark, ISO Manufacture
Company name:	Avanos USA, United States
Agent in UAE:	Health Point Hospital
Email:	m.boutros@healthpoint.ae

Short Description of the Technology:	COOLIEF* Cooled Radiofrequency Ablation is designed to provide long-term pain relief through the targeted disruption of pain signal transmission in sensory nerves. It is particularly effective for patients who are not suitable candidates for surgery. It uses internally water-cooled electrodes to prevent tissue overheating, allowing for larger areas to be treated without causing damage. FDA-cleared radiofrequency treatment for osteoarthritis knee pain. Technology uses cooled radiofrequency to create a heat lesion at the target nerve, interrupting pain signals, which results in chronic pain relief. • Clinical Evidence/ Efficacy. Population: Patients with chronic pain, especially those with knee, hip, or shoulder pain. Intervention: Cooled Radiofrequency Ablation. Comparator: Traditional pain management techniques like steroid injections. Outcomes: Improved pain relief, reduced need for analgesics, and enhanced quality of life. Effectiveness of COOLIEF vs. Steroid Injections: In a recent clinical study comparing the effectiveness of COOLIEF* Cooled RF versus intra-articular steroid injections for treating osteoarthritis knee pain, COOLIEF* was found to provide significantly greater and longer-lasting pain relief. Numeric Rating Scale Mean baseline pain scores in the CRFA (n = 76; 7.3 ± 1.2) and IAS (n = 75; 7.2 ± 1) cohorts were not different (P = 0.55, Wilcoxon rank sum test) . Within both study groups at 1, 3, and 6 months, mean pain score was reduced (P < 0.0001 at each data point, paired Student t test) relative to baseline. CRFA > IAS (P = 0.02). There were no procedure-related serious adverse events. Improvement Metrics: 1. COOLIEF* provided up to 24 months of pain relief for some patients. 2. The study demonstrated that patients treated with COOLIEF*

	experienced greater reductions in pain and improvements in physical function compared to those receiving steroid injections. 3. Patients treated with COOLIEF* reported higher satisfaction rates compared to those who underwent conventional treatments. • Safety/ Risk issues. 1. Patients with surgical complications can use other methods of treatment. 2. No safety issues or recalls have been reported. •Place in therapy/ diagnosis. Patients with chronic pain conditions, particularly those who are resistance and non responsive to standard of care medications: Anti-inflammatories, opioids, steroid injections. and those those unsuitable for surgery: Joint replacements, which carry higher risks and longer recovery times.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	
COOLIEF* provides a minimally invasive approach to pain management, demonstrating significant benefits in terms of patient comfort and long-term pain relief. We recommend **the approval of the use of this technology** for Market entry with the following conditions: 1. Implementation of a structured training program for healthcare providers on the use of COOLIEF* technology and must be certified in its operation and safety protocols. 2. Ensure that all safety precautions and guidelines provided by Avanos are strictly followed to prevent risks such as RF burns and unintended stimulation. 3. Continuous monitoring of patient outcomes to ensure the technology's effectiveness and safety. 4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees. 5. Provision of regular updates and reports about the product to DOH upon request. **Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.	

Technology Image


Population, setting and intended user for Technology "Cooled Radiofrequency Ablation"

- **Population/ Intended User;**
  - Patients with chronic pain conditions, particularly those unsuitable for surgery.
- **To be performed by:**
  - Trained and certified healthcare professionals specializing in pain management.
- **Clinical Setting:**
  - Outpatient clinics, pain management centers.
- **Condition of use:**
  - To be used in accordance with manufacturer guidelines and clinical best practices.
- **Exclusion criteria:**
  - Patients with contraindications to radiofrequency treatments or those who may not benefit from minimally invasive procedures. Full assessment of patients with comorbid conditions to avoid potential complications.