Health Technology Review	
Technology Ref.:	HTA24028
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Technology Name/Version/Model:	IonicRF™ Generator, Model number: RFG-IONIC
Approvals by International Bodies (year):	MOHAP classification letter U.S. FDA approval (2020)
Manufacturer/ Company name, country of Origin	Abbott, United States
Agent in UAE:	Al Amin Medical Instruments LLC
Class/ Type	Class IIb Medical Device Directive 93/42/EEC as amended by 2007/47/EC, Annex IX, Rule 9 – Radiofrequency Ablation System Generator.
Licensed Indications	Management of various chronic pain, including: • Neck • Upper and lower back • Sacroiliac joint • Facial pain
Cost and Comparisons with standard of Care	**Cost Effectiveness:** Studies have shown that IonicRF™ Generator can significantly reduce the need for opioid medications, which are often used for managing chronic pain. This reduction can lead to lower medication costs and decrease the risk of opioid dependency and associated healthcare costs. **Comparison with Standard of Care:** Compared to surgical options, medications and physical therapy, the IonicRF™ Generator offers longer-lasting relief, which can be more cost-effective in the long run despite higher upfront cost.
Administration/ Use	IonicRF™ Generator (RFG-IONIC) involve careful patient selection, precise electrode placement, and controlled delivery of radiofrequency energy to ablate target nerves. This minimally invasive procedure offers significant pain relief for patients suffering from chronic pain that has not responded to other treatments.

Short Description of the Technology:	**Introduction:** The IonicRF™ Generator is designed to precisely target specific nerves responsible for transmitting pain signals. By delivering controlled radiofrequency energy, it generates heat that creates thermal lesions on the nerve tissue, effectively blocking pain signals from reaching the brain.

Mechanism of Action:
The procedure begins with the precise placement of a specialized electrode at the target site. This placement is guided by imaging techniques such as fluoroscopy or ultrasound to ensure accuracy. The IonicRF™ Generator produces radiofrequency energy, which is delivered through the electrode. This energy generates heat at the tip of the electrode. The radiofrequency energy heats the targeted nerve tissue to a temperature typically between 60°C and 80°C. This controlled heating creates a thermal lesion, effectively ablating the nerve. The precision of the device allows for the selective ablation of the nerve tissue responsible for transmitting pain signals while minimizing damage to surrounding tissues. By creating a thermal lesion, the IonicRF™ Generator deactivates the targeted nerves. This interruption prevents the transmission of pain signals from the affected area to the brain, thereby reducing or eliminating the sensation of pain.

Clinical Evidence/ Efficacy:
Studies shows that most people have some pain relief after radiofrequency ablation, but the amount varies by cause of pain and location. Pain relief can be immediate in some people, occur within 10 days in other people or may take up to three weeks in others.
Pain relief can last from six months to 12 months.
A total of 21 randomized controlled trials meeting appropriate inclusion criteria were assessed in this evaluation. A total of 5 observational studies were assessed. In the lumbar spine, for long-term effectiveness, there is Level II evidence for radiofrequency neurotomy and lumbar facet joint nerve blocks, whereas the evidence is Level III for lumbosacral intraarticular injections. In the cervical spine, for long-term improvement, there is Level II evidence for cervical radiofrequency neurotomy and cervical facet joint nerve blocks, and Level IV evidence for cervical intraarticular injections. In the thoracic spine there is Level II evidence for thoracic facet joint nerve blocks and Level IV evidence for radiofrequency neurotomy for long-term improvement.

- Key Studies and References:

1. ClevelandClinic. https://my.clevelandclinic.org/health/treatments/17411-radiofrequency-ablation. Accessed October 2020.
2. Manchikanti L, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. Pain Physician 2015; 18:E535-E582
3. Pope JE, Cheng J. Facet (Zygapophyseal) Intraarticular Joint Injections: Cervical, Lumbar, and Thoracic. Injections for Back Pain. 129-135. ClinicalKey.com. Accessed October 2020.

Studies (PICO):

1. Population: patients suffering from chronic pain, particularly those with conditions such as lower back pain, sacroiliac joint pain, and facet joint syndrome.
2. Intervention: treatment using the IonicRF™ Generator, which employs

	radiofrequency ablation (RFA) to manage chronic pain. The procedure involves the use of radiofrequency energy to create thermal lesions in specific nerve tissues to block pain signals. 3. Comparator: conventional treatments for chronic pain, including opioid medications, physical therapy, steroid injections, and surgical interventions. The efficacy, safety, and patient outcomes of the IonicRF™ Generator are compared to these standard treatments. 4. Outcomes: - Reduction in pain intensity and frequency, measured by standardized pain scales (e.g., Visual Analog Scale (VAS), Numeric Rating Scale (NRS)). - Improved physical function and quality of life. - Reduced reliance on opioid medications, and lower incidence of adverse effects compared to traditional treatments. Safety/ Risk issues: Risk issues: • Hazardous electrical output. The generator is for use only by qualified medical personnel. • Electric shock hazard. This device presents an electric shock hazard under certain conditions. • Explosion hazard. Should not be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. • Fire hazard. This device presents a fire hazard under certain conditions. Should only use recommended non-flammable agents for cleaning and disinfection whenever possible. • • Pooling hazard. Flammable solutions may pool under the patient or in body depressions, such as the umbilicus, and in body cavities, such as the vagina. • Ignition hazard. • Risk of RF burns and unintended stimulation. • Risk of RF burns to patient. Place in therapy/ diagnosis A valuable for patients whose chronic pain has not responded to conservative treatments such as medications, physical therapy, or injections. This makes it a critical option for patients looking for effective pain relief without the need for more invasive surgical procedures

Health Technology Assessment Team Recommendation:	Approved

Summary of Review:

The IonicRF™ Generator is an advanced device offering a tailored approach to pain management for patients who have not responded to other treatments. It is effective in targeting multiple discrete areas of the body for pain relief.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. IonicRF™ Generator, Model number: RFG-IONIC.
2. Ensure that all healthcare professionals using the IonicRF™ Generator are adequately trained and certified in its operation and safety protocols.
3. Ensure that all safety precautions and guidelines provided by Abbott are strictly followed to prevent risks such as RF burns and unintended stimulations.
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 "Ionic Radiofrequency Generator"

- **Population/ Intended User**:
  - Patients suffering from chronic pain have not found relief through conservative treatments.
- **To be performed by**:

- Qualified healthcare professionals.

- **Clinical Setting:**
  - Hospital or specialized pain management clinics.
- **Condition of use:**
  - Used in accordance with the manufacturer's instructions and under medical supervision.
- **Exclusion criteria:**
  - Patients with active implants such as pacemakers, or those with conductive implants should be evaluated individually for safety.