



Health Technology Review	
Technology Ref.:	HTA22034
Technology Name:	Cryoflex CRYO-S Painless
Approvals by International Bodies:	CE-Marked
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Short Description of the Technology:	CRYO-S Painless device is special design for cryoanalgesia. It is a transcutaneous, micro invasive and highly effective pain management method using the effect of freezing nerves. The greatest advantages of this method are the breaking or reduction of patient's addiction to analgesics, including opioids
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The device is using the cryoanalgesia technology, it is a specialized technique for providing long-term pain relief in interventional pain management settings. It's a technique where the cold temperature used to reduce the pain signal to the brain by freezing the responsible nerves part for pain. Cryoanalgesia disrupts the nerve structure and creates Wallerian degeneration, but leaves the myelin sheath and endoneurium intact. Which allow a relief from pain without causing the damage to the nerve for several months. It's a minimally invasive procedures that may enhance the patient quality of life. The procedure shall be done in clinical setting, using a CT scan or ultrasound device to allocate the targeted nerves and using a local anaesthetic. The device uses for several pain management cases such as Acute postoperative pain from thoracotomy, Facial pain syndromes, Perineal neuropathies, etc.</p>	
Advantages	Disadvantages



<p>Technology Efficacy: The technology proven efficacy for pain relief potentially lasting weeks to months for patients with Chronic pain condition such as: occipital neuralgia, meralgia paresthetica and other, it may serve as a form of pre-emptive anaesthetic and may facilitate prolonged relief.</p>	<p>Risk: There are few relative or absolute contraindications to cryoneurolysis; these include anticoagulation, bleeding disorders, localized infection, cryoglobulinemia, cold urticarial, paroxysmal cold haemoglobinuria and Raynaud’s syndrome. Risks include bleeding, bruising, and if the ice ball involves the skin frostbite, alopecia, depigmentation and/or hyperpigmentation. Some newer cryoprobes specifically designed to treat superficial nerves integrate a skin warmer that protects the skin and hair from the freezing temperature. Damage to surrounding tissue may occur if the probe is moved prior to an adequate thaw period, as the tissues can adhere to the probe. Infection appears to be extremely rare.</p>
<p>Safety: Micro invasive procedure, Complications are minimal and are largely related to the procedure itself, especially the location of the nerve to be blocked, there is no effect on nearby tissues</p>	<p>Restricted conditions: The procedure shall be guided by ultrasound device in a clinical setting and performed by physicians with appropriate sterile preparation.</p>
<p>Reversible effect; the technology targeted axon in nerve (the part that carry the pain signal to brain) which regenerates with a rate of 1 mm to 2 mm per day until nerve signalling is fully restored, while the structural components of the nerve are not affected.</p>	<p>Temporary solutions for pain relief; Patients should be fully aware that a cryoanalgesia procedure usually is not a permanent solution</p>
<p>Enhance Quality of life in patients with chronic pain conditions; it help in managing the patient chronic pain by providing them temporary relief, and it could be an alternative option of drugs and thus reducing the drugs intake such as analgesics, including opioids</p>	
<p>Fast recovery: Fast return to normal activities – no hospitalization required and the procedure Can be repeated.</p>	
<p>Device: its CE Marked device, complies with the requirements of ISO 13485: 2016, under the supervision of TUV NORD Poland with no recall or safety notice registered.</p>	

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

1. The Medical device shall be used by Expert Physician in a clinical setting .
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the

approval process.

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 “Cryoflex CRYO-S Painless”

- **Population/ Intended User;**
 - Patients with chronic pain
 - Best patients for cryoanalgesia are those with chronic pain at the level of over 5 in visual analogue scale (VAS)
 - Clinical application:
 - Knee pain prior or secondary to infrapatellar branch of the saphenous nerve, anterior femoral cutaneous nerve, genicular nerve after knee arthroplasty or total knee replacement
 - Various types of peripheral neuropathy
 - Diabetic neuropathy
 - Low back pain and lower extremity pain secondary to lumbar facet joint pathology, pseudosciatica
 - Phantom pain
 - Morton’s neuroma, heel pain
 - Sacroiliac joint pain, cluneal neuralgia, obturator neuritis
 - Chest wall pain with multiple conditions including post-thoracotomy neuromas, persistent pain after rib fractures and post herpetic neuralgia in thoracic distribution
 - Abdominal and pelvic pain secondary to ilioinguinal, iliohypogastric, genitofemoral, subgastric neuralgia, pudendal neuralgia
 - Craniofacial pain secondary to trigeminal neuralgia, posterior auricular neuralgia, and glossopharyngeal neuralgia
 - Upper extremity pain secondary to suprascapular neuritis and other conditions of peripheral neuritis
- **To be performed by:**
 - Recommended for Pain Management Specialists:
 - Anesthesiologists
 - Neurosurgeons
 - Orthopedists
 - Spine Surgeons
 - Interventional Radiologist
- **Clinical Setting:**
 - Hospitals and specialized clinics.
- **Condition of use:**
 - Procedure recommended especially when traditional methods prove to be unsatisfactory.
- **Exclusion criteria:**
 - Other conflicting medical issues