



Health Technology Review	
<b>Technology Ref.:</b>	HTA23033
<b>Technology Name:</b>	Thyroid ablation by laser
<b>Approvals by International Bodies:</b>	Echolaser X4 is FDA approved for Soft Tissue Ablation CE certified
<b>Company name:</b>	<b>Mediclinic</b>
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<b>Short Description of the Technology:</b>	<p>It is a procedure intended for surgery for benign lesions;</p> <ul style="list-style-type: none"> <li>- Big thyroid nodules</li> <li>- Nodules increasing size</li> <li>- Symptomatic lesion</li> <li>- Lesions causing compressing effects</li> </ul> <p>Done as day case;</p> <ul style="list-style-type: none"> <li>- In operating theatre under deep sedation and local anaesthesia</li> <li>- Procedure time 60-90 minutes depend on the case and nodules size and number</li> <li>- Patient will stay hours post the procedure</li> </ul> <p>Equipment needed</p> <ul style="list-style-type: none"> <li>- Laser machine</li> <li>- Fibre-laser</li> <li>- Ultrasound machine</li> </ul>
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<b>Health Technology Assessment Team Recommendation:</b>	<b>Approve</b>
<b>Summary of Review:</b>	
<p>Laser ablation is a procedure to reduce the size of benign thyroid nodules that are symptomatic. The laser treatments are performed through a needle inserted into a thyroid nodule, it is outpatient treatment to reduce the size of benign thyroid nodules that are symptomatic and may cause difficulty swallowing, neck discomfort, or foreign body sensation, as well as for cosmetic reasons. The technique consists in the destruction of the tissue by the insertion therein of optical fibers which convey the light energy, causing a complete and not reversible lesions necrosis. The therapeutic outcome is the reduction in volume of the nodule, and as a result of local symptoms, such as compression, and reduction or loss of visibility of nodular goiter.</p>	
<b>Advantages</b>	<b>Disadvantages</b>
Laser ablation offers numerous benefits, including avoiding surgery, eliminating medication dependency, and preserving the	This procedure should only be done by a clinician with experience in the procedure and specific training in thyroid ultrasound and



thyroid gland's function.	preferably by Interventional Radiologists who are expert in minimally invasive image guided procedures.
Minimally invasive procedure done in an outpatient setting using local anaesthesia only without the need for general anaesthesia or deep sedation.	Relative contraindications to thyroid LA: 1. Untreated clotting disorders 2. Thyroid nodules with high suspicion features for malignancy on ultrasound 3. Abnormal vocal cord function
The treatment is well tolerated for patient with very minimal complications than surgery.	It is usually requiring two benign FNA (fine needle aspiration) before implementing the procedure.
The technology reduces symptoms and improve cosmetic appearance by making the nodule smaller while very important is preserving thyroid function.	Patients should be assessed to exclude thyroid cancer before the procedure by two separate fine needle aspiration procedures or thyroid nodule core biopsy.
Device - Echolaser X4 <ul style="list-style-type: none"> <li>• is FDA approved for Soft Tissue Ablation</li> <li>• is CE certified</li> </ul>	The evidence of efficacy of laser ablation in malignant disease is still limited.
Laser ablation may be more useful in patients with pacemakers, small isthmus nodules, and spongiform nodules.	

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

1. The approval on the technology of thyroid ablation by laser for patients with proven benign thyroid nodule.
2. Evidence of training by the physician who will perform the procedure (radiologist or interventional radiologist).
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. 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

Device - Echolaser X4





## Population, setting and intended user for Technology “Thyroid ablation by laser”

- **Population/ Intended User;**
  - Thyroid Laser ablation can be used in the following patients with proven benign thyroid nodules [usually will need 2 benign biopsies]:
    - Neck compressive symptoms such as dysphagia, dyspnea or neck discomfort due to large thyroid nodule(s)
    - Cosmetic concerns about the size and/or appearance of the goiter
    - Autonomous thyroid nodules causing subclinical or overt hyperthyroidism
- **To be performed by:**
  - The laser ablation therapy performed by interventional radiologists.
- **Clinical Setting:**
  - Outpatient setting; Hospitals, special surgery centers.
- **Condition of use:**
  - LA is not first-line treatment for malignant or suspicious thyroid lesions, but has been used in the following conditions:
    - Papillary thyroid microcarcinoma where patient is unwilling or unfit for surgery.
    - Surgically Unresectable thyroid cancer.
    - Cervical lymph-node recurrence of differentiated thyroid cancer.
  - it is usually requiring two benign FNA (fine needle aspiration) before implementing the procedure).
- **Exclusion criteria:**
  - LA is not suitable for patients with:
    - Untreated clotting disorders
    - Thyroid nodules with high suspicion features for malignancy on ultrasound
    - Abnormal vocal cord function