

Appendix B – Full Indications for Use Statement

The following is the full Indications for Use statement proposed by IceCure Medical, which includes indications cleared in prior 510(k)s in addition to the new indications proposed in this submission.

ProSense™ cryoablation system is indicated for treatment of patients with early stage, low risk breast cancer* for the treatment of breast cancer with adjuvant endocrine therapy. ProSense™ cryoablation system is also indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, thoracic surgery, gynecology, oncology, proctology, urology as detailed below.

*Patients with early stage, low-risk breast cancer are patients ≥ 60 years of age with prognostic stage 1A defined as unifocal tumor size ≤ 1.5 cm, ER+/PR+/-, HER2-, histological grade 1-2 infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0).

- **Urology** - ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH).
- **Oncology** - ablation of cancerous or malignant tissue and benign tumors and palliative intervention.
- **Dermatology** - ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions.
- **Gynecology** - ablation of malignant neoplasia or benign dysplasia of the female genitalia.
- **ENT** Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth.
- **General Surgery** - Ablation of tumors, breast fibroadenomas, leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions. Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions. Destruction of warts or lesions. Palliation of tumors of the oral cavity, rectum, and skin.
- **Thoracic Surgery** - ablation of arrhythmic cardiac tissue and cancerous lesions.
- **Proctology** - ablation of benign or malignant growths of the anus and rectum and hemorrhoids.

The ProSense™ cryoablation system should be used with an imaging device (such as an ultrasound device or CT) to provide real-time visualization of the cryosurgical procedure.