IceSense3™ Cryoablation System for breast fibroadenoma

TECHNOLOGY

The IceSense3™ Cryoablation System, developed by IceCure Medical Ltd., is a device which uses extreme cold (cryoablation) to treat symptomatic breast fibroadenoma (benign breast tumour).

Cryoablation which destroys or ablates tissue has been used before, though not routinely in the UK, to treat both cancerous and non-cancerous tumours of the kidney, prostate and liver.

IceSense3™ has been developed specifically for breast tumours and employs a small probe, which is guided using ultrasound through the skin to the target breast tumour. Extremely cold temperatures are then delivered through the probe to ablate breast tumour cells. The body then reabsorbs the destroyed cells over time. There may be a palpable mass (lump or area that can be felt under the skin) until the body naturally reabsorbs the treated cells and this may take days or months, according to the original size of the tumour.

The procedure is performed using a local anaesthetic. According to the company, no sutures are required and women can return to normal activity quickly. The procedure can take place in a doctor’s consulting room and typically takes 10-15 minutes. According to the company the system also holds promise as a potential treatment option for malignant breast tumours.

IceSense3™ is FDA approved and CE marked for benign and malignant breast tumours and is commercially available for the treatment of breast fibroadenoma in the US. The company intends to launch IceSense3™ in the UK at some point, but there is no timeframe at present.

The Visica 2™ Cryoablation System (Sanarus) is an older technology that uses the same freezing material, for the treatment of fibroadenomas and is available for use in the US.

POTENTIAL FOR IMPACT

Breast lumps are a common condition, with most breast lumps, about 9 out of 10, being benign. A common type of benign breast lump is a fibroadenoma; a smooth, well-rounded solid lump made up of fibrous and glandular tissue, which has a rubber-like texture and moves easily under the skin when pressed. A fibroadenoma will sometimes disappear, but it can remain and grow larger, particularly during pregnancy.
Current practice for treating benign breast tumours is watchful waiting. However, in some cases, surgery may be required to remove a lump, but this is not usually clinically necessary unless the lump is large, growing or causing other symptoms.

According to the company the IceSense3™ cryoablation non-surgical procedure offers patients, who wish their fibroadenoma to be removed, a minimally invasive and painless option where they can resume normal daily activity the same day with no stay in hospital required.

Cryoablation is not routinely used in the NHS yet, but there is increasing clinical interest in percutaneous ablation techniques as an alternative for open surgery, usually for small malignant tumours or small benign tumours. Given that current treatment for breast fibroadenoma is usually watchful waiting the potential impact of the IceSense3™ Cryoablation System on NHS resources and patient care is unclear. However, if proven to be clinically and cost effective it may release resources in terms of surgical theatre time and staffing for those cases where removal is desirable.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


UNPUBLISHED COMPLETED


ONGOING TRIALS


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This Alert is based on information from the company and a time-limited internet search.