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CRYOABLATION LUNG

Safe and effective treatment for pulmonary tumours

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Images courtesy of Prof. Thierry de Baere,
Gustave Roussy Cancer Campus, Villejuif, France

1 Overview of Lung Cryoablation

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INNOVATION IN ABLATION

Building on Boston Scientific's commitment in Interventional Oncology, we have expanded our portfolio of minimally invasive therapies with the leading technology in cryoablation.

- Flexibility of needle options to tailor your treatment
- Precise control allows you to sculpt the optimal ablation zone
- Progressive cryoablation software platform simplifies procedure
- Advanced technology drives innovative capabilities

> *Percutaneous cryoablation is attractive to many interventional radiologists because of its feasibility, safety, excellent computed tomography (CT) visualisation of the iceball, low post-operative pain and low morbidity and mortality.*
>
> **Pusceddu C et al. 2013[1]**

> *CT-guided percutaneous cryotherapy was associated with low procedural morbidity, even with freezing near mediastinal structures, which also appeared to heal without substantial scarring or sequelae.*
>
> **Wang H et al. 2005[7]**

*Quote refers to cryoablation of primary and metastatic lung tumours.
Please note that BTG Cryoablation products are not indicated for use in cardiac tissue.

A SAFE AND EFFECTIVE MINIMALLY INVASIVE THERAPY

- Proven efficacy in primary and metastatic tumours[1-5]
- Excellent safety profile[1-8]
- Real-time control of iceball with images that correlate to pathologic ablation zone[1-10]
- Can be performed under conscious sedation
  – Minimal pain associated with the procedure[1-4,6-8]
  – Allows for breath-holding if desirable[4,8]
- Suitable for lesions in locations close to critical structures that may preclude other ablative technologies[3,6,8]

PRESENTATION
CT scan showing 32 mm sarcoma metastasis abutting the pleura

CRYOABLATION
Geometry of IceRod™ 1.5 PLUS needles used for cryoablation

> *The absence of major damage to collagen fibres makes cryoablation an attractive option for lesions located near the mediastinum, pericardium, diaphragm, or pleura.**
>
> **Yilmaz S et al. 2016[8]**

TABLE 1: LUNG CRYOABLATION: AN ESTABLISHED SAFETY PROFILE WITH LOW RATES OF SEVERE COMPLICATIONS AND SELF-LIMITING SIDE EFFECTS

STUDY	PATIENTS/TUMOURS PRIMARY	PATIENTS/TUMOURS METASTATIC	PNEUMOTHORAX (REQUIRING CHEST TUBE)	HEMOPTYSIS/ HEMOSPUTUM	PLEURAL EFFUSION	COMPLICATIONS > CTCAE 3 (GRADE)
Wang et al. 2005[7]	165/196	22/38	12% (1.2%)	62%	14%	NA
Kawamura et al. 2006[9]		20/35	50% (4.5%)	36.4%	27%	0%
Zemylak et al. 2010[10]	27/27		37% (N/A)	22%	NA	6% (3)
Yamauchi et al. 2011[11]		24/55	63% (3%)	43%	70%	NA
Inoue et al. 2012[12]	13/NA*	104/NA*	61.7% (11.9%)	36.8%	70.5%	2.2% (3)
Yamauchi et al. 2012[13]	22/34		28% (4.5%)	24%	31%	0%
Zhang et al. 2012[4]	46/46		19.6% (4.4%)	39.1%	NA	0%
Pusceddu et al. 2013[1]	11/11	21/23	21% (0)	0	NA	0%
de Baere et al. 2015[3]		40/60	NA (18.8%)	0	0	0%
Moore et al. 2015[5]	45/47		51% (14.9%)	40%	NA	NA

Images courtesy of Professor Thierry de Baere, Gustave Roussy Cancer Institute, Villejuif, France

2 Lung Cryoablation: Results Primary Tumours

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STUDY FOCUS

Five-Year Survival after Cryoablation of Stage 1 Non-Small Cell Lung Cancer in Medically Inoperable Patients

Moore W et al. 2015

- Retrospective, single-centre study to evaluate 5-year survival, cancer-specific survival and progression-free survival
  – 45 patients/47 NSCLC tumours (T1a: n=14; T1b: n=33)
  – Mean follow-up time: 51 months (+/- 10)
- 5-year overall survival: 67.8%
  – 5-year cancer-specific survival: 56.6%*
  – 5-year progression-free survival: 87.9%*
- Procedure did not impact pulmonary function
- Average length of hospital stay: 1.6 days (median 1.0 day, range 1-16)
- Survival rates compare favourably with those published for sublobar resection, lobectomy, VATS and stereotactic radiation therapy

> *Cryoablation is associated with good overall long-term survival with minimally significant complications.*
>
> **Moore W et al. 2015[4]**

CT Computed tomography
CTCAE Common Terminology Criteria for Adverse Events
ECOG Eastern Cooperative Oncology Group
KPS Karnofsky performance scale
NSCLC Non-small-cell lung carcinoma
SCC Squamous Cell Carcinoma
VATS Video-assisted thoracic surgery

* Cancer-specific survival: Cancer recurrences and all deaths counted as events
Progression-free survival: Cancer-related deaths counted as events

2 Lung Cryoablation: Results Primary Tumours (cont.)

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LOCAL CONTROL RATE

OVERALL SURVIVAL

> *Cryoablation ... a viable therapeutic option for patients with stage 1 NSCLC who are deemed medically inoperable.*
>
> **Moore W et al. 2015[5]**

3 Lung Cryoablation: Results Metastatic Tumours

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STUDY FOCUS: THE ECLIPSE TRIAL

Interim Analysis at One Year Evaluating Cryoablation of Metastatic Lung Tumours in Patients – Safety and Efficacy[3]

de Baere T et al. 2015

- Prospective, single-arm, multi-centre study
  – 40 patients/60 pulmonary metastases/48 procedures
  – 35 patients/52 pulmonary metastases included in interim one-year follow-up*
- No adverse events CTCAE >3 (Table 1)
- No significant pain (CTCAE ≥2) reported after cryoablation
- Most patients discharged within one day
- No significant change from baseline in ECOG performance or KPS scores
- Quality of life was maintained

> *Cryoablation is a safe and effective treatment for pulmonary metastases with preserved quality of life following intervention.*
>
> **de Baere T et al. 2015[3]**

CT	Computed tomography
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
KPS	Karnofsky performance scale
NSCLC	Non-small-cell lung carcinoma
SCC	Squamous Cell Carcinoma
VATS	Video-assisted thoracic surgery
CR	Complete response
LF	Local failure
PR	Partial response
SD	Stable disease

* Follow-up will continue to 5 years. 5 patients not included in 1-year follow-up: 1 unrelated death; 1 disease progression outside lung; 1 did not have imaging; 2 lost to follow-up

3 Lung Cryoablation: Results Metastatic Tumours (cont.)

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LOCAL CONTROL RATE

OVERALL SURVIVAL

Evaluation of cryoablation of metastatic lung tumours demonstrates 96.6% & 94.2% local control at 6 & 12 months respectively.

de Baere T et al. 2015[3]

4 Cryoablation Needles: Isotherm Data 37° Gel

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> *The advantages of cryoablation in the lung include the ability to perform the ablation under local anaesthesia with breath-holding, which is important for successful ablation of small lesions near the diaphragm, as well as the visibility of the ablation area (iceball) on CT and little or no pain during or after the procedure.*[1]
>
> **Yilmaz S et al. 2016**[8]

ICEROD™ 1.5 FAMILY

Optimal spacing: 1.0–1.5 cm

IceRod™ 1.5 CX 90° Cryoablation Needle*

0°C	36mm x 53mm
-20°C	26mm x 45mm
-40°C	16mm x 39mm

IceRod™ 1.5 PLUS 90° Cryoablation Needle

0°C	34mm x 52mm
-20°C	25mm x 45mm
-40°C	16mm x 40mm

IceRod™ 1.5 90° Cryoablation Needle

0°C	50mm x 44mm
-20°C	39mm x 34mm
-40°C	29mm x 24mm

0°C	59mm x 53mm
-20°C	49mm x 43mm
-40°C	39mm x 33mm

0°C	60mm x 61mm
-20°C	51mm x 51mm
-40°C	40mm x 42mm

ICESPHERE™ 1.5 FAMILY

Optimal spacing: 1.0–1.5 cm

IceSphere™ 1.5 90° Cryoablation Needle

0°C	31mm x 36mm
-20°C	22mm x 28mm
-40°C	13mm x 23mm

IceSphere™ 1.5 S 90° Cryoablation Needle

0°C	46mm x 39mm
-20°C	36mm x 29mm
-40°C	26mm x 19mm

IceSphere™ 1.5 CX 90° Cryoablation Needle

0°C	52mm x 48mm
-20°C	43mm x 37mm
-40°C	34mm x 28mm

0°C	55mm x 58mm
-20°C	45mm x 47mm
-40°C	36mm x 39mm

1 Quote refers to cryoablation with primary and metastatic tumours

*Track Ablation: Radial width 2.3mm; Length 30mm

FOR MORE INFORMATION ON CRYOABLATION
VISIT US AT **IOABLATION.COM**

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Cover images are courtesy of Professor Thierry de Baere,
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