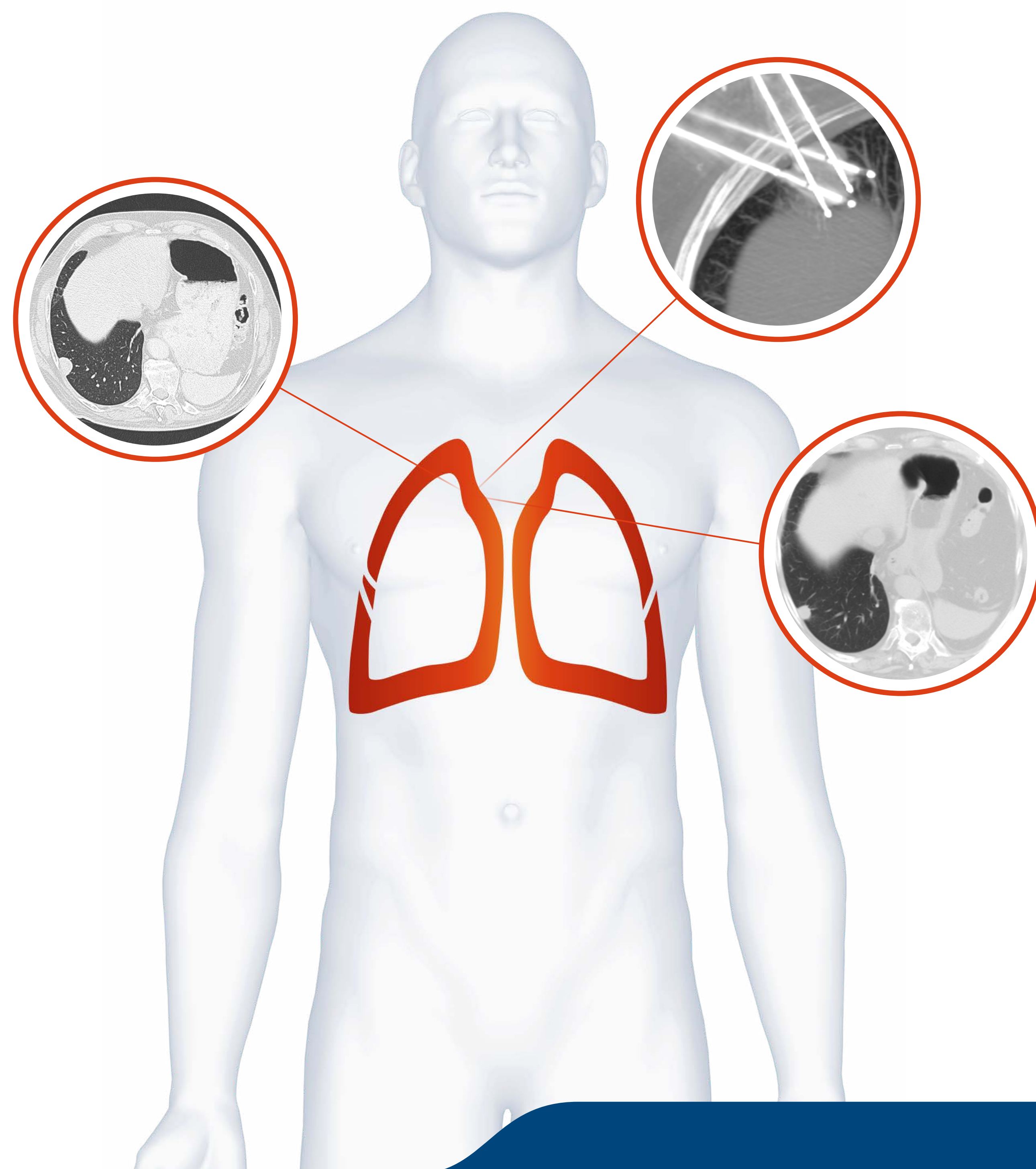


# CRYOABLATION LUNG

Safe and effective treatment  
for pulmonary tumours

*Click to select a topic*

- 1 Overview of Lung Cryoablation
- 2 Lung Cryoablation: Results Primary Tumours
- 3 Lung Cryoablation: Results Metastatic Tumours
- 4 Cryoablation Needles: Isotherm Data 37° Gel





1 Overview of Lung Cryoablation

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<sup>1</sup>

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.

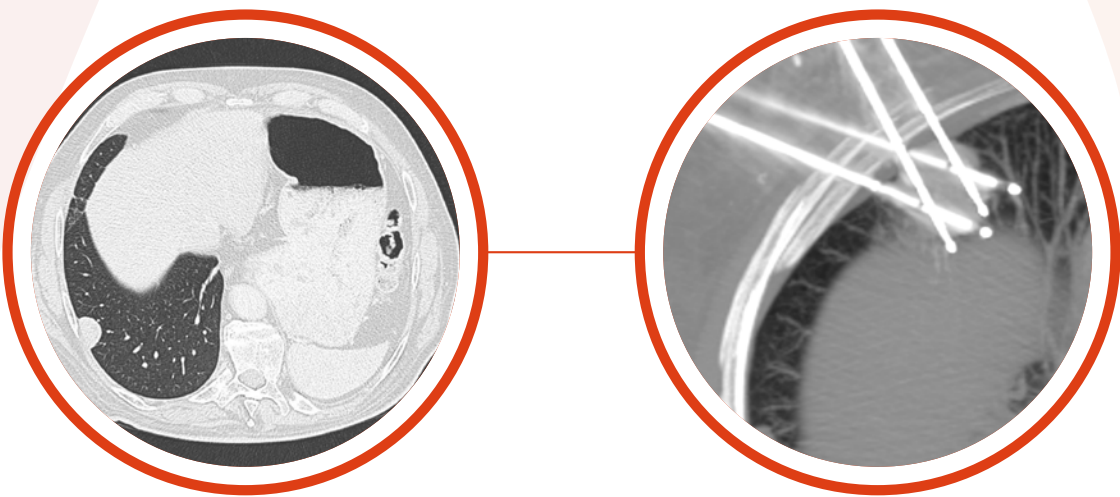
Wang H et al. 2005<sup>7</sup>

\*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<sup>1-5</sup>
- Excellent safety profile<sup>1-8</sup>
- Real-time control of iceball with images that correlate to pathologic ablation zone<sup>1-10</sup>
- Can be performed under conscious sedation
  - Minimal pain associated with the procedure<sup>1-4,6-8</sup>
  - Allows for breath-holding if desirable<sup>4,8</sup>
- Suitable for lesions in locations close to critical structures that may preclude other ablative technologies<sup>3,6,8</sup>

PRESENTATION  
CT scan showing  
32mm sarcoma metastasis  
abutting the pleura



CRYOABLATION  
Geometry of  
IceRod™ 1.5 PLUS  
needles  
used for cyroablation

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<sup>8</sup>

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

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

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

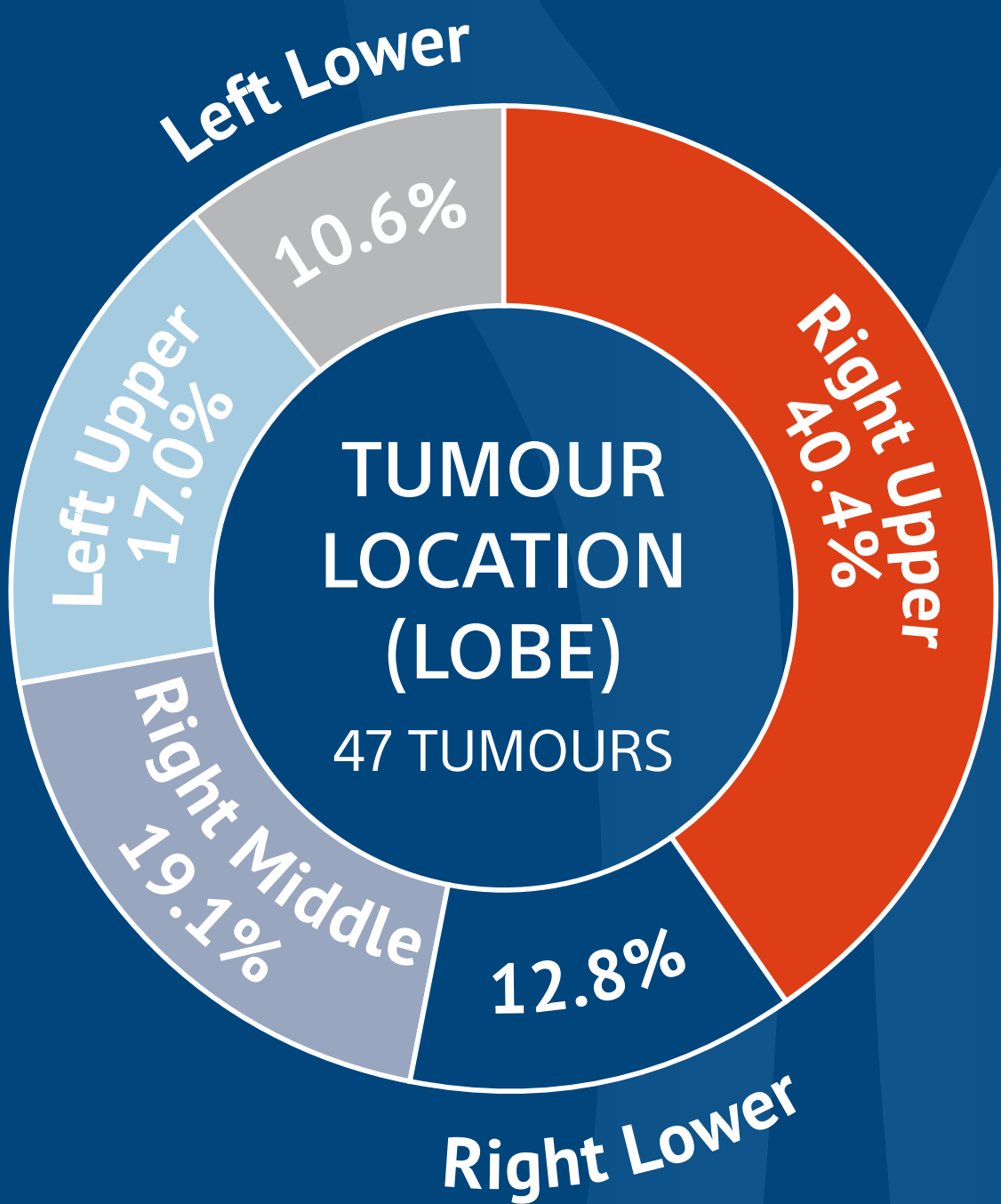
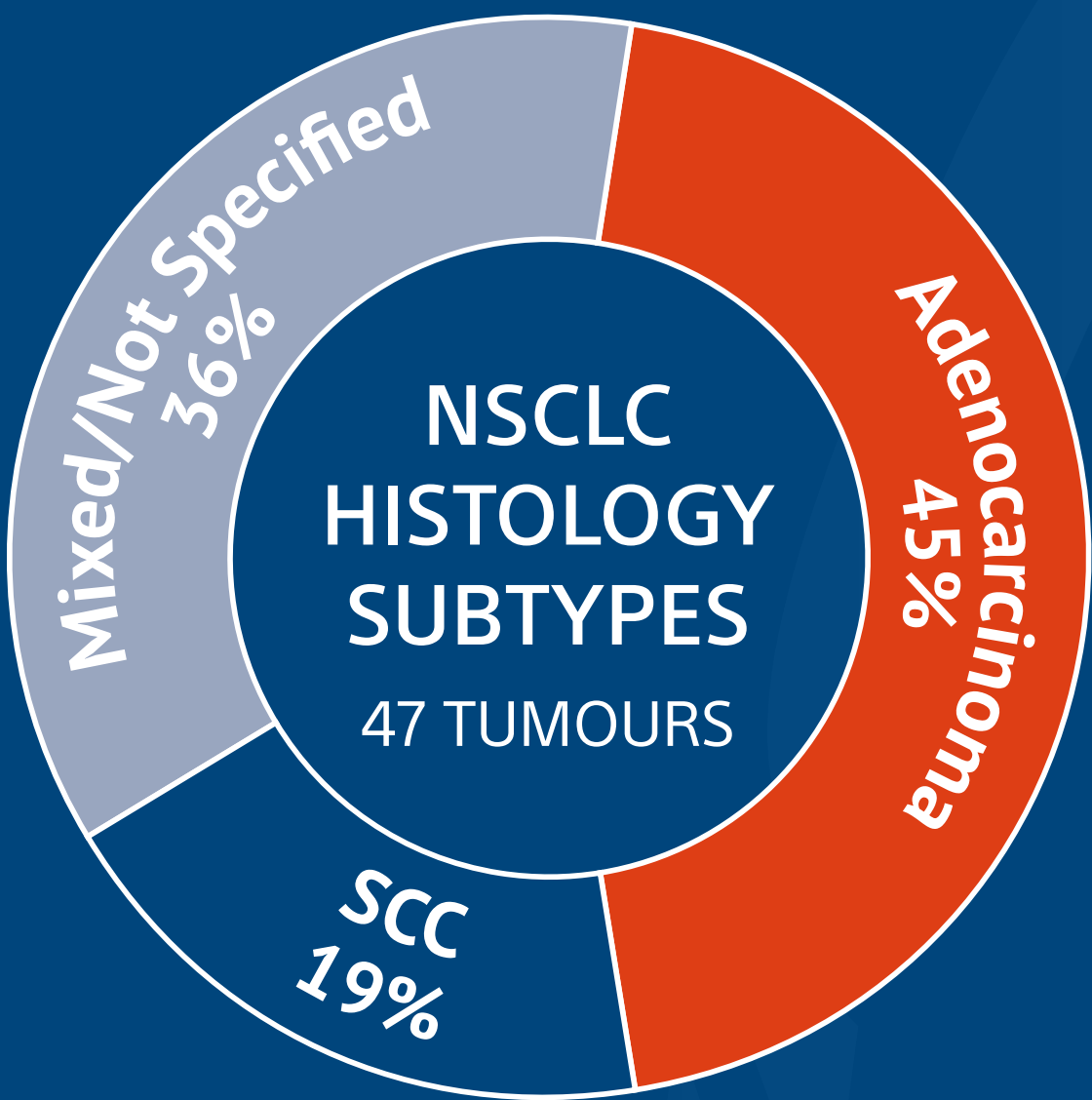
## 2 Lung Cryoablation: Results Primary Tumours

### 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<sup>4</sup>

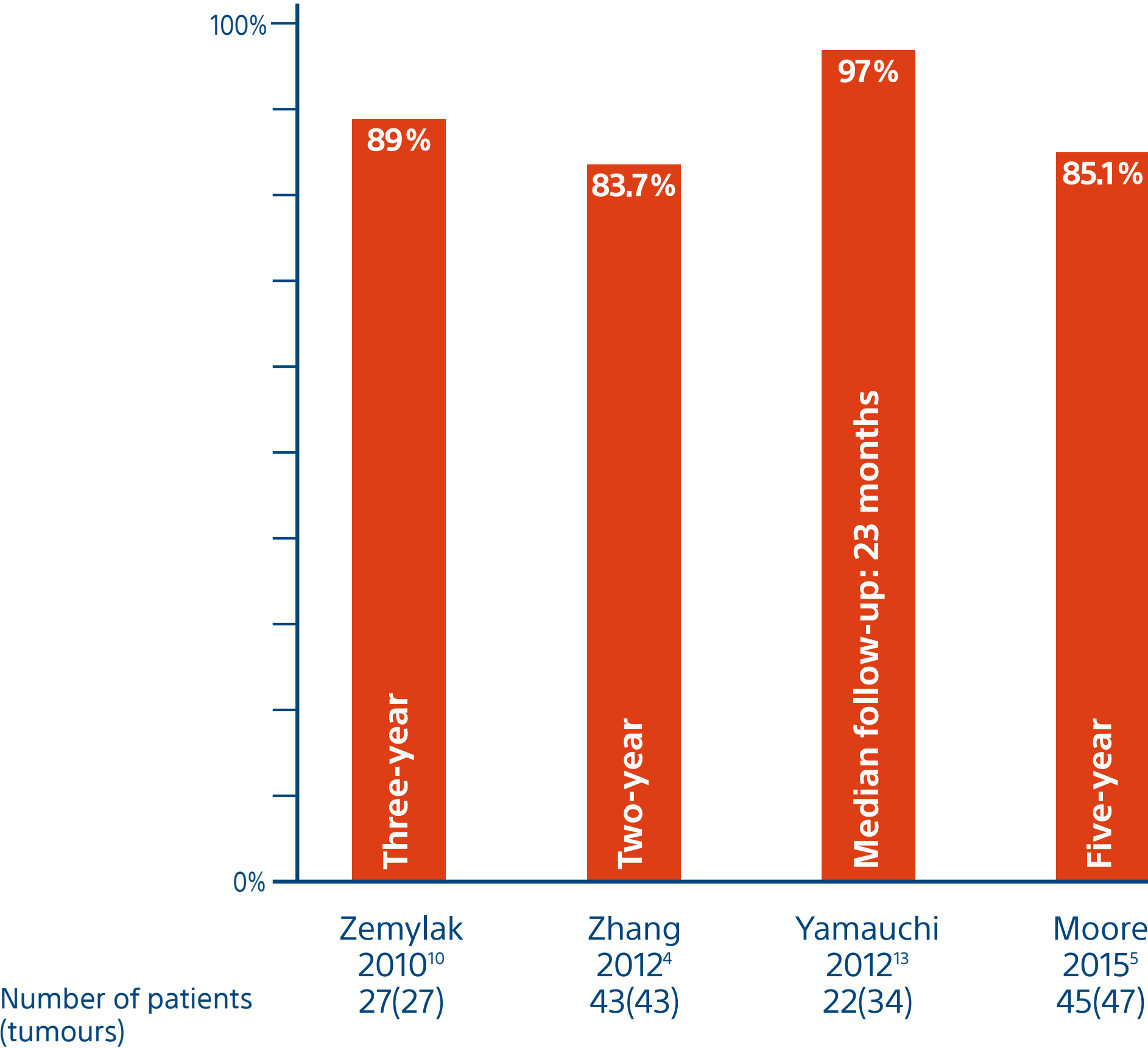
CT Computed tomography  
CTCAE Common Terminology Criteria for Adverse Events  
ECOG Eastern Cooperative Oncology Group  
KPS Karnofsky performance scale  
NSCLC Non-small-cell lung carcinoma  
SCC Squamous Cell Carcinoma  
VATS Video-assisted thoracic surgery

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

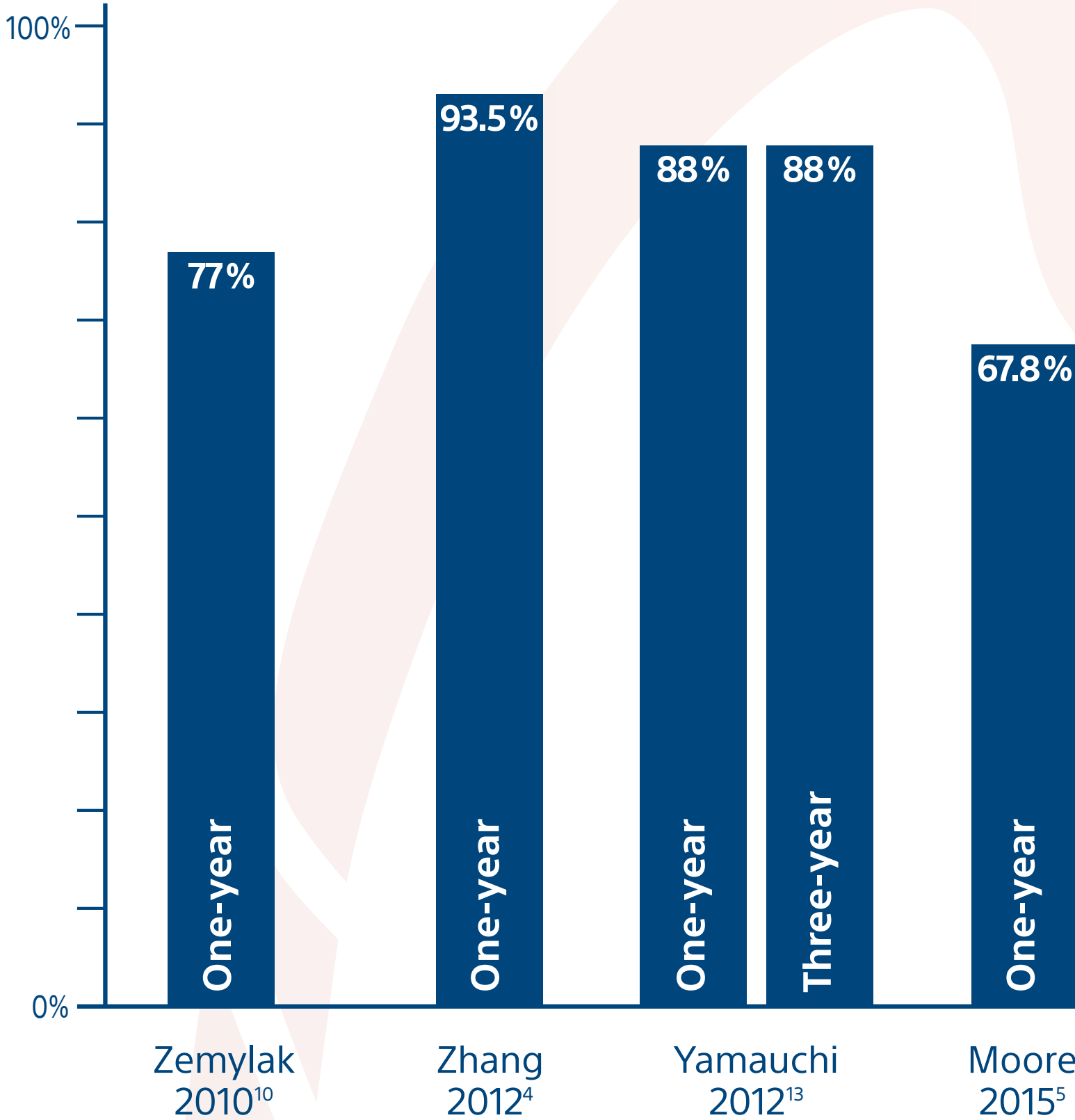


2 Lung Cryoablation: Results Primary Tumours (cont.)

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<sup>5</sup>



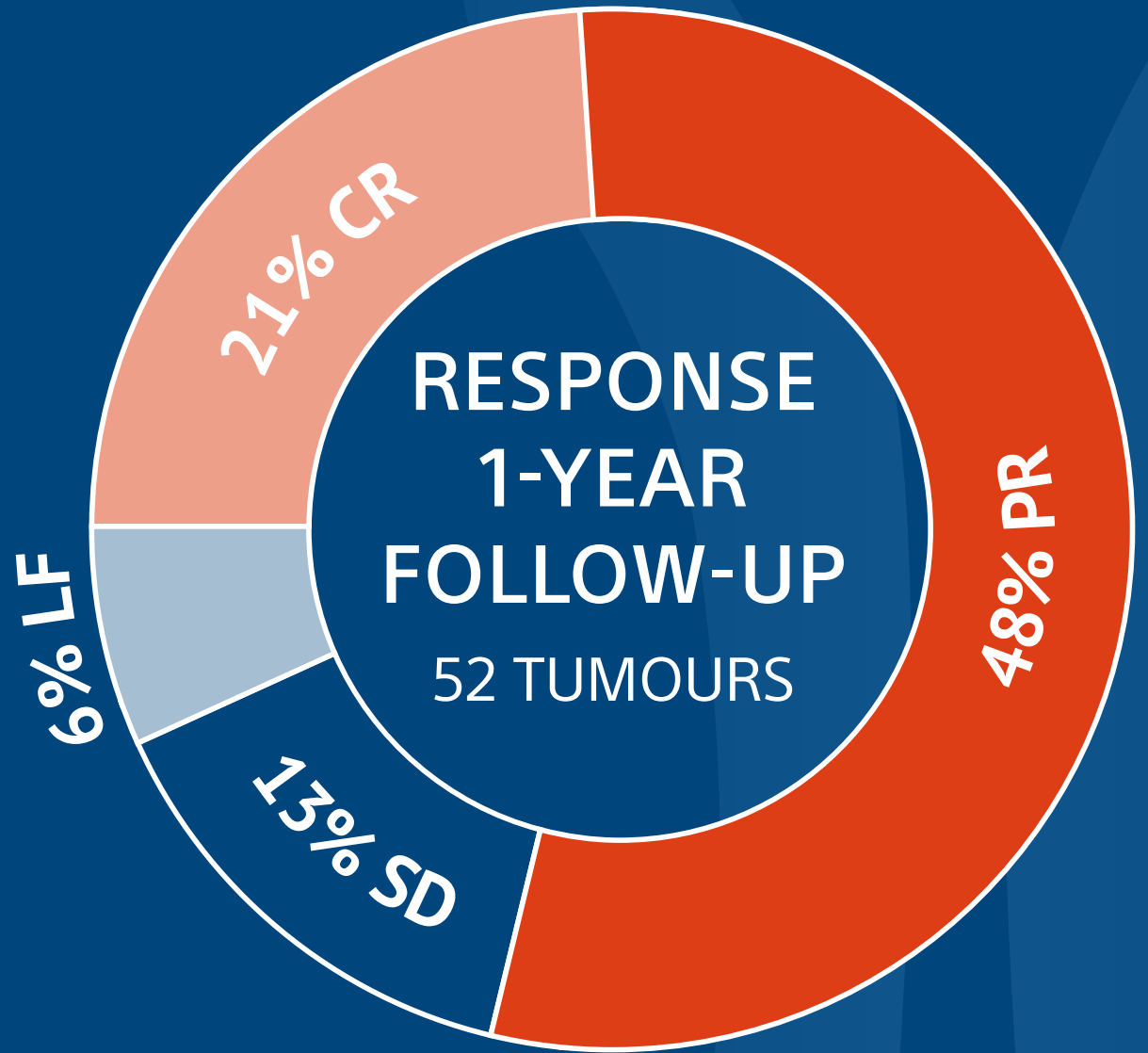
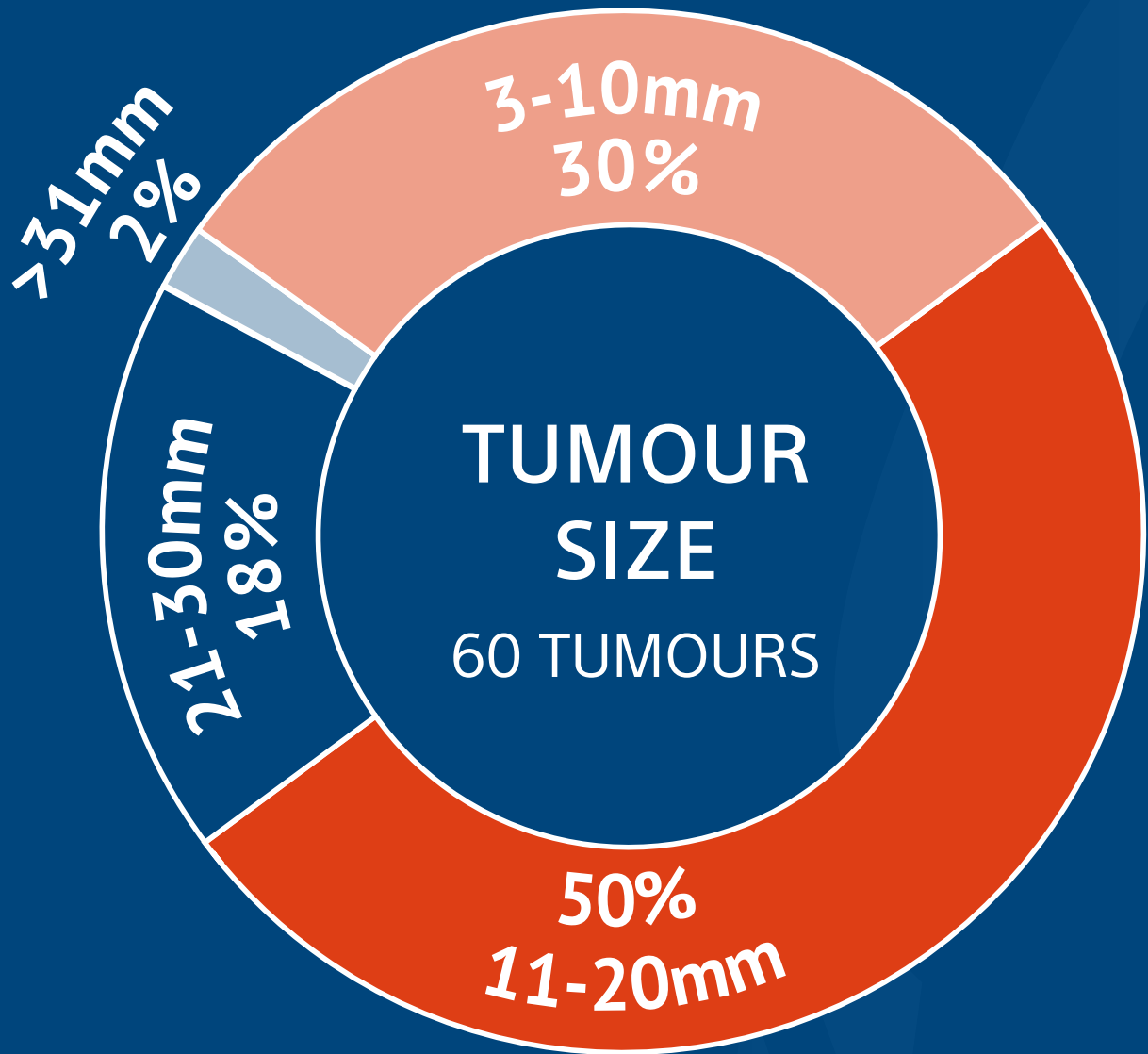


### 3 Lung Cryoablation: Results Metastatic Tumours

#### STUDY FOCUS: THE ECLIPSE TRIAL

Interim Analysis at One Year Evaluating Cryoablation of Metastatic Lung Tumours in Patients – Safety and Efficacy<sup>3</sup>  
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<sup>3</sup>

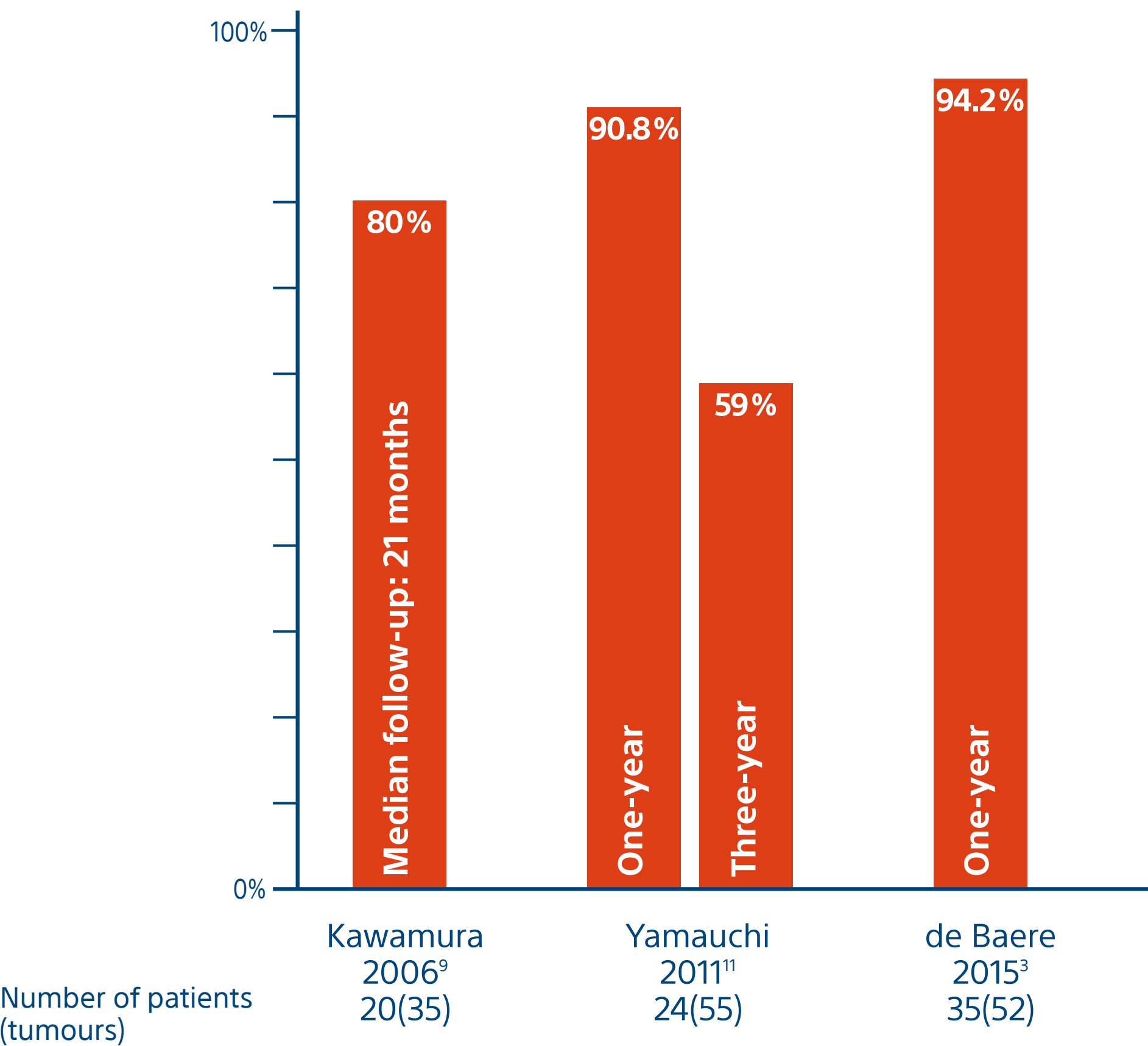
CT Computed tomography  
CTCAE Common Terminology Criteria for Adverse Events  
ECOG Eastern Cooperative Oncology Group  
KPS Karnofsky performance scale  
NSCLC Non-small-cell lung carcinoma  
SCC Squamous Cell Carcinoma  
VATS Video-assisted thoracic surgery  
CR Complete response  
LF Local failure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

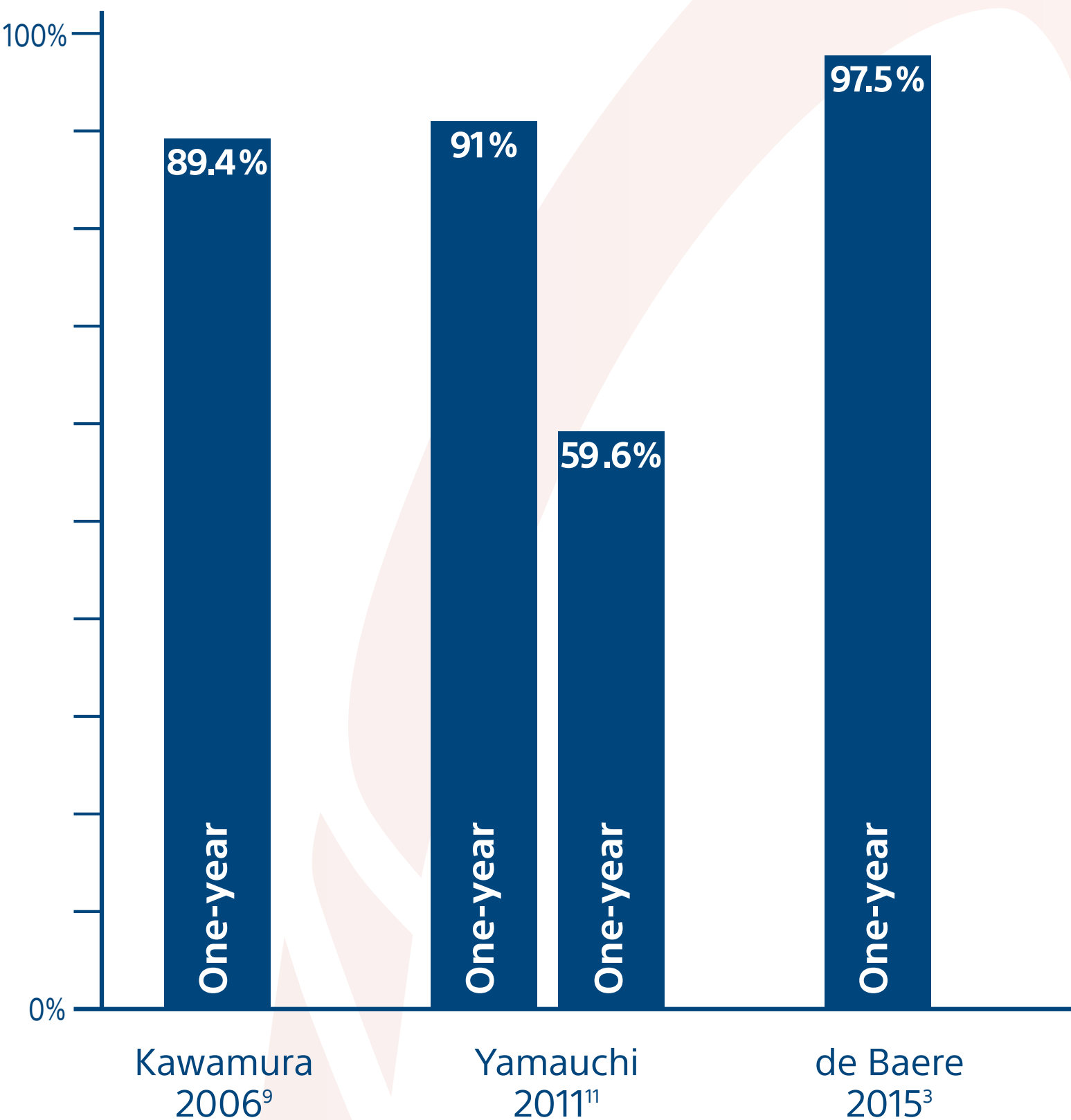


3 Lung Cryoablation: Results Metastatic Tumours (cont.)

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<sup>3</sup>



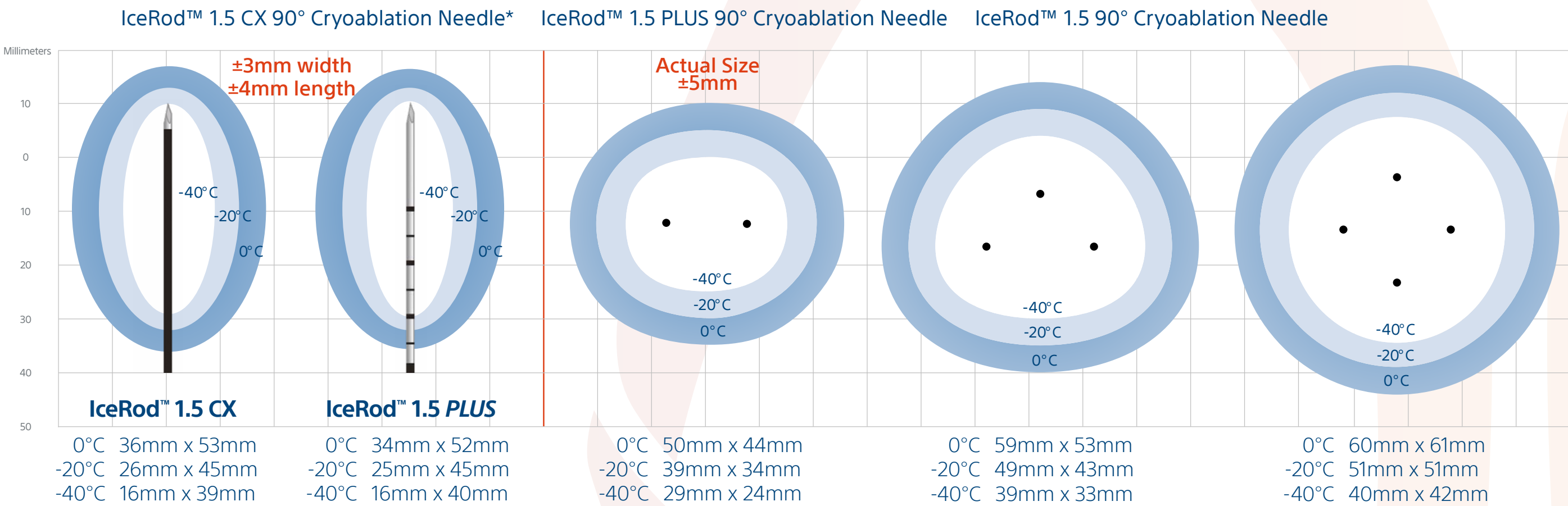
4 Cryoablation Needles: Isotherm Data 37° Gel

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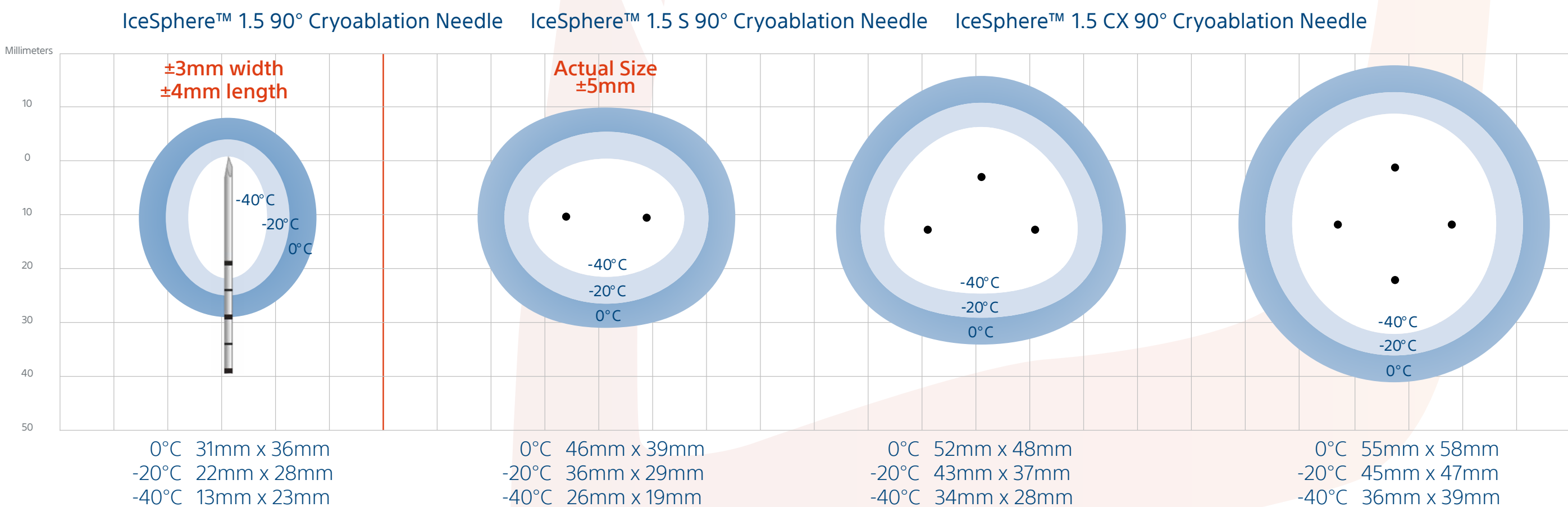
The advantages of cryoablation in the lung include the ability to perform the ablation under *local anaesthesia with breath-holding*, which is important for successful ablation of small lesions near the diaphragm, as well as the visibility of the ablation area (iceball) on CT and little or no pain during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

Yilmaz S et al. 2016<sup>8</sup>

ICEROD™ 1.5 FAMILY  
Optimal spacing: 1.0–1.5 cm



ICESPHERE™ 1.5 FAMILY  
Optimal spacing: 1.0–1.5 cm



<sup>1</sup> 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](http://IOABLATION.COM)

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