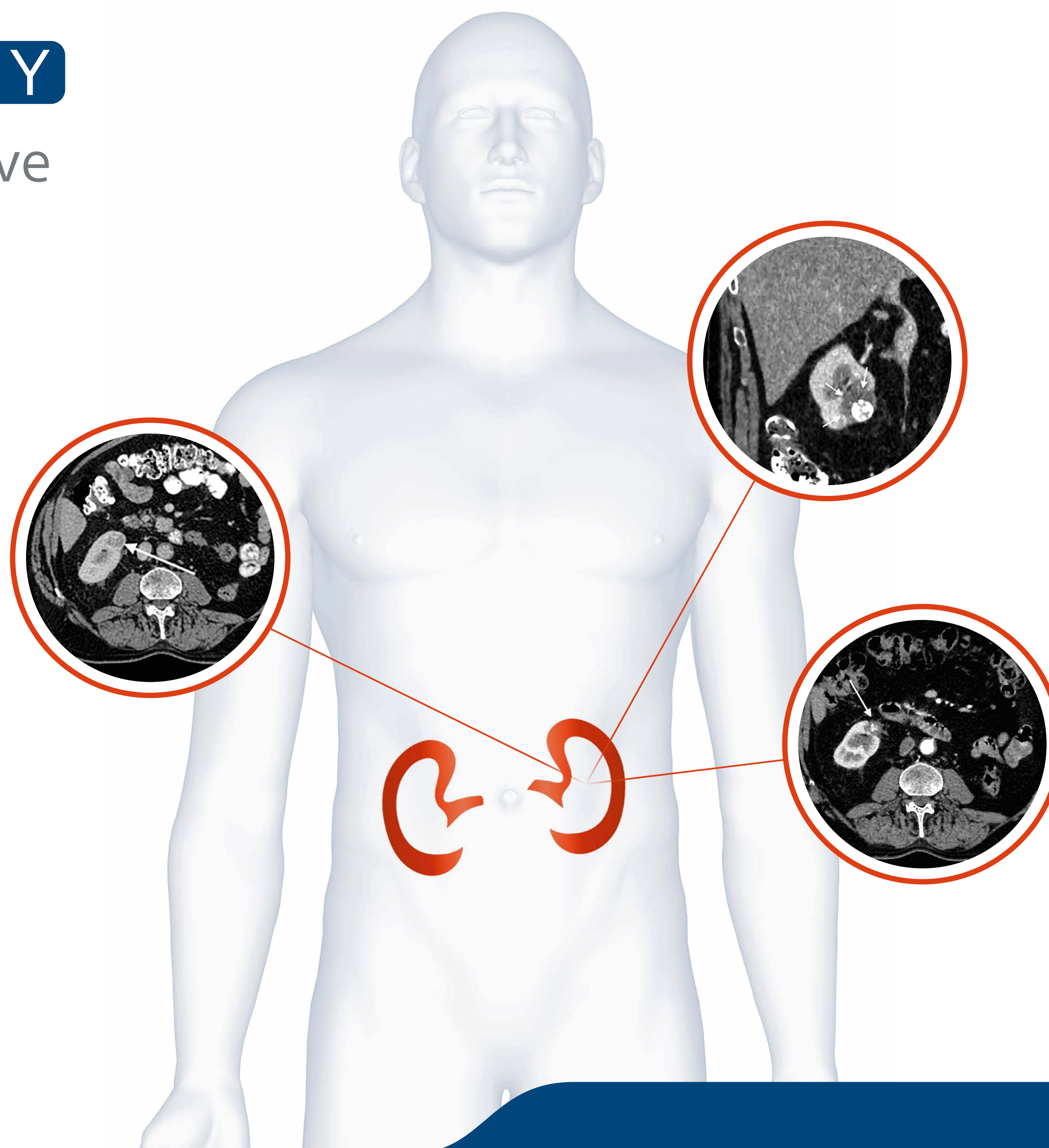


CRYOABLATION KIDNEY

Well-established, minimally invasive treatment for kidney cancer

Click to select a topic

- 1 Overview of Renal Cryoablation
- 2 Renal Cryoablation vs Other Therapies: Results
- 3 Survival, Efficacy and Safety
- 4 Cryoablation Needles: Isotherm Data 37° Gel



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



1 Overview of Renal 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.

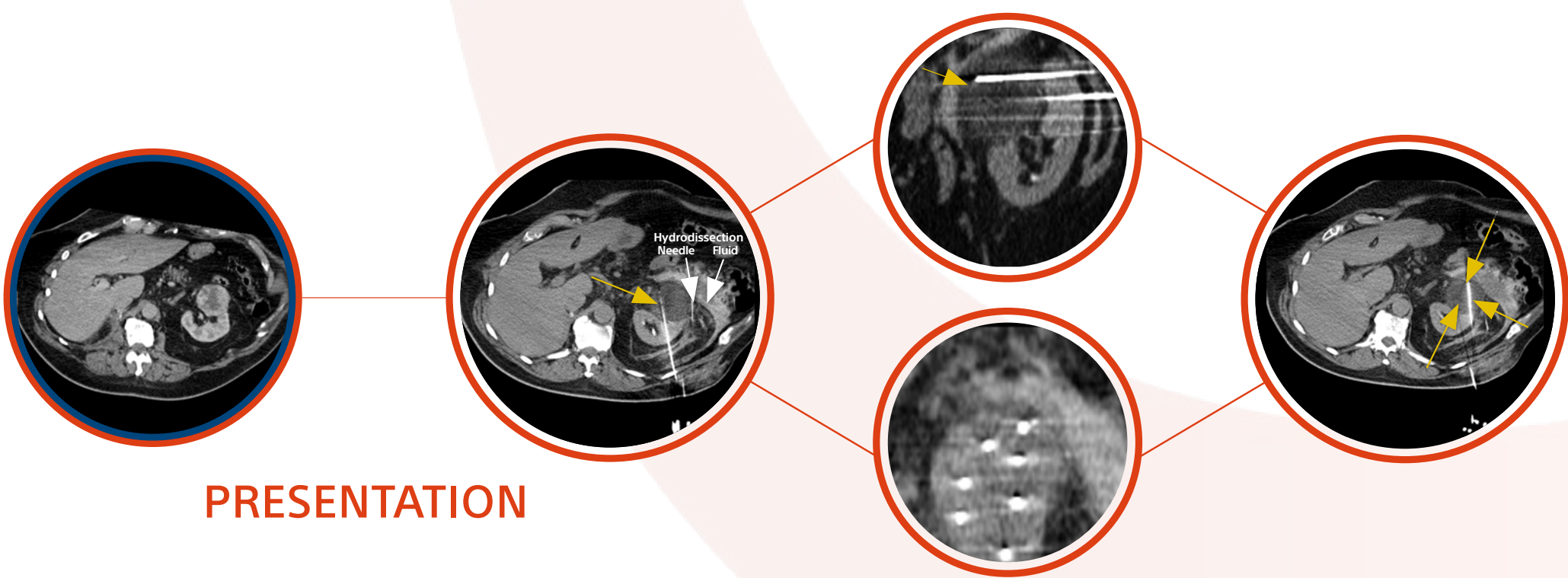
- Flexibility of needle options to tailor your treatment
- Precise control allows you to sculpt the optimal ablation zone
- Progressive cryoablation software platform simplifies procedure
- Advanced technology drives innovative capabilities

AN ESTABLISHED, PROVEN THERAPY THAT GIVES YOU VISIBILITY AND CONTROL

- Comparable outcomes to resection/LPN with lower complication rate and shorter hospital stay²
- Over 15 years of published data³
- EuRECA Registry comprising over 800 patients (on-going)⁴
- Improved outcomes versus RFA^{3,5,6}
- Suitable for use in traditionally ‘unablatable’ tumour locations:
 - Into the collecting system^{7,8}
 - Near critical structures²
- Effective in T1a and T1b tumours^{*2,9}

*A recent study by Breen et al. demonstrated that on multivariable analysis, there was no significant difference between outcomes from cryoablation of T1a vs T1b RCC tumours in terms of treatment efficacy, complication rates or recurrence-free survival. Earlier studies, while showing efficacy in both T1a and T1b tumours, have shown a lower rate of efficacy in the T1b disease.

CRYOABLATION OF 7CM RCC WITH HYDRODISSECTION TO PROTECT ADJACENT STRUCTURES



PRESENTATION

Images courtesy of Dr Alex King, University Hospital Southampton, Southampton, UK

Cryoablation has the clear merit of physically demonstrating its tissue effects through the *radiologically demonstrable iceball* that is induced around the clustered cryoprobes and this *permits the ablation to be carefully assessed during the course of the procedure.*

Breen DJ et al. 2013¹

Oncologic outcomes of imageguided renal cryoablation for RCC are *competitive with those of partial nephrectomy* and are associated with a *low complication rate.*

Breen DJ et al. 2018²

Cryoablation results in fewer retreatments, *improved local tumour control* and may be associated with a *lower risk of metastatic progression* compared to RFA.

Kunkle DA & Uzzo RG. 2008³

CRYOABLATION

Hypodense iceball formation; the ice is ‘sculpted’ to match the tumour morphology Visibility of leading edge of iceball (yellow arrows) allows confirmation of tumour coverage with appropriate parenchymal ‘safety’ margin

C-D: Clavien-Dindo (adverse event classification)
CRYO: Cryotherapy
CT: Computed tomography
LPN: Laparoscopic partial nephrectomy
OS: Overall survival
PN: Partial nephrectomy
RCC: Renal cell carcinoma
RFA: Radiofrequency ablation



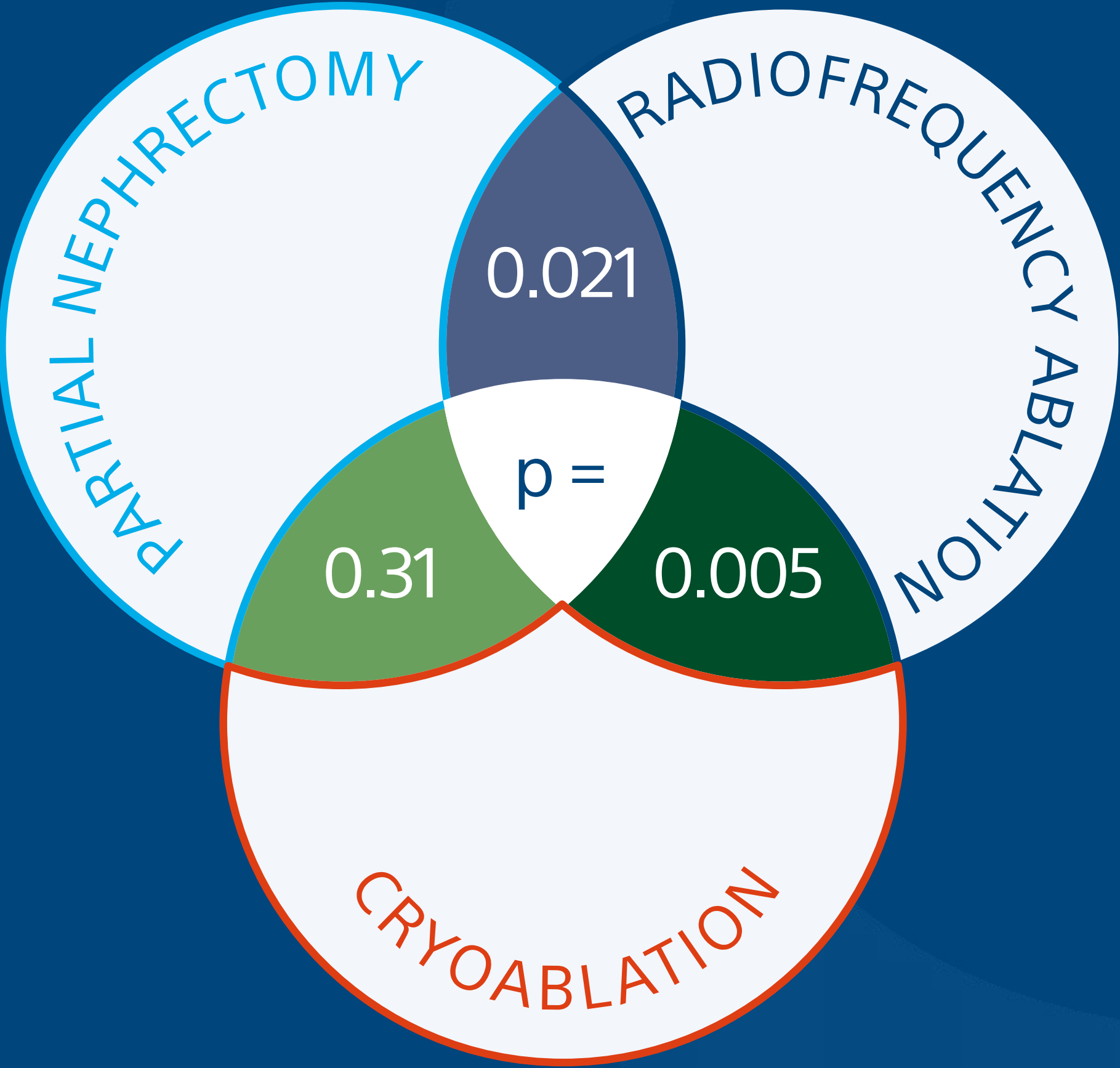
2 Renal Cryoablation vs Other Therapies: Results

Metastases-free survival was superior for PN and cryoablation patients when compared with RFA for cT1a patients.

Thompson RH et al. 2015⁵



METASTASIS-FREE SURVIVAL:
PARTIAL NEPHRECTOMY VS ABLATION FOR CT1 RENAL MASSES⁵



Graphic generated from
Thompson RH et al. 2015.

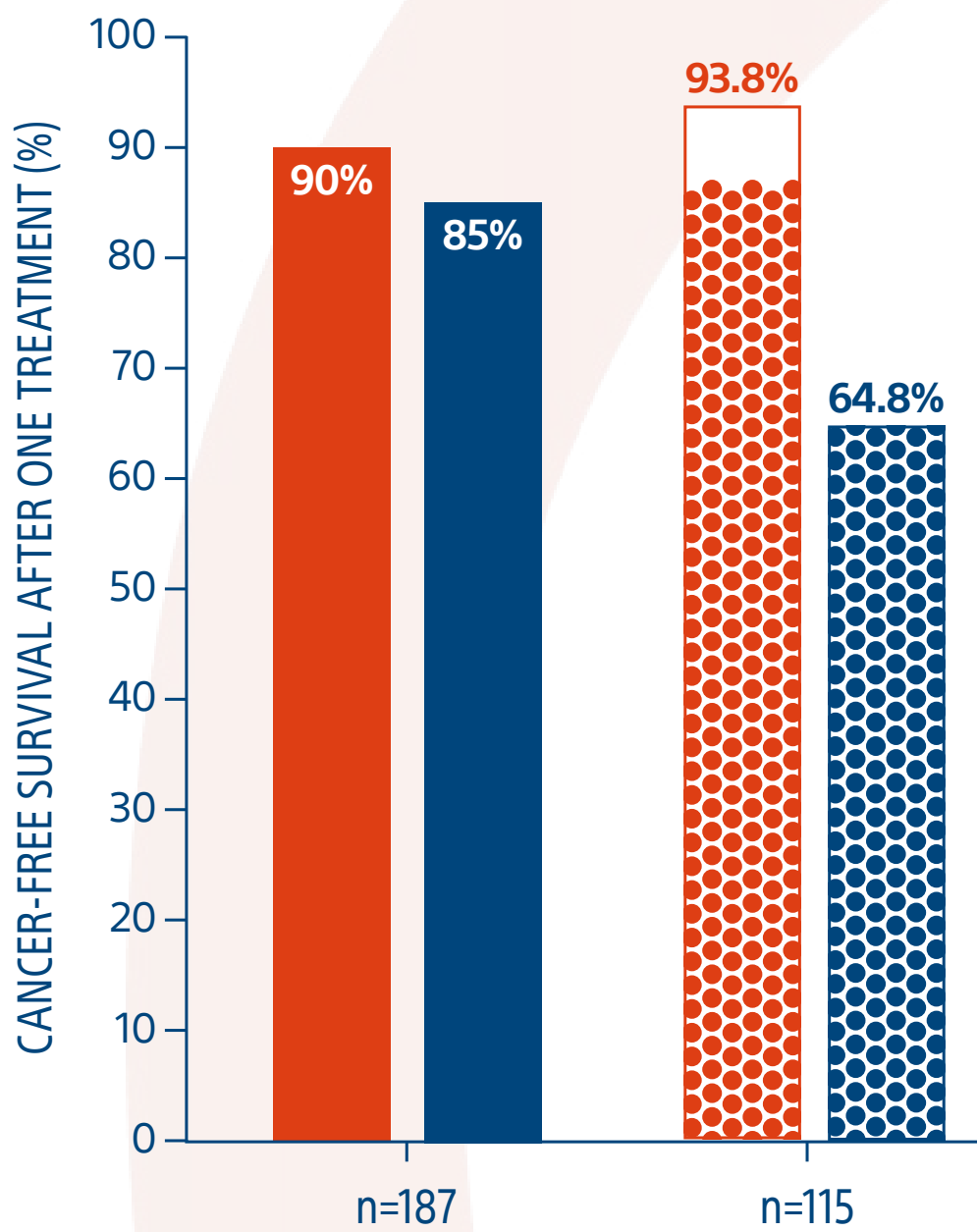


2 Renal Cryoablation vs Other Therapies: Results (cont.)

3.1 cryo vs RFA

MEASUREMENT OF TREATMENT SUCCESS:
CRYOABLATION vs RADIOFREQUENCY
ABLATION (RFA)¹⁰

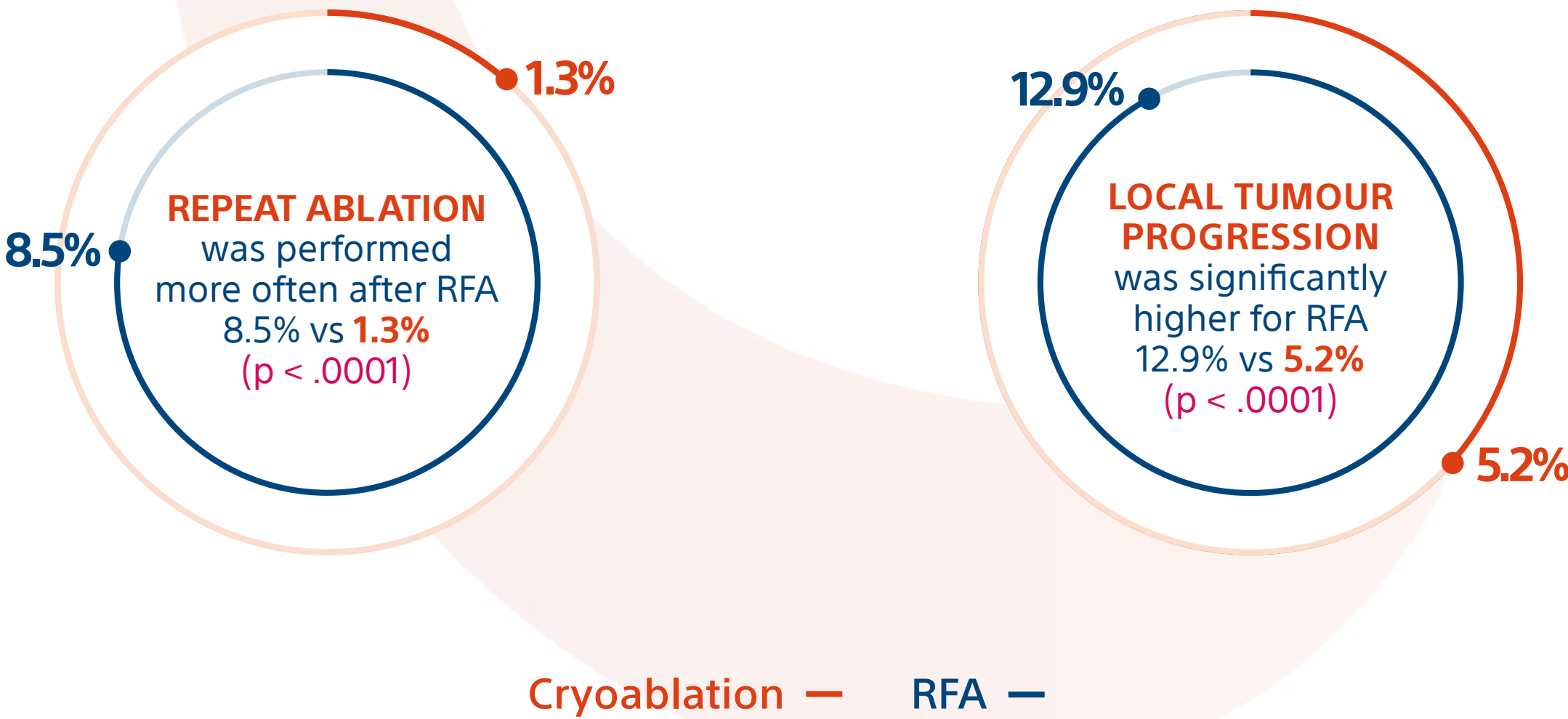
IMAGING ALONE MAY OVER-ESTIMATE TREATMENT SUCCESS WITH RFA



A poor correlation was observed between post-RFA imaging and post-RFA biopsy results at 6 months.¹⁰

Cryoablation RFA
Radiographical Measure Pathological Measure

CRYOABLATION vs RFA
OF SMALL RENAL MASSES³



Graphs generated from Kunkle DA et al. 2008 meta-analysis of 47 ablation series (22 cryoablation and 25 RFA)



2 Renal Cryoablation vs Other Therapies: Results (cont.)
3.2 Cryo vs Heat Ablation

OVERALL SURVIVAL:
CRYOABLATION VS
HEAT-BASED ABLATION
IN T1A RCC.⁶

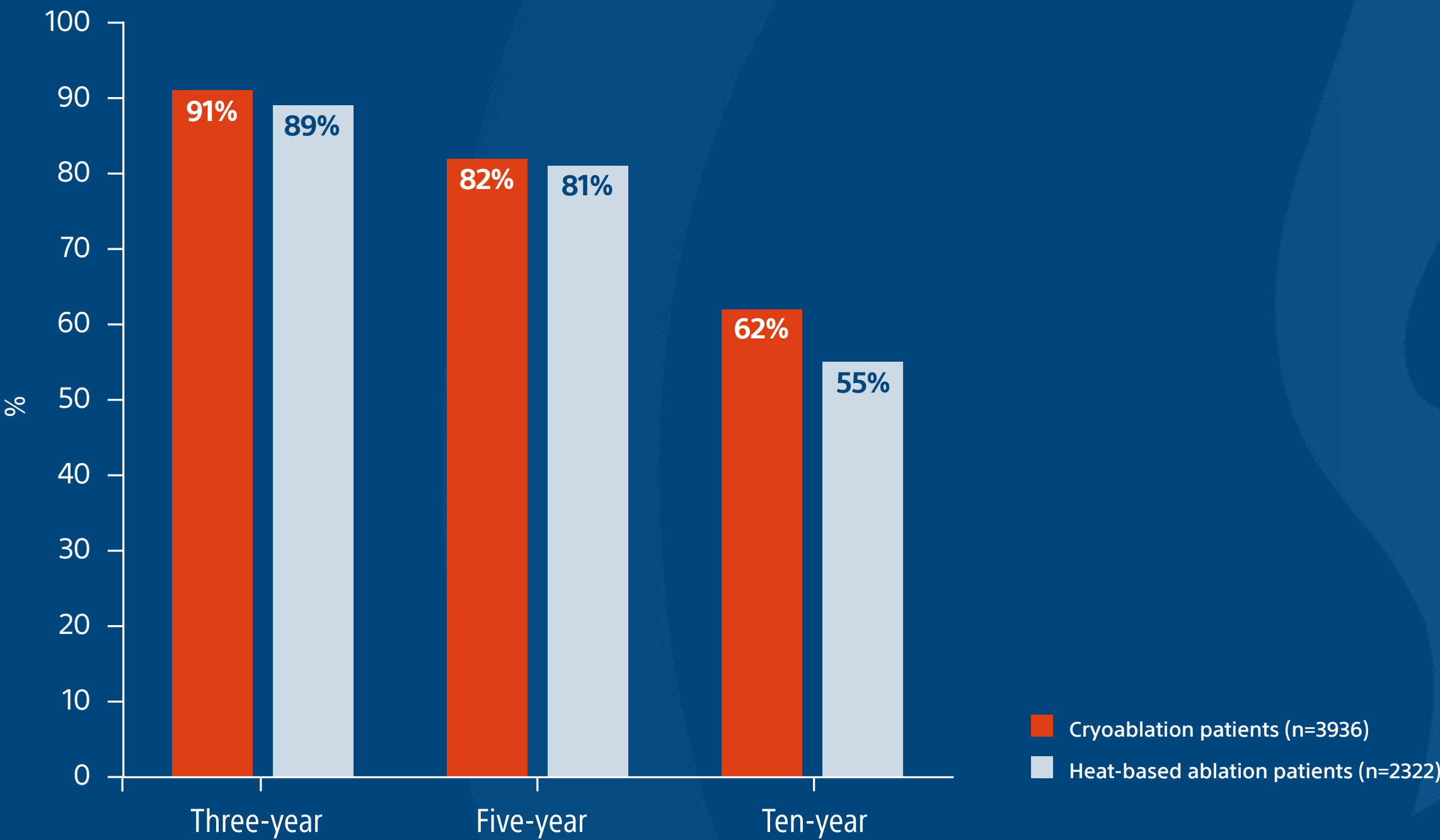
WU J ET AL. 2019. SECOND XIANGYA HOSPITAL,
CENTRAL SOUTH UNIVERSITY, HUNAN, PEOPLE'S
REPUBLIC OF CHINA

”

Overall, cryoablation may be associated
with *longer overall survival* compared with
heat-based thermal ablation in cT1a RCC.

Wu J et al. 2019⁶

KAPLAN-MEIER SURVIVAL ESTIMATES
MEDIAN FOLLOW-UP: 4 YEARS



In propensity-score-matched patients:

- Median overall survival (n=2269 in each group) was **11.3** years for cryoablation vs **10.4** years for heat-based ablation (p = .016)*
- For tumours ≤2cm (n=755 in each group), there was no significant difference in median overall survival

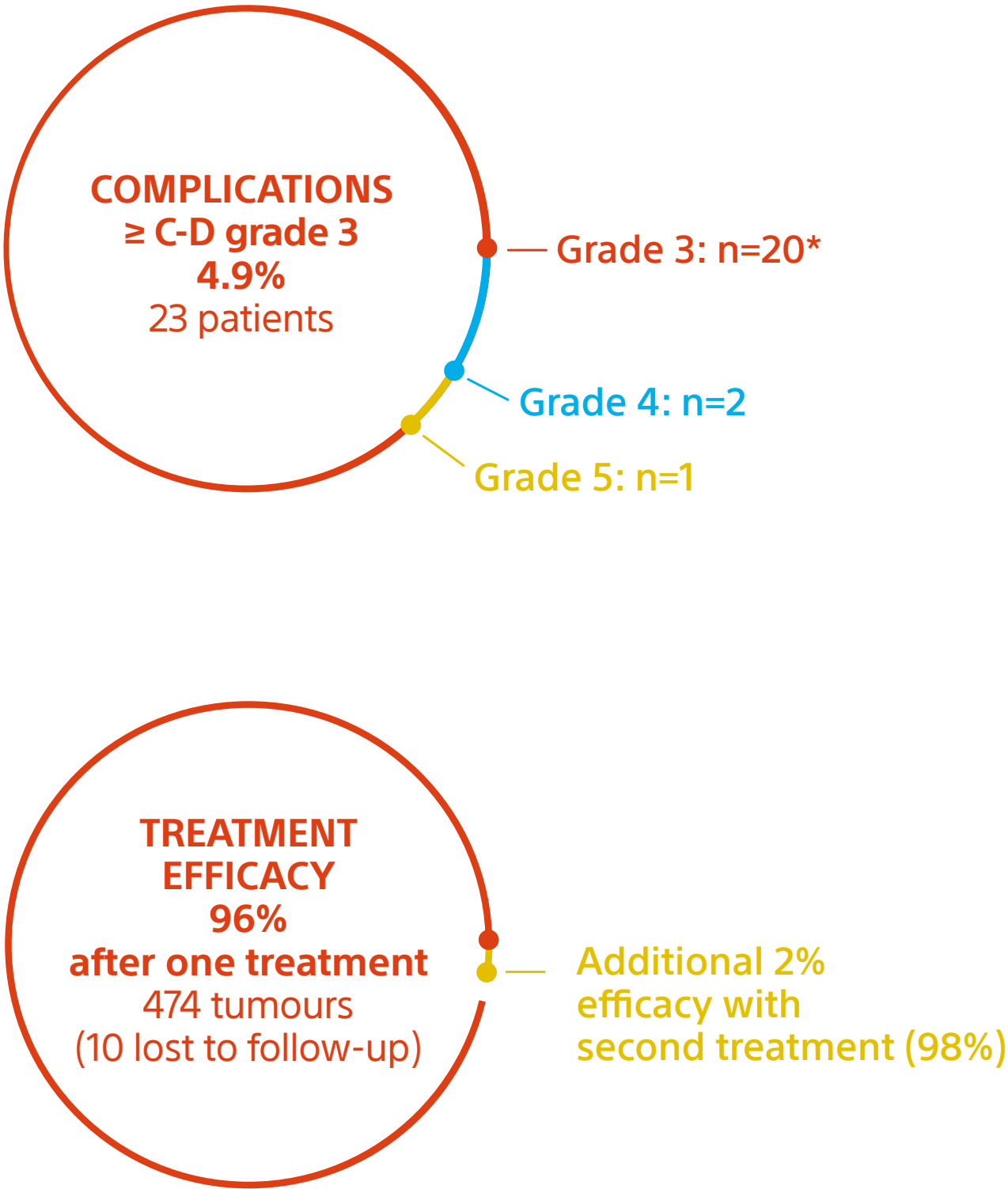
*Hazard ratio 1.175, 95% CI 1.03–1.341



3 Survival, Efficacy and Safety

STUDY FOCUS: IMAGE-GUIDED CRYOABLATION FOR SPORADIC RCC
THREE- AND FIVE-YEAR OUTCOMES IN 220 PATIENTS WITH BIOPSY-PROVEN RCC²

Breen DJ et al. 2018. University Hospital Southampton NHS Trust, Southampton, United Kingdom.



- Retrospective analysis of single-centre, prospective registry established to evaluate image-guided renal cryoablation in terms of:
 - Long-term oncological efficacy
 - Treatment efficacy
 - Safety
- Median hospital stay of 1.0 day (range 0-8)

“The median hospital stay of 1 day (range 0-8 days) was also notable... This compares favourably with a median PN stay of 4 days.”

Breen DJ et al. 2018²

PARAMETER	Entire Population Treated	Subpopulation with ≥3 months follow-up
Number of patients	433	220
Number of tumours	484	221
Mean size, cm (+/- standard deviation)	3.3 (1.05)	3.4 (0.97)
Median size, cm (range)	3.2 (0.9-6.7)	3.4 (1.3-6.2)
Number (%) tumours ≤4cm/clinical T1a	375 (77.5%)	166 (75.1%)
Number (%) tumours >4cm/clinical T1b	109 (22.5%)	55 (24.9%)

*10 patients experienced pneumothorax (treated with chest drain) due to needle placement across the pleural reflection. Practice has now been modified to negate risk with more oblique needle placement and enhanced use of hydrodissection.



3 Survival, Efficacy and Safety (cont.)

Five-year oncologic outcomes after image-guided cryoablation for clinical T1 renal cell carcinoma are competitive with those of resection at a lower complication rate.

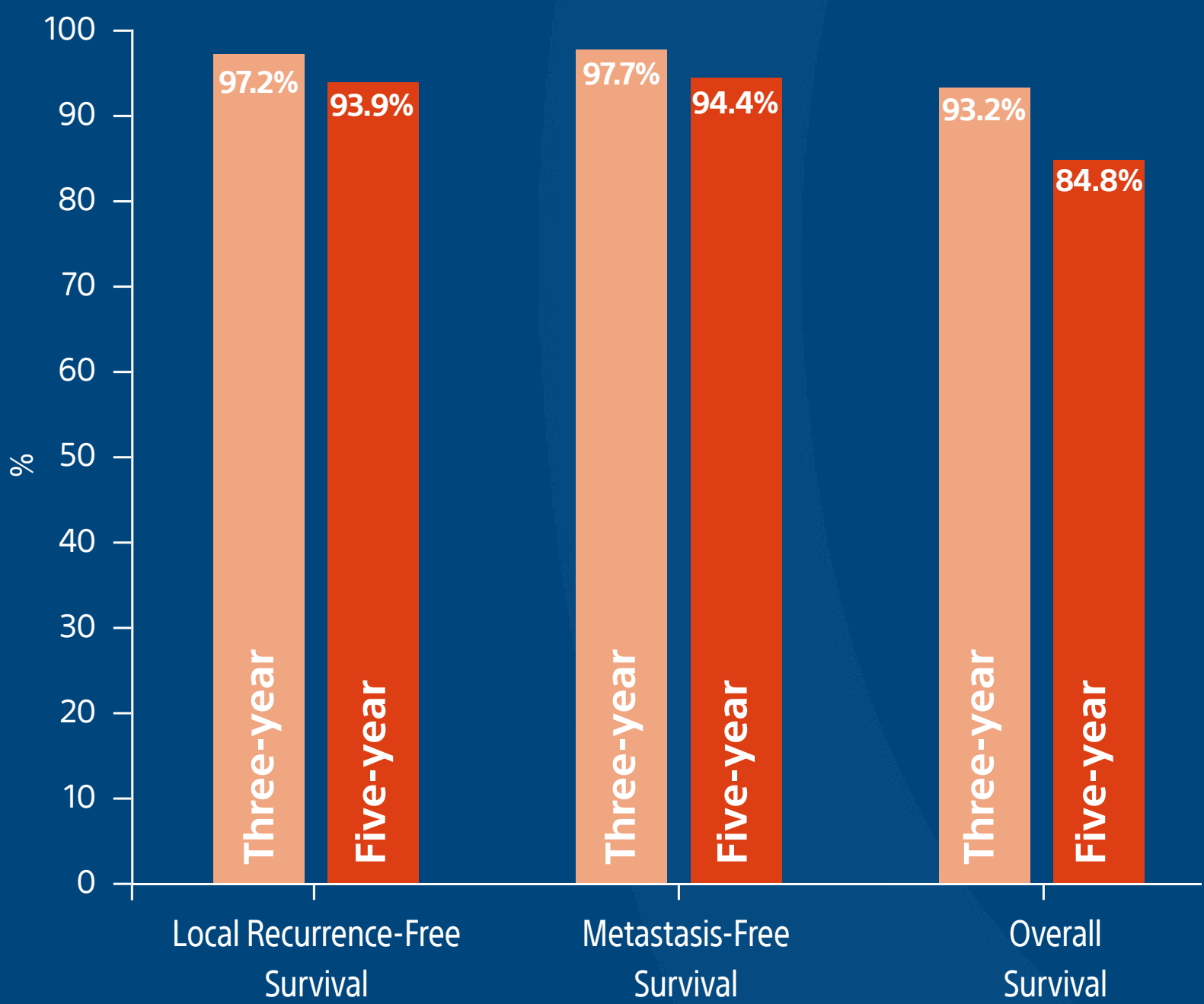
Breen DJ et al. 2018²



CANCER-FREE AND OVERALL SURVIVAL

KAPLAN-MEIER SURVIVAL ESTIMATES FOR 220 PATIENTS WITH ≥3 MONTHS' FOLLOW-UP

Median follow-up: 31.1 months



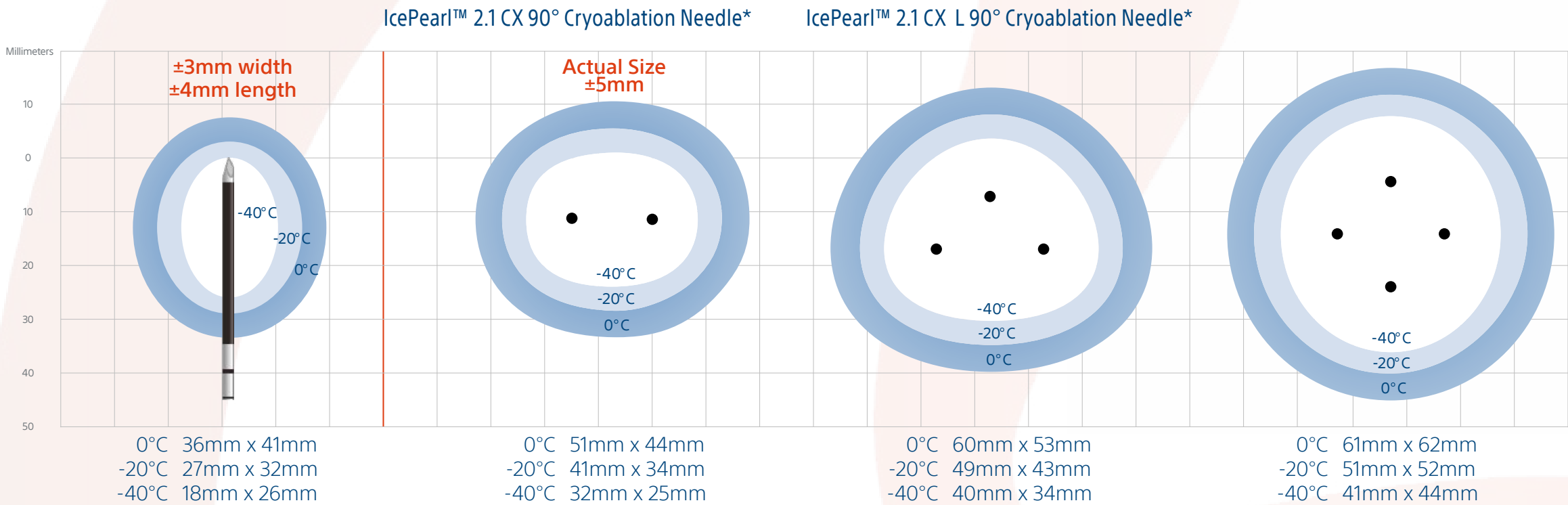
4 Cryoablation Needles: Isotherm Data 37° Gel

From a technical viewpoint, cryoablation has the theoretical advantage of *real-time ablation zone monitoring*.

Pirasteh A et al. 2011¹²

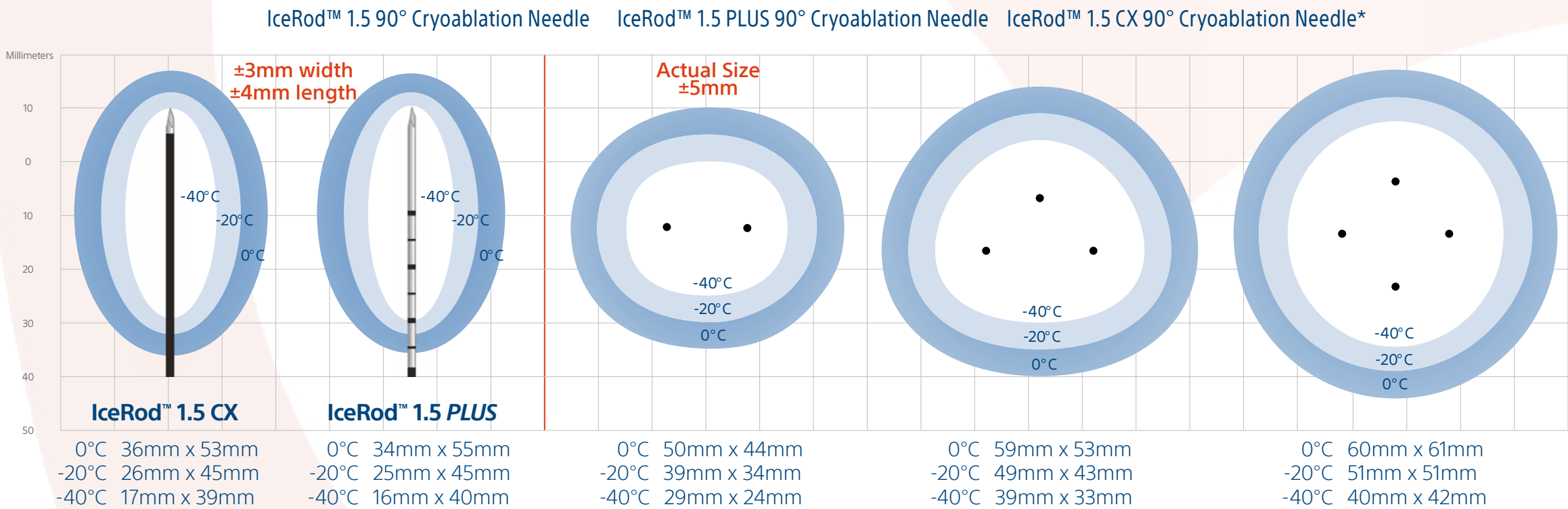
ICEPEARL™ 2.1 CX FAMILY
Optimal spacing: 1.0–1.5cm

* Track Ablation: Radial width 2.1mm; Length 13mm

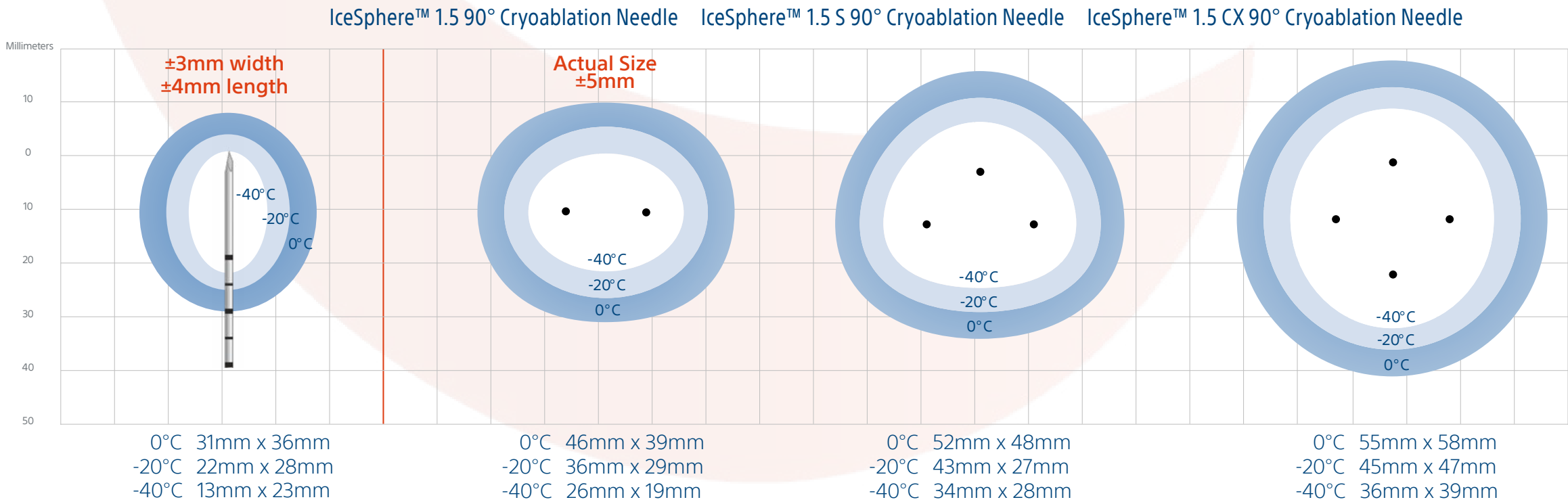


ICEROD™ 1.5 FAMILY
Optimal spacing: 1.0–1.5cm

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



ICESPHERE™ 1.5 FAMILY
Optimal spacing: 1.0–1.5cm



FOR MORE INFORMATION ON CRYOABLATION
VISIT US AT IOABLATION.COM

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