

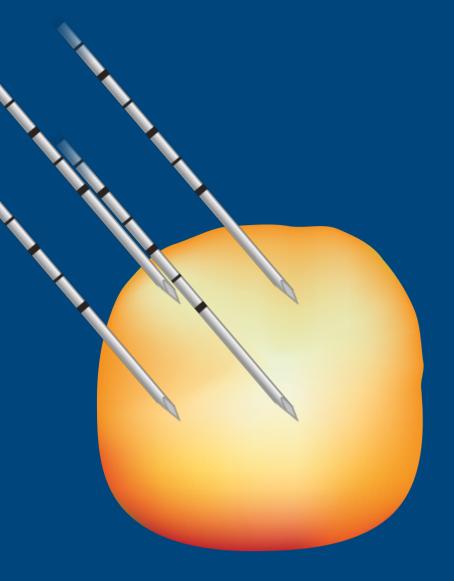


CRYOABLATION

Treatment Planning



CREATING ICE



Iceball dimensions presented in this guide are provided to assist clinicians in selecting the cryoablation needle(s) and needle placement to appropriately ablate the target area. To optimize appropriate margins, needles should be placed to create lethal ice beyond the perimeter of the target tissue 5-10mm depending on tissue type.

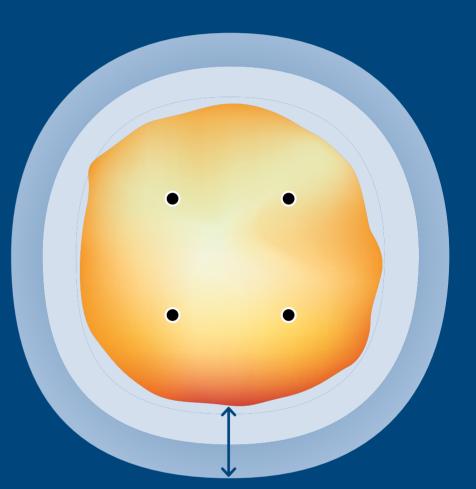
To optimize tumor coverage and provide appropriate margins, use of multiple needles is recommended. Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball.

In clinical use, patient anatomy, tissue and tumor properties affect

needle placement. Needle type, number of needles placed, tissue and tumor characteristics, surrounding vasculature and treatment duration affect iceball size.

Intraoperative imaging is important to monitor iceball formation throughout the procedure and is key to a successful cryoablation.

Isotherms represented in this guide were conducted in a laboratory setting in either 37°C temperature controlled gel. Isotherm measurements were made following two 10-minute freeze cycles separated by a 5-minute passive thaw on each needle type and size.

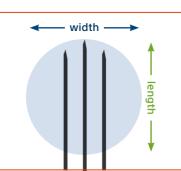


Extend ice 5-10mm beyond tumor edge

CRYOABLATION ISOTHERM DATA 37°C

1 Needle ← width →

Side view (width ±3mm x length ±4mm)



Top view/ Projection in 2D (width ±4mm and length ±4mm)

NEEDLE PLANNING GUIDE

 Choose needle type and number of needles to surround the tumor with lethal ice based on application, tumor location and tumor size

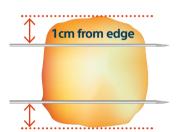
NOTE:

0°C is the visible edge of the iceball and is not lethal

 Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball

NOTE:

Needles spaced too far apart risk areas of non-lethal ice



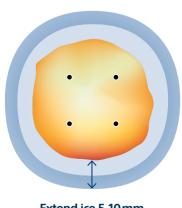
Needle tips extend 5-10 mm beyond tumor edge

- Place needles no further than 1cm from the tumor's edge
- Extend the needle tip beyond the distal edge of the tumor to ensure appropriate coverage with lethal ice

NOTE:

-20°C ice extends less than 5mm beyond the needle tip

• Use imaging to confirm iceball completely engulfs the tumor with a 5-10 mm margin depending on tissue type



Extend ice 5-10 mm beyond tumor edge

IceSeed[™] 1.5 Family

Optimal spacing: 1.0 cm

IceSeed™ 1.5 Straight Needle: FPRPR3201 IceSeed™ 1.5 90° Needle: FPRPR3202

Shaft Length: 17.5cm Shaft Diameter: 1.5mm / 17G

IceSphere[™] 1.5 Family

Optimal spacing: 1.0–1.5 cm

IceSphere™ 1.5 Straight Needle: FPRPR3558 IceSphere™ 1.5 90° S Needle: FPRPR3560 IceSphere™ 1.5 90° Needle: FPRPR3561 IceSphere™ 1.5 CX 90° Needle*: FPRPR3573

*Track Ablation: Radial width 2.1-2.5mm; Length 14mm Shaft Length: S10cm / 17.5cm Shaft Diameter: 1.5mm / 17G

IceRod™ 1.5 CX Family

Optimal spacing: 1.0–1.5 cm

IceRod™ 1.5 PLUS 90° Needle: FPRPR3508 IceRod™ 1.5 iThaw Needle: FPRPR4009 IceRod™ 1.5 90° CX Needle*: FPRPR3533

*Track Ablation: Radial width 2.3mm; Length 30mm Shaft Length: 17.5cm Shaft Diameter: 1.5mm / 17G

IcePearl™ 2.1 CX Family

Optimal spacing: 1.0-1.5 cm

IcePearl™ 2.1 CX Straight Needle*: FPRPR3603 IcePearl™ 2.1 CX 90° Needle*: FPRPR3601 IcePearl™ 2.1 CX L 90° Needle*: FPRPR3617

-20-

-40--50-

-20-

*Track Ablation: Radial width 2.1mm; Length 13mm Shaft Length: 17.5cm / L23cm Shaft Diameter: 2.1mm / 14G

IceFORCE[™] 2.1 CX Family

Optimal spacing: 1.5–2.0 cm

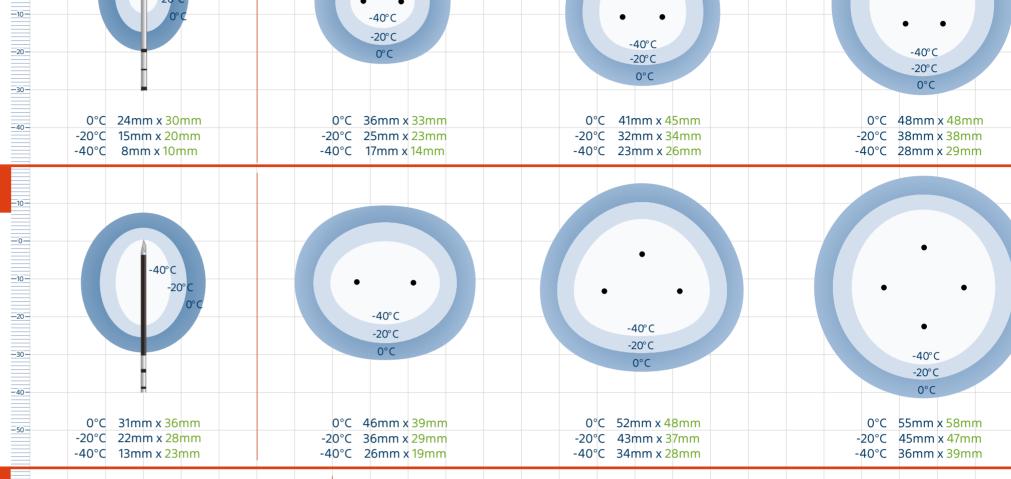
IceFORCE™ 2.1 CX Straight Needle*: FPRPR3604 IceFORCE™ 2.1 CX 90° Needle*: FPRPR3602 IceFORCE™ 2.1 CX L 90° Needle*: FPRPR3618

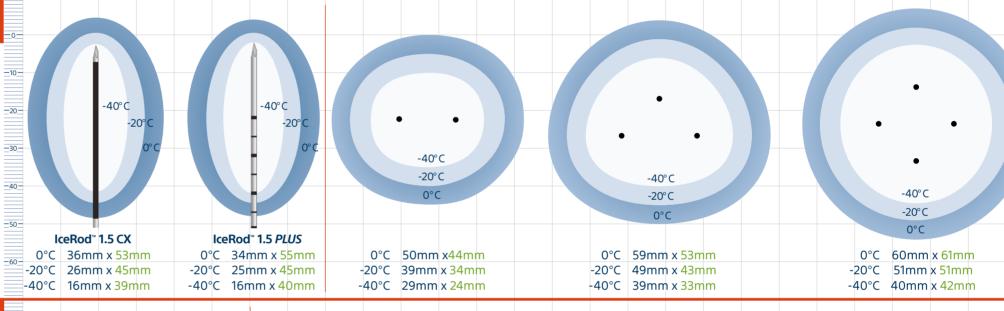
*Track Ablation: Radial width 2.5mm; Length 29mm Shaft Length: 17.5cm / L23cm Shaft Diameter: 2.1mm / 14G

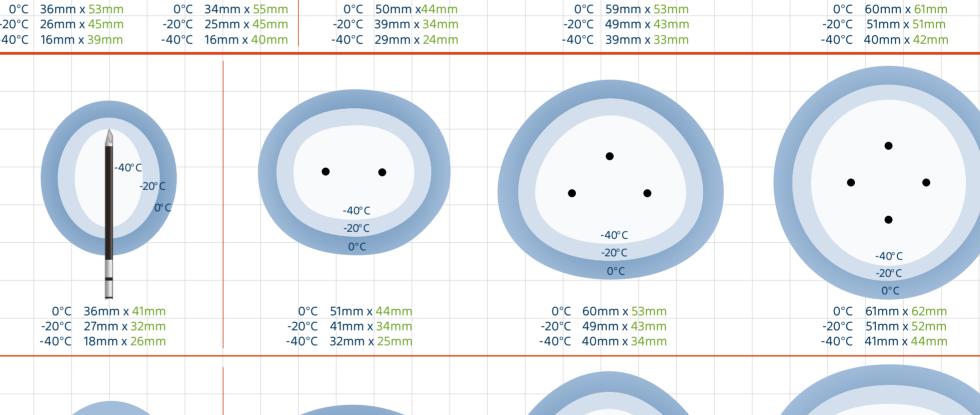


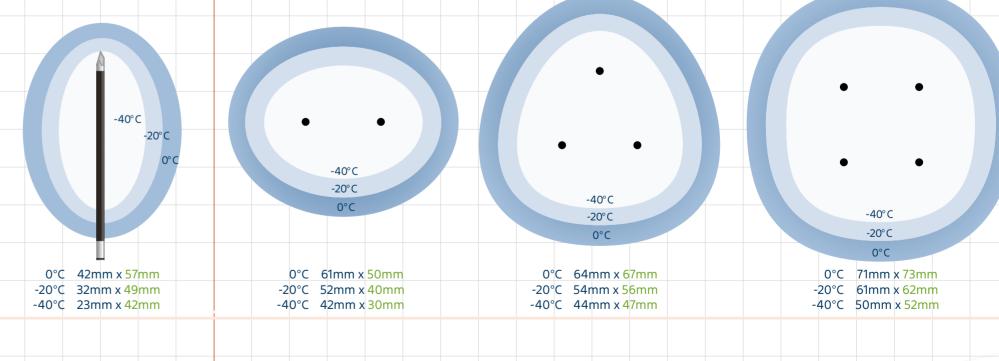
-40°C

>1 Needle









ORDERING INFORMATION CRYOABLATION PORTFOLIO OF NEEDLES

The following chart lists 90° and straight needles. Please contact your representative or customer service for MRI compatible needles, needle kits and cryoablation systems.

Cryoablation Needles	REF	Shaft Length / Gauge	Track Ablation Radial Width / Length
IceSeed™ 1.5 90°	FPRPR3202	17.5cm / 17G	
IceSeed™ 1.5 Straight	FPRPR3201	17.5cm / 17G	
IceSphere™ 1.5 90°	FPRPR3560	17.5cm / 17G	
IceSphere™ 1.5 S 90°	FPRPR3561	10cm / 17G	
IceSphere™ 1.5 CX 90°	FPRPR3573	17.5cm / 17G	1.7mm / 14mm
IceSphere™ 1.5 Straight	FPRPR3558	17.5cm / 17G	
IceRod™ 1.5 PLUS 90°	FPRPR3508	17.5cm / 17G	
IceRod™ 1.5 CX 90°	FPRPR3533	17.5cm / 17G	2.3mm / 30mm
IceRod™ 1.5 i-Thaw° Straight	FPRPR4009	17.5cm / 17G	
IcePearl™ 2.1 CX 90°	FPRPR3601	17.5cm / 14G	2.1mm / 13mm
IcePearl™ 2.1 CX L 90°	FPRPR3617	23cm / 14G	2.1mm / 13mm
IcePearl™ 2.1 CX Straight	FPRPR3603	17.5cm / 14G	2.1mm / 13mm
IceFORCE™ 2.1 CX 90°	FPRPR3602	17.5cm / 14G	2.5mm / 29mm
IceFORCE™ 2.1 CX L 90°	FPRPR3618	23cm / 14G	2.5mm / 29mm
IceFORCE™ 2.1 CX Straight	FPRPR3604	17.5cm / 14G	2.5mm / 29mm



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