

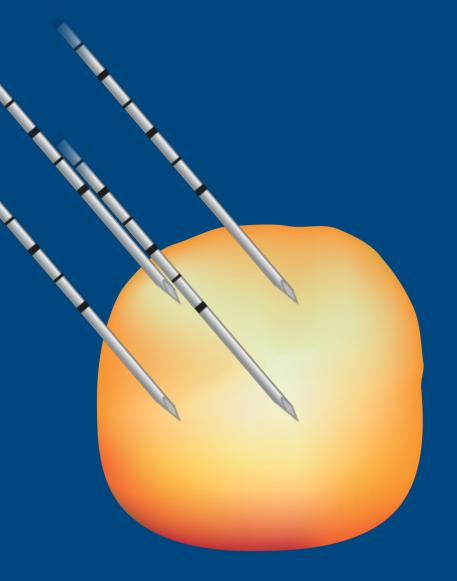


CRYOABLATION

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 5-10 mm depending on tissue type.

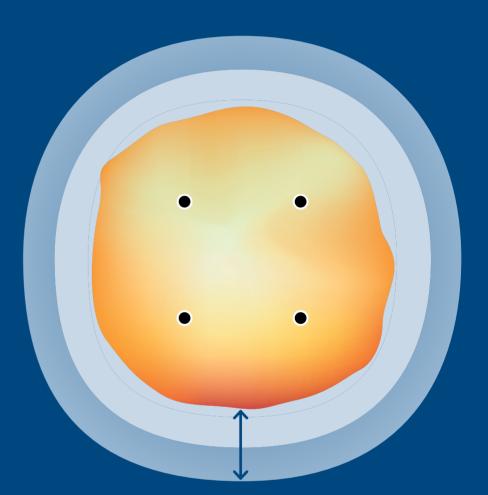
To optimize tumor coverage and provide appropriate margins, use of multiple needles is recommended. Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball.

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.

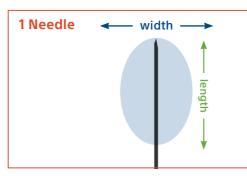
Intraoperative imaging is important to monitor iceball formation throughout the procedure and is key to a successful cryoablation.

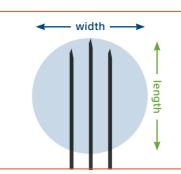
Isotherms represented in this guide were conducted in a laboratory setting in either 37° C temperature controlled gel. Isotherm measurements were made following two 10-minute freeze cycles separated by a 5-minute passive thaw on each needle type and size.



Extend ice 5-10 mm beyond tumor edge

CRYOABLATION ISOTHERM DATA 37°C





>1 Needle

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

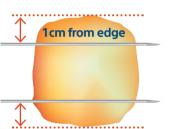
NOTE:

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



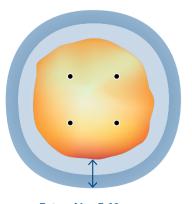
Needle tips extend 5-10 mm beyond tumor edge

- 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: H7493962232010 IceSeed™ 1.5 90° Needle: H7493962332020

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

IceSphere[™] 1.5 Family

Optimal spacing: 1.0–1.5 cm

IceSphere[™] 1.5 Straight Needle: H7493962535580 IceSphere[™] 1.5 90° S Needle: FPRPR3560 IceSphere[™] 1.5 90° Needle: H7493962735610 IceSphere[™] 1.5 CX 90° Needle*: H7493961535730

*Track Ablation: Radial width 2.1-2.5 mm; Length 14 mm Shaft Length: S10 cm / 17.5 cm Shaft Diameter: 1.5 mm / 17 G

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*: H7493961435330

*Track Ablation: Radial width 2.3 mm; Length 30 mm Shaft Length: 17.5 cm

Shaft Diameter: 1.5 mm / 17 G

IcePearl™ 2.1 CX Family

Optimal spacing: 1.0–1.5 cm

IcePearl™ 2.1 CX Straight Needle*: H7493961836030 IcePearl™ 2.1 CX 90° Needle*: H7493961636010 IcePearl™ 2.1 CX L 90° Needle*: H7493962036170

*Track Ablation: Radial width 2.1 mm; Length 13 mm Shaft Length: 17.5 cm / L23 cm Shaft Diameter: 2.1 mm / 14 G

IceFORCE[™] 2.1 CX Family

Optimal spacing: 1.5-2.0 cm

IceFORCE™ 2.1 CX Straight Needle*: H7493961936040 IceFORCE™ 2.1 CX 90° Needle*: H7493961736020 IceFORCE™ 2.1 CX L 90° Needle*: H7493962136180

*Track Ablation: Radial width 2.5 mm; Length 29 mm Shaft Length: 17.5 cm / L23 cm Shaft Diameter: 2.1 mm / 14 G



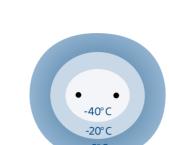
0° C 24mm x 30mm

-20° C 15mm x 20mm

-40° C 8mm x 10mm

__0_

__10 __20 __30 __40_



0° C 36mm x 33mm

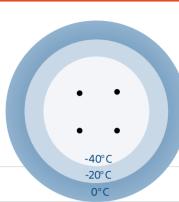
-20° C 25mm x 23mm

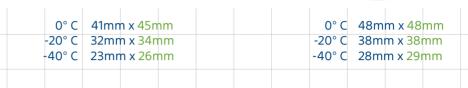
-40° C 17mm x 14mm

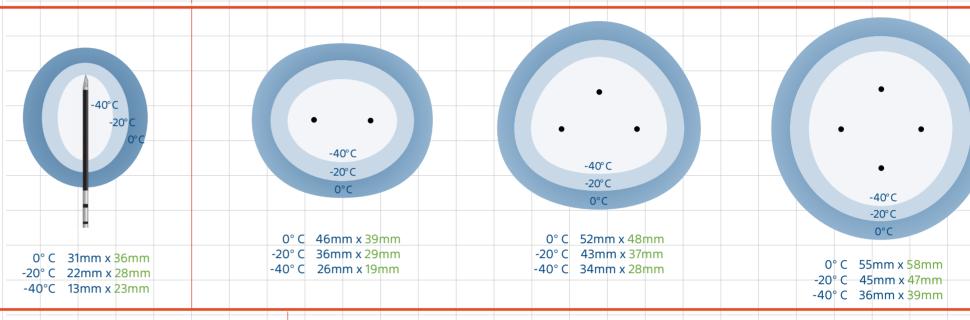


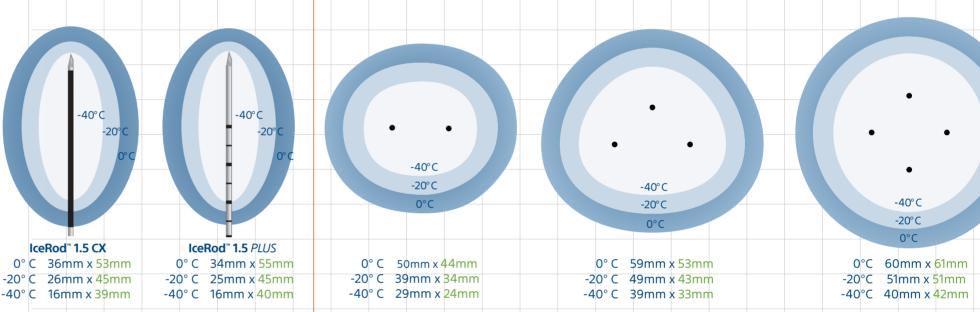
Top view/ Projection in 2D (width ±4 mm and length ±4 mm)

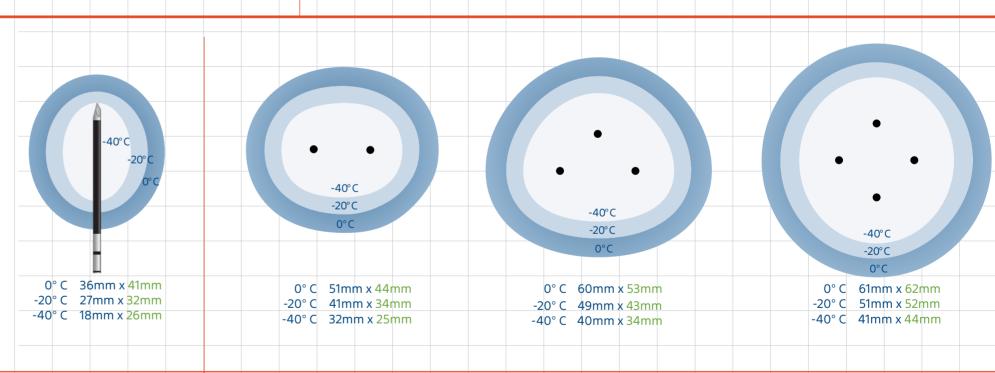
Multiple-needle treatment

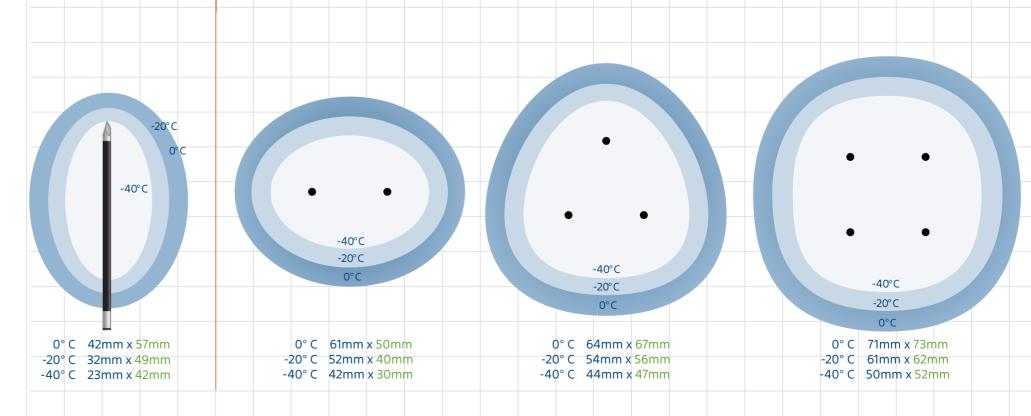












ORDERING INFORMATION CRYOABLATION PORTFOLIO OF NEEDLES

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°	H7493962332020	17.5 cm / 17 G	
IceSeed™ 1.5 Straight	H7493962232010	17.5 cm / 17 G	
IceSphere™ 1.5 90°	FPRPR3560	17.5 cm / 17 G	
IceSphere™ 1.5 S 90°	H7493962735610	10 cm / 17 G	
IceSphere™ 1.5 CX 90°	H7493961535730	17.5 cm / 17 G	1.7 mm / 14 mm
IceSphere™ 1.5 Straight	H7493962535580	17.5 cm / 17 G	
IceRod™ 1.5 PLUS 90°	FPRPR3508	17.5 cm / 17 G	
IceRod™ 1.5 CX 90°	H7493961435330	17.5 cm / 17 G	2.3 mm / 30 mm
IceRod™ 1.5 i-Thaw° Straight	H7493964940090	17.5 cm / 17 G	
IcePearl™ 2.1 CX 90°	H7493961636010	17.5 cm / 14 G	2.1 mm / 13 mm
IcePearl™ 2.1 CX L 90°	H7493962036170	23 cm / 14 G	2.1 mm / 13 mm
IcePearl™ 2.1 CX Straight	H7493961836030	17.5 cm / 14 G	2.1 mm / 13 mm
IceFORCE™ 2.1 CX 90°	H7493961736020	17.5 cm / 14 G	2.5 mm / 29 mm
IceFORCE™ 2.1 CX L 90°	H7493962136180	23 cm / 14 G	2.5 mm / 29 mm
IceFORCE™ 2.1 CX Straight	H7493961936040	17.5 cm / 14 G	2.5 mm / 29 mm



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