

NEEDLE PLACEMENT GUIDE

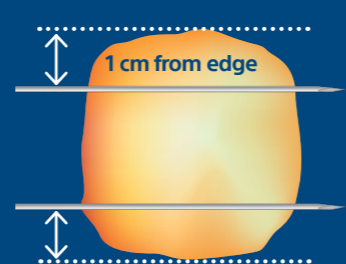
To optimize tumor coverage and provide appropriate margins, the use of multiple needles is recommended. Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball. In clinical use, patient anatomy, tissue, and tumor properties affect needle placement. Needle type, number of needles placed, tissue and tumor characteristics, the surrounding vasculature, and treatment duration also affect iceball size. Monitoring iceball formation provides direct control throughout the procedure and is the key to a successful cryoablation.

Iceball dimensions are provided to assist users 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.

Needle testing was conducted in a laboratory setting in 37 °C temperature controlled gel. Isotherm measurements were made following two 10-minute freeze cycles separated by a 5-minute passive thaw cycle.

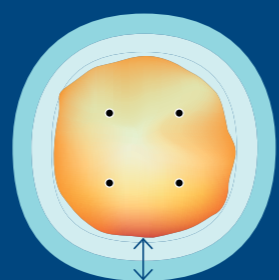
- Select needles appropriate for the application, tumor location, and tumor size
- Choose needle type and number of needles to surround the tumor with lethal ice
Note: 0 °C ice (the visible edge of the iceball) is not lethal
– An iceball must extend 5-10 mm beyond the tumor margin for appropriate coverage
- Space needles as recommended on the chart
- Place needles no further than 1 cm from the tumor edge

Needle tips extend 5-10 mm beyond tumor edge



- Extend the needle tip beyond the distal edge of the tumor to ensure appropriate coverage with lethal ice
Note: the -20 °C ice extends less than 5 mm beyond the needle tip
- Needles spaced closer than recommended may result in a smaller iceball than desired and non-lethal ice on the periphery of the tumor*
- Needles spaced too far apart risk areas of non-lethal ice between needles*
- Confirm with imaging that the iceball completely engulfs the tumor with a 5-10 mm margin

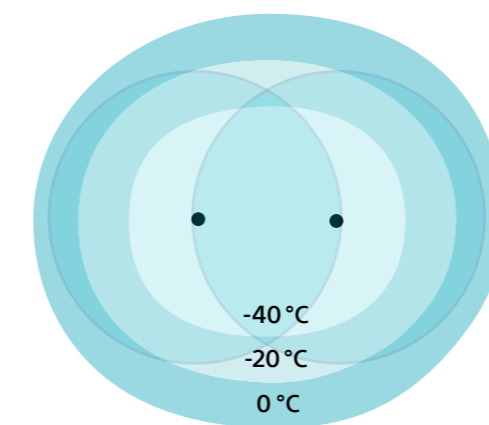
Extend ice 5-10 mm beyond tumor edge



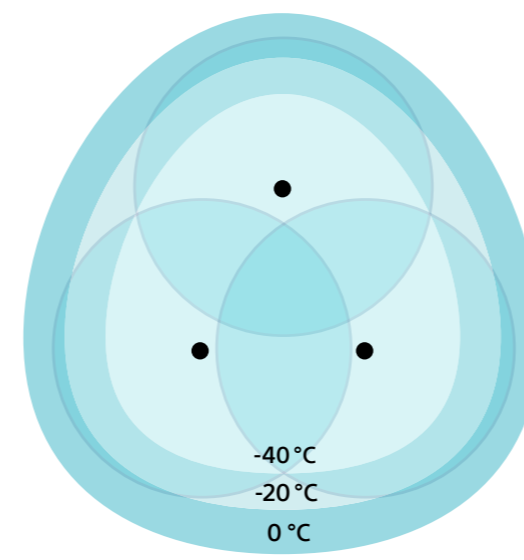
NEEDLE SPACING

Use multiple needles to fully cover a target site and provide a suitable margin

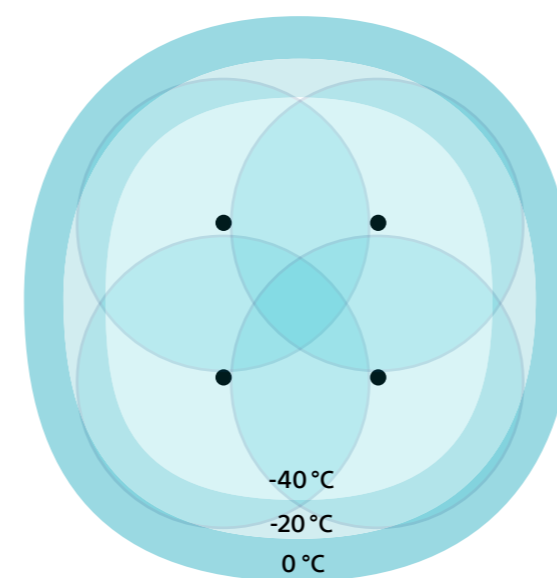
- Space needles as recommended on the chart
- Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball*
- Needles spaced too far apart risk areas of non-lethal ice*



2 needle placement



3 needle placement



4 needle placement

ORDERING INFORMATION

The following chart lists CX needles; contact your local Boston Scientific representative for our Classic and MRI conditional needle features and order numbers.

CRYOABLATION NEEDLES	PART NUMBER	CONFIGURATION	SHAFT DIAMETER (MM / GAUGE)	SHAFT LENGTH (CM)	HANDLE COLOR	TRACK ABLATION RADIAL WIDTH / LENGTH
IcePearl™ 2.1 CX	FPRPR3603	Straight	2.1 mm / 14 G	17.5 cm	White	2.1 / 13 mm
IcePearl™ 2.1 CX	FPRPR3601	Angled 90°	2.1 mm / 14 G	17.5 cm	White	2.1 / 13 mm
IcePearl™ 2.1 CX L	FPRPR3617	Angled 90°	2.1 mm / 14 G	23 cm	White	2.1 / 13 mm
IceForce™ 2.1 CX	FPRPR3604	Straight	2.1 mm / 14 G	17.5 cm	Gray	2.5 / 29 mm
IceForce™ 2.1 CX	FPRPR3602	Angled 90°	2.1 mm / 14 G	17.5 cm	Gray	2.5 / 29 mm
IceForce™ 2.1 CX L	FPRPR3618	Angled 90°	2.1 mm / 14 G	23 cm	Gray	2.5 / 29 mm
IceRod™ 1.5 CX	H7493968535330	Straight	1.5 mm / 17 G	17.5 cm	Red	1.7 / 14 mm
IceRod™ 1.5 CX	FPRPR3533	Angled 90°	1.5 mm / 17 G	17.5 cm	Red	2.3 / 30 mm
IceSphere™ 1.5 CX	H7493968435730	Straight	1.5 mm / 17 G	17.5 cm	Yellow	1.6 / 14 mm
IceSphere™ 1.5 CX	FPRPR3573	Angled 90°	1.5 mm / 17 G	17.5 cm	Yellow	1.7 / 14 mm
IceSeed™ 1.5 CX	H7493968333170	Straight	1.5 mm / 17 G	17.5 cm	Black	1.6 / 14 mm
IceSeed™ 1.5 CX	H7493967433170	Angled 90°	1.5 mm / 17 G	17.5 cm	Black	1.6 / 14 mm
IceSeed™ 1.5 CX S	H7493967233100	Angled 90°	1.5 mm / 17 G	10 cm	Black	1.6 / 14 mm

*Shah TT, et al. Modeling cryotherapy ice ball dimensions and isotherms in a novel gel-based model to determine optimal cryo-needle configurations and settings for potential use in clinical practice. Urology. 2016;91:234-240.



Cryoablation Needles Indications, Safety, and Warnings
<https://www.bostonscientific.com/cryoneedles-indications>



ICEfx™ Cryoablation System Indications, Safety, and Warnings
<https://www.bostonscientific.com/icefx-indications>



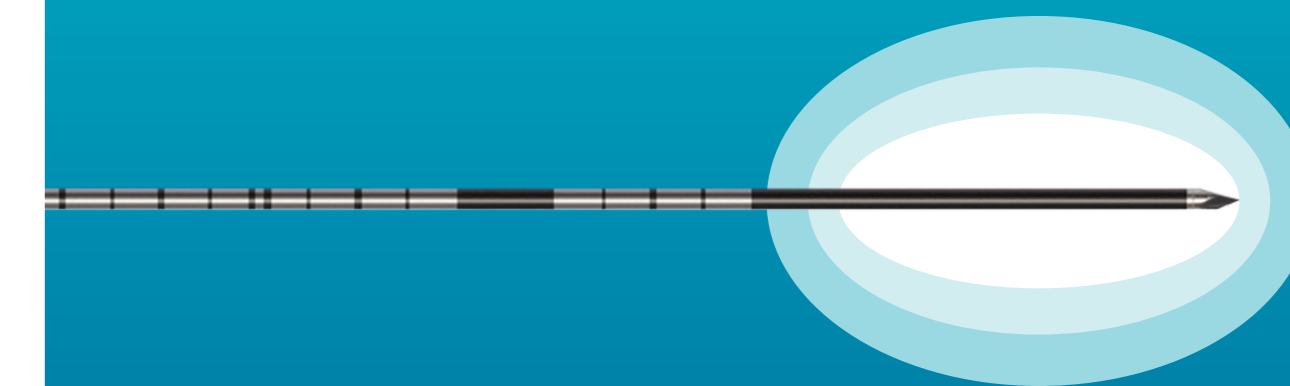
Visual ICE™ Cryoablation System Indications, Safety, and Warnings
<https://www.bostonscientific.com/visualicecryo-indications>

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CX NEEDLES ISOTHERM GUIDE

Treatment Planning



Boston Scientific
Advancing science for life™

Interventional Oncology and Embolization
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To order product or for more information contact customer service at 1.888.272.1001.

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