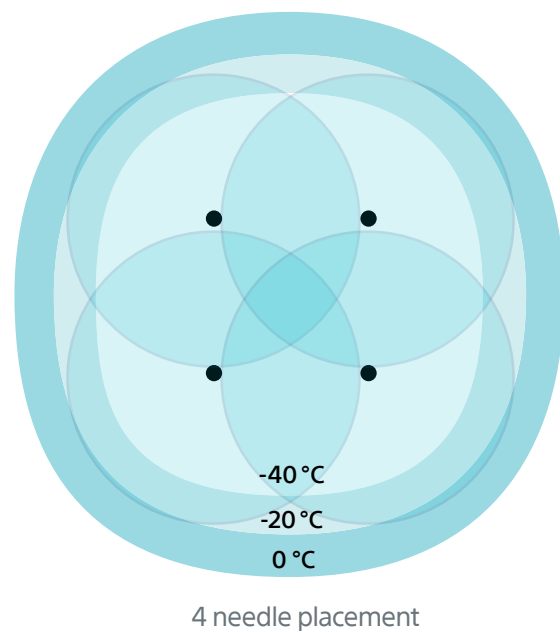
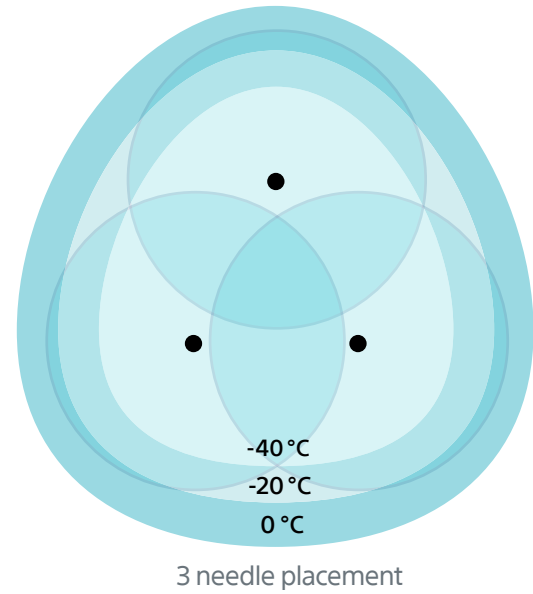
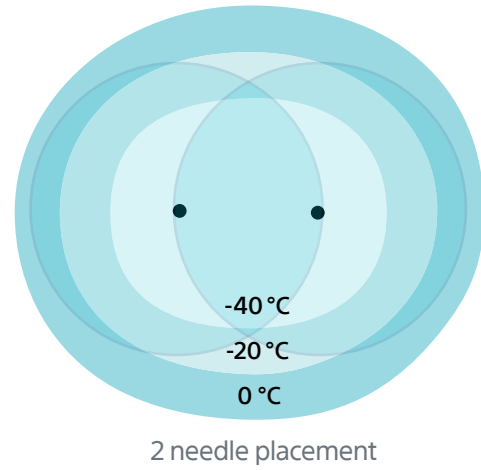


NEEDLE SPACING

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



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.

CX CRYOABLATION NEEDLES	PART NUMBER	CONFIGURATION	SHAFT LENGTH/GAUGE	TRACK ABLATION RADIAL WIDTH/LENGTH
IcePearl™ 2.1 CX Cryoablation Needle	FPRPR3603	Straight	17.5 cm/14 G	2.1/13 mm
IcePearl 2.1 CX Cryoablation Needle	FPRPR3601	Angled 90°	17.5 cm/14 G	2.1/13 mm
IcePearl 2.1 CX L Cryoablation Needle	FPRPR3617	Angled 90°	23.0 cm/14 G	2.1/13 mm
IceForce™ 2.1 CX Cryoablation Needle	FPRPR3604	Straight	17.5 cm/14 G	2.5/29 mm
IceForce 2.1 CX Cryoablation Needle	FPRPR3602	Angled 90°	17.5 cm/14 G	2.5/29 mm
IceForce 2.1 CX L Cryoablation Needle	FPRPR3618	Angled 90°	23.0 cm/14 G	2.5/29 mm
IceRod™ 1.5 CX Cryoablation Needle	FPRPR3533	Angled 90°	17.5 cm/17 G	2.3/30 mm
IceSphere™ 1.5 CX Cryoablation Needle	FPRPR3573	Angled 90°	17.5 cm/17 G	1.7/14 mm

CRYOABLATION NEEDLES (IceSeed 1.5, IceSphere 1.5, IceSphere 1.5 CX, IceRod 1.5, IceRod 1.5 PLUS, IceRod 1.5 i-Thaw, IceRod 1.5 CX, IcePearl 2.1 CX and IceForce 2.1 CX) and **ICEFX and VISUAL ICE CRYOABLATION SYSTEMS**

INDICATIONS: The Gallil Medical Cryoablation Needles and Systems are intended for cryoablative destruction of tissue during surgical procedures. The Cryoablation Needles, used with a Gallil Medical Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. Gallil Medical Cryoablation Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors and skin lesions) by the application of extremely cold temperatures. A full list of specific indications can be found in the respective Gallil Medical Cryoablation System User Manuals. **CONTRAINDICATIONS:** There are no known contraindications specific to use of a Gallil Medical Cryoablation Needle. **POTENTIAL ADVERSE EVENTS:** There are no known adverse events related to the specific use of the Cryoablation Needles. There are, however, potential adverse events associated with any surgical procedure. Potential adverse events which may be associated with the use of cryoablation may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/coronary ischemia, arrhythmia, atelectasis, bladder neck contracture, bladder spasms, bleeding/hemorrhage, creation of false urethral passage, creatinine elevation, cystitis, diarrhea, death, delayed/non healing, disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, genitourinary perforation, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure, pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary insufficiency/failure, rectal pain, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, rectourethral fistula, scrotal edema, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPI obstruction/injury, urethral sloughing, urethral stricture, urinary fistula, urinary frequency/urgency, urinary incontinence, urinary leak, urinary renal leakage, urinary retention/oliguria, urinary tract infection, vagal reaction, voiding complication including irritative voiding symptoms, vomiting, wound complication, and wound infection. **PI-719210-AA.**

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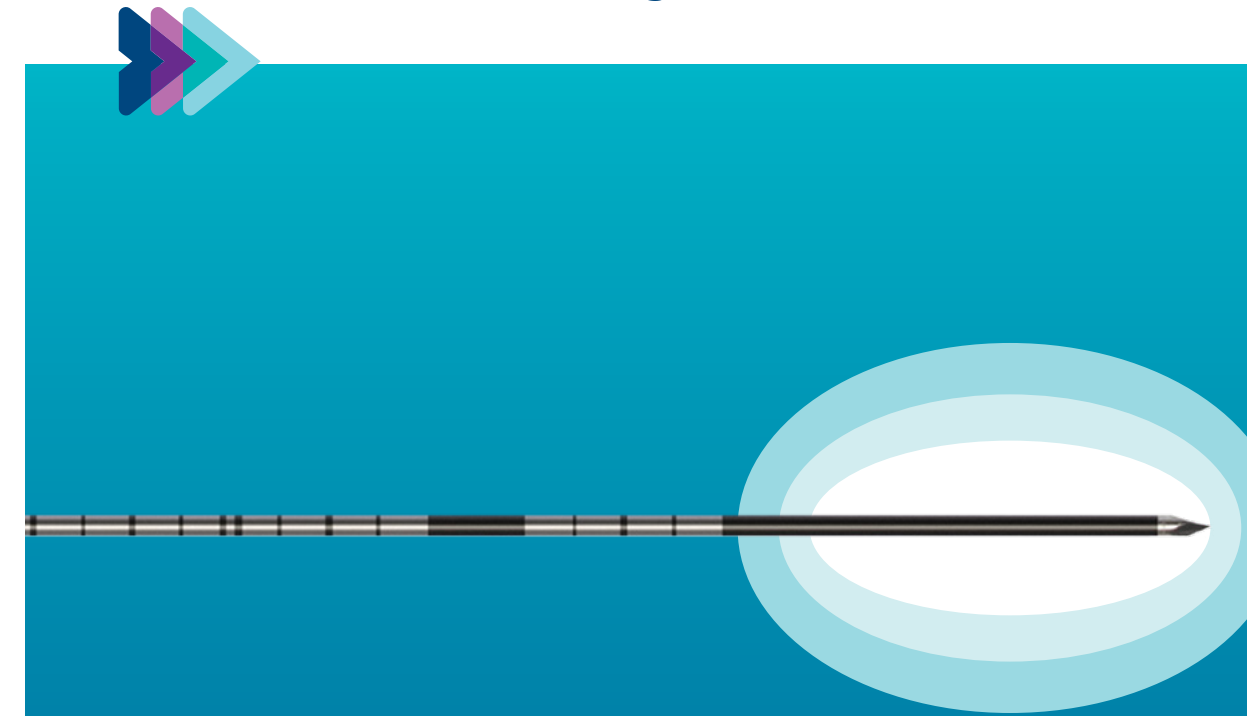
To order product or for more information contact customer service at 1.888.272.1001.

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PI-754604-AB

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CX NEEDLES ISOTHERM GUIDE Treatment Planning



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 also affect iceball size. Monitoring iceball formation provides direct control throughout the procedure and is key to 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.

NEEDLE PLACEMENT GUIDE

- Select needles appropriate for the application, tumor location and tumor size

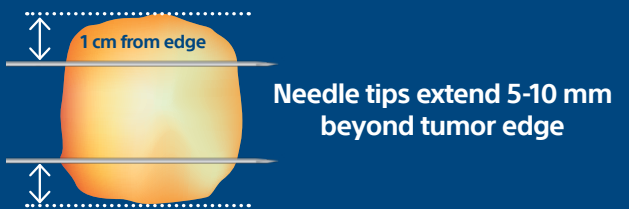
- Choose needle type and number of needles to surround the tumor with lethal ice

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



- 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

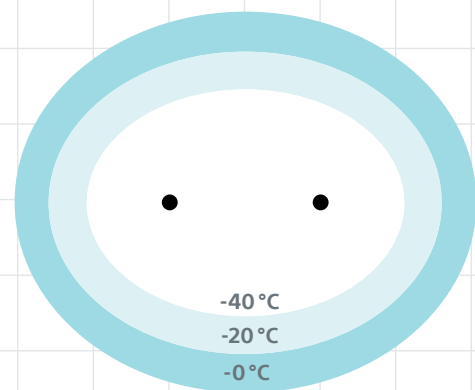
- Confirm with imaging the iceball completely engulfs the tumor with a 5-10 mm margin



IceForce™ 2.1 CX

Optimal spacing: 1.5–2.0 cm
14 gauge needle / 17.5/23 cm length

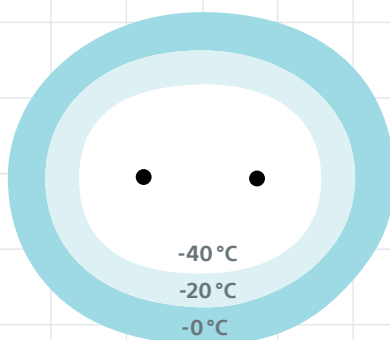
Two Needles
0 °C 61 mm x 50 mm
-20 °C 52 mm x 40 mm
-40 °C 42 mm x 30 mm



IcePearl™ 2.1 CX

Optimal spacing: 1.0–1.5 cm
14 gauge needle / 17.5/23 cm length

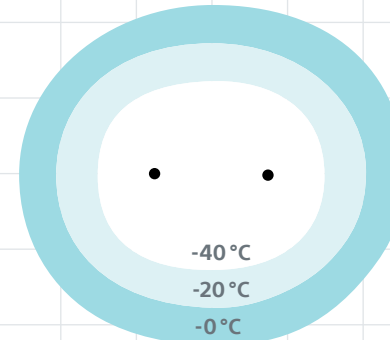
Two Needles
0 °C 51 mm x 44 mm
-20 °C 41 mm x 34 mm
-40 °C 32 mm x 25 mm



IceRod™ 1.5 CX

Optimal spacing: 1.0–1.5 cm
17 gauge needle / 17.5 cm length

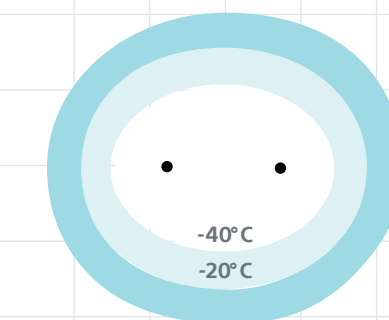
Two Needles
0 °C 49 mm x 44 mm
-20 °C 39 mm x 34 mm
-40 °C 29 mm x 24 mm



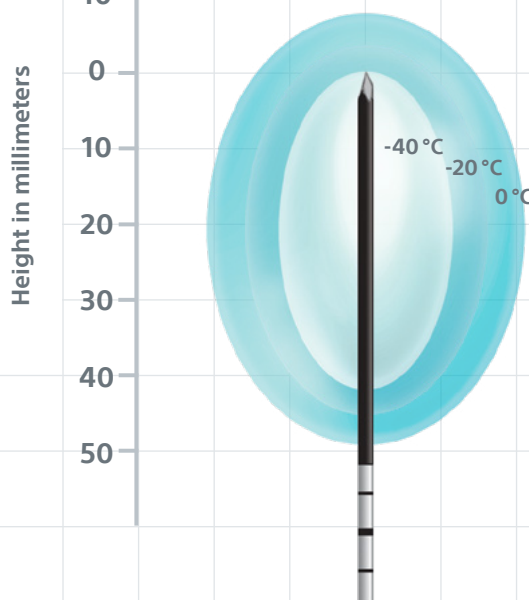
IceSphere™ 1.5 CX

Optimal spacing: 1.0–1.5 cm
17 gauge needle / 17.5 cm length

Two Needles
0 °C 46 mm x 39 mm
-20 °C 36 mm x 29 mm
-40 °C 26 mm x 19 mm

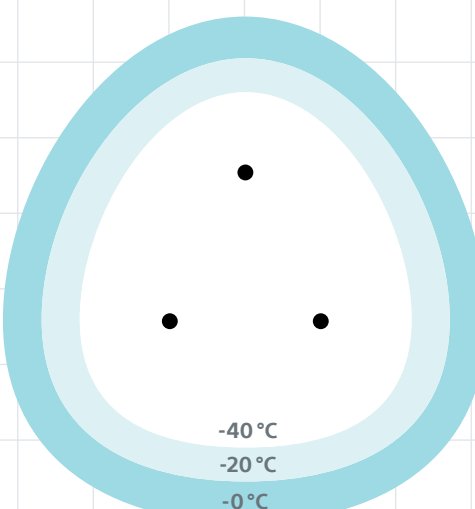


One Needle
0 °C 42 mm x 57 mm
-20 °C 32 mm x 49 mm
-40 °C 23 mm x 42 mm

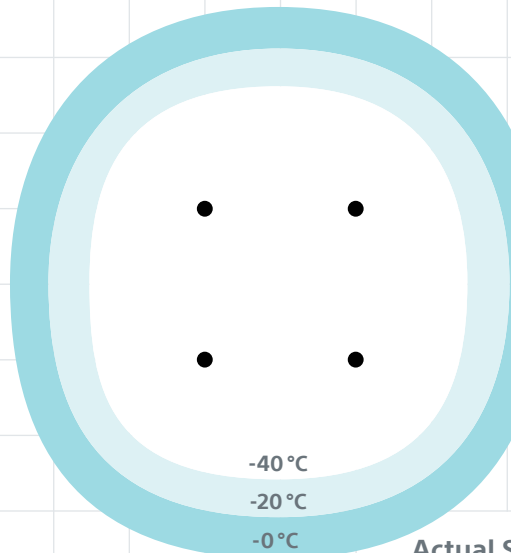


±3 mm diameter
±4 mm height

Three Needles
0 °C 64 mm x 67 mm
-20 °C 54 mm x 56 mm
-40 °C 44 mm x 47 mm

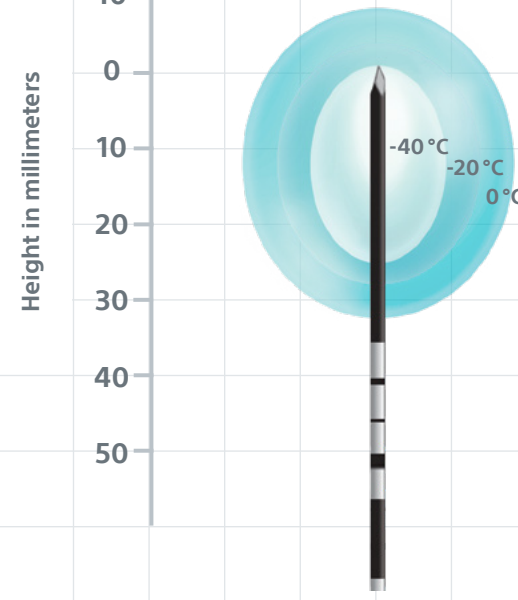


Four Needles
0 °C 71 mm x 73 mm
-20 °C 61 mm x 62 mm
-40 °C 50 mm x 52 mm



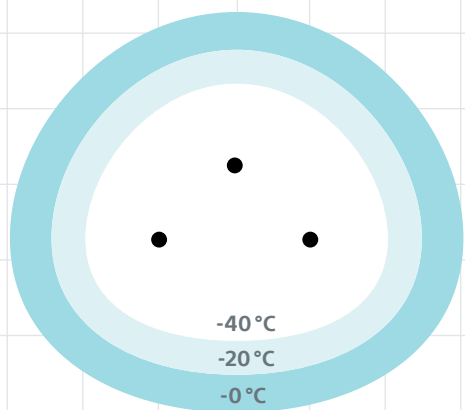
Actual Size ±5 mm

One Needle
0 °C 36 mm x 41 mm
-20 °C 27 mm x 32 mm
-40 °C 18 mm x 26 mm

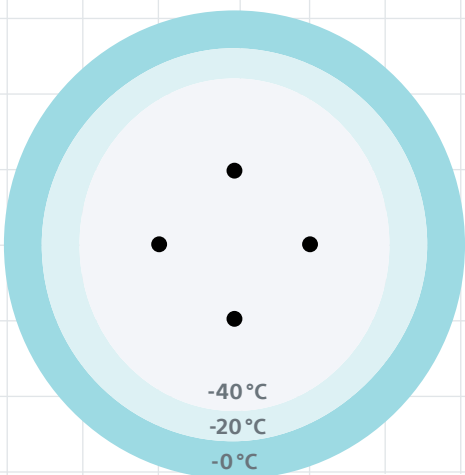


±3 mm diameter
±4 mm height

Three Needles
0 °C 60 mm x 53 mm
-20 °C 49 mm x 43 mm
-40 °C 40 mm x 34 mm

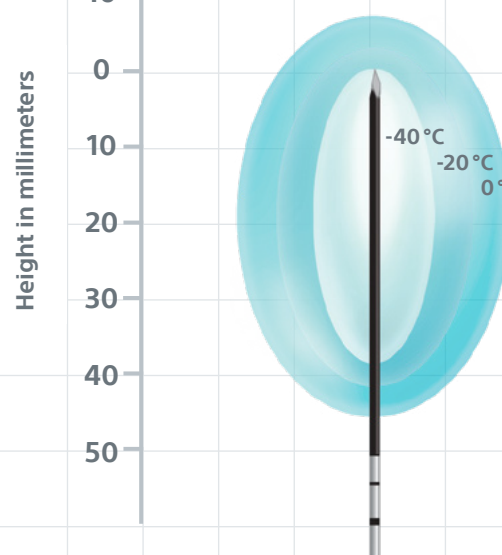


Four Needles
0 °C 61 mm x 62 mm
-20 °C 51 mm x 52 mm
-40 °C 41 mm x 44 mm



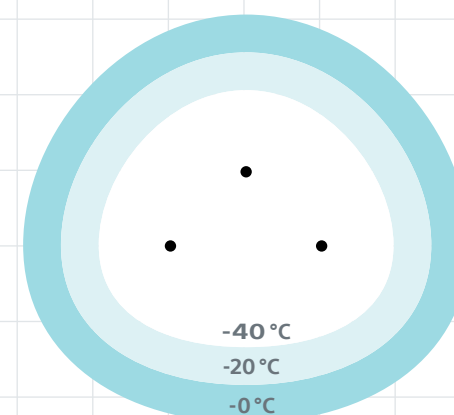
Actual Size ±5 mm

One Needle
0 °C 36 mm x 53 mm
-20 °C 26 mm x 45 mm
-40 °C 16 mm x 39 mm

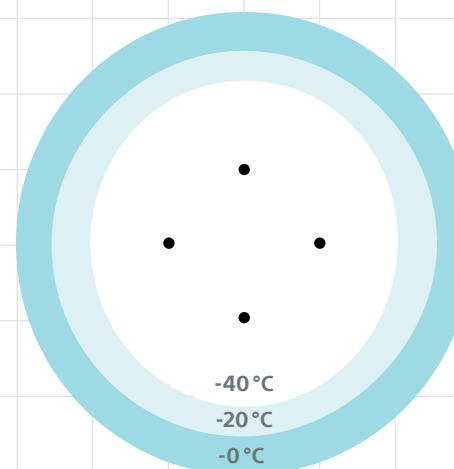


±3 mm diameter
±4 mm height

Three Needles
0 °C 59 mm x 53 mm
-20 °C 49 mm x 43 mm
-40 °C 39 mm x 33 mm

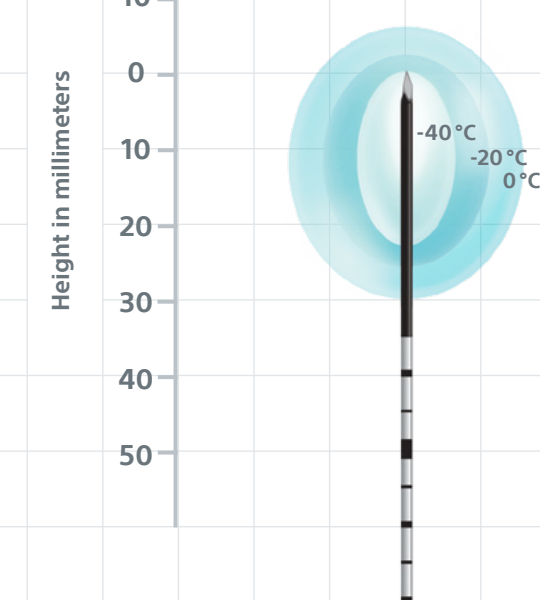


Four Needles
0 °C 60 mm x 61 mm
-20 °C 51 mm x 51 mm
-40 °C 40 mm x 42 mm



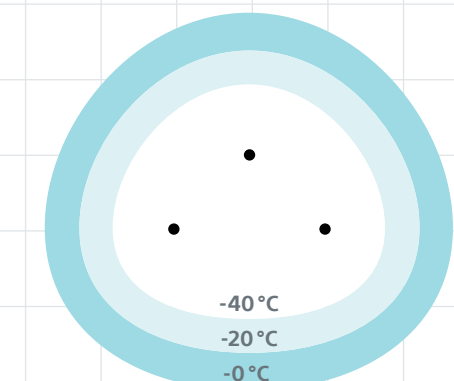
Actual Size ±5 mm

One Needle
0 °C 31 mm x 36 mm
-20 °C 22 mm x 28 mm
-40 °C 13 mm x 23 mm

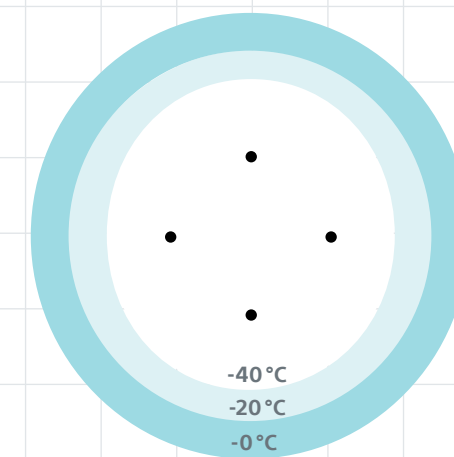


±3 mm diameter
±4 mm height

Three Needles
0 °C 52 mm x 48 mm
-20 °C 43 mm x 37 mm
-40 °C 34 mm x 28 mm



Four Needles
0 °C 55 mm x 58 mm
-20 °C 45 mm x 47 mm
-40 °C 36 mm x 39 mm



Actual Size ±5 mm