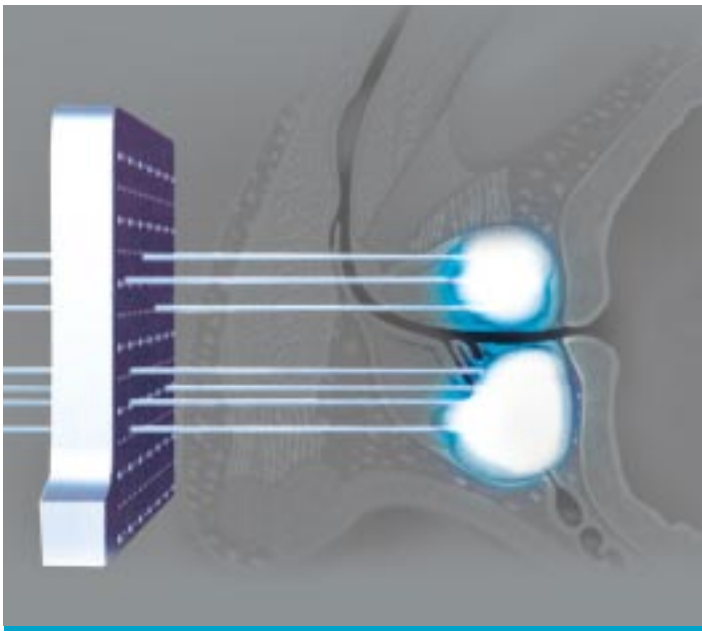
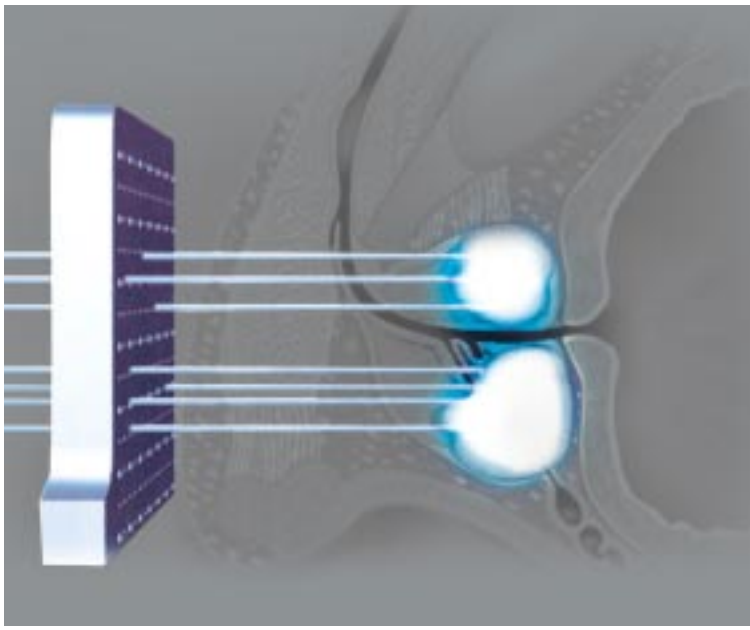
SeedNet™ Gold



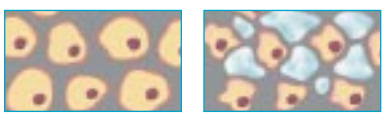
Cryotherapy offers a minimally invasive treatment option for prostate cancer

ONCURA



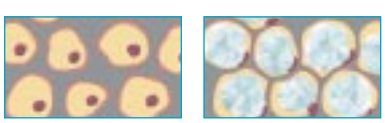
Cryotherapy offers a minimally invasive treatment option for prostate cancer

Mechanisms of cryogenic necrosis



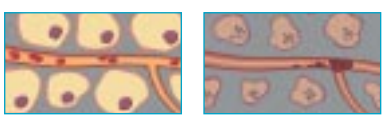
Cell dehydration

Extracellular ice crystal formation causes a hyperosmotic extracellular environment that dehydrates cells and damages cell constituents.[1]



Intracellular ice formation

Intracellular ice formation results in disruption of organelles and cell membranes leading to cell death.[1]



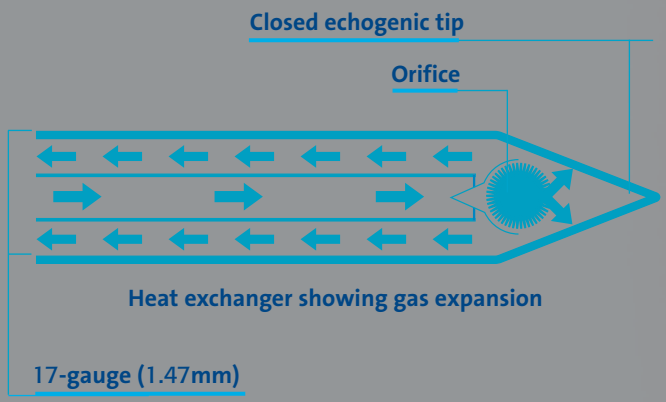
Ischemia

Ischemia leads to anoxia, endothelial damage and formation of thrombi.[1]

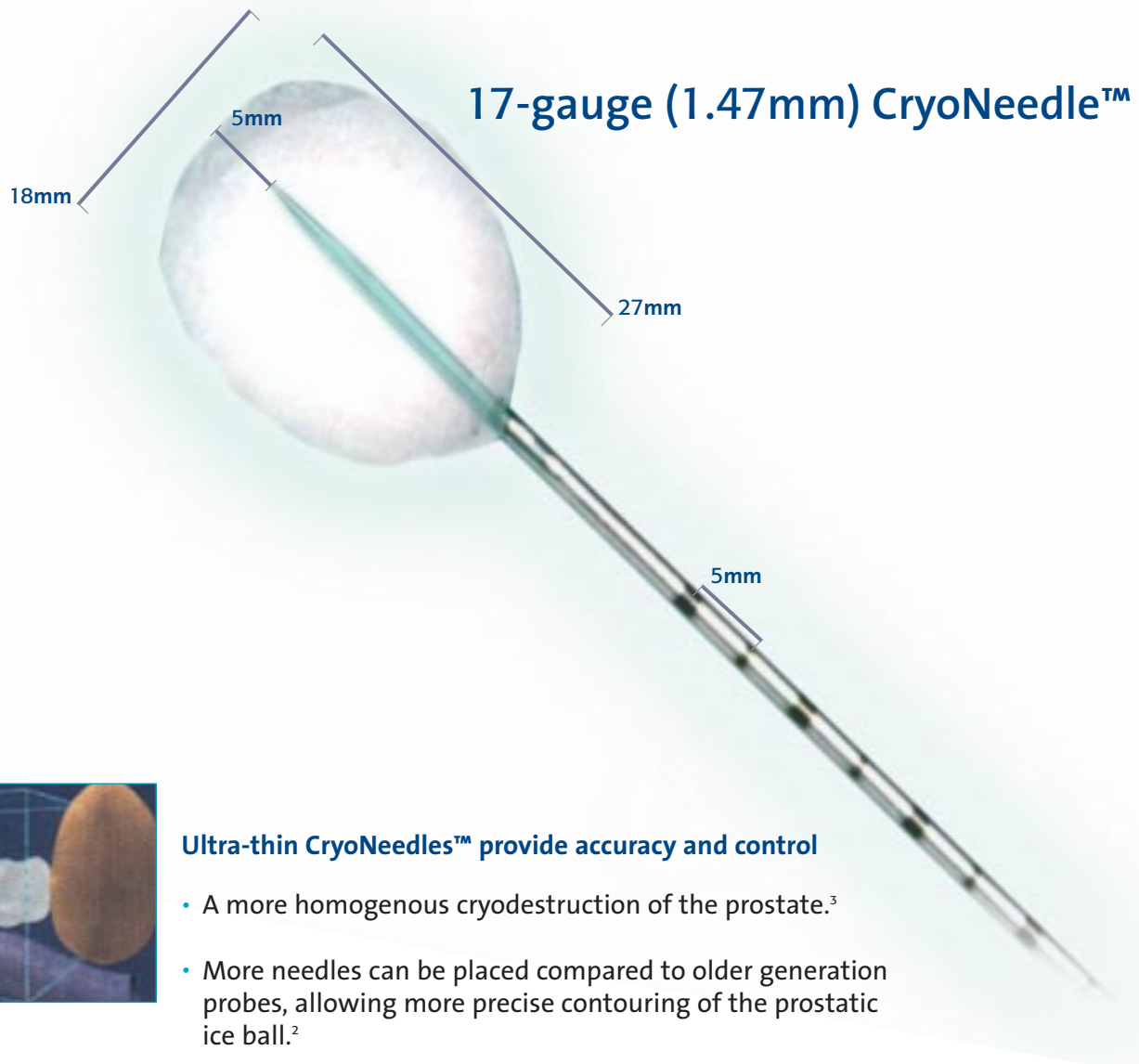
Accurate delivery of cryotherapy using 3rd generation technology

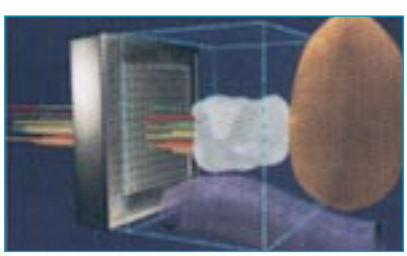
Unique technology incorporates the use of pressurized gases and Ultra-thin 17-gauge CryoNeedles™.

- Pressurized argon gas (-187°C) and pressurized helium gas (67°C) is used to thaw the organ according to the Joule-Thompson effect, in which different gases undergo unique temperature changes when depressurized according to unique gas coefficients.[2]
- The change from liquid cryogens, of previous generations, to gaseous cryogens allows the use of smaller diameter needles.



17-gauge (1.47mm) CryoNeedle™

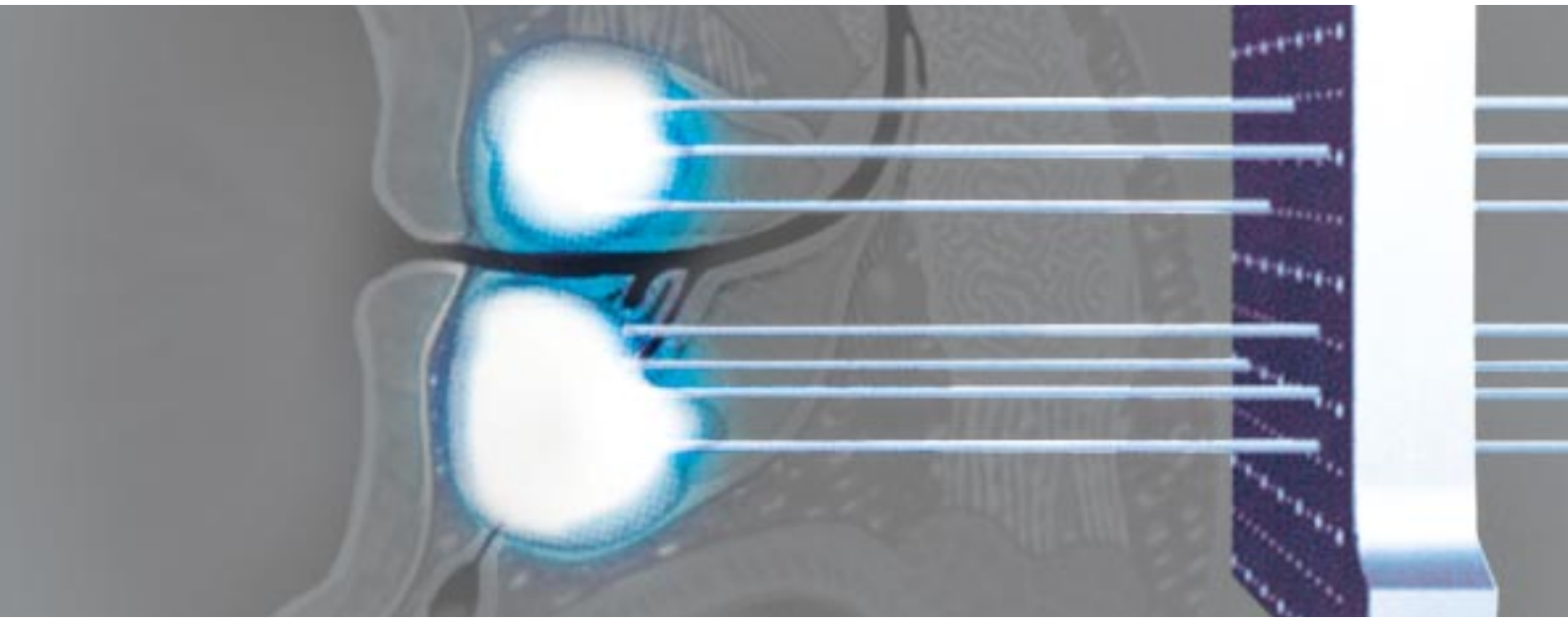




Ultra-thin CryoNeedles™ provide accuracy and control

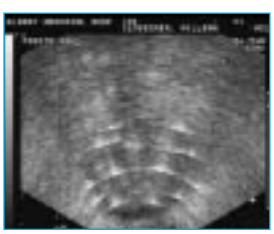
- A more homogenous cryodestruction of the prostate.[3]
- More needles can be placed compared to older generation probes, allowing more precise contouring of the prostatic ice ball.[2]

Small diameter CryoNeedles™ have significantly decreased complication rates associated with cryosurgery[2]



Simple percutaneous procedure with a relatively short learning curve[2]

- Plug and Freeze™ technology using a 5mm template allows accurate CryoNeedle™ placement.
- Echogenic tipped CryoNeedles™ allow optimal visualization under TRUS.[3]



Procedure

Step 1:
The patient is placed in the lithotomy position.

Step 2:
Through a 5mm brachy-style template, up to 25 CryoNeedles™ (depending on the size and shape of the prostate) are percutaneously inserted under direct TRUS guidance according to a pre-determined configuration. Up to 5 thermosensors can be used to monitor intra-prostatic temperature.

Step 3:
Urethral protection is provided by a urethral warming catheter.

Step 4:
Under real time TRUS imaging and temperature monitoring, two freeze/thaw cycles are employed, ensuring a minimum temperature of -40˚C throughout the prostate tissue.

SeedNet™ Gold

Efficacy of cryotherapy

- 7 year actuarial biochemical disease free survival was 68% and 61% in the medium and high risk patients respectively in a series of 590 patients treated with primary cryotherapy. The mean follow-up was 5 years (the PSA definition of biochemical failure was defined as >0.5ng/ml).[4]

3rd generation cryosurgery appears to be well tolerated and minimally invasive[2]

- Urologists should consider (3rd generation) salvage cryosurgery as a minimally invasive alternative with its decrease in complication rates compared to previous salvage cryosurgery series.[2]

	3rd generation Han et al (n=122)[2]	Previous generations Long et al (n=975)[5]
Incontinence	3%	7.5%
Rectal urethral fistula	None	0.3%
Impotence	87%	93%

Cryotherapy of the prostate is safe and simple to perform[3]

"Patients in whom radiation has failed as a primary therapy and who undergo cryoablation, experience substantially lower complication rates than had they undergone radical prostatectomy"

(Cohen J.K. Editorial: Cryotherapy comes of age. J. Urol. Vol.170,1131, October 2003)

3rd generation cryotherapy - safety, morbidity and preliminary PSA results of 122 cases[2]

Primary cryotherapy patients

• PSA at 12 month follow-up 0.4ng/ml or less	74%
• Incontinence (pads)	3%
• Urge incontinence (no pads)	5%
• Transient urinary retention	3.3%
• Rectal discomfort	2.6%
• Impotence	87%
• Fistulas	None

Salvage cryotherapy patients

• Fistulas	None
• Incontinence (pads)	11%

SeedNet™ Gold

3rd generation, user-friendly system

- Computer workstation that allows:
  - data input
  - procedure selection
  - comprehensive monitoring of system performance
- Patented Plug and Freeze™ technology
- Patented 17-gauge CryoNeedles™
- Up to 25, 17-gauge (1.47mm) CryoNeedles in 5 groups
- Freezing and thawing – Autofreeze™ option
- 5 integrated temperature sensors

CryoNeedle™ Manifold

References:

1. Gage A.A., Baust J. Mechanisms of tissue injury in cryosurgery. Cryobiology. 1998;37:171-186.
2. Han K-R. et al. Treatment of organ-confined prostate cancer with third generation cryosurgery: preliminary multicentre experience. J. Urol.2003;170:1126-1130.
3. Cytron S. et al. Active rectal wall protection using direct transperineal cryo-needles for histologically proven prostate adenocarcinomas. European Urology 44(2003)315-321.
4. Bahn D.K. et al. Targeted cryoablation of the prostate: 7 year outcomes in the primary treatment of prostate cancer. Urology 60 (Supplement 2A) August 2002.
5. Long J.P. et al. Five-year retrospective, multi-institutional pooled analysis of cancer-related outcomes after cryosurgical ablation of the prostate. Urology 57(3),2001;518-523.
6. Image courtesy of Ulrich K.Fr. Witzsch, M.D.

Oncura Inc.
401 Plymouth Road, Suite 130
Plymouth Meeting, PA 19462

Tel: 877 639 2796
Fax: 215 868 0970
Ordering and Customer Service: 800 633 4123
Email: info@oncura.com
www.oncura.com

ONCURA

CE 0473