

Cryotherapy offers a minimally invasive treatment option for prostate cancer

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 invasive²

- 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

	3 rd 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 perform³



“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)

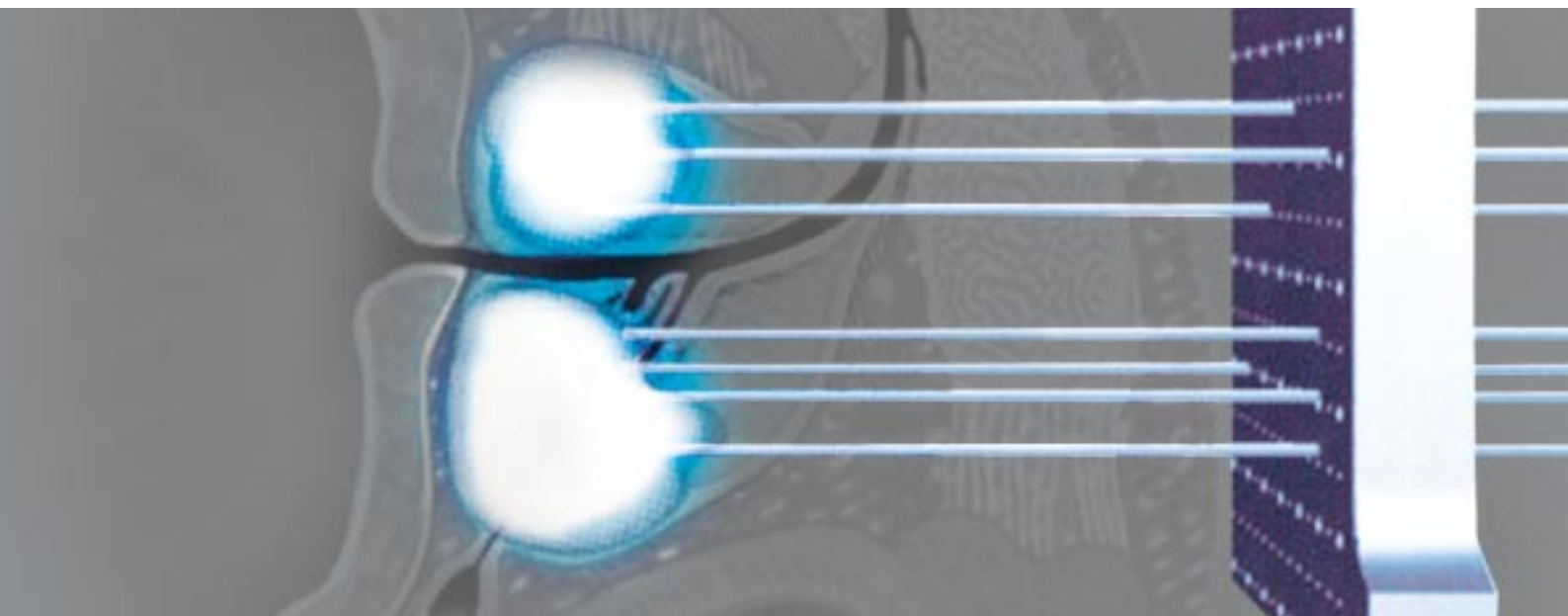
3rd generation cryotherapy - safety, morbidity and preliminary PSA results of 122 cases²

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%



Simple percutaneous procedure with a relatively short learning curve²

- 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.



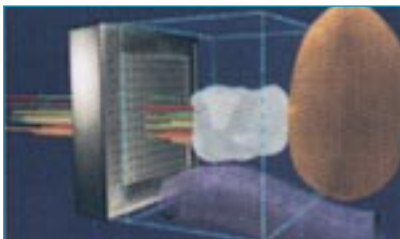
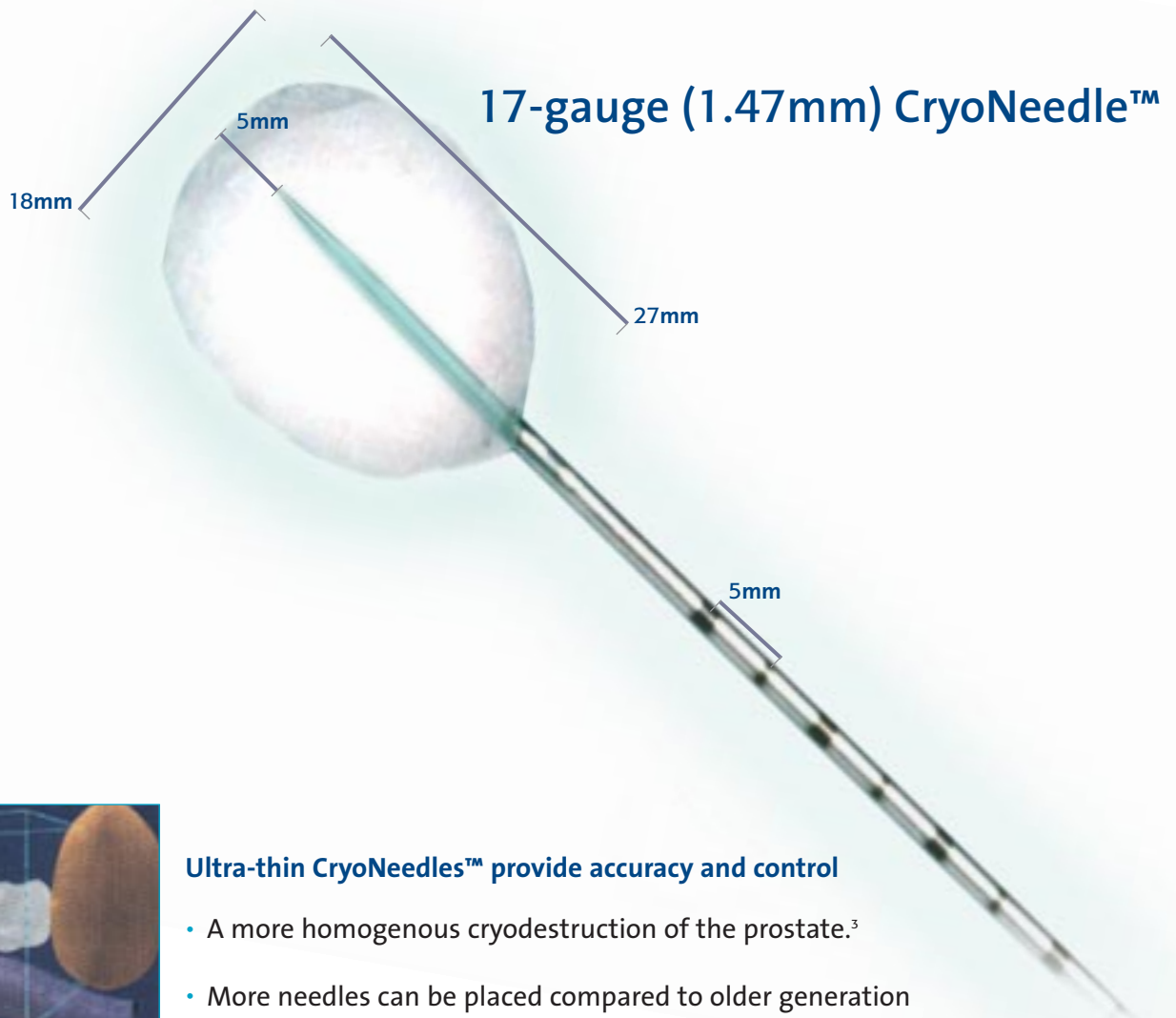
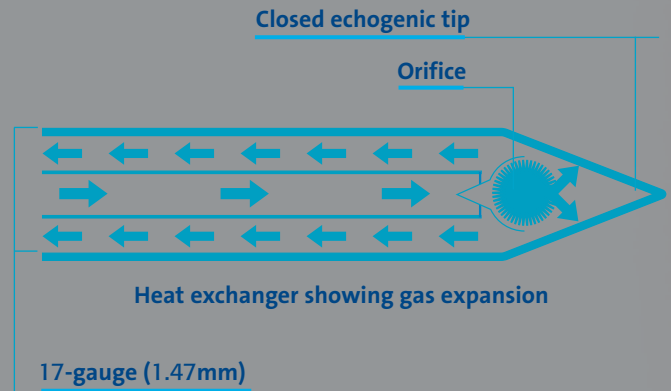
Step 4:

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.

Accurate delivery of cryotherapy using 3rd generation technology

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

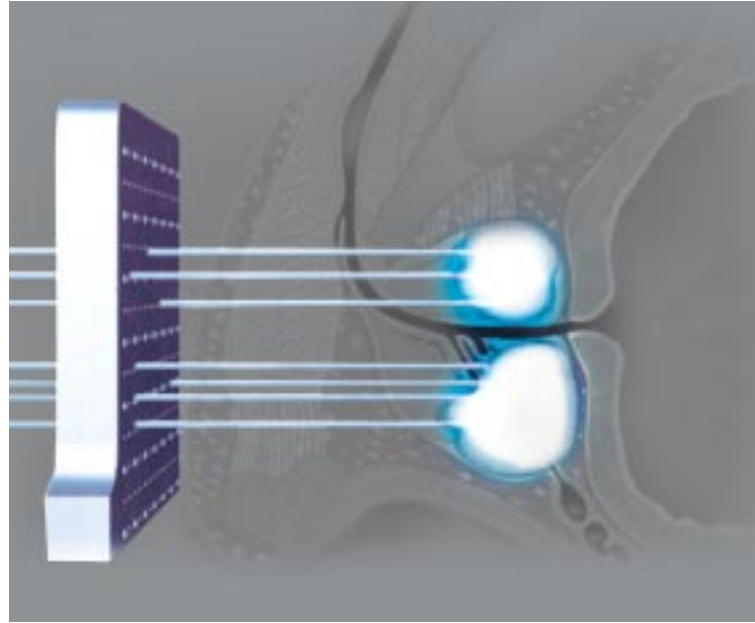
- Pressurized argon gas (-187°C) and pressurized helium gas (67°C) is used to thaw the organ according to the Joule-Thompson effect, in which different gases undergo unique temperature changes when depressurized according to unique gas coefficients.²
- The change from liquid cryogens, of previous generations,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



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 cryosurgery²



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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

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

Touchpad

Power Control Panel

- System On/Off
- Power On indicator
- Emergency STOP

CryoNeedle™ Manifold



References:

1. Gage A.A., Baust J. Mechanisms of tissue injury in cryosurgery. *Cryobiology*. 1998;37:171-186.
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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.

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Locking Wheels

- Independent locking
- Heavy duty casters