UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 8, 2025**

AngioDynamics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50761**	**11-3146460**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
14 Plaza Drive, Latham, New York		**12110**
(Address of Principal Executive Offices)		(Zip Code)

(518) 795-1400

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ANGO	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 – Regulation FD Disclosure.

On January 8, 2025, AngioDynamics, Inc. ("AngioDynamics"), will host the virtual NanoKnife Irreversible Electroporation (IRE) Prostate Investor Event. The presentation slides are furnished herewith as Exhibit 99.1.

The presentation slides furnished pursuant to Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section. Furthermore, the presentation slides shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Forward-Looking Statements

This document and its attachments contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding AngioDynamics' expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "projects", "optimistic," or variations of such words and similar expressions, are forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ materially from AngioDynamics' expectations, expressed or implied. Factors that may affect the actual results achieved by AngioDynamics include, without limitation, the scale and scope of the COVID-19 global pandemic, the ability of AngioDynamics to develop its existing and new products, technological advances and patents attained by competitors, infringement of AngioDynamics' technology or assertions that AngioDynamics' technology infringes the technology of third parties, the ability of AngioDynamics to effectively compete against competitors that have substantially greater resources, future actions by the FDA or other regulatory agencies, domestic and foreign health care reforms and government regulations, results of pending or future clinical trials, overall economic conditions (including inflation, labor shortages and supply chain challenges including the cost and availability of raw materials), the results of on-going litigation, challenges with respect to third-party distributors or joint venture partners or collaborators, the results of sales efforts, the effects of product recalls and product liability claims, changes in key personnel, the ability of AngioDynamics to execute on strategic initiatives, the effects of economic, credit and capital market conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, the ability of AngioDynamics to obtain regulatory clearances or approval of its products, or to integrate acquired businesses, as well as the risk factors listed from time to time in AngioDynamics' SEC filings, including but not limited to its Annual Report on Form 10-K for the year ended May 31, 2024. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

Item 9.01 – Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Presentation slides for the NanoKnife Irreversible Electroporation (IRE) Prostate Investor Event, dated January 8, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANGIODYNAMICS, INC.
(Registrant)

Date: January 8, 2025

By: /s/ Lawrence T. Weiss
Name: Lawrence T. Weiss
Title: Senior Vice President, Chief Legal Officer and Corporate Secretary

Exhibit 99.1


NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE
Investor Event
Revolutionizing Prostate Care:
Transforming Treatment. Driving Value.

Notice Regarding Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding AngioDynamics' expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "projects," "believes," "seeks," "estimates," "optimistic," or variations of such words and similar expressions, are forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ materially from AngioDynamics' expectations, expressed or implied. Factors that may affect the actual results achieved by AngioDynamics include, without limitation, the scale and scope of the COVID-19 global pandemic, the ability of AngioDynamics to develop its existing and new products, technological advances and patents attained by competitors, infringement of AngioDynamics' technology or assertions that AngioDynamics' technology infringes the technology of third parties, the ability of AngioDynamics to effectively compete against competitors that have substantially greater resources, future actions by the FDA or other regulatory agencies, domestic and foreign health care reforms and government regulations, results of pending or future clinical trials, overall economic conditions (including inflation, labor shortages and supply chain challenges including the cost and availability of raw materials), the results of ongoing litigation, challenges with respect to third-party distributors or joint venture partners or collaborators, the results of sales efforts, the effects of product recalls and product liability claims, changes in key personnel, the ability of AngioDynamics to execute on strategic initiatives, the effects of economic, credit and capital market conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, the ability of AngioDynamics to obtain regulatory clearances or approval of its products, or to integrate acquired businesses, as well as the risk factors listed from time to time in AngioDynamics' SEC filings, including but not limited to its Annual Report on Form 10-K for the year ended May 31, 2024. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

3 Year Strategic Transformation

Drive Portfolio Transformation

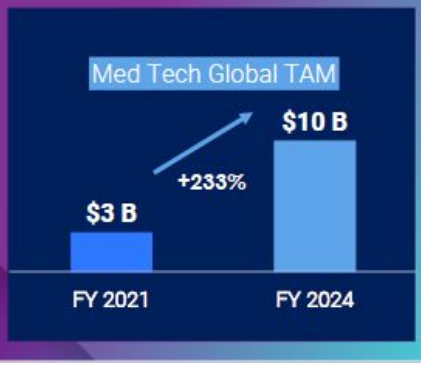
Exited and/or divested certain non-strategic businesses, reallocating resources into differentiated technologies, an expanded and robust R&D pipeline, and investing in clinical data generation while exploring new indications to drive growth opportunities.

Improve Financial Profile and Capital Structure

Through strategic business development efforts, we recapitalized our balance sheet and transformed our portfolio to drive future margin expansion and sustained profitable growth.

Pursue Larger, Faster Growing Markets

Significantly expanded the scope of our Med Tech portfolio through R&D, M&A, and clinical/regulatory initiatives by entering the mechanical thrombectomy market, capitalizing on the solid PAD market, and building on the under-penetrated prostate focal therapy market.

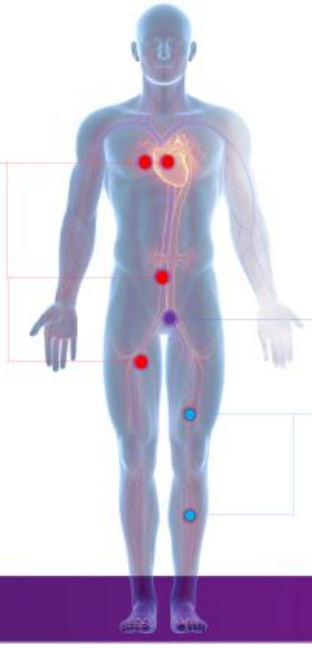


AngioDynamics

A leading medical technology company driving sustained growth and profitability through its commitment to expanding treatment options, enhancing patient outcomes, and improving quality of life, with a strategic focus on combating cardiovascular disease and cancer.

Venous Thromboembolism (VTE)
$5.3B US TAM

ANGIOVAC CANNULA & CIRCUIT ALPHAVAC



Prostate Care
$2.7B Global TAM ($780M US)

NANOKNIFE Irreversible Electroporation (IRE) PROSTATE

Peripheral Artery Disease (PAD)
$760M US TAM

AURYON

NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE

To Become

The Standard Function-Preserving Treatment For Men With Prostate Tumors

An innovative, versatile,
hour-long prostate treatment*[1,2]

*Treatment time does not include patient prep, anesthesia initiation or recovery room time.
1-2 See reference page

The NanoKnife System Is Poised To Change The Standard of Care

The First Non-Thermal, Radiation Free Ablation Technology

- The only FDA cleared technology that uses electricity to destroy prostate tissue
- Robust IP Portfolio

Clinical Outcomes Patients and Physicians Need

- Over 2,600 patients have been treated under protocol with 32 peer-reviewed studies
- The only technology with an Ablate and Resect Trial [3]

Building Momentum and Strong Commercial Viability

- FDA clearance and CE Mark Approval for prostate tissue
- IRE CPT 1 codes for prostate and liver approved 9/2024 and effective 01/2026

Proven Go-To Market Strategy For Developing New Markets

- Comprehensive clinical support, physician education, and patient awareness initiatives
- Combined with one of the largest dedicated sales and clinical teams within our market

3 - See reference page


NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE
Prostate Cancer*
*The NanoKnife System indications for use vary per region. Please refer to the indications for use for approved use per region

Prostate Cancer Is...

Prevalent

The most diagnosed male cancer in 112 countries, including the U.S.[4]

1.50M annual diagnoses[5] worldwide

300K annual diagnoses in the U.S.

On The Rise

Incidence projected to double by 2040[4]

Aging populations
Increasing life expectancy

The projected rise in prostate cancer cases cannot be prevented by lifestyle changes or public health interventions.

-The Lancet Commission on Prostate Cancer: Planning for the Surge in Cases

Debilitating

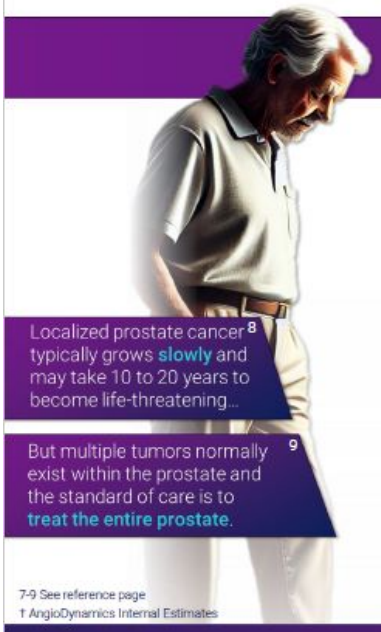
Takes more healthy years from men's lives than any other cancer[6]

- Financial
- Mental Health
- Independence
- Family and friends

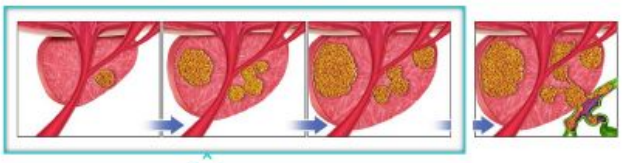
4-6 See reference page

Men Only Have Two Standard Options For Treatment

Radical surgery or external beam radiation therapy



90% Of men are diagnosed with localized disease[7]



Localized prostate cancer[8] typically grows **slowly** and may take 10 to 20 years to become life-threatening...

But multiple tumors normally exist within the prostate and the standard of care is to **treat the entire prostate.**[9]

25% **72%**

Active Surveillance† | **Definitive Therapy†**

Low Risk | Intermediate Risk | High Risk

7-9 See reference page
† AngioDynamics Internal Estimates

angiodynamics

REV 01 GL/ON/PR/3126

NANOKNIFE Irreversible Electroporation (IRE) PROSTATE

The Standard of Care Forces Men to Compromise

Between Their Quality of Life or Controlling Their Cancer

Active Surveillance

~25%

Of patients will avoid treatment, but this group will have more clinical progression, metastases, and androgen-deprivation therapy initiation when compared with patients who undergo definitive therapy[10]

Treatment-free survival rates at:[11]

Active Surveillance
Possibility of cancer progression

Definitive Treatment
Risk of serious long term urological side effects

Radical Surgery[12]

Erectile Dysfunction

Urinary Incontinence

Radiation Therapy[12]

Erectile Dysfunction

Urinary Incontinence

13

	Low Risk	Intermediate Risk	High Risk
Neoadjuvant ADT	30.2%	48.5%	79.1%
Treatment Failure*	9.7%	22.7%	42.9%

*at 8-year follow-up

10-13 See reference page

Focal Therapy is a Middle Ground Treatment Option

Which aims to destroy the index lesion while preserving the natural anatomy, continence and erectile function[14]

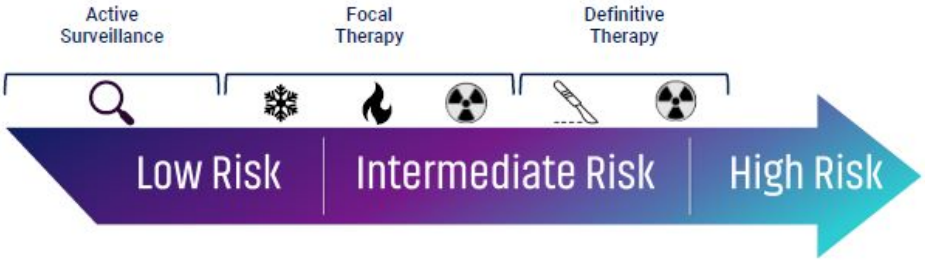
Advanced Imaging

Patient Selection

"Index Lesion"

Most lethal metastatic prostate cancers originate from a single cell within the 'Index Lesion' of the prostate.[15]

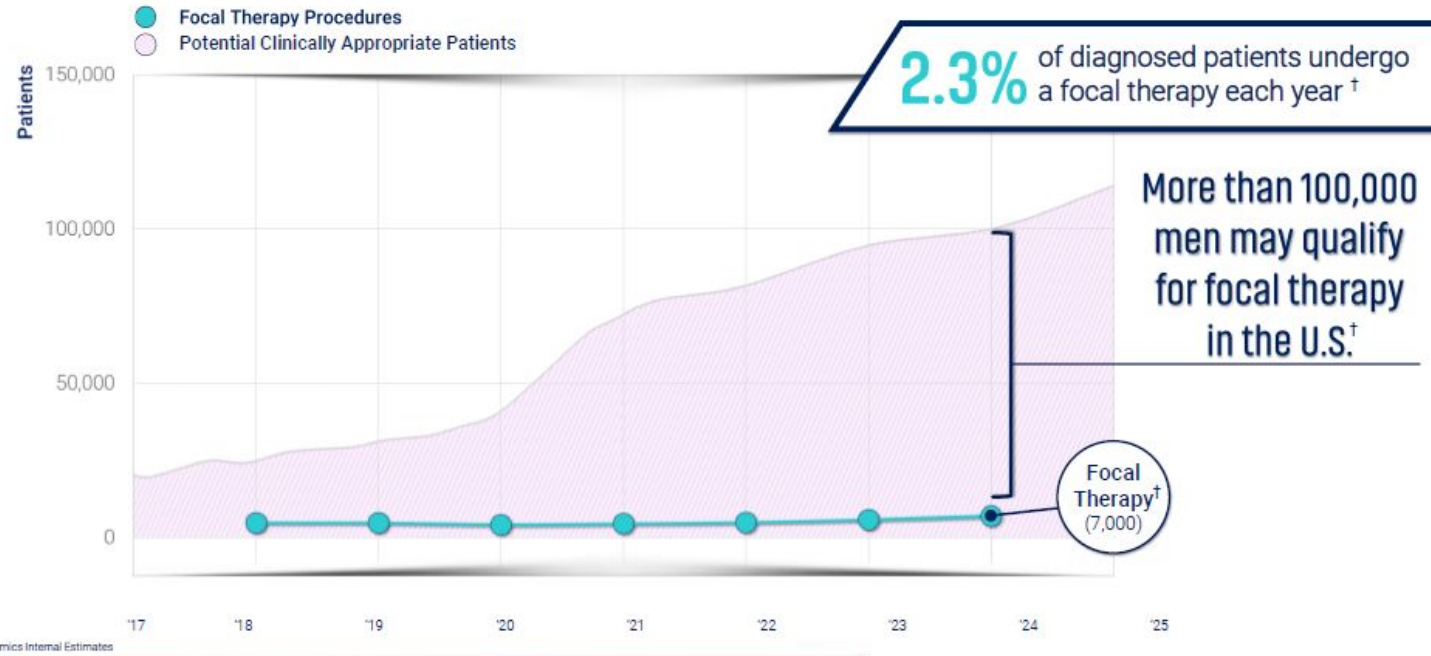
=



Accurate treatment of just the index lesion can control progression or recurrence of the disease.[14]

14-15 See reference page

Despite Patient Benefit, Focal Therapy Lacks Adoption



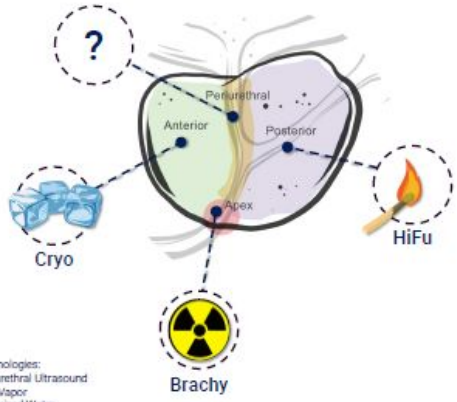
2.3% of diagnosed patients undergo a focal therapy each year †

More than 100,000 men may qualify for focal therapy in the U.S.†

† AngioDynamics Internal Estimates

A Fragmented Market Reduces Access For Patients

Today, focal therapy options are only ideal for a specific segment of the prostate.



Other Technologies:
- Transurethral Ultrasound
- Water Vapor
- Pressurized Water
- Nano Particles
- Microwave
- Laser

A piecemeal approach to focal therapy is prohibitive to broader physician adoption and limits patients' access to care.

Physician Challenges

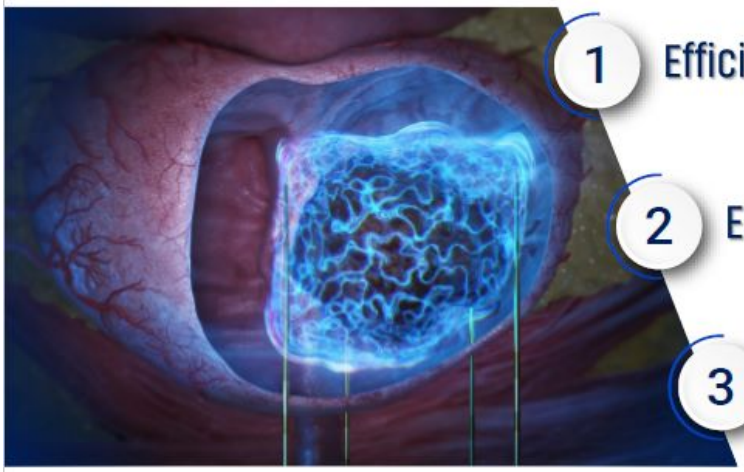
- Learning Curve
- Time Constraints
- Reproducible Results

Facility Challenges

- Increased Costs
- Complex Integration
- Support & Staffing

The NanoKnife System Is The Only All-In-One Solution

That Can Enable Broad Physician Adoption And Improved Care For Patients



1. Efficiently Treat All Segments Of The Prostate[1,2]
2. Easy Clinical Integration[1,16]
3. Strong Clinical Outcomes[1,3,17,18,19]

1-3, 16-18 See reference page

NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE

One-Of-A-Kind Technology

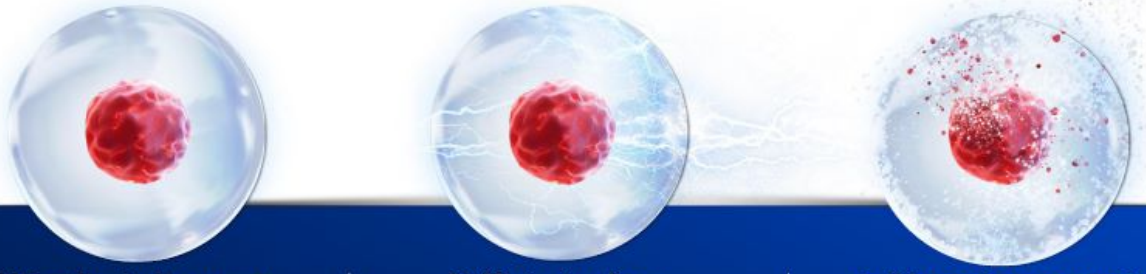
The NanoKnife System Resources

NanoKnife System Prostate Procedure Animation

NanoKnife System Mechanism of Action Animation

The NanoKnife System Is The Only Irreversible Electroporation (IRE) Device Cleared For Prostate Tissue

Non-ionizing
Non-thermal



IRE selectively targets cell membranes[20]

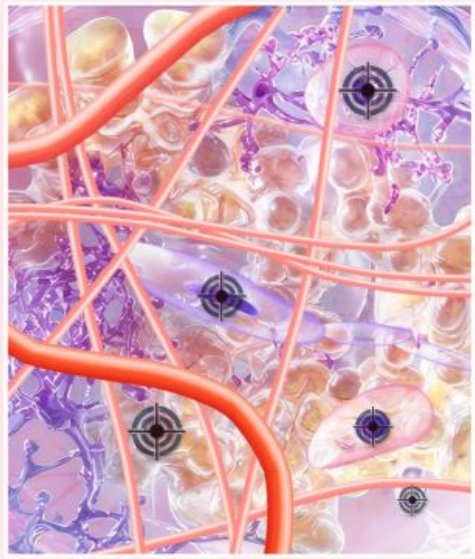
Sufficient voltage permanently opens the ion channels of the cell[20]

Cell loses homeostasis leading to cell death[20]

20 – See reference page

IRE Allows Preservation of The Underlying Tissue Structure

And Aims to Preserve the Nerves, Urethra, and Urinary Sphincters [21,22]



Targeted by IRE
- Resident Cells
- Diseased Cells

Not targeted by IRE
- Proteins
- Collagen

21,22 - See reference page

NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE

Backed by Real World Experience and Compelling Clinical Evidence

FDA Guidance Paves The Way For the NanoKnife System's Innovation

In Prostate Tissue Ablation

The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.

Indication before PRESERVE Trial

International Prostate Data
32 publications
2,642 patients

1. Efficiently Treat All Segments Of The Prostate [1,2]
2. Easy Clinical Integration [1,16]
3. Strong Clinical Outcomes [1,3,17,18,19]

1-3, 16,19 See reference page

Regulatory Clarity
Encourages Innovation
Prioritizes Patient Safety

*Clinical studies should establish a technologies ability to:

1. Effectively ablate targeted prostate tissue
2. Minimize damage to surrounding areas

*For detailed information, refer to the FDA's guidance document titled "Clinical Investigations for Prostate Tissue Ablation Devices."

Validating International Data In A U.S. Population

PRESERVE

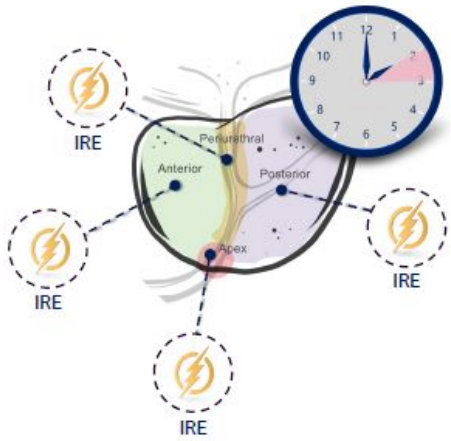
Pivotal study of the NanoKnife System for ablation of prostate tissue in patients with intermediate-risk prostate cancer

Prospective Biopsy Monitored Cohort
Collaboration with the SUO-CTC
17 U.S. sites
121 patients
12-Months Follow Up

The NanoKnife System's Versatility and Efficiency Set It Apart

Efficiently Treat All Segments Of The Prostate[1,2]

CONFIRMED



*Treatment time does not include patient prep, anesthesia initiation or recovery room time.
1,2 – See reference page

The PRESERVE Study Experience

Location of Lesions Treated

Anterior	41.7%
Posterior	58.3%

Apex	40.8%
Base	15.0%
Midline	44.2%

Procedural Information

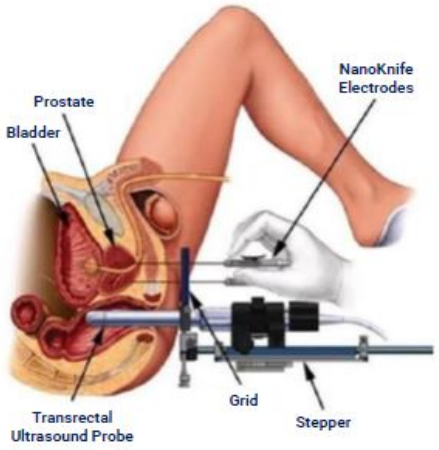
Mean Procedure Time	54.1 Minutes
Mean # of Electrodes	4.3

Integrating The NanoKnife System Is Straightforward

The Treatment Utilizes Existing Imaging and Biopsy Skills

Easy Clinical Integration[1,16]

CONFIRMED



1,16 – See reference page

The PRESERVE Study Experience

Study Size

Subjects	121
Clinical Sites	17
IRE-naïve Sites	14

Gleason Score

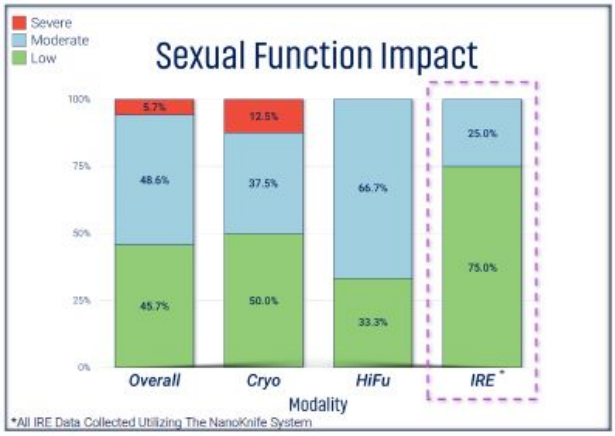
Gleason 3+4	80.2%
Gleason 4+3	19.8%

The NanoKnife System Provides Strong Clinical Outcomes

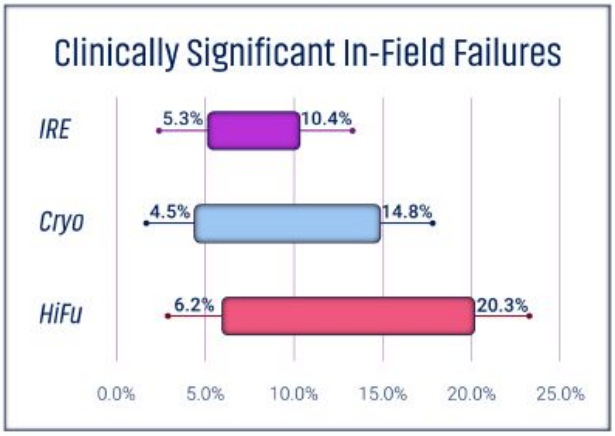
A 2024 meta-analysis and systematic review of all primary studies reporting outcomes for focal therapy [23]

nature Prostate Cancer and Prostatic Diseases

IRE has the lowest impact on sexual function compared to Hifu and Cryo



And provides strong ablation of targeted tissue



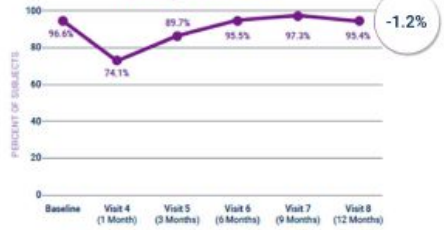
23 – See reference page

PRESERVE PIVOTAL STUDY

U.S. Experience Confirms Strong International Data

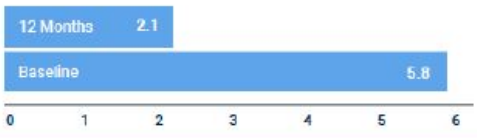
Strong Clinical Outcomes[1,16,17,18,19] CONFIRMED

Urinary Continence



Erectile Function

Median PSA



Efficacy & Safety Outcomes

In-Field Control** 84%

Clinically Significant Disease (95% CI)

***Rate of negative in-field biopsy at 12 months ≤ 3 mm of Gleason ≤ 6 disease in any biopsy core is insignificant*

Device Related SAEs

4/121 (3.3%)

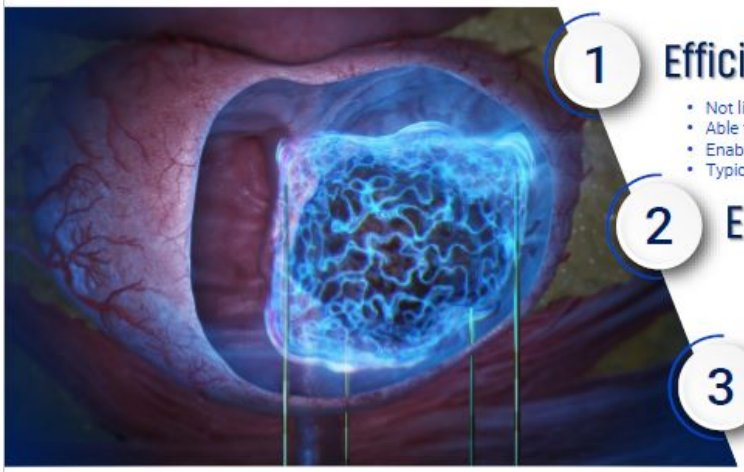
1/121 = Grade 2 (Outcome 3 = Recovered/resolved)

3/121 = Grade 3 (Outcome 3 = Recovered/resolved)

*Data on file – Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue (PRESERVE)

The NanoKnife System Is The Only All-In-One Solution

That Can Enable Broad Physician Adoption And Improved Care For Patients



1 Efficiently Treat All Segments Of The Prostate[1,2]

- Not limited by gland size, tumor location, or calcifications
- Able to ablate across the urethra, nerves, and urinary sphincters
- Enables physicians to build expertise in a single technology
- Typically, an hour procedure*

2 Easy Clinical Integration[1,16]

- High level of experience with needle-based procedures
- Uses existing imaging and biopsy skills

3 Strong Clinical Outcomes[1,3,17,18,19]

- Reliable ablations with no skip lesions or heat sink
- Increased margin expansion without negatively impacting erectile or urinary function
- Does not restrict future treatment options

*Treatment time does not include patient prep, anesthesia initiation or recovery room time
1-3, 16-19 See reference page

NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE

Commercial Opportunity

Powering Growth: A Proven Recurring Revenue Model

Recurring Revenue

Single-Use Disposable
Electrodes (2-6 per procedure)

Capital Equipment

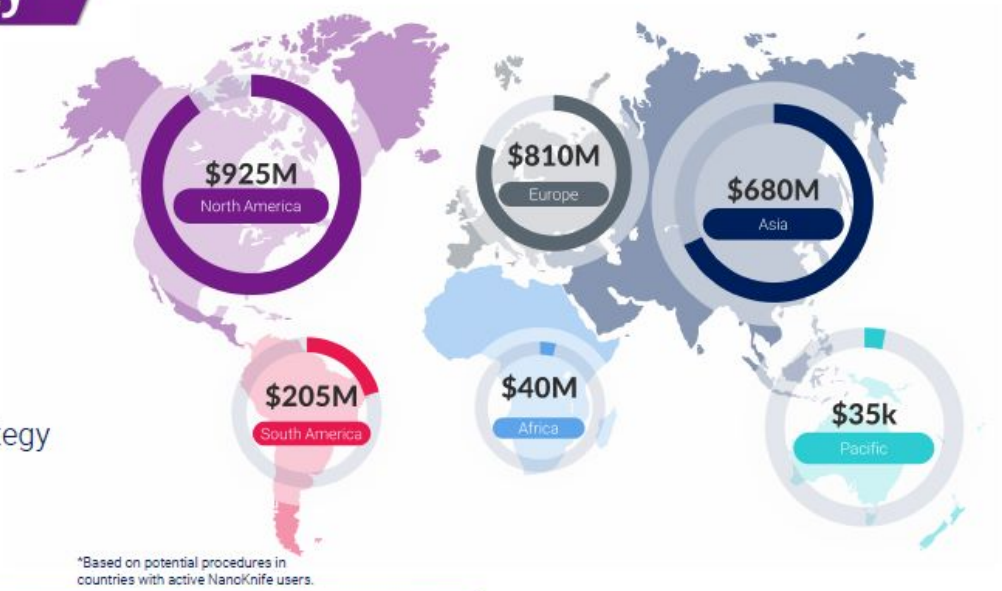
Hardware
Software
Accessories

Prostate Cancer Represents A Large Global Market

$2.7B Opportunity

Key Market Penetration Tactics

1. Regulatory Approvals
2. Market Access
3. Strong Go-To Market Strategy



*Based on potential procedures in countries with active NanoKnife users.

Broad Regulatory Approvals/Clearances Unlock A Global Opportunity

FDA U.S. FOOD & DRUG ADMINISTRATION

The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

PRESERVE
Pivotal Study of the NanoKnife System for the ablation of prostate tissue in patients with Intermediate-Risk Prostate Cancer

CE EU-MDR

The NanoKnife System is indicated for the ablation of prostate tissue in patients with intermediate risk prostate cancer.

MDR Submission
32 publications
across 2,642 patients

Fueling Growth Through Reimbursement And Economic Value

1 North America

- **US Coverage:** IRE included in the **Medicare Fee Schedules** for ASC and Hosp Outpatient settings **effective 01/2021**
- **US Coding:** **IRE CPT 1 codes** for prostate and for liver **approved** 9/2024 and **effective 01/2026**
- **US Payment:** APC 5362 – HOPPS 2025 national average payment **$10,411** (+6% yoy)

- **Canada:** **WIRED Trial**: Designed to be a prospective, non-randomized study in 100 subjects treated at up to 5 clinical sites.

2 Europe

- **United Kingdom:** Institute for Health and Care Excellence (NICE) upgraded the use of the NanoKnife System to **"Special Arrangements"** allowing hospitals to start new services while collecting more data. **PART Trial (RCT)** comparing the effectiveness of partial prostate ablation vs radical prostatectomy across 800 patients.

- **Sweden:** Prostate Cancer IRE Study (**PRIS**): **A randomized controlled trial** comparing focal therapy to radical treatment in localized prostate cancer – evaluating functional and oncological outcomes + an economic evaluation of each technique.

- **Netherlands:** **ENFORCE Trial** – A Dutch government sponsored and funded **RCT** that includes the NanoKnife System for prostate treatment.

3 Asia

- **China:** Included in the Beijing medical insurance catalog: patients can be **reimbursed 85%** of the cost of the surgery and electrodes, **effective from 10/20/24**

Building Markets With Patient Outreach and Physician Education

Direct Sales & Partnerships

- Enhanced Customer Relationships
- Improved Product Utilization
- Market Agility

Patient Awareness

There is an increasing trend toward using the internet as the **first source of health information** compared to family/friends/coworkers, health care professionals, and traditional media.

-US Health Information National Trends Survey

Physician Finder

Physician Education

Hands-on Training

Master Course and Life Symposium

NANOKNIFE
Irreversible Electroporation (IRE) PROSTATE

U.S. Snapshot: Strong Foundation of Customer Advocates

Active Sites at the End of Q2 2024 Create a Strong Opportunity for Growth in the Future

Active Physicians ‡
~140

3,000 Target Urologist Working In The U.S.

Physician Acquisition

Active Facilities‡
~120

Significant Upside Upon Full Program Integration

Procedural Adoption

Care Site‡

ASC	20%
Private/Public	24%
Academic Center	56%

Growth Across All Segments Of Urologic Care

‡ Internal AngioDynamics Data As of Q2 2024

REV 01 GL/ON/PR/3126

NANOKNIFE

NANOKNIFE
Irreversible Electroporation (IRE)

Accelerating Innovation & Market Leadership

- Large and growing addressable market
- Innovative, versatile, ~hour-long prostate treatment*
- Addresses an unmet need for physicians, their facility, and their patients
- Backed by strong clinical evidence
- Upcoming Category 1 Payment effective 01/2026
- Strong revenue model built for growth
- Commercial team capable of developing new markets through education

*Treatment time does not include patient prep, anesthesia initiation or recovery room time

REV 01 GL/ON/PR/3126

References

1) Data on file - Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue (PRESERVE)
2) Scheltema, Matthijs J et al. "Impact on genitourinary function and quality of life following focal irreversible electroporation of different prostate segments." Diagnostic and interventional radiology (Ankara, Turkey) vol. 24,5(2018): 268-275. doi:10.5152/dir.2018.17374
3) Van den Bos, W., et al. "Histopathological outcomes after irreversible electroporation for prostate cancer: Results of an ablate and Resect study." *Journal of Urology*, vol. 196, no. 2, Aug. 2016, pp. 552–559, https://doi.org/10.1016/j.juro.2016.02.2977.
4) The Lancet Commission on prostate cancer: planning for the surge in cases James, Nicholas D et al. The Lancet, Volume 403, Issue 10437, 1683 – 1722
5) Cancer in men: Prostate cancer is #1 for 118 countries globally. American Cancer Society. (2024, September 27). https://www.cancer.org/research/acs-research news/prostate-cancer-is-number-1-for-118-countriesworldwide.html#:~:text=An%20estimated%201.5%20million%20men,Norway%2C%20Sweden%2C%20and%20Barbados.
6) Global Burden of Disease 2019 Cancer Collaboration, Kocarnik JM, Compton K, et al. Cancer incidence, mortality, years of life lost, years lived with disability, and disability-adjusted life years for 29 cancer groups from 2010 to 2019: A systematic analysis for the Global Burden of Disease Study 2019 [Supplement]. JAMA Oncol. 2022;8(3):420-444. doi:10.1001/jamaoncol.2021.6987
7) Therapies for clinically localized prostate cancer | effective health care (EHC) program. (n.d.). https://effectivehealthcare.ahrq.gov/products/prostate-cancer-therapies-update/clinician
8) Klotz, Laurence. "Active surveillance and focal therapy for low-intermediate risk prostate cancer." *Translational andrology and urology* vol. 4,3 (2015): 342-54. doi:10.3978/j.issn.2223-4683.2015.06.03
9) Løvf, Marthe et al. "Multifocal Primary Prostate Cancer Exhibits High Degree of Genomic Heterogeneity." *European urology* vol. 75,3 (2019): 498-505. doi:10.1016/j.eururo.2018.08.009
10) Kumar, Ravi et al. "The use of focal therapy for the treatment of prostate cancer in Canada: Where are we, how did we get here, and where are we going?." *Canadian Urological Association journal = Journal de l'Association des urologues du Canada*, 10.5489/cuaj.8888. 7 Oct. 2024, doi:10.5489/cuaj.8888
11) Timilshina, N et al. "Long-term Outcomes Following Active Surveillance of Low-grade Prostate Cancer: A Population-based Study Using a Landmark Approach." *The Journal of urology* vol. 209,3 (2023): 540-548. doi:10.1097/JU.0000000000003097
12) Donovan JL, Hamdy FC, Lane JA, et al. Patient-Reported Outcomes 12 Years after Localized Prostate Cancer Treatment. Supplemental Table S1A-D [published correction appears in NEJM Evid. 2023 Jun;2(6):EVIDx2300122. doi:10.1056/EVIDx2300122]. NEJM Evid. 2023;2(4):EVIDoa2300018. doi:10.1056/EVIDoa2300018
13) Zumsteg, Z. S., Spratt, D. E., Romesser, P. B., Pei, X., Zhang, Z., Polkinghorn, W., McBride, S., Kollmeier, M., Yamada, Y., & Zelefsky, M. J. (2015). The natural history and predictors of outcome following biochemical relapse in the dose escalation era for prostate cancer patients undergoing definitive external beam radiotherapy. *European Urology*, *67*(6), 1009–1016. https://doi.org/10.1016/j.eururo.2014.09.028
14) Bedi N, Reddy D, Ahmed HU. Targeting the cancer lesion, not the whole prostate. Transl Androl Urol. 2020 Jun;9(3):1518-1525. doi: 10.21037/tau.2019.09.12. PMID: 32676439; PMCID: PMC7354301.
15) Liu, Wennuan et al. "Copy number analysis indicates monoclonal origin of lethal metastatic prostate cancer." Nature medicine vol. 15,5 (2009): 559-65. doi:10.1038/nm.1944

References

16) Cussenot O and Stricker P. Irreversible Electroporation for Patients with Localised Prostate Cancer: Expert Opinion on this Versatile Therapeutic Approach. EMJ Urol. 2021;9(1):56-62.
17) Fainberg, Jonathan et al. "Targeted Ablation Using Ultrasound-Guided Irreversible Electroporation of Index Tumors (TARGET Study): Prospective Development Study Evaluating Safety, Patient-Reported Outcomes, and Oncologic Efficacy." Urology practice, 101097UPJ0000000000000666. 17 Jul. 2024, doi:10.1097/UPJ.0000000000000666
18) Blazevski A, Scheltema MJ, Yuen B, et al. Oncological and quality-of-life outcomes following focal irreversible electroporation as primary treatment for localised prostate cancer: A biopsy-monitored prospective cohort. European Urology Oncology. 2020;3(3):283-290. doi:10.1016/j.euo.2019.04.008
19) De la Rosette, Jean et al. "A Multicenter, Randomized, Single-blind, 2-Arm Intervention Study Evaluating the Adverse Events and Quality of Life After Irreversible Electroporation for the Ablation of Localized Low-intermediate Risk Prostate Cancer." The Journal of urology vol. 209,2 (2023): 347-353. doi:10.1097/JU.0000000000003051
20) Geboers, B., Scheffer, H. J., Graybill, P. M., Ruarus, A. H., Nieuwenhuizen, S., Puijk, R. S., van denTol, P. M., Davalos, R. V., Rubinsky, B., de Gruijl, T. D., Miklavčič, D., & Meijerink, M. R. (2020). High-Voltage Electrical Pulses in Oncology: Irreversible Electroporation, Electrochemotherapy, Gene Electrotransfer, Electrofusion, and Electroimmunotherapy. Radiology, 295(2), 254–272. https://doi.org/10.1148/radiol.2020192190
21) Onik, Gary, et al. "Irreversible electroporation: Implications for prostate ablation."Technology in Cancer Research & Treatment , vol. 6, no. 4, Aug. 2007, pp. 295–300, https://doi.org/10.1177/153303460700600405.
22) Blazevski, Alexandar, et al. "Focal ablation of apical prostate cancer lesions with irreversible electroporation (IRE)."World Journal of Urology, vol. 39, no. 4, 2 June 2020, pp. 1107–1114, https://doi.org/10.1007/s00345-020-03275-z.
23) Tay, K.J., Fong, K.Y., Stabile, A. et al. Established focal therapy—HIFU, IRE, or cryotherapy—where are we now?—a systematic review and meta-analysis. Prostate Cancer Prostatic Dis (2024). https://doi.org/10.1038/s41391-024-00911-2

Indications for Use

Statements:
The NanoKnife System must be operated by properly qualified personnel only.
Caution: Federal (USA) law restricts the use of the system by or on the order of a physician.
Refer to Directions for Use and/or User Manual provided with the product for complete instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

Indications for Use
US: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

Canada: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

EU: The NanoKnife System is indicated for the ablation of prostate tissue in patients with intermediate risk prostate cancer.

Contraindications:
Ablation procedures using the NanoKnife System are contraindicated in the following cases:
Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators
Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts.
Ablation of lesions of the eyes, including the eyelids.
Patient history of Epilepsy or Cardiac Arrhythmia
Recent history of Myocardial Infarction.

Warnings:
EU Only: The NanoKnife device has been evaluated for the ablation of prostate tissue in patients with intermediate risk prostate cancer. The use of this device in other organs for other disease states has not been fully evaluated.
Clinical Issues (Including Arrhythmia, Hypertension, and Thrombus Risks)
Patients with Q-T intervals greater than 500 ms (milliseconds) are at an increased risk for inappropriate energy delivery and arrhythmia. Verification of proper function of a synchronization device before initiating energy delivery is essential in these patients.
Asynchronous energy delivery (90 PPM (Pulses Per Minute)) might trigger atrial or ventricular fibrillation, especially in patients with structural heart disease. Ensure that proper interventions (e.g. defibrillator) and appropriately trained personnel are readily available for dealing with potential cardiac arrhythmias.
Using QRS synchronization devices whose output is not compatible with the specifications listed in this manual may result in arrhythmias including ventricular fibrillation.
Adequate precautions should be taken for patients with implantable electrical devices. Note the contraindication in certain patients.
There are potential risks associated with the location of the ablation: near the pericardium (tachycardia), or near the vagus nerve (bradycardia).
Additional patients may be at risk with insufficient muscle blockade or anesthetic analgesia (reflex tachycardia and reflex hypertension); patients with abnormal sinus rhythm prior to an ablation (arrhythmia); patients with a history of hypertension (hypertension); or patients with partial portal venous thrombosis, low central venous pressure (CVP), and a prothrombotic condition (venous thrombosis).

Use of Electrodes:
Avoid repeated vascular insult during electrode placement.
As anticipated with a needle-related procedure, repeated vascular insult due to multiple insertions into a vessel by an electrode during electrode placement may cause thrombus.
Ensure continuous image guidance during the needle placements. Failure to do so can lead to traumatic injury to surrounding structures.
Care should be taken during electrode placement in areas that require tissue be separated or retracted to avoid surrounding tissue damage.
To avoid risks of infection, always maintain the electrodes' protective packaging (cap, tubes, etc.) when the electrodes are not placed in the patient.
Only electrode probes with intact electrical insulation must be used. Any electrodes with damaged electrical insulation must be discarded immediately and not connected to the NanoKnife Generator.
To preserve the electrode's sterility do not remove the electrodes from the packaging until the User is ready to apply the electrode to the patient.
Do not use the electrodes after the expiration date printed on their packaging. Observe the electrodes manufacturer's specific instructions (e.g., printed on the electrodes' packaging).
Only use AngioDynamics Electrode Probes with the NanoKnife System Generator.
Maintain electrical separation of the electrodes from safety ground by doing the following
Disconnect any electrode from the Generator that is not applied to the patient.
Avoid any clamping of the electrode's cable, unless explicitly instructed or authorized by the electrode's manufacturer.
Do not connect any devices (e.g., measurement) to the electrodes unless they have been supplied by and specifically indicated for such a use by the manufacturer.

Indications for Use

Use of Generator (including Electrocution Hazard)
No modification of this equipment is allowed.
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
The Generator internally produces voltages that are dangerous and may be fatal. The Generator does not contain parts serviceable by the User, and should not be opened.
Do not use the Generator in the presence of flammable or explosive gas mixtures.
For electrical safety, the Generator needs grounding. Use only medical grade main power supply cords, e.g., those supplied by the manufacturer.
Before plugging the Generator to the main, ensure that the main power cords are not damaged. Replace them if any damage is noticed – main cords cannot be repaired.
Do not connect or disconnect the Generator from the main power cord with wet hands.
Confirm that the main power cord will be connected to a properly grounded electrical outlet.
Whenever necessary, replace Generator fuses only with fuses specified in this manual.
Maintenance should be carried out only by trained personnel. The Generator must undergo periodic preventative maintenance as specified in the Maintenance and Service.
The NanoKnife User Manual is a fundamental part of the Generator and should always accompany it. Users must refer to this manual for correct and complete information on the use of the Generator.

Potential Adverse Effects (Rest of world):
Adverse effects that may be associated with the use of the NanoKnife system include, but are not limited to the following:
Arrhythmia
Atrial fibrillation or flutter
Bigeminy
Bradycardia
Heart block or atrioventricular block
Paroxysmal supraventricular tachycardia
Tachycardia
Reflex tachycardia
Ventricular tachycardia
Ventricular fibrillation
Damage to critical anatomical structure (nerve, vessel, and/or duct)
Dysuria
Epididymitis
Erectile Dysfunction
Fistula formation
Haematuria
Hematoma
Hemorrhage
Hemothorax
Infection
Pneumothorax
Prostatitis
Reflex Hypertension
Unintended mechanical perforation
Urethral sludge
Urethral stricture
Urinary incontinence
Urinary retention
Urosepsis
Vagal Stimulation, asystole
Venous Thrombosis

Potential Adverse Effects (US)
Adverse effects that may be associated with the use of the NanoKnife system include, but are not limited to the following:

- Abdominal Pain
- Arrhythmia
  - Atrial fibrillation or flutter
  - Bigeminy
  - Bradycardia
  - Heart block or atrioventricular block
  - Paroxysmal supraventricular tachycardia
    - Reflex tachycardia
    - Ventricular tachycardia
  - Ventricular fibrillation
- Bladder spasm
- Damage to critical anatomical structure (nerve, vessel, and/or duct)
- Fistula Formation
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Pneumothorax
- Reflex Hypertension
- Unintended mechanical perforation
- Urinary retention
- Vagal stimulation, asystole
- Venous thrombosis