



Sonablate® 500 System Training

June, 2003



Sonablate® 500 System



Multifunctionality:

Imaging

Treatment Planning

BPH Therapy

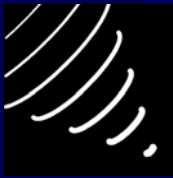
PC (Localized) Therapy

Clinically Superior:

Bloodless

Lower Complications

Repeatable Treatment



Benefits of HIFU

Feature	Advantage	Benefit
Image Guided Therapy	Real Time Monitoring & Accurate Treatment Planning	Less Patient Complications
Noninvasive Treatment	Less patient trauma and no radiation	Fewer patient complications; Less Doctor Risk
Quantitative Noninvasive Feedback & Monitoring	Provides Real Time Monitoring of Treatment Effects	More Complete Treatments; Higher Doctor Satisfaction & Confidence
Precise & Repeatable Treatment	Better Treatment Control: Disease Can Be Retreated if Recurrent	More Options For Patients; Better Outcomes With Less Complications
Multiple Application Functionality	Used For Multiple Prostate Diseases	Multiple Revenue Opportunities For User



System Components



**Articulating Probe Arm
For Universal Table
Fixation**

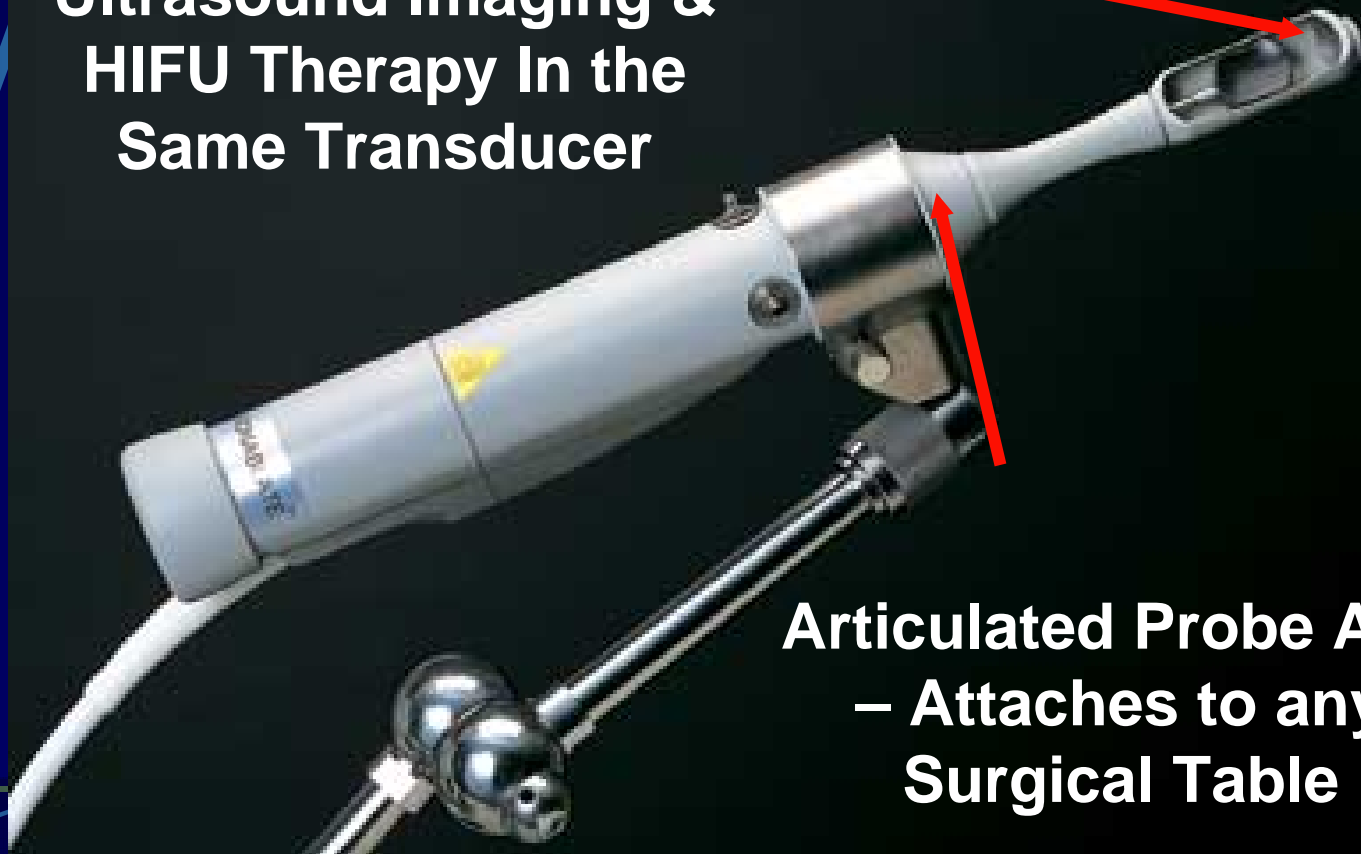
**Real-Time Ultrasound
Imaging & HIFU
Therapy Probe**

**Automatic Chiller
System (Sonachill™)**

**Sonablate® Console
With Real-Time
Imaging and Feedback**

Sonablate® 500 Probe

**Proprietary Real-Time
Ultrasound Imaging &
HIFU Therapy In the
Same Transducer**



**Articulated Probe Arm
– Attaches to any
Surgical Table**

Sonablate® 500 Software

The screenshot displays the Sonablate 500 software interface for HIFU prostate treatment. The top status bar shows 'Sonablate 500 -- HIFU Prostate Treatment Version 1.7J [3.0] (c) 2000 Focus Surgery, Inc.' and patient information: 'Site: UNIV OF VIENNA', 'Patient: KAL', and 'Probe: SN5510 4.0/2.0'. The main interface is divided into several sections:

- Navigation:** PREPARE, IMAGE, PLAN, THERAPY (selected), VOLUME.
- Images:** Four ultrasound images in a 2x2 grid. The top-left image shows a red outline and a yellow arrow pointing to a specific area. The top-right image shows a red box and a yellow arrow pointing to a specific area. The bottom-left image shows a green outline. The bottom-right image shows a yellow box and a red arrow pointing to a specific area.
- Parameters:** 4.0 A, Grid Meas., Zone Zone, Bypass power, 37.0 watts, [37.0].
- Timing:** 0:25:39 total, 0:03:00 elapsed, 0:22:39 remaining.
- Temperature:** probe temperature 17.5 C, SonaChill pump chiller.
- Reflectivity:** reflectivity index 16, RF amplifier 0.0 watts, 2.4 seconds.
- Buttons:** Scan, Freeze, Scan, Pause.
- Verification:** Image verification 06/20/2001, Therapy verification 06/20/2001.
- Status:** STATUS, Status: _AUTO_ saving screen to disk file...
- Footer:** Image: Apr 23, 2002 9:50:52 AM

**Reference
Images Show
HIFU
Echogenicity**

**Real-Time
Temperature and
Reflectivity
Measurement**

**Real Time Bi-
Plane Reference
Images Pre-
Treatment**



Science of HIFU

High Intensity Focused Ultrasound:

Low Intensity at
Transducer Face
(20-40 Watts)

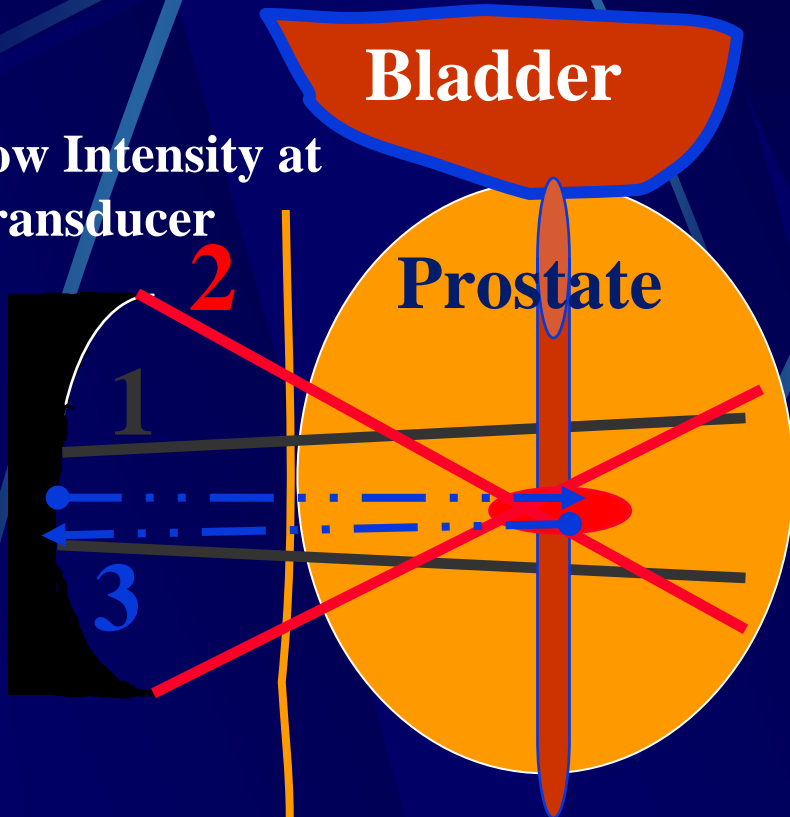


Translates to Very
High Site Intensity
at the Focus Point
(1600 - 2000
Watts/Cm²)



High Intensity Focused Ultrasound

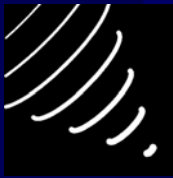
Low Intensity at
Transducer



Transrectal HIFU Transducer

Versatility of Ultrasound:

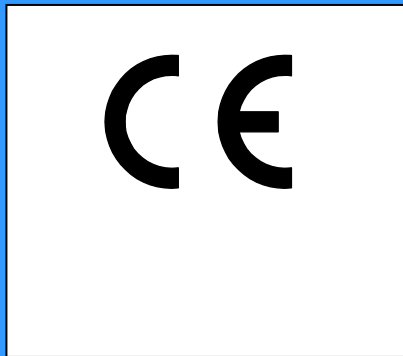
1. Real Time Imaging
2. High Intensity Therapy Beams(HIFU)
3. Feedback Pulse: Tissue Attenuation



Sonablate® 500



EN ISO 9001:1994



Regulatory Status:

ISO 9000-2000 Certified

Japan MHW Approved

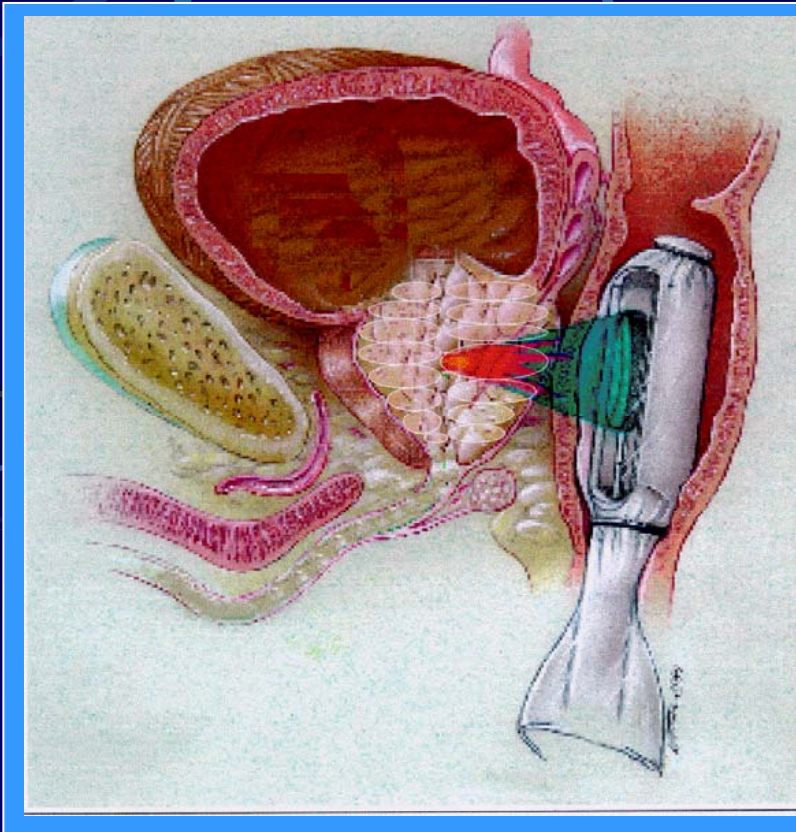
CE Mark - 7/01

Canada CMDCAS - 8/01

Sonablate® 500 PC Therapy

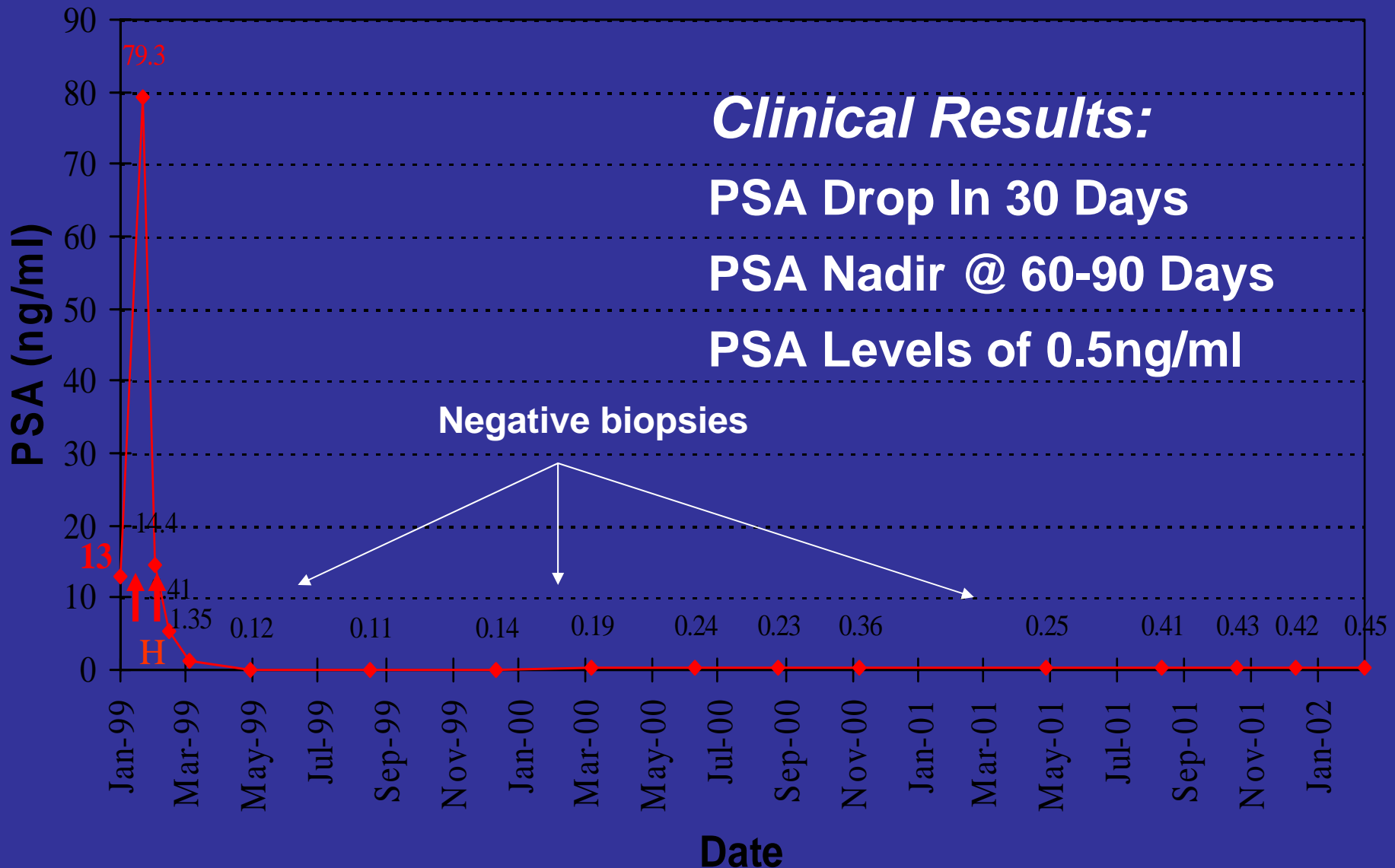
Cancer Benefits:

- Bloodless Surgery
- Repeatable Therapy
- 20% Impotency
- 10% Incontinence
- Image-Guided
- Precise



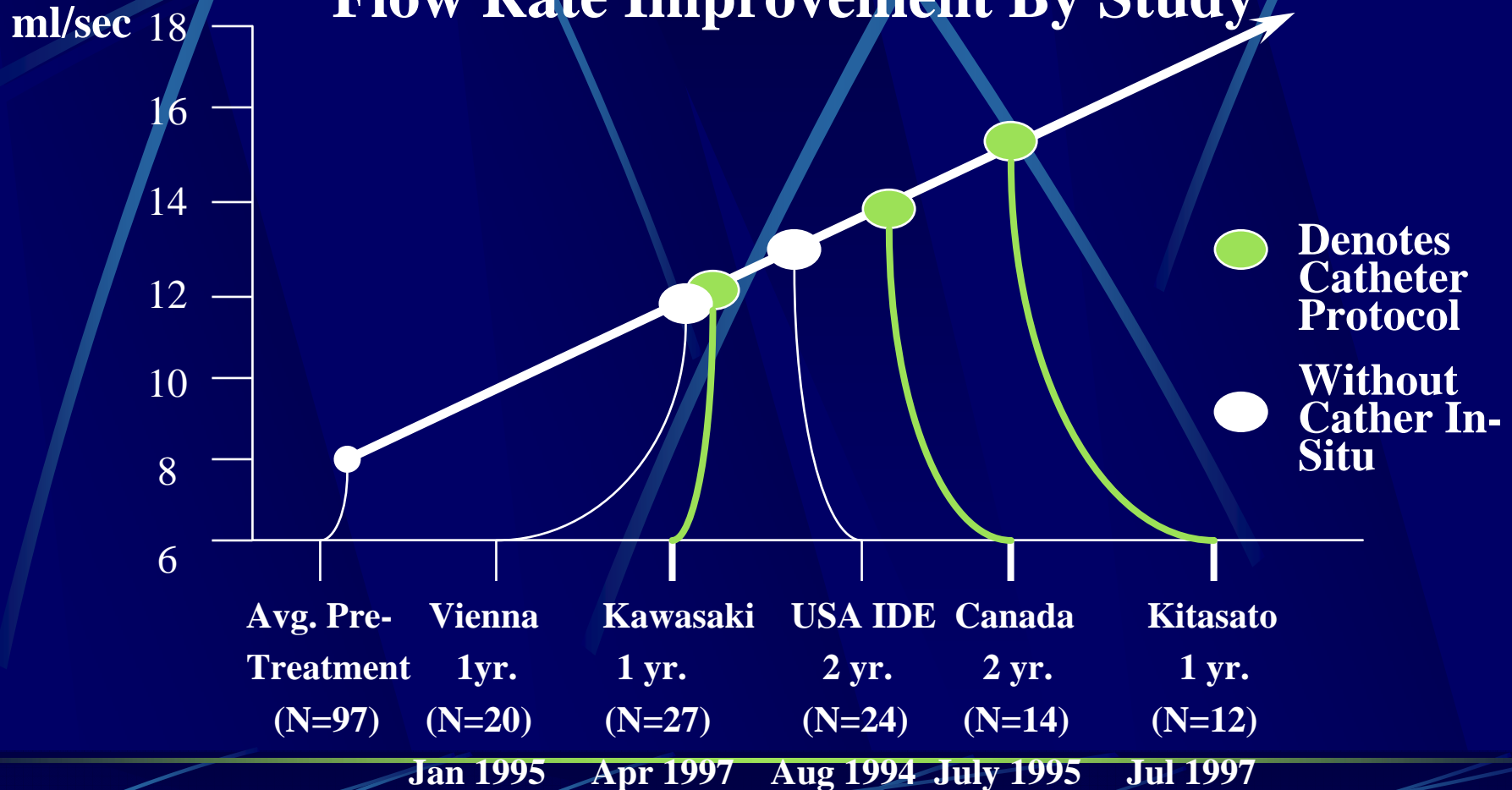
** Patient Data From Kitasato University (Tokyo, Japan) & Indiana University Medical Center Phase I Studies*

HIFU PC Therapy – Three Year Follow Up





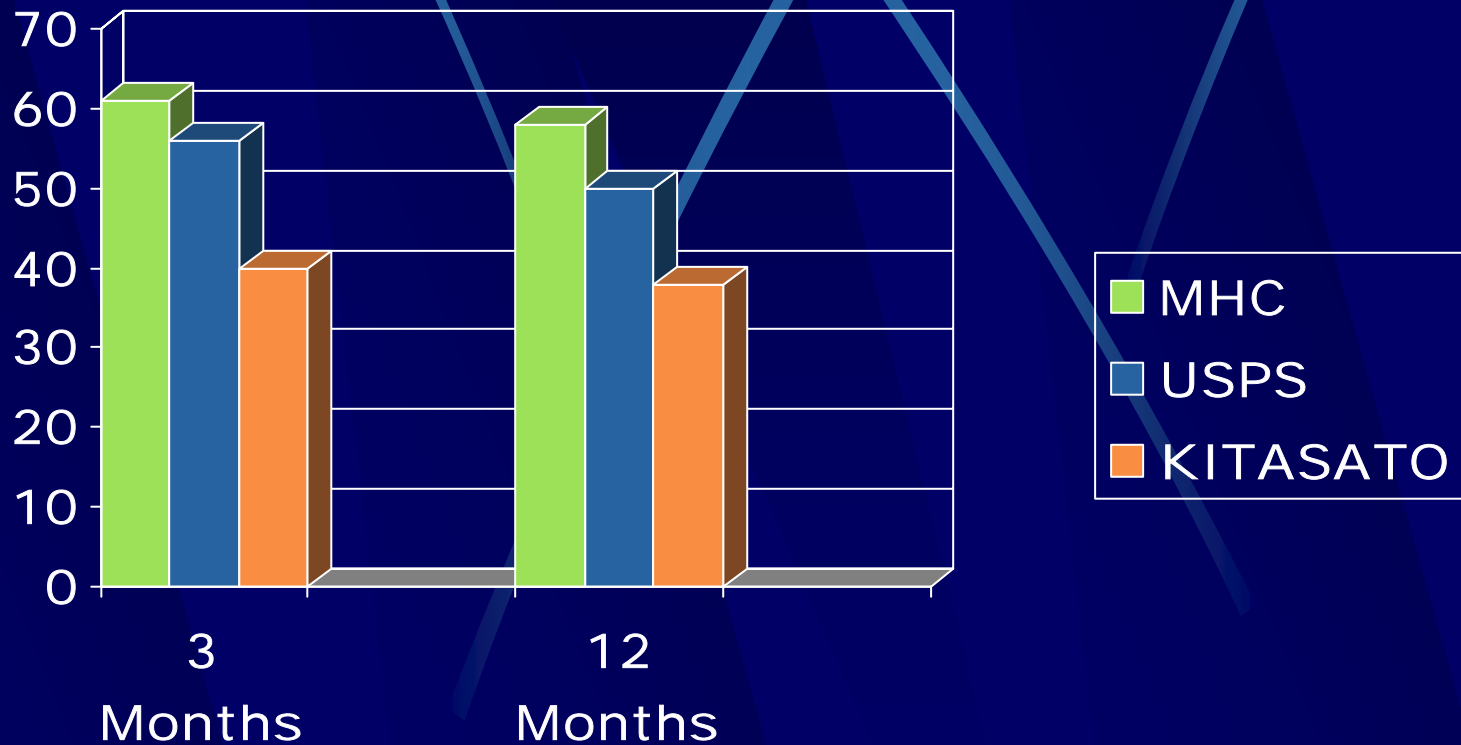
BPH QMAX Improvement Flow Rate Improvement By Study





BPH IPSS Improvement

(% IMPROVEMENT)



Sonablate® 500 BPH Therapy



Complications:

Transient Hematospermia	17%
Transient Macrohematuria	9%
Dysuria	8%
Transient Retention	6%
Transient Microhematuria	6%
Urinary Tract Infection	4%
Epididymitis	0%
Retrograde Ejaculation	0%
Erectile Dysfunction	0%
Urethral Strictures	0%
Incontinence	0%
Rectal Lesion	0%

** Cysto Photos From Indiana University Medical Center*



Sonablate® 500 Standard System:

Sonablate® 500 Control Console

Sonachill™ Automatic Active Chilling System

Sonablate® Imaging/Therapy Probe

Multifunctional Articulated Probe Arm

User Manual

Accessory Kit



Sonablate® 500 Safety Features:

- Sonachill™ Automatic Active Chilling System**
- RIM™ - Reflectivity Index Measurement**
- Temperature Measurement System**

(Both RIM™ & Temperature Feature Automatic System Shut-Off)



Treatment Monitoring

- 15 Sector and 15 Linear Reference Images
- Real-time Probe Tip Temperature Measurement (37oC off)
- Real-time Rectal Wall Distance Measurement
- Real-time Reflectivity Index Measurement (RIM™)
- Time to Treat Status / Percentage Completion Update
- Alarm Text Messages



System Pricing & Training:

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