

Owner: Amelia Medical  
 Agent/s: Jan Walridge  
 Inventor/s: William Jones MD  
 Management: Chose not to disclose

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 May 24, 2010

**Non-Confidential**

## TUNA Needle Extraction Device

The following information resulted from the analysis of this innovation by the e-Zassi™ Technology Assessment Software Platform. The TUNA Needle Extraction Device is a medical device used in the benign prostatic hypertrophy (BPH) segment of the urology market. It is designed as reusable, for multiple patient use. It is expected to be used in the hospital (inpatient department) by a surgeon. Improved clinical outcome for the patient are expected as a result of using the TUNA Needle Extraction Device.

### Nature of Technology – Summary Table

Type of Device:	Medical Device	<a href="#">Learn more</a>
Device Regulatory Classification:	US: Class II, Class II EU: Class IIb	<a href="#">Learn more</a>
Regulatory Status:	US: A regulatory submission is required, but not yet filed EU: A regulatory filing is required but has not been submitted	<a href="#">Learn more</a>
Primary Intended Use:	Treatment	<a href="#">Learn more</a>
Primary and Secondary Users:	Surgeon, Physician (Specialty Practice)	<a href="#">Learn more</a>
Key Purchasing Decision Maker:	Surgeon	<a href="#">Learn more</a>
Reimbursement Outlook:	Likely existing coverage applies	<a href="#">Learn more</a>
Intellectual Property Status:	No patents are issued Patent applications are pending	<a href="#">Learn more</a>
Clinical Specialty / Market:	Urology	<a href="#">Learn more</a>
Market Segment / Sub-Segment:	Benign prostatic hypertrophy (BPH) / Transurethral Needle Ablation	<a href="#">Learn more</a>
Pre-Clinical / Clinical Research Status:	Pre-clinical in-vitro testing is complete. Animal testing is complete. First-in-man trial is complete	<a href="#">Learn more</a>
Advantages and Benefits:	Improved clinical outcome for the patient Shorter surgical procedure time	<a href="#">Learn more</a>
Grant Matching Results:	Technology assessment resulted in no grant match.	<a href="#">Learn more</a>
Manufacturing Build Status:	Three dimensional computer model(s) Functional, clinical product	<a href="#">Learn more</a>

### Maturity of Innovation





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## Regulatory

This section of the report includes the likely US and EU regulatory parameters and classifications for the technology.

### US Regulatory

**US Regulatory Status:** A regulatory submission is required, but not yet filed

**FDA Submission No.:** Not Applicable

**FDA Clearance/Approval Date:** Not Applicable

**FDA Regulation / Device Classification / Predicate Product Code / Regulatory Pathway:**

**FDA Regulation No:** 876.4300

**FDA Regulation Name:** endoscopic electro-surgical unit and accessories

Product Code	Product Code Title	Classification	Regulatory Pathway
FAR	Unit, Electro-surgical	Class II	510(k)
FAS	Electrode, Electro-surgical, Active, Urological	Class II	510(k)
FBJ	Cord, Electric For Transurethral Surgical Instrument	Class II	510(k)
FDB	Plate, Patient	Class II	510(k)
FDI	Snare, Flexible	Class II	510(k)
FDJ	Snare, Rigid Self-Opening	Class II	510(k)
FDL	Wristlet, Patient Return	Class II	510(k)
FEH	Electrode, Flexible Suction Coagulator	Class II	510(k)
FFI	System, Alarm, Electro-surgical	Class II	510(k)
FGW	Clamp, Electrical	Class II	510(k)
FHC	Adaptor To The Cord, For Transurethral Surgical Instrument	Class II	510(k)
FHY	Jelly, Contact, For Transurethral Surgical Instrument	Class II	510(k)
FHZ	Desiccator, Transurethral	Class II	510(k)
KGE	Forceps, Biopsy, Electric	Class II	510(k)
KNS	Unit, Electro-surgical, Endoscopic (With Or Without Accessories)	Class II	510(k)
NLR	Unit, Electro-surgical, Endoscopic (With Or Without Accessories), Reprocessed	Class II	510(k)
NLT	Snare, Flexible, Reprocessed	Class II	510(k)
NLU	Forceps, Biopsy, Electric,	Class II	510(k)



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	Reprocessed		
NLV	Electrode, Flexible Suction Coagulator, Reprocessed	Class II	510(k)
NLW	Electrode, Electrosurgical, Active, Urological, Reprocessed	Class II	510(k)
NWI	Kit, Electrode, Electrosurgical	Class II	510(k)
OEJ	Transurethral Electrosurgical Unit, Benign Prostatic Hyperplasia	Class II	510(k)
OEK	Water-Induced Thermotherapy System, Benign Prostatic Hyperplasia	Class II	510(k)

## European Union (EU) Regulatory

**EU Regulatory Status:** A regulatory filing is required but has not been submitted

**EU Device Classification / Regulatory Pathway:**

Classification	Class IIb	Regulatory Pathway	CE Mark / Technical File / Full Quality Management System

The TUNA Needle Extraction Device may be classified as a Class IIb device according to the European Union (EU) Medical Device Directive. Class IIb devices typically are surgically invasive devices for short term use, radiotherapy devices, and long-term-use or implantable devices.

The information presented within this report does not represent or intend to be an opinion, a suggestion, a comment, or a decision from the FDA, or any of its authorities, agents, employees, or third party representatives. This information is an estimate and is intended as preparation for conversations with the appropriate regulatory authority or regulatory consultant. All aspects of the technology must be evaluated in order to make an accurate classification. The regulatory authority or regulatory consultant can assist in fully assessing the technology. Ultimately, the regulatory authority reserves responsibility for classifying a new medical device.

## Clinical

### Pre-Clinical Research Status

The following table is an overview of the pre-clinical trials that involve the use of animals.

Table I – Pre-Clinical Research Status	
<b>In-Vitro Bench Testing Status:</b> Pre-clinical in-vitro testing is complete	<b>Animal Testing Status:</b> Animal testing is complete



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## Clinical Research Status

The following table is an overview of the clinical trials that involve the participation of human subjects.

Table II – Clinical Research Status	
<b>Types of Human Clinical Research Conducted:</b> First-in-man Trial	<b>Pilot Trial Results (US, EU):</b> None Provided
<b>Clinical Trials Location:</b> United States	<b>Pivotal Trial Results (US, EU):</b> None Provided
<b>Clinical Data Available to Support Claims:</b> User reports the data does not support any claim at this time	<b>Regulatory Confirmation of US/EU GCP Compliance:</b> Yes
<b>Clinical Research Published:</b> No	<b>Which regulatory body confirmed GCP Compliance?</b> U.S. Food and Drug Administration
<b>FDA Clinical Strategy Meeting: Met with FDA prior to clinical trials</b>	

Table III – Overview of Essential Documents Collected for Clinical Trial(s)	
<b>Type of Essential Documents Collected for Clinical Trial(s):</b> Essential documents were collected during the clinical conduct of the trial as outlined in ICH GCP Section 8.3 No essential documents were collected	<b>Specific Essential Documents Collected During the Trial(s) (ICH GCP 8.3]*:</b> Signed informed consents

## Reimbursement

### US Reimbursement

The overall potential coverage was calculated as a function of a variety of inputs. The following table describes the likelihood of the TUNA Needle Extraction Device having existing reimbursement coverage in the US:

<b>Overall Potential Coverage:</b>	Likely existing coverage applies
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The author completing this assessment has provided the following US reimbursement code status:

<b>ICD-9-CM:</b>	An ICD-9-CM code is identified
<b>CPT:</b>	A CPT code is identified
<b>HCPCS:</b>	An HCPCS code is identified



## German Reimbursement

In Germany there are two different reimbursement systems; the German Diagnostic Related Group (G-DRG) system; and the doctor's fee scale reimbursement system, EBM-Code: (Einheitlicher Bewertungsmaßstab = EBM). The following table describes the likelihood of the TUNA Needle Extraction Device having existing reimbursement coverage in Germany:

<b>G-DRG:</b>	A G-DRG code is identified
<b>EBM-Code:</b>	An EBM-Code is identified
<b>OPS:</b>	An OPS code is identified
<b>Therapeutic Appliance List:</b>	A Therapeutic Appliances List code is identified
<b>ICD-10:</b>	An ICD-10-CM code exists

## Intellectual Property

The following information characterizes the intellectual property status of the TUNA Needle Extraction Device.

### Patent Status

- No patents are issued
- Patent applications are pending

A written opinion from a patent attorney evaluating the patentability of the TUNA Needle Extraction Device was rendered.

### Intellectual Property Ownership and Encumbrances

At this time, and based on the provided information, others do not have intellectual property rights to the TUNA Needle Extraction Device.

It is uncertain if encumbrances or contractual obligations for the TUNA Needle Extraction Device exist. More information is needed to determine if such obligations exist for the TUNA Needle Extraction Device.

### Public Disclosure and Public Use

The following table provides information on the status of public disclosure and public use for the TUNA Needle Extraction Device:

Public Disclosure and Use	Status	Date of Occurrence
Public Use:	No Public Use has occurred	None Provided
Public Disclosure:	Public Disclosure has not occurred	None Provided



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## Trademark and Copyright Status

The following table provides information on the trademark and copyright status of the TUNA Needle Extraction Device:

Trademarks and Copyrights	Status	Type
Trademarks:	No trademark	NA
Copyrights:	No copyright	NA

## Litigation Status

The TUNA Needle Extraction Device is not involved in litigation or a legal dispute.

## Technology Platform Considerations

The TUNA Needle Extraction Device is identified as a product versus a technology platform.

## Product Development and Manufacturing

The innovator has reported the following information regarding the manufacturing status of the TUNA Needle Extraction Device:

- manufacturer selected or being considered
- has experience with the TUNA Needle Extraction Device or similar device type
- registered with FDA
- ISO certified
- successful FDA QSIT audit no findings (significant deficiencies)
- has an ISO 14971 risk management system in place

## Medical Device Design Control Development Phase

The innovator has reported the following for the TUNA Needle Extraction Device:

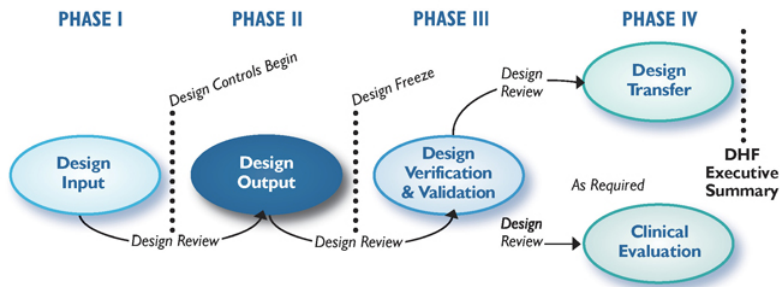
Level of planning:	Design/Development Plan
Level of documentation:	Full engineering drawing package (human/clinical product)
Product build status:	Three dimensional computer model(s), Functional, clinical product
Design control system:	In compliance to Good Manufacturing Practices (GMP)
Development stage:	Phase II Design Output

The following chart depicts the typical formal design control process phase with the current phase of development (Phase II Design Output) highlighted.



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The following depicts the status of the design control deliverables at the time of this report:

## Phase I Design Input

The concept document complete and released to formal documentation control	Complete
The marketing/user needs specification complete and released to formal document control	Complete
The design specification complete and released to formal document control	Complete
The hazard analysis complete and released to formal document control	Complete
The design failure mode and effects analysis (DFMEA) complete and released to formal document control	Complete
The process failure mode and effects analysis (PFMEA) drafted	Complete
The phase I design input design review conducted and approved	Complete

## Phase II Design Output

The design input document updated and under formal document control	Complete
The device master record (DMR) complete, updated, and under formal document control	Incomplete
The risk analysis updated and under formal document control	Complete
The master design verification and validation plan established	Complete
The suppliers selected and qualifications in process	Incomplete
The initial transfer cost of goods sold (TCOGS) drafted	Incomplete
The phase II design output design review conducted and approved. The minutes from the design I input design review examined and all action items sufficiently closed out.	Incomplete

## Phase III Design Verification and Validation

The design specification testing including all label performance claims complete	Incomplete
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The biocompatibility and accelerated aging and/or ship testing complete	Complete
The manufacturing and quality procedures under formal document control and training initiated	Incomplete
The process validation (PV) protocols drafted, installation qualifications (IQs) and/or operational qualifications (OQs) complete, and the process qualifications (PQs) and product performance qualifications (PPQs) approved	Incomplete
The final manufacturing plan and the transfer cost of goods sold (TCOGS) established and up to date	Incomplete
The regulatory submission, clinical investigational exemption (IDE), or the institution review board (IRB) protocols and preparation fully complete	Incomplete
The phase III design verification and validation design review conducted and approved. The minutes from the phase II design output design review examined and all action items sufficiently closed out.	Incomplete

## Phase IV Design Transfer

The process validation (PV), installation qualification (IQ), operational qualification (OQ), process qualification (PQ), product performance qualifications (PPQs), and supplier qualifications approved	Incomplete
The device master record (DMR) complete, updated, and under formal document control	Incomplete
The training and pertinent documentation updated and complete	Incomplete
The design-related material review boards (MRB) closed and corrective action requests (CAR) implemented	Incomplete
The bill of materials (BOM) successfully transferred to manufacturing and/or the procurement specialist. Also, ownership of tools, machines, and gauges documented	Incomplete
The initial build order submitted and the forecast updated	Incomplete
The phase IV design transfer design review conducted and approved. The minutes from the phase III design verification and validation design review examined and all action items closed.	Incomplete

## Material Biocompatibility Considerations and Status

The user provided the following information for the technology during the interview process:

<b>Device Type:</b>	Medical device that includes software
<b>Patient Contact Type:</b>	Direct patient contact with intact skin, intact mucous membranes, tissue, tissue fluid, bone or dentin for less than 60 minutes
<b>Sterility Requirements:</b>	Sterile when manufactured and sterile when used

Biocompatibility Test:	Current Status:
Cytotoxicity	Complete
Sensitization	Complete
Irritation or Intracutaneous Reactivity	More Information Required



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System Toxicity (Acute) and Pyrogenicity	Complete
Sub-chronic Toxicity (Sub-acute)	Not Required
Biocompatibility Genotoxicity Test Status	Not Required
Biocompatibility Implantation Test Status	Not Required
Haemocompatibility	Incomplete
Chronic Toxicity	Not Required
Carcinogenicity	Incomplete
Reproductive Developmental	Not Required
Biodegradable	Not Required

## Grant Eligibility

The technology assessment did not match the TUNA Needle Extraction Device to a US state grant program. Also, there was no match found within the National Institute of Health (NIH) Parent Announcement/Omnibus Solicitation PHS 2009-2 SBIR/STTR Program Descriptions and Research Topics.

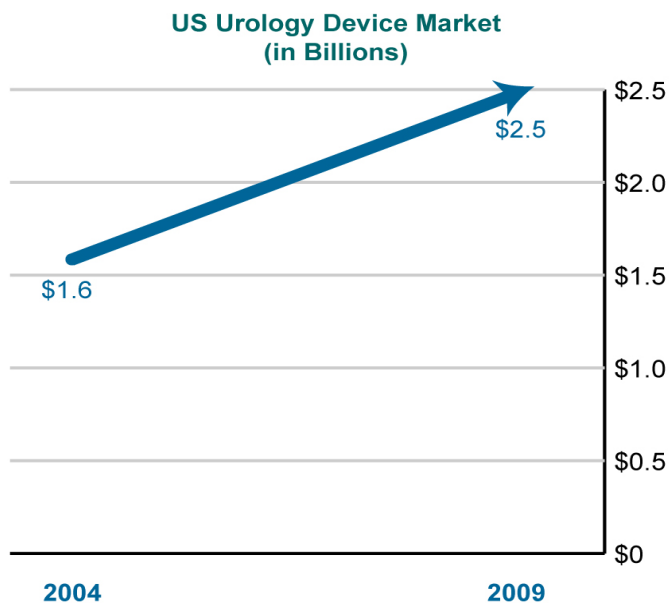
## Market Landscape

### US Urology Market

The United States urological device market is approximately \$1.6 billion. By 2010, this market, which includes devices for urinary incontinence (UI), benign prostatic hyperplasia (or hypertrophy) (BPH), kidney stone management, prostate cancer, and erectile dysfunction (ED), plus urological endoscopes and devices for ureteral access and nephrostomy, is projected to generate \$2.5 billion in revenues. The most rapidly growing segments of the market are the UI, BPH, ED, and ureteral access segments. Nearly 1.4 million urological procedures, including UI, BPH, stone management, prostate cancer, and ED, were performed in 2005.

### Competition - US Urology

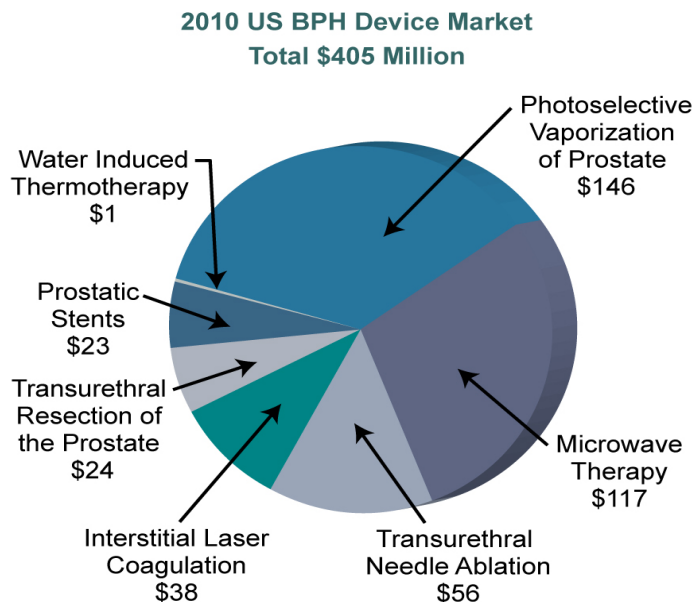
The leading competitors in the US Urological Device Market, in order of declining market share, are C.R. Bard's Bard Urological Division, AMS, Boston Scientific, Gyrus ACMI, Mentor Corporation, Karl Storz, Laserscope, Oncura, Kendall Healthcare, and Gynecare. Bard Urological is by far the largest player, holding leading positions in incontinence, prostate cancer, ureteral access, and stone management. Their incontinence line includes urinary catheters and drainage bags, urethral bulking agents and vaginal slings.



(Millennium Research Group, *US Markets for Urological Devices*, 2006)

## Benign Prostatic Hypertrophy Market Segment

Examples of products and/or procedures in the benign prostatic hypertrophy (or hyperplasia) (BPH) segment include microwave therapy (MT) devices, photoselective vaporization of the prostate (PVP) devices, transurethral needle ablation (TUNA) devices, interstitial laser coagulation (ILC) devices, prostatic stents, and water-induced thermotherapy (WIT) devices.



The US BPH market is valued at almost \$240 million in 2006, and is expected to grow to \$404.7 million in 2010, with PVP the fastest growing segment. The MT and TUNA markets are also expected to grow, however, the rate of increase will be influenced by the availability of favorable reimbursement and long-term efficacy data. The transurethral resection of the prostate (TURP) segment is expected to decline due to the high rate of complications associated with the procedure.

(Millennium Research Group, *US Markets for Urological Devices, 2006*)

### Transurethral Needle Ablation Device Segment

Clinical studies using the transurethral needle ablation (TUNA) procedure show improved outcomes with fewer complications than with prostate surgery. Growth in this market is expected to increase as more clinical studies are published supporting TUNA as a safe and effective treatment for benign prostatic hyperplasia (BPH) and as reimbursement becomes more favorable.

In 2005, the TUNA device market, including both disposable devices and capital equipment, was \$41.3 million (\$37.2 disposables, \$4.1 capital equipment). The segment is expected to grow at a compound annual growth rate (CAGR) of 6.3% through 2010 to \$56.6 million.

### Competition

In 2006, Medtronic was the only competitor in the TUNA market. Their product, the Prostiva RF Therapy system, was introduced in 2006, and was preceded by the Precision and Precision Plus systems.

(Millennium Research Group, *US Markets for Urological Devices, 2006*)



## European Urology Market

The 2006 European urological device market comprised of France, Italy, Germany, and the United Kingdom, was greater than \$750 million. This market includes devices for urinary incontinence (UI), benign prostatic hyperplasia (BPH), kidney stone management, prostate cancer, and erectile dysfunction (ED), plus urological endoscopes and devices for ureteral access and nephrostomy.

More than 75% of the urological device market is made up of incontinence products, which will experience moderate growth through 2011 due to a growing elderly population and the adoption of higher priced fixationless vaginal slings. The urethral bulking agent segment will also grow. By 2011 the incontinence market segment will total \$690 million.

The stone management device segment, including lithotripsy devices, ureteral stents, holmium lasers and stone retrieval devices, totaled \$60 million in 2006. Through 2011, increased adoption of holmium laser technology will drive the segment's growth.

Urological endoscopes are experiencing a shift from rigid to more expensive flexible endoscopes, which will drive up the segment's compound annual growth rate (CAGR).

The 2006 European prostate cancer market was valued at more than \$20 million. Reimbursement is a key driver in this segment. Availability of reimbursement for brachytherapy procedures is spurring growth in seeds, while changes in reimbursement have restrained sales of capital equipment.

The BPH market segment in 2006 was valued at nearly \$15 million. Transurethral Resection of the Prostate (TURP) was the preferred treatment among European doctors, followed by the placement of prostatic stents. Lack of awareness and adequate reimbursement has restrained growth of some of the newer minimally invasive technologies.

The ED device market segment was more than \$6 million in 2006. The market's growth has been limited by widespread use of oral medications as opposed to devices. Slow growth is expected in this segment through 2011.

### Competition

Leading competitors in the European Urological Device Market, in order of declining market share, include Coloplast, AstraTech, Gynecare, Hollister, Bard Urological, Karl Storz, B. Braun, Manfred Sauer, and Medical Services.

(Millennium Research Group, *European Markets for Urological Devices*, 2007)

Additional European Union market subsegment information is not available for the TUNA Needle Extraction Device.

Additional information related to the minimally invasive surgery products market is located in the appendix.

Minimally Invasive Surgery (MIS) Devices and Equipment Overview

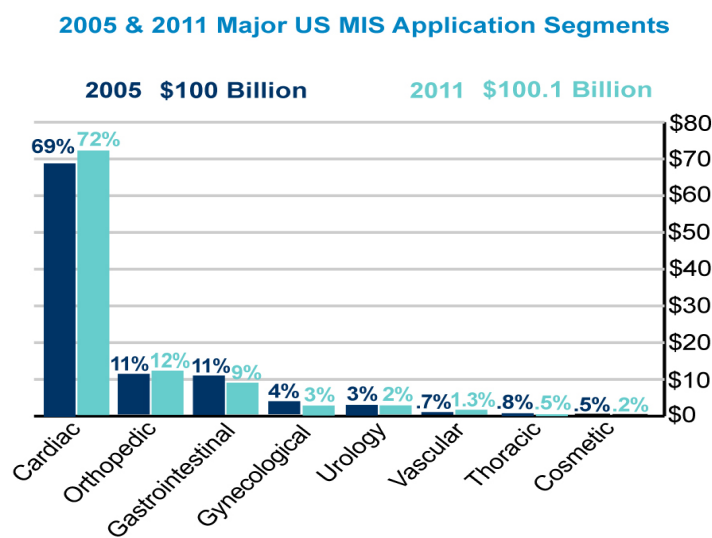


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Minimally invasive surgery is defined as surgery that is conducted with a minimum of trauma to the patient, without making a large incision in the body. The MIS market includes devices for a wide variety of anatomical uses and that fall into a number of different technological categories.

The following chart illustrates the Major US MIS Application Segments, 2005 and 2011 (% of Total Sales).<sup>1</sup>



Minimally invasive surgical procedures (closed or local surgery) are less invasive and traumatic to the body than open invasive surgery. These procedures involve use of laparoscopic devices and remote-control manipulation of instruments with indirect observation of the surgical field through an endoscope or similar device, and are carried out through the skin or through a body cavity or anatomical opening. This may result in shorter hospital stays, or allow outpatient treatment.

Special medical equipment may be used, such as fiber optic cables, miniature video cameras, and special surgical instruments handled via tubes inserted into the body through small openings in its surface. The images of the interior of the body are transmitted to an external video monitor and the surgeon has the possibility of making a diagnosis, visually identifying internal features, and then performing surgery based on these findings.

The following chart illustrates the US Forecast for MIS Devices and Equipment Market Sales by Application through 2011 (\$ millions)<sup>1</sup>.

The global MIS devices and instrument market is estimated at \$14.9 billion in 2008, with an average annual growth rate (AAGR) of 7.5%. Revenues in 2018 are expected to top \$30 billion<sup>1</sup>.

Minimally invasive devices and equipment include<sup>1</sup>:



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- Monitoring/visualization equipment
- Robotics/computer-assisted surgery
- Electrosurgical and auxiliary equipment
- Endosurgical instruments
- Surgical devices (stents, catheters, guidewires, etc.)

The following table identifies the US Forecast for MIS Equipment Types Through 2011 (\$ Millions).<sup>10</sup>

### US Forecast of MIS Sales by Equipment Type Through 2011 (\$Millions)

Equipment	2005	2006	2011	AAGR% 2006-2011
Surgical Devices	4,970	5,253	7,780	8
Monitoring/ Visualization	822	861	1,133	6
Endosurgical Instruments	705	740	956	5
Electrosurgical & Auxiliary Equipment	568	596	774	5
Robotics/ Computer-Assisted	212	219	258	3
<b>Total</b>	<b>\$7277</b>	<b>\$7669</b>	<b>\$10,901</b>	<b>7%</b>



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## **Natural Orifice Transluminal Endoscopic Surgery (N.O.T.E.S)**

N.O.T.E.S utilizes flexible endoscopes through the mouth, anus or vagina to enter the abdominal, pelvic and thoracic cavities<sup>1</sup>. NOTES procedures have continued to gain popularity since 2004 when the first transgastric peritoneoscopy was performed. The advantages of NOTES procedures may include the potential for painless, scar-less, and nearly recovery-free surgery, reduced risk of adhesions, reduced complications from wounds, reduced use of anesthesia, shorter hospital stays, and better cosmesis. There are potential risks, such as when creating an incision through the stomach lining, which is not a sterile environment.<sup>9</sup>

There are also advanced therapeutic endoscopic applications incorporating some of the newer NOTES technology. Endolumenal procedures such as endoscopic submucosal dissection (ESD) use tools to grasp, manipulate, spread, divide, cauterize, cut, suture and re-appose tissue.<sup>9</sup>

## Contemporary Insights

N.O.T.E.S. provides tremendous opportunities to go beyond current minimally invasive procedures. New innovations have occurred over a short span of time.

### Pancreatic pseudocysts

With use of a computer- powered surgical stapler developed by Power Medical Interventions the surgeon and gastroenterologist (working as a team) is able to see where to properly place the stapler. Once the stapler is in position, one jaw of the stapler is placed into the pseudocyst, and the other jaw is left in the stomach. The stapler is closed and fired to create a permanent connection between the two hollow spaces to allow pseudocyst contents to drain naturally out into the stomach and intestines<sup>4</sup>.

On March 26, 2008, the first NOTES procedure of its kind, the removal of an inflamed appendix through a patient's vagina, was performed by the UC San Diego Medical Center<sup>3</sup>.

Removal of woman's gall bladder through the vagina<sup>1</sup>.

What is believed to be the first transvaginal NOTES™ partial gastrectomy was performed in Osaka, Japan, on August 13, 2008<sup>8</sup>.

In the first clinical application of NOTES endoscopic peritoneoscopy, in Japan, for preoperative staging in a patient with pancreatic cancer, iransgastric peritoneoscopy provided the ability to reach various areas of the abdominal cavity<sup>8</sup>.

In April 2007, NewYork-Presbyterian Hospital surgeons performed what is thought to have been the nation's first NOTES surgery—a transvaginal cholecystectomy procedure<sup>6</sup>.

## Competitors

<sup>5</sup>Karl Storz - GI video endoscopes

<sup>5</sup>EndoGastric Solutions - EsophyX and StomaphyX products

<sup>2</sup>Apollo Endosurgery, Inc.

<sup>7</sup>Power Medical Interventions



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## Resources

<sup>1</sup>April 26, 2007,

[www.straightfromthedoc.com/50226711/natural\\_orifice\\_translumenal\\_endoscopic\\_surgery\\_notes\\_removed\\_gall\\_bladder\\_with\\_minimal\\_external\\_incisions.php](http://www.straightfromthedoc.com/50226711/natural_orifice_translumenal_endoscopic_surgery_notes_removed_gall_bladder_with_minimal_external_incisions.php)

<sup>2</sup>Apollo Endosurgery, Inc., [www.highbeam.com/doc/1G1-169587155.html](http://www.highbeam.com/doc/1G1-169587155.html), PRNewswire, October 8, 2007

<sup>3</sup>[www.medicalnewstoday.com/articles/102157.php](http://www.medicalnewstoday.com/articles/102157.php), New York-Presbyterian Hospital/Columbia University Medical Center were able to remove a woman's gall bladder through the vagina with the use of a flexible endoscope with only minimal external incisions.

<sup>4</sup>[Clinicaltrials.gov/ct2/show/NCT00541593?cond=%22Pancreatic+Pseudocyst%22&rank=1](http://Clinicaltrials.gov/ct2/show/NCT00541593?cond=%22Pancreatic+Pseudocyst%22&rank=1)

<sup>5</sup>Business Wire, March 31, 2008, [www.highbeam.com/doc/1G1-177264570.html](http://www.highbeam.com/doc/1G1-177264570.html)

<sup>6</sup><http://www.or-live.com/nyp/2104>, In April 200, NewYork-Presbyterian Hospital surgeons performed what is thought to have been the nation's first NOTES surgery—a transvaginal cholecystectomy procedure.

<sup>7</sup>[www.globenewswire.com/newsroom/news.html?d=149145](http://www.globenewswire.com/newsroom/news.html?d=149145)

<sup>8</sup>[www.ingentaconnect.com/content/bsc/den/2008/00000020/00000004/art00008](http://www.ingentaconnect.com/content/bsc/den/2008/00000020/00000004/art00008), Abstract: Natural Orifice

Translumenal Endoscopic Surgery for Preoperative Staging in a Pancreatic Cancer Patient, **Authors:**

Kitano, Seigo; Yasuda, Kazuhiro; Shibata, Kohei; Yoshizumi, Fumitaka; Kawaguchi, Koji; Suzuki,

Kosuke; Ohta, Masayuki; Inomata, Masafumi; Shiraishi, Norio, **Source:** Digestive Endoscopy, Volume 20, Number 4, October 2008 , pp. 198-202(5)

<sup>9</sup>[www.journalofmas.com/article.asp?issn=0972-](http://www.journalofmas.com/article.asp?issn=0972-9941;year=2007;volume=3;issue=2;spage=43;epage=46;aulast=Pearl)

9941;year=2007;volume=3;issue=2;spage=43;epage=46;aulast=Pearl, Natural orifice transluminal

endoscopic surgery: Past, present and future, Authors: Jonathan P Pearl, Jeffrey L Ponsky

Department of Surgery, Case Western Reserve University School of Medicine Cleveland, OH, USA

[www.journalofmas.com/article.asp?issn=0972-](http://www.journalofmas.com/article.asp?issn=0972-9941;year=2007;volume=3;issue=2;spage=43;epage=46;aulast=Pearl)

9941;year=2007;volume=3;issue=2;spage=43;epage=46;aulast=Pearl, Journal of Minimal Access Surgery

<sup>10</sup><http://www.olympus-global.com/en/news/2008b/nr080901endoe.cfm>

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