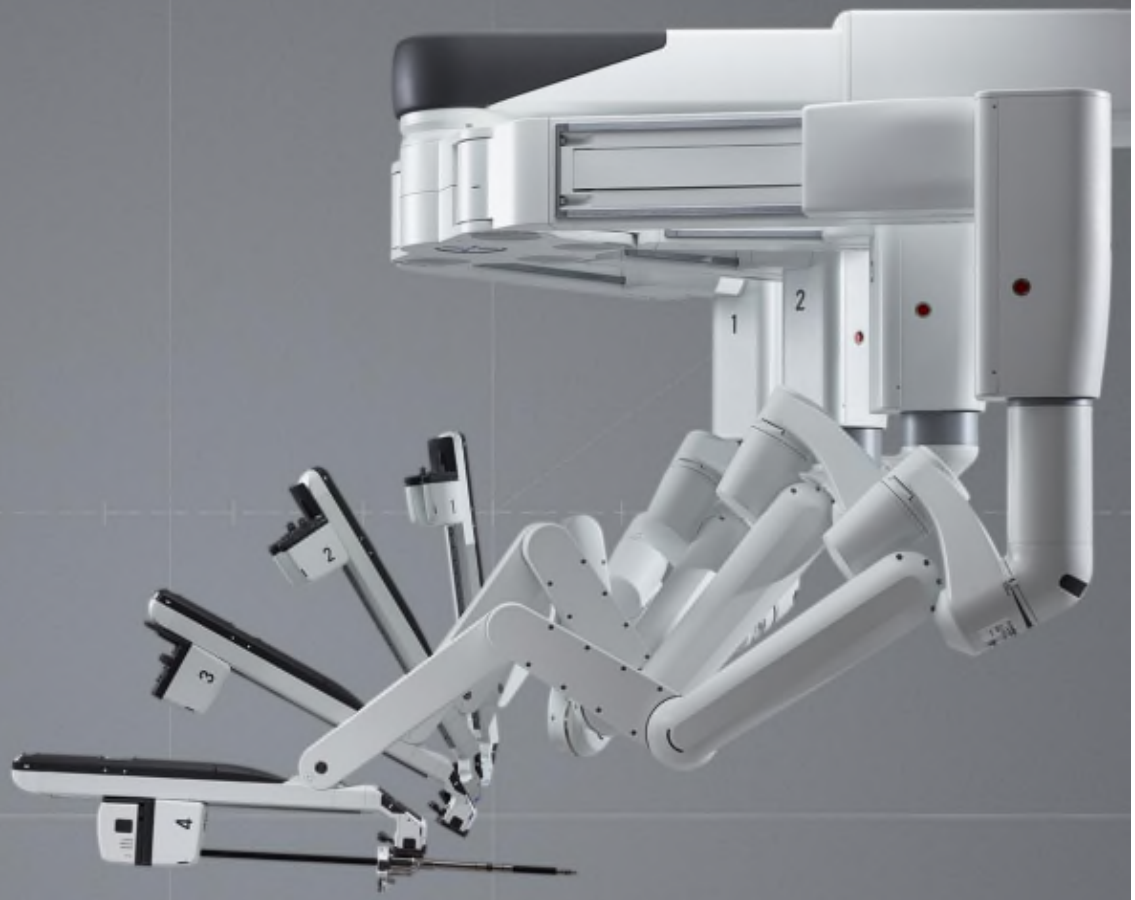
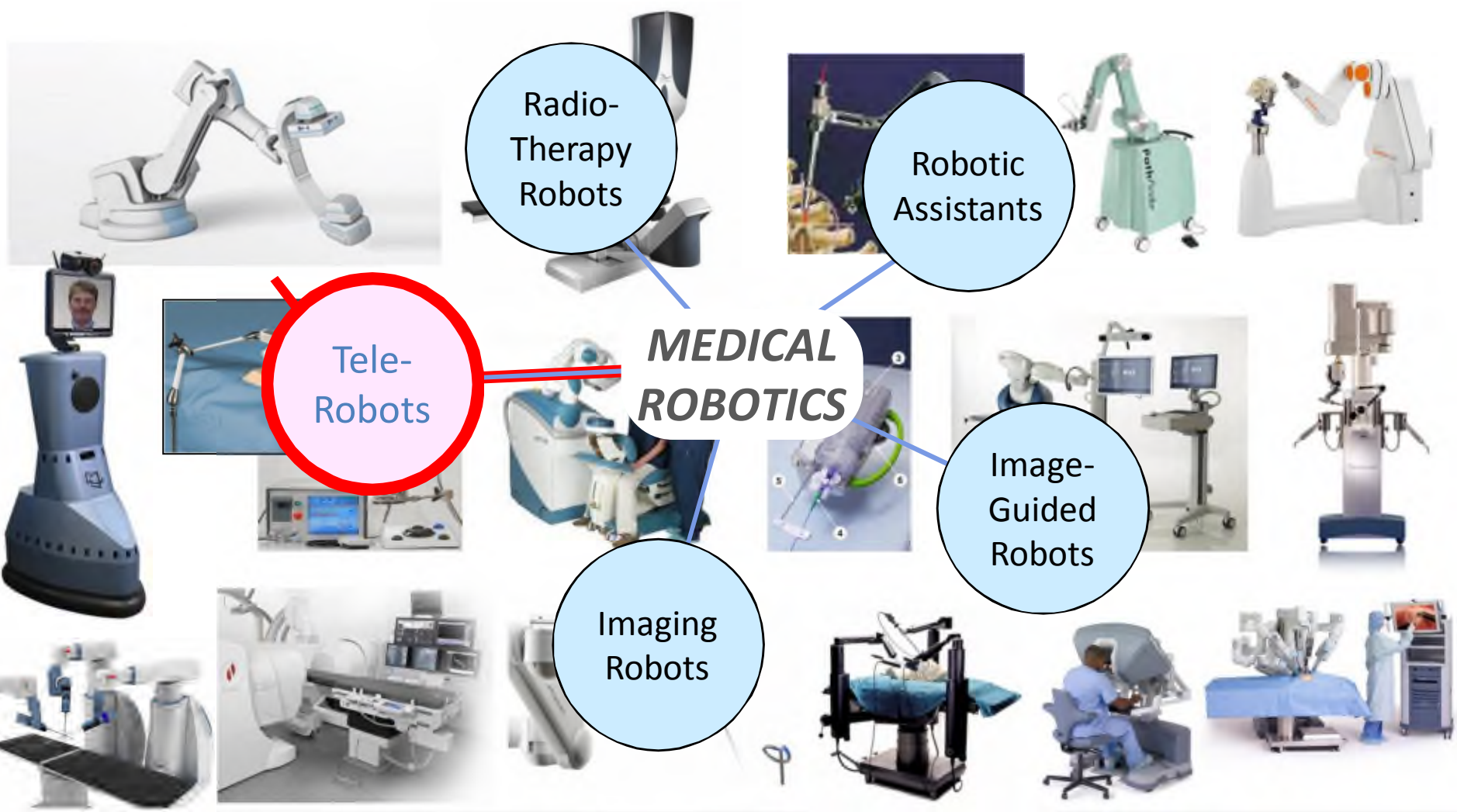
da Vinci and Beyond…

Simon DiMaio, Ph.D.
Intuitive Surgical

21 July 2014



Medical Robots as Products



The Anatomy of a TeleRobotic System

Surgeon Console

Control System

Patient-Side Manipulator

The Anatomy of a TeleRobotic System (Sensei, Hansen Medical)

Surgeon Console

Control System

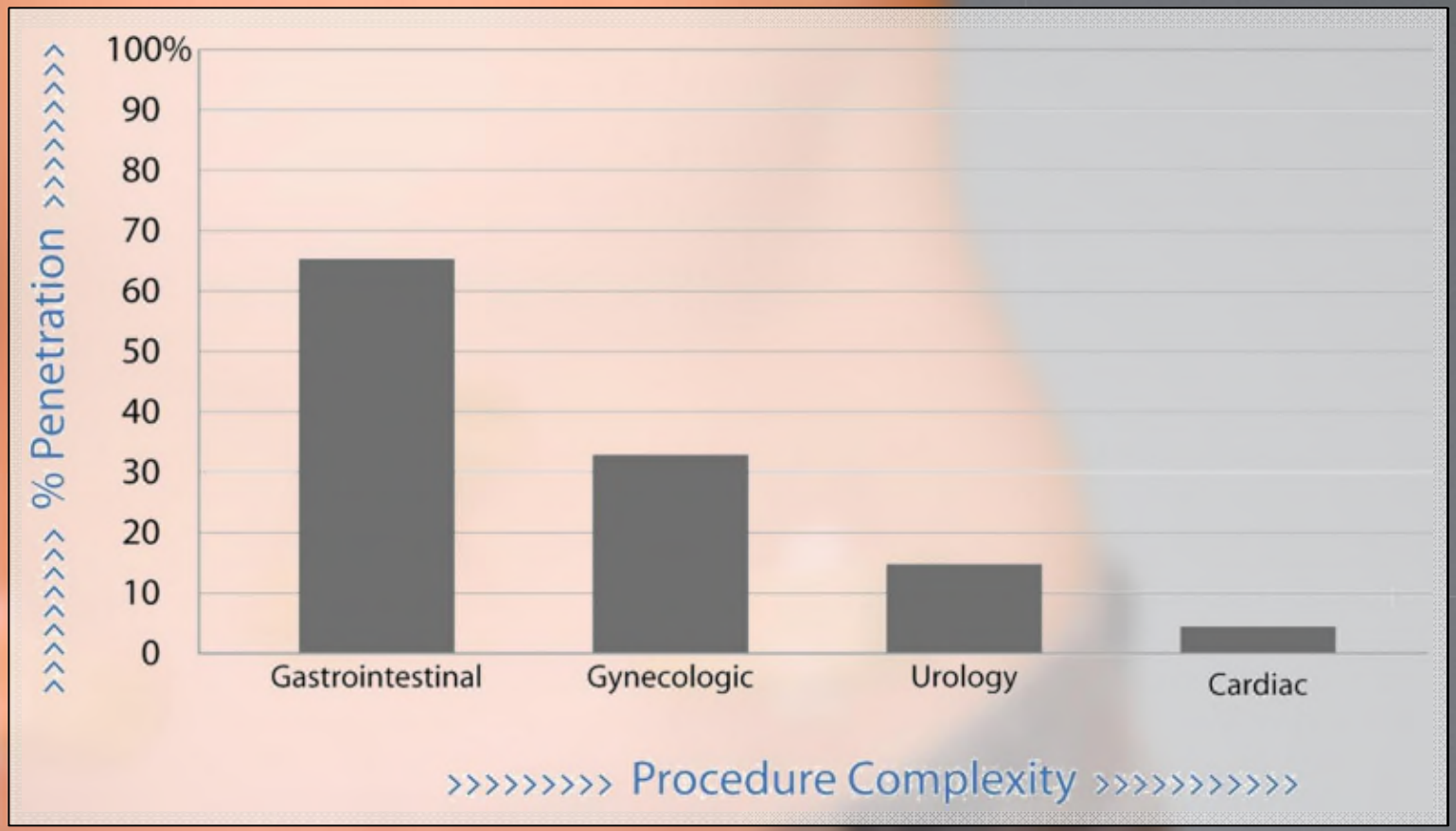
Patient-Side Manipulator

The da Vinci System in Motion

Manual Laparoscopy (1980's)

Dr. Philippe Mouret ~ 1987
Credited with first lap chole procedure in France in 1987

Laparoscopic oophorectomy
(removal of the ovaries) ~ early 1990's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100%
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80
70
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50
40
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20
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Gastrointestinal
Gynecologic
Urology
Cardiac
>>>>>>>>> Procedure Complexity >>>>>>>>>>>

1980's – Advancements in Robotics

- 1980's offered tremendous advancements in microelectronics and computing.
- Robotic telepresence technology began to reach new heights (and depths).

Nuclear material robotic arm ~ 1981


Deep Sea Robotics ~ 1985

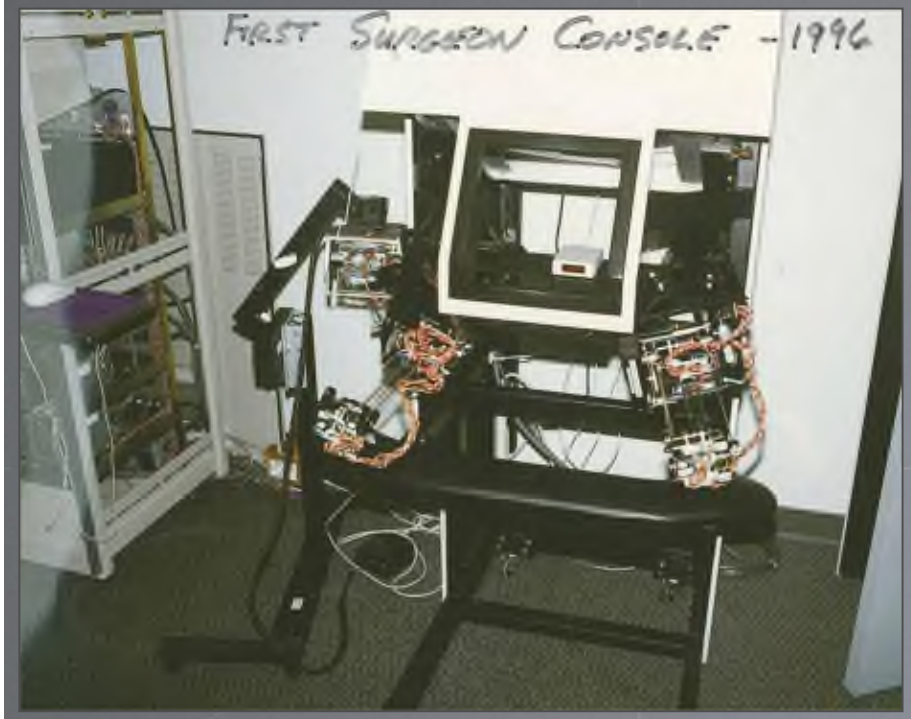

Robot "Jason Jr." Titanic wreck ~ 1986

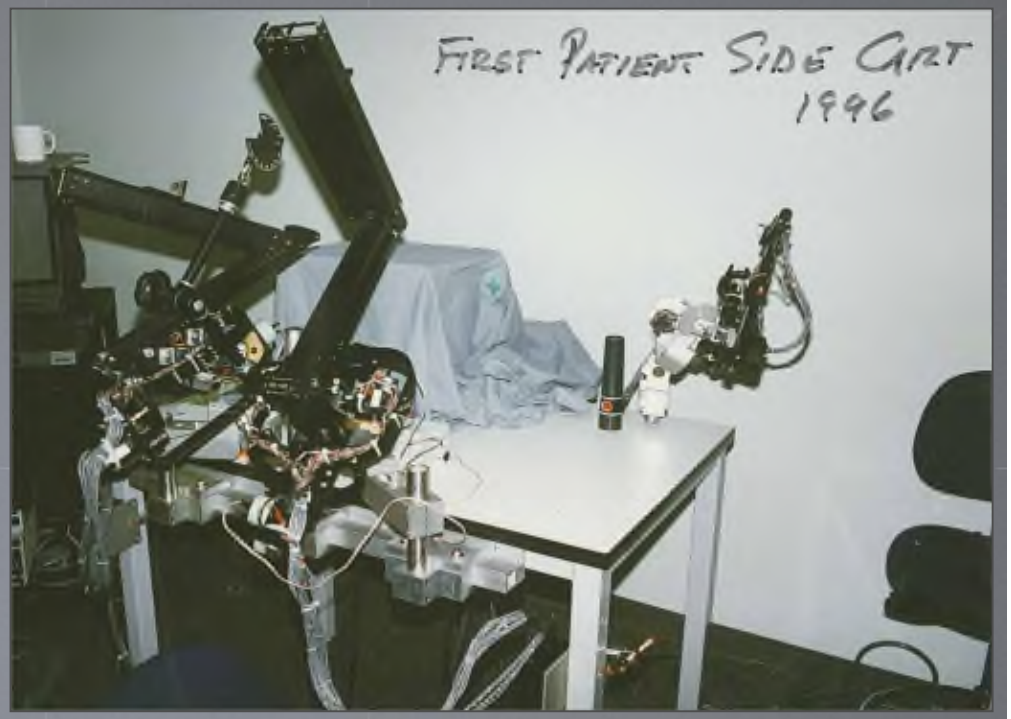
NASA Robotic Arm ~ 1981

Robotics meets Surgery

- In the 1990's, several groups recognized the opportunity to use tele-robotic technology to overcome laparoscopic challenges:

First Surgical Console and Patient-side Manipulators (1996)





The *da Vinci Si* Surgical System

Surgeon Console

Surgeon Console

Patient Side Cart

Vision Cart

The *da Vinci Xi* (April 2014)

What value can MIS offer to the Patient?

- Reduced pain.
- Reduced scarring.
- Reduced blood loss.
- Fewer complications.
- Faster return home, to work, and to normal activity.
- Fewer side effects (incontinence, impotence, infertility).
- Better cancer diagnosis and control (sometimes).

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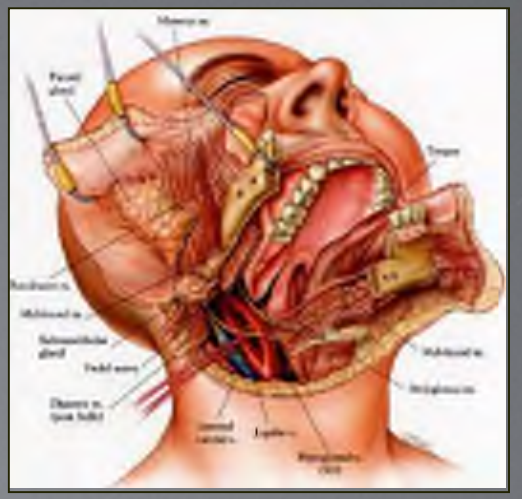
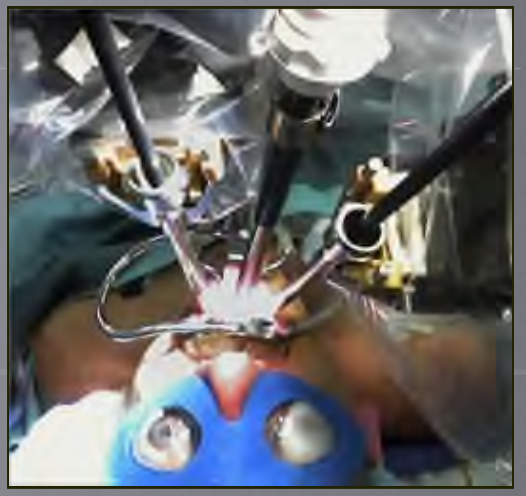




Focus Procedure Areas

>500,000 da Vinci procedures performed in 2013

Cardiothoracic

- Mitral Valve Repair
- Coronary Revascularization
- Lobectomy – lung cancer

Gynecology

- Hysterectomy – benign and endometrial cancer
- Sacral Colpopexy – pelvic floor reconstruction
- Myomectomy – removal of debilitating fibroids

Urology

- Prostatectomy – prostate cancer
- Nephrectomy – kidney cancer
- Cystectomy – bladder cancer
- Pyeloplasty – kidney reconstruction

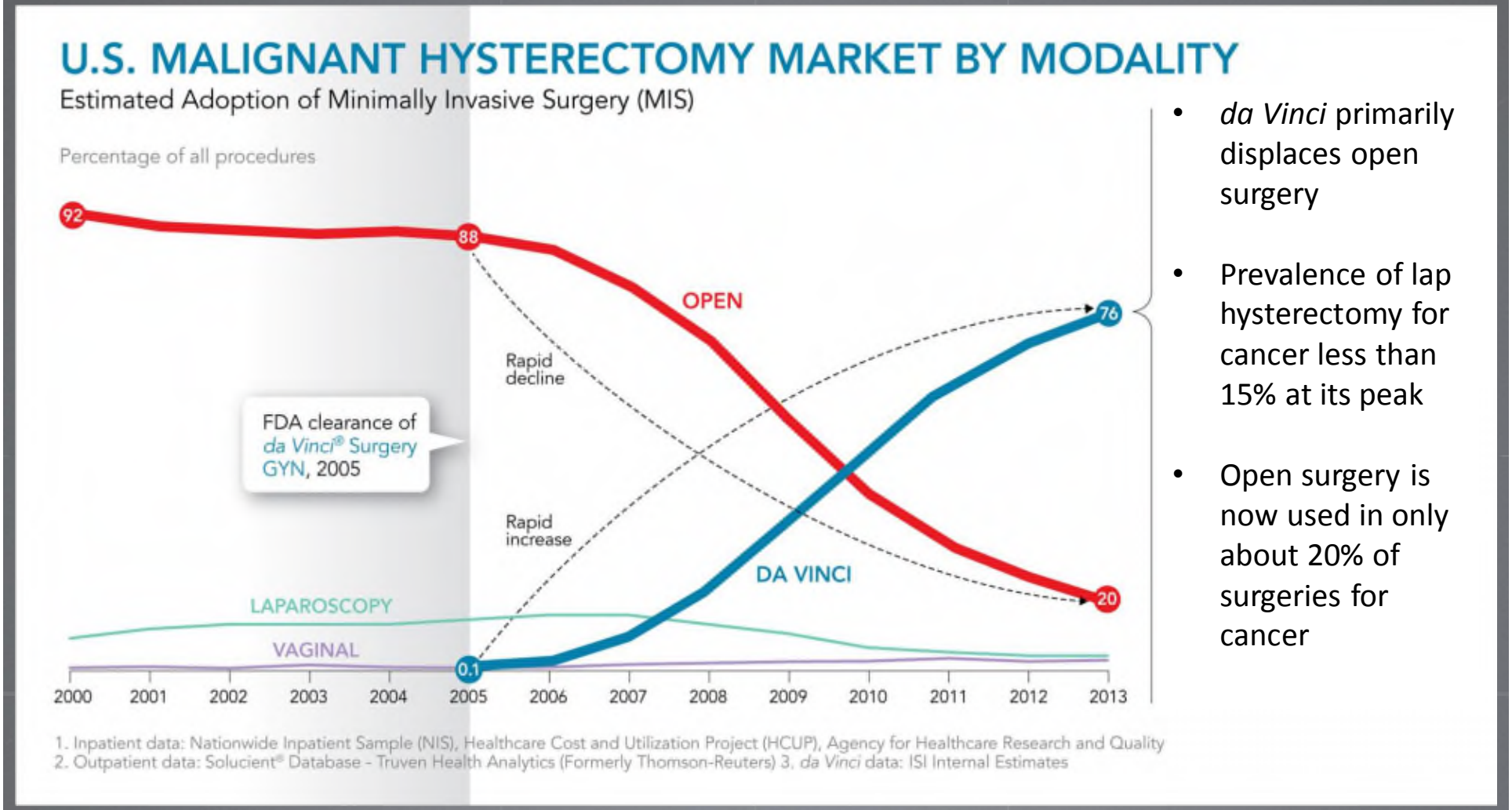
General Surgery

- Lower Anterior Resection – colorectal cancer

Head and Neck Surgery

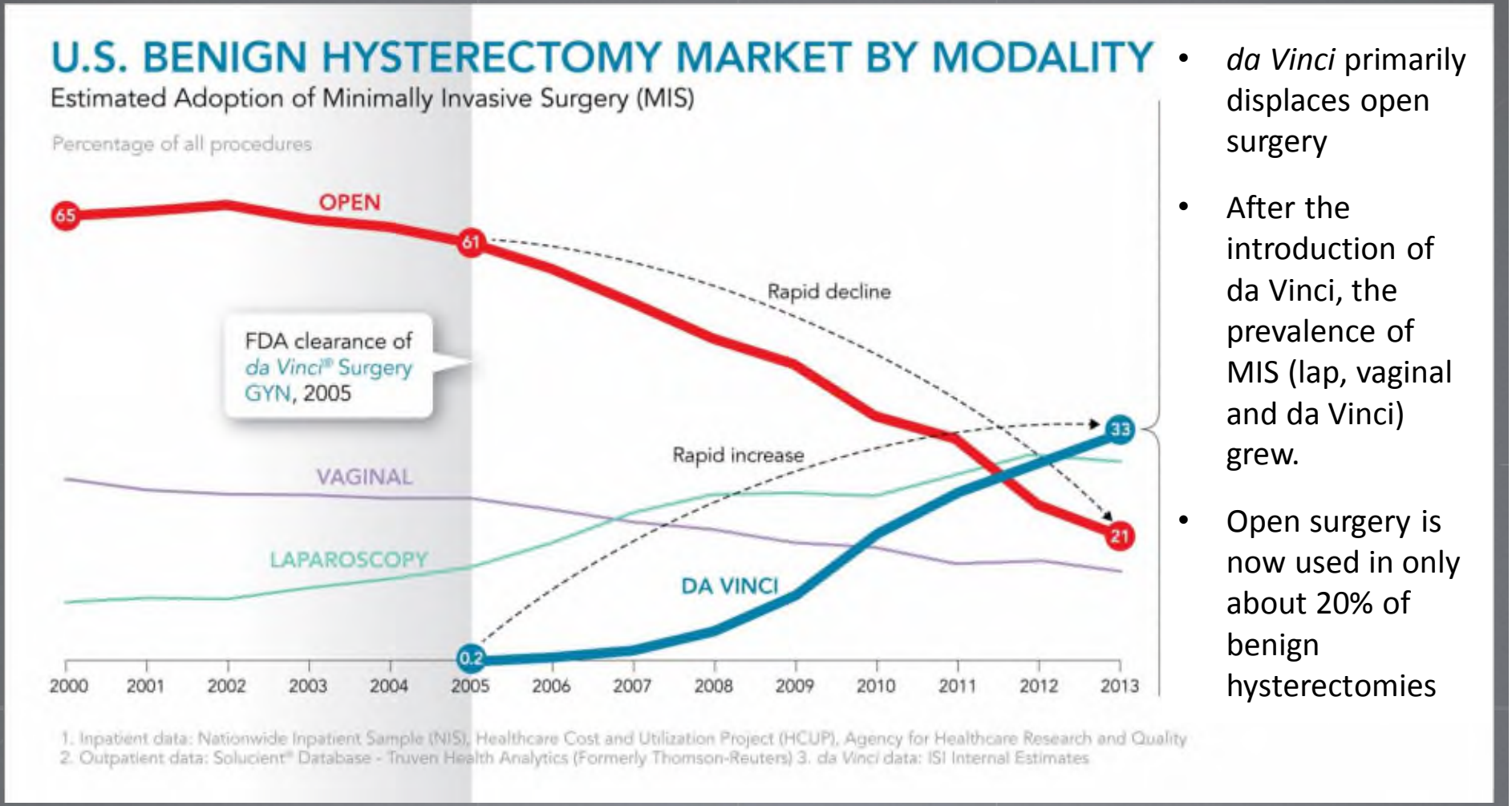
- Trans-oral Robotic Surgery (TORS) – throat and base-of-tongue cancer

Open vs MIS trends in the US: Malignant Hysterectomy



- *da Vinci* primarily displaces open surgery
- Prevalence of lap hysterectomy for cancer less than 15% at its peak
- Open surgery is now used in only about 20% of surgeries for cancer

Open vs MIS trends in the US: Benign Hysterectomy



- *da Vinci* primarily displaces open surgery
- After the introduction of da Vinci, the prevalence of MIS (lap, vaginal and da Vinci) grew.
- Open surgery is now used in only about 20% of benign hysterectomies

da Vinci Platform Evolution

1999

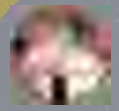
da Vinci
- Robot-assisted MIS
- Introduction of 4th arm (2003)

2006

da Vinci S
- 3D HD Vision

2009

da Vinci Si
- Dual Console option



- SKILLS SIMULATOR

- FIREFLY

- SINGLE-SITE

- ADVANCED INSTRUMENTATION

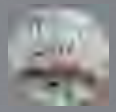
- SYSTEM NETWORKING

2014

da Vinci Xi
- Multi-quadrant access
- “Chip-on-tip” 3D HD vision

- PATIENT-SIDE SKILLS

- INTEGRATED ENERGY



- TABLE INTEGRATION (FUTURE RELEASE)

- SINGLE PORT SURGERY (FUTURE RELEASE)

Observations

- Platform iterations take a long time.
- “Add-on” technologies iterate faster.
- A shift to multiple-platforms is imminent.
- Question:

  What factors have driven evolution directions?

Design Drivers

- The OR environment.
- The team of users.
- Intended clinical indications.
- Some trade-offs:
  - Usability (surgeon vs assistant vs OR staff)
  - Versatility (procedures, indications, patients)
  - Surgical performance
  - Size
  - Cost
  - …what else?

This is a media photograph!

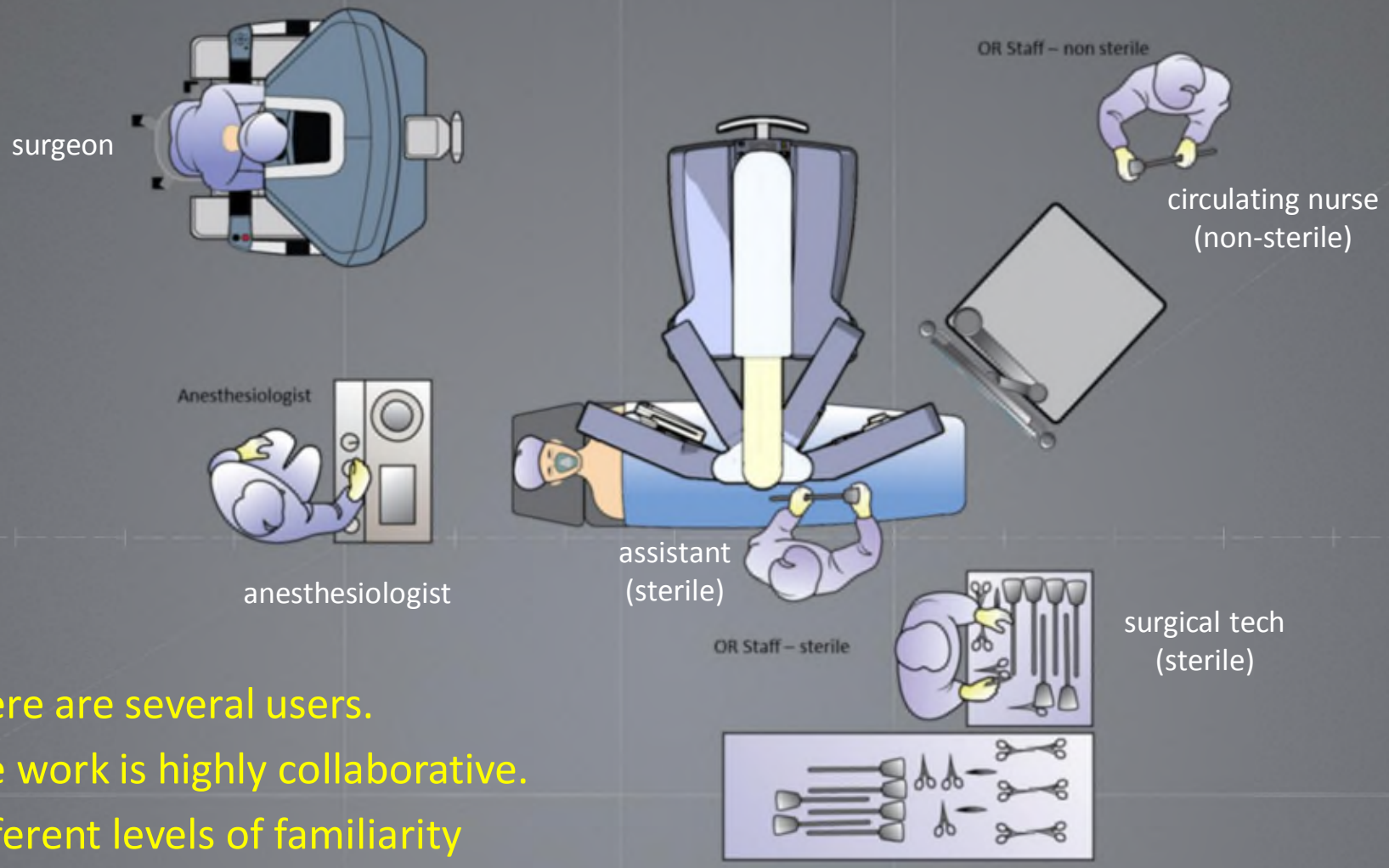
This is reality: the OR environment

This is reality: the OR environment

This is reality: the OR environment

This is reality: the environment

A Team of Users



- There are several users.
- The work is highly collaborative.
- Different levels of familiarity with the system.

Back to basics: Components of Surgery

- **Preparation**
  - operating room, patient, equipment
- **Access**
  - incision, insufflation, cannulation, (re)docking
- **Exposure**
  - manipulation, retraction, dissection
- **Assess**
  - visualization, palpation
- **Resection**
  - transection, clamping/sealing, cutting, hemostasis
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  - suction, morcellation
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  - suturing, stapling, fusing, anchoring
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Impact on the OR:
- Patient positioning
- Size and mobility
- Impact on workflow
- Procedure flexibility

Impact on the OR

- Design philosophy:
  one cart…multiple procedure applications.
- Trade-offs:
  - Size, Versatility, Modularity, Ease of setup

Si-e

Xi

Sp

Impact on the OR

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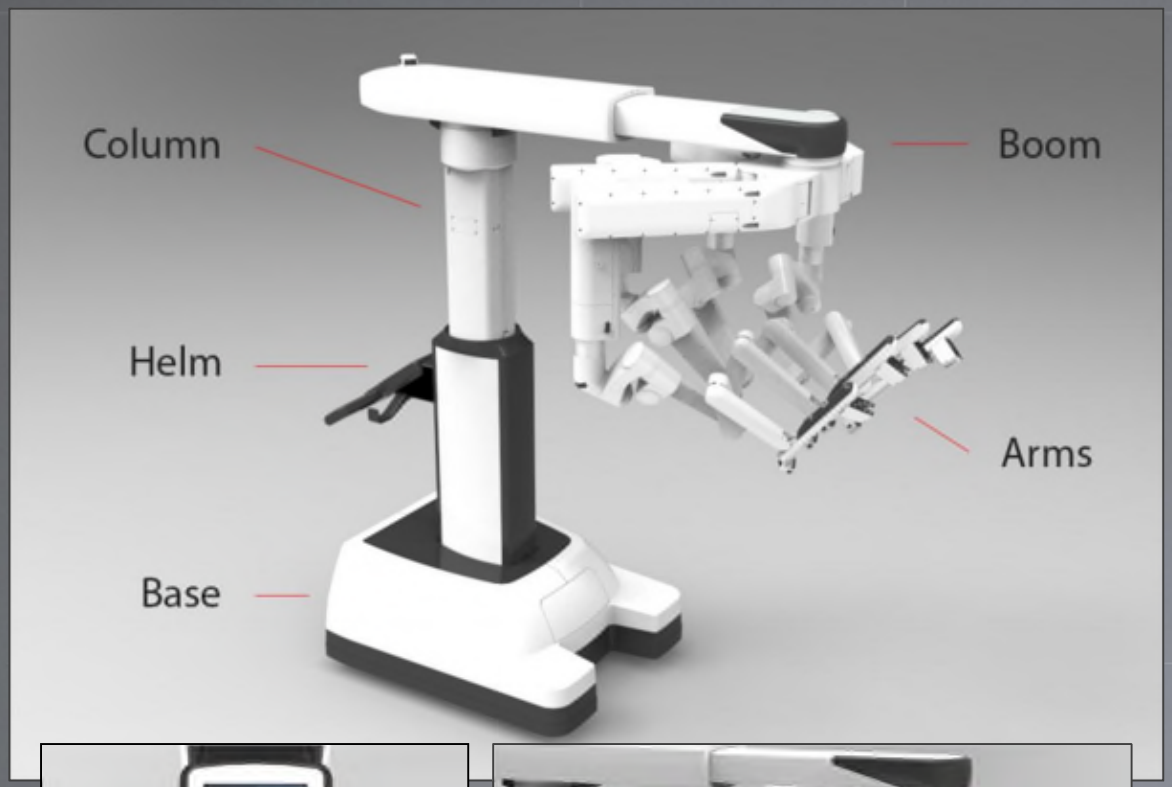
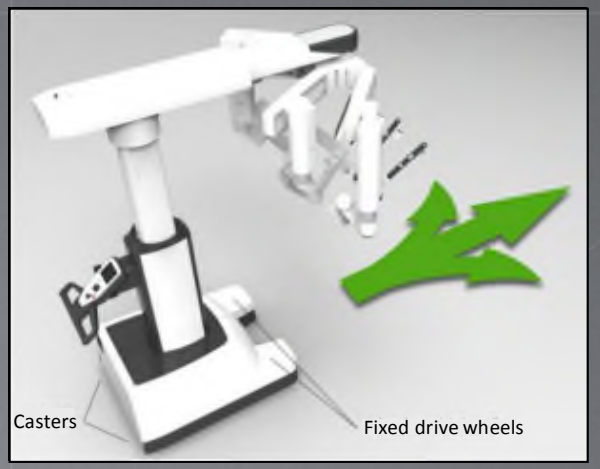
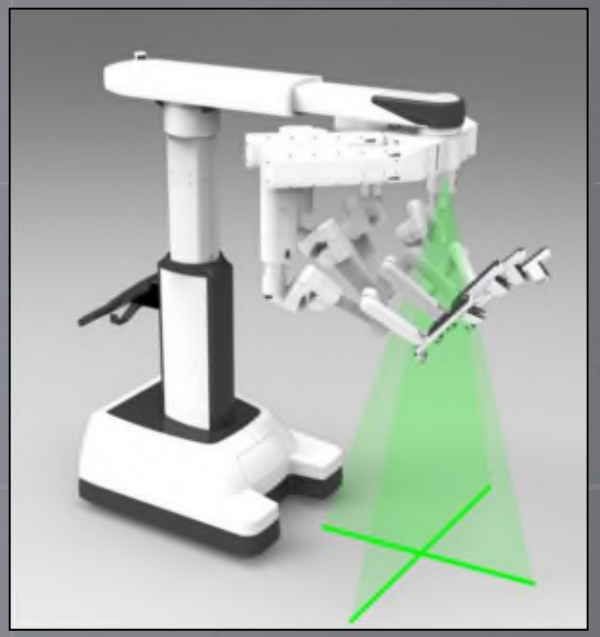
Alf-X SOFAR

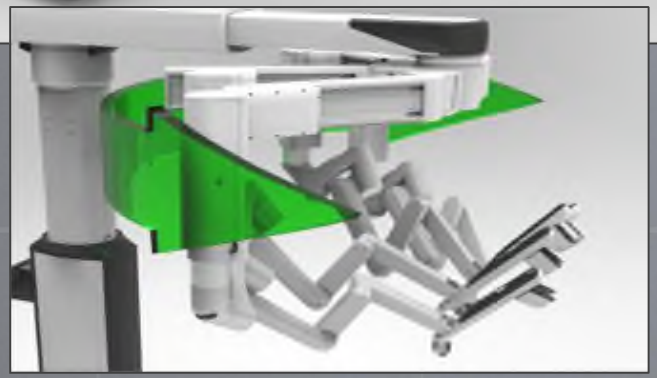
Xi

Architecture of the Xi Cart and Gantry

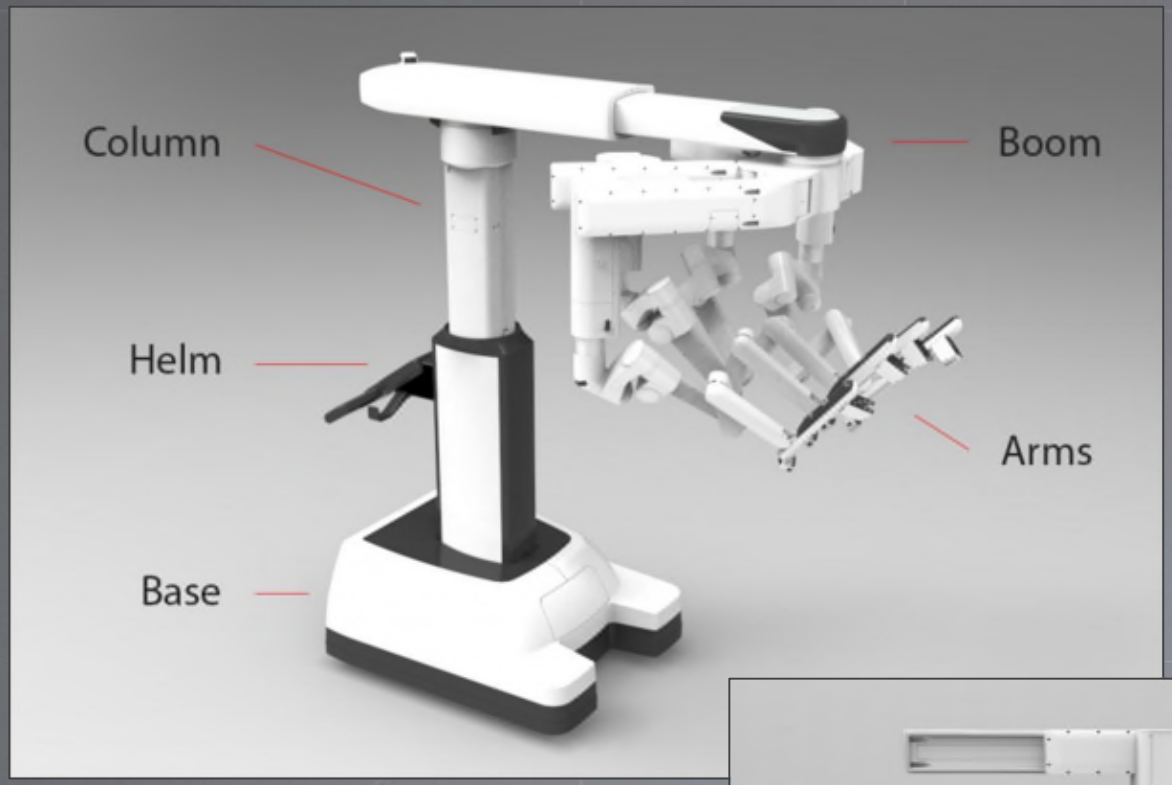


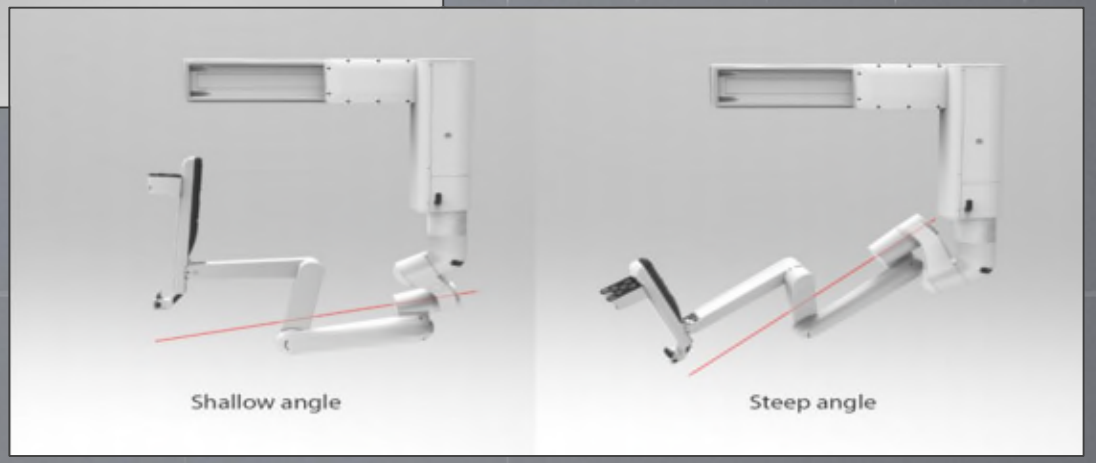






Architecture of the Xi Arms





Impact on the workflow: Guided Set Up

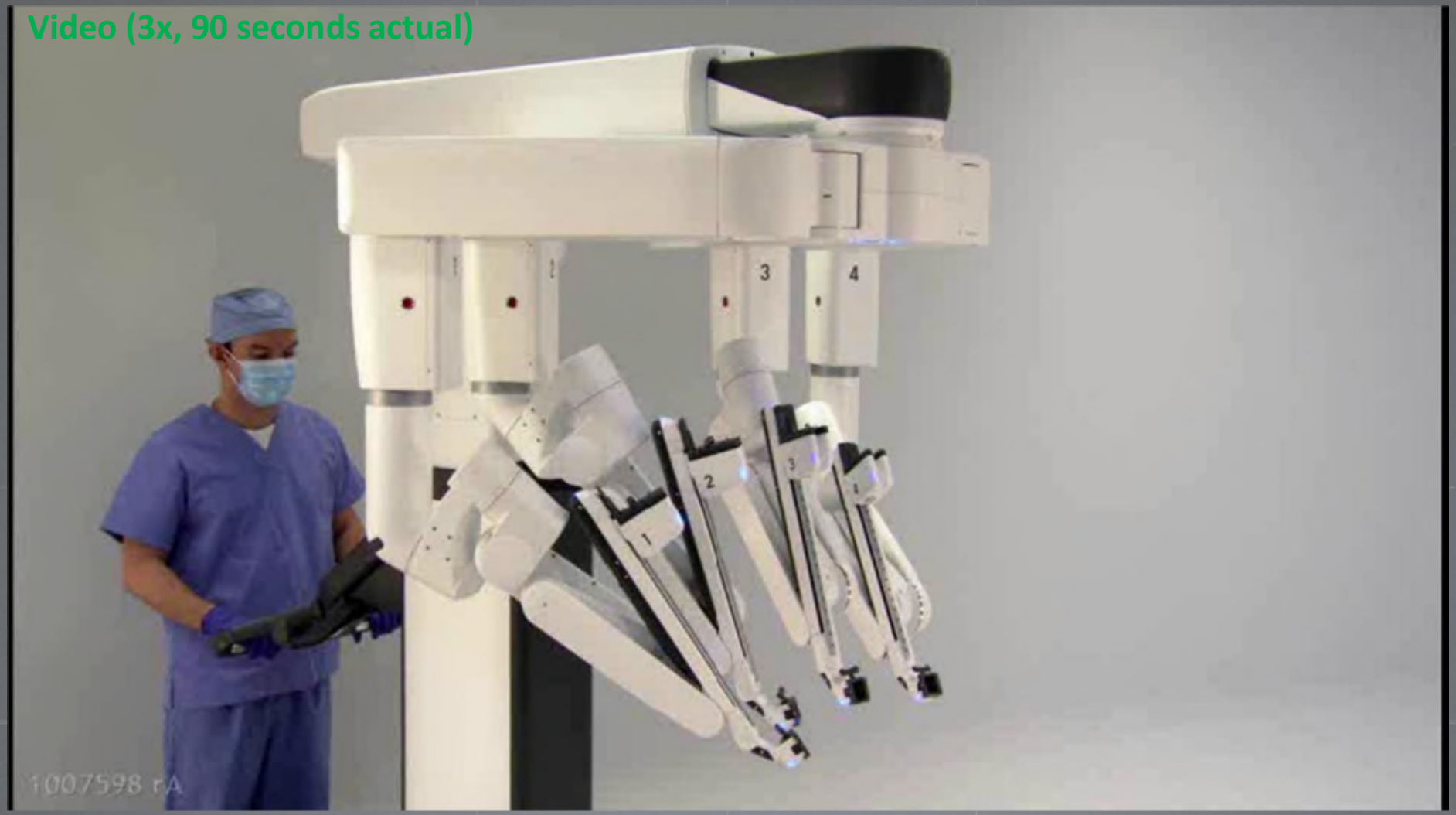
video

Impact on the workflow: Guided Set Up

Impact on workflow: Avoiding Buttons

Bringing it all together: Rapid Setup

Video (3x, 90 seconds actual)



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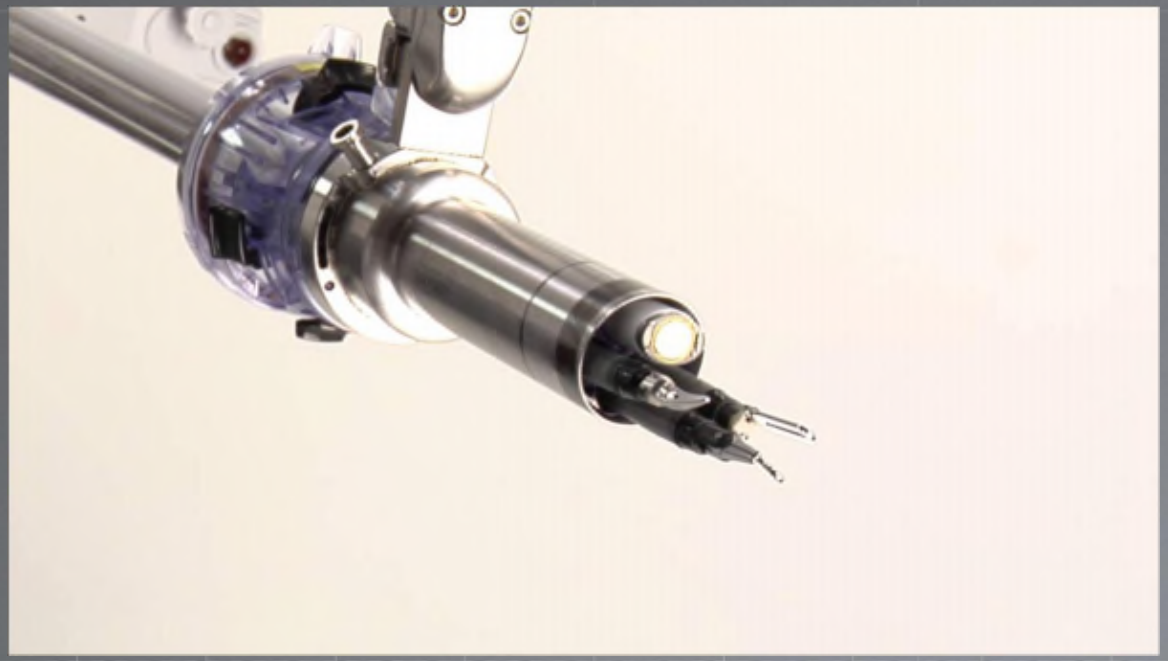
Surgical field:
- Multiple ports
- Single port
- Natural orifice
- Number of quadrants
- Range of motion

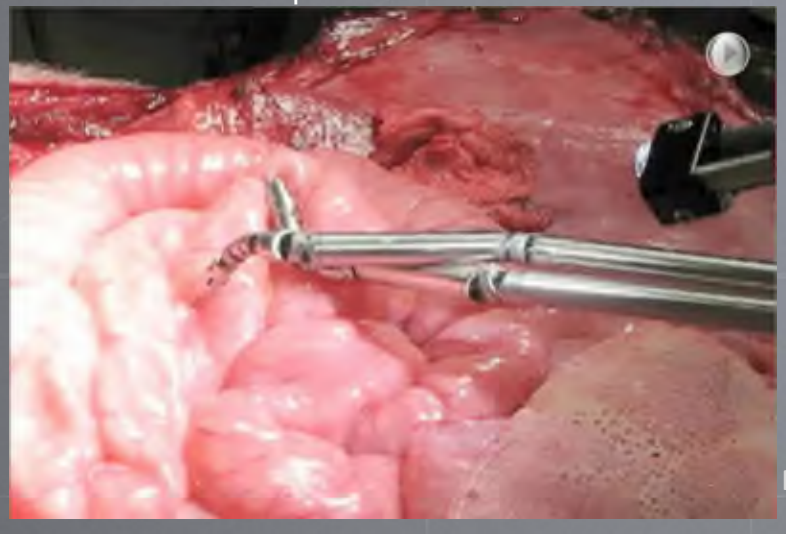
Workspace Flexibility

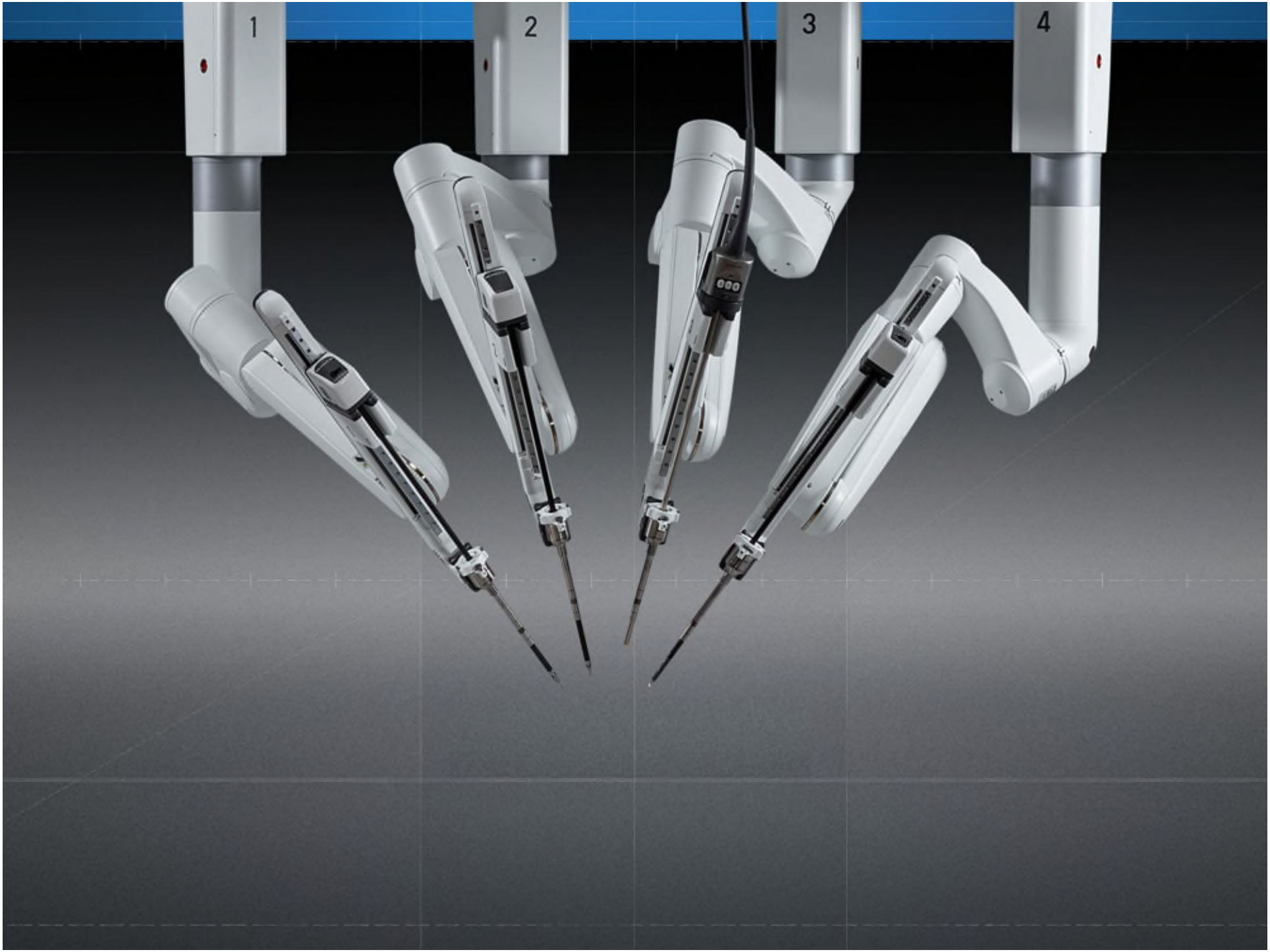
- Trade-offs:
  - multi- vs. single-incision
  - range of motion vs. rapid multi-quadrant

Multi- vs Single-port Access



Not available for sale. In development.

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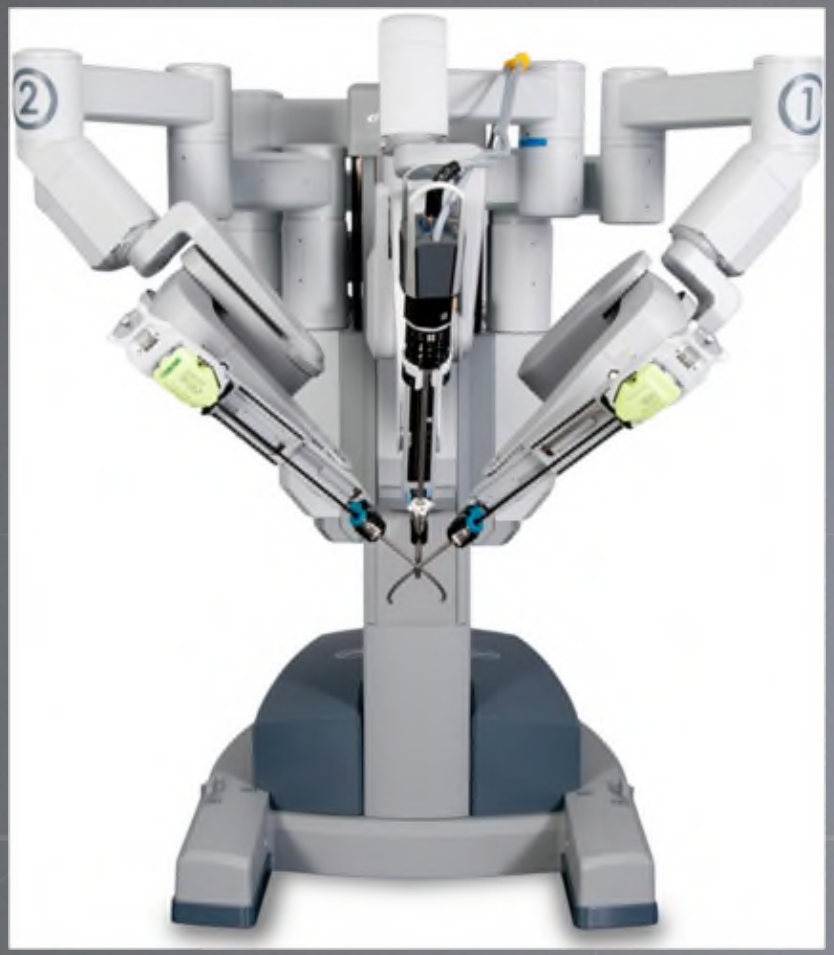
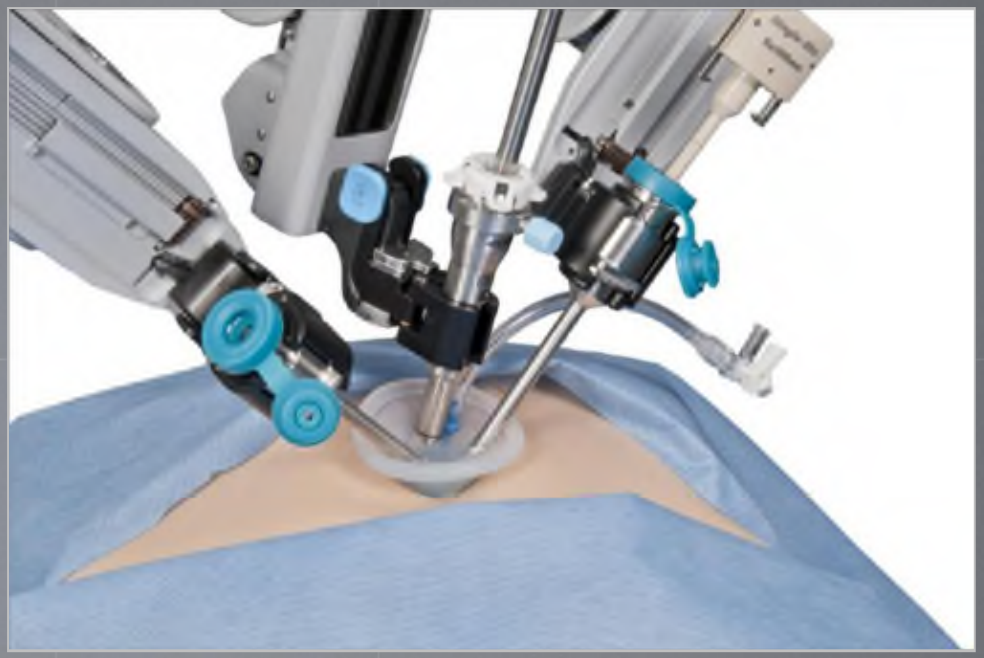
SingleSite Access with Multiport Platform





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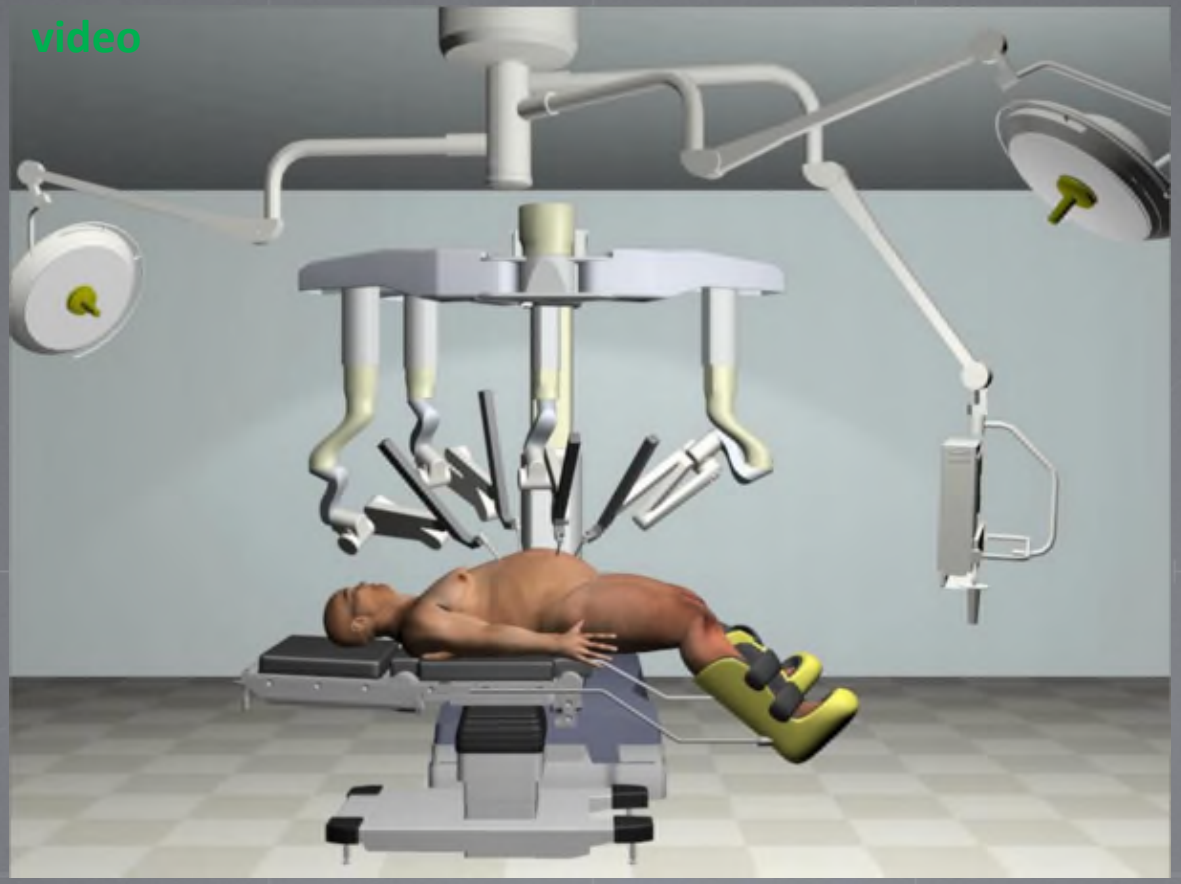
Surgical capability:

- Dexterity and precision
- Range of motion
- Stiffness and force
- Number of instruments

Surgical Capability

- Trade-offs:
  - Rigid versus flexible
  - Wristed versus non-wristed
  - Surgeon autonomy (how many hands?)

Surgical Capability: Not just instruments…



* Product feature not yet available. In development.

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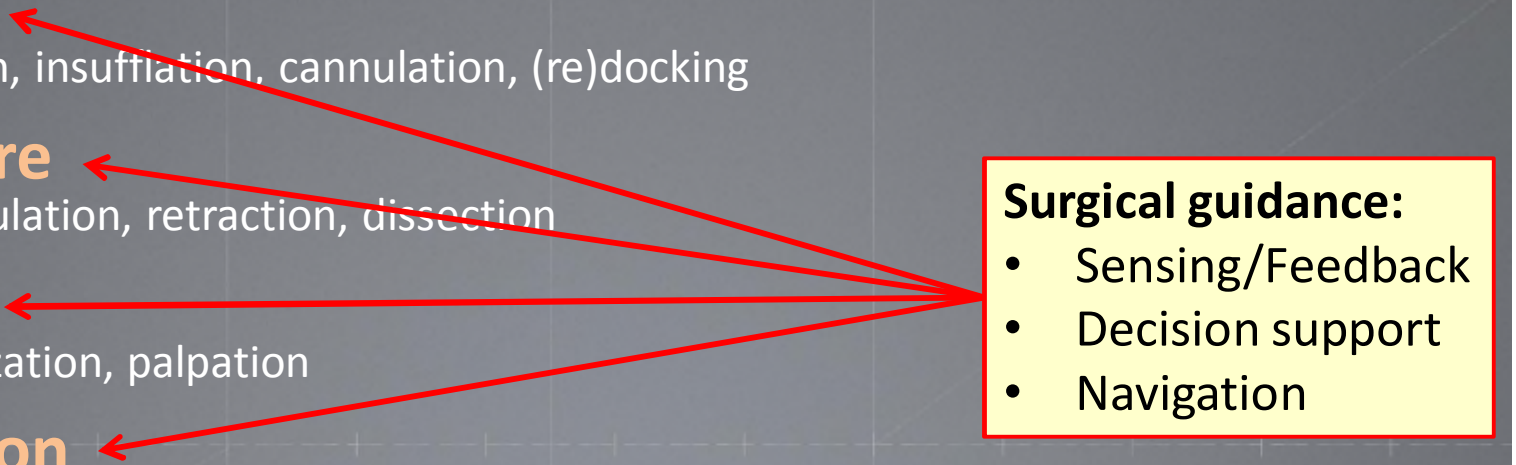
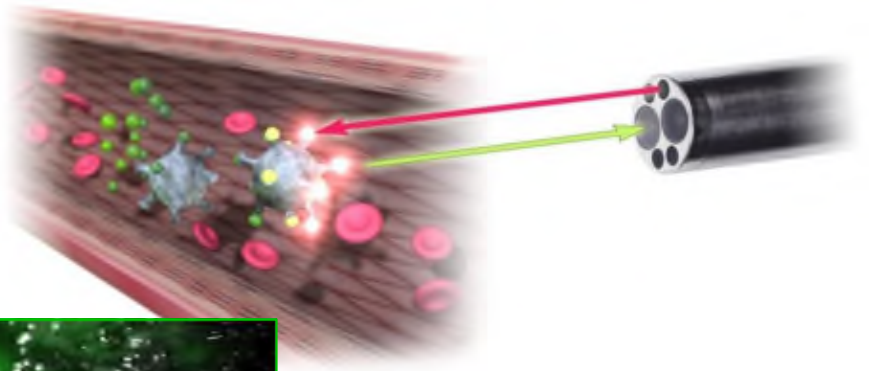


Surgical Guidance & Decision-making

- Fluorescence imaging
- Open opportunities:
  - Image guidance?
  - Haptics, Palpation?



Advanced Imaging: Fluorescence Imaging

Augmented Vision: The Image-Guided Surgical Cockpit

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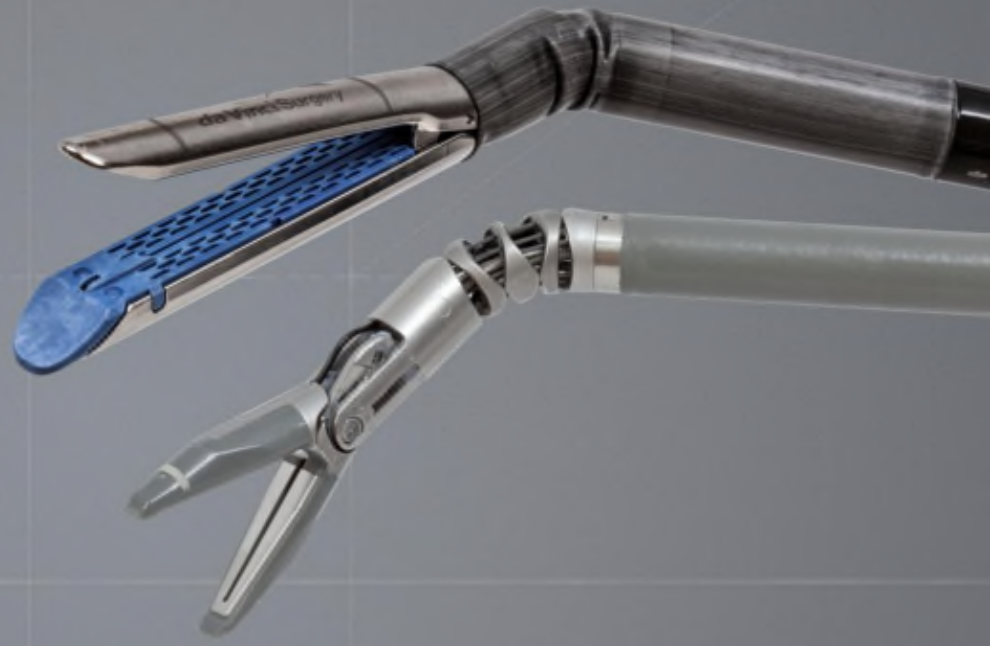
Tissue interaction:
- Specialized instruments
- Interchangeable instruments

Tissue Interaction

- Trade-offs
  - Diameter versus functionality & performance
  - Ability to exchange instruments quickly
  - Single versus multi-use
  - Cost



Advanced Instruments
EndoWrist® One™ Vessel Sealer

Advanced Instruments
Endowrist Stapler

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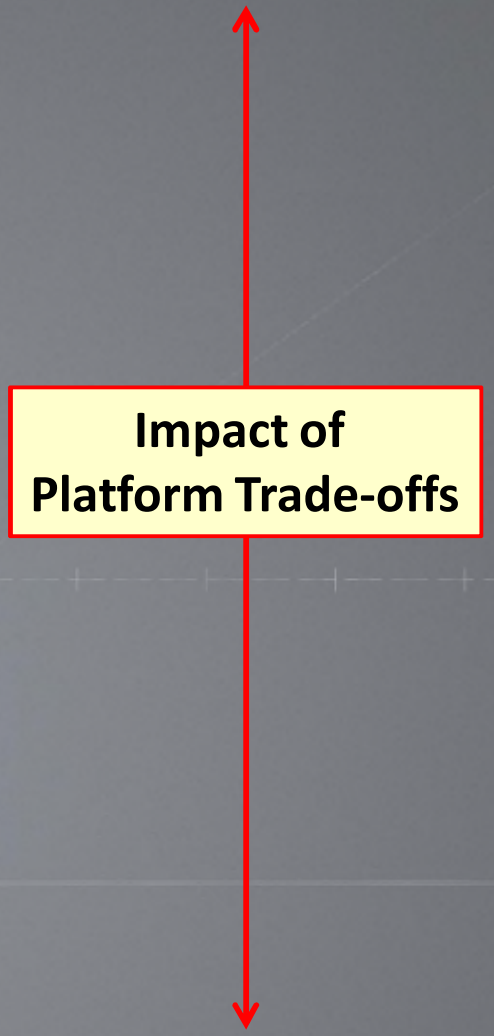


Platform Trade-offs

SIMPLE/BENIGN CASES — OPEN COMPLEX CASES

da Vinci Si

Support for *Single-Site*® & Some Complex Cases

da Vinci Si-e

Designed for *Single-Site & Simple Cases**

da Vinci Xi and Sp

Optimized for Complex Cases

Opportunities: Ideals in Surgery

1. See disease perfectly.
2. Resect diseased tissue, spare healthy tissue.
3. Reconstruct with precision.
4. Leave as if no surgery was required.

Opportunities:
How is technology taking us closer to the Ideal?

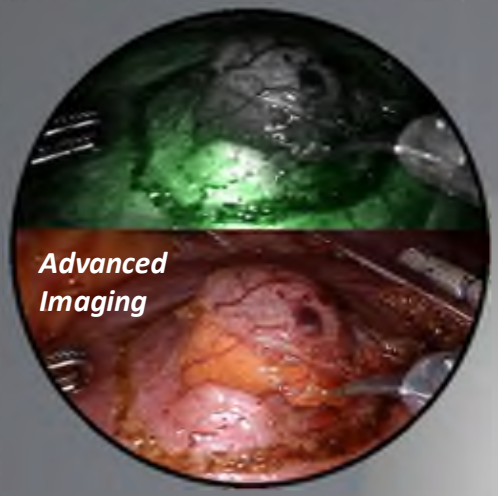
Surgeon Console | *Control System* | *Patient-Side Manipulator*

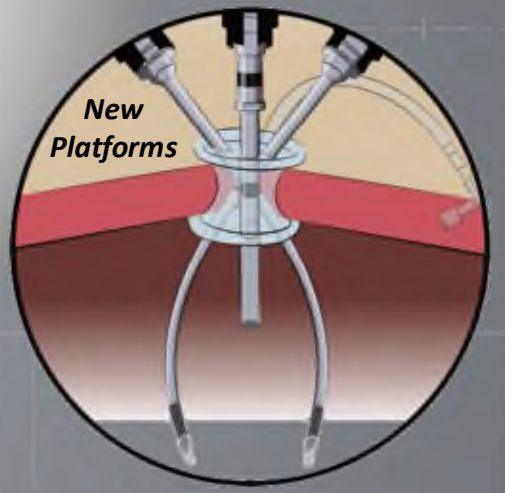
The “Software in the Middle”

Surgeon Console | *Control System* | *Patient-Side Manipulator*

Stabilize
Scale
Augment
Extend
Navigate
Anticipate
Warn
Guide
Automate

Our Technology Development Focus



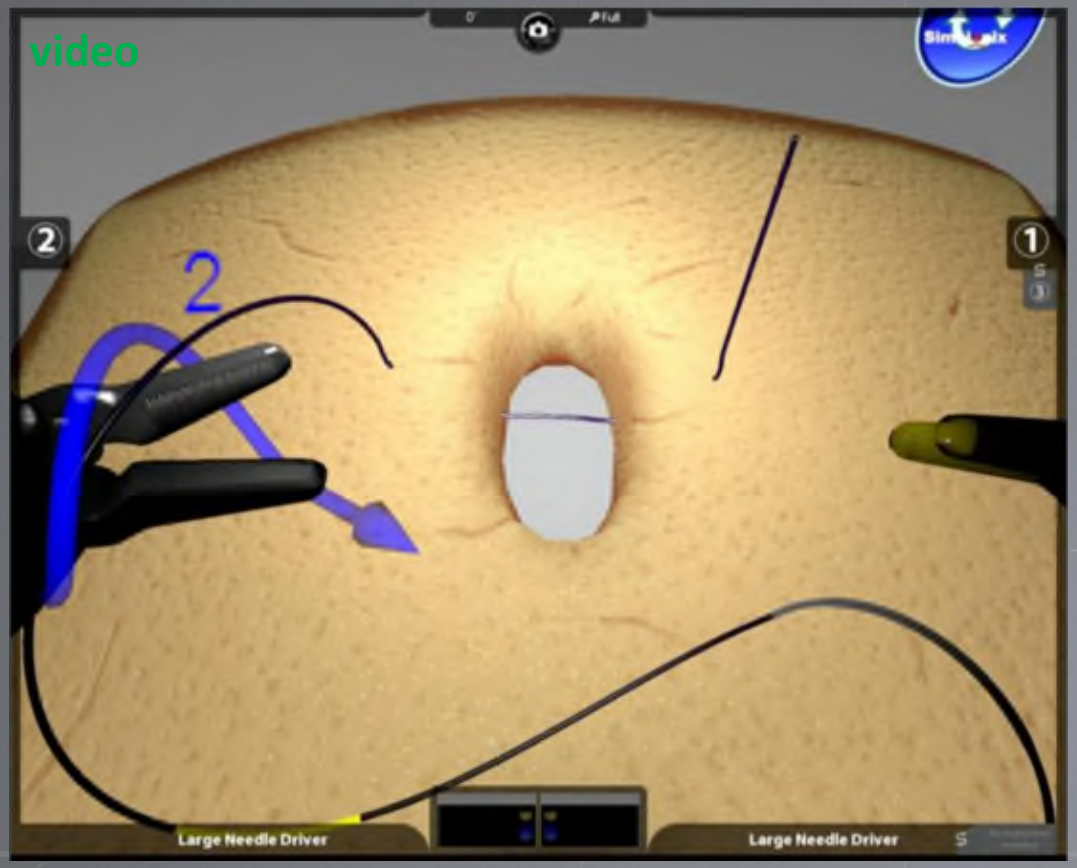


The Role of Simulation

video

- Pre-product visualization.
- Product preview.
- Console training.
- Patient-side training.

The Role of Simulation



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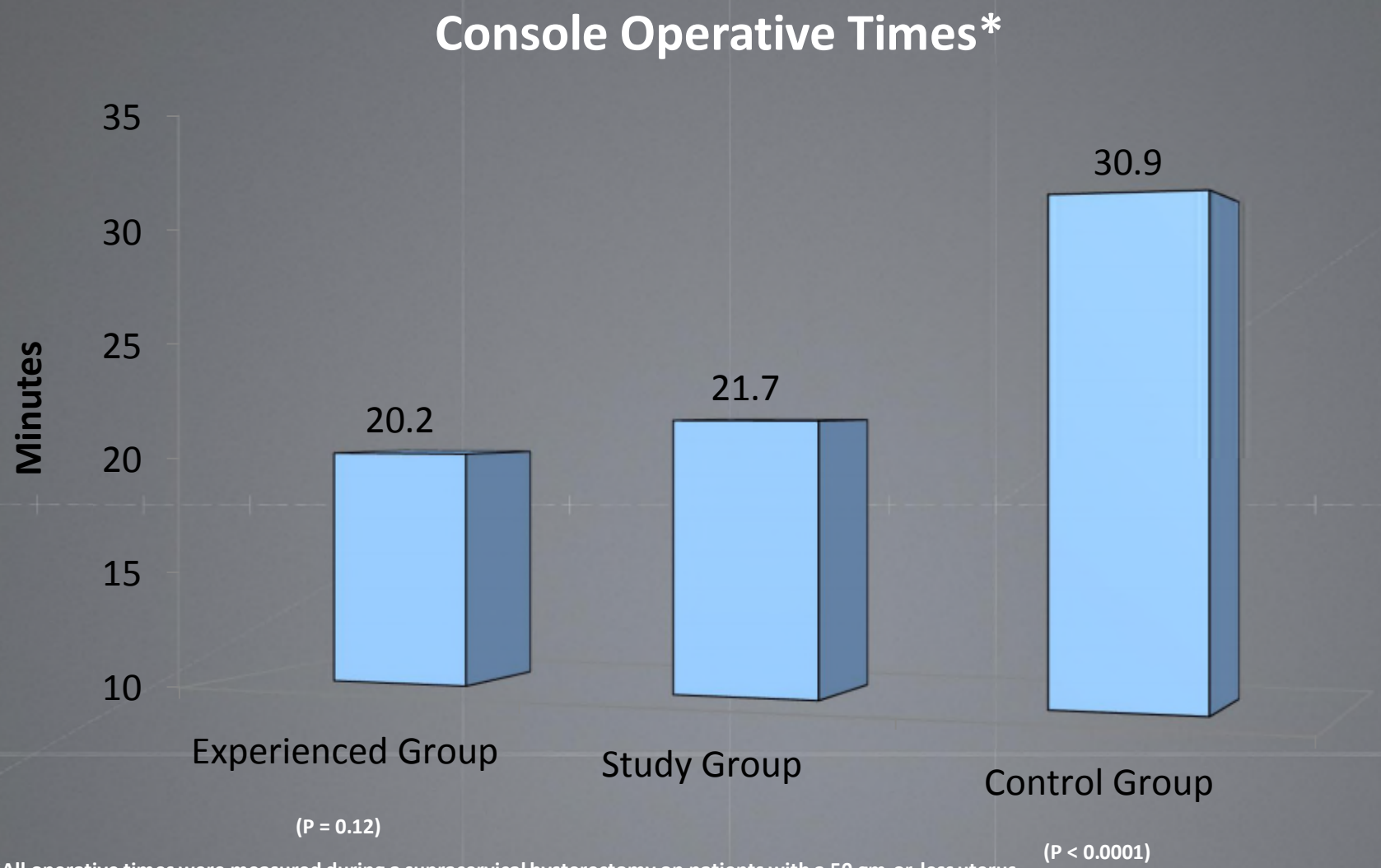
Simulator Impact: Morristown Study



*All operative times were measured during a supracervical hysterectomy on patients with a 50 gm-or-less uterus
Accepted for publication in Female Pelvic Medicine & Reconstructive Surgery; Dr. Patrick Culligan.

Some Challenges

- Complexity
- Regulation
- Litigation
- Cost

Product Development Cost and Complexity

- It took ~9 years and >$250M for Intuitive to reach profitability.
- 2013 R&D investment totaled $167 million, or ~$320 per patient.
- A *da Vinci* system is composed of >35,000 individual components (counting down to resistors) from >300 suppliers (direct).
- There are >2 million lines of embedded run-time code. Almost half of this code is related to safety and redundancy.
- A typical software verification will consist of ~40,000 test cases.
- The formally-maintained design history file is >10,000 pages of documentation.

Complexity: The Product Ecosystem

- da Vinci
- da Vinci S
- da Vinci Si
- da Vinci Si-e
- da Vinci Xi
- da Vinci Firefly
- da Vinci Single-Site
- da Vinci Skills Simulator
- Instruments
  (8mm: 44; 5mm: 12; 12mm: 1)
- Endoscopes
  (12mm & 8.5mm: 18)
- Accessories
  Cannulas, obturators, seals, drapes, sterile adapters, energy cables, sterilization trays, light guides, etc.

Challenges: Economic Cost vs. Value

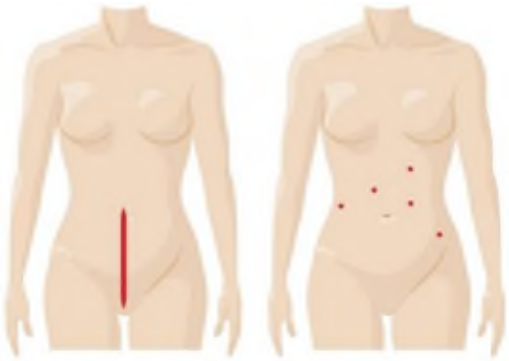
- **Direct Costs**
  - System capital expense, service contracts, and training.
  - Instruments and accessories.
- **Direct Savings**
  - Avoided supply costs and operating expenses (e.g., length of hospital stay).
  - Reduced re-admissions costs (due to complications & recurrence).
- **Overall health & quality of life outcomes, including…**
  - Cancer control (effect on positive margin rates)
  - Cancer diagnosis, improved lymph removal (malignant gynecology)
  - Continence, potency (prostatectomy)
  - Fertility (myomectomy)
  - Avoided sternotomy (cardiac procedures)
  - Reduced rate of dialysis (partial nephrectomy vs. full nephrectomy)
  - Reduced pain during recovery (feeding tube for throat cancer surgery).
  - Faster return to work and other normal activities.
- **Avoided costs of expensive non-surgical therapies (e.g., radiation therapy).**
- **Reduced long-term capital investment (fewer beds built/maintained).**
- **Surgeon focus and productivity.**

Challenges: Economic Cost vs. Value

Outcomes and Cost Comparisons After Introducing a Robotics Program for Endometrial Cancer Surgery

OBSTETRICS & GYNECOLOGY
VOL. 119, NO. 4, APRIL 2012
Lau et al. Jewish General Montreal

- Minimally invasive procedures increased from 17% to 98% in 2 years
- Historic cohort n=160; Robotic cohort n=143
- Robotic cohort:
  - Longer OR time (233 vs 206 minutes)
  - Fewer adverse events (13% vs 42%)
  - Less blood loss (50 ml vs 200 ml)
  - Reduced median hospital stay (1 vs 5 days)
  - Lower overall hospital costs ($7644 vs $10,368)
    - with amortization/maintenance, ($8,370 vs $10,368)
  - Reduced recurrence rates (11 cases vs 19)



Economic Analyses – Same subject, same journal*, different conclusions

Wright, *et al*

- Laparoscopic population
- Excludes open surgery
- Cost-to-charge and direct costs: "Lap < robotic"
- Conclusion: Lap less expensive than robotics for this subset of patients

Leitao, *et al*

- Total population approach
- Includes open surgery
- 6-month direct costs: "Lap < robotic < open"
- Conclusion: By reducing open surgery, robotics yields savings on a population basis

Direct, comprehensive cost analysis—*on a population basis*—yields a more accurate assessment of the cost-to-treat impacts for hospitals and the healthcare system overall.

*Both studies published in May 2014 edition of *Obstetrics & Gynecology* evaluating uterine cancer.

What might the future hold?

This was the Automobile roughly 15 years in…

The Future Through the Lens of Research

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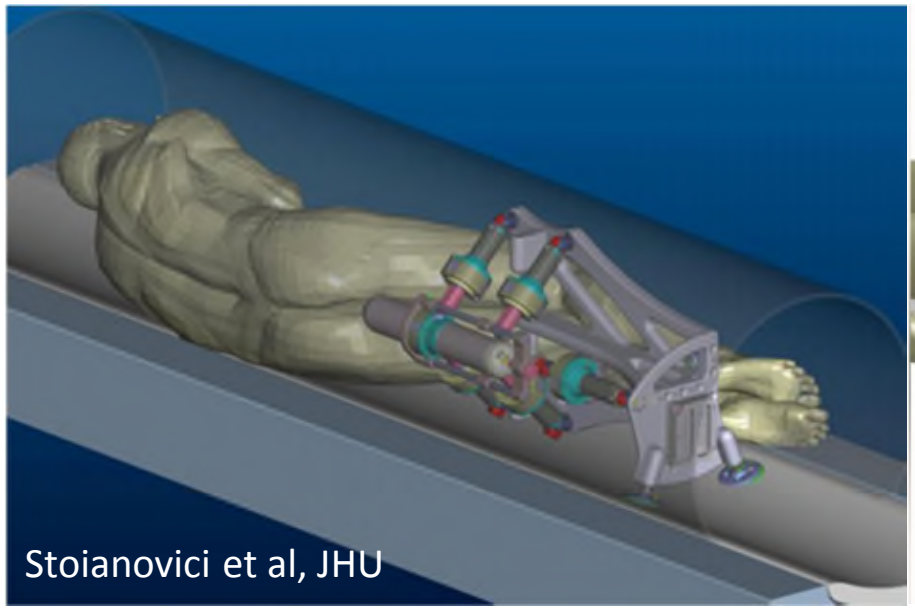
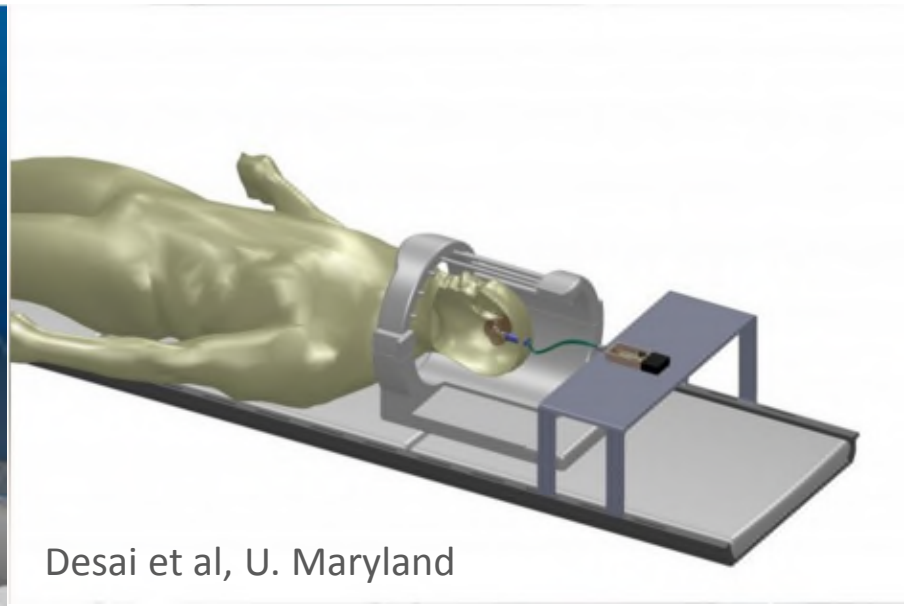
The Future Through the Lens of Research

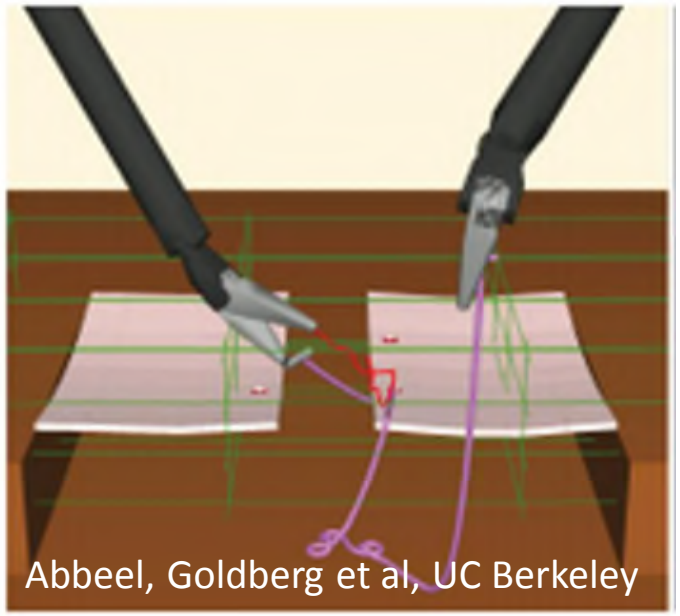


Stoianovici et al, JHU

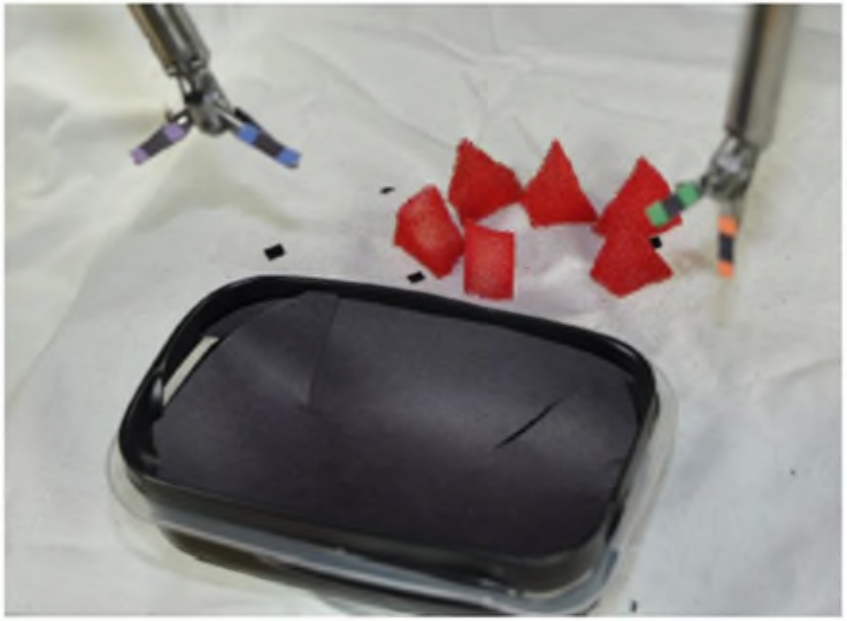


Desai et al, U. Maryland

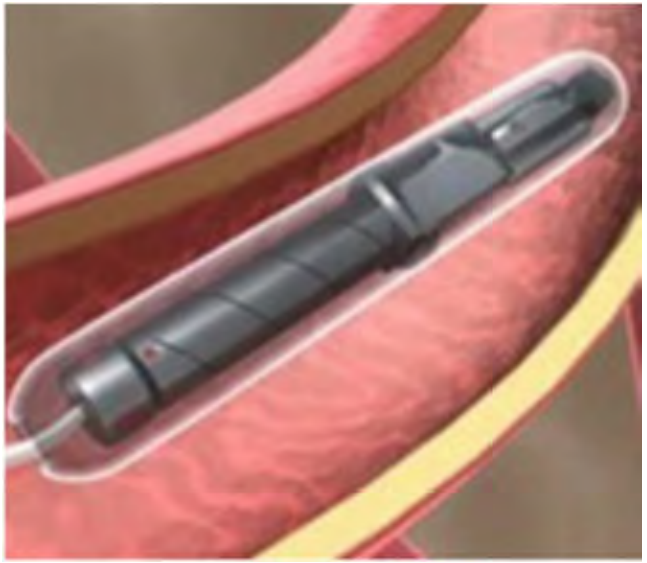
The Future Through the Lens of Research



Abbeel, Goldberg et al, UC Berkeley



The Future Through the Lens of Research



Concluding Thoughts

- Robots are just one part of a complex system.
- The overall goal is to enable greater shift to MIS.
- There are many system design trade-offs.
- User-centric design tries to balance the needs of a team of users.
- Different system architectures for different clinical needs.
- There are many opportunities, particularly in surgical guidance and decision support.


1
2
3
4
INTUITIVE
SURGICAL