Robotic Surgery

Arm yourself with the latest information on pricing, performance, clinical efficacy, and safety

Surgical robots are proliferating and there are more than a dozen systems on the market. Intuitive Surgical still has a monopoly on robotic laparoscopic surgery—but for how long? Is the da Vinci Xi a revolution or an evolution?

In the age of healthcare reform, creating value is essential and the C-suite is more involved than ever in purchasing decisions. The value proposition for robotic surgery is controversial because of:

- high capital, service, and recurring costs
- lack of additional reimbursement from insurers
- serious, high-profile patient injuries
- wide-ranging clinical outcomes

1 in 4 US hospitals has at least 1 da Vinci robot

67% of all da Vinci robots (n=3,317) in the world are installed in the US

79% of all da Vinci robotic procedures in the world are performed in the US

Incremental cost per da Vinci procedure = $3,000 to $6,000

570,000 worldwide da Vinci robotic procedures in 2014: 178% compared to 2009

What procedures can be performed?

The clinical evidence is low to moderate in terms of quality and quantity for all of the most common robotic surgeries.

In the US, da Vinci-assisted gynecologic and urologic procedure volumes have plateaued. General surgeries such as laparoscopic cholecystectomy, hernia, and colorectal resection have increased dramatically in the past three years.

What is the current state of laparoscopic robotic surgery?

What does the future hold?

Potential Competitors

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Key Features</th>
<th>Regulatory Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medrobotics</td>
<td>Flex</td>
<td>Single-port, snake-like, cleared only for transoral surgery</td>
<td>FDA 510(k) cleared July, 2015</td>
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<tr>
<td>SOFAR</td>
<td>Telelap ALF-X</td>
<td>Multiple port, 3 or 4 arms, haptic feedback, reusable instruments</td>
<td>CE marked March, 2014</td>
</tr>
<tr>
<td>Titan Medical</td>
<td>SPORT</td>
<td>Single-port, snake-like, designed for small to medium surgical field</td>
<td>None (Projected 2017)</td>
</tr>
<tr>
<td>TransEnterix</td>
<td>SurgiBot</td>
<td>Single-port, hybrid of robotics and traditional laparoscopy</td>
<td>FDA 510(k) submitted June, 2015</td>
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</table>

What procedures can be performed?

Major Procedure Types (% of 449,000 US da Vinci procedures)

- Gynecology (52%)
- General Surgery (24%)
- Urology (20%)
- All Other (4%)

Clinical Evidence

- High
- Moderate
- Low

Incremental cost per da Vinci procedure = $3,000 to $6,000

570,000 worldwide da Vinci robotic procedures in 2014: 178% compared to 2009
How does the Xi differ from the other da Vinci models?

Introduced in April 2014, the da Vinci Xi is the latest iteration of Intuitive Surgical’s surgical robot. Compared to the da Vinci Si and Si-e, the Xi is better suited for multi-quadrant surgery because all 4 arms are mounted on an overhead boom, enabling repositioning without the need to undock the system. Also, the Xi arms are longer and slimmer than previous versions, which may improve anatomical access.

Key Features | Xi | Si | Si-e
--- | --- | --- | ---
Number of robotic arms | 4 | 4 | 3
Single-site surgery | ✓ | ✓ | ✓
Overhead boom | ✓ | | |
Laser targeting guidance | ✓ | ✓ | ✓
Compatible instruments | | ✓ | ✓
Large surgical field procedures | ✓ | ✓ | ✓
Fluorescence imaging | Std | Opt | Opt

*Awaiting FDA Approval

During the first year it was launched, the da Vinci Xi accounted for more than 80% of all EMI member interest in da Vinci robots.

What is the State of Your Robotic Safety Program?

<table>
<thead>
<tr>
<th>Source: ECRI Institute Webinar Survey, 2013</th>
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<tr>
<td>73%</td>
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<tr>
<td>25%</td>
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<td>15%</td>
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Deaths related to surgical robots = 144

How do you keep it safe?

**Safety Committee**

- Multi-disciplinary committee that will consist of robotic surgeons, OR managers, anesthesiology, risk management, quality, and technical personnel

  - Enforce credentialing
  - Amend privileging/training pathways
  - Approve da Vinci assisted procedures
  - Address safety concerns

**Surgeon Training**

- Vendor general training
- Observe procedure-specific cases
- Serve as bedside assistant
- Perform surgical team simulation and cadaver training
- Proctored sessions

3,000 per physician per training or proctoring session

**Annual Privileging**

- Perform at least 20 procedure-specific robotic surgeries
- Review clinical outcomes during monthly inter-departmental meeting and annual privileging process
- Require simulation and cadaver exercises if outcomes are inadequate or procedure volume is insufficient
- Score ≥90% on simulation training modules

**Medical Device Alerts**

- Track ECRI Institute safety hazards associated with the robot as well as its instruments and accessories

In the past year, there were 6 alerts for the da Vinci Xi including 3 high priority problems that may lead to patient injury.

How does the Xi differ from the other da Vinci models?

- Intuitive Surgical’s surgical robot.
- Compared to the da Vinci Si and Si-e, better suited for multi-quadrant surgery.
- All 4 arms are mounted on an overhead boom.
- Xi arms are longer and slimmer.
- Increased access to anatomical space.

**What is the State of Your Robotic Safety Program?**

- 73% have a rigorous safety program.
- 25% believe program needs improvement.
- 15% do not have a safety program.

**Deaths related to surgical robots = 144**

**How do you keep it safe?**

**Safety Committee**

- Multi-disciplinary committee.
- Enforces credentialing.
- Manages privileging/training pathways.
- Approves da Vinci-assisted procedures.
- Addresses safety concerns.

**Surgeon Training**

- Vendor general training.
- Procedure-specific observations.
- Simulated and cadaver-based training.
- Proctored sessions.

3,000 per physician per training or proctoring session.

**Annual Privileging**

- Performs at least 20 procedure-specific robotic surgeries.
- Reviews clinical outcomes.
- Requires simulation and cadaver exercises.
- Scores ≥90% on simulation training modules.

**Medical Device Alerts**

- Tracks ECRI Institute safety hazards.

In the past year, there were 6 alerts for da Vinci Xi.

The Xi has been a success in the first year of its launch.

**ECRI Institute Member Interest: da Vinci Robot Models**

- da Vinci Si-e: 4%
- da Vinci Xi: 24%
- da Vinci Si: 82%

**Average Quoted Prices: da Vinci Robot Models**

- da Vinci Si-e: $1.79M
- da Vinci Si: $1.85M
- da Vinci Xi: Dual Console $2.31M
- da Vinci Xi: Single Console $1.91M

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**In the past year, there were 6 alerts for the da Vinci Xi.**

- 3 high priority problems.
- May lead to patient injury.

**How does EMI help?**

- The EMI Applied Solutions Group can help.
- Establish and maintain a robust robotic surgery program.
- Pre-empt safety issues.

**Take the next step.**

For expert, independent advice on your robotic surgery program, contact (610) 825-6000, ext. 5655, e-mail consultants@ecri.org, or visit www.ecri.org/roboticsurgery.