

FDA wonders whether robotic surgery is intuitive after all



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A study suggesting that Intuitive Surgical's da Vinci robot is no safer than standard laparoscopic surgery had little effect on Intuitive's share price when it was published in JAMA just over a week ago. News that the FDA has begun looking into reports of complications was not so easily weathered, however: Intuitive's shares fell 11% to \$509.89 late on Thursday. The stock has since recovered a little, now standing at \$537.30, but confidence in the firm's surgical robots could be less likely to bounce back.

Intuitive has always argued that the high price of the da Vinci technology – the system sells for more than \$1.5m – is justified by its greater safety and reliability compared with laparoscopic procedures. If evidence is found to challenge this sales could plummet – and if confidence in Intuitive's device is shaken there could be read-through to other companies, such as Hansen Medical and Mako Surgical, which sell similar technology.

Design flaws vs user error

The FDA has written to surgeons who use the da Vinci system to canvass their opinions of complications, outcomes and dangers with the robot. Reports of complications have increased recently, the agency says, and it wants to find out if this is due to poor technique on the part of the operators or a mechanical fault.

The system is responsible for the vast majority of Intuitive's revenue, which reached \$2.2bn in 2012. If the FDA were to ascribe adverse events to technological flaws with the da Vinci, and subsequently restrict its indications, or even recall it – though this is unlikely – the company would feel it keenly.

In a sense, it would help Intuitive greatly if doctors were to confess to being less than perfectly competent. Whether this is likely to happen is another matter.

Even if the FDA's investigation puts Intuitive in the clear, the JAMA study's findings could still harm sales. The researchers found that average per-procedure costs with laparoscopic hysterectomy were \$6,671, compared with \$8,854 with the da Vinci, but the two techniques had similar complication rates.

Lennox Ketner, an analyst at Bank of America Merrill Lynch, wrote that the study would not damage sales of the system. This is because the patients treated using the da Vinci are those for whom laparoscopy is unsuitable, and the study states that robotic surgery is still preferable to open surgery, despite being more expensive.

Use of the system to perform hysterectomies in the US will grow by 15% in 2013/14, Mr Ketner said.

Nevertheless the message many hospitals might take from this study, and a similar one published in August 2012 regarding thyroid surgery, is that \$1.5m is a lot to spend on a machine that confers no benefit over laparoscopy.

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