FlexDex Needle Driver™ for minimally invasive laparoscopic surgical suturing

TIMEFRAME: Estimated earliest commercial availability in the UK

<table>
<thead>
<tr>
<th>Currently unclear</th>
<th>Now</th>
<th>6 months</th>
<th>1 year</th>
<th>18 months</th>
<th>2 years</th>
<th>Over 2 years</th>
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TECHNOLOGIES

The FlexDex Needle Driver™, developed by FlexDex, Inc., is a laparoscopic instrument intended for use in all patients undergoing laparoscopic surgical procedures requiring intensive suturing.

The FlexDex Needle Driver™ comprises three main components: the FlexDex Virtual Center™, the Infinity Handle™ and the 3-Axis Wrist Gimbal. The FlexDex Virtual Center™ reproduces the surgeon’s natural hand movements one-to-one at the articulating instrument jaw. The Infinity Handle™ enables opening and closing of the jaw while its rotation dial allows the surgeon to rotate the instrument. The 3-Axis Wrist Gimbal reduces instrument jaw tremor and allows for the expansion of the surgical working area inside the patient.

The company expect to receive a CE Mark for the FlexDex Needle Driver™ by the middle of 2017, and plan to launch the device in the UK NHS by May 2018.

POTENTIAL FOR IMPACT

Laparoscopic surgery, also known as keyhole surgery, allows surgeons to access the inside of the abdomen and pelvis without having to make large incisions in the skin. During laparoscopic surgery the surgeon makes one or more small incisions in the abdomen through which to insert the laparoscope, other surgical tools, and a tube to pump gas into the abdomen to enable the surgeon to see better and operate. The difficulty in handling the surgical instruments, the lack of tactile perception, the transmission of normal hand tremors and the limited working area add to the technical complexity. Some patients, moreover, require extensive suturing inside the body, which can be difficult to perform with current laparoscopy tools.
FlexDex Inc. state that the FlexDex Needle Driver™ is the first low cost mechanical device that provides robot-like control in laparoscopic surgery. They state that compared to standard devices, the Wrist Gimbal provides support to the surgeon's hand, wrist-like dexterity, natural force feedback and intuitive control for complex suturing, knot-tying and fine dissection.

FlexDex Needle Driver™ may provide much greater freedom of movement than standard instruments, facilitate easier and safer dissections, and reduce operating time. The device may avoid the cost and complexity of robotically controlled laparoscopy procedures and could enable surgeons to perform more complex laparoscopic procedures avoiding the trauma and complications associated with open surgical procedures.

This technology is predicted to have an impact on the following domain of the NHS Outcomes Framework ([www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk](http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk)):

**Domain 3** Helping people to recover from episodes of ill health or following injury.

### EVIDENCE

#### PUBLISHED PAPERS


### ONGOING STUDIES

No ongoing studies were identified for this technology.

### INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.

### Lay summary

*The FlexDex Needle Driver™* is a device used to make stitches inside the body during laparoscopic surgery, also known as keyhole surgery. During laparoscopic surgery the surgeon makes small cuts in the skin, pumps gas and inserts surgical instruments into the abdomen. Although laparoscopic procedures avoid open surgery, the difficulty in moving the surgical instruments, the lack of normal feeling through the instruments and the limited operating area inside the body add to the difficulty of these operations. The company that make the FlexDex Needle Driver™ say that this device will increase manual dexterity, increase support of the surgeon's hand and allow the surgeon to perform more difficult stitches inside the body. FlexDex Needle Driver™ may avoid the cost and complexity of robotically controlled laparoscopy procedures and could enable surgeons to perform more complex laparoscopic procedures avoiding the trauma and complications associated with open surgical procedures.