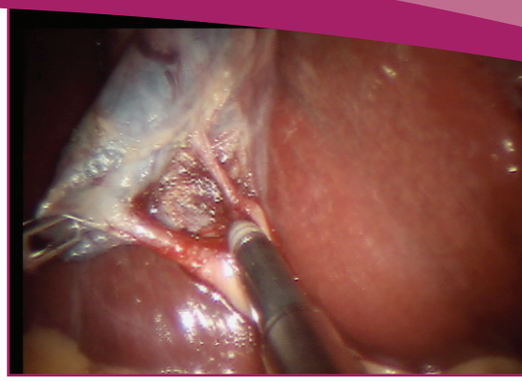
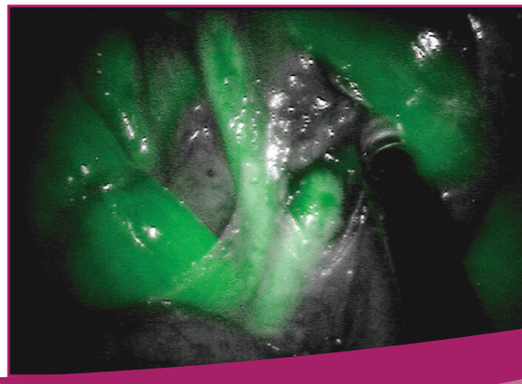
da Vinci®

CHOLECYSTECTOMY

WITH *SINGLE-SITE*® TECHNOLOGY

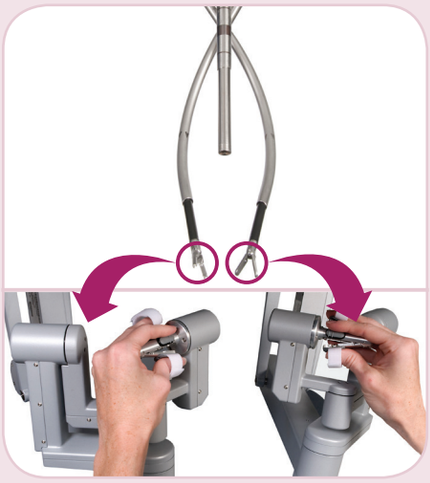




Solutions for single-access cholecystectomy

INTUITIVE SURGICAL®

da Vinci® *Single-Site*®



***Intuitive*® Motion**
Advanced system software correlates the surgeon's hand movements to the instrument tips, restoring *Intuitive* control to what would otherwise be cross-handed surgery.

- High-definition 3D vision
- Precise instrumentation
- *Intuitive*® motion

Single-Site® Port

Surgeon Benefits

Maintain the safety and reproducibility of a multi-port laparoscopic cholecystectomy while providing the potential patient benefits of a single-access approach.[1,2]

The vision, dexterity and control provided by the *da Vinci*® *Si*™ System with *Single-Site*® technology offers surgeons the following potential benefits compared to manual single-port laparoscopy:

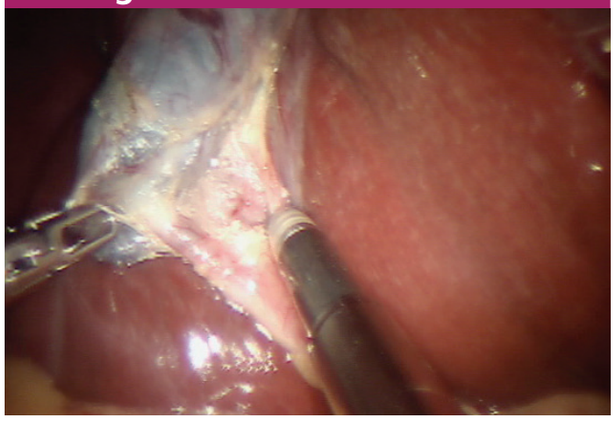
- Excellent identification of biliary anatomy[1]
- Precise dissection of Calot's triangle[3]
- Stable gallbladder retraction and exposure[1]
- Excellent ergonomics and minimal instrument clashing[1,3,4]
- Short learning curve[4,5]

Cholecystectomy using *da Vinci*® *Single-Site*® instrumentation may have an increased risk of incision-site hernia and could result in longer operative time.

Application Highlights

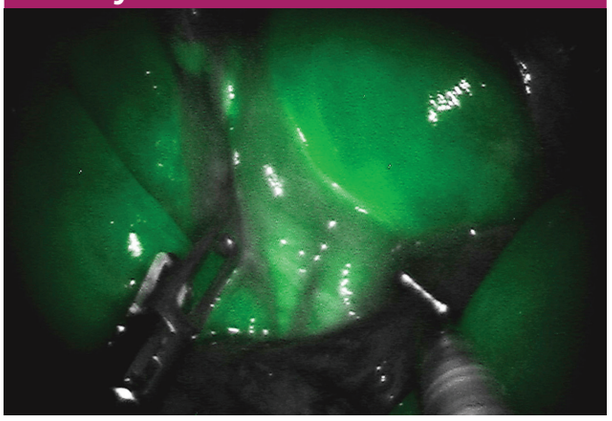
Four ways *da Vinci* technology facilitates a precise single-incision cholecystectomy:

Triangle of Calot Dissection



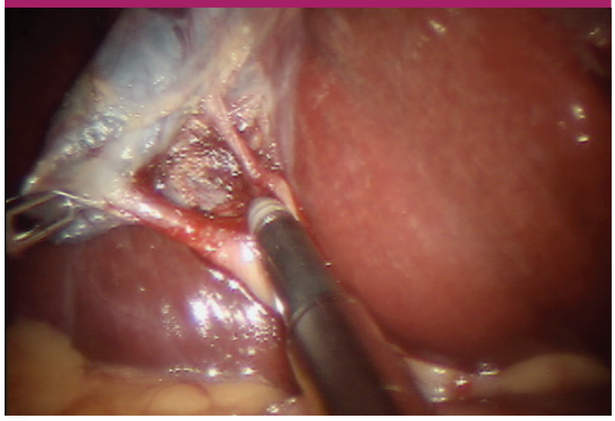
Triangulated instrumentation and a stable camera provide a consistent view of the surgical field to facilitate skeletonization of the cystic artery and duct for a safe dissection of Calot's triangle.

Biliary Duct Visualization



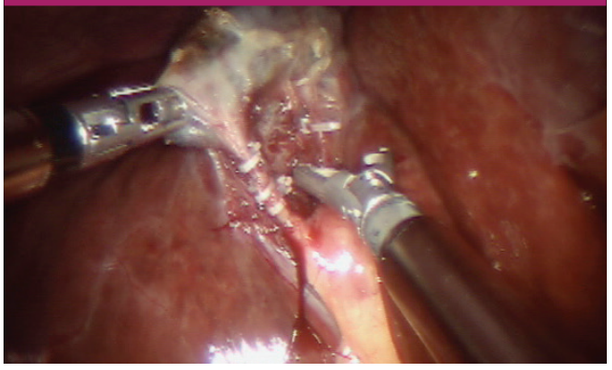
Firefly™ Fluorescence Imaging can be used to identify at least one extrahepatic biliary duct including the common bile duct, common hepatic duct and cystic duct, offering confidence in identification of normal and abnormal biliary anatomy.

Critical View Identification



The *da Vinci* System's high-definition 3D vision with up to 10x magnification provides clear visualization of the cystic artery and duct. Attainment of the critical view is further enabled by the surgeon's ability to provide precise, lateral countertraction on the infundibulum.

Cystic Artery and Duct Ligation and Division



The tremor-free *Single-Site Hem-o-Lok*® Clip Applier facilitates accurate ligation and subsequent division of the cystic artery and duct.

For technology videos visit

www.daVinciSurgeryCommunity.com

Clinical Data

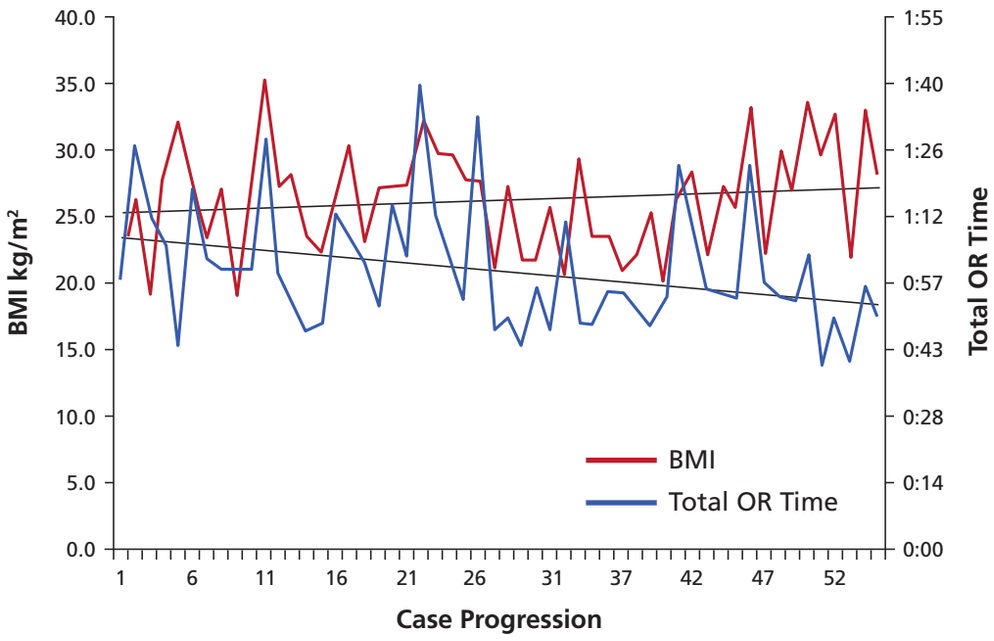
Learning curve and early clinical outcomes for a robotic surgery novice performing robotic single site cholecystectomy*

McIntosh BB, Angus AA, Sahi SL. Int J Med Robotics Comput Assist Surg (2013).

Early clinical outcomes from a novice robotic surgeon demonstrated a correlation between BMI and OR time for the first 40 cases. During the last 15 cases, however, operative time decreased even as patient BMI increased, providing a strong indication of the learning effect.

Author comment: "Our total operative times are easily comparable to those of published data for single-port laparoscopic cholecystectomy and approaching those of data published for standard laparoscopic cholecystectomy."

Study limitation: single surgeon experience



Real-time near-infrared (NIR) fluorescent cholangiography in single-site robotic cholecystectomy (SSRC): a single-institutional prospective study*

Spinoglio G, Priora F, Bianchi PP, Lucido FS, Licciardello A, Maglione V, Grosso F, Quarati R, Ravazzoni F, Lenti LM. Surg Endosc (2013).

Author comment: "In this study, prior to dissection we were able to delineate the cystic duct in 42 patients (93%) and at least one biliary structure in 100% of the cases...Fluorescence cholangiography decreases the concern of misidentification of the biliary anatomy with no need for additional technical expertise."

Biliary Tree Visualizations Using *Firefly*™ Fluorescence Imaging	
Before Dissection of Calot's Triangle	
One duct visualized	45/45 (100%)
Two ducts visualized	41/45 (91%)
Three ducts visualized	39/45 (86%)

Outcomes	
Conversions	0%
Intra-operative complications (including bile duct injury)	0%
Post-operative complications	0%

Study limitation: single-center experience

For additional data pertaining to these studies visit

www.daVinciSurgeryCommunity.com

Potential Patient Benefits & Risks

POSSIBLE BENEFITS:

- Low rate of major complications[4]
- Low conversion rate to open surgery[4]
- Virtually scarless surgery[4]
- Minimal pain[1]
- Short hospital stay[3*]
- Low blood loss[6*]
- Low rate of wound infection[3*]
- High patient satisfaction[1]

* Results similar to single incision laparoscopy.

POSSIBLE RISKS INCLUDE:

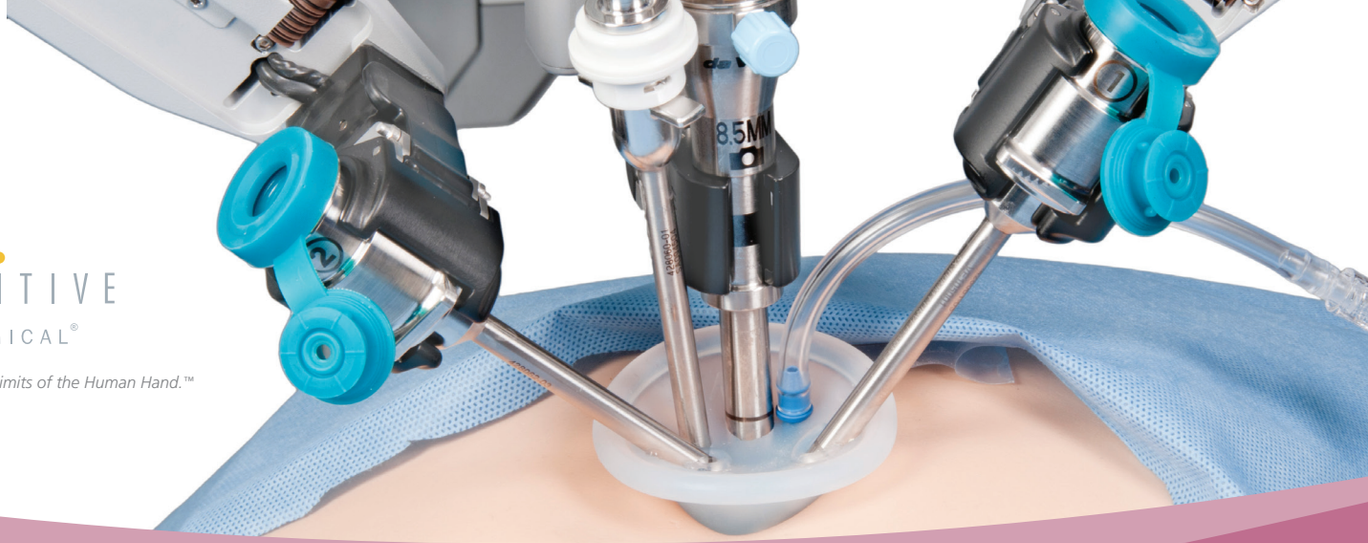
- Injury to bile ducts, liver, pancreas
- Injury to small or large intestine
- Pancreatitis (inflammation of the pancreas)

In addition to the above risks, there are risks related to minimally invasive surgery, including *da Vinci Single-Site* Cholecystectomy, such as multiple incisions, conversion to another surgical technique, urinary retention and hernia (bulging tissue) at the incision site.[1,7]

EndoWrist® Instruments Offered for ***da Vinci***® Cholecystectomy

	STANDARD/*S,Si* PNs	APPLICATIONS
	**Cadiere Forceps** **428055**	⁘ Grasping
	**Permanent Cautery Hook** **428090**	⁘ Dissection ⁘ Electrocautery
	***Hem-o-lok***® **Clip Applier** **428053**	⁘ Ligation
	**Curved Scissors** **428057**	⁘ Transection ⁘ Dissection ⁘ Sharp Cutting
	**Maryland Dissector** **428050**	⁘ Dissection ⁘ Grasping

	STANDARD/*S,Si* PNs	APPLICATIONS
	**Crocodile Grasper** **428059**	⁘ Grasping
	**Fundus Grasper** **428058**	⁘ Grasping
	**Suction Irrigator** **428054**	⁘ Suction/Irrigation
	***Single-Site*** **Port** **428065**	⁘ Single-use, directed entry port of cannulae, instrumentation and an 8.5 mm endoscope
	**5 mm X 300 mm Curved Cannula** • **#1 Arm 428061** • **#2 Arm 428062** • **5 mm Flexible Obturator 428064**	⁘ Establish port entry for *Single-Site* instrumentation and other compatible instruments and accessories



INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

www.IntuitiveSurgical.com
www.daVinciSurgery.com

Worldwide Headquarters
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304
Tel: +1.408.523.2100
Fax: +1.408.523.1390

Asia Pacific Headquarters
Room 2051, 20th Floor
No. 989 Chang Le Road
Shanghai 200031 P.R. China
Tel: +86.21.5116.6881
Fax: +86.21.5116.6899

European Headquarters
Intuitive Surgical Sàrl
1, chemin des Mûriers
1170 Aubonne,
Suisse
Tel: +41.21.821.20.20
Fax: +41.21.821.20.21

To contact a representative or receive additional information, visit www.intuitivesurgical.com or call Intuitive Surgical Customer Service in the U.S. at 1.877.408.3872, in Europe at +41 21 821 20 00 or +800 0 821 20 20 or in the rest of the world, 1.408.523.2100.

*Intuitive Surgical, Inc. did not provide financial support for this study; lead author has received remuneration for peer-to-peer education unrelated to this study.

While clinical studies support the use of the *da Vinci*® Surgical System as an effective tool for minimally invasive surgery for specific indications, individual results may vary. For complete technical information, including full cautions and warnings, please refer to the product documentation.

Single-Site® Instruments for the *da Vinci*® *Si*™ System bear the CE mark. This device is cleared for commercial distribution in the U.S. for laparoscopic cholecystectomy, and for hysterectomy and salpingo-oophorectomy for benign conditions. The *Intuitive Surgical*® *da Vinci*® *Single-Site*® Instruments and Accessories used with the *da Vinci*® *Si*™ Surgical System are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single-incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the *Single-Site* Port. The safety and effectiveness of *Single-Site*® Instrumentation for use in the performance of general laparoscopic abdominal and pelvic surgery procedures have not been established. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments, including *Single-Site* Instrumentation. General contraindications for endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery.

The *da Vinci*® Fluorescence Imaging Vision System (*Firefly*™ Fluorescence Imaging) is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci* Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow, and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the *da Vinci* Fluorescence Imaging Vision System is intended for adjunctive use only in conjunction with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Hem-o-lok® ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure. *Hem-o-lok* Ligating Clips are not intended for use as a fallopian contraceptive tubal occlusion device. *Hem-o-lok* Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

[1] Wren SM, Curet MJ. Single-port robotic cholecystectomy results from a first human use clinical study of the new *da Vinci Single-Site* surgical platform. Arch Surg. 2011 Jun 20. [2] Kroh M, El-Hayek K, Rosenblatt S, Chand B, Escobar P, Kaouk J, Chalikonda S. First human surgery with a novel single-port robotic system: cholecystectomy using the *da Vinci Single-Site* platform. Surg Endosc. 2011 Nov;25(11):3566-73. Epub 2011 Jun 3. [3] Spinoglio G, Lenti LM, Maglione V, Lucido FS, Priora F, Bianchi PP, Grosso F, Quarati R. Single-site robotic cholecystectomy (SSRC) versus single-incision laparoscopic cholecystectomy (SILC): comparison of learning curves. First European experience. Surg Endosc. 2012 Jun;26(6):1648-55. doi: 10.1007/s00464-011-2087-1. Epub 2011 Dec 17. [4] Pietrabissa A, Sbrana F, Morelli L, Badessi F, Pugliese L, Vinci A, Klersy C, Spinoglio G. Overcoming the challenges of single-incision cholecystectomy with robotic single-site technology. Arch Surg. 2012 Aug;147(8):709-14. [5] McIntosh BB, Angus AA, Sahi SL. Learning curve and early clinical outcomes for a robotic surgery novice performing robotic single site cholecystectomy. Int J Med Robotics Comput Assist Surg (2013). [6] Buzad FA, Corne LM, Brown TC, Fagin RS, Hebert AE, Kaczmarek CA, Pack AN, Payne TN. Single-site robotic cholecystectomy: efficiency and cost analysis. Int J Med Robot. 2013 May 2. doi: 10.1002/rcs.1507. [7] National Institutes of Health. Gallbladder Removal Surgery. Available from: http://www.nlm.nih.gov/medlineplus/ency/article/002930.htm