

# The KARL STORZ Solution

ICG and Video Choledochoscope Solutions  
for Treating Gallbladder disease



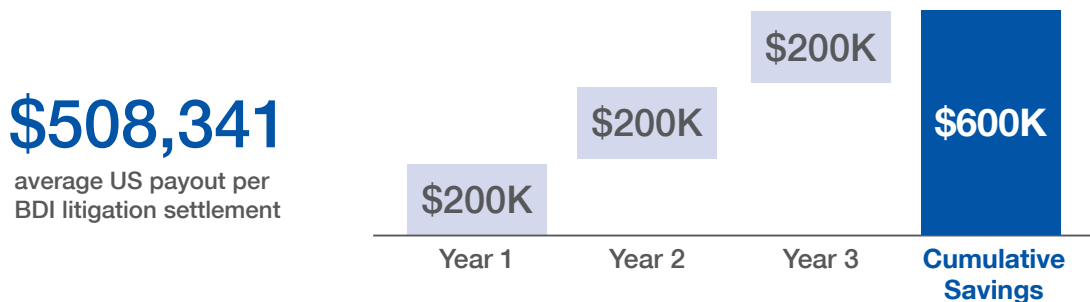
## Technologies to Treat Gallbladder Disease while Reducing Hospital Expenses

Over 1 million laparoscopic cholecystectomies were performed in the US in 2015 making it the most commonly performed procedure in general surgery.<sup>i</sup> The risk of bile duct injury (BDI) during laparoscopic cholecystectomies is 0.3-0.6% which means there are roughly 3000-6000 bile duct injuries per year in the US.<sup>ii</sup> Bile duct injuries are a major concern as these complications can prove costly for the hospital as a result of extended stays, cost of management, and litigation. BDI adds an average of 32 days of inpatient hospitalization and 10 days of outpatient care, while the increased cost to manage a minor BDI is approximately \$24,000. A major BDI can jump to approximately \$120,000.<sup>iii</sup> On top of these expenses are the litigation fees as BDI is the most likely injury associated with a successful claim (86%)<sup>iv</sup> and the average payout per litigation in the US is \$508,341.<sup>v</sup>

At least 3-10% of patients undergoing laparoscopic cholecystectomy will have common bile duct (CBD) stones.<sup>vi</sup> Currently, most of these stones are treated with a second procedure (ERCP) that has its own risks and increases costs. Performing a laparoscopic choledochoscopy and stone removal at the time of a laparoscopic cholecystectomy reduces the cost of the care for each patient with CBD stones by \$5000 per case and also eliminates the risk of complications associated with the second procedure.<sup>vii</sup>

### Cumulative 3-year hospital cost savings with Common Bile Duct Exploration (CBDE)

Cumulative 3-year cost savings of \$5000 per case<sup>1</sup> from treating laparoscopic cholecystectomy patients with choledocholithiasis through CBDE in place of ERCP<sup>2</sup>



<sup>1</sup> Hospital costs are based on one lap cholecystectomy case with CDL, requiring treatment through CBDE or ERCP. *National analysis of in-hospital resource utilization in choledocholithiasis management using propensity scores. Surgical Endoscopy, 2006.*

<sup>2</sup> Hospital costs are based on 400 annual lap cholecystectomies, with 10% of the cases as CDL, requiring treatment through CBDE or ERCP. *National analysis of in-hospital resource utilization in choledocholithiasis management using propensity scores. Surgical Endoscopy, 2006.*

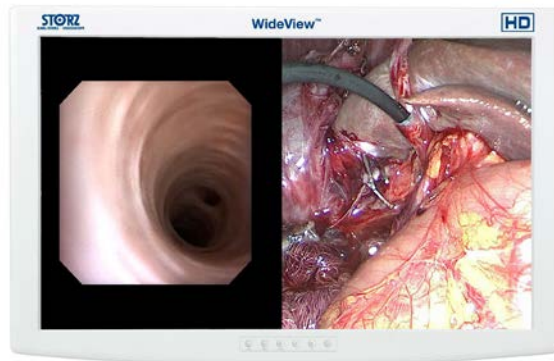


### NIR/ICG – Bile Duct Identification

NIR/ICG technologies enable visualization of structural landmarks beneath the tissue surface using near-infrared (NIR) imaging to detect distribution of Indocyanine green (ICG) within the tissue in real time. By injecting the ICG dye approximately 45 minutes prior to operating, surgeons are able to employ the NIR/ICG system by observing the dye that has been concentrated in the bile and is not clearly visible in white light. In more common terms, a roadmap of the biliary structures is created which clearly shows where the surgeon should and, more importantly, should not cut.

## Video Choledochoscope – Common Bile Duct Exploration

The KARL STORZ Video Choledochoscope is an 8.5 Fr. flexible scope designed to easily and safely navigate the common bile and hepatic ducts while visualizing and removing gallstones. The Video Choledochoscope, in conjunction with IMAGE1 S™, requires only one surgical tower which reduces equipment redundancies, reduces the OR equipment footprint, and allows the best view possible by utilizing a digital endoscope image of the bile ducts.



## The KARL STORZ Value Differentiators

### Reduced Risk of Complications

- **Lowered Risk of BDI**  
The use of fluorescence imaging with the KARL STORZ NIR/ICG system enables the surgeon to clearly identify the bile ducts during a laparoscopic cholecystectomy and potentially reduces/eliminates the risk of bile duct injury.
- **Reduction of Procedures**  
Laparoscopic Common Bile Duct Exploration can be performed with a KARL STORZ video choledochoscope at the same time as a laparoscopic cholecystectomy to remove gallstones in the bile ducts and only requires one procedure for the patient.

### Reduction of Equipment Redundancy (Improve Operational Efficiency while Reducing Capital Acquisition Costs)

- **Single IMAGE1 S™ Tower Utilized**  
With the IMAGE1 S™ modular architecture, only a single video tower is necessary for use of NIR/ICG, white light imaging, and the video choledochoscope.
- **Picture in Picture**  
The Picture-in-Picture or “split-screen” capability of IMAGE1 S™ displays two scope images simultaneously on one screen. Both the laparoscopic and common bile duct images are present which allows the surgeon to view all aspects of the procedure on one monitor.

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- i. US markets for laparoscopic devices 2014, Millenium Research Group, Inc. RPUS30LA13. October 2013; pg. 92.
  - ii. Berci, G et al. – Laparoscopic Cholecystectomy: first, do no harm, second, take care of bile duct stones. *Surg Endosc.* 2013 Apr; 27(4):1051-4. Doi: 10.1007/s00464-012-2767-5. Epub 2013 Jan 26.
  - iii. Savader SJ, Lillemoe KD, Prescott CA, et al. Laparoscopic cholecystectomy-related bile duct injuries: a health and financial disaster. *Ann Surg.* 1999; 225(3):268-273
  - iv. Carroll BJ, Birth M, Phillips EH. Common bile duct injuries during laparoscopic cholecystectomy that result in litigation. *Surg Endosc.* 1988 Apr; 12(4): 310-3.
  - v. McLean TR. Risk management observations from litigation involving laparoscopic cholecystectomy. *Arch Surg.* 2006 Jul;141(7): 643-8.
  - vi. Koc, B, Karahan, S, Adas, GT, et al. Furat TutaComparison of Laparoscopic Common Bile Duct Exploration and ERCP/S LC for Choledocholithiasis: A prospective randomized study. Poster session, SAGES 2013 Annual Meeting. Accessed 12/21/17. <https://www.sages.org/meetings/annual-meeting/abstracts-archive/comparison-of-laparoscopic-common-bile-duct-exploration-and-ercps-lc-for-choledocholithiasis-a-prospective-randomized-study>
  - vii. Hospital costs are based on one lap cholecystectomy case with CDL, requiring treatment through CBDE or ERCP. *National analysis of in-hospital resource utilization in choledocholithiasis management using propensity scores. Surgical Endoscopy, 2006.*



...evolution continues

**STORZ**  
KARL STORZ — ENDOSKOPE

*THE DIAMOND STANDARD*

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