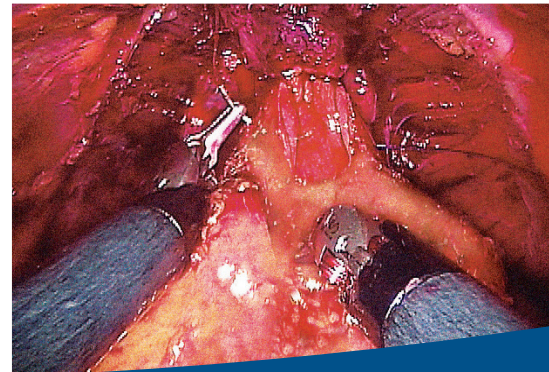
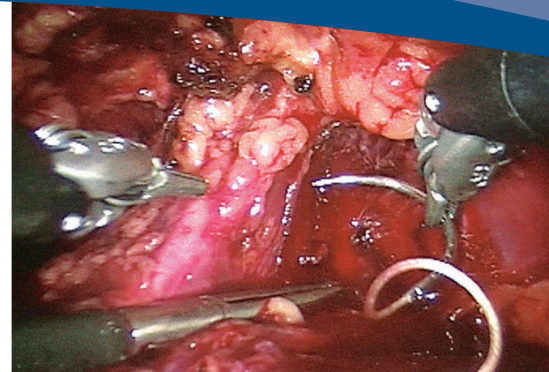


*da Vinci*  
RADICAL CYSTECTOMY



Solutions for minimally invasive urologic surgery

# The *da Vinci* Surgical System



## 3D HD Vision

3D HD visualization facilitates accurate identification of the ureters while accessing the correct anatomical angles.

## Dual Console: Available exclusively on the *da Vinci* S1™

Dual console capability allows an additional surgeon to provide an assist or can facilitate teaching and proctoring by connecting a second surgeon console.

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

## Surgeon Benefits

### Enables surgeons to offer an effective, minimally invasive surgical approach for cystectomy

The visualization, precision, dexterity and control provided by the *da Vinci* Surgical System offers the following potential surgeon benefits versus open cystectomy:

- ❖ Favorable operative, pathologic and short-term clinical outcomes<sup>1,2,3</sup>
- ❖ Precise and rapid bladder removal with minimal blood loss<sup>5</sup>
- ❖ Enhanced ability to preserve the neurovascular bundles in appropriately selected patients<sup>5</sup>
- ❖ More rapid return of bowel function<sup>1,3</sup>

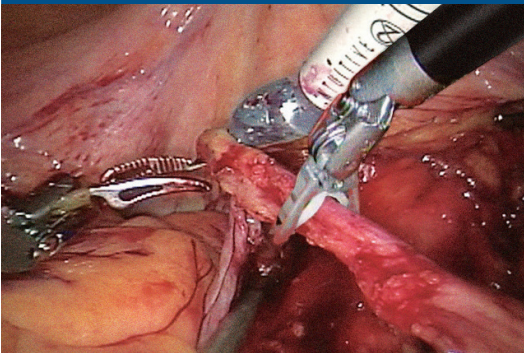


Monopolar  
*Hot Shears*™

# Application Highlights

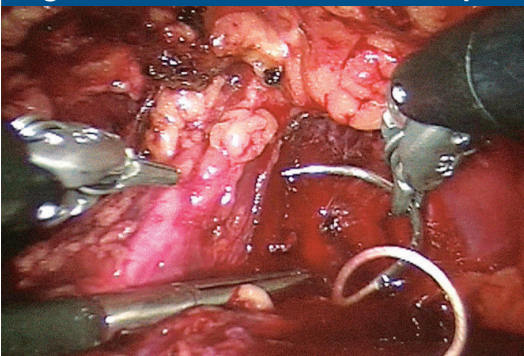
## Six ways *da Vinci* technology facilitates a precise cystectomy:

### Ureteral Dissection and Isolation



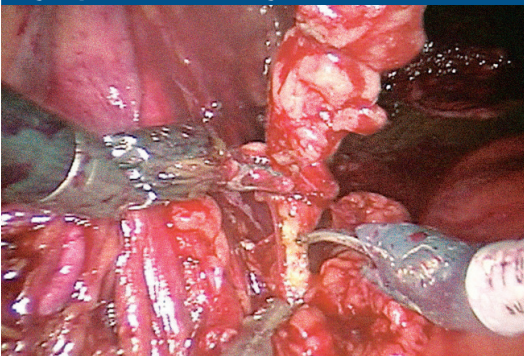
The *da Vinci* System's 3D HD vision and *EndoWrist* Instrumentation facilitate accurate identification and dissection of the ureters. Additionally, ligation of the ureters can be precisely carried out with the aid of the *Hem-o-lok*® Large Clip Applier.

### Ligation of the Dorsal Venous Complex



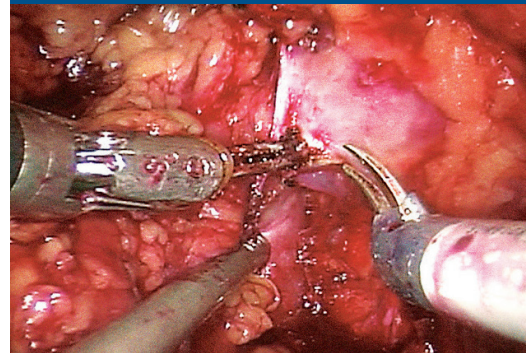
Accessing the correct anatomical angles while suture-ligating the Dorsal Venous Complex (DVC) can be accurately performed with the aid of the *EndoWrist* Needle Drivers and *da Vinci* 3D HD endoscopic camera.

### Lymphadenectomy



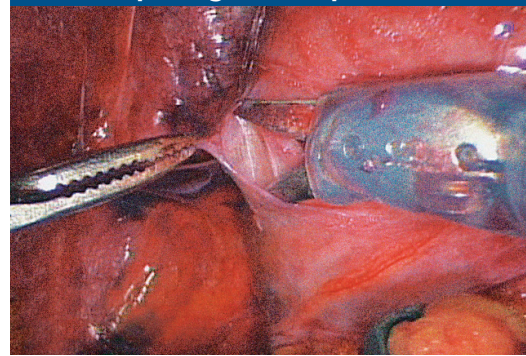
The dexterity provided by the *EndoWrist* Instrumentation facilitates a more precise and comprehensive dissection of lymphatic tissue.

### Bladder Dissection



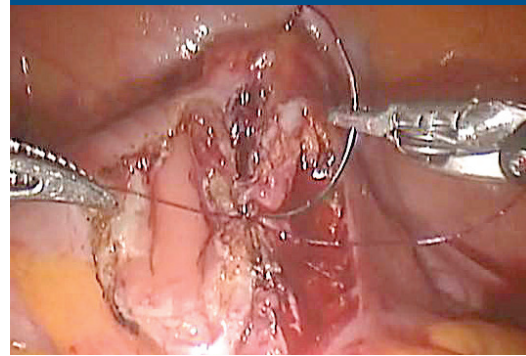
The articulation of the *EndoWrist* Instruments enables dissection of posterior, lateral and anterior bladder attachments.

### Nerve-Sparing Techniques



The access provided by the *EndoWrist* Maryland Bipolar Forceps and curved scissors allows for a cauter-free, nerve-sparing dissection in select male and female patients.

### Urethra-Neobladder Anastomosis



Creation of a watertight urethra-neobladder anastomosis can be achieved using the *EndoWrist* Needle Drivers for precise needle and suture placement.

For technology videos visit  
[www.daVinciSurgeryCommunity.com](http://www.daVinciSurgeryCommunity.com)

# Clinical Data

## Prospective randomized controlled trial of robotic versus open radical cystectomy for bladder cancer; Perioperative and pathologic results<sup>1</sup>

This single-institution study with limited clinical and oncologic follow-up, showed that while robotic cystectomy required longer operative times, it demonstrated patient benefits over open cystectomy including estimate blood loss (EBL), time to normal bowel function and less in-house analgesia usage.<sup>1</sup>

	Mean difference (95% CI)	Open adjusted mean	Robotic adjusted mean	p value
EBL, ml	292 (144, 439)	564	273	0.0003
Time to BM, d	11.1 (0.4, 1.7)	4.3	3.2	0.0033
In-house analgesia, mg (morphine sulfate equivalents)	57.9 (14.1, 101.7)	151.6	93.6	0.0110*
OR time, h	-0.70 (-0.88, -0.52)	3.5	4.2	<0.0001
Clavien units	1.13 (0.00, 2.27)	2.8	1.7	0.0503
Length of stay, d	0.59 (-0.88, 2.05)	6.0	5.4	0.4210*

BM = bowel movement; CI = confidence interval; EBL = estimated blood loss; OR = operating room

\*Not statistically significant

## A Comparison of Postoperative Complications in Open versus Robotic Cystectomy<sup>2</sup>

This prospective study (n=87) demonstrated that patients undergoing robotic cystectomy experienced less excess blood loss, a lower rate of blood transfusion, and a significantly shorter length of stay when compared to open cystectomy.<sup>2</sup> Furthermore, robotic cystectomy patients experienced a lower rate of overall complications and a significantly lower rate of major complications (Clavien III-V) than open cystectomy patients.<sup>2</sup>

	Open	Robotic	p value
Mean operative time, h (±SD)	5.95 (±2.2)	6.25 (±1.5)	0.29*
Mean EBL, ml (±SD)	1172 (±916)	460 (±299)	<0.0001
Mean PRBC transfused, units (±SD)	3.65 (±3.9)	1.42 (±1.6)	<0.0001
Median LOS, d (range)	8 (3-60)	5.5 (3-28)	<0.0001

SD = standard deviation; EBL = estimated blood loss; PRBC = packaged red blood cells; LOS = length of stay;

PSM = positive surgical margins

	30 d			90 d		
	Open	Robotic	p value	Open	Robotic	p value
Patients, no.	104	83	-	104	77	-
Patients with complications, no. (%)	61 (58.7)	34 (41.0)	0.04	64 (61.5)	37 (48.1)	0.07*
Patients with major complications, no. (%)	31 (29.8)	8 (9.6)	0.007	32 (30.8)	13 (16.9)	0.03

\*Not statistically significant



For additional data pertaining to these studies visit  
[www.daVinciSurgeryCommunity.com](http://www.daVinciSurgeryCommunity.com)

# Potential Patient Benefits & Risks

## POSSIBLE BENEFITS COMPARED TO OPEN SURGERY:











- ❖ Lower risk of major complications,<sup>2,8</sup> including death<sup>8</sup>
- ❖ Less blood loss<sup>1,3,4,5</sup> and lower rate of blood transfusions<sup>2,7</sup>
- ❖ Less need for narcotic pain medicine<sup>1</sup>
- ❖ Quicker return to a normal diet<sup>7</sup>
- ❖ Shorter hospital stay<sup>2,3,7</sup>
- ❖ Quicker recovery of bowel function<sup>1,3</sup>
- ❖ Minimal scarring

## POSSIBLE RISKS INCLUDE:

- ❖ Ileus (blocked bowel)
- ❖ Urinary leak
- ❖ Deep vein thrombosis (blood clot often in the leg)



## EndoWrist® Instruments Optimized for da Vinci® Cystectomy

STANDARD/S,Si PNs	FEATURES	STANDARD/S,Si PNs	FEATURES
 <p><b>Hot Shears™ (Monopolar Curved Scissors)</b> 400179/420179 Requires Tip Cover: 400180</p>	<ul style="list-style-type: none"> <li>❖ Combined scissors and monopolar cautery</li> <li>❖ Tapered tip profile</li> </ul>	 <p><b>PK™ Dissecting Forceps</b> 400227/420227 Requires Instrument Cords: 400228 (for PK/SP) 400229 (for G400)</p>	<ul style="list-style-type: none"> <li>❖ Grasping, dissecting and coagulating tissues and pedicles</li> </ul>
 <p><b>Maryland Bipolar Forceps</b> 400172/420172</p>	<ul style="list-style-type: none"> <li>❖ Curved, tapered jaw design</li> <li>❖ Fenestration at jaw base</li> </ul>	 <p><b>ProGrasp™ Forceps</b> 400093/420093</p>	<ul style="list-style-type: none"> <li>❖ Grasping and retracting</li> </ul>
 <p><b>Large Needle Driver</b> 400006/420006</p>	<ul style="list-style-type: none"> <li>❖ Carbide-insert style jaws</li> <li>❖ Diamond pattern jaw profile</li> </ul>	 <p><b>Cobra Grasper</b> 400190/420190</p>	<ul style="list-style-type: none"> <li>❖ Grasping and retracting</li> </ul>
 <p><b>Hem-o-lok® Clip Applier, Large</b> 400230/420230</p>	<ul style="list-style-type: none"> <li>❖ EndoWrist architecture</li> <li>❖ Robotically enabled instrument</li> </ul>	 <p><b>Permanent Cautery Hook</b> 400183/420183</p>	<ul style="list-style-type: none"> <li>❖ Mobilizing and dissecting tissues</li> </ul>
 <p><b>Fenestrated Bipolar Forceps</b> 400205/420205</p>	<ul style="list-style-type: none"> <li>❖ Fenestrated wide jaw profile</li> <li>❖ Bipolar energy</li> </ul>	 <p><b>Round Tip Scissors</b> 400007/420007</p>	<ul style="list-style-type: none"> <li>❖ Cutting and dissecting tissues and pedicles</li> </ul>



# INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

All surgeries carry risks of adverse outcomes. 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. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments. General contraindications for endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Be sure to read and understand all information in the applicable user manuals, including full cautions and warnings, before using *da Vinci* products. Failure to properly follow all instructions may lead to injury and result in improper functioning of the device. Unless otherwise noted, products featured are cleared for commercial distribution in the U.S. and bear the CE mark. For availability and clearances outside the US, please check with your local representative or distributor. We encourage patients and physicians to review all available information. Clinical studies are available through the National Library of Medicine at [www.ncbi.nlm.nih.gov/pubmed](http://www.ncbi.nlm.nih.gov/pubmed).

## The PK® Dissecting Forceps

The PK Dissecting Forceps and PK instrument cords are intended to be used with the *da Vinci* and *da Vinci S/Si* Surgical System for endoscopic manipulation of tissue including: grasping, dissecting, approximation, coagulation, retraction and ligation. The PK Dissecting Forceps may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument or make it impossible to remove from the cannula. The PK Dissecting Forceps is not intended for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube. The PK Dissecting Forceps is classified as a BF applied part. This instrument is hence not suitable for direct cardiac applications.

## Hem-o-lok® Clip Applier

*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.

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<sup>1</sup> Nix, J., et al., Prospective randomized controlled trial of robotic versus open radical cystectomy for bladder cancer; Perioperative and pathologic results. *Eur Urol*, 2009. <sup>2</sup> Ng, C.K., et al., A comparison of postoperative complications in open versus robotic cystectomy. *Eur Urol*, 2009. <sup>3</sup> Pruthi, R.S. and Wallen, E.M., Robotic assisted laparoscopic radical cystoprostatectomy; Operative and pathological outcomes. *J Urol*, 2007. <sup>4</sup> Menon, M., et al., Robot-assisted radical cystectomy and urinary diversion in female patients; Technique with preservation of the uterus and vagina. *J Am Coll Surg*, 2004. 198(3); p. 386-93. <sup>5</sup> Menon, M., et al., Nerve-sparing robot-assisted radical cystoprostatectomy and urinary diversion. *BJU Int*, 2003. 92(3); p. 232-6. <sup>6</sup> Guru, K.A., et al., Robot-assisted radical cystectomy versus open radical cystectomy; assessment of postoperative pain. *Can J Urol*, 2007. 14(6); p. 3753-6. <sup>7</sup> Wang, G.J., et al., Robotic vs open radical cystectomy; prospective comparison of perioperative outcomes and pathological measures of early oncological efficacy. *BJU Int*, 2008. 101(1); p. 89-93. <sup>8</sup> Yu HY, Hevelone ND, Lipsitz SR, Kowalczyk KJ, Nguyen PL, Choueiri TK, Kibel AS, Hu JC. Comparative Analysis of Outcomes and Costs Following Open Radical Cystectomy Versus Robot-Assisted Laparoscopic Radical Cystectomy: Results From the US Nationwide Inpatient Sample. *Eur Urol*. 2012 Jun;61(6):1239-44. Epub 2012 Mar 30.