Computer-enhanced laparoscopic abdominal surgery

Background

The U.S. Food and Drug Administration (FDA) recently gave clearance to Intuitive Surgical, Inc., a Mountain View, CA–based company to begin selling its da Vinci™ Surgical System in the United States. The clearance allows the System to be used for such laparoscopic abdominal surgical procedures as removing the gall bladder (cholecystectomy) and surgically correcting gastroesophageal reflux (Nissen fundoplication).

The da Vinci System is often referred to as a robotic surgery device, which is a misnomer. Robotic surgery devices are designed to perform entirely autonomous movements after being programmed by a surgeon. The da Vinci System is a computer-enhanced surgical system, which interposes a computer between the surgeon’s hands and the tips of micro instruments. The system replicates the surgeon’s movements in real time. It cannot be programmed, nor can it make decisions on its own to move in any way or perform any type of surgical maneuver.

The da Vinci System consists of

- a surgeon’s viewing and control console, which has an integrated, high-performance three-dimensional vision system
- a patient sidecart consisting of three robotic arms that position and precisely maneuver endoscopic instruments
- an endoscope and a variety of articulating instruments

Surgeons operate the computer-enhanced system while seated at the console viewing the three-dimensional image of the surgical field. Their natural hand, wrist, and finger movements on the instrument controls are seamlessly and directly translated into corresponding micromovements of the instrument tips positioned inside the patient.

Computer-enhanced surgery may soon be performed for more than laparoscopic abdominal procedures. Institutions are currently involved in clinical trials that are using the da Vinci System for heart operations. One promising future application is for beating heart coronary artery surgery, which is not an operation that can be done laparoscopically. If successful, this procedure would allow surgeons to do minimally invasive heart surgery without having to go through the breastbone and making a large incision in the ribs.

Involved specialties General surgeons, gynecologists, urologists, plastic surgeons, and vascular surgeons
The American College of Surgeons (ACS) publishes Statement on Laparoscopic and Thoracoscopic Procedures. In the statement, the ACS says that in response to inquiries about appropriate qualifications for performing laparoscopic and thoracoscopic procedures, the college has consistently emphasized the need for training and experience in these or any other operations for which a surgeon requests privileges.

Moreover, the college has strongly suggested that each hospital maintain an accurate registry of each surgeon’s experience with minimal access operations, and encourages surgeons to assist one another in order to gain the maximum experience with the new technology and to share the value learned from each patient. Comparative results can provide excellent education and result in better patient outcomes.

A basic principle for any surgical procedure is that a qualified surgeon should perform it. In light of this principle, the ACS wishes to make the following statement:

For optimum quality patient care, laparoscopic and thoracoscopic surgical procedures should be performed only by surgeons who are qualified through documented training and experience to perform comparable open thoracic and abdominal surgical procedures and to manage their potential complications. The surgeon must have the judgment, training, and capability to proceed immediately to a standard open surgical procedure if necessary.

The Society of American Gastrointestinal Endoscopic Surgeons publishes Guidelines for Granting of Privileges for Laparoscopic and/or Thoracoscopic General Surgery. The basic premise of the guidelines is that the surgeon must have the judgment, training, and capability to immediately proceed to a traditional open abdominal procedure when circumstances dictate it.

This document is to serve as a guide for granting privileges in laparoscopic surgery as an integral part of surgical practice. Surgeons who are experienced in operating in the abdomen are familiar with anatomy, tissue tolerance, organ compliance, and pathological processes and should readily develop laparoscopic proficiency that should be assessed regardless of the number of procedures performed.

Training and determination of competence

A. Formal residency training in general surgery
Prerequisite training must include satisfactory completion with board eligibility or certification from residency programs in general surgery accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the equivalent body if the program is based outside the United States or Canada.

B. Determination of competence in laparoscopic surgery
1. A surgical residency program that incorporates structured experience in laparoscopic general surgery should be completed. The applicant’s program director should confirm in writing the training, experience, and actual observed level of competency, which could include case lists, as is done for other procedures in surgery.

2. The surgeon should demonstrate proficiency in laparoscopic surgical procedures and clinical judgment equivalent to that obtained in a residency program. The requirements for documentation and demonstration of competence are determined by the appropriate credentialing and qualifications committee.

3. For those surgeons without residency training that included laparoscopic surgery or without documented prior experience in these areas, the training should include didactics, hands-on experience, participation as a first assistant, and performance of the operation under proctorship. The basic minimum requirements for training should be as follows:

a. Completion of approved residency training in general surgery, with privileging in the comparable open procedure for which laparoscopic privileges are being sought.
b. Training in laparoscopic general surgery by a surgeon experienced in laparoscopic surgery, or completion of a didactic course sponsored by an institution or society accredited by the ACGME. Such a course should include instruction in handling and use of laparoscopic instrumentation, establishment of safe peritoneal access, tissue handling, knot tying, equipment utilization, as well as hands-on experience in specific categories of procedures for which the applicant desires privileges. The individual must demonstrate to the satisfaction of an experienced physician course director/preceptor that he or she can perform a given procedure from beginning to end. The physician course director must document in writing such proficiency for each catego-
ry of procedure in question. The course content and procedures should clearly include material specific to the category of procedure for which privileges are sought. Attendance at short courses that do not provide supervised hands-on training or documentation of proficiency is not an acceptable substitute.

c. Proctoring by a laparoscopic surgeon experienced in the same or similar procedure(s) until proficiency has been observed and documented in writing.

C. Proctoring
Recognizing the limitations of written reports, proctoring of applicants for privileges in laparoscopic surgery by a qualified, unbiased staff surgeon experienced in general and laparoscopic surgery is recommended. The privileging body of the hospital should develop the procedural details of proctoring and provide them to the applicant.

Proctors may be chosen from existing staff or solicited from surgical endoscopic societies. The proctor should be responsible to the privileging committee and not to the patient or to the individual being proctored.

Documentation of the proctor's evaluation should be submitted in writing to the privileging committee. Criteria of competency for each procedure should be established in advance and should include evaluation of familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, time taken to complete the procedure, and successful completion of the same.

It is essential that proctoring be provided in an unbiased, confidential, and objective manner. A satisfactory mechanism for appeal must be established for individuals for whom privileges are denied or granted in a temporary or provisional manner.

D. Monitoring of laparoscopic performance
To assist the hospital privileging body in the ongoing renewal of privileges, there should be a mechanism for monitoring competence. It should be done through existing quality assurance mechanisms, which should include monitoring utilization, diagnostic and therapeutic benefits to patients, complications, and tissue review in accordance with previously developed criteria.

E. Continuing education
Continuing medical education related to laparoscopic surgery
should be required as part of the periodic renewal of privileges. Attendance at appropriate local, national, or international meetings and courses is encouraged.

F. Renewal of privileges
For the renewal of privileges, an appropriate level of continuing clinical activity should be required. In addition to satisfactory performance as assessed by monitoring of procedural activity through existing quality assurance mechanisms, continuing medical education relating to laparoscopic surgery should also be required.

The American Board of Surgery offers certification in general surgery. The general requirements for certification include the following:

• The applicant must be actively engaged in the practice of surgery as indicated by holding admitting privileges to a surgical service in an accredited health care organization, or be currently engaged in pursuing additional graduate education in a component of surgery or one of the other recognized surgical specialties
• The applicant must hold a permanent, unconditional, unrestricted and active license to practice allopathic or osteopathic medicine in a state or jurisdiction of the United States or province of Canada

The educational requirements for certification include the following:

A. Undergraduate medical

• Graduation from an accredited school of allopathic or osteopathic medicine in the United States or Canada
• Graduates of schools of medicine from countries other than the United States or Canada must present evidence of Final Certification by the Educational Commission for Foreign Medical Graduates

B. Graduate education in surgery

• Satisfactory completion of a minimum of five years of progressive education following graduation from medical school in a program in surgery accredited by the ACGME or the Royal College of Physicians and Surgeons of Canada.
• Completion of all phases of graduate education in surgery in a program in surgery so accredited.
• Candidates who enter programs on or after July 1, 1995, must have, in a program accredited for a minimum of five years, at least 54 months of clinical surgical experience with progressively increasing levels of responsibility. There must be no less than 36 months devoted to the primary components of general surgery.
• The applicant must have 12 months in the capacity of chief resident in general surgery. The board considers the terms chief resident and senior resident to be synonymous and to mean the 12 months in the program in which the resident assumes the ultimate clinical responsibilities for patient care under the supervision of the teaching staff. The majority of the 12 months of chief residency must be served in the final year.

Experience in surgical pathology and endoscopy is considered to be clinical surgery, but obstetrics and ophthalmology are not. No more than a total of 12 months during junior years may be allocated to any one surgical specialty other than general surgery.

Operative experience requirements for certification

• Applicants for examination must meet the criteria established by the Residency Review Committee for Surgery (i.e., a minimum of 500 procedures in five years and a minimum of 150 procedures in the chief/senior year). This must include operative experience in each of the areas of primary responsibility in general surgery.
• Each applicant must submit a tabulation of the operative procedures performed as surgeon, the number of patients for whom the applicant had primary responsibility that required critical care irrespective of previous operative history, and the number of patients with multiple organ trauma where a major general surgical operation was not required. Moreover, the applicant must indicate his or her level of responsibility (e.g., surgeon chief, surgeon junior, teaching assistant, first assistant).

The general surgeon must be capable of employing endoscopic techniques, particularly proctosigmoidoscopy, colonoscopy, esophagogastroduodenoscopy, laparoscopy, and operative choledochoscopy.

According to Barry Gardiner, MD, consultant to Intuitive
San Ramon Regional Medical Center
San Ramon, CA

Surgical and director of minimally invasive and computer-enhanced surgery at the San Ramon (CA) Regional Medical Center, using the word robotic to describe the da Vinci Surgical System when it is used for FDA-approved laparoscopic abdominal procedures is a misnomer. What Intuitive Surgical has developed is a computer-enhanced laparoscopic surgery system that provides physicians with the following advantages:

• An articulated wrist inside the patient, which gives more flexibility and more dexterity. It also enhances precision and control because the surgeon can scale moves (a three-centimeter move at the console becomes a one-centimeter move inside the patient).
• A more comfortable ergonomic position that makes fatigue less an issue.
• The System provides for better vision. A three-dimensional view is preferable to a two-dimensional view.

"Training in the da Vinci Surgical System was the important issue with the FDA," explains Gardiner, "so Intuitive developed a three day course to instruct surgeons and their surgical teams how to operate the equipment." The surgeons who take the course are already privileged to do the procedures that they will be performing with the da Vinci System and these privileges include both open surgery and laparoscopic surgery.

The Intuitive training course includes

• didactics
• hands-on practical training with the device at the bench top
• hands-on surgery with a cadaver
• troubleshooting scenarios for such problems as disconnected cables or dirty camera lenses

"When there are more surgeons trained in the da Vinci System," says Gardiner, "the training courses may shift to the institutions where the technology is located." Then surgeons can be trained by observing or assisting at operations and their initial cases will be proctored by physicians who already have privileges. Gardiner cannot give an exact number of how many cases need to be proctored because it can vary from doctor to doctor. "There are some people who can sit down with the device and they're perfectly safe and competent right out of the blocks whereas there are others who never will be," he says. "But most doctors will fall into a wide range in between."
In regard to reappointment, Gardiner agrees with the idea that the more procedures physicians perform the better they get to be. “If you’re going to use this technology, use it,” he says. “Surgeons shouldn’t be doing just the occasional case.” It’s a sophisticated system and he considers that it should be used on a weekly basis or certainly every other week, which would total out to 25 procedures a year.

“What is also exciting about this technology is that it allows abdominal procedures to be done laparoscopically that cannot be done that way today,” adds Gardiner. He cites radical prostatectomy as an operation that’s perfectly positioned for the da Vinci device.

“It’ll make this a mainstream laparoscopic procedure,” he says, “and since there are some 200,000 of these operations done annually, it’ll be good for the urologists and good for the patients.”

CRC draft criteria

Basic education: MD or DO
Minimum formal training: The successful applicant must have completed an ACGME/American Osteopathic Association (AOA)-approved residency training program in surgery that included advanced laparoscopic training. In addition, the applicant must demonstrate the successful completion of a formal course in computer-enhanced laparoscopic abdominal surgery that included preceptorship by a surgeon experienced with the computer-enhanced system.
Required previous experience: The applicant must be able to demonstrate that he or she has successfully done at least 25 computer-enhanced laparoscopic abdominal surgery procedures in the past 12 months.

Note: A letter of reference should come from the director of the applicant’s computer-enhanced laparoscopic abdominal surgery training program or from the chief of surgery at the institution where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained com-
petence by showing evidence that they have successfully performed at least 50 computer-enhanced laparoscopic abdominal surgery procedures in the past 24 months.

In addition, continuing education related to computer-enhanced abdominal laparoscopic abdominal surgery should be required.

For more information

For more information regarding computer-enhanced surgery, contact:

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Fax: 310/314-2585
Web site: www.sages.org
Privilege request form
Computer-enhanced laparoscopic abdominal surgery

In order to be eligible to request clinical privileges for computer-enhanced laparoscopic abdominal surgery, an applicant must meet the following minimum threshold criteria:

• Basic education: MD or DO

• Minimal formal training: The successful applicant must have completed an ACGME/AOA-approved residency training program in surgery that included advanced laparoscopic training. In addition, the applicant must demonstrate the successful completion of a formal course in computer-enhanced laparoscopic abdominal surgery that included preceptorship by a surgeon experienced with the computer-enhanced system.

• Required previous experience: The applicant must be able to demonstrate that he or she has successfully done at least 25 computer-enhanced laparoscopic abdominal surgery procedures in the past 12 months.

• References: A letter of reference should come from the director of the applicant’s computer-enhanced laparoscopic abdominal surgery training program or from the chief of surgery at the institution where the applicant most recently practiced.

• Reappointment: Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully performed at least 50 computer-enhanced laparoscopic abdominal surgery procedures in the past 24 months.

In addition, continuing education related to computer-enhanced laparoscopic abdominal surgery should be required.

I understand that in making this request I am bound by the applicable bylaws or policies of the hospital and hereby stipulate that I meet the minimum threshold criteria for this request.

Practitioner's signature: _______________________________________________________

Typed or printed name: _________________________________________________________

Date: _________________________________________________________________________
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