Laparoscopic Nissen fundoplication

Background

A laparoscopic Nissen fundoplication (LNF) is a procedure commonly used to help patients who suffer from gastrointestinal esophageal reflux disease. The surgery reinforces the lower esophageal sphincter (the area between the esophagus and the stomach) to prevent backflow of gastric acids into the esophagus, which can be harmful to the patient over time. This is accomplished by wrapping the top of the stomach (known as the gastric fundus) around the lower esophagus. The surgery is performed laparoscopically, eliminating the need for open surgery with large incisions. According to the Cardiothoracic Surgery Network, patients generally stay one day recovering from surgery.

Possible complications during surgery include wrapping the stomach too tightly, injury to other organs, and pneumothorax (collapsing of the lung). Postoperatively, patients may experience bloating or dysphasia, delayed stomach emptying, and hematoma.

Involved specialties

General surgeons (particularly those specializing in gastrointestinal, colorectal, and minimally invasive surgery) and thoracic surgeons

Positions of specialty boards

AOBS

The American Osteopathic Board of Surgery (AOBS) accepts certification for examination for osteopathic physicians who are specializing in general surgery. Candidates for certification by the American Osteopathic Association (AOA) through AOBS must document the following:

➤ Graduation from an AOA-accredited college of osteopathic medicine candidates must document evidence of an unrestricted license prior to taking the examination.

➤ Conformity to the standards set forth in the AOA Code of Ethics.

➤ Membership in good standing of the AOA or the Canadian Osteopathic Association throughout the certification process.

➤ Satisfactory completion of an AOA-approved OGME-1 residency year.

For certification in general surgery, the candidate must complete four years of training in general surgery if training began prior to 2008. For candidates who
began their residency training with the required OGME-1R internship year effective in the academic year 2008, five years of training are required.

AOBS also certifies physicians specializing in cardiothoracic surgery. Candidates who began training prior to 2008 must complete four years of training in general surgery followed by two years of training in cardiothoracic surgery. For candidates who began their residency training with the required OGME-1R internship year effective in the academic year 2008, five years of training in general surgery followed by two years of training in cardiothoracic surgery is required.

AOBS does not publish requirements specific to LNF.

**ABS**

In its *Booklet of Information-Surgery*, the American Board of Surgery (ABS) states that it requires five years of progressive residency training in general surgery from an Accreditation Council for Graduate Medical Education (ACGME)—or Royal College of Physicians and Surgeons of Canada (RCPSC)—accredited program. Candidates for certification must meet the following requirements:

➤ Sixty months of residency training with no more than three residency programs
➤ No fewer than 48 weeks of full-time experience in each residency year
➤ At least 54 months of clinical surgical experience with progressively increasing levels of responsibility over the five years in an accredited surgery program, including no fewer than 42 months devoted to the content areas of general surgery
➤ Completion of Advanced Cardiovascular Life Support, Advanced Trauma Life Support®, and Fundamentals of Laparoscopic Surgery
➤ No more than six months during all junior years assigned to nonclinical or nonsurgical disciplines
➤ The entire chief resident experience in either the content areas of general surgery or thoracic surgery
➤ Acting in the capacity of chief resident in general surgery for a 12-month period
➤ Two final residency years in the same program

The ABS publishes the following operative requirements for candidates in general surgery:

➤ 750 operative procedures in five years, including at least 150 operative procedures in the chief resident year
➤ A minimum of 25 cases in the area of surgical critical care patient management
➤ Applicants may count up to 50 cases as teaching assistant toward the 750 operative case total; however, these cases may not count toward the 150 chief year cases

ABS does not publish specific requirements for LNF.
ABTS

The American Board of Thoracic Surgery (ABTS) awards certification in thoracic surgery, which may be achieved by completing one of the following four pathways and fulfillment of the other requirements. These pathways must provide adequate education and operative experience in cardiovascular and general thoracic surgery.

➤ Pathway One is the successful completion of a full residency in general surgery approved by the ACGME, followed by the successful completion of an ACGME-approved thoracic surgery residency. Successful completion of a 4/3 general surgery/thoracic surgery joint training program approved by the ACGME fulfills the requirements of Pathway One.

➤ Pathway Two is the successful completion of a full residency in general surgery or cardiac surgery approved by the RCPSC, followed by the successful completion of an ACGME-approved thoracic surgery residency.

➤ Pathway Three is the successful completion of a six-year integrated thoracic surgery residency developed along guidelines established by the Thoracic Surgery Directors Association and approved by the ACGME.

➤ Pathway Four is the successful completion of an ACGME-approved vascular surgery residency that can lead to primary certification, followed by the successful completion of an ACGME-approved thoracic surgery residency.

Candidates must have knowledge of both normal and pathologic conditions of both cardiovascular and general thoracic structures, including congenital and acquired lesions of both the heart and blood vessels in the thorax, as well as diseases involving the lungs, pleura, chest wall, mediastinum, esophagus, and diaphragm.

ABTS requires operative experience including an annual average of 125 major operations performed by each resident. The total number of major cases varies based on the length of the training program.

ABTS does not publish requirements specific to LNF.

Positions of societies, academies, colleges, and associations

ACS

The American College of Surgeons (ACS) and the Association of Program Directors in Surgery jointly developed the Surgical Skills Curriculum for Residents. It requires training modules in different surgical areas, including LNF.

ACS does not publish a specific number of LNF procedures to achieve competency.
SAGES

The Society of Gastrointestinal and Endoscopic Surgeons (SAGES) has published Guidelines Institutions Granting Privileges Utilizing Laparoscopic and/or Thoracoscopic Techniques. SAGES advises that documented training and experience include:

➤ A case list and applicant’s primary role
➤ Complications
➤ Outcomes
➤ Conversion to traditional techniques
➤ A summary letter from director

SAGES requires completion of an accredited surgical residency recognized by ACGME, or the equivalent if outside the United States or Canada. It also requires one of the following:

➤ A residency or fellowship program that provided structured training in laparoscopic and/or thoracoscopic surgery.
➤ A structured training curriculum that may include Fundamentals in Laparoscopic Surgery certification, video training, or interactive computer training modules. The curriculum should include didactic sessions and hands-on experience with inanimate and/or animate models, as well as an “appropriate number of opportunities for the applicant to observe, assist, and serve as primary operator for the procedure for which privileges are being sought.”

SAGES also requires that applicants meet one of the following experience requirements:

➤ Documented experience with the appropriate volume of cases of the procedure in question, judged by the chief of surgery
➤ Complimentary experience with a surgeon trained in laparoscopic and/or thoracoscopic surgery in which the applicant is trained in traditional open technique
➤ Experience with a proctor/preceptor

STS

The Society of Thoracic Surgeons (STS) is a nonprofit membership organization with a focus on education, research, and advocacy in cardiothoracic surgery. On its website, STS lists LNF among the procedures that a general thoracic surgeon could perform. However, STS does not publish requirements specific to LNF.

ACGME

The ACGME Program Requirements for Graduate Medical Education for General Surgery, last updated in 2008, does not mention LNF specifically. ACGME requires that a participant in a training program spend at least 54 months of the 60-month program on clinical assignments in surgery, with documented experience in
emergency care and surgical critical care in order to enable residents to manage patients with severe and complex illnesses and with major injuries; and 42 months of these 54 months must be spent on clinical assignments in the essential content areas of surgery, which are:

- Abdomen and its contents
- Alimentary tract
- Skin, soft tissues, and breast
- Endocrine surgery
- Head and neck surgery
- Pediatric surgery
- Surgical critical care
- Surgical oncology
- Trauma and nonoperative trauma (burn experience that includes patient management may be counted toward nonoperative trauma)
- Vascular system

ACGME also publishes Program Requirements for Graduate Medical Education in Thoracic Surgery, which requires residents in an approved thoracic surgery program to complete a minimum of 125 major cases annually; the categories for these cases include but are not limited to the lungs, pleura, chest wall, esophagus, mediastinum, diaphragm, thoracic aorta, great vessels, congenital heart anomalies, valvular heart diseases, and myocardial revascularization. The curriculum must include education in basic and advanced laparoscopic surgery. The document does not contain specific requirements for LNF.

**AOA**

The AOA, in conjunction with the American College of Osteopathic Surgeons, publishes Basic Standards for Residency Training in Surgery and the Surgical Specialties, which states that the required training includes laparoscopic procedures. Residents in general surgery must perform 60 basic laparoscopy procedures and 25 advanced laparoscopy procedures to complete the program. The document does not contain specific requirements for LNF.

**Positions of subject matter experts**

**Robert D. Fanelli, MD, FACS, FA**

**Pittsfield, Mass.**

Training varies for LNF and other minimally invasive surgeries, though a good training program will provide experience in LNF, according to Robert Fanelli, MD, FACS, FA, of Northern Berkshire General Surgery in Pittsfield, Mass., a SAGES board member and chairman of the SAGES Guidelines Committee. General, thoracic, minimally invasive, gastrointestinal, and colorectal surgeons perform LNFs, though gastrointestinal physicians do not.
According to Fanelli, the best way to learn the procedure is with an experienced physician. However, a surgeon experience in laparoscopic surgery and anti-reflux surgery would be able to learn the technique for LNF based on previous experiences, says Fanelli. He also recommends watching training videos or attending meetings and short courses to pick up the specifics of the procedure.

ACGME includes LNF as part of its core general surgery curriculum, according to Fanelli. As far as the number of procedures to achieve or evaluate competency, Fanelli says it could vary.

“We’re trying not to rely on numerical credentialing but instead rely on an expert trainer looking at what the resident or fellow is capable of doing, and then commenting on whether that’s a competent practitioner with respect to LNF, as opposed to a formula,” says Fanelli.

However, once competency is established, continuing competency is easier to obtain.

“It would be completely conceivable for someone who goes from doing 50 or 60 of these in training or even on a yearly basis, to three the next year. I have no doubt that they would perform them competently. These are skills that we use every single day during laparoscopic surgery, and so I think that the maintenance of competency is less of an important issue with this operation,” says Fanelli. He notes that if organizations are credentialing for basic and advanced laparoscopic procedures separately, LNF would fall in advanced, similar to laparoscopic adrenal surgery, laparoscopic colorectal surgery, gastric bypass, and paraesophageal hiatal hernia surgery.

**W. Scott Melvin, MD**

*Columbus, Ohio*

SAGES president **W. Scott Melvin, MD**, professor of surgery, chief of the Division of General and Gastrointestinal Surgery, and director of the Center for Minimally Invasive Surgery at The Ohio State University and the Arthur G. James Cancer Hospital and Research Institute, says surgeons must have adequate operative experience with advanced laparoscopy, specifically gastrointestinal procedures, either in residency or fellowship, or in clinical practice, but he does not believe a specific number of procedures should determine competency. He also stresses quality and performance reviews for maintenance of competency.

Advanced laparoscopic procedures that require mobilization, resection, and/or manipulation of the GI tract utilize skills similar to those required for LNF, says Melvin. A bariatric surgeon would have adequate technical skills to perform an LNF.
Melvin notes that the ACS and SAGES have co-endorsed a position statement that indicates that practitioners performing advanced laparoscopy should be certified in SAGES’ Fundamentals in Laparoscopic Surgery curriculum. Those recommendations are being incorporated into one of the mandates for accredited training programs, according to Melvin.

**Positions of accreditation bodies**

**CMS**

CMS has no formal position concerning the delineation of privileges for LNF. However, the CMS Conditions of Participation (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

- Individual character
- Individual competence
- Individual training
- Individual experience
- Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.
CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

**The Joint Commission**

The Joint Commission has no formal position concerning the delineation of privileges for LNF. However, in its *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s
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performance within the hospital (for renewal of privileges)

➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
➤ A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
➤ A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
➤ Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in
which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for LNF. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for LNF. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual...
practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding LNF.

**Minimum threshold criteria for requesting privileges in LNF**

**Basic education:** MD or DO

**Minimal formal training:** Successful completion of an ACGME- or AOA-approved training program in general surgery or cardiothoracic surgery.

**Required current experience:** Demonstrated current competence and evidence of the performance of at least 25 LNF procedures in the past 12 months or completion of training in the past 12 months.
References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Candidates for reappointment should demonstrate current competence and evidence of the performance of at least 50 LNF procedures in the past 24 months based on results of ongoing professional practice evaluation and outcomes.

In addition, continuing education related to LNF should be required.

For more information

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