THE INTERNATIONAL SOCIETY FOR GYNECOLOGIC ENDOSCOPY

Viale Regina Margherita157
00198 Rome Italy

E-Mail: secretariat@isge.org
Web: www.isge.org

ACCREDITATION IN ENDOSCOPY

Walter Costantini – Bruno van Herendael

1. Definition

The board of the International Society of Gynaecological Endoscopy (ISGE) establishes a task force for the accreditation in Gynaecological Endoscopy, both Hysteroscopy and Laparoscopy with the aim to inform, check and accredit the practising gynaecological surgeon on the base of criteria defined in this text. The aim is to define and accredit the organisational, clinical and executive qualities of the gynaecological surgeon. Furthermore gynaecological theatre suites will be accredited on the base of their organisational and structural capacities.

The accreditation process is based on the voluntary submission of the gynaecological surgeon and the theatres sites to the criteria defined in this text.

The task force will establish the criteria on the base of a strict Peer Review System.

The visiting expert therefore will not express a subjective evaluation on the qualities of the gynaecological surgeon. The visiting expert will apply coherent measurements on the different consecutive steps of an endoscopic operation considered to be essential by the task force to assure an efficient and secure endoscopic intervention.

To facilitate the correct application of the different parameters it is advisable, for the visiting experts, to be selected - on the basis of their individual surgical experience and reflective capacities - out of a pool of expert endoscopists who offer their collaboration on a voluntary basis with as primary interest to inform the gynaecological surgeon to be accredited.

2. Structure of the Accreditation Task Force (TFAGE)

The organization of the "ISGE Taskforce for Accreditation of Gynaecological Endoscopy" (TFAGE) resides within the Board of the ISGE.

- **The EXCO of the ISGE under the guidance of its president installs a Task Force for the Accreditation consisting of members of the Board of the ISGE according to the ISGE Bylaws.**
- **The Honorary Secretary and the secretarial office assure the correspondence with the membership and coordinate the applications and announce the decisions taken to the individual member.**
- **The "Task Force for the Accreditation of Gynaecological Endoscopy" (TFAGE) works and deliberates within the legal frame of the country where the applicant resides.**

2.1 The composition of the Task Force is set as follows:

- **One co-opted member of the ISGE out of the country of residence of the applicant. This member changes with every application according to the country of residence of the applicant. The co-opted member advises the TFAGE on the legal frame applicable in the country where the applicant resides.**
- **One permanent member of the EXCO ISGE appointed to head the TFAGE, or his or her substitute.**
- **One permanent member – not necessary but preferably an ISGE member – staff member of the university that patronizes the TFAGE in the specific country of residence of the applicant.**
- **One temporary member out of the ISGE Board who goes and performs the physical observations at the site where the applicant practises.**
- **One permanent member, the Honorary Secretary, who is the link between the TFAGE and the secretarial office.**
- **One permanent member, the President of the ISGE, who sanctions the decisions of the TFAGE after being presented with the specific file and signs the Accreditation of the applicant together with the Vice-President and the member of the university patronizing the TFAGE.**

2.2 The activities of the TFAGE

- **The activities of the TFAGE are performed through electronic communication between the different members.**
- **Simple majority without the possibility of a veto confirms the decisions.**
- **The TFAGE will accredit members three times in one calendar year, during both annual conferences of the ISGE and during one other supplementary meeting through electronic communication or a physical meeting according to the necessities.**
- **The decisions of the TFAGE will be communicated to the applicant within two weeks after the date the decision is taken.**

- **The composition of the TFAGE changes every third year with the election of the new Vice-President.**
- **The Board of the ISGE has the power to dismiss every single member of TFAGE at any moment in time provided a 2/3 majority of the Board of the ISGE sanctions the reason for the dismissal.**

2.3 The evaluation of the different parameters

- **The different consecutive steps included within the measurement scale (parameters) have to be evaluated and adapted every three years within the Board of the ISGE.**
- **The different experts who did go and witness the specific circumstances in the different countries will advise the Board.**
- **The Board through the President of the ISGE will communicate the deliberations of the Board to the General Assemble ISGE to achieve maximal transparency. The General Assemble then sanctions these deliberations as to imply the changes in the current practice of the TFAGE.**
- **A report of the different specific changes is made by the Honorary Secretary to be communicated to the general membership as to make the deliberations available to each and every member of the ISGE.**

3. Structure of the Accreditation

The creation of the Accreditation of an endoscopic surgeon coupled with the objective measurement of the complexity of the different steps of a surgical procedure implies a classification of the procedures and the different steps, in view of their complexity and difficulties in the execution of the procedures and the different steps. This allows for the creation of a number of categories of surgeons able to perform with objective success the requested steps in a given endoscopic procedure both at the moment of obtaining the Accreditation and later at extending the Accreditation.

3.1 Original Gynaecological Endoscopic Procedures to be accredited.

- **Under the name Original Endoscopic Procedure are included all the different consecutive steps needed to obtain a positive end result in a clinical indication.**
- **This implies that one intervention – indicated to solve the patients problem – can include within its execution more than one Original Endoscopic Procedure for witch a standard of criteria concerning the execution of the different steps can be objectively interpreted.**
- **This implies that in the latter case the Original Endoscopic Procedure can also be accredited.**
- **The Original Endoscopic Procedure in the hands of an expert endoscopists has to comply to the following criteria:**

1.1 Its indication viewed in the light of *risk versus benefit* may not exceed the indications of the same procedure performed by any other way of access.

***1.2* Its indication viewed in the light of *cost versus benefit* should never exceed in a major way the costs of the same procedure performed by any other way of access.**

***1.3* Its execution is based on one or more surgical acts recognised by the surgical community as being typical.**

***1.4* Severe complications or collateral effects, that are the subject of epidemiological studies on *cause versus effect basis*, do not question its clinical potential.**

- **In establishing a referral classification for the accreditation of gynaecological endoscopic surgery two levels are necessary:**

  1.1 The first level (LEVEL I) groups the procedures that should be learned during the residency at the University to obtain the degree of surgery in gynaecology. Here two controls are needed:

    1.1.1 A specific and adequate post university formation.

    1.1.2 A periodical confirmation of the reliability of the formation.

  1.2 The second level (LEVEL II) groups all the procedures that correspond with the criteria mentioned above and will constitute the objectives of the accreditation process.

  1.3 All other procedures, that are not listed under LEVEL I –II can not be used in the accreditation process and will be catalogued as EXPERIMENTAL PROCEDURES or procedures of LEVEL III.

- **The classification set by the TFAGE in 2016 consists of the following procedures where the annotation b/ stands for BASIC and the annotation a/ for advanced**

LAPAROSCOPY

LEVEL I	**I basic**	***Diagnostic Laparoscopy.** ***Laparoscopic Biopsy.** ***Laparoscopic Needle Aspiration.** ***Laparoscopic ovarian Drilling "Golf Ball".**
	I advanced	***Laparoscopic Endometriosis treatment stage 1-2.** ***Laparoscopic treatment of EU pregnancy.** ***Laparoscopic Sterilization.** ***Laparoscopic adhesiolysis grade 1-2.** ***Ovariectomy and/or Salpingectomy for benign indications.**
LEVEL II	**II basic**	***Endometriosis treatment grade 3.** ***Laparoscopic Adhesiolysis grade 3-4.** ***Appendectomy.** ***Treatment of benign adnexal pathology.** ***Treatment of corneal EU pregnancy.** ***Frimbiolysis and fimbrioplasty.** ***Salpingoneostomy.** ***Laparoscopic assisted vaginal hysterectomy (LAVH).** ***Utererine Sacral nerve ablation (LUNA).** ***Myomectomy of pedunculated fibroids.**
	II advanced	***Endometriosis treatment grade 4 or more.** ***Total Laparoscopic Hysterectomy.** ***Treatment of suspicious masses.** ***Pelvic lymphadenectomy.** ***Nerve sparing surgery.** ***Tubal reconstruction by end-to-end anastomosis.** ***Laparoscopic myomectomy of intra-mural or large sub serous fibroids.** ***Ovariectomy and salpingectomy for oncological indications.**

Hysteroscopy

LEVEL I		***Diagnostic Hysteroscopy.** ***Eye – Directed Biopsy.**
LEVEL II	**2 basic**	***Uterine Metroplasty on partial septum.** ***Endometrial Ablation.** ***Polypectomy.** ***Myomectomy grade 0-1.** ***Tubal Cannulation.** ***Sterilization Techniques.**
	2 advanced	***Metroplasty on total septated uterus with cervical septum.** ***Myomectomy grade 2.** ***Intra-Uterine adhesions and Asherman treatment.**

3.2 Establishing of the Entities within the Accreditation

3.2.1 Individual Entities:

The classification into two levels of the Recognised Endoscopic Procedures – that an endoscopic surgeon can perform within the scope of the normal professional activity – is what leads the TFAGE to define two specific and distinct entities.

3.2.1.1 *The list of the Gynaecological Endoscopists*

Here are listed the surgeons who claim to have obtained – by means of attending basic courses approved by the TFAGE – the necessary theoretical and practical knowledge judged to be sufficient for a efficacious and safe performance of the operations listed at level I and who confirms – by means of a portfolio - to have performed a minimal number of said interventions. The significance of such an accreditation is based on the principle of "Interest of use" and touches only marginally the principle of " Difficulty of execution".

This means that the accreditation of such an endoscopist is just a confirmation of the fact that the TFAGE confirms that the endoscopist knows the technique and that the endoscopist has participated in a course that in the end allowed the endoscopist to execute an operation of level I in the "protected" environment of the hospital nearest to the practice of the endoscopist. Being listed in the list of Gynaecological Endoscopists therefore means that the interventions by indication and by necessity are the ones indispensable for every gynaecological division who claims an endoscopic division.

3.2.1.2 *The Register of the Gynaecological Endoscopic Surgeons*

Here the TFAES groups the surgeons who, by assessments as defined within this accreditation, are estimated to be able to continuously perform procedures of level II with the needed efficiency and safety.

The listing comprehends a laparoscopic and a hysteroscopic part with independent channels of entry and of control.

Considering the distinction in "basic" and "advanced" operative gestures the TFAGE distinguishes within the two levels the following 7 categories:

- **I Basic Laparoscopic Level = 1bLap**
- **I Advanced Laparoscopic Level = 1aLap**
- **I Basic Hysteroscopic Level = 1Hyst**
- **II Basic laparoscopic Level = 2bLap**
- **II Advanced Laparoscopic Level = 2aLap**
- **II Basic Hysteroscopic Level = 2bHyst**
- **II Advanced Hysteroscopic level = 2aHyst**

The TFAGE guarantees the possibility to progress or regress from level to level on the requisites as described within the accreditation.

3.3 Practical Entities: the TFAES has established the potential of the gynaecological endoscopic surgery that can be used with good results and within the safety margins and therefore accredits a number of centres for gynaecological endoscopy listed within:

3.3.1 *The Register of Gynaecological Endoscopic Units.*

Here these gynaecological endoscopic units are listed that have proved, through tests established by the TFAES, to be able to assure, with continuity over time, to be able to allow by structural measures - architectural and personnel - the execution of gynaecological endoscopic procedures of the I and the II level, both hysteroscopy and laparoscopy, within the margins of the needed efficacy and safety.

4. Procedures to enlist

The voluntary candidature to be inserted within one of the latter listings has to be submitted to the TFAES, respecting the modalities specified, to be assessed.

The Three consecutive Steps of the ISGE Accreditation are described

4.1 Preliminary testing First Step The LASST test

The First Step **for the preliminary testing the ISGE joins hands with the ESGE in using the system LASST brought to perfection by the Academy of ESGE. This test is available during the congresses and courses of the ISGE. It is a combination of hands on and hand eye coordination. This test must be passed with good results before being allowed to the second step.**

4.2 Inscription in the list of Gynaecological Endoscopists

The Second Step **inscription in the list of Gynaecological Endoscopists, be it for hysteroscopy or for laparoscopy follows the certification to have attended with good results a course of the following requisites:**

4.1.1 Theoretical didactics on the subject = minimal 16 hours - Theoretical
4.1.2 Hands on or Simulation = minimal 8 hours – Lab Hands on
4.1.3 Observing Surgery = minimal 8 procedures Preceptorship
4.1.4 One to One live surgery = Tutorship completion of at least 8 interventions of level I.

The latter is the final condition to allow for an entry to the Third Step within the list of the Gynecological Endoscopists. *If the tutorship did not have place it means that the certificate has to be accompanied by a certification of one of the experts of the TFAES that the candidate is able to perform level I interventions.*

Acceptance to the list of Gynaecological Endoscopists contains that the candidate receives recognition for the Basic level (Level I) unless there is prove that the surgical activity certifies an advanced level (Level II). Thereafter the transition to on or the other level – in both directions – is possible every second year on basis of the level of surgical activity of at least 20 surgeries of the advanced level.

4.2 Inscription in the Register of Gynaecological Endoscopic Surgeons *Third and Final Step*

4.2.1 Individual Registration. The access to the accreditation, be it in hysteroscopy or in laparoscopy, can be obtained through three different ways:

***4.2.1.1 Residential assessment*.**

This way is reserved for the gynaecologists who do not have access to an endoscopic surgical activity within the confines of a regular hospital environment. For these gynaecologists a period of 16 weeks in a department recognised by the TFAES is necessary to obtain the accreditation. During this period the candidate has to perform in autonomy at least 15 endoscopic procedures of level II certified by the expert responsible of the Endoscopic Unit.

4.2.1.2 *In Hospital assessment*.

This way is reserved for the gynaecologists who work within the confines of a hospital where the possibility exists, under the tutorship of one of the more expert colleagues, to acquire the necessary skills and knowledge to perform endoscopic procedures efficiently in a safe way. These gynaecologists can request the TFAES an evaluation of their endoscopic activity by the expert of the TFAES in their own theatre. To be allowed to the register and move to an higher level the candidate has to certify to have executed at least 25 surgeries of level II or him or her being listed in the list of Gynaecological

Endoscopists where the biannual evaluation of the case load has revealed over 50% of procedures performed of level II.

The accreditation is given after evaluation of the expert of the TFAES of the number and the level of the surgeries performed and the observation of a level II surgery by TFAGE.

4.2.1.3 *Assessment by the TFAES.*

This way is reserved for these endoscopists who for years have performed surgeries of level II or higher and want to be registered as Gynaecological Endoscopic Surgeon. These surgeons can ask for insertion in the register by sending documentation to the TFAES that proves their endoscopic activity. The board of the TFAES will evaluate this documentation. The judgement of the board of the TFAES is without the possibility to appeal. The surgeon will be registered - as a Gynaecological Endoscopic surgeon - for level I or level II, in laparoscopy or hysteroscopy or both, according to the documentation or I provided to the TFAES.

4.2.2 *Registration of a Gynaecological Endoscopic Unit*.

To have access to the accreditation a unit needs to be able to provide proof that the necessary conditions, both on the level of materials and personnel - for both hysteroscopic and laparoscopic procedures and for the whole spectrum of level I and level II procedures are present on a permanent basis.

To be valid the request has to be signed by medical director of the hospital and the director of the department. The request has to be accompanied by documentation comprising the details on the instrumentation and equipment available in the unit as well as the endoscopic facilities. Furthermore the unit has file the request accompanied by a statement allowing at random inspections of the facility and the case lists by inspectors of the TFAES.

The accreditation is given after evaluation of the expert of the TFAES of the number and the level of the surgeries performed.

4.3 Methods of Evaluation

A check – with an evaluation that remains homogeneous and balanced although performed by different people – on an activity where the quality is based the efficacy of different autonomous components is build by two analytical phases.

The first identifies and get the components together.

The second identifies and measures the critical points of every single individual component.

Identification of the components of a process boils down to the identification of the working units that are given a degree of autonomy and 'primitive' responsibility for a specific result. This means that we are able to exclude a large number of units carrying a 'delegated' responsibility.

In the field of endoscopy a degree of autonomy can be given to the 'operator' and to the 'unit' that supplies infrastructure, instruments, materials to use and assistance to the surgeon.

In every single of these components, the production phases have to be identified and within these the elements that are necessary to get a satisfactory result at the end of the process (critical points). All the critical points have to receive a numeric value so that the summation of these scores in optimal conditions, as far as the quality is concerned for the two components, equals 100 points (quality of the endoscopic service at 100%)

There is a need however to 'calculate' the individual qualities of these two components as to 'prove' to the users of an endoscopic service the credit they can put into it. This requires separated evaluations for accreditation into the different registers.

The acceptance of a surgeon into the accreditation register for Gynaecological Endoscopic surgeons can be done by an evaluation away from the usual endoscopic theatre – the unit - as this evaluation depends on the score given to a 'component' interchangeable with the usual unit.

In the same way the acceptance of a unit into the register of Gynaecological Endoscopic Units is due to the evaluation of the critical points that constitute its competence in its structure and the personnel dedicated to the endoscopic procedures.

The activities of the Endoscopic Surgeon presuppose a *"preoperative phase"* consisting of the patient being *brought into* the operating theatre and being *prepared* for the operation, an *"operative phase"* – this phase requires *knowledge*, *control* and specific

executive manual capacities **– and a** ***postoperative phase*** **–here the main items are** ***assistance***, ***postoperative therapy*** **and** ***discharge*** **with follow-up.**

The activities of the unit can be observed taking into account the quality of the ***different entities*** **procuring the services as there are** ***the theatre***, ***the out patient departments*** **and** ***the stations***, **the evaluation of the** ***surgical equipment*** **through the presence of the** ***endoscopic instruments*** **and** ***equipment*** **, the evaluation of the** ***functionality of the organization*** **of the unit by evaluating the** ***personnel*** **involved, the** ***handling of the patients*** **and the way** ***appointments for recoveries*** **are made.**

The selection of the critical points within the different entities described has to be completed by the identification of the behavioural variables of each of the critical points to witch a conventional value is given as to permit for an assessment that can be challenged.

All conventional attitudes – more especially these that want to reflect the quality in numbers – require the definition of their own logic of reference.

The first (logic A) refers to the attribution of the relative value concerning the two components in the production of the final result.

The second (Logic B) refers to the correction mechanism into the summary of the values that originally are not comparable.

The third (Logic C) refers to the compensation for primary discretion in the single assessments.

When talking about the success of the performance of an endoscopic unit we did evaluate the success in a ratio of component ***surgeon*** **60% and to the component** ***department*** **40 %.**

The summation of the values given to each of the critical points therefore has to remain within the specific percentage given to each of the components (Logic A).

The final value however of each of the components could in the summation compensate for defaults that are inacceptable. It was therefore decided to give to some critical points a note of being indispensable within the group of functional entities.

These critical points are for the ***"surgeon"*** ***Knowledge, Ability and Attention*** **for the** ***"Department"*** **the critical points of** ***Responsibility, Quality and Effort*****.**

For each of these groups it has been decided to establish a minimal number of points (malus), when under this limit there are no points to be collected for this particular critical point (Logic B).

Not withstanding this last correction we have to have in mind that the assessment takes place during a single inspection using estimations that maintain reduced discretional power.

It is therefore necessary to reduce the decisional power of the observer to 80 %, so that the maximum number of points to be given to the *operator* is fixed ad 48 and a maximum of 32 to the *department* (Logic C).

To compensate the reduction of the upper level in scores there are multiplying values (bonus) in part objective.

The first "bonus" evaluates the self-control of the surgeon in complicated situations: moments of high significance to interpret the level of the obtained surgical experience (final score increased by 10 % or even 20 % in view of the promptitude of the reaction to the emergency).

The second "bonus" - of use in all the estimations (Operator and Departments) - observes the auto-didactic capacity based on a specific fact as there is the *Work Load* the more important the latter the more this fact will create potential to maintain and to develop the capacity of both the two components of the endoscopic service.

In relation to the magnitude of the *Work Load* the final score for the surgeon will be increased by 15 % to 30 % and for the department from 25 % to 50 %.

Using this last artifice in the calculation brings the observer to award the surgeon with a score (Index of Quality Surgeon – IQS) that will reach 72 points in optimal conditions and a score for the department (Index Quality Department – IQD) of 42 points equally in optimal conditions.

This does not mean that the quality of the candidates is higher than the conventional maximum but rather that within a unit when put together the compensative capacity between the two components equals or is even higher than the 100 mark if calculated as a whole or exceeds the 60 or 40 when calculated for both components separately. This mark corresponds with "Laude" in university language.

This method allows for more elasticity in the scoring during the quality – quantity transformation whilst remaining faithful to reality where, as we know, *surgeons* can be found who are able to overcome – within limits – a less than satisfactory infrastructure whilst vice versa *departments* can aid to the development of surgeons through their organizational qualities.

The lower limit of the IQS is set at 37 points (maximum set at 60) and the IQD is set at 24 (maximum set at 40)

4.4 Procedure of scoring for the Laparoscopic Register

The structure of the scoring system developed here after (type of the evaluation and the scores) reflects the current state of the science of the execution of endoscopic surgery that can be expected from surgeon and departments.

Bringing it up to date, as will be necessary due to the evolution of the technique and the behaviour of the referral clinics, will not need reformulating the rules written down here but can be made by the Board of Observers after being approved by 2/3 of the TFAGE. The adapted structure can than be part of the norm applied by the Administrative Secretary of the TFAGE.