Patient safety
Solutions

RECOMMENDING BEST PRACTICES

Managing the risks associated with laser energy in urology

How can complications be avoided for patients (and professionals)?

September 26, 2024

What is it?

The laser (*Light Amplification by Stimulated Emission of Radiation*) is a source of optical radiation (ultraviolet, visible, infra-red).

Despite its advantages (reduced post-operative pain and surgical site infections, improved wound healing, precise cutting and reduced blood loss), the use of lasers could have some risks for patients when it is misused or in case of technical dysfunctions which, in certain conditions, can lead to serious complications resulting in death.

In this context, the French Urology Association (*Association française d'urologie*, AFU) has launched among urologists a declarative survey in April 2021 (1) which identified more than 40 deaths following flexible laser ureteroscopy over the last 15 years (for approximately 50,000 to 60,000 procedures per year in France).

Knowing that the great majority of these events are avoidable, the AFU aimed to propose solutions to improve patient safety.

Promoter of this patient safety solution (PSS): AFU, urological surgery approved body for the accreditation of doctors and medical teams[1].

This PSS is aimed at all healthcare professionals involved in the management of male urinary disorders or in the management of urinary calculi using laser energies (urologists, anesthetists, biomedical engineers, risk managers, hospital pharmacists, nurses, etc.).

The objective is to propose concrete actions to prevent, recuperate or mitigate the adverse events associated with laser energy in urology.

1. www.urofrance.org/pratiques-professionnelles/accreditation-des-medecins.

HAS
HAUTE AUTORITÉ DE SANTÉ

A patient safety solution…

The aim of a PSS is to reinforce preventive measures and make it possible to either eliminate the consequences of an adverse event in the making (recuperate), or to reduce their impact (mitigate), by providing professionals with a practical tool to implement in their day-to-day work.

The "Laser energy in urology" PSS is the result of work carried out by the AFU on the basis of lessons learned from an in-depth analysis of adverse events reported by urologists in the accreditation feedback database, as well as from a practice survey and a review of the literature.

Data reported to the French Agency for the Safety of Medicines (*Agence nationale de sécurité du medicament*, ANSM) were also consulted.

As part of the follow-up of this PSS, any difficulties encountered during its implementation should be communicated to the AFU, so that it can assess the need to revise or update it.

...derived from analysis of adverse events…

The AFU has identified 149 adverse events that occurred during the use of laser energies in the last ten years (2):

- flexible and rigid ureteroscopies (URS) for the treatment of stones by laser (n = 93; 62%);
- enucleation of the prostate (Holmium and Thulium) (n = 30; 20%);
- laser vaporization of the prostate (n = 26; 18%).

The main causes identified were:

- non-functional or unavailable equipment or materials (n = 71);
- communication problems between perioperative professionals (n = 23);
- ambulatory surgery incidents (n = 23);
- poor management of anticoagulants (n = 15);
- unavailable preoperative biological tests (n = 5);
- inappropriate antibiotic prophylaxis (n = 5);
- lack of professional competence (n = 4);
- inappropriate therapeutic strategy (n = 3).

Following the creation of a "laser" risk specific item in the accreditation program, 59 new adverse events were reported.

...and a practice survey

A practice survey was sent out in February 2023 to 1884 urologists. Of the 177 respondents, 66% were involved in accreditation, and most of them (96%) reported that the use of laser energy represented a majority or fairly frequent part of their activity. Some 46% of respondents indicated that they were not aware of good practices relating to the risks of laser energy and how to manage them, and 54% never informed patients of the specific risks associated with laser energy.

The main adverse events observed were laser or equipment malfunctions (73%) and laser fiber fractures (69%).

The main consequences were stenosis (40%), hemorrhage (34%), fire and thermal tissue damage (26%), infection (20%) and eye damage (19%).

Of the respondents, 19%, 21% and 22% respectively stated that they had no means in place to prevent an adverse event, cancel out the consequences of an adverse event in progress[2], or to reduce their impact[3]. For 36% of respondents, a checklist for the use of laser energy in urology would allow reducing their occurrence.

2. The error is made but rectified before it has any consequences (e.g. an antibiotic prophylaxis is prescribed in the operating theatre but the nurse becomes aware of the existence of an allergy to penicillin in the medical file and alerts the prescriber, who amends the prescription accordingly).

3. The accident is confirmed, but the consequences are limited (e.g. a patient who had not received antibiotic prophylaxis is in septic shock, but blood cultures were taken very early on and the germ identified, an intensive care bed is immediately available and treatment is started quickly).

Prerequisites

To avoid adverse events associated with the use of laser energy in urology, some prerequisites must be met.

Professionals training on laser energy and different fibers use

- Realize the usual checks, taking into account the following items:
  - the availability and quality of equipment and consumables (generator, fiber, pedal, etc.), and that alternative equipment is available (do not use equipment that is not recommended);
  - the integrity of the device and its connections;
  - performing the generator self-test (note that a fault may still occur intraoperatively without prior detection by the self-test);
  - the number of times the fibers have been used as mentioned on the sterilization sheet (must be less than the manufacturer's recommendations);
  - the integrity of the packaging and the sterilization indicator for reusable fibers.

The people responsible for its implementation (urologists, anesthetists, nurses, risk managers, pharmacists) are identified. It is made available and integrated into the patient's medical record (ideally electronically), regardless of how the patient is admitted. It is based on good information and communication within the team, giving priority to a single tool for sharing information between all involved professionals (surgeon, operating theatre, biomedical engineer, pharmacy, manufacturers).

- Set up the operating theatre to avoid conflicts between the tubing, cables, camera, etc. and the laser fiber; wind and secure the laser fiber on the table.
- Complete step 1 of the "Surgical Safety Checklist" (3).
- Announce the desired settings at the start of the intervention, aloud and by visual check.
- Check the level and quality of irrigation.

Peroperative

- Wear eye protection for professionals working within one meter of the fiber. When using fluoroscopy, dedicated eye protection is recommended.
- Check that there are no flammable substances (such as alcoholic antiseptics) at the surgical site.
- Check the condition of the laser fiber and, if necessary, cut off its distal end (preferably with ceramic scissors) or replace the shield if it is damaged.
- Do not bend the fiber excessively (unpacking, storage, use), do not weaken it (crushing by instrument, tightening by tauric joint, etc.) and maintain it with a damp compress.
- Maintain a safe distance between the distal end of the laser fiber and the ureteroscope (easy visual reference: one quarter of the screen) to avoid damaging the ureteroscope.
- Set up pressurized saline solution bags connected to the fiber cooling circuit and monitor the flow and return of saline solution before delivering laser energy.
- Adjust the settings, depending on the desired effect on the stones or tissues:
  - during ureteroscopy, the energy should be adjusted initially to achieve the desired effect, then the frequency should be adjusted while respecting the maximum power level and favoring the minimum effective power:
    - *in the ureter:* do not exceed the maximum energy (1J), frequency (10Hz) and power (10W maximum) thresholds required depending on the type of operation (lithotripsy for pulverizing and fragmenting ureteral calculi, etc.) and the location of the stone.
    - *in renal cavities:* do not exceed the frequency (30Hz) and power (25W maximum) thresholds required depending on the location of the stone.
- During percutaneous nephrolithotomy (PCNL), powers of 30W can be used depending on the size of the fiber and the characteristics of the stone.
- In the treatment of benign prostatic hyperplasia (BPH), the surgical site should be continuously irrigated with saline solution at room temperature. Avoid any direct contact between the laser fiber and the patient's tissues (risk of overheating and fiber fracture).
- In upper urinary tract surgery, low irrigation pressure is required (40 - 60 cm of water above the patient). The use of an access sheath could improve the flow of irrigation and thereby reduce the in vivo temperature in the renal cavities[4].

Postoperative

- Check the tip of the laser fiber immediately postoperatively and/or the absence of metal residue in the resection site or renal cavities.

4. Only one study is available in humans (4) which does not allow these results to be generalized to all devices.

- In the operative report, indicate the type of laser used, the fiber, the laser parameters and the total energy delivered.
- Give the patient an information sheet on the post-operative course of treatment and what to do in case of emergency.

What not to do

GENERATORS

DO NOT rely
blindly on generator presets.

DO NOT position
the generator far from the instrument table.

DO NOT forget
to put the generator on standby at the end of the operation.

OPTICAL FIBER

DO NOT place
any instruments on the laser fiber that could damage it.

DO NOT tension
the laser fiber.

What can be done in the event of an accident when using laser energy (recuperate)?

Skin burns

- Take your foot off the laser activation pedal and put the generator into stand-by mode or press the emergency stop button.
- Irrigate the lesion with sterile liquid at room temperature (physiological serum) and follow the procedure set up in the department.
- Check and search for other burn sites, particularly at points of contact between the patient and the operating table.

Ocular burns

- Follow the procedures described in figure 1.

Visceral lesions (pyelo, ureter, bladder, prostate, urethra)

- Adapt the technical repair procedure according to the location of the lesion (ureteral stent, bladder catheter, etc.).
- Adapt your post-operative monitoring to the various risks of lesions developing during the operation.

Fires

- Press the emergency stop button.
- Follow the procedures described in figure 2.
- The distribution of the "fire in the operating theatre" practical sheet (5) is the responsibility of the risk manager and the operating theatre board. It must be discussed and approved by the hospital medical commission

Intracorporeal fiber fracture

- Extract the fiber fragment using a dedicated basket catheter. In the event of difficult extraction with intracavitary bleeding impairing visibility, stop the ureteroscopy, fit a double J (or JJ) catheter and reschedule a new ureteroscopy at a later date.
- In BPH surgery, fragments can be extracted cystoscopically using foreign body pliers.

Other damage to equipment during the operation

- In case of the foot pedal malfunctions, use another pedal or another generator, or postpone the operation.
- Isolate the equipment and inform the referrer and involved professionals that the equipment is unavailable.

Figure 1. Procedure to adopt in case of accidental ocular laser exposure

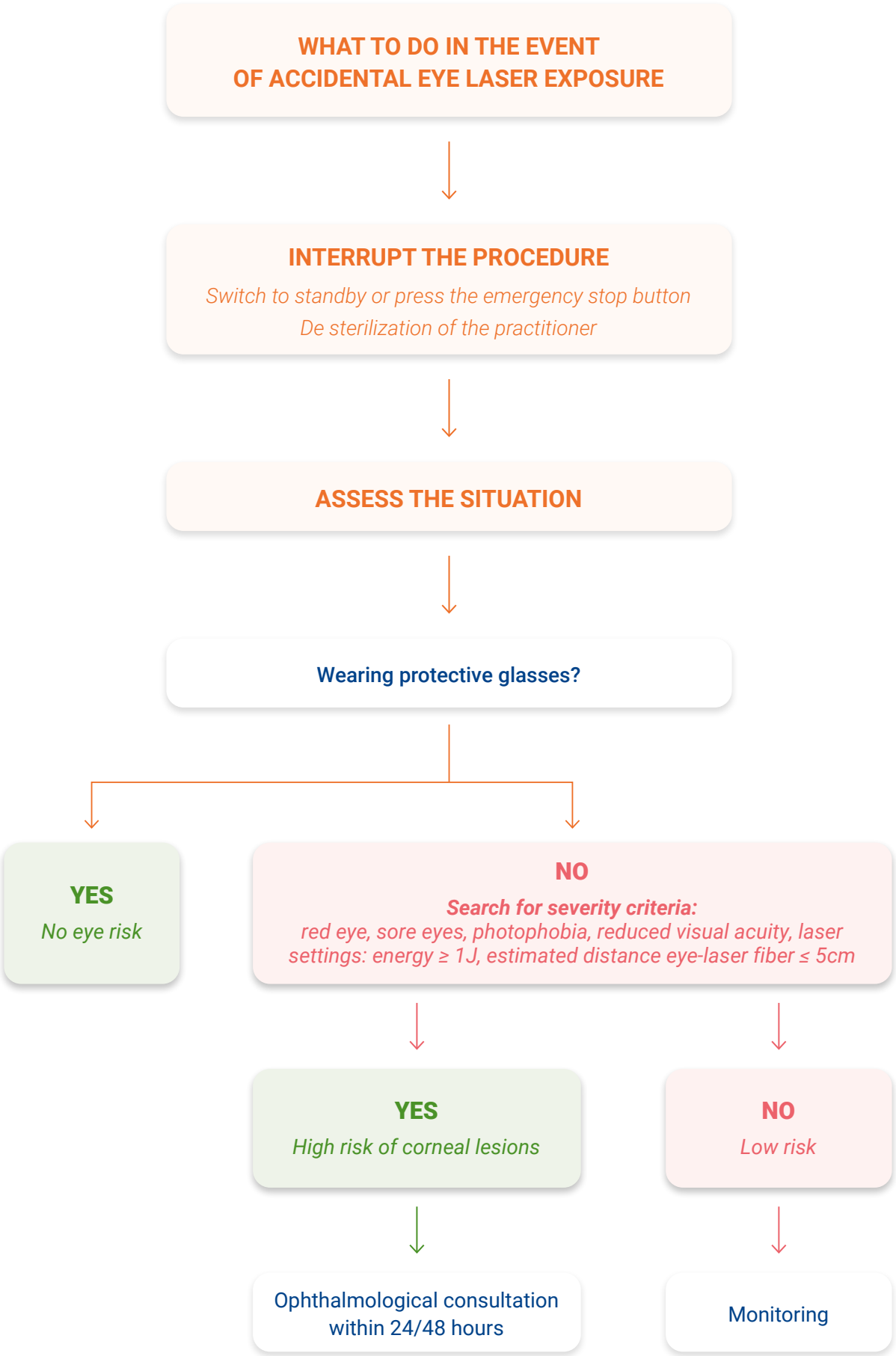
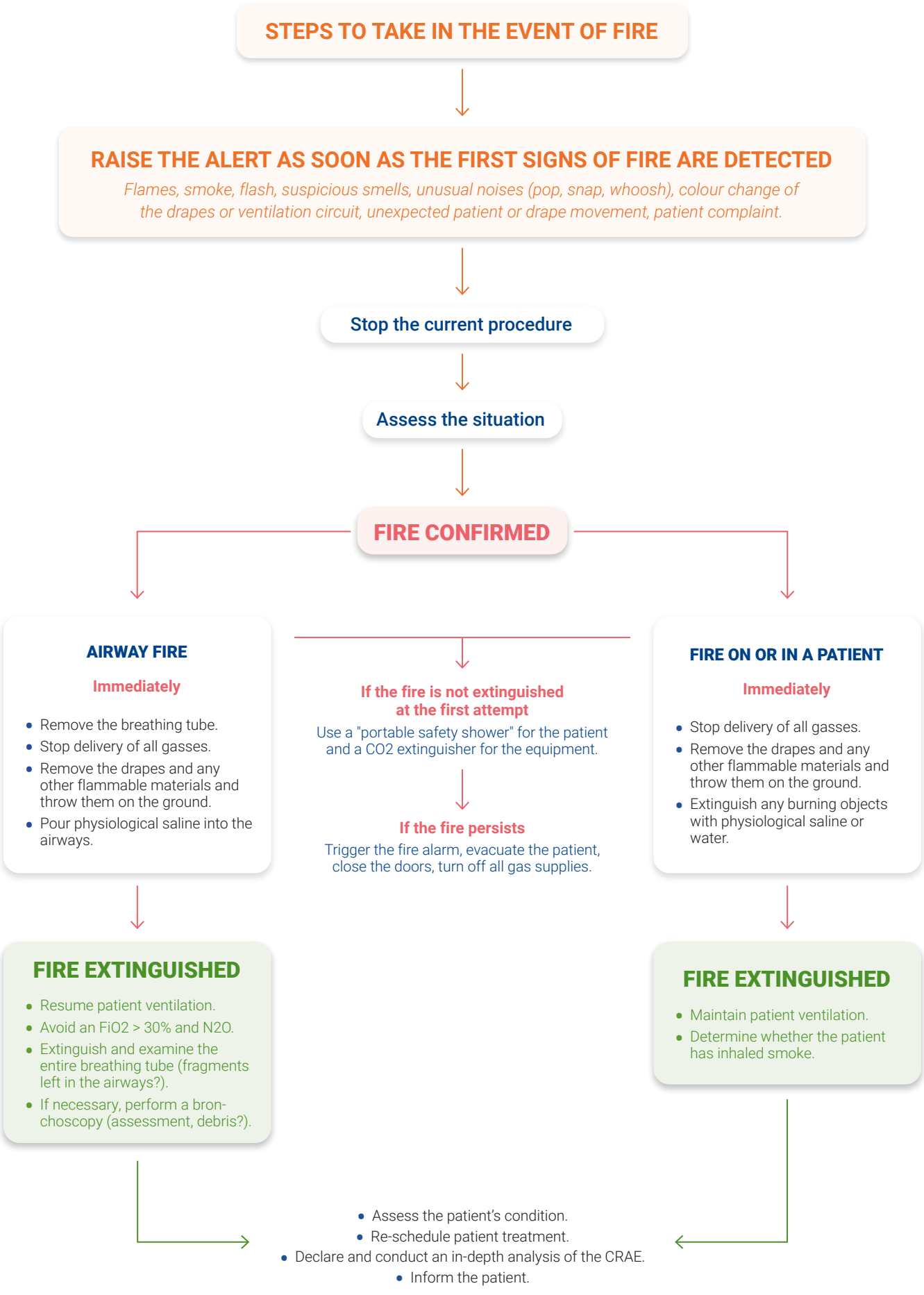


Figure 2. Procedure in the event of accidental thermal laser exposure



What can be done to reduce the consequences of an adverse event that has occurred? (mitigate)

At patient level

- Record the nature of the incident and/or lesion in the intervention report.
- Record the adverse event in the Surgical Safety Checklist.
- Inform the patient of the nature of the damage and to contact the care establishment in case of complications at home (fever, fatigue, etc.).
- Monitor the patient's condition.
- Record in the patient's file the information given to the patient and the monitoring period.
- Suggest investigation of possible visceral lesions or stenoses in case of unexplained postoperative symptoms, or in case of a possible suspected accident:
  - check for upper urinary tract stenoses using imaging;
  - check for persistent lower urinary tract problems by endoscopy.

At hospital level

- Report the adverse event to the relevant people in the hospital (material safety officer, risk manager for analysis by morbi-mortality review, feedback committee, etc.), in the establishment's reporting system and to the manufacturer. To enable a proper analysis of the adverse event, it is essential to:
  - keep the incriminated equipment, including all disposables, and first alert the biomedical manager, pharmacist and/or medical device vigilance correspondent;
  - trace the model(s) used and the laser power, generator settings and equipment used;
  - specify any contextual elements such as the preparation protocol, patient positioning on the operating table, location of the return electrode and other equipment used, and identify the power sockets used.
- Implement corrective actions, monitor and measure their effectiveness.
- Review equipment and operating procedures if needed.

Adverse events can be reported to the accreditation system database. In addition, it is mandatory to report to the national agency[5] any serious adverse event and/or any incident or risk of incident involving a medical device (material vigilance/safety).

5. signalement.social-sante.gouv.fr.

Implementation of the PSS

The "laser energy in urology" PSS is a new tool that can be integrated into the policy of improving the quality of care and risk management in urology. It aims to reinforce safety barriers through close collaboration between the various healthcare sectors and the surgical equipment managing teams. The aim of this PSS is to help identifying strengths and opportunities for improvement. By assessing what already exists, what is lacking or what is not in line with the proposed guidelines, it will be possible to draw up an improvement plan tailored to the size and activities of the teams. This could involve reinforcing existing measures or training, or creating additional safety barriers. The implementation of this PSS must be the subject of broad consultation within the departments concerned: the pharmacy, the operating theatre team and the various professionals who must coordinate their efforts to improve patient safety.

Steps in a team-based approach to improving professional practices

- Step 1: **organize your approach** (project group set-up, organisation and provisional schedule).
- Step 2: **assess the key points** of the PSS within your structure (example: the key point is implemented "never"/ "sometimes" / "regularly" / "systematically").
- Step 3: **draw up an overview of the initial assessment** performed (see assessment overview sheet) and jointly define the improvement actions to be implemented and monitored with the team (see action sheet).
- Step 4: **assess** the results of the actions implemented.

Some examples of possible improvement actions

The examples given can be adapted to the sector of activity concerned.

→ Elaboration a fire prevention and management protocol for the operating theatre.

→ Staff training.

→ Analysis of practices using a grid based on the PSS.

→ Monitoring of indicators (number of annual adverse events linked to the use of laser energy in urology).

Assessment overview

To be completed jointly as a team to assess the implementation of the key points of the PSS within your organisation.

Date:

List of participants (last names, first names, positions, sector):

Analysis results, strong points, points to be improved:

Conclusion and action plan (to be completed by one or more action sheets):

Action sheet

Complete one sheet per action to be implemented.

Action implemented	
Objective	
Description	
By whom?	
Calendar	
How?	
Monitoring and assessment procedures	

Progress status	
Date:	☐ Planned ☐ In progress ☐ Done ☐ Assessed

Methodology

Expertise composition

A multi-professional and multidisciplinary working group (16 members) was set up. It comprises 9 urologists, 1 gynecologist, 1 anesthetist, 1 risk manager, 1 hospital pharmacist, 1 methodologist and 2 patients representatives.

Developer

French Urology Association (*Association française d'urologie*, AFU)

Maison de l'Urologie, 11 rue Viète, 75017 Paris

afu@afu.fr

Referes to contact for any questions relating to the study

- Dr Stéphane Bart, manager and AFU expert, stephane.bart@ght-novo.fr
- Dr Bertrand Pogu, manager and AFU expert, bpogu@ch-chalonsenchampagne.fr

Steering committee

- Stéphane Bart, urologist, Pontoise (coordinator)
- Bertrand Pogu, urologist, Châlons-en-Champagne (co-coordinator)
- Maher Abdessater, urologist, Pontoise (project leader)
- Steeve Doizi, urologist, Paris (project manager)
- Frédéric Panthier, urologist, Paris (project leader)
- Diana Kassab, methodologist - Project Manager, AFU, Lyon, Paris

Working group composition

- Aubert Agostini, gynecologist-obstetrician, Marseille
- Julien Anract, urologist, Paris
- Adeline Jardin, state-registered nurse, Tours
- Souhil Lebdai, urologist, Angers
- Benoit Malval, urologist, Rouen
- Christine Pinaton, patient, Ile-de-France
- François-René Roustan, urologist, Toulon
- Salmon Selvarajah, risk manager, Pontoise
- Géraldine Serry, hospital pharmacist, Pontoise
- Amélie Toussaint, anaesthetist, Pontoise
- Jean-Pierre Thierry, patient, Ile-de-France

Management of conflicts of interest

The members of the working group communicated their public declarations of interest to the HAS. They are available to view on the website dpi.sante.gouv.fr.

They were analysed according to the analysis grid of the HAS guidelines for the declaration of interests and management of conflicts of interest (6).

The interests declared by the members of the working group were deemed to be compatible with their involvement in this work.

The work was funded by AFU.

Consultants

- Dr Christophe Panthier, ophthalmologist, Paris
- Jean-Christophe Born, Virginie Di Betta, French National Agency for the Safety of Medicines and Health Products (Agence nationale de sécurité du médicament et des produits de santé, ANSM)

Drafting the PSS

The working methodology was based on the PSS drafting guide approved by the HAS Board in May 2012 (7). It includes:

- **literature search:**
  - consultation of HAS "Flash Patient Safety" sheets (8),
  - search on the websites of public and professional organizations for professional guidelines or systematic reviews published less than 10 years ago;
  - search on PubMed® database to identify studies published since 2000, in French or English (keywords: "laser" AND "urology + stones + BPH + techniques" AND "safety");
- analysis of adverse events in the urology accreditation feedback database;
- opinion of a multidisciplinary, multi-professional working group.

Given the lack of high-level evidence, PSS drafting was based on the **experts consensus method**:

- drafting of an initial version by the steering group ;
- reviewing by the working group to give a formal opinion (comments) on content and form (online questionnaire based on the "HAS type 2 PSS" assessment grid [9]);
- meeting between the steering group and the working group to discuss discrepancies.

Information used to produce this PSS

Analysis of adverse events in the feedback database

The AFU has taken an interest in the use of laser energy in urology due to the growing number of adverse events reported in the accreditation feedback database. Between May 2016 and December 2020, 1,376 CRAEs linked to urological procedures were reported, including 149 adverse events occurring during the use of laser energy (2). A "laser" risk situation has been created in the urology accreditation program to encourage accredited urologists to report adverse events on this subject, leading to the reporting of 59 new adverse events between April 2021 and September 2023. A total of 208 adverse events have therefore been identified on this subject.

As the declarations recorded in the accreditation feedback database are not exhaustive, it was not possible to give a precise frequency of accidents that have occurred.

Practice survey

A practice survey was sent out in February 2023 to 1,884 French urologists (including 544 trainees) using Survey Monkey® software. The feedback from the 177 respondents focused in particular on:

- the proportion of the laser energy used in their activity;
- the training they have received;
- their knowledge of good practice to manage lasers potential risks;
- the main adverse events observed during the use of laser energy ;
- possible means of preventing the occurrence of an adverse event;
- possible steps to cancel the consequences of an emerging adverse event;
- possible ways to reduce the consequences of an adverse event that has occurred
- the need for a checklist relating to the use of laser energy in urology.

Bibliographic note

Several French and international guidelines describe the role of lasers in urology and set out recommendations for managing the risks associated with their use (10-20).

Thermal risk

The thermal risk of laser treatment and its management have been evaluated in several studies (21-31).

It is similar for Holmium:YAG and Fibred Thulium lasers, depending mainly on the frequency and average power used (32, 33).

Open irrigation systems, refrigerated irrigation, ureteral access sheaths, laser power < 40 W and shorter laser activation intervals allow maintaining intra-renal temperatures at values accepted during the URS and PCNL.

Thermal risk prevention	
Thermal dose	Temperatures < 43°C for 120 min
Laser pulses, power	< 40 W (power depending on where the stones are destroyed (10 W max recommended in the ureter, 20-25 W max in the pyelo-caliceal cavities)
Laser exposure time	Undetermined
Laser activation intervals	Short
Pedal activation time	Short, ODC (operator duty cycle = percentage of time the laser pedal is activated) < 50%.
Safety access guide	Add
Laser fiber diameter	Small
Avoid the following laser settings	0.2 J/50 Hz; 0.6 J/6 Hz; 0.8 J/8 Hz; 1 J/10 Hz and 1 J/20 Hz can produce temperatures harmful to ureteral tissue when used for 60 seconds in the absence of irrigation flow (max frequency of 30 Hz with 20-25 W in the pyelo-caliceal cavities and 10 W in the ureter)

Mitigating thermal risk	
Open continuous flow	Objective -> Temperature < 45°C
Irrigation	4°C (prefer irrigation at room temperature)
Irrigation flow	> 30 mL/min (with access sheath if possible to increase flow)
Stones	Stones not incarcerated

Recovery	
Pain	Check for ureterohydronephrosis (ultrasound or CT scan)
Hydronephrosis	Analysis of stenosis and proposed surgical treatment.
Ureteral stenosis	Analysis of the location of the stenosis and its length, with surgical treatment to be proposed

Risk of damage to the laser fiber

The risk of fracture of the laser fiber and damage to the endoscope is a reason for relocating an inferior calcification stone , particularly for the Holmium:YAG (34). This risk is not found with the Thulium Fiber laser. With regard to the loss of power at the output of the laser fiber, it is recommended that in case of intraoperative loss of efficiency, the laser fiber should be cut with ceramic scissors (35). Adverse events involving fiber fractures and intraoperative intracorporeal tip loss have been described (36).

Risk of damage to other devices

It is suggested that several instruments should not be introduced through the same endoscope channel, either for upper or lower tract surgery. Sections of the safety guide and/or an extraction basket during ureteroscopy have been described (37, 38).

Eye injury

In the event of accidental exposure to laser radiation, the rate of eye damage is estimated at 37.9% of cases (39). Damage ranges from slight abrasions of the cornea to total blindness (40).

For distances of less than 5 cm from the distal end of the laser fiber, conventional eyeglasses minimize the ocular injury risk (41, 42).

Stenosis

Urethral strictures have been reported at 6 months post-operatively (43-45).

Serious adverse events

Four cases of rectal perforation have been reported after prostatic photovaporization (PVP) with a laser using an endorectal probe (46).

Safety distance

During flexible ureterorenoscopy, a «safety distance» of 3 mm from the ureteroscope camera was reported when using the fiber laser to avoid damage to the tip of the ureteroscope (47).

Description of the risk situation

Context of the risk situation

LIt concerns all situations in the operating theatre requiring the use of a laser device for the treatment of urological pathologies.

These PSS apply to patients being treated for kidney, ureter or bladder stones, as well as endoluminal tumors, strictures and BPH, whatever their age, situation or gender.

There are many reasons for this risky situation:

- human: a lack of professional skills;
- technical (clinical complexity, technical manipulation): bad management of the laser generator, laser or fiber parameters, inappropriate management of anticoagulants, antibiotic prophylaxis or therapeutic strategy;
- organizational (patient information on equipment and sterilization): lack of interprofessional communication in perioperative situations, preoperative biological examinations not available, defective equipment or material, lack of communication on the non-availabilitý of a material, error in the distribution of a material or non-sterile material (e.g. perforation of packaging).

The consequences, which are progressively more serious, include ureteral or urethral strictures, sclerosis of the bladder neck, bleeding, loss of a kidney, kidney failure and repeated infections.

Scenario for the occurrence of the risk situation

The event may occur during scheduled surgery, when the surgeon realizes that the equipment (generator, fiber or other accessory) required is not available (absent, non-functional, fiber not sterile, etc.) at the time of the operation. The surgeon may even have to interrupt an operation when the patient is ready. The surgeon must then choose between stopping the operation and resuming it later with suitable equipment, thereby risking complications for the patient, or changing the operating technique initially planned, or even changing the type of equipment programmed.

Validation of the solution and monitoring over time

Validation procedures

The chosen solution has been validated by the AFU. Information will be disseminated by the AFU in the form of a newsletter, a presentation at congresses and by posting the PSS on the AFU and HAS websites after validation by the board. It will also be provided by the organizations associated with its drafting.

Methodology assessment

The methodological quality of the PSS was assessed by 4 experts, representing accreditation approved bodies in visceral and digestive surgery (Fédération de chirurgie viscérale et digestive, FCVD), ORL and cervico-facial surgery (ORL-DPC), orthopedic and traumatological surgery (Orthorisq) and gynecology-obstetrics (Gynerisq), using a HAS-PSS assessment grid (9). Criteria that were not met were submitted to the AFU, which completed the missing information.

PSS follow-up and updates

PTo compensate for the formalized expert consensus approach and definitively validate the PSS, prolonged monitoring of each solution and its impact is required. It is therefore mandatory to :

- transfer solutions into practice ;
- evaluate their effects and correct them if needed.

Initially, PSS will be included in the annual accreditation program for doctors in the specialty, so that it can be implemented by members. Its implementation will be a prerequisite for meeting the requirements of the accreditation system (individual or team). A specific risk situation has been created in the urology accreditation program to ensure that the measure is monitored and effective.

Secondly, it will be possible to :

- carry out practices survey among urologists, on the use of the key points 24 months after implementation of the PSS. This could take the form of an analysis of the new adverse events reported or a survey conducted by the AFU among accredited doctors on their satisfaction (readability, availability of the PSS, improvements to be made, etc.), their knowledge and their practices (improvements made, morbi-mortality review, procedures, etc.).
- to create a national register of urological complications, including those related to laser energy, and thus contribute to the registers for the specialty. These registers provide structured feedback, both collectively for the AFU and individually for teams of urologists, which will subsequently enable teaching on the management of these complications.

The PSS may be updated in case of developments in equipment or changes in practice, according to results obtained and difficulties encountered in applying it.

References

1. Association française d'urologie. Morbi-mortalité en urétéroscopie souple par laser, de l'art du bon réglage. Communication au congrès de l'AFU (CFU), le 18/11/2023 – État de l'art N°15 [En ligne] 2022. www.calameo.com/read/0069193924b2adbcd568e

2. Abdessater M, Pogu B, Michel P, Avrillon V, Bart S. Les évènements indésirables dus à l'usage du laser au bloc opératoire en chirurgie urologique : retour d'expérience des évènements indésirables associés aux soins (EIAS). Prog Urol 2021;31(13):785. dx.doi.org/10.1016/j.purol.2021.08.066

3. Haute Autorité de santé. Les check-lists pour la sécurité du patient. Mis à jour le 23 mai 2024. Saint-Denis La Plaine: HAS; 2018. www.has-sante.fr/jcms/c_1518984

4. Teng J, Wang Y, Jia Z, Guan Y, Fei W, Ai X. Temperature profiles of calyceal irrigation fluids during flexible ureteroscopic Ho: YAG laser lithotripsy. Int Urol Nephrol 2021;53(3):415-9. dx.doi.org/10.1007/s11255-020-02665-x

5. Fédération de chirurgie viscérale et digestive, Haute Autorité de santé. Comment gérer les risques associés à l'utilisation du bistouri électrique ? Saint-Denis La Plaine: HAS; 2018. www.has-sante.fr/jcms/c_2882414/fr/comment-gerer-les-risques-associes-a-l-utilisation-du-bistouri-electrique

6. Haute Autorité de santé. Déclarations d'intérêts et gestion des conflits d'intérêts. Guide de déontologie. Saint-Denis La Plaine: HAS; 2023. www.has-sante.fr/upload/docs/application/pdf/guide_dpi.pdf

7. Haute Autorité de santé. Solutions pour la sécurité du patient. Méthode d'élaboration Saint-Denis La Plaine: HAS; 2012. www.has-sante.fr/upload/docs/application/pdf/2023-09/methode_solutions_pour_la_securite_du_patient_ssp.pdf

8. Haute Autorité de santé. Flash Sécurité Patient. Mis à jour le 05 avr. 2024. Saint-Denis La Plaine: HAS; 2024. www.has-sante.fr/jcms/p_3240311/fr/flash-securite-patient?id=p_3240311&preview=true

9. Haute Autorité de santé. Attribution du label de la HAS à des solutions pour la sécurité du patient élaborées par les organismes agréés pour l'accréditation des médecins et des équipes médicales. Solutions pour la sécurité du patient de type 2. Saint-Denis La Plaine: HAS; 2024. www.has-sante.fr/upload/docs/application/pdf/2024-02/guide_labellisation_ssp2.pdf

10. Association française d'urologie. Recommandations de bonne pratique pour la prise en charge des calculs et de la lithiase urinaires: diagnostic, traitement, suivi et prévention secondaire – argumentaire [En ligne] 2022. www.urofrance.org/recommandation/recommandations-de-bonne-pratique-pour-la-prise-en-charge-des-calculs-et-de-la-lithiase-urinaires-diagnostic-traitement-suivi-et-prevention-secondaire-argumentaire/?date=&themes=&search=

11. Bhojani N, Andonian S, Watterson JD, Dushinski JW, Shayegan B, Schuler TD, et al. Canadian Urological Association best practice report: Holmium: YAG laser eye safety. Can Urol Assoc J 2020;14(12):380-2. dx.doi.org/10.5489/cuaj.6941

12. Lerner LB, McVary KT, Barry MJ, Bixler BR, Dahm P, Das AK, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part II-surgical evaluation and treatment. J Urol 2021;206(4):818-26. dx.doi.org/10.1097/JU.0000000000002184

13. Lee JY, Andonian S, Bhojani N, Bjazevic J, Chew BH, De S, et al. Canadian Urological Association guideline: management of ureteral calculi. Can Urol Assoc J 2021;15(12):E676-E90. dx.doi.org/10.5489/cuaj.7581

14. Elterman D, Aube-Peterkin M, Evans H, Elmansy H, Meskawi M, Zorn KC, Bhojani N. UPDATE - Canadian Urological Association guideline: male lower urinary tract symptoms/benign prostatic hyperplasia. Can Urol Assoc J 2022;16(8):245-56. dx.doi.org/10.5489/cuaj.7906

15. Goucher G, Saad F, Lukka H, Kapoor A. Canadian Urological Association best practice report: diagnosis and management of radiation-induced hemorrhagic cystitis. Can Urol Assoc J 2019;13(2):15-23. dx.doi.org/10.5489/cuaj.5788

16. Savoie PH, Murez T, Neuville P, Ferretti L, Rocher L, Van Hove A, et al. French AFU cancer committee guidelines - Update 2022-2024: penile cancer. Prog Urol 2022;32(15):1010-39. dx.doi.org/10.1016/j.purol.2022.08.009

17. Neuzillet Y, Pradere B, Xylinas E, Allory Y, Audenet F, Loriot Y, et al. French AFU cancer committee guidelines-Update 2022-2024: non-muscle-invasive bladder cancer (NMIBC). Prog Urol 2022;32(15):1102-40. dx.doi.org/10.1016/j.purol.2022.08.006

18. Marom R, Roberts W. Laser lithotripsy and heat: when should we worry? [En ligne] 2022. auanews.net/issues/articles/2022/december-2022/laser-lithotripsy-and-heat-when-should-we-worry

19. Peyrot S, Brochard G, La Bacle C. Risques infectieux des fumées laser : exemple des papillomavirus humains. Références en santé au travail 2013;(135):125-33.

20. European Association of Urology. EAU Guidelines on urolithiasis. Arnhem: EAU; 2024. uroweb.org/guidelines/urolithiasis

21. Bauer KD, Henle KJ. Arrhenius analysis of heat survival curves from normal and thermotolerant CHO cells. Radiat Res 1979;78(2):251-63. dx.doi.org/10.2307/3575042

22. Burns JA, Kobler JB, Heaton JT, Lopez-Guerra G, Anderson RR, Zeitels SM. Thermal damage during thulium laser dissection of laryngeal soft tissue is reduced with air cooling: ex vivo calf model study. Ann Otol Rhinol Laryngol 2007;116(11):853-7. dx.doi.org/10.1177/000348940711601111

23. Kim AHA, G.D. Laparoscopic laser injury. Dans: Surgeons SoL, ed. Prevention and management of laparoendoscopic surgical complications. Miami: SLS; 1999.

24. Thomsen S, Pearce JA. Thermal damage and rate processes in biologic tissues. Dans: Welch AJ, van Gemert MJC, ed. Optical-Thermal Response of Laser-Irradiated Tissue. Dordrecht: Springer Netherlands; 2011. p. 487-549.

25. van Rhoon GC, Samaras T, Yarmolenko PS, Dewhirst MW, Neufeld E, Kuster N. CEM43°C thermal dose thresholds: a potential guide for magnetic resonance radiofrequency exposure levels? Eur Radiol 2013;23(8):2215-27. dx.doi.org/10.1007/s00330-013-2825-y

26. Hutchens TC, Blackmon RL, Irby PB, Fried NM. Hollow steel tips for reducing distal fiber burn-back during thulium fiber laser lithotripsy. J Biomed Opt 2013;18(7):078001. dx.doi.org/10.1117/1.jbo.18.7.078001

27. van de Berg NJ, van den Dobbelsteen JJ, Jansen FW, Grimbergen CA, Dankelman J. Energetic soft-tissue treatment technologies: an overview of procedural fundamentals and safety factors. Surg Endosc 2013;27(9):3085-99. dx.doi.org/10.1007/s00464-013-2923-6

28. Molina WR, Silva IN, Donalisio da Silva R, Gustafson D, Sehrt D, Kim FJ. Influence of saline on temperature profile of laser lithotripsy activation. J Endourol 2015;29(2):235-9. dx.doi.org/10.1089/end.2014.0305

29. Butticè S, Sener TE, Proietti S, Dragos L, Tefik T, Doizi S, Traxer O. Temperature changes inside the kidney: what happens during holmium:yttrium-aluminium-garnet laser usage? J Endourol 2016;30(5):574-9. dx.doi.org/10.1089/end.2015.0747

30. Kallidonis P, Kamal W, Panagopoulos V, Vasilas M, Amanatides L, Kyriazis I, et al. Thulium laser in the upper urinary tract: does the heat generation in the irrigation fluid pose a risk? evidence from an in vivo experimental study. J Endourol 2016;30(5):555-9. dx.doi.org/10.1089/end.2015.0768

31. Aldoukhi AH, Ghani KR, Hall TL, Roberts WW. Thermal response to high-power holmium laser lithotripsy. J Endourol 2017;31(12):1308-12. dx.doi.org/10.1089/end.2017.0679

32. Æsøy MS, Juliebø-Jones P, Beisland C, Ulvik Ø. Temperature profiles during ureteroscopy with thulium fiber laser and holmium:YAG laser: findings from a pre-clinical study. Scand J Urol 2022;56(4):313-9. dx.doi.org/10.1080/21681805.2022.2104367

33. Æsøy MS, Juliebø-Jones P, Beisland C, Ulvik Ø. Temperature measurements during flexible ureteroscopic laser lithotripsy: a prospective clinical trial. J Endourol 2024;38(4):308-15. dx.doi.org/10.1089/end.2023.0660

34. Haddad M, Emiliani E, Rouchausse Y, Coste F, Doizi S, Berthe L, et al. Impact of the curve diameter and laser settings on laser fiber fracture. J Endourol 2017;31(9):918-21. dx.doi.org/10.1089/end.2017.0006

35. Haddad M, Emiliani E, Rouchausse Y, Coste F, Berthe L, Doizi S, et al. Impact of laser fiber tip cleavage on power output for ureteroscopy and stone treatment. World J Urol 2017;35(11):1765-70. dx.doi.org/10.1007/s00345-017-2053-1

36. Patel NH, Uppaluri N, Iorga M, Schulman A, Bloom JB, Phillips J, et al. Device malfunctions and complications associated with benign prostatic hyperplasia surgery: review of the manufacturer and user facility device experience database. J Endourol 2019;33(6):448-54. dx.doi.org/10.1089/end.2019.0067

37. Honeck P, Wendt-Nordahl G, Häcker A, Alken P, Knoll T. Risk of collateral damage to endourologic tools by holmium:YAG laser energy. J Endourol 2006;20(7):495-7. dx.doi.org/10.1089/end.2006.20.495

38. Morais N, Terribile M, Mota P, Cicione A, Dionísio S, Carvalho-Dias E, et al. Resistance of different guidewires to laser injury: an in-vitro experiment. Minerva Urol Nefrol 2018;70(6):624-9. dx.doi.org/10.23736/s0393-2249.18.03050-3

39. Doizi S, Audouin M, Villa L, Rodríguez-Monsalve Herrero M, De Coninck V, Keller EX, Traxer O. The eye of the endourologist: what are the risks? A review of the literature. World J Urol 2019;37(12):2639-47. dx.doi.org/10.1007/s00345-019-02667-0

40. Althunayan AM, Elkoushy MA, Elhilali MM, Andonian S. Adverse events resulting from lasers used in urology. J Endourol 2014;28(2):256-60. dx.doi.org/10.1089/end.2013.0451

41. Villa L, Cloutier J, Compérat E, Kronemberg P, Charlotte F, Berthe L, et al. Do we really need to wear proper eye protection when using Holmium: YAG laser during endourologic procedures? results from an ex vivo animal model on pig eyes. J Endourol 2016;30(3):332-7. dx.doi.org/10.1089/end.2015.0232

42. Paterson NR, Fitzpatrick R, Blew B, Denstedt J, Watterson J. Perceptions and practice patterns of holmium laser goggles in endourological procedures: an unnecessary evil? J Endourol 2019;33(2):146-50. dx.doi.org/10.1089/end.2018.0432

43. Morozov A, Taratkin M, Kozlov V, Tarasov A, Bezrukov E, Enikeev M, et al. Retrospective assessment of endoscopic enucleation of prostate complications: a single-center experience of more than 1400 patients. J Endourol 2020;34(2):192-7. dx.doi.org/10.1089/end.2019.0630

44. Sun J, Shi A, Tong Z, Chi C. Green Light photoselective vaporization of the prostate: a safe and effective treatment for elderly high-risk benign prostate hyperplasia patients with gland over 80 ml. Lasers Med Sci 2018;33(8):1693-8. dx.doi.org/10.1007/s10103-018-2521-x

45. Lerner LB, Rajender A. Laser prostate enucleation techniques. Can J Urol 2015;22 Suppl 1:53-9.

46. Fardoun T, Mathieu R, Vincendeau S, Della Negra E, Corbel L, Couapel JP, et al. Risque de perforation rectale liée à l'utilisation de l'échographie endorectale au cours de la photovaporisation prostatique au laser en intention de traiter : à propos de 4 cas. Prog Urol 2015;25(2):101-6. dx.doi.org/10.1016/j.purol.2014.11.005

47. Talso M, Emiliani E, Haddad M, Berthe L, Baghdadi M, Montanari E, Traxer O. Laser fiber and flexible ureterorenoscopy: the safety distance concept. J Endourol 2016;30(12):1269-74. dx.doi.org/10.1089/end.2016.0209

The PSS produced by accreditation approved bodies and published by the HAS are developed in accordance with the methodological guide "Attribution du label de la HAS à des solutions pour la sécurité du patient élaborées par les organismes agréés pour l'accréditation des médecins et des équipes médicales". This PSS meets the criteria of the type 2 PSS development quality assessment grid.

HAS HAUTE AUTORITÉ DE SANTÉ

AFU ASSOCIATION FRANÇAISE D'UROLOGIE