HAUTE AUTORITÉ DE SANTÉ

KEY POINTS & SOLUTIONS ...PATIENT SAFETY

FCVD

Fédération de chirurgie viscérale et digestive

Managing the risks associated with electrosurgical devices[1]

Validation: October 2018 / Release: November 2018

Why is it important?

Surgeons and interventional physicians routinely use the electrosurgery to produce tissue effects such as for coagulation or tissue dissection. Electrosurgical devices apply a high-frequency (HF) alternating electrical current, between two electrodes to produce desired biological effects on tissues. The electrosurgical pencil for cutting and coagulation is the most frequently used electrosurgical device. This device can be “monopolar” or “bipolar” depending on the position of the return electrode either far away from the effective electrode on the instrument (monopolar) or closely integrated at the tip of the instrument (bipolar). The use of these devices can produce care-related adverse events (CRAEs) which the treating physician has to be aware of to minimise risk. Both the surgeon and the endoscopist are supposed to declare adverse events to their respective accreditation body. These CRAEs are generally related to dysfunction, inappropriate instrument use or simply due to the underlying physics such as the presence of an electromagnetic field that can cause stray energy pathways.

Factors such as instrument complexity, surgical site environment and lack of knowledge of the instruments used on the patient, promote and aggravate the occurrence of a CRAE, whose consequences are primarily skin or visceral burns. If unrecognised or incorrectly managed, these CRAEs can have serious consequences for the patient.

To ensure optimum procedural safety for both the patients and physicians, the use of the electrosurgical instrument requires appropriate knowledge of the underlying physics and function of each instrument and the observation of certain preventative steps when using the devices. [2].

We propose a support tool for managing the risks associated with the use of electrosurgical devices that consists of a list of key elements design to increase patient safety. This safety tool may subsequently be expanded and adapted to new technical developments in device manufacturing and surgical indications as well as specific adaptations to medical subspecialties.

This patient safety solution (PSS) applies to the use of monopolar or bipolar electro-surgical devices (high-frequency electrosurgery), both in the operating room and at interventional suites.

It is intended for interventional teams (surgeons, practitioners, state-registered scrub nurses, state-registered anaesthesia nurses, circulating nurses and technicians, OR manager and endoscopy nurses), for biomedical staff and for sterilisation staff. It supplements the recommendations made by electrosurgery instrument manufacturers.

This PSS is based on the in-depth analysis of accidents associated with the thermal diffusion and dispersion of electrical current, leading to CRAEs occurring and reported during its use. It aims to propose concrete actions (safety barriers) to prevent, recover or attenuate the risks associated with the use of electrosurgery.

In the context of the monitoring of this PSS, any difficulties encountered during its implementation must be submitted to the Haute Autorité de Santé (HAS – French national authority for health) that coordinates the work group. This will facilitate the main goal of this work group pertaining its patient safety mandate and the assessment of electrosurgical device usage and its complications. This includes ongoing revisions and updates of the PSS in collaboration with the approved body for visceral and digestive surgery, the FCVD (sponsor).based on the available data

1. The term electrosurgical pencil refers to any high-frequency electrosurgical device used in the operating room and at interventional suites.
2. The term “interventional suites” refers to the operating room and to the other technical platforms (endoscopy, etc.).

Sponsor

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Associated bodies

Association française d'urologie

Collège français des anesthésistes-réanimateurs

OA Chirped chirurgie infantile

Collège évaluation formation accréditation en hépato-gastro-entérologie

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Chirurgie plastique, reconstructrice et esthétique

Société française de chirurgie thoracique et cardio-vasculaire

Chirurgie vasculaire

Société française d'endoscopie digestive

Association Française des Ingénieurs Biomédicaux

Association française des ingénieurs biomédicaux

Union nationale des associations d'infirmier(e)s de bloc opératoire diplômé(e)s d'État

Groupement infirmier pour la formation en endoscopie

Care-related serious adverse events identified by the HAS in the national database of feedback concerning care-related serious adverse events (REX-EIGS database)...

Two CRSAEs declared in 2018 reported a fire in the operating room caused by the use of alcohol-based prep solutions and an electrosurigal pencil.

- *CRSAE 1. Operating room fire during an emergency caesarian section*

Swabbing with an alcohol-based prep solution was performed before a skin incision was made with an "monopolar" electrosurgical device in coagulation mode. Immediately the patient reported pain and a burning smell was detected. The gynaecologist noted pale bluish-yellow flames on the right-hand side of the surgical drape. The team immediately removed the drapes and extinguished the fire with water.
General anaesthesia was performed and the infant was extracted and handed over to the paediatrician. The burn unit of the closest university hospital was contacted. The patient was maintained under general anaesthesia pending arrival of the air ambulance for transfer to the university hospital burn unit.
The root cause analysis highlighted the fact that the three components of the fire triangle were present: ignitor (monopolar electrosurgical device), alcohol-based prep solution and oxygen. Key finding: Due to the emergency situation, the alcohol-based prep solution was not allowed sufficient time to dry.

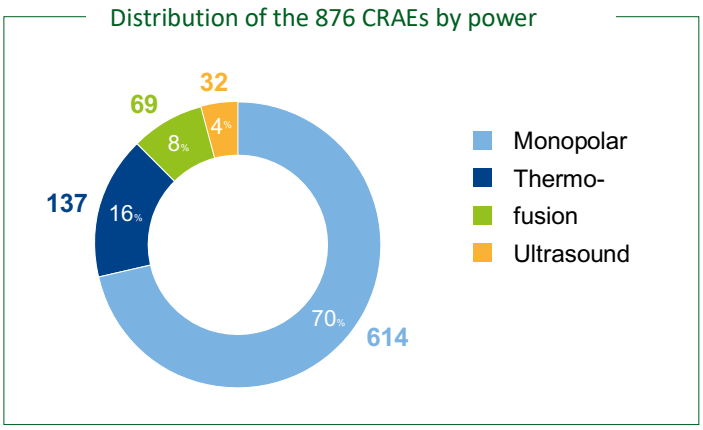
- *CRSAE 2. Fire in a procedure room used for an outpatient surgical procedure*

The team positioned the patient and prepared the equipment. Anaesthetic induction was performed.

The scrub nurse handed the surgical intern an alcohol-based prep solution for skin prep. The operative field was swabbed abundantly with the alcohol based prep. The incision was performed with a monopolar electrosurgical device. The surgeon and his assistant then noted an abnormal noise and a sensation of heat under the drape. The surgeon then removed the drape, noting a hole in in the drape between the patient's thighs, followed by small flames. The surgeon was able to smother the fire by applying a stack of sterile drapes. At the end of the procedure, when removing the drapes, the surgeon noted third-degree burns around the both inner thighs. A dressing was applied. The surgeon gave the patient an initial briefing concerning the event that had occurred. The patient was transferred to full hospitalisation for treatment of the burns.
The root cause analysis highlighted the following points:
The alcohol-based prep solution vapours, that had built up under the drape during swabbing, ignited in contact with an electric arc created by the electrosurgical device at the time of the incision.
The prep solution drying time was complied with, but some product ran of the operative field and pooled on the table under the patient. Key finding: There were no absorbent materials placed under the patient at the time. The operating table cushions were only protected by a cloth draw sheet.

… and care-related adverse events (CRAEs) derived from the physician and medical team accreditation feedback database (FCVD REX database)...

Examination of this REX database led the FCVD to identify and analyse 876 declarations made between 2009 and 2016 regarding CRAE's due to electrosurgical devices.Four primary device types were involved: monopolar electrosurgical pencil, bipolar electrosurgical device, thermo-fusion, and ultrasound (see graph below). Several declarations incriminated the cold light cable used for laparoscopy.



These CRAEs nearly always impacted patient safety with two thirds of the declarations being considered as CRSAEs. The monopolar electrosurgical device, the most frequently used of the reported instruments by surgeons, was the source of the largest number of declarations. The four main accidents identified for this device were: skin burns (26% of declarations); visceral burns (thermal diffusion; 19%); faulty sheathing (laparoscopy; 16%) and fire (11%).

In most cases, systemic analysis was able to identify the underlying causes: both lack of knowledge of the basic rules of electrosurgical devices and lack of appropriate training in their use were, by far, the leading causes identified. Other causes were highlighted: accidents associated with incorrect installation, pedal positioning, inadvertent device triggering, alarm cut-off, change of equipment, faulty sheathing, patient positioning (Trendelenburg, etc.), lack of instrument path vision, thermal diffusion, and incorrect generator settings. It was noted that in particularly with high voltage generator settings dangereous electric arcing and stray energy pathways were observed. In this study however, little information could be derived from accidents related to equipment malfunction and failure, the incorrect placement of the return electrode on the patient, or from incidents linked to interference with other instruments such as pacemakers.

It is important to mention that over the same period, a second approved body - Plastirisq - recorded 163 CRAE declarations for cases of skin burns and operating room fires.

Finally, as the declarations recorded in the REX database are not exhaustive, we cannot determine a precise accident incidence.

… lead to the drafting of the patient safety solution (PSS) “Managing the risks associated with electrosurgical device use”

This PSS proposes a list of key points intended to increase organisational and professional safe practices and to determine a number of actions for improving electrosurgical device safety.

These key points revolve around the three phases of safety barrier analysis: preventing, recovering and attenuating the risks associated with the use of an electrosurgical device.

Part 1.

Managing the risks associated with the use of an electrosurgical device: key points for all surgical specialties

PSS

- Prerequisites
- Prevent (the occurrence of the adverse event)
- Recover (cancel the consequences of an emerging adverse event)
- Attenuate (the consequences of an adverse event that has occurred)

Factsheets

- Fire in the operating room
- Pacemakers

Implementing the PSS

Key points for safe practice

To avoid the CRAEs associated with high-frequency electrosurgery, some prerequisites must be met.

Safety prerequisites

■ Operating room/physicians

Training in electrical risks and device use is required for all members, and for any newcomers.

This training focuses on:

- generator operation and adjustment to achieve the desired effect with minimum power setting;
- patient and return electrode installation conditions: best practices in the right place;
- risks of interference with other medical devices;
- burn and fire risks, along with fire fighting means (identification, training, etc.);
- use of prep solutions (SF2H 2016, ANSM 2012 and 2018);
- steps to assure operating room fire prevention and management (see operating room fire sheet).

Communication concerning generator adjustment is shared amongst and understood by the team members.

■ Electrosurgical devices

- Manufacturer guidelines are available, accessible and applied.
- Device maintenance is performed at the frequency defined by the medical equipment manager, and maintenance protocols are in place.
- A biomedical engineer/technician is present in the establishment (equipment monitoring, maintenance and verification, vigilance, etc.).

Equipment must not be used without prior training

Implementation of recommended electrosurgical practices by scrub nurses.

Patient safety is a priority for the scrub nurses. Electrosurgery is a high-risk technology for the patient which can cause injury or even death. This technology is constantly progressing, it is therefore important that the scrub nurses be familiar with the equipment, its use and maintenance, but also with the potential risks for patients and staff. The AORN[3] has published a series of best practices guidelines for all perioperative staff in order to keep risks during the acquisition and use of electrosurgical devices to a strict minimum (Spruce, 2012). These guidelines apply to monopolar, bipolar, argon and ultrasound generators, with specific recommendations for coeliosurgery, open surgery and evacuation of surgical fumes. Procedures should be drawn up, periodically reviewed, updated and readily available.

3. AORN: *Association of periOperative Registered Nurses*.

WHAT NOT TO DO

RETURN ELECTRODE

- **DO NOT apply gel** to the return electrode,
- **DO NOT cut it** or **alter it in any way**,
- **DO NOT stick the** return electrode to a bone prominence, scar tissue, or to damp or inflamed skin.

GENERATORS

- **DO not change the generator effect settings** without first checking the electrical circuit and without clear and appropriate communication between the members of the surgical team.
- **DO NOT turn off** the alarms.

ELECTRO-SURGICAL KNIFE

- **DO NOT cross and mingle** the electrosurgical instrument wires. Keep them separate from each other
- **DO NOT use a metal support.**
- **DO NOT place** the electrosurgical device and its accessories, or the camera with the light cable onto the surgical drape.

How to PREVENT accidents

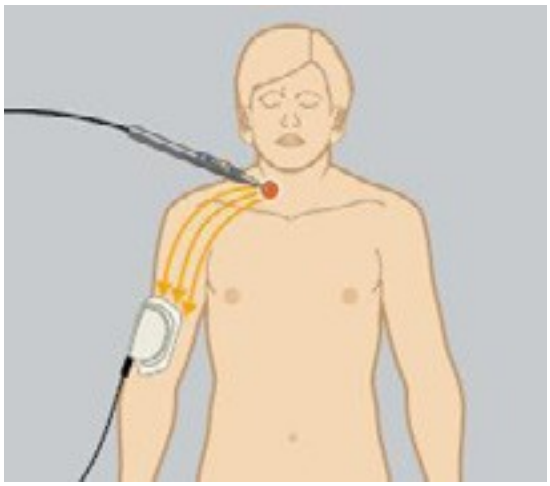
PLAYERS	STEP	ACTIONS
Intervention site manager	Before the procedure	■ Ensure that the technical platform team has been trained in the risks of electrosurgery. ■ Ensure that the physicians have been trained in the use of any new devices.
Biomedical engineer/technician	Before the procedure	■ Check the equipment: preventive maintenance and electrical tests at defined intervals. ■ Ensure that the devices are compatible. ■ Ensure that the cables and connectors are compatible with the instruments used on the electrosurgical device. ■ When commissioning new devices, ensure that the user manual is available, that users have been effectively trained and that the adjustments in place match the requirements. ■ Provide the physicians with a phone number to call in the event of an emergency.
Equipment sterilisation or reprocessing manager	Before the procedure	■ A reusable device fault detection protocol is in place.
Circulating nurses or state-registered scrub nurses technicians and endoscopy nurses	Before the procedure	■ Check the device • Ensure that the generator functions correctly, check accessory integrity (electric wires, return electrodes, pedals, etc.). • Check the generator settings and ensure that information is transmitted, particularly during phase 1 of the HAS "Patient safety in the operating room" *check-list* (HAS 2016). • The alarms are enabled. ■ Patient installation • Ensure that there are no contact points between the examination or operating table with metal or conductive equipment not isolated from the floor. • Avoid patient contact with any metal elements of the examination or operating table. • Remove any of the patient's clothes that contain flammable textiles (e.g.: Nylon). • Observe the drying times [3] and avoid stagnation of alcohol-based solutions. Ensure that the patient is not in contact with damp items (draw sheets, diaper, absorbent material, positioning block, etc.) and replace them if necessary.

PLAYERS	STEP	ACTIONS
Circulating nurses or state-registered scrub nurses technicians and endoscopy nurses	Before the procedure	■ Return electrode and electrosurgical device installation • Use a return electrode suited to the patient's weight and height, particularly in paediatrics. • Ensure that the electrode is correctly positioned and adhered, preferably on the outer face of the arm or thigh, in a well-vascularised muscular area (less current resistance). • If possible, position the electrode near to the surgical site. • Affix the electrode once the patient has been installed. • If the patient has a metal implant (prosthesis, pacemaker, etc.), this latter must not be on the path between the return electrode and the active electrode (electrosurgical device). • Use dual zone plates or plates fitted with an equipotential ring. • Point the edge opposite the connection strip towards the surgical site (see diagram page 11). • Ensure that no liquids (urine, swab, etc.) come into contact with the return electrode. • The electrosurgical device controls must be positioned ergonomically and such that they are easy to use by the operator. • Untangle the electrosurgical device cables and cords before use. Do not secure them with metal objects (clamps).
Surgeon, anaesthetist and resuscitation specialist, interventional physician, state-registered anaesthesia nurse, state-registered scrub nurse	Before the procedure	■ Equipment, installation • Last device and patient installation check, the the operating indicator must be audible. • Ensure that the team is familiar with the equipment and that this latter is operational. The operator coordinates the adjustment and ensures that generator information is transmitted during phase 2 of the HAS "Patient safety in the operating room" *check-list*. ■ In patients with a stimulator: pacemaker or ICD (see factsheets) • Whenever possible, prefer the use of a bipolar electrosurgical device or other advanced power source. • If a monopolar electrosurgical device is used, ensure that the electrical dispersion field associated with the position of the return electrode is remote from the stimulator unit or electrodes. • Ensure that a magnet and defibrillator are available in the OR. An external overdrive device must be available in the event of emergency.

PLAYERS	STEP	ACTIONS
Operators and physicians	During the procedure	■ Ideally, the electrosurgical device should be activated using low-voltage currents. Coagulation episodes should be intermittent and brief. Open circuit activation, or using carbon-coated ends must be avoided. ■ Adapt the settings to tissue conductivity (resistance). ■ Take into consideration the potentiation of the thermal effects of electrosurgery when using the active electrode in contact with metal elements such as clips or staples. ■ In surgery, the risk of electrical dispersion is prevented by using bipolar mode. ■ Place the electrosurgical device in an insulating box when not in use.
Medical team/nurses or state-registered scrub nurses	After the procedure	■ Where applicable, check cardiac stimulator (e.g.: pacemaker/defibrillator, etc.) operation, as per the preoperative instructions of the referring cardiologist (see factsheet). ■ After removing the return electrode, check for skin lesions both under and around the plate area.

Diagrams. Positioning the return electrode on the patient

The return electrode must be placed as close as possible to the surgical site in order to make the current path through the patient's body as short as possible.



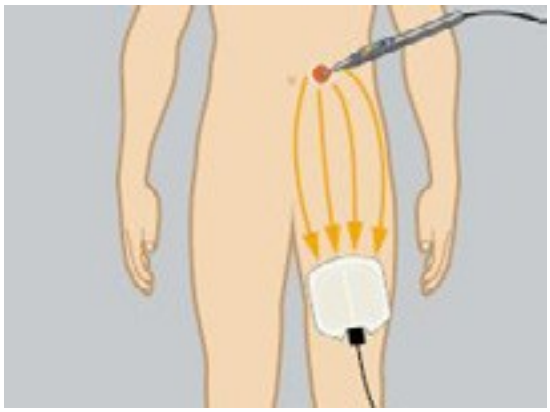
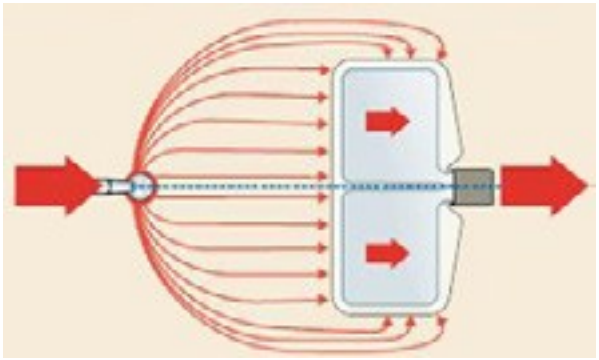


Photo credits: ERBE

The axis of the return electrode should be directed towards the surgical site (see diagram below) to ensure better current distribution over both plate zones. According to manufacturers, this point is critical as the generator monitors current return symmetry from both parts of the plate.

Active electrode



Return circuit to generator

Steps to take in the event of an accident when using the electrosurgical device (RECOVER)

Depending on the seriousness of the event, specific steps are taken immediately (see table below). Indeed, lesions not detective perioperatively only become visible belatedly and constitute a cause for repeat surgery.

ADVERSE EVENT	ACTIONS TO IMPLEMENT
Skin burns	■ Irrigate the lesion with preferably sterile liquid at ambient temperature (physiological saline) and follow the procedure in place within the service. ■ Check and look for other burn sites, particularly at points of contact between the patient and the operating table.
Visceral lesions (wounds, burns, etc.)	■ Adapt the technical repair procedure to the significance of the observed lesion (abstention, clips, sutures, resection, drainage, etc.). ■ If the repair falls outside your field of expertise, seek specialist advice. ■ Adapt your postoperative monitoring according to the various evolving risks of the visceral lesions observed perioperatively.
Fire at the intervention site and in the operating room[4]	■ Implement the steps to take in the event of an operating room fire[5] (see factsheet Steps to take in the event of a fire in the operating room).

IMPORTANT in the event of demonstrated CRAE

- 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, the power, electrosurgery 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. These data may be relevant to better understanding the causes of the incident.

4. The point of origin of the fire resides in the combination (fire triangle) of a fuel (alcohol-based prep solution, rubber probe, paper drape, patient), a comburent (oxygen-rich atmosphere, nitrous oxide) and a power source (electrosurgical device, cold light).
5. Distribution of the “fire in the operating room” factsheet is the responsibility of the risk manager and of the operating room council. It must be discussed and approved during an EMC meeting.

Steps to take in the event of a complication related to electrosurgical device use (ATTENUATE)

The occurrence of an adverse event during use of a power source implies that the following actions must be performed.

RECIPIENT	ACTIONS TO IMPLEMENT
With the patient	■ Inform the patient of the nature of the damage (HAS guide, 2011). ■ Monitor the patient's condition in the event of a confirmed perioperative electrical incident. ■ Raise the possibility of a visceral lesion of electrical origin in the event of an unexplained postoperative aggravation.
In the patient's record	■ Note the information given to the patient. ■ Note the nature of the incident and/or of the lesion in the operative report. ■ Note the adverse event that occurred in the operating room in the 3rd part of the HAS 2016 *check-list*. ■ Note the patient's monitoring period, in the event of an incident recovered perioperatively.
With the establishment	■ Notify the CRAE to the contact persons of the establishment (materiovigilance contact, risk manager for analysis by MMR, feedback committee, etc.), in the establishment's declaration system and to the manufacturer. ■ Inform the physicians and biomedical manager and/or pharmacist in charge of medical devices. ■ Implement corrective actions and monitor and measure their effectiveness. ■ Revise the equipment and procedures for use if necessary.
To the ANSM	■ Report any serious incidents or risk of serious incident or serious adverse event, using the materiovigilance declaration form.
To the ARS	■ Report any CRSAEs.
To the approved accreditation bodies	■ Declare the care-related adverse events (CRAEs) in the accreditation information system.

“Electrosurgical device and fire in the operating room” factsheet

Fire prevention

Avoid using a power source near an comburent-rich atmosphere (oxygen concentration greater than ambient air and/or presence of nitrous oxide).

Arrange the surgical drapes in such a manner as to minimise the build-up of comburent (avoid “pouches and tents”).

Observe the drying time (3 minutes) of the prep solutions used for skin preparation.

Lightly moisten any dressings, pads and sponges used near a power source, move all others away.

Collaboration between surgeon and anaesthetist: fire risk assessment during phase 2 of the *check-list* and joint decision of the best perioperative strategy.

Is this a high fire risk procedure?
(high risk if a power source is used near a comburent-rich atmosphere, e.g.: head and neck surgery)

YES

Each healthcare professional present knows the instructions for preventing and managing fire in the operating room, along with their individual role.

The surgeon is warned of the proximity of a comburent-rich atmosphere.

In the event of upper airway, head and neck surgery:

- prefer tracheal intubation or use a laryngeal mask in the event of deep sedation, or for oxygen-dependent patients;
- prefer the use of a cold knife to incise the trachea;
- if necessary, use a laser-resistant tracheal tube;
- if a power source must be used in the airways:
  - state the intention to use it,
  - reduce the concentration of oxygen delivered to the minimum required by the patient,
  - stop nitrous oxide delivery,
  - wait 3 minutes before using the power source.

NB: the term power source is used in its broadest sense; electrosurgical device and electrosurgery, whatever the mode, laser.

Steps to take in the event of fire

Raise the alert as soon as the first signs of fire are detected

flames, smoke, flash, suspicious smells, unusual noises (pop, snap, whoosh), colour change of the drapes or ventilation circuit, unexpected patient or drape movement, patient complaint.

Stop the current procedure

Assess the situation

Fire confirmed

Airway fire

Immediately

- Remove the breathing tube.
- Stop delivery of all gasses.
- Remove the drapes and any other flammable materials and throw them on the ground.
- Pour physiological saline into the airways.

If the fire is not extinguished at the first attempt

Use a "portable safety shower" for the patient and a CO_2 extinguisher for the equipment.

If the fire persists

Trigger the fire alarm, evacuate the patient, close the doors, turn off all gas supplies.

Fire on or in a patient

Immediately

- Stop delivery of all gasses.
- Remove the drapes and any other flammable materials and throw them on the ground.
- Extinguish any burning objects with physiological saline or water.

Fire extinguished

- Resume patient ventilation.
- Avoid an FiO2 > 30% and N2O.
- Extinguish and examine the entire breathing tube (fragments left in the airways?).
- If necessary, perform a bronchoscopy (assessment, debris?).

Fire extinguished

- Maintain patient ventilation.
- Determine whether the patient has inhaled smoke.

- Assess the patient's condition.
- Re-schedule patient treatment.
- Declare and conduct an in-depth analysis of the CRAE.
- Inform the patient.

“Electrosurgical device and pacemakers” factsheet

Interaction between electrosurgical device and implanted pacemaker[6]

Pacemaker operation

- Pacing and listening to spontaneous cardiac activity functions, identified by a 3-4 letter code:
  single chamber: sensor most frequently ventricular, in sentinel mode (VVI);
  - dual chamber: atrial and ventricular sensors, most frequently in DDD mode.
- Activity sensor, used to increase the heart rate in the event of effort (VVIR or DDDR).
- Resynchronisation function: 3rd sensor placed in the wall of the left ventricle to resynchronise the contraction of the 2 ventricles in the event of severe left bundle branch block and heart failure.

Consequences of electromagnetic interference (EMI) with the electrosurgical device

- Pacing inhibited during EMI, leading, if prolonged, to ventricular bradycardia.
- Transient switch to asynchronous mode (VOO).
- Switch to backup asynchronous mode with certain units, requiring re-programming to restore normal operation.
- High ventricular rate in the event of EMI during atrial stage (dual chamber pacemaker).
- Random and irreversible re-programming of certain pacemaker parameters (exceptional).

Preoperative assessment

- Nature of the rhythm disorder and of the associated heart disease.
- Patient dependence on the pacemaker.
- Functional symptoms and/or ECG anomalies: search for an ill-suite mode, progression of heart disease or pacemaker malfunction.
- Pacemaker characteristics (pacemaker logbook or cardiologist’s opinion):
  brand and model: essential for examining the unit in the event of malfunction;
  - number of sensors and pacing mode;
  magnet mode: variable response according to model; most frequently switch to VOO or DOO asynchronous mode, though sometimes test period or lack of response;
  - date of last verification: 6 months for a dual chamber and 1 year for single chamber.

Preoperative re-programming

- Re-programming to asynchronous mode (VOO or DOO): proposed in the event of predictable EMI, in pacemaker-dependent patients (lack of consensus).
- De-programming of the function of pacing control by an activity sensor: may be proposed in the event of predictable EMI (lack of consensus).

6. Sheet drafted by the French college of anaesthetist and resuscitation specialists (CFAR).

- Reduction of the risk of interference with the electrosurgical device or of its consequences
  - Organisation allowing a malfunction to be rapidly handled: specialist opinion for device verification, temporary external pacing, external electric shock and cardiopulmonary resuscitation.
  - Presence of a cardiologist's magnet in the OR.
  - Continuous ECG rate and pulse oxymeter wave monitoring.
  - Use of the lowest possible coagulation current.
  - Prefer bipolar mode over monopolar.
  - Brief and intermittent application of coagulation.
  - Do not place the unit between the earth plate and the coagulation site (monopolar electrosurgical device).

- Magnet application to the unit
  - Do not use it systematically; magnet mode is not a "rescue mode" to restore a defective pacemaker; its usefulness is determined by the pacemaker's response to the magnet.
  - If magnet mode causes a switch to VOO asynchronous mode: the magnet can be applied in the event of pacing inhibition by EMI.
  - If magnet mode causes the pacemaker to switch to test or re-programming mode: no indication.

- Postoperative period
  - Postoperative verification of the unit according to the instructions of the referring cardiologist consulted prior to surgery.
  - Possible re-programming if the program was changed preoperatively.

“Electrosurgical device and pacemakers” factsheet

Interaction between electrosurgical device and implanted cardioverter defibrillator (ICD)[7]

Functions of the ICD

- Detection of tachycardia or ventricular fibrillation.
- Delivery of an internal electric shock or high-frequency pacing.
- Combined pacing and listening functions over 1 or 2 chambers (see pacemaker page).

Consequences of electromagnetic interference (EMI) with the electrosurgical device

- Erroneous recognition of arrhythmia and inappropriate delivery of an electric shock.
- Failure to recognize ventricular arrhythmia.
- Interference with the pacing function identical to that of pacemakers (see pacemaker page).

Preoperative assessment

- Nature of the rhythm disorder and of the associated heart disease (particularly heart failure).
- History of defibrillations or cardioversions and patient dependence on pacing.
- Implanted device characteristics (ICD logbook or cardiologist’s opinion):
  brand and model: essential for examining the unit in the event of malfunction;
  - number of sensors anti-arrhythmia function and pacing mode;
  - magnet mode: for the 5 brands of implantable ICDs in France: transient inhibition of the anti-arrhythmia function, with no impact on pacing; for some ICDs: permanent inhibition of this function until reprogramming;
  - date of last verification: 3 to 6 months.

Perioperative management of anti-arrhythmia and pacing functions

- Anti-arrhythmia functions must be inhibited in the event of predictable EMI:
  either by preoperative reprogramming by a cardiologist (instrument adapted to unit):
  - the patient must be monitored within a structure capable of immediately handling a rhythm disorder (operating room, recovery room, continuing care unit),
  - the anti-arrhythmia function should be reactivated by the cardiologist immediately after surgery;

  or by transient inhibition, by applying a magnet to the unit (preferred method):
  - the magnet is applied to the ICD unit immediately prior to electrosurgical device use
  - while the magnet is applied, the patient should be monitored to immediately manage any rhythm disorders
- Perioperative management of the pacing function: similar to that of pacemakers, though application of a magnet to the unit has no effect on the pacing mode.

7. Sheet drafted by the French college of anaesthetist and resuscitation specialists (CFAR).

- Reduction of the risk of interference with the electrosurgical device or of its consequences
  - Organisation allowing immediate response to ventricular arrhythmia or dysfunction: specialist opinion for device verification, external electric shock (self-adhesive electrodes and paddles), temporary external pacing and cardiopulmonary resuscitation in the event of circulatory system inefficiency.
  - Placement of self-adhesive external defibrillation electrodes to the thorax, in anteroposterior position (particularly if peroperative access to the thorax is difficult).
  - Presence of a cardiologist's magnet in the OR.
  - Continuous ECG rate and pulse oxymeter wave monitoring.
  - Use of the lowest possible coagulation current.
  - Prefer bipolar mode over monopolar.
  - Brief and intermittent application of coagulation.
  - Do not place the unit between the earth plate and the coagulation site (monopolar electrosurgical device).

- Perioperative management of ventricular arrhythmia
  - Stop all sources of EMI (including the electrosurgical device) and check the heart rhythm.
  - If the anti-arrhythmia function has been de-programmed: deliver an external electric shock (EES) with electrodes in anteroposterior position, at the usual amperage. The EES can damage the unit.
  - If the anti-arrhythmia function has been inhibited by magnet:
    - remove the magnet from the unit to reactivate the anti-arrhythmia function;
    - check for the presence and effectiveness of internal electric shock delivery or cardioversion by the ICD;
    - in the event of failure, apply an EES as per the aforementioned procedure. The EES can damage the unit.

- Postoperative period
  - Postoperative verification of the unit according to the instructions of the referring cardiologist consulted prior to surgery.
  - Possible re-programming if the program was changed preoperatively.

Implementing the PSS

The key points and solutions for the management of risks associated with electrosurgical device use in the operating room and at intervention sites represent a tool that can be integrated into the intervention site care safety improvement and risk management policy, under the EMC's responsibility. The tool is intended to improve teamwork within healthcare establishments when using an electrosurgical device. It is the responsibility of the healthcare establishment's management, EMC, operating room committee chairs or intervention site manager, to formalise the actions to take and associated responsibilities in a document (operating room charter, etc.).
The points laid down in this PSS can be used as a tool for the assessment of organisational and professional practices. They can help in assessing existing elements, shortcomings and deviations from the proposed guidelines. The assessment results should be used to propose an improvement plan adapted to team size, to practices and to the environment. This plan may involve the reinforcement of measures or of existing training courses, or in the creation of new alerts and actions to initiate additional safety barriers. Their implementation shall be monitored and, if necessary, reassessed.
The approved bodies for the accreditation of physicians can henceforth include this tool in their risk management programmes and contribute to its assessment.
An example improvement approach is proposed in the following pages; it can be adapted to the sector of activity in question.

Example of possible implementation

Should you so wish, based on these key points, you can define an improvement approach for team-based professional practices. For this:

- Step 1: organise your approach (project group set-up, organisation and provisional schedule).
- Step 2: assess the key points of the PSS.
  The following ranking system is proposed:
  0 : missing
  1 : in project phase
  2 : under development, or partially met
  3: completed
  4: monitored and assessed according to procedures adapted to your sector of activity (supporting documents, investigation, meeting minutes, audit, tracer patient, etc.).
  N/A: if the criterion is not applicable. Non-applicability must be justified.
- Step 3: draw up an overview of the assessment performed
  (see sheet appended) and define improvement goals.
- Step 4: make a joint decision concerning the improvement actions to implement and monitor (see sheet appended).

Some examples of possible improvement actions:

- Drafting of an operating room fire prevention and management protocol (algorithm), approved by the EMC, displayed, displayed at all intervention sites, regularly updated and known by all teams working at the intervention sites.
- The operating room committee, or the intervention site management, regularly addresses (agenda) the problems associated with electrosurgical device use: staff training, equipment purchase and maintenance, communication of CRAE data, etc.
- Implementation of intervention site staff training in the use of electrosurgical equipment and fire training involving biomedical staff.
- Drafting of an equipment maintenance procedure with the biomedical staff.
- Declaration, in-depth analysis and follow-up of CRAEs linked to electrosurgical device use (burns, fire, etc.).
- Medical device vigilance declaration(s).
- In-depth MMR analysis of CRAEs linked to electrosurgical device use.
- Analysis of practices by means of a grid drawn up from the PSS.
- Indicator monitoring (annual number of CRAE linked to electrosurgical device use, etc.).

Assessment overview

Date:

List of participants: last names, first names, positions:

Sector of activity:

Analysis results, strong points, points to be improved:

Improvement goals:

Conclusions and action plan (to be supplemented by one or more action sheets):

Action sheets

N.B. : fill in 1 sheet per action implemented.

Key point(s) concerned / problems identified: Action implemented:	
Objective	
Description	
By whom?	
When?	
How?	

Follo
Implementation schedule
Monitoring and assessment procedures

In charge of monitoring
Wh

Progress: ☐ Not ☐ Plann ☐ In ☐ Compl ☐ Assess

date:

Part 2.

Sheets specific to certain medical specialties

Some specialties wished to emphasise certain points specific to their practices, in addition to the information available in part 1 of the document.

Each sheet, drafted by the approved body in question, takes these elements into consideration. It is intended for the following specialties:

- Visceral and digestive surgery;
- Gastroenterology;
- Paediatric surgery;
- Gynaecology-obstetrics;
- Orthopaedic and trauma surgery.

Visceral and digestive surgery specificities

Visceral burns

During visceral and digestive surgery, in the event of recognized peroperative burns

- A visceral burn (small intestine, colon, etc.) must be traced in the operative report and medical file and requires postoperative surveillance to detect any secondary complications that could lead to unscheduled repeat surgery.
- Such burns contraindicate outpatient management.

Laparoscopic surgery: the “hidden” risk

Many visceral burn-related CRAEs are ignored as they occur outside of the laparoscope’s field of vision. They are the result of untimely active electrode activation, or of electric current dispersion in direct contact with the tissues, or indirectly via other conductive equipment (gripping forceps, retractors, metal clips, staples, etc.). They are promoted by electrical coupling phenomena that may occur when using high-voltage current and/or porous or improperly insulated equipment
it is thus important, during any laparoscopic procedure:

- to check the integrity of laparoscopic instrument sheathing;
- to work with low voltages;
- to prefer the section or blend modes over pure coagulation mode;
- to not use mixed trocars combining metal and insulating components;
- to avoid activating the electrosurgical device electrode in contact with a line of staples;
- to avoid actuating the active electrode in open circuit (no contact with the tissue), or to activate a carbon-coated electrode;
- to check electric circuit integrity before increasing the power;
- to review the abdominal cavity at the end of the procedure, to detect any remote burns that may have been missed;
- to mention this risk in the event of abnormal postoperative progression.

Training

A national survey of digestive surgeons involved in accreditation revealed that most of these latter lacked knowledge of and training in the risks associated with the use of these power sources.
The specialty has implemented training sessions for surgeons and their teams, through an e-learning programme and simulation workshops. These training courses are intended, more broadly, for all operating room players, whatever their specialty.

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Website of the FCVD approved body: www.chirurgie-viscerale.org

Gastroenterology specificities

Electric generator use in digestive endoscopy

In France, 20% of generators sold are to digestive endoscopy centres. In 2016, the French society for digestive endoscopy (SFED) estimated the number of colonoscopies performed at 1,060,000 (Bernardini, 2017). These endoscopic procedures, frequently therapeutic in nature, are conducted in specific locations that are not necessarily operating rooms, by gastroenterologists assisted by nurses specifically trained in digestive endoscopy (state-registered endoscopy nurses).

1. Formation à l'utilisation des générateurs en endoscopie digestive (Canard JM, Lecomte et al.)

- Training of endoscopist physicians
  These physicians must have been trained in the use of electric generators, with postgraduate training in hepato-gastroenterology, supplemented by continuing education diplomas in interventional endoscopy, continuing vocational training, conference attendance, etc.
- State-registered endoscopy nurse training
  The training course must combine the theory and practice of practised and mastered skills. As the endoscopy discipline is constantly evolving, to ensure that knowledge is regularly updated, the initial training is reinforced by periodic specific training. Continuing professional development is proposed for the operation and precautions for the use of electric generators.
- Checks multiple times per day
  Each time a room is opened, and before each procedure, the "Digestive endoscopy patient safety check-list" includes checking the patient's identity, the scheduled procedure, but also ensuring that the appropriate equipment is provided and prepared (www.has-sante.fr/portail/upload/docs/application/pdf/2011-_01/2010_cl_endoscopie_digestive_sfed_has.pdf). Thus, during point 3 of the *check-list*, check the plate, connections, argon and CO_2 cylinder levels, along with the present of orthopaedic prostheses or electrostimulators.

2. The patient

To eliminate usage errors, the patient must absolutely be prepared with appropriate non-conductive and non-flammable clothes.

3. Prevention of ignition and explosion risks

In the event of upper digestive tract endoscopy requiring monopolar current, there is a risk of burns. The nasal O_2 supply should be stopped, or an oro-tracheal tube should be used.

During colonoscopy in an unprepared colon, procedures involving electric current, particularly monopolar current, are hazardous. Indeed, in an unprepared colon, the fermentation gases (methane CH_4 and dihydrogen H_2) are prone to explode in the presence of dioxygen (O_2) and an electric arc (La Brooy 1981, Ladas 2007).
Checking colon preparation quality during point 6 of the HAS *check-list* and during the colonoscopy procedure itself (per-endoscopic lavage, Boston score establishment and tracing) virtually eliminates this risk. No data prove that using CO_2 protects against the risk of explosion in the absence of preparation.

4. Special case of electrostimulators

4.1 General precautions: to minimise the risk of interaction with electrostimulation devices, the return electrode should be positioned more than 15 cm away from the electrostimulation device (including sensors). Cutting/coagulation impulse durations must not exceed 5 seconds. Attempts must be made to keep voltage as low as possible. Wherever possible, prefer bipolar mode (not widely available in endoscopy). In monopolar mode, the return electrode must be placed as far away as possible, and in such a manner that the current path from the electrode to the return electrode DOES NOT pass through the electrostimulator. Finally, upon completion of the procedure, check the electrostimulator according to the preoperative recommendations made by the anaesthetist and/or referring cardiologist.

4.2 Precautions specific to pacemakers: pay close attention to the safety rules for all oeso-cardial and left angular colic procedures. An overdrive electrode must be available in the event of pacemaker malfunction (ANSM guidelines). Moreover, for automatic implantable defibrillators, in order to avoid untimely electric shocks, the defibrillation function should be disabled by placing a magnet on the cardiac prosthesis (Crossley, 2011).

4.3 Precautions specific to nerve stimulators with medullary, cerebral, gastric or pelvic electrode, etc. (Yeoh, 2007): ensure that the patient has deactivated the stimulator (with his/her remote control) before endoscopy and anaesthesia. Avoid repeated activations/deactivations.

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Websites of the bodies: www.cefa-hge.fr (OA) ; sfed.org; www.gife.fr

Use of electric generators and specific points relative to paediatric surgery

Monopolar or bipolar electric generators are used virtually systematically in paediatric surgery. The specificities are similar to the general specificities and those of the other bodies. The main risks are of skin burns or internal lesions. Surgeons must be particularly vigilant, however, due to the low weight of certain children (premature baby and infant surgery) and to the tissue fragility (skin and other tissues).

1. Precautions concerning the electrosurgical device
   - Place the electrosurgical device handle on the instrument table to avoid burns caused by inadvertently pressing a digital control.
   - Shield the metal electrode.
   - Observe the paediatric technical constraints listed by the supplier (low-voltage).
   - Prefer the use of bipolar mode whenever possible.
2. Precautions concerning mattresses/heated covers
   - Monitor the temperature.
   - Make sure that there is no interface between the air outlet and the child.
3. Precautions concerning the “cold” light
   - Connect the cold light once all other equipment has been installed.
   - At the end of the procedure, return the connected device.
   - Use an instrument pouch.
4. Precautions concerning swabbing
   - The surgeon should prepare the swabs to ensure that their size is compatible with the child’s weight.
   - Wring out +++ the swabs before applying to the child in order to remove any surplus disinfectant used in contact with the child.
   - Avoid liquid flow in areas such as the sacrum, folds, etc.
   - Pay attention to retention areas such as the umbilicus, etc.
   - Observe the drying times, in particular for ++ alcohol-based products.
   - Remove the drapes used to demarcate the swabbing before applying the surgical drapes, in order to avoid any residual liquids in contact with the child.
   - Prefer the use of silicone positioning blocks over absorbent blocks.
5. Promote knowledge of and training in the use of the various instruments (return electrode monopolar plate: size adapted to the child’s weight, not on a visible bone structure, correct adhesion, electric generator, electrosurgical device handle, heated covers and mattresses, etc.).

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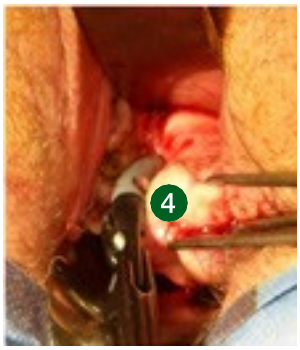
Gynaecology-obstetrics specificities

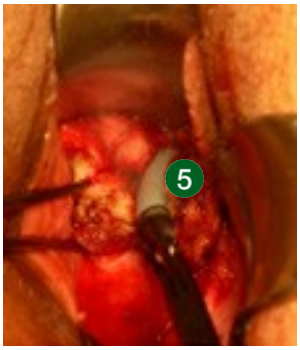
To reduce ureteral lesions during vaginal hysterectomy
by the thermo-fusion method

Since 2009, the REX database data show a worrying number of ureteral lesions, practically unknown before this date and systematically linked to the use of thermo-fusion during vaginal hysterectomy. The frequency of these complications would appear to be less than 1% and the French scientific literature only rarely reports this type of complication.
Nevertheless, the severity of these uereteral lesions occurring during a routine gynaecology surgical procedure led the approved body Gynérisq to review the technical guidelines published to date (Clavé 2017, Kroft 2011).

These guidelines can be summarised in 6 points:

1. Work at the centre of the vaginal cavity: perform the thermo-fusion while remaining at the centre of the vaginal cavity serves to keep the ureter at distance, the electrosurgical device handle remaining in the axis of the vagina.
2. Suction off the vapours: this procedure may seem anecdotal, but it is justified by the temperature drop at the site that it induces by a "ventilation" effect.
3. Push back the base of the bladder using a bayonet type valve: this is standard practice in vaginal surgery, allowing ascension and providing distance from the ureters.
4. Keep the jaws of the forceps in "cheek-to-cheek" contact with the edge of the uterus.
5. For the uterine pedicle, use the forceps with their concave surface pointing outwards +++: this is the most important technical change: if the thermo-fusion forceps are used in the same manner as conventional forceps, there is a risk of placing the knee of the forceps dangerously close to the ureter.
6. Apply thermo-fusion without voltage to the anatomical structures, thus optimising the haemostatic properties of thermo-fusion.





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Website of the Gynerisq approved body: gynerisq.fr

Orthopaedic and trauma surgery specificities

Skin burns in arthroscopic surgery

The use of mono- or bipolar radio frequency probes in arthroscopic surgery has led to the emergence of skin burns related to liquid flow.
Direct burns caused by the use of the very poorly named “cold light” are also a matter of concern.
The severity of lesions observed (50% of second-degree burns, occasional third degree burns) led Orthorisq to issue a communication on this subject in 2014.
Flow-related lesions were observed 4 times more frequently in shoulder arthroscopy than knee arthroscopy. They were sometimes noted at a distance from the operating area. In all cases, removal of irrigation liquid was defective.

5 recommendations were made:

1. Use the electrocoagulation probe discontinuously in short bursts.
2. Connect the irrigation liquid removal cannula correctly and ensure that there is sufficient flow.
3. Prefer connection to a source of suction, else use gravity, making sure that there are no leaks.
   Take particular care to ensure that the removed liquid does not contact the skin.
   Prefer the use of devices that display or monitor intra-articular temperature.
5. Be aware of the risk of burns due to liquid flow, but also that due to direct contact with the “cold” light.

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Part 3.

PSS drafting note

Study organisation

- Work group composition
- PSS drafting
- PSS monitoring over time

Bibliographic note

- Analysis overview
- References

Study organisation

Work group composition

A multi-profession and multidisciplinary work group (22 members) was formed, consisting of:

- nine approved bodies for accreditation;
- two biomedical engineers;
- one hospital pharmacist;
- two scrub nurses.

Last name	First name	INSTITUTION
Auber	Frédéric	OA Chirped (OA de chirurgie infantile)
Bart	Stéphane	AFU (OA de chirurgie urologique)
Borie	Frédéric	FCVD (OA de chirurgie viscérale et digestive)
Bourgeois	Laurent	Biomedical engineer
Boy	Lauriane	Hospital pharmacist
Deleuze	Alain	FCVD
Didier	Julien	Biomedical engineer
Dray	Xavier	CEFA HGE (OA d'hépato-gastro-entérologie), SFED (Société française d'endoscopie digestive)
Eglin	Georges	Gynerisq (OA de gynécologie-obstétrique)
Faillot	Thierry	Collège de neurochirurgie (OA)
Foult	Hervé	Orthorisq (OA de chirurgie orthopédique et traumatologique)
Gravié	Jean-François	FCVD
Gugenheim	Jean	FCVD
Hepner	Yves	Plastirisq (OA de chirurgie plastique, reconstructrice et esthétique)
Karam	May	UNAIBODE (State-registered scrub nurse)
Ludwig	Brigitte	UNAIBODE (State-registered scrub nurse)
Mathonnet	Muriel	FCVD
Mertes	Jean-Paul	CFAR (OA d'anesthésie-réanimation)
Tollon	Christophe	Collège de neurochirurgie
Tracol	Philippe	Orthorisq
Yavordios	Patrick-Georges	CFAR
Zarka	Marc	Orthorisq

For HAS, the department of assessment and tools for treatment quality and safety (EvOQSS)
Dr Bruno Bally, deputy head of department.
Christiane Dosseh, project manager.

Management of conflicts of interest
Participation in the work group is subject to a public declaration of interests by the members.
All 22 members of the work group published a public declaration of interests on the DPI-SANTE website (www.dpi.sante.gouv.fr). No conflicts of interest pertaining to the topic covered were detected.

PSS drafting

The work method was based on the PSS drafting guide approved by the HAS College in May 2012. It combines analysis of the REX database, the expert opinions of a multidisciplinary work group (see composition above) and the data from the literature, when available.
The work group (WG) convened a first time on 07 April 2017 and defined the content of the tool best suited to use in daily practice for ensuring the safety of the patient operated upon:

- the key points for better controlling the risks associated with the use of electrosurgery during procedures;
- the key points for preventing and managing risks of fire in the operating room and at intervention sites.

As few studies on human factors in this topic is available in the literature, the content of the PSS is primarily derived from confronting know-how with feedback (CRAE analysis).
In light of the CRAE analysis results presented by FCVD during the initial meeting, with the ensuing expert debate, it appeared that the power source most frequently incriminated in declared CRAEs is electrical power (electrosurgical device). The work group thus decided to name the PSS "Management or risks associated with electrosurgical device use".
The initial version of the PSS was reviewed by the work group members, the 14 approved bodies active in the accreditation system, the French society for operating room nursing assessment and research (SOFERIBO), the National union of state-registered scrub nurse associations (UNAIBODE), the French society for digestive endoscopy (SFED) and the French association of biomedical engineers (AFIB), to render a formal (commented) opinion concerning the substance and form.
The review group's comments were analysed and debated by the work group convened in plenary session on 10 January 2018 on HAS premises. A new version drafted during the meeting following the various arbitrations, was approved by all WG members. Two examples of CRSAE concerning a fire in the operating room and derived from the new HAS CRSAE database (2018), were added.

PSS follow-up and updates

The PSS will initially be included in the annual accreditation programme in the form of a general recommendation. Its implementation will be a prerequisite for meeting the requirements of the accreditation system (individual or team). Each approved body will be in charge of compiling the declarations into a report, with dysfunctions following PSS application.
It will then be possible, 24 months after implementation, to assess practices based on use of the key points. This could take the form of a survey conducted by the approved bodies and submitted to the approved physicians, in terms of satisfaction (legibility, PSS availability, suggested improvements, etc.), knowledge (is the content of the PSS known?), practices (improvements achieved, MMR, procedures) and results (number of CRAEs declared).
An update may be considered depending on equipment developments, or changes to practises.

Bibliographic note

In the international literature, the causes and mechanisms identified (Siddaiah-Subramanya, 2017) are similar to those found in the accreditation system CRAE analysis. These studies also mention a risk of accident associated with the use of power sources of circa 0.1 to 0.4%, for all types of surgery. This risk is doubtless underestimated, with three times more incidents reported in some situations such as laparoscopy. Their true (large-scale) incidence, however, is difficult to quantify without a prospective register and despite the regulatory obligation to submit materiovigilance declarations.
For information, in the United States, in 2017 the Food and Drug Administration estimated between 200 and 600 fires on patients each year, causing severe burns with 2 to 5 deaths, along with approximately 40,000 patients burned by electrical surgical instruments.
The literature also highlights lack of knowledge concerning electrosurgical device use (Meeuwsen, 2017 and Jones EL, 2017), along with a growing awareness of the need to propose electrosurgical device usage training to professionals (Jones SB, 2017).
In France, there are no precise figures, but estimates pertaining to visceral and biliary wounds, intestinal wounds, along with interference with implantable cardiac devices. Moreover, reports of fire and burn risks after concomitant use of an alcohol-based prep solution and an electrosurgical device have regularly been declared to the French health products safety agency (ANSM). In 2009, this latter issued best practices guidelines for the use of alcohol-based prep solutions, which were updated on 19 March 2012 (ANSM, 2012). A new materiovigilance alert was issued on 26 February 2018 following a new serious incident that occurred in October 2017 (ANSM, 2017).

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