Clinical Assessment

Report by

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Assessed Object:

RF Unit and CPC Plasma Coagulator

Basis of Assessment:

EC Guidelines 93/42/EEC (MDD)

Test Objective:

Test of the submitted clinical data with regard to guideline conformity

Report

In accordance with the guideline 93/42/EEC of the European Council

dated June 14, 1993

By Dr. med. U. Fuhrmann

Surgeon

The report is being requested by Söring GmbH

Re.: Söring RF units and CPC plasma coagulator

The assessment is based on a three-month period of tests performed on occasion of conventional surgery (hepatectomy, liver transplants, resections of large retroperitoneal tumours, and surgery in the anorectal area). The unit was also applied in thorax surgery for pleurodesis and for haemostasis of large wound areas after decortication. In the sector of least invasive surgery, we used the unit for coagulation of the liver bed after complex cholecystectomy and during a laparoscopic partial hepatectomy.
The assessment of the unit mainly focuses on the practical aspects, with a distinction being made between the RF coagulator and the beamer. The purely technical assessment can only be performed by appropriately authorised institutions. The medical and especially the surgical assessment shall focus on the following criteria:

1. Coagulation effect and cutting performance as well as output control in visceral surgery,
least invasive surgery
thorax surgery
2. Convenience of operation and handling
3. Stability and reliability
4. Security and service life, sterility

Chapter 1.
The unit to be tested combines a conventional bipolar RF coagulator with an inert gas coagulator. The task of this surgical tool is to effect a coagulation by means of RF current in order to reduce the loss of blood during surgery. The unit allows RF power to be transferred to the tissue via a metallic cutting edge or a larger electrode and also via an inert gas ionised by the RF current that, as a plasma, locally generates heat which results in a superficial coagulation (inert gas beamer, briefly: beamer). The unit allows both techniques to be applied during surgery. The handpieces for the RF components with RF cutting edge and beamer are separated.

The output power can be easily controlled on a clearly structured display by appropriately trained assistants. In the cutter mode, even heavily adipose subcutaneous tissue of bad conductivity can be easily cut with little bleeding. Even larger bypass veins of the abdominal wall which may cause heavy bleeding especially during laparotomy for liver transplantation are being safely coagulated with risk of starting to bleed again.
Spot coagulation via tweezers is always reliable. The output power required is sufficient in all cases. The output stages are suitable for practical use.

The output for beam coagulation is designed in analogy to conventional coagulation. The inert gas flow is matched to the RF output but can also be separately adjusted. The area coagulation is very effective; the positive effect becomes specially visible during coagulation of large area retroperitoneal bleeding and bypass veins. Using a reduced output, layered dissection of accretions is possible without risk of coagulation necroses with secondary perforation of hollow organs. The handpiece features a short tip for easily reachable, superficial tissue and also a long tip that has proven its worth in deeper regions that can be less ideally reached.
For least invasive laparoscopic cholecystectomy, a reduced inert gas flow is applied because on some occasions a pneumomediastinum was observed after higher flow rates (Farello 1992). The coagulation effect, e.g. on the liver bed after laparoscopic cholecystectomy is sufficient under these circumstances; this instrument therefore is a valuable supplement for this area of surgery. The beamer proves very effective even in this sector when large areas of capillaries must be coagulated, e.g. in the case of chronic colecystitis, laparoscopic heparectomy and sometimes sigma resection. In case of an acutely edematous cholecystitis, it is even possible sometimes to free the gall bladder out of the liver bed; however, the formation of smoke and vapours deteriorates the visibility, making frequent cleaning of the optics necessary. Handpieces with a lateral exit for the inert gas are an ideal supplement. Especially in least invasive surgery, this results in more freedom so that otherwise inaccessible areas can be easily reached.
This handpiece has also proven its worth during thoracoskopic surgery, e.g. in case of pleurodesis or decortication. Schippers who performs a pleurodesis of the upper thorax aperture for relapse prophylactics with the beamer confirmed our positive

experience (Schippers 1994). As the thorax wall is not as flexible as the abdominal wall due to the ribs, the freedom won by the lateral exit of the inert gas beam is of special importance.
There is no doubt that the indication options have not yet been fully evaluated and that there is a potential for an even more beneficial application of this method.

Chapter 2.
When fitting the various different handpieces, the unit uses a detection system for automatically setting the required parameters for RF current or inert gas flow and for testing these parameters during a self test. This significantly facilitates handling and application in various areas, such as least invasive and conventional surgery, while at the same time providing additional security.
The applicators as such can be handled very conveniently and are very ergonomic. They are activated with a foot switch that turns on the RF current.
The cables are elastic and of a low weight. They hardly impede the handling of the handpiece. They can be easily and quickly replaced once they have become unsterile.

The elongated handpieces for least invasive surgery can be readily introduced through 5-mm trocars. The gas flow is automatically reduced; this is a vital feature because air embolism has been described after beamer application occurring, however, in case of gas flow rates also applied during conventional surgery.

The comprehensive and well-structured operating instructions cover all steps necessary for commissioning and controlling the RF generator and the beamer. Operation is described in a clearly understandable language, accompanied with good illustrations, ensuring reliable reactions of the unit. Error messages are only understandable up to a certain degree, requiring expert help in most cases (see: Self test).

Chapter 3.
Before starting, the unit performs a self test of a certain duration; this ensures the security and reliability of the system.

The unit has a robust design, exchanging the inert gas bottle is easily done, the handpiece adapters engage securely with a discernible click, the seals are sufficient.

Chapter 4.
As has been mentioned before, the unit performs a self test indicating any system errors that may occur prior to starting. The unit also features a fully developed warning system that issues an appropriate warning in case of errors or when a handpiece has been disconnected. The inert gas volume can also be displayed to

ensure replacement of the cylinder in due time, eliminating the risk of an interruption or disturbance during surgery.
The handpieces feature a screw-type adapter for tips of different lengths; these connections are reliable and tight. The connections are sufficiently robust to prevent loosening of the tips even in case of blunt resection with the tip and to maintain good electrical contact. The isolation is more than sufficient; puncturing of the radio frequency has not yet occurred. The surfaces are smooth without projections. Cleaning of the handpieces poses no problems once the application tips are removed; all blood remainders and other items are removed. The handpieces are suitable for autoclave sterilisation. Sterility can thus be fully ensured.

All in all it can be stated that the tested unit has proven its worth in clinic application. It had been deliberately put to test in complex surgery where in most cases the beamer was used. The radio frequency generator is sufficiently powerful and works reliably, the output stages are well defined for both the cutter and the coagulation mode. The handpieces and the flexible leads allow good and easy handling. The standard RF component and the beamer are well adapted to each other; however, the partial components can only be used one at a time.
All in all, the RF device and CPC plasma coagulator are an important supplement to the range of surgical instruments; under consideration of the latter point we can therefore agree to an approval of the unit.

Dr. med. U. Fuhrmann

Reference

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