# GYNAECOLOGY

GYNAECOLOGICAL APPLICATIONS FOR BOWA ELECTROSURGICAL SYSTEMS

HYSTEROSCOPY | ADNEXA RESECTIONS | HYSTERECTOMY | ENDOMETRIOSIS | MASTECTOMY | CONISATION

## IMPORTANT INFORMATION

BOWA-electronic GmbH has taken the greatest possible care in the drafting of this brochure and in the accuracy of the information contained herein. However, it is not possible to rule out errors completely.

No claims may be asserted against BOWA on the basis of the recommended settings, information and data presented. Should legal liability result, it will be limited to intentional and gross negligence. All information on recommended settings, points of application, duration of application and the use of the instruments is based on clinical experience. Some centres and physicians will have a preference for settings that differ from those recommended here.

The values given herein are guideline values only and must be verified by the user.

Depending on the individual circumstances, it may be necessary to deviate from the information given in this brochure.

Medical technology is continuously advancing through ongoing research and clinical experience. Therefore, it may be advisable to depart from the settings recommended here.

To improve readability we may refer to either the female or male gender throughout our publications. Naturally, the information applies equally to both genders.

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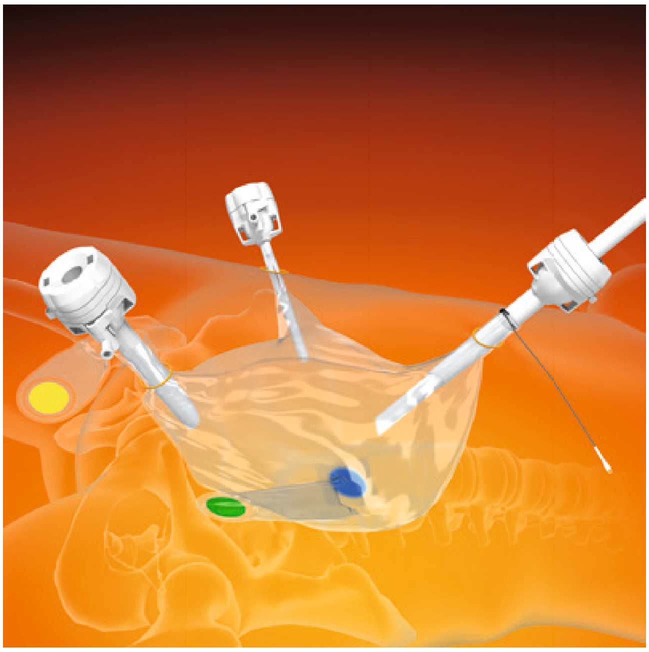
# PRODUCTS FOR GYNAECOLOGY

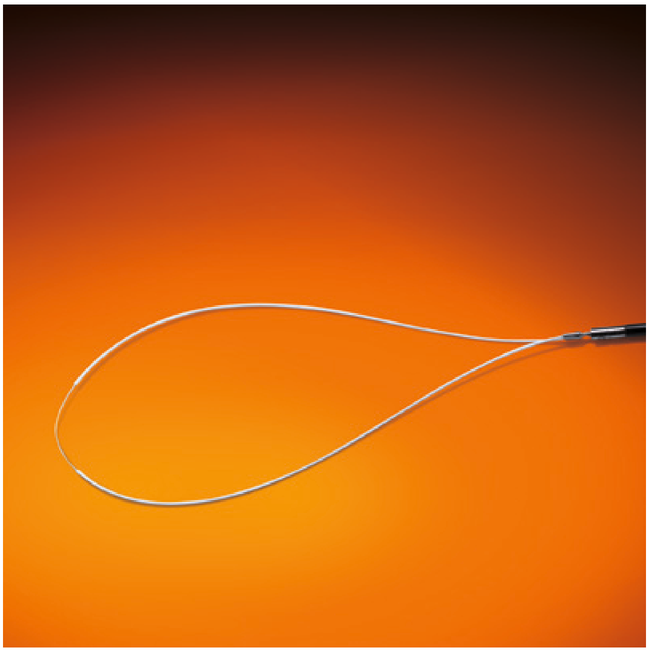
**Gynaecology work station**



**MetraBag** Tissue morcellation

**LOTUS** Ultrasonic scalpel

**ERGO 315R** Vessel sealing



**MetraLOOP**

**BiZZER** Bipolar scissors

**TissueSeal PLUS** Vessel sealing

# 1 | FUNDAMENTALS OF MODERN HIGH-FREQUENCY SURGERY

## 1.1 | THE HISTORY OF ELECTROSURGERY[1]

The concept of treating tissue with heat dates back to the era of Egyptian papyri and took the form of ferrum candens ("glowing iron") throughout antiquity up to the surgical use of ligatura candens (electrical cutting snare) following the discovery of galvanocautery in the 19th century.

It was not until the 20th century that high-frequency surgery (HF surgery) was developed in its current form. In this surgery, heat is generated directly within the tissue itself. This is different to previous techniques in which heat was transferred to the tissue through heated instruments.

The first universal instruments based on thermionic valves were developed around 1955, followed by transistor-based instruments in the 1970s and the argon beamer in 1976. Microprocessor-controlled HF surgical instruments have been available since the start of the 1990s. These allowed, for the first time, numerous parameters to be varied to precisely match the current characteristics to the treatment.

## 1.2 | FUNDAMENTALS OF MODERN HF SURGERY[1]

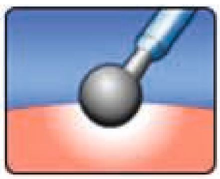
Depending on its nature, value and frequency, the action of electrical current on tissue may be described as electrolytic (destructive), faradic (stimulating muscles and nerves) or thermal. HF surgery is based on alternating currents with a frequency of at least 200 kHz, with the thermal effect dominating. Its effect is primarily dependent on the time for which the tissue is exposed to the current, the current density and the specific resistance of the tissue, which generally decreases with increasing water content or blood circulation. In practice, it is also necessary to consider the portion of current that flows past the target tissue and can heat and damage other regions (such as during irrigation).

## 1.3 | ELECTROCOAGULATION[1]

A coagulation effect results if the tissue is heated relatively slowly to a temperature of more than 60 °C.

*BOWA ARC 400 electrosurgical unit*

This haemostasis involves numerous changes in the tissue, including the denaturation of protein, the evaporation of intra- and extracellular water and the shrinkage of the tissue.

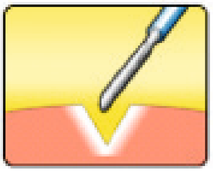


*Mode icon for moderate coagulation*

Various types of coagulation are used in HF surgery. The procedures differ depending on the characteristics of the current and application; these include contact coagulation, forced coagulation, desiccation (coagulation through a needle electrode), spray coagulation (fulguration), argon plasma coagulation (APC), bipolar coagulation and bipolar vessel sealing.

## 1.4 | ELECTROTOMY[1]

HF surgical cutting is achieved using currents greater than 200 V and a high current density at the active electrode. The high level of energy applied in this process causes the cell membranes to burst and the tissue to be separated. The aim is to be able to generate a stress-free cut with a dosed haemostasis.



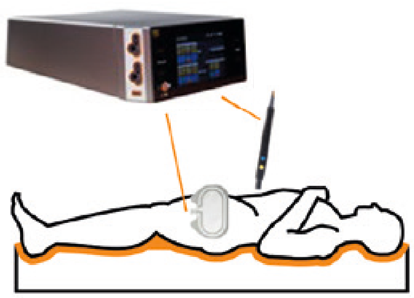
*Mode icon for standard cut*

HF surgery enables additional coagulation of wound margins by modulating the current (voltage elevation with pauses). It may be a smooth cut or a cut with more coagulation, depending on the intensity. BOWA ARC generators can regulate and adjust the intensity of haemostasis in up to 10 steps, until the desired tissue effect is reached.

## 1.5 | MONOPOLAR TECHNOLOGY[1]

Monopolar HF surgery uses a closed current circuit in which the current flows from the active electrode of the instrument through the patient to a neutral electrode with a large surface area and then back to the generator.

The contact area between the tip of the monopolar instrument and the tissue is small, meaning that the highest current density of the current circuit is reached at this point, producing the desired tissue effect.



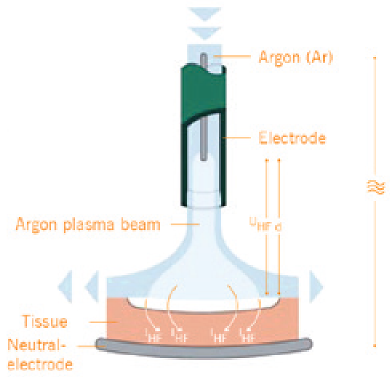
*Monopolar operating principle*

Due to the large surface area and special design of the neutral electrode, which forms the opposite pole, localised heating is reduced to a minimum in this area.

## 1.6 | ARGON PLASMA COAGULATION (APC)[1]

This monopolar procedure is a non-contact method in which the HF current flows through ionised argon gas into the tissue, so that there is no contact between the electrode and the tissue, and tissue cannot adhere to the electrode.

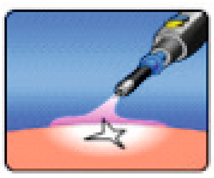
Argon, a chemically inert and non-toxic noble gas that is naturally present in the air, is delivered to the surgical site through a probe. It flows in the ceramic tip past a monopolar HF electrode to which high voltage is applied. Once the required field strength has been reached, it starts to ionise to form plasma, with development of a blue flame (the “argon beam”).




*Operating principle for argon plasma coagulation*

The electrically conductive plasma is directed automatically in the beam to the point of lowest electrical resistance and coagulates the tissue at that location at temperatures starting from 50 – 60 °C. The gas keeps oxygen away and thus prevents carbonisation (charring) that might otherwise impede the surgeon’s view due to smoke production as well as result in poor wound healing or post-operative bleeding.

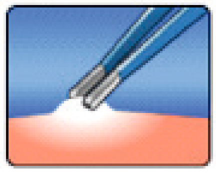
These effects enable procedures that have a low rate of complications and are safe for effective haemostasis and the devitalisation of tissue anomalies through homogeneous surface coagulation at a limited penetration depth.



*Mode icon for argon open*

## 1.7 | BIPOLAR TECHNOLOGY[1]

With bipolar HF surgery, two active electrodes are integrated into the instrument. The current flows only locally through the tissue between these two electrodes, rather than the entire body of the patient. This means that a neutral electrode is not required.

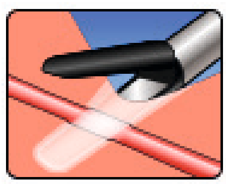


*Mode icon for bipolar method*

## 1.8 | VESSEL SEALING

Conventional electrocoagulation is unsuitable for blood vessels with a diameter of more than about 2 mm. To ensure haemostasis and to seal the vessels permanently, it is necessary to use bipolar methods or ligation: The vessel or tissue bundle is gripped using a special instrument and subjected to a constant defined pressure. Multiple automatically controlled cycles of electric current with adjustable electrical parameters depending on the tissue type are then applied to fuse the opposing vascular walls together.

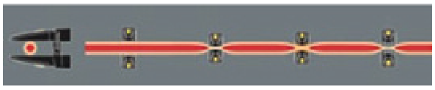
In most cases it is not necessary to prepare the vessels individually; entire tissue bundles containing vessels can be grasped and fused. The desired effect can be recognised by the translucent white coagulation zone, within which the tissue can be safely separated. In critical situations, two seals can be made next to each other and the incision made between them. Bipolar vessel sealing can seal vessels up to 7 mm in diameter.



*Mode icon LIGATION*

As the tip of the instrument is hot, care must be taken to maintain a safe distance from susceptible tissue structures and to avoid inadvertent coagulation as a result of accidental touching or when setting down the instrument.

Various studies[2–6] have shown that vessels sealed in a bipolar procedure remain securely closed. In these studies, the burst pressure was over 400 mmHg in more than 90 % of cases (in some cases, up to 900 mmHg), and thus significantly above the blood pressure values of around 130 mmHg encountered in practice.



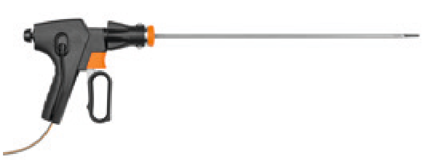
*Process of vessel sealing*

Histology shows that haemostasis in conventional coagulation involves shrinkage of the vessel wall and thrombus development.

In contrast, vessel sealing is associated with a denaturation of collagen with fusion of the opposing layers, while the internal elastic membrane remains largely intact, since its fibres only undergo denaturation above 100 °C.

A transition zone exhibiting thermal damage of about 1 – 2 mm in width and immunohistochemical changes of about double that width are observed lateral to the sharply defined homogeneous coagulation zone. This is followed by a sterile resorptive inflammation, primarily in the surrounding connective tissue, without any evidence of even temporary insufficiency of the sealing.

The advantages of bipolar vessel sealing over other methods such as ligation, sutures and the use of clips include the speed of preparation, the rapid and reliable sealing of vessels, the certainty that no foreign materials will be left in the patient and the lower costs. This results in a shorter operating time, reduced blood loss and thus less stress for the patient.



*BOWA ERGO 315R*

The ligation instruments ERGO 315R, TissueSeal® PLUS and LIGATOR® are particularly attractive because they can be re-used and thus ensure maximum cost-effectiveness.

BOWA sealing instruments are suitable for a wide range of applications, including open and laparoscopic procedures in surgery, gynaecology and urology.

## 1.9 | ELECTROSURGERY – GENERAL CONSIDERATIONS[1]

The user must be familiar with the function and use of the instruments (e.g. instruction according to the MDD, training by the manufacturer).

### 1.9.1 | SAFETY PRECAUTIONS TO AVOID ELECTROSURGICAL COMPLICATIONS[1]

- Checking insulation
- Using the optimum power setting to achieve the desired tissue effect
- Not activating if current circuit is open
- Not activating when near or in direct contact with another HF instrument
- Using bipolar electrosurgery

### 1.9.2 | NEUTRAL ELECTRODE[1]

Neutral electrodes are generally used as disposable items in HF surgery for monopolar applications. They are used to close the current circuit between the patient and HF generator on the passive side.

The main risks associated with the improper use of a neutral electrode are localised overheating or even burning of the skin at the point of contact and incorrect functioning of the HF instruments.

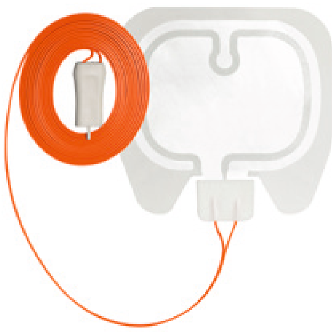
To prevent these unwanted effects, only neutral electrodes that are in perfect working order and free from defects are to be used. The intended therapeutic application for the neutral electrode, the patient population (adult or child) and the patient's body weight must all be taken into account. Any metal jewellery must be removed in advance.

The application site of the neutral electrode should be chosen so that the current pathways between the active and neutral electrodes are as short as possible and run longitudinally or diagonally to the body, as muscle conductivity is higher along the direction of the fibrils.

Depending on the part of the body undergoing surgery, the neutral electrode should be attached to the closest upper arm or thigh, but not closer than 20 cm to the surgical site and at a sufficient distance from the ECG electrodes or implants (such as bone pins, bone plates or endoprostheses). The neutral electrode must be attached so that no fluid can accumulate in the vicinity of the electrode. The electrode should be attached to clean skin without too much hair growth, and the skin must not be broken or damaged. Any agents applied to clean the skin should be allowed to dry fully. The electrode must be in full contact with the skin.

The neutral electrode must be fully in contact with the skin since the heat generated is proportional to the surface area of the electrode. The EASY neutral electrode monitoring of BOWA generators stops all monopolar activations if the contact of the neutral electrode is insufficient, in order to ensure maximal patient safety.

Particular care must be taken with patients who have pacemakers or implantable cardioverter defibrillators. Follow the instructions of the manufacturers of these devices. If necessary, the cardiologist



*BOWA EASY Universal neutral electrode*

responsible for the patient should be consulted.

No adverse effects have been reported in association with the use of monopolar HF surgery in pregnancy. However, for safety reasons it is recommended that bipolar HF procedures should be used.

The packaging of the neutral electrode should only be opened immediately before use. Once the packaging has been opened, the electrode may be used for up to 7 days, provided that it is stored in a dry place between 0 °C and 40 °C. Each electrode may only be used once and must be disposed of afterwards.

## 1.10 | INTEGRITY OF EQUIPMENT

All instruments, cables and other devices must be in perfect working order and inspected for damage before each use.

All instruments must function smoothly in their intended functions and operating modes.

Instruments that do not function correctly, are contaminated or have been used previously must not be used.

If a malfunction occurs in an instrument during treatment, the power supply must be interrupted immediately to prevent unwanted current flow or damage to tissue.

Defective devices and instruments may only be repaired by qualified personnel.

If the foot pedal is not being used, it must be kept at a sufficient distance away to prevent its accidental actuation.

## 1.11 | NEUROMUSCULAR STIMULATION (NMS)

NMS, or muscular contraction due to electrical stimulation, is a phenomenon observed in electrosurgery in general and in monopolar procedures in particular.

Appropriate use of muscle relaxants in patients significantly reduces the incidence of NMS. The advantages include a reduction in the likelihood of accidental thermal damage, the consequences of which may include intestinal perforation as a risk associated with these procedures.

## 1.12 | CONTACT WITH CONDUCTIVE OBJECTS

The patient must be sufficiently shielded against contact with conductive objects to prevent unwanted current flow and possible injury.

The patient must therefore lie on a dry, non-conductive surface.

If metal clips are present in the areas in which HF instruments (e.g. with loops or APC) are being used, they must be kept at a sufficient distance.

# 2 | FUNDAMENTALS OF ULTRASOUND SURGERY

## 2.1 | THE HISTORY OF ULTRASOUND SURGERY

(7) The first written document investigating ultrasound was published in 1774 by the Italian physicist Lazaro Spallanzani. He analysed the basic mechanism of navigation by bats in darkness. Bats use sound instead of light to orient themselves.

In 1880, Pierre and Jacques Curie discovered that electricity can be generated in a quartz crystal by means of mechanical vibration. This phenomenon is called piezoelectric effect.

In 1986, Boddy et al. published a research paper documenting the development of a hand-held ultrasonic scalpel.[8]

The first device using mechanical energy, i.e. ultrasound, was introduced for laparoscopy in the 1990s.[9]

## 2.2 | FUNDAMENTALS OF ULTRASOUND SURGERY

Ultrasound is sound waves in a frequency range above the limit of human hearing.

The frequencies of ultrasound surgery devices are between 20 kHz and 200 MHz. To be able to transmit the ultrasonic power to tissue, the instruments must be made of materials that are relatively rigid.

Ultrasonic scalpels have been used for laparoscopic surgery since the 1990s. From a technological point of view, an ultrasonic scalpel is a mechanical instrument with a vibrating blade.

The “motor” that generates ultrasound in an ultrasonic system is called a transducer. Using crystals with piezoelectric properties, the transducer converts electrical energy into mechanical vibration energy.

An alternating electrical current is passed through the crystal stack to make it expand and contract in order to achieve the mechanical movement of the waveguide.

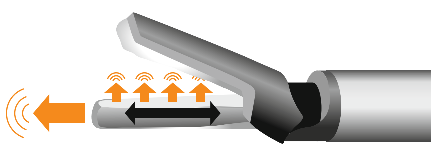
(10) Ultrasonic scalpels, which oscillate at a frequency of 36,000 Hz, act as a simultaneous cutting and coagulation instrument. The denaturation of proteins and the breaking down of hydrogen bonds in the cells leads to the formation of a sticky coagulum. This is achieved without the energy transfer of an electrical current. Vessels with highly structured proteins demonstrate stronger coagulation.

The ability to change the power settings on these devices allows for a wide range of micromotion amplitudes, which then directly determine the rate of the cut and the amount of haemostasis. Higher settings lead to an increase in micromotions and faster cutting, but reduced haemostasis. A lower power setting means a decrease in micromotions and thus slower cutting with increased haemostasis. This is particularly useful for larger blood vessels or lymph vessels with a diameter of up to 5 mm.

## 2.3 | LOTUS TECHNOLOGY

(11)Two different vibration modes of ultrasonic shears are well established: longitudinal and torsional.

Conventional ultrasonic instruments move longitudinally (lengthwise). Energy is fed in a linear direction through to the tip of the instrument, which results in stray energy being dissipated there. Unintended distal perforation of the tissue is also possible.



Schematic depiction

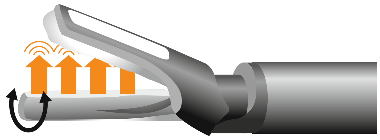
The BOWA LOTUS ultrasonic system works with patented torsion ultrasound technology, which makes the LOTUS ultrasonic scalpel particularly efficient.

In the LOTUS system, the energy is directed perpendicular (90 degrees) to the axis of the blade. Coupled with the blade geometry, the energy is focused in the region of the jaw.

When compared to conventional longitudinal instruments, the torsion energy generated in the LOTUS system reduces stray energy dissipation at the tip of the instrument.

Vessels are sealed quickly and reliably using the LOTUS ultrasonic scalpel.

The patented torsional ultrasonic technology makes the LOTUS system especially efficient.



Schematic depiction

LOTUS DISSECTING SHEARS

Dissecting shears were specifically designed for rapid and precise haemostatic tissue preparation. The thin curved shears have focusing grooves and enable accurate dissection at the desired location.

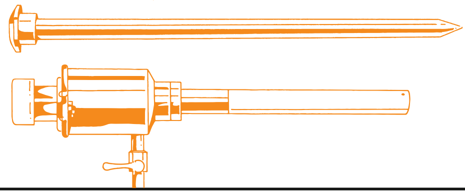
# 3 PRACTICE & METHODS

There is an increasing trend towards an endoscopic approach for surgical procedures in gynaecology. However, an open access route is still relevant for certain diseases, such as ovarian carcinomas. In general, almost all high-frequency (HF) surgical instruments can be used for both open access and endoscopic access. In this brochure, we describe the basics of modern HF surgery and common gynaecological diseases. The most appropriate instruments for the various surgical procedures are also described.

Endoscopy and laparoscopy are now used as standard in clinics and are considered routine procedures. Technical risks are rare but – as with open surgery – perforation, injury to surrounding structures or bleeding may occur.

The terms endoscopy and laparoscopy refer to a number of procedures, which are named depending on the part of the body being operated on. For example, a "gastroscopy" is a visual inspection of the interior of the stomach, using minimally invasive methods. Similarly, a "pelviscopy" is a visual inspection of the pelvic region.

## STANDARD INSTRUMENT SETS FOR A PELVISCOPY TRAY[12]

| | |
|---|---|
| Veress needle  | Trocars (11 and 6 mm)  |
| Allis forceps  | Overholt forceps  |
| Hook scissors  | Metzenbaum scissors  |
| Excision forceps  | Needle holder with straight jaw  |
| Suction irrigation tube  | |

## 3.1 | HYSTEROSCOPY[12, 13]

Hysteroscopy is an endoscopic method for the investigation, diagnosis and surgery of the uterine cavity, as well as the cervical canal. The instrument is inserted vaginally. Dilation of the portio and the cervical canal may be necessary, depending on the diameter of the instruments. A resectoscope may then be used to remove tissue.

High-frequency currents are used for haemostasis and to remove tissue. The indications for hysteroscopy are:

- Bleeding disorders
- Unusual ultrasound findings
- Diagnosis of benign and malignant tumours in the uterus
- Removal of polyps or myoma nodes that extend into the uterine cavity
- Diagnosis of factors that may lead to infertility, such as incorrect development or adhesions of the uterine cavity (e.g. uterine septum)
- Follow-up after previous procedures on the uterus
- Location and removal of spirals

The following procedures can be undertaken using a resectoscope as part of a hysteroscopy:

- Endometrial ablation / resection

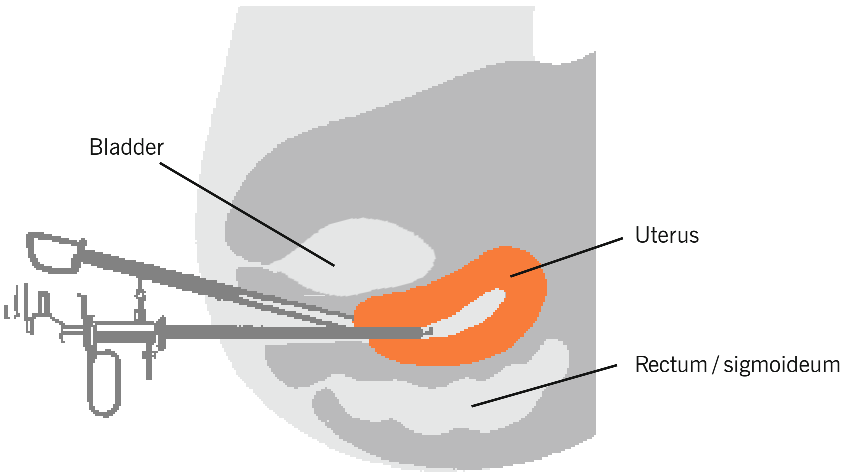
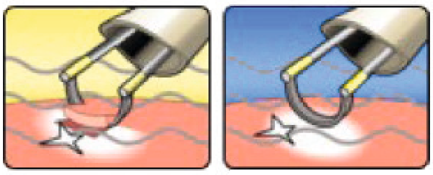



*Diagram of a hysteroscopy*

- Removal of myomas
- Removal of polyps
- Division of septum
- Removal of adhesions from the uterine cavity



*Mode icon for bipolar resection*

Although using a resectoscope is a safe and well-established method, there are also possible risks and complications involved, such as perforation, rupture or bleeding. The instructions of the manufacturer in the user manual must be followed.

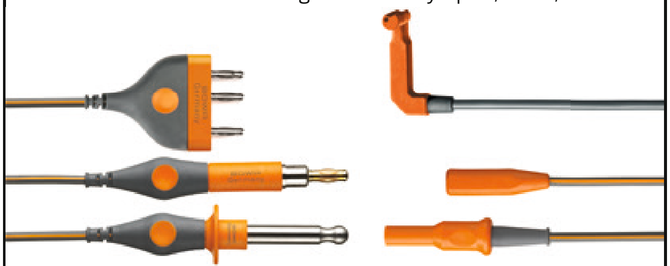
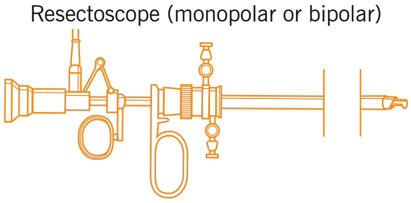
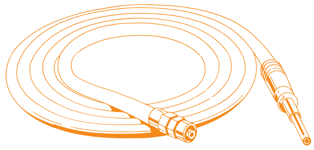
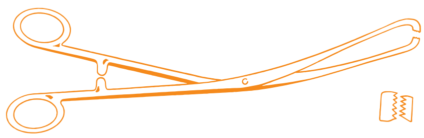
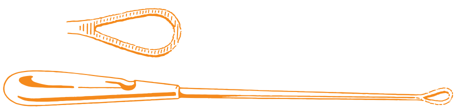
Monopolar or bipolar electrodes and loops or a rollerball may be used, depending on the requirements.

An electrolyte-free irrigation solution is required for monopolar applications. A rare complication that can occur is hypotonic hyperhydration ("TUR syndrome"). This is when electrolyte-free irrigation solution enters the bloodstream and can result in hyponatremia and hypervolaemia.

Possible consequences are circulatory disorders with nausea and confusion. However, this complication is very rarely seen in centres with sufficient experience, and can be avoided by using a bipolar resectoscope [14, 15].

Adhesiolysis can be rapidly and adequately treated in patients with placenta accreta or placenta percreta using argon plasma coagulation during a hysteroscopy[16–18].

## RECOMMENDED INSTRUMENTS FOR HYSTEROSCOPY[12]

| | |
|---|---|
| BOWA ARC 400 HF generator<br> | BOWA Comfort connecting cable for Olympus / Wolf / Storz<br> |
| Resectoscope (monopolar or bipolar)<br> | Fibre optic cable<br> |
| Optics<br> | Schroeder tenaculum<br> |
| Hegar uterine dilators<br> | Kristeller vaginal speculum<br> |
| Recamier or Sims curettes<br> | Sims uterine probe<br> |

## 3.2 | ADNEXA RESECTION

The most common reason for unilateral or bilateral removal of the adnexa (= ovaries and fallopian tubes; adnexectomy, adnectomy, salpingo-oophorectomy) is a suspected malignant tumour in this region, ectopic pregnancy or ovarian torsion.

A salpingectomy without removing the ovaries is sometimes necessary due to tubal pregnancy, a unilateral ovariectomy (oophorectomy) due to cysts or torsion of the fallopian tubes and a bilateral ovariectomy to switch off hormone production, for example in patients with mammary carcinoma.

Laparoscopy may be performed initially in patients with suspected changes to the adnexa for the purposes of confirmation. If a tumour is suspected, then the ovary should be completely removed, either endoscopically or in open surgery, depending on the circumstances. If a malignant tumour is detected, open surgery appropriate to the stage of the tumour combined with platinum-containing chemotherapy continues to be the decisive factor for the prognosis of the ovarian carcinoma. A decision on lymphonodectomy, bilateral adnectomy, HE, peritoneal resection, omentectomy, etc. depends on the stage of the tumour and factors such as age, co-morbidity, etc.

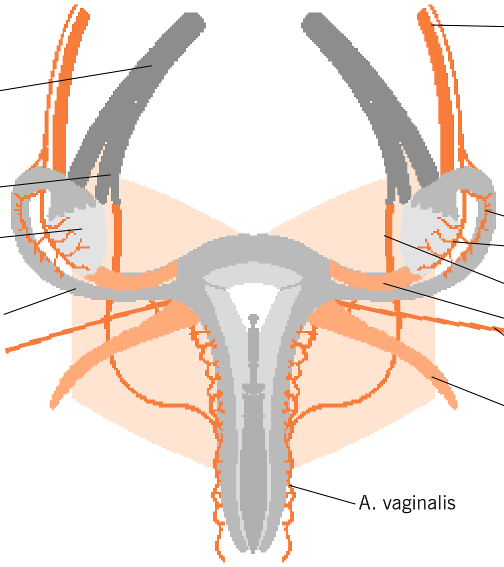



*Diagram of the uterus*

In cases of proven malignancy or in borderline cases, tissue samples should be taken during surgery and staging for histochemical preparation, and a lymphadenectomy should be performed. Further procedures should then be discussed with a gynaecological oncologist [19–21].

Electrosurgical procedures may also be used with these interventions in a wide range of applications. For example, bipolar vessel sealing is particularly suited to ligature of the vessel-carrying suspensory ligaments, such as the suspensory ligament of the ovary, and is also a valuable procedure for omentectomy.

Sensitive tissue must, however, still be protected against unwanted heating damage.

## RECOMMENDED INSTRUMENTS FOR LAPAROSCOPIC ADNEXECTOMY (IN ADDITION TO A STANDARD PELVISCOPY TRAY)[12]

| | |
|---|---|
| BOWA ARC 400 HF generator  | ERGO 315R reusable vessel sealing instrument  |
| Bipolar laparoscopic instrument  | |

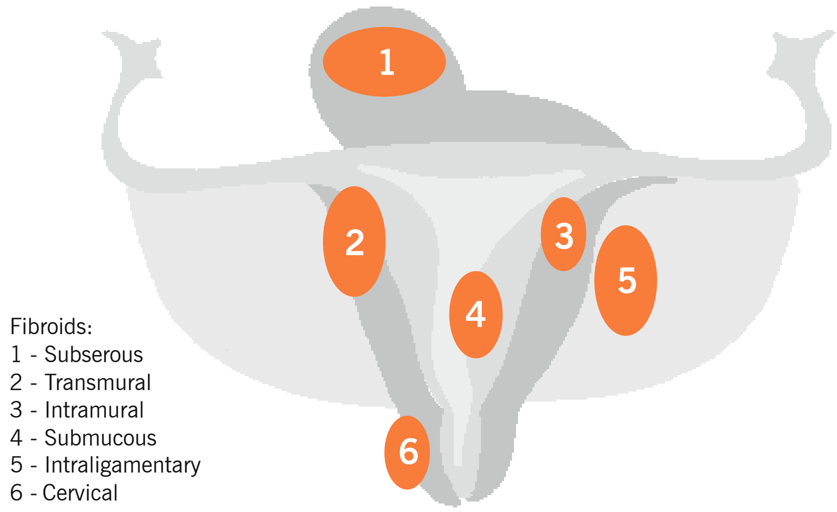
## 3.3 | HYSTERECTOMY

It may be necessary to partially or completely remove the uterus for various reasons, such as in cases of therapy-resistant dysfunctional bleeding disorders, myoma (uterus myomatosus), endometriosis or tumours[22].

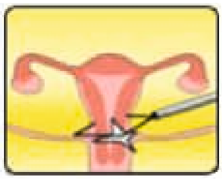
Both abdominal and vaginal access routes may be used for open procedures and endoscopic procedures. The procedure chosen depends on various factors, such as the primary disease and co-morbidity, as well as the experience of the surgeon. The procedures include abdominal hysterectomy, vaginal hysterectomy, TLH (total laparoscopic hysterectomy), LAVH (laparoscopy-assisted vaginal hysterectomy), LASH (laparoscopy-assisted supracervical hysterectomy) and extended LASH[23].

With the exception of the ligaments that extend in a posterior direction to the rectum and the os sacrum, all of the suspensory ligaments and supplying arteries and veins can be sealed in a bipolar manner during a hysterectomy. Bipolar vessel sealing leads to a significantly shorter surgery time in an abdominal hysterectomy[24].

Other electrosurgical procedures can be used, for example for opening the abdominal wall and for haemostasis. The use of bipolar vessel sealing significantly reduces the operating time, blood loss and the need for transfusion[25].




*Localisation of myomas*

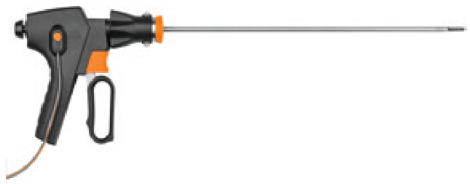
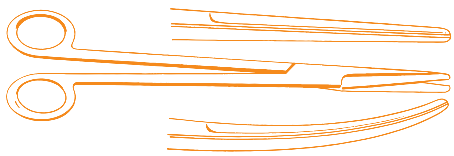
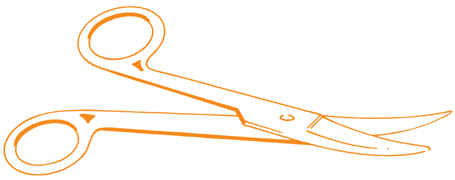
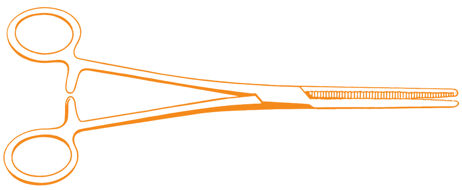
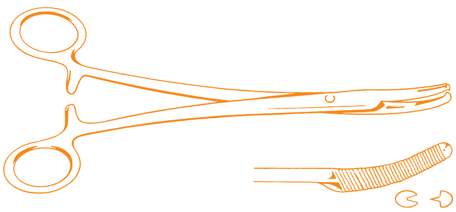
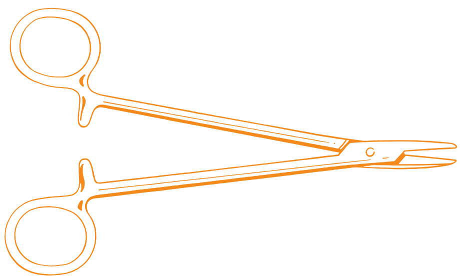


*Mode icon for MetraLOOP*

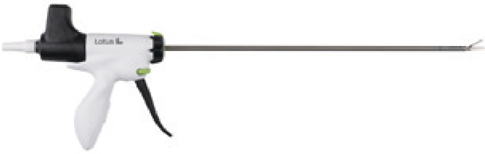
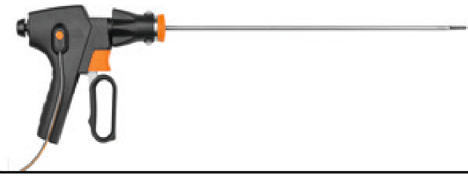
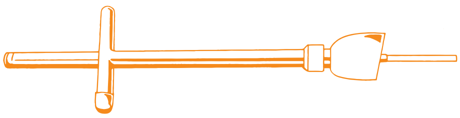
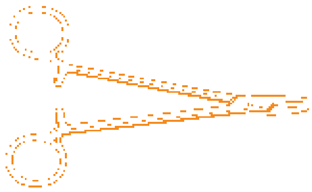
It is important to prevent thermal damage to the ureters and maintain a sufficient safety margin from temperature-sensitive tissue in the region, in particular nerves and the intestines.

In endoscopic hysterectomy procedures, a vessel-sealing instrument assists in the preparation of the upper suspensory apparatus with the proper ligament of the ovary and the round ligament. The tubes and the broad ligament of the uterus can also be coagulated and separated. In the LASH procedure, loops for removing the corpus may save time while simultaneously increasing safety with regard to the risk of injury to the bladder and intestines.

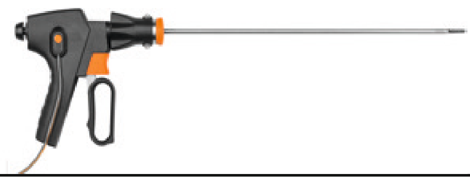
## RECOMMENDED INSTRUMENTS FOR LAVH AND VAGINAL HYSTERECTOMY (IN ADDITION TO A STANDARD PELVISCOPY TRAY)[12]

| | |
|---|---|
| BOWA ARC 400 HF generator<br> | ERGO 315R reusable vessel sealing instrument<br> |
| BOWA TissueSeal PLUS<br> | Monopolar laparoscopic hook<br> |
| Scherback speculum<br> | Doyen speculum<br> |
| Wertheim hysterectomy clamp<br> | Sims scissors<br> |
| Cooper scissors<br> | Péan clamps<br> |
| Mikulitz clamps<br> | Hegar needle holder<br> |

## RECOMMENDED INSTRUMENTS FOR TLH (IN ADDITION TO A STANDARD PELVISCOPY TRAY)[12]

| | |
|---|---|
| BOWA ARC 400 HF generator | BOWA LOTUS LG4 generator |
|  |  |
| BOWA LOTUS ultrasonic shears | ERGO 315R reusable vessel sealing instrument |
|  |  |
| Bipolar laparoscopic instrument | Monopolar laparoscopic hook |
|  |  |
| Hohl uterine manipulator | Hegar needle holder |
|  |  |

## RECOMMENDED INSTRUMENTS FOR LASH (IN ADDITION TO A STANDARD PELVISCOPY TRAY)[12]

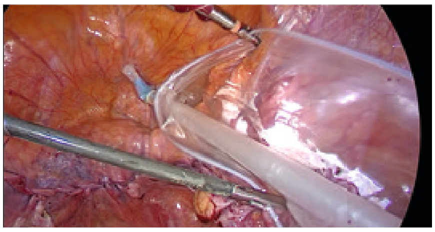
| | |
|---|---|
| BOWA ARC 400 HF generator | MetraLOOP loop for removal of the uterus |
|  |  |
| ERGO 315R reusable vessel sealing instrument | Bipolar laparoscopic instrument |
|  |  |

| MetraBag | ERGO 300 morcellator |
|---|---|
|  |  |

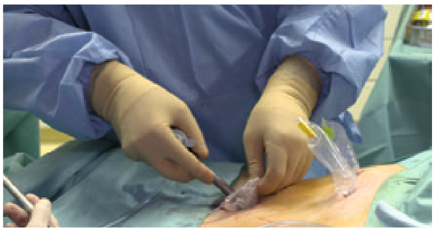
## 3.4 | MetraBag

Minimally invasive approaches have become well established in the majority of surgical fields over the last 20 years and more. Suitable isolation bags and morcellation bags must be available so that patients can continue to benefit extensively from this minimally invasive technique.

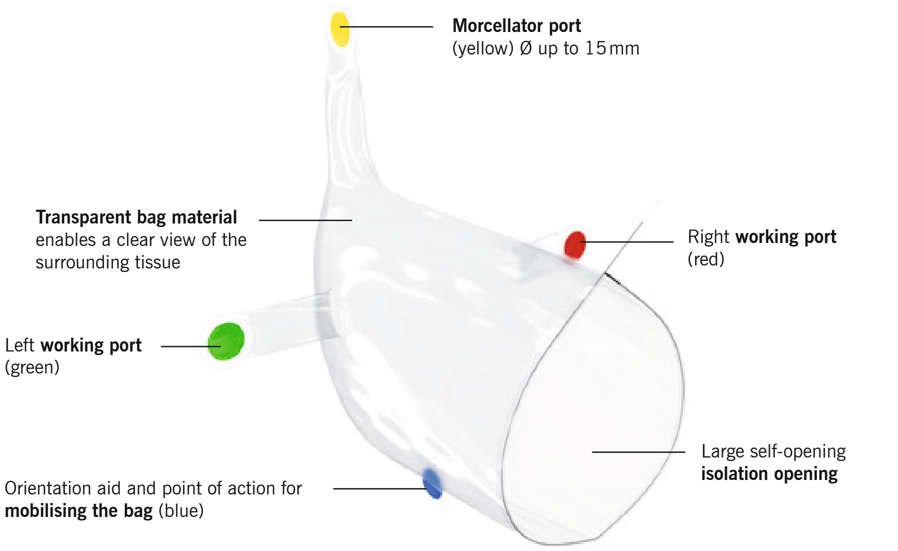
Hysterectomies and myomectomies are among the most common operations performed in the field of gynaecology. To ensure safe morcellation with minimal cell dispersion and containment of the excised material, BOWA offers a system that allows morcellation in an enclosed space.



*Intraoperative unrolling of the MetraBag*



*Positioning of the working ports to be used*




*MetraBag*

## 3.5 | ENDOMETRIOSIS

Endometriosis is defined as the presence of endometrium-like cell clusters outside the uterine cavity. It is one of the most common gynaecological diseases during the child-bearing years and is regarded as oestrogen-dependent. The main symptom is pain in the lower abdomen and, frequently, infertility. There is an associated morbidity that is noteworthy.

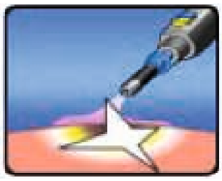
Since the aetiology and pathogenesis of endometriosis have not been definitively clarified, no causal therapy has been possible to date. Nevertheless, some diagnostic and therapeutic measures have proven effective in reducing the symptoms and overall morbidity caused by the disease.

In pathological/histological terms, endometriosis is a benign disease. It can, however, spread to other organs through infiltration and require extensive surgery.

The primary therapeutic aim is the laparoscopic removal of peritoneal lesions. It is not clear whether the various approaches – coagulation, vaporisation or excision – are of equal value.

The most effective treatment for ovarian endometriosis is its surgical removal. Surgical laparoscopy is the most suitable method for this[26,27].

A Cochrane analysis has shown that the best results are achieved through ovary-preserving removal (extraction) of the cyst body, compared with thermal destruction using high-frequency current, laser vaporisation or argon plasma coagulation, with regard to pain and rates of recurrence and pregnancy.

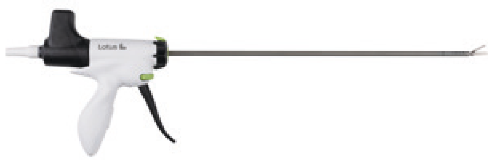


*Mode icon argon*

Treatment of ovarian endometriosis with medication alone is insufficient and is not recommended. Administration of a GnRH analogue before surgery may lead to a reduction in the size of the endometrium. In sano resection is the preferred option for symptomatic, deep-infiltrating endometriosis. Various approaches are possible for this, including vaginal resection, laparoscopy, laparoscopy-assisted vaginal procedure and laparotomy. If the endometriosis is manifest in other organs (rectosigmoid, bladder and ureter), pre-surgical planning and advice must be provided to the patient with input from specialists in visceral surgery and/or urology. If the patient wishes to have children, it is necessary to retain the uterus, which may necessitate an incomplete resection of the endometriosis[26].

Within the scope of laparoscopy, most endometriosis lesions can be safely treated using argon plasma coagulation[28–30].

### RECOMMENDED INSTRUMENTS FOR ENDOMETRIOSIS (IN ADDITION TO A STANDARD PELVISCOPY TRAY)

| | |
|---|---|
| BOWA ARC 400 HF generator<br> | ARC PLUS argon coagulation device<br> |
| BOWA LOTUS LG4 generator<br> | BOWA LOTUS ultrasonic shears<br> |
| Argon handle with electrode<br> | Bipolar laparoscopic instrument<br> |

## 3.6 | MASTECTOMY

The most common reason for a mastectomy is cancer. The aim of surgery is removal of the primary tumour with a sufficient safety margin and possible lymphonodectomy (sentinel, axilla dissection). Depending on the findings, some of the breast tissue may be retained (partial resection: segmental or quadrant resection) or a (modified) radical mastectomy is performed, if necessary with inclusion of the axillary lymph nodes, which is also possible in the sentinel approach. It is also possible with a neoadjuvant approach.

Breast-retaining therapy with subsequent radiation therapy of the entire breast is equivalent to a single modified radical mastectomy in terms of survival.

A modified radical mastectomy should be performed for the following indications:

- Diffuse, extensive calcification of a malignant nature
- Multicentricity
- Incomplete removal of the tumour (including intraductal components), including after repeated resection
- Inflammatory mammary carcinoma (also after successful neoadjuvant therapy)
- Anticipated unsatisfactory outcome in cosmetic terms with breast-retaining therapy
- Contraindications for subsequent radiation after breast-retaining therapy
- Request of the informed patient[31]

The current S3 Guidelines should be followed where possible, since failure to observe them may lead to a significantly poorer outcome[32].

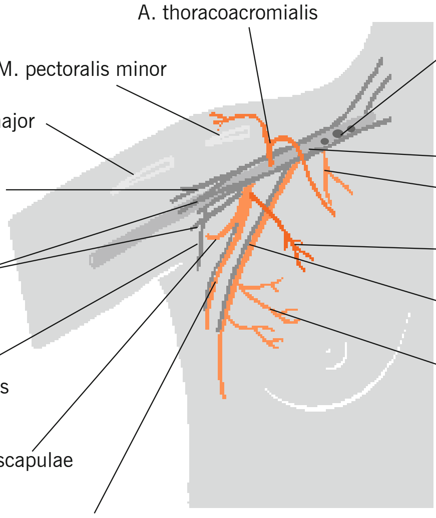



*Diagram of the vascular system of the breast*

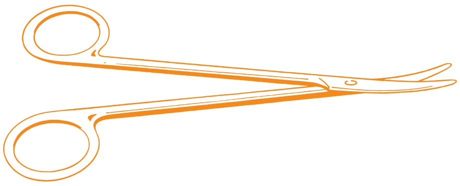
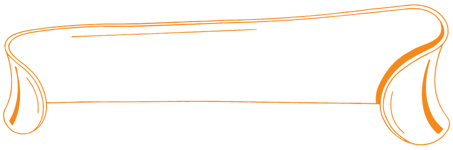
Electrotomy and electrocoagulation may be used in procedures for the breast and axilla, together with bipolar vessel sealing for ligature of the supplying vessels. Care must be taken to protect the nerves within the region being operated on (e.g., the long thoracic nerve and branches of the brachial plexus, such as the thoracodorsal nerve) to avoid postoperative paralysis or sensory damage.

*Mode icon forced mixed*

It is recommended that a surgical smoke evacuation system be used to remove the significant amounts of smoke generated during electrosurgery, to ensure a clear view of the surgical site.

## RECOMMENDED INSTRUMENTS FOR MASTECTOMY (IN ADDITION TO A STANDARD PELVISCOPY TRAY)

| BOWA ARC 400 HF generator | SHE SHA smoke evacuation system |
| --- | --- |
|  |  |

| | |
|---|---|
| BOWA SHE SHA handle  | BOWA BiZZER bipolar scissors  |
| Preparatory scissors  | Skin hooks  |
| Roux hooks  | |

## 3.7 | CONISATION[12]

Cervical conisation is performed if, in the course of cancer screening, there are abnormal cytological findings (smear test) and further clarification is required, despite a colposcopy (examination of the vagina and cervix uteri with a microscope at a magnification between x3.5 and x30) and targeted tissue sampling.

Conisation is performed in the following cases[(28)]:

- Necessity for complete histological assessment for CIN (cervical intraepithelial neoplasia)
- Discrepancy between cytological and colposcopic findings
- Changes in the cervical region that cannot be seen

Conisation is a surgical procedure[(34)] that is usually performed under complete or partial anaesthesia, with localised anaesthesia in rare cases. In this procedure, tissue in the region of the external orifice of the uterus (portio) is removed. Conisation can be performed using various surgical techniques (scalpel, laser or electrical loop). The preferred option today is the use of an electrical loop (LLETZ – Large Loop Excision of the Transformation Zone or LEEP – Loop Electrical Excision Procedure).

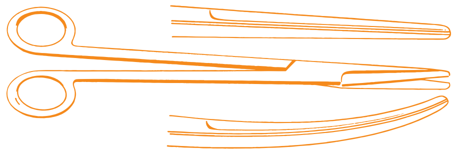
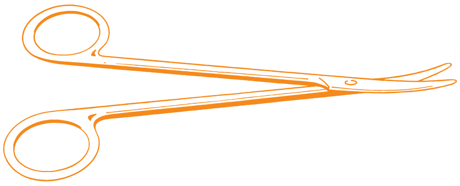
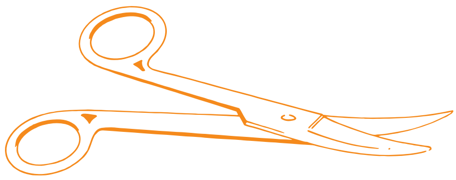
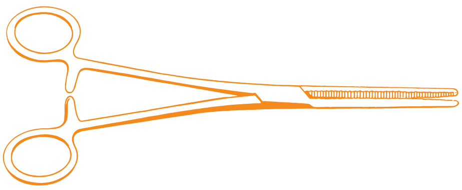
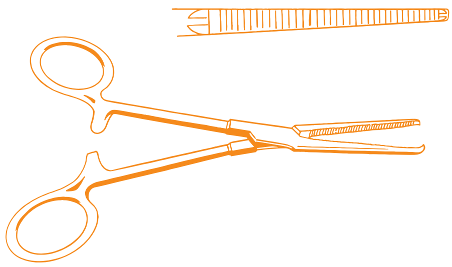
*BOWA LLETZ electrode*

Before the procedure, the bladder of the patient is generally emptied by inserting a catheter. After disinfection, opening of the vagina and, in some cases, local injection of a medication into the uterus to reduce bleeding, tissue in the region of the external orifice of the uterus is removed in the form of a cone. The depth and width of the cone depends on the age of the patient and on the pre-operative findings. If the operation is performed with an electrical loop, less tissue is generally removed than with a classical knife conisation.

It is recommended that a surgical smoke evacuation system be used to remove the significant amounts of smoke generated during electrosurgery, to ensure a clear view of the surgical site.

Curettage is then carried out in the region of the uterus neck using a curette. At the end of the procedure, the resulting wound area is electrically treated to seal it. In rare cases it may be necessary to insert a tamponade into the vagina to stop blood loss, but this can be removed a few hours later.

## RECOMMENDED INSTRUMENTS FOR CONISATION (IN ADDITION TO A STANDARD PELVISCOPY TRAY)

| | |
|---|---|
| BOWA ARC 400 HF generator<br> | SHE SHA smoke evacuation system<br> |
| Ball electrode<br> | BOWA SHE SHA handle<br> |
| LLETZ electrode<br> | Sims scissors<br> |
| Metzenbaum scissors<br> | Cooper scissors<br> |
| Péan clamps<br> | Kocher clamps<br> |

# 4 RECOMMENDED PROCEDURES BY DIAGNOSIS

The various procedures typically depend on the specific diagnoses. The following table shows the procedures and corresponding diagnoses. Deviations from these may be required depending on the clinical situation and the rules of the discipline. The applicable regulations must be observed for each discipline.

| PROCEDURE (OPS 2015) | DIAGNOSIS (ICD 10-GM) |
|---|---|
| Hysteroscopy (OPS 1-672) | **As diagnostic**<br>Detection of intrauterine bleeding<br>Clarification of suspected pathologies<br>Staging of endometrial carcinoma<br>Tracking of endometrial hyperplasia<br>Clarification of unclear cytology findings<br>Search for the reasons for infertility<br>Diagnosis of congenital malformation of the uterus<br><br>**As therapy**<br>Intrauterine foreign bodies (T19.3)<br>Polyp of the uterine body (N84.0)<br>Myoma of the uterus (D25.-)<br>Endometriosis (N80.0)<br>Intrauterine synechies (N85.6)<br>Congenital malformation of the uterus (Q51.-)<br>Transcervical access to the fallopian tubes |
| Adnexa resections (OPS 5-651, 5-652) | Follicle cysts of the ovary (N83.0)<br>Ovarian cysts (N83.2)<br>Ovarian torsion (N83.5)<br>Ovarian carcinoma (C56.-)<br>Ectopic pregnancy (O00.1)<br>Oophoritis (N70.-)<br>Unknown neoplasia in the ovaries (D39.1)<br>Benign neoplasia in the ovaries (D27.-) |
| Hysterectomy (OPS 5-683) | Polyp of the uterine body (N84.-)<br>Benign neoplasia in the uterus (D24.-, D25.-)<br>Malignant neoplasia in the uterus (C54.-)<br>Endometriosis (N80.-)<br>Uterine prolapse (N81.2-4) |
| Mastectomy (OPS 5-87) | Benign neoplasia in the mammary gland (D24.-)<br>Malignant neoplasia in the mammary gland (C50.-)<br>Hypermastia (N62.-) |
| Cervical conisation (OPS 5-671) | **As diagnostic**<br>Necessity for complete histological assessment for CIN (cervical intraepithelial neoplasia)<br>Discrepancy between cytological and colposcopic findings<br>Non-visible changes in the cervical region |
| Plastic reconstruction of the uterine tube (tuboplasty; OPS 5-666) | Infertility of tubal origin (N97.1) |

# 5 INDICATIONS & SETTINGS

The recommended instrument settings are listed in the following table for the different procedures. Deviations from these may be required depending on the clinical situation and the rules of the discipline. The applicable regulations must be observed for each discipline.

| PROCEDURE | INDICATION/ PROCEDURE | TECHNIQUE | INSTRUMENT | MODE | | SETTING | | NOTES |
|---|---|---|---|---|---|---|---|---|
| | | | | ICON | DESIGNATION | EFFECT | POWER | |
| LAPAROSCOPIC INTERVENTIONS | Hysterectomy (LASH) | Monopolar | LASH loop (e.g. MetraLOOP) | | MetraLOOP | 2 | – | CAVE: Maintain distance from nearby structures |
| | | | MetraBag | | In-bag morcellation | | | |
| | Laparoscopy Hysterectomy (e.g. LASH, TLH, LAVH) Adnex resection Endometriosis Tubal ligation Tuboplasty | | Monopolar lap. instrument | | Laparoscopy | 3–6 | 70–100 W | Always follow the general safety instructions for monopolar techniques |
| | | | | | Laparoscopy | – | 40–90 W | |
| | | | | | Forced mixed | 2–3 | 40–80 W | |
| | | | | | Argon open | – | 60–100 W | |
| | | Bipolar | Bipolar lap. instrument | | Laparoscopy | – | 40–70 W | |
| | | | Bipolar lap. scissors | | Bipolar scissors | – | 40–80 W | |
| | | | | | Bipolar scissors | – | 40–80 W | |
| | | | Sealing/ ligation instrument | | ARCSeal | – | – | Do not grab too much tissue |
| | | Ultrasound/ LOTUS | LOTUS scissors | | HIGH/LOW | | | |
| VAGINAL INTERVENTIONS | Hysteroscopy | Monopolar | Monopolar resectoscope | | Resection | 2–4 | – | Use non-conductive irrigation fluid (e.g. Purisole®) |
| | | | | | Resection (coagulation) | – | 60–90 W | |
| | | Bipolar | Bipolar Resectoscope | | Resection | 1–2 | – | Use saline solution as irrigation fluid; keep contact with the tissue during coagulation |
| | | | | | Resection (coagulation) | – | – | |
| | Conisation Hysterectomy (vag.) | Monopolar | Monop. instruments (e.g. LLETZ electrodes, knife electrodes) | | Standard | 3–7 | 80–150 W | Always follow the general safety instructions for monopolar techniques |
| | | | | | Forced mixed | 2–3 | 40–80 W | |
| | | | | | Spray | 2–4 | 80–120 W | |
| | Hysterectomy (vag.) | Bipolar | Bipolar coagulation instruments (e.g. forceps) | | Standard forceps | – | 30–80 W | |
| | | | | | Standard forceps AUTOSTART | – | 30–80 W | |
| | | | Bipolar scissors | | Bipolar scissors | – | 40–80 W | |
| | | | | | Bipolar scissors | – | 40–80 W | |
| | | | Sealing/ligation instrument | | TissueSeal PLUS | – | – | Do not grab too much tissue |
| OPEN INTERVENTIONS | Mastectomy Hysterectomy Tuboplasty | Monopolar | Monop. instruments (e.g. LLETZ electrodes, knife electrodes) | | Standard | 3–7 | 80–150 W | Always follow the general safety instructions for monopolar techniques |
| | | | | | Forced mixed | 2–3 | 40–80 W | |
| | | | | | Spray | 2–4 | 80–120 W | |
| | | | | | SimCoag | 2 | 60–120 W | |
| | | Bipolar | Bipolar coagulation instruments (e.g. forceps) | | Standard forceps | – | 30–80 W | |
| | | | | | Standard forceps AUTOSTART | – | 30–80 W | |
| | | | Bipolar scissors | | Bipolar scissors | – | 40–80 W | |
| | | | | | Bipolar scissors | – | 40–80 W | |
| | | | Sealing/ligation instrument | | TissueSeal PLUS | – | – | Do not grab too much tissue |

# 6 FAQ – USING THE BOWA TECHNOLOGY IN GYNAECOLOGY

**How does the EASY system work?**

The EASY system is used to monitor split electrodes, recognise detachments and stop all monopolar activations in the event of a malfunction, so that the risks of burns at the point of contact of the electrode are reduced to a minimum.

A dynamic reference resistance is set for the use of the neutral electrode. Once the measured resistance at the neutral electrode is 50% greater than the reference resistance, the EASY system stops monopolar activation, issues an audible signal and displays an error message.

**What are the advantages of bipolar resection?**

When bipolar methods are used, current flow is localised between the two electrodes on the instrument. This means that tissue is heated locally and the risk of damage to deeper structures is reduced. As no neutral electrode is required, there is no danger of tissue being burned.

Bipolar resection permits the use of NaCl as a conductive irrigation solution and thus lowers the risk of TUR syndrome.

**What is TUR syndrome?**

During monopolar procedures using non-conductive irrigation fluids, the solution can enter the bloodstream when the veins are opened during surgery, which may result in excess fluid, disturbance of the electrolyte balance and hyponatraemia.

The resulting symptoms are varied and can affect the central nervous system (e.g. headaches, cerebral oedema, convulsions or coma), the cardiopulmonary system (e.g. blood pressure disorders, pulmonary oedema, cyanosis) or cause general problems (e.g. abdominal pain, hypothermia and blood clotting disorders such as disseminated intravascular coagulopathy – DIC).

**What are the risks associated with bipolar resection?**

Continuous irrigation must take place and continuous activations must be avoided to prevent injury caused by heating of the irrigation solution.

If a resectoscope with a conductive external shaft is used, conductive lubricating gels must be used, otherwise the urethra could be damaged.

**If bipolar resection is used, could the patient make sudden jerking movements?**

This reaction is observed less frequently with bipolar resection, but it is recommended that anaesthesia be used if the resection is performed in the proximity of nerves.

**What is the purpose of the BOWA ARC CONTROL feature?**

The minimum power level required for a reproducible tissue effect is achieved with the arc in a fraction of a second and only the minimum quantity of energy required is delivered to the patient.

**How is the effect of the bipolar resection adjusted on the instrument?**

Three effects are available: Effect 1 for needle/knife electrodes and small loops, effect 2 for loop electrodes and effect 3 for vaporisation.

**Why is a high initial cutting power necessary?**

The powerful initial cutting mode means that the arc is deployed without delay, resulting in a smooth cutting effect without any jagged movements. The high power is only delivered during the initial cutting phase and is reduced within a fraction of a second. This is a feature of the ARC 400 and the ARC 350.

**What is the purpose of the BOWA COMFORT cable?**

The plugs are fitted with an RFID chip to enable clear identification of the instrument. The parameters are selected automatically, coupled with release of the power required for the application.

**Which resectoscopes can be used?**

BOWA offers connecting cables for monopolar and bipolar resectoscopes from Storz, Wolf and Olympus.

**Can connecting cables from the resectoscope manufacturers be used with BOWA generators?**

In bipolar resection procedures only BOWA connecting cables are to be connected to BOWA ARC generators, as these meet the requirements for the high initial cutting power and are equipped with a chip to enable maximum power.

**Can BOWA cables be used with instruments from other manufacturers?**

The connecting cables have been developed specifically for use with BOWA ARC generators with COMFORT function and are not compatible with instruments from other manufacturers.

**Can the BOWA ARC generator be used for other applications?**

The BOWA ARC 400 is an interdisciplinary electrosurgical unit that can be used in all electrosurgical disciplines.

**Can accessories from other manufacturers be connected to it?**

Standard accessories can be connected directly without an adapter, using the corresponding socket configuration.

**Can the BOWA ARC 400 also be used to seal vessels?**

BOWA offers the ARC 400 for ligation and use with numerous reusable instruments for laparoscopy and open surgery.

**How many times can BOWA cables be reused?**

BOWA guarantees that its cables with instrument identification will withstand 100 autoclave cycles.

The instrument logs and displays the number of uses. Any use of the cables beyond the specified service life is the responsibility of the user.

**How can I tell if an instrument is reusable or for single use?**

The single-use symbol is clearly marked on all BOWA single-use instruments.

Always consult the user manual before using an instrument.

**What is the difference between torsional and longitudinal ultrasound?**

In longitudinal movement, the energy is conducted through the tip of the instrument, in a lengthwise direction.

In torsional ultrasound, however, energy is generated in the transverse direction of the instrument.

**What are the differences between the frequencies at which LOTUS operates compared to Harmonic?**

LOTUS operates at 36,000 Hz and Harmonic at 55,000 Hz.

**How can I see the frequency at which LOTUS is operating?**

Once LOTUS is initiated, the LCD on the back of the LG4 generator displays the operating frequency.

**What are the maximum and minimum operating frequencies for a LOTUS transducer?**

35,500 to 36,600 Hz.

**What type of energy does LOTUS rely on to work?**

LOTUS uses pressure energy to coagulate, seal and cut tissue. The Harmonic scalpel uses only friction energy.

**What size vessels can LOTUS seal?**

LOTUS can seal vessels up to 5 mm (Ching S, 2007).

**How much rotation does LOTUS have?**

Due to the positioning of the transducer, LOTUS can rotate up to 200°.

360° rotation is achieved with a “quarter turn of the wrist in either direction”.

**How do I know which power setting the LG4 generator is on?**

The LG4 generator displays the power setting using the Mode Ring on the front of the generator.

3 blue segments indicates ULTRA LOW power.

7 blue segments indicates LOW power.

5 yellow segments plus the 7 blue segments represents HIGH power.

**Is it possible to coagulate tissue without cutting the tissue?**

When using the LOW power setting and a moderate closing of the branches, coagulation without separating the tissue is possible.

**What temperature does LOTUS reach during activation?**

Research by Ching (2007) compared the LOTUS scalpel to the Harmonic scalpel. The findings showed that the heating and cooling profile of both scalpels was similar.

However, higher temperatures were recorded at the tip of the Harmonic scalpel. The temperature of both scalpels ranges between 60° and 160° C. However, a higher temperature was recorded in the tissue when the Harmonic scalpel was used.

**When does the reusable transducer need to be changed?**

The LG4 generator will display the service life of each transducer on the LCD upon setup. Once 98 % of the transducer's service life is reached, the front of the generator displays "FINAL SURGERY".

At the end of the operation and after the transducer is disconnected or the generator is switched off, it is then locked and can no longer be used.

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FOR YOUR NOTES

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4–10
72810 Gomaringen / Germany

Phone +49 (0) 7072-6002-0
Fax +49 (0) 7072-6002-33
info@bowa.de I bowa-medical.com

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