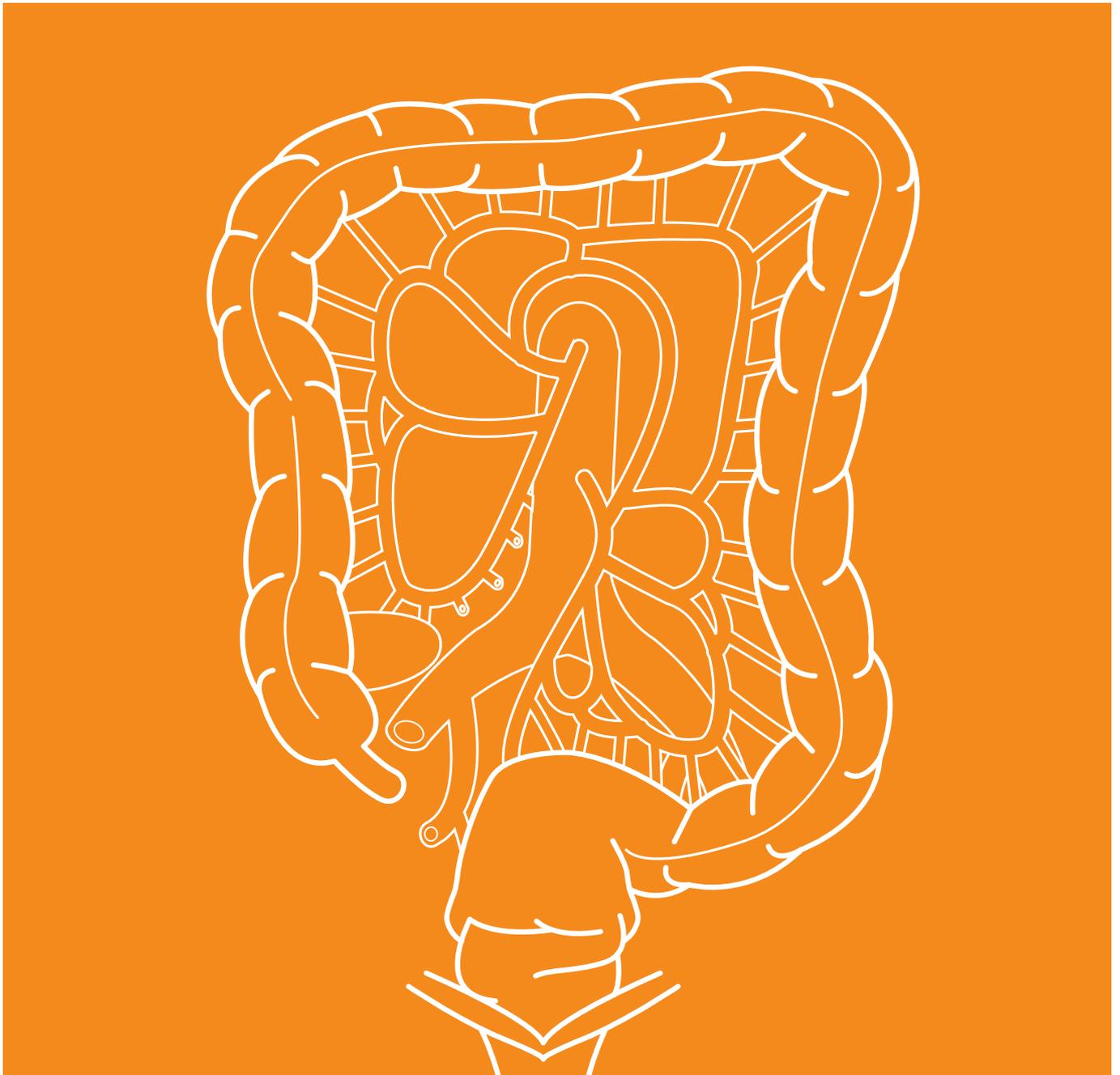


GENERAL SURGERY



SURGICAL APPLICATIONS USING BOWA ELECTROSURGICAL SYSTEMS AND ULTRASONIC SCALPELS
FUNDAMENTALS OF MODERN HIGH-FREQUENCY SURGERY | FUNDAMENTALS OF ULTRASOUND SURGERY | PRACTICE AND METHODS | RECOMMENDED SETTINGS | REFERENCES

IMPORTANT INFORMATION

While BOWA-electronic GmbH & Co. KG has taken the greatest possible care in drafting this brochure, mistakes may nonetheless occur.

BOWA is not liable for any damages arising from the recommendations for settings or other information contained herein. Any legal liability is limited to wilful intent and gross negligence.

All information on recommended settings, points of application, duration of

application and instrument use is based on clinical experience. Some centres and physicians may prefer settings other than those recommended here.

The settings indicated herein are for guidance only. The user is responsible for checking their viability.

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

Medical technology is advancing continuously through ongoing research and clinical development. For this reason, too, it may be expedient to deviate from the settings indicated in this brochure.

Although our published material may specify a particular gender for the sake of readability, any statements naturally apply equally to both genders.

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1

FUNDAMENTALS OF MODERN HIGH-FREQUENCY SURGERY

1.1 | A BRIEF HISTORY OF ELECTROSURGERY⁽¹⁾

The concept of using heat to treat tissue is first documented in ancient Egyptian papyrus scrolls, continued down through Greek and Roman times in the form of the ferrum candens (cauterising iron) and is further evidenced in the use of the ligatura candens (cutting snare) following the invention of galvanocautery in the 19th century.

However, the development of high-frequency surgery (HF surgery) as we know it today did not begin until the 20th century. HF surgery involves the generation of heat inside the tissue itself, whereas previous techniques required the transfer of thermal energy from the heated instruments employed.

The first multi-purpose devices based on thermionic valves were developed in 1955, followed by transistor-based devices in the 1970s and argon beamers in 1976. Microprocessor-controlled HF surgical devices have been available since the early 1990s. These high-precision instruments made it possible for the first time to modify a range of parameters enabling precise adjustment of the electric current for specific treatment purposes.

1.2 | FUNDAMENTALS OF MODERN HIGH-FREQUENCY SURGERY⁽¹⁾

Depending on its nature, value and frequency, the action of electrical current on tissue may be electrolytic (destructive), faradic (stimulating nerves and muscles) or thermal. HF surgery uses alternating current at frequencies of at least 200 kHz, with the thermal effect predominating. The thermal effect mainly depends on tissue-current exposure time, current density and the specific resistance of the tissue, which basically declines as the water content or blood supply increases. Another important practical factor to consider is the portion of current flowing past the target site, possibly leading to thermal damage in other areas (for example during irrigation, the risk being higher with monopolar than bipolar techniques).

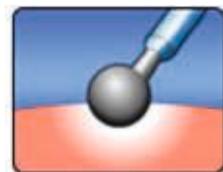
1.3 | ELECTROCOAGULATION⁽¹⁾

A coagulation effect is produced when tissue is heated very slowly to more than 60 °C.



BOWA ARC 400 Electrosurgical Unit

This process of coagulation results in numerous changes to the tissue including protein denaturation, evaporation of intracellular and extracellular water, and tissue shrinkage.



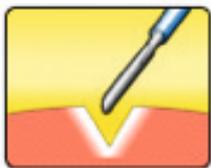
Mode icon for moderate coagulation

Various types of coagulation are used in HF surgery. The techniques differ according to the characteristics of the electric current and route of administration and include contact coagulation, forced coagulation, desiccation (coagulation using an inserted needle electrode), spray coagulation (fulguration), argon plasma coagulation (APC), bipolar coagulation, and bipolar tissue sealing.

1.4 | ELECTROTOMY⁽¹⁾

A cutting effect is achieved by raising tissue temperature very rapidly to more than 90–100 °C, producing a build-up of steam in the cells which destroys the cell walls and then acts as an insulator. An arc voltage thus develops between the electrode and the tissue, ultimately causing

(recurrent) sparking at voltages starting from about 200V with a very high current density at the base points. This arc will form regardless of the surrounding media (e. g., air or liquid).



Mode icon for standard cut

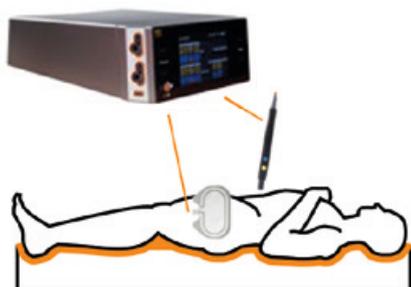
HF surgery enables additional coagulation of wound margins by modulating the current (voltage elevation with pauses). The type of cut may be smooth or jagged depending on the intensity. BOWA arc generators can fine-tune the degree of jaggedness to as many as 10 different levels depending on the requirements.

Other thermal effects of current with less relevance in HF surgery include carbonisation (charring starting from approx. 200 °C) and vaporisation (at several hundred degrees Celsius).

1.5 | THE MONOPOLAR METHOD⁽¹⁾

Monopolar HF surgery uses a closed circuit in which current flows from the instrument's active electrode through the patient to the large-surface neutral electrode and back to the generator.

The area of contact between the tip of the monopolar instrument and the patient's tissue is small. The highest current density in the circuit is achieved at this point, thereby producing the desired thermal effect.



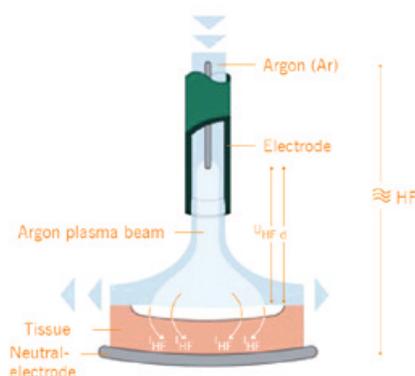
Monopolar operating principle

The large surface area and special design of the neutral electrode acting as the opposite pole reduce local build-up of heat to a minimum.

1.6 | ARGON-PLASMA COAGULATION (APC)⁽¹⁾

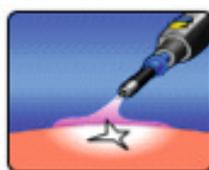
APC is a monopolar method in which the HF current flows through ionised argon gas into the tissue in a manner that avoids direct contact between the electrode and the tissue (non-contact method) and hence prevents adhesion of tissue to the electrode.

Argon is a chemically inert and non-toxic noble gas found naturally in the air. It is delivered through a probe to the surgical site and flows in the ceramic tip past a monopolar HF electrode to which a high voltage is applied. Once the required field strength has been reached, a process of ionisation to plasma begins and a blue flame appears (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 so prevents



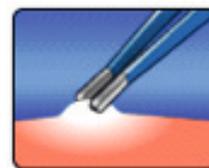
Mode icon for argon - open

any carbonisation (charring) that might otherwise impede the surgeon's view due to smoke production and result in poor wound healing or postoperative bleeding.

These effects enable safe procedures with a low rate of complications, facilitating effective coagulation and devitalisation of tissue anomalies while providing homogeneous surface coagulation at limited penetration depths.

1.7 | THE BIPOLAR METHOD⁽¹⁾

In bipolar HF surgery, the current is restricted locally to the area between the two active electrodes integrated in the instrument and does not flow through the whole of the patient's body. Hence, a neutral electrode is not required.



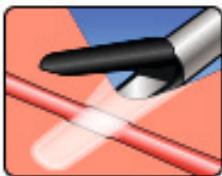
Mode icon for bipolar method

1.8 | TISSUE SEALING

Conventional electrocoagulation is unsuitable for blood vessels with diameters exceeding approximately 2 mm. Bipolar tissue sealing or ligation is necessary to be sure of achieving haemostasis and a durable vessel seal. The vessel or tissue bundle is grasped using a special instrument and compressed at a constant defined pressure. A number of 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.

Individual visualisation of the vessels prior to the procedure is unnecessary in most cases. Entire tissue bundles containing vessels can be grasped and fused. The desired effect is indicated by a translucent white coagulation zone within which the tissue can be safely separated. In individual cases it may be advisable to seal the vessel in two places some distance apart and make an incision between those sites. Bipolar sealing is technically feasible up to a vessel diameter of approximately

10mm and has been clinically validated for diameters of up to 7 mm.



Mode icon LIGATION

Since the tip of the instrument will be hot, care should 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 demonstrated that vessels sealed in this manner remain sealed. Burst pressure in these studies was higher than 400mmHg in more than 90% of cases (in some cases as high as 900mmHg) and thus well above the blood pressures of around 130mmHg typically encountered in real life.



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 denaturation of collagen with fusion of the opposing layers, while the internal elastic membrane remains largely intact since its fibres only undergo denaturation at temperatures above 100°C.

A transition zone exhibiting thermal damage of about 1–2mm in width and immunohistochemical changes of about double that width are observed lateral to the sharply circumscribed homogeneous coagulation zone. Sterile resorptive inflammation then develops mainly in the surrounding connective tissue with no evidence of even temporary seal failure.

The advantages of bipolar vessel sealing over other methods such as ligation, sutures and vascular clips include the speed of preparation, rapid and reliable sealing of vessels, the certainty that no foreign materials will be left in the patient, and lower cost. The benefits include shorter surgery times, reduced blood loss and hence a better patient experience.



BOWA ERGO 315R

The concept of reusability results in maximum cost-effectiveness and is an added incentive to use the BOWA ligation instruments ERGO 315R, NightKNIFE®, Tissue-Seal® PLUS and LIGATOR®.

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

1.9 | ELECTROSURGERY – GENERAL⁽¹⁾

Users should be familiar with the function and use of the devices and instruments (user training in compliance with the Medical Devices Directive/training by the device manufacturer).

1.9.1 | SAFETY PRECAUTIONS TO PREVENT ELECTROSURGICAL COMPLICATIONS⁽¹⁾

- Check the insulation
- Use the lowest effective power setting
- Activation of current flow should be short and intermittent only
- Do not activate while the current circuit is open
- Do not activate near or in direct contact with another HF instrument
- Use bipolar electro-surgery

1.9.2 | NEUTRAL ELECTRODE⁽¹⁾

Neutral electrodes are generally supplied as disposable accessories in HF surgery for monopolar applications and are used to

close the current circuit between the patient and the HF generator on the passive side.

The main risk associated with improper use of a neutral electrode is localised hyperthermia to the point of skin burns at the contact site and poor HF device function.

These problems can be avoided by using neutral electrodes that are in perfect working order and free of defects. The intended therapeutic application, patient population (adults or children) and patient's body weight must all be taken into consideration and any metal jewellery should be removed in advance.

The site of application of the neutral electrode should be selected 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 nearest upper arm or thigh but not closer than 20 cm to the surgical site and at a sufficient distance from ECG electrodes or any implants (such as bone pins, bone plates or artificial joints). In a supine patient, the neutral electrode must be attached to the upper side of the patient's body to avoid sticking in an area where fluids may collect and flood the device. The electrode should be attached to clean, intact and uninjured skin without too much hair growth. Any agents applied to clean the skin should be allowed to dry fully. The electrode must be in full contact with the patient's skin.



BOWA EASY Universal
neutral electrode

Full contact of the neutral electrode with the skin is necessary because the heat generated is proportional to the electrode contact area. EASY neutral electrode monitoring in BOWA generators maximises patient safety by stopping monopolar activation in the event of insufficient skin-electrode contact.

Special care should be taken in patients with pacemakers and implantable cardioverter defibrillators. Follow the manufacturer's instructions and consult the patient's cardiologist if necessary.

There are no reports of adverse events in association with the use of monopolar HF surgery in pregnancy. However, bipolar HF procedures are recommended as a safety precaution.

The neutral electrode should not be removed from its packaging until immediately before use but may be used for up to 7 days after opening if stored in a dry place at 0°C to 40°C. Electrodes are for single use only and must be disposed of afterwards.

1.10 | INTEGRITY OF EQUIPMENT

All devices, cables and other equipment employed should be in perfect working order and checked for defects prior to use.

Check the devices for smooth performance in all the proposed functions and operating modes.

Do not use devices that are defective, contaminated or have been used before.

In the event of device malfunction during treatment, interrupt the power supply immediately to prevent unwanted current flow and possible tissue damage.

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

If you are not using the foot pedal, keep it at a safe distance to avoid any inadvertent use.

1.11 | NEUROMUSCULAR STIMULATION (NMS)

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

Adequate use of muscle relaxants in the patient significantly reduces the incidence of NMS. The benefits include a reduction in the likelihood of accidental thermal damage, the consequences of which may include perforated bowel in procedures associated with that risk.

1.12 | CONTACT WITH CONDUCTIVE OBJECTS

Patients should be adequately protected from contact with conductive objects to prevent unwanted current flow and possible injury.

Patients should therefore be placed on a dry and non-conductive surface.

Take care to ensure sufficient distance from any metal clips in areas where HF devices (such as snares or APC) are in use.

2 | FUNDAMENTALS OF ULTRASOUND SURGERY

2.1 | HISTORY OF ULTRASOUND SURGERY

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

In 1880, Pierre & Jacques Curie discovered that electricity may be created in a crystal of quartz under mechanical vibration. This phenomenon is called piezoelectric effect.

In 1986, Boddy et al., published a research paper that documented the development of a hand held ultrasonic scalpel.⁽⁸⁾

In the 1990s the first ultrasonic mechanical energy device for laparoscopy was introduced.⁽⁹⁾

2.2 | FUNDAMENTALS OF ULTRASOUND SURGERY

Ultrasound is simply the name given to sound waves at frequencies above the limit of human hearing.

Frequencies of ultrasonic waves are higher, between 20 kHz and 200 MHz. To

transmit this vibration the media used in ultrasonic devices has to be relatively stiff.

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

The “motor” used for generating ultrasound in an ultrasonic system is called the transducer. The transducer converts electrical energy to mechanical vibration energy using crystals displaying the piezoelectric effect.

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

⁽¹⁰⁾Oscillating at a frequency of 36,000 Hz, ultrasonic scalpels effectively act as a simultaneous cutting and coagulation instrument. Proteins are denatured and the hydrogen bonds are broken down in cells resulting in a sticky coagulum being left. This is achieved without the energy transfer of an electrical current. Vessels that have a higher protein structure have greater coagulation.

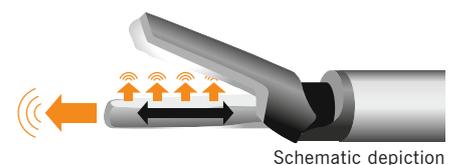
The ability to change the power settings on such a device allows for a range of micromotion amplitudes, this in turn directly

dictates the rate of cutting and the amount of haemostasis. Higher settings result in an increase in micromotions and faster cutting but a reduction in haemostasis. A lower power setting results in a decrease in micromotion and, subsequently, a slower cutting with increased haemostasis, which is useful for larger blood vessels or lymphatics up to 5 mm in diameter.

2.3 | LOTUS TECHNOLOGY

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

The conventional ultrasonic instruments are moving longitudinally. The energy is fed in a linear direction through to the tip of the instrument, which leads to stray energy being dissipated there. Inadvertent distal penetration of tissue is possible.



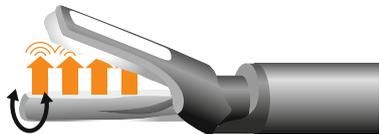
The BOWA LOTUS ultrasonic system is working with the patented torsional ultrasonic technology which makes the LOTUS ultrasonic scalpel especially efficient.

The LOTUS system's energy is perpendicular (90 degrees) to the axis of the blade. Coupled with the blade geometry, this focuses the energy into the jaw area.

The torsional energy generated in the LOTUS system reduces stray energy dissipation at the tip of the device, when compared to conventional longitudinal instrument.

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

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



Schematic depiction



LOTUS DISSECTING SHEARS

Dissecting shears are specifically designed for fast, precise haemostatic tissue dissection. The thin curved blade has focusing grooves and facilitates accurate dissection at the desired location



LOTUS LIVER RESECTOR

The liver resector is specifically made for use on liver parenchyma tissue. The larger contact surface creates a stronger haemostatic effect.

3

PRACTICE & METHODS

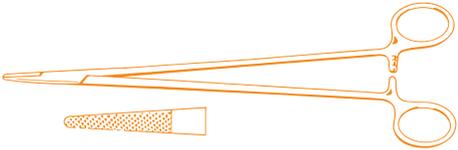
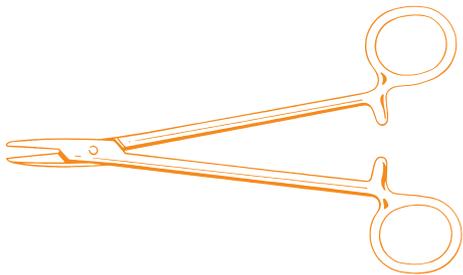
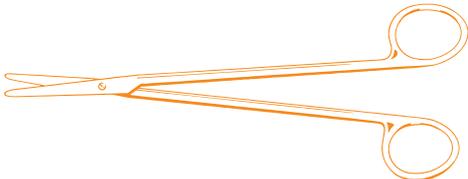
Following on from the description of the fundamentals of modern high-frequency surgery provided above, the following section of this brochure presents the most common surgical entities and explains which instruments are useful for specific surgical procedures. Endoscopy is a big and growing trend in surgery. Basically every high-frequency (HF) surgical device is available both for open surgery and endoscopy.

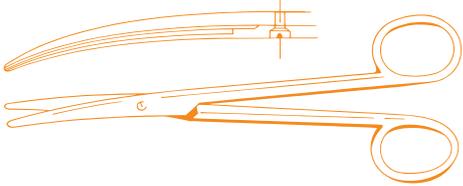
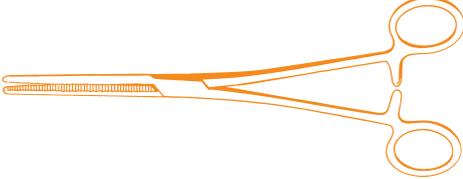
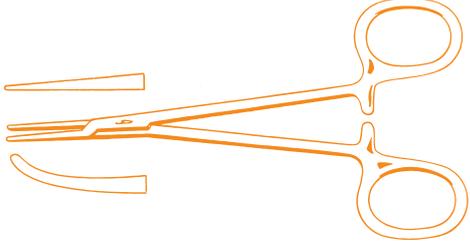
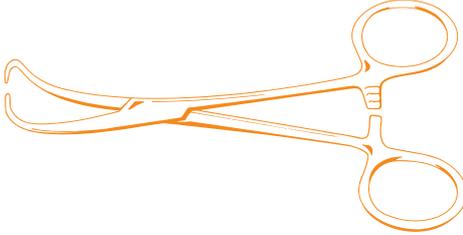
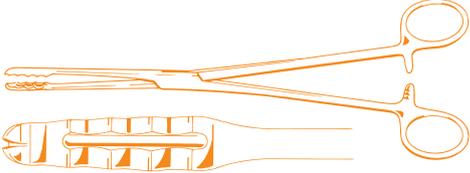
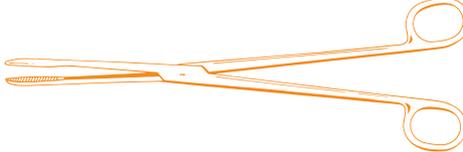
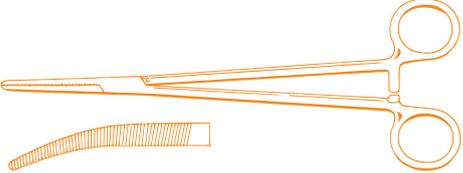
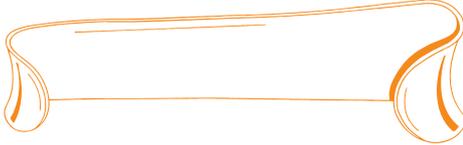
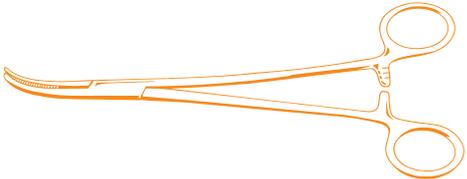
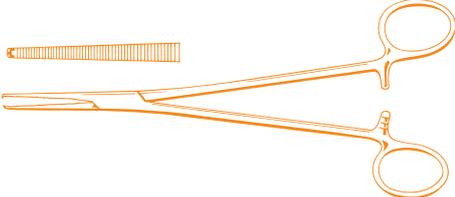
Endoscopy and laparoscopy have become the standard of care and are routine procedures in surgery today. Technical risks are rare but – as with open surgery – perforation, injury to surrounding structure or bleeding may occur.

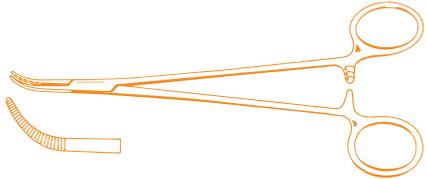
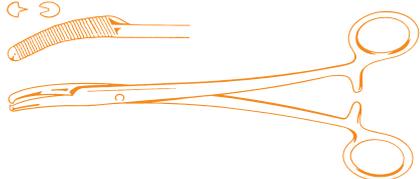
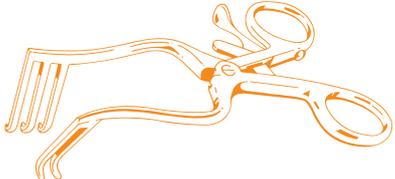
Endoscopy and laparoscopy are related terms. The main differences concern the approaches and target organs involved (procedures involving viewing the inside

of an organ/body cavity: endoscopy; procedures involving an incision through the abdominal wall intraperitoneally: laparoscopy) and type of instrument (flexible: endoscopy; rigid: laparoscopy). The relatively new surgical technique called “NOTES” (Natural Orifice Transluminal Endoscopic Surgery: surgery using natural body orifices) tends to blur the distinctions between the two terms somewhat.

3.1 | STANDARD INSTRUMENTS FOR OPEN SURGERY

<p>Scalpel</p> 	<p>DeBakey needle holder</p> 
<p>Mayo-Hegar needle holder</p> 	<p>Metzenbaum scissors</p> 

<p>Lexer dissecting scissors</p> 	<p>Rochester-Péan artery forceps</p> 
<p>Halsted-Mosquito artery forceps</p> 	<p>Backhaus towel forceps</p> 
<p>Ulrich cotton swab forceps</p> 	<p>Maier dressing forceps</p> 
<p>Bengolea artery forceps</p> 	<p>DeBakey forceps</p> 
<p>Surgical forceps</p> 	<p>Kocher retractor</p> 
<p>Volkman retractor</p> 	<p>Roux retractor</p> 
<p>Overholt-Geissendörfer artery forceps</p> 	<p>Heiss artery forceps</p> 

<p>Mixer-Baby dissecting forceps</p> 	<p>Mikulicz peritoneal forceps</p> 
<p>Allis-Thoms tissue holding forceps</p> 	<p>Fritsch abdominal retractor</p> 
<p>Weitlaner retractor</p> 	<p>Kidney dish</p> 
<p>HF handpiece</p> 	<p>Electrodes for handpiece</p> 
<p>BOWA TissueSeal PLUS vessel sealing instrument</p> 	<p>Bipolar forceps</p> 
<p>BOWA ARC 400 HF generator</p> 	<p>BOWA ARC PLUS</p> 
<p>Argon handle</p> 	<p>Rigid Argon coagulation electrode</p> 
<p>BOWA SHE SHA smoke evacuator</p> 	<p>BOWA SHE SHA handle</p> 

ULTRASONIC INSTRUMENTS FOR OPEN SURGERY

BOWA LOTUS LG4 generator



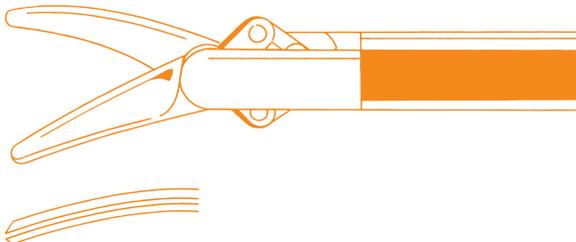
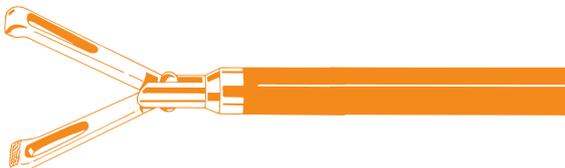
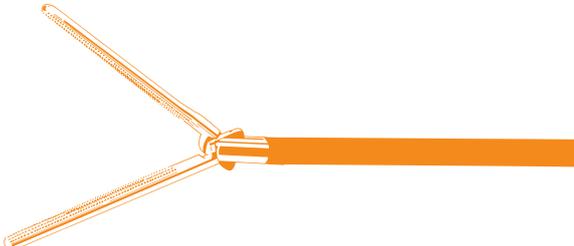
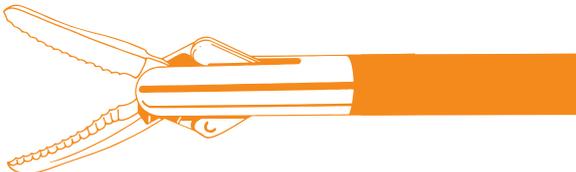
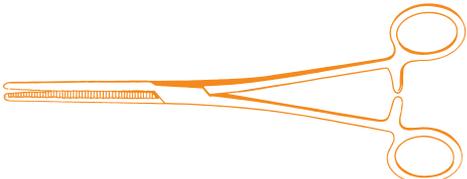
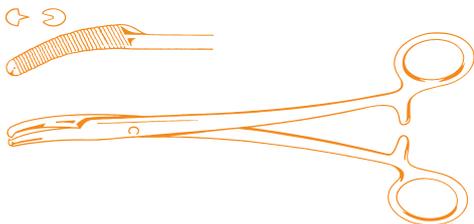
BOWA ultrasonic dissector



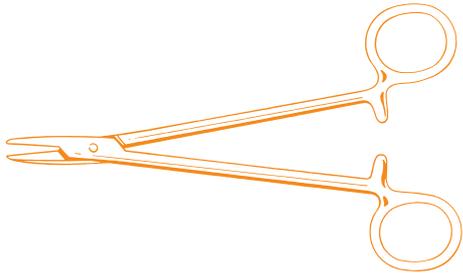
BOWA ultrasonic liver resector



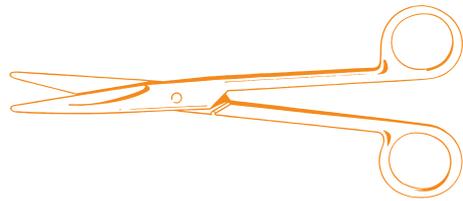
3.2 | STANDARD INSTRUMENTS FOR LAPAROSCOPIC SURGERY

<p>Scalpel</p> 	<p>Laparoscopic scissors</p> 
<p>Laparoscopic Metzenbaum scissors</p> 	<p>Laparoscopic coagulation and dissection electrode – “L” shaped</p> 
<p>Laparoscopic Duval grasper</p> 	<p>Laparoscopic DeBakey grasper</p> 
<p>Laparoscopic Kelly forceps</p> 	<p>Suction irrigation cannula</p> 
<p>Laparoscopic retractor</p> 	<p>Laparoscopic needle holder</p> 
<p>Laparoscopic clip applier</p> 	<p>Maier dressing forceps</p> 
<p>Rochester-Pean artery forceps</p> 	<p>Mikulicz peritoneal forceps</p> 

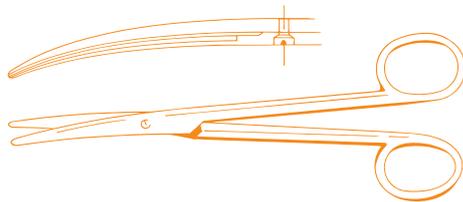
Mayo-Hegar needle holder



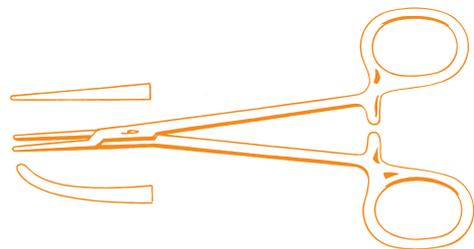
Metzenbaum dissecting forceps



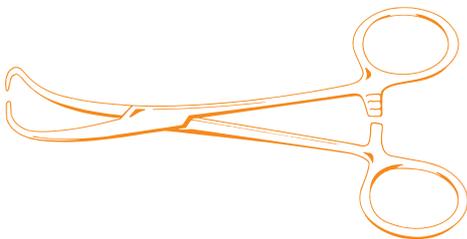
Mayo-Lexer dissecting forceps



Halsted-Mosquito artery forceps



Backhaus towel forceps



DeBakey forceps



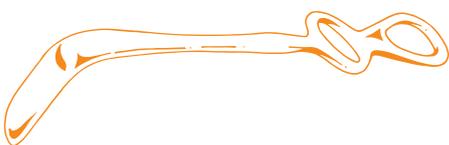
Surgical forceps



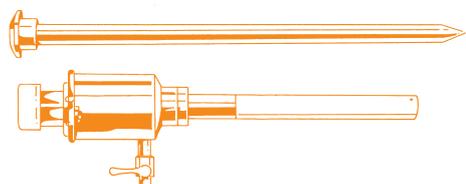
Veress needle



Langenbeck retractor



Trocars



<p>HF-handpiece with electrode</p> 	<p>Monopolar HF cable</p> 
<p>Bipolar HF cable</p> 	<p>BOWA ARC 400 HF generator</p> 
<p>BOWA SHE SHA smoke evacuator</p> 	<p>ERGO 315R reusable vessel sealing instrument</p> 
<p>ERGO 310D vessel sealing instrument</p> 	<p>Laparoscopic bipolar instruments</p> 

ULTRASONIC INSTRUMENTS FOR LAPAROSCOPIC SURGERY

BOWA LOTUS LG4 generator



BOWA ultrasonic dissector



BOWA ultrasonic liver resector



3.3 | VISCERAL/GENERAL SURGERY

3.3.1 | THYROIDECTOMY

Total or subtotal removal of the thyroid gland is performed in most cases to remove a mechanical obstruction (such as a large nodular goitre) or for functional purposes (if hyperthyroidism is present) but may also be carried out if malignancy is suspected. The procedure may be done using conventional technique or by minimally invasive video-assisted thyroidectomy (MIVAT).

In thyroidectomy, all the vessels supplying blood to the thyroid may be sealed by the bipolar method⁽¹²⁾. Sealing should take place at a safe distance from sensitive tissues, notably the trachea and nerves (vagus nerve and superior, inferior and recurrent laryngeal nerves).

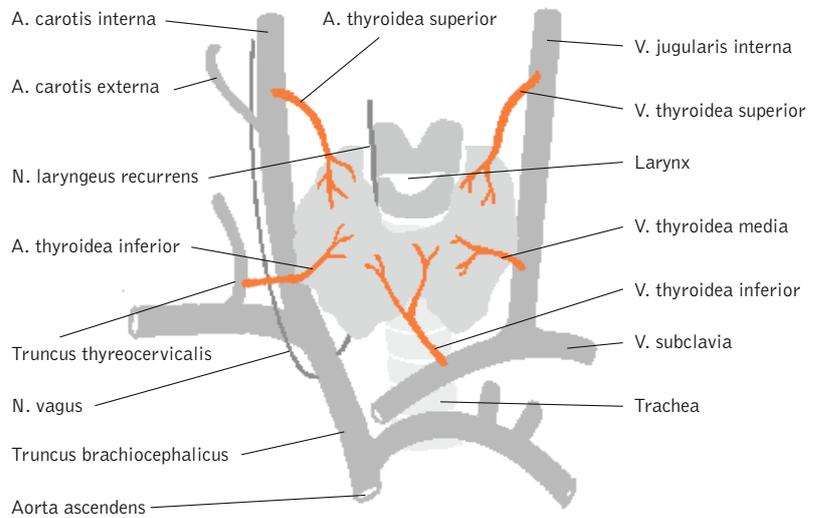
Bipolar vessel sealing for sutureless thyroidectomy significantly reduces surgery times and complications (including bleeding, recurrent laryngeal nerve palsy, hypoparathyroidism and wound infections)⁽¹³⁻¹⁵⁾. At least one preserved parathyroid gland is sufficient to prevent postoperative hypocalcaemia⁽¹⁶⁾.

Besides a bipolar vessel sealing instrument, an ultrasonic dissector like the LOTUS instrument can be used.

The subcutaneous fat and platysma are carefully dissected with the LOTUS to avoid bleeding. The first vessel to be ligated is the middle thyroid vein (when present), or the small veins between the jugular vein and the thyroid capsule. The upper pedicle including the superior thyroid artery and vein must be carefully mobilised, until optimal visualisation of the different branches is achieved. After good exposure the vessels are separated from the larynx. The vessels are then selectively ligated either by conventional vascular clips, bipolar vessel sealing or by an ultrasonic dissector. The parathyroid glands are then dissected and freed from the thyroid gland. Once all the vessels have been clipped, and mobilisation is complete, the thyroid gland can be removed.

ADDITIONAL NOTES:

The distal tip of any ultrasonic scalpel should be kept as cool as possible (so as



Anatomical overview of the thyroid

not to cause any unintentional damage to the larynx or any other structures).

3.3.2 | HERNIAS

A hernia is a defect in which an organ or part of it is displaced through the wall of the cavity containing it. Hernias are described as internal or external depending on their presentation. A hernia is called external if it is visible from the outside or the hernial orifice proceeds from the inside of the body outward to the skin. A hernia that cannot be detected without assistance is located inside the body and is hence termed internal.

Hernias of whatever kind have these three features in common:

- Hernial orifice: Hernias occur only in the presence of hernial orifices (weak spots) in the abdominal wall. These occur in most cases during embryonic development but may develop later in life following transabdominal surgery (laparotomy or laparoscopy; called trocar site hernia in the latter case).
- Hernia sac: A hernia sac develops when abdominal wall layers come apart due to permanent intraabdominal pressure or a coughing bout. This

pouch-like bulge is usually lined with peritoneum and full of hernial contents.

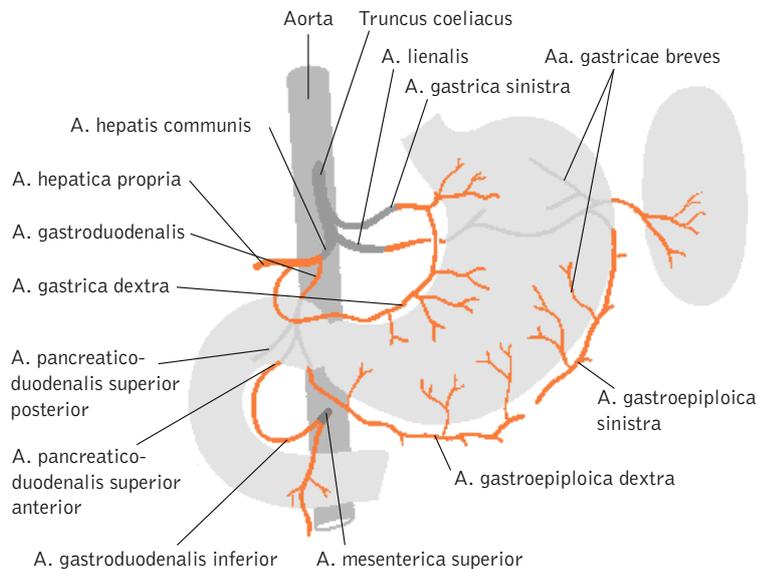
- Hernial contents: The contents of the hernial sac may be composed of organs contained within the cavity such as a small bowel loop, part of the greater omentum or part of the stomach in a hiatal hernia.

The type of surgery indicated depends on the nature of the hernia (e.g. inguinal hernia, femoral hernia or diaphragmatic hernia), symptoms and the patient's comorbidities.

According to the medical indications, there are several surgical techniques available. For example open interventions as Mayo, Bassini, Shouldice or Lichtenstein procedure or laparoscopic techniques as the TAPP (Transabdominal Pre-Peritoneal) procedure or the TEP (Totally Extraperitoneal) procedure.

3.3.3 | NISSEN FUNDOPLICATION

Nissen fundoplication may be indicated in chronic gastroesophageal reflux disease secondary to hiatal hernia or lower oesophageal sphincter dysfunction in patients who have not responded to conservative treatment⁽¹⁷⁾.



Anatomical overview of the stomach

of the stomach from the greater omentum, including the division of the gastocolic ligament, towards the gastrosplenic ligament can be dissected.

Moreover the left gastric vessels are exposed by retracting the pancreas. These are clipped or sealed with the LOTUS.

As a last step the lesser curve of the stomach is then skeletonised with LOTUS.

3.3.5 | CHOLECYSTECTOMY

Cholecystectomy is the surgical removal of the gallbladder. Surgical options include open surgery and laparoscopy. Laparoscopic cholecystectomy is the gold standard today.

Cholecystectomy is indicated in the presence of:

- symptomatic gallstones
- acute cholecystitis (ideally during the first 48 to 72 hours or in a symptom-free interval 6 weeks after an episode of acute inflammation)
- chronic cholecystitis (with and without stones)
- gallstone obstruction of the cystic duct
- gallstone pancreatitis
- malignancy

Laparoscopic surgery may be significantly more complex in the following indications and should be considered only if the surgeons involved have very high levels of expertise in minimally invasive surgery:

- severe abdominal adhesions
- biliary gastrointestinal fistula
- Mirizzi syndrome (a rare form of obstructive jaundice)
- portal hypertension

Laparoscopic surgery increases the risk of miscarriage in the final trimester of pregnancy. Therefore, conventional cholecystectomy is the preferred option in this setting.

In the conventional (open) procedure, access to the gallbladder is usually obtained by a right subcostal incision. Calot's triangle and the distal third of gallbladder are dissected to expose the cystic duct and artery which are ligated and divided; and the gallbladder is dissected off the liver bed. The wound is closed following haemostasis.

In a Nissen fundoplication, the gastric fundus is wrapped around the distal oesophagus to keep it in the abdominal cavity and to reconstruct the normally acute angle between the oesophagus and the entrance to the stomach (angle of His). Bipolar vessel sealing can be used to open the lesser omentum and cut the gastrosplenic ligament with division of the short gastric vessels for mobilisation of the gastric fundus.

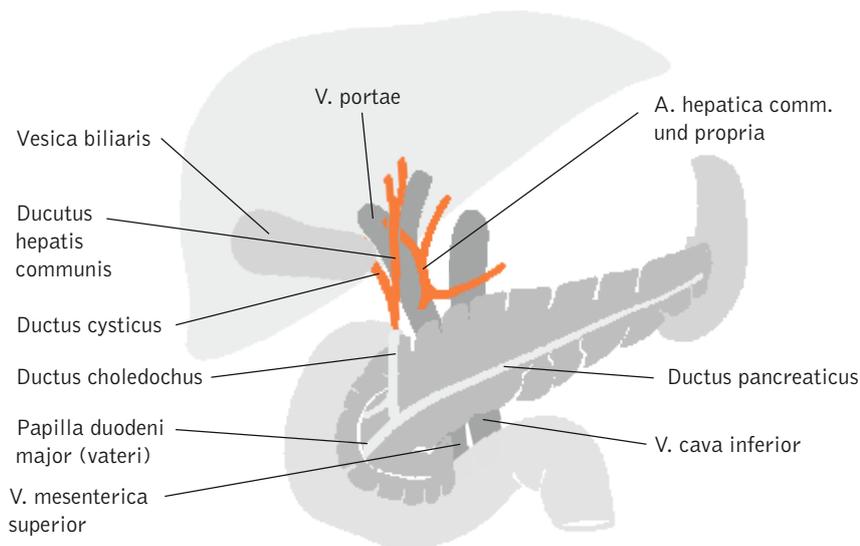
In a Nissen fundoplication, an ultrasonic dissector like the LOTUS instrument can be used for following steps:

- The gastrohepatic omentum is divided with Lotus to locate the gastro-oesophageal (GE) junction (area between oesophagus and stomach.) The next step will be to divide the phreno-oesophageal ligament to mobilise the gastric cardia (where the contents of the oesophagus empty into the stomach.) Then the right and left crus of the diaphragm are then skeletonised and extensive dissection is undertaken around the oesophageal hiatus.
- The gastric fundus (upper part) is then mobilised and short gastric vessels divided to ensure the wrap of the stomach is tension free.

3.3.4 | GASTRECTOMY

Numerous procedures are available for partial or full surgical removal of the stomach depending on the surgical indication, location and extent of resection and also on the type of anastomosis. Almost all gastrectomies performed today are to treat cancer. Elective ulcer surgery has become virtually obsolete since the availability of proton pump inhibitors. Any surgical interventions are emergency procedures to treat cases like perforated ulcers or bleeding that cannot be controlled by endoscopy or radiology. Cancer surgery options include total gastrectomy, partial distal gastrectomy (80% resection) and wedge resections. Various reconstruction options apply in the first two cases (including Billroth I, Billroth II and Roux-en-Y reconstruction). Apart from the coeliac trunk itself, basically all of the arteries and their branches emerging from it are amenable to bipolar sealing. It is important to keep a safe distance from temperature-sensitive tissues, in particular the pancreas during dissection of the greater curvature of the stomach.

With the ultrasonic dissector, for example the LOTUS instrument, the greater curve



Anatomical overview of the pancreas and its surroundings

During laparoscopic cholecystectomy the surgical site is accessed using laparoscopic instruments. The cystic duct and cystic artery are dissected at the base of the gallbladder and then clipped and tied. The gallbladder is dissected from the liver bed. The gallbladder is generally removed at the end of the procedure by umbilical trocar incision. A laparoscopic tissue extraction bag is used if necessary.

For the removal of the gallbladder an ultrasonic dissector like the LOTUS instrument can be used to dissect any adhesions around the gallbladder and the surrounding liver. An incision is made through the visceral peritoneum in which the gallbladder is encased. The cystic duct and artery are then skeletonised and clipped, one clip above (gallbladder side) and two below (cystic duct side).

The ultrasonic instrument is used to cut between the clips (avoiding activation against metal) and dissect the gallbladder away from the liver.

3.3.6 | PANCREATICODUODENECTOMY (WHIPPLE PROCEDURE)

Pancreaticoduodenectomy is the surgical treatment for patients with carcinoma of the head of the pancreas or papillary neoplasms⁽¹⁸⁾. The intervention may be by the Whipple procedure with distal gastrectomy and removal of the gallbladder and bile duct or by a modified procedure (stomach and pylorus-preserving pancreaticoduodenectomy). Total pancreatectomy may also be performed.

Various options for subsequent anastomosis also exist (including Roux-en-Y and Billroth II). Bipolar vessel sealing can be used extensively in both procedures but not in the immediate proximity of the residual pancreas, common hepatic duct or large veins (superior mesenteric vein, portal vein, inferior vena cava).

An ultrasonic instrument like the LOTUS is used during a Whipple procedure to dissect the gastro-colic ligament, dissect and divide the right gastric artery (between the clips) and the lesser omentum. The

LOTUS ultrasonic dissector can also be used for dividing the cystic artery and the hepatic peritoneal bed. Also the pancreas can be transected and the ascending part of the duodenum is mobilised using an ultrasonic dissector.

3.3.7 | LEFT/DISTAL PANCREATECTOMY

Left pancreatectomy – possibly with preservation of the spleen or with splenectomy and/or radical lymphadenectomy (for cancer of the tail of the pancreas) – may be necessary to treat trauma or cancer of the pancreas.

Again, bipolar vessel sealing can be used extensively in this procedure but not in the immediate proximity of the large veins (superior mesenteric vein, portal vein, inferior vena cava).

Bipolar sealing of the branches of the splenic veins may be used to preserve the spleen and prevent bleeding⁽¹⁹⁾.

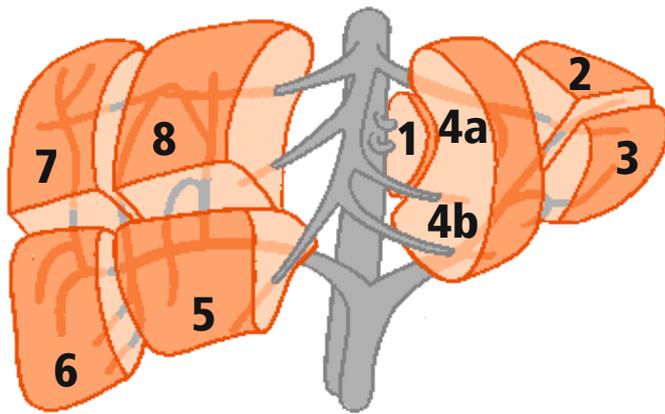
The first step is to use an ultrasonic dissecting shears for the left pancreatectomy, to section the lienorenal ligament and to dissect the subjacent fascia lateral to the spleen. Moreover the small pancreatic veins can be sealed by the LOTUS when visualised.

3.3.8 | HEPATECTOMY

An imaginary line between the inferior vena cava and the gallbladder divides the liver anatomically into a right hepatic lobe and a left hepatic lobe. Resection of the liver on this basis is called right or left hemihepatectomy.

Segmental resection follows the hepatic veins which mark the boundaries between the segments (hepatic segments I to VIII; segment IV is subdivided into IVa and IVb). Full demarcation of the segments can be done by radiology, corrosion casting or intraoperative ultrasound. Atypical hepatectomy procedures such as wedge resections do not follow segment boundaries.

Electrotomy can be used to open the liver capsule. Ligature should always be used for large vessels. Bipolar vessel sealing is recommended for peripheral blood vessels and bile ducts.



Anatomical overview of the liver segments

The better bile duct seal reduces the incidence of leaks, resulting in significantly shorter hospital stays⁽²⁰⁾.

Argon-plasma coagulation (argon beamer, APC) is an option for coagulation of the liver parenchyma in the resected area⁽²¹⁾. The penetration depth is low enough to prevent any additional tissue damage⁽²²⁾. Argon gas for coagulation stops surface bleeding with a very high degree of reliability^(23, 24).

The use of bipolar instruments to divide the liver parenchyma reduces operating times significantly⁽²⁵⁾.

For the removal of liver segments 1, 2, 3 and 4 the liver resector which uses ultrasonic movements in order to divide the falciform ligament as well as to achieve deep dissection into the liver parenchyma toward the hepatic vein.

3.3.9 | LIVER TRANSPLANTATION

Transfusion-free surgery (“Transfusion-Free Medicine and Surgery Program”) is now an option through the use of various methods to lower blood loss in orthotopic liver transplantation procedures.

These options include the use of lasers instead of scalpels and argon beam coagulators instead of thermal coagulators. Either option reduces the very high blood loss associated with liver transplantation

procedures. Controlled low central venous pressure (CVP) during anaesthesia supports the process.

Other key factors include the use of cell savers (intraoperative cell salvage, or ICS) and acute normovolaemic haemodilution (ANH). ICS recovers, cleans and re-infuses blood lost during surgery. With ANH, whole blood is taken from the patient in the immediate preoperative period and replaced with a colloid solution. This lowers the haematocrit to a predefined target

level. It is held stable during the procedure by re-infusing the removed whole blood or cell saver blood as needed.

These methods help to avoid transfusing donated blood, thus lowering the risk of infection, reducing blood bank demand and cutting costs⁽²⁶⁾.

3.3.10 | APPENDECTOMY

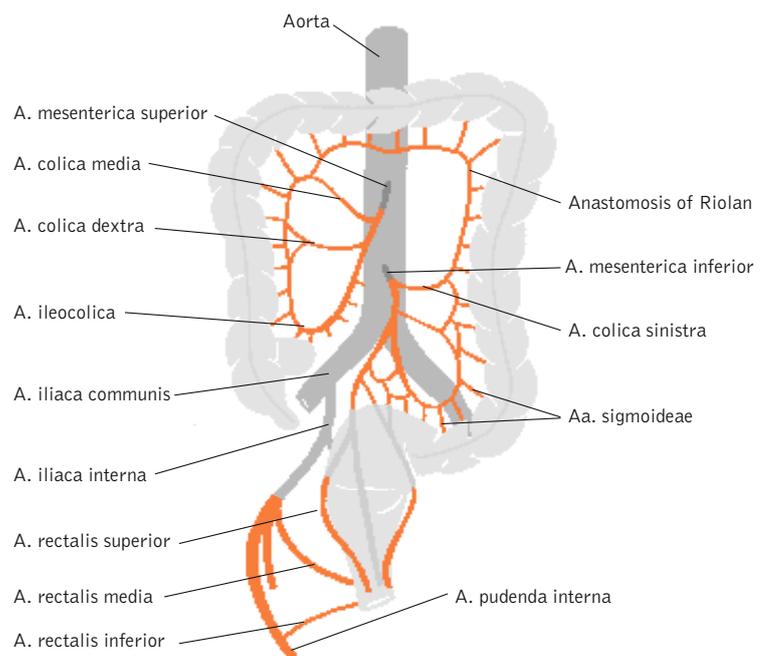
Appendectomy is the surgical removal of the vermiform appendix.

Appendectomy is indicated in the presence of:

- any clinical signs suggestive of appendicitis
- documented appendicitis.

Laparoscopy is now the standard of care throughout Germany for the treatment of appendicitis⁽²⁷⁾.

Blood supply to the vermiform appendix is cut off by ligature or electrocoagulation. The appendix is then ligated at the base and divided. Ligature is performed by the conventional method using absorbable sutures. With the laparoscopic procedure, the stump is closed using a stapler, Röder knot or special clip. The benefit of inserting a closed draining system in the presence of severe infection is controversial.



Anatomical overview of the large bowel

3.3.11 | SMALL OR LARGE BOWEL RESECTION

Bowel resection procedures are generally performed to treat benign or malignant neoplasms, diverticula or ischemia.

This diversity is reflected in the range and extent of potential interventions. Bipolar vessel sealing achieves reliable and durable sealing of all the blood vessels involved, including all of the mesenteric blood vessels apart from the superior mesenteric artery itself⁽²⁸⁾. Additionally, it offers an optimal solution for the mobilisation of the colon.

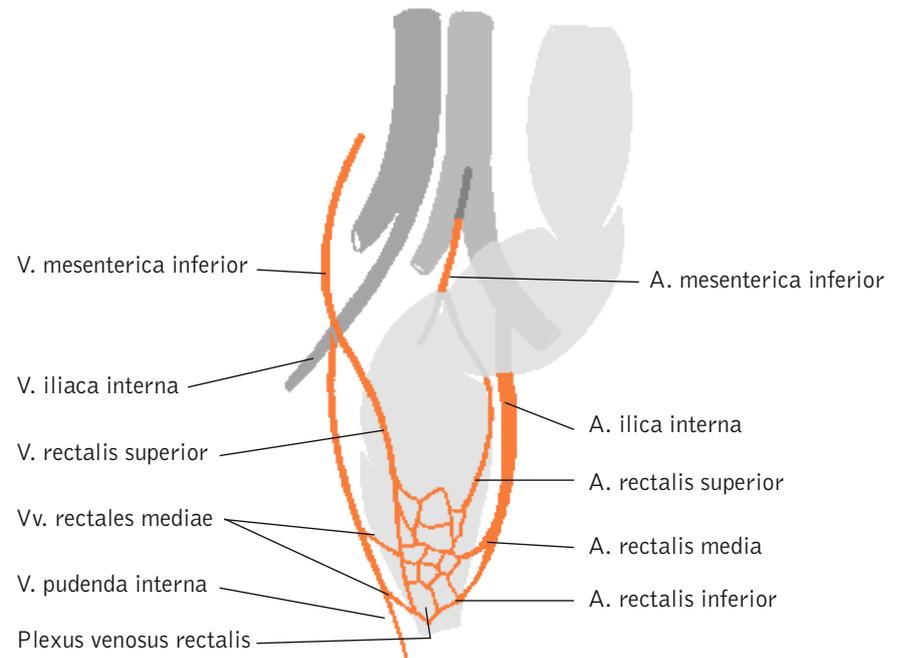
Bipolar sealing of the terminal ileum is a simple, reliable and low-cost option for short-term closure of the proximal resection margin in right laparoscopic hemicolectomy⁽²⁹⁾.

The laparoscopic procedure is preferable to open surgery in this instance as it enables quicker mobilisation of patients and significantly reduces hospital stays while providing equivalent long-term outcomes⁽³⁰⁾.

An ultrasonic dissector like LOTUS can be used to dissect the omentum from the sigmoid. As a next step, LOTUS can be used to free the sigmoid colon from its supporting structure and divide it from the remaining large intestine. An ultrasonic scalpel will be also used to free the rectum from its surrounding structures.

3.3.12 | HAEMORRHOIDECTOMY

Haemorrhoids are vascular structures in the anal canal. They become pathological



Anatomical overview of the rectum

or piles when swollen or inflamed. At this point the condition is technically known as haemorrhoidal disease. Haemorrhoids originate in the rectal venous plexus (haemorrhoidal plexus) above the pectinate line (dentate line). This structure supports stool control in the anal canal and is mainly supplied by the unpaired superior rectal artery, the most distal branch of the inferior mesenteric artery, the middle rectal artery (branching from the internal iliac artery) and the inferior rectal artery (branching from the internal pudendal artery).

In contrast, external haemorrhoids are located below the anocutaneous line (Hilton's white line) and are entirely varicose.

Bipolar vessel sealing can be used for ligation and removal of haemorrhoidal bundles near the base. Bipolar sealing achieves better outcomes in particular for grade IV haemorrhoids involving the removal of larger tissue quantities during haemorrhoidectomy⁽³¹⁾.

4

RECOMMENDED SETTINGS: A QUICK GUIDE

Recommended settings are given in the table below. Depending on the clinical setting and applicable standards of the relevant specialist discipline, it may be

necessary to deviate from the information shown here. The applicable standards of the relevant specialist discipline should always be complied with.

BOWA-electronic GmbH has used utmost care during creation. Nevertheless, errors cannot be completely excluded.

No claims against BOWA can be made based on the recommended settings and the information and data contained therein. Therefore if any legal liability arises, it is limited to intent and gross negligence.

Individual centres and doctors may favour other settings regardless of the stated recommendations.

Depending on the individual circumstances it may be necessary to deviate from the details given here.

All information on recommended settings, application sites and the use of instruments is based on clinical experience.

The specifications are only approximate and must be verified by the surgeon for their applicability.

Medicine is constantly evolving because of ongoing research and clinical experience. For this reason, it may be useful to deviate from the information contained herein.

ELECTROSURGICAL SETTINGS

PROCEDURE	INDICATION / PROCEDURE	TECHNIQUE	INSTRUMENTS	MODE		SETTING		REMARKS		
				ICON	DESCRIPTION	EFFECT	POWER			
LAPAROSCOPIC INTERVENTIONS	Colectomy, Gastrectomy, Lobectomy, Cholecystectomy, Appendectomy, Fundoplication	Monopolar	Monopolar laparoscopic instrument		Laparoscopy	3-6	70-100 W	Always follow the general rules for monopolar techniques		
					Laparoscopy	-	40-90 W			
					Forced mixed	2-3	40-80 W			
					Argon open	-	60-100 W			
		Bipolar	Bipolar laparoscopic instrument	Bipolar laparoscopic instrument		Laparoscopy	-	40-70 W		
						Bipolar scissors	-	40-80 W		
							-	40-80 W		
						Sealing- / Ligation instrument	ARCSeal	-		-
		OPEN SURGERY	Laparotomy, Colectomy, Cholecystectomy, Gastrectomy, Appendectomy, Thyroidectomy, Bowel resection, Pancreas resection, Liver resection, Liver transplantation, Haemorrhoidectomy	Monopolar	Monopolar instruments (e. g. knife electrodes)		Forced mixed	2-3	40-80 W	Always follow the general rules of monopolar techniques
							Spray	2-4	80-120 W	
	SimCoag					2	60-120 W			
Bipolar	Bipolar coagulation instruments (e. g. forceps)			Bipolar coagulation instruments (e. g. forceps)		Forceps standard	-	30-80 W		
						Forceps standard AUTOSTART	-	30-80 W		
						SimCoag	-	30-60 W		
	Bipolar scissors			Bipolar scissors	Bipolar scissors		Bipolar scissors	-	40-80 W	
							Bipolar scissors	-	40-80 W	
	Sealing / ligation instrument				TissueSeal PLUS	-	-	Do not grab too much tissue		

ULTRASONIC SETTINGS

PROCEDURE	INDICATION / PROCEDURE	TECHNIQUE	POWER LEVEL	DESCRIPTION	OUTCOME
GENERAL SURGERY	Thyroidectomy, Nissen Fundoplication, Gastrectomy, Cholecystectomy, Pancreatico-duodenectomy (Whipple procedure), Anterior resection, Small bowel resection, Right hemicolectomy	Ultrasonic Shears	Ultra Low Power 	On the Ultra Low power setting, the generator's voltage is at its lowest resulting in the smallest amount of waveguide amplitude of all three power settings.	A very controlled, haemostatic coagulation and seal on tissue with the slowest cut time.
			Low Power 	On the Low power setting, the generator's voltage is in the middle between Ultra Low and High power. This results in a greater amount of waveguide amplitude than the Ultra Low power setting but less waveguide amplitude than the High power setting.	Low power offers the user a controlled haemostatic seal and coagulation with the ability to perform a faster cut in comparison to Ultra low.
			High Power 	On High power the voltage is at its highest and therefore the waveguide amplitude at its greatest.	A faster cut time compared to Ultra Low and Low power. High power should be used on avascular tissue.
LIVER	Hepatectomy, Left pancreatectomy, Left lateral, Liver resection – removal of liver segments 2 or 3, Liver wedge, Open left resection, Open right liver resection	Ultrasonic Liver Resector	Ultra Low Power 	On the Ultra Low power setting, the generator's voltage is at its lowest resulting in the smallest amount of waveguide amplitude of all three power settings.	As a result of the active blade profile, Ultra Low is not recommend for the parenchyma.
			Low Power 	On the Low power setting, the generator's voltage is in the middle between Ultra Low and High power. This results in a greater amount of waveguide amplitude than the Ultra Low power setting but less waveguide amplitude than the High power setting.	Low power offers the user a controlled haemostatic seal and coagulation with the ability to perform a faster cut in comparison to Ultra Low.
			High Power 	On High power the voltage is at its highest and therefore the waveguide amplitude at its greatest.	A faster cut time compared to Ultra Low and Low power. High power should be used on avascular tissue.

5

FAQ – BOWA IN SURGERY

How does the EASY system work?

The EASY system monitors split neutral electrodes, detects detachments and stops monopolar activations in the event of malfunction, thereby minimising the risk of burns at the electrode application site.

A dynamic reference resistance is set when applying the neutral electrode. If the measured resistance at the neutral electrode is 50% higher than the reference resistance, the EASY system will stop monopolar activation, give an acoustic signal and show an error code on the display.

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.

Why is a high initial cutting power required?

The powerful initial cutting support facilitates immediate onset of the arc, resulting in a smooth cutting effect with no jerking movements. The high power is delivered directly only during initial cutting and is then downregulated within a fraction of a

second. The ARC 400 and ARC 350 have the technology to deliver this feature.

What is the purpose of the BOWA COMFORT cable?

The plug is 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.

Can I use BOWA cables with devices from other manufacturers?

The connecting cables have been designed specifically for use with BOWA ARC generators with COMFORT functionality and are not compatible with devices from other manufacturers.

Can I use the BOWA ARC generator for other applications?

BOWA ARC generators are interdisciplinary electrosurgical devices suitable for use in every electrosurgical application.

Can I use accessories from other manufacturers?

You can connect standard accessories directly via a suitable jack configuration without an adapter.

Can I use the BOWA ARC 400 to seal vessels?

BOWA provides ligation as an option for the ARC 400 in addition to a wide range of reusable laparoscopic and open surgery instruments.

What is the service life of BOWA COMFORT cables?

BOWA cables with instrument identification are guaranteed to work for 100 autoclave cycles.

The instrument logs and displays the number of uses. Any utilisation beyond the specified life cycle is the user's own responsibility.

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 manual before using an instrument.

What is the difference between torsional and longitudinal ultrasound?

Torsional sound waves are twisting waves. Longitudinal sound waves move in the direction that the transducer is mounted in.

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

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

How can I see the frequency that LOTUS is operating at?

Once LOTUS is initiated, the LCD on the back of the LG4 generator will show you the operating frequency.

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

35,500 to 36,600 Hz.

What energy type does LOTUS rely on to work?

LOTUS uses compressional energy to coagulate, seal and cut tissue. The Harmonic scalpel uses only frictional.

What size vessel can LOTUS seal?

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

How much rotation does LOTUS have?

Due to the positioning of the transducer, LOTUS will 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 will show you what power setting you are on 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?

Yes, however, LOTUS does not have a dedicated coagulation button, instead this is achieved by using your grip pressure and with an adjustment to your surgical technique and/or power setting.

What temperature will 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 were similar.

However, a higher temperature was recorded at the tip Harmonic scalpel. The temperature of both scalpels ranges between 60° and 160°, but 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 life time of each transducer on the LCD upon setup. Once 98% of the transducer's life time is reached, the front on the generator will indicate "FINAL SURGERY".

At this point at the end of the operation and once the transducer is disconnected or the generator is turned off it will be locked out and not be able to be used again.

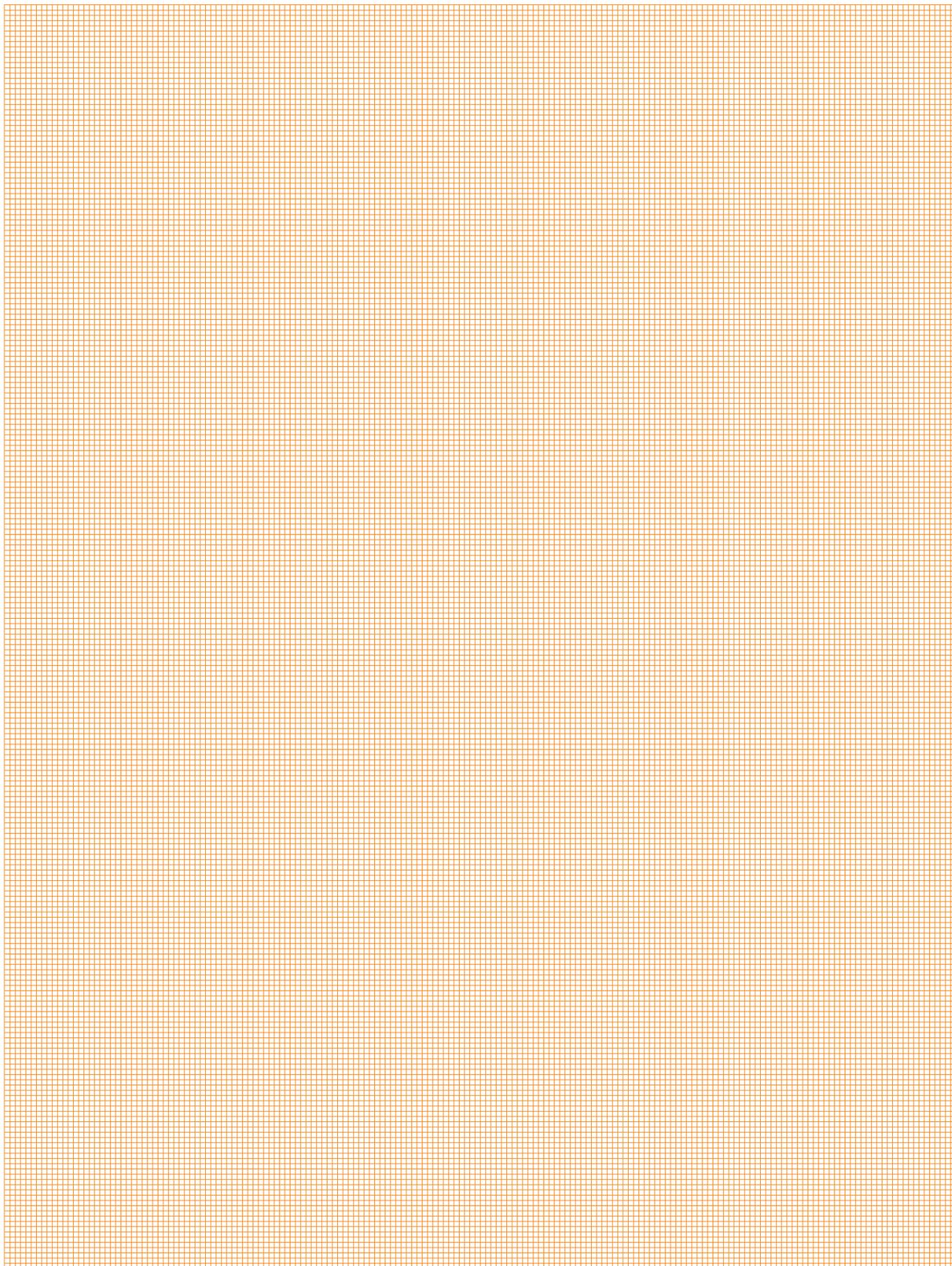
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FOR YOUR NOTES



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