72. Surgical Scissors

Surgical Sciss

Reiner Haag, Wilfried Storz

Scissors still represent an indispensable tool for any surgical discipline, in medical practices no less than in clinical departments. It is probably safe to say that among all surgical instruments, scissors are used the most frequently – prior, during, and after the operation. Using scissors is extremely easy, with the benefits being not only excellent, but manifold and almost unlimited. In fact, there is hardly any better universal alternative when it comes to transecting or dissecting tissue or cutting sutures or any other kind of auxiliary materials. Yet in spite of the easy handling, the demands made on the surgeon or nurses are very high and complex as well – and they differ according to the task at hand. This has led to the development of a wide range of scissors that includes no less than 2000 different versions of the product.

72.1 The History of Scissors

The question of where and when scissors were exactly invented has not been finally solved to date, but there are justified reasons to assume that the first scissor-like devices came into use between 1300 and 600 BC.

72.1.1 Paired Knives

In their most primitive form, scissors consisted of two matching knives whose cutting edges were sim-

Fig. 72.1 Paired blades

Fig. 72.2 Paired blades

Fig. 72.3 Spring bow scissors

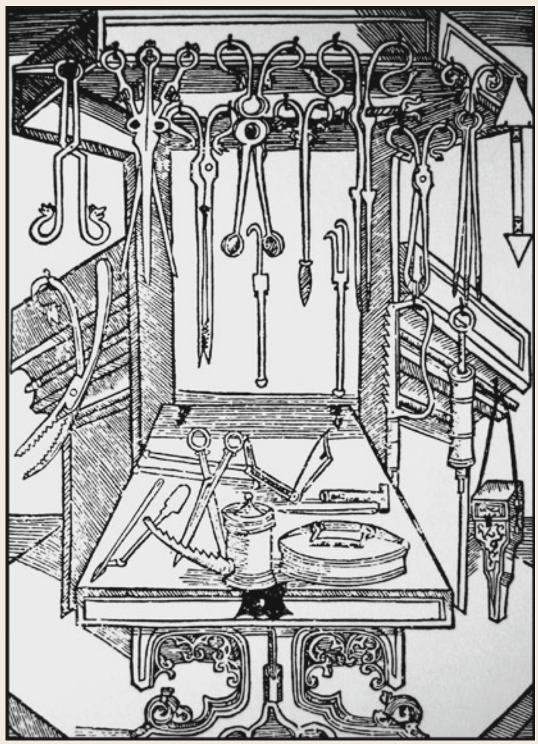

Fig. 72.4 The chamber with surgical instruments of Brunschwig

ply moved towards each other. As these paired blades were not connected to each other, the user had to work with both hands. The left hand held and supported one of the knives from below while the right hand guided the other, upper knife in such a way that the cutting edges glided closely past each other in a shearing or cutting motion while the user applied moderate pressure (Figs. 72.1, 72.2).

72.1.2 End-Jointed Scissors

End-jointed scissors represented a further advancement. They consisted of two blades that were hinged together at their back ends by way of a bolt. Their use was rather cumbersome, as the two blades had to be pressed upon each other for cutting and subsequently had to be pulled apart manually.

72.1.3 Bow Scissors

Compared with end-jointed scissors, spring bow scissors (omega-shaped back end) represent a significant improvement because they can be operated single-handedly and open by themselves due to the mechanical tension in the material. The first products of this sort probably date back to 300 BC (Fig. 72.3).

72.1.4 Pivoted Scissors

As more and more experience was gained in steel processing and user demands grew, pivoted scissors were increasingly used from the 13th century. This, in turn, led to new fields of use, not least in surgery. However, it was not until 1497 when H. Brunschwig, in his surgery book, presented a chamber full of surgical instruments, among them a pair of scissors (Fig. 72.4).

72.2 The Function and Design of Scissors

Depending on their design and field of use, surgical scissors are intended for transecting tissue, bones, organs, dressing materials, and other medical supplies. Moreover, scissors are quite frequently used for dissecting and manipulating certain tissue structures and organs, due to the fact that they are extremely easy to handle and give the surgeon a *feel* that provides valuable feedback information, thus allowing vital conclusions to be drawn.

The fields of use and practical application of surgical scissors are highly varied and extremely complex. This explains why there is such a multitude of different types and variants to choose from. However, the basic design is identical for all the different types of scissors (Fig. 72.5). At the front or distal end there are the blades, the shanks with the eye rings constitute the handle or back end, and somewhere in the middle there is the pivot or box lock.

When cutting with a pair of scissors, the tissue to be severed is grasped with the blades. As the instrument is closed, the cutting point travels along the blades from the box lock to the tips. This is termed the *action* of a pair of scissors. It is essential here that the mechanical tension between the two blades remains constant from the middle of the blades all the way to the tips. A satisfactory cut performance and quality cannot be achieved if this requirement is not met.

The length of the cut depends on the length of the shear blades and/or the length of the tissue seized by the blades. It is important here that the cutting edges of the blades are geometrically arranged in such a way that a very acute crossing angle is obtained when closing the scissors. This ensures that the tissue is cleanly transected at each cutting point – and only there.

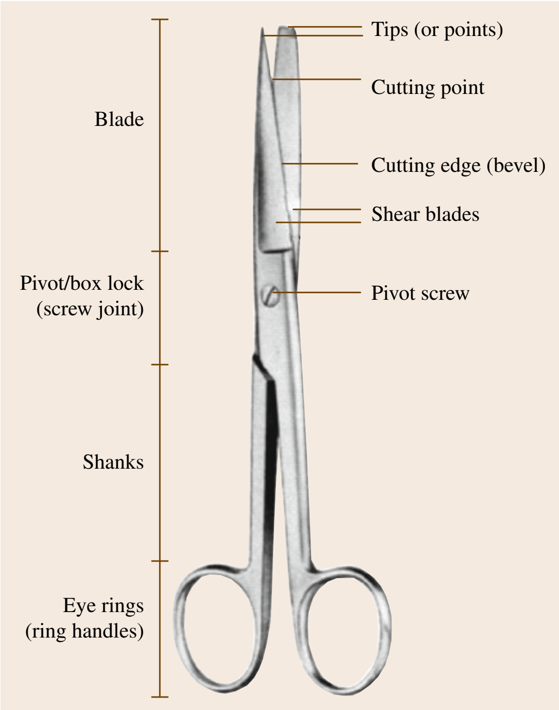

Fig. 72.5 General main parts of a pair of scissors

72.3 Materials

The most fundamental prerequisite for a high-quality pair of surgical scissors is the use of high-quality, forged steel satisfying EN ISO 7153-1:2000 requirements.

Commonly used steels include:

- 1.4117/X38CrMoV15 with a carbon content of 0.38%, a chromium content of 15% and a molybdenum content of 0.5%
- 1.4034/X46Cr13 with a carbon content of 0.42–0.50% and a chromium content of 12.5–14.5%
- 1.4021/X20Cr13 with a carbon content of 0.16–0.25% and a chromium content of 12–14%.

The following general rule applies: the higher the carbon content, the higher the hardness; and the higher the chromium content, the higher the corrosion resistance. The hallmark of hard-metal scissors is their gilded handles. There are two ways of fabrication.

72.3.1 Soldering a Hard-Metal Inset into the Cutting Edge

A hard-metal plate is soldered into the milled-out part of the scissor blade. This plate is extremely hard. However, due to the three different metals involved that occupy different positions in the electrochemical series, potential differences can lead to corrosion as a result of instrument reprocessing. Scissors with significantly curved blades are difficult or even too costly to manufacture using this method.

72.3.2 Welding Hard Metal in Place

Stellite, a hard metal alloy with a carbon content of 2.4%, a chromium content of 33%, and a tungsten content of 13% is welded into the milled-out part of the blade. Since this produces a hard weld, the scissor blade must subsequently be ground in a complex and time-consuming process. However, as only two materials are involved in this case, it is easier to create strongly bent blades.

72.3.3 Special Coatings

Hard-metal scissors featuring a special, super-hard coating are increasingly offered. Their surface hardness (Vickers hardness, HV) ranges between 2000 HV and 5000 HV.

Commonly used materials for coatings are:

- AlTiN Aluminum titanium nitrite, anthracite-colored
- TiN Titanium nitrite, gold-colored
- ZrO_2 Zirconium oxide, grayish.

User benefits include:

- Increased life due to the extremely high surface hardness
- Due to their darker color, AlTiN scissors minimize light reflections
- Less friction due to superior surface reticulation (cross-linkage); this results in smoother action and facilitates cleaning.

72.3.4 Titanium Scissors

For special applications, e.g. in an open MRI environment where antimagnetic materials are required, titanium scissors are an excellent choice. As titanium is an amorphous material, however, the manufacturing processes are significantly more complex and time-consuming, so they have to be completely separated from conventional machining processes. To take an example: The use of grinding belts previously used for conventional metal scissors would pose a risk of metal particles being ground into the titanium surface, thus leading to artifacts in the MR image in open MRI procedures and, consequently, to poorer image quality. In the worst case, the image would even be useless. Besides, the brittle material shortens the product's life, reduces cutting performance and makes the opening and closing action less smooth, compared with conventional scissors.

72.4 Manufacture of Surgical Scissors

The ease with which scissors can be used stands in marked contrast to the complexities of the manufacturing process. The whole cycle is made up of many single working steps. While machining is possible in some respects, there is still a lot of manual craftsmanship involved in the process. Even today, the production of high-quality scissors requires the skill of experienced surgical technicians or specialized *scissor makers*. Of course, their work is supported by advanced manufacturing technology. Nonetheless, precision working is a must in all production stages in order to achieve optimum results. The following table provides an overview of just the most important steps in the process, distinguishing between conventional manufacturing and an advanced process based on robotics and CNC technology (Figs. 72.6, 72.7).

72.4.1 Steps in the Production Cycle

Steps 1–6 of the preproduction cycle and step 1 of the final production cycle are *automated and standardized parts* of advanced manufacturing processes using robots and CNC technology.

Optional Technical Features of Surgical Scissors

Preproduction:

1. Drill core hole
2. Mill joint area projection (box lock corner)
3. Mill shanks

Table 72.1 Technical variants of surgical scissors

Surgical scissors	Description
Standard, without TC (hard-metal inset) (Fig. 72.8)	Low cost
With knife-type grinding	Sharp, knife-type cut
With knife-type grinding and bevel	Sharp and effortless, knife-type cut Minimized traumatization
With knife-type grinding, bevel and microtoothing	Sharp and effortless, knife-type cut Minimized traumatization Prevents tissue slippage
With TC, soldered or welded (Fig. 72.9)	Excellent edge retention
TC, with knife-type grinding	Sharp, knife-type cut Increased edge retention
TC, with knife-type grinding and bevel	Sharp and effortless, knife-type cut Minimized traumatization Increased edge retention
TC, with knife-type grinding, bevel and microtoothing	Sharp and effortless, knife-type cut Minimized traumatization Prevents tissue slippage Increased edge retention
TC, with serrated edge	Excellent edge retention Prevents tissue slippage Increased edge retention as standard
With ceramic coating (Fig. 72.10)	Long-term edge retention Excellent gliding property Glare-free surface Easy to clean
Titanium (Fig. 72.11)	Antimagnetic, thus MRI-compatible Only half the weight of steel scissors Effortless use, prevents fatigue

Fig. 72.6 Manufacturing of scissors in 1980

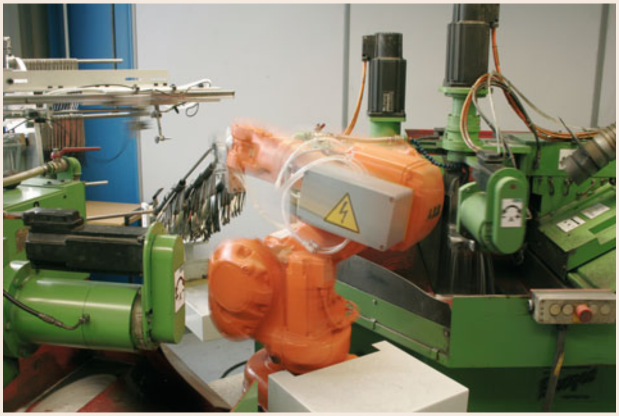

Fig. 72.7 Manufacturing of scissors in 2010

4. Prepare locations for hard-metal insets
5. Bend upper and lower blades
6. Tap lower shear blade and counterbore upper shear blade
7. Align lower/upper blade
8. Weld lower/upper blade
9. Grind blades on outside and inside

Final production:

1. Grind eye rings on outside and inside
2. Mount/rough-grind
3. Check prior to tempering (hardening)
4. Wash (remove lubricants, etc.)
5. Tempering and annealing
6. Check hardness
7. Mount/prepare for polishing

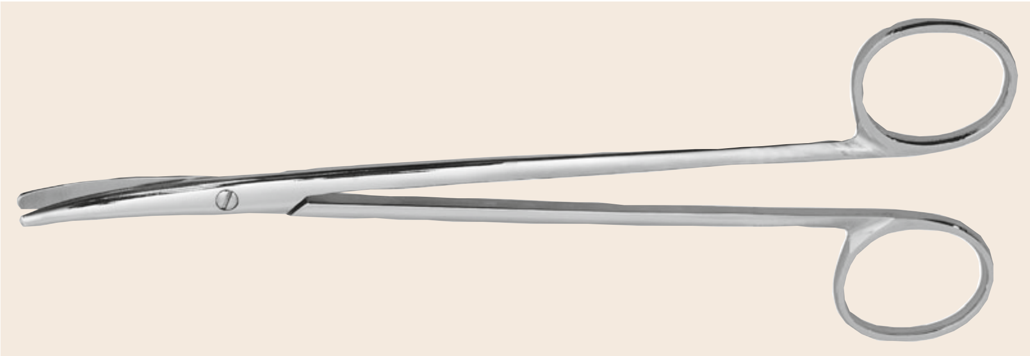

Fig. 72.8
Standard scissors

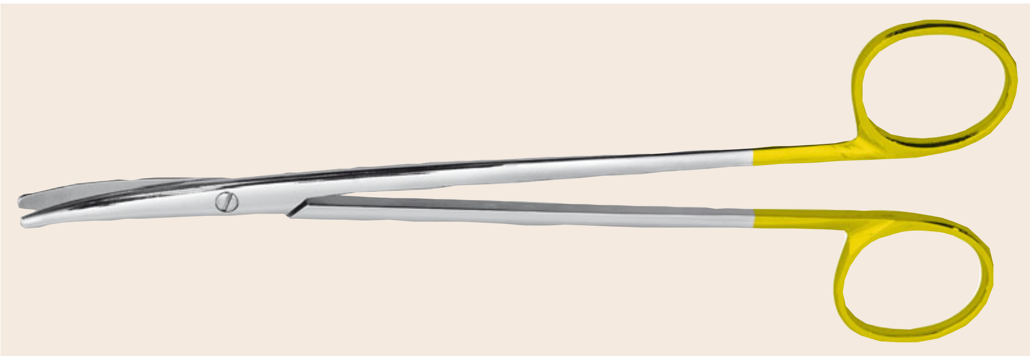

Fig. 72.9
Standard scissors with TC

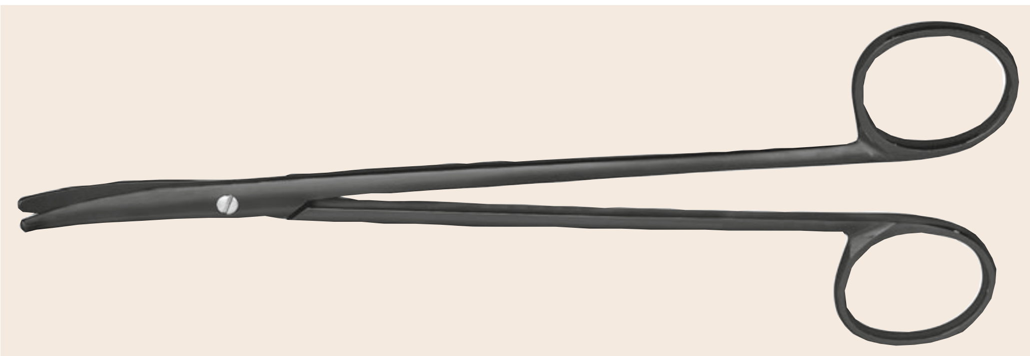

Fig. 72.10
Standard scissors with ceramic coating

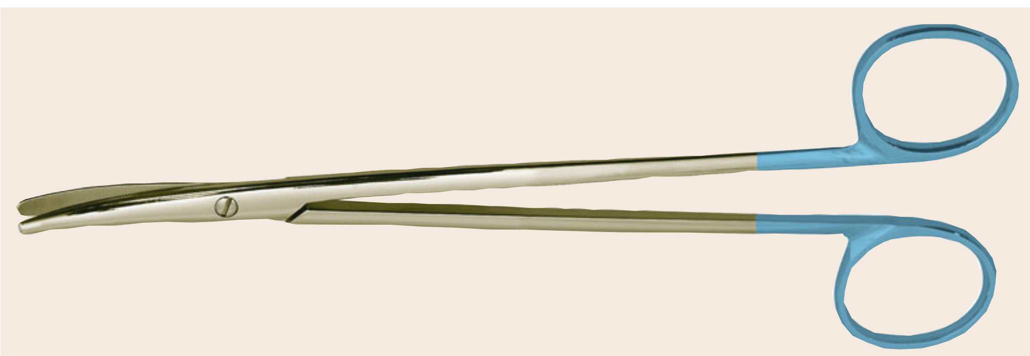

Fig. 72.11
Standard titanium scissors

8. Polish
9. Check
10. Wash/electropolish
11. Stamp, break edges, brush box lock
12. Depolish, brighten handles
13. Wash
14. Finalize, sharpen bevel of lower blade
15. Check
16. Wash
17. Gold-plate eye rings
18. Wash
19. Letter
20. Passivate
21. Final inspection

72.5 Diversification Overview

72.5.1 Surgical Standard Scissors

This type of scissors is usually used for cutting auxiliary materials needed for operations, e.g. dressing materials, flexible drain tubes, and – mostly – sutures. However, these scissors are also used for tissue transection in many surgical fields. Standard scissors are routinely included in almost all surgical instrument sets.

Types of Scissors

Standard scissors are medium strong to sturdy scissors, in straight and bent-up design.

Basis Sturdy Models. Blade tip designs are:

- Pointed/pointed (Fig. 72.12)
- Blunt/blunt (Fig. 72.13)
- Pointed/blunt (Fig. 72.14)
- The classic example blunt/blunt and bent-up, so-called Cooper scissors (Fig. 72.15a,b).

Scissor Lengths

Various lengths of scissors are commonly at the disposal of the surgeon. They cover lengths from 11 to 20 cm.

72.5.2 Surgical Scissors – Dissecting Scissors

Field of Use

Dissecting scissors (Fig. 72.20) are frequently used in surgical interventions – specifically where tissue needs to be transected and dissected in the deeper regions of the surgical site. Tissue cutting is done simply by closing the scissors effortlessly, whereas dissection is

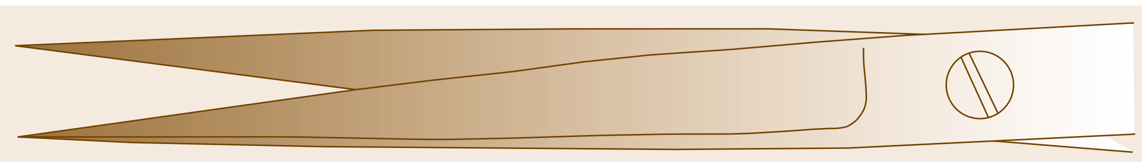

Fig. 72.12 Pointed/pointed blade tip design

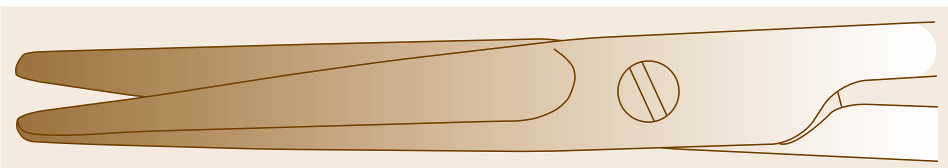

Fig. 72.13 Blunt/blunt blade tip design

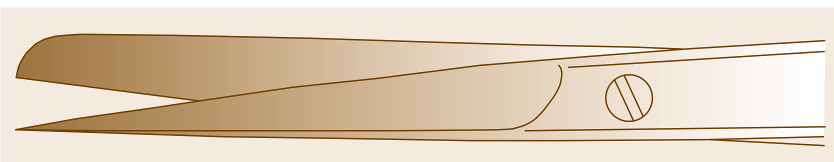

Fig. 72.14 Blade tip design pointed/blunt

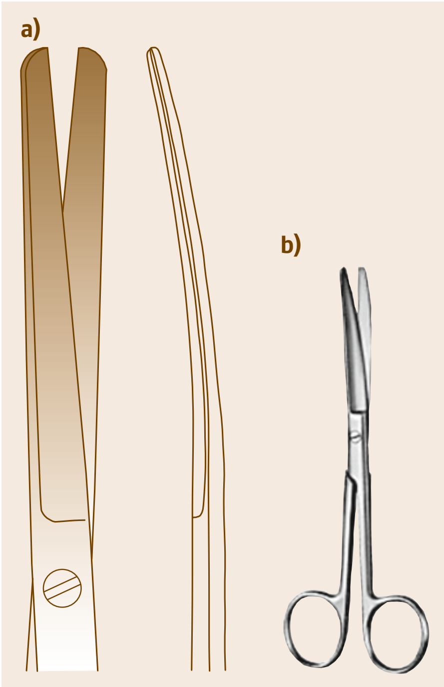

Fig. 72.15a,b Blunt/blunt and bent-up scissors, so-called Cooper scissors

performed by spreading the blades repeatedly in a *snapping* action. Blunt dissection (enucleation) is done with the scissors closed.

Wrongly though, dissecting scissors are frequently used also for cutting sutures during ligations. While this is understandable from the point of view of convenience (no need to exchange scissors), such use clearly reduces edge life. Special ligature scissors are available for cutting suture material.

Most Frequent Use

Mainly in soft tissue, abdominal and visceral surgery.

Types of Scissors

Medium-strong to slim, elegant, bent-up scissors, straight dissecting scissors are seldom used.

Most Importantly Used

By Lexer and Mayo (Figs. 72.21, 72.22), Metzenbaum, and Mayo-Stille. The best-known examples are the Metzenbaum scissors (Figs. 72.23, 72.24).

Typical Features

The hallmark of dissecting scissors are their rounded tips and the round back of the shear blades. When closed, these scissors must form smooth, round dissect-

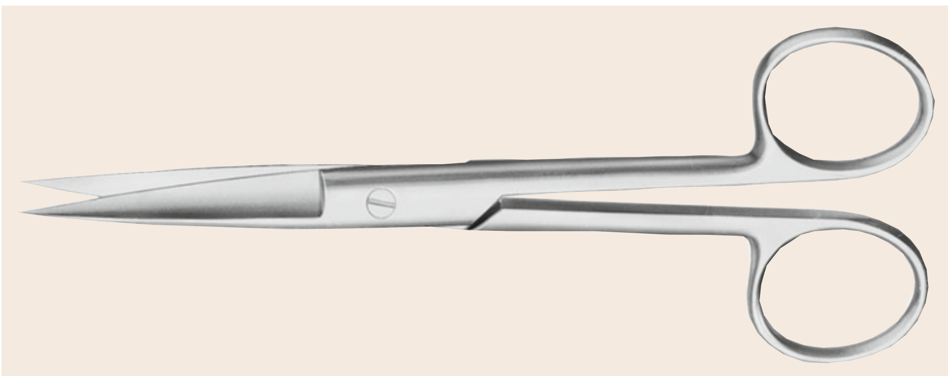

Fig. 72.16 Surgical scissors, length 11 cm

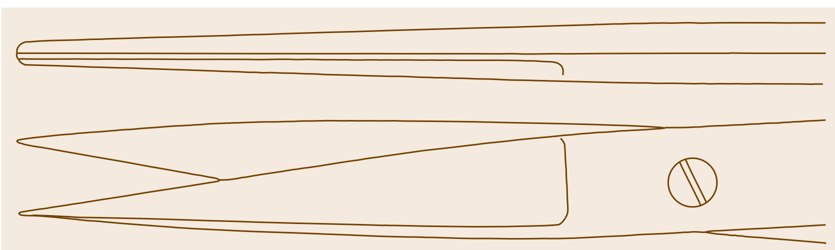

Fig. 72.17 Surgical scissors, length 16 cm

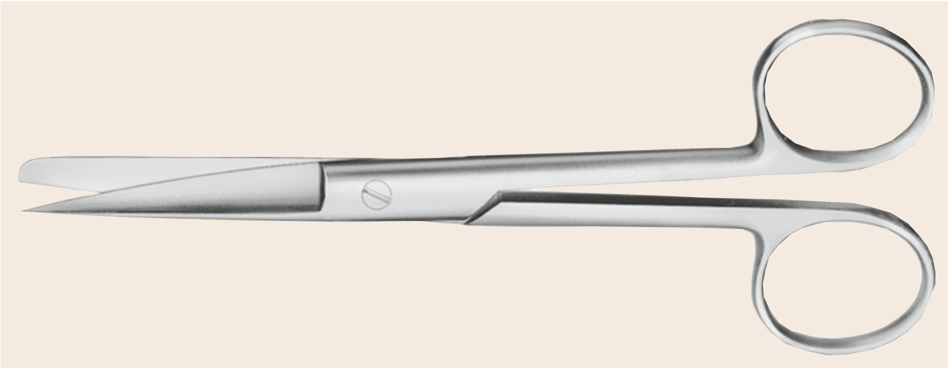

Fig. 72.18 Surgical scissors, length 18 cm

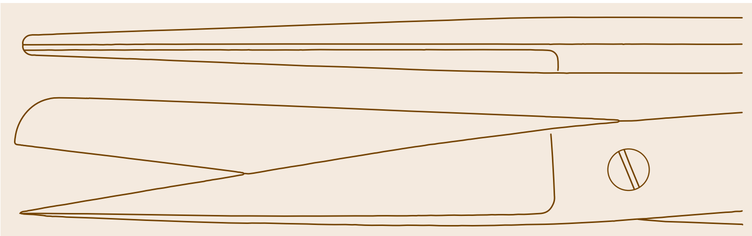

Fig. 72.19 Surgical scissors, length 20 cm

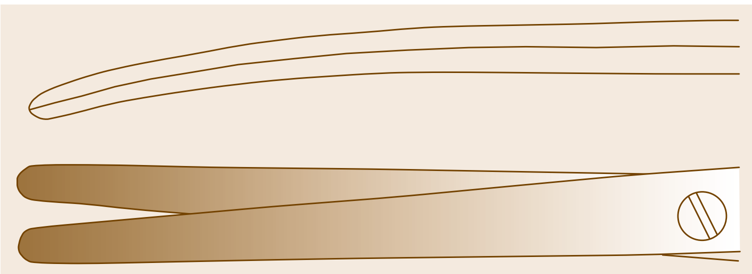

Fig. 72.20 Dissecting scissors

ing instruments without any edges or protrusions on the blades. Another important requirement is their smooth action ensuring an even cutting performance to give the surgeon a perfect *feel* for the tissue to be divided.

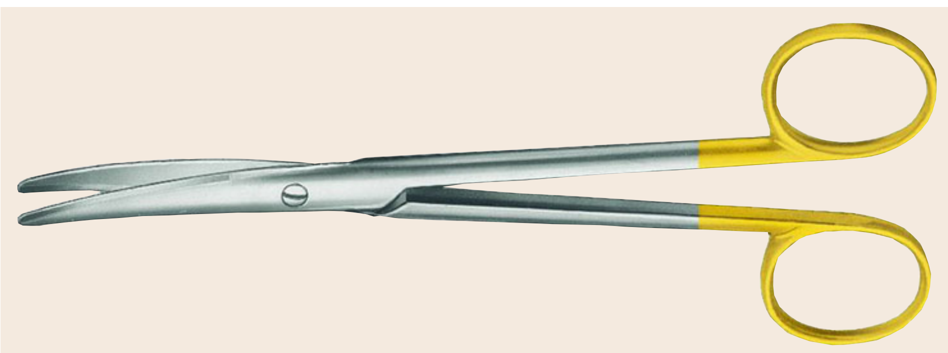

Fig. 72.21 Mayo and Lexer scissors

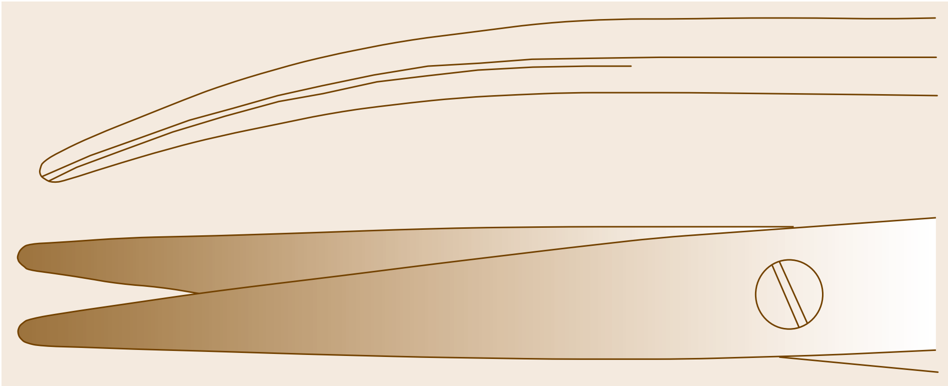

Fig. 72.22 Mayo and Lexer scissors

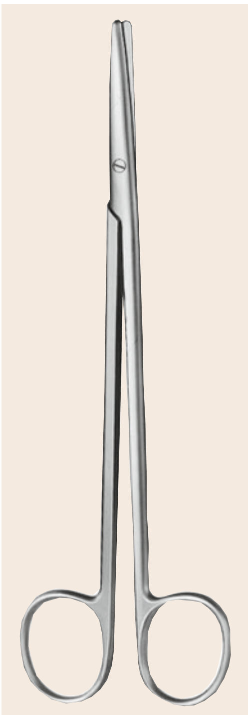

Fig. 72.23 Metzenbaum scissors

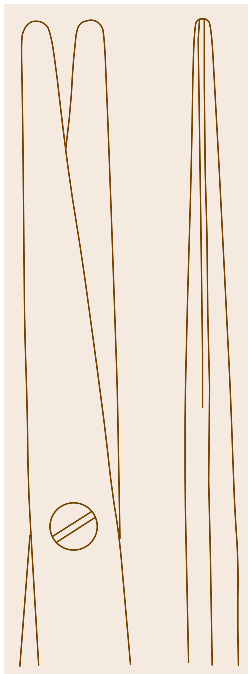

Fig. 72.24 Metzenbaum scissors

72.5.3 Suture or Ligature Scissors

Field of Use

Once the wound has healed on the surface, the sutures are removed using suture or ligature scissors. To this end, the surface ligation is simply cut with such a pair of scissors and anatomical or dressing forceps are then used to pull out the sutures.

Types of Scissors

An important feature is the slim design of one of the blades to ensure that it can be easily slid underneath the ligation to cut the suture without applying any pressure to the postoperative scar or tension to the suture. Some models feature a *suture groove* at the distal end of one of the cutting blades. This prevents the suture from slipping off the scissor blades. Delicate, pointed-pointed scissors (similar to

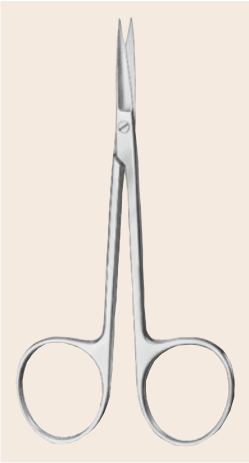

Fig. 72.25 Iris scissors

Fig. 72.26 Spencer scissors

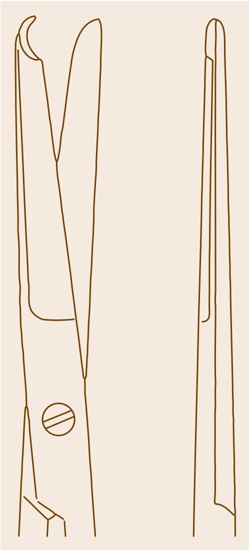

Fig. 72.27 Spencer scissors

iris scissors) are also used sometimes for this purpose.

Scissor Lengths

Various lengths of scissors are available from 9 to 15 cm.

72.5.4 Wire Cutting Scissors

Field of Use

For certain interventions (e.g. cerclages), flexible metal wires are used as suture or fixation materials. To

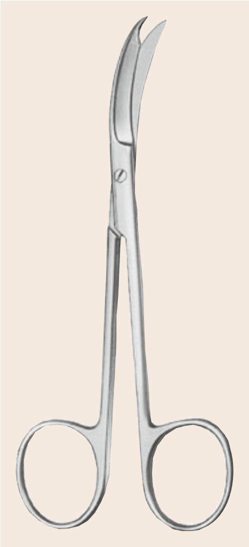

Fig. 72.28 Northben scissors

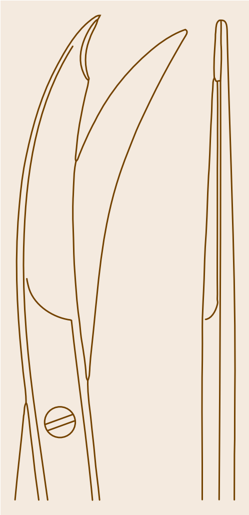

Fig. 72.29 Northben scissors

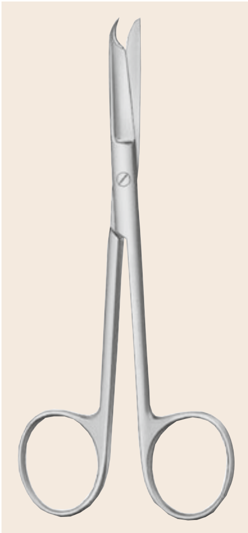

Fig. 72.30 Spencer ligature sicssors

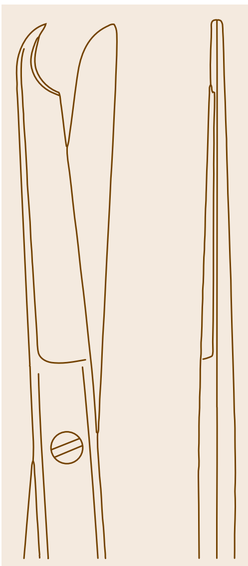

Fig. 72.31 Spencer ligature scissors

cut such materials, short and stout scissors are required.

Typical Features

The shear blades are extremely short as they are exclusively intended for cutting wires and not for providing a clean cut through tissue or dressing material. Some models include a *wire cutter* for secure grasping of the wire and have angled cutting blades.

Scissor Lengths

Various lengths of scissors are available with lengths from 10 to 16 cm.

72.5.5 Microsurgical Scissors

Microsurgical or microscissors are used across a wide range of fields nowadays, including almost all special disciplines (periodontology, endodontics, plastic surgery, hand surgery, orthopedics, cardiac surgery, vascular surgery, pediatric and neonatal surgery, gynecology, urology, neurosurgery, and ophthalmology).

Every microsurgical operation – including tendon, nerve and vascular suturing usually performed under the microscope – requires precise, light-weight mi-

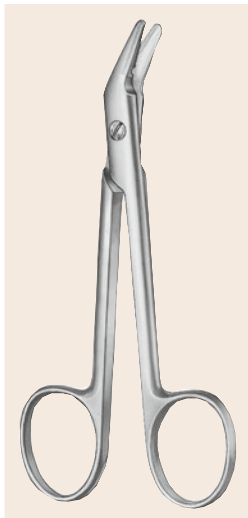

Fig. 72.32 Universal scissors

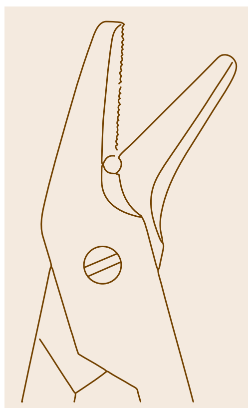

Fig. 72.33 Universal scissors

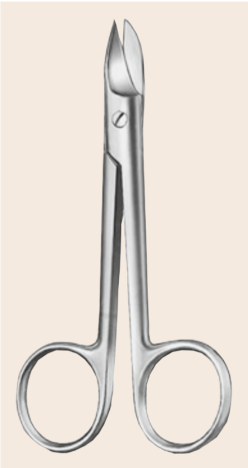

Fig. 72.34 Beebee scissors

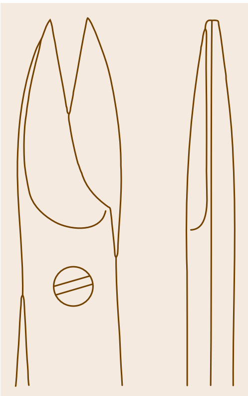

Fig. 72.35 Beebee scissors

croinstruments perfectly fitting the surgeon's hand for ultrafine interventions.

Fig. 72.36 Microsurgical scissors

Types of Scissors

Adventitia scissors have sharply pointed tips and straight blades. They are primarily used for freshening up and trimming structures that have already been prepared by blunt dissection. Besides, they are used for cutting fine sutures (>8/0). Dissecting scissors have rounded tips (designed for blunt dissection) and curved blades. They are used for severing nerves and vessels

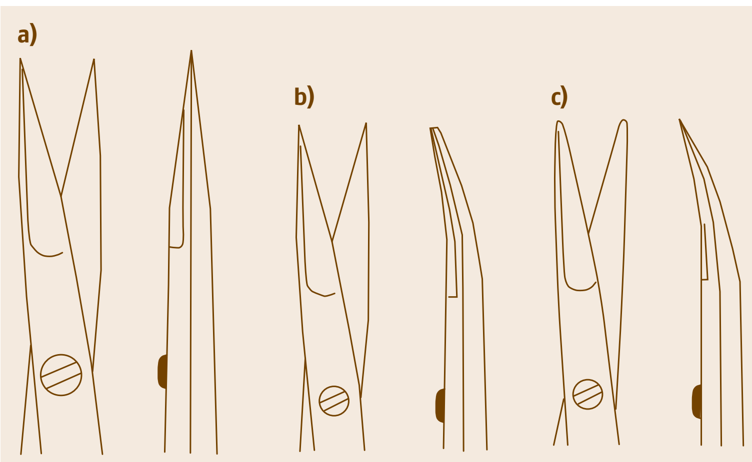

Fig. 72.37 **(a)** Adventitia scissors,**(b)** dissecting scissors,**(c)** toothed scissors

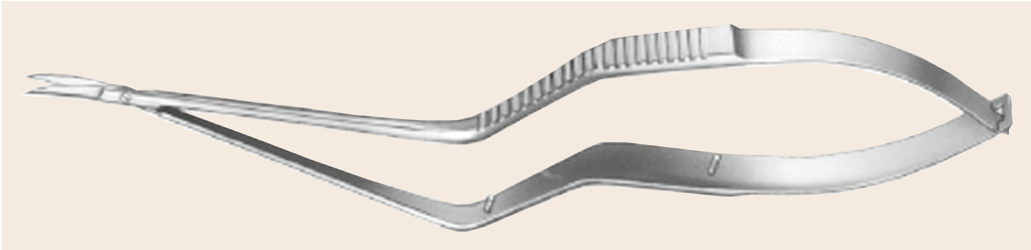

Fig. 72.38 Microscissors

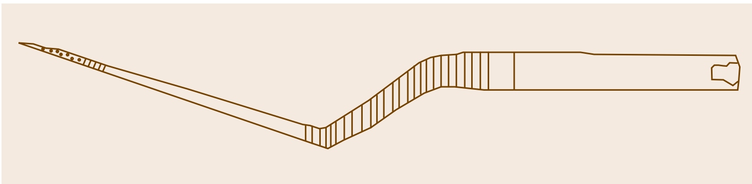

Fig. 72.39 Microscissors

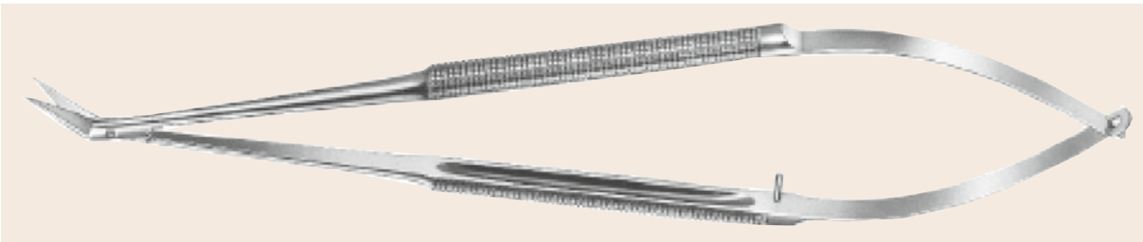

Fig. 72.40 Microscissors

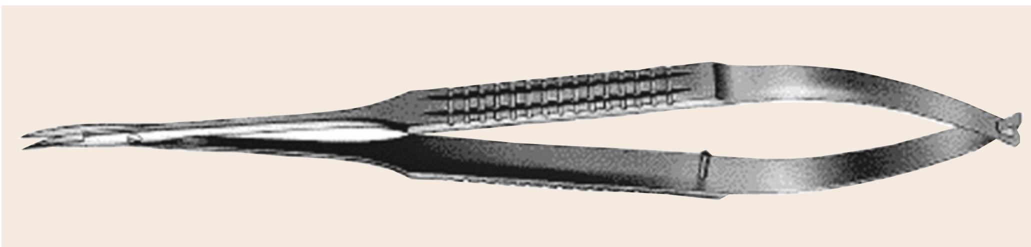

Fig. 72.41 Coronary scissors

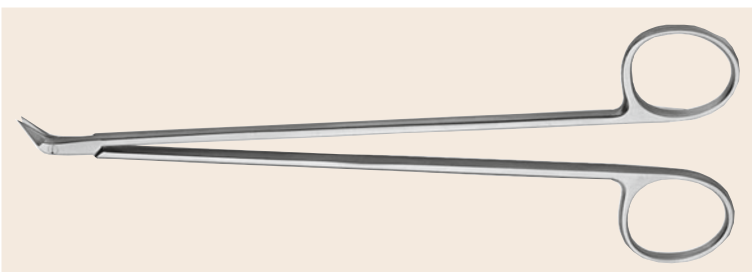

Fig. 72.42 Micro-Hegemann

from surrounding structures (soft tissue, lymph nodes) or from each other while leaving them fully intact. Toothed scissors offer the best controlled cut including the dissection of nerve tissue.

An important differentiation must be made between microscissors with round handles and those with flat handles. Round handles support the rotational movement required when passing the needle through the tissue. Nowadays, round-handle instruments are predominantly used.

Microscissors can be made of steel or titanium. Titanium scissors frequently have diamond-coated cutting edges for increased edge life and significantly lower weight.

Designs

Straight, bent-up, angled (with different angulation).

Important Users

Castroviejo, Micro-Hegemann, Barraquer, Vannas, Yasargil, Jacobson.

Scissor Lengths

Various lengths of scissors are available from 9 to 24 cm.

72.5.6 Vascular Scissors

Field of Use

Vascular scissors are used for cutting and dissecting anywhere in the arterial and venous system of the human circulation (peripheral, central, and coronary vessels). In addition, they are suitable for cutting sutures. Depending on vessel diameter, different models and designs are used, including microscissors. Particularly long vascular scissors (Potts–Smith) are also suitable for opening other ducts of the human body (such as the biliary duct for removing gallstones).

Types of Scissors

A basic differentiation is made between adventitia and dissecting vascular scissors. Adventitia scissors have

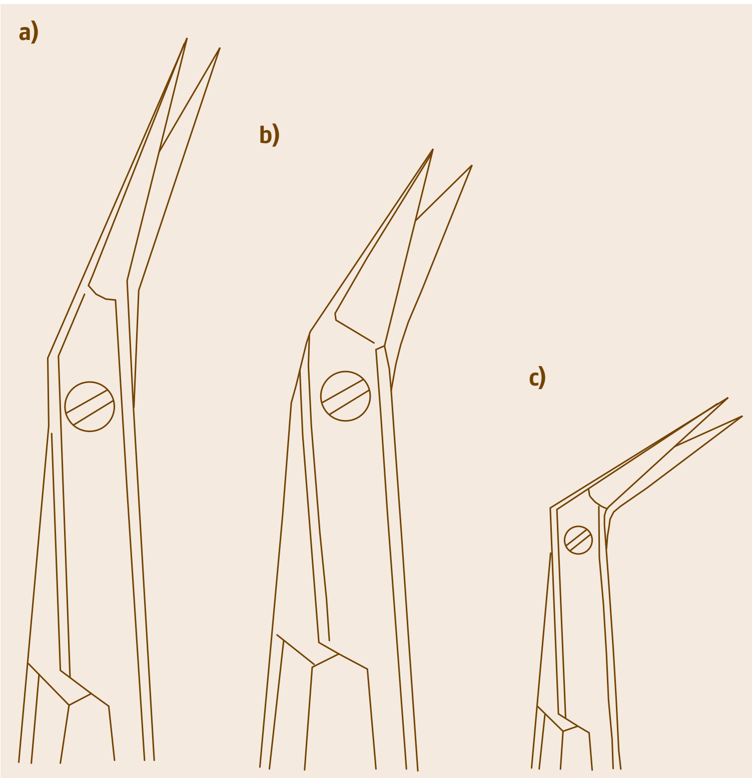

Fig. 72.43 **(a)** 25° angled coronary scissors, **(b)** 45° angled coronary scissors, **(c)** 60° angled coronary scissors

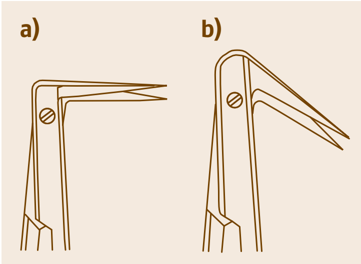

Fig. 72.44 (**a**) 90° angled coronary scissors, (**b**) 125° angled coronary scissors

two pointed tips, while dissecting scissors have two blunt tips. There are also models with a finely toothed blade to offer an even better, more controlled cut in certain situations.

Designs
Straight, bent-up, angled (with different angulation).

Important Users
Potts, Potts-Smith, De Bakey, Diethrich, Hegemann, Favoloro.

Typical Features
Adventitia scissors have straight blades for an optimal cut offering the smallest possible cutting surfaces. The extremely fine tips are intended for high-precision trimming without obstructing the surgeon's field of view. Dissecting scissors have ergonomically curved blades to ensure that the surgeon can fully concentrate on his task instead of the position of his hand. Safe dissection is guaranteed by the rounded tips.

Scissor Lengths
From 13 cm to 24 cm.

72.5.7 Gynecological Scissors

Field of Use
Exclusive use on the internal female genital organs.

Most Frequent Intervention
Hysterectomy (vaginal/abdominal total extirpation of the uterus with or without adnexectomy).

Types of Scissors
Uterine scissors, parametrium scissors (also called hysterectomy scissors).

Fig. 72.45 Favaloro scissors

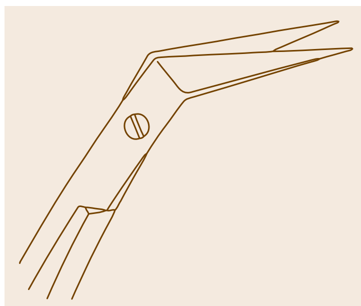

Fig. 72.46 Favaloro scissors

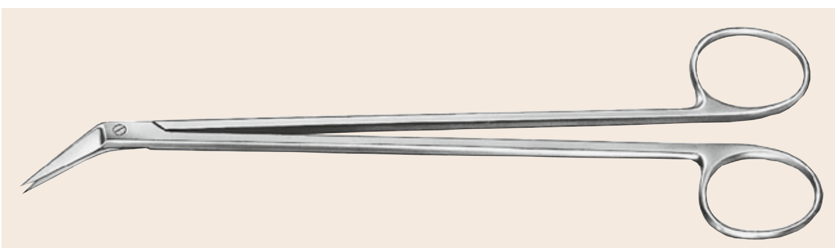

Fig. 72.47 Potts-Smith scissors

Most Important Users
Sims, Siebold, Wertheim.

Typical Features
All in all these are very stout scissors with short, bent-up blades. Both tips are always blunt. When closed they offer a round tip for dissecting and spreading.

The blades must be very short in relation to the shanks because this provides the leverage required for putting adequate pressure on the cutting edges. The blades as such must be sufficiently thick to prevent their

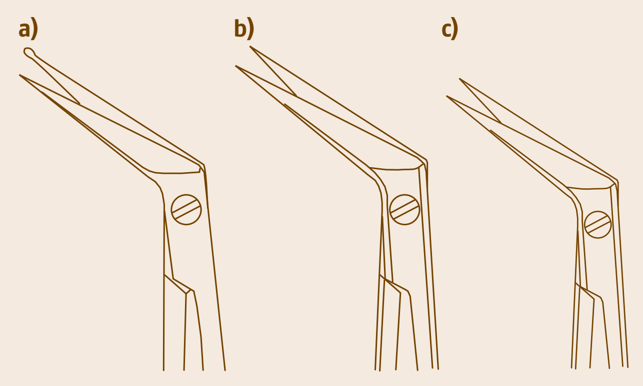

Fig. 72.48 **(a)** 60° angled Potts–Smith scissors button ended, **(b)** 60° angled Potts–Smith scissors, **(c)** 40° angled Potts–Smith scissors

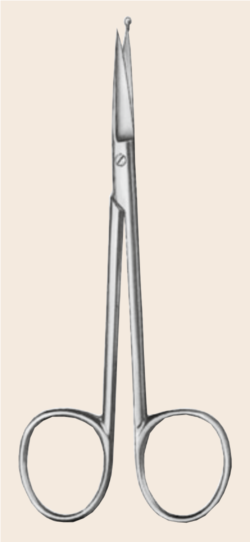

Fig. 72.50 Vascular scissors

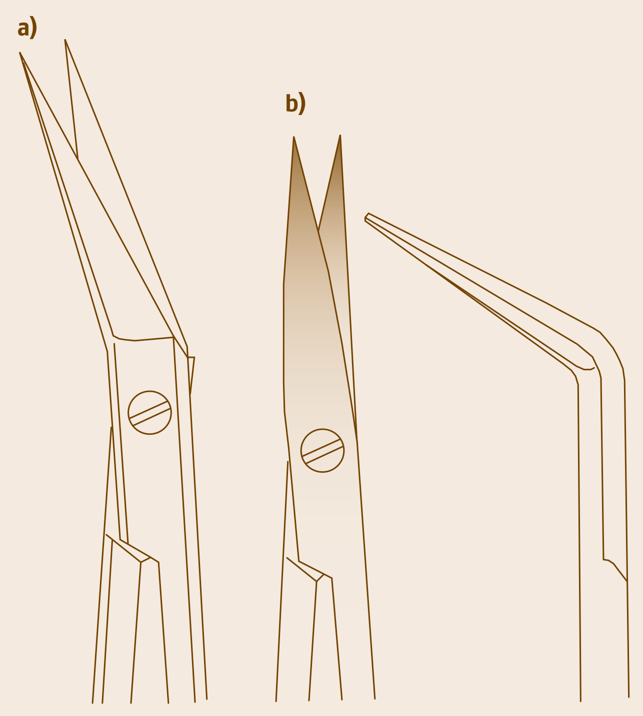

Fig. 72.49 **(a)** 25° angled Potts–Smith scissors, **(b)** Bent-up Potts–Smith scissors

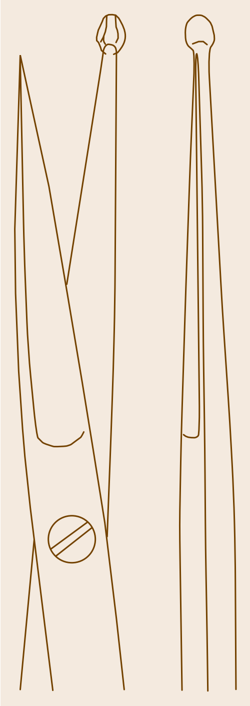

Fig. 72.51 Vascular scissors

Fig. 72.52 Angled scissors

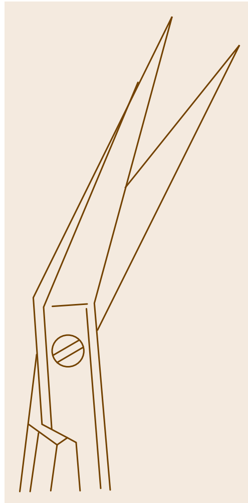

Fig. 72.53 Angled scissors

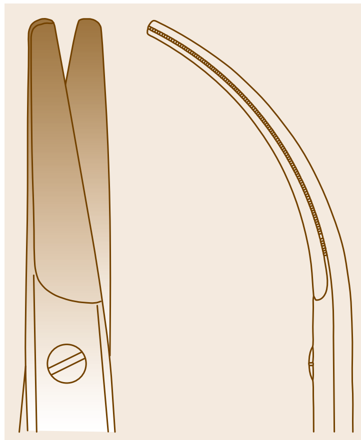

Fig. 72.54 Gynecological scissors

being pushed apart when transecting rough tissue (e.g. in the parametrium), thus ensuring a clean cut.

Scissor Lengths

20–28 cm.

72.5.8 Gynecological Scissors for Obstetrical Use

Fields of Use

For episiotomy to prevent perineal laceration/rupture or facilitate surgical delivery. For cutting off the umbilical cord (omphalotomy).

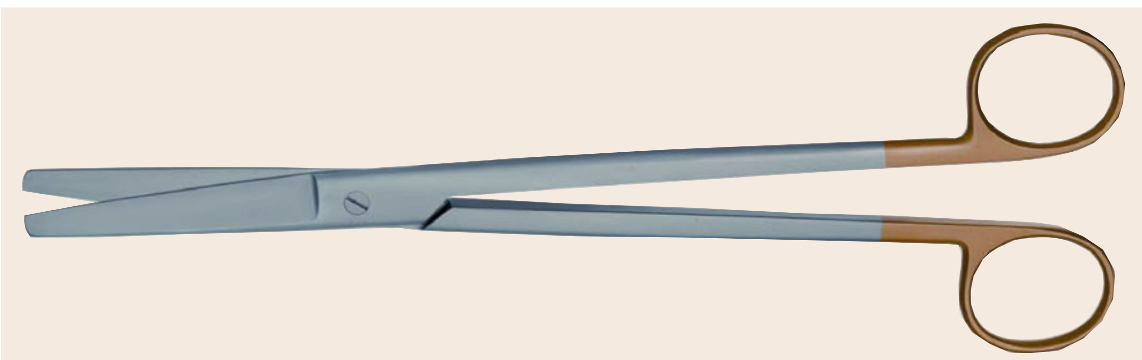

Fig. 72.55 Sims uterine scissors

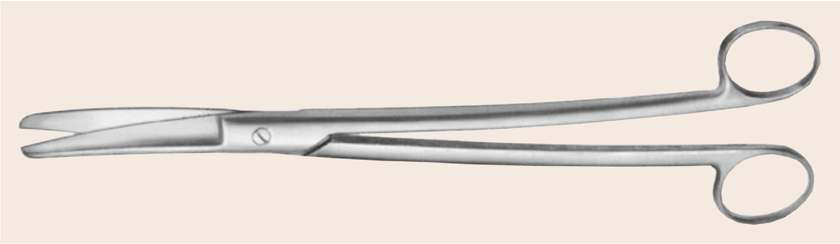

Fig. 72.56 Sims–Siebold scissors

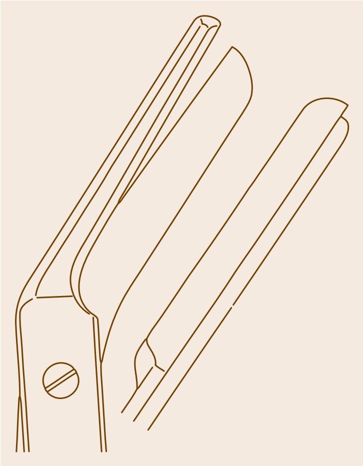

Fig. 72.57 Episiotomy scissors, Braun-Stadler

Types of Scissors
Episiotomy scissors, umbilical scissors.

Most Important Users
Braun-Stadler, Waldmann, Busch, Schuhmacher.

Typical Features
Episiotomy scissors are sturdy scissors with bent (elbowed or lunated) blades to protect both the mother and the baby against injury. The crescent-shaped blades are designed for best adaptation to the skull of the baby when inserting the scissors into the obstetric canal. A clean and even cut in such rough tissue must be guaranteed as well.

Umbilical scissors are short, stout scissors which are available in various designs all of which guar-

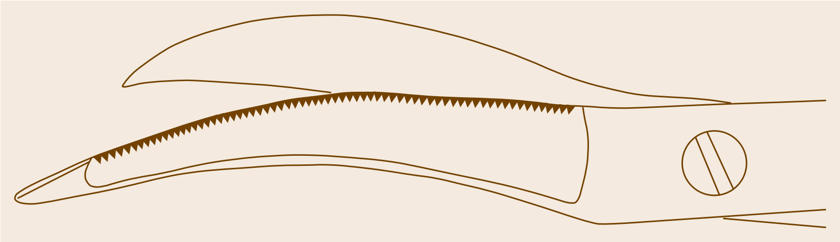

Fig. 72.58 Episiotomy scissors, Waldmann

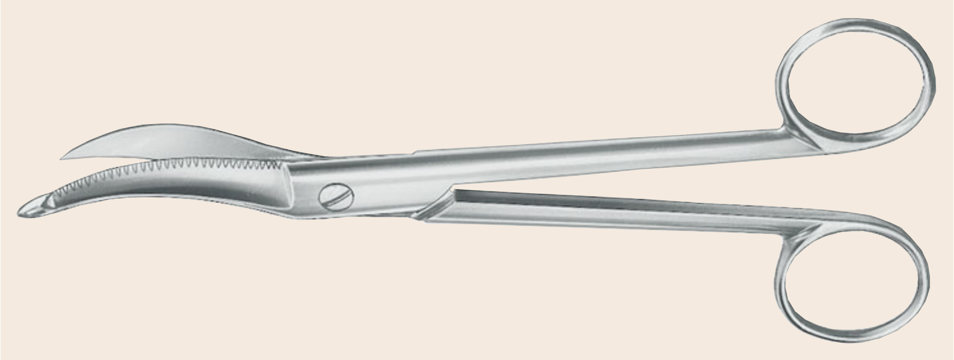

Fig. 72.59 Episiotomy scissors, Waldmann

Fig. 72.60 Episiotomy scissors, Braun-Stadler

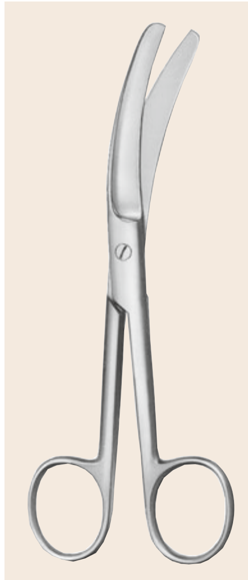

Fig. 72.61 Umbilical scissors, Busch

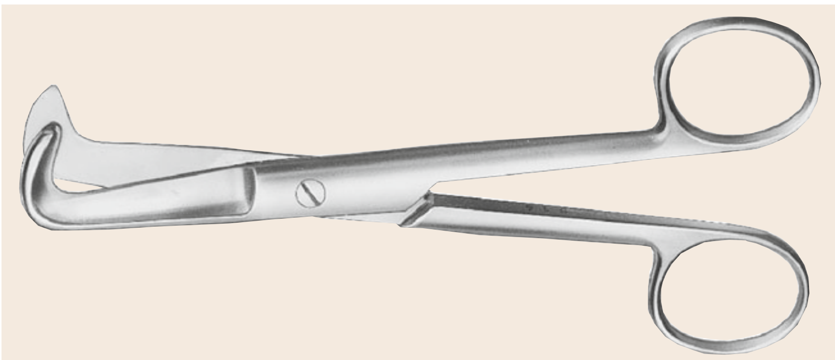

Fig. 72.62 Umbilical scissors, Schuhmacher

antee a clean and safe transection of the umbilical cord.

Scissor Lengths

14–22 cm.

72.6 Handling and Care

Surgical instruments, including all surgical scissors, may be used only for their intended purpose in the specified medical fields by adequately trained and qualified personnel. It is the treating physician's or user's responsibility to select the appropriate models for specific applications or surgical uses, provide adequate training and information on the proper handling of the instruments, and ensure sufficient experience in using them.

Prior to their first use and before each subsequent use, as well as before returning them to the manufacturer for repair, maintenance, or service, the instruments must be cleaned, disinfected, and sterilized in accordance with standardized processing instructions derived from a whole body of legal and normative provisions (laws, regulations, standards, guidelines, and recommendations).

It should be noted that proper processing and care are essential for retaining the function and value of these high-quality products – which constitute important material assets for any hospital – over many years.

Important standards, guidelines and recommendations include:

- The joint recommendation issued by the Robert Koch Institute (RKI) and the German Federal Institute for Drugs and Medical Devices (BfArM) on *Hygiene requirements for processing medical devices* (*Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten*). It requires a quality management and validated procedures for processing reusable medical devices.
- DIN EN ISO 15883 standard specifies and defines the requirements for cleaning and disinfecting apparatus (washer-disinfectors) and for validating the processes used.
- DIN EN ISO 17664 standard specifies the information to be provided by the manufacturer with regard to proper reprocessing of medical devices.

72.6.1 General Instructions

The processing cycle for medical devices generally includes:

- Preparatory work (pretreatment, collecting, precleaning, and dismantling where applicable)
- Cleaning, disinfecting, final rinse, drying
- Visual inspection for cleanness and perfect condition of the material
- Care and repair
- Functional tests
- Labeling
- Packaging, sterilization, release, and storage.

Table 72.2 Highest value for contaminations in feed water

Substance/property	Feed water
Evaporation residue	≤ 10 mg/l
Silicates (SiO_2)	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Rest of heavy metal residues (except iron, cadmium, lead)	≤ 0.1 mg/l
Chlorides (Cl^-)	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0.5 mg/l
Conductivity (at 25 °C/77 °F)	≤ 5 µS/cm
pH-value (degree of acidity)	5–7.5
Appearance	colorless, clear, no sediments
Hardness (total of alkaline earth ions)	≤ 0.02 mmol/l

Note: Compliance with limits should be checked using recognized analytical methods

72.6.2 Materials Used in Scissor Manufacturing

Apart from the standardized materials (DIN EN ISO 7153-1) used, which are described in a separate chapter, there are a number of other parameters that should also be observed during processing because they are important factors for retaining the value of the instruments in the long term.

72.6.3 Water Qualities

Due to the high quantities required in the processing cycle, water is an essential factor for achieving a good cleaning result in any machine cleaning process. Depending on the type of items to be processed, the water quality can adversely affect their long-term value retention, specifically as the overall salt content (evaporation residue) of the water can lead to unwelcome deposits on the processed goods, thus causing damage to the material.

An unfavorable water composition, therefore, can adversely affect both the process used and the appearance and materials of the instruments. Consequently, the water quality should be assessed and taken into consideration from the start, i. e. when planning the sanitary installations. For example, excessive chloride concentrations can lead to pitting on the instruments, while other substances – such as silicates/silicic acids – can cause discoloration (staining, spotting). In addition to all the natural substances contained in the water, rust may also be found in tap water. Rust is invariably a result of corroded piping, forming deposits on the instruments that subsequently lead to stains (extraneous rust) and corrosion. This can be prevented by using demineralized water for the final rinse!

The DIN EN ISO 15883-1 standard (item 6.4.2.2) provides a list of parameters that should be checked and assessed under any circumstances. DIN EN 285 (Appendix B, Table B1) specifies limit values for the boiler feed water of a steam sterilizers. Such water quality can be recommended for the final rinse of machine-based instrument processing cycles. The values in Table 72.2 can be recommended for orientation.

Fig. 72.63 Formation of rust due to multihour immersion in physiological saline

72.6.4 Preparation for Cleaning and Disinfection

The first steps are already taken in the operating room (OR). Wherever possible, residues of hemostatic, skin disinfecting or lubricating agents, or acid medicines should be removed before storing the instruments away for reprocessing after use.

Stainless steel instruments should never be immersed in physiological saline (NaCl solution) because extended contact with this medium will lead to pitting and stress-crack corrosion.

Formation of rust is due to multihour immersion in physiological saline. The improper practice of *throwing off* instruments after use is a source of damage, especially for scissors. Hard-metal scissors are particularly critical instruments since their insets are very brittle, in spite or because of their hardness. Improper handling (e.g. allowing them to drop on the tips) can lead to loss of the hard-metal insets (tip break-off or cutting edge nicks). However, nicking cannot occur in scissors with welded-on hard-metal edges.

It is important to store the instruments properly on instrument trays suitable for machine cleaning. Effective cleaning requires jointed instruments (such as forceps, pliers, scissors) to be processed in open conditions in order to minimize overlapping surfaces. Microsurgical instruments such as microscissors must be stored on special racks or using suitable supports for proper fixation (Fig. 72.64).

72.6.5 Manual Cleaning and Machine Cleaning

Machine cleaning should be given preference over manual cleaning. In any case, effective cleaning is a prerequisite for effective disinfection and subsequent sterilization. Thermal disinfection should be preferred over chemothermal disinfection methods. Standardized cleaning and disinfection can best be achieved with machine cleaning. The international standard EN ISO 15883, as well as national guidelines and recommendations require the exclusive use of validated machine cleaning processes.

72.6.6 Machine Cleaning and Thermal Disinfection

For thermal processes, the disinfecting effect is usually determined parametrically. To this end, the F value used for sterilization with moist heat was translated into the A_0-*value concept* for thermal cleaning and disinfecting processes using moist heat and as such integrated into the DIN EN ISO 15883 standard. A disinfecting method using moist heat is expected to guarantee that a defined temperature maintained over a defined period of time has a predictable lethal effect on vegetative microorganisms. The appropriate lower temperature limit has been set to 65 °C (149 °F).

The decisive criterion for defining the required temperature impact is the heat resistance (thermoresistance) of the vegetative microorganisms to be killed. This parameter is quantitatively expressed in the D value.

Fig. 72.64 Instrument tray for storing and fixing delicate instruments

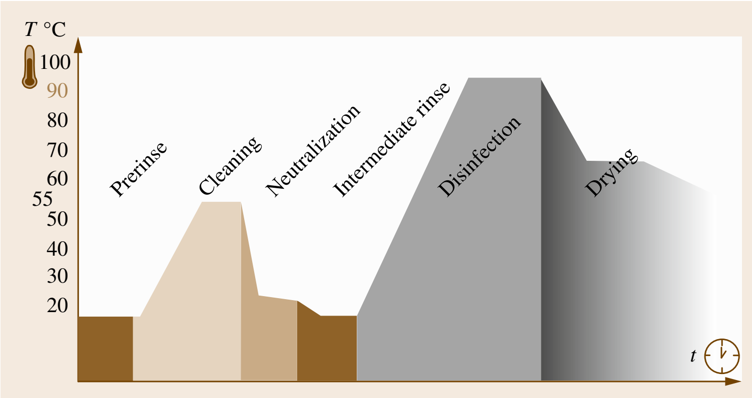

Fig. 72.65 Machine processing program with thermal disinfection typically includes the steps shown (after [72.1])

A_0, the time equivalent (in s) given by the disinfecting process at 80 °C (176 °F) in relation to a microorganism with a z value of 10 ° (50 °F).

Terms/Parameters

- A — Time equivalent (in s) at 80 °C, by which a defined disinfecting effect can be achieved.
- A_0 value — Killing power expressed as time equivalent (in seconds) at a temperature of 80 °C that is process-transferred to the product, for microorganisms with $z = 10$ °C.
- Z value — Temperature change (in K) required for changing the D value by a factor of 10.
- D value — Decimal reduction value, the time (in min) required at a defined temperature for killing 90% of a population of microorganisms.

The structure of the program to be used depends on the (e.g. hygienic) performance requirements and the goods to be processed (Fig. 72.65).

The following steps are processed with thermal disinfection:

1. *Prerinse*: Pure cold water (demineralized if available) to remove coarse soiling and foaming substances.
2. *Cleaning and process chemicals*: Warm or cold water (demineralized if available); cleaning is normally done at 40–60 °C (104–140 °F) for at least 5 min.
   A differentiation is made between alkaline and neutral cleaners. Neutral cleaning agents usually contain nonionic, low-foam tensides, and products with or without enzymes are used for this purpose.
   If the recommendations of the vCJD Task Force (see corresponding RKI guideline) are followed, a cleaner solution with a pH-value higher than 10 must be used.
   Should the water used contain excessive chloride concentrations, this can cause pitting and stress-crack corrosion on the instruments. Using alkaline cleaners or demineralized water minimizes such corrosion.
3. *First intermediate rinse – warm or cold water*: Adding an acid-based neutralizer facilitates the removal of alkaline cleaner residues. Even when using neutral cleaners, it is advisable to use a neutralizer if the water quality is poor (e.g. if the salt content is high). This prevents the formation of deposits.
4. *Second intermediate rinse*: Pure warm or cold water (demineralized if available), no additions.
5. *Thermal disinfection/final rinse*: Demineralized water, with thermal disinfection carried out at temperatures of 80–95 °C (176–203 °F) using an appropriate exposure time according to the A_0 concept (DIN EN ISO 15883). Using demineralized water prevents the formation of stains/spotting, deposits and corrosion. If a final rinse agent is added to shorten the drying time, make sure that it is both biocompatible and compatible with the instruments to be processed.
6. *Drying*: Sufficient drying must always be ensured, either as part of the automatic cleaning program or by taking adequate measures. As concerns the process chemicals used, it is mandatory to observe the product manufacturer's instructions regarding concentration, temperature, and exposure time. This is important for obtaining best results while treating the instruments as gently as possible. Automatic liquid dosing devices must be controllable. Other methods will not be discussed here.

72.7 Inspection, Testing, and Care

Sufficient cleanness is a basic prerequisite for successful sterilization. The instruments must be macroscopically clean, i. e., free from any visible residues (to be verified by inspection). Critical areas such as the handle structures, joints or jaw grooves, atraumatic toothing in particular, need to be checked with special care.

Care measures must be taken prior to performing the functional checks. This requires the targeted application of care agents to joints, box locks, threads, and friction surfaces (e.g. of scissors, forceps, punches) following careful cleaning and disinfection. As this prevents metal-on-metal friction, it helps to prevent fretting corrosion.

Requirements for care agents suitable for surgical instruments are:

- Paraffin/white-oil basis
- Biocompatible according to the valid European or US pharmacopoeia
- Approved for steam sterilization procedures and vapor-permeable.

Instruments may never be treated with care agents containing silicone, as this could lead to stiff action and jeopardize the effectiveness of steam sterilization. As the various instruments are designed for specific purposes (e.g. scissors), inspections must be such that instruments which no longer serve their purpose will be sorted out reliably. If in doubt, appropriate inspection and test measures should be agreed upon with the manufacturer of the product. Instruments that are returned to the manufacturer for repair must first be sent through the entire cleaning and sterilization cycle for hygienic reasons.

72.8 Packaging

As a rule, medical devices must be sterilized in suitable packaging (Figs. 72.66, 72.67). Instruments for use in the OR are assembled as complete, intervention-specific sets/trays and packaged as such. For thermostable instruments, steam sterilization should be preferred.

The purpose of packaging systems for terminally sterilized medical devices is to enable sterilization, provide physical protection, maintain their sterility up to the time of use, and allow for their aseptic placement for use in the OR. The general requirements applying to packaging for terminally sterilized medical devices, including validation requirements for forming, sealing, and assembly processes, have been defined in the DIN EN ISO 11607 series. In addition, parts 2 to 10 of the DIN EN 868 series contain test methods and reference values for specific materials used for preformed sterile barrier systems and for packaging systems.

Fig. 72.66 Instrument tray according to DIN 58952-3, loaded

Fig. 72.67 Reusable sterilization container according to ISO 11607 and DIN EN 868-8

72.9 Current Terminology

Sterile Barrier System

Minimum packaging that prevents the ingress of microorganisms and allows the product to be placed ready for use in aseptic condition at the point of use.

Protective Packaging

Material configuration designed to prevent damage to the sterile barrier system and its contents from the time of assembly to the time of use.

Packaging System

Combination of sterile barrier system and protective packaging

Sterile Barrier System + Protective Packaging = Packaging System

Materials and (preformed) sterile barrier systems considered suitable (depending on the sterilization method used) are:

- Paper bags, sealable transparent pouches, and reels
- Plastic film constructions (composite foils)
- Sterilization paper (smooth, creped)
- Nonwoven wrapping materials
- Form/fill/seal (ffs) processes
- Packaging processes (e.g. four-side closure)
- Reusable sterilization containers.

72.10 Steam Sterilization with Saturated Steam

Reference standards: DIN EN 285:2006+A2:2009 and DIN EN ISO 17665-1 1:2006. The current standard is a validated method of steam sterilization, usually at 134 °C (273.2 °F).

The sterilization and holding times are subject to national regulations and guidelines and, therefore, cannot be defined globally. It is the operator's responsibility to ensure that the reprocessing/sterilization performed with given CSSD equipment, materials, and personnel achieves the desired results. This requires validation and routine monitoring of the process.

72.10.1 Steam Quality

The steam used for sterilization must be free from impurities and must not adversely affect the sterilization process or damage the sterilizer or the goods to be sterilized. To ensure this, the reference values specified in Tables B.1 + B.2 of EN 285 (Table 72.3) for the quality of the boiler feed water and the condensate must not be exceeded. Noncompliance can lead to corrosion due to rust particles from the piping system, for example, or to instrument

Table 72.3 Suggested maximum values of steam impurities in steam sterilizers (after [DIN EN 285 (edition 2009-08)])

	Table B.2 Steam condensate feed line	**Steam condensate after contact with sterilized products**	**Table B.1 Feeding water for steam generation**
Evaporation residue	– mg/l	$\leq$ 30 mg/l	$\leq$ 10 mg/l
Silicon dioxide	$\leq$ 0.1 mg/l	$\leq$ 0.1 mg/l	$\leq$ 1 mg/l
Iron	$\leq$ 0.1 mg/l	– mg/l	$\leq$ 0.2 mg/l
Cadmium	$\leq$ 0.005 mg/l	– mg/l	$\leq$ 0.005 mg/l
Lead	$\leq$ 0.05 mg/l	– mg/l	$\leq$ 0.05 mg/l
Rest of heavy metals	$\leq$ 0.1 mg/l*	$\leq$ 0.1 mg/l	$\leq$ 0.1 mg/l*
Chloride	$\leq$ 0.1 mg/l	$\leq$ 0.5 mg/l	$\leq$ 2 mg/l
Phosphate	$\leq$ 0.1 mg/l	$\leq$ 0.1 mg/l	$\leq$ 0.5 mg/l
Conductivity (at 25 °C)	$\leq$ 3 μS/cm	$\leq$ 35 μS/cm	$\leq$ 5 μS/cm
pH-value	5–7	–	5–7.5
Appearance	Colorless, clean, without sediment	Clean, colorless	Colorless, clean, without sediment
Hardness	$\leq$ 0.02 mmol/l	mmol/l	$\leq$ 0.02 mmol/l

*Except iron, cadmium, lead

staining (discoloration) due to excessive silicic acid content.

If humidity is retained inside packaging systems, this can also lead to rusty instruments. Adequate measures to prevent residual humidity can be agreed upon with the manufacturer of the sterilizer.

72.10.2 Release and Storage

Follow-up treatment after sterilization includes:

- Intermediate storage of the hot sterile items immediately after removal from the sterilizer, to allow them to cool down (half an hour is usually sufficient)
- Sorting of the sterile goods with inspection for cleanness, dryness, and integrity (including packaging and labeling)
- Checking/assessing the sterilization result based on the quality records of the lot documentation
- Sorting out and blocking sterilized items that fail to meet the requirements
- Release for use.

These tasks may only be carried out by authorized personnel. Transport should be effected according to commissioning requirements, but always with adequate protection. It is recommended to use containers and transport them in closed trolleys.

Proper Storage

A dust-free and dry environment is an essential requirement for protected storage of sterile goods and prevention of corrosion damage. For the same reason, temperature fluctuations should be avoided. The maximum permitted storage period depends on the type of packaging and the storage conditions. This means up to six months for sterile supplies packaged in compliance with standard requirements and stored in a dust-free room. Storage beyond the expiration date – which has to be determined by the user in each case – is not permitted.

72.11 Quality Characteristics

72.11.1 Material

A basic prerequisite for best quality is the use of high-quality, forged steel satisfying ISO 7153-1-2000 requirements. The raw materials of reproducible high quality should preferably be of German origin. Commonly used steels are 1.4117, 1.4034 and 1.4021.

72.11.2 Surface

An optimal surface treatment comprises several working steps:

- First, at least 0.3 mm of the surface of the blank must be ground off to remove slag inclusions and surface defects. This creates the basic conditions needed for reliable resistance to corrosion.
- This is followed by mechanical polishing and, preferably, additional electropolishing.
- Finally, the product receives its surface appearance (mirror, matte, or glass bead-blasted finish).

To consistently meet the growing demands in the field of instrument reprocessing (e.g. due to the use of high-alkaline cleaners), a passivation step is increasingly added, especially for high-quality instruments. This optimizes the chromium–iron ratio on the surface of the instrument. The objective is to enrich the surface with as many of the *nobler* chromium molecules as possible in order to improve the instrument's resistance to the chemical attacks typically encountered during reprocessing, thus enhancing its resistance to corrosion.

72.11.3 Form

The closed scissor tips must fit perfectly so cutting with the tips is also possible. The fit of the two blades is good in closed scissors if one covers the other exactly.

72.11.4 Action

Scissors should be easy to open and close, with the blades gliding smoothly in place over each other. Moreover, their operation must be balanced to offer an even and controlled cut over the entire length of the blades (i. e. from the start of the cut, with the instrument wide open, to complete closure). Blades with adequate hollow grinding on the inside support smooth action.

72.11.5 Eye Rings

The eye rings are the working surfaces for the fingers. Their ergonomic shape should ensure pain-free and nonfatiguing handling even for extended periods. The inside of the eye rings, in particular, must provide a smooth, burr-free surface finish.

72.11.6 Quality of Cut

The material to be cut must be transected cleanly and smoothly. No *slippage* may occur and the material must not get squeezed between the blades, either, so they must be sharp. The cutting performance is supported or enhanced by the so-called *bevel* – i. e. additional grinding (chamfering) of the cutting edge of the lower blade. Ideally, the bevel should form an angle of 75° relative to the cutting edge. An adequate mechanical tension between the shear blades – ideally as low as possible and as high as necessary – ensures a good cutting performance. Test methods differ greatly, given the complex and diverse demands resulting from the different materials to be cut – ranging from human tissues to sutures. For example, coarse surgical scissors are performance-tested using multilayer cotton material, whereas the cutting efficiency of delicate microsurgical scissors is verified with ultra-fine latex.

72.12 Future Developments

72.12.1 Users

The high-quality scissors currently available on the market offer very high quality standards. Nonetheless, the requirements on surgical instruments continue to grow as a result of the new and improved surgical techniques being used. This trend is additionally fostered by the cost and time pressure that also affects the operating room, translating into a growing need for ever better surgical instruments – more durable, precise, and functional.

72.12.2 Industry

In the industrial sector, an enormous range of new opportunities for improving certain functions has been developed in recent years. Innovations from the fields of nano and coating technology, along with new materials such as ceramics, nitinol or carbon fibers, are bound to gradually replace existing functions of surgical instruments over time – and most likely improve them as well. This trend is enhanced by the potential use of new manufacturing technologies.

A relatively recent example from the history of scissors is the development of bipolar scissors. Apart from the conventional cutting and dissecting functions, bipolar scissors additionally offer a hemostatic function due to the simultaneous use of HF current. The clinical advantage derives from the fact that no instrument exchange is required, as the cutting, dissecting and coagulating functions are integrated into a single instrument. An additional benefit comes into play because users are already familiar with the instrument, so there is no real need to change the accustomed surgical technique. This saves the surgeon a lot of time and besides, he can fully concentrate on his task.

In terms of development and manufacture, completely new steps and methods were required to enable the use of two current potentials at the distal end of a pair of scissors as required for bipolar current application. With the given constraints, this necessitated the use of new insulation materials such as ceramics because only with a ceramic cutting edge (coated or pure) was it possible to fit the instrument with an insulating edge. Its production, in turn, called for a completely new manufacturing technique termed *ceramic injection molding* (CIM) that requires relatively complex molds, but then the resulting parts are always fully identical in size and shape.

Consequently, the metal base body of the scissors must always be fully identical as well. A perfect form fit is particularly crucial where the ceramic element is to be bonded to the metal body, as otherwise a poor fit would lead to fracture of the element during mounting. In addition, the whole process must be well matched to the opposite scissor blade to ensure the smooth action of the instrument under slight mechanical tension. In terms of controlled production conditions, this can only be achieved if the scissors or metal blades consistently have the same size and shape – which also means that manual production steps must be completely eliminated and all parts must be machined, ideally by robot-assisted CNC manufacturing. Only this approach allows the meaningful production of reproducible parts. While on the surface, the design of bipolar scissors needed just a few changes, consistent implementation actually led to enormous production process modifications requiring extremely high investments.

72.13 Bipolar Scissors

For some time now, bipolar scissors (Fig. 72.68) have been used in almost all surgical disciplines. Preferred fields of application in clinical use are (among others):

- Intestinal surgery (e.g. hemicolectomy, sigmoidectomy)
- Urology (e.g. prostatectomy)
- ENT (e.g. neck dissection)
- General surgery (adhesions)
- Gynecology (e.g. hysterectomy).

Outlook

Continued development will be of great importance, with focus on specialized, indication-specific multifunctional instruments. It will certainly be a challenge to enhance the solidity and durability of the scissors while

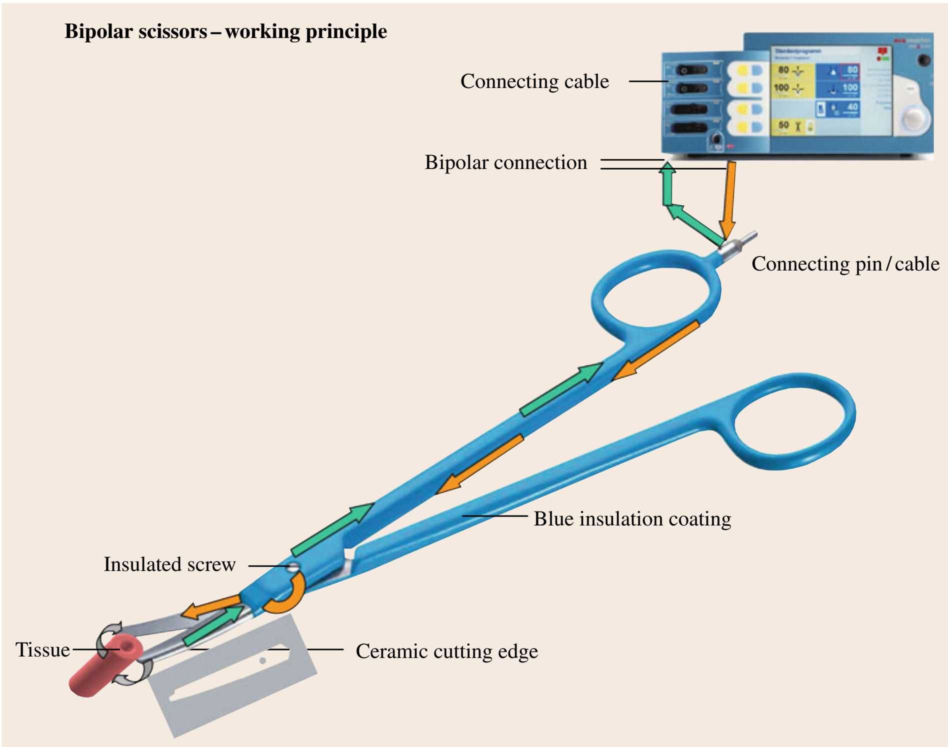

Fig. 72.68 Bipolar scissors – working principle

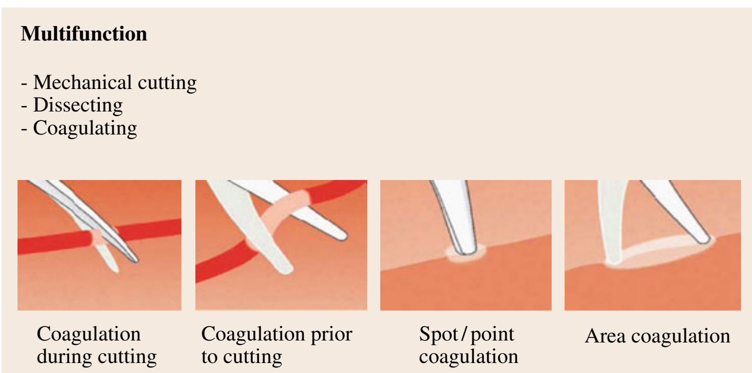

Fig. 72.69 Multifunction of bipolar scissors

making their use still easier in daily practice. Moreover, to ensure the greatest possible safety for the patients, it will also be important for users, surgeons, and surgical staff to keep themselves well-informed about the current and future developments taking place in the industry.

Further Reading

- DIN EN 285:2009-08 Sterilization – Steam sterilizers – Large sterilizers (Beuth, Berlin 2009)
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- KLS Martin, Umkirch, Germany, Product Catalogue Instruments
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- J.A. Nideffer: *Learning Surgical Instruments* (CreateSpace, New York 2009)
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72.1 Instrument Processing Working Group: *Proper Maintenance of Instruments*, 8th edn. (IPWG, Mörfelden-Walldorf 2004)