KLS martin GROUP

Surgical Instruments

From the design to maintenance and care and the function test...

Everything you need to know about our instruments!

Table of Contents

Preface 4

KLS Martin Quality Instruments 6-7

General Information
about the entire instrument range 8

Basic Principles
of the maintenance, care and preparation of surgical instruments 9-12

Cutting 13
Scissors....14
Wire cutting pliers 15
Punches 16
Bone rongeur forceps 17
Osteotomes, chisels, gouges 18
Scalpels 19

Holding/Gripping 21
Clamps 22
Needle holders 23
Forceps 24
Rongeurs 25
Forceps/pliers 26

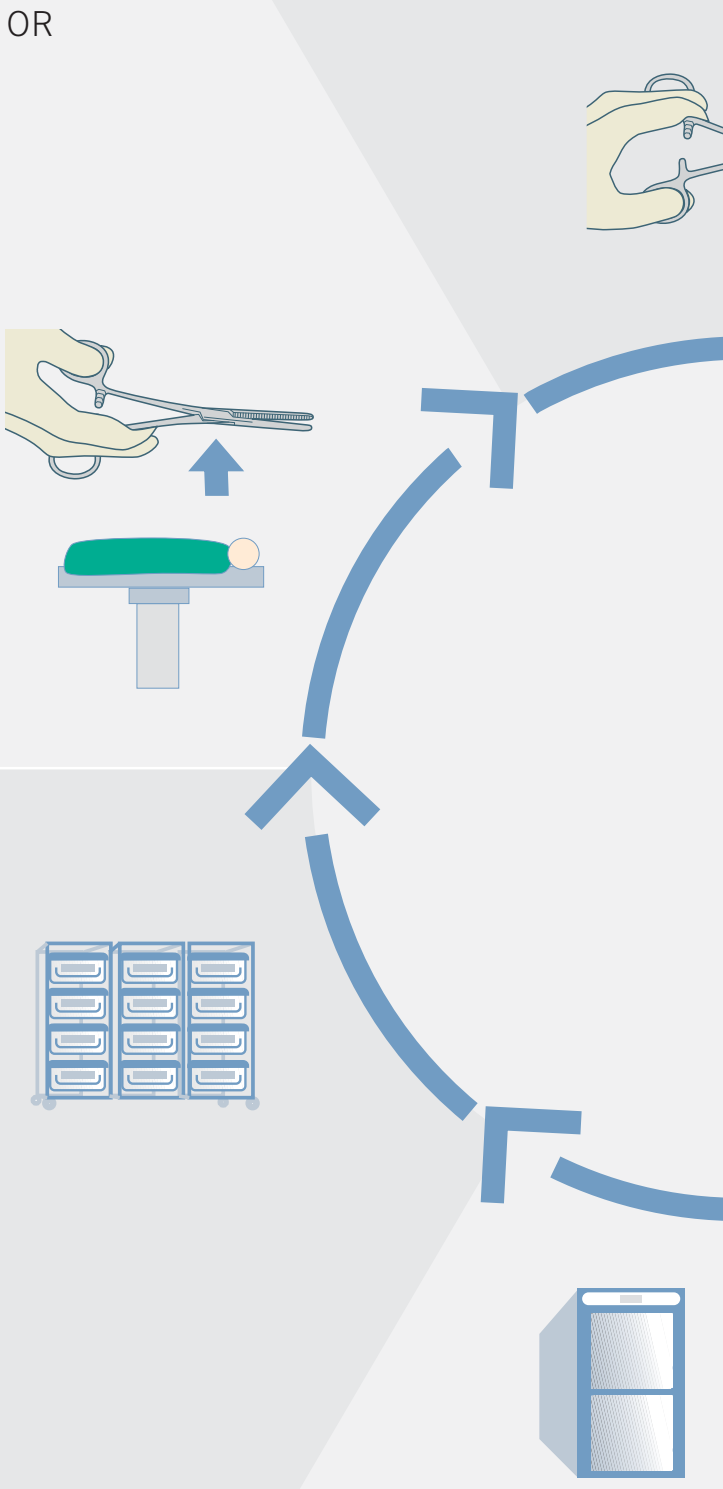
Suctioning/Rinsing 27
Suction cannulas 28
Cannulas 29

Spreading 31
Wound spreaders 32
Abdominal retractors 33
Wound hooks 34
Rib retractors 35
Specula 36
marManagement 38
TestKit 39

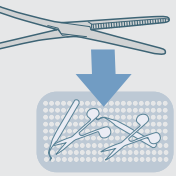
Preface

In order to maintain the value of high quality instruments, maintenance, care and preparation play a very important and central role.

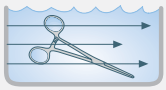
This brochure aims to clarify basic questions about these points and give an overview of the diversity of high quality instruments provided by the KLS Martin Group and give the intended use of each of the product features.



Disposal



Cleaning



Ultrasound

Machine cleaning

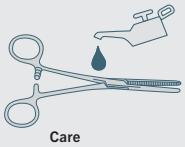
Final rinsing with demineralized water

Manual cleaning

All new instruments have to be washed at least three times before they can be included in the instrument cycle.

Single use

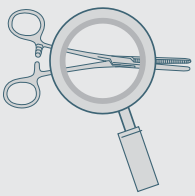
Sterile Supplies Cycle

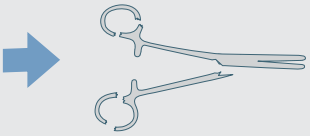


Care

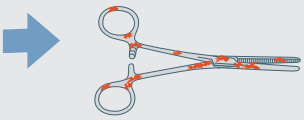
Max. in the first lock

Functional test

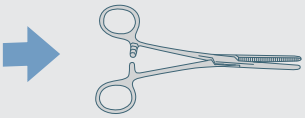




Defective instruments



Rusting instruments



Instruments for other sterilization procedures

STERILE

Sterilization

Care and Functional Tests

KLS Martin Quality Instruments

Medical devices are subject to a set of uniform laws throughout the European Union. In this context, the EC Directive concerning medical devices places rigid quality demands on surgical instruments as well. Any manufacturer must heed and meet these requirements, as non-complying products are barred from being placed on the European single market. Similar regulations are in place in the United States and Japan. Other countries have started preparing and implementing their corresponding regulations.

Introduction
As an international supplier of medical devices, the KLS Martin Group has always given top priority to quality issues with regard to its surgical instruments. In fact, quality was a priority in our company long before legal regulations were put in place. Furthermore, since we have always gone a good deal beyond legal requirements, it is not surprising that competent KLS Martin employees have contributed greatly to the preparation and continuous improvement of both German and international standards governing the function, shape and quality of the various different instruments.

Development
It goes without saying that before an instrument can be manufactured, it must be designed first. The KLS Martin product divisions are, so to speak, the mediators and interpreters between the market and the design engineers. For any new instrument, they identify and define the features and properties desired by the user. In many cases, this involves bringing the development department in contact with leading surgeons, physicians or researchers. This collaboration is frequently reflected in the name given to the new product.

Once the requirements have been established, the design engineers can start developing the new instrument. Where new product series are concerned, we usually make use of our good relationships with leading research and testing institutes. All development efforts, including the tests performed and insights gained, are duly documented in the course of the design and development process. Upon completion of the development phase, the new product is validated against both the requirements defined by the product division and those defined by the law. A declaration of conformity is issued only for products that successfully passed these tests. The design is then released for production.

Materials
The materials used for the manufacture of surgical instruments are nationally and internationally standardized. As most instruments require a high mechanical strength for proper functioning, we are using hardenable chromium steels with a low to medium carbon content. In fact, a chromium content of at least 12.5% is required in order to guarantee sufficient corrosion resistance. As nickel-chromium steels, which have a distinctly higher corrosion resistance, are not heat-treatable, they can only be used for trays and specific large-surface instruments (see Annex “Current reference standards for KLS Martin products“).

Raw Materials
The first step in manufacturing surgical instruments is forging a blank. There are only few certified specialized smithies that are capable of manufacturing such blanks in line with KLS Martin’s specifications regarding the material, shape and dimensions.

Only stainless steel of European origin is used as a source material for manufacturing the blanks. Each steel batch is delivered with a recognized test certificate, and the blanks produced from this source material are likewise duly documented. The quality systems of these contractors have been well aligned with KLS Martin’s own quality system. This guarantees that any product can be easily traced to the extent required by the law.

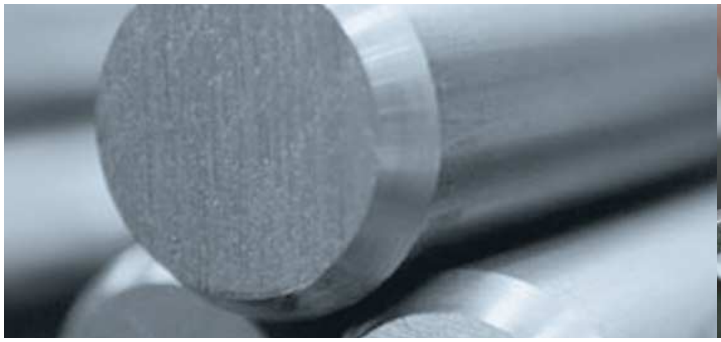
Manufacture
Based on the technical documentation established, the product then enters the manufacturing stage. All manufacturing specifications are subject to quality management. Any changes made on the product can therefore be easily tracked and pinned down at any time.

The manufacturing process is a batch process because the enormous variety of instruments required by our customers does not allow for serial production. This means that almost all instruments are, to a large degree, hand-made. Intermediate tests and inspections are clearly defined steps in the process and as such included in the manufacturing documentation.

Heat Treatment
From a functional and reprocessing perspective, the most important step in the manufacturing process is the heat treatment. The heat treatment gives those instruments that are made of hardenable chromium steels the required strength, tenacity and corrosion resistance. In contrast, instruments made of nickel-chromium steels are not hardenable, which means that the use of such steels is limited to special instruments.

In a first step, called “hardening” or “quenching”, the instruments are heated to a temperature of more than 1,000°C (1,832°F). At this very high thermal level, the chromium-carbon compounds previously encapsulated in the material dissolve completely, distributing uniformly in the steel. To preserve this ideal structure, the steel is “frozen“ by cooling it down fast, which results in a needle-type structure that gives the instrument the strength required for fulfilling its function. At the same time, the uniform distribution of the chromium content enhances the corrosion resistance to such a degree that the instruments are fully corrosion-resistant as long as the user respects the conditions specified for instrument processing.

In a second step, called “tempering”, the instruments are kept at a temperature of about 250°C (482°F) for several hours. This treatment reduces the tensions present in the instrument. As a result, the tempered instruments are significantly more elastic and less prone to fractures.



Proper heat treatment is directly reflected in the measured hardness values (see Annex “Current reference standards for KLS Martin products“). Lower (substandard) hardness values indicate insufficient heat treatment and, therefore, a lack of functionality and corrosion resistance.

Function and Finish
Following the heat-treatment stage, specially trained instrument makers give the instruments their final shape, function and finish.

Notably, Tuttlingen is the only place in the world with a system of technical colleges and training institutions specially adapted to the needs associated with the manufacture of surgical instruments and medical devices. Highly qualified employees adapt each individual instrument to its intended function. Therefore, most instruments are really “hand-made”.

The instruments’ finish has undergone changes lately as a result of more powerful operating lights and video camera systems being used in the OR. In spite of their superior corrosion resistance, mirror-finish instruments are available today only by special order because their light-reflecting surfaces tend to produce an irritating effect during operations. This is why state-of-the-art instruments feature a matte surface today. Whether such non-glare finish is achieved with glass beads or plastic brushes depends on the particular function of the instrument.

Final Inspection and Marking
On its way through the manufacturing cycle, each instrument undergoes a number of specified checks and tests, each of which is duly documented. Nonetheless, KLS Martin also insists on carrying out a classic final inspection. For each instrument, written inspection instructions and an inspection drawing have been put in place, against which every manufacturing batch is carefully checked. This final inspection is also documented in detail. Only those instruments that have passed this final examination are allowed to enter the next stage, where they are marked, cleaned and released for packaging and storage.

By affixing the CE-mark to the product, the manufacturer provides quality assurance. All products carrying this label fully comply with the “essential requirements” specified by the EC Directive concerning medical devices (MDD) as well as with KLS Martin’s documented and validated internal product profiles. As KLS Martin is convinced of the top quality of its surgical instruments, all instruments are covered by a lifetime warranty.

Current Reference Standards for KLS Martin Products

Standard	Content of the standard
DIN EN ISO 9001	Quality management systems - requirements
DIN EN ISO 13485	Medical devices – quality management systems - requirements for regulatory purposes
DIN EN ISO 14971	Medical devices – application of risk management to medical devices
DIN EN ISO 7153-1	Surgical instruments – metallic materials - part 1: stainless steel
DIN EN ISO 17665-1	Sterilization of health care products – moist heat - part 1: requirements for the development, validation and routine control of the sterilization process for medical devices
DIN 50103-3	Testing of metallic materials – Rockwell hardness testing – part 3: modified Rockwell scales Bm and Fm for thin sheet steel
DIN 58298	Medical instruments – materials, finishing and testing
DIN 58299	Serrations for surgical instruments; profile angles, groove distances
DIN 58300	Joints for surgical instruments
DIN EN ISO/IEC 17050-1	Conformity assessment – supplier's declaration of conformity – part 1: general requirements
DIN EN 60601-1	Medical electrical equipment – part 1: general requirements for basic safety and essential performance
MDD 93/42 Annex I	Basic requirements, annex I
MDD 93/42 Annex II	MDD 93/42 Annex II contains "EC declaration of conformity" (complete quality assurance system)
DIN EN ISO 17664	Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices. This information is available on the internet at http://kls-martin.com/phnet/
ASTM A967-5	Standard specification for chemical passivation treatment of stainless steel

This information is available on the internet at
http://kls-martin.com/phnet/

General Information about the entire Instrument Range

The instruments must be cleaned, disinfected and sterilized in accordance with our preparation instructions before the first use, before each additional use and before they are returned for repair, maintenance or service. The instruments can lead to premature wear and/or risks for the patient and the user.

Ensure that the following instructions are understood and taken into account:

- Every user must read the operating instructions carefully and note them.
- All of the warnings, precautions and hazard alerts must be taken into account in particular.
- The operating instructions must be available to the user at all times. This text relates to both men and women, however references to both he and she have been omitted in order to make the text more readable.

Product Liability and Warranty

Description for use

The instruments may only be used for their intended purpose in the specified medical fields, with use being restricted to adequately trained and qualified personnel. The treating physician or user is responsible for selecting the right instrument(s) for the surgical task / application at hand as well as for their safe handling. This includes ensuring an adequate level of training, knowledge and experience.

Warranty

Risk of Damage to the Instruments due to improper Use!

The responsibility for proper instrument cleaning, disinfection und sterilization rests with the operator / product user. Be sure to observe your national / local regulations, including potential restrictions.

KLS Martin, as the manufacturer of the products, accepts no liability for direct or consequential damage caused by improper use, handling, processing, sterilization or maintenance. Unauthorized instrument repair (by firms or persons not specifically authorized by KLS Martin to perform such work) shall void the warranty given!

Non-observance of these notices, as well as improper handling or use of products supplied by us, will void your rights under the warranty. Consequently, KLS Martin shall not be liable for any resulting damage in such cases.

Hotline

Should you have any questions on how to handle the unit / product or question on its clinical application, please do not hesitate to contact the Product Management:

Tel: +49 7461 706-352
Fax: +49 7461 706-312

Basic Principles of the Maintenance, Care and Preparation of Surgical Instruments

Danger of infection due to non-sterile handling!
Improper sterilization and non-sterile handling of the instruments can lead to serious health hazards for patients. All instruments must be cleaned and sterilized before using them or the first time, as well as prior to each subsequent use.
We recommend that all new stainless steel instruments be cleaned separately before being introduced into the instrument cycle in order to positively influence the formation of the passive layer. In particular, brand-new stainless steel instruments are more susceptible to surface changes due to the influence of products already in the process.

Processing, Cleaning, Care, Disinfection and Sterilization

Inspection and Testing Prior to Reuse

Before each use, the instruments must be thoroughly inspected for damage such as fractures, cracks or deformation, as well as for functional reliability. Special attention must be paid to cutting edges, tips, joints, box locks, ratchets and all movable parts. Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. Worn, corroded, deformed, porous or otherwise damaged instruments must be disposed of. Alternatively, corresponding measures can be initiated (e.g. surface treatment), see also the recommendations by the Instrument Processing Working Group (AKI):
http://www.a-k-i.org > AKI-brochures > Red brochure

Due to their alloy, stainless steel instruments typically develop a passive film in the form of a protective layer. However, this film does not protect them well against chemical attack by chloride ions and aggressive media and liquids!

Therefore, in addition to the instrument manufacturer's endeavors to select the right materials and process them carefully, the user must make an important contribution by ensuring proper instrument processing along with adequate and regular care.

Machine Cleaning

General Notices

It is always preferable to use machines (washer-disinfectors) for instrument cleaning and disinfection because, unlike manual procedures, machine processes can be easily standardized.

Be sure to observe and follow the operating and loading instructions provided by the machine manufacturer. In addition, only the cleaning agents recommended by the manufacturer should be used for the application at hand.

- Jointed instruments should always be processed in open condition. Be sure to arrange the items so that the water can easily flow out of cannulations, blind (non-through) holes and hollow bodies.
- Complex instruments must be totally taken apart before cleaning.
- For instruments with long or narrow lumens, standard procedures should be used only if the hot disinfectant can easily flow through the lumens and safe rinsing is guaranteed.
- The instrument trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- Store the instruments correctly in the tray. Be sure to prevent "rinsing shadows"!
- In accordance with DIN EN 868-8:2009 and DIN 58953-9:2010 and for ergonomic reasons, the following maximum loads are recommended:
  - Size 60 x 30 cm: 10 kg
  - Size 47 x 30 cm: 7 kg
  - Size 30 x 30 cm: 5 kg
- When removing the instruments from the machine after cleaning, be sure to check them for cleanness (visible dirt). This especially applies to cannulated instruments or those with blind holes. If necessary, repeat the cleaning cycle or pre-clean manually.
- The final rinse must guarantee that any residues left after the cleaning stage are completely removed. Be sure to use only fully demineralized water for the final rinse!

Wet and Dry Disposal

"Wet disposal" and "dry disposal" are basically different cleaning procedures.

- Dry disposal:
  Following use in the OR, the instruments are deposited for return to the CSSD in dry condition, without applying a disinfectant or immersing them in a disinfecting solution. So for dry disposal, the instruments are not to be cleaned with or placed in a physiological saline solution.
  If pre-cleaning is necessary after use, the instruments must be rinsed or wiped clean immediately.
  Generally, we recommend return transport in dry condition inside a closed transport container without adding fluids, cleaning detergents or disinfectants.

- Wet disposal:
  Immediately after use, the instruments are to be placed into a non-fixating cleaning and disinfecting solution.
  Please observe the instructions provided by the manufacturer of your disinfectant.
  Generally, we recommend return transport in dry condition inside a closed transport container without adding fluids, cleaning detergents or disinfectants.

Detergents and Disinfectants as well as Temperature Ranges

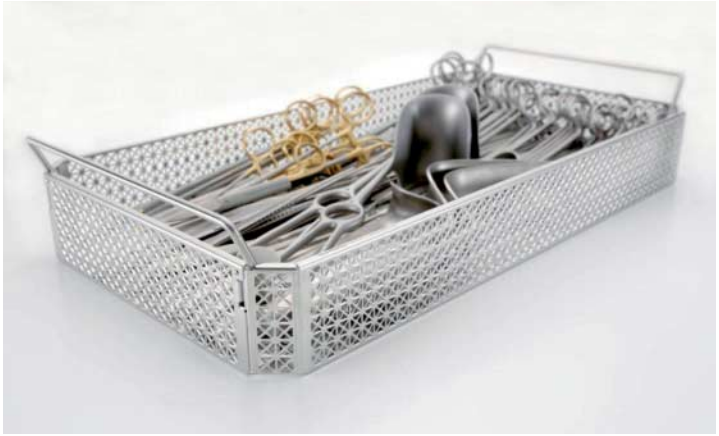
When selecting the cleaning agent system used, this must be taken into account,
- that it is basically suitable for the cleaning of invasive medical devices made of metals and plastics,
- that - if no thermal disinfection is used - an additional suitable disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/ clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, and that
- that the chemicals used are compatible with the products.

When selecting detergents and disinfectants, make sure that the following ingredients are not present:
- organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- Alkalis/strong alkalis/neutral/enzymatic cleaner (max. permissible pH value 8.5) mandatory for products made of aluminium or other alkali-sensitive materials or alkaline cleaner (max. permissible pH value 11)
- organic solvents as a base component (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agent (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant as well as the specifications for rinsing must be adhered to.

Use of neutral-pH treating agents recommended!

Metallic coated surfaces (e.g. SolidBlack) and all titanium components may show material changes after only a short while if alkaline cleaning



agents or acidic neutralizers are used. These are usually grayish or brownish minor discolorations of the coated surface or a fading of the anodized titanium. According to current research, this does not affect the functionality. Hydrogen peroxide must not be used on SolidBlack coatings. A high degree of material preservation is achieved by using pH-neutral treatment agents.

Media containing chlorides attack surfaces!
Water with a chloride content exceeding 120 mg/l can attack the surfaces of your instruments during cleaning. If you use water with a chloride content of less than 120 mg/l, you still need to take the concentration effect during drying into account as well.

Ensure reliable drying!
Reliable drying is an essential factor for successful sterilization!

Manual Cleaning

Whether a product is validated for a manual procedure can be reviewed at www.klsmartin.com/processing. Due to the substantially lower efficiency and reproducibility, a manual process – even when using an ultrasound bath – should only be applied when a machine-based process is not available. Be sure to prevent residues from drying on the instruments as this would make proper cleaning and disinfection more difficult than necessary.

The following should be observed in manual cleaning processes:

- When choosing a cleaning detergent, the compatibility with the material as well as the suitability for and the efficiency in the cleaning of medical devices must be considered.
- Use a suitable brush for cleaning lumens, cannulations, blind holes and cavities, making sure that every part of the inner surface can be properly accessed.
- Use a soft brush and a neutral or mildly alkaline detergent for removing blood and other residues.
- Never use metal brushes or metal sponges for manual cleaning.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Clean jointed instruments in closed as well as open condition.
- Take instruments fully apart where applicable.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes and other areas that are hard to access.

- Suitable trays or baskets (e. g. sterilization trays or wire baskets) must be used for storing surgical instruments properly during the cleaning process.

Ultrasonic Treatment

Effective ultrasonic cleaning requires placing the surgical instruments into suitable sterilization trays or wire baskets in an open condition. As the use of plain warm water alone cannot produce satisfactory results, it is necessary to add a suitable cleaning agent. Be sure to observe and follow the manufacturer's instructions with regard to concentration as well as temperature. Since an excessive dirt content of the cleaning solution has an adverse effect on the cleaning results, the solution must be replaced at regular intervals in accordance with the manufacturer's instructions. In the same manner, prescribed immersion or ultrasonic treatment times must be strictly observed.

As a rule, ultrasonic cleaning must always be followed by a rinsing cycle. Be sure to check the instruments (where applicable) for loosened components after the ultrasonic bath. To prevent water spots ("spotting"), fully demineralized or distilled water should be used for the final rinse.

Chemical Disinfection

- The solutions employed for chemical disinfection must always be used in accordance with the manufacturer's instructions. They have to be basically suitable for the cleaning and disinfection of invasive medical devices made of metals and plastics. Furthermore, suitable for ultrasonic cleaning (no foaming).
- Only disinfectants with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval/ clearance/registration or CE marking) and compatible with the cleaning agent must be used.
- The used detergents and disinfectants must not include the following ingredients:
  - organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
  - Alkalis/strong alkalis/neutral/enzymatic cleaner (max. permissible pH value 8.5) mandatory for products made of aluminium or other alkali-sensitive materials or alkaline cleaner (max. permissible pH value 11)
  - organic solvents (e.g. alcohols, ethers, ketones, benzines)
  - Oxidizing agent (e.g. hydrogen peroxide)
  - halogens (chlorine, iodine, bromine)
  - aromatic/halogenated hydrocarbons
- Combined cleaning/disinfectants should not be used
- Occupational safety measures must be observed in accordance with national regulations.

Inspection after Cleaning

- Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits.
- Instruments with stains or spots must be withdrawn from service at once and given special treatment.
- Check the instruments, and in particular their connections, for fractures, cracks, deformation, damage and proper function.

- If damage or malfunction is detected, the instrument must also be withdrawn from service immediately.
- The DIN 96298-3 Medical Instruments - Terms, measurement methods and tests Part 3: Tests can be used to support functional testing.

Instrument Care

"Care" means treating the instruments with instrument oil or milk (white oil-in-water emulsion). Instruments with joints or box locks (scissors, forceps, clamps, etc.) or with metal sliding surfaces (rib shears, punches, etc.) must be treated with steam-sterilizable care agents based on paraffin oil. The paraffin oil must comply with the pharmacopoeia in force at the time and must be physiologically safe as specified in the German Pharmacopoeia ("Deutsches Arzneibuch", 10th edition (DAB 10)", "European Pharmacopoeia (Ph. Eur.)" or "United States Pharmacopoeia (USP)".

Care agents prevent metal-on-metal friction, thus ensuring the easy movement of your instruments. Laser-marked products can be adversely affected when using basic cleaning agents containing phosphoric or hydrofluoric acid because the marking may fade away and the coding function get impaired or lost as a result.
As a rule, surgical instruments must be subjected to regular care, which means each time before a functional test is carried out. At the same time, it is important to prevent "gumming" of the joints due to an accumulative effect, especially in instruments that are continuously in use.

Sterilization

Prior to Sterilization

- Prior to sterilization, the instruments must be adequately packaged according to EN 868, ISO 11607, e. g. using containers,
- The packaging method used must comply with the relevant

standards.
- Check the instruments for cleanness and integrity.
- Clean and disinfect the instruments and rinse them with distilled water, then dry them carefully,

Steam Sterilization

Danger of Infection due to non-sterile Handling!

Improper sterilization and non-sterile handling of the instruments can lead to serious health hazards for patients. Sterilization must be carried out according to a validated steam sterilization process, for example in a sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance) and validated in accordance with ISO 17665 requirements. Other sterilization procedures are not permitted.

It is essential to keep the steam free from any foreign bodies such as rust particles and other impurities. This helps to prevent instrument corrosion or surface damage caused by deposits. The steam used for sterilization must comply with EN 285:2009. The user instructions provided by the steam sterilizer manufacturer must be duly observed.

Instruments incorporating locks or ratchets must be sterilized in an open condition or with the ratchet set to the first notch.
The following program variants can be used:

	Steam sterilization with fractionated pre-vacuum		
	Procedure 1	Procedure 2	Procedure 3
Pre-fractionation	Min. 3 x	Min. 3 x	Min. 3 x
Medium	saturated steam	saturated steam	saturated steam
Holding time	5 min (or longer)	5 min (or longer)	4 min (or longer)
Sterilization	134°C (273.2°F),	132°C (269.6°F),	132°C (269.6°F),
temperature	plus tolerance	plus tolerance	plus tolerance
Drying time	20 min	20 min	20 min

The basic suitability of the products for effective steam sterilization was demonstrated by an independent, officially accredited and recognized (§ 15 (5) MPG) test laboratory using the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum process as well as a commercially available instrument oil based on paraffinic white oil without additives (oils of the joints and friction surfaces). Typical conditions in hospitals and medical practices as well as the procedure described above were taken into account.

In specific, the following sources should be observed for cleaning, instrument care, disinfection and sterilization:

- ISO 17664: “Sterilization of medical devices/Information to be provided by the manufacturer for the processing of resterilizable medical devices”
- EN 285: “Sterilization - Steam sterilizers - Large sterilizers”
- ISO 17665-1: Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN 556-1: Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
- Recommendation of the Instrument Preparation Working Group (Arbeitskreis Instrumenten-Aufbereitung / AKI), http://www.a-k-i.org, “Proper Maintenance of Instruments”
- Recommendation of the German Society for Hospital Hygiene (Deutsche Gesellshaft für Krankenhaushygiene / DGKH), http://www.dgkh.de, “Hygiene Requirements for Reprocessing Medical Devices”
- Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Springal Institute for Drugs and Medical Devices (BfArM), http://www.rki.de, “Hygiene Requirements for Reprocessing Medical Devices”

Information concerning alternative Sterilization Methods
Steam sterilization has established itself as a very safe and reliable sterilization method all over the world and therefore is considered the method of choice for goods to be sterilized that are insensitive to temperature and humidity. To this end, reference is usually made to steam sterilization using a validated steam sterilization process (see also EN 554). Consequently, there is no necessity to use other sterilization methods – e. g. low-temperature plasma (LTP) sterilization or formaldehyde or ethylene oxide – for sterilizing steam-sterilizable medical devices. Since plasma sterilization is the subject of controversial discussion among experts with regard to its effectiveness in cavities and lumina, KLS Martin does not perform validation of sterilization processes using gas/plasma sterilizers for steam-sterilizable medical devices. However, sterilization plant operators are free to validate their own alternative sterilization procedures for the medical devices to be sterilized.

Storage and Transportation

- Store the instruments in a clean, cool and dry place.
- Protect them against mechanical damage.
- Use adequate containers / packaging for safe storage and transportation.
- Handle with utmost care; never throw these products or allow them to fall down.
- Use approved sterilization packaging (complying with EN 868 / ISO 11607 requirements, for example) for sterilization and subsequent transportation and storage.
- When returning products, be sure to clean and disinfect all items and use sterile packaging.

Processing Restrictions, Disposal

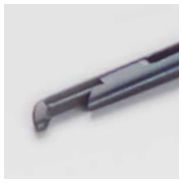
Frequent reprocessing has little effect on the surgical instruments. The product life of a surgical instrument is essentially determined by wear and tear and possible damage during use. Please dispose of your instruments in accordance with relevant local regulations, or have them properly recycled, once they have reached the end of their life cycle.

The national regulations for waste disposal must be complied with!

Cutting

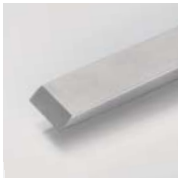
Scissors

Wire Cutting Pliers



Punches

Bone Rongeur Forceps



Osteotomes, Chisels, Gouges

Scalpels

Scissors

Tissue, wound edges, sutures

Surgical scissors, iris scissors

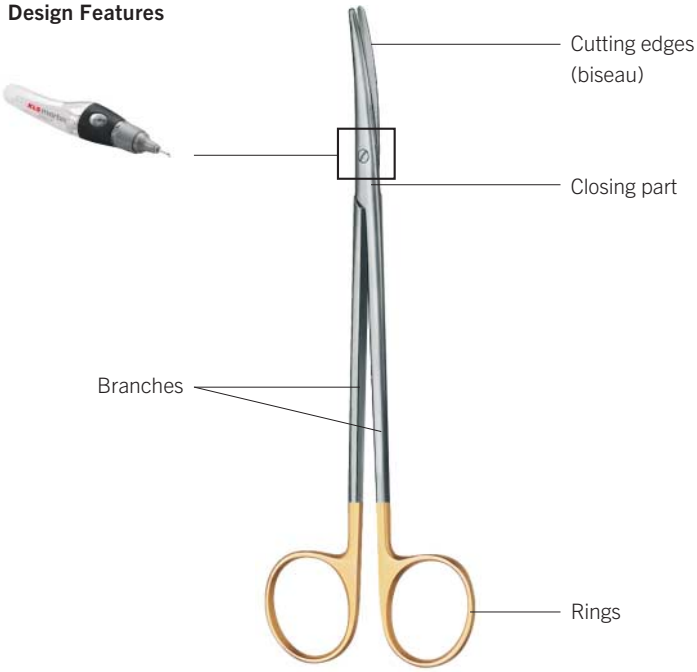
Vessel and dissecting scissors

Test material: PE foil (1.2)

Description for use

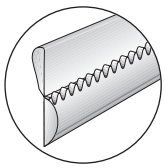
Scissors with and without carbide inserts
Scissors are used for cutting, pricking, scraping and dissecting of vessels, tissues, bones and organs during operations or for cutting dressing material or to size other medical auxiliary materials. They are used in all surgical disciplines.

Design Features



Before using the scissors, the following points must be taken into consideration:
- The area marked must be oiled
- Visual control for impurities or surface changes
- The end parts of the scissors must be checked for breakages
- The cutting edges must be checked for integrity

	Various different designs
highMed	Scissor edge/knife edge
TC GOLD sutureCut	Suture material scissors
TC GOLD	Tungsten carbide in working end
AQUILA TC GOLD	Tungsten carbide with knife edge/serrated edge
TCC BlackLine	Tungsten carbide with knife edge/serrated edge, Solid Black coated
SuperCut	Serrated edge/knife edge
ST	Serrated edge/scissor edge



One cutting edge toothed, one cutting edge with a microtome blade. Serrated blades prevent the tissue from moving, knife blades ensure a precise, atraumatic cut without the tissue being squeezed.

Wire Cutting Pliers

Replaceable carbide plates

Non-replaceable carbide plates

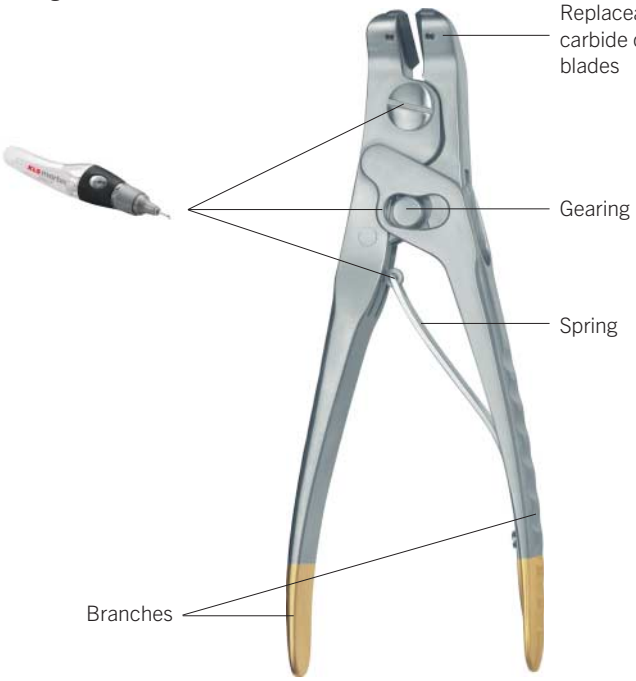
Test material: Carton (1.5)

Description for use

Forceps/pliers are used to hold, grasp, position and prepare bone material, tissue, implants and rounded sticks and auxiliary surgical materials. They are used in all surgical disciplines. In medicine, wire cutting pliers are frequently used to cut bone wires. The maximum wire diameter to be cut can be determined on the basis of the features of the wire.

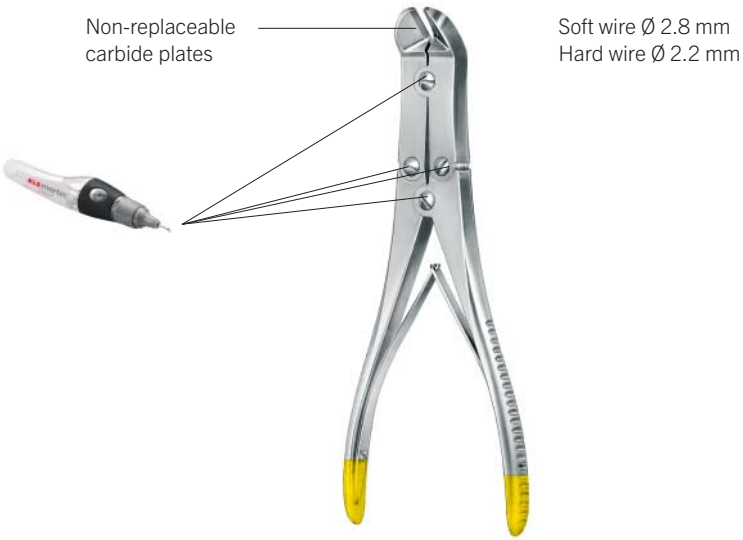
For soft wires up to Ø 2.8 mm / for hard wires up to Ø 2.2 mm

Design Features



Before using the wire cutting pliers, the following points must be taken into consideration:

- The areas marked must be oiled
- The cutting blades must be checked for damage
- If necessary replace carbide cutting blades
- A test cut can be carried out with Kirschner wire



Punches

Our range includes various different punches, including punches which cut upwards and downwards.

Cut upwards

Cut downwards

St Stainless steel

SB Solid Black
Hard-coated surface
(for extended life)

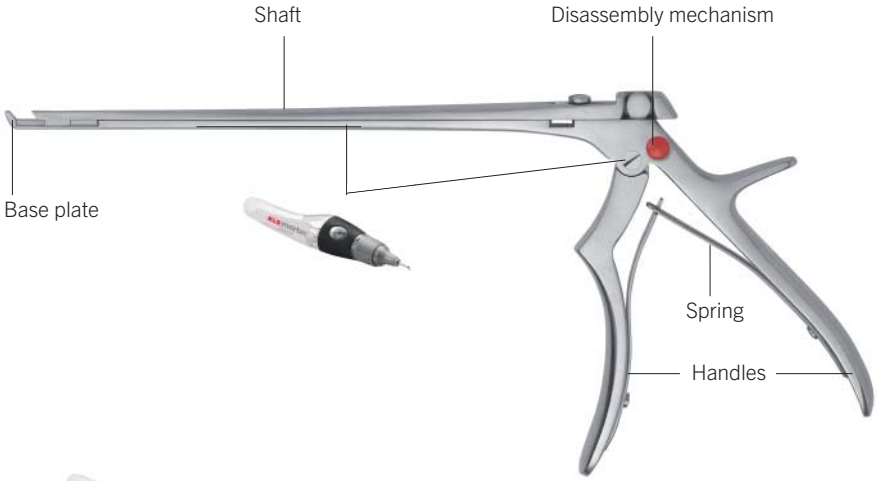
Gold spring = thin base plate

Test material: PE foil (1.4)

Description for use

Punches are used for preparation of cartilage and bones as well as tissue removal. They are used in all surgical disciplines.

Design Features



The punches must be disassembled before cleaning using a simple, rapid disassembly mechanism. This ensures 100% cleaning of the punches.

Before using the punches, the following points must be taken into consideration:

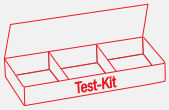
- The area marked must be oiled
- Visual control for impurities or surface changes
- The end parts of the punches must be checked for breakages
- The punch must open and close easily
- The cutting edges must be checked for integrity
- A test cut must be carried out using a special KLS Martin silicone strip

In order to ensure 100% cleaning of our punches, special cleaning and storage trays are available for our demountable punches.

Bone Rongeur Forceps

Standard design

Bone rongeur forceps
with double gearing

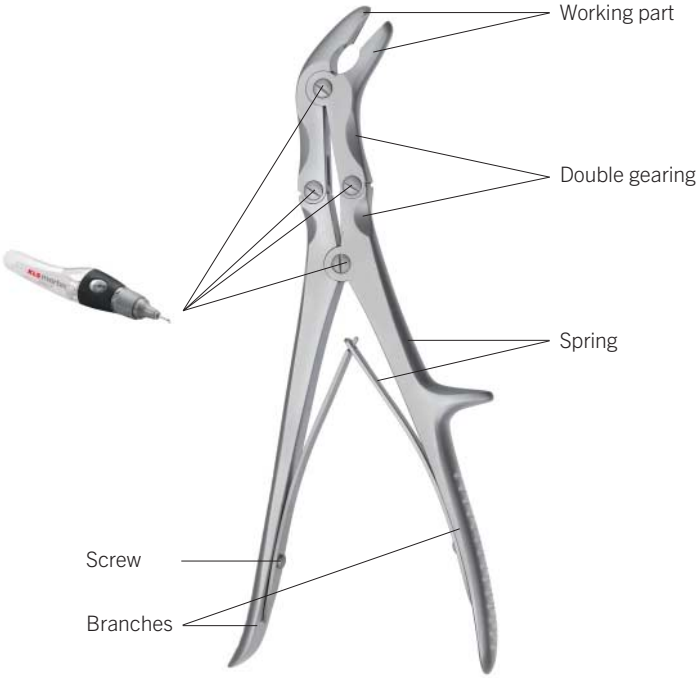


Test material: Carton (1.5)

Description for use

Forceps/Pliers are used to hold, grasp, position and prepare bone material, tissue, implants and rounded sticks and auxiliary surgical materials. They are used in all surgical disciplines. Bone rongeur forceps are used to prepare parts of the cartilage and bone. They are also used to sever fine bones. They are primarily used in orthopedics.

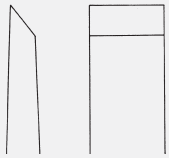
Design Features



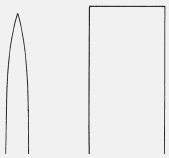
Before using the bone rongeurs/forceps, the following points must be taken into consideration:

- The areas marked must be oiled
- Visual control for impurities or surface changes
- The end joints must be checked for breakages
- Checking whether all of the necessary screws are still present
- The cutting edges must be checked for integrity
- Checking whether the working ends close in parallel
- A test cut must be carried out using a special KLS Martin box (the front 2/3 of the working end must cut cleanly)

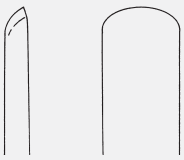
Osteotomes
Chisels
Gouges



Working part chisel



Working part osteotome



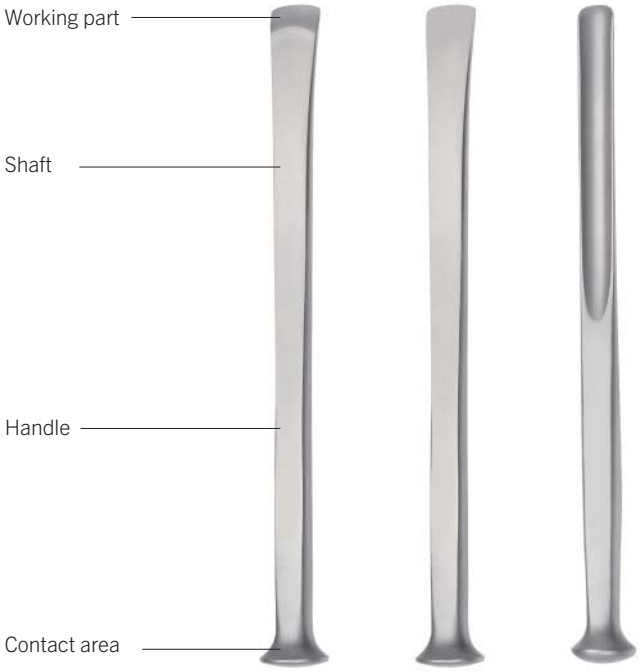
Working part gouge

Test material: Plexiglass tube (1.3)

Description for use

Chisels, osteotomes and gouges are used for cutting, pricking, scraping and dissecting of vessels, tissues, bones and organs during operations or for cutting dressing material or to size other medical auxiliary materials. They are used in all surgical disciplines.

Design Features



Before using the chisels, osteotomes and gouges the following points must be taken into consideration:

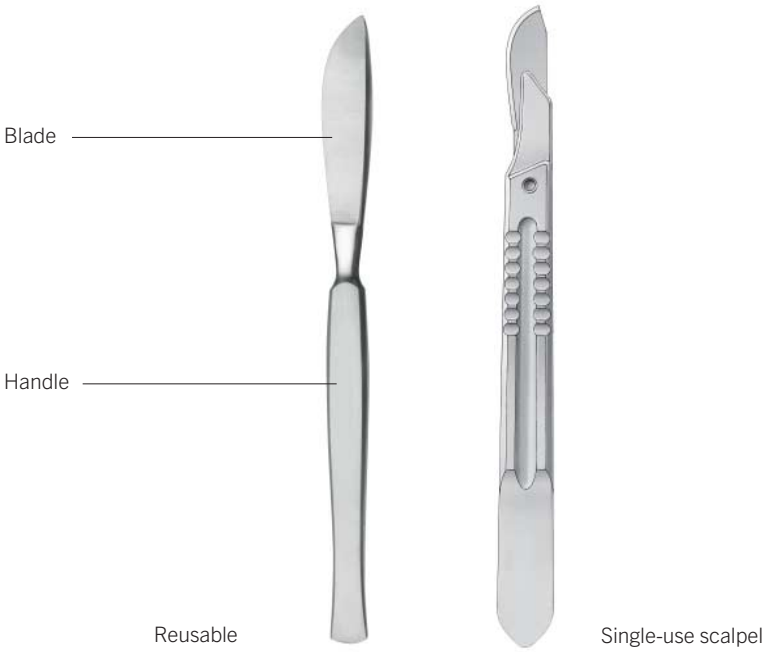
- The cutting edges may not have any nicks
- Visual control for impurities or surface changes

Scalpels

Description for use

Scalpels and knives are used for cutting and puncturing skin, tissue, vessels and organs in surgical applications. They are used in all surgical disciplines.

Design Features



Before using the scalpels, the following points must be taken into consideration:

- The cutting blades must be checked for damage
- Visual control for impurities or surface changes

In order to dispose of the single-use scalpel safely, please use KLING-EX (10-199-00-01) specially developed by KLS Martin for this purpose. This can be used to dispose of the blades quickly and safely.

Test material: PE foil (1.1)

Holding/Grasping

Clamps

Needle Holders

Forceps

Rongeurs

Forceps/Pliers

Clamps

Atraumatic clamps:

De Bakey toothing

De Bakey baby toothing

Cooley toothing

Test material: Plastic plates, paper (1.6)

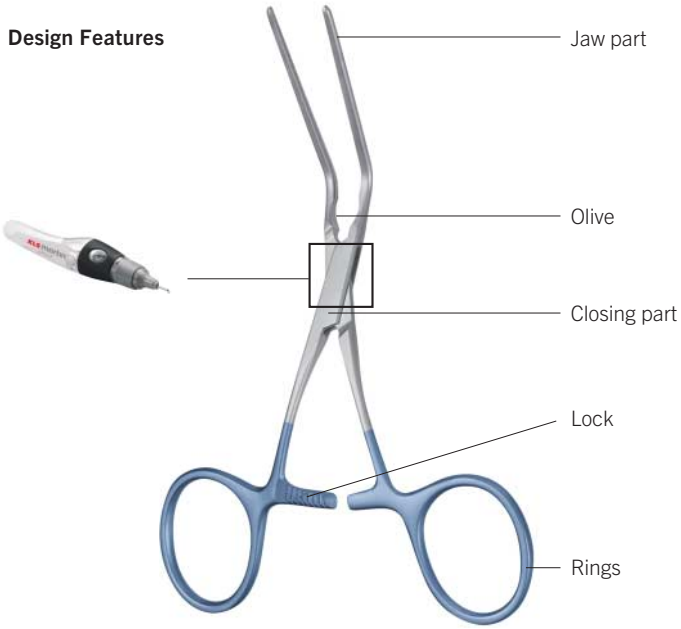
Description for use

Clamps are used for grasping and/or fixing of bodily tissue, skin, organs, bones or inserted implants, materials, accessories and aids such as swabs, drains, sutures, plasters, etc. They are used in all surgical disciplines.

They are classified as follows:

- Hard gripping clamps
- Soft gripping clamps
- Atraumatic clamps
- Anatomical clamps
- Surgical clamps

Design Features

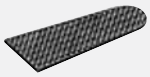


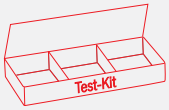
Before using the clamps, the following points must be taken into consideration:

- The area marked must be oiled
- Visual control for impurities and surface changes
- The toothing must be checked for integrity
- The end joints must be checked for breakages
- The clamp must close correctly on the working part
- The lock must lock in place and may not unlock independently

Needle Holders

The following carbide inserts are used for
TC GOLD needle holders

	Division	recommended for suture material
	Standard 0.5 mm	0.6 – 4.0
	Mini 0.4 mm	4.0 – 6.0
	Micro 0.3 mm	5.0 – 12.0
	Smooth -	5.0 – 12.0



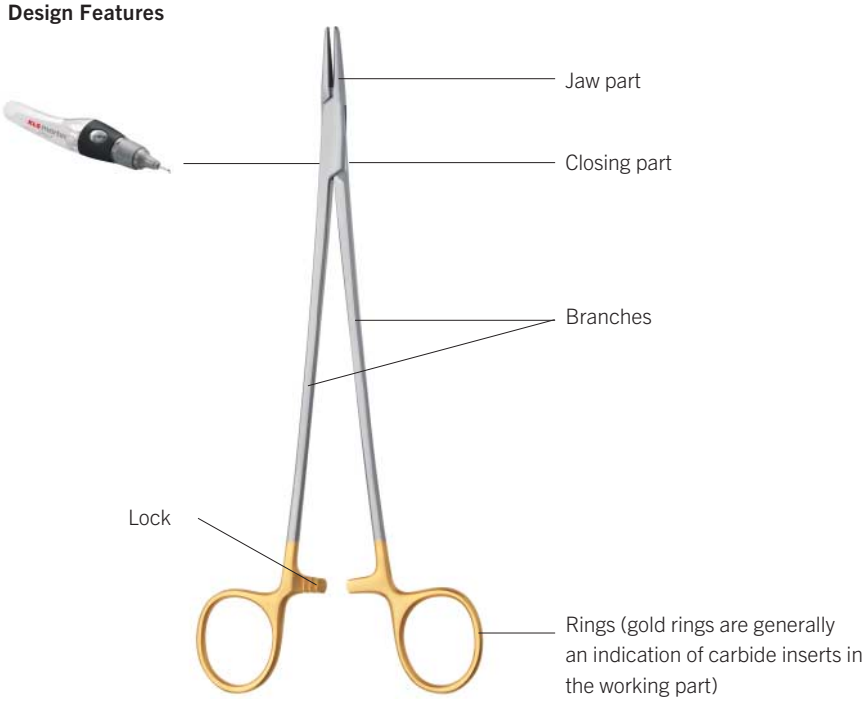
Test material: PTFE, wires (1.7)

Description for use

Needle holders are used for holding and grasping needles. They are used in all surgical disciplines.

The right choice of needle holder is important. The appropriate needle holder can be determined using the list on the left hand side.

Design Features



Before using the needle holders, the following points must be taken into consideration:

- The area marked must be oiled
- Visual control for impurities and surface changes
- The end joints must be checked for breakages
- The carbide inserts must be checked for integrity
- The lock must lock in place and may not unlock independently
- The carbide inserts must be able to be closed into one another

Forceps

Anatomical

Atraumatic
(e.g. De Bakey toothing)

Surgical
(mouse teeth)

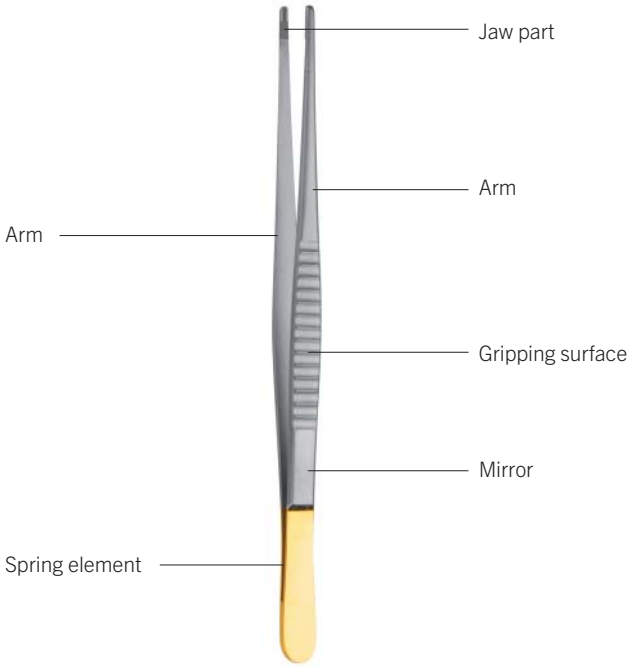
Visual inspection (1.8)

Description for use

Foreps are used for grasping and/or fixing of bodily tissue, skin, organs, bones or inserted implants, materials, accessories and aids such as swabs, drains, sutures, plasters, etc. They are used in all surgical disciplines.

Forceps are divided into three main categories:
- Anatomical forceps
- Atraumatic forceps
- Surgical forceps

Design Features



Before using the forceps, the following points must be taken into consideration:
- Visual control for impurities and surface changes
- Check working ends for integrity
- In the closed position, the working ends must lie on top of one another perfectly
- The spring part must be checked for fissures

Rongeurs

Straight

Angled upward

Angled downward

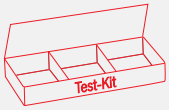
St

Stainless steel

SB

Solid Black

Hard-coated surface (for extended life)



Test material: PE foil (1.4)

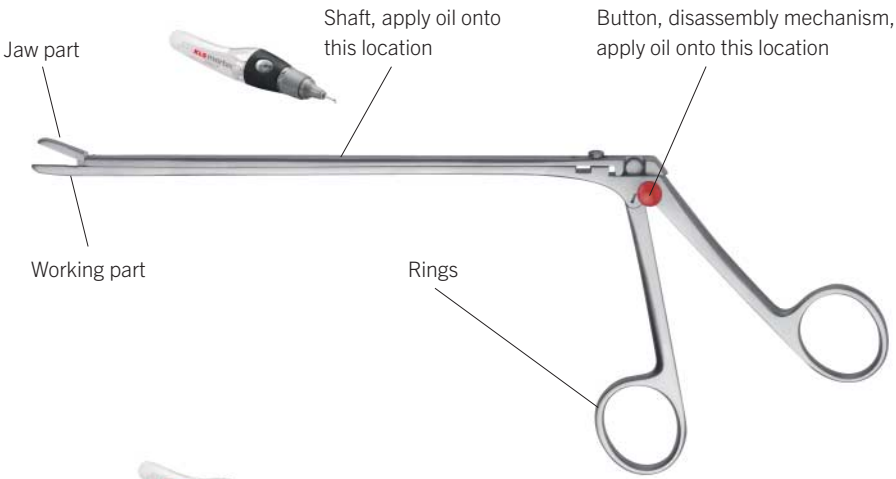
Description for use

Rongeurs are used for preparation of cartilage and bones as well as tissue removal. They are used in all surgical disciplines.

Flat pliers are available in two different designs:

- Standard design
- Flat pliers with carbide inserts

Design Features



The rongeurs must be disassembled before cleaning using a simple, rapid disassembly mechanism. This ensures 100% cleaning of the rongeurs.

Before using the rongeurs, the following points must be taken into consideration:

- The area marked must be oiled
- Visual control for impurities or surface changes
- The end parts of the punches must be checked for breakages
- The punch must open and close easily
- The cutting edges must be checked for integrity
- A test cut must be carried out using a special KLS Martin silicone strip

If there is excessive wear, the carbide inserts can be replaced by an expert from the KLS Martin team.

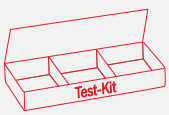
In order to ensure 100% cleaning of our rongeurs, special cleaning and storage trays are available for our demountable rongeurs.

Forceps/Pliers

Standard design

Flat pliers with carbide inserts

TC GOLD



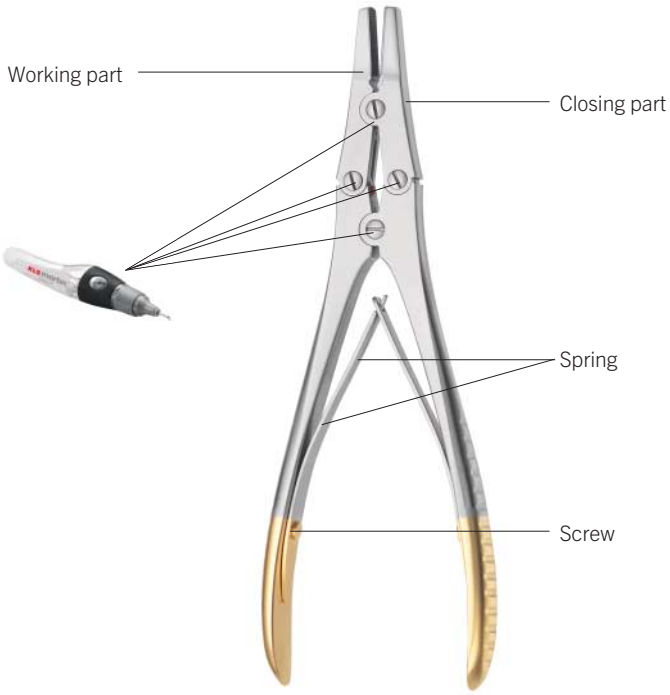
Test material: PTFE, wires (1.7)

Description for use

Forceps/pliers are used to hold, grasp, position and prepare bone material, tissue, implants and rounded sticks and auxiliary surgical materials. They are used in all surgical disciplines.

Flat pliers are available in two different designs:
- Standard design
- Flat pliers with carbide inserts

Design Features



Before using the flat pliers, the following points must be taken into consideration:
- The areas marked must be oiled
- Visual control for impurities or surface changes
- The end joints must be checked for breakages
- The carbide inserts must be checked for integrity

If there is excessive wear, the carbide inserts can be replaced by an expert from the KLS Martin team.

Suctioning/Rinsing

Suction Cannulas

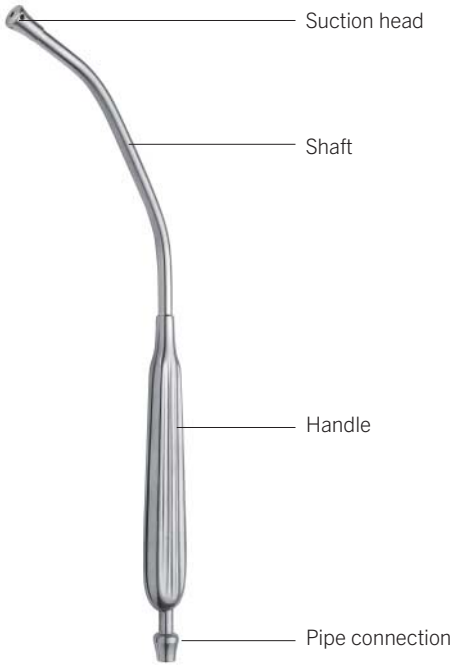
Cannulas

Suction Cannulas

Description for use

Suction units, suction cannulas and irrigation cannulas are used for suction of liquids and rinsing of tissue parts as secretion, blood, fat and/or saline solution from the operating area. They are used in all surgical disciplines.

Design Features



Non-demountable instruments with rinse connection must be sufficiently rinsed with detergent/ disinfectant cleaning solution. Sufficient throughflow must be ensured!

Before using the suction cannulas, the following points must be taken into consideration:

- The tip must be removed and the holes examined for blockages
- Visual control for impurities or surface changes
- All connections must be checked for fissures or leaks
- The shaft must be checked for deformities

Visual inspection (1.8)

Cannulas

Description for use

Suction units, suction cannulas and irrigation cannulas are used for suction of liquids and rinsing of tissue parts. They are used in all surgical disciplines. A cannula is a hollow needle which is used to inject or tap patients with fluids or medication using a syringe. The end of a cannula is mostly filed at an angle in order to make a small cut when entering the tissue.

Design Features

Cannulas are used with a Luer Lock connection as standard.
This makes it easy to attach them to a syringe.

The very sharp tip of the cannula means there is a high risk of injury.

Before using the cannulas, the following points must be taken into consideration:

- The tip must be checked for damage
- Visual control for impurities or surface changes

Luer Lock connection cannula

LL connection syringe

Visual inspection (1.8)

Spreading

Wound Spreaders

Rib Retractors

Abdominal Spreaders

Specula

Wound Hooks

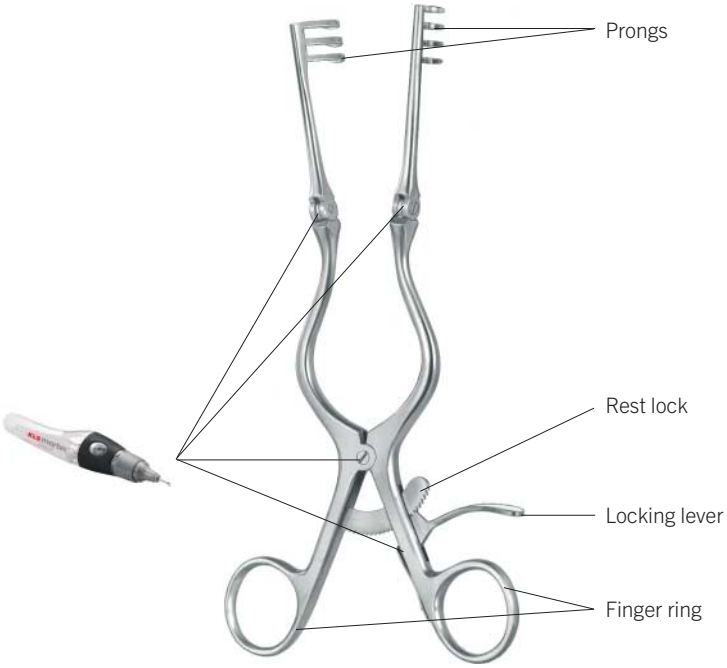
Wound Spreaders

Special design with central valve

Description for use

Wound spreaders are used for retracting the operation field. Unlike tissue retractors, wound spreaders are self-holding instruments. This is mostly achieved using a rest lock.

Design Features



Wound spreaders are available in the following designs:

- Blunt
- Sharp
- Semi-sharp
- Full-blade
- Rigid working parts
- Movable working parts (with a joint)

Before using the wound spreaders, the following points must be taken into consideration:

- The areas marked must be oiled
- The end joints must be checked for breakages
- The function of the rest lock must be checked
- The working ends (teeth) must be checked

Visual inspection (1.8)

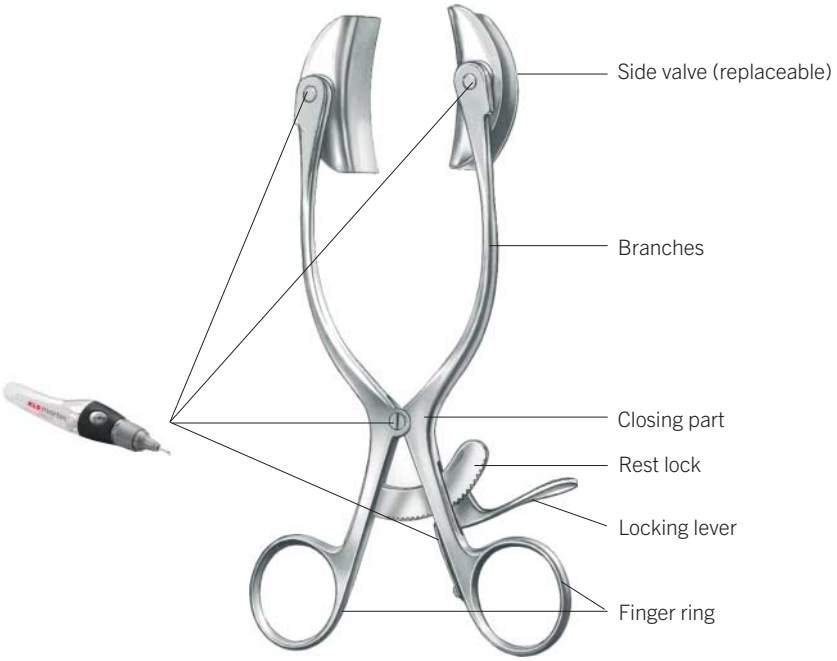
Abdominal Spreaders

Description for use

Abdominal spreaders are used for retracting the operation field. Unlike tissue retractors, abdominal spreaders are self-holding instruments. This is mostly achieved using a rest lock.

Special design with a central valve

Design Features



Abdominal spreaders are available in the following designs:

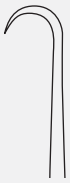
- With rigid working parts
- With movable working parts
- Special design with a central valve

Before using the abdominal spreaders, the following points must be taken into consideration:

- The areas marked must be oiled
- The end joints must be checked for breakages
- The function of the rest lock must be checked
- The leaves must be checked for burrs
- The working ends must be checked for movement

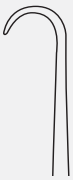
Visual inspection (1.8)

Wound Hooks

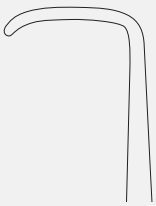


sharp

blunt



semi-sharp



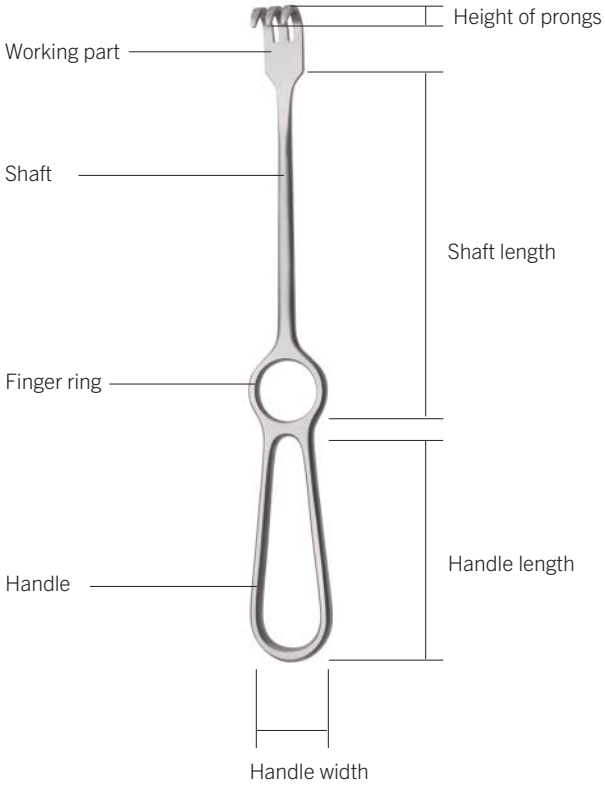
full-blade

Visual inspection (1.8)

Description for use

Wound hooks, levers and spreaders are used to hold and lift or position tissue, organs and bones and to spread wound edges. They are used in all surgical disciplines.

Design Features



Tissue hooks are available in various different designs:

- Sharp
- Blunt
- Semi-sharp
- Full-blade
- One-pronged
- multi-pronged

Before using the wound hooks the following points must be taken into consideration:

- Visual control for impurities and surface changes
- Check working ends for integrity

Rib Retractors

Rib retractors are available in various different materials:

St Stainless steel

Ti Titanium

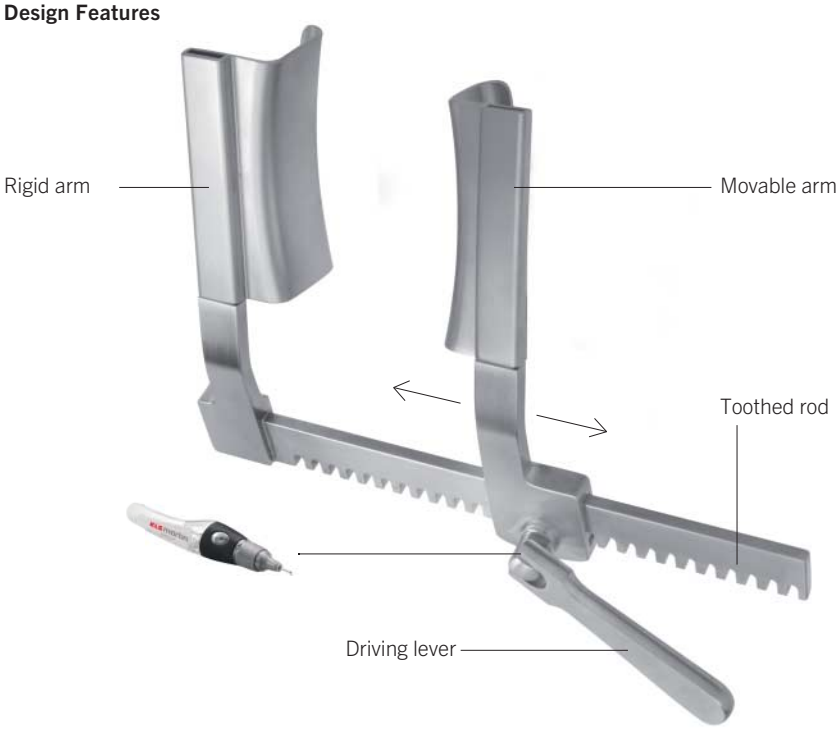
Al Aluminum

Visual inspection (1.8)

Description for use

Retractors are used for retracting the operation field. In medicine, rib retractors are used to spread the sternum during a heart operation.

Design Features



Rib retractors are available in various different materials:
- Stainless steel
- Aluminum
- Titanium

Only mild alkaline cleaners may be used in the preparation of aluminum rib retractors. The rib retractor must be completely disassembled for this.

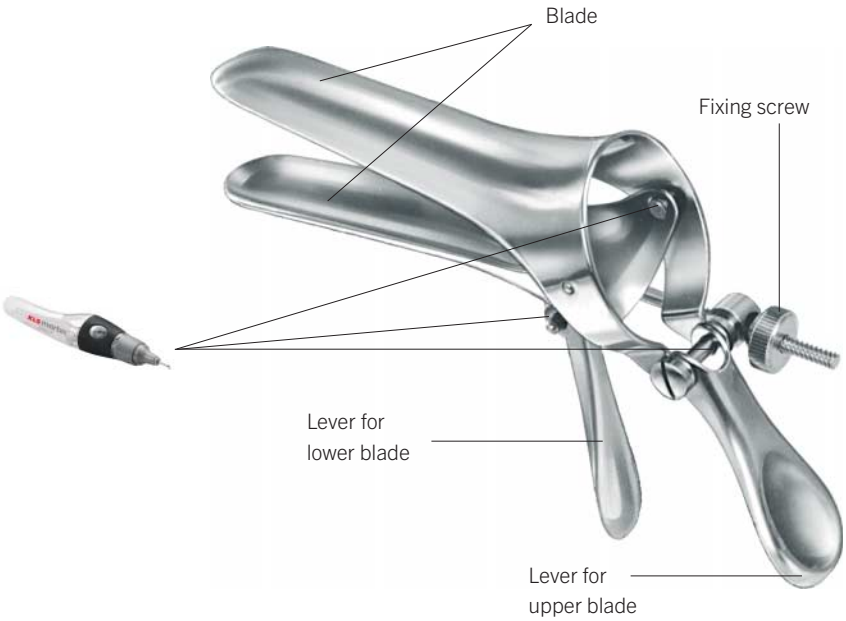
Before using the rib retractors, the following points must be taken into consideration
- The area marked must be oiled
- Visual control for impurities and surface changes
- The working ends must be checked for movement
- The functionality of the driving lever and the toothed rod must be checked

Specula

Description for use

A speculum is a medical examination instrument which is primarily used in gynecology and ear, nose and throat medicine.

Design Features



Before using the specula, the following points must be taken into consideration:

- The areas marked must be oiled
- Visual control for impurities and surface changes
- Blades must be checked for burrs and damages
- The ease of movement of the lever must be examined
- The end joints must be checked for breakages
- The working ends must be checked for movement

Visual inspection (1.8)

Surgical Instruments
16,000 ways to operate

marManagement

KLS Martin presents a concept for efficient instrument management in your hospital or department!
The marManagement concept consists of three modules which can be used individually or combined:

Instrument Audit

- Quantitative and qualitative analysis of instruments
- Classification of the instruments according to different quality levels
  - as new
  - in need of repair
  - in need of replacement
- The result is the documentation of the instruments with the appropriate quality level along with recommendations concerning cleaning and handling

Repair Service marRep

- Repair with original manufacturer spare parts
- Service agreements
- Advantages through official repair:
  - Extended lifetime
  - Functional maintenance
  - Reduces absence of the products
  - Limited patient risk

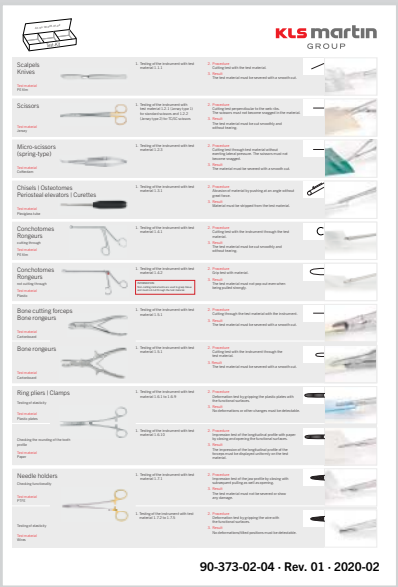
Set Optimization

- Improvement can only be achieved by means of continuous optimization
- Analysis of the instruments which are actually used during the surgery with the help of the user
- Reduction/optimization of the content of the tray to increase the efficiency of the clinics

Test-Kit

In order to achieve a qualitative function control and high standard repair quality, our Test-Kit 90-903-07-04 is available.

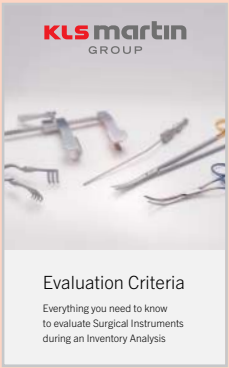
Poster Test-Kit



Our Test-Kit has defined materials for different function tests. For further information please contact us at **marManagement@klsmartin.com**

Evaluation Criteria

Our evaluation criteria for the function test are shown in the document 90-460-02-05. This ensures full transparency of our evaluations within the instrument audit and maintenance of surgical instruments



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