System dedicated to the removal of broken endodontic instruments from root canals

AESCULAP CHIFA
ERS – ENDO REMOVAL SYSTEM

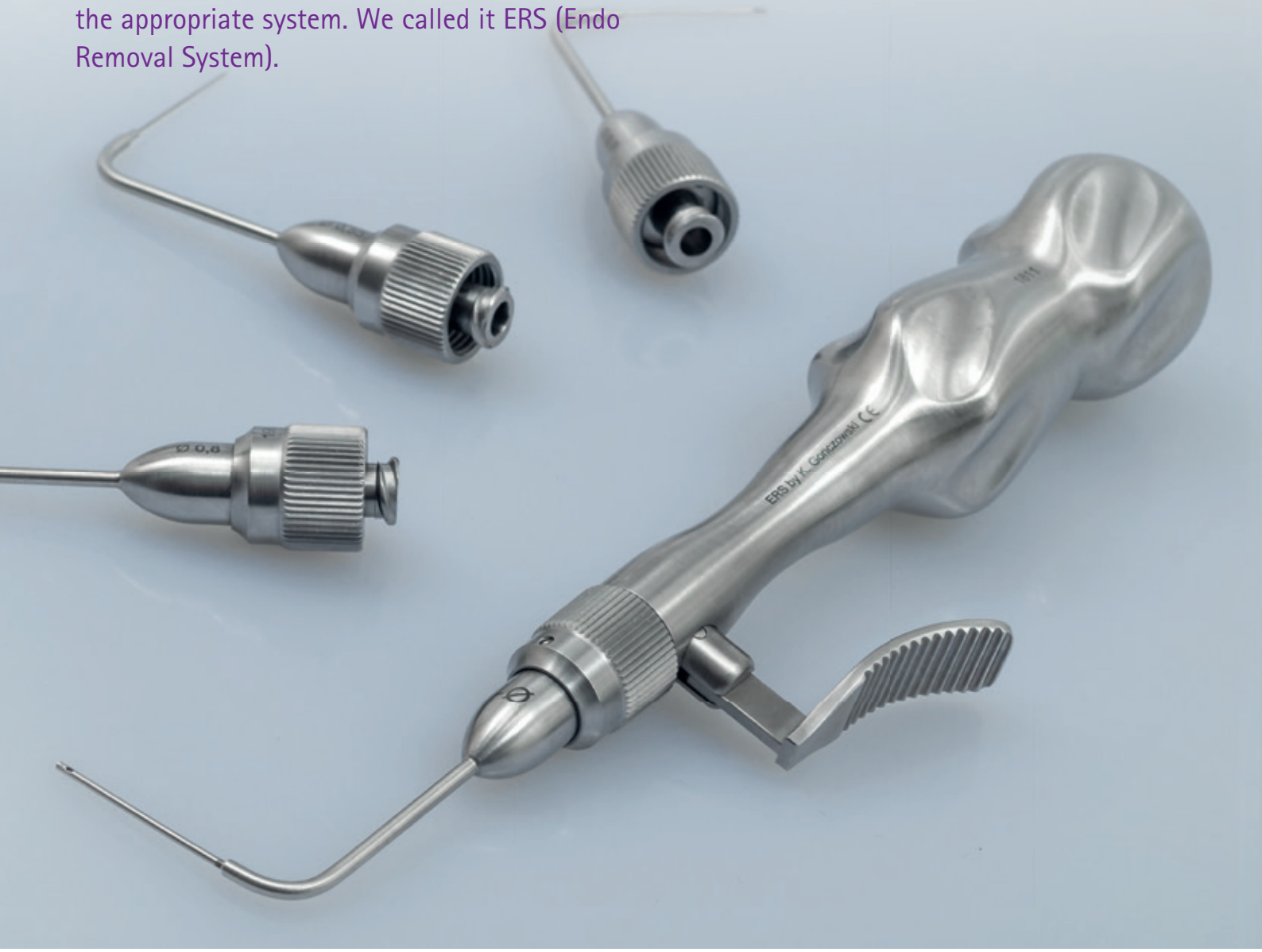
DESIGNED BY DR KRZYSZTOF GONCZOWSKI

ERS – ENDO REMOVAL SYSTEM

REACH FURTHER

OPEN UP TO NEW POSSIBILITIES

Behind every correctly done procedure of removing broken endodontic instruments stands the appropriate system. We called it ERS (Endo Removal System).



Introduction

DEAR COLLEAGUES,

Removing a broken piece of an endodontic instrument is one of the most demanding procedures performed by dental surgeons. The ultrasonic method is most commonly used for removing broken pieces of endodontic instruments. It involves dislodging and activation of the broken instrument piece using a vibrating ultrasonic tip without water cooling under visual control of a dental microscope. The key disadvantage of this method is that the broken instrument piece cannot be directly grabbed. This method is also associated with a high risk of further fragmentation of the removed piece. All too often, once the old root filling material in the root canal or the root dentin are broken down, it is not technically feasible to remove the broken piece as it is, for example, stuck firmly or too deeply located inside a narrow and angled root canal. If this is the case, one solution is to use dedicated clamping microinstruments together with an endodontic microprobe and an endodontic microlever to remove the broken piece of an instrument in a quick and reproducible manner, without any risk of complications, such as canal wall perforations or further fragmentation of the damaged instrument by ultrasounds. ERS® was designed and made of top-quality surgical steel for ergonomic and comfortable use under the control of a dental microscope. The first version of the system was designed and released in 2010. The system was modified in 2015 by adding a new unique structure consisting of a patent-protected movable wedge and microwindows. The original ERS® was designed to be used mainly for removing broken pieces of manual or machine-operated endodontic instruments with the maximum angle of convergence of 2-4 degrees. In 2019, a brand new version of the system was introduced featuring optimized retaining force of the removed instrument piece, simplicity of operation, sterilization effectiveness, and the ability to remove rotating and reciprocating instruments with higher taper. So let's open up to new possibilities and reach further.

Kind regards and I wish you all as rare as possible the need of using the ERS system in cases of own endodontic treatment;)

Dr. Krzysztof Gończowski
Author of system ERS

ERS – ENDO REMOVAL SYSTEM

REACH FURTHER

ALL YOU NEED.

Modular endodontic instrument, designed according to your individual needs.

ERS - is an abstract for an innovative system with technological improvements that sets it apart from other available solutions. ERS gives you flexibility of choice and various options treatment with ONE system. It combines simplicity and versatility allowing the operator to take the individual case approach.

Available module elements:

- Handle
- Working tip with the movable wedge 1,0mm
- Working tip with the movable wedge 0,8mm
- Working tip with the movable wedge 0,7mm
- Working tip with the movable wedge 0,55mm

The unique features of the new ERS® beta version of 2019 are as follows:

- **Extremely firm and stable grasp of a broken piece of an endodontic instrument** (as small as 0,55 mm of accessible length of the broken piece). If broken endodontic instruments with a long, thin active surface passing through a microwindow are removed (e.g. Lentulo spiral or C-File, D-File, S-File or K-File types of files), the retention force of the instrument is only one of its kind on the market and allows for smooth, quick and safe removal of the broken instrument, even if it is stuck in the bone of alveolar process extending beyond a root canal! In this clinical case the ultrasonic dislodging of the instrument would be associated with a risk of its further fragmentation.

- **No additional costs of worn single-use parts** (all ERS® components can be reused and re-sterilized).

- **No complicated procedure of instrument preparation**
  You only need to insert the selected microtip onto a universal handle, it is not necessary to assemble the ligature each time the system is used!

- **Very high resistance to mechanical damage**
  Extremely stable and simple structure resistant to misuse.

- **Precisely operating system of automatic wedge or ligature return to the starting position – Blow-back System.**
  If you fail to grasp the broken piece, release the trigger switch on ERS® handle and the wedge or the loop (depending on the selected microtip) will return to the starting position. You do not have to remove the locking element by hand!

- **Effective sterilization**
  Detachable universal handle and all microtips are fitted with a permanently attached universal Luer-lock connector. No adaptors are necessary to effectively disinfect and clean the inside of the tip with a water jet.

- **The angle of convergence of the movable wedge** is designed to effectively lock inside the tube both tiniest instruments having a low angle of convergence as well as state-of-art rotating and reciprocal files having a high taper (up to 8 degree).

DESCRIPTION OF THE SYSTEM

ERS – ENDO REMOVAL SYSTEM

HANDLE

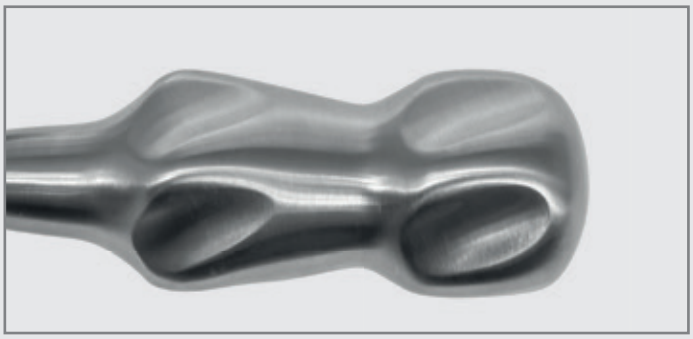
The ERS system is a universal set of instruments dedicated to the removal of broken parts of endodontic instruments from root canals under visual control (surgical microscope).

SYSTEM ADVANTAGES:

- The system is easy to use and cheap in maintenance – **it is not necessary to buy any consumable elements.**
- All the parts of the ERS system are intended for **multiple disinfection and sterilization.**
- One universal screwable handle matching to **all** the types of working tips – lower cost and simple as well as effective disinfection, cleaning and sterilization.

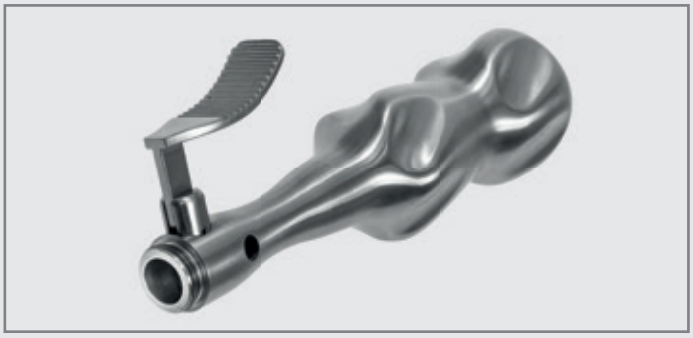
MODULE ELEMENT

HANDLE



Light (empty inside), ergonomically designed handle that fits the hand perfectly.

The surface of the handle is equipped with spiral grooves facilitating a secure hand grip with the use of all types of gloves (latex, nitrile, vinyl), also when saliva is present.



Specially designed durable trigger lever of ergonomic shape that perfectly fits the thumb fingertip of both right and left hand. The contact surface with the operator's finger was widened and covered with a special texture increasing friction and facilitating precise work with the trigger, even when the finger is covered with patient's saliva.

Long travel of the trigger! An extremely important feature that enables to properly dose the strength of grip of the broken instrument by precisely choosing the degree of pulling out of the blocking wedge or tightening the ligature loop.

DESCRIPTION OF THE SYSTEM

ERS – ENDO REMOVAL SYSTEM

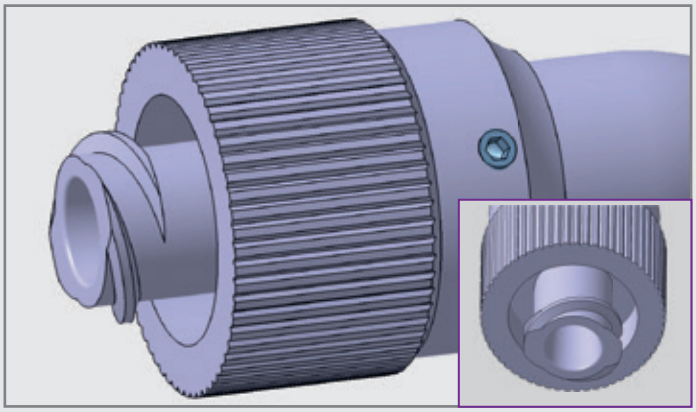
HANDLE

The system is universal for both the right-handed and the left-handed dentists and is adapted to work in **EVERY** position of operator's hand grip: forehand, backhand, proximal, distal. Threaded bush of each working tip is rotatably mounted on the shank of the tip that enables a precise, smooth and very easy regulation of setting of any working angle of the tip in relation to the long axis of the trigger lever.

MODULE ELEMENT

TECHNOLOGY

All the working tips are equipped with a **PERMANENTLY** joined Luer-lock thread. After finished work, it is not necessary to use any special adapters to perform effective disinfection and cleaning of the **INSIDE** of the tip with a stream of liquid under pressure. The thread also fits to the classical Luer type syringes, but it is recommended to use Luer-lock type syringes for washing and disinfection of the inside of the tips. They allow to generate higher fluid pressure without the risk of a sudden disconnection of the connection between the syringe and the working tip. Working tips have permanently engraved markings that are not subject to degradation during the sterilization process.



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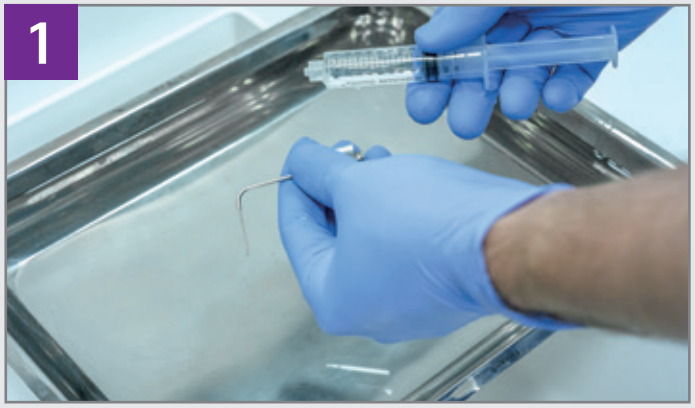

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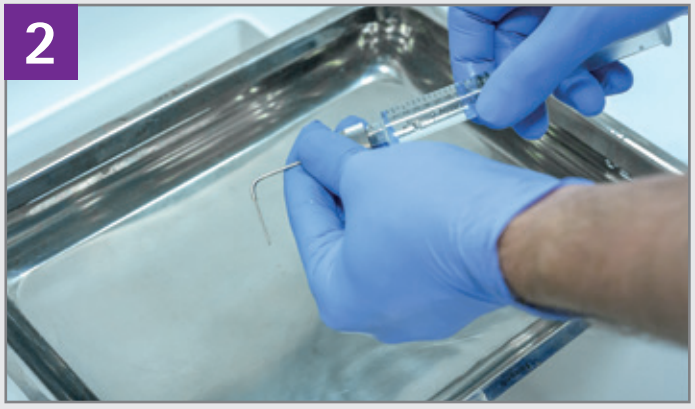


3

DESCRIPTION OF THE SYSTEM

ERS – ENDO REMOVAL SYSTEM

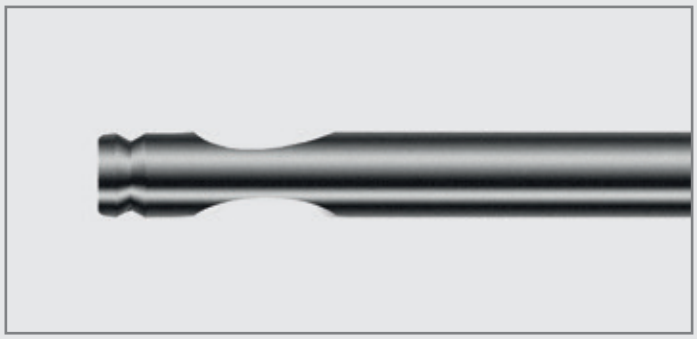
WORKING TIP WITH THE MOVABLE WEDGE

Simple design resistant to user errors and mechanical damage. In comparison to the alpha version from 2010, fragile movable parts that could be quickly worn or damaged have been eliminated.

Patent no. 226063 since March 2015

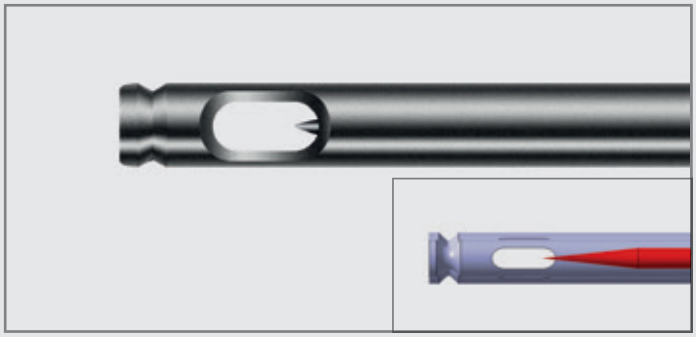
Currently it is manufactured in 4 sizes (outer diameter of the tube): 1,0mm, 0,8mm, 0,7mm and 0,5mm.

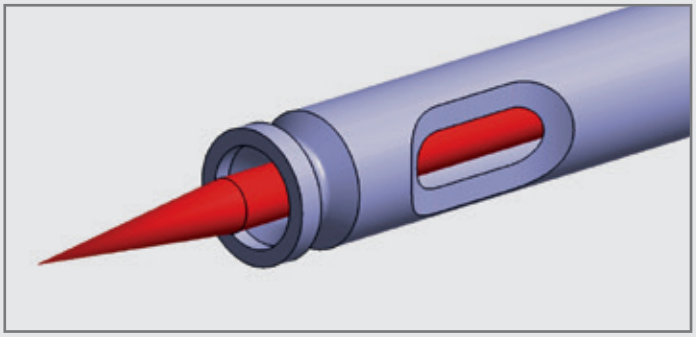
Outer diameter [mm]	1,0	0,8	0,7	0,55
Internal diameter [mm]	0,75	0,55	0,5	0,4
Internal diameter including embossment [mm]	0,5	0,4	0,35	0,25



Just behind the circular embossment there are two opposite microwindows with a diameter of 1mm / 0,4mm. They allow to insert the tube onto the broken instrument at an acute angle (and not only 180°), while still observing it under the microscope!

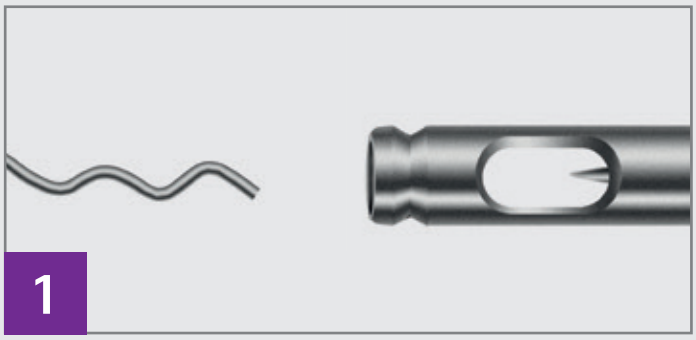
It is a unique feature of the ERS system!

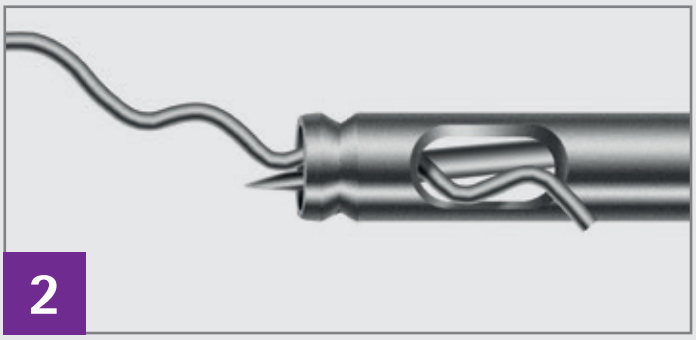


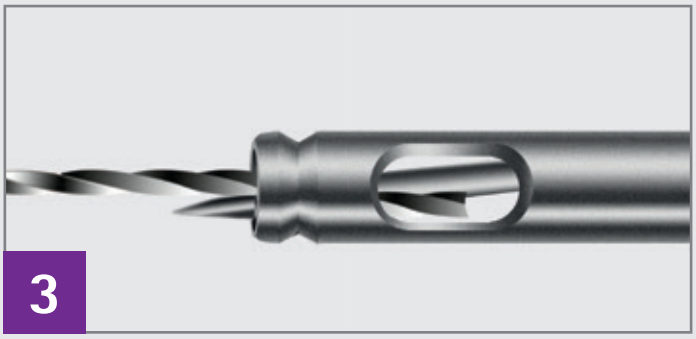


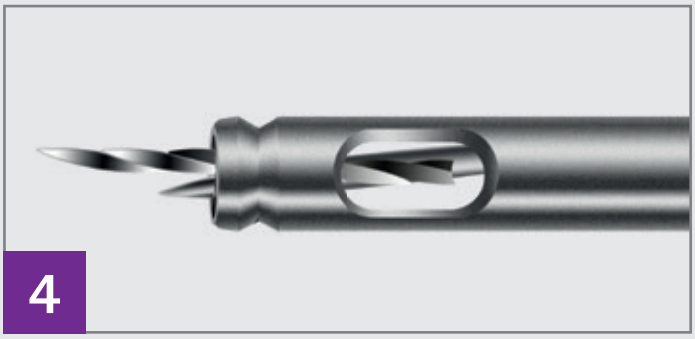
MODULE ELEMENT

TECHNOLOGY



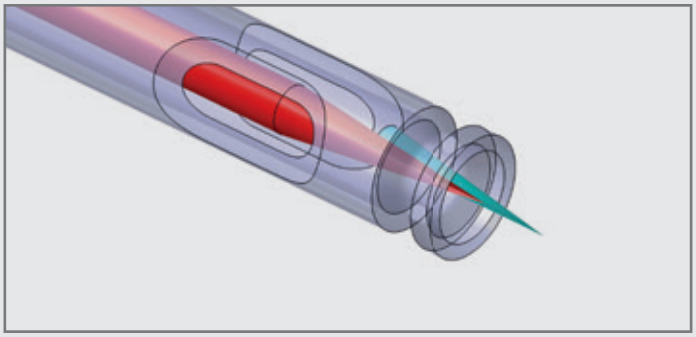


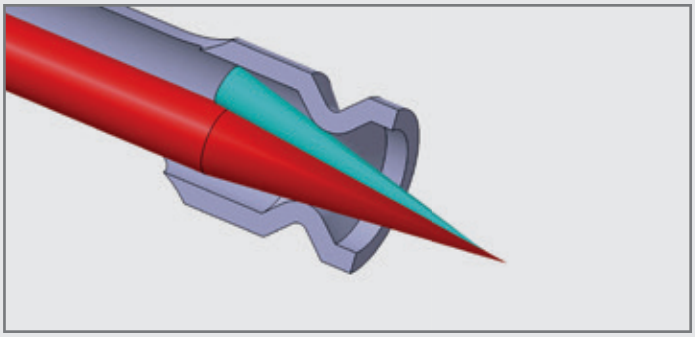




The microwindows also serve as the additional mechanical retention in the event when a part of the broken instrument passes outside the tube. **This is an absolutely unique feature of the ERS system providing extremely high grip strength of the broken instrument.** In the case of removing long and thin instruments (convergence angle of 2o and less), e.g. Lentulo needle, which are wedged and stuck partly outside the root canal in the alveolar bone or in the maxillary sinus, the use of ERS system is particularly recommended due to the risk of further breaking of the removed fragment when trying to use ultrasound systems.

The angle of convergence of the movable wedge is chosen in a way to effectively block inside the tube both the thinnest instruments with a low angle of convergence, and modern rotary or reciprocal files with a high angle of convergence (even up to 8°).





DESCRIPTION OF THE SYSTEM

ERS – ENDO REMOVAL SYSTEM

TECHNOLOGY

Inside the tip there is a strong spring, which guarantees smooth and extremely simple operation of the system thanks to the function of automatic reversing of the movable blocking wedge in the case of releasing the pressure on the trigger ("blow back system"). Long travel of the trigger combined with a strong spring tension ensures the doctor a high comfort of work, because it is possible to choose the strength of the grip of the broken instrument very precisely by the degree of pulling out the blocking wedge. The system of automatic return of the wedge to the starting position (hidden inside the tube outside the microwindows) after releasing the pressure on the trigger - "blow back system" - allows quick and effective work in the root canal in case of not gripping the broken instrument. There is no need to perform ANY additional steps to repeat the attempt to grip the broken instrument in the root canal – just release the pressure on the trigger!

THE AUTHOR

KRZYSZTOF GONCZOWSKI

Krzysztof Gonczowski DDS, PhD, MSc

Specialist of Conservative Dentistry and Endodontics

Dr Krzysztof Gonczowski graduated from the Jagiellonian University in Kraków (2000). In between 2001 and 2008 he worked and lectured as an assistant at the Institute of Dentistry Jagiellonian University (Division of Preventive Dentistry and Endodontics). Since 2001 he has also maintained his own private practice in Krakow. Dr Gończowski holds a Polish (ID No.: 2658170) and a Norwegian (ID No.: 10037928) dental license. He practises both in Poland and in Norway. In 2005 he received his PhD from Jagiellonian University and in 2007 completed his specialty in Endodontics and Conservative Dentistry. He is a two time participant of research fellowship programs in Germany, at the University of Cologne and the University of Munich. Since 2005 he has lectured and run practical courses for dentists in Poland and around the world (in over 35 countries in Europe, North America, Asia and Africa) in the scope of endodontics, efficient and comfortable local anesthesia, sedation in dentistry and dental tourism. Dr. Gonczowski is a member of several Polish and international scientific societies: ESE (European Society of Endodontology), ERC (European Resuscitation Council), SAAD (Society for the Advancement of Anaesthesia in Dentistry). He has over 45 research publications in Polish and international dentistry journals and received many prestigious awards for his research. Amongst others he is a four time recipient of CED Travel Stipend (IADR) as well as the Espertise Talent Award Europe for Young Scientists. In 2010 he designed a system of microinstruments for removing the broken endodontic instruments from the root canals - Endo Removal System®.

STAGES OF PROCEDURE USING ERS SYSTEM

DESIGNED BY DR. K. GONCZOWSKI

1. **Preliminary identification of location and type of broken instrument with RVG and/or CBCT:**

   a. Identification of the appropriate root canal where the instrument fragment is located, as well as the depth and position of the broken piece

   b. Determination of the presumed type and size of the damaged instrument – the type of the selected microtip depends on the type and size of the removed piece

2. **Getting wide access to the broken instrument with the aid of a dental microscope while maintaining maximum tissue protection:**

   a. Any suitable rotating or reciprocal endodontic instruments, including Gates-Glidden, Largo-Peeso or Beutelrock drills, can be used to widen access to the lumen of the root canal. Munce Discovery drills are highly recommended, or even indispensable. Various types of ultrasound tips can also be used (without water cooling) either with a diamond abrasive or silicon carbide brushes (slower wear and tear, better cutting performance).

   b. Trepan-like sleeve burs can be used during the final stage of the root canal extension over the broken instruments to reduce operating time, but also involve high loss of the tooth tissues. Therefore it is recommended to use an angular (typically 120o) ultrasonic tip with force reduction as well as smooth, rounded and sharp pointed files made of metal alloys that can be PERMANENTLY bent to the shape of the root canal to remove dentine and the old root filling material.

   c. No less than 0,8 mm of the removed piece should be exposed to obtain an effective gripping force of the broken instrument piece. The larger the piece of a broken instrument inserted inside the microtip, the higher its gripping force. The maximum holding force can be obtained by inserting the broken piece into the microtip and by evaluating it to the side through one of 2 microwindows located ca. 0,6 mm from the entrance.

   d. Heavy rinsing of the root canal is recommended while operating inside the root canal above the broken instrument

piece, either with sodium hypochlorite (NaOCl) or disodium edetate (EDTA), in both cases with an addition of surfactants. The detergents reduce the surface tension of NaOCl and EDTA, which more readily permeate to narrow spaces between the wall of a root canal and the broken instrument piece. The sonic activation of NaOCl is a necessary element of the root canal rinsing procedure. The most recommended sonic activation method is to use an air scaler with a single-use NON-CUTTING plastic tip as it produces no iatrogenic complications (no risk of perforation or notch excision e.g. EDDY – VDW®), offers high effectiveness of root system decontamination, and it is easily accessible and inexpensive.

e. It is recommended to use special-purpose solvents to remove old filling material in the root canal over the broken instrument. Methylene chloride is also recommended because of very high effectiveness in dissolving Gutta-percha pins and Endomethasone pastes as well as ultra-low surface tension. Alternatively, chloroform, orange oil and eucalyptol can be used.

3. Dislodging and activation of the piece of broken instrument using an ultrasonic system:

a. It is recommended to use an angular (typically 120o) ultrasonic tip with force reduction as well as smooth, rounded and sharp pointed files made of metal alloys that can be PERMANENTLY bent to the shape of the root canal. The procedure is performed under visual control of a dental microscope, without water cooling, in a pulse mode (avoid overheating – take breaks every 10-15 s while working with ultrasounds). Counter-clockwise circular movements are performed around the broken piece. The exception are broken reciprocating instruments with a left sided thread, such as Reciproc VDW or WaveOne Dentsply Maillefer, in which case clockwise rotation is recommended.

b. If the broken instrument piece is made of a Ni-Ti alloy and it is located in a curved root canal (partially behind the curvature), it is recommended to cut the root dentin with the use of an ultrasonic tip ON THE INNER SIDE OF THE CURVATURE. This is determined by the properties of the alloy that the broken piece is made of. This type of alloy has a tendency to return to its original straight alignment. Therefore if the incision is performed on the outer wall of the curvature, the broken piece will remain in a bent position in the place where its end rests on the canal wall and will lodge more firmly within the root canal.

c. As soon as the first signs of the fragment loosening are observed under the microscope, the cavitation phenomenon can be taken advantage of, caused by the vibrations of the thin ultrasonic tip within a space bound by hard walls of the root canal. The phenomenon of acoustic microflow of fluid in the vicinity of the broken element facilitates the transfer of kinetic energy from the vibrating ultrasonic tip to the fragment being removed – the liquid being denser than air more effectively transfers these vibrations.

d. If the broken fragments are long and are firmly wedged inside the root canal, or they are partially beyond the canal inside the bone of alveolar process, the force generated by the ERS® instrument may be sufficient to dislodge it while avoiding the risk accompanying ultrasonic dislodging of the instrument. In this case ultrasonic dislodging of the instrument involves a risk of further fragmentation of the proximal section of the broken instrument at an even deeper level of the canal, typically at the boundaries of the removed filler material or at the most distal extent of the root dentin preparation. This type of complication is typical of broken long fragments of Lentulo spirals, manual negotiating files, or silver points.

4. Gripping and removal of a broken instrument piece using ERS system:

a. The type of ERS® microtip is selected depending on the location, size, and angle of convergence of the broken fragment being removed. NOTE: Not all microtips are available in all countries! Currently (microtips with a movable wedge):

- 1,0 mm in diameter – removal of rotating and reciprocating instruments with a high taper (> 6 degrees)
- 0,8 mm and 0,7 mm in diameter – removal of rotating and reciprocating instruments with a low taper (< 6 degrees), manual instruments and Lentulo spirals

STAGES OF PROCEDURE USING ERS SYSTEM

DESIGNED BY DR. K. GONCZOWSKI

- 0,55 mm in diameter – removal of very thin pieces of tips of rotating and reciprocating instruments with a low taper (< 6o) and small fragments of manual instruments and Lentulo spirals – NOTE! A microtip WITHOUT microwindows behind initial serration!
- 0,8-0,6 mm (cone) endodontic microlever – a universal auxiliary tool with a very simple structure to facilitate careful dislodging and gripping of the broken instrument piece

b. The entry path of ERS® microtips with a movable wedge does not have to an extension of the long axis of a broken piece (180 degrees). This is very important from a clinical point of view as typically it is not technically feasible to gain rectilinear access, otherwise the tooth structure would have to be significantly affected. All diameters of microtips with a movable wedge, except for the smallest one (0,55 mm) are designed to grasp the instrument at a 45 degree angle. Two microwindows placed opposite each other, the size of 0,4/1mm at a distance of around 0,6mm from entrance to the tube are designed for visual control of the entry path under a dental microscope whenever there is a sharp access angle to the broken piece; the microwindows also create an additional point of reference during removal of the instrument.

c. Operating a microtip with a movable wedge:

- Introduce the instrument into the lumen of the properly widened root canal all the way down to the level of the broken instrument piece.
- Insert the sleeve on the exposed piece of a broken instrument to the minimum depth of 0,8 mm – the longer instrument piece is placed inside the tube, the higher the retention force. The maximum retention force can be produced when the broken instrument passes through a lateral microwindow.
- Smoothly press the trigger switch on ERS® handle as far as it will go.
- Remove the broken instrument piece from the root canal by pulling the microtip out without releasing the grasp.

- If the broken instrument slips out of the microtip, release the trigger switch and the blow-back system will automatically withdraw the movable wedge to the inside of the tube. This mechanism allows to immediately repeat the attempt to grip the broken tool WITHOUT having to remove ERS® from the root canal to prepare it for another grasping attempt.
- After several unsuccessful attempts to grasp and remove the broken instrument you should expose a longer section of the instrument to increase retention force inside the tube and/or improve mobility of the instrument piece by more effectively dislodging it using an ultrasonic tip NOTE! The longer the exposed piece of the broken instrument, the higher the risk it will be fragmented during an attempt to dislodge it with ultrasounds!

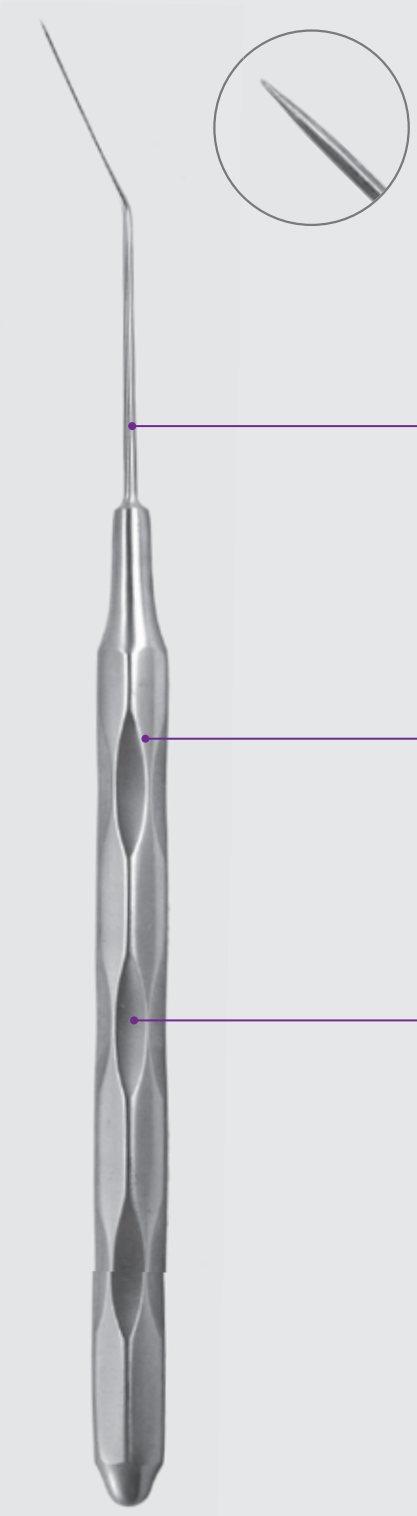
- Remove the foreign body from the root canal by pulling the microtip out without releasing the grasp.

d. Endodontic microlever + endodontic microprobe – two-handed technique with direct visual control under a microscope and in the light reflected from a mirror held by an assistant. These are very simple auxiliary instruments to facilitate careful dislodging and grasping of a broken instrument piece. They can be used separately, but their usefulness in removing broken instruments is very limited owing to their low retention force:

- Introduce the microlever into the lumen of the properly widened root canal all the way down to the level of the broken instrument piece.
- Place the semi-open sleeve over no less than 1-1,5mm of the exposed instrument piece (0,8 mm is enough with automatic microtips with the blow-back system and movable wedge). The broken piece should pass through the cone in the proximal part of the sleeve. A 5 mm window is placed behind the cone, and it is not mandatory to maintain a linear alignment of access to the broken instrument. The long axis of the microlever does not have to be an extension of the long axis of the removed instrument piece. This instrument also operates at the angle of 45 degrees.
- Place the microprobe end in the microlever window and press it to the inside of the groove and move down as far as it will go while using the wedge to block the broken instrument inside the cone in the proximal part of the sleeve.
- Remove the broken instrument from the root canal by pulling the microlever and the microprobe out without releasing the grasp – NOTE! This requires considerable manual dexterity and the help of a properly trained assistant (both physician's hands are busy – microtips with a movable wedge can be operated with one hand only!)

ADDITIONAL ACCESSORIES

ENDODONTIC MICRO PROBE - BENT



SP-015-195-ZMS

Overall length: 195 mm
Working part length: 30 mm
Working part diameter: 0,5 mm

WORKING PART

The long and sharply pointed working part allows the micro probe to be introduced deep inside the root canal without obscuring the field of vision while using the microscope.

STAINLESS STEEL

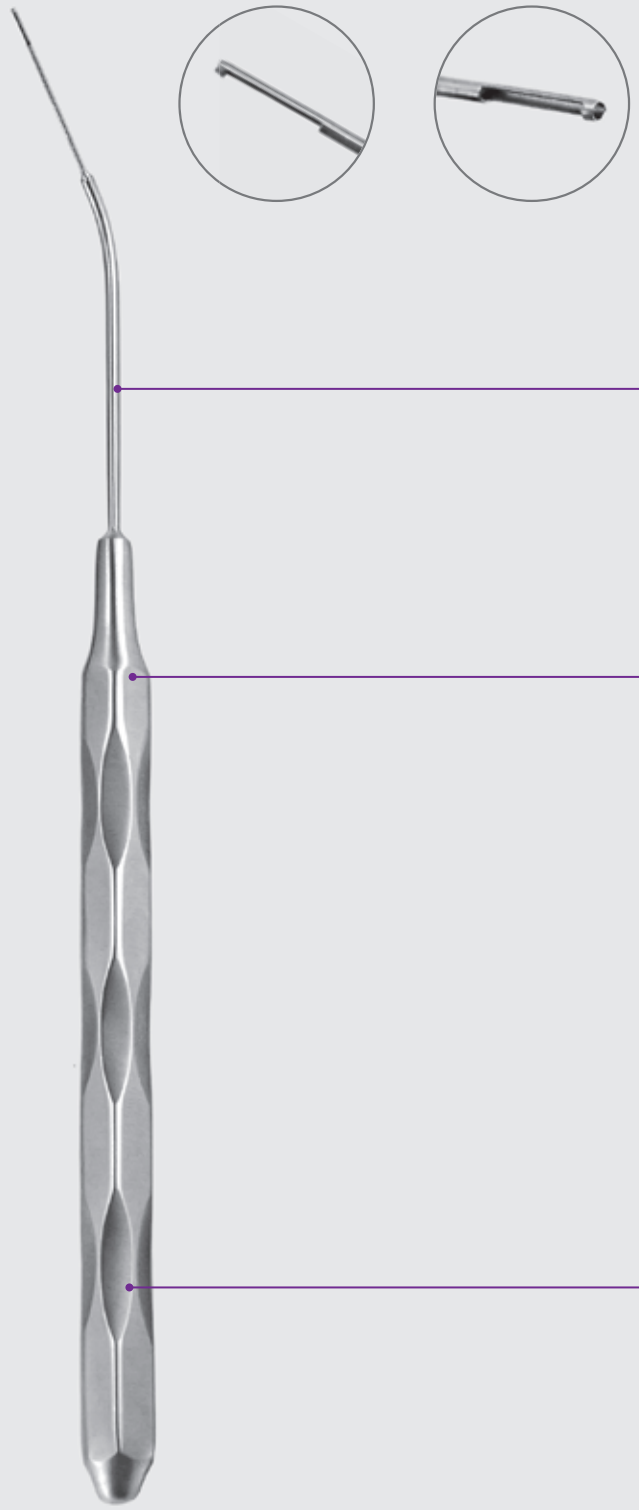
Stainless steel with plastic properties so that the micro probe can be bent to fit the shape of the root canal.

HANDLE

A light and ergonomic non-slip handle with a large diameter and profiled cuts for stable grip of the instrument.

ADDITIONAL ACCESSORIES

ENDODONTIC MICRO LEVER



SP-017-008-PMS

Overall length: 205 mm
Working part length: 7,5 mm
Working part diameter (circular cutting edge): : 0,6 mm

WORKING PART

The long and thin working part allows the micro lever to be introduced deep inside a root canal without covering the field of vision under the microscope.

SEMI OPEN TUBE

The working part has the shape of a semi-open tube with a sharp cutting edge at the top. After the first 1 mm the rounded cutting edge turns into a cone that widens towards the handle, which is responsible for blocking the released fragment of a broken endodontic instrument. Above the cone there is a small window through which one can view through the microscope the depth to which the micro lever is introduced to the broken instrument. The semi-open tube makes it possible to clean the working part with mandryl to remove retention material (depending on the expected bonding power: sticky wax or glassionomer cement), block the broken instrument with an endodontic micro probe or introduce a loopshaped piece of thin endodontic wire when using the „lasso" method.

HANDLE

A light and ergonomic non-slip handle with a large diameter and profiled cuts for a stable grip of the instrument.

PRODUCTS

ADDITIONAL INFORMATION

	SYMBOL	DESCRIPTION
	SP-119-001-PMK	Handle
	SP-119-009-PMK SP-119-002-PMK SP-119-010-PMK SP-119-011-PMK	Working tip with the movable wedge 1,0mm Working tip with the movable wedge 0,8mm Working tip with the movable wedge 0,7mm Working tip with the movable wedge 0,55mm
	SP-015-195-ZMS	Endodontic micro probe-bent
	SP-017-008-PMS	Endodontic micro lever
STERILIT 	JG600 - 2 tips included	AESCULAP® oil spray, in aerosol can (ozonefriendly), for maintenance of instruments prior to sterilization. Physiologically inert acc. to DAB and § 31 LMBG
STERILIT 	JG598	AESCULAP® instrument oil, for box locks, ratchets etc. prior to sterilization. Physiologically inert acc. to DAB and § 31 LMBG
	Brochure D05601	Reprocessing of instruments in dental practice.

INSTRUCTION FOR USE

SYSTEM DEDICATED TO THE REMOVAL OF BROKEN ENDODONTIC INSTRUMENTS FROM ROOT CANALS

BEFORE USE please read the following instructions carefully. Product for dental use only.

Characteristics

Product made manually of high quality grade specialist stainless steel.

Storage conditions

This product should be stored in a place, where temperature and humidity are not subject to sudden variations. Places with high temperatures and humidity should be avoided.

First use

This product has been delivered as a **non-sterile** device. Before its first use the device must be inspected and sterilised, according to principles described in section: Inspection and maintenance.

Inspection and maintenance

1. Checking operability and functionality

Before each use the device must be inspected to confirm proper working order. During visual inspection attention must be paid to defects, cracks or surface contaminations.

End of device's life does not depend on the number of processing cycles (that is, cleaning, disinfection

and sterilisation). It is defined by normal wear and tear and damages arisen through its usage.

2. Initial washing and disinfection

Before washing, remove any remaining dirt by rinsing tool with water drawn into a Luer Lock syringe (Fig. 1) through connecting the syringe to the cone at the tip of the instrument (Fig. 2). Repeat this process at least three times. During the process you should force the element to move inside the cannula by pressing andreleasing the tip with Luer Lock cone (Fig. 3). This will facilitate removal possible impurities.

You should not:

- exceed 2 hours between application and cleaning
- use fixative temperatures (> 45˚C) during pre-treatment cleaning
- use fixing disinfectants (active substances, aldehyde, alcohol)

Fig. 1

Fig. 2

Fig. 3

Hand washing/ Disinfection:

It is recommended to use washing-disinfecting agents indicated for that purpose e.g. Stabimed® recommended by Aesculap Chifa Sp. z o.o. Instructions and reservations given by the manufacturer of the product must be followed. Pass the cleaning and disinfecting agent through the cannula with a syringe as described in previous point. If possible, ultrasonic washing is recommended. Washed instruments rinse under running water, inside of the cannula through connecting the syringe to the cone at the tip of the instrument. For final rinsing use demineralised water. At the end visual inspection of the purity of the surface and controlling any damages of the instrument must be made.

Washing in washer-disinfector:

It is recommended to use washer-disinfector agents indicated for that purpose e.g. Helimatic® recommended by Aesculap Chifa Sp. z o.o. Washing must be performed according to recommendations of a device manufacturer and its instructions for use. Before washing in washer-disinfector, the microtip of the instrument must be flushed by washer-disinfector agent according to the point 2 (Initial washing and disinfection). Disinfection should be carried out in the temperature of 90°C by bathing in demineralised water without detergents, for about 15 minutes. Then the device should be dried.

WARNINGS:

Instruments, due to their delicate construction, require special attention when cleaning.

3. Preparation for sterilization

Before sterilization, moving parts of the instruments should be greased with oil. For this purpose, it is recommended to use a lubricant e.g. Sterilit. Please ensure that the maximum allowed loading of the steam sterilizer provided by the manufacturer was not exceeded.

4. Sterilisation

The instrument, after its prior washing, disinfection and drying, should be subject to sterilisation process, by means of devices and in conditions compliant with effective standards. Recommended method of sterilisation is by means of water vapour under overpressure (high-temperature method).

Parameters:

Temperature: 134°C, pressure: 2 atm. above atmospheric pressure (overpressure), minimum time of exposure to sterilising agent: 5 minutes.

Steam sterilization according to DIN EN ISO 17665.

Guarantee

General warranty conditions for multiple-use medical instruments

Aesculap Chifa Sp. z o.o. guarantees that this product is free of any faults either in material or workmanship. The company gives 2-year guarantee for manufactured instruments.

The condition for using the guarantee is the application of products as per their intended use, as well as proper preparation, handling and sterilisation according to information included in these instructions for use.

In the case of fault being found during guarantee period, we kindly request sending the decontaminated instrument together with the information on the type of defect found directly to the company to the address present here in in manufacturer section. Please, attach to the package document confirming the purchase. If a defect is found after the warranty period, Aesculap Chifa Sp. z o. o. has the option of repairing products as part of technical service. Contact details available in "authorized service" section.

Guarantee shall not cover:

1. Wear resulting from normal course of usage (e.g. blunting of blades, surface wear of working part, wear of connection elements and thus excessive play in connections) and similar cases mentioned in general conditions of guarantee,
2. Misuse, application not as per intended use;
3. Corrosion damages (e.g. corrosion pits, surface discolouration) created as a result of inproper cleaning, disinfection and sterilization processes;

   Mishandling in the process of cleaning and maintenance during their preparation for reuse or storage, by:

   - inadequate disinfecting and cleaning agents,
   - **misuse of disinfecting agents,**
   - **incorrect methods of washing and cleaning,**
   - **missing maintenance (greasing) of connecting elements or using inadequate maintenance agents;**
   - **incorrect sterilisation, for instance through inadequate quality of sterilising vapour or incorrect parameters of sterilisation process, etc.;**

4. **If repairs are found by an unauthorized service center.**
   The product may only be used and used by persons who have the necessary training, knowledge and experience.
   Aesculap Chifa Sp. z o. o. is not responsible for damages resulting from the use of tools supplied by it, which were unfit for use, or which were subjected to any modifications and improvements made by the user without the knowledge of the manufacturer.

Authorized service

After every cleaning and disinfection, the instruments should be subjected reviews to ensure safety and appriopriate functioning. It is recommended to send cutting instruments to the service technical, every 6 to 10 months. Any questions regarding repairs and maintenance should be directed to manufacturer's authorized service.

ATS Aesculap Technical Service
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ats.acp@bbraun.com
www.chifa.com.pl/ats

Warning

Pay as much attention as possible to patient's safety and apply this product as per its intended use and information included in the attached instructions for use.

The instruments should not be subject to:

- Surface marking not authorized by the manufacturer, both mechanical (through impact or vibration methods) and electrochemical or laser;
- Long-term effects of chemicals

When cleaning, use a detergent intended for medial application. You must not use detergents intended for household application. For more information on this, go to section Inspection and Maintenance of these instructions for use. The use of damaged instruments is prohibited. Never repair the instrument by yourself. Service and repairs should always be entrusted exclusively to trained and qualified employees of our authorized service.

Producer

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More information on how to handle instruments and details of our offer can be found at:
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CE marking in accordance with Directive 93/42/EEC
02/2019

CE

MADE IN POLAND

UNIQUE FEATURES OF ERS SYSTEM

BLOW-BACK SYSTEM
Automatic system reversing the movable blocking wedge to the starting position

UNIVERSAL MICROTIPS
All microtips fit on one handle

ROTATING THREAD
Universal system adapted to work in every position of operator's hand grip

CONTOURED HANDLE TRIGGER
Ergonomic shape that perfectly fits the thumb
Anti-skidding surface of the trigger
Long travel that enables to properly dose the strength

EASY CLEANING
Handle and all microtips fit Luer Lock syringes

ERGONOMICALLY DESIGNED HANDLE
Spirally grooves surface of the handle and its light (empty inside) facilitate a secure hand grip with the use of all types of gloves

ONE-HAND SYSTEM
One hand system – no need to use any of additional accessories during the procedure

EASY ASSEMBLING
Simple procedure for preparing the instrument for work. Just screw the selected microtip in the universal handle, no need to assembly ligature every time

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