
	<h2>Instructions for use Suction Tube</h2>  <h3>unsterile</h3>	<p>Reda Instrumente GmbH Gänsäcker 34 78532 Tuttlingen (Germany) Tel. +49(0) 7462/9445 0 Fax. +49 (0) 7462/9445 20 Email: info@reda-instrumente.de</p>
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10-566 Cannula, suction Suction Tubes
13-845 flushing device, Obturator
15-206 Cannula, other

SRN-No. DE—MF—000005592

RD-1572 and 69458-00, R072-050330-048, R320-220190-030, R320-220190-130, R320-260240-030, R320-260240-130, R320-285270-030, R320-285270-130, 05130-10, 05140-08, 05150-21, 05150-27, 05160-02, 05160-03, 05170-24, 05300-xx 40093-30, 40094-40, 41295-12, 41301-15, 41301-20, 41301-35, 41304-06, 41304-08, 41304-10, 41303-09, 41303-12, 41303-15, 41305-30, 41295-05, 41295-06, 41295-07, 41295-08, 41295-09, 41295-10, 41295-11, 41295-12, 41295-15, 41297-07, 41297-08, 41297-09, 41297-10, 41299-03, 41299-05, 41299-07, 41290-21, 41300-00, 41301-15, 41301-20, 41301-25, 41301-35, 41303-09, 41303-12, 41303-15, 41304-06, 41304-08, 41304-10, 41305-20, 41305-30, 41307-03, 41307-04, 41307-05, 41307-06, 41308-00, 44300-00, 44301-00, 47331-20, 47331-25, 47331-30, 47331-40, 47332-20, 47332-25, 47332-30, 47332-40

BASICS

A.

It is imperative that all requirements and special information described in these instructions are met or taken into account. Otherwise, the products may not be used for clinical use. The specific instructions for use that may be attached to the products must also be observed. If you are unsure or have any questions, please contact us before using the products.

These instructions for use cannot replace training, care and the state of the art at the user. We therefore assume that the relevant legal provisions, standards and recommendations (e.g. of the RKI or AKI) are known (see under "Standards / References") and therefore limit ourselves to the instructions and information to be followed by the user for each product which are important for our products. The reasons for these instructions and the dangers arising from non-compliance are listed in the legal provisions and recommendations.

Repair and maintenance may only be carried out by authorized specialists.

The product may only be operated with the accessories and spare parts specified in the operating instructions and in the combinations specified there. Accessories and wearing parts as well as other combinations may only be used if they do not affect performance features or safety requirements and they are expressly intended for the intended application.

Before each use and return, the product must be processed in accordance with the instructions for use to protect patients, users and third parties. Technical changes reserved!

Due to further developments, the illustrations and technical data may differ slightly













It should only be used by trained, surgically trained medical specialists who have been instructed in the relevant procedures in the context of generally recognized training courses and only taking into account the relevant literature.

All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

Read these instructions carefully before using your new device for the first time. You protect yourself, the patient and any third parties from damage that can result from incorrect connection, damage or improper operation!









B. INFORMATION AND SYMBOLS ON LABELS

	Sign for „Manufacturer Item-No.“		Sign for „LOT-No./Serial No.“
	Symbol for „Attention“		Symbol for „Non-sterile“
	Symbol for „Manufacturer“		Symbol for „Temperature limit“
	Symbol for „Keep dry.“		Vor Sonnenlicht schützen
	Sign for „Follow IFU“		Symbol for „UDI Code“

Instructions for use: Suction tubes (english)



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	Symbol for „Distributor“		Sign for „Model number“
	Symbol for „MEDICAL DEVICE“		Symbol for „Production date“



1. DESCRIPTION AND PRODUCT-SPECIFIC INFORMATION

Our products are surgical instruments that are intended for multiple use. The products are medical products in the sense of national and international laws for products in human medicine.



2. INTENDED USE

The products are suction tubes (suction, other; suction, rinsing devices) and their accessories as well as cannulas.

Cannulas, also known as hollow needles or hypodermic needles, are hollow needles used in medicine to penetrate (puncture) human tissue and to inject or withdraw liquids or gases (e.g. wound irrigation).

Suction tubes are tubes with which liquids (blood, saliva, secretion, etc.) can be aspirated.

Depending on the field of application, suction instruments differ in shape, lumina, length and diameter of the suction tube and shape of the suction opening. Perforation of the suction tube allows suction of a larger surgical area.

They are also used as surgical aids, for example, to prepare cartilage or hold away tissue during septal correction, or to suction away excess fat during liposuction.

They are inserted into the body through a natural body opening or non-natural (surgical) access.

Suction tubes are connected to a suction device with a flexible connection.

Suction and irrigation devices are mainly used in laparoscopic, gynecological, urological, ophthalmic and arthroscopic procedures as well as in ENT surgery but also in other surgical disciplines. They are used to aspirate and rinse blood, secretions, mucus and pus, etc. in the area of the surgical field or wound.

3. INTENDED USE

3.1 Cannula, Suction (UMDNS: 10-566).

A cannula is a hollow needle that can be inserted into the human body, preferably into body cavities or the vascular system, alone or through a stylet.

Depending on their diameter and composition, cannulas are used to draw off or administer liquids or gases.

Suction cannulas are blunt cannulas intended for aspiration of blood or other fluids from the surgical area in the course of a surgical procedure. The suction cannulas are connected to suction instruments (electronic suction devices or syringes (for manual suction)).

3.2 Cannula, other (UMDNS: 15-206)

A cannula is a hollow needle that can be inserted into the human body, preferably into body cavities or the vascular system, alone or through a stylet.



Depending on their diameter and composition, cannulas are used to draw off liquids or gases.

3.3 Suction and irrigation devices (UMDNS: 13-845).

Suction and irrigation devices are mainly used for laparoscopic, gynecological, urological and arthroscopic procedures. They are used to aspirate and irrigate the surgical field. Blood and fluids up to tissue fragments are aspirated. The products are connected to an irrigation and/or suction pump by means of connecting hoses. A corresponding connecting tube is connected to the adaptation part of the suction and irrigation devices by means of a Luer-Lock system, for example. The hose end is then connected to a pre-designed pump. The pumps can be either a pure suction pump, a pure irrigation pump or a combination of both. During the operation, the suction and irrigation instrument is manually guided by the user to the desired location to begin irrigation or suction. Various systems, such as a tap driver, a trumpet valve or a pedal can be used to switch between irrigation, suction and occlusion.

Suction-irrigation instruments are combination instruments for endoscopic surgical techniques. After insertion into a body cavity through



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a trocar sleeve, bleeding vessels can be flushed free for better visibility. Irrigation fluids or body fluids can be aspirated without changing instruments. Suction-irrigation instruments are operated by the surgeon's hand.

Suction-irrigation handles are usually connected to surgical suction or suction-irrigation devices via a silicone hose for vacuuming excess liquid from the surgical site during procedures.

Eicken antrum cannulas can be used for accurate suction or aspiration and sampling of the desired nasal mucosa. Aspiration tubes are been used for short- or medium-term nutritional support, and also for aspiration of stomach contents. Continuous flow resectoscopy sheath are used for maintain a clear field of vision, increase the cutting speed, shorten the operation time, and reduce surgical damage and complications during scroscopic surgery. LACRIMAL cannula can be used for the irrigation and probing of the lacrimal duct.

Liposuction Cannula used in areas with skin irregularities as an equalizer, injector, and suction cannula.

Vascular irrigation cannula used for inject fluid solutions into the vessels. Hemorrhoidal suction ligatures used for to disrupt blood flow to hemorrhoidal tissue by means of a ligature placed around the hemorrhoid base with aspirating or suction.

YASARGIL tubes used for an enhanced view of the operating site by aspirating or suction debris and fluids.

4. INDICATION

4.1 Indication Cannula Suction /Suction tube

A cannula is a hollow needle that can be inserted into the human body, preferably into body cavities or the vascular system, alone or via a stylet. Depending on their diameter and composition, cannulas are used to withdraw or administer liquids or gases. Also used for vacuuming excess liquid from the surgical site during procedures.

4.2 Indication Cannula, other

A cannula is a hollow needle that can be inserted into the human body, preferably into body cavities or the vascular system, alone or via a stylet. Depending on their diameter and composition, cannulas are used to withdraw or administer liquids or gases. Also used for accurate suction or aspiration and sampling of the desired nasal mucosa.

4.3 Indication of suction and irrigation instruments

On the one hand, suction and irrigation instruments are used to aspirate blood or other liquids from the surgical area; on the other hand, irrigation liquid or gas can be fed into the surgical area via the irrigation connection in order to irrigate it or to generate an overpressure.

5. MATERIALS USED

Surgical instruments are made of stainless steels according to ISO 7153-1 and EN 10088-3.

6. INTENDED PATIENT GROUP

- Suction tubes are applicable during the whole life cycle of a human being.
- Suction tubes can be used on female, male and diverse persons taking into account the indication, product specific indication, contraindications.
- The evaluation of the patient's anatomy and physiology is carried out by the user, taking into account the indications, product-specific indications, contraindications and notes to be taken into account, which can be found in the instructions for use. With regard to mental stress in the contraindications, we point out that patients who are not mentally capable of understanding and following the instructions of the physician are not allowed to undergo minimally invasive application with the help of suction and irrigation instruments.

7. USER

It should be used only by skilled, surgically trained medical personnel who have been instructed in the appropriate procedures during generally accepted training courses and only with due regard to the relevant literature.





8. CONTRAINDICATIONS

- Incorrect application / misuse of the function
- Use on the central cardiovascular system and directly on the central nervous system
- Not to be used in neurosurgery or on spinal columns
- Immunosuppressive therapy
- Severe systemic disease that makes survival after surgery unlikely
- Blood clotting disorders/embolic or thrombotic tendencies
- Acute and chronic infections affecting the affected region of the body
- Muscle, nerve, or vascular disease affecting the affected region of the body.
- Evidence or presumption of a septic/infectious surgical site
- Known allergy and/or known foreign body reaction.
- Alcohol and/or drug abuse
- Epilepsy

The instrument should not be used if, in the opinion of the responsible physician, the risks to the patient outweigh the benefits.

Instruments which are used consciously on patients with a prion-based disease (transmissible spongiform encephalopathy disease, CJD, BSE, etc.) or on patients suspected of having one of these diseases are not safe to be reused and must be disposed of as per approved hospital procedures.



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9. POSSIBLE COMPLICATIONS

In most cases, any complications that may arise are not directly related to the use of an instrument, but rather are caused by the wrong choice of the patient, by inadequate training and by imprecise handling. If excessive forces are applied, unwanted tissue or bone injuries can lead to impairments or even break the instruments. It is therefore essential to use the instruments carefully.

In order to rule out complications due to damage to the instruments, the material used must always be checked before use.

The instruments may only be used by trained personnel.



10. USE OF ORIGINAL PRODUCTS

The devices and accessories were developed and manufactured for common use. No part of the system should be replaced by a product from another manufacturer, even if the product appears to be visually (and possibly in terms of dimensions) comparable or identical to the original product. Using products from other manufacturers together with products from REDA Instrumente GmbH can result in incalculable risks and / or contamination of the material; or devices and accessories do not match, which can endanger the patient, user or third parties.



11. COMBINATIONS

Suction / irrigation instruments are provided with a hose connection, Luer-Lock connection, hose connector, Luer stopper and handle. The suction / irrigation instruments are operated by the surgeon. Suction-irrigation handles are usually connected to surgical suction devices or suction-irrigation devices via a silicone hose.ents used. The connection ends have standardized sizes and can be connected with an adapter (Luer ABNT NBR ISO 594-1). Then the suction /irrigation instruments are connected, in the operating room, to a disposable suction tube either at the connection end or at the connection end of the adapter .



12. BASIC WARNINGS AND PRECAUTIONS

The products are delivered UNSTERILE! The packaged products are marked accordingly.

After receiving the products, check their identity, completeness, integrity and function. Packaging is not sterilization packaging.

Before each use of instruments, they must be examined for breaks, cracks, deformations, damage and functionality. Areas such as cutting edges, points, keys, locks, notches and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out. This includes also intraoperative damage of the instruments.

The attending physician and all other persons involved in the handling of the products are responsible for having appropriate product knowledge based on the latest technology standards within their area of activity. This enables the correct handling of the products and prevents health or safety risks for patients, users or third parties.

The relevant product catalogs, videos, technical specifications, instructions from medical device consultants, working groups, seminars, specialist courses, publications, etc. serve as sources of information for the products. A corresponding product training - including the handling of the products must be carried out before clinical use

The indications for use for the products represent a group of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The attending physician is responsible for the correct selection of the patient, the assessment of the indication and the selection of the instrument.

The attending physician should discuss in detail with the patient the expected treatment result with the use of the products. Particular attention should be paid to a post-operative consultation and the need for regular medical check-ups.

The products must be handled and stored carefully. Damage or scratches to the instrument can significantly impair the strength and fatigue resistance of a product.

The patient must be instructed in proper post-operative hygiene and should be instructed to inform the treating physician immediately of any unusual changes in the surgical area. The patient should be constantly monitored if a change in the operating area is noticed



After contact with or use on patients with Creutzfeldt-Jacob Disease * (CJD) or its variants, we decline any responsibility for the use! In this context, please note that you may have contaminated the unused instruments in the trays.

* CREUTZFELDT-JAKOB-DISEASE (CJD)

In the case of patients with Creutzfeldt-Jacob disease, suspected CJD or possible variants of this disease, the respective applicable national regulations regarding the reprocessing of the instruments must be applied.

After use on patients with Creutzfeldt-Jacob disease or its variants, we decline any responsibility for re-use. We recommend disposing of the instruments. Processing and re-use in accordance with the RKI guideline is entirely the responsibility of the user!



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13. REPAIRS / RETURNS

Do not carry out repairs yourself. Service and repairs may only be carried out by appropriately trained and qualified persons. If you have any questions about this, contact the manufacturer or your medical technology department.

Defective products must have gone through the entire reconditioning process before being returned for repair or before they are disposed!



14. PROCESSING, CLEANING, DISINFECTING THE INSTRUMENTS

A. GENERAL BASICS

All products must be cleaned, disinfected and sterilized before use. The product packaging and protective transport packaging are fundamentally unsuitable for sterilization and must be removed before reprocessing! Effective cleaning and disinfection is an essential prerequisite for efficient sterilization.

As part of your responsibility for the sterility of the instruments during use, please ensure that only sufficiently device- and product- specific validated procedures are used for cleaning / disinfection and sterilization, that the devices used (WD, sterilizer) are regularly maintained and checked and that the validated parameters are adhered to in each cycle.

Please also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements with regard to effective prion inactivation.

B. CLEANING AND DISINFECTION

Basics

For the cleaning and disinfection of the instruments and components, a mechanical process (washer-disinfector / disinfector) should be used if possible. A manual process - also using an ultrasonic bath - should only be used if a machine process is not available due to its significantly lower effectiveness¹.

¹ The use of a manual cleaning and disinfection process must be secured by an additional product and process-specific validation under the responsibility of the user.



Use only approved agents (RKI, VAH, etc.)! Both slightly alkaline and pH-neutral cleaning agents can be used. Contact with hydrogen peroxide (H₂O₂) is to be avoided.

During reprocessing, the temperature acting on the instrument should not exceed 140 ° C.

Only suitable chemicals (ideally with corrosion protection) in the correct dosage according to the instructions of the cleaning agent manufacturer may be used.

The water used in the treatment must, if not explicitly specified, at least meet the requirements of the Drinking Water Ordinance (TrinkwV).

Use only sufficiently validated methods for cleaning / disinfection / sterilization.

Information and recommendations of the manufacturer (devices, cleaning agents) must be observed

Machine cleaning / disinfection (WD)

When selecting the WD, make sure that,

- that the WD has a proven effectiveness (e.g. DGHM or FDA approval or marking according to DIN EN ISO 15883),
- that if possible a tested program for thermal disinfection (at least 5 min at 90 ° C or A0 value > 3000) is used (with chemical disinfection there is a risk of disinfectant residues on the instruments),
- that the program used is suitable for the instruments and contains sufficient rinsing cycles,
- that suitable water (e.g. Aqua purificata / Aqua purificata valde) is used for rinsing, and that the air used for drying is filtered and thus does not reduce the hygiene status at this point,
- that the WD is regularly serviced and checked.

When selecting the cleaning agent system used, it is important to ensure that



- that this is basically suitable for cleaning the instruments,
- that - if thermal disinfection is not used - a suitable disinfectant with tested effectiveness (e.g. VAH / DGHM or FDA approval or marking) is also used and that this is compatible with the cleaning agent used and
- That the chemicals used are compatible with the instruments and components.

The concentrations specified by the manufacturer of the cleaning agent and, if applicable, disinfectant must be adhered to!

Procedure:

1. Place the instruments in the WD. Make sure that the instruments and components do not touch each other and that they are



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aligned so that no large amounts of liquid can remain on the products.

2. Start the program.
3. Remove the products from the WD at the end of the program.
4. Check and pack the products as soon as possible after removal (see chapter "Control" and "Packaging", if necessary after additional drying in a clean place).

Tube:

When pre-cleaning the pipes, rinse them at least 3 times using a disposable syringe (at least 10 ml, with larger diameters correspondingly more volume).

C. CONTROL

Check all instruments and components for damage and soiling and separate out damaged and soiled products. Instrument oils must not come into contact with the instruments!

D. MAINTENANCE

Put disassembled instruments back together.

If possible, instrument oils should not be used. If use is nevertheless desired, care should be taken to ensure that only instrument oils (white oil) are used that are approved for steam sterilization, taking into account the maximum sterilization temperature used, and that have a tested biocompatibility.

E. PACKAGING

Sort the cleaned and disinfected products into the sterilization trays and pack them in single-use sterilization packaging (single or double packaging) and / or sterilization containers that meet the following requirements:

- according to DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to-10
- suitable for steam sterilization (temperature resistance up to at least 137 ° C (279 ° F), sufficient steam permeability)
- Sufficient protection of the instruments and sterilization packaging from mechanical damage
- Regularly serviced according to the manufacturer's specifications (sterilization container)

F. STERILIZATION

Instruments should be sterilized by moist heat sterilization method with 270 °F (132°C) for 3 to 15 minutes (Validated in accordance with EN ISO 17665-1-2006 prior to use in surgery. It is recommended that sterilization temperatures should not exceed 280°F (137°C).

Only the sterilization processes listed below are to be used for sterilization; other sterilization methods are not permitted.

Steam sterilization:



- Fractional vacuum process / pre-vacuum process or gravitation process2 (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO / ANSI AAMI ISO 17665 (valid picking and product-specific performance assessment)
- Maximum sterilization temperature 134 ° C (273 ° F; plus tolerance according to DIN EN ISO / ANSI AAMI ISO 17665)
- Sterilization time (exposure time at the sterilization temperature) at least 3 min3 at 132 ° C (270 ° F) / 134 ° C (273 ° F)
- 2 The less effective gravitational method may only be used if the fractional vacuum method / pre-vacuum method is not available.
- Holding time: at least 3 minutes; maximum 18 min.
- Drying time: at least 10 minutes.

Evidence of the basic suitability of the instruments for effective steam sterilization was provided by an independent, accredited test laboratory using the steam sterilizer "Systec V-150, Systec Labor-Systemtechnik, Wettenberg "using the fractional vacuum process and the gravitational process. The procedure described above was taken into account here.

The flash sterilization process is generally not permitted. In addition, do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

Sterilization Method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying Time (minimum)
Pre-Vacuum	Wrapped	132°C	4 minutes	10 minutes
Pre-Vacuum	Wrapped	134°C to 137°C	3 minutes	10 minutes
Pre-Vacuum	Wrapped	135°C	3 minutes	10 minutes
Gravity Displacement	Wrapped	132°C to 135°C	10 minutes	10 minutes



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DANGER! STERILIZATION IS NOT A REPLACEMENT FOR CLEANLINESS!

G. STORAGE

After sterilization, the instruments must be stored dry and dust-free in the sterilization packaging.

Operating, storage and transport conditions.

Operating conditions	+10°C bis +40°C, 30% bis 75% rel. Humidity, Air pressure 700 hPa bis 1060 hPa
Storage and transport conditions	-20°C bis +60°C, 10% bis 90% rel. Humidity, Air pressure 700 hPa bis 1060 hPa

H. MATERIAL RESISTANCE

When choosing cleaning agents and disinfectants, please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids
- stronger alkalis (pH > 11 not permitted, mildly alkaline cleaners recommended)
- organic solvents (alcohols, acetone, ...), petrol
- halogenated hydrocarbons, chlorine, iodine
- ammonia

All instruments, sterilization trays and sterilization containers may only be exposed to temperatures no higher than 137 ° C (279 ° F)!

I. MULTIPLE PROCESSING

If an instrument has been removed from the sterile packaging or the instrument tray and, in accordance with the previous descriptions, not used and not discarded or sorted out for other reasons, it can be reprocessed. This also applies to instruments that have already been reprocessed once or several times. However, please note the restriction from Section 12, last paragraph, regarding Creutzfeldt- Jacob disease (CJD).

Repeated processing does not result in any dimensional changes and, according to our current knowledge, no material changes. However, we would like to point out that due to the accumulation of detergent residues, the biological compatibility of the instrument can no longer be given. This is the responsibility of the user to monitor.

Holes:

When pre-cleaning, rinse the holes at least 3 times using a disposable syringe (at least 10 ml, with larger diameters correspondingly more volume).



15. Information on reprocessing validation

The following test instructions, materials and machines were used for validation:

Cleaning agent (machine):	Neodisher FA; Dr. Weigert (alkaline) Endozime Fa. Ruhof (Enzymatically)
Cleaning agent (manual):	Enzol Enzym, Detergent, Johnson&Johnson
Disinfectants (manual):	Cidex OPA, Johnson&Johnson
Neutralizer:	Neodisher Z; Dr. Weigert
Washer-disinfectant:	Miele G 7736 CD Miele Slide-in cart E 327-06 Miele MIC-Cart E450
For details see reports:	SMP GmbH #01707011901 (mach. cleaning) MDS GmbH #135196-10 (man. Cleaning / disinfection) Nelson Labs #200432706-02 (Sterilization) MDS GmbH Review 084183-10 (Sterilization)

If the chemicals and machines described above are not available, it is the user's responsibility to validate his process accordingly.

16. REUSABILITY/ Service life

The instruments of REDA Instrumente GmbH are intended for repeated use. The service life depends on the type and duration of use, as well as handling, storage and transport. The products are subject to wear and tear due to their use.

The average service life is approx. 3 years. Careful inspection and functional testing before use is the best way to identify and discard an instrument that is no longer functional.

17. DISPOSAL



Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

18. WARRANTY / GUARANTEE

The operator / product user is responsible for the proper cleaning, disinfection and sterilization of products. National regulations.

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including restrictions, must be observed.

REDA Instrumente GmbH only delivers tested and error-free products to its customers.

All our products are designed and manufactured in such a way that they meet the highest quality standards. Liability for products that have been modified, misappropriated or improperly treated or used compared to the original is excluded.

- improper use
- improper use, application or handling
- improper preparation and sterilization

- improper maintenance and repair
- Failure to observe the instructions for use
- mechanical modification and adjustments

19. Standards - References

- AKI1 - Guide "Instrument reprocessing done right"
- RKI2 - recommendation: "Hygiene requirements for the reprocessing of medical products"
- DIN EN 285 large steam sterilizers
- DIN EN 13060 small steam sterilizers
- DIN EN ISO 15883-1-3 washer-disinfectors
- DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10 packaging materials
- DIN EN ISO 17664 / ANSI AAMI ST81 sterilization - information from the manufacturer
- DIN EN ISO 17665-1 sterilization process - moist heat

1 AKI: Instrument reprocessing working group

2 RKI: Robert-Koch-Institut



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