Instruction of use

Suction tubes, Suction cannulas

REF 10-XXX-XX - 40-XXX-XX

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General information:
In purchasing this instrument, you have acquired a superior-quality product, and information on its correct handling and use is detailed below. Please read and observe these user instructions carefully to minimise hazards for both patients and users in as far as possible. Only skilled personnel who have been appropriately trained should be entrusted with use, disinfection, cleaning and sterilisation.

Please note that our instruments are delivered in an unsterilised condition and should be cleaned, disinfected and sterilised prior to initial use.

Suction tubes are available in different designs and:

- suction tube diameters
- working lengths
- overall lengths
- optional mandrin
- with or without grip plate
- with or without suction interrupter
- different tube connections (Luer lock, Luer taper, taper)
-

For detailed information on available sizes and variants, please refer to our catalogue.

List of the applicable products:

10-804-10	10-829-20	10-903-16	10-905-04	10-912-03	10-942-05	10-955-15	10-965-15	10-973-07
10-804-12	10-900-01	10-903-17	10-905-05	10-912-10	10-942-18	10-955-18	10-965-20	10-973-08
10-804-15	10-900-04	10-903-18	10-906-05	10-912-11	10-944-01	10-955-20	10-965-30	10-973-09
10-804-20	10-900-06	10-903-19	10-906-06	10-912-12	10-944-02	10-956-15	10-966-12	10-973-10
10-805-15	10-900-08	10-903-20	10-906-07	10-912-13	10-944-03	10-956-18	10-966-15	10-973-11
10-806-10	10-901-05	10-903-21	10-906-30	10-913-01	10-944-05	10-956-20	10-966-20	10-973-12
10-806-12	10-901-07	10-903-22	10-906-35	10-913-15	10-944-06	10-956-25	10-967-12	26-099-23
10-806-15	10-901-09	10-904-05	10-906-40	10-913-20	10-944-07	10-957-01	10-967-15	26-311-05
10-807-12	10-902-06	10-904-06	10-906-55	10-913-25	10-944-08	10-957-02	10-967-20	26-311-07
10-807-15	10-902-07	10-904-07	10-906-99	10-913-35	10-944-09	10-957-25	10-970-03	26-311-09
10-807-20	10-902-08	10-904-08	10-907-00	10-914-10	10-944-10	10-957-26	10-970-04	26-660-21
10-810-01	10-902-09	10-904-09	10-908-07	10-915-06	10-944-12	10-957-30	10-970-05	26-697-14
10-810-02	10-902-10	10-904-10	10-908-09	10-915-08	10-944-14	10-957-31	10-970-06	26-698-14
10-810-03	10-902-11	10-904-11	10-908-25	10-917-08	10-944-15	10-957-40	10-970-07	26-699-20
10-810-04	10-902-12	10-904-12	10-908-30	10-919-10	10-944-18	10-957-41	10-970-08	26-700-20
10-815-18	10-902-15	10-904-15	10-909-20	10-921-07	10-944-20	10-958-25	10-970-09	26-700-21
10-817-15	10-902-23	10-904-25	10-909-25	10-923-08	10-944-22	10-958-26	10-970-10	35-301-01
10-817-20	10-902-24	10-904-26	10-910-15	10-925-09	10-944-25	10-958-30	10-970-11	35-301-02
10-817-25	10-902-25	10-904-27	10-910-16	10-931-16	10-944-30	10-958-31	10-970-12	35-301-03
10-817-30	10-902-26	10-904-28	10-910-17	10-931-27	10-944-55	10-958-40	10-971-03	35-301-04
10-817-40	10-902-27	10-904-29	10-910-18	10-935-27	10-944-56	10-958-41	10-971-04	35-303-04
10-818-03	10-902-28	10-904-30	10-910-20	10-937-32	10-944-57	10-960-05	10-971-05	35-309-03
10-818-04	10-902-29	10-904-31	10-910-21	10-938-01	10-944-58	10-960-07	10-971-06	35-309-04
10-818-05	10-902-30	10-904-32	10-910-22	10-938-02	10-944-59	10-960-10	10-971-07	35-309-06
10-818-06	10-902-31	10-904-35	10-910-23	10-938-03	10-944-60	10-960-13	10-971-08	35-309-08
10-820-05	10-902-32	10-904-45	10-910-24	10-938-04	10-944-62	10-960-15	10-971-09	35-309-10
10-820-06	10-902-34	10-904-46	10-910-25	10-938-05	10-944-64	10-960-20	10-971-10	35-309-12
10-822-10	10-902-35	10-904-47	10-910-26	10-938-06	10-944-65	10-960-25	10-971-11	35-309-14
10-822-15	10-902-45	10-904-48	10-910-27	10-939-01	10-944-68	10-960-30	10-971-12	35-309-50
10-822-20	10-902-46	10-904-49	10-910-33	10-939-02	10-944-70	10-962-03	10-972-03	35-309-99
10-822-25	10-902-47	10-904-50	10-910-35	10-939-03	10-944-72	10-962-05	10-972-04	40-036-30 A
10-822-30	10-902-48	10-904-51	10-910-36	10-939-04	10-944-75	10-962-07	10-972-05	40-036-36 A
10-822-35	10-902-49	10-904-52	10-910-37	10-939-05	10-944-80	10-963-03	10-972-06	40-036-48 A
10-822-40	10-902-50	10-904-55	10-910-45	10-939-06	10-947-07	10-963-05	10-972-07	40-037-30 A
10-822-50	10-902-51	10-904-65	10-911-01	10-940-10	10-947-09	10-963-07	10-972-08	40-037-36 A
10-824-14	10-902-52	10-904-66	10-911-02	10-940-15	10-947-12	10-963-20	10-972-09	40-037-48 A
10-824-18	10-902-55	10-904-67	10-911-03	10-940-20	10-947-18	10-963-24	10-972-10	40-038-36 A
10-828-01	10-903-05	10-904-68	10-911-04	10-940-25	10-947-19	10-964-00	10-972-11	
10-828-02	10-903-06	10-904-69	10-911-05	10-941-30	10-947-20	10-964-05	10-972-12	
10-828-03	10-903-07	10-904-70	10-911-31	10-941-40	10-947-21	10-964-07	10-973-03	
10-828-04	10-903-08	10-904-71	10-911-32	10-941-50	10-951-20	10-964-09	10-973-04	
10-828-05	10-903-09	10-904-72	10-912-01	10-942-03	10-951-25	10-964-12	10-973-05	
10-828-06	10-903-10	10-904-75	10-912-02	10-942-04	10-951-30	10-965-12	10-973-06	

Purpose / Indication:
Suction instruments are designed to suction blood and other fluids and small tissue fragments out of the operating area during a surgical intervention. They are intended for connection to a suctioning device via a flexible connection, but are controlled by hand.

⚠ Suction instruments are not intended for use in direct contact with the central nervous system or the correction of defects of the heart or central circulatory system!

Contraindications:
Patients for which, in the opinion of the attending physician, a general operating risk exists, or where the suction instrument cannot be used for the patient without a risk.

The instrument is used exclusively by skilled medical personnel specially trained in the operating technique.

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The attending physician is also responsible for ensuring that operating personnel and his or her staff have adequate knowledge in the handling of the instruments.

⚠ Selection of a suitable suction instrument is incumbent upon the experienced user.

No other specific contraindications are known.

User and safety instructions:
Failure to observe these user and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

⚠ All types of reusable suction instruments should be cleaned, disinfected and sterilised completely prior to initial use and any other use.

⚠ The suction instrument must be inspected prior to every use for correct function, visible damage and wear (e.g. cracks or fractures). The consistency of suction instruments must be assured prior to every use.

⚠ The packaging is unsuitable for the high temperatures encountered during autoclaving and should be disposed of prior to initial sterilisation.

⚠ Do not overstress the instruments. Overstressing due to excessive application of force can cause breakage, bending and malfunctions in medical products and lead to injuries to the patient or user. Bent instruments should not be bent back into the initial position, as there is a risk of breakage.

⚠ Do not use a damaged or defective product. Withdraw any damaged product immediately, label and exclude from any further use.

⚠ When connecting suction instruments to the suction pump, ensure that connection of the flexible connection tube is secure and tight at all times during use.

⚠ We recommend machine conditioning of suction instruments, as these instruments should be classified in the Critical B group with special requirements corresponding to RKI recommendations. See Sections A. D. E. F.

⚠ Select a vacuum capacity (negative pressure) on the suction pump that is appropriate for the surgical intervention and the volume of fluid to be suctioned. An excessive vacuum capacity can lead to the damaging of delicate tissue structures, while an inadequate suction capacity may fail to remove any volume of fluid which has gathered with the required efficiency.

⚠ Observe the operating instructions of the suction pump manufacturer.

Use:
Connection of suction instrument to the suction pump:
Fit a suitable tube to the tube connection on the suction cannula.
Connect the tube to an appropriate surgical suctioning device.

Regulation of suction capacity during the operation:
The user can regulate the suction capacity with the aid of the optional interrupter hole on the suction cannula (e.g. to prevent suctioning of delicate structures). The capacity configured on the suction pump determines the maximum negative pressure on the suction cannula and, consequently, the maximum suction capacity of the cannula.

- Suctioning: Cover the suction interrupter on the grip plate with your thumb.
- No suctioning: Remove your thumb from the suction interrupter on the grip plate.
- Regulate the suction capacity (only possible with suction cannulae with a drop-shaped suction interrupter).
- The desired suction capacity is achieved by partially covering the suction interrupter on the grip plate as required.

Following use:
Suction instruments should be conditioned immediately after use. Where this cannot be guaranteed, suction instruments must be laid in a cleaning solution to prevent them drying out and any lumens becoming blocked. A suitable mandrin should be used to prevent any blockages.

Handling of suction instruments:
All surgical instruments should in all cases be handled with extreme care during transportation, cleaning, care, sterilisation and storage. This applies in particular to fine suction cannulae with small diameters.

New instruments should undergo at least three machine cleaning cycles prior to initial sterilisation. This leads to the formation of a passivated layer on the surface that protects the instrument against discolouring and corrosion.

New instruments should be stored in indoor air without protective packaging in a closed cabinet / drawer. It is important to ensure that pertinent hygienic regulations are adhered to in each case.

In the case of new instruments which are to be stored for a longer period of time, we recommend that they be removed from the sealed plastic bag and treated with a medical oil approved for sterilisation.

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General instructions for reconditioning:

- Responsibility for professional treatment and preparation lies with the operator of the respective central sterile supply department and his or her assistants.
- The treatment and preparation of medical products which are to be used in a low-bacteria or sterile condition should be realised employing suitably validated procedures and taking manufacturer specifications into consideration in a manner that guarantees the verifiable success of the procedure and ensures that the safety and health of patients, users or third parties are not endangered. Evidence of compliance should be compiled for treatment.
- Manufacturer specifications regarding the concentration, temperature, exposure, etc. of respective cleaning and disinfecting agents should be adhered to during treatment and preparation.
- Excessive concentrations of chemicals can lead to damage on instruments and contribute to rendering the laser or electrolytic labelling illegible.
- Treatment and preparation of instruments should be realised as soon as possible after use to avoid damage to the instruments.
- Professional treatment and preparation of suction tubes begins on the operating table.
- New and repaired suction tubes should pass through the complete treatment and preparation cycle prior to use!
- It is imperative that suction tubes exhibiting visible damage be withdrawn immediately and professionally repaired.
- Damaged suction tubes can jeopardise the success of an operation!

Process for treatment and preparation of suction instruments:

Recommendation:
Frequent reconditioning has a minor impact on instruments. Product service life is normally determined by wear and damage caused by use.

Suction tubes exhibiting visible damage should be returned to the manufacturer for professional repair.

Preparation at location of use:
Directly after use, coarse dirt should be removed from suction tubes by immersion in cold tap water (<40°C). Do not use any fixing detergents or hot water (>40°C), as this will lead to fixation of residue which may negatively influence the success of cleaning. Moreover, blocking of the cannula should be prevented through rinsing of the cavities with a syringe.

Transportation:
Suction tubes should be kept in a closed container for safe transportation. This should prevent any damage to the instruments.

A. Preliminary cleaning:

- The suction instruments are disassembled in as far as possible and the components immersed in cold tap water for 10 minutes, ensuring that any lumens are filled with water. Use a suitable mandrin where appropriate to open the lumens in advance.
- Using a soft brush, thoroughly clean all component parts of the suction instruments and mandrins individually under flowing cold tap water until all visible impurities are removed.
- Subsequent to this, thoroughly rinse all positions difficult to access such as hinges, contact surfaces, internal lumens, cavities, bored holes and threads with the water pistol (water jet pistol with a static water pressure of >2 bar) for a minimum of 20 seconds.
- Repeat this process until all visible impurities have been removed.

In the case of severe dirt or caking, preliminary cleaning is recommended in a US bath with the following parameters:

- Place the suction tubes in the metal sieve so that they do not touch each other.
- Immerse completely in a 0.8% Cidezyme solution.
- All cavities should be filled with the solution (fill lumens with a syringe if necessary).
- Clean at room temperature and 35 KHz. for >10 min.
- Following preliminary ultrasound cleaning, the suction instruments are removed and cavities, bored holes and threads rinsed with cold tap water from a water pistol for a minimum of 20 seconds in pulse mode.

B. Manual cleaning:

⚠ Manual cleaning can only be recommended if machine conditioning in a cleaning and disinfecting unit is impossible.

- Place the suction tubes in the metal sieve so that they do not touch each other.
- Immerse completely in a 0.8% Cidezyme/Enzol or Mucadont Zymaktiv cleaning solution.
- All cavities should be filled with the solution (fill lumens with a syringe if necessary).
- Clean at 45°C and 35 KHz. for > 10 minutes.
- Following ultrasound cleaning, the instruments are removed and cavities, bored holes and threads rinsed with cold tap water from a water pistol for a minimum of 20 seconds in pulse mode.
- The suction instruments are finally rinsed with cold, demineralised water.

C. Manual disinfection:

⚠ Manual disinfection can only be recommended if machine conditioning in a cleaning and disinfecting unit is impossible.

The instruments are immersed completely in a 4% Mucocit-T solution and disinfected at room temperature for between 5-10 minutes.

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After removal from the disinfection bath, lay the instruments in demineralised water and rinse thoroughly. Dry after rinsing and realise sterilisation with damp heat.

D. Machine cleaning, thermal disinfection and drying:
Machine processes were validated with a Miele cleaning and disinfecting unit, model 7836CD.

Place the suction instruments in a disassembled state into a mesh tray on the infeed carriage. Where possible, connect suction instruments with lumens directly to the rinsing nozzles of the cleaning and disinfecting unit using a tube. Start the cleaning process with the following minimum settings:

1. 2 min. preliminary cleaning with cold tap water (16 °C ±2 °C).
2. Drain
3. 5 min. cleaning at 55°C. Dispense 0.5% MediClean forte with tap water.
4. Drain
5. 3 min. neutralisation with cold demineralised water (20 °C ±2 °C).
6. Drain
7. 3 min. rinsing with cold demineralised water (20 °C ±2 °C).
8. Drain

Settings for thermal disinfection:
Realise machine thermal disinfection, taking national requirements regarding the A0 value into consideration (see ISO 15883).

9. 2 min. rinsing with warm demineralised water (>40°C)
10. Heat to disinfecting temperature ≥93°C*.
11. Holding time at >90°C* for ≥ 10 min.

*Disinfecting temperatures relate to the upper and lower switching points of the cleaning and disinfecting unit thermostat.

⚠ It is the responsibility of the user to validate its process appropriately if the previously described chemicals and machinery are not available.

Drying:
12. The cleaning and disinfecting unit program should assure a drying duration of at least 20 minutes at max. 93°C.
13. Following expiry of the drying duration, the suction tubes are immediately taken out of the cleaning and disinfecting unit.

Manual drying:
If necessary, additional manual drying can be accomplished with the aid of a lint-free cloth. Dry suction instrument cavities with sterile compressed air.

It is the obligation of the user to ensure that the reconditioning process
and the necessary operating media, material and personnel are suitable for achieving the required results.

The technological state of the art and national laws demand that these processes and the operating media used are kept in a validated and maintained condition.

E. Care, functional testing and packaging:
A careful visual inspection of suction instruments for cleanliness is conducted following the cleaning and disinfecting process. If residual impurities are identifiable, the entire cleaning and disinfecting process should be repeated until residue-free cleaning can be confirmed.

⚠ If cleaning is not possible, the instrument should be withdrawn and excluded from further use. The instrument should be disposed of in this case.

The suction tubes and their component parts should then be inspected for possible damage such as cracks and concealed, loose or missing parts. Reassemble all component parts subsequent to this and check the function of the instrument.

Treat threads and hinges with an approved medical maintenance oil. The oil used (e.g. paraffin conforming to Ph. Eur.) should not affect subsequent sterilisation.

⚠ Withdraw defective suction tubes, label them and exclude from any further use. Take note of any risk of injury if appropriate.

Packaging:
Only use standardised and approved packaging materials and systems (EN 868 Part 2-10, ISO 11607 Part 1 + 2, DIN 58953)

Suction instruments should be packaged in a manner that excludes the possibility of damage to the sterile barrier.

⚠ Instruments should not be sterilised in the protective and transportation packaging sent with the delivery.

F. Sterilisation with damp heat:
Sterilisation of products is preferably realised using the fractionated pre-vacuum method (pursuant to ISO 13060 / ISO 17665 and EN ISO 285) while

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taking respective national requirements into consideration.

- 3 pre-vacuum phases with at least 60 mbar pressure.
- Heating to a sterilisation temperature of typically 134°C.
- Holding time: typically 5 minutes.
- Drying time: minimum 10 minutes.

The above specifications are recommendations of RKI/KRINKO for sterilisation with damp heat. These specifications were validated for our suction instruments with the SMP No.23616 study at reduced settings (132°C, 4 min. holding time.

⚠ Other regional and national regulations and directives may apply.

⚠ With regard to the treatment and preparation of medical products, a separate conditioning process should be employed in the case of patients suffering or suspected of suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), or the instrument should be disposed of.

Storage:
The storage conditions of the packaging manufacturer for maintaining an effective sterile barrier apply when it comes to the storage of sterilised instruments. The instruments themselves do not require any special storage conditions.

Repairs:
Do not carry out unilateral repairs. Servicing and repairs should only be realised by suitably trained and qualified personnel. Please contact the manufacturer or your medical technology department should you have any questions in this respect.

⚠ Defective products should undergo the entire reconditioning process prior to being returned for repair. Moreover, return shipmnet form from AS Medizintechnik GmbH should be included in each return delivery. This can be found in the service section on our website (www.AS-Medizintechnik.de). Where incidents which must be reported are involved, these must be reported with our Incident report form.

Disposal:
No special measures are necessary with regard to disposal. Observe respectively applicable national or international laws and regulations during disposal.

Treatment validation, studies, information:
The following materials and machinery were used to validate individual treatment steps. Information in this respect can be obtained from the manufacturer.

Manual cleaning:	
Cleaning agent:	ASP: Cidezyme/Enzol Merz Hygiene GmbH: Mucadont Zymaktiv
Ultrasound bath:	Bandelin Sonorex RK 1028H
Manual disinfection:	
Disinfectant:	Merz Hygiene GmbH: Mucocit-T
Machine cleaning:	
Cleaning agent:	Neodisher MediClean forte (Chemische Fabrik Dr. Weigert GmbH & Co. KG, REF 405033)
Cleaning/disinfecting unit:	Miele 7836CD
Infeed carriage;	Miele E 327
MIC carriage	Miele E 429

Explanation of symbols used:

LOT Batch designation

REF Order/catalogue number

⚠ Warning, safety instructions

Observe user instructions

CE 0483 CE marking and identification number of notified body

Manufacturer

Disclaimer:
AS Medizintechnik GmbH only delivers tested and flawless products to its customers. All our products are designed and manufactured to meet the highest quality standards. Any liability for products which have been modified from the original, misused or incorrectly conditioned or employed is

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excluded.

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