

PAJUNK®

Suction / Irrigation System

Minimally Invasive Surgery



Instructions for Use

Special notice



Please read the following information and operating instructions carefully.



Caution: Federal law restricts this device to sale by or on the order of a physician. The device may only be used by qualified medical staff in accordance with these user instructions.

PAJUNK® does not recommend any particular treatment method. Professional medical staff are responsible for the way in which the device is used and for patient selection.

In addition to these instruction for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.

Failure to comply with the user instructions invalidates the warranty and puts patient safety at risk.

If used in combination with other products, it is essential that the compatibility information and user instructions for these other products are taken into account. A decision regarding the combined use of devices from different manufacturers (where they do not constitute treatment units) is the responsibility of the user.



The device must not be used under any circumstances if there are good reasons to suspect incompleteness or damage.

Device description / compatibility



REF 1298 series, 1288 series, 1295 series



Please see the valid Declaration of Conformity for a detailed article list.

The suction/irrigation system of each series consists of suction/irrigation handles with instrument channel / trumpet valve / double trumpet valve, pistol handle, suction/irrigation tubes.

Please use suction/irrigation instruments with compatible, medically approved suction/irrigation pumps and/or saline bags and tubes only. Check that the suction/irrigation tubes are safely attached on the handles.



Connection: LUER / thread

	1298-00-xx	1288-50-xx	1295-00-xx
1298-61-00	X		
1298-62-00	X		
1298-41-00	X		
1298-01-00	X		

REF	1298-00-xx	1288-50-xx	1295-00-xx
1298-71-00	X		
1298-81-00	X		
1288-50-00		X	
1295-21-00			X


Service life

The end of device life is determined primarily by wear, damage caused by use, careful handling and appropriate storage.

The instrument must be thoroughly checked by the manufacturer after every 200 reprocessing cycles. If the device is used after having clearly exceeded its service life, warranty expires and patient safety is put at risk. If the device is modified/manipulated (e.g. repair carried out by third parties), warranty expires and patient safety is put at risk.

Intended use


Irrigation and aspiration of irrigation fluid in the operation field

 Warning:
The instrument is not suitable for MRI use!

Indications

Minimal Invasive Surgery

Contraindications


 *Under no circumstances is the device to be used in the event of known material incompatibilities and/or known interactions.*


Contraindications usually depend on the minimally invasive procedure that is carried out.

Complication


Allergic reactions (Ni)



Complications usually depend on the minimally invasive procedure that is carried out.


 *Users must inform patients of complications typically associated with the procedure.*

 *If complications occur while using the device, follow the protocols of your organisation. If this does not resolve the complications, or if they are regarded as serious or untreatable, carefully stop the procedure and remove invasive device components from the patient.*


Warnings

 *for reusable product:*


1.  Please make absolutely sure that you clean and sterilise all devices delivered in non-sterile condition before using them for the first time!
2.  If an instrument has been contaminated, always process it immediately after use (see instructions for manual pre-cleaning)!
3. Subject the device to a visual and functional check before every use.
4. Sort damaged or faulty instruments and replace them.
5. The service life of wearing parts is limited. Always check wearing parts for damage prior to every use, and replace them if necessary.

 *in the application:*

1. Take care to use products of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. Regular check the accessories.
3. Treat the valve tappet only with a lubricant approved for medical purposes (valve grease, lubricating grease – article no. 1298-98) to guarantee ease of operation and tightness.

 *for use with other compatible products:*

1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages.
2. Only the devices of the same series (1298/1288/1295) can be connected to and used with each other. Only the devices of the same series (1298/1288/1295) are compatible with each other.

 *further warning indications:*

1. You must routinely take general precautions for handling blood and bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.
2. Please note that the continued use of a device of the same type must be assessed cumulatively as described in the legislation on medical devices, even after the device has been exchanged or replaced.

Sequence of use

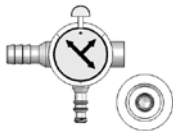
1. Use the assembled instrument according to the selected indication (normally using a port/trocar sleeve).
2. Disassemble the instrument after use according to the instructions for disassembly.
3. Dispose of disposable components in a safe way.
4. Clean and autoclave reusable components.

Two-way valve (1288-50-00)

Disassembly:



Complete instrument.



1) Unscrew the suspended holding plate completely from the valve cock.



2) Press the valve cock down until it gets loose from the valve body.
 3) Now clean the components according to the instructions in chapter "Processing".
 4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Adaptable suction/irrigation tube (1288-50-06)

Disassembly:



Complete instrument.



1) Unscrew the suction/irrigation tube from the handle/valve.
 2) Remove the O-ring.
 3) Now clean the components according to the instructions in chapter "Processing".
 4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Adaptable suction/irrigation tube (1288-50-11)

Disassembly:



Complete suction/irrigation tube.



- 1) Unscrew the suction/irrigation tube from the handle/valve.
- 2) Remove the O-ring.
- 3) Now clean the components according to the instructions in chapter "Processing".
- 4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Adaptable suction/irrigation tube (1298-00-xx)

Disassembly:



Complete suction/irrigation tube.



- 1) Unscrew the suction/irrigation tube from the handle/valve.
- 2) Remove the O-ring.
- 3) Now clean the components according to the instructions in chapter "Processing".
- 4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Suction/irrigation system with trumpet valve (1298-01-xx)



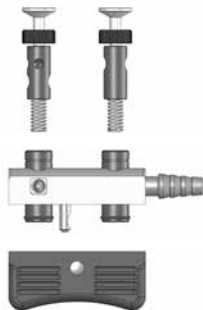
- 1 Valve piston/tappet
- 2 Body
- 3 Cap

Disassembly:



- 1) Unscrew the nut on the valve piston/tappet completely. Pull the valve piston/tappet upwards out of the instrument.
- 2) Unscrew the cap at the bottom of the valve completely and remove it.
- 3) Now clean the components according to the instructions in chapter "Processing".
- 4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care".

Suction/irrigation system with double trumpet valve (1298-41-00)



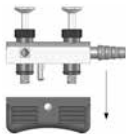
- 1) Valve piston/tappet
- 2) Body
- 3) Grip plate

Disassembly:

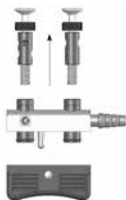


Complete instrument

Suction/irrigation system with double trumpet valve (1298-41-00)



1) Press the suspended button on the grip plate and pull the black grip plate downwards while keeping the button pressed.



2) Unscrew the nuts on both valve pistons/tappets completely. Pull the two valve pistons/tappets upwards out of the instrument.

3) The springs are loosely fastened to the valve pistons/tappets and can be removed. In addition, the two outer O-rings can be removed.

4) Now clean the components according to the instructions in chapter "Processing".

5) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Suction/irrigation pistol handle with two-way valve (1298-61-00, FlowSys Ergo 1298-81-00)







- 1 Valve cock
- 2 Holding plate
- 3 Handle

Disassembly:





Complete instrument

**Suction/irrigation pistol handle with two-way valve
(1298-61-00, FlowSys Ergo 1298-81-00)**

		<p>1) Unscrew the suspended holding plate completely from the valve cock.</p>
		<p>2) Press the valve cock down until it gets loose from the valve body.</p> <p>3) Now clean the components according to the instructions in chapter "Processing".</p> <p>4) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!</p>

**Suction/irrigation pistol handle with two-way valve
(1298-71-00)**

	<p>1 Handle</p> <p>2 Valve cock (1299-61-03)</p> <p>3 Holding plate (1299-61-04)</p> <p>4 Valve attachment</p> <p>5 Trap-door valve insert</p>
<p>Disassembly:</p>	
	<p>Complete instrument</p>

Suction/irrigation pistol handle with two-way valve (1298-71-00)



- 1) The valve attachment can be removed from the handle by pressing the small button. Keep the button pressed for removal.

- 2) Unscrew the trap-door valve insert from the valve attachment by turning in anti-clockwise direction. The two-way valve in the handle can be disassembled as follows:



- 3) Unscrew the suspended holding plate completely from the valve cock.



- 4) Press the valve cock down until it gets loose from the valve body.
- 5) Now clean the components according to the instructions in chapter "Processing".
- 6) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

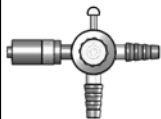
Adaptable suction/irrigation tube (1295-00-xx)



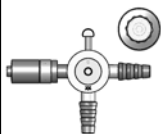
- 1) Unscrew the suction/irrigation tube from the handle/valve. The suction/irrigation tube cannot be disassembled any further.
- 2) Now clean the components according to the instructions in chapter "Processing".
- 3) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

Two-way valve (1295-21-00)

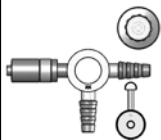
Disassembly:



Complete instrument



1) Unscrew the suspended holding plate completely from the valve cock.



2) Press the valve cock down until it gets loose from the valve body.
3) Now clean and autoclave these three (3) components.
4) Now clean the components according to the instructions in chapter "Processing".
5) Perform maintenance according to the instructions in chapter "Maintenance, inspection and care"!

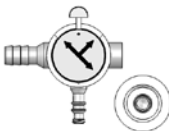
Assembly

Two-way valve (1288-50-00)

Assembly:



The disassembled instrument consists of valve body, valve cock and suspended holding plate.



1) Put the valve cock in the valve body. Please make sure that the lug of the valve cock engages in the unilateral groove on the valve body.

Two-way valve (1288-50-00)



- 2) Screw the suspended holding plate onto the threaded pin.
- 3) Now sterilise the components according to the instructions in chapter "Processing".

Adaptable suction/irrigation tube (1288-50-06)

Assembly:



- 1) Check the O-ring and slide it onto the suction/irrigation tube.

It is absolutely necessary to replace damaged or porous O-rings by new ones!



- 2) Now sterilise the components according to the instructions in chapter "Processing".

Completely assembled instrument.

Adaptable suction/irrigation tube (1288-50-11)

Assembly:



- 1) Check the O-ring and slide it onto the suction/irrigation tube.

It is absolutely necessary to replace damaged or porous O-rings by new ones!

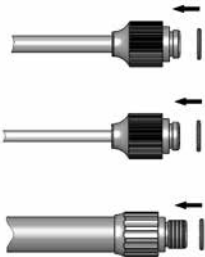
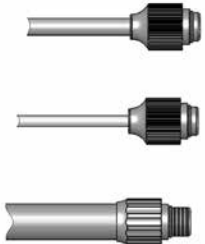


- 2) Now sterilise the components according to the instructions in chapter "Processing".

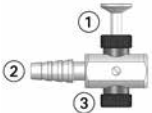
Completely assembled suction/irrigation tube.

Adaptable suction/irrigation tube (1298-00-xx)

Assembly:

	<p>1) Check the O-ring. It is absolutely necessary to replace damaged or porous O-rings by new ones! 2) Slide the O-ring onto the suction/irrigation tube.</p>
	<p>3) Now sterilise the components according to the instructions in chapter "Processing". Completely assembled suction/irrigation tube.</p>

Suction/irrigation system with trumpet valve (1298-01-xx)

	<p>1 Valve piston/tappet 2 Body 3 Cap</p>
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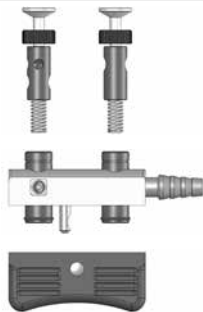
Suction/irrigation system with trumpet valve (1298-01-xx)

Assembly:



- 1) The disassembled instrument consists of valve body, cap and valve piston/tappet.
- 2) Carefully put the greased valve piston/tappet into the opening of the valve. Make sure that the small pin in the opening engages in the unilateral groove on the valve piston/tappet.
- 3) Put the cap onto the bottom side of the instrument and screw it tight against the spring force.
- 4) Now sterilise the components according to the instructions in chapter "Processing".

Suction/irrigation system with double trumpet valve (1298-41-00)




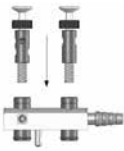
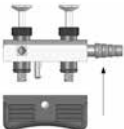
1) Valve piston/tappet

2) Body

3) Grip plate

Suction/irrigation system with double trumpet valve (1298-41-00)

Assembly:







	<p>The disassembled instrument consists of valve body, grip plate, valve piston/tappet and springs.</p>
	<p>1) Insert the springs into the greased valve piston/tappet. Then insert the piston/tappet with one (1) hole carefully into the valve opening pointing towards the tube connection, and the one with two (2) holes into the valve opening pointing away from the tube connection. Make sure that the small pin in the opening engages in the unilateral groove on the valve piston/tappet.</p>
	<p>2) Slide the black grip plate from below onto the instrument while keeping the button pressed. Make sure that the large pin between the two valve openings engages in the corresponding groove of the grip plate.</p> <p>3) Now sterilise the components according to the instructions in chapter "Processing".</p>

Suction/irrigation pistol handle with two-way valve (1298-61-00, FlowSys Ergo 1298-81-00)


		<p>1 Valve cock 2 Holding plate 3 Handle</p>
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Suction/irrigation pistol handle with two-way valve (1298-61-00, FlowSys Ergo 1298-81-00)

Assembly:






		<p>The disassembled instrument consists of handle, valve cock and holding plate.</p>
		<p>1) From the rear, push the valve cock completely into its middle position.</p>
		<p>2) Screw the suspended holding plate onto the threaded pin of the valve cock and screw it tight. 3) Now sterilise the components according to the instructions in chapter "Processing".</p>

Suction/irrigation pistol handle with two-way valve (1298-71-00)


	<p>1 Handle 2 Valve cock (1299-61-03) 3 Holding plate (1299-61-04) 4 Valve attachment 5 Trap-door valve insert</p>
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Suction/irrigation pistol handle with two-way valve (1298-71-00)

Assembly:

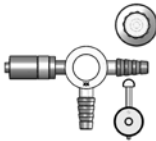
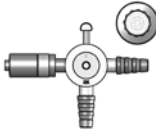
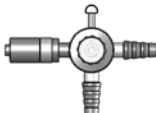
	<p>The disassembled instrument consists of handle, valve cock, holding plate, valve attachment, trap-door valve insert and suction/irrigation tube (not shown).</p>
	<p>1) Screw the trap-door valve insert into the valve attachment. Make sure that the seal is correctly seated in the trap-door valve insert.</p>
	<p>The two-way valve in the handle is disassembled as follows:</p> <p>2) From the rear, push the valve cock completely into its middle position.</p>
	<p>3) Screw the suspended holding plate completely onto the valve cock.</p>
	<p>4) Put the valve attachment onto the handle while keeping the button pressed and slide it on until it reaches the stop. Now you can release the button. The valve attachment is firmly seated onto the handle.</p> <p>5) Screw the suction/irrigation tube in the valve attachment and screw it tight.</p> <p>6) Now sterilise the components according to the instructions in chapter "Processing".</p>

Adaptable suction/irrigation tube (1295-00-xx)

	<p>1) Screw the suction/irrigation tube onto the handle/valve.</p> <p>2) Now sterilise the components according to the instructions in chapter "Processing".</p>
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Two-way valve (1295-21-00)

Assembly:

	<p>The disassembled instrument consists of valve body, valve cock and suspended holding plate.</p>
	<p>1) Put the valve cock in the valve body. Please make sure that the lug of the valve cock engages in the unilateral groove on the valve body.</p>
	<p>2) Screw the suspended holding plate onto the threaded pin of the valve cock and screw it tight. 3) Now sterilise the components according to the instructions in chapter "Processing".</p>

Processing

General information

-  *Whenever you are working with contaminated instruments, follow the personal protection guidelines of the trade association and similar organisations. Wear appropriate protective equipment and ensure that you have had the necessary vaccinations.*
-  *Risk of infection: Incorrect processing of instruments puts patients, users and third parties at risk of infection and can impair the performance of the instrument.*
-  *Instruments used on patients known to have or suspected of having Creutzfeldt-Jakob disease or other prion diseases must be disposed of after one use in accordance with specific national requirements.*
-  *Always comply with the procedures, equipment and devices validated for the user / operator / central sterilisation unit and check them for compatibility with the information provided here.*
-  *When making up and using solutions, comply with the information on concentration and exposure time provided by the manufacturers of the chemicals. Non-compliance can damage the instrument.*
-  *Further information on instrument processing can be found at www.a-k-i.org*

Preparation at the place of use

If an instrument has been contaminated, always clean it immediately after use. To prevent material from drying and adhering to the instrument, large particles of contamination, corrosive solutions and medicinal products must be removed immediately after application of the medicinal product, for example by wiping and rinsing (dry disposal).

Transport

Use suitable transport containers to transport instruments to the reprocessing site in order to rule out the possibility of them constituting a hazard or undergoing external contamination.

Dry disposal is always preferred, whenever possible. Avoid long storage times.

Preparation before mechanical cleaning

If an instrument has been contaminated, always process it immediately after use. If the instrument is a multi-piece device, dismantle it into its constituent parts (see chapter on instructions for dismantling).

Pre-cleaning the surfaces:


Use a brush (no steel brush) or sponge to remove visible contamination or heavy dirt from the surface of the instrument under cold running water (<40 °C; drinking water quality).

Pre-cleaning cavities / lumens:

Use a suitable brush (no steel brush) to clean the working channels, lumens and cavities of the instrument under cold running water (<40 °C; drinking water quality). Rinse gaps, grooves and cavities approx. 10 seconds with a pressurised water pistol, fitted with an irrigation attachment if necessary.

Manual cleaning / manual disinfection

Manual disinfection is not necessary.

 **Warning:** Exclusively manual processing is not permitted. Manual cleaning must always be followed by mechanical cleaning and disinfection.

Mechanical cleaning and disinfection

Instrument sets must only be cleaned and disinfected in a suitable cleaning and disinfection machine (CDM).

Use the Vario TD programme to clean thermostable instruments.

PAJUNK® has validated and approved the following cleaning and disinfection process in accordance with DIN EN ISO 17664 or DIN EN ISO 15883:

- Vario TD process parameters:
 - 1 minute pre-washing with cold tap water, drinking water quality, <40 °C
 - Draining
 - 3 minute pre-cleaning with cold tap water, drinking water quality, <40 °C
 - Draining

If Neodisher® Mediclean forte is used:

- 10 minutes cleaning at 55 °C (+5/-1 °C), dosage acc. to the following table and demineralised water

If Neodisher® MediZym is used:


- 10 minutes cleaning at 45 °C (+5/-1 °C), dosage acc. to the following table and demineralised water
- Draining
- 3 minutes rinsing with demineralised water (<40 °C)
- Draining
- 2 minutes rinsing with demineralised water (<40 °C)
- Draining
- 5 minutes thermal disinfection at 93 °C (± 2 °C) (A0 =3000) and demineralised water
- Draining
- 30 minutes hot air drying at >60 °C (in the cleaning chamber)

Chemical	Manufacturer	Category	pH value	Dosage
Neodisher Mediclean forte	Dr. Weigert	Alkaline detergent	10.4 - 10.8*	0.5 % (5 ml/l)
Neodisher MediZym	Dr. Weigert	Enzymatic detergent	7.6 - 7.7 *	0.5 % (5 ml/l)


* Data in accordance with manufacturer data sheet

Connect individual parts with lumens and channels directly to the cleaning and disinfection machine. Connect non-dismountable instrument sets with cleaning channel, if any, directly on the Luer-Lock port to the special lumen-cleaning element in the cleaning and disinfection machine. Use cleaning adapter 1292-43-98 to clean and disinfect 3-mm instruments.

When selecting the cleaning programme, bear in mind the material from which the instrument to be cleaned is made (e.g. stainless steel for medical instruments, chromed surface, aluminium).

 Always comply with the instructions of the device and detergent manufacturers.

Drying

 The instrument may need to be manually dried after cleaning.

Maintenance, inspection and care

Leave the instrument set to cool to room temperature.

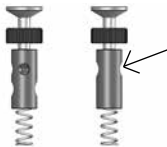
Perform a visual check on the cleaned and disinfected instrument, paying attention to cleanliness, completeness, damage and dryness.

If any contamination or residue is found during this check, the instrument must undergo another complete cleaning and disinfection process.

Any parts of the instrument that are found to be damaged, incomplete, corroded, bent, broken, torn or worn must be removed or replaced.

Always check O-rings for damage prior to use, and replace them if necessary.

Dry the instrument again if there is any residual moisture.



For articles 1298-01-00 and 1298-41-00: grease the valve piston/tappets using a suitable grease (PAJUNK® art. no. 1298-98).

Reassemble the dismantled instrument set according to the assembly instructions.

! PAJUNK® recommends that instruments be handled carefully and gently, and that this user manual be closely followed, in order to maximise their useful life. The useful life of the instrument depends to a very large extent on careful handling and the performance of appropriate care and maintenance measures.

Packaging system

Only use standardised and permitted packaging systems in accordance with EN 868 parts 2-10, EN ISO 11607 parts 1+2, DIN 58953.

Sterilisation

! *Warning: Instruments used on patients known to have or suspected of having Creutzfeldt-Jakob disease or other prion diseases must be disposed of after one use in accordance with specific national requirements.*

PAJUNK® has validated and approved the following process:

Steam sterilisation:

The fully mounted instrument must be sterilised in accordance with a validated steam sterilisation process (e.g. steriliser according to DIN EN 285 and validated according to DIN EN 17665-1).

When following the fractionated vacuum procedure, sterilise according to the 134 °C/ 3-bar programme, with a minimum holding time of 5 minutes (in accordance with the recommendations issued by the Robert Koch Institute and the German Federal Institute for Drugs and Medical Devices). The drying time is 30 minutes.

Allow devices / instruments to cool to room temperature before using them again. Keep instrument sets that have undergone steam sterilisation in suitable containers used only for this purpose.

Transport to the place of use

Use suitable transport systems.

Reprocessing restriction

The end of device life is determined primarily by wear, damage caused by use, careful handling and appropriate storage.

Frequent reprocessing in accordance with the reprocessing instructions supplied by the manufacturer does not affect the instruments' performance.

Repair

Devices sent to PAJUNK® for repair under warranty or at the user's expense must be thoroughly cleaned and sterilised before being sent back. Sterility must be noted on the covering letter or package.

Operating and storage conditions



Temperature limit +10 °C to +30 °C



Humidity limitation 20 % to 65 %



Keep away from sunlight



Keep dry

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.



Any serious incident that has occurred while using the device should be reported to the manufacturer and the corresponding authorities of the country the user and/or patient are residing in.



PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling



Manufacturer



Catalogue number



Do not use if package is damaged



Keep dry



Humidity limitation



Caution



Date of manufacture



Batch code



Non-sterile



Keep away from sunlight



Temperature limit



Consult instructions for use



Caution: Federal law restricts this device to sale by or on the order of a physician



MR unsafe



Advice



Information



Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body



Quantity



Translation



Medical device



XS190172H_Englisch 2020-01-20



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