Ackermann medical

c|spine

Cervical Interbody Cage System

with Ridge

c|spine

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Company Profile

We, the Ackermann Medical GmbH & Co. KG, have our head office in Schaffhausen in Switzerland.Since almost one decade we are specialized in the development and production of medical products for spinal surgery. Therefore it is our matter of course to garant our company conforms to the highest medical standards according to FDA, 93/43/EEC (CE), ISO 13485:2003.
Since the beginning of 2013 we are building up a direct sales of implants and instruments for spinal surgery in Germany.

Concentration on the Essentials

We have made it our mission to produce only products offering maximum benefit to patients, the attending physicians, and customers.
Therefore we have committed ourselves offering our goods in the best possible quality at consistently low prices.

This is not only due to our own production and development, but also to our consistent concentration on the essentials

- no compromises in quality
- optimization of the sales management
- responsible marketing

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

c|spine

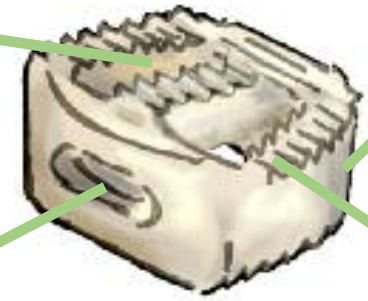
The c|spine Cage System

The Ackermann c|spine is an interbody PEEK or Titanium cage system with our without ridge, designed for anterior fusion of the cervical spine.
Highest biocompatibility is ensured due to certified and approved medical grade materials. The unique anatomical design and the perforated texture allow for the best possible fusion of the cervical vertebra. Integrated tantalum markers support the positioning of the cage and provide post-operative follow-up capabilities.

c|spine consists of pure, medical grade PEEK (VESTAKEEP® by EVONIK) material or highest-grade Titanium, in strict adherence to highest quality guidelines. The organic, thermally stable polymer excels by proven adhesion, sterilization and biocompatibility characteristics, is x-ray-lucent and without artifacts.
The c|spine product range includes a full implant and trial set, made in Germany. Size indicator and depth stop allow for a fast and safe implantation technique of this unique product line. c|spine is the ideal solution in interspinous implantation, for both the patient and the treating surgeon.

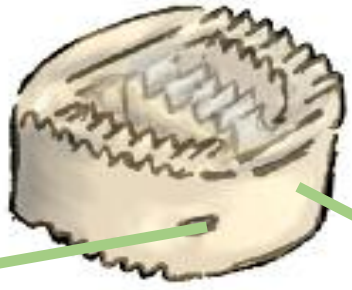
Large graft window
for maximized fusion

Highest grade materials
PEEK by EVONIK or Titanium



Threaded interface
for controled, secure and precise implant insertion

Aggressive serration
for secure fixation and to resist migration



Tantalum markers
for positioning and postoperative follow-up

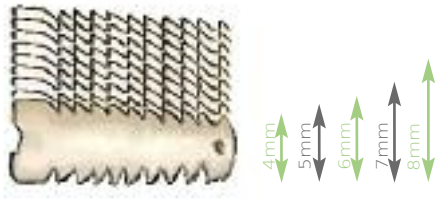
Tapered nose
for ease of insertion and self-distraction

c|spine

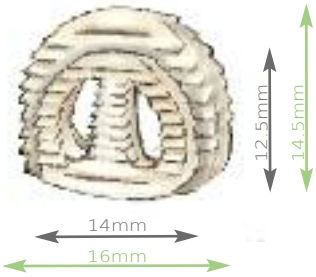
Intended Use | Indications | Contraindications

Ackermann provides a full range of sizes with heights from 4 mm to 8 mm and footprints of 14.5 x 16 mm and 12.5 x 14 mm.

Heights



Footprints



Intended Use

The c|spine implants are used with the purpose of providing support for spondylosis and restoration of the spinal columns profile.
For additional stabilization, the c|spine implant should be filled with autologous graft or bone substitutes.

Indications

The c|spine implants are intended to be used for:

- degenerative disc disease
- prolapsed intervertebral disc
- pseudarthrosis
- degenerative scoliosis
- revision surgery

Contraindications

The c|spine implants are NOT intended to be used for:

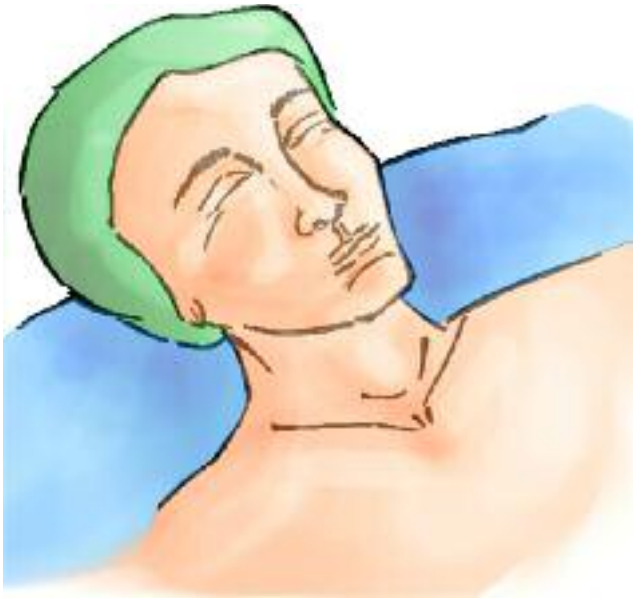
- leukocytosis
- osteoporosis
- patients with fractures or tumors in the spine area
- patients with spine associated infections
- psychiatric disorder
- pregnancy
- patients with proven materiel allergy or tendency to react to foreign bodies

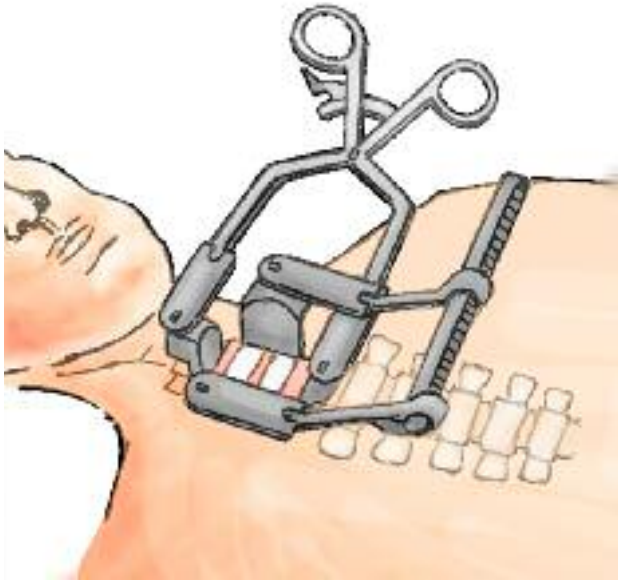
ONE | Patient Positioning and Access

Position the patient in a supine position on an operating table. To hold the patient´s neck in slight extension support it with a cushion. To emphasize the reclination, elevate the thorax using a pad roll. The patient´s neck should now be in a sagittally neutral position.
Make sure that the patient´s arms are laterally positioned.
Locate the correct level under x-ray radiation (An x-ray c-arm is recommended) and perform an anterior incision over the concerned segment.
Cut a rectangular window in the anterior longitudinal ligament and annulus fibrosus, matching the width of the c|spine cage.

Note

| When treating C6 – C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases, both vertebrae should be completely visible.





TWO | Positioning of the Retractor and Annular Window

After incising, insert the retractor.
Careful placement of the retractor is required to avoid soft tissue damage.
For further treatment, cut a rectangular window in the anterior longitudinal ligament and annulus fibrosus which matches the width of the c|spine cage.

Note for Treatment of the Platysma

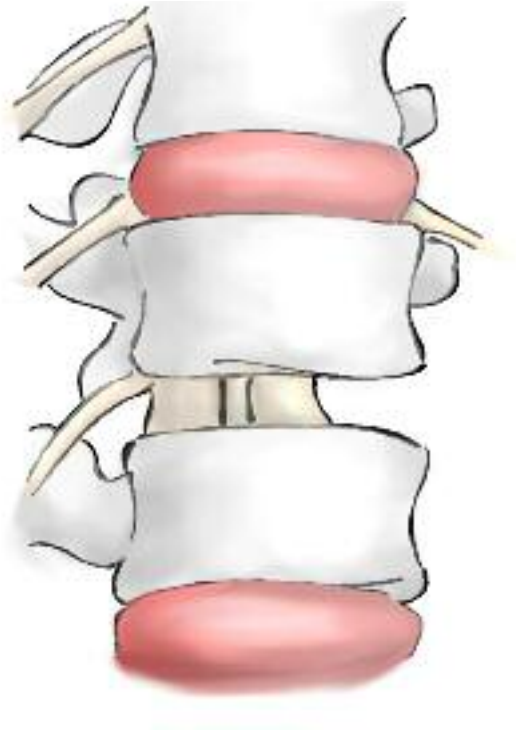
| The subcutaneous tissue may be separated caudally, cranially, and medially from the platysma.
The platysma itself can be pushed apart in the fiber´s direction. To hold the platysma´s borders use a retractor or two surgical tweezers.

THREE | Discectomy

For entire removal of the intervertebral space use the instruments of the Ackermann DISCECTOMY line *[catalog 70]*.

Note

| The endplate´s integrity may be preserved to avoid subsequent sinking of the cage.



FOUR | Distraction

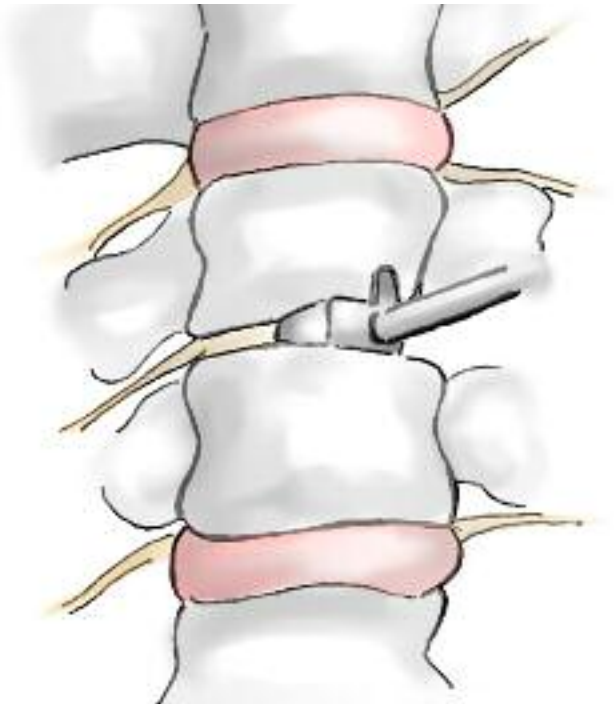
When the discectomy is completed, remove all superficial cartilaginous layers of the endplates to expose bleeding bone.
An adequate distraction is necessary for the restoration of the intervertebral disc´s height and the vascular supply of the autologous cage. Therefore, use a c|spine rasp in combination with the c|spine handle *[70-7433]*.

Note

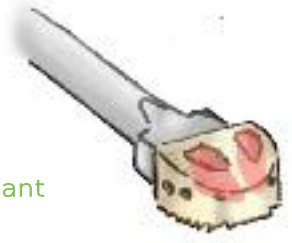
| It is necessary to remove any osteophytes to receive a decompression of the neural structures and avoid the risk of a partial compression at the cage.
| Excessive cleaning may result in removal of bone,which underlies the cartilaginous layers and weakens the endplates.

FIVE | Sizing of the Implant

To determine the right implant size use c|spine trials.
Height, width, and depth of the intervertebral space, the preparation technique, and the patient's anatomy will affect the selection of the trial implant.
Once you have chosen a trial from the c|spine trial set *[70-7476SET]*, screw it on the c|spine handle *[70-7433]*.
To check the trial´s position use radiographic imaging. The trial must fit tightly and accurately in the intervertebral space without damaging the endplates. To maximize segment stability through tension in the longitudinal ligament and the annulus fibrosus use the largest possible trial.
If the trial is too big or too small select a smaller or larger size and repeat the procedure. The heights of the trials match the heights of the c|spine implants including their serration.
To avoid a too deep insertion of the trial and any damage of the nerves, our c|spine trials are equipped with a safety stop.



before the filling of the implant



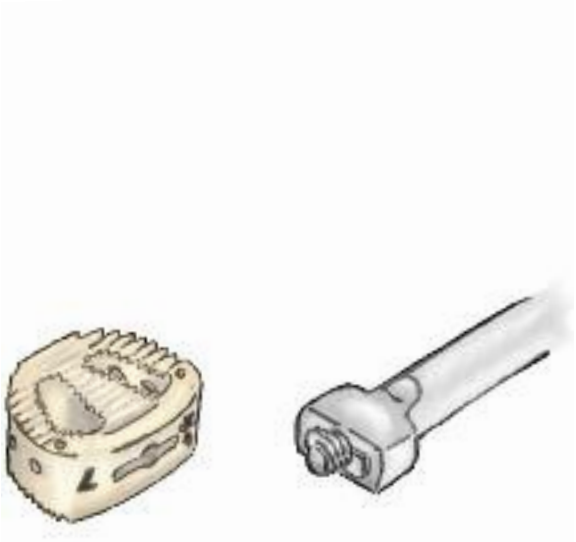
after the filling of the implant

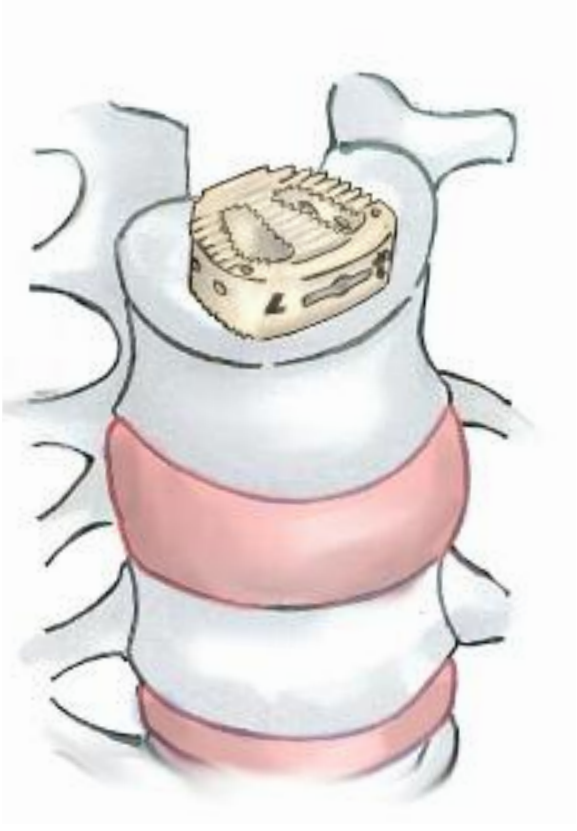
SIX | Filling of the c|spine Implant

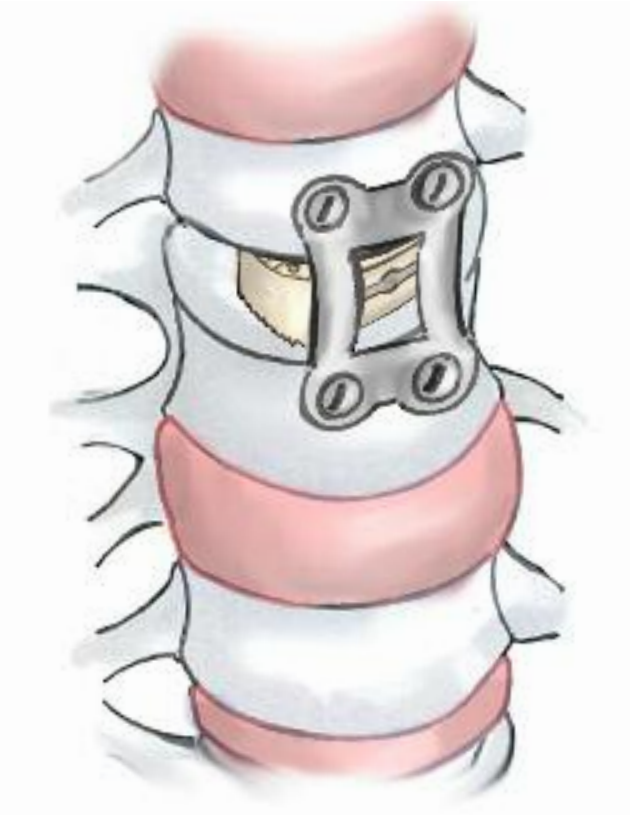
Before introducing the implant, it has to be filled with autologous graft or bone graft substitute. This requires the bone graft substitute to be loaded and carefully compressed into the graft window of the c|spine implant by use of a cancellous bone impactor.
Please make sure to comply with the instructions of the manufacturer.

SEVEN | Final Implant Positioning

Attach the c|spine cage onto the c|spine applier *[70-7609]* by turning the knob on the handle of the instrument. Make sure that the cage is tightly secured to the applier.
The cage applier is equipped with a safety stop to avoid a deep penetration into the spinal canal and prevents any other kind of damage.
Insert the c|spine cage into the intervertebral space.
If required, it is possible to carefully position the cage using a hammer. It is recommended to use the Ackermann hammer *[58-6788]* with teflon caps and silicone handle.
Once the cage is embedded in the intervertebral space, release the implant from the applier by unscrewing the knob. Carefully remove the applier.

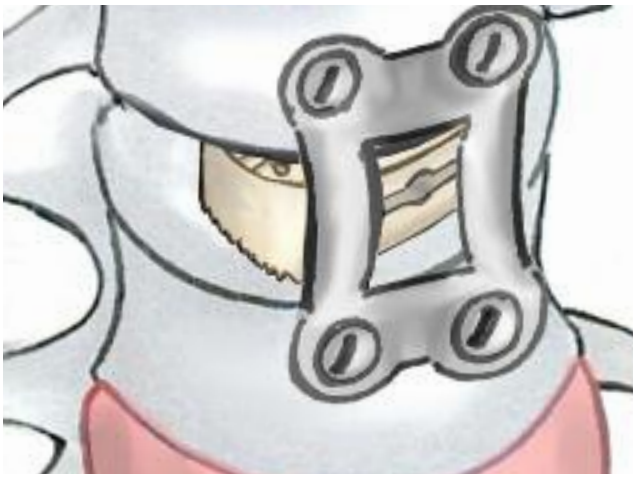






EIGHT | Supplemental Fixation

After successfully inserting the cage it is recommended to fix a cervical plate system (e.g. the Ackermann a|spine cervical plate system). a|plate increases the fusion process and provides a stronger postsurgical stability.



NINE | Wound Closure

After fully fixating the implants and, potentially a cervical plate, free the platysma and carefully remove the retractor.
The incision of the skin can be closed by stitches or small surgical skin staplers. Anti-inflammatory medication may be indicated.

TEN | Postoperative Care

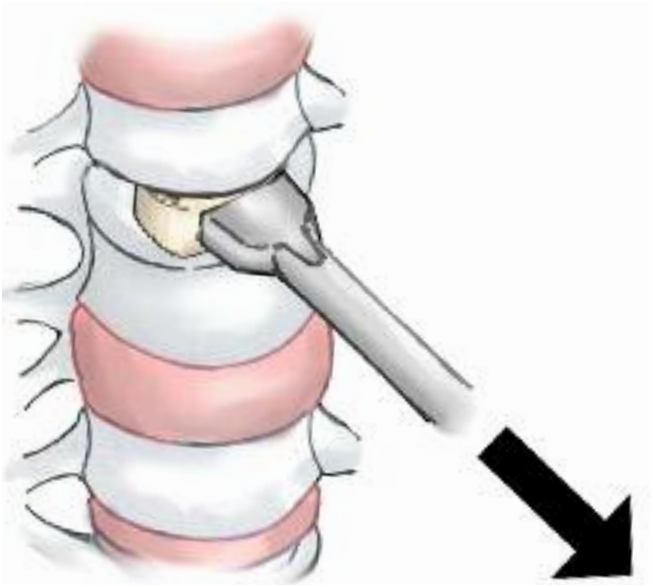
Before the patient is discharged, a radiographic control has to be performed, which should be repeated after four to six months.
For patients displaying postoperative symptoms a cervical orthosis or a medication for muscle relaxation may be indicated.

ELEVEN | Removal of the Implant

If the cage has to be removed, the entire anterior surface of the implant needs to be exposed *(see: ONE | Patient Positioning and Access)*. In case of advanced bone fusion it is recommended to use an osteotome.
Securely attach the c|spine applier *[70-7609]* to the c|spine cage *(see SEVEN | Final Implant Positioning)*. Remove the implant from the intervertebral space.
Make sure that neither parts of the implant nor bone graft material enters the spinal canal.

Note

| Tilting of the applier must be avoided to prevent implant separation or damage.
| An extracted c|spine implant may not be reused.



c|spine

Implants made of EVONIK PEEK

	D 12.5 mm x W 14 mm
EVONIK PEEK	Height [mm]
70-7406	4
70-7407	5
70-7408	6
70-7409	7
	D 14.5 mm x W 16 mm
EVONIK PEEK	Height [mm]
70-7401	4
70-7402	5
70-7403	6
70-7404	7
70-7405	8

c|spine

Implants made of Titanium

	D 12.5 mm x W 14 mm
Titanium	Height [mm]
70-7406TI	4
70-7407TI	5
70-7408TI	6
70-7409TI	7
	D 14.5 mm x W 16 mm
Titanium	Height [mm]
70-7401TI	4
70-7402TI	5
70-7403TI	6
70-7404TI	7
70-7405TI	8

c|spine PoRo

Osteoconductive, porous implants made of Titanium

	D 12.5 mm x W 14 mm
Titanium - Porous	Height [mm]
70-7406TI-P	4
70-7407TI-P	5
70-7408TI-P	6
	D 14.5 mm x W 16 mm
Titanium - Porous	Height [mm]
70-7402TI-P	5
70-7403TI-P	6
70-7404TI-P	7

Trials	D 12.5 mm x W 14 mm
for all cages from page 12 to 14	Height [mm]
70-7440 ► SET PART	4
70-7425 ► SET PART	5
70-7426 ► SET PART	6
70-7427 ► SET PART	7
70-7427-8	8
Trials	D 14.5 mm x W 16 mm
for all cages from page 12 to 14	Height [mm]
70-7441 ► SET PART	4
70-7428 ► SET PART	5
70-7429 ► SET PART	6
70-7430 ► SET PART	7
70-7431 ► SET PART	8

c|spine
Instrumentation

Ackermann offers diverse instruments for safe and successfull use of the c|spine implants, which are available separately or in full instrumentation sets.

Implant Holder	
70-7609 ► SET PART	c|spine implant holder

The implant holder is used to insert, or if necessary remove the c|spine implant.

Trial Holder	
70-7433 ► SET PART	c|spine trial holder

The trial holder is used to insert the trials in the intervertebral space for size determination.

Chisel	
70-7423	D 12.5 mm x W 14 mm
70-7424	D 14.5 mm x W 16 mm

The chisels are available in two different footprints based on the trial and implant sizes. They are used to spread the vertebraes postoperatively.

Rasps	D 12.5 mm	D 14.5 mm
Height [mm]	x W 14 mm	x W 16 mm
4	70-7423R ► SET PART	70-7424R ► SET PART
5	70-7423R-5	70-7424R-5
6	70-7423R-6	70-7424R-6
7	70-7423R-7	70-7424R-7
8	70-7423R-8	70-7424R-8

The rasps are available in two different footprints based on the trial and implant sizes. They are used to spread the vertebraes postoperatively.

c|spine
Instrumentation

Hammer	
58-6788	hammer *(fits into 70-7476SET container)*
The hammer with silicon handle and teflon cap is used for support when inserting the implant into the inervertebral space.	

Instrumentation Sets	
▸70-7476SET	c|spine set with tray, insert for instruments and instruments
Assembly	1 x container
	1 x insert for instruments
	9 x trials by default (opt. adjustable)
	2 x rasps
	1 x trial holder
	1 x implant holder
All components of the kit are autoclavable and reusable. If neccessary every component is separately available, too.	

Place of Use (immediately after use)

IMMEDIATELY after each use (within no more than 10 min. or before drying of contaminants) the instruments need to be cleaned and impurities removed under running water, using a soft brush or cloth used solely for this purpose. NEVER use a metal brush, steel wool or other cleaning devices containing metal in order to avoid the imminent risk of corrosion. Rinse under cold, running water until all visible impurities and contaminants have been successfully removed.

Storage and Transport

Place instruments in a container. Keep the inside of the container moist/wet (no contaminants shall dry).Reprocess all instruments soonest possible.

Preparation for Cleaning

Soak instruments in cold water for at least 5 min. and clean them, using a soft brush or cloth which are being used solely for this purpose. NEVER use a metal brush, steel wool or other cleaning devices containing metal in order to avoid the imminent risk of corrosion. Afterwards, wash down the entire surface of the instrument for 10s. by use of a cleaning gun (min. continuous pressure of 4 bar); articulate moveable parts constantly during the preliminary cleaning. Instruments featuring lumina and/or LuerLock flush channels are to be rinsed for an additional 10s. after visibly clear water has flown from the ports. Place the instruments in an ultrasonic bath for 10min. (35-40kHz for min. 5min. or longer acc. to specifications). Prior to switching on the ultrasonics make sure that all lumina, sheaths, etc. are filled with cleaning fluid!
Note that the preliminary cleaning – even the use of a disinfectant – is only intended as a preparatory step and DOES NOT replace the actual disinfection!

Mechanical Cleaning

Make sure that multiple instruments do not come in contact with each other; especially different materials such as titanium, brass, aluminum, stainless steel, etc. need to be cleaned separately in order to avoid formation of a rust film. Composite instruments (particularly stainless steel combined with ceramics) shall be placed with sufficient distance away from other products to prevent damage arising from the pressure of different thermal expansions.

Instruments have been tested with the following devices:

Washer-Disinfector G 7735 CD (Miele)

1. washing cycle: alkaline program (No 105)
2. washing cycle: enzymology program (No 105)

Washer-Disinfector G 7836 CD (Miele)

1. two component alkaline/enzymatic program
2. OxiVario

Washer-Disinfector Niagara SI PCF (Medisafe) (RECOMMENDED)

1. Cleaning process with pulsed ultrasonic irrigation
2. Cleaning process without pulsed ultrasonic irrigation

The water which is to be used needs to be sterile or nearly sterile (<10 microbes/ml) and low in endotoxins (< 0.25 units/ml). The air which is being used for drying needs to be cleaned by means of micro filters which are regularly checked and maintained. A maintenance schedule has to be documented.

Manual Cleaning

Mechanical cleaning is mandatory with these products as they are classified as class „critical B" according to the RKI/BfArM-recommendations.

Disinfection

Take the instruments and place them into the disinfecting bath (Caution: products need to be fully immersed; at least 1cm below the liquid surface).
Multiple instruments shall not come in contact with each other; especially different materials such as titanium, brass, aluminum, stainless steel, etc. need to be disinfected separately in order to avoid formation of a rust film. Composite instruments (particularly stainless steel combined witto prevent damage arigising from the pressure of different thermal expansions. Rinse all the lumina of the instrument at least five times using a sterile syringe (min 50ml) and disinfectant.

After disinfection

Remove products and rinse for at least 5 min. under running water until all disinfectant is removed from the instruments (the water which is to be used needs to be sterile or nearly sterile with <10 microbes/ml and low in endotoxins with < 0.25 units/ml).
Constantly articulate moveable parts.
Rinse all the lumina of the instrument with water at least five times using a sterile syringe (min 50ml).

Disinfectants that have been successfully tested are

1. Alkaline, Neodisher FA, pH 12.2, Dr. Weigert
2. Enzymatic, deconex 23 Neutrazym, pH 9.7, Borer
3. 2-Component Alkaline/Enzymatic, deconex TWIN PH, pH 10.9, deconex TWINZYME, pH 7, Borer
4. 2-Component Alkaline, Sekumatic FR, pH 12.1; Secumatic OxiVario. PH 7.8; Neutralizer: Sekumatic FNZ, pH 2.2, Ecolab
5. Enzymatic; M20029 3E-Zyme Scope Plus, pH 6.1, Medisafe
6. Enzymatic + Ultrasound, M20029 3E-Zyme Scope Plus, pH 6.1, Medisafe

Drying

After cleaning and disinfection place the instruments into suitable containers. Make sure that there is NO residue of the disinfectant.
When drying as part of the cleaning/disinfection cycle is completed make sure that a temperature of 150°C/300°F is not exceeded.
All operations need to take place in a clean, monitored environment!

Maintenance

Apply a small amount of high-grade surgical lubricant on all joints or other moveable parts which are supposed to move smoothly. Sort out all blunt or damaged instruments.
Clearly damaged instruments (cracks on the insulation, breakage, strongly bleached polymer handles or coatings) are NOT to be reused but repaired or disposed of.

Testing and Inspection

Jointed instruments are to be tested for ease of movement (avoid too much backlash). The functionality of ratchet mechanisms needs to be checked. All instruments: visually check for damage and wear. Blades should be even and without notches. Long and narrow instruments (especially jointed instruments) should be particularly checked for damages. If instruments are part of a larger set they are to be checked together with all associated components.

Packaging

Individually: a standardized packaging material may be used. The size of each bag needs to match the individual instrument so that there is no tension applied on the sealing.
Sets: sort instruments into designated trays or place on multi-purpose sterilization trays. Blades need to be protected; the weight of each tray may not exceed 8kg (18lbs). For the trays an adequate packaging procedure is to be used.

Sterilization

All products have been precleaned to an extent which allows for processing and sterilization by use of the equipment stated here. This only applies to a processing method according to these instructions within a system that has been configured and validated in compliance with ISO 17665 and in which all cleaning/disinfecting devices comply with ISO 15883. With the result of the sterilization process greatly depending on the equipment that is being used a sterilization validation acc. to ISO 17665 MUST be performed at the place of use prior to the first application. All products MAY be used only if the result of this validation is positive.

For the sterilization of medical devices various methods can be applied. Regarding products manufactured by Ackermann, gravity steam sterilization with a fractionated process is recommended.

Temperature	134°C – 137°C (273°F – 279°F)
Pressure	3 bar
Duration	5 min

Please comply with all recommendations issued by the manufacturer of your sterilization device with regard to handling and loading. Instruments that are to be sterilized need to be thoroughly exposed to the steam, including inner surfaces. Before using the instruments they need to be cooled down to room temperature.

Other durations and/or temperatures may also be applied. However, when doing so deviations of parameters should be validated (Caution: contact the manufacturer of your autoclave to confirm temperatures and/or sterilization durations). Temperature inside the autoclave should not exceed 139°C/182°F. This could cause possible damage to handles, insulation or other non-metallic components. Do not sterilize using hot air or Processing and Sterilization Instructions of Medical Devices (acc. to ISO 17664) flash autoclave methods.

In case only pre-vacuum sterilization can be performed, please adhere to the following parameters:

for Europe (except Switzerland and France)

Sterilizer type	pre-vacuum
Preconditioning pulses	3
Preconditioning pressure	30 psia
Minimum temperature	134°C
Cycle time	5 min.
Sample configuration	individually wrapped

for Switzerland and France

Sterilizer type	pre-vacuum
Preconditioning pulses	3
Preconditioning pressure	30 psia
Minimum temperature	134°C
Cycle time	18 min.
Sample configuration	individually wrapped

others	
Sterilizer type	pre-vacuum
Preconditioning pulses	3
Preconditioning pressure	30 psia
Minimum temperature	132°C / 270 °F
Cycle time	4 min.
Sample configuration	individually wrapped

Storage

Store instruments secured against mechanical damage. Use additional wrapping to protect against dust. Do not stack instruments which are packed sterile; especially do not place heavy items on top in order to avoid damage to the sterile packaging of other instruments.
Products need to be stored in a clean and dust-free environment at moderate temperatures of 19° - 25°C (66° - 77°F) and humidity of 40 - 60% (to avoid the risk of embrittlement of the sterile packaging AND of plastic components, especially handles).

Additional Information

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

Warnings

ALL INSTRUMENTS MUST BE CLEANED, DESINFECTED AND STERILIZED PRIOR TO EACH USE.
All reusable Ackermann products are shipped in non-sterile condition. Before the first use transport packaging, coarse dust/pieces of paper/packaging remains need to be removed and each product processed and sterilized according to these instructions. All products have been precleaned to an extent which allows for processing and sterilization by use of the equipment stated here. This only applies to a processing method according to these instructions within a system that has been configured and validated in compliance with ISO 17665 and in which all cleaning/disinfecting devices comply with ISO 15883.
THOROUGH CLEANING AND DISINFECTION IS CRUCIAL FOR AN EFFECTIVE STERILIZATION!
Especially in Germany, the adherence to and knowledge of the RKI/BfArM-recommendations is the prerequisite for these instructions. In accordance with EU Directive 93/42 processing is NOT permitted in Germany without comprehensive awareness of these guidelines!
Processing must only be carried out by personnel explicitly designated by §4 Abs. 3 MPBetreibV after verifying their qualification! Strong cleaning agents may cause fading of markings.

Limitations on Reprocessing

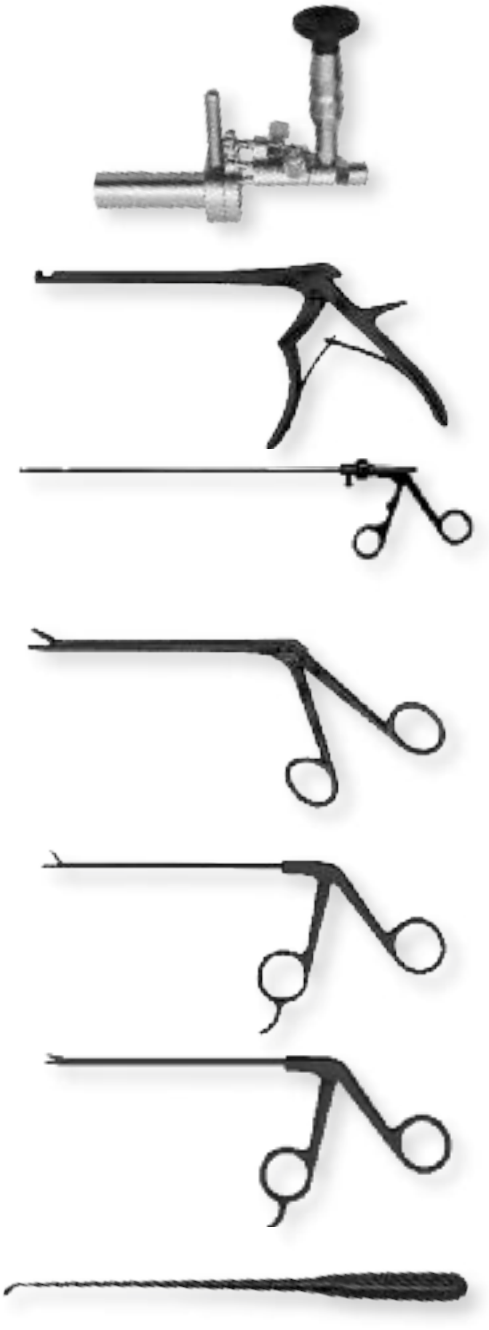
Instruments have been validated for 50 cycles, based on an average treatment.
Products that have been marked as single-use (acc. to DIN EN 980 2008-11/figure 5.2) MUST NOT be reprocessed! With such products materials are being used that are NOT reprocessable under normal conditions or do not withstand more than one sterilization process and, therefore, may break during surgery if reprocessed! (this applies to practically all single-use products featuring plastic components)

c|spine

Supplementary Equipment

Complementary to our c|spine implants Ackermann offers a wide range of discectomy and neuroscopic instruments.

Vertibroscope and rotative holding disk	
70-7040	Rotative holding disk holds the endoscope and allows 360° rotation with 30° view
70-7180	Vertibroscope for discectomy, 30° rotatable, with light-transmission, lenses made of saphire
Kerrison rongeur	
70-7060	30°, 2 mm jaw, 250 mm WL
70-7065	40°, 2 mm jaw, 250 mm WL
70-7070	90°, 2 mm jaw, 250 mm WL
70-7075	90°, 3.5 mm jaw, 330 mm WL, rotatable
70-7076	40°, 3.5 mm jaw, 330 mm WL, rotatable
Micro conchotome, 250 mm WL	
70-7080	5 mm jaw, 45° upwards arched
70-7085	3 mm jaw, 45° upwards arched
70-7090	5 mm jaw, 45° straight
70-7095	3 mm jaw, 45° straight
Micro forceps, 2 mm jaw, 200 mm WL	
70-7086	45° angled upwards
70-7091	straight
70-7092	straight, spoon with teeth
Micro scissors, 2 mm jaw, 200 mm WL	
70-7097	single action, cutting 90° towards the handle
Curette, 272 mm overall length	
70-7100	3 mm jaw, 45° angled
70-7105	5 mm jaw, 45° angled
70-7106	5 mm jaw, 90° angled

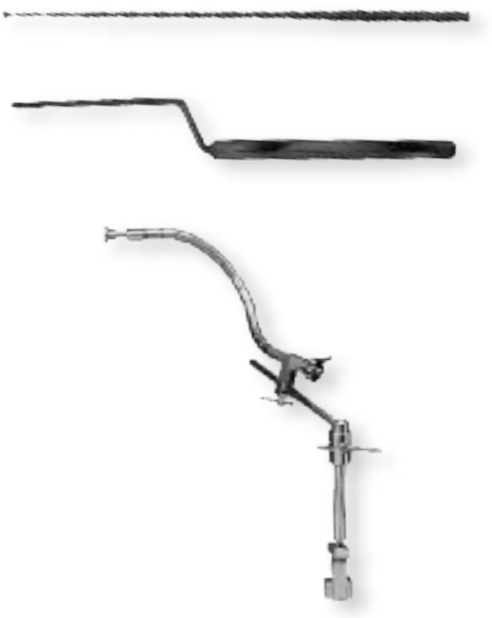


c|spine

Supplementary Equipment

Suction tube, 272 mm overall length	
70-7110	without spatula tip
70-7111	with spatula tip
Bipolar forceps, 1.2 mm jaw, bayonet, 280 mm overall length	
70-7115	straight
70-7120	angled
Bipolar cable	
70-7130	
Nerve manipulator, 90° angled - knurled handle	
70-7135	1 mm tip, 272 overall length
70-7142	3 mm tip, 30 mm spatula length, curved upwards
70-7146	1.5 mm ball tip, 5 mm angled, 200 mm WL
70-7147	1.5 mm ball tip, 9 mm angled, 200 mm WL
Spatula, 90° angled, 200 mm WL - knurled handle	
70-7139	spatula size 7 mm x 4 mm, knurled handle
Nerve retractor, knurled handle	
70-7140	wide tip, 272 mm overall length
70-7143	3 mm tip, 30 mm spatula length, 200 mm WL
Nerve manipulator, 272 mm overall length	
70-7136	1.5 mm tip, 90° angled
70-7137	1 mm tip, 90° angled
70-7141	3 mm jaw, spatula form

Ball tip dissector, 272 mm overall length	
70-7145	90°, 1.5 mm tip
Bayonet knife, 272 mm overall length	
70-7150	2 mm tip
70-7155	1 mm tip
Neurosurgical retraction arm	
70-7190	to hold the rotative disk and the vertibroscope



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