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ky|spine

Balloon Kyphoplasty

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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, designs and accessories are subject to change without any notice or obligation on behalf of the manufacturer.

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Indications | Design | Instrumentation Set

Indications

- Primary and secondary osteoporosis
- Fracture or collapse of vertebral bodies
- Trauma and tumor diseases

Design

The percutaneous ky|spine balloon kyphoplasty system allows for a minimally invasive treatment of thoracic or lumbar vertebral compression fractures. Short procedures with low complication rate, usually performed on an outpatient basis, lead to an immediate pain relief and a substantial improvement of mobility and stability of the spine.
The comprehensive set supports mono-, as well as multisegmental approaches and its optimized design ensures a notiably simplified positioning.

Instrumentation Set

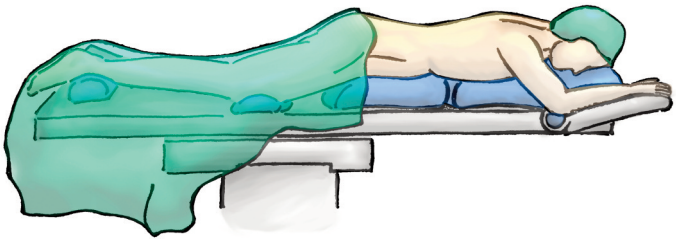
The entirely single-use and sterile packed set contains all neccessary instrumentation, including the inflation device. A special pump allows for a measured application of pressure while controlling the volume of the balloon. Various balloon catheters in lengths ranging from 10 to 22 mm allow for individual compatibility.

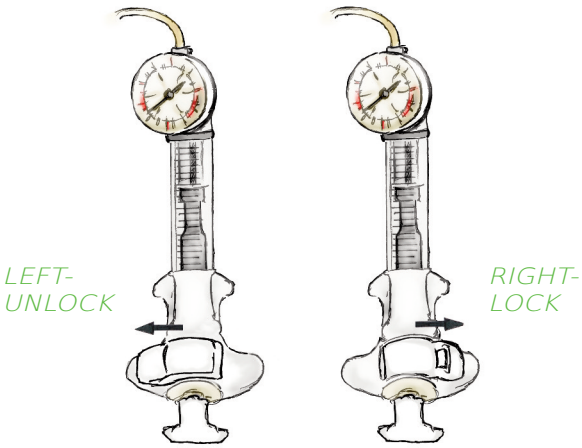
ONE | Patient Positioning and Access

Position the patient in a prone position on an operating table. Use lumbar support to avoid intraoperati ve bleeding caused by abdominal compression.
Locate the correct level under x-ray radiation (an x-ray c-arm is recommended) and perform a median incision over the concerned segment. The incision should be made carefully to avoid any subcutaneous damage.

Note

| After dissection, the musculus erector spinae may be separated laterally to obtain the required exposure of the vertebrae and their facet joints.



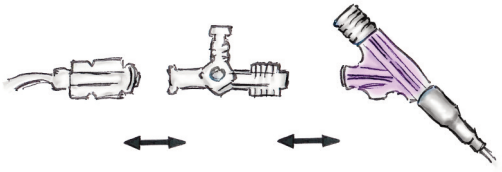


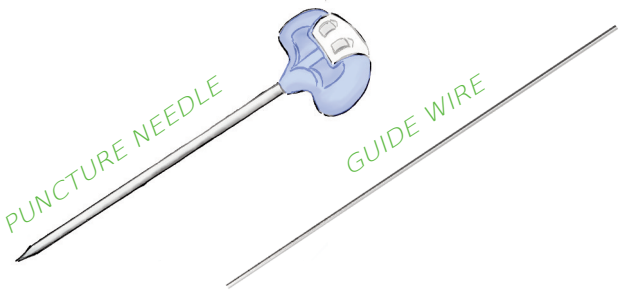
TWO | Preparation of the Balloon Expander

Push the locking lever on the balloon expander's handle to the right to move the spindle stepwise forwards. Turn it to the left to move the spindle backwards and forwards infinitely variable.
Afterwards pull contrast media via the 3 way adapter into the cylinder of the expander. Remove the surplus air in the expander or the hose by turning the spindle. Make sure the pos-tion of the balloon expander is upwards vertically.

THREE | Connect the Balloon Expander with the Balloon Catheter

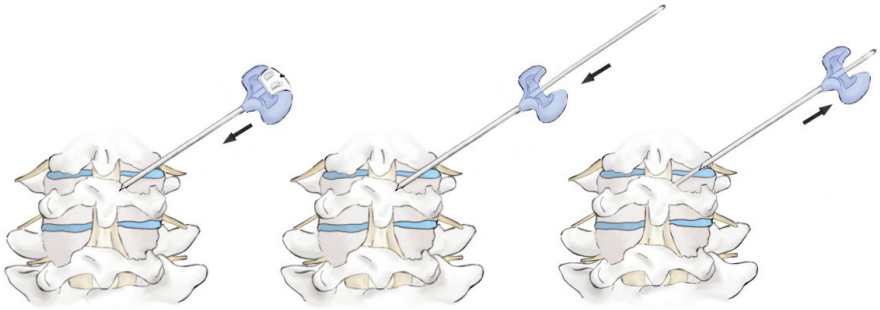
Now, the hose of the Balloon Expander needs to be connected with the Balloon Catheter. For easier handling use the 3 way adapter and / or the ventil. Make sure, the balloon is completely deflated and vented before the dilation starts.

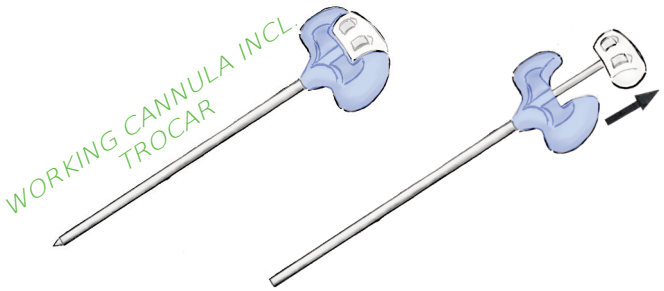




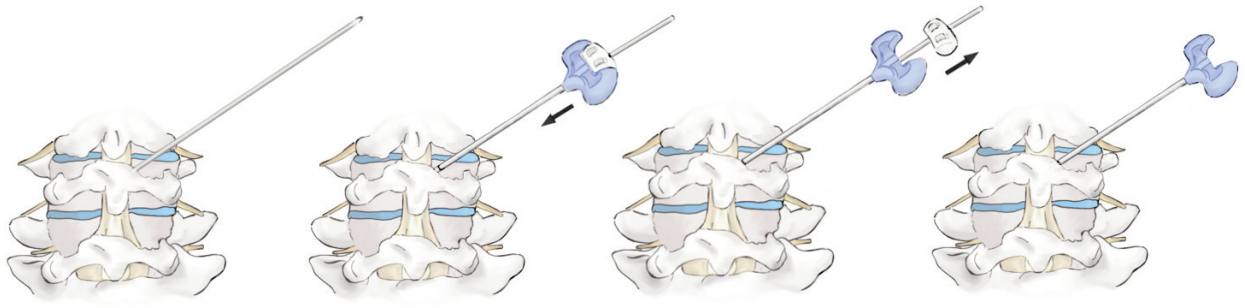
FOUR | The transpedicular Access

By the use of a x-ray c-arm insert the cannulated bone puncture needle transpediculary into the vertebral body. After the punction remove the punction needle and insert the guide wire through the cannula. Then exchange them with the working cannula and the working trocar.





Insert the working cannula and the working trocar through the guide wire. The cannula used before needs to be removed. The trocar stays. The access will be repeated on the opposite sided pedicle.

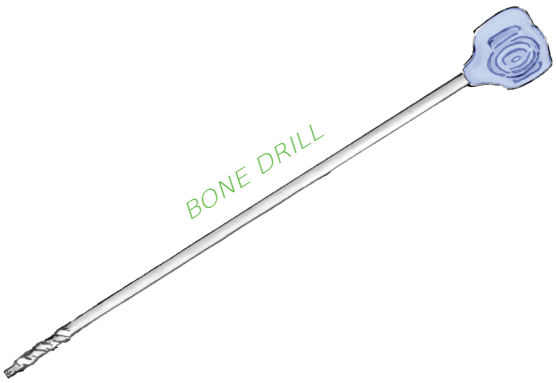


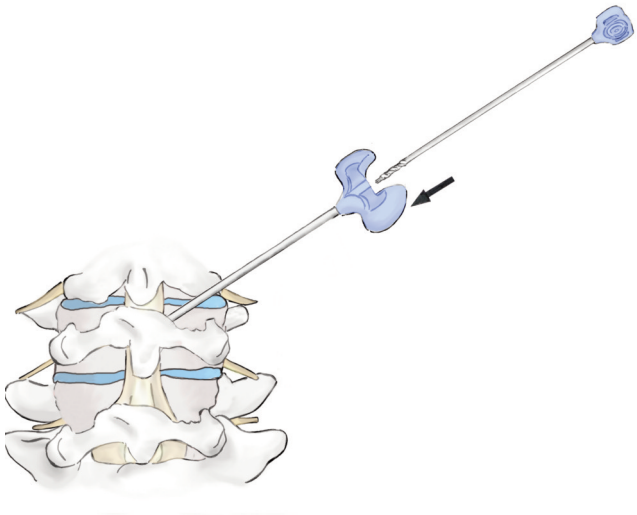
FIVE | Preparation of the Vertebral Body

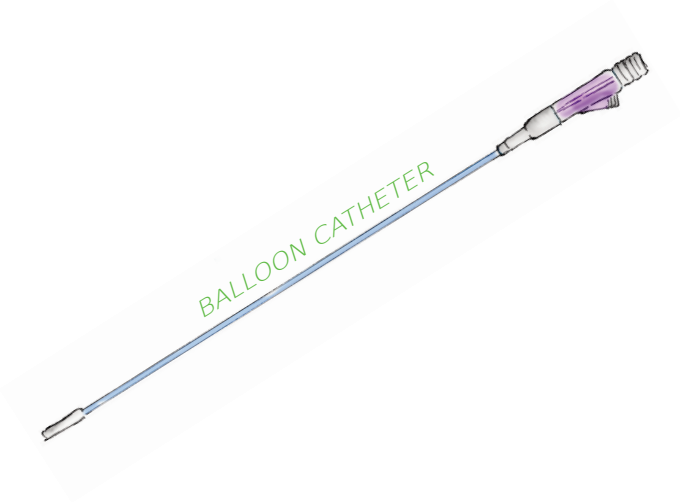
Insert the bone drill through the trocar, whereby there will be created automatically an open access for the usage of the Balloon Catheter in the vertebral body.

Note

| Check the procedure with an x-ray c-arm and make sure the lumen of the trocar is free of particles and bone fragments.







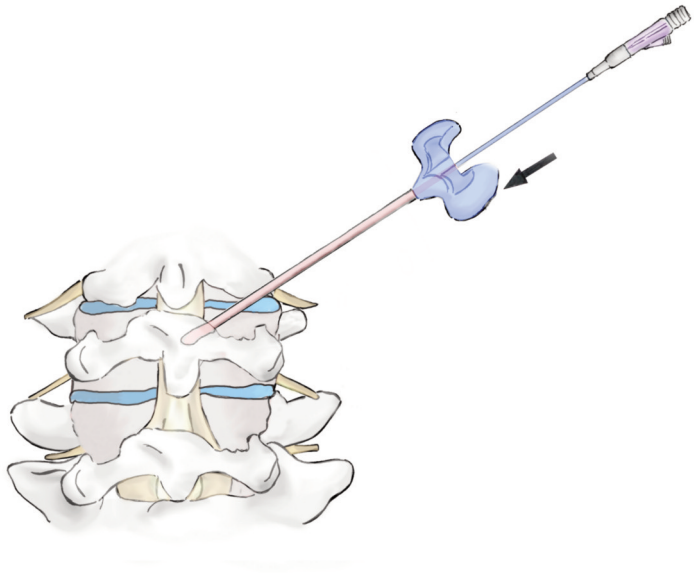
SIX | Insertion of the Balloon Catheter

The Balloon Catheter is inserted through the working cannula into the vertebral body. Stretch the balloon by turning the spindle at the handle under continuous control with the x-ray c-arm.

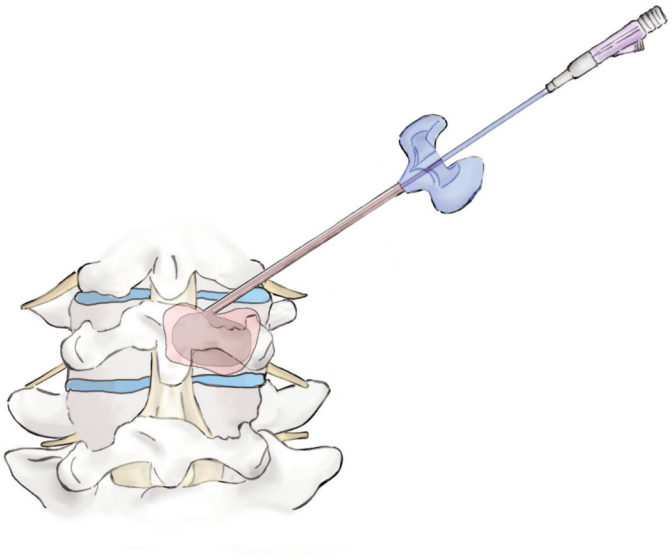
The balloon can be delated to a maximum of 30 Bar (440 PSI).
Afterwards remove the Balloon. The Trocar stays.

Note

When having a bilateral access, dilating both Balloon Catheters at the same time is recommended.



BALLOON CATHETER BEFORE DILATION



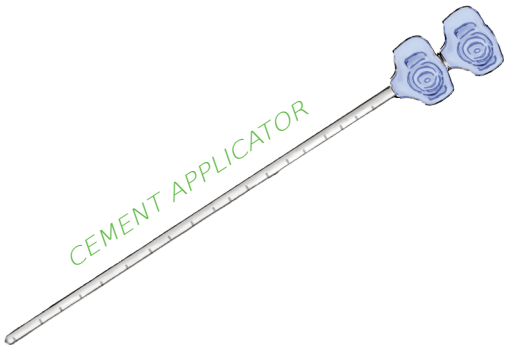
BALLOON CATHETER AFTER DILATION WITH A MAXIMUM OF 30 BAR (440 PSI)

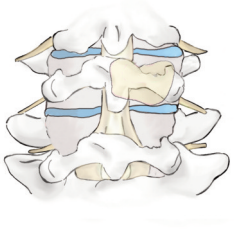
SEVEN | Insertion of the Cement

Initially, mix the powder and the fluid of the used cement *[cement+70-7989ZM]*. Wait until the bone cement has the appropiate viscosity for the application.
Fill the cement applicator with the ready-to-use cement. Insert the cement applicator through the trocar and applicate the bone cement with the bolster of the cement applicator.
Afterwards, remove the cement applicator and the working trocar. The procedure needs to be repeated until the vertebral body has reached the desired filling.

Note

| For the right viscosity please note the instruction of the cement's manufacturer !
| The application of the cement needs to be done by realtime-control with a x-ray c-arm.





EIGHT | Wound Closure

Small incisions in the skin merely has to be closed by a skin suture or plaster.

NINE | Postoperative Care

After a kyphoplasty a long-term bed rest or similar is not necessary.
Usually the patient can stand up and move immediately without pain.
Therefore the hospitalization of a patient after a kyphoplasty is limited only to a few days.

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Balloon Kyphoplasty Sets

2 x Balloon expander
70-7986

2 x Balloon catheter
70-7985 / 70-7985-22

2 x Guide wire
70-7979BL

2 x Bone puncture needle
70-7981

1 x Bone drill
70-7983

6 x Cement applicator
70-7987

2 x Working cannula
70-7978

Product code	Product description
Set *(contains s.a.)*	
70-7991-16	Double balloon set, 16 mm, without cement
70-7991-22	Double balloon set, 22 mm, without cement

70-7998SET

Product code	Product description
70-7989	Teknimed (double pack)
70-7990	Teknimed Spine (single pack)
70-7998	Minimix LV cement mixer
70-7998SET	Minimix LV cement mixer with 2 syringes
70-7999	Syringe (20 ml)

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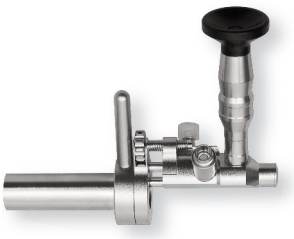
Supplementary Equipment

Complementary to our ky|spine products 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



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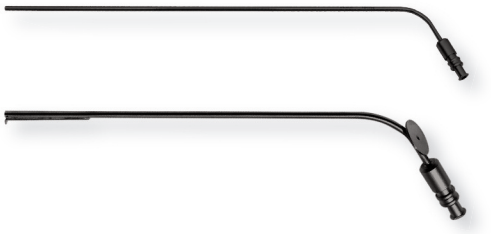
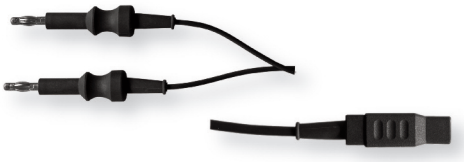
Suction tube, 272 mm overall length	
70-7110	without spatula tip
70-7111	with spatula tip
Bipolar forceps, 1.2 mm jaw, bayonet, 280 mm overall length	
70-7115	straight
70-7120	angled
Bipolar cable	
70-7130	
Nerve manipulator, 90° angled - knurled handle	
70-7135	1 mm tip, 272 overall length
70-7142	3 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





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Supplementary Equipment

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

Notes

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