joimax®
Endoscopic Spine Experts

MultiZYTE® *Sacroiliac*

Product Usage Guide

Step-by-Step description of the endoscopic
pain treatment of the sacroiliac joint syndome (SIJS)

Acknowledgments

The image and documentation materials used in this surgical technique are compiled from various surgeries performed by Dr. Richard Ibrahim, Prim. Dr. Eugen Ladner, and Dr. Jörg Fischer. Our special thanks and appreciation go to them.

Dr. Richard Ibrahim

Prim. Dr. Eugen Ladner

Dr. Jörg Fischer

Endoscopic pain treatment of SIJ arthropathy/ sacroiliac joint syndrome

Dorsal pain is an enormous medical challenge, for the patient as well as for the attending physician and for society.[1] It is among the most common reasons for seeing the family doctor. According to estimates, up to 85% of all people suffer from dorsal pain at least once in their lives.[2]

During the first third of the 20th century, the sacroiliac joint (SIJ) was considered the main cause of dorsal pain in the lumbosacral area, being described as the source of local and emanating pain as early as 1905.[3,4,5,6] Since disc herniation moved into the focus of attention as the cause of dorsal pain in 1934[7], it has almost completely ousted appreciation of SIJ pathologies. In consequence, the SIJ as a cause of dorsal pain was hardly noticed for a long time. Only in recent years has the clinical significance of the sacroiliac joint been recognized again.

The prevalence of SIJ Syndrome (SIJS) in diagnosed dorsal pain is 15 to 30%.[8] After previous lumbar surgery, the prevalence may be much higher, especially in cases of lumbar or lumbosacral fusion. In patients with prior lumbosacral fusion, the prevalence of SIJ-related pain is 43%, making it one of the most common causes of dorsal pain.[9]

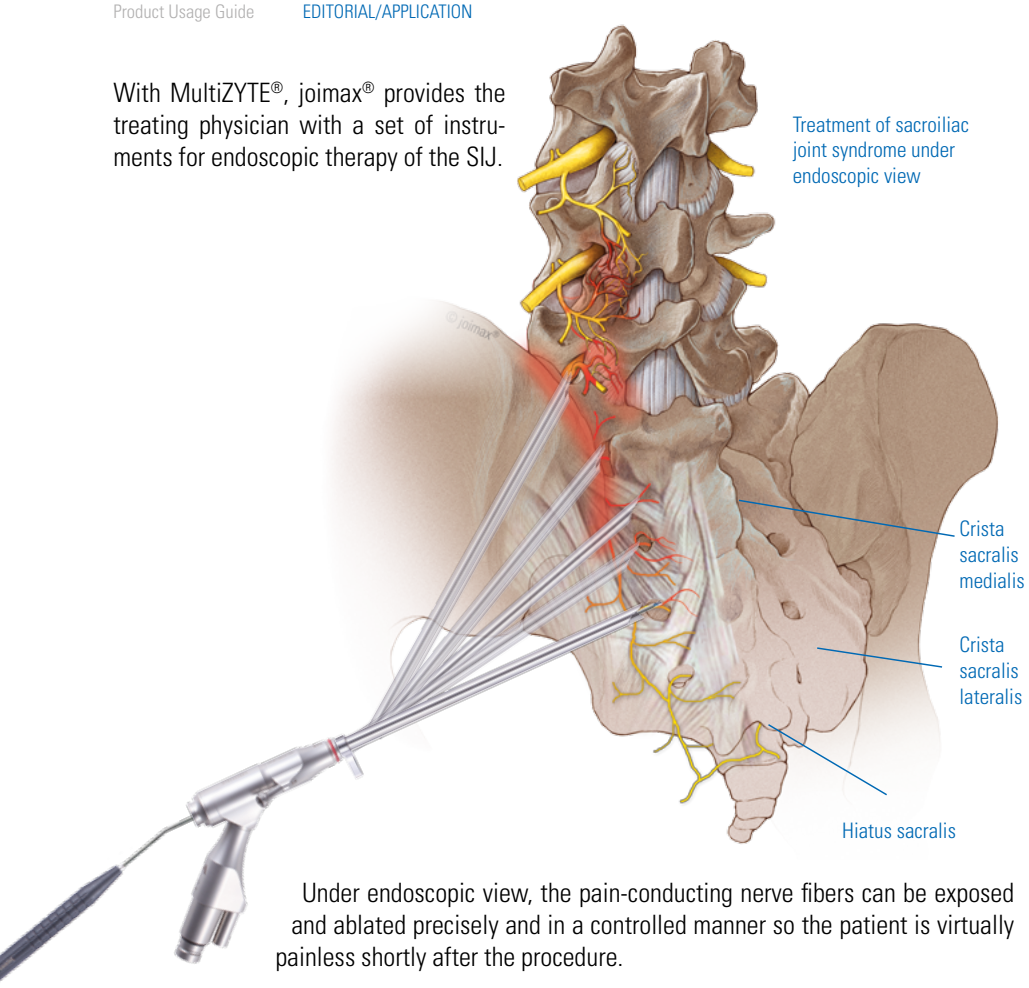
In a further study, the reason for this effect was found: The incidence of degenerative changes in the sacroiliac joint was significantly higher there after lumbar or lumbosacral fusion than it was in the control group, namely 75% vs. 38.2%.[10] This alarmingly high figure clearly shows the extent to which fusions of spinal segments affect adjacent segments due to reduced mobility and altered transmission of force.

SIJ syndrome as a comprehensive term for all pain-triggering pathological changes in the SIJ and should therefore be considered as a possible differential diagnosis in cases of dorsal pain[11], especially in patients with previous lumbar or lumbosacral fusion.

Typically, the sacroiliac joint syndrome manifests as unilateral or bilateral lumbosacral dorsal pain that can be enormously intensified during certain movements, as well as by prolonged lying down, and that may also emanate into the buttocks or thighs. On average, 45% of the cases concern the dextral and 35% of the cases the sinistral SIJ. A bilateral symptomatology can be detected in 20% of the cases examined.[12]

By combination of several pain provocation tests, SIJ-related dorsal pain can be clinically diagnosed: The combination of at least three tests results in a sensitivity of 85% to 94% and a specificity of 78% to 79%.[13,14] Imaging methods such as radiography, CT and MRI can be used as further options. However, as a clear cause of pain, the SIJ can be identified only with the aid of a diagnostic block.

With MultiZYTE®, joimax® provides the treating physician with a set of instruments for endoscopic therapy of the SIJ.



Under endoscopic view, the pain-conducting nerve fibers can be exposed and ablated precisely and in a controlled manner so the patient is virtually painless shortly after the procedure.

Depending on the indication, the joint capsule can also be treated during the same procedure. Here the joint is punctured or irrigated, or overlapping tissue growth is removed, by means of various instruments.

Application

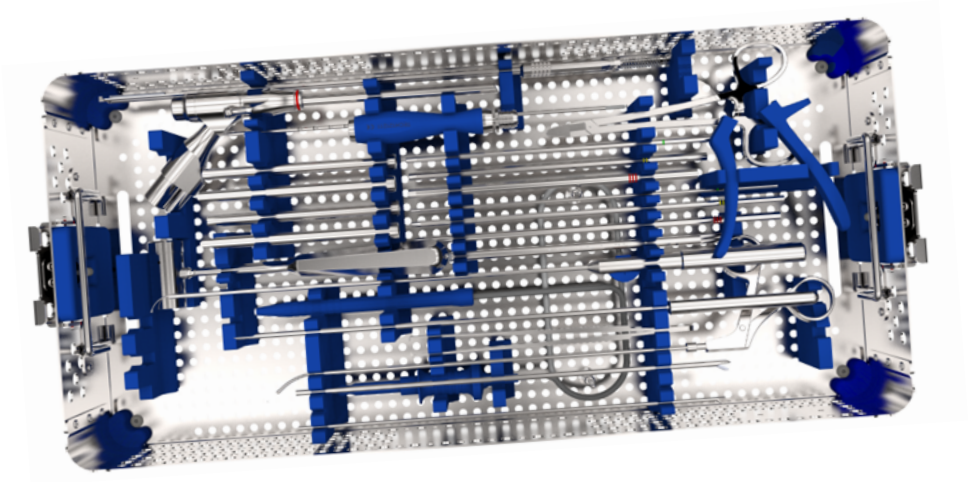
Being an endoscopic treatment, joimax® MultiZYTE® Sacroiliac can be used for targeted pain therapy in various pathologies of the SIJ. Beyond this, joimax® MultiZYTE Sacroiliac can be used for puncture and irrigation of the joint and for removal of tissue.

Selected indication

- Chronic pain in the lower back
- Painful degenerative changes of the sacroiliac joint, e.g. SIJ osteoarthritis
- Postoperative complaints after lumbar surgery
- Hypermobility due to loosening of the ligament apparatus
- SIJ trauma
- Inflamation of SIJ
- Static overload syndrome

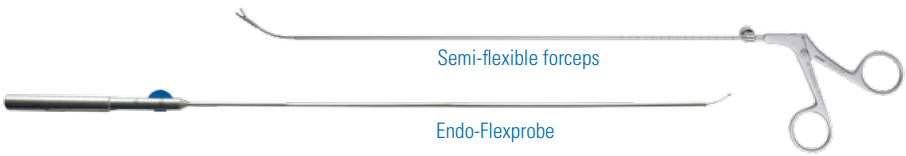
Advantages of the treatment method

- Long-term therapy success through endoscopically controlled procedures, confirmed by first study data[15]
- Effective, targeted treatment using radiofrequency
- Small incision, therefore almost no scar tissue
- Preservation of the mobility of the sacroiliac joint
- Minimally invasive surgery
- Short regeneration time
- Can be performed under local anethesia
- Treatments of multiple levels possible through one incision



MultiZYTE® Instrument Set

The MultiZYTE® instrument set includes instruments designed for safe minimally invasive access and endoscopic denervation. In addition, the set includes a variety of tools for removing tissue and preparing the nerve fibers, such as grasping and cutting forceps as well as Endo-Kerrisons.

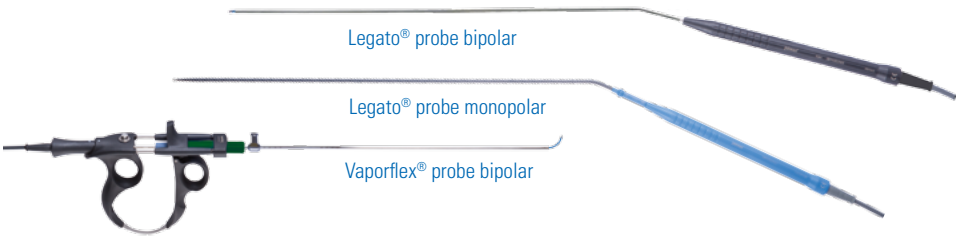


REF	Designation
MUSFV	MultiZYTE® Instrument set with container, without laminoscope
LS6342125C	Full HD Laminoscope, Combo*
LS6342125O	Full HD Laminoscope, Ocular*

* Working length 125 mm, 6.3 mm OD, working channel with an ID 3.7 mm, optical angle 30°, 1 suction and 1 rinsing channel with 1.5 mm diameter each.

Disposables

JMSN18GW11	Needle 18G 11 cm + guidewire 30 cm, pack of 10
JMPP27025	Legato® probe monopolar ball-tip, sterile, disposable, pack of 5
JBPP27025	Legato® probe bipolar ball-tip, sterile, disposable, pack of 5
JVP27525S	Vaporflex® probe 275, bipolar, sterile, disposable, pack of 5



Handpieces and Handles

JMPH352504	Legato® handpiece, monopolar, cable for Endovapor®2
JBPH352506	Legato® handpiece, bipolar, cable for Endovapor®2
JVH27527S	Vaporflex® set 275, handle and shaft
JVC35020	Vaporflex® cable with plug for Endovapor®2
JVK2-275	Vaporflex® KIT2 for Endovapor®2 incl. handpiece, shaft, cable, spare sealing rings and sterilization tray with plug

Other cables with different plugs upon request.

RF/HF generator

JEVS0201	joimax® Endovapor®2

STEP 1

Preparation

The following instruments and components are required for this procedure:

- MultiZYTE® instrument set
- Laminoscope combo or eyepiece
- Endoscopic equipment, e.g. joimax® Camsource®, Vitegra®, Versicon® pump
- Endovapor® 2 RF/HF generator for joimax® probes
- Radiofrequency probe (Legato® monopolar and bipolar probes or Vaporflex® bipolar probe)
- Patient draping, e.g. joimax® patient insulation drape
- Marking pen (e.g. from the joimax® access set TDAK0020)
- joimax® needle-wire set or joimax® access set TDAK0020
- Tubing set for irrigation pump, rinsing fluid, camera cable cover
- Optional in case of local anesthesia: needles for local anesthesia, local anesthetic
- Optional in case of discography: X-ray contrast agent

Diagnostics

By combining several pain provocation tests, SIJ-related dorsal pain can be clinically diagnosed. In a further step, imaging methods such as X-ray, CT and MRI can be used. As a clear cause of pain, however, the SIJ can be determined only by means of a diagnostic block.

Note:
In order to obtain a better X-ray image of the sacral region, the patient is recommended to purge prior to the procedure, or to dispense with foodstuffs forming intestinal gas.

STEP 2

Positioning/Anesthesia

The procedure can be performed in analgosedation or general anesthesia without relaxation. For further information, please see the joimax® brochure "Anesthesia Options".

Placement of the patient

Prone position

The patient lies in prone position on a radiolucent table. If desired, a pillow can be pushed under the abdomen for convenient placement. The disinfection and sterile draping of the patient's back follow. Using the image converter, the lumbar segments L4 and L5 to be treated, as well as the sacral foramina S1 to S3, are imaged in AP view.

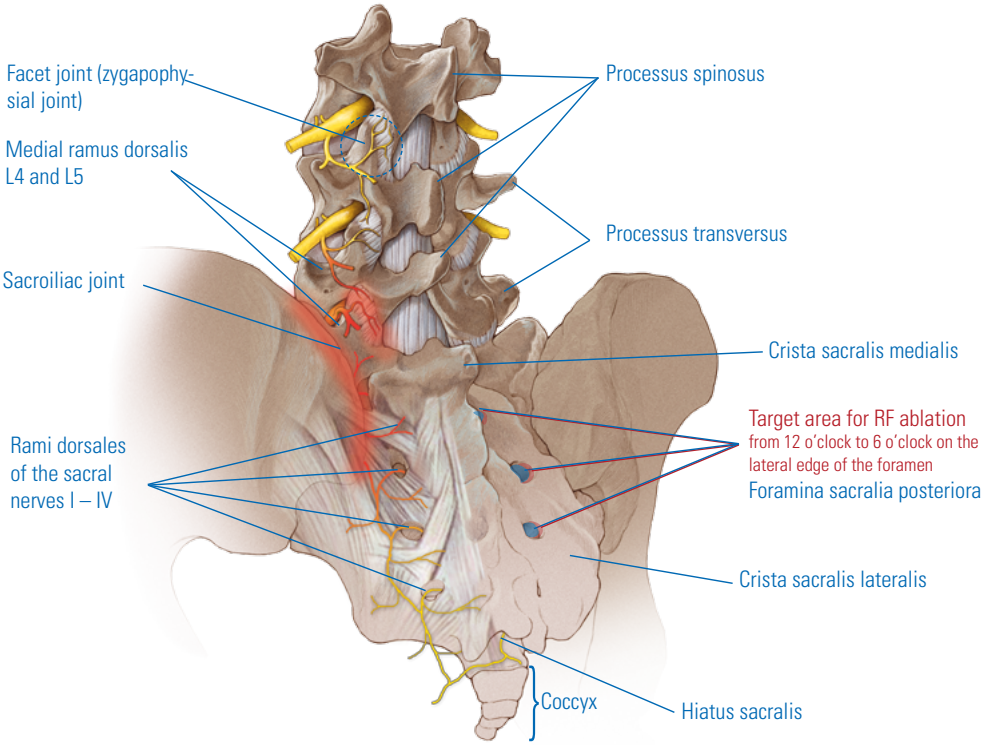
AP radiography L4 to S3

In this case, it may be helpful for the endoscopic ablation of the ramus dorsalis medialis of L4 and L5 to first image the lumbar spine centrally, and to image the sacrum for the subsequent treatment S1 to S3.

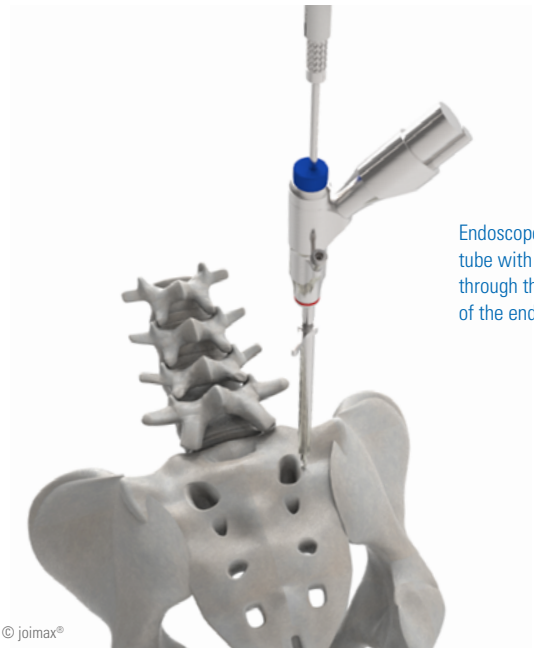
The positioning is optimal for the lumbar area when the spinal processes are imaged centered between the pedicles in the AP radiography.
Despite exact positioning, slightly oblique imaging may also be necessary. As can be seen in the X-ray image, the facet joint or the SIJ gap, respectively, should also be visible.

Patient in prone position

Anatomy and target structures



Target areas



Endoscope through working tube with Endo-Kerrison through the working channel of the endoscope

STEP 3

Access marking

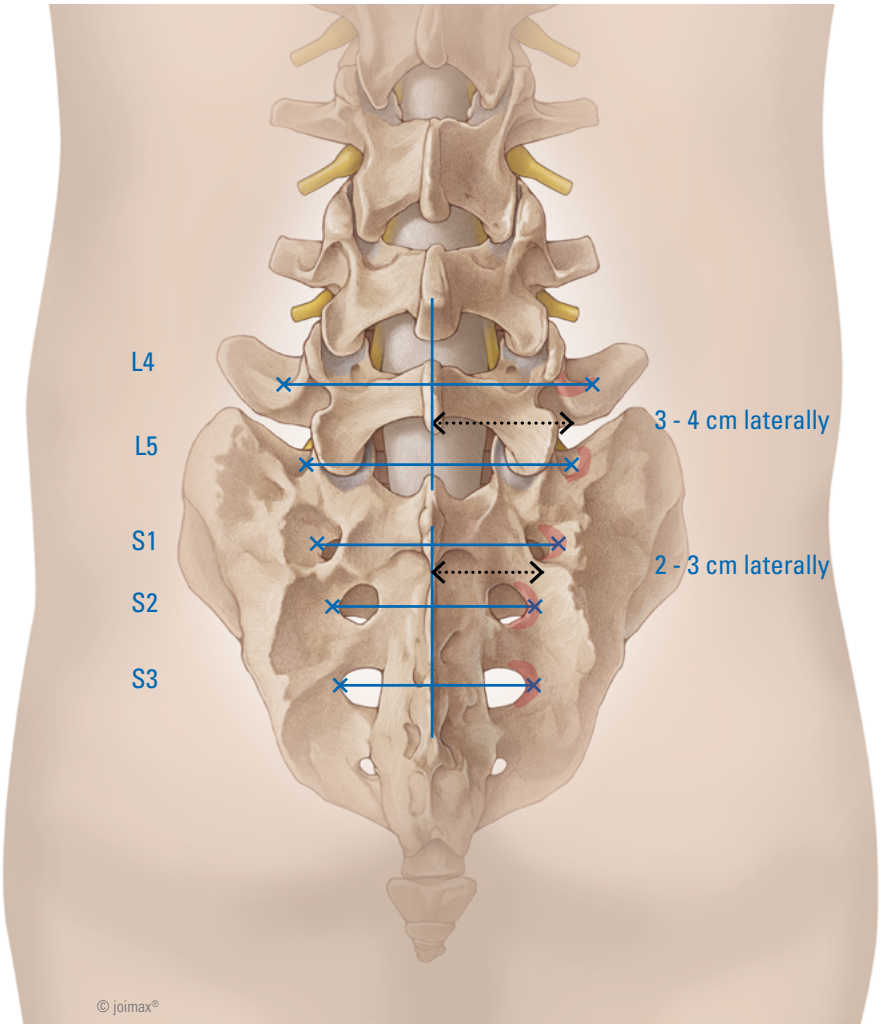
Markings on the skin can facilitate the positioning of the needles for access and support correct placement. It is useful to mark the spinal processes, the base of the transverse processes (processus transversi), the crista sacralis mediana, and the lateral margin of the sacral foramina.

L4 and L5 Approximately 3 – 4 cm laterally to the spinal process, parallel to the line formed by the spinal processes.

Target point:
- L4: Base of the processus transversus L5
- L5: Base of the processus articularis superior S1

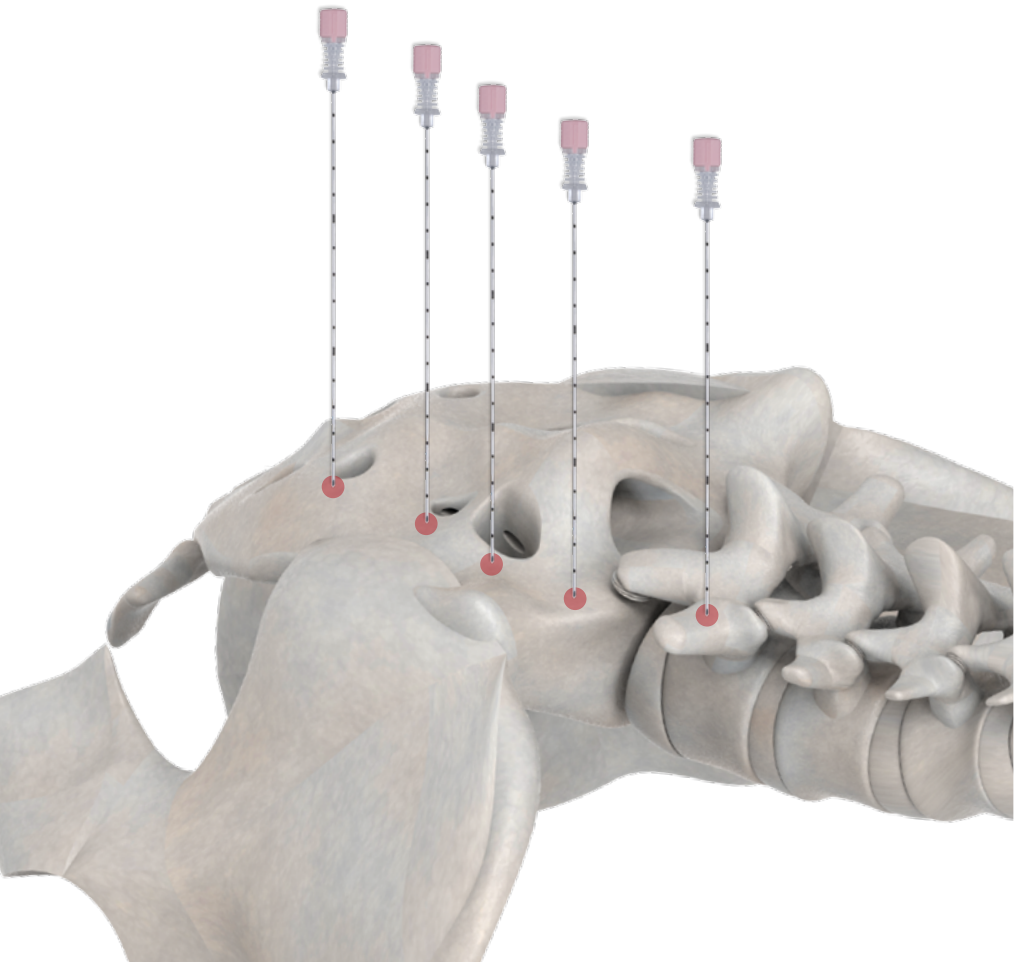
S1 – S3 About 2 – 3 cm laterally to the crista sacralis medialis.

Target point:
- About 5 mm laterally to the lateral edge of the sacral foramina S1 – S3.



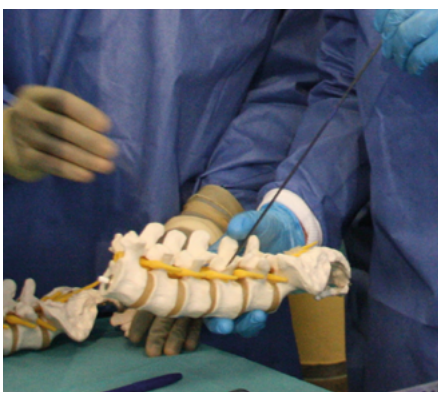
STEP 4

Access options



Note on access:
Basically, an individual access should be provided for each target point of the treatment.

Although it is possible to reach several target points via a single access, it has proved useful to provide a separate access point for each treatment point.



Access planning

Various options are available for access:

Option 1: Access with 18G needle + guidewire (joimax® needle wire set)

18G needle

Guidewire

Guiding rod, marked green, yellow, red

Guiding tube, marked green, yellow, red

Option 2: Access with guiding rod

18G needle

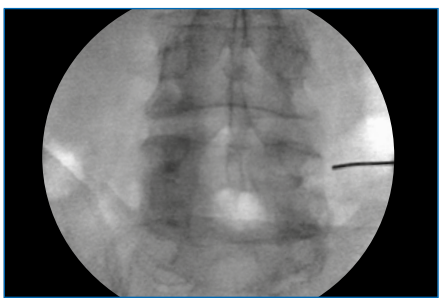
Guidewire

Double cannulated guiding rod: can be used instead of guiding rod and guiding tube

STEP 5A

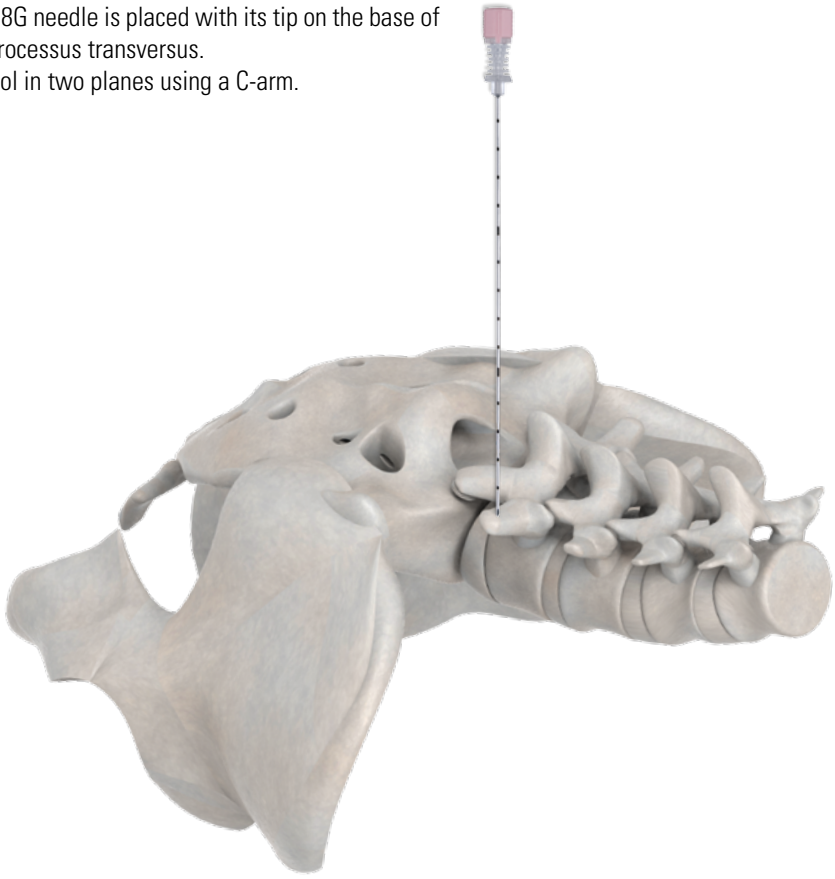
Access L4/L5

In the following, access option 1, with needle and guidewire, is described step by step in more detail.



Introduction needle

The 18G needle is placed with its tip on the base of the processus transversus.
Control in two planes using a C-arm.



The stylet is pulled out, and a guidewire is introduced. The needle is then removed, and the wire remains in position. Now the skin is incised approx. 1 cm at the location of the guidewire, in order to be able to place the subsequent instruments.

Stepwise dilatation of the soft tissue by means of the Seldinger technique using the joimax® dilatators in ascending size according to the traffic-light principle: Green, yellow, red.

Guiding rod, GRC241025, marked green

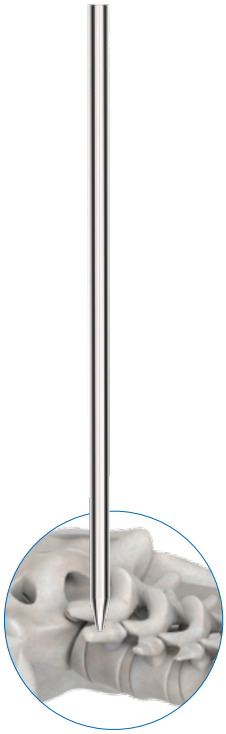
Guiding tube GTC202838, marked green

Guiding tube GTC194353, marked yellow,

Guiding tube GTC185363, marked red

First, carefully slide the green-marked guiding rod forward over the guidewire until you feel the base of the processus transversus. Check the position using the C-arm. The green-marked guiding tube can then be advanced over the placed guiding rod.

Proceed accordingly with the guiding tubes marked yellow and red.



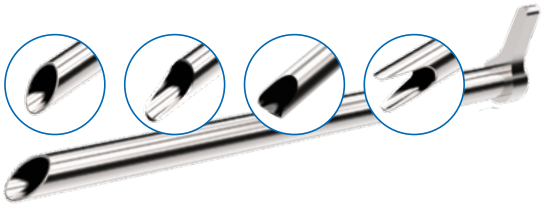
A further possibility is to dilate the tissue in a single step with the double cannulated guiding rod GRD196315. The working tube can be directly inserted via the latter.

☝ **Caution:**
Only for experienced users.

The selected working tube is then advanced via the red-marked guiding tube, and its correct position is checked and documented using the C-arm.

Now the guiding tubes can be removed, and the endoscope carefully inserted into the working tube.

Various working tubes are available to allow optimal placement of the distal opening on the target field.



STEP 6A

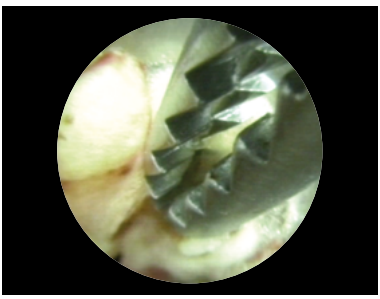
RF-Treatment L4/L51

The Endo-Flexprobe is a good orientation tool for the palpation of the individual tissue structures. This provides a good overview of the anatomy.

Endo-Flexprobe

Detail

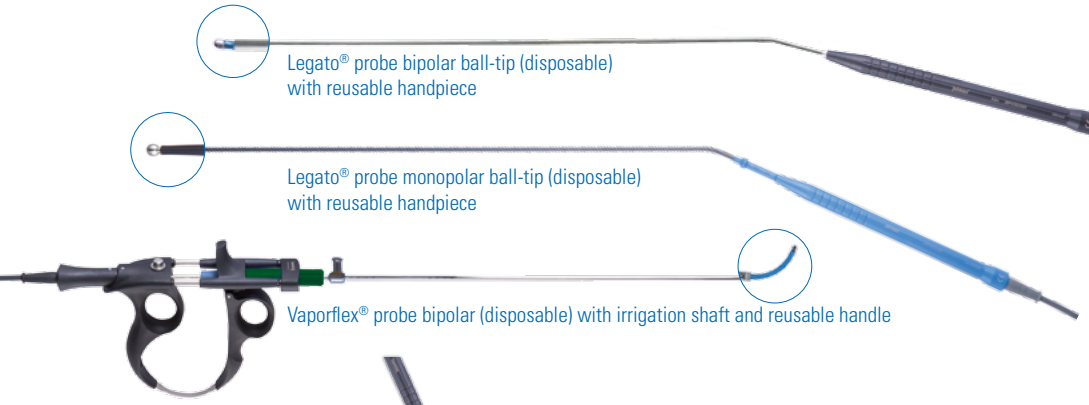
Under endoscopic view, tissue can now be ablated to visibly expose the ramus medialis dorsalis of the spinal nerve L4. Experience shows that it is advantageous to remove as little soft tissue as possible in order to avoid unnecessary bleeding.

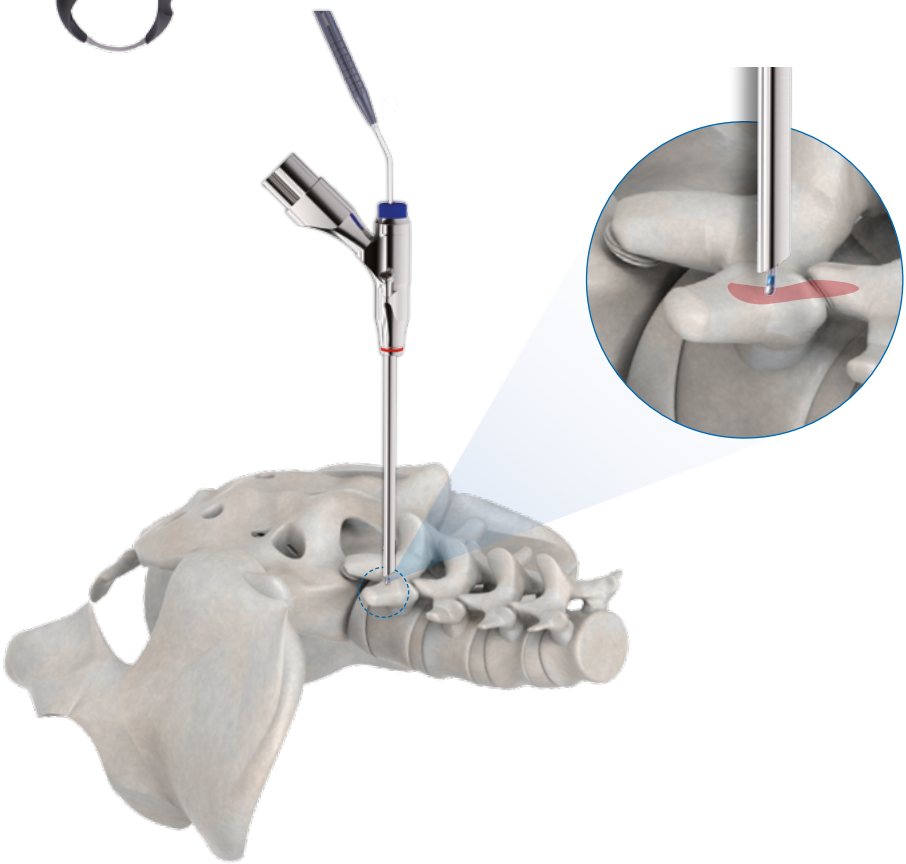


Medial exposure through the endoscope

Viewing direction of the endoscope: Medially in the direction of the facet joint

Using a radiofrequency probe such as the joimax® Legato® probe monopolar or bipolar or the Vaporflex® probe bipolar, the pain-conductive nerve fiber braid can now be ablated by moving the probe tip from the base of the transverse process along in the direction of the facet joint.





Then the previous steps are to be repeated accordingly for L5.
Here the target is the sulcus at the base of the SAP (processus articularis superior) S1.

Note

In case of a facet joint effusion, the facet joint can also be opened by means of partial removal of the joint capsule using forceps and punches and rinsed. This should be documented by imaging. The resected tissue can be sent in for histological examination.

STEP 5B

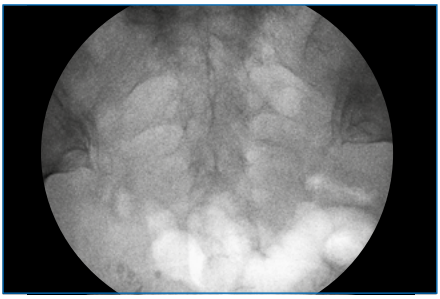
Access S1-S3

Following the treatment of L4 and L5, access is gained to the sacral foramen S1 to S3.

At this point, access option 1 with needle and guide wire, is described step by step in more detail. Alternatively, access via the double cannulated guide rod is possible here, too.

The 18G needle is placed at the lateral edge of the sacral foramen S1.

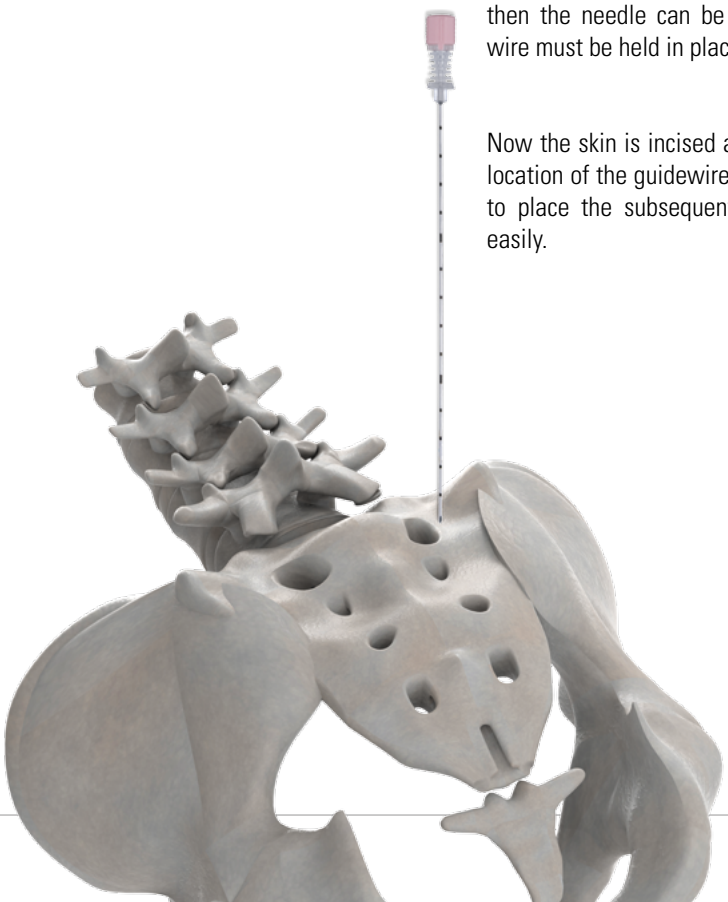
Control is carried out in two planes using a C-arm.



Needle introduction

A guidewire is inserted through the needle; then the needle can be removed. Here the wire must be held in place to avoid shifting.

Now the skin is incised approx. 8 mm at the location of the guidewire, in order to be able to place the subsequent instruments more easily.



Stepwise dilatation of the soft tissue using the joimax® dilators in ascending size according to the traffic-light principle: Green, yellow, red.

Guiding rod, GRC241025, marked green

Guiding tube GTC202838, marked green

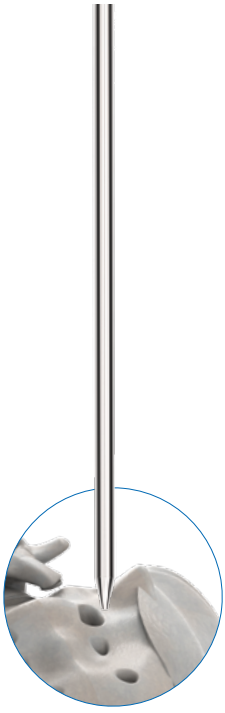
Guiding tube GTC194353, marked yellow,

Guiding tube GTC185363, marked red

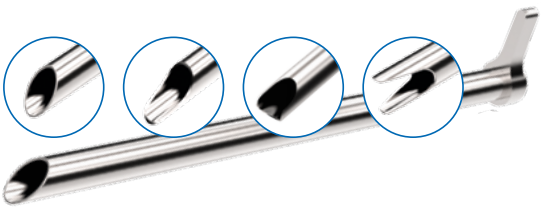
First, slide the green marked guiding rod onto the guidewire and carefully push the latter forward until you feel the massa lateralis of the sacral bone. Check the position using the C-arm. The green-marked guiding tube can then be advanced over the placed guiding rod. Proceed accordingly with the yellow- and red-marked guiding tubes.

A further possibility is to dilate the tissue in a single step with the double cannulated guiding rod GRD196315. The working tube can be directly introduced via the latter.

☝ **Caution:** Only for experienced users.



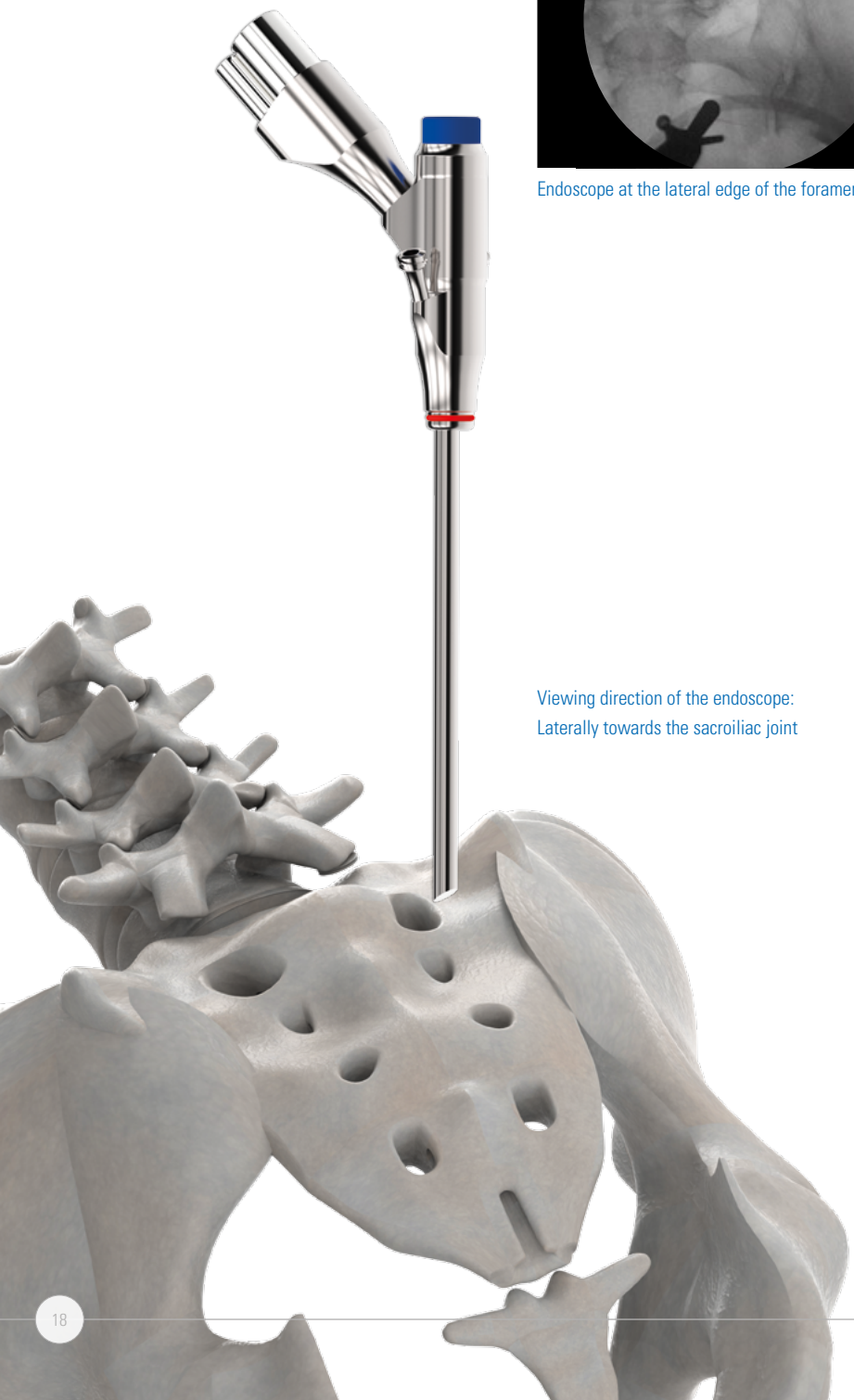
The selected working tube is then advanced via the red-marked guiding tube, and its correct position is checked by means of the C-arm.



There are various working tubes available.

Now the guiding tube can be removed, and the endoscope carefully inserted.

Endoscope at the lateral edge of the foramen

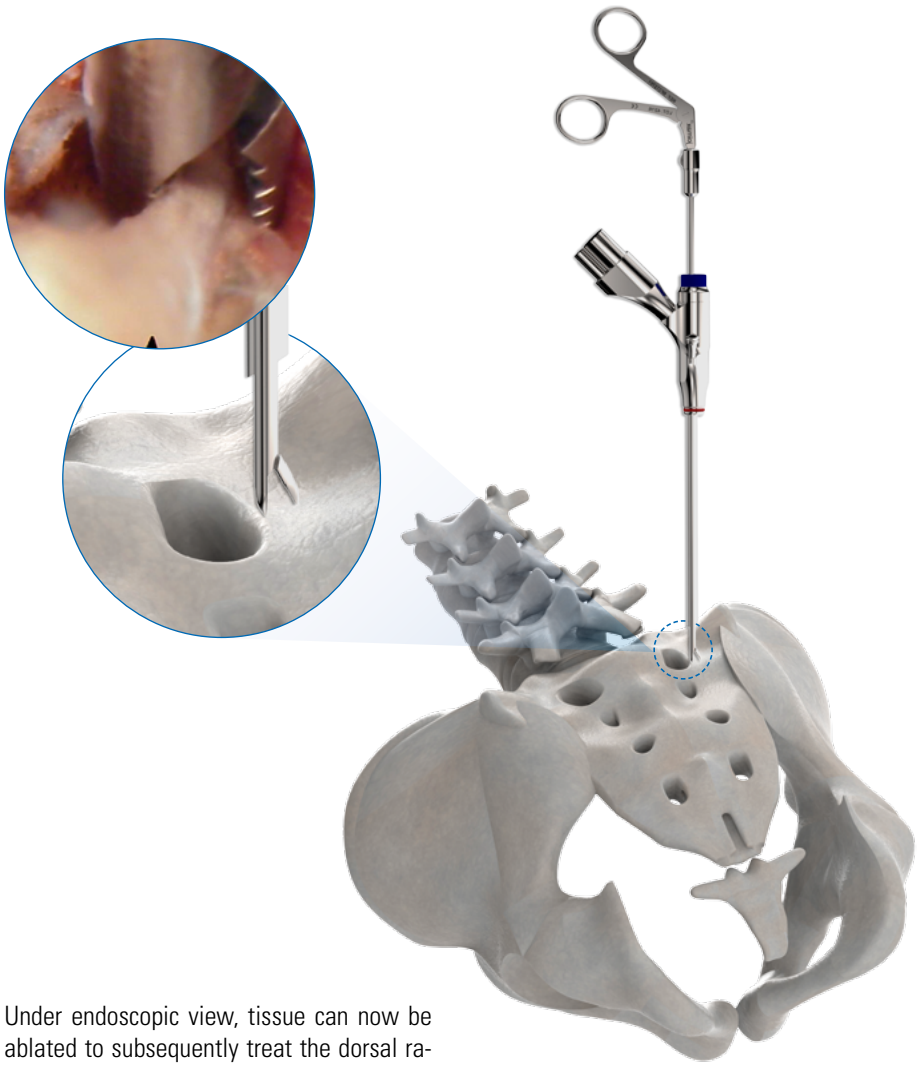


Viewing direction of the endoscope:
Laterally towards the sacroiliac joint

STEP 6B

RF-Treatment S1-S3

The Endo-Flexprobe is a good orientation tool for the palpation of the individual tissue structures. This provides a good overview of the anatomy.



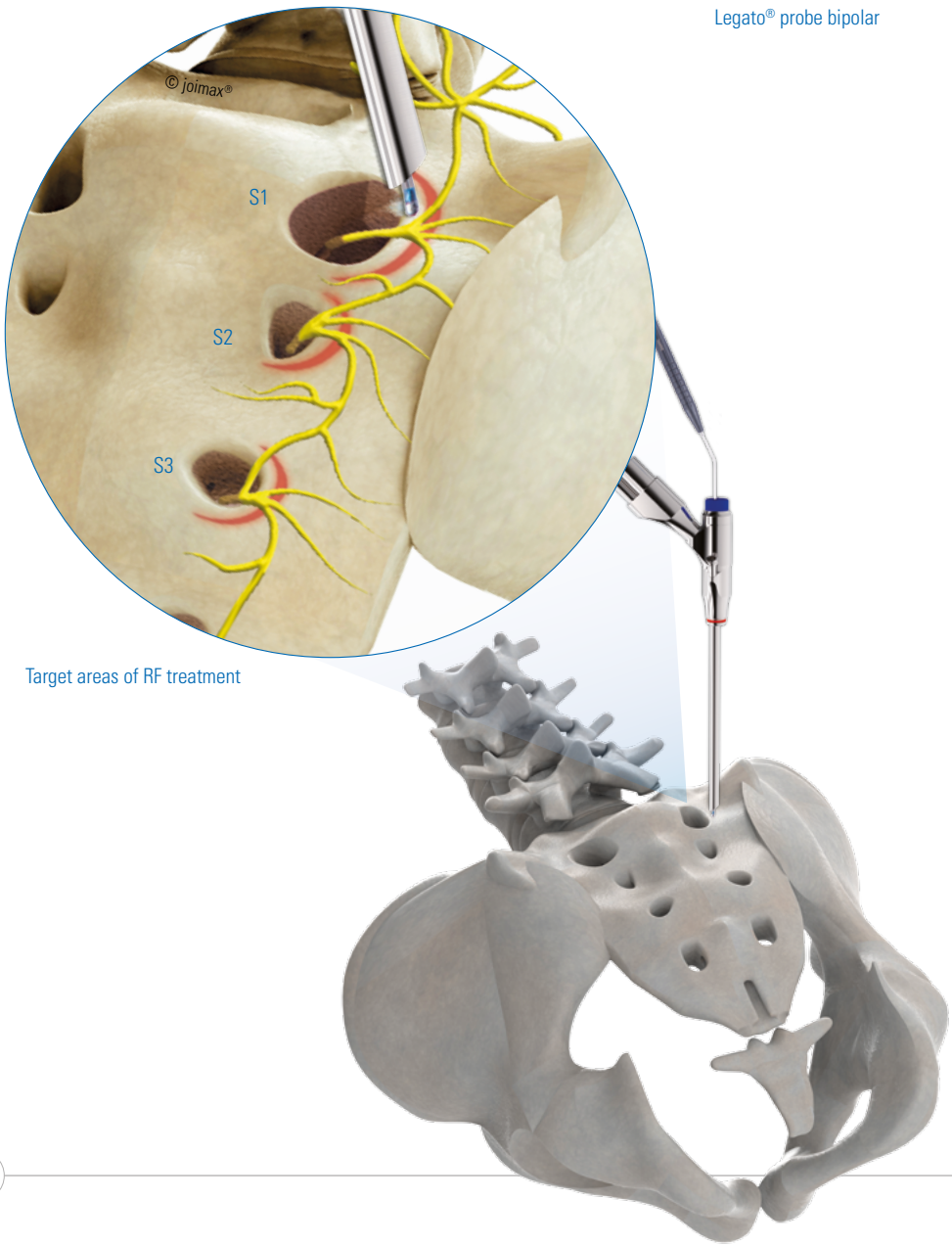
Under endoscopic view, tissue can now be ablated to subsequently treat the dorsal ramus of the sacral nerve S1 (nervus sacralis posterior S1) with the RF probe.

Using a radiofrequency probe such as the joimax® Legato® probe monopolar or bipolar or the Vaporflex® probe bipolar, the pain transmitting nerve fibers (rami dorsales of the nervi sacrales I – III) can now be treated. For this purpose, the tip of the probe is moved in a semi-circular fashion on the lateral edge of the sacral foramina S1 – S3: sacral foramina on the right-hand side in the area from 12 o'clock to 6 o'clock, sacral foramina on the left-hand side in the area from 6 o'clock to 12 o'clock.

Note

The exact course of the nerve fibers differs from patient to patient, but in most cases, the nerve fibers are located in the region of the lateral margin between 12 o'clock to 6 o'clock or 6 o'clock to 12 o'clock, respectively.[16]

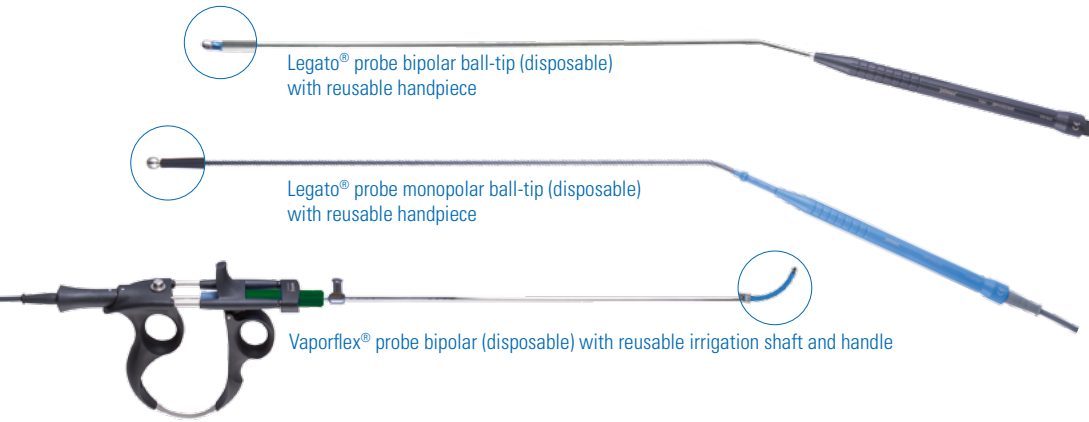
Legato® probe bipolar



Target areas of RF treatment

Repeat the previous steps for S2 and S3 correspondingly.

At the end of the treatment, the incisions are checked once more and closed with a skin suture.



Energy settings for joimax® RF/HF generators

Endovapor® 2, Endovapor® or SurgiMax™ Plus

Always start with a low energy setting and increase the energy output as required. If possible, check the temperature at the probe tip during the procedure.

Endovapor® 2: For many standard operations, device settings are pre-programmed and can be extended as required.
The Vaporflex® and Legato® RF probes are connected and used under the Spine Vap, Spine Coag and Rhizotomy programs.

RF/HF-Generator	Bipolar Hemo	Bipolar Turbo	Spine
joimax® Endovapor® /SurgiMax™ Plus	40	25	-
joimax® Endovapor® 2	30	-	30

Warnings and precautions

joimax® shall not be held responsible for any complications or risks that may arise from any of the following:

- Incorrect diagnosis
- Selection of too high or low energy settings of RF/HF generator
- Too long or too short activation times of the Legato® probes monopolar and bipolar or Vaporflex® probe bipolar
- Insufficient hygiene
- Improper treatment, e.g. placement of the patient before, during and after surgery

These products may be used only by a physician familiar with this application and according to the current medical standard. For this purpose, joimax® offers its CM3 Training Program with special workshops for each surgical method.

Please note that the relevant instructions for use for all products are to be read and understood.

Terms of warranty

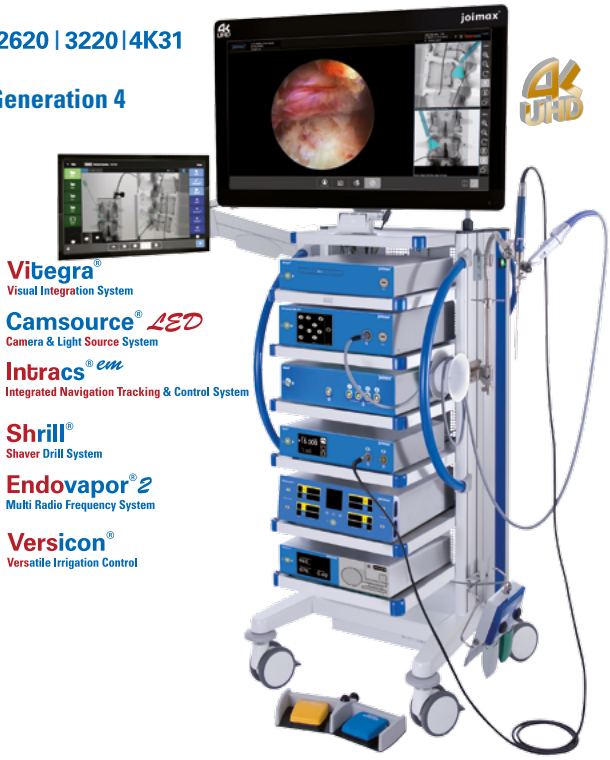
The terms of warranty are based on the general terms and conditions of joimax® and the warranty services indicated for each product.

Everything from a single source: high quality equipment for endoscopic procedures on the spine

JFMS 2620 | 3220 | 4K31

joimax® Endoscopy Tower | Generation 4

The expert solution for spinal surgery and neurosurgery. All devices are optimally matched and have been developed specifically for sensitive structures.



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OPMULTISACEN; TD_MULT_14_PI_010; Rev. 002; Sept. 2018