

Neurolyser XR® – Clinician Questions & Answers

What is the Neurolyser XR?

The Neurolyser XR is a non-invasive, X-ray-guided device for thermal ablation of neural tissue using a therapeutic ultrasound system.

The Neurolyser XR is designed to deliver clinical outcomes comparable to radiofrequency ablation (RFA), while eliminating the need for invasive procedures and extensive sterile preparation. This non-invasive approach reduces procedural discomfort and overall cost while streamlining workflow and improving clinic efficiency.



Is the Neurolyser XR commercially available?

The Neurolyser XR is authorized for commercial use in the USA, Europe, UK, and Canada for the treatment of facet-mediated chronic low back pain.

What conditions are treated with Neurolyser XR?

The Neurolyser XR is approved for the thermal ablation (neurolysis) of the medial branch nerve of the lumbar facet joint(s) (L1 to L5) as a treatment of chronic low back pain of at least 6 months duration with confirmed diagnosis of lumbar facet related chronic low back pain based on a positive response to lumbar branch block or results of the previous denervation.

What makes Neurolyser XR a non-invasive procedure?

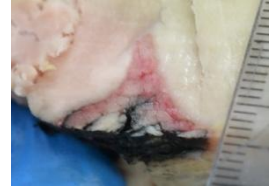
Neurolyser XR delivers therapeutic ultrasound energy through intact skin without probes, incisions, or any physical penetration into the body.

What is the mechanism of action?

The Neurolyser XR delivers focused acoustic energy to the desired location. A focal thermal lesion results in coagulative necrosis of the targeted nerve, interrupting nociceptive signal transmission from the joint. Surrounding tissues are spared due to the precise focal geometry and integrated safety controls.

What is the thermal lesion size and geometry of the Neurolyser XR?

The thermal lesion diameter on the bone tissue interface can reach up to 15 mm diameter or more and up to 10mm into the soft tissue, depending on the energy settings. The energy distribution spreads outward from the bone into the soft tissue in a shape often described as a 'Hershey's chocolate kiss,' with the base on the bone surface.



The temperature in the treatment area is above 80 degrees Celsius.

The lesion can be created on the bone tissue interface at any depth between 1 to 8 centimeters from the skin.

What are the technical and acoustic properties of the Neurolyser XR HIFU transducer?

The transducer is a 4-element annular array with a central aperture to allow clear visibility of the patient anatomy on the x-ray image when the device is in place. This transducer is rated to operate clinically in the range of acoustic powers between 10W and 40W and deliver up to 1000J in a single continuous wave sonication.

The acoustic intensities generated are high enough to produce a lesion when the focus intersects with a boney interface, but not high enough to produce a lesion in soft tissue in the absence of bone.

How does the Neurolyser XR compare to conventional RFA?

Key distinctions include:

- **Noninvasive vs invasive**
- **Acoustic energy vs radiofrequency energy**

Targeting is performed using a combination of X ray and computerized navigation, which may reduce radiation exposure Clinical intent and target anatomy are similar to lumbar RFA.

How does Neurolyser XR compare to RFA in terms of effectiveness?

Clinical and pre-clinical studies led by treating physicians have demonstrated safety and effectiveness of the Neurolyser XR. In all the studies conducted so far, there were zero severe or serious, procedure- or device-related adverse events. The single arm, 30 patient study¹ reported an 82.6% success rate in 6 months. A more recent blinded, double arm randomized, USA pivotal study² have shown a very strong statistical significance at 6 month post procedure of the Neurolyser arm compared to the control arm (sham).

What is the typical procedure time?

Total procedure time is typically approx. **20 minutes**, depending on the number of levels. Active energy delivery per lesion or sonication is **50 seconds**, preceded by a **20 second sensory test**.



Reduced setup and targeting steps may shorten room utilization compared to RFA.

How does Neurolyser XR reduce procedural complexity?

- No need for sterilization of the device or the room
- No need for nursing support during the procedure
- No lesion size titration or probe rotation
- No damage to soft tissue in the event of a mistargeting if the acoustic focus does not intersect bone

This results in a more standardized and reproducible workflow across operators.

Can a sonication be paused and resumed during treatment?

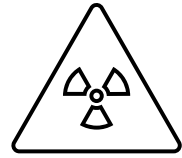
Yes. If a sonication is stopped partway through delivery, it can be resumed without requiring additional energy, provided that it is restarted within approximately 30 seconds. This allows flexibility during treatment while maintaining efficiency.

¹ Fluoroscopy-guided high-intensity focused ultrasound neurotomy of the lumbar zygapophyseal joints: a prospective, open-label study

² Submitted to publication

How does the Neurolyser system impact radiation exposure?

Targeting is performed using a combination of limited X-ray imaging and optical guidance, avoiding repeated fluoroscopic imaging for needle placement or repositioning.



This could reduce radiation exposure for both patients and staff and may lead to lower overall radiation exposure.

What anesthesia or sedation is required?

The procedure is performed with the patient awake.

In some patients, mild sedation may be required for pain control.

Real-time patient feedback must be maintained throughout treatment.

What pain or other sensations should be expected during treatment?

Patients may experience localized warmth, pressure, cramps, transient muscle activation, or even transient exacerbation of baseline pain during the final part of the energy delivery. Symptoms are resolved promptly once energy delivery stops.

What is the post-procedure recovery profile?

- Fast discharge
 - Quick recovery period
 - Minimal post-procedural pain and restrictions
 - Rapid return to baseline activity
 - No puncture-site care or wound management
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How fast is the pain reduction following the procedure?

The onset of analgesic effect may be immediate.

The overwhelming majority of the patients report symptomatic improved by the 2nd day post procedure.

Are there restrictions after the procedure?

There are typically no post-procedure restrictions. Patients may shower, resume normal activities, and continue medications the same day.

Who is an appropriate candidate?ⁱ

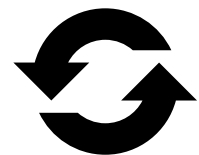
- Patients with painful lumbar spondyloarthropathy
 - Patient selection process and workup is identical to the one done before Lumbar RFA procedure (diagnostic blocks, previous RFA etc)
 - Note that spinal cord stimulators, pacemakers, DBS, or immunocompromising conditions may not necessarily be contra indicated (unlike RFA).
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What are the contraindications?

- Pregnant or breastfeeding
 - History of lumbosacral spine surgery
 - Metal hardware or foreign objects at lumbosacral spine
 - Extensive scarring at treatment area
 - Uncontrolled coagulopathy
 - Osteoporosis with absolute risk of spinal fracture at > 10% over 10 years
 - Rheumatologic disease-causing spine pain, currently receiving active treatment
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Can the procedure be repeated?

Yes, the procedure can be repeated similarly to RFA if pain recurs and clinical criteria are met.

**Is Neurolyser XR safe for patients with implanted devices?**

Yes. Provided that the implant is not in the beam path and targeted area.

What is the risk of infection?

There is no risk of infection as the skin is not breached and no foreign instruments are introduced into the body.



What is the overall clinical and economic benefit to a practice?

Neurolyser XR offers lower procedural costs through reduced staff requirements, cost related to sterilization and improved clinic throughput.

Is it possible to damage the spinal root during Neurolyser XR treatment?

While in theory it is possible to damage the spinal root if the acoustic focal spot intersects the opening of its bony canal, in practice it is very improbable to create due to the difference in depth and location between the targeted medial branch nerve and the exit of the spinal root bony canal.

Even if the acoustic focal spot intersects the opening of the bony canal, the incidence angle of the energy with the bone is very steep resulting in a significant reflection of the energy, making the probability of harm even lower.

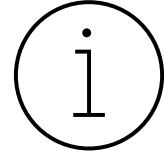
Is Neurolyser XR procedure covered?

It depends on the reimbursement system in each territory.

In the USA, because the Neurolyser XR procedure involves all the key elements of the descriptor language of CPT codes 64635 and 64636, these codes may be appropriate to report the procedure.

Other countries where Neurolyser XR procedures were reimbursed are Italy, Spain and Germany.

Where can I get more information?



1. More information on the Neurolyser XR is available at the FUSMobile website: www.fusmobile.com
2. News, press releases and social media posts are available here: <https://www.fusmobile.com/blog>
3. Peer reviewed publications on the device and technology are available here: <https://www.fusmobile.com/publications>
4. More information on focused ultrasound technology is available on the Focused Ultrasound Foundation: <https://www.fusfoundation.org>
5. FUSMobile Support line number: 610-NeuroXR (610-638-7697)

Summary

The Neurolyser XR provides a non-invasive alternative to lumbar RFA, with the potential advantages of reduced procedural complexity, shorter procedure time, and decreased radiation exposure, while maintaining comparable clinical results and outcomes.

This document is intended for clinician education and does not replace formal training or instructions for use.

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