Molina Clinical Policy
Percutaneous Image-Guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis
Policy No. 351

Last Approval: 12/10/2025
Next Review Due By: December 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Lumbar spinal stenosis (LSS) is the narrowing of the intraspinal canal, lateral recess, and/or neuroforamen. LSS is generally caused by degenerative changes of the spine and is a common cause of disability in people aged 60 years and older. Degenerative arthritis of the spine (spondylosis) is the most common cause of LSS, but it can be also caused by degenerative or acquired conditions ([1]Levin 2025). First-line treatment typically includes conservative methods such as pharmacotherapy (e.g., analgesic and anti-inflammatory drugs), physical therapy, and epidural steroid injections. Surgical treatment may be indicated in patients with severe pain, constant neurological symptoms, failure of conservative methods, or in the setting of progressive neurological decline. Surgical intervention aims to decompress the neural structures at the level of stenosis and correct any instability. Traditional surgical options for LSS include decompression alone or decompression with spinal fusion. Decompression may involve laminectomy, laminotomy, foraminectomy, or facetectomy in the affected vertebrae. When indicated, spinal fusion may be performed with or following decompression, particularly in cases of instability or deformity (e.g., spondylolisthesis, scoliosis, kyphosis). Open laminectomy (with or without spinal fusion) is the current standard of care for LSS. (Hayes 2025; [2]Levin 2025).

Percutaneous image-guided lumbar decompression (PILD), sometimes referred to as minimally invasive lumbar decompression (MILD), is a procedure performed to increase the dimensions of the spinal canal by debulking the hypertrophied ligamentum flavum and potentially small amounts of the lamina to achieve nerve or canal decompression. PILD is performed under x-ray guidance (e.g., fluoroscopic, CT), typically with contrast media to visualize the compressed area. A small incision is made to access the spine and the entire procedure is performed without any direct visualization of the surgical area. PILD is typically performed on an outpatient basis using local anesthesia and sedation, and is a proposed treatment for symptomatic LSS unresponsive to conservative therapy and a less invasive alternative to traditional surgery. Other examples of minimally invasive spinal decompression surgery include microscopic and/or endoscopic techniques; however, unlike PILD, these techniques allow for direct visualization of the spine (Hayes 2025).

Regulatory Status

Currently, PILD is performed almost exclusively with the proprietary surgical kit, mild®, by Vertos Medical Inc. The device initially received FDA 510(k) marketing clearance in 2006 as the X-Sten MILD Tool Kit, model MTK-0001 (X-Sten Corp.), which is described as a set of specialized surgical instruments intended for percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. Subsequent clearances include the Vertos Medical mild® Device Kit in 2010, and the Vertos mild Device Kit (model MDK-0002) in 2024 (Vertos Medical Inc.). These subsequent devices are considered substantially equivalent to the predicate device with the same indication for use. The surgical kit is regulated as an arthroscope and a Class II medical device under product codes HRX and HAE in the FDA 510(k) database.

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COVERAGE POLICY

Percutaneous image-guided lumbar decompression (PILD) or minimally invasive lumbar decompression (MILD) (e.g., the mild® procedure) for spinal stenosis, is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, there is low quality evidence in the peer-reviewed published medical literature to support the long-term safety and efficacy of percutaneous image-guided lumbar decompression (PILD), or minimally invasive lumbar decompression (MILD) (e.g., the mild procedure, Vertos Medical Inc.), for lumbar spinal stenosis (LSS). The available studies are of lower quality with short follow-up of one to two years, and long-term efficacy and safety of the procedure are unknown. Some current limitations of studies include limited follow-up, lack of blinding, high attrition, absence of power analyses, reliance on subjective patient-reported measures, lack of prospective data, variable inclusion and exclusion criteria, lack of conservative treatment protocols before PILD, and missing data for outcomes and endpoints. Large, well-designed randomized controlled trials (RCTs) are needed to demonstrate the clinical utility of the procedure compared with established standard medical and surgical approaches.

Randomized Controlled Trials

Deer et al. (2024) published the two-year results from the MOTION study, a prospective, multicenter, RCT designed to evaluate the safety and efficacy of PILD using the mild procedure (Vertos Medical Inc.) combined with conventional medical management (CMM) compared to CMM alone in patients with LSS and neurogenic claudication due to hypertrophic ligamentum flavum. The study originally enrolled 155 participants randomized in a 1:1 ratio, with 131 (64 mild procedure + CMM and 67 CMM only) participants completing the 2-year follow-up. Both groups were allowed conservative and low-risk interventional therapies (e.g., physical therapy, steroid injections, radiofrequency ablation). At the 2-year follow-up, 57.8% of patients in the mild + CMM group continued to receive CMM, compared to 100% at baseline. Outcomes were assessed using validated objective and subjective measures, including the Oswestry Disability Index (ODI), Numeric Pain Rating Scale (NPRS), Zurich Claudication Questionnaire (ZCQ), and a standardized Walking Tolerance Test. At two years, the mild + CMM group demonstrated significant, yet often variable improvement across outcome measures when compared to baseline, with a mean ODI improvement of 14.6 $\pm$ 20.1 points (95% CI: 9.6-19.7, $p < 0.0001$), a mean improvement in walking tolerance of 197% ($p = 0.0002$), an NPRS (back) improvement of 2.3 $\pm$ 2.9 (95% CI: 1.6-3.0, $p < 0.0001$), an NPRS (leg) improvement of 4.0 $\pm$ 3.2 (95% CI: 3.2-4.8, $p < 0.0001$), a ZCQ (symptom severity) improvement of 0.7 $\pm$ 1.0 (95% CI: 0.5-1.0, $p < 0.0001$), and a ZCQ (physical function) improvement of 0.5 $\pm$ 0.8 (95% CI: 0.3-0.7, $p < 0.0001$). 2-year comparisons of mild + CMM to CMM alone could not be made due to substantial loss of evaluable participants who underwent subsequent lumbar spine interventions by two years (77.6% of the CMM alone group). The most common subsequent intervention was the mild procedure, with 9 patients crossing over prior to 1-year follow-up and 33 patients crossing over after 1 year. No device or procedure-related adverse events were reported in either group throughout the two-year period, and rates of unrelated serious adverse events were similar between groups (18.2% in the mild + CMM group vs. 16.7% in the CMM alone group, $p = 0.8351$). The authors concluded that the mild procedure, when combined with CMM, provides durable improvements in pain, function, and walking capacity for patients with symptomatic LSS secondary to hypertrophic ligamentum flavum. Study limitations include data imputation due to high crossover rates and variability in CMM use. The study was sponsored by Vertos Medical Inc.

[1]Deer et al. (2022) conducted a prospective, multicenter, RCT, called the MOTION study, comparing the mild

procedure (Vertos Medical Inc.) in combination with nonsurgical CMM vs CMM alone. 138 patients were included in the study and randomized in a 1:1 ratio to make up 69 participants per group. The CMM control group received any conservative or low-risk interventional therapies that are standards of care as deemed appropriate per patient by the site investigator. The mild + CMM group received the mild procedure as a first-line therapy. The groups were analyzed at a one-year follow-up. Objective outcomes were measured with real-world assessments, including improvement in walking, incidence of subsequent lumbar spine interventions, and safety. The Walking Tolerance Test demonstrated that patients in the MILD + CMM group achieved a statistically significant mean improvement of 258% in walking time to onset of severe symptoms compared with a 64% mean improvement for patients in the CMM alone group. Subsequent lumbar spine surgical interventions were undergone in 26.1% of CMM patients, compared with 5.8% of mild + CMM participants. There were no device- or procedure-related adverse events reported in either study group. Subjective outcomes revealed that the mild + CMM group experienced a 16.1-point composite ODI mean improvement, compared with a 2.0-point mean improvement for patients in the CMM alone group. ZCQ patient satisfaction also indicated that mild + CMM participants were statistically significant in their satisfaction with the treatment than were CMM participants. The study was sponsored by Vertos Medical Inc. (ClinicalTrials.gov NCT03610737).

Staats et al. (2016, 2018) conducted a prospective, multicenter, RCT for the purpose of providing level 1 evidence to support the safety and effectiveness of MILD. The study compared outcomes for 143 patients treated with MILD versus 131 treated with epidural steroid injections. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. ODI, NPRS, and ZCQ were used to evaluate function and pain. Safety was evaluated by assessing incidence of device- and procedure-related adverse events. At 6 months, all primary and secondary efficacy results provided statistically significant evidence that MILD is superior to the active control. At 2 years, ODI improved by 22.7 points, NPRS improved by 3.6 points, and ZCQ symptom severity and physical function domains improved by 1.0 and 0.8 points, respectively. There were no serious device-/procedure-related adverse events, and 1.3% experienced a device-/procedure-related adverse event. MILD showed durability, and there was no evidence of spinal instability through 2-year follow-up. Reoperation and spinal fracture rates are lower, and safety is higher for MILD versus other lumbar spine interventions, including interspinous spacers, surgical decompression, and spinal fusion. Limitations include lack of patient blinding due to considerable differences in treatment protocols, and a potentially higher non-responder rate for both groups versus standard-of-care due to study restrictions on adjunctive pain therapies. The study was funded by Vertos Medical Inc. (ClinicalTrials.gov NCT02093520).

Systematic Reviews and Meta-Analyses

Orhurhu et al. (2025) performed a systematic review and meta-analysis to evaluate the safety and efficacy of PILD for patients with LSS and neurogenic claudication. Only prospective studies were included in the review, and 15 studies met inclusion criteria, which consisted of 7 RCTs and 8 nonrandomized prospective studies. The total population was approximately 1400 participants who had failed conservative medical management (e.g., physical therapy, home exercise, analgesics, and/or epidural steroid injections. Most PILD procedures were performed on levels L2-L5, and follow-up durations ranged from 6 weeks to 2 years, with a median follow-up time of 1 year. Pain and functional outcomes were measured using the Visual Analog Scale (VAS) or NPRS, and the ODI. Clinically significant improvement was defined as a reduction of $\geq$ 3 points on a 0-10 pain scale or a $\geq$ 30% improvement in ODI. Across all studies, PILD produced statistically significant improvement in pain and functional outcomes from baseline. Nine of 14 studies reported pain scores achieving clinically significant improvement and 11 of 13 studies using ODI reported clinically meaningful functional improvement. In comparative RCTs, PILD outperformed control groups that contained conservative medical management, such as epidural steroid injections. For adverse events, 2 studies reported complications included postoperative headache, transient hip pain, deep vein thrombosis with pulmonary embolism, and small bowel herniation. 13 of the 15 studies reported no major complications, and PILD was generally characterized as a safe procedure performed with local anesthesia, with minimal recovery time and low opioid use rates. The authors concluded that “the MILD procedure” (PILD) is a safe and effective treatment for LSS in appropriately selected patients who fail conservative therapy, specifically symptomatic neurogenic claudication related to LSS.

Zhang et al. (2025) performed a systematic review and meta-analysis to evaluate the efficacy and safety of the mild procedure (Vertos Medical, Inc.) for patients with LSS caused by ligamentum flavum hypertrophy. A total of 12 clinical trials met inclusion criteria, which included both randomized and cohort study designs, for a total of 500 participants. Pain was measured primary with the VAS, where disability was measured with the ODI. The pooled mean VAS reduction was 3.11 points (95% CI 2.82-3.40, $p < 0.00001$). In 8 trials, VAS reduction was 3.06, 2.74, and 2.88 at < 6

months, 6-12 months, and ≥ 12 months respectively. The mean ODI improvement was 13.61 points (95% CI 11.09-16.13, p < 0.00001). Similarly to VAS, in 8 trials ODI improvement was sustained across 12 months, with mean improvement measured at 12.45, 15.40, and 13.04 at < 6 months, 6-12 months, and ≥ 12 months respectively. Overall, these changes exceeded study thresholds for clinically meaningful improvement (≥ VAS reduction and ≥ 10 improvement in ODI points). Reported adverse reactions had an overall reported incidence of 8.2%, with the most common complications being transient soreness, ecchymosis, and procedural pain. Among the 500 patients, no neurological deficits or dural tears were reported. When compared to open lumbar decompression surgery, which has estimated complication rates of 9.4% for dural tears, 9% for iatrogenic neurological deficit, and 14% for bleeding, the mild procedure appears to have a favorable safety profile, according to the authors. While funnel plot analysis showed no significant publication bias, and heterogeneity was deemed generally low (I^2 < 50% for all outcomes), several study limitations were noted by the authors, including variable inclusion and exclusion criteria, lack of standardized conservative treatment protocols before mild, reliance on subjective patient-reported measures (VAS and ODI), and the inclusion of retrospective data. The authors concluded that mild appears to be a safe and effective surgical technique for patients with LSS from ligamentum flavum hypertrophy. To confirm this, more well-designed RCTs are needed.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Hayes (2025) performed a health technology assessment to assess the safety and effectiveness of PILD for LSS. The authors note the PILD is most commonly, if not exclusively, performed via the mild procedure using the proprietary surgical kit, mild, by Vertos Medical. The authors also note that the phrase and acronym MILD, or minimally invasive lumbar decompression, is widely used in the literature and often in a nonspecific manner that could indicate general minimally invasive spinal decompression surgeries that use smaller incisions than traditional surgery, such as those that use a surgical microscope or endoscope. Regardless, almost the entire evidence base for PILD involves the use of the proprietary surgical kit, mild, by Vertos Medical. The authors conclude that an "overall low-quality body of evidence" supports the safety of PILD via the mild procedure, and that it "may result in clinically and statistically significant improvements over the short to intermediate term" for patients with symptoms of LSS secondary to hypertrophy of the ligamentum flavum with or without neurogenic claudication. However, "substantial uncertainty exists regarding its long-term durability of benefit and its effectiveness" when compared to other minimally invasive procedures.

Mekhail et al. (2021) conducted a single center retrospective longitudinal observational cohort study evaluating the 5-year outcomes of patients who underwent the mild procedure (Vertos Medical Inc.) between the years of 2010 – 2015. The primary outcome was measuring the incidence of patients who needed a subsequent open lumbar decompression surgery at the same level as the mild procedure intervention; and secondary outcomes were measuring pain via NPRS and opioid utilization. A total of 75 patients underwent the mild procedure, eight patients of those 75 were either lost to follow up, deceased, or no longer living in the United States; of the remaining participants 9 underwent an open surgical decompression after the mild procedure. No major complications were reported in any of the mild procedures performed. All participants reported a statistically significant (p < 0.0001 for each time point) reduction in NRS rating at the 3, 6, and 12 month follow ups post mild. Eighteen of the 75 participants were being treated with opioids prior to the mild procedure, after the mild procedure there was a statistically significant change in opioid medications utilization between baseline and 3, 6, and 12-months after mild treatment (p = 0.0048, p = 0.0015, and p = 0.0067, respectively). The study demonstrated that the mild procedure significantly reduced the need for open surgical lumbar decompression; however, the retrospective nature and small study population are limitations and emphasize the need for larger RCTs to validate the findings.

National and Specialty Organizations

The **American Society of Pain and Neuroscience (ASPN)** published a consensus guideline on the *best practices for minimally invasive lumbar spinal stenosis treatment*. The consensus statement pertaining to PILD was as follows: "PILD should be considered for the treatment of mild-to-moderate LSS in the presence of neurogenic claudication, with less than or equal to a grade 2 spondylolisthesis, and with a contribution of spinal narrowing with at least 2.5 mm of ligamentum flavum hypertrophy. Grade A; Level of certainty high; Level of evidence 1-A." This statement was formulated via a systematic review of the current literature ([2]Deer 2022).

The **ASPN** also published an *evidence-based clinical guideline of interventional treatments for low back pain*. The authors state that the PILD procedure is only indicated for the treatment of LSS secondary to ligamentum flavum hypertrophy, and the following criteria should be met before a patient is considered a candidate for PILD: presence of symptomatic LSS (e.g., neurogenic claudication), and confirmation of central or foraminal LSS secondary to ligamentum flavum hypertrophy (≥ 2.5 mm) with radiographic imaging (CT or MRI). The authors note that most patients with LSS remain asymptomatic, and approximately 10% of the population over the age of 70 will suffer from symptoms secondary to LSS. While standard of care for LSS has historically been open laminectomy with or without spinal fusion, open surgery can expose patients to increased complications and extended hospital stay (Sayed et al. 2022).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar [Effective until 12/31/2025]
62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar [Effective on 01/01/2026]
62331	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure) [Effective on 01/01/2026]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025	Policy reviewed. No change to coverage criteria. Title changed to "Percutaneous Image-Guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis."
12/11/2024	Policy reviewed. No changes to coverage criteria.
12/13/2023	Policy reviewed, no changes to coverage criteria, updated references. IRO peer reviewed by a board-certified physician in Orthopedic Surgery in October 2023.
12/14/2022	Policy reviewed, no changes to coverage criteria, updated references.
12/08/2021	Policy reviewed, no changes to criteria; included AANS guidance; updated references; CPT code G0276 removed.
12/09/2020	Policy reviewed, no changes to criteria; no new clinical studies to support coverage.
12/10/2019	New policy.

REFERENCES

1. Deer TR, Chafin TB, Costandi SJ, Qu H, Kim C, Jassal N, et al. The MOTION study: Two-year results of a real-world randomized controlled trial of the mild® procedure for treatment of lumbar spinal stenosis. Pain Pract. 2024 Jan;24(1):109-119. doi: 10.1111/papr.13293. Epub 2023 Sep 3. PMID: 37661347.
2. [1]Deer TR, Costandi SJ, Washabaugh E, et al. The MOTION Study: A Randomized Controlled Trial with Objective Real-World Outcomes for Lumbar Spinal Stenosis Patients Treated with the mild® Procedure: One-Year Results. Pain Med. 2022 Apr 8;23(4):625-634. doi: 10.1093/pm/pnac028. PMID: 35167700; PMCID: PMC8992575.
3. [2]Deer TR, Grider JS, Pope JE, et al. Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): Consensus Guidance from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2022 May 5; 15:1325-1354. doi: 10.2147/JPR.S355285. PMID: 35546905; PMCID: PMC9084394.
4. [1]Levin K. Lumbar spinal stenosis: Pathophysiology, clinical features, and diagnosis. Updated September 23, 2025. Literature review current through September 2025. Accessed October 24, 2025. https://www.uptodate.com.

5. [2]Levin K. Lumbar spinal stenosis: Treatment and prognosis. Updated March 27, 2025. Literature review current through September 2025. Accessed October 24, 2025. https://www.uptodate.com.
6. Hayes. Percutaneous image-guided lumbar decompression via mild procedure (Vertos Medical Inc.) for lumbar spinal stenosis. Health Technology Assessment Published May 13, 2025. Updated September 23, 2025. Accessed October 29, 2025. https://www.evidence.hayesinc.com
7. Mekhail N, Costandi S, Nageeb G, Ekladios C, Saied O. The durability of minimally invasive lumbar decompression procedure in patients with symptomatic lumbar spinal stenosis: Long-term follow-up. Pain Pract. 2021 Nov;21(8):826-835. doi: 10.1111/papr.13020. Epub 2021 May 13. PMID: 33942964; PMCID: PMC9291913.
8. Orhurhu V, Brancolini S, Zheng D, Snyder S, Jevotovsky DS, Chopra H, et al. Minimally Invasive Lumbar Decompression (MILD) in Patients with Lumbar Spinal Stenosis: A Systematic Review of Randomized and Prospective Trials. J Pain Res. 2025 Jul 11;18:3527-3540. doi: 10.2147/JPR.S521038. PMID: 40667531; PMCID: PMC12262078.
9. Sayed D, Grider J, Strand N, Hagedorn JM, Falowski S, Lam CM, et al. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022 Dec 6;15:3729-3832. doi: 10.2147/JPR.S386879. Erratum in: J Pain Res. 2022 Dec 24;15:4075-4076. doi: 10.2147/JPR.S402370. PMID: 36510616; PMCID: PMC9739111.
10. Staats PS, Chafin TB, Golovac S, et al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43(7):789-794. doi: 10.1097/AAP.0000000000000868.
11. Staats PS, Benyamin RM, MiDAS ENCORE Investigators. MiDAS ENCORE: Randomized controlled clinical trial report of 6-month results. Pain Physician. 2016;19(2):25-38.
12. United States Food and Drug Administration (FDA). 510(k) premarket notification. VERTIFLEX DIRECT DECOMPRESSION SYSTEM. Product code HRX. 510(k): K122662. https://www.fda.gov.
13. United States Food and Drug Administration (FDA). 510(k) premarket notification. VERTOS MEDICAL MILD DEVICE KIT. Product code HRX. 510(k): K093062. https://www.fda.gov.
14. United States Food and Drug Administration (FDA). 510(k) premarket notification. Vertos mild Device Kit (MDK-0002). Product code HRX, HAE. 510(k): K233800. https://www.fda.gov.
15. United States Food and Drug Administration (FDA). 510(k) premarket notification. X-STEN MILD TOOL KIT, MODEL MTK-0001. Product code HRX. 510(k): K062038. https://www.fda.gov.
16. Zhang XY, Zhao JL, Wang YJ, Luan J, Lin HQ, Wang D. The Efficacy of the Minimally Invasive Lumbar Decompression (MILD®) Procedure: A PRISMA-compliant Systemic Review and Meta-analysis. Pain Physician. 2025 Mar;28(2):71-81. PMID: 40168556.