

Avania

MedTech's Trusted Champion

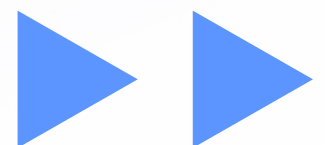
MedTech Industry Pulse

February 2026 Update



Executive Summary

- ▶ **111 MedTech Clinical Trial starts in Feb 2026 – 30.6% increase vs Feb '25 / (11.2%) drop vs Jan '26**
 - YTD Cardiovascular, Neurology, Ophthalmology & Oncology represent 48% of all study starts
- ▶ **Over \$200M raised in January 2026 combined between Neurent Medical, Chamber, Temple & Polares Medical**
 - AI technologies gaining momentum with VC investors
- ▶ **5 PMA Approvals granted to Synergy Spine Solutions, Allurion Technologies, Empirical Spine, Inc., Novocure & Contamac, Ltd**
- ▶ **2 DeNovo Approvals**
 - Delivery Date AI by Ultrasound AI
 - Amferia Wound Dressing by Amferia AB
- ▶ **219 510(k)s filed – down 8.7% from January 2026**



MedTech Companies With Funding Reported in Feb 2026

Company	Country	FundingStage	Amount	Focus
Neurent Medical	Ireland	Series C	€62.5M	Minimally invasive ENT device for chronic rhinitis treatment (NEUROMARKSystem)
Chamber	USA	Series A	\$60M	Data & AI-enabled cardiology care platform to manage heart disease
Temple	U.S. / India	Seed	\$54M	Brain monitoring wearable
Polares Medical	Switzerland & US	Series C	\$50M	Developing the MRace posterior leaflet replacement system for mitral regurgitation
ShanX Medtech	Netherlands	Seed round	~€24M	Rapid diagnostic system identifying the most effective antibiotic in around one hour
Omniscient Neurotechnology	Australia	Series D	\$20M	AI-enabled connectomics tools for brain mapping, neurosurgery, stroke, TBI
Lifeaz	France	Equity funding / expansic	€13M	Paris-based connected defibrillator developer
Avisi Technologies	USA	Series A	\$10.7M	Glaucoma surgical implant (VisiPlate@platform)
Enspire DBS Therapy, Inc.	USA	Series B1	\$10.3M	Deep brain stimulation therapy for post-stroke recovery
Synchrony Medical	USA	Venture/Investor Fundin	\$5.0M	At home respiratory care and airway clearance system (LibAirty™)
Brainomix	UK/EU/USA	Series C extension	£4.8M	AI-powered radiology imaging platforms (stroke & lung fibrosis)
AI-Stroke	USA	Seed round	\$4.6M	AI platform for pre-CT stroke triage
Hemi Health	Denmark	Seed round	~€4M	Neuro D Tx + sensor-integrated platform / migraine & concussion care
JuneBrain	USA	Private funding + ETC	~\$3.4M	Wearable AI retinal imaging platform tied to neurological disease diagnosis
ATRO Medical	Netherlands	Equity financing	€3M	Artificial meniscus implants
Neupulse	UK	Equity funding / expansic	£3.0M	Wearable neuromodulation device (median nerve stimulation) for Tourette's
Orthofuse	UK	Seed funding	€2.2M	3D-printed orthopedic implant systems
VoiceMed	Italy	First funding round	€1M	AI/voice biomarker based remote respiratory monitoring / screening
Entirety Biomedical	USA	Seed financing	\$1.2M	Bioabsorbable orthopedic fixation implants
Neuropacs	USA	Early Stage	~\$1 M	AI-driven neurological diagnostics for parkinsonian disorders

Artificial Intelligence (AI) based companies gaining momentum



YTD MedTech Planned / Completed Mergers & Acquisitions

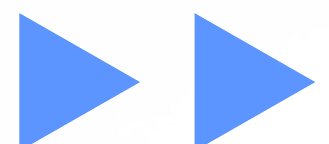
Buyer	Target	Approx. Value / Focus
Smith & Nephew	Integrity Orthopaedics	~\$450M, Rotator cuff repair devices
Boston Scientific	Valencia Technologies	Neuromodulation tech
BioStem Technologies	BioTissue Surgical & Wound Care	~\$15M + milestones, Surgical & wound care products
W. L. Gore & Associates	Conformal Medical	Structural heart implants
Haemonetics	Vivasure Medical	~€185M, Vascular closure devices
Resonetics	Resolution Medical	Expands structural heart and neuromodulation design & mfg
Boston Scientific	Penumbra	~\$14.5 B, vascular/neuro devices
BD & Waters	n/a (combination)	Diagnostics & biosciences
Medtronic	CathWorks	~ \$585 M, cardiac devices
Precision IO Group/Quantum Surgical	NeuWave Medical	Robotics + tumor ablation tech
Zavation	ChoiceSpine	Spine devices
GCM	Kettmann Machining	Precision medtech mfg
Maxx Orthopedics	TracPatch	Remote ortho monitoring
Danaher	Masimo	\$9.9B, Patient monitoring
Guardant Health	MetaSight	\$59M, Diagnostics
Tactile Medical	LymphaTech	\$6.8M + milestones, Lymphedema / Digital + device



Medtech Regulatory & Market Access - February 2026

M2026: Five markets, One Mandate: Quality, AI, and Digital Health Converge

February brought the biggest US quality system overhaul in 30 years, the first generative-AI chatbot to earn FDA Breakthrough Designation, and hard EUDAMED deadlines for Europe. Global regulators are converging on AI governance and mutual recognition.



Navigating Global Disruptions

Operational Impact Assessment for MedTech Trial Sponsors

Concurrent global disruption is compounding risk for MedTech clinical trials and device supply chains worldwide. This briefing summarizes the operational landscape as of March 5, 2026.



Operational Impact to MedTech Clinical Trials

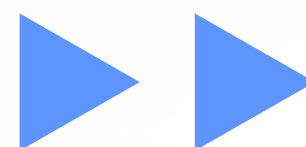
Clinical trial site-level risk assessment, supply chain rerouting, and data continuity planning has become a priority in affected regions

Dynamic Trade and Tariffs Situation in the U.S.

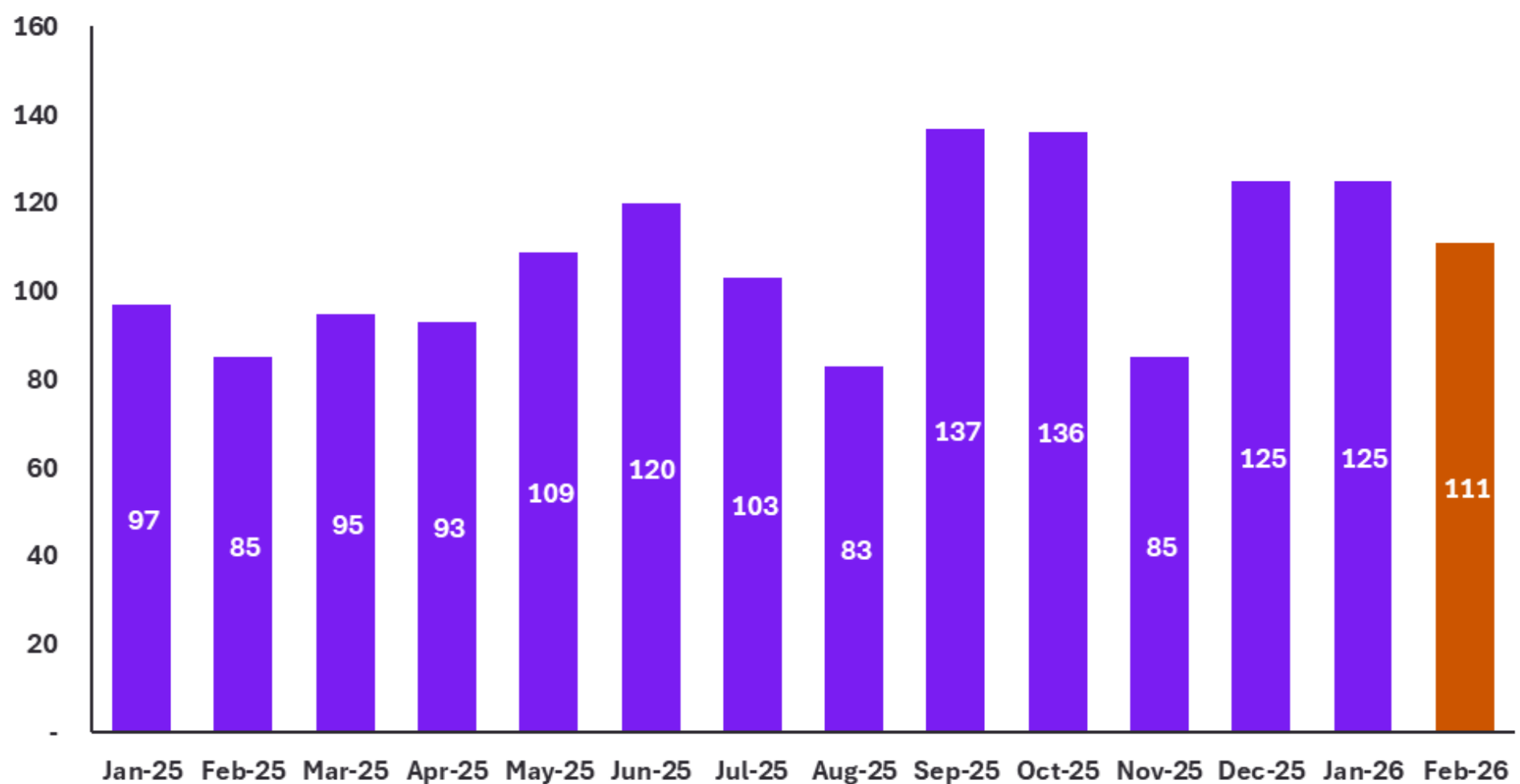
- ▶ Medical devices are not exempt from US tariffs (10-50% by country of origin). Spring 2026 will have critical Section 232 investigation that impacts the 62% of imported US medical devices
- ▶ Clinical Trial Sponsors should reassess landed cost impact on study budgets and customs timing for investigational product.

Navigating Ongoing Trial Disruptions in the Middle East

- ▶ **Shipment and Flight Delays:** Regional trials may be impacted by airspace closures in Iran, UAE, Qatar, Kuwait, Bahrain, Iraq, & Lebanon from Feb 28. Sponsors with active trial sites in the Gulf, Israel, and Lebanon face shipment delays and site disruption.
- ▶ **Healthcare IT Outages:** Cloude data center damage (AWS) in UAE and Bahrain on March 2 mark the first major cloud strike impacting public health via military action. Electronic systems in the Middle East trial sites for EDC, eCOA, or safety databases should verify data integrity and confirm backup and archival to unaffected regions; ensure access to offline or paper systems where needed.



Monthly Device Clinical Trial Starts

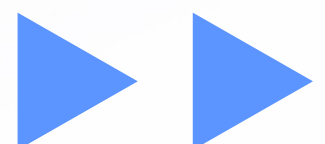


**Feb '26 clinical trial starts up 30.6% vs Feb '25
(down 11.2% vs Jan '26)**

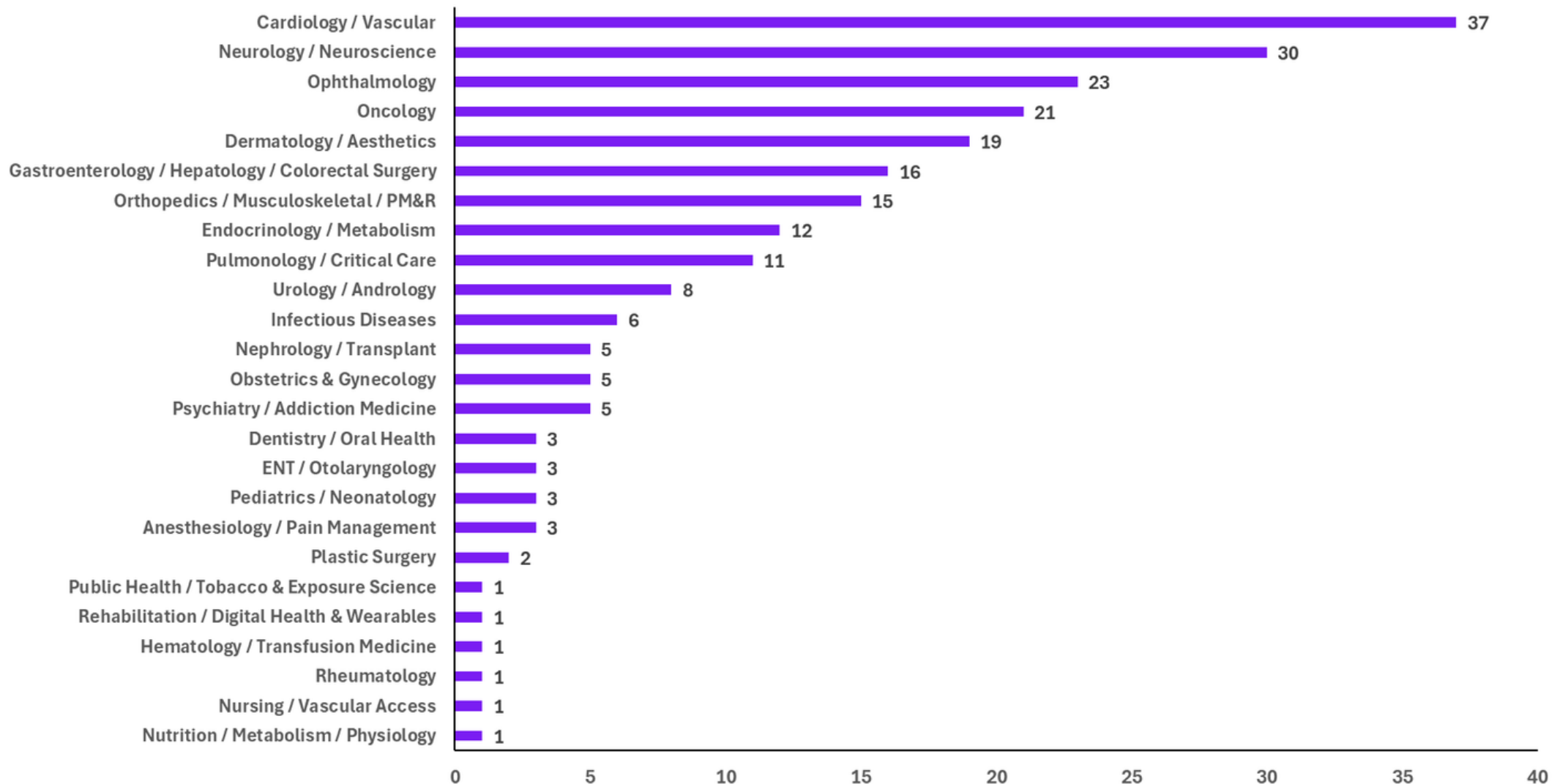
▶ **Source:** ClinicalTrials.gov

▶ **Search parameters:**

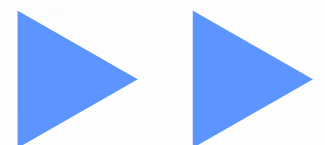
- Start dates between 1/1/25 – 1/31/26
- Device indication
- Interventional studies
- Industry funded



February 2026 Device Clinical Trial Starts by Therapeutic Area



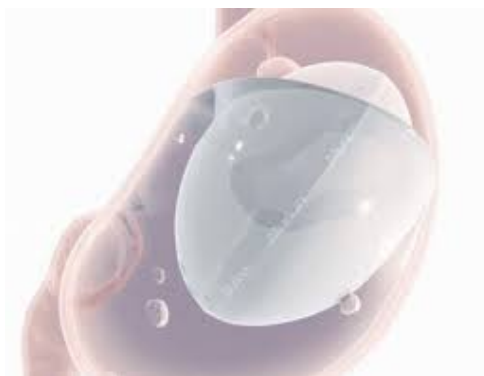
- ▶ Cardiovascular, Neurology, Ophthalmology & Oncology 48% of all study starts
- ▶ Therapeutic designation per Co-Pilot
- ▶ Trial data per ClinicalTrials.gov: Interventional, industry funded, device indication



February 2026 PMA Approvals



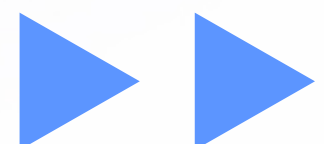
- ▶ Sponsor: Synergy Spine Solutions, Inc
- ▶ Device: Synergy Disk
- ▶ The first and only artificial cervical disc designed to improve alignment & provide intentional motion preservation, using time-tested & trusted materials



- ▶ Sponsor: Allurion Technologies, Inc
- ▶ Device: Allurion™ Gastric Balloon System
- ▶ Only FDA approved Smart Capsule that transforms into a gastric balloon combined with expert nutrition support & comprehensive digital tools



- ▶ Sponsor: Empirical Spine, Inc
- ▶ Device: LimiFlex Dynamic Sagittal Tether
- ▶ A new potential alternative to spinal fusion for patients receiving surgical decompression for grade 1 lumbar degenerative spondylolisthesis with spinal stenosis



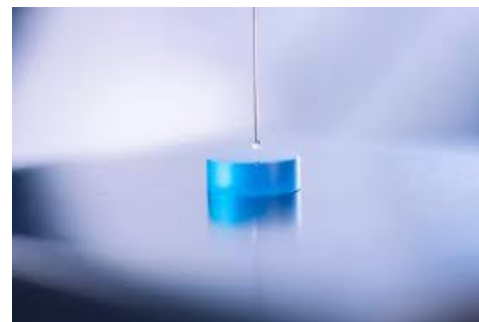
February 2026 PMA Approvals

novocure™



- ▶ Sponsor: Novocure
- ▶ Device: Optune Pax
- ▶ Intended for treatment of adult patients with locally advanced pancreatic cancer, concomitant with gemcitabine and nab-paclitaxel

Contamac®



- ▶ Sponsor: Contamac, Ltd.
- ▶ Device: Optimum Infinite (tisilfocon A) Orthokeratology Lenses II
- ▶ Lenses for overnight wear indicated for use in the reduction of refractive error in non-diseased eyes.



February 2026 De Novo Approvals

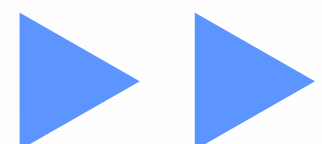
Delivery Date AI

- ▶ Sponsor: Ultrasound AI
- ▶ Review Advisory Committee: Radiology
- ▶ A newly FDA-cleared, cloud-based software that predicts a baby's birth date using second- and third-trimester ultrasound images. It uses deep-learning to analyze fetal development, providing a more precise, objective, and personalized alternative to traditional calendar-based dating methods.

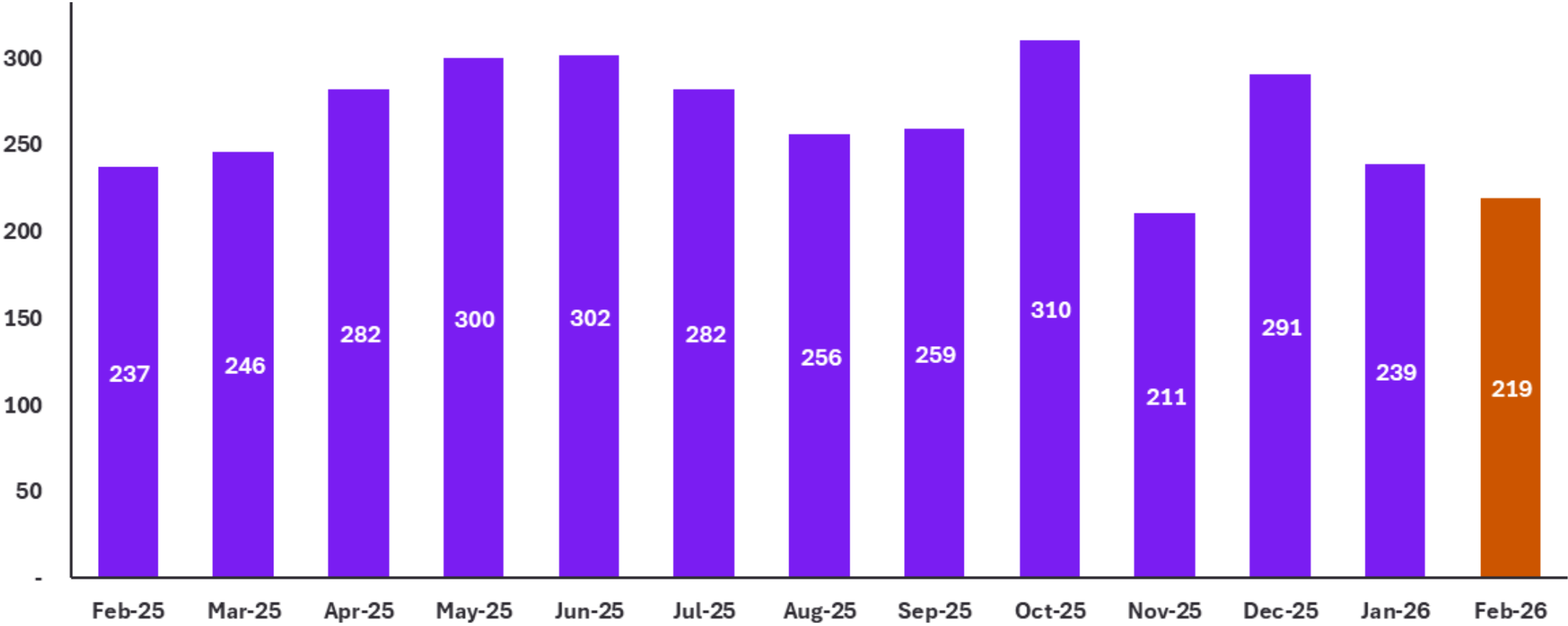


Amferia Wound Dressing

- ▶ Sponsor: Amferia AB
- ▶ Review Advisory Committee: General & Plastic Surgery
- ▶ “When applied as a solid wound dressing pad, Amferia’s wound dressing can bind and kill 99.99% of bacteria, providing an effective, clean environment for wound recovery.”



510(k) Monthly Trend – Feb '26 down 8.7% from Jan '26



Source: www.fda.gov



Ready to Advance
Your MedTech

Innovation?

Partner with Avania And experience the difference of the MedTech-only CRO: trusted expertise, collaborative engagement, and proven results.

Email us at info@avaniaclinical.com