

WHITE PAPER

CIRCLES FOR PERIPHERAL NERVE STIMULATION TREATMENT PROTOCOLS

October 2025

TABLE OF CONTENTS

PNS FOUNDATIONAL SCIENCE	2
ADVANCED MECHANISMS OF ACTION: PERIPHERAL, SPINAL, AND CORTICAL MODULATION	2
CURRENT AND EMERGING INDICATIONS FOR PNS THERAPY	3
CRITICAL GAPS IN EFFICACY OPTIMIZATION	4
MARKET OVERVIEW.....	4
COMPREHENSIVE MARKET SIZING, SEGMENTATION, AND GROWTH PROJECTIONS.....	5
PNS AS AN OPIOID-SPARING ADJUNCT THERAPY	5
REGULATORY COMPLIANCE AND REIMBURSEMENT.....	6
NAVIGATING FDA PATHWAYS AND DEVICE CATEGORIZATION.....	6
CPT CODING, PAYER COVERAGE POLICIES, AND FINANCIAL VIABILITY	7
LEGAL RISK ASSESSMENT: FRAUD, COMPLIANCE, AND THE FALSE CLAIMS ACT.....	7
REAL-WORLD EVIDENCE (RWE) OBSERVATIONAL PROTOCOLS	8
CIRCLES OP 1: POST-AMPUTATION PAIN (RWE)	8
CIRCLES OP 2: GENICULAR NERVE STIMULATION FOR CHRONIC KNEE PAIN.....	9
CIRCLES OP 3: TARGETED STIMULATION FOR REFRACTORY POSTHERPETIC NEURALGIA	10
CONCLUSIONS.....	11
REFERENCES	13