MCRA's Regulatory and Reimbursement Team Helped Move icotec Through Commercialization

Client Need

icotec, a Swiss medical device company focused on Carbon/PEEK spinal implants for the surgical management of patients who require spinal stabilization that would benefit from optimized imaging techniques, most notably patients with active spinal infections and spinal tumors, engaged with MCRA for assistance with interacting with FDA and payers.

"MCRA has been instrumental in securing both Breakthrough Device Designation (BDD) and New Technology Add-on Payment (NTAP) for icotec's innovative BlackArmour products. Their expertise and dedicated effort throughout the regulatory process were crucial in achieving these milestones. MCRA's understanding of the intricacies involved in FDA submissions and reimbursement strategies has undoubtedly accelerated our path to bringing these breakthrough technologies to the patients who need them most. We extend our heartfelt gratitude to the MCRA team for their exceptional support and partnership in this significant achievement."

Carter Lonsberry, Executive Board Member, icotec

MCRA Approach

MCRA's regulatory and reimbursement leaders collaborated with icotec's multi-disciplinary team to design a Breakthrough Device Designation strategy that would offer both regulatory and reimbursement benefits to icotec's growing portfolio. MCRA submitted the BDD and subsequent 510(k)s in concert with the CMS submission to support a favorable New Technology Add-On Payment (NTAP) decision, which would provide an additional payment to hospitals to encourage the use of icotec's device.

MCRA THERAPY: Spine

MCRA SERVICES: Regulatory and Reimbursement

Outcome

MCRA helped icotec achieve breakthrough status for their Vader Pedicle System, interbody cage family, KONG Cervical and Thoracolumbar VBRs, and Anterior Cervical Plate as well as successful clearance for the 510(k)s for each system. With MCRA's help icotec was approved for NTAP add-on payments for their infection Indications and currently is on track to obtain additional NTAP approval for its stabilization Indications.

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