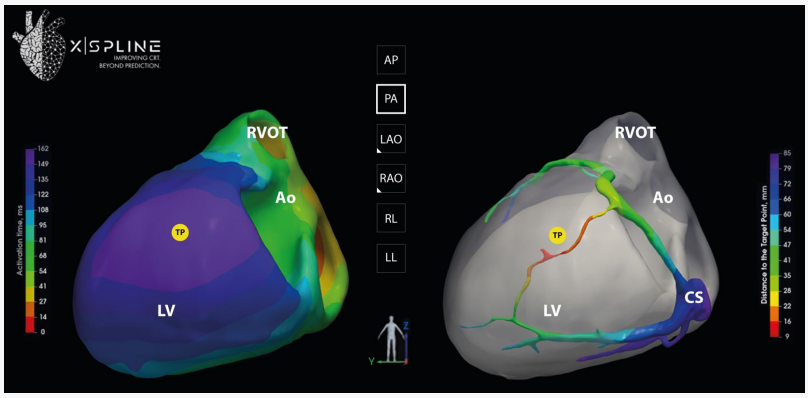
XSpline SPA Announces Successful First Clinical Case in Duke University Hospital, Durham, NC

BOLZANO, BZ, ITALY, August 17, 2023 /EINPresswire.com/ -- XSpline SPA, an innovative start-up company incorporated in Bolzano, Italy, in collaboration with Dr. Daniel Friedman, today announced the successful completion of the first patient's enrollment in Duke University Hospital, Durham, NC, USA. This landmark event marks a pivotal phase in the international multicenter prospective clinical study known as CRT-DRIVE (ClinicalTrials.gov ID: NCT05327062) for Cardiac Resynchronization Therapy (CRT) DeliveRy, guided by non-Invasive electrical and VEnous anatomy assessment.



3D Epi-Endocardial Activation Color Map (Left) and 3D Structure of Coronary Sinus (CS) Veins with Distance to Target Point (TP) Color Map (Right)

The initiation of this trial in the U.S. is of significant importance, as it broadens the geographical reach of the CRT-Drive study. Moreover, by extending beyond Europe to embrace the United States, a global leader in clinical trials, the expansion acknowledges the unique role of XSpline company in the development of noninvasive cardiac mapping and clinicalelectrophysiology. It also aligns with the company's commitment to engage both European and American clinical expertise in a collaborative pursuit of medical innovation.
Mr. Werner Rainer, CEO of XSpline company, emphasized the significance of the trial, stating, "The inclusive nature of this study, covering both European and American patients, adds tremendous value. It allows us to explore and refine the innovative AI-guided approach of XSpline technology on a broader, international scale."

The CRT-DRIVE clinical study aims to enroll a total of 150 patients across 16 centers in the U.S. and Europe, providing a diverse and comprehensive patient base. This strategic study places XSpline at the forefront of exploring new horizons in individualized CRT treatment strategies, guided by the company’s state-of-the-art technology. Unlike other systems, XSpline's technology does not require multichannel ECG recording or body surface potential mapping. Instead, it generates a 3D panoramic electro-anatomical map using a standard 12-lead ECG, a first-of-its-

kind innovation in the world of cardiac electrophysiology. Moreover, XSpline technology ensures full compatibility with existing clinical standards, supporting formats like HL7, Physionet, DICOM, and various ECG formats.

XSpline's integrated suite of medical-grade visualization tools offers groundbreaking functionality in cardiac electrophysiology. These tools include a high-performance 3D electroanatomical viewer and an interactive navigator for LV lead placement, together with a multimodality DICOM viewer and an ECG viewer equipped with measurement capabilities. Alongside these features, proprietary algorithms enable the automatic detection of the latest activation zone and utilize unique processes to identify target points in an AI-based segmentation of CS veins structure. This system also provides automatic calculation of detailed morphology characteristics of each CS vein and its tributaries, giving the physician the ability to select patient-specific LV electrodes and delivery systems. Therefore, this comprehensive toolkit serves as an essential resource in the EP lab for various CRT implantations, aiding clinicians in achieving the highest level of CRT response through tailored, patient-specific treatment strategies. Additionally, XSpline technology includes predictive capabilities to determine who will respond to the treatment and who will not, guiding the selection of CRT implantation techniques even before the procedure begins, all with the objective of optimizing patient outcomes.

Dr. Daniel Friedman of Duke University Hospital expressed great enthusiasm for the technology, stating, "XSpline's innovative approach to cardiac mapping, including AI-based identification of the correct target zone for LV lead implantation, represents an extraordinary advancement in precision and personalization. I'm particularly excited about the potential to use this innovative technology to deepen our understanding of cardiac electrophysiology during Conduction System Pacing, a new trend in treating patients with heart failure and conduction system disorders. The ability to visualize and analyze the activation during various modes of pacing will undoubtedly open new doors in patient care and lead to more targeted, effective interventions."
The initiation of this clinical trial at Duke University Hospital marks an essential step toward the potential widespread application of this groundbreaking technology. This development paves the way for an increasing number of clinics to adopt the technology in the future, aligning with XSpline's mission to revolutionize cardiac electrophysiology care through individualized treatment strategies and innovative predictive technologies.
XSpline company acknowledges the immense contributions of Dr. Daniel Friedman, clinical research coordinators Meghan E. Pergola and Elyse Wilson, along with the dedicated team at Duke University Hospital. Together, they have all played pivotal roles in the partnership, and the company expresses gratitude for their collaborative efforts in this significant clinical study and ambitious project.

About XSpline SPA:
XSpline SPA is a Bolzano-based start-up focused on advancing cardiac treatment through non-invasive technology. XSpline's technology represents the forefront of personalized cardiac resynchronization therapy, guided by AI-based segmentation and 12-lead ECG noninvasive panoramic mapping.

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