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국문 강연제목:

**상대정맥용 중심순환계폐색술용혈관내카테터 제품의 국내 도입을 위한
희소의료기기 제도 개선 방안 마련**

영문 강연제목:

**Establishing improvement measures for the Humanitarian Use
Devices for the introduction of Catheter, intravascular, occluding,
central circulation products for the Superior Vena Cava(SVC) in Korea**

Abstract: Ranked second among the leading causes of death in Korea, cardiovascular diseases, including arrhythmias, have been increasing annually. Over the past five years, the number of patients with arrhythmias, a prevalent type of cardiovascular disease, has increased by 25%. Early diagnosis and appropriate treatment are crucial for managing cardiovascular arrhythmias. However, many individuals remain untreated due to regulatory issues in Korea, particularly regarding the challenges associated with lead removal surgeries. Therefore, this study systematically analyzes the issues with the domestic humanitarian use devices by examining the analogous system in the United States, which implements a systematic approach to humanitarian use devices and their approval. Through the analysis of clinical cases and the risk-benefit assessment of humanitarian use devices under an HDE designation approach, as well as the demonstration of the safety and efficacy of the Catheter, intravascular, occluding, central circulation products for the Superior Vena Cava(SVC), this research aims to propose improvements to the domestic humanitarian use devices , ultimately providing alternative treatments for patients who have been unable to receive care.

**Brief Biosketch 동국대학교 의료기기산업학과 석사졸업(Master of Science from
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