THE GALIEN FOUNDATION

PRODUCT: **Abbott's MitraClip™ Transcatheter Mitral Valve Repair System**

COMPANY: Abbott

THERAPEUTIC AREA & INDICATION:
Mitral valve regurgitation

ABOUT THE PRODUCT

Approximately four million people in the U.S. alone experience mitral regurgitation (MR), a progressive, serious condition in which the heart's mitral valve does not close completely, allowing blood to flow backward into the heart preventing it from moving properly out to the rest of the body. MitraClip is a first-of-its-kind transcatheter mitral valve repair (TMVr) therapy that represents a safe and effective treatment option for patients with MR who would otherwise go untreated. For patients ineligible for open-heart surgery to treat their MR, MitraClip has become a groundbreaking therapy option in the 75 countries around the world where it's approved.

THE GALIEN FOUNDATION

PRODUCT:
PK Papyrus Covered Coronary Stent System

COMPANY: BIOTRONIK

THERAPEUTIC AREA & INDICATION:
Coronary artery perforations

ABOUT THE PRODUCT

Built on BIOTRONIK's ultrathin stent platform, PK Papyrus is the first FDA approved device for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. The covered stent is available in 17 sizes, expanding treatment options and helping avoid the need for emergency coronary artery bypass grafting. PK Papyrus is the only 5 French compatible covered coronary stent available in the United States.

THE GALIEN FOUNDATION

PRODUCT: **Edwards SAPIEN 3 Ultra™ Transcatheter Heart Valve System**

COMPANY: Edwards Lifesciences

THERAPEUTIC AREA & INDICATION:
Aortic stenosis

ABOUT THE PRODUCT

The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System was approved in 2019 for the relief of aortic stenosis in low-risk patients with symptomatic heart disease due to severe native calcific aortic stenosis. Aortic stenosis is a severe heart condition in which the opening of the aortic valve narrows, blocking blood flow from the heart to the rest of the body. The SAPIEN 3 Ultra valve is a less invasive catheter-based therapy, performed on a beating heart. The SAPIEN platform of valves is the most clinically studied transcatheter valve in history. More than 650,000 patients globally have benefited from TAVR.

THE GALIEN FOUNDATION

PRODUCT: **INSPIRIS RESILIA™ Aortic Valve**

COMPANY: Edwards Lifesciences

THERAPEUTIC AREA & INDICATION:
Aortic valve replacement

ABOUT THE PRODUCT

The INSPIRIS RESILIA aortic valve sets a new benchmark for surgical aortic valve replacement. It's the first tissue valve to introduce several innovative valve technologies: the potentially more durable RESILIA tissue and the VFit expandable frame. The INSPIRIS valve represents a shift in the paradigm for patients, especially younger and more active patients, who are debating the durability and life-style implications of mechanical and tissue valves. With INSPIRIS, patients have an option that is designed with features to promote durability and facilitate future valve replacement procedures utilizing less-invasive methods.

THE GALIEN FOUNDATION

PRODUCT: **CCM® Therapy for Heart Failure**

COMPANY: Impulse Dynamics

THERAPEUTIC AREA & INDICATION:
Congestive heart failure

ABOUT THE PRODUCT

CCM therapy, delivered by the Optimizer system, is a breakthrough treatment that can help many people with heart failure feel better and improve their quality of life. The minimally invasive, implantable device is the first therapy of its kind designed to improve contractility of the heart. The therapy is a safe and effective device-based treatment option for many heart failure patients who are no longer adequately responding to medications to manage symptoms or slow the progression of heart failure. Prior to its FDA-approval in 2019, these patients had few, or no, effective options available to them.

THE GALIEN FOUNDATION

PRODUCT: **Implantable System for Remodulin®**

COMPANY: Medtronic

THERAPEUTIC AREA & INDICATION:
Pulmonary arterial hypertension

ABOUT THE PRODUCT

The Implantable System for Remodulin® (ISR) is a fully implantable drug delivery system that provides continuous intravenous delivery of Remodulin® for patients suffering from PAH. Delivery of Remodulin® with the ISR addresses an unmet medical need and offers significant, clinically meaningful benefits relative to the current external drug delivery methods for Remodulin®. Since the patient population and drug is the same with external and implanted drug delivery systems, the efficacy of Remodulin® in treatment of PAH would not be anticipated to change. However, major benefits of the implanted system include reductions in the severity and rate of occurrence of harmful and potentially fatal events associated with external systems, and an improved quality of life.