Final Report Summary

Observational Post Market Clinical Study – Evolution® Duodenal Stent System

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Study Name (Global Clinical Number): MDR-20101

Investigation type	Post-Market, Observational Study
Investigation design and methods used	Retrospective, Multicenter, Observational Clinical study Region/countries where the data is collected: EMEA/France Study objective: • To confirm the long-term performance and safety outcomes of the Evolution® Duodenal Stent System • To ensure the continued acceptability of the benefit-risk ratio • To identify previously unknown side-effects and monitor the identified side-effects and contraindications • To identify and analyse emerging risks based on factual evidence • To identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct Inclusion/exclusion criteria: Patients that had a procedure with the Evolution® Duodenal Stent System in the period 01 July 2016 to 30 June 2023 (inclusion period was extended mid-way through the study execution, study plan amended 15 March 2024) and with a plan for follow-up at the same site. A patient was deemed ineligible for inclusion in the study if the patient or their legally authorized representative objected to collection and processing of their data (non-objection letters replaced the informed consent processes) or if deceased patients had set

	post-mortem instruction against processing of their health data. Enrollment strategy: Patients with the most recent procedure was identified first and then identification of consecutive patients was continued until at least 105 eligible patient datasets were collected with a maximum of 69 patient datasets per participating clinical site (2/3 of total patient datasets to be collected). Non-objection letters were sent to patients in this order. Patients were included in the study as the clinical sites received a non-objection back from the patients. Due to the study being amended mid-way to maximize patient enrollment, the order of enrollment was not consecutive for all datasets in the study.
Sponsorship	Cook Research Incorporated 1 Geddes Way West Lafayette, IN 47906 USA
Date of first and last patient enrolled	This data collection effort includes patient datasets with index procedures between February 2018 and December 2021.
Number of active sites and location of the active sites	Two clinical sites in France (CHU de Montpellier and Hôpital Beaujon) contributed data. Both sites are closed.
Number of patients included	109 patients
Follow-up duration	6 months
Period of data summary	Data entry and follow-up for the study began on 14 February 2023 and a database lock was performed on 10 April 2025.
Summary of data	**Data availability:** In summary, 100% of patients (109) had procedure and post-operative data available to 6 months. **Patient demographics:** The average age of the study cohort was 66.7 years, and the male sex proportion was slightly higher (57.8% vs. 42.2%). **Performance outcome:** Five of the 109 patients did not have clinical assessment information within 14 days. Therefore, clinical success, defined as ability to tolerate oral intake or improvement in Gastric Outlet Obstruction Score [GOOS] or relief of symptoms up to 14 days post-procedure, was analysed among 104 patients. Clinical success was observed among 74.0% of patients (77/104; 95% CI, 65.6%-82.5%).

	Safety outcome: For the safety outcome of device or procedure related adverse events and device deficiencies, 1 device deficiency (0.9%, 1/109) was reported. No procedure- or device-related adverse events were reported.
Final conclusion	Overall, this post-market study of Evolution® Duodenal Stents provides continued evidence for the safety and performance of these devices in daily practice. Clinical success was observed among 74.0% of patients (77/104; 95% CI, 65.6%-82.5%) and no procedure- or device-related adverse events were reported. Although 74% does not meet the performance goal specified in the study plan (77%), the confidence interval includes the performance goal used to calculate the sample size, supporting continued device use. One adverse event (biliary obstruction) and 1 device issue (obstruction) were reported. No off-label use was observed.