

# Legacy Sponge-on-a-String Esophageal Cell Collection Device Subject of Class II FDA Recall

*EsophaCap device recalled due to recent publication of serious device failures*

*Lucid Diagnostics' EsoCheck® unaffected by recall and remains the gold standard for non-endoscopic cell collection*

NEW YORK, May 9, 2024 /PRNewswire/ -- **Lucid Diagnostics Inc.** (Nasdaq: LUCD) ("Lucid" or the "Company") a commercial-stage, cancer prevention medical diagnostics company, and majority-owned subsidiary of PAVmed Inc. (Nasdaq: PAVM, PAVMZ) ("PAVmed"), announced that the legacy EsophaCap sponge-on-a-string (SOS) esophageal cell collection device, which it briefly supplied to third-party institutions for their own research studies, has been subjected to a [Class II FDA recall](#) due to two serious device failures reported in a recent publication of one of these studies. EsophaCap is not a commercial Lucid product.

"Approximately 16,000 Americans tragically die each year from highly-lethal esophageal cancer. Professional society guidelines now recommend non-endoscopic biomarker testing to detect early esophageal precancer and prevent cancer," said [Lishan Aklog, M.D.](#), Lucid's Chairman and Chief Executive Officer. "Brillo pad-like sponge-on-a-string (SOS) devices, first introduced in the early 1990s, indiscriminately scrape cells from the stomach, esophagus and mouth, limiting their efficacy. In addition, troubling reports of serious device failures have plagued SOS devices for many years, leading to multiple Class II FDA recalls similar to this one. All SOS devices, including repackaged and/or rebranded versions, have fundamentally the same design and limitations as those that have been previously subjected to FDA recalls."

Dr. Aklog added, "In stark contrast, Lucid's [EsoCheck® Esophageal Cell Collection Device](#), with its patent-protected Collect+Protect™ technology, is a modern groundbreaking technology. EsoCheck allows for precise, targeted collection of cells for esophageal precancer testing using the [EsoGuard® Esophageal DNA Test](#), resulting in unprecedented early precancer detection. EsoCheck's gentle approach to noninvasive cell collection is a dramatic and elegant improvement over decades-old SOS technology. It has proved particularly critical in detecting early short segment precancer (SSBE), which accounts for at least 70% of cases in the at-risk target population and is responsible for at least half of all future cancers. Unlike most SOS devices, EsoCheck has never caused any serious adverse events nor been associated with reportable device failures in over 10,000 procedures."

The technology underlying the EsophaCap SOS was first FDA-cleared in 1993 and then again in 2020 ([K203450](#)). Lucid acquired the technology for research purposes in 2021 and supplied it to two academic institutions for their ongoing research studies until early 2022. In a recently-published research [article](#) of one of these studies, two patients suffered from serious device failures, specifically SOS detachments, one of whom required invasive endoscopic retrieval. These detachments were similar to previously-reported detachments of the Cytosponge Cell Collection Device, an SOS manufactured by Medtronic, which led to two Class II FDA recalls, including a June 2023 [open global recall](#), which remains in effect. In this most-recent recall, Medtronic reported to FDA that patients "*may be at increased risk of the sponge detaching from the string during removal of the device from the patient, which could lead to device fragments in patient, obstruction, airway obstruction, secondary intervention, secondary intervention (with the primary procedure), supraglottic airway obstruction, and aspiration.*" In an accompanying Urgent Field Safety Notice sent to customers in the United Kingdom, Medtronic reported "*nine (9) customer complaints where the sponge detached from the string during the removal of the device from the patient. All nine (9) patients underwent an unplanned urgent secondary intervention (upper endoscopy) where the detached sponge was retrieved from the stomach or esophagus*" between December 2022 and May 2023.

As the manufacturer of record, Lucid proactively informed the FDA of the reported device failures and concluded that a Class II recall of the EsophaCap SOS was necessary and was made effective as of April 25, 2024. Notice Letters were sent to the two research institutions which had been supplied with devices.

## About Lucid Diagnostics

Lucid Diagnostics Inc. is a commercial-stage, cancer prevention medical diagnostics company, and subsidiary of

PAVmed Inc. (Nasdaq: PAVM). Lucid is focused on the millions of patients with gastroesophageal reflux disease (GERD), also known as chronic heartburn, who are at risk of developing esophageal precancer and cancer. Lucid's [EsoGuard® Esophageal DNA Test](#), performed on samples collected in a brief, noninvasive office procedure with its EsoCheck® Esophageal Cell Collection Device - the first and only commercially available tool designed with the goal of preventing cancer and cancer deaths through widespread, early detection of esophageal precancer in at-risk patients.

For more information, please visit [www.luciddx.com](http://www.luciddx.com) and for more information about its parent company PAVmed, please visit [www.pavmed.com](http://www.pavmed.com).

### **Forward-Looking Statements**

This press release includes forward-looking statements that involve risk and uncertainties. Forward-looking statements are any statements that are not historical facts. Such forward-looking statements, which are based upon the current beliefs and expectations of Lucid's management, are subject to risks and uncertainties, which could cause actual results to differ from the forward-looking statements. Risks and uncertainties that may cause such differences include, among other things, volatility in the price of Lucid's common stock; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance Lucid's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from Lucid's clinical and preclinical studies; whether and when Lucid's products are cleared by regulatory authorities; market acceptance of Lucid's products once cleared and commercialized; Lucid's ability to raise additional funding as needed; and other competitive developments. In addition, Lucid continues to monitor the COVID-19 pandemic and the pandemic's impact on Lucid's businesses. These factors are difficult or impossible to predict accurately and many of them are beyond Lucid's control. In addition, new risks and uncertainties may arise from time to time and are difficult to predict. For a further list and description of these and other important risks and uncertainties that may affect Lucid's future operations, see Part I, Item 1A, "Risk Factors," in Lucid's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as the same may be updated in Part II, Item 1A, "Risk Factors" in any Quarterly Report on Form 10-Q filed by Lucid Diagnostics after its most recent Annual Report. Lucid disclaims any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in its expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

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