

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 15, 2023**

**Surmodics, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Minnesota**  
(State or Other Jurisdiction  
of Incorporation)

**0-23837**  
(Commission File Number)

**41-1356149**  
(IRS Employer  
Identification No.)

**9924 West 74th Street**  
**Eden Prairie, Minnesota**  
(Address of Principal Executive Offices)

**55344**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 952 500-7000**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.05 par value	SRDX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On March 15, 2023, at 10:40 a.m. Eastern Time, Gary Maharaj, President and Chief Executive Officer, and Tim Arens, Senior Vice President of Finance and Chief Financial Officer, of Surmodics, Inc. (the “Company”) will make a presentation to the investment community at the Oppenheimer Annual Healthcare Conference. The Company representatives will present the investor information attached to this report as Exhibit 99.1.

A webcast of the full presentation will be available at the following URL: <https://surmodics.gcs-web.com/events-and-presentations>. The presentation will be archived on the Company’s website for 90 days following the webcast.

The information in this Item 7.01, Exhibit 99.1, the webcast of the investor presentation, and the recording of the presentation shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liabilities under Section 18, nor shall such information be deemed incorporated by reference into any filings of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Surmodics Investor Information March 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SURMODICS, INC.

Date: March 15, 2023

By: /s/ Timothy J. Arens  
Timothy J. Arens  
Senior Vice President of Finance and Chief Financial Officer

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**Gary Maharaj**  
President and CEO

**Tim Arens**  
Senior Vice President of Finance, IT and CFO

**March 2023**



# Safe Harbor

Some of the statements made during this presentation may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements that are not historical or current facts, including statements about predictable cash flow, accelerated revenue growth, product pipeline and catalysts in high-growth market segments, sustainable long-term growth, access to capital, opportunities to drive strong, sustained revenue growth, expected revenue growth and annual growth rates, expected contributions to fiscal 2023 revenue growth, our fiscal 2023 strategic objectives, the potential addressable markets, and market growth rates, for our products, advancing the regulatory strategy for the premarket approval of the SurVeil™ drug coated balloon (“DCB”), expectations regarding meetings with the U.S. Food and Drug Administration (“FDA”) regarding our applications for premarket approval of the SurVeil DCB, future potential revenue from our Development and Commercialization Agreement with Abbott Vascular, Inc., including a future milestone payment, expected sequential growth in the customer base for Pounce™ Thrombectomy and Sublime™ Radial Access Devices, as well as targeted year-end customers and year-over year revenue growth for such products, expectations regarding completion of the 5-year follow-up in the TRANSCEND study, fiscal 2023 financial guidance, statements about available capital, expectations about improving cash flow, statements about investments in long-term value creation, and estimates of future revenues related to the TRANSCEND study, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) our ability to successfully develop and commercialize our SurVeil™ DCB (including realization of the full potential benefits of our agreement with Abbott), A vess™ DCB, Sundance™ DCB and other proprietary products; (2) whether and when the FDA grants premarket approval to the SurVeil DCB (3) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market and sell products incorporating our technologies; (4) possible adverse market conditions and possible adverse impacts on our cash flows; (5) our ability to successfully and profitably commercialize the Pounce venous thrombectomy system; (6) current and future supply chain constraints; (7) whether anticipated increases in our operating expenses are effective in generating profitable revenues; (8) whether we realize the benefits of recent organizational changes without adverse impacts on our operations; and (9) the factors identified under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at <https://surmodics.gcs-web.com> and at the SEC website at [www.sec.gov](http://www.sec.gov). Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

Caution: SURVEIL, SUNDANCE and AVESS Drug-Coated Balloons are investigational devices. Limited by Federal (or United States) law to investigational use.

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# Surmodics at a Glance



**SURMODICS**

(NASDAQ: SRDX)

We are a **Medical Technology** company focused on driving innovation to improve the prevention and detection of disease.

- Year Founded: 1979
- Locations:
  - Minneapolis, MN
  - Ballinasloe, Ireland
- Total Employees: ~450<sup>(1)</sup>
- Fiscal 2022 Revenue: \$100 million
- Market Capitalization: ~\$250 million<sup>(2)</sup>

<sup>(1)</sup>As of 12/31/2022

<sup>(2)</sup>As of 3/13/2023

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# Investment Highlights

- Core businesses operate at a significant commercial scale, generating strong, predictable cash flow
- Multiple, innovative vascular intervention devices to accelerate revenue growth profile
- Vascular intervention devices focused on large, underpenetrated markets: \$3.8B addressable opportunity<sup>(1)</sup>
- Innovative product pipeline with catalysts in multiple high-growth market segments
- Experienced leadership team executing multi-year strategy to drive sustainable, long-term growth
- Recently enhanced balance sheet and access to capital to support strategic initiatives

<sup>(1)</sup> Estimated cases using relevant technology compared to total addressable cases  
Patient figures and addressable market sizes are for U.S. Markets and are based on Management  
Estimates as well as Public Health and Industry Data.

# Experienced Leadership Team



**Gary R. Maharaj**  
President and Chief Executive Officer  
(Joined 2010)



**Timothy J. Arens**  
Senior Vice President of Finance and  
Information Technology and  
Chief Financial Officer  
(Joined 2007)



**Gordon S. Weber**  
Senior Vice President of Legal,  
General Counsel & Secretary  
(Joined 2020)



**Joseph J. Stich**  
Senior Vice President of  
Human Resources and  
President of In Vitro Diagnostics  
(Joined 2010)



**Teryl L.W. Sides**  
Senior Vice President and  
President of Vascular Interventions  
(Joined 2018)



**Charles W. Olson**  
Senior Vice President and  
President of Medical Device Coatings  
(Joined 2001)



# Where we are today and where we're headed...

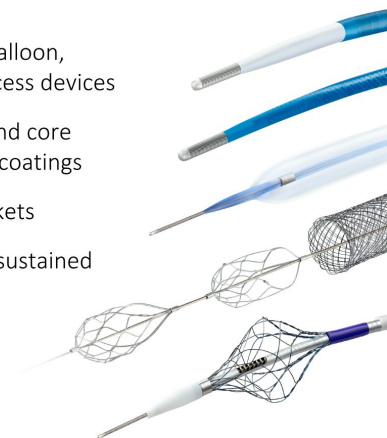
## Core Businesses: Medical Device Performance Coatings & In Vitro Diagnostics (IVD) Components

- Stable businesses with significant commercial scale (~\$84 million combined annual revenue in FY'22); growing modestly
- Strong gross margins
- High ROIC and cash flow generation



## Growth Opportunity: Vascular Intervention Devices

- Differentiated drug-coated balloon, thrombectomy and radial access devices
- Leverages R&D capabilities and core competency in performance coatings
- Large, underpenetrated markets
- Opportunity to drive strong, sustained revenue growth



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# Vascular Interventions: Product Portfolio and Pipeline

## DRUG-COATED BALLOONS

For Lower-limb Interventions



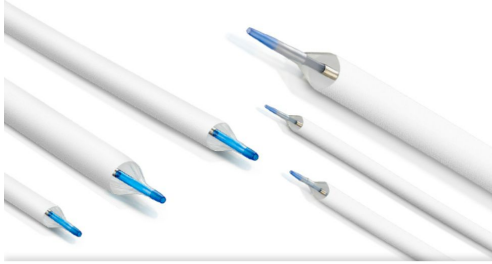
Surveil™  
DRUG COATED  
BALLOON

PRE-COMMERCIAL



Sundance™  
DRUG COATED BALLOON

PRE-COMMERCIAL



## MECHANICAL THROMBECTOMY

For Arterial and Venous Clot Removal



Pounce™  
Thrombectomy

(FOR ARTERIAL  
THROMBECTOMY)



Pounce™  
VENOUS  
Thrombectomy

PRE-COMMERCIAL

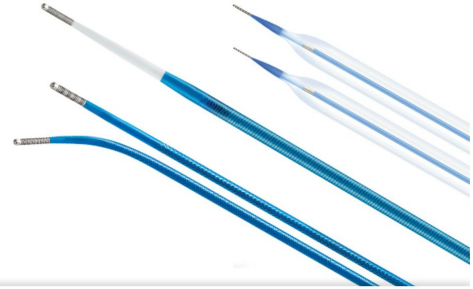


## RADIAL ACCESS PORTFOLIO

For Peripheral Interventions



Sublime™  
Radial Access




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# Vascular Interventions: Addressing large, underpenetrated markets in the U.S.

Product Platform	Condition(s) Addressed	Addressable Market Opportunity	Market Penetration <sup>(1)</sup>	Market Growth (3-Year CAGR)
	Peripheral Artery Disease Above-the-Knee	\$1.0 B	~25%	~17%
	Peripheral Arterial Occlusion	\$0.8 B	~12%	~18%
	Peripheral Artery Disease Radial Access Products	\$0.4 B	<10%	~40%
	Venous Occlusion (including those caused by Deep Vein Thrombosis)	\$1.6 B	16%	~64%
<b>Total</b>		<b>\$3.8 B</b>	<b>~15%</b>	<b>~26%</b>

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(1) Estimated cases using relevant technology compared to total addressable cases. Addressable market opportunity and market growth are for U.S. Markets and are based on Management Estimates as well as Public Health and Industry Data.

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# Fiscal 2023 Strategic Objectives

1 >



## Surveil™ Drug-Coated Balloon

Advance regulatory strategy with the goal of achieving FDA Pre-Market Approval (PMA)

2 >



## Pounce™ Thrombectomy (Arterial) and Sublime™ Radial Access platforms

Develop direct sales force and advance commercialization of platform products

3 >



## Medical Device Coatings and In Vitro Diagnostics offerings

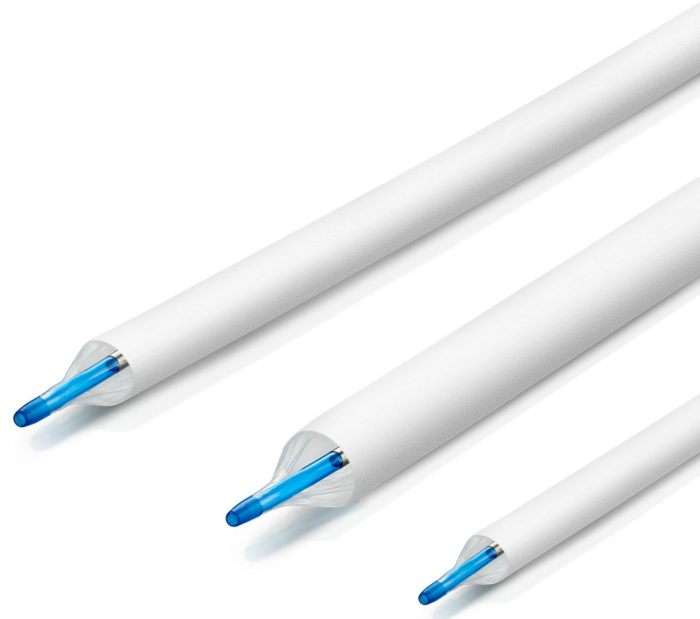
Drive revenue and cash flow growth

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# SurVeil™ DCB: Product Overview

## Overview

- Designed to treat peripheral artery disease in the vessels above the knee using a proprietary drug-excipient formulation to reduce the likelihood of restenosis

## Advantages

- Designed to deliver similar therapeutic outcomes to other DCB's, with a lower drug dose
- Better efficiency of drug transfer
- Reduction in downstream embolization

## Clinical Evidence

- TRANSCEND pivotal trial (446 patients, 65 global sites): [primary safety and efficacy endpoints met](#)
- Two-year data showed a primary patency rate of 70.8% of subjects for SurVeil™ DCB subjects, vs. 70.4% for IN.Pact® Admiral® DCB (control arm) subjects



Check here for  
product specs and  
TRANSCEND trial  
24-month data



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SurVeil™ DRUG-COATED BALLOON

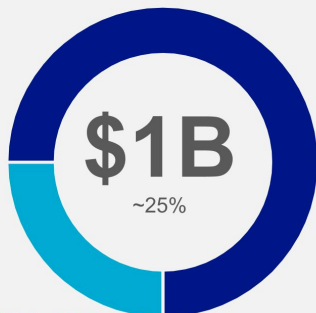
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# SurVeil™ DCB: Market Opportunity & Commercial Strategy

## Peripheral Artery Disease Above-the-knee Annual, Addressable U.S. Market<sup>(1)</sup>

~500,000

Annual, Addressable  
Above-the-knee Procedures



~120,000

Annual Above-the-Knee  
DCB Procedures

(1) Patient figures and market penetration based on Management Estimates,  
iData Research reports as well as Public Health and Industry Data  
(2) Total DCB cases as a percent of total procedures

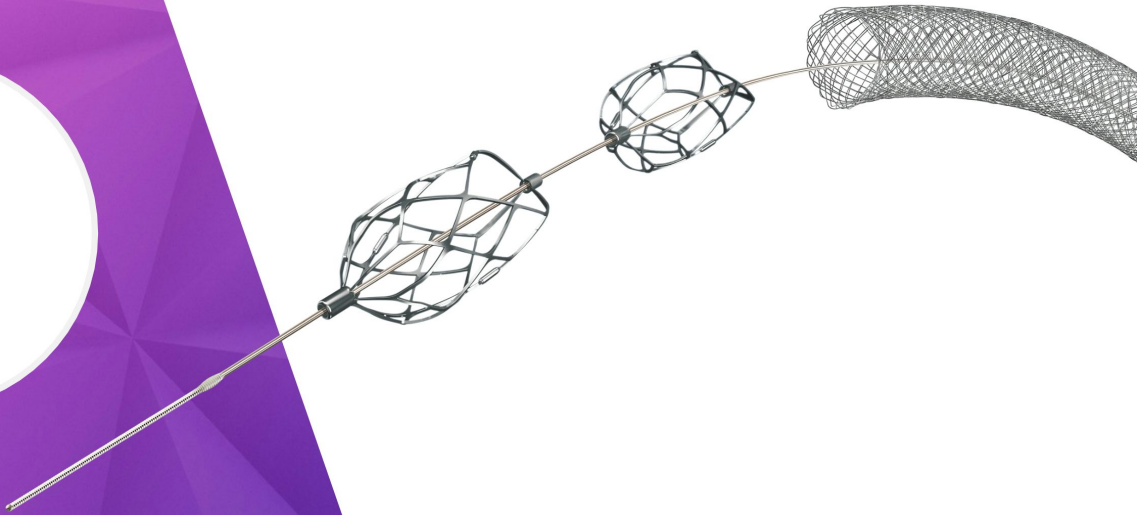
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## Commercial Strategy & Strategic Objectives

- Development & Distribution Partnership secured with Abbott
  - Upon FDA Pre-Market Approval (PMA), Surmodics will manufacture and sell SurVeil™ DCB to Abbott
  - Abbott's salesforce will commercialize SurVeil™ DCB and share profits with Surmodics
- FY'23 objective:
  - Advance regulatory strategy, with the goal of achieving PMA

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# Pounce™ Thrombectomy System (Arterial): Product Overview

**Brachial Arterial Embolus**

**Subclavian Arterial Thrombus**

**Superior Mesenteric Arterial (SMA) Thrombus**

**Tibial Arterial Embolus**

**Superficial Femoral Arterial (SFA) and Profunda Thrombus**

Download Procedure Overview Sheet

Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

## Overview

- Designed to capture and remove clots from occluded arteries in the peripheral vasculature

## Advantages

- Designed to provide efficient and effective clot removal, restoring blood flow quickly without the need for capital equipment or lytic drugs <sup>(1)</sup>, lessening the potential for an ICU stay
- Intuitive, simple set up; limited learning curve
- Unique design makes it easy to remove large quantities of organized (hard) or fresh (soft) thrombus through a low profile, 7-French sheath

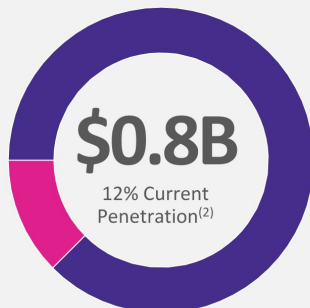
(1) FIM data Charing Cross Symposium: 100% procedure success; 95% of cases did not require thrombolytics; successfully covered wide range of clot and organized debris - Surmodics data on file.

# Pounce™ Thrombectomy System (Arterial): Market Opportunity & Commercial Strategy

## Arterial Clot Removal Annual, Addressable U.S. Market

**185,000**

Peripheral Arterial  
Occlusion Patients



**23,000**

Patients treated with arterial  
clot removal procedure

(1) Patient figures and market penetration based on Management Estimates as well as Public Health and Industry Data  
(2) Total mechanical thrombectomy cases as a percent of total procedures

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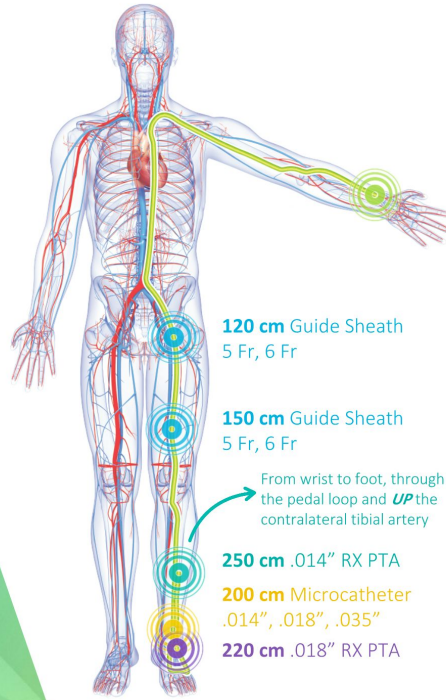
## Commercial Strategy & Strategic Objectives

Commercializing Pounce™ Thrombectomy System in the U.S.  
via direct sales force:

- FY'22 achievements:
  - Hired and onboarded direct sales force
  - Scaled commercialization to include all U.S. territories
  - Launched improved device handle
  - Advanced new product pipeline with Pounce™ LP and XL thrombectomy programs
- FY'23 objectives:
  - Advance commercialization efforts and marketing programs
  - Initiate Pounce™ LP Limited Market Evaluation (LME)
  - Initiate Pounce™ PROWL registry

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**120 cm** Guide Sheath  
5 Fr, 6 Fr

**150 cm** Guide Sheath  
5 Fr, 6 Fr

From wrist to foot, through  
the pedal loop and **UP** the  
contralateral tibial artery

**250 cm** .014" RX PTA

**200 cm** Microcatheter  
.014", .018", .035"

**220 cm** .018" RX PTA

**Sublime™**  
Guide Sheath



**Sublime™**  
Microcatheter



**Sublime**  
RX PTA **014**



**Sublime**  
RX PTA **018**



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# Sublime™ Radial Access: Platform Overview

**Radial Access** is the new frontier in peripheral interventions, with significant benefits, compared with standard transfemoral access, for patients and practitioners alike

## ✓ Reduced complications

50–80% relative risk reduction in access site complication<sup>1,2</sup>

## ✓ Reduced bleeding

47% reduction in major bleeding and a 77% reduction in complications<sup>1,3</sup>

## ✓ Rapid recovery

Quick ambulation and early discharge frees up staff, beds and resources to increase volume<sup>1,4</sup>

## ✓ Positive patient experience

Patients experienced less pain and greater walking ability post-procedure<sup>1,5</sup>

<sup>1</sup>As compared to transfemoral access in coronary procedures

<sup>2</sup>Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *Lancet* 2011;377:1409-20.

<sup>3</sup>Ferrante G, et al. Radial Versus Femoral Access for Coronary Interventions Across the Entire Spectrum of Patients with Coronary Artery Disease. A Meta-Analysis of Randomized Trials. *JACC: Cardiovascular Interv.* Vol 9(14), 25 July 2016:1419-1434.

<sup>4</sup>Lindner SM, McNeely CA, Amin AP. The Value of Transradial: Impact on Patient Satisfaction and Health Care Economics. *Interv Cardiol Clin.* 2020 Jan;9(1):107-115.

<sup>5</sup>Cooper C, El-Shiekh R, Cohen D, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *Am Heart J.* 2010; 138(3), 430-436.

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## Overview

- Designed to treat stenosed arteries from the thigh to the foot via radial (wrist) access point

## Advantages

- **Sublime™ Radial Access** products provide a unique combination of length, profile and deliverability relative to competitive products, allowing physicians to access lesions previously inaccessible from radial access
- **Sublime™ Radial Access Guide Sheath**
  - Kink resistance – 60% better kink resistance<sup>1</sup>
  - Radial Strength – 15% stronger<sup>1</sup>
  - Torque Transmission – 1.3X better torque response<sup>1</sup> resulting in better support and pushability through tough lesions
  - Thin-walled design allows physicians to leverage radial access with more patients
- **Sublime™ RX PTA Dilatation Catheters**
  - Crossability<sup>1</sup> and pushability<sup>1</sup> exceed other PTA balloons
  - Our 250 cm 014" Sublime™ RX PTA catheter is 25% longer than any other commercial 014" PTA balloon

<sup>1</sup>Based on average measurements from bench testing by Surmodics, Inc. Data on file.

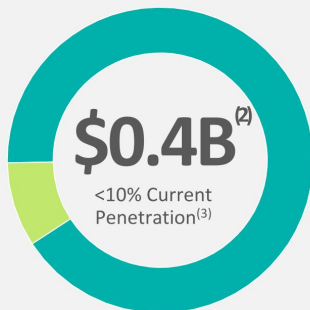


# Sublime™ Radial Access: Market Opportunity & Commercial Strategy

## Radial Access Annual Addressable U.S. Market<sup>(1)</sup>

**840,000**

Patients treated with  
ATK or BTK Interventions



**~75,000**

Patients treated with radial  
access interventions

(1) Patient figures and market penetration based on Management Estimates, iData Research reports as well as Public Health and Industry Data

(2) Estimated market size if all patients were treated with available Sublime™ devices

(3) Total radial access cases as a percent of total procedures

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## Commercial Strategy & Strategic Objectives

Commercializing Sublime™ Radial Access Platform products in the U.S. via direct sales force:

- FY'22 achievements:
  - Hired and onboarded direct sales force
  - Scaled commercialization to include all U.S. territories
  - Drove clinical and market awareness through the execution of radial peer-to-peer training courses
- FY'23 objective:
  - Advance commercialization efforts and marketing programs
  - Achieve FDA 510(k) clearance for Sublime™ Microcatheter and initiate Limited Market Evaluation (LME)

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# Financial Summary

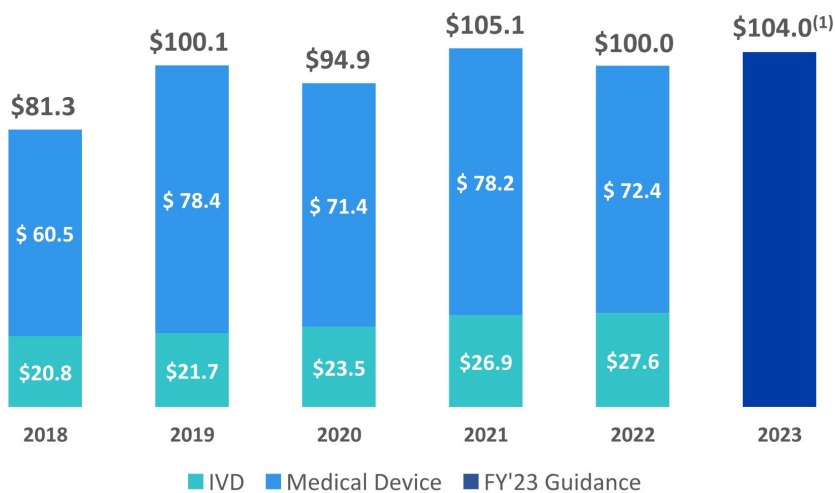
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# Significant Commercial Scale with Multiple Catalysts for Future Growth

- 5-year CAGR of 6.5% through FY'22
- FY'23 Revenue growth to benefit from:
  - Contributions from initial commercialization of key, approved products (Pounce™ System and Sublime™ Platform)
  - Single-digit revenue growth in our Medical Device Coatings and In Vitro Diagnostics offerings

## Annual Revenue - Millions



<sup>(1)</sup> Midpoint of guidance ranging from \$102 - \$106 million

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# FY'23 Financial Guidance Overview

Total Revenue: \$102 to \$106 million, up 2% to 6% year-over-year

GAAP Diluted Loss per Share<sup>(1)</sup>: \$(2.40) to \$(2.00), compared to \$(1.96) in FY'22

Non-GAAP Diluted Loss per Share<sup>(2)</sup>: \$(2.09) to \$(1.69), compared to \$(0.95) in FY'22

- GAAP and Non-GAAP diluted loss per share reflect continued investment in our Pounce™ thrombectomy and Sublime™ radial access products, as well as the impact of the spending reduction plan initiated in the second quarter of our FY'23

(1) GAAP earnings per share is the estimated fiscal 2023 diluted earnings per share as determined by U.S. generally accepted accounting principles.

(2) Non-GAAP earnings per share adjusts GAAP earnings per share for estimated fiscal 2023 acquired intangible amortization totaling \$0.23 per share, net of tax as well as restructuring expenses totaling \$0.08 per share, net of tax.



# Available Capital & Capital Allocation Priorities

**Focused on maintaining liquidity, ensuring access to capital and enhancing cash management...**

## Available Capital (\$M) <sup>(1)</sup>

Cash	\$26.4
Revolving Line-of-Credit <sup>(2)</sup>	\$8.9
Term Loan <sup>(2)</sup>	\$50.0
<b>Total Available Capital</b>	<b>\$85.3</b>

(1) As of December 31, 2022

(2) Our five-year credit agreement with MidCap Financial consists of up to \$100 million in term loan financing (\$25 million at MidCap's discretion) and a \$25 million revolving credit facility, availability of which is based upon eligible inventory and receivables

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**...while positioning Surmodics to generate strong, sustainable growth and enhance future value**

## Invest in Long-term Value Creation

### Support the Core Medical Device Coatings & IVD Businesses

- Optimize revenue and cash flow performance

### Drive Growth of Key New Products

- Support Abbott's U.S. commercialization of SurVeil™ DCB upon FDA Approval
- Advance the initial U.S. commercialization Pounce™ System & Sublime™ Platform products

### Invest in Innovation

- Drug-coated balloons
- Thrombectomy platform
- Radial access platform





# Key Developments & Related Expectations

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# Rapid Progress Towards Clarity of Requirements for Submission of an Amended SurVeil PMA Application



**In January 2023, the FDA informed us that our SurVeil™ DCB PMA application was not approvable, based upon biocompatibility and labeling concerns (the “FDA Letter”)**

- Since receipt of the FDA Letter, we have made significant early progress towards a submission of an amended PMA application:
  - ✓ Multiple discussions with the FDA Management regarding process clarity and pace
  - ✓ A Submission Issues Request (“SIR”), our formal request for a review meeting to discuss the FDA Letter, has been submitted to the FDA, much earlier than previously anticipated
  - ✓ The FDA has responded quickly, and a review meeting is already scheduled

We are confident that the outcome and follow-up from our upcoming FDA meeting will provide clarity on the pathway and requirements to submit an amended PMA application in an approvable form in the near future

# Our Market Development of Pounce™ Thrombectomy and Sublime™ Radial Access is Gaining Traction

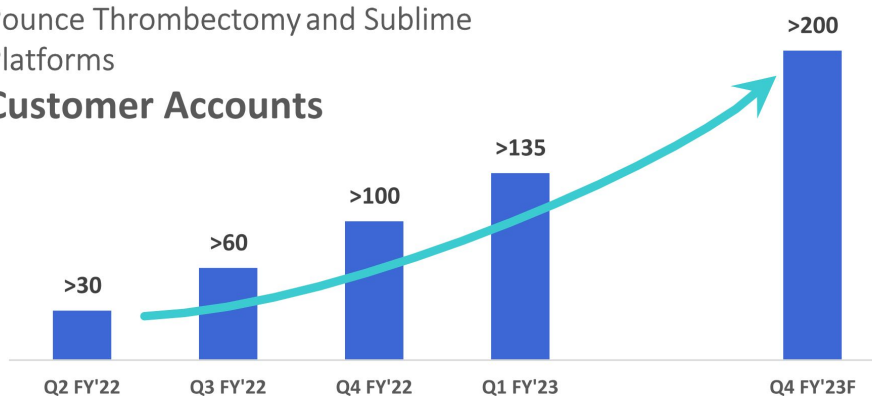
## Pounce™ Thrombectomy (Arterial) and Sublime™ Radial Access platforms together are becoming a growth catalyst

- The customer base has been and is expected to continue to grow sequentially
- We expect continued account growth to drive strong revenue growth, benefiting from a growing pipeline of prospective customers
- Product sales growth is contributing significantly to Surmodics' overall revenue growth

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## Pounce Thrombectomy and Sublime Platforms

### Customer Accounts



**We are targeting to finish FY'23 with:**

**>200 Customers and ≈ 300% Year-Over-Year Revenue Growth**

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 **SURMODICS**

# We are Focused on Improving Cash Flow

## Cash flow improvement to come from multiple sources

- We recently implemented a spending reduction plan and communicated expectations to reduce our quarterly cash use to approximately \$3.5-\$4.0 million beginning Q3 FY'23
- We remain committed to reducing our use of cash and returning to positive cash flow and earnings by:
  - Disciplined ongoing expense management, including our recent spending reduction measures
  - Growth in total revenue and gross profit, driven by strong contributions from sales of our Pounce™ thrombectomy and Sublime™ radial access products

# Summary: Significant Upside Potential

- Surmodics' experienced leadership team is executing a multi-year strategy to drive sustainable, long-term profitable growth
- Our core businesses continue to operate at a significant commercial scale, generating strong, predictable cash flow
- The successful commercial launch and early market development of multiple, innovative vascular intervention devices, each focused on large, underpenetrated markets, has begun to impact our revenue growth significantly in FY'23
- Our innovative product pipeline, including our SurVeil™ DCB, and important additions to our Pounce™ Thrombectomy and Sublime™ Radial Access platforms are promising catalysts in multiple, high-growth market segments
- We have recently enhanced our balance sheet and access to capital to support our strategic initiatives, while also reducing spending and prioritizing investment in our key strategic growth initiatives

Caution: SURVEIL Drug-Coated Balloons are investigational devices.  
Limited by Federal (or United States) law to investigational use.

Caution: Federal (US) law restricts POUNCE and SUBLIME devices to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

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# Appendix

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# Strategic Agreement with Abbott



**Abbott**



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## February 27, 2018 – Abbott and Surmodics Announced Agreement for Next-Generation Drug-Coated Balloon Development and Commercialization

- Exclusive worldwide commercialization rights for SurVeil™ drug-coated balloon (DCB) for superficial femoral artery (SFA)
- We have received \$60.8 million in total milestones from Abbott
- Final milestone of \$27 million (\$24 million if achieved after June 30, 2023) due upon receipt of PMA approval from the FDA provided Abbott chooses to commercialize the product and does not exercise their right to terminate the agreement if PMA approval is obtained after December 31, 2023
- Revenue to be realized from product sales to Abbott, including a base transfer price plus a share of profits from Abbott sales of the device

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 **SURMODICS**

# Surveil™ DCB: Impact to Financials

**\$61M of the potential \$88M** of Surveil™ DCB upfront and potential milestone **payments** have been achieved through Q1 FY2023

Payment	Amount	Date
Upfront License Fee	\$25M	Feb 2018
TRANSCEND Enrollment Milestone	\$10M	Aug 2019
CE Mark Milestone	\$10.8M	June 2020
Clinical Report Milestone	\$15M	Feb 2021

**~87% of the estimated total \$35M – \$40M TRANSCEND Clinical Study costs** were incurred through Q1 2023

Upfront and milestone revenue is recognized based upon the % of the TRANSCEND study costs incurred<sup>(1)</sup>

Caution: SURVEIL Drug-Coated Balloons are investigational devices. Limited by Federal (or United States) law to investigational use.

## TRANSCEND Study Cost Schedule<sup>(1)</sup>

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Value Creating Event	Abbott Agreement Signed	TRANSCEND Enrollment Complete	CE Mark Received	Final Clinical Report Delivered				5-year Follow-Up Complete
Estimated % of TRANSCEND Study Costs Incurred <sup>(1)</sup>	~18%	~51%	~65%	~76%	~85%	~92%	~97%	~100%

## Surveil™ Milestone Revenue Recognition Schedule

Revenue (\$ in millions)	FY 2021A	FY 2022A	FY 2023E
Upfront License Fee	\$2.6	\$2.3	\$1.6 - 1.8
TRANSCEND Completion Milestone	1.0	0.9	0.7 - 0.8
CE Mark Milestone	1.1	1.1	0.7 - 0.8
Clinical Report Milestone	11.3	1.0	1.0 - 1.1
PMA Approval Milestone	-	-	-
<b>Total Surveil Upfront &amp; Milestone Revenue</b>	<b>\$16.0</b>	<b>\$5.7</b>	<b>\$4.0 – 4.5</b>
Cumulative Revenue	\$45.9	\$51.6	\$55.6 - \$56.1
% recognized <sup>(1)</sup>	~76%	~85%	~92%

(1) TRANSCEND costs incurred following the execution of the Surveil™ DCB development and distribution agreement with Abbott Vascular and not the actual cost from study inception

We expect to recognize the entire \$60.8 million associated with the license fee and achieved milestones over the period ending fiscal 2025; revenue from the up-to \$27 million of outstanding milestones (if any) will be recognized over the same time period, beginning in the period of achievement

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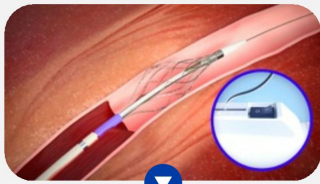




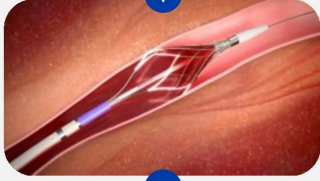
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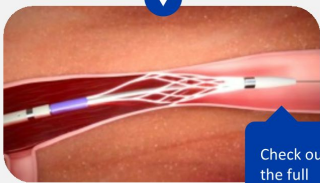
# Pounce Venous Thrombectomy: Product Overview



The basket is expanded to maintain vessel wall contact. (vessel range 6 - 16 mm)



The extraction screw is activated and removes clot at the point of collection.



The basket dynamically adjusts to vessel anatomy, controlled by a constant-tension spring located in the handle.

Check out the full animation



**Caution:** Federal (US) law restricts these devices to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

## Overview

- Designed to separate, macerate and remove clots from occluded veins in the peripheral vasculature

## Advantages

- Shorter device profile, compared to competitive mechanical devices, simplifies the procedure
- Lower profile, 10 French design reduces potential for access site complications
- Uniquely designed to limit the number of passes required to remove the clot, resulting in lower procedure time and fewer potential complications
- No use of lytic drugs required in most cases<sup>(1)</sup>

<sup>(1)</sup> No thrombolytics used in 84.2% of cases in a 19-patient clinical study.

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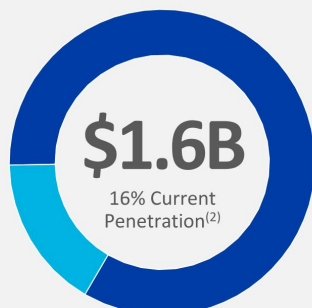


# Pounce™ Venous Thrombectomy: Market Opportunity & Commercial Strategy

Venous clot removal, Including Deep  
Vein Thrombosis (DVT)<sup>(1)</sup> Annual,  
Addressable U.S. Market

**270,000**

Addressable  
Procedures<sup>(1)</sup>



**\$1.6B**

16% Current  
Penetration<sup>(2)</sup>

**44,000**

Patients treated with  
mechanical thrombectomy

(1) Our devices have not received DVT disease state clinical indication clearance at this time. Patient figures based on Management Estimates as well as Public Health and Industry Data

(2) Total mechanical-only clot removal cases as a percent of total procedures

## Commercial Strategy & Strategic Objectives

Commercializing Pounce™ Thrombectomy System and the Sublime™ Radial Access Platform products in the U.S. via direct sales force:

- Commercializing Sublime & Pounce products in the U.S. via direct sales force
  - FY'22 objectives:
    - Completed manufacturing validations
  - FY'23 objective:
    - Conduct Pounce™ Venous Thrombectomy System clinical product evaluations

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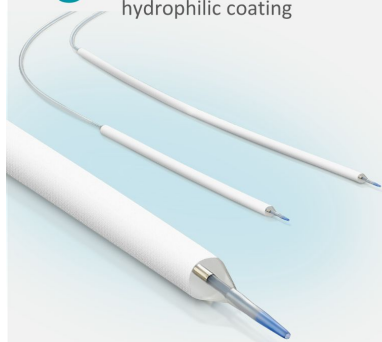


# Sundance™ Sirolimus-coated Balloon: Product Overview

**1 Uniform sirolimus drug coating**  
Sirolimus + Proprietary Excipient  
360° uniform coating coverage

**2 Surmodics .014" PTA platform**  
2 – 4 mm diameter  
20 – 220 mm lengths

**3 Hydrophilic shaft coating**  
Surmodics Serene™  
hydrophilic coating



**Caution:** SUNDANCE Drug-Coated Balloons are investigational devices. Limited by Federal (or United States) law to investigational use.

## Overview

- Designed to treat peripheral artery disease in the vessels below the knee using a proprietary drug-excipient formulation to reduce the likelihood of restenosis

## Advantages<sup>(1)</sup>

- Excellent drug coating durability
- Higher levels of drug transfer and unique ability to achieve sustained therapeutic levels in tissue
- Robust, lasting biological effect

## Clinical Evidence

- SWING first-in-human (FIH) study results presented at the 2022 Amputation Prevention Symposium in Lugano, Switzerland by Dr. Ramon Varcoe
- FIH data demonstrating an excellent safety profile and the lowest binary restenosis at six months (36%), compared to relevant below-the-knee trials

(1) Based on average measurements from bench and preclinical testing sponsored by Surmodics, Inc. Data on file.

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# Medical Device Coatings

## Performance COATINGS



HYDROPHILIC



HEMOCOMPATIBLE



DRUG-DELIVERY

# The Magic Is In The Coating

## Estimated Distribution of Surmodics' Royalty Revenues

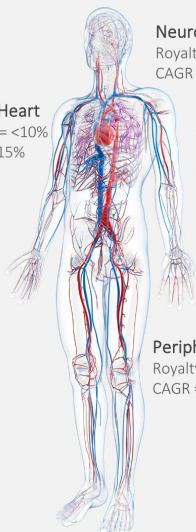
ROYALTY REVENUE DISTRIBUTION<sup>1,2</sup>

<10%

25%-35%

### Structural Heart

Royalty Rev = <10%  
CAGR = 12-15%



### Neurological

Royalty Rev = 25-35%  
CAGR = 5-9%

### Cardiovascular

Royalty Rev = 25-35%  
CAGR = (1)-2%

### Peripheral Vascular

Royalty Rev = 25-35%  
CAGR = 4-6%

1. Based upon Surmodics' historical royalty revenue mix  
2. CAGRs = Needham & Associates and Company estimates

Surmodics' coatings are critical to the successful delivery of medical devices used in complex procedures where maneuverability and control are essential



### Hydrophilic

Low friction and low particulates to improve deliverability



### Hemocompatible

Active and passive coatings; customizable to blood compatibility and durability requirements



### Drug-Delivery

Durable and biodegradable coatings using proprietary polymers to control delivery rates and mechanical properties

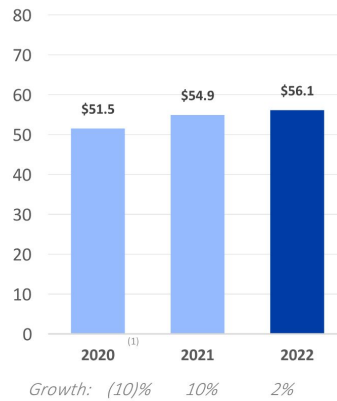


# A Stable Foundation For Future Growth

## Medical Device Coatings

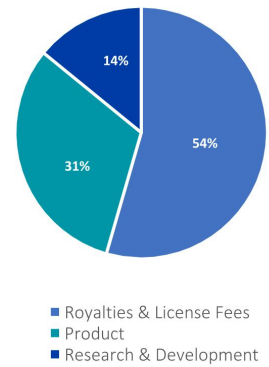
- Over 150 license agreements among 100 customers
- 34 U.S. patents issued; 79 International patents Issued
- Royalty rates for new licenses typically range from 2-3% for the device application
- Product gross margins on the high end of medical device industry averages
- Our Medical Device Coatings revenue is expected grow in the low-to-mid-single digits, annually

ANNUAL COATINGS REVENUE  
(MILLIONS)

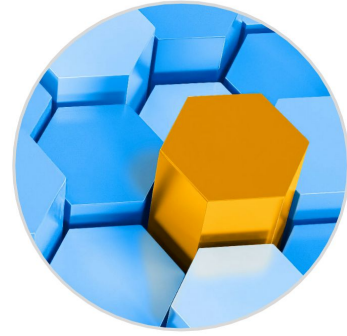


*(1) Impacted by COVID-19 as well as patent expiration for our 4th generation coating*

REVENUE BREAKDOWN



# In Vitro Diagnostics (IVD)



**AMP UP THE SIGNAL.**  
DIAL DOWN THE NOISE.

# Leading Provider of Components for In Vitro Diagnostic (IVD) Tests



Protein stabilizers, diluents & blockers



ELISA substrates



Microarray slides & surfaces



Antigens & antibodies from DIARECT™ part of BBI solutions™



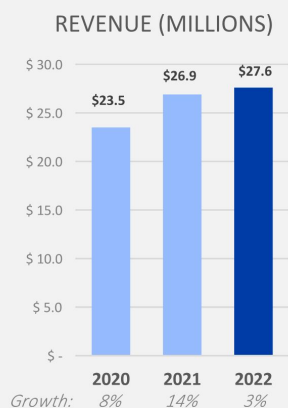
Stop solutions & support reagents

## In Vitro Diagnostics

- Our components are used in test kits sold by the majority of the top ten global in vitro diagnostics companies
- > 1000 unique customers in several categories: Kit manufacturers, R&D institutions, Distributors and OEM's
- Point of care testing and regulatory changes are disrupting the market and represent opportunity for market share growth

# Continued Outstanding Results

## IN VITRO DIAGNOSTICS



- Our IVD business is expected to continue to deliver low-to-mid-single digit revenue growth annually
- Strong and growing customer base with broad portfolio of differentiated products
- Strong operating margin of approximately 47% of revenue, or \$13.1 million in FY2022
- The \$15-\$17B global immunoassay market is expected to grow 2-3%, annually<sup>1)</sup>

1. Global market based on management estimates as well as industry data

# Clinical Advisors



**Gary Ansel, MD, FACC**  
**Clinical Advisor** — Interventional  
 Cardiology  
 Healthcare Insights



**Stephen Black, MD**  
**Clinical Advisor** — Vascular Surgeon  
 St. Thomas Hospital



**Marianne Brodmann MD, PhD**  
**Clinical Advisor** — Interventional Cardiology  
 Division of Angiology Medical University Graz



**William Gray, MD**  
**Clinical Advisor** — System Chief,  
 Division of Cardiovascular Disease  
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## CLINICAL ADVISORS



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 Ohio Health Heart and Vascular Service



**Michael Lichtenberg,**  
**Clinical Advisor** — Interventional  
 Angiologist  
 Klinikum Hochsauerland



**Constantino Peña, MD**  
**Clinical Advisor** — Vascular and  
 Interventional Radiology  
 Miami Cardiac & Vascular Institute



**Ken Rosenfield, MD**  
**Chair Advisory Board** —  
 Interventional Cardiology  
 Massachusetts General Hospital



**Peter Schneider, MD**  
**Clinical Advisor** — Vascular Surgery  
 University California San Francisco



**Prof. Ramon Varcoe**  
**Clinical Advisor** — Vascular Surgeon  
 Prince of Wales Hospital



**Renu Virmani, MD, FACC**  
**Clinical Advisor** — Cardiovascular  
 Pathologist  
 CVPath