



Robotic Surgical Procedure to Address Alzheimer's

February 9, 2026



1



Introduction

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BIOSTAR CAPITAL

Managing Director

Corindus Vascular Robotics

President & CEO

Boston Scientific

Senior Vice President

MOON SURGICAL

AVS

PULSE ENTRAVASCULAR UTHOTRIM

HORIZON SURGICAL SYSTEMS

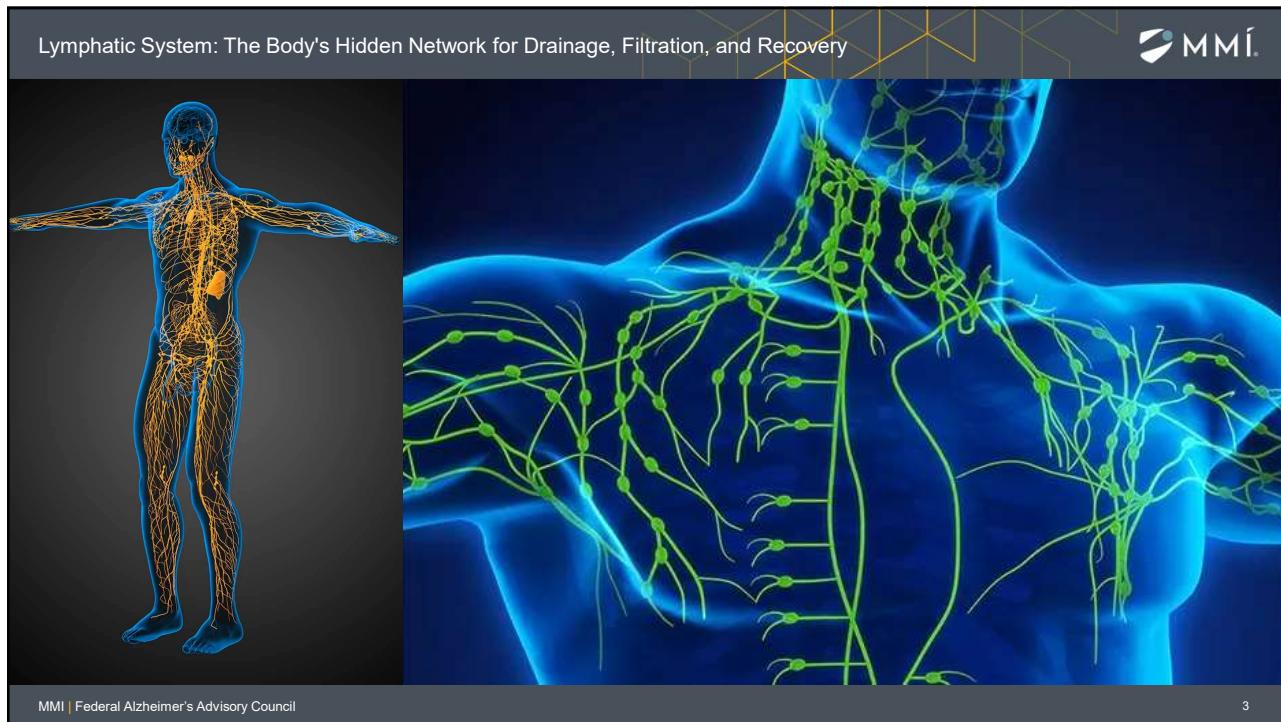
HYPERION

Mark Toland

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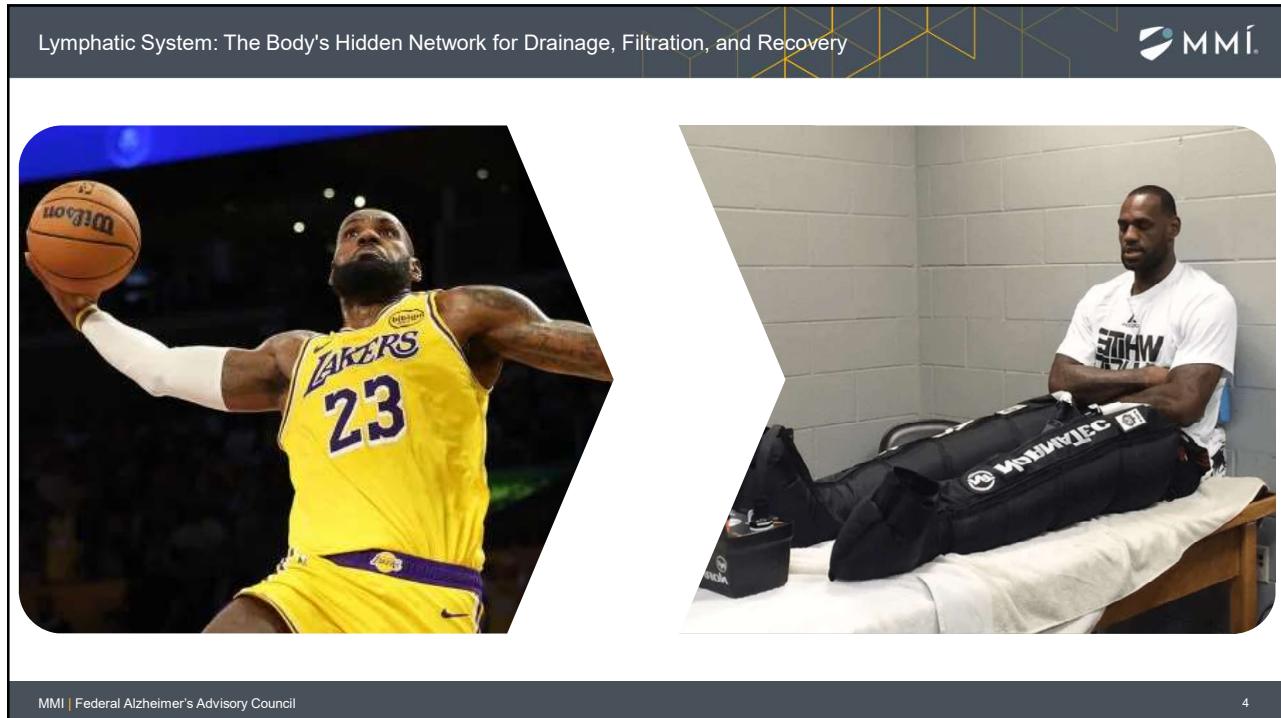
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2



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3



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4

2

Discovering the Brain Lymphatic System

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Discovery (2015)

Functionality

Treatment Proposal (2025)

Lymphatic vessels discovered in CNS

Improving lymphatic drainage in people with Alzheimer's could lead to better outcomes

Recognizing the Lymphatic - Neurodegenerative Diseases
[Link](#)

A Proposed Role for Lymphatic Supermicrosurgery in the Management of Alzheimer's Disease: A Primer for Reconstructive Microsurgeons

Sponsored by MMI

JP Hong, MD, PhD
Professor and Chief
Department of Plastic and Reconstructive Surgery
Asan Medical Center, Seoul South Korea

5

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Lymphatic Vessels Discovered in Central Nervous System | National
Meningeal lymphatic vessels at the skull base drain cerebrospinal fluid | Nature
Boosting brain's waste removal system could improve Alzheimer's outcomes | National Institutes of Health (NIH)

Promising outcomes 5 weeks after a surgical cervical shunting procedure to unclog cerebral lymphatic systems in a patient with Alzheimer's disease | General Psychiatry
Thieme E-Journals - Archives of Plastic Surgery / Abstract

Patient-Driven Demand Accelerating Science

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>5,000 Lymphatic Surgeries completed with promising results

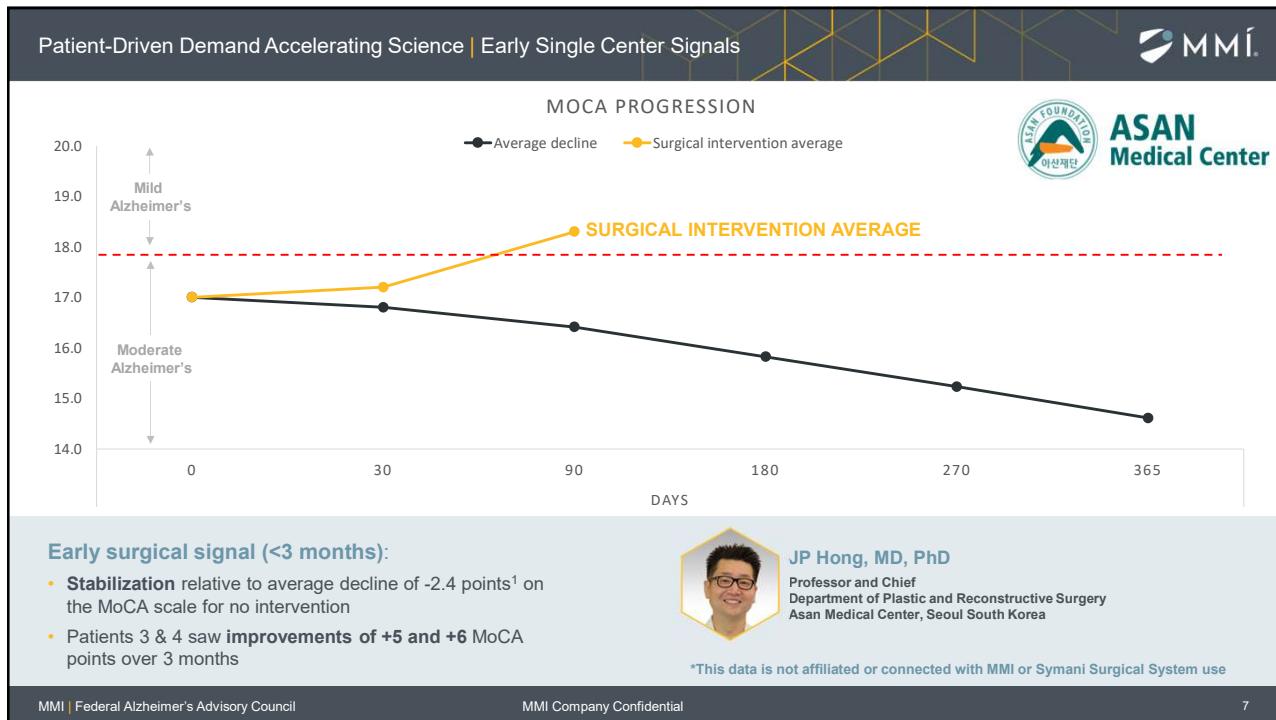
Patients exhibiting cognitive and motor function improvements shortly after procedure¹

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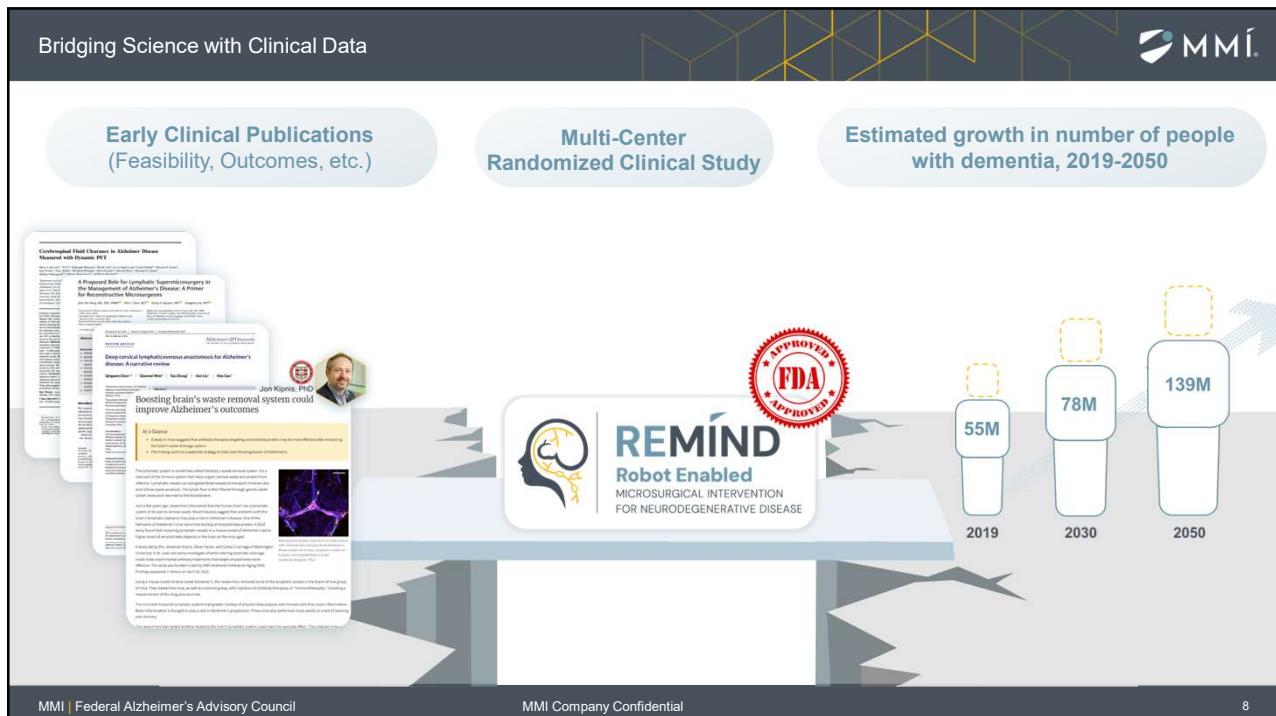
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1. Jianping Ye et al. A Surgical Therapy for Alzheimer's disease with lymphaticovenular anastomosis. Sage, Journal of Alzheimer's Disease Reports. September 2025.

6



7



8

Industry-Driven Research

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FDA APPROVED

September 5, 2023

MMI North America, Inc.
Via Zamboni 30
US Regulatory Affairs Specialist
Microsurgical Intervention, Inc.
Via Eraldo Giannini 54
Pisa, Italy
0502055

Re: G20205
Title: Device Name: Syntac Surgical System
Dated: August 6, 2023
Page: 7 of 7255
CRS Category: A
Attachment: 1 of 1 One Year from the Date of This Letter

Dear Zamboni Amico:

The Food and Drug Administration (FDA) has reviewed your Investigational Device Exemption (IDE) application regarding your feasibility study ("REMIND Robot-Enabled Microsurgical Intervention for Neurodegenerative Disease: Early Feasibility Safety Study") for a significant risk device. Your submission was amended via results dated:

- September 4, 2023, to revise the clinical study protocol to clarify the technical requirements of each subject and the number of subjects required for each procedure (microsurgical intervention) and add study stopping rules.
- September 4, 2023, to revise the clinical study protocol to clarify the study stopping rules language, provide a revised draft of the data and safety monitoring board (DSMB) charter with clarifications on the DSMB's role in the study, and provide a revised DSMB meeting and revisions to the informed consent document (ICD) to clarify the study risks.

FDA has determined you have provided sufficient data in support initiation of a pivotal clinical study, this amendment is acceptable, and the revised investigation is safe to proceed. Your IDE application is therefore approved, and you may begin your investigation after you have obtained institutional review board (IRB) approval. Your investigation is limited to 3 United States (U.S.) institutions and 5 U.S. subjects.

Your IDE application has been approved as a staged study. You may request approval to expand enrollment to additional sites and additional subjects after the first 4 subjects are enrolled. Your IDE application provides the procedure and 30-day follow-up safety data for the first 4 subjects treated in the study and are comprised DSMB meeting minutes.

U.S. Food & Drug Administration
Silver Spring, MD 20993

Clinical Application

Study Design

2026

2027

2028

Alzheimer's Lymphatic Repair

Alzheimer's Lymphatic Repair

Multi center, early feasibility safety study (15 patients, 3 sites)

Multi center, pivotal safety and efficacy study (300 patients, 30 sites)

Enrollment

Enrollment

24-30 Month Sprint: Generating clinical data and securing regulatory approval, alongside strong interest from providers, payers, investors and government agencies

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9

REMIND EFS Site Update

Sites In Progress
(up to 3 sites FDA approved)

BAPTIST HEALTH

Stanford MEDICINE

JACOBS INSTITUTE

YALE NEW HAVEN HEALTH

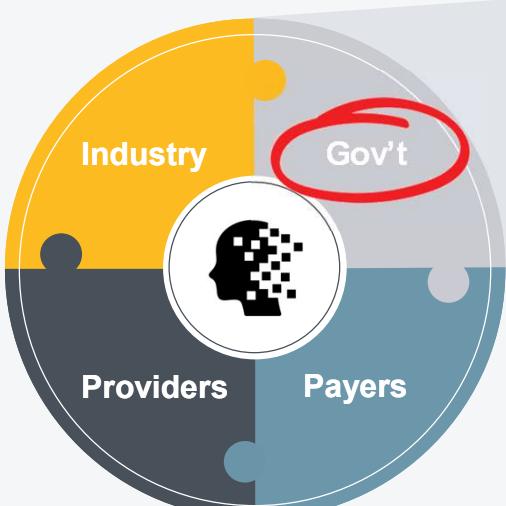
Staged Study Design

- » Patients Enrolled – 5
- » FDA review
- » Patients Enrolled- 10

10

Next 24 Months: Essential Government Levers for Surgical Alzheimer's Innovation

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Essential Government Levers

- Clinical Study Approval**
September 2025
- Funding to Accelerate Clinical Data**
2026
NIH
- Scalability with Pre Market Clearance**
2027 / 2028
FDA | NIH | CMS

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11