# ACHEVING ENDOVASCULAR EXCELLENCE

We believe in changing the paradigm for improvement in healthcare





# **WE BELIEVE ...** IN THE POWER OF COLLABORATION

Welcome to the Jacobs Institute's Simulator Laboratory. We are delighted to announce our partnership with Mentice. In collaboration, Mentice and the Jacobs Institute provide an unparalleled simulator program borne from firstclass technology and rooted in a clinical setting. Simulators provide a cost effective, life-like alternative to animal models. Naturally, better training reduces potential for litigation. Studies show that the Mentice VIST is a safe, effective playground to test new devices. Our partnership with Mentice begins a new chapter in medical collaboration and innovation. We sincerely hope you enjoy your time at the Jacobs Institute and your experience with the Mentice Vist-Lab.

### DR. L. NELSON HOPKINS



L. Nelson Hopkins, MD **Chief Executive Officer** The lacobs Institute

At Mentice we are passionate about changing the training paradigm in healthcare. Today, very few argues against the use of simulation but still most training is performed according to the traditional apprentice model. No physician should be allowed to operate on a real patient prior to acquiring and verifying the appropriate skills in a simulated and safe environment. The Jacobs Institute, under the leadership of Dr Nick Hopkins, is clearly leading the way by integrating a multi-disciplinary practice together with a world class training center. We are very excited about the opportunity to be working together with the Jacobs Institute in our mission to change the way we view the use of simulation.

#### GÖRAN MALMBERG



**Chief Executive** Officer/President Mentice AB

**"COME INNOVATE WITH US,** WHERE IDEAS IMPROVE LIVES..."

# THE JACOBS INSTITUTE

**Playground for Innovation** 

Created in memory of the late Lawrence D. Jacobs, MD, by his brother Jeremy Jacobs and his family, the Jacobs Institute is dedicated to creating next-generation technologies in vascular medicine through collaboration of clinicians, researchers, industry, and entrepreneurs.

Located on the Buffalo Niagara Medical Campus, the Jacobs Institute strategically sits between University at Buffalo's Clinical and Translational Research Center and Kaleida Health's Gates Vascular Institute. The Institute inspires collisions and collaborations of the best minds, along with industry, to:

- Develop the next generation of medical technology in global vascular devices in our i2C (idea to Commercialization)
- Advance physician training by offering the latest simulation technologies in our Training Center
- Support the recruitment of world class clinicians, academics, researchers, and entrepreneurs in global vascular diseases

## THE JACOBS INSTITUTE'S

Transdisciplinary Approach to Improve Public Health

Interactions among the different vascular disciplines and vascular scientists are limited by distance and work schedules. Scientists are usually on a separate campus and in different departments, typically with little interdepartmental interaction. While the ability to collaborate across disciplines is well-established as a strategy in many fields, its practice in medicine remains perfunctory at best.

When appropriate translational research scientists (engineers, physicists, cell biologists.) interact with specialists in vascular intervention (cardiologists, vascular surgeons, radiologists, neurologists, and neurosurgeons), fascinating synergies arise. Problem solving is enhanced. Patient care is improved. Innovations in medicine are generated, and op-





portunities for entrepreneurship arise. We have a unique opportunity at Gates Vascular Institute, the Jacobs Institute, UB Clinical and Translational Research Center, and the Toshiba Stroke and Vascular Research Center. In a building designed around breaking silos and forcing transdisciplinary collisions, we can develop, harness, and test these strategies and their effects on delivery, research, and training for vascular disease.

The Jacobs Institute's unique model and situation makes it the ideal place to institute behaviors and actuate strategies to fully explore and develop transdisciplinary collaboration, to improve public health.

# **INDUSTRY PATHWAY** FOR SUCCESS

TRANSDISCIPLINARY APPROACH TO IMPROVE PUBLIC HEALTH

The Jacobs Institute is pleased to offer our partners a variety of services devoted to training and streamlining the product development process by providing related functions in our space including:

### PARTNERSHIPS TO TREAT Vascular disease

Collaboration at its core involves connecting previously unrelated professions. The Jacobs Institute develops unique, strategic industry partnerships through collaboration. We take pride in establishing partners in manufacturing, simulation, product development,

physician training, and more. The Jacobs Institute forges relationships that advance the treatment of vascular disease.

### **TRAINING PHYSICIANS BETTER**

Physicians learning new techniques, industry representatives, and students all need to train and hone their surgical skills. Training Center equipment includes multiple work stations and equipment, vascular models, simulation devices, imaging, and more, necessary for maximizing physician training. We aim to be the preeminent east coast training facility, making Buffalo a destination for companies seeking a high-tech space and top-notch physician expertise.

## İ2C

The JI's idea to Commercialization Center (i2C) provides a place where scientists, clinicians, entrepreneurs, small businesses, and industry partners can come develop, test, and ultimately commercialize next-generation vascular medical devices.

## CUSTOMIZED, LIFE-LIKE SURGERY SIMULATION

There is a tremendous need in the vascular interventional community for human vascular simulators that realistically replicate surgical techniques performed in a human body.increase safety by providing the opportunity to train physicians and to practice noninvasive catheter techniques before applying them in real patients. Additionally, simulators and robots enable medical professionals to test a vascular device's performance for product development or improvement.

# **FIRST CLASS SIMULATION** AT THE JACOBS INSTITUTE PRODUCT TESTING. RESEARCH. EXPERIENCE.

The Jacobs Institute provides first-class simulator technology, thanks to Mentice. We provide simulation with numerous modules allowing for endless possibilities. Tailored tutorials are offered to insure a positive experience for you and your guests.

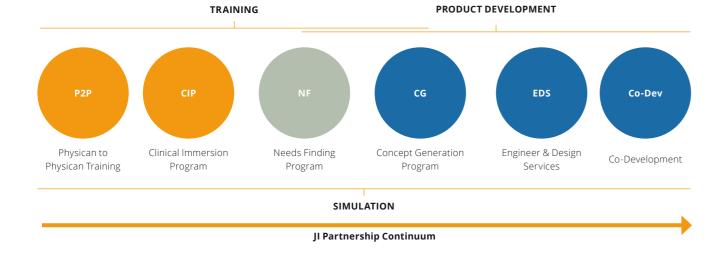
The Jacobs Institute's simulator program caters to an array of disciplines. With Mentice's Case-It ® software, actual patient data can be uploaded for real life simulation allowing users an incredible "hands-on"

experience. The simulator program provides phy-





## JACOBS INSTITUTE INDUSTRY PATHWAY



sicians and students with a life-like alternative to animal models. The Mentice is also a safe and useful tool for industry and entrepreneurs to train and test new devices. Whether interested in training or research and development, the Jacobs Institute's Simulator Laboratory is the first step toward accelerated progress.

If you are interested in learning about procedures, improving your surgical skills, or testing a new device, please contact our Director of Simulation at simulation@jacobsinstitute.com.



# **Services Offered**

### PROCEDURE REHEARSAL

With CASE-IT® software from Mentice, actual patient data can be used to create a testworthy model.

### **DEVICE TRAINING**

The Jacobs Institute offers specific training courses on numerous vascular modules.

# RESEARCH AND DEVELOPMENT

Simulators offer a low-risk alternative for your research and development needs.

## **PRODUCT TESTING**

The Simulator Laboratory can also facilitate product testing.

# COME INNOVATE WITH US...

# **TRAINING AND EDUCATION IMPACT** – MEDICAL ERRORS AND OUTCOMES

# Patient Safety

Patient safety concerns will always be the ultimate priority within healthcare. However, increasingly complex procedures, new treatment options, increasing interdisciplinary collaboration and a growing number of patients are placing very high demands on today's health care providers. This is further aggravated by working time regulations, staff availability, more complex and sophisticated medical devices, in addition to increased medico-legal action.

# Medical Errors

Preventable medical errors occur today in 8–10% of cases. The annual cost for the health care system in the US alone is approximately 37.6 billion USD (of which 17 billion are estimated as preventable)<sup>1</sup>. A 1998 study estimated that 98,000 Americans die due to medical errors each year (exceeding deaths related to motor vehicle accidents (43,000), breast cancer (42,000), and AIDS (17,000)<sup>2</sup>). Similarly, in Sweden: 12% of the hospitalizations resulted in an adverse event with 70% considered preventable<sup>3</sup>.

# Training and Education

A comprehensive and objective oriented training and education program is a prerequisite to ensure that patient safety stays in focus. The objective is to provide the trainee with an environment in which to learn and practice that emulates the actual cath lab while removing unnecessary patient risk.

## Simulation in Medical Training

Simulators allow physicians to practice in a traineefocused environment without the risk of medico-legal liabilities associated with training in a real patient care context.

The simulated environment provides additional modalities, such as exposure to a broad range of patho-logies, management of complications, isolation of specific procedural tasks and the use of additional visualisation for augmented comprehension and immediate feedback. Trainees can practice repetitively and in full confidence.

# Integration in Hospital Processes

Initiatives to minimize medical errors are an integral part of a hospital's Total Quality Management (TQM) process. A systematic Learning and Education program impacts medical outcomes (such as door-to-balloon time, radiation exposure, communication skills, use of advanced devices and new procedures) and productivity (including procedure times, effective use of equipment and devices). Hospitals with medical simulation programs have documented a significant reduction in clinical errors 4-5.

Mentice Simulation Solutions can complement your comprehensive quality management system with the necessary learning and education systems.

# YOUR BIGGEST CONCERN? THE PATIENT!

# YOUR OBJECTIVE: LEARN, TEACH AND BUILD CONFIDENCE

Procedural Skills Training in a Safe Environment

# Learn By Doing

Retention of knowledge is closely linked to the engagement of the trainee<sup>10</sup>. Simulation training provides deep immersion in the procedural environment. Integration of cognitive knowledge with technical skills creates an engaging and challenging atmosphere that allows the acquisition and advancement in medical treatment competence.

# Teach with More Options

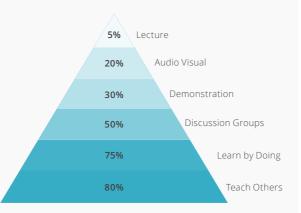
In a simulated environment, additional modalities can be used to strengthen and reinforce the learning experience in a way that real life training never can provide:

- Structures and organ relationships that cannot be seen under fluoroscopy can be visualized (3D visualization for augmented comprehension)
- Critical steps can be practiced over and over again
- Training can be paused and discussed with proctors or peers i.e. can provide immediate performance feedback
- The training can be customised to the needs of the trainee
- Rare events can be safely practiced including team interaction, action analysis and debrief
- Complications can be triggered and resolved
- Objective (quantitative) assessment of technical skills

# Stay Real

The VIST<sup>®</sup> endovascular simulator provides the trainee with the most life-like training experience available today.

The training is based on practicing with real devices and equipment, enabling real techniques with different settings, positioning, handling and deployment possibilities to be learned. This approach to training is very flexible



#### The Pyramid of Learning, D. G. Treichler, 1967

Simulation Training has undisputed advantages over the existing 'learn one, do one, teach one' or apprentice model. This has been confirmed in numerous scientific studies <sup>6-9</sup>.

and does not compromise the quality of the knowledge that the trainee acquires. The training is not completed until the knowledge level has been demonstrated on the simulator.

Mentice's wide range of interventional specialty modules is based on real life cases that provide possibilities for capturing case details for objective assessment, allowing acquisition of expertise and confidence (including making errors) without patient events or harm.

## Get Evidence

Mentice' endovascular simulation solutions are by far the most validated in the industry. This not only provides the trainer and trainee with confidence in the system's usability, but it is also testimony to the level of acceptance, which is based on global scientific research done over the past decade. Mentice simulators have been subjected to studies proving Face Validity (the adequate representation of real world), Content Validity (the completeness of the simulation model), Construct Validity (ability of a tool to measure the trait it purports to measure, often affirmed and inferred by establishing that performance improves with experience). Further studies have addressed Transfer of Skills (if training results in improved performance in reality, which implies that a substantial proportion of the learning task and the transfer task is similar), Concurrent Validity (extent to which the results of the assessment tool correlate with the gold standard for that domain) and Predictive Validity (ability of the training results to predict future performance) <sup>11-20</sup>.

# Build Confidence

Only with the necessary realism and validity that recreates a clinical situation can the trainer develop the necessary confidence for clinical procedures. Mentice VIST® Simulation Solutions have built-in realism, are thoroughly validated and so easy to use, transforming your confidence into a passion for training.



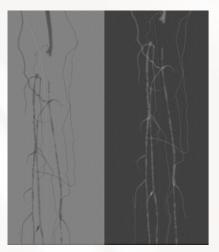
High Fidelity Simulation with Advanced Capabilities



3D view with fossa visualization



**Intuitive User Interface** 



DSA and roadmap functionality

### Real physics simulation

Simulators need to be first and foremost realistic with regards to the intended training objectives. In this respect, Mentice simulators provide the latest in real physics simulation technology, refined with real-life procedural accuracy and utilizing real, actual devices as used in cath-labs all over the world.

### The Virtual Patient

Every VIST® features Cases and Scenarios built from MR, CT or angiographical data and based on the patient's medical report. Mentice develops the virtual patients in collaboration with senior physicians, always with clearcut training objectives in focus. The cases contain demographics, clinical representation, medical history, current medications, lab values and much more information necessary to make a first assessment. Cases and scenarios allow for the selective composition of courses that cater for different levels of expertise and learning using a powerful User Interface across all modules.

A virtual **CathLab** environment mimics all relevant functionality, including state of the art imaging (with full table, C-arm, shutters, image acquisition and management, incl QCA and EF calculation, roadmap/landmarks, fluoro fade, DSA and many more). Advanced functionality is provided, including power injector, aspiration of thrombus, lead placement etc. Additional inte-gration with diagnostic and interventional equipment (such as OCT, FFR, mapping systems and others) is available on request.

Real Procedural Functionalities then allow for the highest available level of realism: operators can choose from the largest set of clinical devices available in the industry (from 0.014" wires to 22F delivery systems). X-ray imaging and device manipulation represent real life response and behaviour, full vitals representation (incl responsive ECG, hemodynamics) add to the immersive experience. Advanced interactions are available in selected procedures (such as deep breathing in transradial coronary) as well as **Complications** Management (such as defibrillation, spasm treatment, dissections, perforations and others). Complex scenario cases are available in selection modules and provide additional challenges in cognitive decision making.

All systems and procedures use real devices (off the shelf), significantly adding realism to the training experience and building up the necessary routine and confidence in using the correct devices that is vital for the acquisition of motor skills. These include complex devices such as recanalisation devices, distal protection devices, coils, ablation catheters, aspiration catheters and transseptal needles.

The system provides immediate debriefing **feedback** by means of visual cues and warnings and as a procedural report at the end of the procedure. These are the key to closed loop learning and complement the proctors' input and observations.

In **summary**, Mentice VIST<sup>®</sup> Simulation Solutions provide the highest available simulation fidelity today - a result of patented, validated and dedicated haptic hardware and a powerful simulation engine – allowing the most realistic emulation of real patients, using real devices in procedures directly derived from patient data.



Integration with real devices (here: ablation catheter)

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VALUE



AAA treated with an endovascular stent graft



TRI access with typical difficulty



AMI patient with clot

# **SIMULATION** – OPPORTUNITIES ABOUND

Medical Simulation Versatility

Mentice VIST<sup>®</sup> simulators provide, due to their flexibility, an ideal simulation solution, which covers mobile and stationary setups, individual and team training, from learning to assessment, from basic motor skills to procedural competence – all in an individually customizable set of procedural modules.

Mobility: Mentice simulators are available in a stationary (VIST<sup>®</sup>-Lab) and a portable (VIST<sup>®</sup> G5) setup. This provides an unmatched versatility covering any kind of training setup (see next page).

**Module Choices:** Customers can choose from a large number of endovascular modules covering all endovascular specialties: radiology, cardiology, vascular surgery, cardiovascular surgery, neuroradiology, electrophysiology, oncology - with new modules being added all the time.

## Enabling objective assessment in different settings

Mentice VIST<sup>®</sup> simulation solutions provide opportunities for measuring performance objectively. Quality standards and standards of proficiency can be evaluated. The use of simulation as a component in the objective certification of skills by statutory bodies is a laudable and achievable goal.

Mentice cooperates with professional medical organizations to define, develop and validate assessment metrics for individual training as well as the certification and recertification of medical professionals.

Mentice simulators can be used in a variety of interactive training formats for teaching and practicing techniques, procedures and teamwork. You have the option to tailor the training approach to the learning objective of each session.

## VIST<sup>®</sup> Simulation Systems

The VIST®-Lab and the VIST® G5 systems share unique advantages in terms of the highest fidelity, clinical realism and use of actual clinical devices.



Full body mannequin, mimics the cath lab environment, one 4K-UHD screen (fluoro, cine and vitals) and a HD touch screen (controls). — VIST<sup>®</sup>-LAB

### VIST<sup>®</sup> G5



Portable high-fidelity simulator, advanced tracking and force feedback, VIST Control Box for fluoroscopy and table controls and HD screen - VIST<sup>®</sup> G5



Dr Elliot Smith, Consultant Cardiologist, Barts and the London NHS Trust, UK.

Individual training

- without proctor.

#### **Training with proctor**

- allowing one-on-one discussion and challenge of decisions made.

#### Small group training -

facilitating peer review and learning from each other.

#### Team training - for

assessing communication skills to optimize patient therapy and prevent medical errors. Allows for procedure planning and discussions on the sequence of the operation in a risk free environment.

#### Specific skill training

- each endovascular procedural step is reproducible, preventing costly mistakes during actual patient care.

#### Master class training

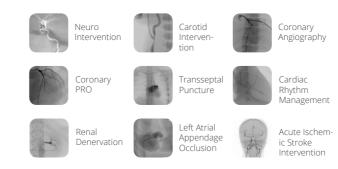
- making it easier to introduce new devices or procedures to large groups.

#### Pre- and post-op train-

ing - to prepare the trainee for patient consultation and potentially stressful situations. Ability to build scenarios and customized clinical protocols to record and report appropriate

### **Mentice<sup>®</sup> Training Modules**

A structured and comprehensive suite of modules with clearly defined learning objectives giving trainees exposure to a wide range of patient scenarios and anatomical variations.



#### Furthermore, industry clients work successfully using one or more of the following options:

details of the procedure. Sales and Marketing product launch promotion and in-service component.

**Product and clinical training** – of industry personnel (sales, marketing and development).

### Professional and clinical **interaction** – with

medical personnel (from novice trainees to experts). Mentice simulation solutions play a vital role in supporting information and training on new procedures

and techniques, by facilitating a uniform and consistent application platform.

#### **Product definition**

and development Mentice simulators provide a valuable test platform for new devices due to their unique true-to-life physics engine. Challenging testing of new devices and features is only one of many new areas where Mentice can make a difference (allowing testing of features, as well as developing best handling).





Uterine Artery



Endovascular



Aortic Valve



Below-the-knee Intervention



Frauma

# **MAXIMIZE** YOUR RETURN

Virtual Reality Simulation Costs and Benefits

In an increasingly tight financial environment, the cost/ benefit ratios are always being questioned. This is why the economical value of simulation is of the utmost importance.

#### REDUCE CATH LAB USAGE

Use of simulation can reduce the actual time residents take up in the cath lab.

#### WORKING TIME REGULATIONS

European/US directives on working time mean significantly less training hours for doctors. Trainees must acquire their skills on fewer patients and therefore simulators provide a viable alternative to procedural cath lab training.

#### ANIMAL LAB COSTS

Aside from ethical considerations, the use of simulators is a cost effective alternative to training on animals<sup>22</sup>.

#### AUTOMATED OBJECTIVE ASSESSMENT VS PURE OBSERVATIONAL ASSESSMENT

Automated objective assessment of trainee progress and performance can significantly reduce the time required to visually assess and validate a trainee's performance.

#### LITIGATION COSTS

Lastly, and the most difficult to capture advantage, lies in the avoidance of litigation, as well as in documenting the provision of training and progress by using simulation.

For industrial customers, the use of simulation has further significant and tangible benefits:

#### DECREASE TIME-TO-MARKET OF NEW DEVICES

Use of dedicated simulators significantly shortens the learning and adoption curve of new devices, both for one's own staff as well as end users, resulting in a faster time to market.

# ACCELERATED ADOPTION OF NEW PROCEDURES

Likewise, simulators can considerably accelerate the uptake of new treatment techniques/procedures.

# PREPARATION FOR CLINICAL TRIALS

In order to ensure all clinical investigators participating in trials for new devices are trained and will perform procedures following a certain protocol, simulation can be a valuable tool.

#### REDUCED USE OF SAMPLES

Using simulated devices and procedures can significantly reduce the number of devices needed for training physicians.

# IMPROVED INTERACTION IN THE INITIAL ROLLOUT PHASE

Using simulation in the early phase of a product launch can help identify and address product and positioning shortfalls early in the process and thus, reduces the costs for late modifications.

#### CUSTOM MADE DEVICES SUITABLE FOR A VARIETY OF MARKETING NEEDS

Mentice, the leader in endovascular simulation, with a comprehensive range of simulation platforms and a dedicated team of industry experts can help you customize simulators to your very specific needs. Contact us for more information.

# "SIMULATOR TRAINING IS 4–16 TIMES LESS EXPENSIVE THAN TRAINING ON ANIMALS"<sup>22</sup>

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# **IMPROVING** PATIENT SAFETY

**FOUNDED IN 1999,** Mentice is the world leader in endovascular medical simulation, providing qualified solutions for training and assessment of medical professionals. With a focus on minimally invasive techniques and procedures, Mentice enables training in a realistic, riskfree environment.

**MENTICE INTRODUCED** the world's first endovascular simulator in 2001 – the VIST<sup>®</sup> – and has since been the market leader with the world's largest install base of simulators for endovascular intervention.

**MENTICE SIMULATORS** are the most validated endovascular training systems. The advantages are well documented and include, enhancing clinical performance, reducing cost, and, ultimately, Improving Patient Safety.

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