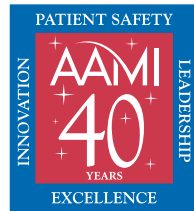




The Founding of AAMI



In the mid-1960s, a group of pioneering physicians, inventors, and manufacturers looked into the future and saw possibility. They realized that breakthroughs with transistors, plastics, synthetic materials, and modernized manufacturing processes had the potential to launch a Golden Age for medical devices, opening the door to treatments that only a few years earlier would not have been possible. They also knew that without vision and leadership, the doors to this promising future might never be fully opened. Without effective standards, appropriate regulation, education, and better support of a young, emerging industry—then a plethora of small companies—brilliant medical devices might never achieve their full potential to save lives.

These physicians and inventors knew that in order to bring new technologies and new treatments to patients, they would need to generate industry-wide cooperation and interdisciplinary communication among those who would be able to help usher in this Golden Age. They would need the help of the physicians who inspired, invented, and used medical devices; the manufacturing industry that would build safe devices and deliver them to the point of care; engineering personnel who would maintain the devices; and a government eager to bring medical devices under its regulatory watch.

The story of AAMI's founding is the story of how a diverse group of experts who shared an interest in the advancement and safety of medical devices worked together to create a new organization, one that would ensure that the promise of emerging technologies would be realized.

*CLOCKWISE, FROM
TOP LEFT: The six
members of AAMI's first
Manufacturer's Advisory
Board, formed in 1965.
John Post, Warren (Zeph)
Lane, Arthur C. Beall,
and Bob Allen at an
early AAMI meeting.
John Abele in a shot
from a 1966 newsletter.
AAMI's 1967 president
and vice president,
Arthur C. Beall [left]
and Harry Collumbine.
AAMI leaders pose for a
picture during MEDAC '67.*

The Mid-1960s: Explosive Growth in Medical Devices Creates Opportunities, Risks

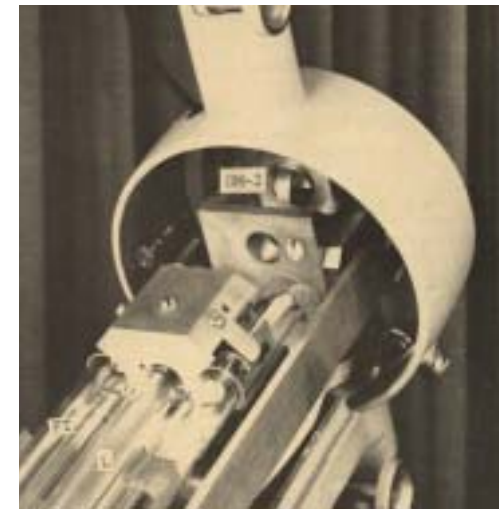
By 1965, the use of medical devices in patient care was expanding rapidly. Medical devices were having a major impact on patient outcomes, and many physicians had a very personal relationship with devices. Physician-inventors like Arthur C. Beall, Jr., and Dwight Harken were struggling to find engineers to translate their ideas into lifesaving medical devices. At the same time, businessmen-engineers like Earl Bakken of Medtronic and John Abele, who later founded Boston Scientific, needed doctors to help their fledgling medical device companies refine and market their products.

Technicians in the armed services like Burt Dodson were running organized medical equipment programs, but the concept hadn't yet made its way into the private sector. Rumblings of problems with equipment safety in hospitals were laying the foundation for the full-blown electrical safety scare of the early 1970s. FDA was looking closely at medical devices, trying to determine how to regulate the technologies that were having such an impact on patient care.

And in Boston, MA, a handful of men looking to capitalize on the medical technology boom created a new organization they named the Association for the Advancement of Medical Instrumentation.



Early devices featured in AAMI's journal, Medical Instrumentation.



40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1965

First *AAMI News* bulletin published September 1.

1966

First AAMI annual meeting, called MEDAC '66, held in July in Boston, MA.

1966

John Post hired, first executive director of AAMI.

1965: AAMI Is Launched

Robert D. Hall, Robert J. Allen, and their colleagues were in the advertising business and worked for small high-tech companies in the Boston area. They had an idea to start an expo and a journal with advertising, hoping to attract manufacturers of medical devices. They approached John Abele, who was then working for a small medical device company, with their idea and recruited him to help them get the organization off the ground.

They realized that they needed to create a structure to attract physicians who could lend legitimacy to their efforts, so in 1965 they filed the articles of organization to create AAMI and began recruiting physicians to serve on its board of directors. The men created a green, pocket-sized pamphlet that described what AAMI was about, and succeeded in getting an article about the new organization in *The New York Times*.



Robert J. Allen and his colleagues in the marketing business came up with the idea of AAMI, generating revenue through an expo and journal.

THE NEW YORK TIMES, SUNDAY, JANUARY 2, 1966

FIELD OF MEDICINE TO GET VITAL AID

Physicians and Makers of Instrumentation Link Up

By JOHN H. FENTON

Special to The New York Times

BOSTON, Jan. 1—The final steps were completed here this week in setting up a communications system between the medical profession and manufacturers of medical instrumentation.

The setup has already been chartered as the Association for the Advancement of Medical Instrumentation, a nonprofit Massachusetts organization. The final acceptances of places on medical and manufacturers' advisory boards have been received.

Dr. John P. Merrill, director of the cardio-renal division of the Peter Bent Brigham Hospital, is chairman of the medical board. John Abele, vice president of Advanced Instruments, Inc., of Newton, Mass., is chairman of the manufacturers' board.

The association, called Amy by its founders, was the result of expressions by medical professionals, researchers, developers and manufacturers of medical instrumentation that there was a serious gap in communications between supplier and user.

The agency is to serve as an international forum for introducing and improving medical instrumentation through evaluation standards, symposiums and exhibitions and education, research and scholarships.

Problem of Transition

Operating on the premise that the proliferation of medical knowledge in the last five years has created a problem in the physician's transition "from the little black bag to the little black box," the new association has scheduled its first symposium in Boston, July 25-29.

Computers are examples of medical instrumentation used for administrative purposes, said Mr. Abele the other day. Those already were automating hospital procedures as well as being used for research analyses, he said.

"Integration of modern communication systems and automatic copying, photographing and printing equipment into hospitals and clinics are also classified as administrative medical instrumentation," Mr. Abele said.

But the transition to the black box, he went on, "has been considerably slowed by lack of meaningful interaction between the medical men and engineering groups."

With the increasing number of patients for each physician, Mr. Abele said, the development and practical use of medical instrumentation will permit the medical man to spend more time with individual patients.

Mr. Abele said that automatic monitoring instruments that recorded vital physical data on several patients at one time and reported those to a central nursing stations was an example of the use of instrumentation.

Need Becomes Critical

"As patients become numbers entered into a hospital computer, the need for radically improved communications between doctors and their engineer collaborators becomes critical," said Mr. Abele.

"Since nonstaff doctors will be entrusting their patients to the care of computerized systems and other automatic medical instrumentation, communicating the techniques, advantages and limitations to them is also important."

Among the companies that have accepted places on the manufacturers' advisory board, in addition to Advanced Instruments, Inc., are the American Optical Company, Arthur D. Little, Consolidated Electrodynamics Corporation, a subsidiary of Bell & Howell Company; International Equipment Corporation and the Smith Kline Instrument Company, a division of Smith Kline & French Laboratories.

Dr. Merrill's medical advisory committee includes Dr. Lewis W. Bluemle, director of the Clinical Research Center, University of Pennsylvania Hospital, Philadelphia; Dr. Milford N. Croll, director of the Nuclear Medicine Center, Hahnemann Medical College and Hospital, Philadelphia, and Dr. Matthey M. Patton, pathologist, Sacred Heart General Hospital, Eugene, Ore.



Where did AAMI's name come from?

Robert D. Hall, an advertising executive, came up with the name Association for the Advancement of Medical Instrumentation as a play on the name of the AAAS, American Association for the Advancement of Science.

1966

First issue of AAMI journal *Medical Instrumentation* published in July.

1967

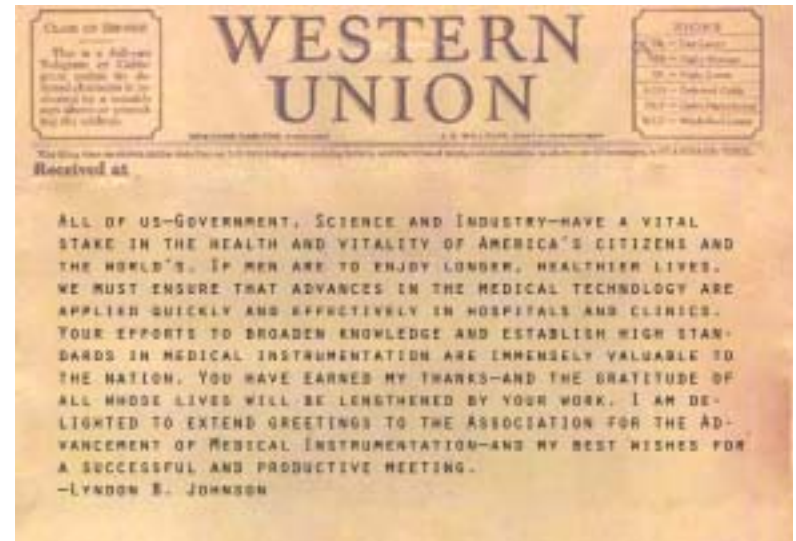
AAMI standards committee, chaired by Charles D. Ray, MD, announces in a March report AAMI's plans to enter the standards arena.

The AAMI Idea Catches On

AAMI's first newsletter appeared on September 1, 1965, and the journal premiered in July 1966. But the event that garnered AAMI the most attention was its first meeting, named MEDAC '66. It was attended by then FDA commissioner James L. Goddard, MD. Leading surgeons such as Beall and Harken, artificial heart pioneers Michael DeBakey and Adrian Kantrowitz, kidney transplant pioneer John Merrill, and cardiac surgeon and inventor Warren Zeph Lane took part in the meeting.

AAMI was an idea whose time had come. Businessmen (and they were all men then) saw an opportunity for visibility, an opportunity to influence the practice of medicine and see their technologies applied earlier. Physicians saw in AAMI an opportunity to develop education programs, standards, and communications that would perpetuate the flourishing development of exciting new technologies. Many were worried about how pending government regulation would affect innovation and development, and they saw the need for interaction between the stakeholders—doctors, industry, government, researchers, and engineers. AAMI was perceived as a vehicle through which diverse groups could achieve consensus on a number of issues that were defining the field.

Fortunately for AAMI, many leaders in the fields of medicine and business came on board to help the organization get started, taking positions as officers or directors. A manufacturer's advisory board and a medical advisory board were created, adding physicians to the leadership who would lend professional legitimacy to the organization. With so many well-known names in medicine on its side, it did not take long for the organization to get off the ground.



President Lyndon B. Johnson sent a congratulatory telegram to AAMI extending best wishes for a successful meeting.

MEDAC '66 was a dynamite meeting. The giants in medicine attended. Those were the people who changed the world.

John Abele



40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1967

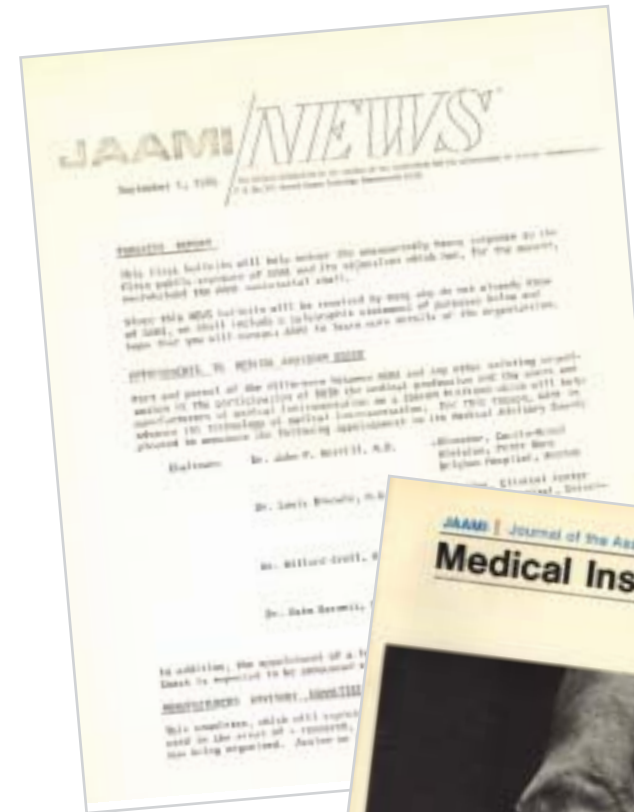
MEDAC '67 held in July in San Francisco, CA. Arthur C. Beall, Jr., MD, elected president.

1967

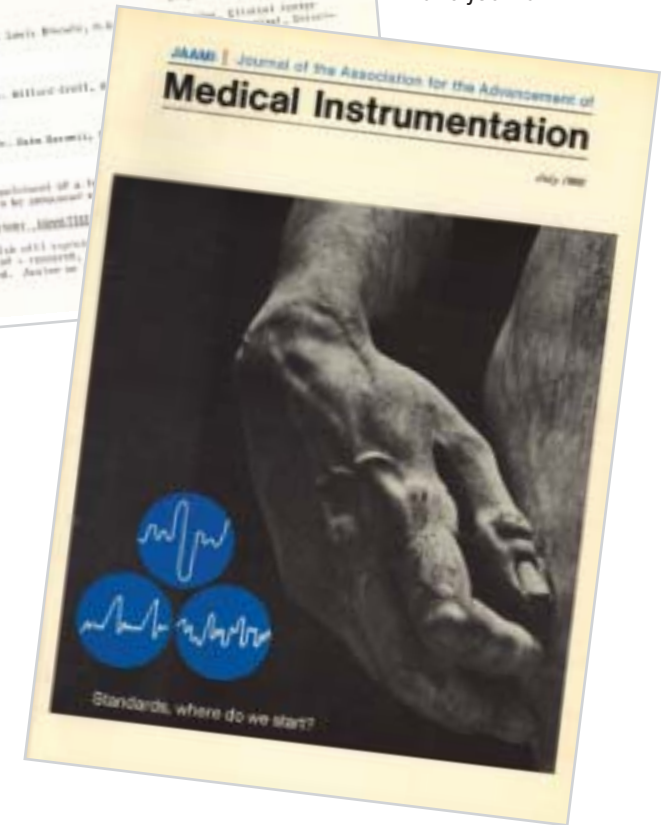
In a September 5 letter, AAMI president Arthur C. Beall announces reorganization of the association, the launch of a fundraising campaign to erase a \$58,000 deficit, and the temporary halt of publication of *Medical Instrumentation* until a new publisher can be found.



Shots from MEDAC '66, AAMI's first meeting.



Cover shots of AAMI's first newsletter and journal.



1967

AAMI announces in November that it will help develop the first biomedical equipment technician (BMET) training programs and study the need for the profession in partnership with the Technical Education Research Center (TERC).

1968

New publishing contract for *Medical Instrumentation* announced with The Williams & Wilkins Company; journal resumes publication with January 1969 issue.

A Bumpy Transition to Physician Control

The transition from the initial organizers to physician control shook up the young organization. Publication of AAMI's journal, *Medical Instrumentation*, was halted while the board found a new publisher—Williams & Wilkins of Baltimore—and a new editor—Harry S. Lipscomb, MD, of the Baylor University College of Medicine. The revamped journal reappeared in January 1969. AAMI's third annual meeting—no longer called MEDAC—took place in Houston, TX, under Beall's leadership.

Significant financial problems also plagued the organization. A 1967 financial review showed that AAMI carried a \$58,000 debt which the board rallied to eliminate. By the end of 1969, with the help of a hugely successful conference on medical device regulation, they had erased the debt and firmly established AAMI as a force in the medical device field.



Warren Zeph Lane [left] as AAMI's treasurer and John Kimbell [right] as one of AAMI's chief fundraisers worked in 1967 and 1968 to erase the \$58,000 debt AAMI had inherited from its earliest leaders.



Harry S. Lipscomb, MD, took over as editor of *Medical Instrumentation* with the July 1968 issue.

Early Leaders Raised Funds to Keep AAMI Afloat

Arthur C. Beall, Jr., and John Kimbell (from Baxter Labs) became AAMI's chief fundraisers. "AAMI borrowed some money from individuals, and in many cases, those debts were forgiven," recalls John Abele. "Art Beall squeezed the arms of his corporate friends, and Medtronic and its founder, Earl Bakken, stepped in and saved AAMI many times."



AAMI Founding—1965 or 1967?

"The real AAMI was created in 1967, despite the founding of the shell that existed prior to that time," says Mike Miller, who came on board as AAMI's chief executive officer in 1969 and still holds that post today. "It's a real tribute to the strength and foresight of those early founders who cared enough and valued the idea of AAMI enough to wrest the organization away and raise the money to keep it going."

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1969

Association office relocated to Washington, DC, area from Boston, MA.

1969

Mike Miller hired as executive director.

1969

Successful fundraising campaigns led by Dwight Harken, Art Beall, and John Kimbell erase debt and give AAMI an operating surplus.

Physician Leaders Position AAMI for Future Success

From 1967 to 1969, AAMI's new physician leaders moved to position AAMI for future success. In light of the new legislative climate that was emerging as FDA regulation of medical devices became inevitable, they relocated the association's headquarters to the Washington, DC, area and began a search for a permanent executive director. They found Mike Miller, who had a law degree and an association management background with experience in lobbying and legislation. In hiring Miller, the board found an executive who would lead AAMI through the next four decades.

Since 1967, AAMI—with its volunteer leaders and growing staff—has had a profound impact on the medical device field. Building on the efforts of its early leaders, the organization has gone on to play key roles in regulation of medical devices, the emergence of the biomedical equipment technician and clinical engineering professions, and the creation of consensus standards and educational programs that have taken on global importance in ensuring the safety of medical devices.

The most important issue facing the young organization was the emerging medical device legislation.



When we interviewed Mike, we could see that he got it, that he was able to see the horizon. Mike understood how to deal with all the constituencies of AAMI and their unique concerns and emotional biases.

John Abele

Mike Miller Recalls the Early Days

"During my early years, volunteer leaders were always there to provide guidance to a very young and inexperienced CEO," says Mike Miller, who has helped to lead AAMI since 1969. He describes those early days as ones of great challenge. "When I arrived at AAMI, two organizational lawsuits were pending; we had no money; we had no staff. Officers had to sign personal notes to make sure payrolls were met. In a sense, AAMI existed in the offices of its leaders."



1969

AAMI holds "A National Conference on Medical Devices," supported through funding from the National Institutes of Health. This conference led to the release of the Cooper Report, which outlined a practical context and framework for legislation that was ultimately approved in the 1976 medical device law.

Founder Profiles

Dr. Beall knew how to work with industry better than anyone. He was devoted to AAMI's mission.

W. Gerald Rainer, MD

Dr. Beall was the epitome of a surgical statesman. He was a mentor to me and hundreds of surgeons he trained.

Kenneth L. Mattox, MD



The Beall Mitral Valve Prosthesis.

Arthur C. Beall, Jr., MD

Dr. Arthur C. Beall, Jr., was one of AAMI's leading founding physicians and served as AAMI's president in its formative years, from 1967 to 1969. He served on AAMI's Board of Directors for many years after and chaired most AAMI committees at one time or another. He helped create the concept of the Annual Conference, membership, standards program, journal, and a number of programs that exist today as he envisioned them. Working with other leaders in the field, Beall helped to develop the leadership and financial support necessary to move AAMI from a young and developing organization to what it is today.

Beall played a leading role in AAMI's efforts to ensure that medical device regulation reflected (and did not hinder) the unique contributions of medical device technology. Along with Dwight E. Harken, MD, Beall was one of the primary people who effectively conveyed the perspective of the patient, medical, industrial, and engineering community to the U.S. Congress. Beall was often referred to as the "Surgical Senator."

Beyond AAMI, Beall made a significant contribution to the healthcare field in general. He was a cardiac surgeon on the faculty of Baylor College of Medicine. In his research endeavors, Beall was well-known in the field of heart valve replacement, at one time developing a valve of his own design, which for several years was one of the most popular mitral valves.



No one contributed more to AAMI's inception, goals, and basic concept than Dr. Beall.

Mike Miller

Art Beall was a mover and a groover, the driving force in lobbying for reasonable legislation.

He projected a good image for AAMI and was an excellent front man.

Larry Pilot

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1970

10 First Arthur C. Beall, Jr., MD Commemorative Lecture delivered by Dwight Harken, MD, during AAMI Annual Meeting. Harken was a last-minute stand-in for scheduled speaker Dr. Carl Walter, who came down with a sudden illness. Short on preparation time but true to form, Harken's presentation on periontogenic diseases was a highlight of the conference. In 1994, Beall would insist that the name of the lecture be changed in honor of his friend and colleague Harken. Beall secured a \$35,000 endowment from Michael W. Dunaway, CEO of PSICOR, to sponsor the award, which to this day is known as the AAMI/PSICOR Dwight Harken, MD Memorial Lecture.



AAMI founders Art Beall [left] and Dwight Harken in 1984.

Dwight Emary Harken, MD

Dwight Harken was one of the driving forces in AAMI's creation in the 1960s and a leader in the association for many years. He served as AAMI's president from 1969 to 1970. It was he who organized the 1969 National Conference on Medical Device Regulation held in Bethesda, MD. This conference led to the release of the Cooper Report which outlined a practical context and framework for legislation that was ultimately approved in the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Significantly for AAMI, this conference was also a financial success and gave the young organization a firm financial foundation for the first time. Harken served as editor of AAMI's journal, *Medical Instrumentation*, from 1974 to 1984.

Harken was truly a pioneer in cardiac surgery. In 1948, he became one of the first surgeons to perform mitral valve surgery on a beating heart. In 1960, he was the first to successfully insert a caged ball valve in the normal anatomic position. He was also first to carry out cardioversion with a Lown cardioverter, first to establish that direct current defibrillation caused less myocardial damage, and first to prove the safety of and to implant a demand pacemaker in a human recipient.

He was a giant in the field, a renaissance man. He often read books in the original Greek or Latin.

John Abele



Dr. Harken stands alone in providing time, energy, and resources to serve AAMI as a leader. He was very dedicated to the concept of AAMI and its success.

Mike Miller

Dwight Harken knew everyone in the field, including at the National Institutes of Health. He provided strong leadership and used his tremendous connections to benefit AAMI.

John Post



1971

Lt. Col. Burt Dodson, USAF, appointed chairman of National Examining Board for BMETs with the goal of creating a certification exam.

1971

AAMI membership exceeds 2,000 individual members.

John Abele

John Abele was an AAMI leader from the very beginning, with his name appearing on the Articles of Organization filed in Massachusetts in



June 1965. He served as chair of AAMI's Manufacturers Advisory Board and on AAMI's Board of Directors. He also volunteered one of his employees, John Post, to serve as AAMI's first executive director. In the mid-1960s, Abele was vice president and general manager of Advanced Instruments, Inc., a manufacturer of laboratory instruments and distributor of the first implantable pacemaker. In 1969 he joined with an inventor in a company called Medi-Tech, which developed catheter-based tools for cardiology. In 1979, he teamed up with Peter Nicholas to form Boston Scientific and today serves as its founder chairman. Boston Scientific is now an \$8 billion worldwide company that focuses on minimally invasive products.

Phillip Bardos

Phillip Bardos was a founding member of AAMI's Manufacturer's Advisory Board and served as assistant chairman of the AAMI Standards Committee in the 1960s. He was then corporate director of development planning at Consolidated Electrodynamics Corp., a subsidiary of Bell & Howell Company. He held a master's degree in electronic engineering from Penn State.



John Post

John Post was AAMI's first executive director in 1966, after graduating from Harvard Business School. He participated in the first MEDAC meeting and managed the next two annual meetings in San Francisco and Houston. In 1968 he joined Hewlett Packard in its Medical



Electronics Division but continued to assist AAMI in several roles, serving as AAMI's treasurer in the early 1970s and playing an active role in AAMI's early electrical safety work. His career at HP included product management, division marketing, manufacturing operations, field service, general management, and field sales.

Carl Berkley

Carl Berkley, an engineer, was an early AAMI board member. He was influential in early AAMI board meetings in establishing AAMI's new physician-based leadership in 1967. Berkley also served as chair of AAMI's Engineering Advisory Board, formed in 1967.



J. Scott Butterworth, MD

J. Scott Butterworth served as AAMI's first president, elected in 1966 at AAMI's first meeting, called MEDAC '66. He also served on the medical review board of AAMI's journal, *Medical Instrumentation*, starting with its second issue. A cardiac surgeon, Butterworth was a past president of the American Heart Association.



John J. Collins Jr., MD

John (Jack) Collins was a cardiac surgeon at Peter Bent Brigham Hospital and protégé of Dwight Harken. He joined AAMI's Board of Directors in 1969 and served as AAMI president from 1970 to 1971. He chaired AAMI's 5th Annual Meeting and played an active role in AAMI's efforts to influence the medical device legislation developed in the early 1970s.



John T. Kimbell

John T. Kimbell, vice president and later CEO of Baxter Laboratories, served on AAMI's Board of Directors for several years. A tireless fundraiser, he helped AAMI become financially stable in its early years. He also played an instrumental role in AAMI's efforts to influence medical device legislation in the early 1970s.



Warren Zeph Lane, MD

Warren Zeph Lane, MD, served as AAMI's treasurer in its formative years until his untimely death in May 1969. He played a key



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role in helping AAMI stabilize its finances in those early days. A thoracic and cardiovascular surgeon, he practiced medicine in both New York and Connecticut. He was a member of AAMI's board of directors since its first election.

Harry S. Lipscomb, MD

Harry S. Lipscomb took over as the first editor of AAMI's journal, *Medical Instrumentation*, in 1968. He continued in that role until 1972, when Dwight Harken became editor. Lipscomb was elected to join AAMI's board of directors in 1968, where he served for several years. Lipscomb was chairman of the department of biochemistry at Baylor University College of Medicine.



W. Gerald Rainer, MD

W. Gerald Rainer attended many of AAMI's earliest meetings and began his service on the Board of Directors in 1969. He served as AAMI's president from 1972 to 1973. He played a role in the passage of the 1976 Medical Device Amendments, actively lobbying Congress on AAMI's behalf. He was also involved in AAMI's very early standards work serving as a member of AAMI standards committees and attending the first European Congress on standards in 1972 and an early International



Organization for Standardization meeting in London. He serves as chair of the Harken Memorial Awards Committee today. A thoracic and cardiovascular surgeon, Rainer is a distinguished clinical professor of surgery at the University of Colorado Health Sciences Center.

Charles D. Ray, MD

Charles D. Ray served as chair of AAMI's first standards board starting in 1966. In that role, he led efforts to define AAMI standards activities and set program policies. He also published many articles in AAMI's journal, *Medical Instrumentation*. Ray was an assistant professor of neurological surgery at the Johns Hopkins University School of Medicine.



Mike Miller

Mike Miller has served as AAMI's CEO since 1969. He has overseen AAMI's efforts in the development of medical device legislation, standards, and regulations. He also has been substantially involved with the development and management of nonprofit association education, communications and standards, business strategies, and programming for more than 35 years. Miller, who holds a law degree from George Washington University Law School, came to AAMI with an association management background and experience in lobbying and legislation.



Over the last four decades, under Miller's leadership, AAMI has grown into a thriving association—a successful alliance of nearly 6,000 diverse members united by the common goal of increasing the understanding and beneficial use of medical instrumentation. Today, Miller oversees a staff of 40 who manage AAMI programs and membership services that have blossomed under his leadership. He also enjoys the support of an 18-member Board of Directors, and the commitment of dozens of dedicated professionals in the medical technology industry who volunteer their time and resources.

“AAMI has been blessed with great staff and volunteer leaders who have contributed greatly to medical device standards development; standards-based educational programs; and medical technology management forums, education, and recognition programs.”

Sylvia Chandler

While not a founder, Sylvia Chandler has been AAMI's longest-serving staff member, second only to Mike Miller. Chandler joined AAMI in October 1978 as an assistant to the Executive Director. She now serves as AAMI's Vice President, Administration, overseeing the association's general office and human resources administrative functions and a three-person accounting department.

“It's been exciting and satisfying to work with so many dedicated, hard-working employees and AAMI leaders over the years and to be involved with such a vibrant, quality-driven organization.”



Pioneers in Medicine Lend AAMI a Helping Hand Early On

Earl Bakken

Earl Bakken, the founder of Medtronic, played an active role in AAMI's early days, often providing financial support to the young organization and served on AAMI's Board of Directors in the early 1970s.



Bakken won the AAMI Foundation Laufman-Greatbatch Prize in 1998 in recognition of his unique and significant contribution to the advancement of medical instrumentation. He developed

one of the first wearable, external, battery-powered, transistorized pacemakers in 1957. Bakken lives in Hawaii today where he is pursuing efforts to link high-tech with high-touch medicine.

Michael E. DeBakey

Michael E. DeBakey, a pioneering cardiovascular surgeon and researcher, served on AAMI's Board of Directors for several years starting in 1966, and frequently published articles in AAMI's journal, *Medical Instrumentation*.



DeBakey was one of the first to perform coronary artery bypass surgery, and in 1953 he performed one of the first successful carotid endarterectomies. He was an innovator in developing an artificial heart. In 2006, at the age of 97, he underwent heart surgery using a procedure that he had pioneered and has now returned to good health.

Wilson Greatbatch

Wilson Greatbatch, an electrical engineer and inventor, invented one of the first implantable cardiac pacemakers. In recognition of his work, he won the AAMI Foundation Harold Laufman Award in 1982. Later in that meeting, he made a generous gift to AAMI of stock in his corporation. That same award now bears his name, the AAMI Foundation Laufman-Greatbatch Prize, and honors those who make unique and significant contributions to the advancement of medical instrumentation.



Greatbatch subsequently developed advanced pacemakers and pacemaker power sources and started several companies. Wilson Greatbatch, Ltd., today manufactures lithium iodide batteries for the pacemaker community; Mennen-Greatbatch Electronics markets hospital medical monitoring equipment that evolved from astronaut physiological instrumentation originally invented for the first U.S. monkey space shots. Greatbatch Gen-Aid, Ltd., provides genetic assistance to medical and agricultural professions, and Greatbatch Enterprises, Inc., is pursuing nuclear power generation and the design of an MRI-compatible pacemaker.

Adrian Kantrowitz, MD

Adrian Kantrowitz, a pioneering cardiac surgeon and inventor, has been an active participant in AAMI meetings through the years and has published articles in AAMI's journal, *Medical Instrumentation*. More recently, Kantrowitz presented the Dwight E. Harken Lecture at AAMI's Annual Meeting in 1998, speaking about "Mechanical Devices to Aid the Failing Heart."



*Pioneering inventors
Earl Bakken and
Wilson Greatbatch
at a medical meeting
in the early 1970s.*

Photo courtesy of the Bakken Library and Museum.

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Edward Duffie's major contributions to the 1991 AAMI reorganization helped refocus the association's strategic priorities and position it for major growth. Also, he is recognized for his leadership in helping to reposition the association's standards program to respond to the globalization of the medical device industry, the increasing role of standards in international regulation, and the need for the international harmonization of standards and regulations. These two leadership roles were pivotal to AAMI success during the last 15 years.

Mike Miller, AAMI chief executive since 1969

Kantrowitz, founder and scientific leader of L-VAD Technology, Inc., performed the first implantation of a left ventricular assist device intended to remain in the body for congestive heart failure treatment in 1966. He performed one of the first heart transplants in the United States and was the first in the world to perform a heart transplant in an infant. He developed an early implantable cardiac pacemaker and developed and introduced the first practical intraaortic balloon pump.

John P. Merrill, MD

John Merrill, the kidney transplant pioneer, lent his name and his prestige to AAMI as early as 1965 as chairman of the association's



Medical Advisory Board. He also served on AAMI's Board of Directors for several years. A nephrologist and surgeon at the Peter Bent Brigham Hospital, Merrill and his colleagues performed the first successful human kidney transplant in 1954 on identical twins.

Renowned surgeon Michael DeBakey debated possible artificial heart designs with Adrian Kantrowitz, MD, at AAMI's first meeting, called MEDAC '66.



Edward R. Duffie, Jr., MD

Edward R. Duffie, Jr., MD, spent 20 years taking care of infants and children with heart disease as a pediatric cardiologist before moving on to Becton Dickinson and Co. as the medical device manufacturer's corporate medical director. It was at BD that Duffie would hone the management and strategic planning skills that he would bring to AAMI in 1982. As chairman of AAMI's Strategic Planning Committee beginning in 1985, Duffie introduced a way of thinking about the future that was markedly different from the strategic and financial planning model the organization had used throughout its early years. As a direct result of Duffie's leadership, AAMI adopted a governance and management model that resulted in a new organizational structure that continues to this day. For his efforts on behalf of the organization, Duffie received the AAMI's Leadership Award in 1994.



Inventor Wilson Greatbatch in a 1991 AAMI News clipping. He built a solar-powered canoe and celebrated his 72nd birthday by traveling a record-setting 142 miles in it. "I spent \$3,000 on the parts for this canoe, and added 300 pounds to its weight, to get a craft which doesn't go quite as fast as the Indians did 200 years ago," he said. Isn't progress wonderful?

