B BRAUN
SHARING EXPERTISE

allianz

Volume 2 ▪ 2017 | The Magazine for Partners of B. Braun's OEM Division

THE EXPERIENCE OF QUALITY:
LONGEVITY AND SHARING EXPERTISE

THE STATE OF THE MEDICAL DEVICE INDUSTRY:
Q & A WITH THE MDMA'S MARK LEAHEY

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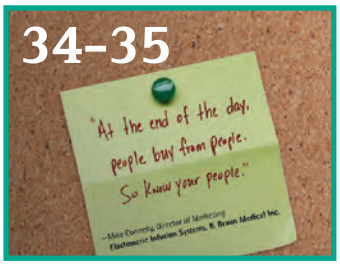

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Volume 2 | 2017

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Tom Black

EDITOR'S NOTE

We're well into 2017, and most of the medical device industry is smiling. While I'll follow the rules of etiquette and not discuss religion, family or politics among mixed company, I think it's safe to say that the assumed elimination of the medical device tax is a welcome development. It gives us more flexibility to reinvest in our businesses and our people – and more quickly develop products that can improve outcomes for patients and safety for healthcare workers.

This is our second edition of *allianz*. And after a very positive response from you, our partners, following our inaugural publication, we are pleased to provide you with more content that will keep you informed and deepen our relationship with you.

This issue features an interview with Mr. Mark Leahey, President and CEO of the MDMA, who provides us with insight about what is going on in our industry and in our nation's capital.

I wanted to take you all to the warm Dominican Republic to tour our beautiful facility there. Unfortunately, I couldn't get the plane tickets and accommodations through the 2017 budget, so we hope an article in *allianz* will suffice!

I have had the opportunity to travel this great country over three decades and meet thousands of talented professionals like you. In our industry, you quickly appreciate the value in many years of service. In this edition, we will highlight the amazing tenure of some of our B. Braun employees and how it translates to our ability to serve you.

Other features include an "Ask the Expert" column on quality, product highlights and our "What I've Learned" page featuring the shareable wisdom our people have acquired over the years.

Thank you all for being true partners to B. Braun Medical. As always, if there is anything we can do for you, please just call or text. We will be sure to help you achieve your 2017 objectives.

In our industry, you quickly appreciate the value in many years of service. In this edition, we will highlight the amazing tenure of some of our B. Braun employees and how it translates to our ability to serve you.

ASK THE EXPERT:

BRIDSEIDA MELENDEZ

Root cause analysis (RCA) is used by organizations to identify why issues are happening, whether they're quality issues, customer comments from the field or regular assessments as part of the continuous improvement process. It is a prescriptive method that brings together specific tools, cross-functional teams and unique skills. Brid Melendez from B. Braun talks about the process and why it is an essential part of quality programs.

Bridseida Melendez is Director of Quality Assurance in Allentown.

Q: Why does great RCA start with a well-defined problem statement?

To know what to study and analyze, you need to know what you're looking for. The more narrowly you can define the problem, the better. If you don't define what the problem is, the process is suspect to scope creep. For example, if the problem is in manufacturing, can you determine if it is isolated to a specific shift, machine or team? Clearly defining the source of the problem will lead to a less complicated evaluation. A well-defined problem statement gets you halfway to resolution.

Q: How does RCA integrate the voice of the customer (VOC)?

It doesn't matter whether the "customer" is an internal one or external one. When you go directly to the people who are raising the issues, you get an unfiltered perspective on what is happening. The VOC is critical to defining the problem. Similarly, the VOC is helpful in developing solutions. They can provide valuable input on potential resolutions based on their needs. Sometimes "the voice" involves observing how people interact with a device in the field or assemble a device on the line. That's important feedback, too.

Q: Why are cross-functional teams important with RCA?

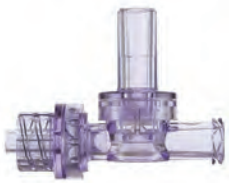
Cross-functional teams allow the issue to be viewed from different perspectives with various types of expertise and fresh eyes. Sometimes people outside of the core team can see things right away. Depending on the issue, we bring in experts from production, quality, engineering (both process and R & D), supply chain and more. Combining that expertise and sharing it with the team is very powerful.

Q: What role does data play in RCA?

Data is the big equalizer on the cross-functional team. It can be difficult for a relatively new employee to challenge someone with decades of experience. Opinions are interpretations; data speaks for itself. The collective analysis of data interjects a level of equality to the process, giving everyone's expertise balanced weight. And data is essential to determine when the issue is resolved or improvements have been realized. You need data to measure success.

If you're looking for a single-source supplier, how about one that has a full range of parenteral






pharmaceutical solutions? Or one with a catalog of valves as thick as a phone book? Or one that



carries all the admixture accessories you could ever pack into a custom kit for your drug or device?




& there's more. Besides a line containing hundreds of products, we offer a full range of capabilities. Project management puts your product on a fast track to market without compromising quality. Our engineering and quality systems maintain exacting standards of excellence. Other services under our roof include full sterilization capabilities and regulatory expertise to ensure compliance in this country and around the world. It all adds up to a single-source supplier that goes far beyond being a vendor to being a true partner.

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DESTROY AFTER SINGLE USE
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THE EXPERIENCE OF QUALITY:
LONGEVITY AND SHARING EXPERTISE

When a company musters a deeply experienced workforce, a few confident assumptions about it are in order. Chances are it earns consistently high marks in quality management. Very likely it stands out in customer commitment and service. And probably it's stocked with talented people who are profoundly dedicated to delivering outstanding performance in their jobs.

These attributes are all part of Sharing Expertise, the core of B. Braun's way of doing business. Longevity and technical mastery, innovation and market knowledge all shape a powerful, comprehensive expertise that benefits both external and internal customers. Experience across every level of the workforce is fundamental to this.

The average term of service for today's B. Braun associate is 12 years. Many of our people have been with us for 15, 25, 35 years or more. One stalwart has been with us more than half a century. (That's since the Lyndon Johnson administration, in case you were wondering.) Together, they constitute an institutional strength that makes it possible to meet the exacting standards that Sharing Expertise implies.

"I think longevity in our ranks speaks well about the culture at B. Braun," said Rob Albert, Senior Vice President and Chief Marketing Officer. (Read Rob's story on page 11.) "Our people have a lot of skills and functional knowledge that help us manage our work for OEM partners exceptionally well."

Here are three associates of whom we're especially proud — and who exemplify the connection between longevity and strong customer relationships.

Among the most senior associates in the B. Braun assembly area is 42-year veteran **Laura Denisi**.

Laura has witnessed extraordinary change across the business. "New machines, multivac packaging, new quality systems," she said. "Medical devices have become safer and more user-friendly. But one thing has been the same: Quality is quality for the people doing the assembly."

The connection between longevity and quality performance, she says, is plain. "When we are on the line so long, we know the job and how we do it. (Management) asks us to see where the processes can be changed and made better to help with cost and quality."

Though her job is in OEM production, Laura took to heart long ago the idea that every device needs to be right, no matter whose name is on the packaging. "When my brother was in the hospital, I looked around and saw all this B. Braun stuff and said to myself, 'Thank God, everything is going to work.'"

Mary Iasiello, currently a document control administrator, has spent her whole working life at B. Braun in Bethlehem. Known as "Mo" to her many friends inside and outside the company, she's still going strong after 43 years on the job.

Mo started on the production floor, but soon moved over to the final inspection area in quality control. She was there 10 years, and eventually advanced to her current position. Her background in several aspects of the company's work makes her a well-rounded employee – and typifies the broad understanding that so many associates acquire in their years here.

"The company does a lot of training," she said, "training on so many different things. Top to bottom, accuracy is really important here."

"I do like the work, even after all these years," she said. "It's challenging, and it makes a difference. Up here in document control, it matters to have that kind of experience in the organization."

Rob Albert's 33 years in the management and executive ranks have produced perhaps a broader view of strengths that the veteran workforce offers the company.

Rob started as an operations/production supervisor, moving on to a series of posts in Pennsylvania and California: OEM sales, acquisition transition team executive, special project team director, head of the pharma marketing team, and eventually on to his current position. With such a varied background across decades of service, he's seen (and shaped) how things work in many aspects of the business.

"People know and trust their colleagues across the organization," he said. "You collaborate with others who share a successful track record. It's easier than always starting something new. Efficiencies that benefit our customers come out of that."

Sustained professional development and smart recruiting at B. Braun, he said, have helped keep the company agile – an important attribute in a veteran firm. "As a growing organization, we're bringing in new ideas and fresh approaches – constantly. This comes from the young professionals who join the B. Braun team right out of school and in the thinking of people who join us from other companies."

But staying limber also happens because it's valued in the corporate culture. "We make it a point always to challenge current ways of thinking," he said. "It generates progress and better ways to serve our markets."

In the end, there is a direct relationship between longevity and Sharing Expertise. It's simple: the more you listen, the more you learn and the more you know, the more you share. It's an idea our people embrace every day.

STREAMLINING OPERATIONS THROUGH LONGEVITY

A long personal history in operations at B. Braun has given many of our staff members deep background in the manufacturing and evolution of medical device technology. For Dave Schleder, Director of OEM & International Operations, his 33 years with the company have fostered a deeply informed view of the connection between experience and excellence.

"Longevity gives you perspective on where the industry has been, where it is now and where it is going," Dave said, "When you've been in operations as long as I have, you have a lot of expertise to share.

"It benefits me all the time. I can talk shop with anyone, whether it's processes like sonic welding or automated equipment or more strategic areas like six sigma or self-directed work teams."

Working with other long-term colleagues, Dave said, creates efficiencies. "We can conduct very important meetings in 15 minutes. We don't need to explain every detail. We can knock it out quickly: boom, boom, boom, people just know. They are very proficient and effective because of their years of service."

And the connection to core principles is clear, Dave said. "We don't say 'Sharing Expertise' in an egotistical way. It's a two-way street. We accept our customers' expertise. We supplement their abilities with ours. That's the value to the customer."

NEW NRFIT™ DESIGN HELPS ELIMINATE IMPROPER CONNECTIONS

It's a common truism that you can't fit a square peg in a round hole. Apply that logic to medical device design, and you have a new standard that helps prevent inadvertent connections.

For years, the standard Luer small-bore connector has been used in almost all medical devices. However, its nearly universal use meant that devices that were never intended to be connected could mistakenly be connected – often with fatal consequences.

Enter the new NRFit connector. It is designed to prevent medical devices meant for neuraxial administration from connecting to devices used for IV, enteral and other applications. Try to connect two incompatible devices, and you will quickly realize the connectors simply do not fit together.

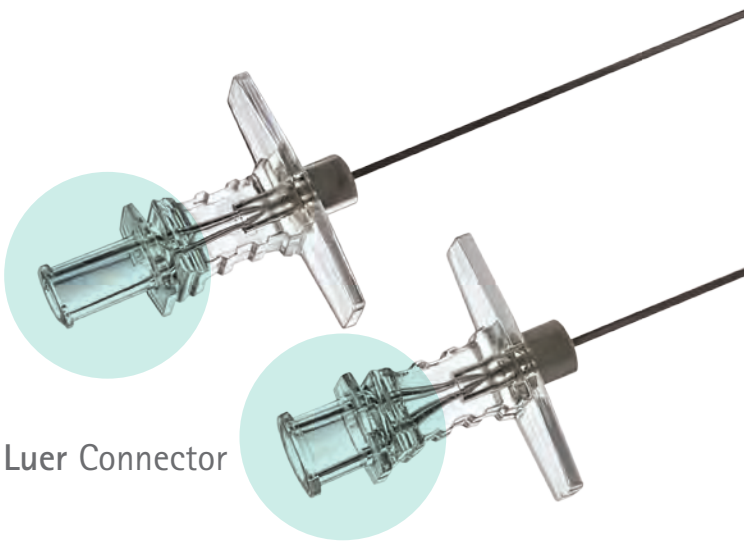
B. Braun has been a central member of the International Organization for Standardization (ISO) committee to develop the new standard – ISO 80369-6 – for small-bore connectors to improve patient safety. By switching to neuraxial products with NRFit connectors (instead of Luer connectors), clinicians should be able to reduce the risk of cross-connection between applications and reduce medication errors.

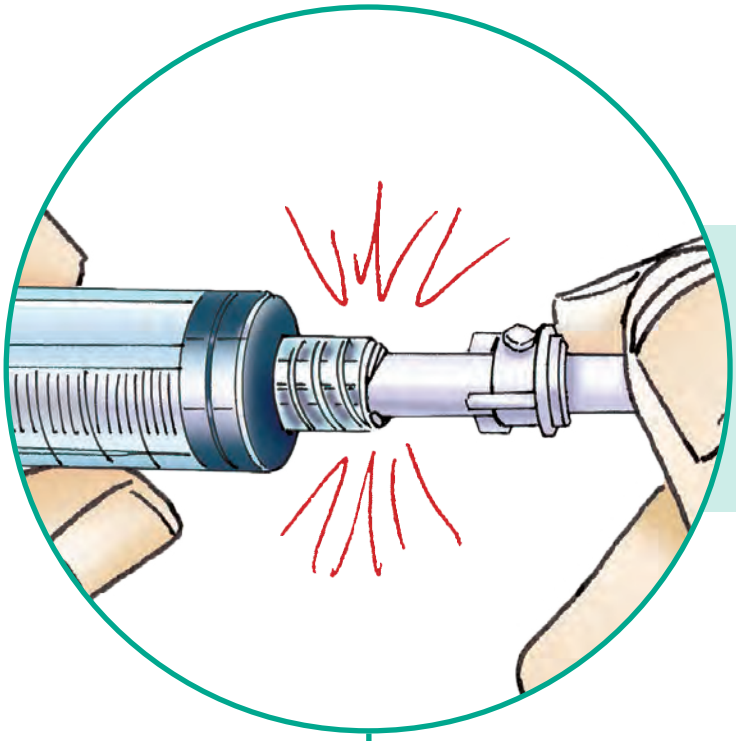
All medical devices that connect to the neuraxial route will eventually use the ISO 80369-6 connector. You will begin seeing the connector as an option on many B. Braun components in the coming months.

Although adoption is voluntary at this point, healthcare facilities are expected to begin converting to meet the ISO standard requiring NRFit connectors to mitigate risk once components are widely available. California has already taken legislative action to mandate that healthcare facilities convert to "mutually incompatible connection systems" (such as NRFit connectors) in epidural products by January 1, 2017. Great Britain has a similar statute for spinals.

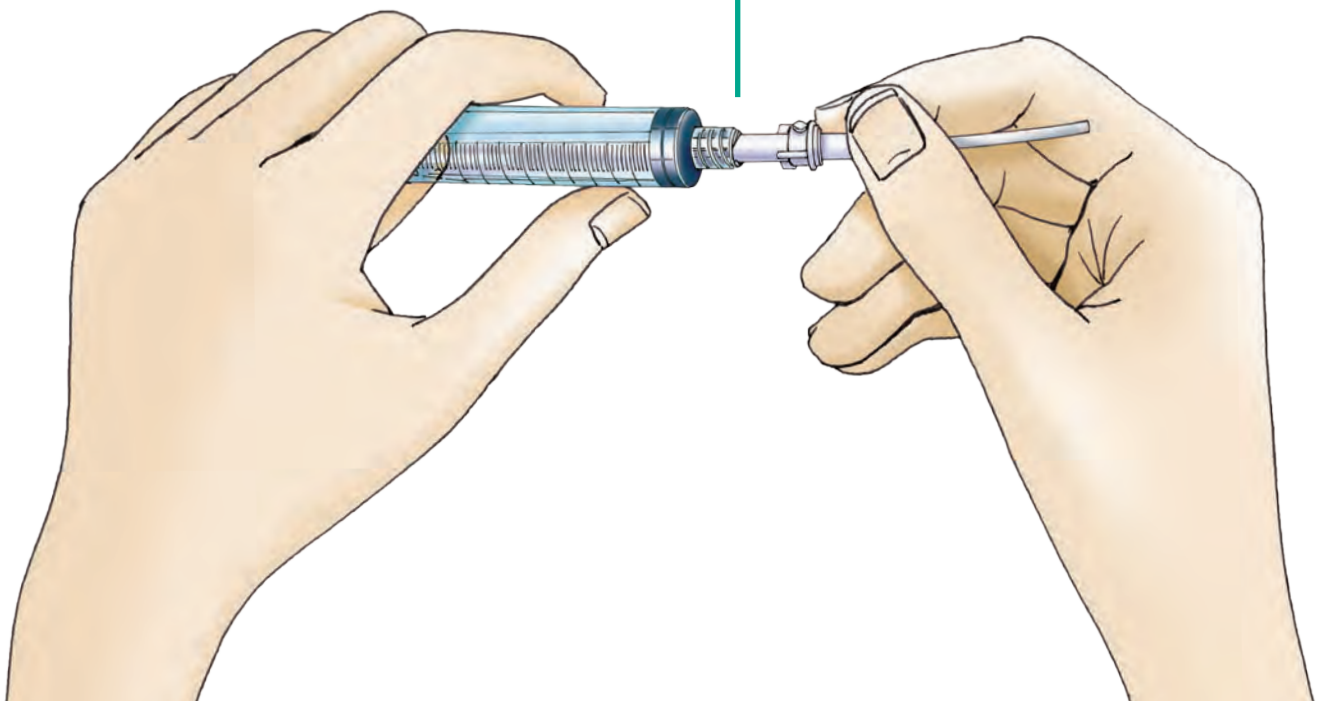
"As an advocate for patient safety, B. Braun has been at the forefront of preparing for this change. We've taken an active role in developing the worldwide standard and helping our customers comply with the evolving industry demands, including transitioning to products with NRFit connectors," said Tom Black, Vice President, OEM & International Divisions Sales and Marketing. "It's about providing the safest possible delivery of medications in the healthcare system."

For more information on reducing misconnection risk, visit **bbraunnrfit.com** or the Global Enteral Device Supplier Association (GEDSA) at **stayconnected.org**.





NRFit products will not fit into improper connectors.



SKILL AND QUALITY IN OUR HANDS –
MANUFACTURING EXCELLENCE IN THE DOMINICAN REPUBLIC

B. Braun's significant payroll contributes substantially to economic activity in workers' communities by putting money in the hands of consumers.

The output at B. Braun's Dominican Republic plant is little short of spectacular. Around 1,600 workers – roughly 76 percent of the site's workforce – perform a staggering 2.5 million manual connections each day for medical devices assembled there. Still more impressive, they carry out this work with extraordinary precision, guided by the stringent rules of international quality certification to which B. Braun adheres.

What does it take to reach this level of achievement? In part, providing thousands of hands with such consistent speed and skill is a product of training and repetitive practice. "Experience and low turnover help the plant meet its requirements," said Eric Roden, General Manager of Dominican Operations.

Success depends, too, on careful planning and management of production and related plant operations. Equally important is a willing and capable workforce, which B. Braun has found – and helped to nurture – in this island nation.

Reaching for 2.5 Million a Day

"Each manufacturing floor employee goes through an established training process," said Eric, "and is qualified in the different manual bonding techniques."

Devising production plans that enable high-volume assembly of IV sets – urology, blood, and others – is the duty of a deeply experienced materials team. "Operational aspects are discussed," Eric said. "If relevant issues must be addressed, action is taken to ensure problems are solved."

Even in a plant producing 120 million finished sets per year, there is no room for compromise in an exacting quality assurance program. "We are ISO 13485 certified, FDA inspected, C-TPAT certified," Eric said. "All these certifications are important because they show that we meet international standards for quality in the medical device business and the security of the products throughout the supply chain.

"Experienced people drive the business and help others reach the goal while complying with good manufacturing practices. We've continued to make work instructions and process standardization cornerstones to continuous improvement."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Part of a Better Life

The Dominican Republic occupies the eastern two-thirds of the Caribbean island of Hispaniola, which it shares with Haiti. With nearly 11 million inhabitants, the nation is the region's largest democracy.

The Las Americas Free Zone Park near the national capital, Santo Domingo, is home to B. Braun's five-building, 200,000-square-foot-plus complex. B. Braun has the industrial park's largest operation, bigger than other multinational corporations such as Rockwell Automation, Wolverine and Hanes.

In a nation where (according to the International Monetary Fund) the estimated per capita share of GNP in 2016 was $7,083, a job with B. Braun means a better life for many families. According to Roden, the cost of living is high in the Dominican Republic, and poverty is widespread. "Working at B. Braun provides our people with food, transportation, materials to improve their houses and the opportunity to get a better education for them and their children. They also get health insurance – which without B. Braun they would not have."

> "We are known as La Familia B. Braun because we operate as a family."
>
> –Eric Roden, General Manager of Dominican Operations, B. Braun Medical

B. Braun's significant payroll contributes substantially to economic activity in workers' communities by putting money in the hands of consumers. The company augments that indirect benefit with direct contributions to the well-being of those places.

Among our community initiatives: backing for the foundation A Roof for My Country, which helps promote safe and sustainable housing; enrichment and enhanced education for young people through JADON, the equivalent of Junior Achievement; and greater access to healthcare and human services via charitable works and our insurance provider in the republic, PALIC.

Through the year, B. Braun sponsors many events that help develop a cooperative spirit in the workforce and the community. The Dominican operation is also thoroughly committed to conservation throughout the Siembra Vida project, which supports environmentally sound practices within the plant and reforestation programs without.

"B. Braun is different than other employers," Roden said. "We are known as La Familia B. Braun because we operate as a family. This sense of belonging transcends the usual employee/employer relationship."

Needle-Free business unit in Allentown, Pa.

While a number of B. Braun's processes are automated, team members play an important role in monitoring quality and ensuring proper function of the high-tech equipment.


MILACRON
FANUC
S-2000
747
ROBOSHOT S/B 110

MEET THE OEM & INTERNATIONAL TEAM

OEM & International Sales, Sales Service, Marketing & Engineering
photographed at B. Braun Medical's corporate headquarters

The OEM & International Staff is a culmination of more than 170 years of medical products experience from the various disciplines that "share expertise" with each other and with our customers. Their main focus is to work together as a team to support the Account Managers and provide each customer with the information needed to be successful.

Their main focus is to work together as a team to provide each customer with the information needed to be successful.

[From left to right] **Reggie Robertson** – Senior Manager, OEM Sales (new to the team); **Chad Laity** – Manager, OEM & International Marketing; **Tom Black** – Vice President, OEM & International Sales & Marketing; **Donna Luckenbach** – Associate Director, OEM & International Sales Services; **Dave Williams** – Director, International Sales; **Lynn Wirth** – Senior Manager, National Accounts and New Business Development; **Dawn Kentner** – Manager, OEM Product Development *[not pictured]*

EDUCATING WHILE ENTERTAINING

TAKING NOTES HAS NEVER BEEN THIS FUN

B. Braun OEM shares more than just medical device expertise. We share a full range of capabilities designed to help you work as efficiently as possible. Understanding what we can do for you doesn't have to be boring:

Our ongoing series of notebooks highlights our useful capabilities, and are offered to customers free of charge. Each of our notebooks highlights one of our many capabilities—like design innovation, packaging and regulatory expertise—by providing entertaining stories and little-known facts about that subject.

Use the sections between the stories for writing, sketching and other activities. The notebooks are excellent tools for recording your thoughts. (Or just doodling.) It's one more way B. Braun OEM is helping the world share expertise.

To get a notebook of your own, visit bbraunoem.com/notebook.

NEW FACES AT B. BRAUN OEM

Chad Zaengle is the OEM Account Manager for the Midwest region. He graduated from Bloomsburg University in 2010 and comes to us with two years of experience in medical sales. He enjoys the outdoors – hiking, hunting, fishing and volunteering as a powerlifting coach for the Special Olympics of NJ. He resides in Breinigsville, Pa., with his wife, Brook, and three-month-old daughter, Kennedy.

Becky Guman is the OEM Account Manager for the Pacific region. She graduated from Lehigh University in 2013, and has spent two years working in higher education at both Lehigh University and Penn State University. Additionally, she worked for two years as an Account Manager Senior Specialist in the financial services sector. Becky resides in Allentown, Pa.

WHAT IS THIS?

A duckbill joint, denoted by "DB" on assembly drawings, is one of multiple standard assembly methods used to create a leak-free fluid path between tubing and components in the manufacture of disposable tubing sets. The DB method temporarily enlarges the inner diameter (ID) of tubing to allow for insertion over the outer diameter (OD) of a barb on a compatible rigid part or piece of tubing. To perform a DB, device jaws are aligned with and inserted into tubing, and are then are activated (opened and closed) via a pneumatically operated foot pedal. The operator uses controlled activation/deactivation of the device jaws to gradually expand the tubing until the tubing ID is large enough to accommodate the barb OD of the mating component. The elasticity of the tubing allows it to return to its original shape after being connected, resulting in a compressive frictional force that creates the desired joint.

SHOW TIME: MAKING THE MOST OF YOUR TRADE SHOW VISIT

Contemporary trade shows are festivals of dazzle and glitz. From a practical standpoint, they provide a chance to re-energize relationships and foster new ones. They can also be sources of information – in such volume that sorting and selecting what's worthwhile can be like drinking from a firehose.

With time, money and attention spans always limited, show visitors must sharpen their attendance plans. "Shows aren't what they used to be," said Howard Revitch, Group Publisher for *Medical Product Outsourcing* magazine. It's easy to be distracted by the magic shows and raffles, he said, and by the sheer scope of contemporary shows, often including vendors in a dizzying range of categories.

"The attendee must do the homework," Revitch said. "Look at the exhibitor list and break it down." Otherwise, you could be one of hundreds of attendees slowly walking the aisles as if they were extras on *The Walking Dead*.


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Device Concept Thru
Heart Valve Crimping Tools
Machine Solutions
MSI

> "There's still a strong value in face-to-face contact."
>
> –Sean Feehan, Vice President, GWF Associates, LLC

Tools of the Trades

Savvy attendees have always arranged visits around specific sourcing needs. Today's attendees call on effective digital tools, said Sean Feehan, Vice President of GWF Associates, LLC, which produces educational, interactive multimedia presentations. Sean is also a board member of the Healthcare Convention and Exhibitors Association.

"Use the tools available to you," Sean said. For instance, many shows offer smartphone applications that keep visitors abreast of the show schedule, supporting better time management. Other apps connect with exhibitors' specific offerings and allow for searching and more efficient time on the floor. (Of course, one needs to download and try the apps for them to actually help.)

RFID technology enables guests to conveniently gather e-literature. In place of brochures often tossed in hotel wastebaskets, information can now be transmitted to visitors' mobile devices and computers. It's easily integrated with post-show reports and presentations. Again, the convenience needs to be balanced with conviction: Dedicate time in your calendar after the show to review materials – otherwise they may languish in your inbox for weeks or months.

Pre-show online research targets must-see exhibitors. International trade show organizer UBM maintains an Advanced Manufacturing online resource center. According to the firm's Nina Brown, Vice President of Events, visitors can "peruse schedules, calendars, educational overviews, networking events, and other complimentary assets that are provided for each event."

In recent years, conferences of narrower scope have emerged as another helpful way to meet capable suppliers efficiently. These closely defined events offer an alternative to big trade show's distractions, although careful selection of opportunities can produce excellent results at even the largest conferences or trade shows.

Find Us at Upcoming Trade Shows	
MD&M East New York City, NY, USA	June 13–15 2017
Outsourced Pharma San Diego San Diego, CA, USA	August 22–23 2017
AdvaMed San Jose, CA, USA	September 25–27 2017
MD&M Minneapolis Minneapolis, MN, USA	November 8–9 2017
BIOMEDevice San Jose San Jose, CA, USA	December 6–7 2017

The Human Touch

What's true for visitors applies to exhibitors, too. New tools and techniques have given the vendors exceptionally economical and effective means to communicate with their critical audiences.

Of course, locating an OEM partner isn't the only reason to attend a show. Learning what's new, looking at industry trends, checking out current marketing efforts, touching base with business established contacts, scouting the competition – these and many others are reasons to attend. "Nothing really takes the place of being there," Feehan said. "There's still a strong value in face-to-face contact."

Tom Black, Vice President of B. Braun's OEM Division echoes that sentiment. "Successful contract manufacturing relationships begin and thrive with significant personal interaction," he said. "Build time into your schedule to get to know the people who will stand behind their company's work. Sometimes e-literature, apps and websites can't communicate nearly as much as a handshake."

THE STATE OF THE MEDICAL DEVICE INDUSTRY

INTERVIEW WITH MARK LEAHEY, PRESIDENT AND CEO OF THE MDMA

Mark B. Leahey, President and CEO of the Medical Device Manufacturers Association (MDMA), is a tireless and effective advocate for the hundreds of medical technology companies represented by the MDMA. Recognizing his unique perspective on the regulatory and legislative environment, *allianz* asked him to join us for an interview on issues of vital concern to our industry.

How permanent do you think the two-year suspension of the medical device tax will be?

Following more than six years of leadership and passionate advocacy, MDMA and our members secured a two-year suspension of the medical device tax at the end of 2015. This milestone was the culmination of work that began when the device tax was first proposed in the summer of 2009. MDMA and our members continue to push passionately for a full repeal of this onerous policy.

The suspension of the device tax was achieved by expanding the coalition of innovators, regional organizations and stakeholders to maximize the voice for device tax repeal, in addition to working with the fervent voice of our industry.

The B. Braun team, led by Caroll Neubauer, B. Braun's Chairman and CEO, was instrumental in championing the repeal efforts by engaging members of Congress. They testified on Capitol Hill, secured earned media and much more. Leadership is acting when others won't – and B. Braun was fighting for patients, innovation and its employees from day one.

It is abundantly clear that the device tax was hurting patient care, innovation and job creation. President Trump has made it clear that he opposes the medical device tax. We will continue to work tirelessly with B. Braun and our other members to ensure the tax is fully repealed.

It is generally regarded that medical device regulation has tightened in the past decade. Do you see that trend continuing?

There is no question that the regulatory environment has become more unpredictable for med tech innovators. A reasonable, efficient and consistent premarket and post-market regulatory system remains a top priority for MDMA.

The association and our members have long been actively engaged with FDA and other stakeholders to bring a risk-based approach to post-market activities. We advanced numerous policies and ideas to enhance the premarket process. When we initiated negotiations with FDA regarding the Medical Device User Fee Act (MDUFA) IV reauthorization, we purposely sought out process improvements to reduce unnecessary delays, provide more accountability and accelerate patient access to new technologies.

We believe that the package we negotiated with FDA will help ensure that the regulatory environment becomes more predictable and transparent for med tech innovators.

> "The regulatory environment has become more unpredictable."
> –Mark Leahey, President and CEO, MDMA

In addition, the 21st Century Cures Act, recently signed into law, had overwhelming bipartisan support. "Cures" contains a number of critical provisions to improve the efficiency and predictability of the medical device review process. These improvements include a new regulatory pathway for certain breakthrough devices, and reimbursement reforms that will require more transparency and process improvements by local Medicare Administrative Contractors and Centers for Medicare & Medicaid Services (CMS).

The legislation also empowers patients to share their perspectives with FDA as part of the review process. Combined, these policies have the potential to deliver on the bipartisan goal of increasing access to safe and effective medical technologies for patients and providers. Such policies will allow this dynamic industry to continue extending life expectancies, improving the quality of life and reducing the costs of treating chronic conditions.

What drivers will cause regulation to tighten or loosen?

The FDA, industry and various stakeholders have been working for years to reauthorize MDUFA. This past summer, we finalized our negotiations. This tentative agreement represents an important step to improve patient access to safe and effective products.

Medical technologies serve as a powerful example of what American ingenuity can accomplish when a predictable and reasonable regulatory system is in place.

Provisions set forth in this agreement will empower the input of patient communities, help ensure that regulators are asking the right questions at the right time, and strengthen the premarket review process with numerous process enhancements.

The tentative user fee agreement contains numerous targeted investments designed to further streamline the regulatory pathways, including:

- Significant process improvements that will provide more clarity, specificity, supervisory oversight and routine quality audits;
- Performance goals for pre-submissions for the first time, with FDA committing to provide meaningful written feedback to innovators at least five days prior to a scheduled pre-submission meeting, and having the meetings within 70 FDA days;
- Improved average total time to decision to 108 days for 510(k)s and to 290 days for PMAs by the end of FY2022;
- Enhanced patient engagement and patient input by levering public/private partnership and building internal capabilities; and
- A pilot to establish the value of real-world evidence (RWE) and linkages among data sources, enabling greater use of RWE to accelerate patient access in the premarket setting.

The new administration has also made regulatory relief a priority and singled out the need for "FDA reforms." MDMA will continue to work with all stakeholders so that the possibilities contained in this proposal are realized, and America's medtech ecosystem remains the gold standard for safety and efficacy.

What has MDMA been doing in the area of patent reform?

Despite increasing momentum to drastically change the nation's patent laws, MDMA has been working with a diverse coalition of life-science stakeholders to prevent a system overhaul that would have penalized medical technology patent holders.

The association continues to support efforts to curb abusive practices of patent assertion entities or "patent trolls." We worked with a growing coalition of innovators to ensure this is not done at the expense of innovation.

For example, MDMA members joined with a group of life-science industries to develop a documentary highlighting just how precious the innovation ecosystem is. We also hosted events that brought in leading policy makers to address the threats in patent reform proposals.

We have supported targeted efforts in the Senate Judiciary Committee to strengthen the patent system such as the STRONG Act introduced by Senator Chris Coons (D-Del). MDMA has backed other amendments to various pieces of legislation that would support intellectul property rights, while opposing provisions in the Patent Act.

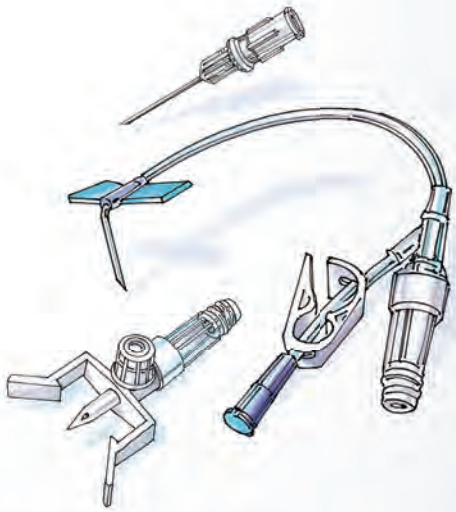
We have also worked with House leaders to gather support for the Targeting Rogue and Opaque Letters Act, which would allow law enforcement agencies to go straight to civil penalties for bad-faith demand letters.

It remains to be seen how the new administration will wade into this issue that is critical to the medical technology industry. In any case, we will continue to vigorously advocate against any proposals that would weaken the intellectual property rights of medtech innovators.

B BRAUN
SHARING EXPERTISE

These things make life convenient.

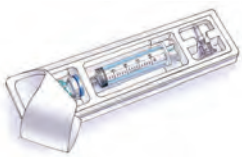
These things make your drug convenient.



Bundle your drug with devices to make administration convenient.

Caregivers have demanding jobs. What if you could help them work smarter by making your drug quick and easy to administer? B. Braun's OEM Division can create a customized bundle of all the devices needed to administer your drug. It'll make your drug convenient for caregivers and separate you from competitors. We offer an extensive selection of proven devices, plus design, regulatory, lab services, packaging and sterilization expertise. It's a full suite of capabilities designed for convenience.

B. Braun Medical | OEM Division | USA | www.bbraunoem.com



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"At the end of the day, people buy from people. So know your people."

—Mike Connelly, Director of Marketing
Elastomeric Infusion Systems, B. Braun Medical Inc.
24 years of service

"Being in this industry is a privilege, as we have the daily opportunity to make a positive impact on a patient's life."

—Carla Carpenter, Director of Marketing Services
B. Braun Medical Inc.
29 years of service

"'THE BEST TEACHER IS YOUR LAST MISTAKE.' DON'T BE AFRAID TO MAKE SOME MISTAKES ALONG THE WAY—THE IMPORTANT THING IS TO BE ACCOUNTABLE AND LEARN FROM THEM."

—Rhonda Gamard, Senior Sales Service Associate
International Division, B. Braun Medical Inc.
23 years of service

"What I've Learned"

"Medical device innovation doesn't always take the form of 'blockbuster' technology, but usually manifests itself in small, incremental improvements which keep advancing us forward."

—Brad Lane, Vice President
Critical Care Marketing, B. Braun Medical Inc.
30 years of service

"We live in a world of perpetual change, and you cannot ever be satisfied with your current position."

—Brian Maser, Vice President of Sales
B. Braun Medical Inc.
38 years of service

"Analyzing risks and benefits is the key to decision making and demonstrating due diligence."

—Rebecca Stolarick, Corporate Vice President
Regulatory Affairs, B. Braun Medical Inc.
27 years of service

"I'M IN A GLASS CASE OF EMOTION!"

—Ron Burgundy

HOW B. BRAUN HAS CHANGED THROUGH THE YEARS

1839 – On June 23, Julius Wilhelm Braun purchases the Rosen-Apotheke, a pharmacy in Melsungen, Germany, and expands it with a mail-order business for local herbs.

1908 – First production of absorbable suture material (catgut) from sheep intestines using Kuhn's method in Melsungen.

1867 – Bernhard Braun registers the company name in the commercial register as "B. Braun" and begins producing pharmaceutical products like migraine sticks and plasters.

1900 – Carl Braun takes over B. Braun from his father.

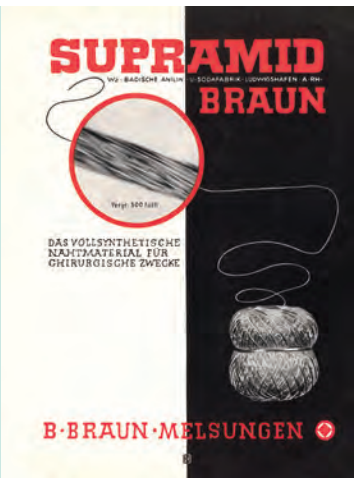
1925 – B. Braun establishes its first foreign production in Milan, Italy.

FROM DRUGGIST...

1929 – Following the death of Carl Braun, his son Otto takes over management of B. Braun.

1935 – Production of Synthofil, a non-absorbable synthetic suture material, begins.

1949 – B. Braun develops Supramid-Braun, a new nylon surgical suture material.

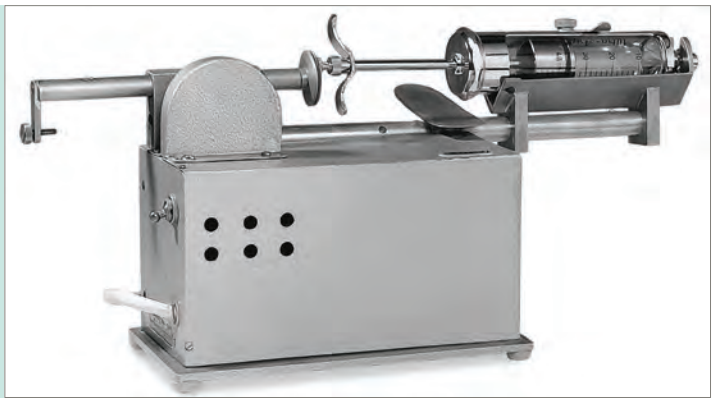


1930 – B. Braun announces first commercially prepared IV solution, Sterofundin®, the basis for all future B. Braun infusion solutions.

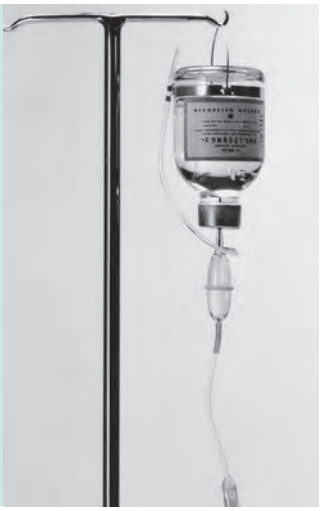
1936 – Dr. Bernd Braun, youngest son of Carl Braun, joins the company as the new manager for scientific affairs and development.

B. BRAUN THROUGH THE YEARS
(CONT.)

1951 – First mechanical injection pump for continuous infusions, predecessor of the Perfusor®, is launched.



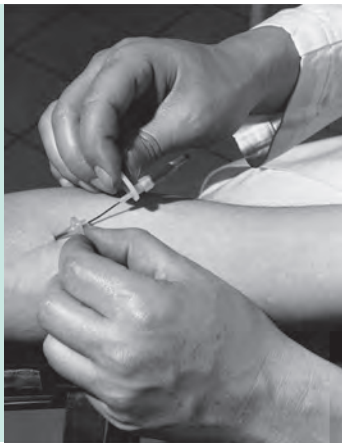
1953 – Production of infusion devices made of glass begins.



1956 – Production of infusion containers made of plastic "infusors" begins.

1957 – George Burke Sr. develops one of the first processes in the world for manufacturing disposable plastic syringes.

1962 – The Braunüle®, the first one-piece cannula made of plastic for continuous infusion, is released for sale.



...TO INNOVATOR...

1977 – Ludwig Georg Braun, the son of Otto Braun, becomes Chairman of the Board.

1972 – FreAmine®, the first crystalline amino acid solution, is released.

1985 – Manufacturing plant built in Allentown, Pa. Phase 1 consisted of sterilization, final packaging and assembly – 65,000 square feet.

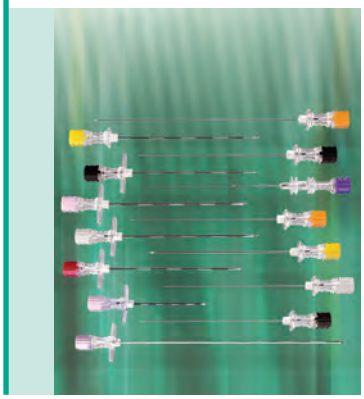
1976 – B. Braun acquires controlling interest in Aesculap AG. The sales of B. Braun Melsungen AG reach 424m Deutsche Mark in fiscal year 1975/76. The number of employees reaches an all-time high of 3,098.

1979 – B. Braun of America is founded with the purchase of Burron Medical Inc. in Bethlehem, Pa.

B. BRAUN THROUGH THE YEARS
(CONT.)

1989 – SAFSITE® ■ B. Braun releases first valve-based needle-free IV system. EXCEL® ■ First containers not manufactured with PVC, DEHP and Latex are introduced.

1992 – Dedication of the new facility in Pfieffewiesen, Germany, designed by the British architect James Stirling.



1990 – B. Braun becomes the global leader in Regional Anesthesia – a position still held today.

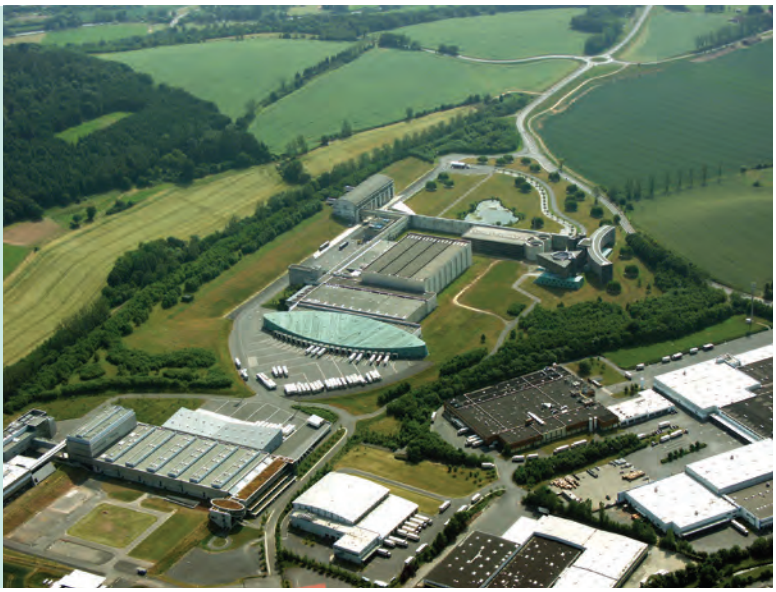
1991 – CAPS® (Central Admixture Pharmacy Services), the first pharmacy outsourcing service, is launched.

1997 – B. Braun acquires McGaw, Inc., with locations in Irvine, Calif., and Carrollton, Texas.

...TO GLOBAL PLAYER.

2001 – DUPLEX® Drug Delivery System is launched – a revolutionary new system designed to make IV antibiotic delivery safer and simpler.

2009 – B. Braun exceeds 4 billion in sales.



2005 – Official opening of the L.I.F.E. infusion solutions factory (Leading Infusion Factory Europe).

2011 – Plant W manufacturing facility opens in response to the increasing demand for B. Braun dialysis machines and infusion pumps.

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B. BRAUN CRYPTOGRAM

Match each number to the correct letter to solve the puzzles.
We've given you some letters to start you off...

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
								9					25	11			2	5							

26 6 18 9 17 4 17 15 9 25 9 5 7 2 4 7 9 11 25

HINT – One of our areas of expertise.

12 18 5 7 11 15 23 9 7 5 4 25 17 12 11 15 14 11 25 3 25 7 5

HINT – One of our many capabilities.

5 11 6 18 7 9 11 25 5 4 25 17 12 11 25 7 4 9 25 3 2 5

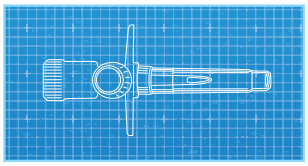
HINT – Part of our product offerings.

5 16 4 2 9 25 20 3 8 14 3 2 7 9 5 3

HINT – Our company mantra.

&

Do you need a supplier that makes managing complicated projects look simple and speeds you to market?



&

How about one with world-class design chops and quality systems for ensuring excellence?

&

Or one that saves time and money with sterilization, packaging and regulatory capabilities all under one large roof?

If your answer is yes, then B. Braun OEM is the only supplier you'll need. Beyond a full roster of capabilities, we offer a vast array of products. You'll find parenteral pharmaceutical solutions in a variety of bags, a thick catalog of standard and custom valves, all the admixture accessories you'll ever need, and the products and capabilities to build a custom kit for your device or drug. It all adds up to a single-source supplier that goes far beyond being a vendor to becoming a true partner. Visit BBraunOEM.com.

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B BRAUN
SHARING EXPERTISE

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