Medical Device Sector Review

ADMET

INTRODUCTION

ADMET serves a plethora of sectors that have demanding material testing requirements. Our systems have been deployed around the globe to satisfy standards requirements, research needs and new product launches. Over the last 5 years we have encountered several key problems specific to the Medical Device sector. This Sector Review will highlight some of those problems and the solutions being deployed. We will also take a look at the big picture spotlighting some of the macro trends within Medical Devices & Equipment including observations by Abbot Laboratories, Medtronic, Stryker, and St. Jude Medical. We also highlight some specific case studies that demonstrate the material testing challenges that companies face and the results that are possible by investing in the best technology. Finally we showcase some specific ADMET material testing configured systems designed for this sector.

Thoughts from Industry Leaders

We've assembled insights from executives at some of the top medical device companies: Abbott Laboratories, Medtronic, Stryker, and St. Jude Medical.

Abbott Laboratories

Below we have summarized some key statements taken from recent presentations from Board directors including the Chairman and CEO Miles White:

- It is worth noting that in 2013 in terms of sales, the Medical Device business represented 25% of Abbott Labs total business at $5.5 Billion of the $21.9 Billion total.
- Similar to other multinationals during 2013, we were impacted by a slowdown in several emerging economies as well as by foreign currency. Abbott was also impacted by a supplier recall in the International Nutrition. We were able to offset these impacts in 2013 in part through selective cost management.
- Our Medical Device business includes our vascular, diabetes care and vision care businesses, and in 2014 we expect continued improvement over full year 2013 driven by growth in emerging markets and the launch of multiple new products to expand our leading share positions. This includes the U.S. launch of MitraClip our first in class product for the minimally invasive treatment of mitral regurgitation which is the most common heart valve condition in the world.
- We expect to launch new peripheral stents in our endovascular portfolio and we will continue to expand our market share with our leading drug eluting product portfolio. We launched the XIENCE Xpedition in August, last year in Japan and we will launch it in China in 2014. We will also continue to expand share of our bioresorbable vascular scaffold, ABSORB outside of the U.S. at the same time we move it through the development process in several key geographies including the U.S., Japan and China.
- In Vision Care, sales increased driven by accelerating growth in our cataract lens business. This business now represents more than 65% of our vision care sales and has been growing well in excess of market growth rates. We expect double-digit sales growth for this business in 2014 with continued positive momentum from new products. And this includes our TECNIS Toric lens in the U.S., our TECNIS OptiBlue lens in Japan and our new Catalys laser cataract system as well as new product launches we expect early this year.
- Diagnostics remains one of our most durable growth businesses consistently delivering mid to high single-digit operational sales growth for the past three years. Full year 2013 sales growth of 8% was balanced geographically with double-digit growth in emerging markets and mid-single-digit growth in developed markets. Margin expansion once again exceeded expectations for the full year, increasing 3% versus 2012. In 2014, we expect strong performance in Diagnostics as we continue to build momentum in core laboratory diagnostics, increased the penetration of our molecular and point-of-care businesses and expand our presence in emerging markets across all three diagnostics businesses.
- In our R&D pipeline, we will continue to invest in the development of several new instrument platforms across the diagnostics portfolio that we expect to launch over the next several years. These new systems add new features that are important to our customers such as speed, scalability, productivity and shorter turnaround time.
- It's worth noting a few trends driving the growth in some of Abbott's products. Mitral valve disease is the most common valvular heart disease and rises with age, with around a 1% prevalence on ages under 45 but around 10% prevalence in ages over 75. In addition the cataract market is a huge opportunity for Abbott with around a 10% incidence in ages 60-64 but rising to a 70% incidence in ages over 80.

These comments bring out the importance of the Medical Devices business to Abbott and show a fairly bullish attitude towards the growth prospects of the business.

Medtronic

Medtronic is a global leader in medical technology producing sales for the year to April 2013 of $16.6 billion. It segments its business into: Cardiac Rhythm Disease Management (30% of sales), Coronary (11%), Structural Heart (7%), Endovascular (5%), Spine (19%), Neuromodulation (11%), Surgical Technologies (8%), Diabetes (9%). The following observations were noted from recent earnings results and analysts commentary:

- In the full year to April 2014, the company expects revenue growth in the range of 3% to 4% on a constant currency basis.
- The main business of Cardiac Rhythm Disease Management (defibrillators and pacemakers) has been suffering in 2013 with weak demand in the US but this is now improving. Drivers for the improvement include inventory increases at hospitals and sales of new products, Evera defibrillator and Viva CRT-D. (Source MDT and seekingalpha)
- Looking forward the company received good news on CoreValue with an earlier than expected FDA approval to sell the system in the US in Q3 of 2014. CoreValue which is approved as a minimally invasive replacement to damaged aortic heart valves in patients too frail for traditional surgery, is the second such device to be approved in the US. Edwards Lifesciences' Sapien was the first product to market, getting approval in November 2011. (Source MDT and Seeking Alpha)
- Omar Ishrak CEO, in commenting on the recent earnings results stated "Medtronic is uniquely positioned to lead the shift to value-based healthcare, directing our products and solutions to help providers, payers, and governments achieve their goals in driving more value into healthcare systems around the world. We are seeing promising results from our early efforts, including both our Cath Lab Managed Services and Cardiocom businesses, and we believe that we have significant opportunities ahead as we transform our company from being primarily a device provider today into the premier global medical technology solutions partner of tomorrow."
- Cory Renauer at seekingalpha.com published some drivers behind the potential growth of Medtronic worth noting:
  - » Medtronic's pacemakers continue to differentiate themselves from the market with features which significantly slow the progression to permanent atrial fibrillation.
  - » The early introduction of CoreValue noted above will boost growth and sales expected to reach $570 million by 2018.
  - » The Diabetes Group have added features and new products which enjoyed early FDA approval which should support market share gains.
  - » Acquisitions could form another tool for growth with the successful integration of Advanced Energy boosting the Surgical Technologies Group and Cardiocom boosting Medtronic's ability to provide monitoring services to patients.

These observations indicate that Medtronic is investing heavily in innovative new products and where appropriate is prepared to make strategic acquisitions. It is very significant that Omar Ishrak is attempting to move the company from a device provider today into the premier global medical technology solutions partner of tomorrow. The political desire to reduce heath care costs is clearly influencing the strategy of Medtronic as it considers how to add value to its customer base.

Stryker

Stryker Corporation is a medical technology company in orthopedic products. Latest results for 2013 show sales of $9 Billion, an increase of 4.2% over the previous year. Below we have summarized some key statements taken from recent presentations from Board directors including the CEO Kevin Lobo and from leading analysts:

- In announcing the latest results for Q4 and full year 2013, Kevin Lobo stated: “We are excited about the breadth of our product portfolio, which spans products and services, as well as implants and capital. Our ongoing investments in R&D, as well as our targeted M&A, positions us well to deliver innovation to our hospital customers. We will continue to focus on our strategy of top line growth, leveraged earnings gains and capital allocation that maximizes the strength of our balance sheet and our healthy cash flow.
- During the recent results presentation, Katherine A. Owen - Vice President of Strategy & Investor Relations made some interesting comments about the recent acquisition of MAKO Surgical. “The MAKO robotic platform has already proven itself capable of achieving consistently reproducible surgical results. As we continue to optimize robotic-assisted surgery, we believe it will further improve clinical outcomes. And longer term, by allowing for bone preparation and geometry and precision not possible with conventional manual instrumentation, there’s a potential to develop new implant designs that are specifically enables robotics capability and functionality.”
- She went on to state, “In the near term, our teams are focused on leveraging Stryker’s considerable sales and distribution capabilities to help drive adoption for MAKO’s current applications. Two areas of initial focus, which we are currently evaluating, are enabling Stryker-marketed implants to be put on the robot software and starting the trial for a total knee application. With close to 20% market share in the unicompartmental knee segment. We believe MAKO has demonstrated excellent market acceptance of their partial knee application. However, our analysis suggest there’s a bigger opportunity in total hips and total knees to leverage Stryker’s reconstructive implants. We look forward to sharing more regarding our plans for robotic-assisted surgery later in 2014.
- Another interesting acquisition, which speaks to trends in the sector, was the recently announced acquisition of Patient Safety Technologies, or PST, for $120 million. Specifically, PST’s Safety-Sponge System helps prevent retained foreign objects (RFOs) in the operating room, thereby improving patient safety and reducing healthcare costs. The system includes bar-coded surgical sponges and towels and integrated barcode scanner and a unique compliance tracking software. RFOs are the most common surgical “never event” in the U.S., and sponges are the most common retained object with approximately 2,300 incidents reported annually at an average cost per incident of over $400,000.
- One analyst commentary published in seekingalpha.com highlighted that earnings had suffered in 2013 due to product recalls; the Neptune Waste Management System, the Rejuvenate, and ABG II hip implants. The testing of products must remain a high priority.
- Another issue cited was the Economist’s commentary that the double digit growth seen by the sector in the past decade had been replaced by a more modest growth pattern due in part to increased regulatory constraints. Healthcare expenditure will see a paltry 0.7% increase in Europe, 2% retreat in Japan but a 9% increase in the Asia-Pacific region.
- Another analyst comment in discussing Stryker’s results was worth noting – the trend of an aging population in most countries coupled by a need to reduce costs would influence all players in the sector. He suggested this would shape strategies to shift from a service-based approach to a value based one. Medical technology companies will have to demonstrate the real economic value of their products and innovation.

St. Jude Medical

St. Jude Medical is a global medical device company headquartered in Saint Paul, Minnesota, United States. The company has more than 20 principal operations and manufacturing facilities worldwide with products sold in more than 100 countries. Sales in 2013 were $5.5 billion, a flat performance compared with 2012. Approximately 50% of sales come from Cardiac Rhythm Management, 18% from Atrial Fibrillation, 24% from Cardiovascular and 8% from Neuromodulation. Below we have summarized some key statements taken from recent presentations from Board directors including the CEO Daniel Starks, the CFO Donald Zurbay and from leading analysts:

- Sales forecasts for 2014 are around $5.6 billion to $5.75 billion, a growth rate of 3% to 5%. Medical Device Excise Tax will shave 0.5% off Gross Margin in 2014. This will be offset by the continuing move to lower cost manufacturing sites including South Carolina, Puerto Rico, Costa Rica and Malaysia.
- Additionally cost reductions over the last 14 months of more than $100m have been achieved by centralizing functions. Prior to 2012, the company operated in a highly decentralized environment. Following a changing pattern in customer priorities the company has made changes to the organization structure, standardizing on processes and building stronger central support services for the divisions.
- An interesting quality point was made by the CEO in the latest results call - “A third major goal we set at the beginning of 2013 was to continue to improve product quality and the robustness of our quality systems. We accomplished our goal of continuous improvement. We have reported to FDA that our remediation at our Sylmar facility is complete and that our Sylmar facility is ready for reinspection.
- CEO Daniel Starks commented on each element of the group and the issues they will be dealing with in 2014:
  - » Cardiac Rhythm Management (CRM) – we are optimistic that St Jude Medical is well positioned to gain at least 50 basis points of additional global CRM market share as we continue to launch new products, such as our Nanostim retrievable leadless pacemaker in Europe and other new products.
  - » Atrial Fibrillation (AF) - Customer feedback in 2013 reinforces our confidence that our MediGuide fluoroless catheter navigation technology has a credible opportunity to become a strong growth driver within our product portfolio. One of the most significant new growth drivers in our AF business for 2014 will be the launch of our TactiCath contact force sensing line of ablation catheters that became part of our portfolio through our acquisition of Endosense in August 2013.
  - » Cardiovascular - Our structural heart business increased 12% on a constant currency, year-over-year basis. This growth came primarily from tissue heart valves and left atrial appendage or LAA closure devices, both of which grew at a double-digit rate. We are optimistic that in 2014, our tissue heart valve and LAA closure revenue will continue to grow at a high single digit or low-double-digit rate. Within this division, the vascular business continues to struggle, the CEO noted, “our vascular business is clouded by the negative impact of low-margin, third-party vascular product sales in Japan. During 2013, third-party vascular product sales in Japan declined approximately $16 million on a constant currency, year-over-year basis. We estimate revenue from this same product category to decline an additional $14 million in 2014, and become less material thereafter to our vascular product sales category.
- In summary, the CEO commented on his goal of delivering sales growth of at least 3%, by stating: “We are confident that our innovation-based growth strategy, supported by our mission to deliver cost effective medical device solutions that saves and improve lives, will enable us to achieve that goal.

Industry Trends

#1 - Slowing Growth: a statistical look at the medical device industry

Revenue for the global medical device marketplace reached $331 billion in 2012(1). Although estimates vary, pundits agree the heady days of double-digit and even high single-digit growth are over as the industry adjusts to the reality of more modest 2% to 5% annual growth through the decade.

According to VisionGain, a London-based business intelligence firm, medical device industry revenue will reach $398 billion by 2017, a 4% CAGR. Among forecast panelists surveyed by Today's Medical Developments for its 2014 forecast (onlinetmd.com), Paul Teitelbaum of Mesirow Financial Investment Banking estimated 5% to 6% industry growth for this year. (2) Bloomberg Businessweek assessed the performance of the industry's top ten players and pegged industry median sales growth at 2.35% in 2013 and estimated 2.79% growth in 2014.

Geographically, the United States continues to dominate the worldwide market with a 45% share of 2012 revenue according to DeciBio, a niche market research and strategy consultancy based in Culver City, CA. During the same period, the other players included the European Union with 25%, Japan with 10%, Asia-Pacific with 8%, and the rest of the world with 12% market share, including emerging markets in China, India, and Brazil. Based on its annual survey of medical device industry participants, Austin, TX's Ermergo Group reports that the two regions with highest expected growth for medical device sales in the next five years are Asia Pacific, with 67.3% of survey respondents ranking it at the top, and South America with 48.7% of respondents. About 61% of respondents expect average growth potential in the regions of North America and Europe.

The industry remains dominated by large multi-nationals. According to a report released in 2013 by the Congressional Research Service, the top five manufacturers – Johnson & Johnson, GE Healthcare, Siemens, Medtronic, and Philips HC – accounted for 28% of global medical device sales. The next five companies – Abbott Labs, Covidien, Boston Scientific, Becton Dickinson, and Stryker – generated 13% of sales. Collectively accounting for 7% of global sales were St. Jude Medical, Baxter, Zimmer, Smith & Nephew, and Biomet. This indicates that fifteen companies generate nearly 50% of worldwide medical device revenue. Small companies, those with fewer than fifty employees, comprise a significant percentage of the remaining market.

Behind the industry's slowing growth are a stricter regulatory environment including the Affordable Care Act's excise tax, longer FDA review, and tightening rules in Europe of CE Mark approval. Adding to margin pressures is increased competition through greater globalization and the emergence of group purchasing organizations (GPOs) which effectively limit the pool of potential customers. Lessening reward for R&D investment and pressuring pricing and profitability are trends related to cost containment initiatives such as lower reimbursement from government programs and increased awareness and cost sensitivity from patients and their healthcare providers.

The impact of slowing revenue growth on net income varies among industry players. For example, Bloomberg Businessweek's "Industry Board 2014" estimates the industry median net income growth for medical devices will be 3.98% this year. Included in this projection are expected variances in individual company performance including Abbott Laboratories, with estimated net income of 6.11% on sales growth of 3.14%, and Medtronic, which is expected to post net income growth of 0.18% in 2014 and sales growth of 2.53%. Overall, Bloomberg Businessweek estimates the industry's median operating margin in 2014 will be 15.96%.

#1 - Slowing Growth: a statistical look at the medical device industry (cont.)

Despite individual companies producing slowing revenue growth, industry players remain largely optimistic in their outlook for 2014, according to Ermergo Group's survey: 71% of the more than 1,000 survey respondents indicated they were somewhat or very positive about prospects for 2014 compared with 68% when the same question was asked in the prior year.

Contributing to the overall optimism are: industry segments expected to experience solid growth, the impact of an aging population, and rising healthcare standards in emerging markets. For example, according to Teitelbaum, the market for interventional neurovascular devices may achieve 30% growth this year; coronary stents may be flat, and revenue from hip and knee implants might actually decline.

According to Frost & Sullivan in its outlook published in July 2013, the top five technology trends expected to drive product development in the medical device industry are:

- Interoperability that integrates medical devices into a connected platform,
- Multifunctional devices that address concerns of available floor space and price as versatile systems that can serve multiple needs,
- Strides in "big data" that reflect IT infrastructure upgrades and advances, which in turn enhance the artificial intelligence functionality for devices,
- Low-cost alternatives/cost-containment initiatives that in turn spur innovation in medical technologies, and
- Nano technology that enables devices and treatments to better influence diseases at the cellular level.

Conventional wisdom is that industry sectors most closely associated with the aging population will experience greater growth. So significant is the over-65 age group to medical device industry expansion, that VisionGain writes in its report Medical Devices Industry and Market Prospects 2013-2023, "the future fate of the industry will be largely determined by whatever happens to the people within this demographic."

According to the United Nations Population Division, the percentage of the world's population over 65 will increase from 7.8% in 2012 to 20% by 2035. In the United States, the over-65 age group accounted for 14% of the population in 2012, and is projected to reach 20% of the U.S. population in 2030. This is fueled by the arrival of the Baby Boomers in a time of longer life expectancy as well as expectations for living actively for years beyond traditional retirement age.

(1) Healthcare Finance News, May 2013.
(2) "2014 Forecast: Optimistic, game changing, transitioning." Today's Medical Developments, February 2014.

#2 - Environment Update: A drag on the industry

For the medical device industry, the Patient Protection and Affordable Care Act (ACA) can be summarized in two words: excise tax. Hotly contested since before going into effect on January 1, 2013, the 2.3% tax charged to manufacturers on their sales of medical devices has now entered its second year. The intention of the tax is to raise approximately $30 billion over 10 years to offset costs associated with ACA implementation. Industry trends related to the medical device excise tax (MDET) include a continuing debate regarding the actual impact of the tax, efforts for repeal, and the strategies underway by medical device companies to absorb the tax.

In a fact sheet released in February 2014, the Advanced Medical Technology Association (AdvaMed) reported findings from its survey of member companies that specifically assessed the impact of MDET after its first year. Overall, the survey supports the contention that MDET represents a significant and negative drag on the industry.

AdvaMed's survey elicited a 15% response rate with responding companies representing approximately 40% of U.S. medical device sales. Key among the survey findings is the loss of 33,000 jobs in the U.S. attributable to MDET. This number is based on a reported loss of 14,000 jobs through workplace reduction and an additional loss of 19,000 due to forgone hiring. AdvaMed reports that this figure significantly increases if indirect job losses in the supply chain and general economy are also taken into consideration.

Additional findings from AdvaMed's survey include 30.6% of respondents attributing R&D expenditure reduction to MDET and nearly 10% of respondents citing MDET in their decision to relocate manufacturing outside the U.S.

In a report issued December 23, 2013 by the Congressional Research Service entitled The Medical Device Excise Tax: Economic Analysis, the authors conclude that from the perspective of traditional economic and tax theory, MDET is "challenging to justify." Nevertheless, with the tax in place, the authors also estimate fairly minor effects, "with output and employment in the industry falling by no more than two-tenths of 1%." According to the report, this result is due to the small size of the tax rate, the exemption of approximately half of output, and the relatively insensitive demand for health services. (1)

Although efforts remain underway to repeal the tax, including an advertisement from AdvaMed that ran in Politico in early April, efforts are also underway to absorb the impact of the tax. According to remarks by St. Jude Medical board directors, MDET is expected to "shave 0.5% off gross margin in 2014." The company reported offsetting this by continuing to move to lower cost manufacturing sites including Puerto Rico, Costa Rica, and Malaysia.

In an article in the Indianapolis Business Journal on May 13, 2013, Zimmer Holdings reported that it has implemented a plan to cut costs by $400 million by 2016. The article cites James Crines, Zimmer's CFO, as saying the cuts reflect a strategy to absorb MDET but the cost savings are also being used to "accelerate certain technology and product development programs, to cover short-term dilution from recently completed acquisitions, to support the continuing build-out of emerging market businesses, and to fund expansion of global sales channels."

#2 - Environment Update: A drag on the industry (cont.)

As these examples suggest, the trend to pursue ways to conserve costs in the wake of the tax and of ACA in general reflects overarching business strategies and responses to broader competitive issues. Added to the challenges and opportunities to absorbing MDET, this year will also see companies adjusting to new requirements for obtaining CE Marking for new products in Europe as changes to the 20-year old product approval framework go through the EU member state adoption process. According to Dutch-based First Clinical and Technical Services, Ltd., a support services company to Europe's medical device industry, there will likely be a transitional period which could last up to five years.

The most significant change affecting medical device manufacturers is the requirement for clinical studies up to five years after CE marking. This change means that no longer is a CE Mark a guarantee to marketability or for early revenue while a new device undergoes the more complex, lengthy approval process in the U.S.

With the uncertainty of the next few years given the changing regulatory environment and its impact, the bottom-line trend for medical device manufacturers and their suppliers is looking inward for opportunities to contain operating costs, strengthen competitiveness, and, of course, innovate.

(1) Gravell, Jane G., Lowry, Sean. The Medical Device Tax: Economic Analysis. Congressional Research Services, December 23, 2013 (#R43342).

#3 - Countering margin pressures: Spotlight on supply chain and internal processes

Medical device manufacturers and suppliers face an expanding list of trends and issues that potentially pressure margins. The regulatory environment, including product design, material testing, manufacturing, and clinical data, now also encompasses the excise tax and shifting purchasing and pricing parameters stemming from the ACA. The competitive environment is rapidly intensifying from both within and without the traditional medtech world as external forces such as new non-medical entrants grab share in what PricewaterhouseCooper describes as the "new health economy." Everyone seems to be using terms such as disruptive, game-changer, or commoditization to signal that a seismic shift is underway.

Against the backdrop of such margin pressures, medical device companies seek efficiencies by looking inward with a spotlight on their supply chains and internal processes. According to Keri Dawson, Vice President of Industry Solutions and Advisory Services at Palo Alto, CA-based MetricStream, medical device manufacturers should focus efforts this year on a "repeatable, methodical, sustainable cost-effective supply network across different medical areas." For Dawson, best practices in these efforts focus on compliance.

In classic turn-a-threat-into-opportunity mode, some industry observers find cause for optimism as the MDET further squeezes margins. "The current situation presents a prime opportunity to unleash a wave of manufacturing innovation in the medical device market to drive down the cost to produce products," writes William Fetter, director of marketing and communications for North Kingston, RI-based Hexagon Metrology Inc.

In his article published in Today's Medical Developments, medical device manufacturing is one of the least innovative among industries in the deployment of advanced technologies in measurement and inspection. (1) Fetter blames the lack of manufacturing innovation on the FDA's 21 CFR.820 regulations that encourage the status quo "even if the status quo is by nature outdated and inefficient." As margin pressures force medical device companies to tease out efficiencies everywhere, Fetter believes that they will experience positive bottom-line results by applying existing inspection and testing technologies to many manufacturing processes. For example, companies should replace any qualitative inspection methods with computer-controlled measuring machines that quantify data through automated means.

Another trend to counter mounting margin pressures is to carefully evaluate outsourcing vs. insourcing decisions and strategies. According to Toronto-based Millennium Research Group (MRG), the global medical device outsourcing market will reach $12 billion by 2018. Fueling this growth are outsourcing strategies with contract manufacturers to reduce production costs, "particularly for high-volume and low-margin devices such as endoscopes and surgical instrumentation." Although outsourcing is a strategy used to increase presence in emerging markets, MRG cautions that quality control concerns have prompted some shift back to U.S.-based manufacturing.

Quality assurance, product R&D, and regulatory compliance top the list of functional areas that should not be outsourced, according to medical device executives surveyed in 2012 by Axendia, a life science consultancy headquartered in Yardley, PA. According to Beware the Fog of Outsourcing, published by Medical Device and Diagnostic Industry (MD+DI) in March 2013, Axendia's report also highlights what it calls "smart sourcing." This trend reflects how companies, once they improve their evaluation of total costs, choose to expand insourcing efforts and consider regionally sourced products for local markets.

#3 - Countering margin pressures: Spotlight on supply chain and internal processes (cont.)

Outsourcing, insourcing, strategic partnering, and finding efficiencies in simply automating and fine-tuning the testing of materials are all part of the arsenal medical device makers will use to counter margin pressures and better prepare for the seismic changes underway in worldwide healthcare.

(1) Fetter, William. Obamacare, the Medical Device Excise Tax, and Manufacturing Innovation. Today's Medical Developments, December 2013.

#4 - Transparency fuels emergence of a value-driven market

Two trends with profound impact on the medical device industry are the drive toward greater transparency in costs and outcomes of care, and the emergence of a consumer-centric, value-based healthcare marketplace. The convergence of these trends is finally arriving in healthcare as has happened in most other marketplaces, according to Prakash Patel, the CEO of Access MediQuip, in an article he authored in October 2013.. (1) “Cost of care, including treatment, devices and other needed equipment and supplies, and the short- and longer-term outcomes of care, including surgical performance as well as device performance and safety are coming together under a value-driven model in a post-reform environment,” he writes.

Behind the trend toward greater transparency are increased demand for clearer and accurate understanding of costs and outcomes, and the “big data” and accompanying analysis required to do so. Patel views the big data requirement for medical device companies to include not only tracking outcomes and effectiveness, but also granular detail on each device and on “the most effective component parts involved in a surgery to support that device, including the right type and number of screws and other requisite parts.” It is through coordinated data sets and analysis that makes pricing crystal clear to everyone, Patel contends.

For many in the medical device industry, transparency represents a new way of doing business but one that is widely viewed as a requirement for staying in business in the coming years. MetricStream’s Keri Dawson, who served as a 2014 forecast panelist for Today’s Medical Developments, stated that the “regulatory environment inclusive of the ACA is growing more and more complex, so more and more transparency is required of participants in all aspects of the healthcare industry, including device manufacturers.” (2)

As transparency enables a deeper, real-time understanding of the connection between cost of therapeutic treatments and their effectiveness, more and more purchasing decisions are being made on the basis of the convergence of cost, outcomes, and other quality factors. As an example, the New York Times recently spotlighted how “some of the most influential medical groups in the nation are recommending that doctors weigh the costs, not just the effectiveness of treatments, as they make decisions about patient care” (April 17, 2014).

A different, but no less dramatic, development is how 24 of the 38 health-oriented companies currently comprising the Fortune 50 are new entrants in healthcare. The perception of new entrants is changing as more receive FDA approval for their products. Chris Wiltz of Medical Device Business writes that new entrants in medtech could “do the same thing to the doctor’s office that Amazon.com did to the local bookstore.” (3)

#4 - Transparency fuels emergence of a value-driven market (cont.)

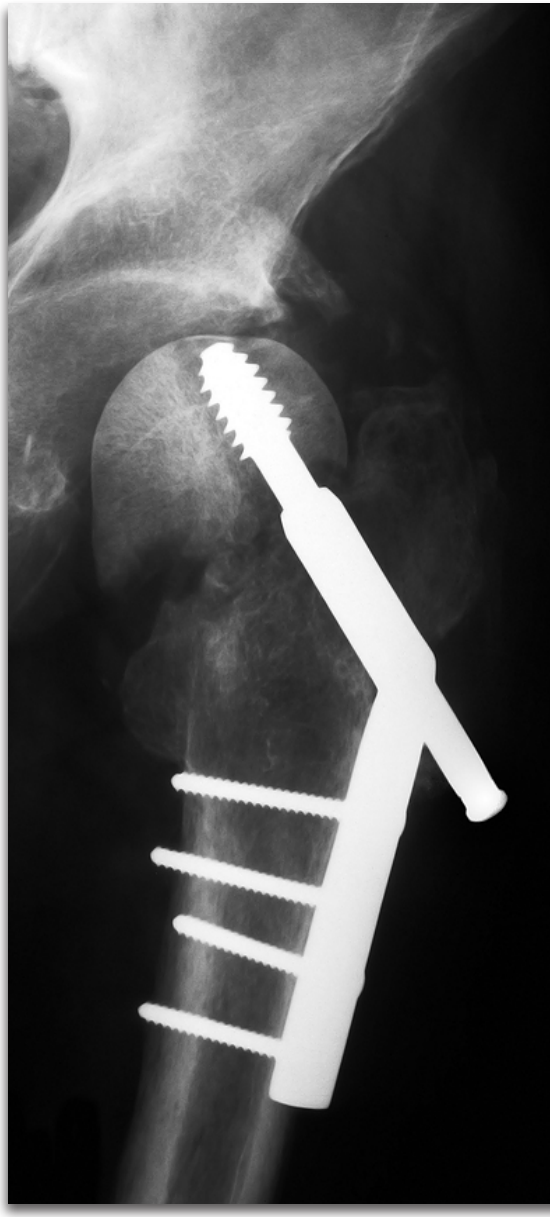
A recent report by the Health Research Institute of PricewaterhouseCoopers defines the key elements of the value-driven healthcare market, or what it calls the “new health economy.” (4) According to PwC, trends toward the new health economy include:

- Patients will be customers first and demand a continuum of well-being,
- Delivery to a care team of a lightening fast analysis of data,
- Shift of care delivery from inpatient to outpatient services and the home,
- Transparency in cost and quality, and
- As money flows from consumers to new market players, today’s disease treatment industry will be replaced by a wide-open health marketplace.

Such developments signal a new era for medical device makers. According to Patel, those hoping to be leaders in this emerging value-based market need a “wrap-around” approach that encompasses population health, prevention strategies, “and a proactive attitude that maximizes value and the patient experience, along with clear and actionable patient education.”

(1) Patel, Prakash. A Disrupted Landscape: The New Medical Device Industry. Access MediQuip, October 16, 2013.
(2) “2014 Forecast: Optimistic, game changing, transitioning.” Today’s Medical Developments, February 2014.
(3) Wiltz, Christopher. Disruptive ‘New Entrants’ Challenge MedTech for Billions in Revenue. Medical Device Business, April 11, 2014.
(4) New Health Economy. PricewaterhouseCoopers, April 2014.

#5 - Greater attention to quality: Device recalls increase



In the fast emerging value-driven marketplace for medical devices, quality is most closely associated with safety and consistent effective outcomes. Combine need for quality and demands for transparency, and one can quickly understand the heightened sensitivity around the Medical Device Recall Report which the FDA published in March 2014. (1)

The FDA's Center for Devices and Radiological Health (CDRH), which issued the report, concluded that the annual number of medical device recalls increased by 97% from 604 recall events in FY2003 to 1,190 in FY2012. The report also concluded that from FY2010 to FY2012, U.S.-based manufacturing firms accounted for approximately 80% of device recalls. Behind each of these findings, CDRH attributes better recall reporting by U.S. companies and the current greater likelihood of U.S. firms to be inspected. According to CDRH, the two industry segments accounting for the majority of the increase in recalls are manufacturers of radiology devices and manufacturers that received 21 CFR 806 observations following FDA inspections.

Another area of key findings by CDRH related to what caused each recall event. Overall, material or component causes accounted for 28% of all recalls, second only to software design failures that resulted in 36% of recalls. "If industry and CDRH can address these problems jointly, we may be able to prevent as many as 400 recalls each year," the CDRH states in the report's introduction.

CDRH reports that the top five specific reasons for recall are nonconforming material or components and software design (device), each with 429 recall events; device design causes (425 recalls); process control (266); and component design (144). Recall reasons also included component change control, process change control, release of material or component prior to receiving test results, and equipment maintenance.

An example of a recent voluntary recall was Covidien's disclosure that it recalled certain lots of its Pipeline Embolization Device and Alligator Retrieval Device because the Teflon material that coats the delivery wires on these products could delaminate and detach – a situation that carries the risk of stroke and/or death. Covidien learned of the issue through internal product testing, a fact that underscores the high visibility and critical nature of material testing in ensuring quality of medical devices.

In the medical device industry, compliance and quality go hand in hand as public trust in device safety and effectiveness is essential. The role of material and equipment testing is significant not only to avoid recalls but also to minimize the impact of a recall if one occurs. According to Exponent, Inc., the publicly traded scientific and engineering consulting company headquartered in Menlo Park, CA, "how well a company manages a recall situation or deals with regulatory non-conformity matters, can affect not only the future viability of the product, the company's liability, and financial loss, but can also affect a company's good name, reputation, and brand equity."

(1) Medical Device Recall Report FY2003 to FY2012. FDA Center for Devices and Radiological Health, March 2014.

#6 - Product Trends: Focus on patient experience and pragmatic cost cutting

According to Frost & Sullivan's Medical Device Market Outlook (July 2013), the following product sectors are poised for greatest growth within the industry:

- Structural heart: includes congestive heart failure products,
- Robotic assistance for surgery and treatment planning. An example is RP-Vitu, a remote presence telemedicine robot from Santa Barbara, CA-based InTouch Health, Inc.,,
- Infection control tools to address concerns of hospital-acquired infections – a$65-billion, problem affecting 1.7 million people in the U.S.,
- Home care, including remote monitoring tools and medical products in home settings, and
- Neuro devices, including interventional and implantable medical devices to treat brain disorders.

The trend toward a value-driven marketplace is evident in the development of these and other medical device sectors. Early in this post-reform era, product development reflects heightened sensitivity to cutting costs and enhancing the patient experience.

According to Jamie Hartford, managing editor of MD+DI, many of the products selected as finalists in this year's Medical Design Excellence Awards (MDEA) were chosen in part because of innovative solutions that help address specific post-reform challenges faced by the healthcare system. For example, Zimmer's Persona Personalized Knee System and accompanying surgical instruments address the need to reduce procedure time, thus saving surgical costs. Persona's implant system also allows for customization with different components for different anatomies, a feature designed with the patient experience in mind.

Another example of a MDEA finalist is Hill Rom's MetaNeb device, which can deliver three therapies in a single product, thus eliminating the need to purchase stand-alone machines. MetaNeb's design also incorporates features to prevent the spread of infection, reflecting the significant need to combat the spread of hospital-acquired infections.

Devices making greater use of minimal invasive technologies help cost containment by aiming to reduce procedure time, decrease complications, and minimize readmissions, the latter being a specific metric singled out by health reform. For example, devices such as the Flex-Xc flexible digital scope, announced by Karl Storz in March 2014, represent products that reach or probe areas of the body through minimal incisions and enable doctors to see and treat disease pathologies.

Other examples of minimally invasive devices are transcatheter heart valves. In addition to treating patients suffering from a narrowing of the aortic valve, such devices are now used to implant tiny pacemakers currently in clinical trials, namely Micra TPS from Medtronic and Nanostim from St. Jude Medical.

According to London-based VisionGain's 2013-2023 industry outlook report, neuromodulation devices represent one of the fastest growing product sectors and accounted for an estimated $5.2 billion in the 2012 global medical device market. Such devices address what VisionGain calls the ongoing unmet clinical need in the treatment of neurological disorders.

#6 - Product Trends: Focus on patient experience and pragmatic cost cutting (cont.)

With the increasing consumer orientation of the healthcare marketplace, it is not surprising that devices targeting patient convenience and overall experience are among product trends. For example, FreeStyle Optium Neo from Abbott Care has a choice of tools to help people who use insulin. But the device also brings the "type of intuitiveness that people take for granted with smartphones," according Brian Buntz and Chris Newmarker of Medical Device Business who wrote about this year's MDEA finalists. (1) According to their article, it should come as no surprise that more medical devices are beginning to resemble Apple products in their appealing, ergo-friendly and multifunctional designs.

As product trends point to devices that cut costs for providers and payers, manufacturers should avoid costly capital equipment and instead focus on minimally or non-invasive devices as well as disposable or consumable devices, according to Mesirow Financial's Teitelbaum. Companies will also need to "conduct trials proving econometric value and improved outcomes in order to justify higher reimbursement levels," he writes. (2)

Gone are bells and whistles for technology's sake. Today's device marketplace is most assuredly being defined by value.

(1) Buntz, Brian and Newmarker, Chris. 6 Trends Reshaping MedTech in 2014. Medical Device Business, April 17, 2014.
(2) "2014 Forecast: Optimistic, game changing, transitioning." Today's Medical Developments, February 2014.

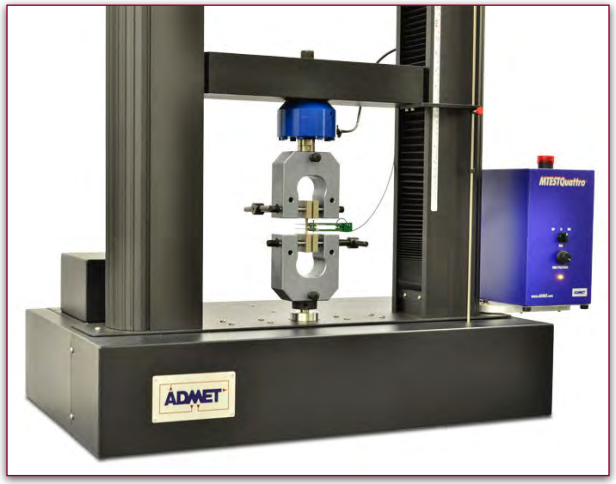
Case Studies

The above macro trends demonstrate some of the challenges facing the Medical Device Sector. It is clear that whether improving existing manufacturing processes or validating new processes and products, companies in the sector should be reviewing their material testing needs and the type of partner who can facilitate their success. We will now focus on three particular case studies which illustrate the challenges faced by three businesses in the sector and how ADMET was able to deliver a solution with excellent results.

University of Massachusetts Invests in ADMET Machine to Test Hip Implants

Challenge

The University of Massachusetts Medical School has been recognized by national and international medical communities as an outstanding institution for research. Within the university, the Department of Orthopedics and Physical Rehabilitation and the Department of Rheumatology form the Musculoskeletal Center of Excellence. This center researches the prevention, diagnosis, treatment, and rehabilitation of musculoskeletal disorders.



One of the center's research projects is led by Dr. John Wixted and studies fracture biology to validate a device that measures fracture healing properties of various orthopedic implants. Dr. Wixted needed a testing machine capable of determining the load sharing between bones and implants during both tension and compression.

Solution

Dr. Wixted chose an ADMET eXpert 2611 Universal Testing Machine to meet the study's challenges. His team attached special sensors to bone implants used in hip repair and placed them in plastic bone substitutes to determine how much force is applied to both the bone and the implant. ADMET's MTESTWindows control system allowed the researchers to capture the test data and easily export it to a spreadsheet for further analysis.

Results

Dr. Wixted has been very pleased with working with ADMET. He explains, "I've been very happy with ADMET from a cost basis, ease-of-use, and ongoing support. It does what we need it to do."

As his research program is nearing completion, Dr. Wixted is already using the flexible eXpert 2611 system for other biomechanical applications. Starting on a new application can be daunting, but ADMET's support ensures that customers are able to utilize all aspects of their system. Dr. Wixted was particularly pleased with his interactions with ADMET's support staff: "They've also been very good with the customer service end of things. Whenever I call with a question, they're very good about getting right back to me with an answer."

With its flexible capabilities and ease of use, ADMET's eXpert 2611 Universal Testing Machine will continue to contribute to UMass Medical School's reputation for research excellence well into the future.

ADMET Machine Satisfies Compression Bend Test Needs of Karl Storz

Challenge

Karl Storz is an international company known for its production of medical instruments and devices. Its product range varies from neuro-endoscopy and cardiovascular surgery to veterinary medicine, gynecology and spine surgery. In particular, Karl Storz has developed meter-long endoscope tubing, which are instruments useful for studying the inside of the human body. With this technology, surgeons can more clearly see into the organs they are performing surgery on and therefore obtain better results.

In order to develop such products for the medical sector, it is a necessity to ensure the strength, safety, quality, and structural properties of endoscope tubing. The ultimate challenge that Karl Storz encountered is the ability to track endoscope flexibility and have better control of their analysis. The company was looking for an easy to use machine capable of measuring deflection rates and conducting compression bend testing on their meter-long endoscope tubing.

Solution

Karl Storz considered building their own compression bend testing machine. However, the cost and time benefits provided at ADMET were viewed as a worthier solution. It would be a longer process to develop a machine on-site compared with investing in standardized systems from ADMET.

The eXpert 5601 1kN single column universal testing machine equipped with the eP2 Digital Controller and GaugeSafe Live Data Exchange Program was purchased along with a custom bend fixture. ADMET also provided the company with on-site installation and training. After receiving the machine, no major issues were encountered and on-site training was helpful for learning quickly how to use the system.

Results

After acquiring and using the eXpert 5601 1kN testing machine, a visible improvement in Karl Storz's materials testing occurred. The company was able to gain more control and information over the quality of their product. This improved their line and ability to assess structural and mechanical properties of their endoscopes. Ultimately, it results in fewer defects for their customers down the line.

Joseph Labenski, a manufacturing engineer for Karl Storz Endovision, stated that his team was "very happy with the system. The ADMET eXpert 5601 testing machine is a great product from a self-established company. The testing system performed as expected and met all of our expectations. It was delivered on time and did not require months of training."

ADMET Expands Orchid Design's Testing Capabilities with Custom Machine

Challenge

Orchid Orthopedic Solutions is headquartered in Holt, Mich. From the main company, a division called Orchid Design does contract product development for orthopedic medical devices from two locations in the United States – Shelton, Conn., and Memphis, Tenn. Further defining the company's niche offerings in the industry is a group within Orchid Design's facility in Shelton that specializes in cutting instruments such as drills, rasps, reamers, and saw blades.

The medical device engineers had a tensile-test machine in the lab, but found they really needed to perform torque measurements. They asked the manufacturer of their existing test machine if it could be adapted for torque testing. The answer was yes, but the cost was prohibitive.

To complicate the situation, they needed to perform two very different kinds of torque tests, says Spencer Shore, a development engineer at Orchid Design. Testing bone screws required a high-torque spindle that could have a low maximum speed. Testing drill bits required a high-speed spindle that would not need as much torque.

Solution

They searched for a vendor that could supply what they were looking for and found ADMET, a manufacturer of materials testing systems that is accustomed to adapting equipment according to customer requirements.

"On cost and customization, they worked with us," Shore says.

Vinny Milano, ADMET account director for biomedical and testing lab sectors, diagnosed what Orchid Design was trying to do and suggested a solution: a tabletop test frame with two interchangeable spindles.

Early in 2013, Orchid Design took delivery of an ADMET eXpert 9612 vertical torsion testing system with an MTESTQuattro PC-based controller. The system came with two interchangeable spindles: the standard 20Nm (177inch-lb) 90rpm spindle and a 2Nm (18inch-lb) 5,300rpm spindle.

Results

The system worked well. "The ADMET system has rounded out and expanded our capabilities, and it has led to new opportunities," Shore says. "For example, a colleague was working on a blade product and when we won the business, we used the testing system to advance the project further, faster."

"Having that test capability has also increased our ability to do cutting edge instrument design and development work," says Peter Bayer, Orchid Design business development manager. "It has allowed us to go to the next level," for example, in comparing a next generation product to a previous version.

"It was great to see our technology configured to meet and exceed the expectations of Orchid Design," Milano says. "To help customers improve their performance and ideally enhance their capabilities are goals we strive for with every project. But it takes a collaborative partner such as Orchid Design to achieve that."

Testing Solutions

A Range of Options to Meet Your Needs

ADMET provides the Medical Device sector a wide variety of technologies to meet their testing needs. We provide systems for testing implants, medical equipment, biomaterials, and tissues. ADMET machines are capable of conducting a range of different tests including tension, compression, peel/adhesion, bend, fatigue, torsion and axial-torsion tests. ADMET offers four types of machinery commonly used for testing in the Medical Device space – Static Universal, Axial-Torsion, Dynamic, and Micro Testers.

System Type	Series	Description	Models	Capacity		Applications
Axial-Torsion	eXpert 8600	Electronic Axial-Torsion Test System		**Axial (kN)**	**Torsion (Nm)**	Bone screws, Biomaterials, Medical Adhesives, Spinal Constructs, IM Nail, Luer Fittings
			8600	0.2	1	
			8602	2.2	20	
			8653	50	100	
Fatigue	eXpert 1900	Servo Hydraulic Dynamic Test System		**Axial (kN)**	**Max Freq. (Hz)**	Bone Plates, Dental Implants, Biomaterials, Stents, Hip and Shoulder Implants, IM Nails, Spinal Constructs
			1910	15	50	
			1911	25		
			1912	50		
	eXpert 3900	Brushless Linear Motor Electrodynamic System	3910	0.4	50	
			3931	1.3		
			3933	3		
			3934	4.3		
	eXpert 5900	Rugged Roller Screw Electrodynamic System	5951	4	15	
			5952	8		
			5955	14		
Static Universal Test Systems	eXpert 5600	Modular Static Actuator		**Axial (kN)**		Biomaterials, Sutures, Endoscopes, Hypodermic Needles, Syringes, Stents, Medical Packaging, Catheters, Medical Gloves, Nitinol
			5601	1		
			5603	2.5		
			5603	5		
	eXpert 7600	Static Axial Single Column Test System	7601	1		
			7602	2.5		
			7603	5		
	eXpert 2600	Static Axial Dual Column Test System	2611	10		Bone Plates, Spinal Constructs, Bone Cement, Nitinol, Bone Research
			2613	50		
			2654	100		
Micro Test Systems	eXpert 4000	Small Scale High Precision Static System	4100	0.45		Stents, Tissue, Biomaterials, Cell Cultivation
			4203	5		
	BioTense	Perfusion Bioreactor		0.07		

Configured Systems for the Medical Device Sector

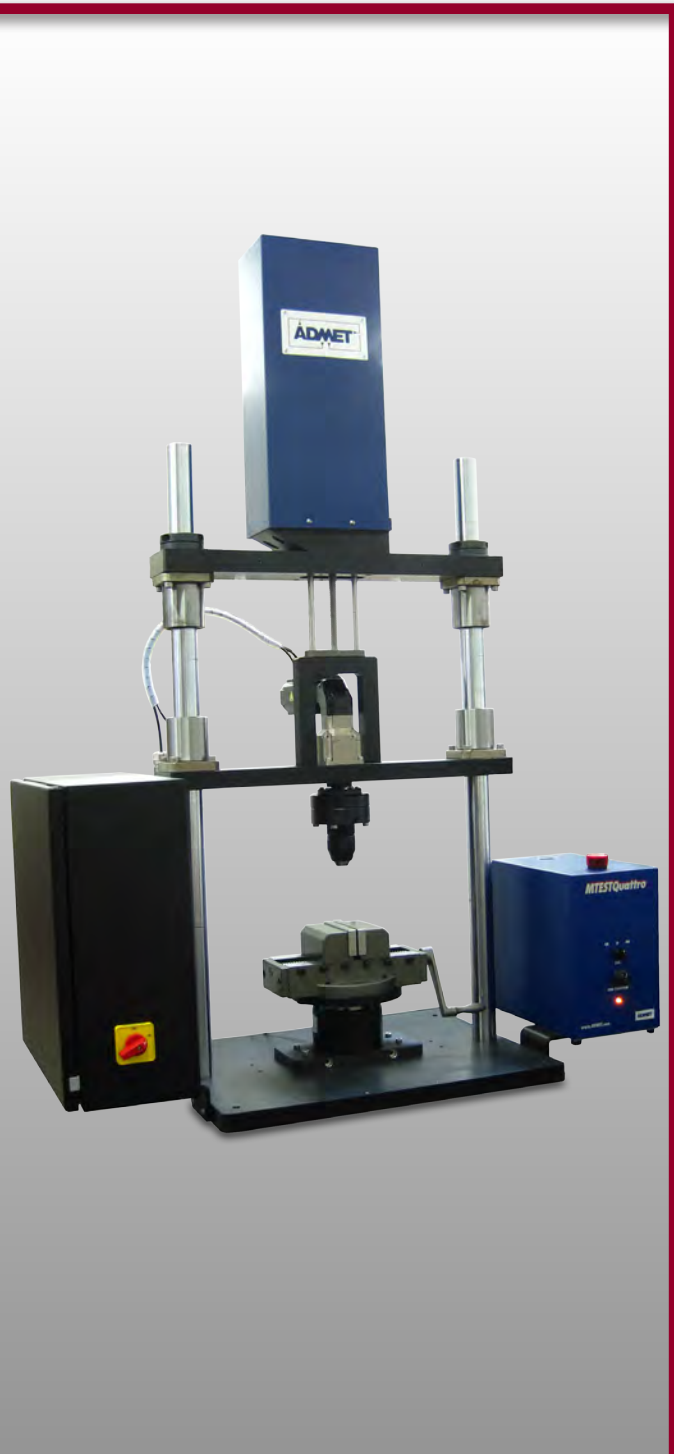
ADMET's customer service is focused on diagnosing the material testing issues present at each company, university, or laboratory. We discuss the challenges in detail, case by case, which allows us to recommend specific system configurations.

ADMET testing systems are capable of conducting tension, compression, fatigue, axial torsion, flexure, and peel tests. We offer a full line of optical and clip on extensometers, baths, heating and cooling systems, grips, fixtures, and load cells. We will also increase the distance between columns, shorten or lengthen the stroke, or add a torsion actuator for biaxial tests to meet your testing needs. We now review our four types of system solutions for the Medical Device sector.

Axial-Torsion Testers

This system is ideal for testing medical adhesives, bone screws, luer fittings, biomaterials, spinal constructs, intramedullary rods, knee implants, and stents. All ADMET axial-torsion systems are controlled by the PC based MTESTQuattro controller. The flexible software and infinite rotating torque actuator allows the end user to perform R&D and quality testing to various ASTM and ISO standards.

Electronic table top load capacities vary with axial loads from 0.2 kN to 50 kN and torque capacities from 1 Nm to 100 Nm.

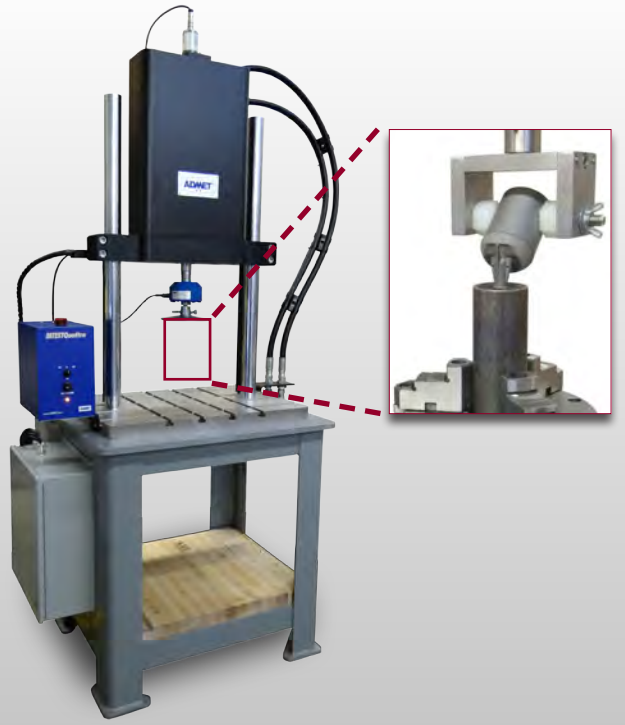


Fatigue Testers

The eXpert 1900, 3900, and 5900 series dynamic testing machines are compact, quiet, and clean electro-dynamic and hydraulic testing systems for determining the durability of materials and components in tension, compression or flexure. eXpert 8902 and 9900 series machines are ADMET's line of electro-dynamic torsion fatigue testing systems. Common applications in the biomedical sector include dynamic testing of bone plates, hip and shoulder implants as well as spinal constructs.

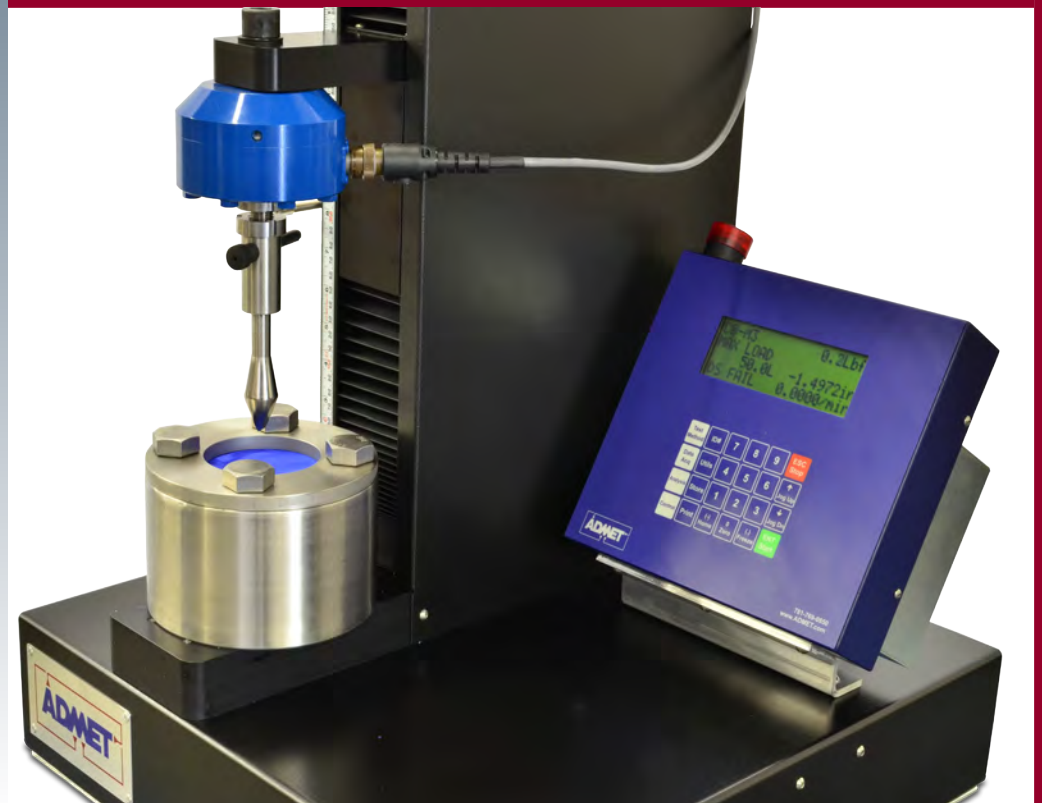
Some key control features include:

- The ability to program sinewave, sawtooth and complex cyclic control profiles
- Mixed Mode Control – perform tests where control and end point channels differ
- External Setpoint Mode – allows for third party function generators to provide external waveforms. Ideally suited for performing fatigue crack growth rate and non-linear fracture toughness tests.
- External Profile Mode – reads a formatted text file real-time and executes spectrum fatigue loading profiles which simulate complicated service load conditions
- Sinewave profiles allow users to adjust the amplitude and frequency on the fly
- Sinwave amplitude control ensures constant amplitude as the material fatigues
- Software position limits terminate the test when the part fails; position limits can be adjusted during the test
- Shared data file allows for third party data logging systems to record data real-time



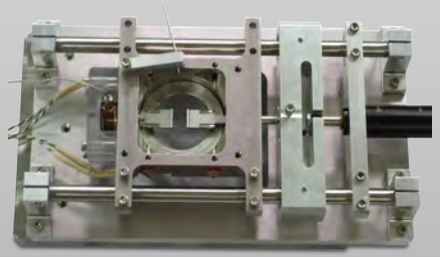
Static Testers

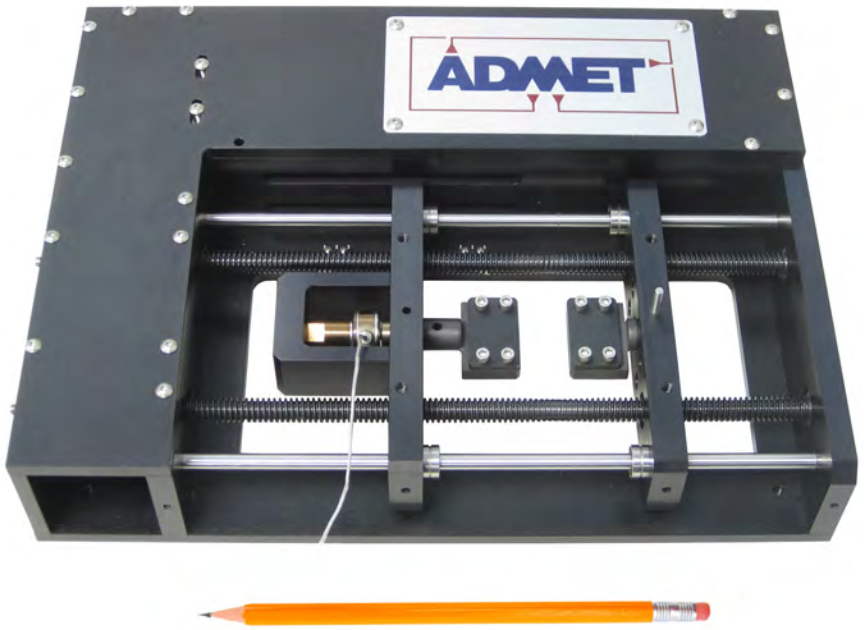
The eXpert 1600, 2600, and 7600 series are robust Universal Testing Machines employed throughout the Medical Device sector. These systems offer a flexible design that enables the end user to perform static tests with a loading capacity ranging from 1 kN to 600 kN. Some common test applications in the Medical Device sector include testing medical adhesives and packaging, needle puncture tests, tensile testing on medical tubing and sutures, as well as bend testing of endoscopes.



Micro Testers

Many industrial sectors are driving innovations in new materials from biomaterials, bone, fibers, threads, thin films, wire and more. However, that innovation requires measuring the mechanical properties of miniature samples. Few materials testing systems are able to measure very low forces and small displacements on samples that can often be difficult to hold. Furthermore, many researchers also have a need to record microscopic material behavior while the sample is under load. The line of eXpert 4000 series MicroTest Systems are ideally suited to meet these demanding testing requirements.





Additional Services for the Medical Device Sector

Once a customer has purchased a materials testing system from us, we offer on-site installation and training. However, our customer service does not stop there. We also provide phone, online, and email support throughout the lifetime of the material testing machine.

If a customer has specific requirements for a piece of equipment, the ADMET team will customize a system according to their needs. We are able to tailor a system for testing large, small, wide, or short specimens and program the machine for faster or slower speeds. All of our machines are equipped with controllers such as the PC-based MTESTQuattro Software Controller or the standalone eP2 Digital Controller.

On top of these services, the ADMET team can engineer a system to include temperature-controlled environmental chambers, fluid baths, specified grips and fixtures, extensometers, and cutting tools. We work with our customers to develop a customized solution that produces the desired results.

About ADMET

ADMET is a leading global manufacturer of innovative material testing systems. We enable customers to conduct comprehensive, repeatable tests to ASTM or ISO standards, while keeping costs under control and seamlessly integrating their testing procedures into their organization. Robust, easy-to-use and consistently accurate, ADMET material testing systems are supplied to the automotive, aerospace, medical device, construction, plastics, metals, test lab, and education sectors as well as major government agencies. Customers include Lawrence Livermore National Lab, GE, DuPont, Boeing, US Steel, John Deere, Bechtel, Medtronic, and Harvard Medical School. The ADMET team has been solving materials testing problems for more than 25 years from basic applications to recent innovative breakthroughs in the medical sector.

For more information, contact Vinny Milano, account director for the Medical Device sector, at (781) 769-0850 x 21 or by email at vmilano@admet.com

Our Customers

Below is a partial list of the customers in the Medical Device sector that have invested in ADMET technology.

ACUMED	Medical Murray
Dentsply Orthodontics	Medtronic
DJO	Naval Medical Logistics Command
Guidant Corp.	Orthobond
IlluminOss	Orthohelix Surgical Designs
Haemonetics Corporation	SOTAX Corporation
Incline Therapeutics	UMass Memorial Medical Center
Karl Storz Endovision	Xeridiem Medical Devices
Luna Innovations	X-Spine Systems

Visit us at www.ADMET.com