MEDICAL DESIGN BRIEFS

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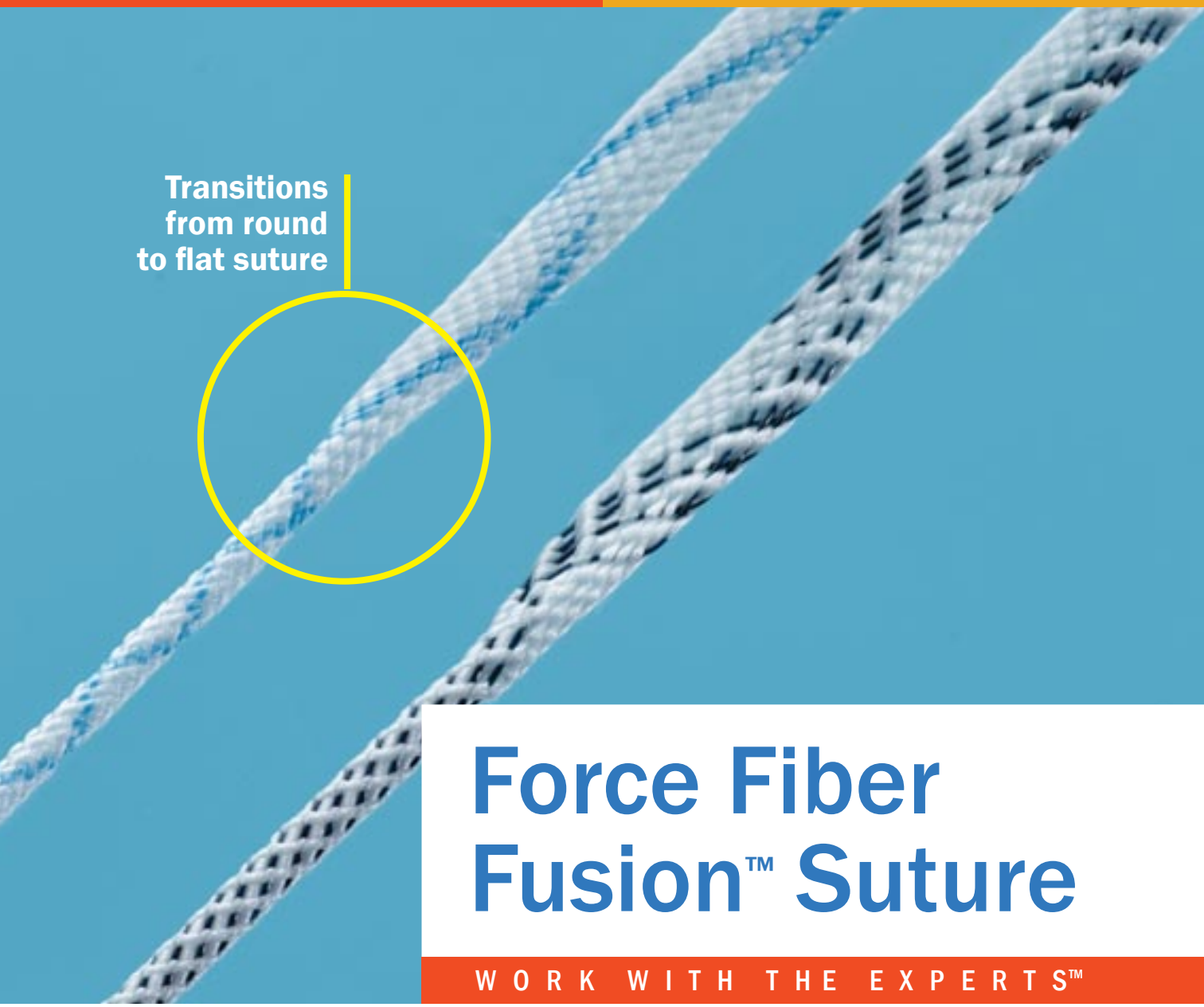

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COLUMN

FEATURES

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DEPARTMENTS

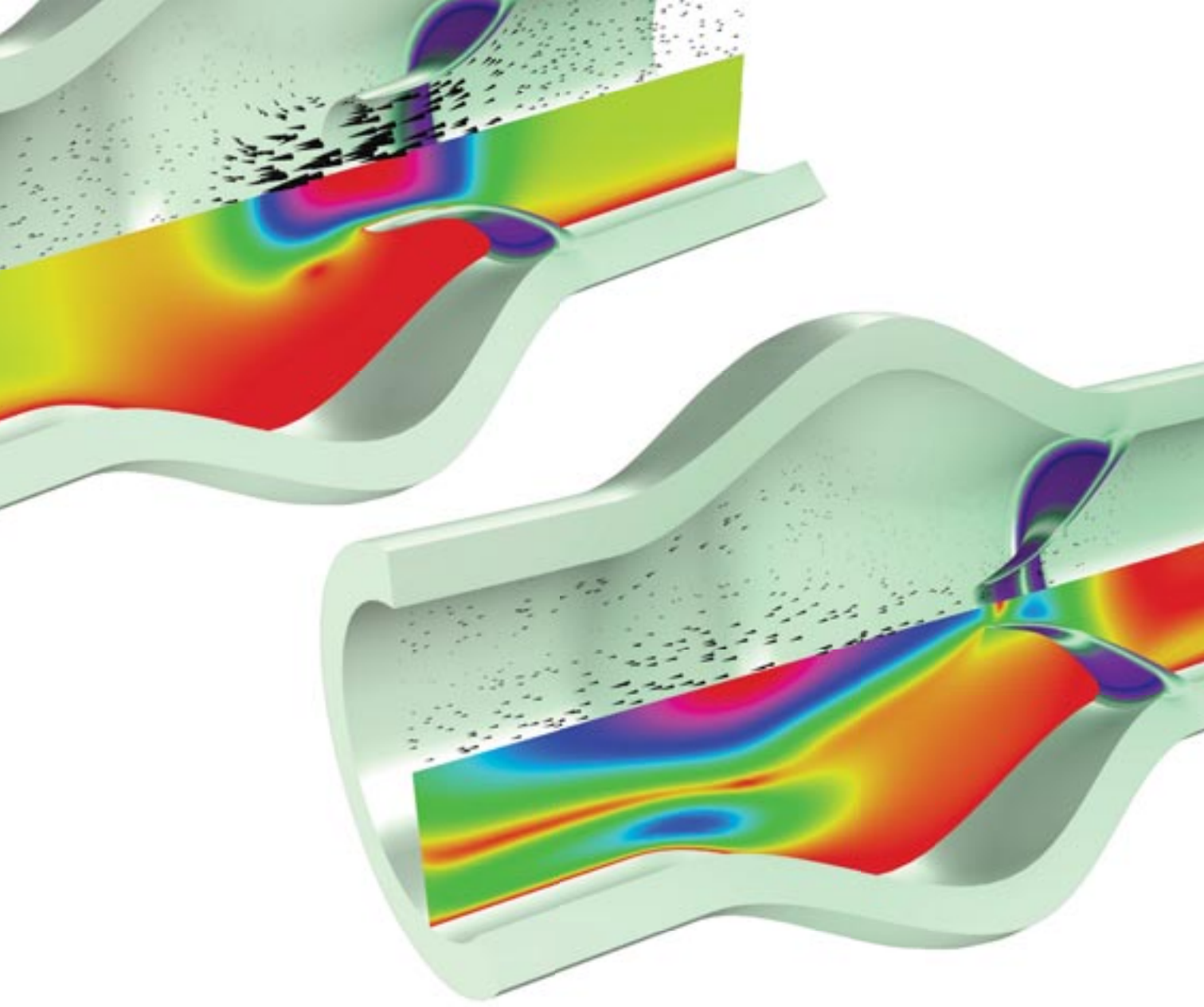
SPECIAL SECTION

Technology Leaders in Electronics

ON THE COVER

The use of multicomponent technology under cleanroom conditions provides an excellent foundation for the development of new medical and pharmaceutical products. Along with cost savings, coextrusion technology offers improved functionality in new tubing products. To understand how this micro-dimensional tubing is currently being used to meet increasingly complex medical engineering requirements, read the article on page 20.

(Credit: Raumedic)



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Medtech M&A on the Rise Again

It appears that the medtech industry has responded to a healthier market by going on a shopping spree. According to EP Vantage, a service of market analysis firm Evaluate, medtech mergers are back. EP says that the sum spent on deals in the first half of 2017 has already surpassed last year's total, "putting 2017 on track to be the second-biggest year for medtech acquisitions in a decade, behind only a mammoth 2015."

"If deal activity continues at the same pace, 2017 could see nearly $98 million spent on medtech M&A — double last year's total — but with only around 150 transactions, versus 234 in 2016," says EP.

While the total number of deals will likely be fewer than 2016, the value of those deals is higher. The firm says the average deal value in the first half of 2017 was above 2016, even when excluding Abbott's $25 billion takeover of St. Jude Medical. It has suggested that medtech buyers are either "being pickier or the pool of targets is dwindling."

The analysts point to several years of medtech consolidation and "a venture capital squeeze that has made it harder for earlier-stage companies to get funding" as a key reason for the limited number of potential target companies.

An analysis of the top 10 acquisitions in the first half of 2017 supports this theory, says EP Vantage. "Apart from the obvious Abbott–St. Jude buy, which made it the number-two cardiology player, other scale-building takeovers include Johnson & Johnson's acquisition of Abbott's eye care business and two deals from Allergan in the aesthetic surgery arena."

EP notes that the aesthetics market has been a particularly attractive area, with 10 takeovers in the first half of 2017. But other areas have been active as well, including vascular, with Terumo's acquisition of Abbott's vascular closure business in January and the Teleflex takeover of Vascular Solutions in February.

"Of course, big players will always be interested in promising new technologies," notes EP, "and five smaller deals by J&J should give younger companies hope, although financial details were not disclosed. With six acquisitions in total, J&J was the most prolific buyer in the first half."

EP says the latest figures "could represent more bad news for start-ups, suggesting that acquirers are eschewing smaller, technology-focused deals in favor of bigger buys aimed at growing their footprint in a particular area."

This is echoed by analysts at Silicon Valley Bank (SVB), who observe that "acquirers continue to focus on buying companies with products that are FDA-approved and commercialized. This puts critical regulatory and commercialization risk squarely on the venture community, increasing investment time and capital required."

In its report, "Trends in Healthcare Investments and Exits 2017," SVB also notes that all seven U.S. commercial M&A deals in 2016 were 510(k) products. "This reflects the investor mind-set of the early 2000s, which focused on products with easier FDA-approval paths, instead of PMAs, which had unpredictable FDA outcomes, says the report.

Sherrie Trigg
Editor and Director of Medical Content

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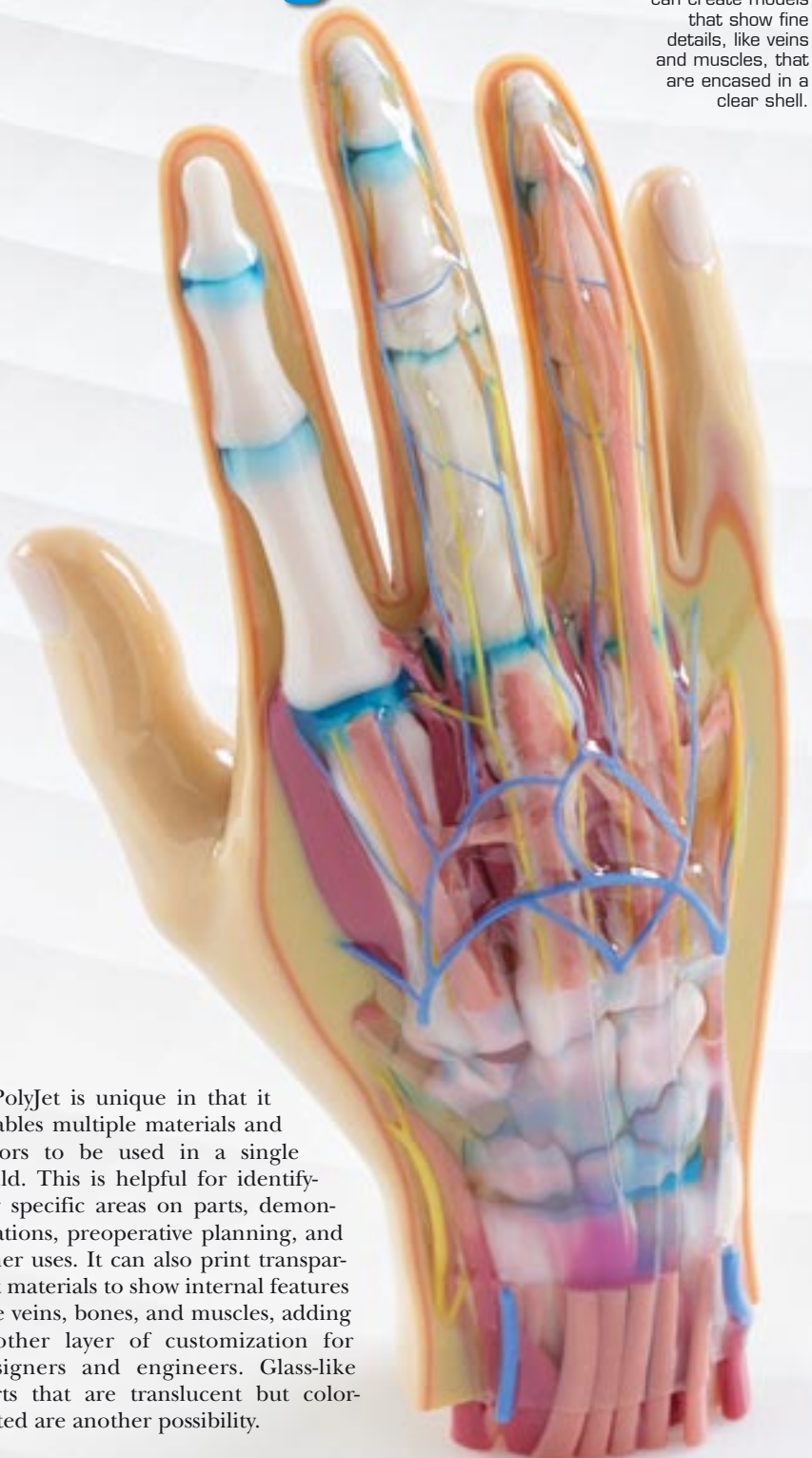
3D Printing: Overcoming Anatomical Model Challenges



PolyJet Multi-Color can create models that show fine details, like veins and muscles, that are encased in a clear shell.

For years, anatomical models have played important roles in hospitals and healthcare facilities. From educational aids to practice dummies, these models serve many functions for patients, students, and medical professionals. Producing them isn't always an easy process though, as designers and engineers balance the need for accurate, aesthetic models with the demand for quick deliveries and production. Not to mention that the customized nature of models — they are representations of patients' unique body parts and organs, after all — means they can be cost-prohibitive to build in low volumes via traditional manufacturing methods. But 3D printing helps overcome those challenges.

PolyJet Multi-Color, a 3D printing method, is one way designers and engineers can ensure that their model designs are built quickly, accurately, and cost-effectively. As the name suggests, PolyJet Multi-Color allows parts to be built in multiple colors with the PolyJet process. This article explores why that's important. It also presents four key aspects of using PolyJet Multi-Color that designers and engineers should understand before taking on their next project, including: how the PolyJet process works, how and why to use multicolor materials, top considerations for designing, and why the urethane casting process is a viable method for production of low volumes of anatomical models.

PolyJet: The Process

Given that it can quickly and cost-effectively print accurate parts, PolyJet is a fairly common process for building anatomical models like hands, kidneys, hearts, and other body parts and organs. With a default build layering at 0.001 in. — and an ability to jet layers as thin as 0.0006 in., thinner than a human hair — PolyJet permits very fine details, a necessity for realistic models. This process also minimizes post-processing and allows for quicker delivery.

PolyJet is unique in that it enables multiple materials and colors to be used in a single build. This is helpful for identifying specific areas on parts, demonstrations, preoperative planning, and other uses. It can also print transparent materials to show internal features like veins, bones, and muscles, adding another layer of customization for designers and engineers. Glass-like parts that are translucent but color-tinted are another possibility.

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Multi-Color: The Materials

Identification is the chief reason medical professionals like incorporating color into anatomical models. Since different areas of complex body parts and organs like the brain and heart can be printed in various colors, clinicians can more easily use the model for its intended function, whether it's as a pre-operative planning device or a practice dummy.

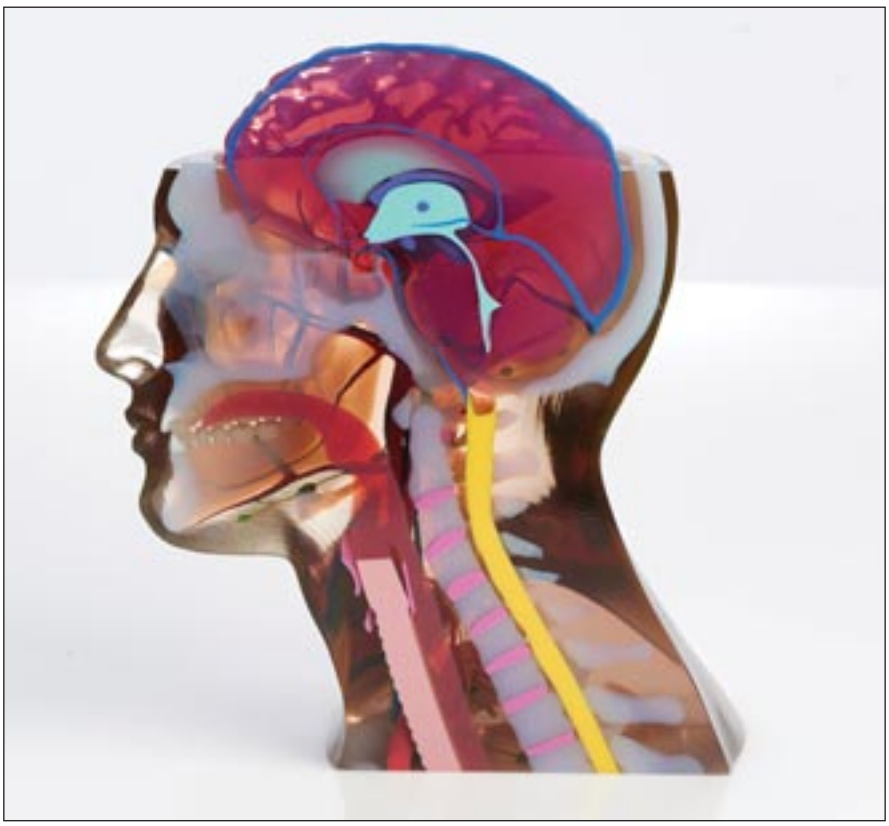
Along with being able to build parts with multiple colors, designers and engineers can design parts that incorporate textures via graphic images, furthering the visual complexity that can be achieved. For anatomical models, that could mean showing disease or other features requiring complex coloring. The result is a part built quickly with the desired visual aesthetic without the need for additional finishing. Here are a few of the primary materials used for creating these types of models:

- **ColorPlusClear**. This material builds parts in opaque and/or color-tinted transparencies. It has the ability to encase colored geometries in a water-clear, glass-like shell, allowing for fine details to be printed. Compatible with the STL file format, ColorPlusClear comes in a 0.00106 in. resolution.
- **VeroClear**. A transparent, rigid, and accurate material that produces fine feature detail. It has high dimensional stability and produces parts quickly and economically. VeroClear is commonly used for clear medical devices, casings, and components for unique reveals, like a liver with veins. With VeroClear, the delicacy of the small veins is a nonissue because the strength of the model comes from the outer shell. This material is available in two layer thicknesses (0.00118 in. and 0.00063 in.).
- **TangoPlus**. A rubber-like, elastomeric material that has a translucent, amber color. An advantage of TangoPlus is that it has no increased costs from secondary processing. It can be used for printing models such as hearts. While offered with the PolyJet process, this material is not included in the PolyJet Multi-Color offering.

Designing: Top Considerations and Choosing a File Type

Here are four key considerations to keep in mind when designing for the PolyJet Multi-Color process.

1. *Trapped volumes*: Building supports in trapped volumes (i.e., cavities that are difficult to reach or are trapped) presents problems. Doing so doesn't allow finishing tools to spray the supports away because they're trapped.
2. *Wall thickness*: Generally, Stratasys Direct Manufacturing prefers wall thicknesses of 0.060 in. or above, and the company's stated minimum thickness is 0.012 in. However, these guidelines come down to geometry and specific project requirements. So, for parts that are encased or supported by another material, thicknesses as small 0.001 in. are possible. However, if there is a part that requires two different textures or colors on either side, the minimum thickness of that wall must be 2 mm, because color applied to models is 1 mm deep and would be seen from the other side.
3. *Air gaps between walls*: If designers don't account for air gaps, then the support material may print in this area, producing individual pieces of assembly instead of a single part.
4. *Overlapping walls*: For parts built via the stereolithography (STL) file format, each unique material has to be its own file. It then has to be correctly located in CAD so that it's built in a single piece, rather than with walls on top of each other. If it's not, then it will produce an error before the build.



Multiple colors and materials can be used to build models depicting highly customized internal features.

Not taking these last two considerations into account can lead to post-processing, which complicates budgets and schedules.

The files. There are two file formats utilized for multicolor PolyJet parts: STL and virtual reality modeling language (VRML). Which one designers choose depends on the part's color and transparency needs, as the file formats assign color and texture graphics to parts in unique ways.

STL (.stl). This shell-based format has a couple distinct advantages. For one, it can incorporate transparency, something VRML cannot do. A lot of medical scans default to STLs as well, making it a simpler transition from segmentation export to designing parts.

Here are some specific cases using STL for PolyJet parts. A colored model using a clear material or color-tinted transparency, like medical models that use clear material to show interior anatomical features, will utilize STL. If the 3D model of the part is separated into shells (i.e., different parts combined together into one assembly), designers

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can choose the colors and level of transparency of each shell. This is also indicated with the PolyJet Color Guide RGD color code and/or checkered pattern, which indicates transparency. Note that with STL, each unique color in the part needs to have its own STL.

For those assemblies that are built as one part, multiple sections of the assembly will be the same color code and submitted as a single STL. For example, someone may design a clear organ with separate yellow, red, and blue tinted areas on the interior. The colored areas are not connected to each other, but since they are part of the assembly, held together by the clear organ, every color will be saved as a single STL. The designer saves time here because individual color codes don't have to be assigned.

Designers can also use third-party STL manipulation software. In those cases, it's best to use a Boolean tool that can add, subtract, and intersect space between two objects. If the Boolean tool is not used, there is a potential that overlapping parts could be assigned a random color by the PolyJet technology, and areas with space between walls may generate supports and could separate during handling.

Finally, it's important to consider the limitations of STL files. A chief restriction is that they do not have the ability to do gradient textures. And while it's still very possible to incorporate multiple colors, it's easier to do so via the VRML file format.

VRML (.wrl). The VRML format is ideal for parts designed with opaque colors or a colored graphic texture. VRML is a standard file format for representing 3D interactive graphics that provides the capability to apply graphic texture, also known as ultraviolet (UV) mapping, to a model. UV mapping essentially places all the color in an image file, which is then applied to the model by software. With more color options than STL, VRML has the ability to produce photorealistic colors.

VRML is usually the best choice when designers are looking to include multiple colors in their designs, as the file format makes it inherently easier to do so. Depending on how color is applied, the color could be within the VRML file itself, or the VRML file could be accompanied by one or more texture files (.bmp, .jpg, .tiff, .png). Color can be applied in VRML format to each face of the geometry, to each individual triangle, or with a graphic texture file. Possible uses for this process include anatomical models that show a colored depiction of heat or stress or a prototype when the graphics on the model are complex, such as a heart with multiple colors.

A special consideration for VRML is dealing with geometries that were assembled to form the final part. In those cases, there may be overlapping individual parts. Any colored surfaces that are 2 mm or less from the opposing surface may be seen in this instance. It is a best practice to combine the individual parts in order to remove any interior geometry.

One feature VRML can't naturally do is transparency because the file type wasn't created with this in mind. However, there are workarounds. One way is by building a model, via VRML files, with nice photo texture on the surface. If a section has to be clear or color-tinted, then it can be built separately and then post-assembled.

While not part of the PolyJet Multi-Color offering, TangoPlus material can be used on PolyJet machines to print models with no increased costs from secondary processing, like this model showing a hematoma.

Urethane Casting: The Highlights

Using PolyJet master casts for urethane casting is becoming more and more popular. Widely used for anatomical models, this process is suited for when companies need greater quantities of models because it is generally more cost- and time-effective to produce them this way.

Designers who are planning on using PolyJet with the intent of using it to create master casts for urethane casting should design in a manner that allows PolyJet parts to be used for the casting process. This step allows for an easier transition between manufacturing methods, thus streamlining the production process.

Putting It All Together

Designing anatomical models doesn't have to be like conducting open-heart surgery. Designers and engineers who understand all key aspects of PolyJet Multi-Color, from the PolyJet process to its design considerations, will be better able to help their teams build quality models both quickly and cost-effectively.

This article was written by Eric Quittem, Product Manager for Fused Deposition Modeling and PolyJet Technologies at Stratasys Direct Manufacturing (Valencia, CA). For more information, visit ***http://info.hotims.com/65855-162****.*

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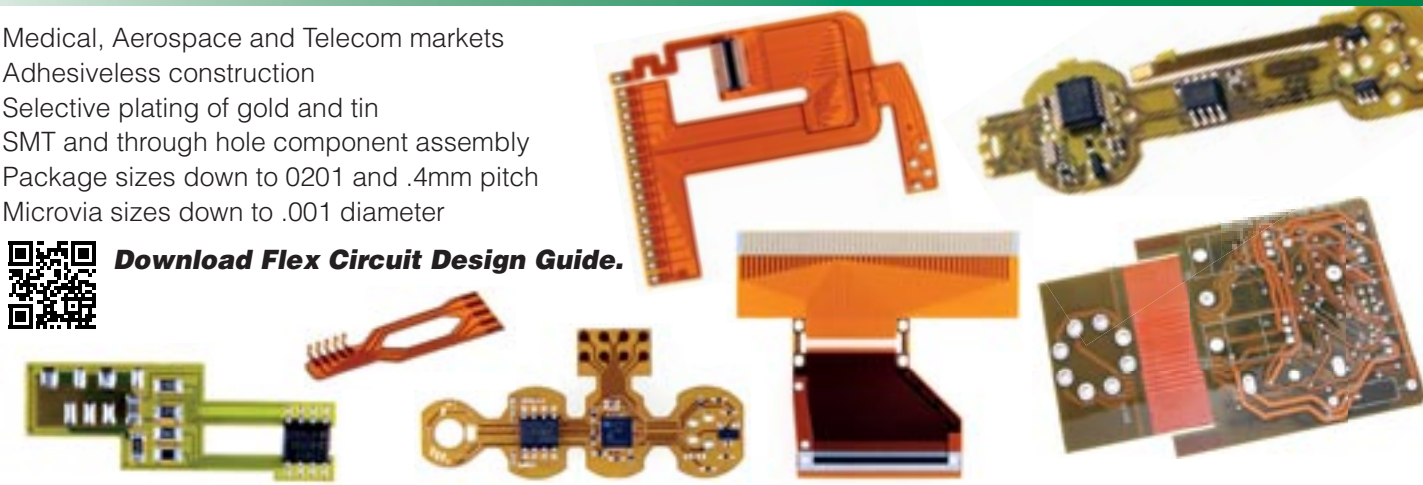

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Sterilization, Packaging, and Materials: CRITICAL CONSIDERATIONS

Ethylene oxide is a colorless, odorless, volatile, and toxic gas. (Credit: Sterigenics)

Single-use medical devices, pharmaceuticals, components, and packaging that need to be sterile must be treated with an appropriate and validated technique. It is also important to formally assess the potential effects of the sterilization process on product and packaging materials.

This article describes the most commonly used industrial sterilization techniques, which are radiation sterilization (gamma and electron beam) and gas sterilization (ethylene oxide), and their effect on commonly used materials.

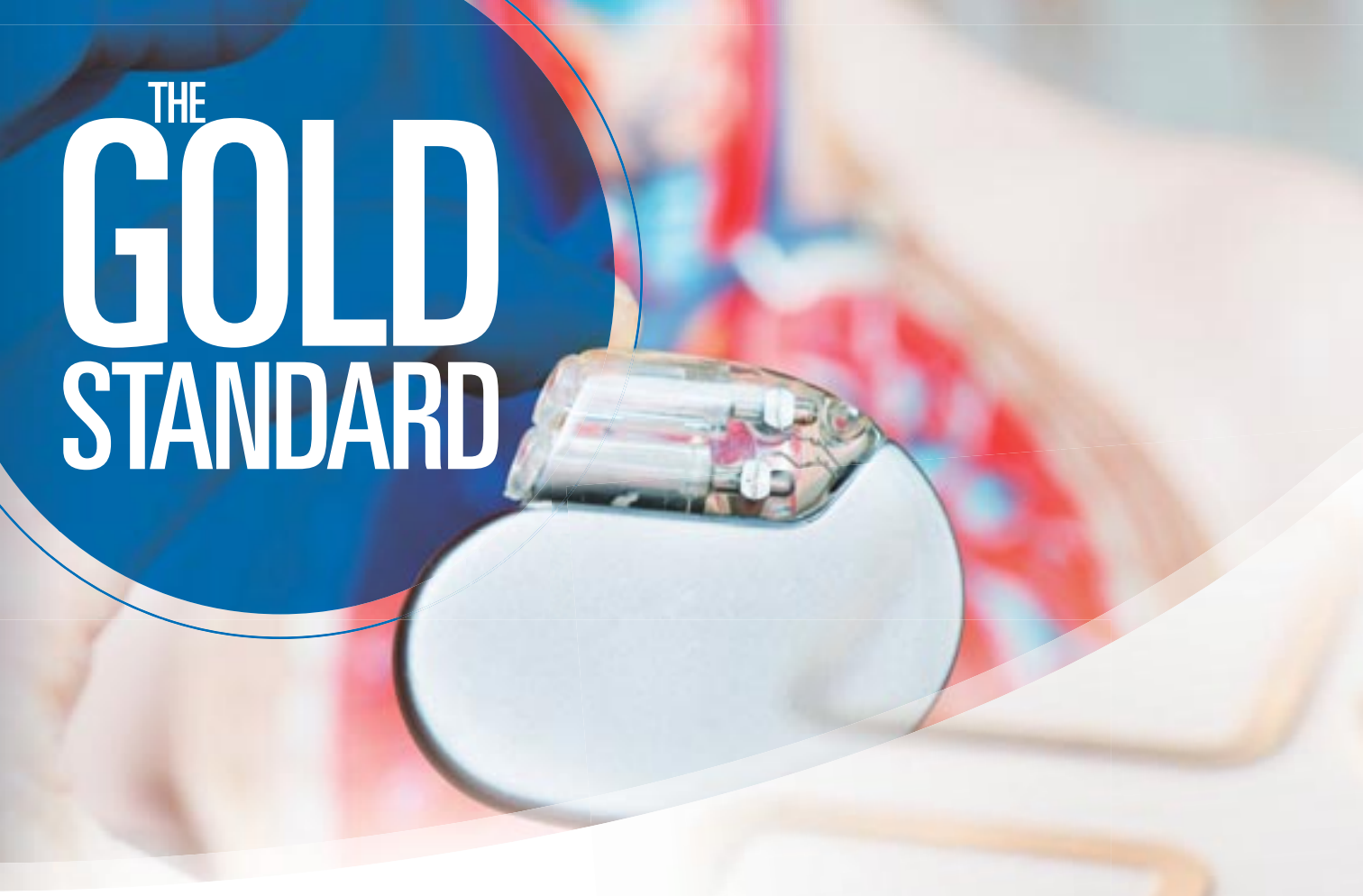
Gamma Sterilization

Gamma sterilization uses a radioactive source, typically Cobalt-60 (60Co), which emits high energy gamma rays. Ionizing radiation can modify physical, chemical, and biological properties of materials. Currently, principal industrial applications of radiation are for sterilization of healthcare products (including pharmaceuticals), irradiation of food and materials modification (such as polymer cross-linking).

Gamma sterilization is a "cold" sterilization technique, where temperature is not a key parameter. Temperature may increase slightly in the product due to ionization, but gamma sterilization may be effective at ambient, refrigerated, or even frozen conditions. The key parameter is the dose received by the product. The dose is dependent on the presentation to the source and the time exposed to the gamma ray source.

Polymers	Highly Compatible	Mostly Compatible	Not Recommended
Thermoplastics	ABS, polyketones, polyimide, polystyrene, polyethylene	PVA, polyurethane, PMMA, polyesters, polyamides, PVC (some discoloration may occur)	Fluorine-based polymers, polyacetals, natural PP, (degraded and tensile properties decreased)
Thermosets	epoxy, unsaturated polyesters, polyimides, polyurethane (aliphatic)	polyurethane (aromatic)	—
Adhesives	epoxy, fluoroepoxy	silicone, acrylic	—
Elastomers	EPDM, rubber, nitrile	silicone, polyacrylic	butyl
Bioresorbables	—	PLA, PGLA	—

Table 1 – Gamma sterilization compatibility with polymers. Note: Though some materials may be listed as "Not recommended," there may be solutions that exist for improving the radiation compatibility for these polymers. For example, there are many ways to formulate polypropylene (PP) to improve radiation compatibility.



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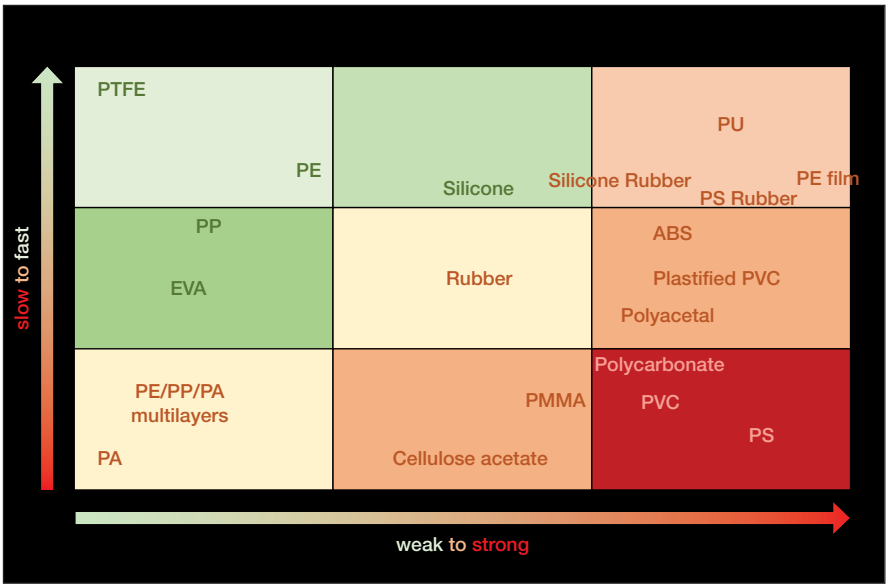

Fig. 1 – Polymers classified by absorption and desorption characteristics.

Polymers	Highly Compatible	Mostly Compatible	Not Recommended
Thermoplastics	ABS, fluorine-based polymers, polyesters, polyamide, polyacetals, polypropylene, polyethylene, PVC	polyurethane, polystyrene (some deformation may occur under vacuum) polymethylmetacrylate (will not support multiple processes)	PVA (degraded and tensile properties decreased)
Thermosets	epoxy, unsaturated polyesters, polyimides	polyurethane	—
Adhesives	acrylic, epoxy, silicone	Water-based adhesives (issues with steam reported)	—
Elastomers	butyl, nitrile, silicone, rubber, EPDM	—	—
Bioresorbables	—	—	PLA, PGLA (degradation occurs due to moisture)

Table 2 – EO sterilization compatibility with polymers.

Gamma rays, emitted from 60Co, are pure energy, similar in many ways to microwaves and x-rays. Gamma rays delivered during radiation sterilization alter chemical bonds by interacting with the electrons at the atomic level. Although gamma rays are highly effective in reducing or eliminating microorganisms, they do not have sufficient energy to impart radioactivity on the device or component being sterilized.

The minimum dose required to sterilize a product is based on its bioburden (i.e., the microbiological contamination on the product) and the maximum acceptable dose is driven by the radiation tolerance, and stability, of the product.

Gamma sterilization may be performed on individual boxes, in irradiation containers usually referred to as totes, or on pallets.

Packaging for Gamma Radiation

Because there is no requirement for pressure or vacuum, gamma radiation eliminates the need for gas permeable packaging materials as required for EO processing. Packaging is developed and formulated for radiation stability. Tough, impermeable packaging materials provide a strong, long-term sterile barrier.

Materials compatibility. Gamma radiation is compatible with many plastics, all metals, and glass (subject to color change). Some polymers, however, are affected either by embrittlement, discoloration, or degradation.

Note that gamma rays generate free radicals that can further react and degrade the materials. The nature of the reactions of these free radicals depends on the nature of the plastics, the presence of oxygen, the absence/presence of additives (antioxidants may be added to limit the free radicals), the dose applied to the material, and other environmental factors. Some polymers that are quite resistant to temperature, chemicals, and acids, such as PTFE, may be extremely sensitive to radiation. Table 1, derived from AAMI TIR 17:2008, ranks polymers according to their relative resistance to radiation.[1]

Electron beam (E-beam) Sterilization

Electron beam sterilization does not use a radioactive source and, instead, product is sterilized by exposure to a concentrated charged stream of accelerated electrons generated by an electron accelerator. Electron accelerators are capable of producing electron beams that are either pulsed or continuous. E-beam radiation is a form of ionizing energy that is generally characterized by its relatively low penetration and high dose rates.

In comparison, gamma radiation has high penetration and low dose rate, while E-beam has high dose rate and low penetration, but either technology can give a reproducible irradiation process.

E-beam irradiation is similar to gamma processing in that electrons alter various chemical and molecular bonds in the exposed product, including within the DNA of microorganisms.

The dose can be delivered to the product much faster than for gamma, but the penetration of the electrons is more limited than gamma rays. The technique is indicated more for low-density and uniform products. Typically, the irradiation container for E-beam processing is the individual product box. The boxes are typically irradiated on one side and then rotated 180 degrees to expose the opposite side.

Packaging for E-beam is quite comparable with that used for gamma and the compatibility with materials is also quite similar, and the information presented in Table 1 may also be applicable for the E-beam process.

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	Gamma Radiation	E-beam	Ethylene Oxide
Penetration	Good penetration into variety of materials	Penetration dependent upon material thickness, density, composition	Good penetration with the use of gas-permeable packaging
Product release	Dosimetric release (immediate, no post-process testing required)	Dosimetric release (immediate, no post-process testing required)	Incubation of biological typically required (seven days incubation). Parametric release may also be used to shorten release time
Material compatibility	Most materials are satisfactory	Most materials are satisfactory	Nearly all material compatible
Residues of sterilizing agent	None	None	EO and ECH residues require a post-sterilization degassing step

Table 3 – The three major sterilization techniques and their characteristics.

Ethylene Oxide

Ethylene oxide (EO) is a medium temperature sterilization method (40–55 °C), and microbiocidal lethality is achieved by chemical reaction (alkylation) of proteins and DNA within bacteria. The alkylation process requires moisture to act as a catalyst to open the epoxy bond, so preconditioning and/or conditioning are an essential part of the ethylene oxide sterilization process

EO is a colorless, odorless, volatile, and toxic gas that is carcinogenic and highly explosive from 2.7 percent in air up to 100 percent. Extreme caution must be taken to use this highly reactive molecule.

EO sterilization is typically a three-step process, starting with preconditioning in a room or cell, then sterilization in a chamber, and finally, desorption of gas in heated aeration in a room or cell. Preconditioning is used to heat up and humidify the products in order to present them in homogeneous favorable conditions for efficient sterilization.

The sterilization step occurs in a closed, airtight chamber, where vacuum is applied to remove air both to facilitate ethylene oxide diffusion and penetration and also to avoid explosive mixtures of ethylene oxide gas. Steam injection is performed to enhance moisture levels in the sterilizer environment and then gaseous ethylene oxide is injected in the chamber.

The gas remains in contact with the products during a defined and validated exposure time and then vacuum is reapplied to remove the EO from the load. Several pulses of nitrogen and/or air then occurs to remove more EO from the load. The key parameters that are playing a role in the sterilization efficiency are temperature, gas concentration, moisture, and exposure time.

The final step is heated aeration, which is typically performed at temperatures between 40° and 50 °C, with air circulation. This final step is necessary to remove the EO from products and packaging and render the products safe for use on a patient (limits in the products are dictated by the nature of product contact with the patient and are defined in ISO 10993-7).

EO sterilizers may have various sizes, and the loads are typically presented in pallets. Some sterilizers may handle a full truckload (>100 m^3 volume).

EO packaging. The packaging used for single-use EO sterilized medical devices or pharmaceutical applications must combine sterile barrier properties and breathability to allow gas penetration and removal. It must also be resistant to vacuum.

Materials compatibility. Ethylene oxide is compatible with many plastics. Metals and glass do not absorb ethylene oxide and are do not present any problems for sterilization. However, ethylene oxide is not suitable for sterilization of the following items:

Electron beam radiation is a form of ionizing energy that is generally characterized by its relatively low penetration and high dose rates.

Gamma sterilization is a "cold" sterilization technique, where temperature is not a key parameter.

- Liquid solutions (EO is highly soluble and will be dissolved rather than sterilize).
- Protein type material (degradation).
- Products placed in non-breathable packaging.

Caution must be taken with the following items:

- Electronic devices, batteries, and powder that may induce exothermic reaction and therefore create an explosion risk.
- Vacuum-sensitive products.
- Mated surfaces (stopcocks, three-way valves).

Ethylene oxide is highly compatible with most plastics and polymers with a few limitations. Table 2 classifies the polymers into three categories: highly compatible, mostly compatible, and not recommended.

EO residues. One of the main negative aspects of EO sterilization is the residues remaining after process. In order to remove of the residual gas (EO) or by-product (ethylene chlorohydrin [ECH], formed in the presence of chlorine ions), a heated aeration step is required. Desorption kinetics is influenced by temperature but also by the nature of materials. The polymers have various absorption, adsorption, and desorption properties. The adsorbed EO is relatively easy to remove during the sterilization cycle, where absorbed EO is more difficult to eliminate.

The material thickness, the available surface, and its relative roughness influences directly the desorption behavior. The chart in Figure 1 classifies the polymers by absorption and desorption characteristics. It is important to note that the chart is not exhaustive; it is based on literature as well as gathered experimental data at industrial scale.[2] Table 3 considers the three major sterilization techniques and presents their respective characteristics.

Conclusion

For many materials used to manufacture medical device and pharmaceutical components and packaging, it is possible to select and validate an appropriate and compatible industrial sterilization technique. To do so, it is important to evaluate the products' physical limitations to select and design the proper sterilization conditions that will provide a sterile and safe product.

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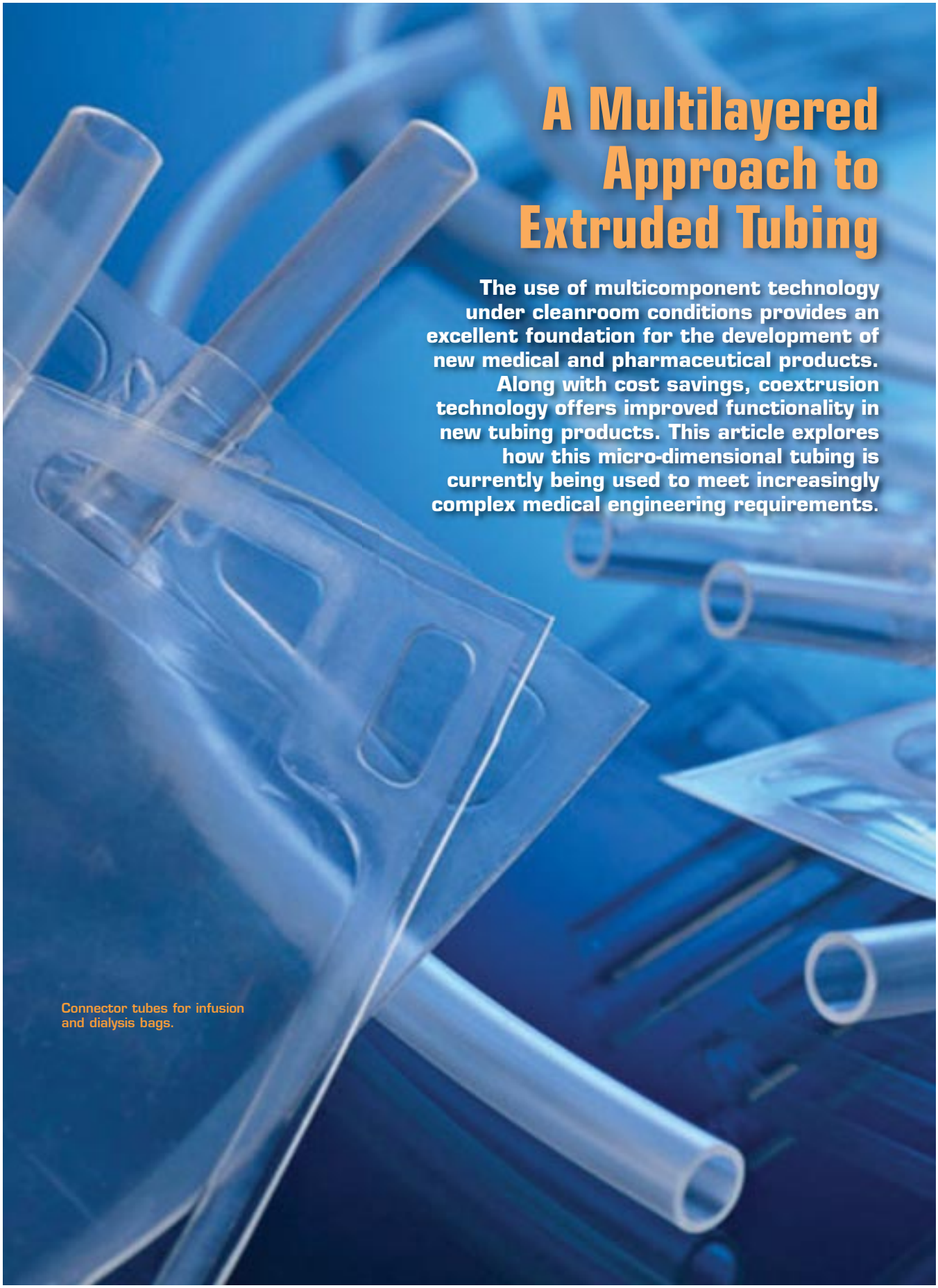
This article was written by Grégory Grams, SteriPro Consultant, EMEAA, for Sterigenics (Oak Brook, IL). For more information, visit ***http://info.hotims.com/65855-165****.*

A Multilayered Approach to Extruded Tubing

The use of multicomponent technology under cleanroom conditions provides an excellent foundation for the development of new medical and pharmaceutical products. Along with cost savings, coextrusion technology offers improved functionality in new tubing products. This article explores how this micro-dimensional tubing is currently being used to meet increasingly complex medical engineering requirements.



Connector tubes for infusion and dialysis bags.

In many cases, coextrusion of multiple polymer layers in the production of micro-dimensional tubing for medical engineering is still uncharted territory. Microextruders allow for the production of multilayer tubing from up to four different polymer materials. The smallest achievable inner tubing diameter is about 100 µm, with a minimal wall thickness of approximately 50 µm.

Microextruders can work at minimal material throughput rates, with an output of less than 30 grams per hour. These micro-extruders can produce and distribute application-specific layer thicknesses. They can also embed several color stripes or x-ray contrast stripes, integrate functional layers, such as layers that provide light-protection properties or to act as a gas barrier. Micro-extruders also enable the use of bonding agents for incompatible polymers to prevent delamination.

Which Materials Can Be Used?

In theory, any polymer can be used in coextrusion. In practice, however, the thermoplastics that are generally used have already proven their worth in other processing techniques in medical engineering and pharmaceuticals: polyurethanes, polyamides, polyolefins, thermoplastic elastomers (TPEs), and to some extent soft polyvinyl chloride (PVC) as well.

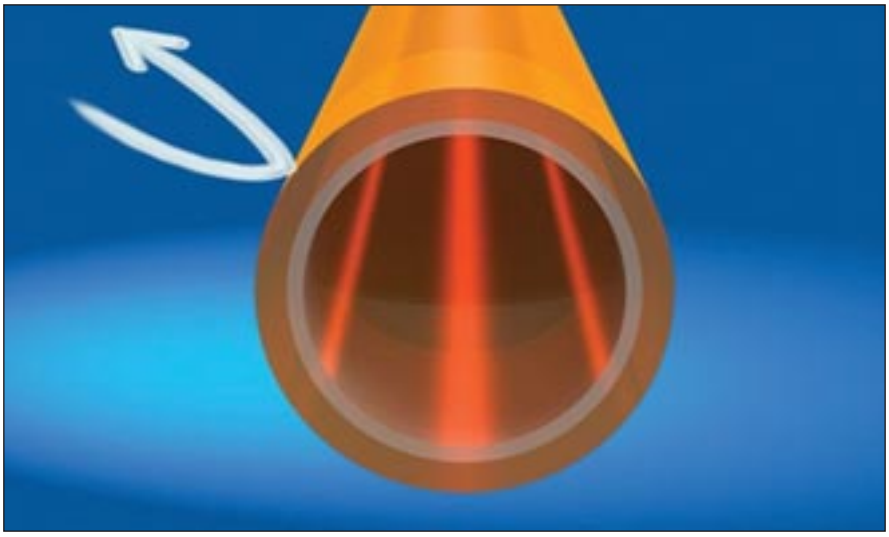
It is critical to use tubing specifically designed for certain applications, such as protecting light-sensitive solutions and ensuring loss-free dosage of sensitive drugs. Raumedic, for example, has developed Rausorb, Rauinert, and Rausonert to address such needs. These three application examples reflect the growing importance of multilayer extrusion in medical engineering.

Light-Sensitive Pharmaceuticals

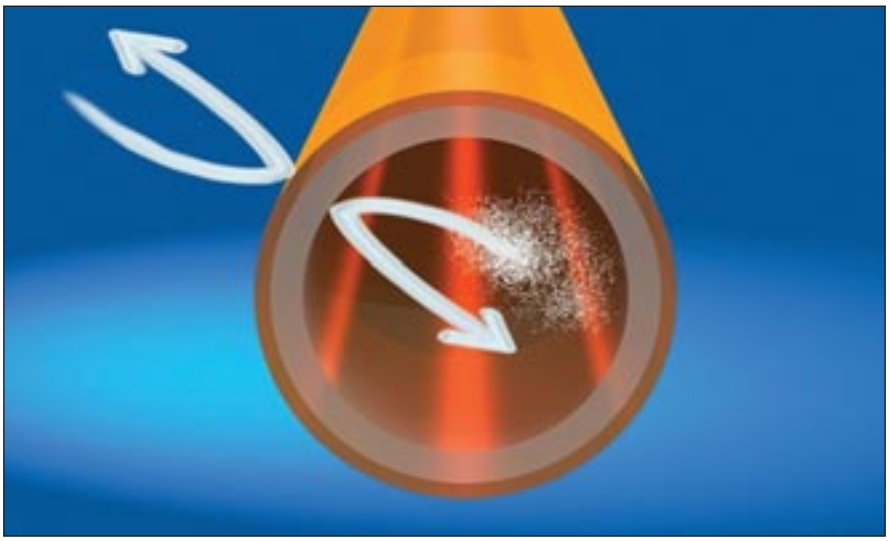
Protecting light-sensitive pharmaceuticals is crucial. Pharmaceuticals that are activated by exposure to light, or that break down in a photochemical reaction are increasingly used for special therapies. Substances like vitamin A and sodium nitroprusside take their activation energy from visible and invisible light in different ranges of wavelengths.

To provide the required protection for these substances, the development of black tubing seemed to solve the problem. This, however, makes it impossible to monitor the infusion solution. As a result, any gas bubbles, impurities, or other problems cannot be detected when they occur.

Coextrusion and multilayer extrusion make it possible to use several different materials in a single tube, thus providing a modern, effective and, in practice, optimized solution for use in a range of medical applications. (Credit: Raumedic)



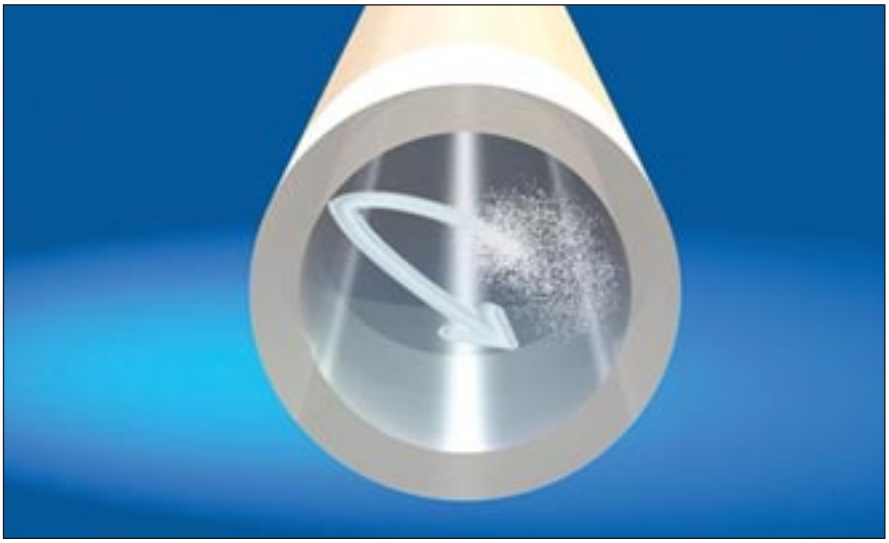
Raumedic Rausorb is designed for light-sensitive solutions. (Credit: Raumedic)



Raumedic Rausonert is designed for loss-free dosage of light-sensitive solutions. (Credit: Raumedic)

Other solutions available on the market involve transparently colored tubing, or windowed tubing made of a clear material including semi-circular segments of light-proof coextrusion materials embedded in the tubing wall. But these solutions do not comply with the applicable pharmacopoeias and relevant standards.

Multilayer tubing meets medical engineering requirements. The inner layer



Loss-free dosage of light-sensitive solutions require specialized materials such as Raumedic's Rauinert. (Credit: Raumedic)

of this special tubing is physiologically harmless. The outer sheath is infused with light-absorbing substances that correspond to the spectrogram of each individual infusion solution. With this technology, any chosen combination of wavelengths in the 220–800 nm range can be largely filtered out. Since each preparation is only sensitive to a very specific set of wavelengths, there are enough ranges remaining to allow for the production of transparent tubing that still blocks all but a negligible amount of light in the critical wavelength ranges. This makes it possible to develop tubing that is specific to individual drugs.

Drug-Compatible Infusion Tubing

For decades, soft PVC has proven its worth as an efficient and easy-to-process material for flexible infusion lines. Even today, well over 90 percent of all infusion tubing is still made from soft PVC. With advances in the development of highly effective new drugs, however, and especially in the oncology domain, an increasing number of problems have begun to arise involving drug compatibility with the PVC tubing material. Many highly sensitive drugs are adsorbed on the tubing's surface, with the result that only a fraction of the intended dose reaches the patient.

Conversely, "undesirable side effects" may occur if plasticizers and other additives are released from the PVC material by the infusion solution. This happens most often when the infusion solution contains fatty substances or lipid-like solubilizers.

Despite these challenges, Raumedic developed Rauinert to enable the continued use of soft PVC as a safe material. The layering most commonly used with this product consists of a low-density polyethylene (LDPE) inner layer, an ethylene-vinyl-acetate-copolymer (EVA) bonding agent, and a PVC outer layer. Polyethylene is chemically neutral in contact with the flow-through medium. The EVA middle layer serves as a bonding agent between the LDPE and PVC layers, since those two materials would not otherwise form a strong bond to one another in the coextrusion process. The outer layer made of soft PVC ensures that the manufacturer of the final infusion tubing sets can conduct all of its processes just as it would with any ordinary PVC tubing. These processes include bonding, packaging, and sterilization, for example.

For drugs that are both light-sensitive and PVC-incompatible, the Rausonert tubing line offers custom-tailored solutions — with regard to the requirements of later processing steps as well. Inert inner tubing layers are coextruded with light-absorbing outer layers. The possible combinations of materials and dimensions are virtually unlimited.

PVC-Free Infusion Bags

As in food packaging technology, a trend toward the use of lightweight, flexible, and unbreakable polymeric materials is developing in containers for infusion solutions, too.

For infusion bags, the first step was the use of PVC films, tubing, and connectors containing plasticizers. Since the early 1990s, there has been an intensive search for alternative materials free of plasticizers and chlorine. For films, the industry quickly achieved adequate levels of quality that had already proven their value in the food industry. The films in question were multilayer films made from polypropylene (PP) or polyethylene/bonding agent/polyester that comply with the requirements for transparency and sterilizability with water vapor at 250 °F (121 °C).

These PVC-free film bags require special filling tubing. Whereas the outer layer should be weldable to all common films, the inner layer should provide excellent bonding to all common connector materials, such as polycarbonate, polypropylene, or hard PVC, during the steam sterilization process. Naturally, this combination of properties cannot be achieved in a single polymer formulation.

Using coextrusion technology, medical filling tubes for infusion bags can be created. This special two-layer tubing is composed of an inner layer of EVA and an outer layer made of TPE. The EVA provides excellent bonding to polycarbonate connectors, but it must be cross-linked to maintain its shape at 250 °F (121 °C).

If polypropylene connectors are preferred, three-layer tubing with a soft PP/soft PP/TPE layering can be used. With this layering, the modified polypropylene in the inner layer provides good bonding to PP injection ports, while the flexibility or stiffness of the tube as a whole can be variably controlled through the formulation of the soft PP middle layer.

Conclusion

Micro-extrusion, the coextrusion of multiple polymer layers to produce micro-dimensional tubing, has enabled the development of application-specific tubing that can be used where traditional materials can't. Application-specific layer thicknesses, embedded color stripes, and functional layers are just a few of the characteristics that make micro-extruded, multilayer tubing a viable alternative to conventional tubing as applications become increasingly complex.

This article was written by Gert Walter, Senior Product Manager, M&S Tubing, for Raumedic, Mills River, NC. For more information, visit ***http://info.hotims.com/65855-160****.*

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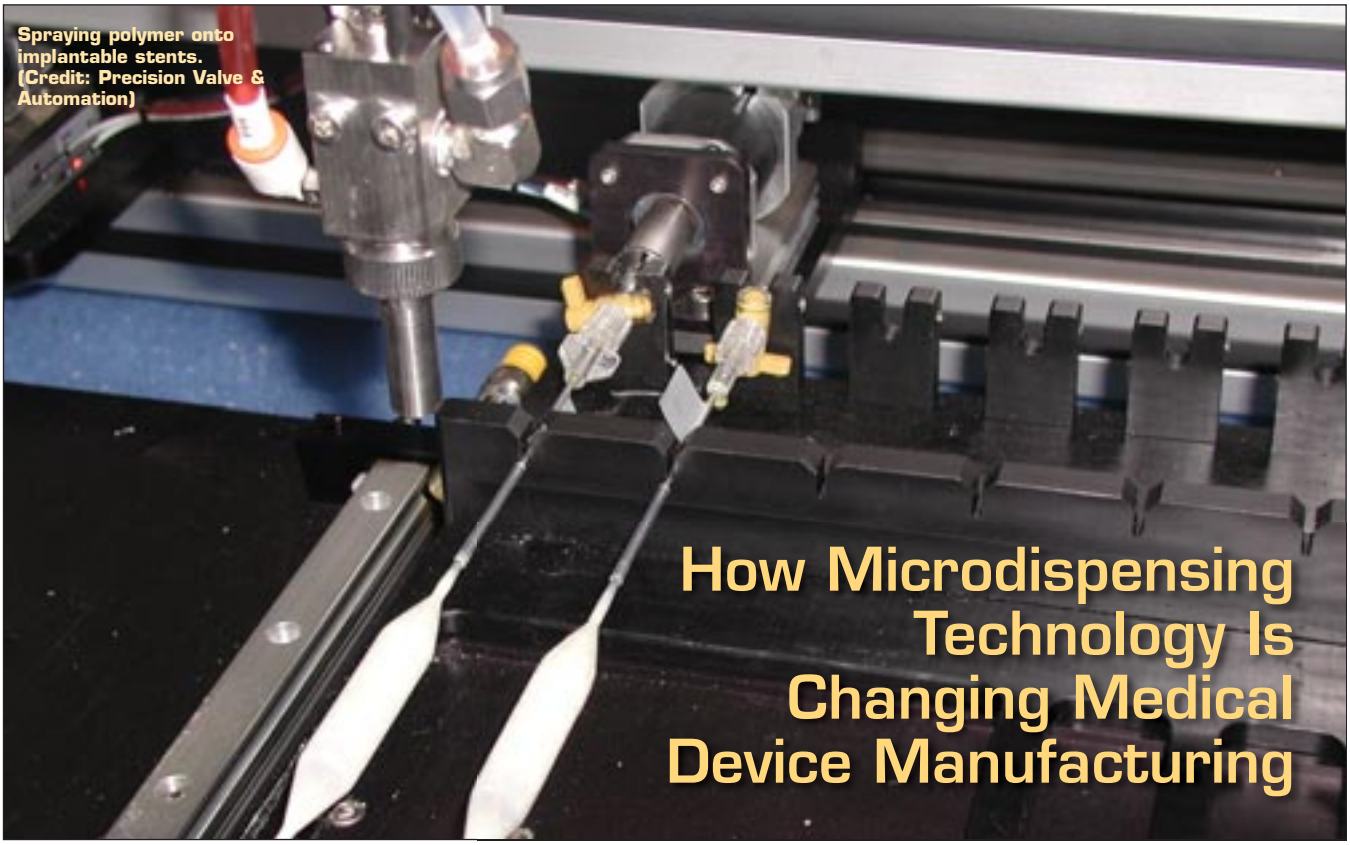


Spraying polymer onto implantable stents. (Credit: Precision Valve & Automation)

How Microdispensing Technology Is Changing Medical Device Manufacturing

A revolution is upon us. Dispense pump technology innovation is quickly bringing improved accuracy, capability, and versatility to medical device manufacturers. This revolution not only opens the doors to creating production processes that were once unimaginable, but also increases the scope of chemistries that manufacturers can consider for these applications. The end result? Greater flexibility in achieving accurate results for small deposits of fluid with the option to choose rapid curing adhesives that reduce work in progress while improving bond strength.

Manufacturers worldwide are relying on their suppliers to use this updated technology and implement new processes. They are quickly turning in their syringes and the variability present in time and pressure dispensing processes for more accurate alternatives. This is particularly relevant in applications requiring smaller dose volumes. Simple time and pressure dispensing systems typically carry a 5–10 percent variation in volumetric accuracy. As manufacturing demands have required smaller deposits, that level of process variation is often unacceptable and physically unachievable in a manual process. Dispensing technology that can provide 1–2 percent shot-to-shot consistency is becoming the norm. While this technology brings added quality to the manufacturing process, the driver is in demand due to the miniaturization of devices.

Demand for microdispensing technology has led users to seek more accurate applicators. In turn, manufacturers have enjoyed additional benefits of microdispensing pumps. These benefits include a significant reduction in minimum deposit volume, increased speed, better chemical flexibility, improved process capability, and subsequently better part quality and a significant reduction in waste.

Progressive Cavity Pumps

Progressive cavity pumps are positive displacement pumps by design. A helical rotor seals tightly against a molded stator as it is rotated. Once sealed, fixed cavities are formed consisting of the resin to be processed. The rate of rotation directly impacts the pump's flow rate. This relationship is direct; as the rotor rpm doubles, so does the subsequent flow rate.

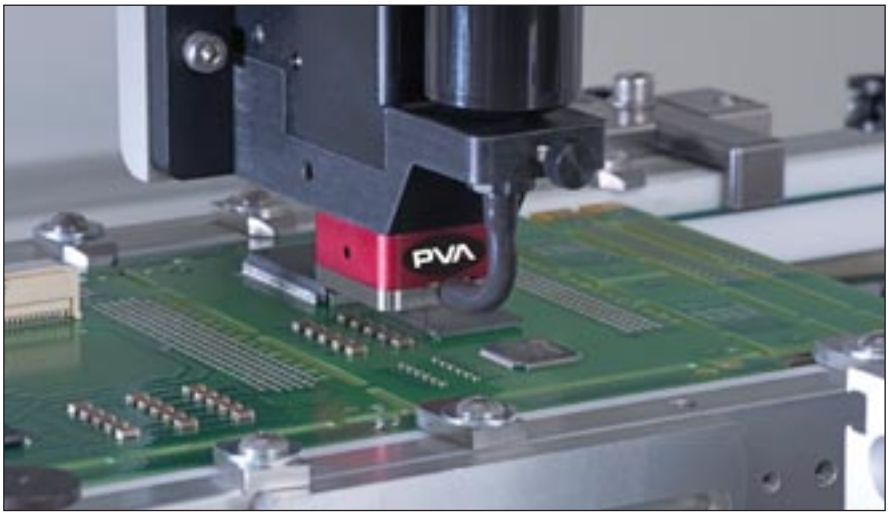
By design, progressive cavity pumps self-seal as the rotor and stator meet, so that low viscosity fluids can be processed without concern of dripping or leaking. A progressive cavity process is also continuous. As disbursement from each cavity overlaps, there is no necessity to recharge or refill the metering area creating a pulse-free dispensing process. Very little shear is created on the chemistry making sensitive or lightly filled materials acceptable to process.

So what does all of this mean to the end user? Progressive cavity pumps provide tremendous volumetric accuracy for small deposits of material. Dosing rates down to 0.03 ml/min are achievable with sub-2 percent accuracy. Microbonding of medical devices requiring dots or beads can be accomplished easily utilizing this advanced technology. Shot size capability is a fraction of time and pressure processes. This opens the door to adhesive applications that may not have previously been considered.

Multi-component formulations can bring an array of benefits to manufacturers from adhesion and mechanical strength to rapid cure times. Dispensing companies are typically weary of chemistries featuring wide mix ratios (out to 10:1) or large viscosity deltas. Wide variations in these relationships between the resin and hardener can make these chemistries difficult to mix sufficiently. These formulations require such a small amount of hardener that any variation in the mix ratio can change the chemical properties or impact the cure schedule. These issues are often compounded as the deposit sizes get smaller because there is little room for error and even less mix time.

In moving the metering process right to the application point with progressive cavity pumps, users can have a high level of confidence in processing two-component chemistries, even if they have wide mix ratios or viscosity deltas. The resin and hardener are not exposed to each other until they depart the pump body and enter a static mixing tube. Since the mixing tube is disposable, daily maintenance is minimal. The segregation of the A and B components also prevents users from having to conduct any routine purging of the metering pump.

The development of progressive cavity technology for 2K materials is driving an increasing number of users to these formulations. Every year there is an increase in 2K materials in the microdispensing market, in particular in the medical device industry. PVA assists those in the medical device field — from the handheld prototyping phase to large-scale production — and ensures that reliable products are perfected. Two-part materials have traditionally been chosen for potting of electrical devices in a housing or a gasket to glue two housings. This was primarily due to limitations in valve technology. Progressive cavity pumps are now the option of choice for valve assembly, implantable devices, and the growing electronics assembly market.



A JDX valve used in underfill of sensitive electronic components. (Credit: Precision Valve & Automation)

Noncontact Jetting

Jetting technology has been present in the dispensing market for decades. This process brings a myriad of benefits to any manufacturing process. It's fast. Jets can generate up to 300 drops per second allowing for rapid processing of a wide range of fluids. A rapid succession of dots generated quickly over a coverage area results in the formation of small beads of adhesive. Because the droplets are projected out of the jet valve, the processing height can remain fixed. The

absence of z-height movements in a robotic application also reduces the processing speed.

Jets are repeatable at very small deposit sizes. Much like progressive cavity pumps, jets should be expected to produce sub-2 percent repeatability. The advantage that jets have over progressive cavity, in addition to the processing speed, is the size of the droplets. Shots as small as 10 nl are achievable with noncontact jets, making these valves an ideal choice as the desired dot or bead size gets smaller.

Jet design concepts can vary widely from sliding valves to pistons to diaphragms. Regardless of the theory of operation, limiting the number of parts that contact the fluid not only reduces the cleaning time, but simplifies the processing of more reactive chemistries that may need to be routinely purged from the dispensing system.

Noncontact jetting systems have a wide range of practical applications for medical device manufacturers. Jets have no equal when combining speed, repeatability, and deposit size. This combination yields less rework and waste while increasing throughput.

Manufacturers can also take advantage of the noncontact nature of jetting valves to help process parts that cannot be successfully dispensed on with traditional needle valves. As beads and dots get smaller in any needle application, the applicator's z-height in correlation to the substrate becomes of greater importance. The gap height and robot speed will be the primary factors in setting the dispense volume in these applications. Let's focus on the gap height. As the distance from the needle tip to the substrate varies, so will a bead's properties. The closer the needle, the flatter or wider the bead will be in relation to its height. As the needle moves further away from the part, the bead will become thinner and taller. These variables can produce inaccurate dispensing of adhesive, a wide range of volume fluctuation, and even voids. This is of particular issue when a flexible part cannot be affixed in a consistent position.

In a manufacturing environment where many medical device applications feature three-dimensional or flexible molded components, the ability to remove z-height variability in needle tip applications is critical to a consistent process. Noncontact jets inherently remove this potential issue with their ability to glide over a part and dispense at a common z-height, even into awkward, hard-to-reach areas. Drops can be dispensed into areas with clearance as small as 300 µm.

Jetting is becoming a constant in medical device manufacturing. The speed, accuracy, and flexibility in processing is in demand, but as bonds and applications continue to get smaller, that is where the jet becomes a necessity. Jets are flexible with higher viscosity chemistries and can often be heated to lower the process viscosity. Many devices are designed without consideration for downstream processes like dispensing. Companies like PVA often take on a consultation role to help develop solutions and implement processes that have never been done before, which is both exciting and challenging.

This article was written by Frank Hart, Sales and Marketing Manager, and Jon Urquhart, Director of Global Application Engineering, for Precision Valve & Automation (Cohoes, NY). For more information, visit ***http://info.hotims.com/65855-163****.*

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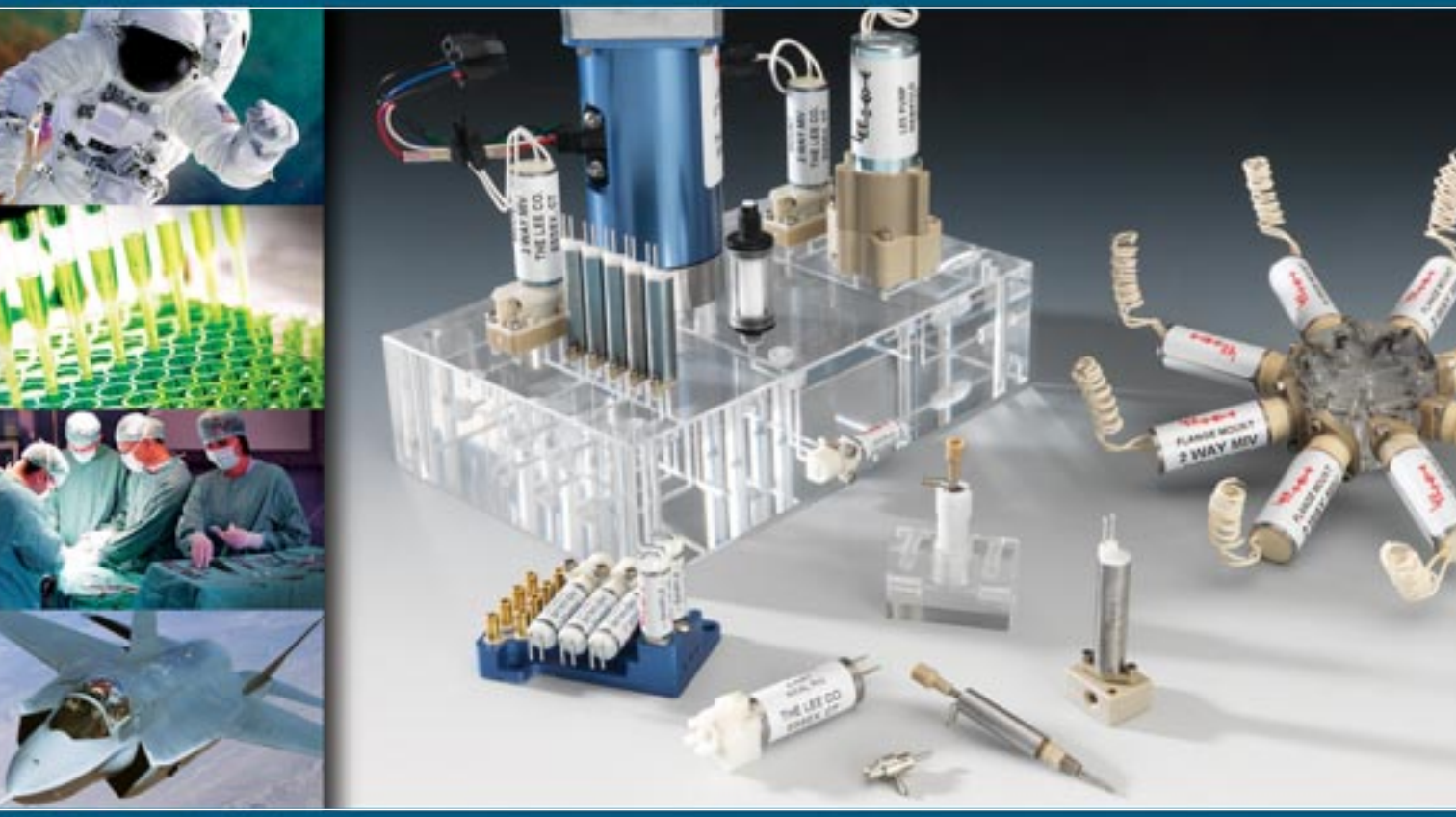

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MAKING THINGS INTELLIGENT: *The Advent of RFID in Medical Devices*

The Internet of Things (IoT) has been described as the interconnection via the Internet of computing devices embedded in everyday objects, enabling them to send and receive data. This article takes IoT one step further and explores this connected world as the Identification of Things. The progression from two-dimensional (2D) UPC codes to a radio-frequency identification (RFID) EPC code is equivalent to putting barcodes on steroids. PaladinID calls these RFID EPC codes smart codes, and here's why. RFID technology is now beginning to advance the efficacy of medical devices as never before.

According to barcode standards association GS1, "When unique EPCs are encoded onto individual RFID tags, radio waves can be used to capture the unique identifiers at extremely high rates and at distances well in excess of 10 m, without line-of-sight contact. These characteristics of RFID can be leveraged to boost supply chain visibility and increase inventory accuracy."

Barcodes have historically been used for device identification, and RFID adds another dimension by enabling authentication and verification, as well as substantially increasing efficiency and accuracy in managing and tracking medical devices throughout the course of the supply chain. From the manufacturer to the medical facility, RFID can reduce errors and redundancies while keeping devices functioning at optimal performance.

Why RFID?

Why is RFID a good solution for medical devices? Consider the FDA requirements that mandate unique device identification (UDI) for medical devices. With a UDI system already in place, barcodes can become smart codes by having RFID sensors embedded in the barcode labels. RFID sensors can be engineered to withstand the high temperatures of sterilization, and by using thermal data logging technologies, hospitals can track assets through use, sterilization, and reuse.

Achieving these benefits ultimately requires connecting with a global RFID network, and as the medical device industry explores IoT opportunities for medical devices and other healthcare assets, it can rely upon the Internet to support a single network for access to websites around the world. As for the required RFID network that will provide businesses with full visibility and track and trace capabilities from the point of manufacture through to delivery to the hospital, clinic, or medical office, there are some considerations to keep in mind. To achieve a systemic RFID network, manufacturers, hospitals, and healthcare facilities need to implement a single technology operating under a uniform global standard.

To date, there has been an adoption delay in the standards required to achieve this vision. As enterprises begin implementing RFID to meet mandates and regulatory requirements as well as to realize the associated business advantages, they are faced with standardizing on either one of the two available frequencies — UHF (ultrahigh frequency) Generation 2 or HF (high frequency), or both. Today, UHF is the de facto choice for case and pallet tracking applications, and it is well proven and deployed worldwide and across industries.

Until now, conventional wisdom has asserted that HF is the proven and better technology for item level (or near-field) applications. While it is true that HF is a proven mature technology, it is now becoming clear that UHF is equally as reliable and ensures stronger performance than HF at the device level. Although HF is limited to operation in the near-field,

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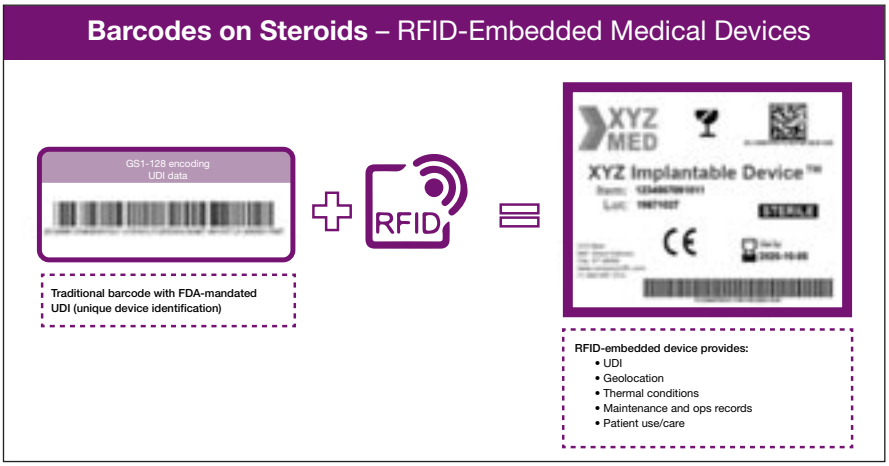


Fig. 1 – Shifting from 2D barcodes to RFID-embedded labels enables them to be an integral part of activities such as inventory management, asset tracking, replenishment, and more.

UHF offers enterprises a single protocol and infrastructure for all applications — from item-level applications on the conveyor belt in the manufacturing plant to the shipping and pallet applications in the storage areas to secure surgical suites in hospitals and clinics. The UHF-RFID protocol offers a global platform that can enable the worldwide and end-to-end supply chain visibility required to streamline operations and reduce costs.

The Benefits of RFID

In May 2017, one of the Northwell Health hospitals, a 245-bed acute care facility, deployed a passive UHF RFID-based solution to identify where its assets are located within zones, thereby improving efficiency and patient satisfaction. This RFID system allows the hospital to locate equipment and other assets such as wheelchairs, IV stands, and rolling monitors within a particular zone or room in real time. Having immediate visibility and understanding whether equipment is in use or ready for use makes the hospital more efficient without adding personnel. The system also enables hospital operations to observe use trends and optimize maintenance and sterilization processes.

This is the beginning of a groundswell shift from 2D barcodes to RFID-embedded labels (see Figure 1). Incorporating RFID into the supply chain improves medical device performance, distribution, and delivery in many areas, including:

- Inventory management — inventory is only valuable when it is available and ready for use.
- Patient tracking — tracking streamlines the care experience and reduces human error.
- Asset tracking — lost or misplaced inventory can cause delay in patient care; ready access to assets improves the overall patient experience.
- Life cycle management — management of assets is critical for those that have a shelf life or require calibration.
- Billing — integrating the data collected with RFID sensors can assist in streamlining billing processes.
- Replenishment — assets that are used can be tracked for replenishment, ensuring available inventory.
- Sterilization tracking and equipment maintenance — alerts can be programmed so that the manufacturer's maintenance requirements can trigger notifications.

"By embedding RFID and its sister technology NFC [near-field communication] in medical devices, we are able to use low-cost technology to enable all these systems to work together. We're making nonintelligent devices intelligent," says Tim Daly, industry expert and co-founder of one of the world's first RFID/NFC-networked platforms.

Here are additional examples of how RFID technologies are being incorporated into hospitals and the medical device supply chain:

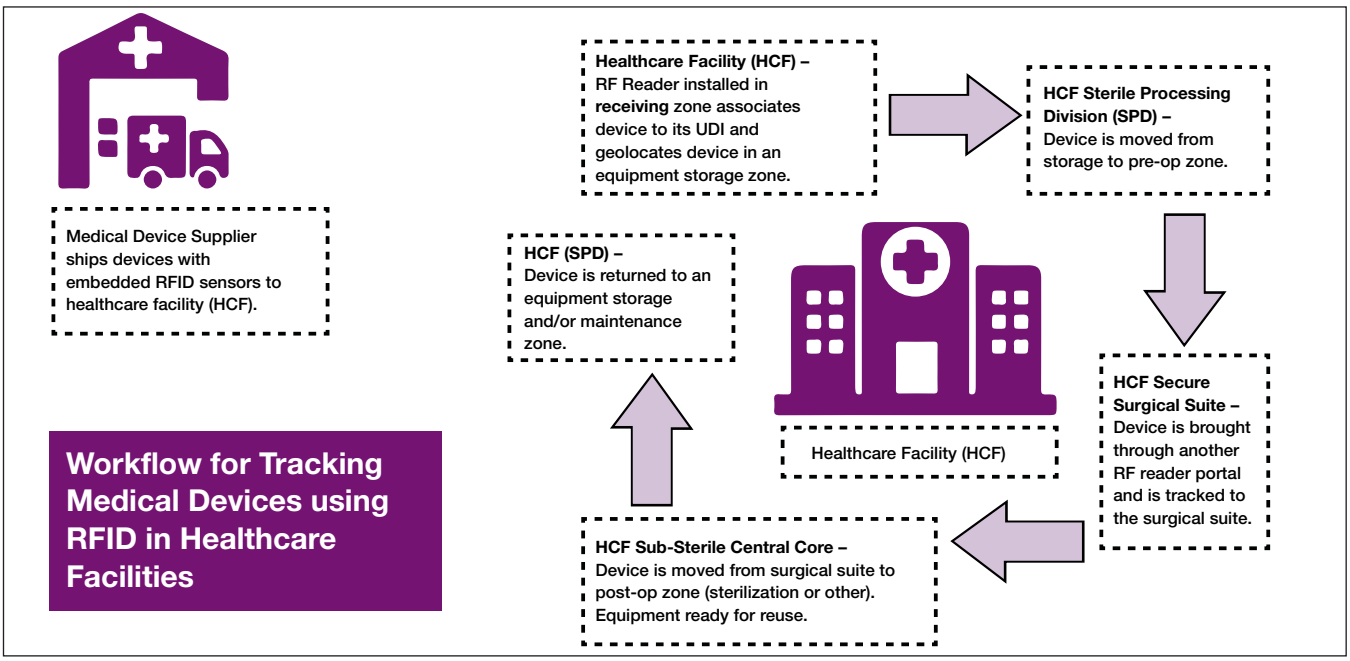


Fig. 2 – Workflow for tracking medical devices using RFID in healthcare facilities. RFID readers are installed at entrances and exits to each zone.

- Operating room management — enabling secure surgical suites and reducing overage and waste in surgical devices and instruments.
- Streamlining the assignment of UDIs — unique device identification to medical devices (FDA requirement).
- Enhancing UDI performance — enabling validation and authentication throughout the entire device life cycle.

The pharmaceutical industry uses RFID to reduce counterfeit or expired drugs. "RFID has already been embraced by pharmaceutical companies as an effective measure to combat the growing counterfeit problem. Implementing RFID technology makes operations accurate and efficient, and it reduces the need to manually scan and track devices," says Neil Mitchell, senior director of Alien Technology (San Jose, CA).

Making the Shift to RFID

RFID technology is expanding into medical equipment and devices. The following discussion presents an overview of how an RFID network can be incorporated into medical devices, and how both hardware and software are integrated within a healthcare facility ecosystem.

RFID systems can be designed to manage temperature sensitivity and withstand sterilization and on-metal conditions where RFID sensors must be encased so that the RF works. Working with providers that can identify the appropriate scanning equipment (readers) and required sensor features is an important first step. Identify a turnkey RFID solutions provider that will support you in connecting existing UDI (FDA required unique device identification) with manufacturing, operations, sterilization, compliance, and maintenance systems. While a thorough approach to connecting these elements is encouraged at the onset, keep in mind that additional links to service, standards, and compliance can be added at any point. Components required for systemwide integration include both software (ID management platform) and hardware: tags, labels, readers, antennas, cables, and multiplexers.

Barcode labels embedded with RFID sensors (smart codes) are either printed and encoded on premise using a simple thermal transfer printer, or they can be provided by an outside vendor. Currently, 30 percent of smart codes in the biotech industry are encoded on-site, and 70 percent are preprogrammed. The smart code labels are associated to the device UDI, effectively connecting a unique device, asset, or surgical tool to the healthcare facility's database (EAS, Oracle, etc.). Device manufacturers are able to install the smart codes during the manufacturing process, and using writeable sensors, the UDI can be associated upon being received by the healthcare facility. Once the smart codes are placed, no line of sight is required to identify, locate, authenticate, and track the device.

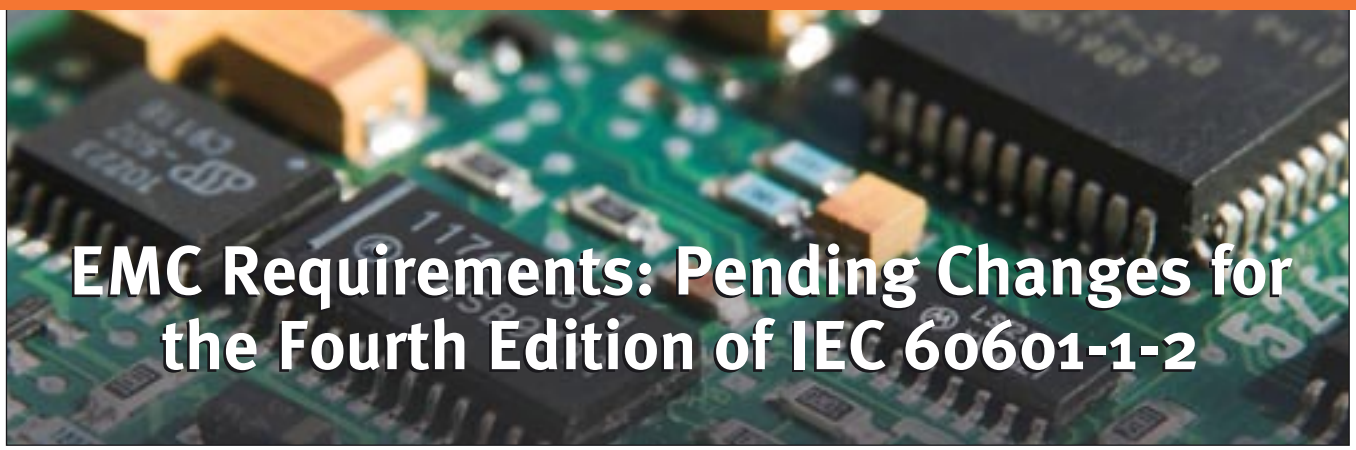
Physical conditions and device casing material dictate the specifications for RFID smart code labels. Facility locations are identified as zones (surgical suites, staging areas, post-op and pre-op, etc.), and RFID readers are installed at the entry/exit portals of these zones (see Figure 2). As the tagged devices move from one zone to another, the RFID reader antenna sends out RF energy, and the smart code data is read by the antenna. As devices and assets move throughout the facility, this activity is recorded in the ID management platform connected to the facility's database.

The data from the ID management platform is associated to the healthcare facility's database to be used for business analytics, visibility, decision tools, etc. For example, a case full of knee replacement parts that each have unique IDs may travel through various portals from a surgical supplier to hospital storage to surgical suite. Once the correct size knee replacement part is used in surgery, the balance of the knee replacement parts can be sent to sterilization (another portal) and returned to hospital storage for reuse. Using RFID to track this entire process produces a chain of custody that not only complies with FDA requirements, but captures vital data for asset management as well as patient care and billing.

Conclusion

RFID has been part of pharmaceutical and retail supply chain for decades, and the medical device supply chain is the next frontier. Device manufacturers, distributors, and hospitals and clinics are gearing up for serialization and allocating funds for the equipment required to implement RFID at all points in the supply chain. The cost of RFID readers is being incorporated into operating budgets as the ROI is established for reducing human error and improving operational efficiency.

This article was written by Dana Ritchie, CEO of PaladinID (Laconia, NH). Contact him at 888-972-5234. For more information, visit ***http://info.hotims.com/65855-164****.*



EMC Requirements: Pending Changes for the Fourth Edition of IEC 60601-1-2

Electromagnetic compatibility (EMC) requirements for medical devices and systems is defined by IEC 60601-1-2. The fourth edition implementation of this EMC standard is on the horizon and is a collateral standard to the IEC 60601-1 medical safety standard. It was issued by the International Electrotechnical Commission (IEC) in February 2014. FDA has deferred compliance for new products from April 1, 2017 to the end of 2018, and the EN 60601-1-2:2007 3rd edition withdrawal date is December 31, 2018. It is expected that the fourth edition EMC standard will be in effect in the EU on or before this date.

There are important changes and additions medical device manufacturers need to know. The category of Risk Management is expanded and the Life Supporting category has been removed. In addition, these new categories have been introduced: Professional Healthcare Facilities, Home Healthcare, and Special Environments. The new edition has significant impact on the medical industry for product design, testing, and documentation. Also, immunity requirements have increased and new requirements added.

This article discusses the significant differences between the third and fourth editions of the EMC standard and how components such as power supplies used in the medical equipment are impacted by the new standard.

The risk management process, now part of the IEC 60601-1-2, 4th edition, requires assessment of "risk resulting from reasonably foreseeable electromagnetic disturbances." This is an additional entry into the medical device risk management file. The term *safety* is defined to

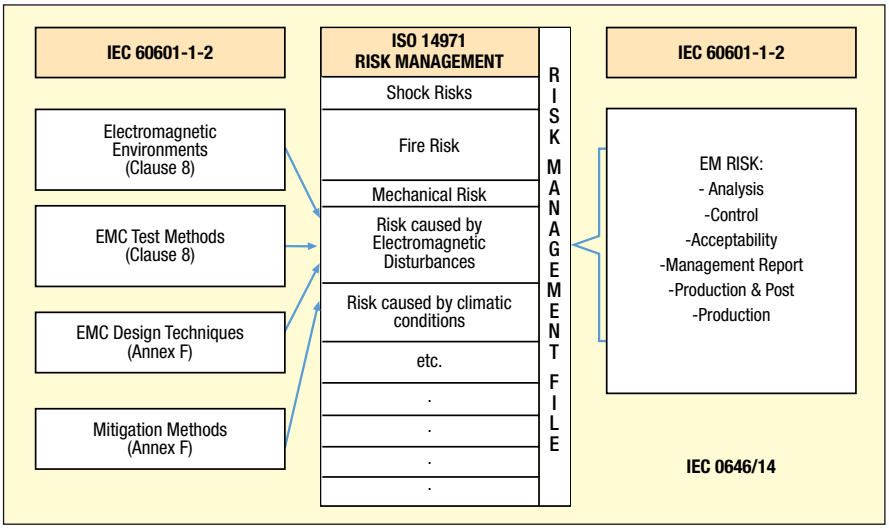


Fig. 1 – Relationship between the EMC standard and the risk management process.[1]

IEC 60601-1-2, 4th ed.				IEC 60601-1-2, 3rd ed.
ENCLOSURE PORT				
Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS		
		Professional healthcare facility	Home category	
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 6 kV contact, ± 2 kV, ± 4 kV, ± 8 kV air
Radiated RF EM fields a)	IEC 61000-4-3	3 V/m, f) 80 MHz - 2,7 GHz, b) 80% AM at 1 kHz, c)	10 V/m, f) 80 MHz - 2,7 GHz, b) 80% AM at 1 kHz, c)	3 V/m for non-life supporting ME equipment 10 V/m for life-supporting ME equipment 80 MHz - 2,5 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10 / Table 9		None
RATED power frequency magnetic fields d) e)	IEC 61000-4-8	30 A/m, g) 50/60Hz	30 A/m, g) 50/60Hz	3 A/m 50/60Hz

Table 1 – Applicable to all the enclosure ports; immunity requirements are defined in Table 4 of the standard.

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mean "freedom from unacceptable risk as defined in ISO 14971. Basic safety and essential performance are included within this definition of safety".[2] The risk management file may need reference to technical rationale, calculations verification plans, and test data. Simply testing at the higher immunity test levels is not sufficient to achieve safety. ISO 14971:2007 includes the following requirements: General requirements for risk management, risk analysis, risk evaluation, risk control, evaluation of overall residual risk acceptability, risk management report, and production and post-production information. The details of these requirements are described in the IEC 60601-1-2, 4th edition standard. Figure 1 shows an outline of how this IEC 60601-1-2, 4th edition standard links to the risk management file.

In discussing the impact and experience of implementing this standard with medical device manufacturers, there is a significant impact in the pretest planning and report generation. There seems to be a consensus that the largest impact is on the initial implementation and setting up the process, plans, and report templates.

This article does not go into detail of this EMC standard, but rather outlines the major changes in the IEC 60601-1-2, 4th edition and provides a comparison to the third edition standard. Although this is a medical device or system level standard, components such as power supplies can play an important role in aiding in system level compliance. Areas where power supplies may be impacted by this standard and the changes to the standard are stressed.

Changes

The fourth edition requires clear pass/fail criteria prior to testing. This is linked to the "Essential Performance and Basic Safety" outlined in the risk management file. A test plan is required that includes what is to be monitored in the equipment during testing. There are increased test levels for the immunity requirements. There are new immunity requirements added that take into consideration the effects from radiofrequency (RF) wireless communications equipment as detailed in Table 9 of the standard. These are not all encompassing; medical device manufactures need to take into account other possible sources of interference that may affect their equipment. The electromagnetic immunity requirements are detailed in tables 4 through 9 of the standard.

Input AC power port				
		IEC 60601-1-2, 4th ed.		IEC 60601-1-2, 3rd ed.
Voltage dips. Notes a) f) p)	IEC 61000-4-11	0 % UT; 0,5 cycle g) at 0, 45, 90, 135, 180, 225, 270, and 315 degrees q)	0 % UT; 0,5 cycle g) at 0, 45, 90, 135, 180, 225, 270 and 315 degrees q)	<5% UT; 0,5 cycle
		0 % UT; 1 cycle) degrees	0 % UT; 1 cycle) degrees	N/A
		70% UT; 25/30 cycles h) Single phase: at 0 degrees	70% UT; 25/30 cycles h) Single phase: at 0 degrees	70% UT; 25/30 cycles null
		No requirement	No requirement	40% V nom for 100 mS

Table 2 – Immunity requirements of the device's AC input ports are defined in Table 5 of the standard.

Input DC power port				
Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS IEC60601-1-2, 4th ed.		
		Professional healthcare facility	Home category	IEC 60601-1-2, 3rd ed.
Conducted disturbances induced by RF fields a) c) d) j)		IEC 61000-4-6	3 V i) 10 V i) in ISM and amateur radio bands between 0,15 MHz and 80 MHz k) 0,15 MHz and 80 MHz 80% AM at 1 kHz e)	3 V i) 10 V i) in ISM and amateur radio bands between 0,15 MHz and 80 MHz k) 0,15 MHz and 80 MHz 80% AM at 1 kHz e)
Electrical transient conduction along supply lines f)	ISO 7637-2 - test pulse 1	Not applicable	As specified in ISO 7637-2 (12 V vehicles DC powered)	Not applicable

Table 3 – DC output ports changes are listed in Table 6 of the standard.

Immunity Requirement Changes and Comparison to Third Edition. Tables 1, 2, and 3 in this article (tables 4, 5, and 6 in the standard) list only the requirements that are different from the third edition and do not list all of the immunity requirements due to the space limitation for this article. Refer to the standard for the complete listing and details on the note references.

Applicable to all the enclosure ports, the immunity requirements are defined in Table 4 of the standard. The electrostatic discharge (ESD) and RF electric fields' immunity are the most significant changes, where the input power supply plays a critical role. For ESD, the discharge potential is between the point of application of the ESD and earth ground. This places high voltages across isolation barriers in the power supply, which arc and can cause damage to the power supply or malfunction of the system if not designed properly.

External radiated electromagnetic fields may cause the output voltage to shift or oscillate if not designed

for these increased levels of interference. To eliminate the influence of the higher RF EM fields, design changes may be needed. Additional components or PCB trace spacing or increased insulation are often the consequence. Additional shielding or RF decoupling may also be necessary.

Immunity requirements of the device's AC input ports are defined in Table 5 of the standard. There are some additional requirements for half cycle drop-outs needing to be tested at various phase angles and a full line cycle dropout. There is the deletion of the 40 percent nominal AC mains operations. However, given that the third edition is still used and will continue to be in some countries for years to come, it is advisable to verify whether this condition is needed for the application.

DC output ports changes are listed in Table 6 in the standard. For an external power supply, this applies to the DC output cables as they are connected to the medical device's DC input port.

Tables 7 and 8 of the standard (not shown, see the standard) apply to patient coupling ports and signal input and output ports. With the higher ESD voltage levels, spacing and insulation requirements also increase to meet this standard. What once passed the third edition requirements may now result in arcing and malfunction or damage to components and circuitry. These changes create increased challenges to reduce product size.

Table 9, not shown here due to its complexity, specifies 15 test frequencies for seven different frequency bands. Significant analysis and test time will be needed during development to verify compliance to these requirements. Also, not all 15 test frequencies apply, but rather are application specific. For that reason, understanding the application will be an important part of this assessment.

Summary

The IEC 60601-1-2, 4th edition will be required in the United States by December 31, 2018 as is the EU EN 60601-1-2:2015 implementation. Implementation throughout the globe will occur at different times, so consideration to both third and fourth editions may be necessary. There are significant changes that require testing to verify compliance. Some fourth edition requirements are not backward compatible with the third edition. Tests are system-level requirements. However, the power supply is an important part of the system to achieve compliance. SL Power Electronics has and continues to support medical applications with products designed to meet the new fourth edition requirements.

References

1. IEC 60601-1-2:2014, Annex F, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

2. IEC 60601-1-2:2014 Annex F.1, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

This article was written by Lorenzo Cividino, Director, Global Applications & Support, for SL Power Electronics (Ventura, CA). For more information, visit ***http://info.hotims.com/65855-167****.*

Addressing Cleaning Challenges for Medical Electronics

The market for medical electronics is huge and growing. The astounding capabilities of digital technology and broadband connectivity are "a perfect storm," enabling doctors to diagnose more accurately and offer therapies more precisely than ever before. They also offer labor-saving benefits that are important in these days of tight medical budgets. For example, products and systems that reduce costs and enable patients and families to do more for themselves — collectively called "wellness management" — are exciting new business opportunities. Remote patient monitoring systems can replace the need for expensive hospital stays. Modern electronics clearly can both improve care and reduce costs. Because of these advantages, the global medical electronics market is expected to reach $4.4 billion by 2022, growing more than 5 percent per annum over the next decade.

With this growth comes the need to ensure that these devices work effectively and reliably. But with the increasing use of complex miniature components with ever-tighter tolerances, managing faults can be problematic. Quality cleaning can make a big difference.

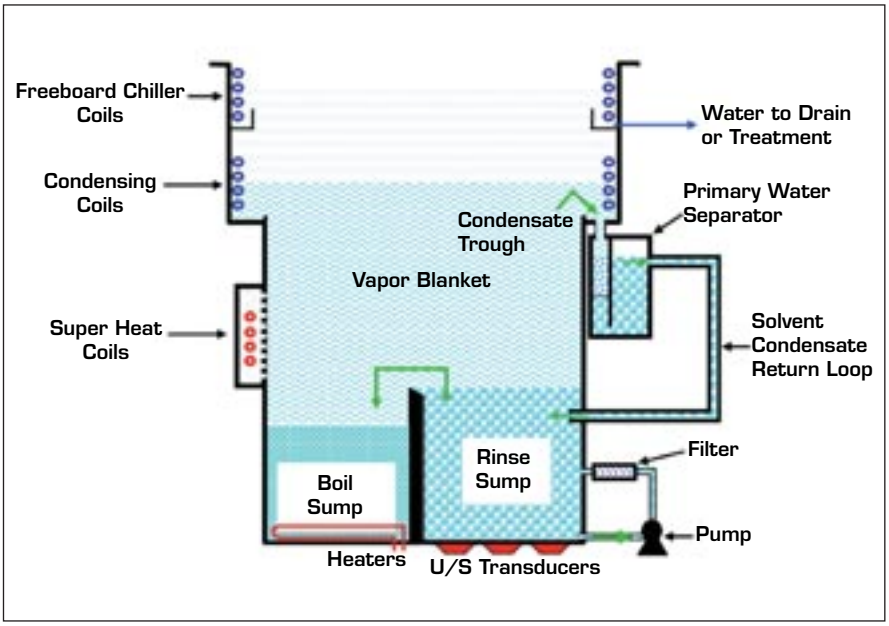

Fig. 1 – The operations of a vapor degreaser are very simple. The solvent is heated to around 40 °C in the "boil sump, "which is the primary cleaning chamber. Solvent vapors (which are equivalent to steam from boiling water) rise from the boil sump and are trapped at the top of the machine. There, they cool and condense back into a liquid state. This fresh, pure condensate is used to rinse parts in the rinse sump, which overflows back into the boil sump to complete the loop. The solvent never wears out, and the system inherently recycles the solvent, saving resources and money.

No Room for Error

Companies designing, manufacturing, and certifying medical electronics face a host of challenges unfamiliar to the makers of traditional consumer electronics. Consumer electronics (CE) cannot be compared to medical electronics (ME). Consumer electronics are all about "good enough" manufacturing. In contrast, medical device companies value safety, quality, and predictability in order to maximize performance and minimize liability. Unexpectedly, many challenging production and performance issues can be minimized with proper post-assembly cleaning of the printed circuit boards (PCBs) and mechanical assemblies used in these systems.

Cleaning is critical for PCB manufacturers as smaller, more densely populated circuit boards become a standard feature in the medical electronic industry. Without it devices will not function as they should and will not stand up to the

rigorous regulations put in place by governing bodies.

Consumer electronics can be built to some very generalized standards. The most commonly used are promulgated by the Institute of Printed Circuits (IPC), which defines the manner in which PCB assembly should be performed. This may sound rigorous, but for the medical world it's not nearly good enough.

The processes used in the development and manufacture of medical electronics offer no room for error. This risk-averse strategy drives the need for products to pass tough regulatory requirements because patient safety is always the priority. Therefore, cleaning should be top of the checklist for manufacturers.

The benchmark standard for medical devices is provided by the International Electrotechnical Commission (IEC) in a document called IEC 60601-1. This standard is applicable to any "electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy to or from the patient."

There is also ISO 10993. This standard evaluates devices within a risk management framework to ensure they are safe. Bioburden, pyrogens, and sterility are all assessed with this process.

Cleaning is critical to ensure that medical electronic devices work as they should and meet the relevant standards and regulations. However, the increasing use of miniature components and complex PCBs make it a challenge.

Mission-Critical Cleaning Methods

The computing power and functionality of modern medical devices is directly proportional to the processing power of the PCBs within them. That power is the result of smaller, more densely populated PCBs that are hard to clean. Better cleaning enables engineers to specify stronger, more active fluxes, which results in better solder joints. Failing solder joints cause a huge percentage of PCB failures, so cleaning is key to their success. Problems with "cold joints," insufficient wetting, bridging, and shorts also can be avoided. In short, better cleaning means better PCBs, which means better medical electronics.

Jay Tourigny, MicroCare senior vice president and Venesia Hurtubise, a chemist with the company, develop a cleaning protocol for a large metal casting in a Branson vapor degreaser. There are numerous factors that can be tweaked in vapor degreasing to optimize cleaning results, throughput, or costs, depending on the goals of the organization.

Vapor degreasers excel at cleaning optical devices, ceramics, PCBs, or metal pieces like these fuel injectors. Solvent cleaning systems are well suited for parts with small apertures, tight stand-offs, and blind vias. Because solvents offer substantially better wetting than aqueous cleaners, they are the optimal choice on complicated shapes, small parts, fragile devices, or in high-volume cleaning environments.

Plus, it's not just fluxes that companies need to be concerned about. Adhesives, conformal coatings, fingerprint residues, etc. all need to be removed. This variety of contamination makes cleaning complex.

In decades' past, aqueous cleaning was acceptable as it was cheap and worked with the PCBs of the time. But as electronic devices become smaller and hotter, with intricate shapes and delicate parts, many manufacturers are opting for solvent cleaning because it delivers better cleaning, more consistently, more quickly, and at a lower cost.

In previous decades, vapor degreasing was the default cleaning process for most industries. In the 1990s, aqueous cleaning became more popular as a "greener" option. Many young engineers today have never seen a vapor degreaser and are unfamiliar with the thermodynamics involved. When the performance and operations of vapor cleaning are explained the whole process seems like magic, especially when compared with the familiar but large, wet and noisy aqueous cleaning systems with which they are familiar.

So, here's the punchline engineers need to realize: advances in solvent technology have changed the game. Innovations are leading to environmentally acceptable cleaning options that outperform aqueous cleaners on today's modern electronics. Modern, nonflammable, environmentally progressive solvent cleaning can make a substantial and relatively inexpensive enhancement to the performance, reliability, and longevity of medical devices. For example, solvents can greatly minimize bioburden issues. Many manufacturers and engineers are discovering that a properly designed and maintained vapor degreaser can be both more effective and more environmentally friendly than an aqueous-based cleaning system, and lower costs at the same time.

Vapor Degreasing Processes

Vapor degreasing is a closed-loop system (see Figure 1) that requires two components: a specially designed clean-

ing machine (which is generically termed a vapor degreaser, even when they're not cleaning greases) and a specially designed low-boiling nonflammable solvent.

In terms of the hardware, vapor degreasing systems usually are comprised of a top-loading, batch-style cleaning machine composed of two chambers: the boil sump and the rinse sump. Both chambers are filled with the cleaning fluid. The machines can cost as little as $20,000 or as much as several million, depending upon the size, throughput, and special features desired. Interestingly, vapor degreasing systems are highly scalable, and you get the same results from a small machine as a large one—a benefit not always available to aqueous cleaning users.

The low-boiling solvents are used as the cleaning agents. These fluids typically boil at 40 °C, compared with water at 100 °C, which means they use much less electricity to clean. These fluids also have a lower surface tension and lower viscosity than water so they easily clean under even the smallest of parts. Most vapor degreasing fluids also are very heavy and dense — typically 20–40 percent heavier than water — which aids in dislodging particulate from components. Lastly, but most importantly, because the cleaning fluid can be tailored for the application, delicate parts are easily cleaned and dried with very consistent results, which is an important factor for medical electronics.

Operations are simple. In the boil sump, the solvent is heated and the parts are immersed and cleaned in the fluid. Once cleaned, the parts are relocated into the rinse sump for a final cleaning in fresh, pure, uncontaminated fluid. The heat in the machine also generates vapor that rises inside the machine until it is captured by refrigerated coils that encircle the perimeter of the system. The refrigeration condenses the vapors back to its liquid state. This pure, clean distillate liquid is channeled into the rinse chamber, which eventually overflows back into the boil sump. This means that every vapor degreaser is inherently a recycling system — a claim no water-cleaning system can make. Properly handled, the solvents never wear out and never need to be replaced.

It is a general rule in cleaning that "you cannot clean if you cannot wet." Better wetting means better cleaning. The relative ability of a fluid to wet a surface can be measured by "the wetting index." This combines the relevant chemical characteristics to predict the quality of the cleaning. The wetting index of a typical, modern, nonflammable solvent is 100 or higher. This contrasts sharply with the wetting index for water, which is 14. Better wetting results faster, better, more consistent, and easier cleaning, especially when compared with aqueous cleaning.

Critically for medical devices, with vapor degreasing, the parts come out

clean, dry, spot-free, and immediately ready for further processing. Depending on the process requirements, vapor degreasing can handle the most challenging and complex shapes to ensure that they are clean.

Solvent Cleaning — a Win-Win Answer

The low viscosity and surface tension ratings of solvents, combined with their volatility, also allow them to clean very effectively, even in small crevices and areas that water in aqueous systems cannot easily penetrate. This is especially important for medical device designers, because it means they are not as limited in product design as they may be with aqueous systems. They can be sure that all the surfaces of the finished product will be effectively cleaned, even under tight-stand-off components.

Solvents are inimical to bacteria, so solvent cleaning ensures a pyrogen-free cleaning environment. This, in turn, enhances the results of subsequent

Modern electronics are easily cleaned in a vapor degreaser because the solvent can be tailored to precisely match the contamination. Importantly — and unlike aqueous cleaners — vapor degreasing is highly scalable, so a small benchtop machine cleans exactly as well as a large, floor-mounted system.

sterilization procedures. Traditional water-based cleaning is, on the other hand, often a significant source of pyrogen contamination.

Water is the primary growth medium for bacteria; therefore, removing water from the manufacturing process eliminates a major source of bioburden. This is one of the main reasons solvent cleaning is becoming the preferred choice. Solvents are hostile to pyrogens, so vapor degreasing greatly simplifies process control requirements for eliminating bioburden. Since the solvents are inherently hostile to the bacterial growth, vapor degreasing offers an easy way to validate bioburden issues in the manufacturing process.

Solvent-based cleaning has other benefits as well, including substantially lower energy consumption, a smaller footprint well-suited for use in the cleanrooms, and minimal capital outlay when compared with a water system.

It is also worthwhile mentioning here that solvent-based cleaning is a simple process with minimal requirements for engineers to oversee on a daily basis to produce clean PCBs. It is also an easy way to touch up the cleaning process at the benchtop.

Today's solvent cleaners are effective at thoroughly cleaning components and will stand up to regulatory requirements imposed by the medical industry. Formulations are now cleaner, greener, safer, and pose fewer bioburden risks. Importantly, they avoid the expense and global warming impact associated with aqueous cleaning technologies as well as the environmental challenges of old-style chlorinated solvents. They can also stand up to the rigorous standards and regulations worldwide.

A well-engineered process can be easily qualified and validated wherever the process is taking place in the world. This inherently reduces the associated costs in the manufacture of medical device components.

Cleanliness Is Key

Medical electronic devices by their very nature are extremely complex and pose many difficulties to the designer. At the end of the day, the proper operation of the device could be a matter of life or death, so reliability is of paramount importance.

Solvent cleaning offers a new option for design engineers. It enables a critical cleaning process that ensures that contaminated PCBs are not the cause of any failure, and that better PCBs can be built and deployed, creating new capabilities. Designers and manufacturers should consider using solvent-based vapor degreasing on their new hardware. New advances in solvent technology mean vapor degreasing not only will be the most reliable solution, but also the most cost-effective.

This article was written by Mike Jones, Vice President, International Sales, for MicroCare Corp. (New Britain, CT). For more information, visit ***http://info.hotims.com/65855-168****.*

Tantalum Capacitors for Medical Applications

Surface mount solid tantalum capacitors are a well-established technology and have been broadly employed in medical devices for decades. There are many reasons to choose tantalum, including their inherent reliability, self-healing capabilities, absence of any known wear-out mechanism, and their ability to pack the highest capacitance values into the smallest case sizes. This article describes the differences between ceramic and tantalum technologies, as well as the different design approaches for commercial and medical-grade capacitors.

Ceramic vs. Tantalum

When engineers are designing a medical device, it's common to have to choose between tantalum and ceramic capacitors.

Multilayer ceramic capacitors (MLCCs) have smaller plate/surface areas and significantly thicker layers than tantalum, but the dielectric materials have a much higher permittivity (i.e., dielectric constant). MLCCs can be manufactured in case sizes that are not practical for tantalum capacitors, 01005 and 0201 for example, but, in larger case sizes, tantalum can offer similar capacitance values to some MLCC technologies.

MLCCs are broken into two classes. Class 1, referred to as NP0 or C0G, are temperature-compensating capacitors and are composed of dielectric materials like titanium dioxide modified with additives of other elements, such as zinc, zirconium, niobium, etc., which are necessary to achieve certain desired linear characteristics. The have predictable temperature coefficients and do not have an aging characteristic. They also offer the most stable capacitance with respect to applied voltage, temperature, and, to some extent, frequency. Class 1 ceramic capacitors have the lowest volumetric efficiency among ceramic capacitors, which results from the relatively low permittivity of their dielectric materials. As such, Class 1 capacitors have lower capacitance values than tantalums or Class 2 ceramics.

Class 2 ceramic capacitors have a dielectric that exhibits high permittivity and, as a result, have better volumetric efficiency than Class 1 capacitors, but lower accuracy and stability. Based on the chemistry of barium titanate, Class 2 capacitors can provide a wide range of capacitance; with the individual cap value depending on the applied voltage. The ceramic dielectric is also characterized by a nonlinear change of capacitance over the temperature range, meaning that Class 2 capacitors age over time.

Tantalum capacitors, on the other hand, do not experience similar aging characteristics and have no known wear-out mechanism. They also achieve high capacitance values by having a large surface area and a very thin dielectric layer. Their internal structure is made up of millions of tantalum particles that are fused together to form a sponge-like structure. If someone were to flatten out this spongy structure, the total surface area would be more than 200 times greater than the footprint of the capacitor body, as shown in Figure 1. Also, in addition to having no known wear-out mechanism, the average reliability of tantalum capacitors actually improves over time (see Figure 2).

In the medical market, MLCCs are typically considered the best choice for applications with capacitance ranges below 1 µF,

Criteria	Commercial	Medical
Burn-in	Yes, 2 hours	Yes, 40 hours minimum for reliability confirmation
Destructive Physical Analysis (DPA)	No	Yes, 5 pieces per lot
Electrical Screening	Yes, 100% electrical screening to spec limits	Yes, 100% electrical screening to 3 sigma DCL standard
Ongoing Conformance	No	Yes
Surge Current	Yes, 100% at room temperature	On request, per MIL-PRF standards
Thermal Shock	No	Yes, 10 cycles
Visual and Mechanical Inspection	Yes, 100%camera for gross defects	Yes, 100% human visual to medical criteria

Table 1 – Differences in manufacturing processes vary greatly between medical tantalum and commercial tantalum capacitors.

and tantalum capacitors are normally chosen for applications with capacitance values at or above 10 µF. In the 1–10 µF range, choices are based on relative size, application requirements for capacitance stability over temperature and voltage, and rated voltage capability.

The Importance of Design

There are many differences between commercial and medical components, starting with the way they are designed, and tantalum capacitors are no different.

The tantalum powder used to make commercial capacitors has a super fine particle size, which translates into higher volumetric efficiency or a higher CV/gram capability, with CV referring to the capacitors' volume of capacitance and voltage. The smaller particle size enables the significant downsizing of existing ratings and a general extension of the capacitance available at a given voltage level. The drawback of these higher CV/gram powders is related to the reduced strength of the connection between the particles due to smaller necks and increased difficulty in depositing the counter electrode material due to small internal pore structures. Finer powders also have a higher oxygen content, which is an impurity that can lead to higher direct current leakage (DCL).

The formation ratio is another way of saying dielectric thickness, and it is based on the voltage that tantalum pellets are formed at rather than the rated voltage of the final component. Commercial components typically have formation ratios that do not exceed 2:1, meaning that a 50-V component will be formed at 100 V. The use of high CV powders restricts the thickness of the dielectric layer; since smaller particles leave less room for dielectric growth, they can only be used to make lower voltage parts. This also means that the 50 percent derating recommendation is even more important for commercial-grade components since the applied voltage is a higher percentage of the formation voltage. Medical components, on the other hand, will typically approach a 4:1 formation ratio, resulting in a thicker dielectric that provides greater reliability in terms of surge current and electric field handling capabilities.

One critical aspect of any medical tantalum capacitor — and, really, all components intended to be used in FDA Class II or III medical devices — is the control of the design and any changes made to it. There is a profound difference in the overall philosophy of components built for consumer electronics compared with those supplied against medical specifications. Commercial component manufacturers follow the general rule that if a design change does not alter the form, fit, or function of the component, then no change notification is required, but medical component manufacturers and their customers have a completely different opinion.

In general, a commercial facility may change the materials used to build parts at-will in order to achieve cost savings or utilize a readily available material supply, but not all designs are created equal in terms of inherent reliability. Commercial products do not have the lot-to-lot control of medical designs or tantalum powders. Medical components have the strictest change control requirements in the industry, and generally require customer approval for changes in design, raw materials, supplier moves, and several other aspects in order to satisfy FDA requirements for Class II and Class III devices.

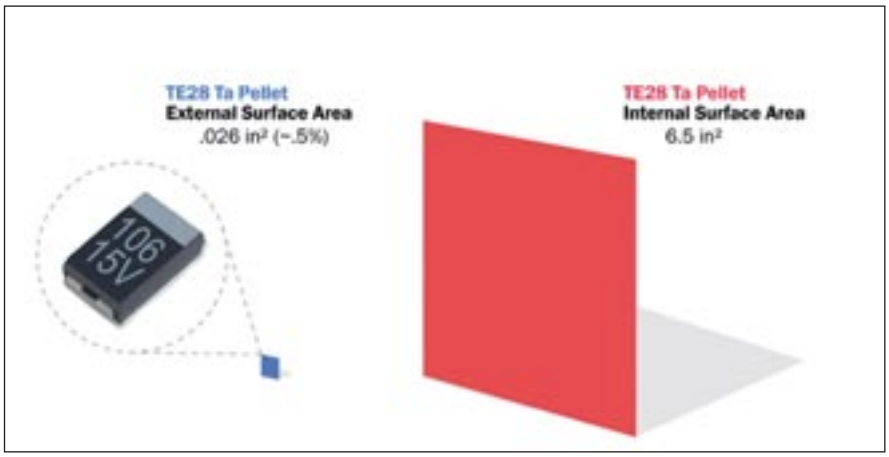

Fig. 1 – Tantalum capacitors achieve high capacitance values by having a large surface area. Their internal structure is made up of millions of tantalum particles that are fused together. If these particles were flattened out, the total internal surface area would be more than 200 times greater than the external footprint of the capacitor body.

Qualification and Process Differences

Once the tantalum components are designed, they go through a rigorous internal qualification process. Requirements from medical customers force manufacturers to have comprehensive change control management systems in place so that any changes are made only after thorough analysis, qualification, and approval from all required parties. In an environment where customers require consistent performance over time, it is necessary to have strict process controls. To supplement the control aspects, it is common practice to have detailed standard operating procedures and robust training programs in place, because these help ensure that operators perform the operations correctly and consistently.

There are also extensive manufacturing execution system (MES) controls in key areas to reduce the opportunity for human error and ensure that the correct process flow and conditions are followed. These systems use barcode scanners and machine lockouts to keep track of the products in process, prevent processes from being skipped or duplicated, and monitor both equipment conditions and personnel during the processing. The use of statistical process control (SPC) can also be implemented throughout medical component production to manage key processes with tighter limits than commercial products would receive. There are many important differences in the manufacturing processes for medical tantalum and commercial tantalum components (see Table 1). Some suppliers even use tighter statistical controls designed to eliminate outliers and maverick lots, which are not common procedures for commercial components.

The most important electrical parameter for a tantalum capacitor is the DCL, which directly affects the battery life of a device and can thus be crucial in medical devices like implantable cardiac pacemakers and implantable cardioverter defibrillators.

DCL is a strong indicator of the quality of the dielectric and the overall reliability of the component. So, conservative designs, change control, maverick lot control, proprietary testing, and tantalum powder selection all contribute to a lower DCL. Medical-grade tantalum capacitors typically have maximum DC leakage levels that are 25–50 percent of the levels specified for commercial capacitors. This lower leakage translates into improved reliability and longer battery life for medical devices.

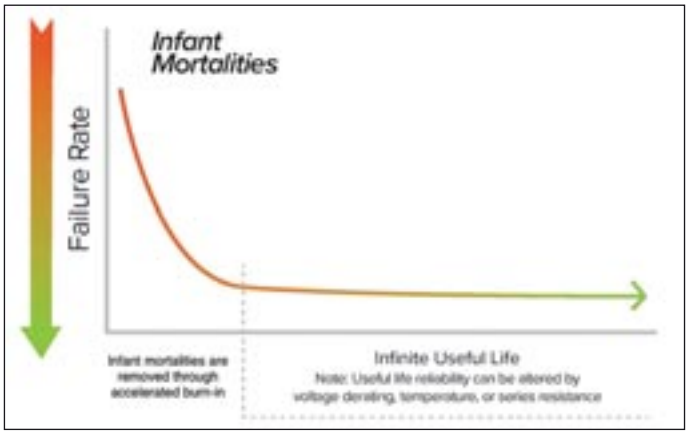

Fig. 2 – Once the initial infant mortalities are removed during accelerated burn-in, the failure rate of tantalum capacitors appears to decrease forever.

Conclusion

There are many reasons to employ tantalum capacitors in medical device designs. The latest technologies, including new process control technologies, the use of conservative design rules, robust change control systems, and the introduction of improved testing methodology, have enabled continuous DCL improvements in tantalum capacitors.

In fact, these technological improvements have already achieved DCL levels that were not considered possible just a few short years ago and, since DCL is the most important electrical parameter for tantalum capacitors, have also resulted in medical-grade tantalum capacitors with notably improved reliability and extended operating lives — both of which are critical design concerns in the medical market.

This article was written by Lizzie Geismar, Senior Product Manager for AVX. For more information, visit ***http://info.hotims.com/65855-169.***

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Target Markets

Medical

Products/Services Offered

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Company Description

New England Wire Technologies, founded in 1898, is a privately held company with an employee stock ownership program located in the beautiful White Mountains of New Hampshire. We are an ISO 9001:2008 registered company with 360 employees operating three shifts, five days a week. Our facilities, located in Lisbon, NH, consist of 338,000 square feet of manufacturing, R&D, quality/testing, tooling/machine fabrication, and office space. Custom wire and cable manufacturing processes include wire drawing, plating, braiding, cabling, and extrusion services.

Our subsidiary, New England Catheter, occupies a 14,000 square foot state-of-the-art facility adjacent to New England Wire Technologies. Calling on the decades of advanced extrusion and wire-processing expertise of New England Wire, New England Catheter excels in thin-wall, close tolerance tubing, bonding layers of thermoplastic to fluoropolymer, and braiding all types of round and flat wire, specializing in tight tolerances, custom designs, and short lead times.

Target Markets

Medical device and electronics manufacturers, OEMs, and medical device/instrument repair companies.

Products/Services Offered

New England Wire Technologies, alongside subsidiary New England Catheter, employs an experienced team of engineers and technical staff who expertly assist our customers in the design, development and testing of custom wire, cable, and tubing products to meet the exacting requirements and performance characteristics of the medical device and electronics industry. Working with customer-supplied requirements, we specialize in product development, concurrent engineering, design for manufacturability, quick-turn prototyping, and unparalleled customer service.

Our products include custom miniature, micro-miniature, single and multiconductor cables, low-noise, high temperature, litz wire, coaxial, vented and hybrid cables, cables with reinforced jackets, medical braids, braid or spiral reinforced tubing, lined catheter shafts, multi-lumen and hybrid tubing...each manufactured to your exacting specification or designed for your unique performance characteristics.

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Heatron's core products include flexible heating elements, cartridge heaters, thick film heaters and circuits, and LED boards and modules. These products can be custom-designed or manufactured to your specifications.

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Upcoming... Webinars

Wired for Success: Advanced Materials for Next-Gen Medical Devices

Tuesday, September 12, 2017 at 11:00 am U.S. EDT

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Turning knowledge into solutions.

Fort Wayne Metals has long been on the forefront in developing improved materials for design solutions. In this Webinar, you will learn about wire that comes off the spool straight and is used in applications ranging from staples to interventional guidewires, wire with a precisely controlled helical micro-groove, and wire that is absorbed by the human body and harmlessly disappears over time.

Speakers:

Eric Dorman
Vascular Therapy Product Manager,
Fort Wayne Metals

Dr. Jeremy E. Schaffer
Director of R&D,
Fort Wayne Metals

This 60-minute Webinar includes:
- Live Q&A session
- Application Demo
- Access to archived event on demand

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Advanced Catheter Manufacturing with Liquid Crystal Polymer Monofilament

Thursday, September 28, 2017 at 2:00 pm U.S. EDT

ZEUS
Turning polymers into possibilities.

Minimally invasive surgical technologies have revolutionized healthcare by making possible a growing variety of complex cardiovascular and neurological interventions. Zeus Industrial Products has identified liquid crystal polymer (LCP) monofilament, a polymer with characteristics suitable to replace the metallic reinforcement braiding used in intravascular access catheters. This Webinar will examine how the use of LCP monofilament is supporting the development of advanced surgical procedures — in cardiology and beyond.

Speakers:

Bruce Anneaux, PhD
Corporate Director,
Research and Development,
Zeus Industrial Products, Inc.

Emily Barnes
Senior Global Market Manager,
Cardiac Rhythm Management/
Electrophysiology,
Zeus Industrial Products, Inc.

Zahidul Wahab, PhD
Senior Research Engineer,
Zeus Industrial Products, Inc.

This 60-minute Webinar includes:
• Live Q&A session • Application Demo • Access to archived event on demand

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Dose Mapping Requirements – Understanding the Historic and Current Practices

Sterigenics SteriPro Advanced Consulting Services

Historically, the Medical Device/Pharmaceutical/Biologics industries have experienced inconsistencies with respect to Gamma PQ Dose Mapping requirements for products deemed as sterile according to ANSI/AAMI/ISO standards. This Webinar discusses historical and current practices, and offers guidance with respect to Gamma PQ Dose Mapping.

Speakers:

Niki Fidopiastis
Director, SteriPro Consulting,
Sterigenics

Kevin O'Hara
Director, Radiation Physics,
Sterigenics

Please visit www.techbriefs.com/webinar454

R&D ROUNDUP

Ultrathin Device Harvests Electricity from Human Motion

An ultrathin energy harvesting system has the potential to harvest electricity from human motion. Based on battery technology and made from layers of black phosphorus that are only a few atoms thick, the device generates small amounts of electricity when it is bent or pressed even at the extremely low frequencies characteristic of human motion.

The energy harvesting device is so thin it can be embedded in fabric. (Credit: John Russell/Vanderbilt)

Because the basic building blocks of the harvester are about 1/5000th the thickness of a human hair, the engineers can make their devices as thin or as thick as needed for specific applications. They have found that bending their prototype devices produces as much energy as 40 μW per square foot and can sustain current generation over the full duration of movements as slow as 0.01 Hz, one cycle every 100 seconds.

The researchers acknowledge that one of the challenges they face is the relatively low voltage that their device produces. It's in the millivolt range. However, they are applying their fundamental insights of the process to increase the voltage.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27337****.*

NanoVelcro Microchips Could Noninvasively Diagnose Prenatal Conditions

A new class of nanoVelcro microchips were prepared with a nano-imprinting fabrication process, which made them more reproducible and faster to make than the previous chips. The device provides sensitive results via a blood test, which is less invasive than currently used methods.

New prenatal testing methods could noninvasively diagnose a fetus' genetic conditions. (Credit: Africa Studio/Shutterstock.com)

Current prenatal tests, such as amniocentesis and chorionic villus sampling are accurate, but are also invasive and increase the risk of a miscarriage. Some less-invasive tests that could be safer are in development but require genetic material that is typically found in short pieces and in very small quantities.

Whole fetal cells containing entire genomes also circulate in a mother's blood. These rare, fragile cells could provide a wealth of information about a fetus' health, but so far, no method is ideal for capturing them. To specifically capture the fetal cells, the team attached an antibody to a marker on the cells' surface. When they tested the blood of 15 pregnant women, they found that the method could enrich for fetal cells. It also accurately determined the sexes of the fetuses, as well as genetic conditions that were previously diagnosed by other methods in nine of the fetuses.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27338****.*

New, More Accurate Software Helps Surgeons Find Liver Tumors

Surgeons can swab a patient's exposed liver lightly on the surface with a special stylus, capturing the shape of the organ during surgery, and a computer can match that image with the CT scan on a screen. This GPS-like ability is far better than guessing where the tumor and vessels are by feeling for them, but even this road map can be off by centimeters and leaves surgeons guessing.

New software simulates the forces being applied during surgery. (Credit: John Russell/Vanderbilt)

Researchers have developed a new surgery-tested software that better marries the CT scan's image with the tracked tool's. It's an advance that stands to help more than a half-million liver cancer patients worldwide each year.

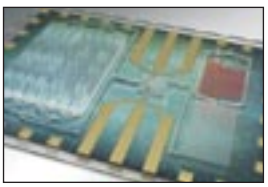
The trick to fixing that error without investing in additional expensive equipment is software that makes a computer model out of the original image of the liver and simulates the forces being applied during surgery — such as packed gauze lifting the liver upward. The computer adjusts the CT-derived GPS map to better match the exposed organ shape in the OR.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27339****.*

Quick Test Detects Sepsis in Single Drop of Blood

A new portable device can quickly find markers of deadly, unpredictable sepsis infection from a single drop of blood. A team of researchers completed a clinical study of the device, which is the first to provide rapid, point-of-care measurement of the immune system's response, without any need to process the blood. This can help doctors identify sepsis at its onset, monitor infected patients, and could even point to a prognosis.

The small, lab-on-a-chip device counts white blood cells in total as well as specific white blood cells called neutrophils, and measures a protein marker called CD64 on the surface of neutrophils. The levels of CD64 surge as the patient's immune response increases. Results from the rapid test correlated well with the results from the traditional tests and with the patients' vital signs.



Rapid test for sepsis counts white blood cells and certain protein markers. (Credit: Janet Sinn-Hanlon)

The team is working to incorporate measurements for other inflammation markers into the rapid-testing device to give a more complete picture of the body's response, and to enable earlier detection.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27340****.*

Self-Learning Device Could Increase Patient Safety

Tiny device enables concurrent medical imaging and recording for diagnostic purposes. (Credit: Shannon Kane/Purdue Research Foundation Image)

A technology being developed could provide an affordable, smart, self-learning device that, when placed into existing MRI machines, could allow medical professionals to monitor patients more effectively and safely, by performing concurrent medical imaging and recording for diagnostic purposes.

The technology could work simultaneously with any MRI system to record electrophysiological signals during MRI scanning. The device aims to learn when to start and stop recording to capture useful signals during MRI operation. The small device can be placed in an MRI system to serve as a platform to combine all other imaging technologies.

The device has a footprint smaller than a penny and could be used safely inside an MRI. Although small, the device is very powerful and allows researchers to record, stimulate, and image the brain or other organs all through the MRI system.

The wireless device is directly powered and operated by the MRI. The researchers say the self-learning device is much more affordable than other commercial systems and provides much better quality in neural recording and stimulation during MRI imaging.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27342****.*

Nontoxic Adhesive Could Lead to New Surgical Glue

A nontoxic glue modeled after adhesive proteins produced by mussels and other creatures has been found to outperform commercially available products, pointing toward potential surgical glues to replace sutures and staples.

Most adhesives do not work well in moist environments because water interferes with the adhesion process. While developing adhesives that overcome this problem is challenging, glues for medical applications must meet an additional requirement: they must be nontoxic and biocompatible.

Rapid test for sepsis counts white blood cells and certain protein markers. (Credit: Janet Sinn-Hanlon)

In efforts to develop better alternatives, researchers have been inspired by natural glues. The new adhesive material is called ELY16, an "elastin-like polypeptide," or ELP. It contains elastin, a highly elastic protein found in connective tissue, and tyrosine, an amino acid. ELY16 was modified by adding the enzyme tyrosinase, converting tyrosine into the adhesive DOPA molecule and forming mELY16. Both ELY16 and mELY16 are not toxic to cells and work well under dry conditions. Modification with DOPA increases adhesion strength in highly humid conditions. Moreover, the modified version is "tunable" to varying environmental conditions and might be engineered to match the properties of different tissue types.

For more information, visit ***www.medicaldesignbriefs.com/component/content/article/1104-mdb/features/27341****.*

Sticking to Skin: How to Overcome Human Factors

Avoid delays, budget overruns, and more by understanding these four challenges.

Critical & Chronic Care Solutions Division, 3M St. Paul, MN

The qualities that make skin an incredible organism are the same ones that make it a challenge to stick to. Engineers may know all too well the headaches that can come with selecting adhesives for their stick-to-skin medical device projects. But it's not all irritations, rashes, and pulled hair.

Understanding the challenges of each project not only prevents some of those side effects, but also instead maximizes comfort for users and produces better end results. Whether it's for a wearable device or an advanced dressing, here are four challenges engineers must consider when developing their next project.

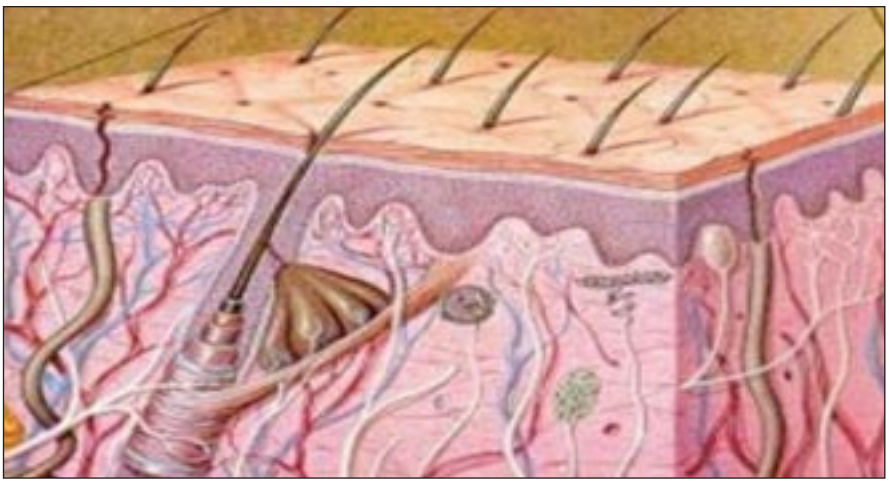
Length of Wear Time

One of the first items engineers must determine is how long the device will be in contact with skin. Since skin essentially renews itself every two weeks, an adhesive that has to stay on for that amount of time will use a different combination of material and backing than one that must only be secured for hours. 3M conducted 8-day and 21-day trials on human volunteers to help medical device manufactures determine the best adhesives for their specific projects. These studies also help to further educate device manufacturers on how to evaluate wear time and the importance of examining skin health. Both studies produced key takeaways for engineers such as questions that must be asked when considering longer- or shorter-term wear, including but not limited to:

- Who is the intended end user?
- Will the adhesive secure a device? If so, how long will that need to be on?
- Where on the body will the device be secured?

Knowing answers to pertinent questions will better steer the project in the correct direction at the start of the process.

It is important to incorporate breathability into the adhesive and backing combination to avoid discomfort.



Human elements, like the amount of oil on the person's skin, hair growth, and application site, all affect adhesion and wear time

The Right Adhesive for the Right Application

Proper adhesive selection can dictate a project's success. After all, not every adhesive is meant for all substrates or applications. Choosing the right one will help the design and development process flow more smoothly, and, hopefully, prevent redoing clinical trials and studies later on. Plus, the proper combination means avoiding other consequences like irritated skin, difficult removal, and a device falling off prematurely.

Here's a quick overview of the most commonly used substrates for medical devices:

- Polyethylene: Soft to the touch, comfortable, easy to work with, and reasonably priced.
- Polyurethane: Great flexibility, soft, can withstand sterilization processes, ideal for wound dressings and other medical needs.
- Polyester: Easy to adhere to, moldable, clear, hard, protective, and inflexible.
- Silicon: Popular for medical devices, difficult to stick to.
- PVC: Flexible, resistant, clear, hard to dispose of, and can negatively interact with tapes due to plasticizer migration.

Choose the Proper Backing

Selecting the right backing for each adhesive is like picking the proper outfit based on the weather. Make the wrong choice, like wearing a winter

coat during a Houston summer, and you will be uncomfortable. Human skin feels the same way about how adhesives and backings are paired. When skin feels suffocated, it may eventually react to whatever is causing the discomfort, so be sure to incorporate breathability into the adhesive and backing combination.

There are other factors to consider as well, particularly when the adhesive is used to adhere an occlusive device for multiple days or weeks. It's key to understand how the device pairs with the adhesive and backing, and to optimize the entire construction to avoid migration of skin irritants. Three other aspects to incorporate into design are moisture management, flexible backing, and backing that extends beyond the device's edge. While the device may be occlusive, incorporating these design considerations can help the skin continue to move, flex, and breathe around the device.

Diversity of Factors Affecting Adhesion and Wear Time

Both adhesion and wear time are greatly impacted by the convergence of human and design factors. Human elements, like the amount of oil on the person's skin, hair growth, and application site, can be difficult to manipulate. Still others are harder or impossible to control, like culture, health, age, and environment. Understanding the differences between wear time and adhesive capabilities on an elderly person's skin as opposed to a baby's might not be top of mind for most engineers, but knowing these nuances will play a critical role in the end use success.

Design-wise, the bottom line is to only ask the adhesive to do what's required of it. While this may seem like obvious advice, there can be a tendency to overdesign and use an unnecessarily strong tape.

Keeping tabs on these four challenges at the start of a project will benefit the product development process, and in turn, the manufacturers, engineers, and end users involved. Not only will the process be more efficient and less costly, but the end products will do their jobs better. Those who neglect addressing these issues may go down the wrong path from the get-go, potentially squandering precious resources, causing delays, and raising budgets.

Negative outcomes can be avoided when engineers and customers work together to mutually understand the nuances and offerings of medical tapes, and how each can affect a particular medical project. Some companies, like 3M, offer engineers support during the entire design and development process by providing a critical lens on projects and offering advice on design and adhesive options. A greater level of success comes with understanding of these stick-to-skin challenges.

This article was written by Diana Eitzman, PhD, Director of Agile Commercialization for 3M's Critical & Chronic Care Solutions Division, and Kris Godbey, Senior Applications Development Engineer at 3M, St. Paul, MN. For more information, visit ***http://info.hotims.com/65855-170.***

Clean Manufacturing: Cold Forming and Environmental Compliance

The precision manufacturing technique offers unexpected cost-reduction opportunities.

Sussex Wire, Inc.
Easton, PA

Cold forming, or cold forging, is becoming a more popular option for manufacturing precision engineered miniature and micro surgical and medical components.[1] Manufacturers that purchase custom cold formed components for their assemblies do so with a view to reduce raw material and labor costs while also improving yield and component reliability. While the parts are generally very small, a large percentage of them contain a wide variety of expensive — and often precious — raw materials, and any reduction of waste adds directly to the bottom line. Cold forming's other advantage of retaining or even improving repeatable quality over alternative methods is another reason it is becoming increasingly popular.

So, while production efficiency, lower cost, and improved yield, strength, and quality are all extremely compelling reasons to choose cold forming, here's an unexpected one: ecological. Many companies employing methods to reduce environmental impact do so either because of regulatory compliance requirements or because of the public relations value; that is, a perception of good corporate citizenship influences consumer preference in esoteric (if not real) terms. However, with cold forming, the ecological advantages translate almost entirely to cost advantages as well.

This net shape micro-screw produces no scrap and has an increased tensile strength due to work hardening through the cold forming process.

The naturally environmentally friendly methods used in cold forming can result in savings from the following categories: virtually no scrap, lower material and recycling costs, reduced overhead cost, and reduced oil cost and consumption. Note: The platform for cost comparison takes into consideration a significantly higher production volume for cold formed parts at an average of 100 PPM versus the typical 20 PPM for machined parts. The savings illustrated below are particularly effective over very long runs.

Virtually no scrap. Very little to no material is sacrificed in part manufacture, except in trimming, which may account for less than 2 percent of the part mass. Cold forming produces a "near net shape" (and frequently a complete net shape) part. Less scrap translates into a reduction in original material cost to manufacture the part.

Lower material and recycling costs. Recycling costs, especially for exotic materials such as gold, silver, and platinum, are much lower for cold forming because machining produces scrap, whereas with cold forming, all materials are near net shape. Recycling costs for exotic materials are higher due to challenges of reclaiming particles and screening impurities after recycling.

Reduced overhead cost. Fewer man-hours are devoted to producing the same number of parts; therefore, the cost per piece includes a much lower contribution of labor cost than machining does. Also, because of cold forming's high production speed, there is a much lower utility cost contribution per part than with a slower process like machining, making the part significantly more energy efficient.

Per 1,000,000 parts	Cold formed part	Machined part	Savings
Material Scrap	$0	$5,080.50	$5,080.50
Energy (based on average rate of $0.10/KWH)	$14.89	$55.56	$40.67
Labor (based on average labor rate of $16/hour, 1 person)	$2,380.96	$8,888.96	$6,508.00
Totals	$2,395.85	$14,025.02	$11,629.17
PPM	112	30	82
Days to complete	6	23	17

Table 1. A comparison of manufacturing costs and savings with cold forming versus machining for a micro-screw.

Per 1,000,000 parts	Cold formed part	Machined part	Savings
Material Scrap	$0	$18,282.70	$18,282.70
Energy (based on average rate of $0.10/KWH)	$16.67	$69.44	$52.77
Labor (based on average labor rate of $16/hour, 1 person)	$2,666.72	$11,110.40	$8,443.68
Totals	$2,683.39	$29,462.54	$26,779.15
PPM	100	24	76
Days to complete	7	29	22

Table 2. A comparison of manufacturing costs and savings with cold forming versus machining for a cannula hub.

For this cannula hub, minimal scrap and increased tensile strength are achieved through the cold forming process.

Reduced oil cost and consumption. Total oil cost is lower for cold forming. Even though it uses a more expensive type of oil that requires greater viscosity than lubricating oil for machining, the faster production speed means less oil usage over time. On average, this results in lubrication cost savings of 10 percent on every full production run.

To illustrate ecological savings using actual products, the following examples of specific parts compare manufacturing costs and savings with cold forming versus machining.

Example 1: Medical Device Insert Screw

A stainless steel medical insert screw is manufactured using cold forming and roll forming as a secondary operation. This net shape micro-screw produces no scrap and has an increased tensile strength due to work hardening through the cold forming process. The high run rates of cold forming positively impact cost and energy efficiency with a savings of 407 KWH per million pieces compared with traditional machining methods. Production runs for the insert screw are in excess of 50,000,000 parts annually (see Table 1).

Example 2: Cannula Hub

An aluminum tubular part that holds a medical needle and screws into a syringe body is manufactured using cold forming with secondary operations for threads. Minimal scrap and increased tensile strength are achieved through the cold forming process. Due to the high run rates possible with cold forming, when compared with traditional machining methods, 528 KWH were saved per million pieces, reducing not only energy cost but the carbon footprint as well. This part runs in excess of 2,000,000 annually (see Table 2).

Bottom line: Ecological imperatives, considered alone, may not be enough to convince medical device buyers to adopt cold forming to solve many of their small component manufacturing needs. But cold forming affords them an opportunity not just to claim a high road of environmental responsibility, but to save some additional cost along the way.

Reference

1. Kardish, Tim, "Where Component Design Functionality and Cost Reduction Converge," *Medical Design Briefs*, October 2014, p. 12–17.

This article was written by Marian Watkins, Marketing Director for Sussex Wire, Easton, PA. Contact her at mwatkins@sussexwire.com. For more information, visit ***http://info.hotims.com/65855-171.***

'Near-Zero-Power' Temperature Sensor Could Make Wearables Less Power-Hungry

The sensor runs on only 113 picowatts of power.

University of San Diego
San Diego, CA

Electrical engineers at the University of California San Diego have developed a temperature sensor that runs on only 113 picowatts of power — 628 times lower power than the state of the art and about 10 billion times smaller than a watt. This "near-zero-power" temperature sensor could extend the battery life of wearable or implantable devices that monitor body temperature, Internet of Things devices, and more.

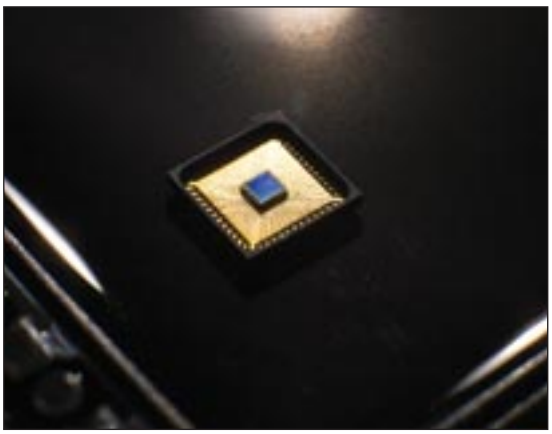
The technology could also enable a new class of devices that can be powered by harvesting energy from low-power sources, such as the body or the surrounding environment, researchers say. The work was published in *Scientific Reports*.

"Our vision is to make wearable devices that are so unobtrusive, so invisible that users are virtually unaware that they're wearing their wearables, making them 'unawearables.' Our new near-zero-power technology could one day eliminate the need to ever change or recharge a battery," says Patrick Mercier, an electrical engineering professor at UC San Diego Jacobs School of Engineering and the study's senior author.

"We're building systems that have such low power requirements that they could potentially run for years on just a tiny battery," says Hui Wang, an electrical engineering PhD student in Mercier's lab and the first author of the study.

Building ultralow power, miniaturized electronic devices is the theme of Mercier's Energy-Efficient Microsystems lab at UC San Diego. Mercier also serves as co-director for the Center for Wearable Sensors at UC San Diego. A big part of his group's work focuses on boosting energy efficiencies of individual parts of an integrated circuit in order to reduce the power requirement of the system as a whole.

One example is the temperature sensor found in healthcare devices. While the power requirement of state-of-the-art temperature sensors has been reduced to as low as tens of nanowatts, the one developed by Mercier's group runs on just 113 picowatts.



This near-zero-power temperature sensor could extend the battery life of wearable or implantable devices (Credit: UC San Diego Jacobs School of Engineering

Minimizing Power

Their new approach involves minimizing power in two domains: the current source and the conversion of temperature to a digital readout.

Researchers built an ultralow power current source using what are called *gate leakage transistors* — transistors in which tiny levels of current leak through the electronic barrier, or the gate. Transistors typically have a gate that can turn on and off the flow of electrons. But as the size of modern transistors continues to shrink, the gate material becomes so thin that it can no longer block electrons from leaking through — a phenomenon known as the *quantum tunneling effect*.

Gate leakage is considered problematic in systems such as microprocessors or precision analog circuits. Here, researchers are taking advantage of it — they're using these minuscule levels of electron flow to power the circuit.

"Many researchers are trying to get rid of leakage current, but we are exploiting it to build an ultralow power current source," Hui says.

Using these current sources, researchers developed a less power-hungry way to digitize temperature. This process normally requires passing current through a resistor — its resistance changes with temperature — then measuring the resulting voltage, and then converting that voltage to its corresponding temperature using a high-power analog to digital converter.

Instead of this conventional process, researchers developed an innovative system to digitize temperature directly and save power. Their system consists of two ultralow power current sources: one that charges a capacitor in a fixed amount of time regardless of temperature, and one that charges at a rate that varies with temperature — slower at lower temperatures, faster at higher temperatures.

As the temperature changes, the system adapts so that the temperature-dependent current source charges in the same amount of time as the fixed current source. A built-in digital feedback loop equalizes the charging times by reconnecting the temperature-dependent current source to a capacitor of a different size — the size of this capacitor is directly proportional to the actual temperature. For example, when the temperature falls, the temperature-dependent current source will charge slower, and the feedback loop compensates by switching to a smaller capacitor, which dictates a particular digital readout.

The temperature sensor is integrated into a small chip measuring 0.15 × 0.15 mm^2 in area. It operates at temperatures ranging from –20° to 40 °C. Its performance is fairly comparable to that of the state of the art even at near-zero-power, researchers say. One trade-off is that the sensor has a response time of approximately one temperature update per second, which is slightly slower than existing temperature sensors. However, this response time is sufficient for devices that operate in the human body, homes, and other environments where temperatures do not fluctuate rapidly, researchers say.

Moving forward, the team is working to improve the accuracy of the temperature sensor. The team is also optimizing the design so that it can be successfully integrated into commercial devices.

A provisional patent is pending for this technology. Contact David Gibbons in the campus Innovation and Commercialization Office at dgibbons@ucsd.edu or (858) 534-0175 for licensing information. The authors acknowledge the Arnold and Mabel Beckman Foundation for support. For more information, visit ***http://jacobsschool.ucsd.edu/news****.*

On the Cutting Edge of Hearing Aid Research

In the United States, nearly 20 percent of the population is reportedly hearing impaired — although that figure could be higher because many people are reluctant to admit they have a hearing problem. Those who are treated rely on miniature and discreet hearing aid devices to improve their hearing, hence their quality of life. Significant R&D effort is required to bring a hearing instrument from a prototype stage to a marketable hearing aid device.

Engineers face daily technical challenges in hearing aid design. Feedback is a major issue that leads to high-pitched squealing or whistling, and limits the amount of gain the aid can provide. "Feedback usually occurs when a hearing aid's microphone picks up sound or vibration inadvertently diverted from what's being channeled into the ear canal and sends it back through the amplifier, creating undesirable oscillations," explains Brenno Varanda, a senior electroacoustic engineer at Knowles Corp. (Itasca, IL).

"For many of Knowles' customers, designing a new hearing aid is a costly, time-intensive process that could take anywhere from two to six years to complete," Varanda explains. Accurate modeling helps designers select speakers, refine vibration isolation mounts, and package components to reduce the amount of speaker energy that is fed back to the microphone. The industry is in dire need of simple transducer models that will expedite that process and provide more effective options to consumers. Complete models of speakers and microphones are quite complex and incorporate many factors that are not necessary for feedback control. "While understanding the electromagnetic, mechanical, and acoustic physics of our transducers is important to transducer designers at Knowles, all of that complexity is not necessarily useful for our customers," Varanda says.

As a global leader and market supplier of hearing aid transducers, intelligent audio, and specialty acoustic components Knowles took a multilateral initiative to develop transducer vibroacoustic models that are easy to implement and compatible with its hearing health customers. The models are intended to help hearing aid designs graduate from a prototype stage to a final product in a more efficient manner without having to sacrifice accuracy.

Hearing Aid Design and Feedback

When designing hearing aids, two major conflicting requirements must be accounted for by engineers. They must be compact and unobtrusive, yet still capable of providing a powerful sound output to overcome the user's hearing loss. The user is far more likely to wear a hearing aid if it is discreet and lightweight. This makes solving the feedback issue more challenging. "A common design challenge is to cram all the hardware components into the smallest space possible without causing feedback instability," Varanda says.

A typical small behind-the-ear (BTE) hearing aid comprises microphones to convert ambient sounds into electrical signals, a digital signal processor and amplifier to process and boost the electrical signals, and a tiny loudspeaker, also known as a receiver (see Figure 1). The receiver, or speaker, "receives" amplified electrical signals and converts them into acoustic energy, or sound, which is then channeled into the ear canal through a tube or an ear mold.

The receiver contains an electromagnetically controlled lever, known as the *reed*, connected to a diaphragm that generates sound through its oscillating motion. The internal electromechanical forces also generate reaction forces which transmit vibrations through the hearing aid package, creating sound that is picked up by the microphone. This signal in turn is magnified by the amplifier and returned again to the receiver, causing feedback. This path is shown in Figure 1.

The 'Black Box' Model

The receiver's only function is to convert the amplified voltage signal from the microphone into sound. While the construction appears simple, the process is rather complex (see Figure 2). The electrical signal is first converted to a magnetic signal, then to a mechanical signal, and finally into an acoustic signal. Each of these steps has its own frequency-dependent characteristics. Understanding the combined effects of all the internal components is vital to the ability of effectively designing receivers for all different hearing aid platforms. Engineers at Knowles have been using complex circuit-equivalents to model all of their internal electrical-magnetic-mechanical-acoustic effects since the 1960s.

Accurately modeling the full complexity of a receiver requires a dauntingly large and complex multiphysics finite element model, making it impractical for fast and efficient hearing aid design. This issue was overcome when Dr. Daniel Warren, a hearing health industry expert in receiver and microphone research, introduced a "black box" model in 2013. The design uses a minimum amount of simple circuit elements to capture the essential electroacoustic transfer function between voltage and output sound pressure level for balanced armature receivers, while leaving out factors that are unimportant to feedback control.

A key step to simplifying the model was when Warren and Varanda demonstrated that the simplified electroacoustic circuit could be converted into a powerful vibroacoustic model

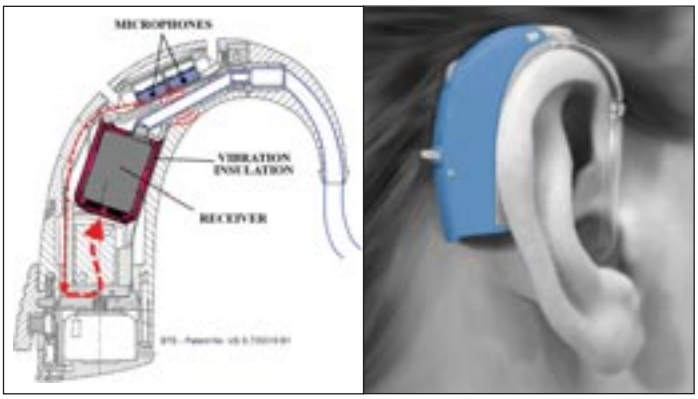


Fig. 1 – A typical BTE hearing aid includes microphones, vibration insulation, and a receiver, among other components. The tight spacing of these components invites troublesome acoustic and mechanical feedback. (Credit: Knowles Corp.)

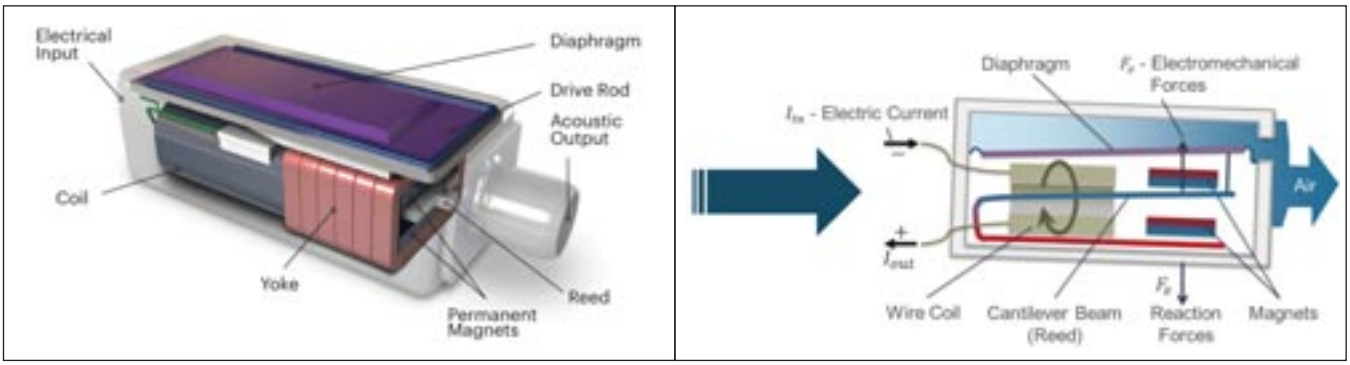


Fig. 2 – A receiver, a key hearing aid component, contains a tiny loudspeaker with an electromagnetically controlled diaphragm that generates sound. Internal electromagnetic forces cause structural vibration that results in mechanical feedback.

while adding very little complexity to the model. "The conversion is achieved by probing a section of the "black box" circuit where the voltage across inductors is directly proportional to the internal mechanical forces responsible for structural vibration," Warren explains.

The "black box" and vibroacoustic models needed to be tested and validated against realistic acoustic and mechanical attachments to the receiver before designers could start using them for product designs. A worldwide collaboration between Knowles and its hearing health customers got started in 2014 to validate the models using the COMSOL Multiphysics® software and industry standard tests.

Working Together on Validation

To validate the models, engineers needed to measure the acoustic output and vibration forces at the same time, using a structure that could be easily modeled in finite element analysis (FEA). Like common hearing aid tests, this test involved connecting a receiver to a short section of tubing leading to an enclosed cavity with a two-cubic centimeter (2 cc) volume, which is a standardized ear canal acoustic load as shown in Figure 3. The acoustic pressure inside the cavity is measured with a laboratory-grade microphone. To help verify the robustness of the model, the receiver was also measured using a complex tubing assembly similar to a BTE hearing instrument. The long tubing in this design varies in diameter, and is long enough to support multiple acoustic resonances. At the same time the acoustic output was being measured, the receiver's structural motion was captured by a laser vibrometer. Both translational and rotational motion were measured by observing the motion at multiple points on the surface of the receiver housing.

Warren and Varanda collaborated with several Knowles customers to perform the measurements described above. With the help of COMSOL Multiphysics, they were able to implement the simplified vibroacoustic circuit model into a simulated replica of the test setup described above. The simulation couples the mechanical interaction between the motion of the receiver and the silicone tubing attachment, thermoviscous losses within the various tubing cross sections, and acoustic pressure loads inside the cavity and tubing with the internal electromagnetic-acoustic effects in the "black box" receiver model.

The COMSOL model revealed the dependence of the output pressure and mechanical forces on the applied voltage, frequency, and material properties. Figure 4 shows the displacement results from the simulation at 3 kHz and the reaction forces coupled to the receiver.

When Varanda compared the results of simulations with the physical measurements, they showed excellent agreement (see Figure 5). The forces acting on the diaphragm and the reed are acoustically dependent on the output sound pressure. However, the coupling between the forces acting on the diaphragm with the structural reaction forces proves to be, as expected, directly proportional.

Spreading the Knowledge

Knowles shares its model to empower engineers at other hearing aid companies to solve their own system feedback troubles. With a complete representation of the acoustic, mechanical, and electromagnetic behavior inside the hardware, designers are well set up to virtually optimize their products.

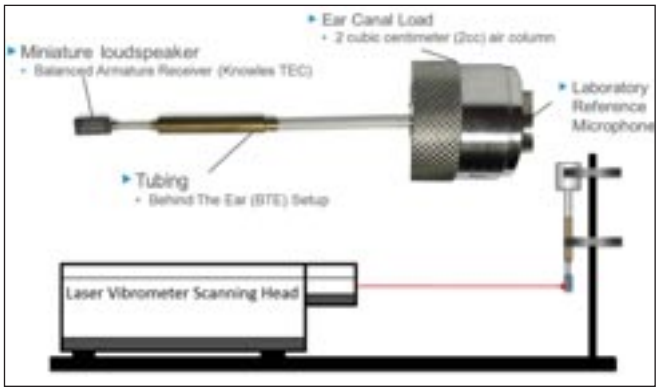


Fig. 3 – Hardware and schematic of the experimental setup.

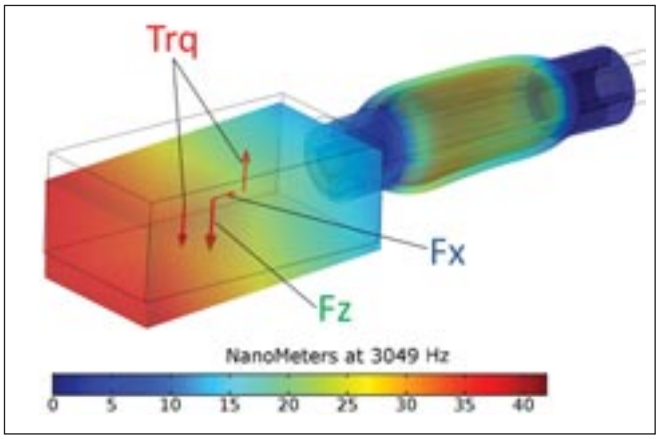


Fig. 4 – Simulation force and displacement results at 3 kHz of the receiver and silicone tube attachment.

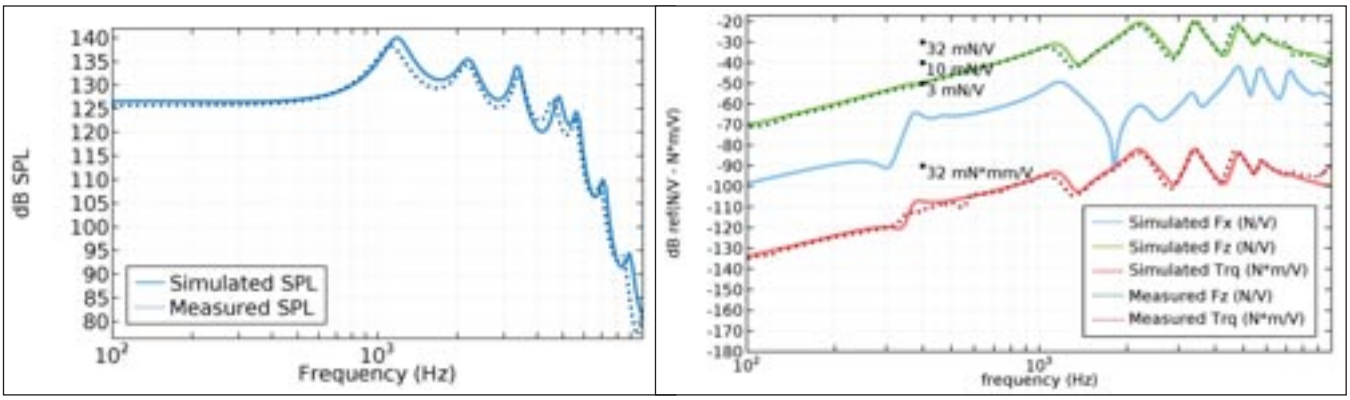


Fig. 5 – Left: Measured (dotted line) vs. simulated (solid line) sound pressure level inside a 2-cc coupler. Right: Measured (dotted line) vs. simulated (solid line) forces and torque acting on the receiver.

"COMSOL is one of the few modeling and simulation tools that can easily couple the lumped 'black box' receiver circuit with acoustics and solid mechanics," says Varanda. "Until now, verifying and optimizing hearing aid designs has been as much art as science. We will be very happy to see new hearing instruments designs that have benefitted from these models."

By joining forces, the intercompany effort has made it easier for everyone in the hearing health industry. "Ultimately, hearing aid designers don't want to get bogged down with complex transducer models and time-consuming simulations. They simply want to focus on their own design and to swap transducers in and out to see how everything will work together," he adds. "This COMSOL model enables them to do this. The behavior of hundreds of transducers can be easily compared for one hearing aid package."

Hearing aid designers now have the ability to reduce feedback and improve overall performance better, faster, and more economically than before, which will lead to more options for people who are hearing impaired.

This article was written by Valerio Marra, Marketing Director at COMSOL, Burlington, MA. For more information, visit ***http://info.hotims.com/65855-166****.*

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

Product of the Month

Miniature LVDT sensors from Hoffman & Krippner, Woodstock, GA, provide precision measurements of position and path in the range of single-digit millimeters. The new Inelta ILAT series sensors are available in models ILAT 2, ILAT4, and ILAT10 for traveling distances of ±1, ±2, or ±5 mm. Because the sensors are only 79 mm long with a diameter of only 8 mm and weight of 30 g (including cable), they can navigate within very tight-fitting conditions.

The sensors are based on the inductive linear variable differential transformer principle in which a coil within the sensor with a primary winding and two secondary windings transforms the linear motions of the measuring sensor contact-free into a single electronic signal. This enables the sensors to operate free from wear and provide a linearity tolerance of <0.25 percent. They are also available with a linearity tolerance of <0.1 percent.

The sensors are enclosed a stainless-steel housing in protection class IP65 (IP67 optional). The nominal temperature rating is 0°–70 °C. The linear guiding operates by virtue of a locking mechanism of the probe and can provide more than 10 million cycles.

For Free Info Visit http://info.hotims.com/65855-173

MEDICAL DESIGN BRIEFS 2017 Product of the Year Finalist

Dynamic Inclination Sensor

A dynamic inclination sensor is available from ASM Sensors, Elmhurst, IL. The POSITILT® PTK29 sensor compensates for dynamic influences to give correct values even when in motion. The sensor measures inclination between ±180° with one axis or ±60° with two axes. Utilizing gyro-compensated MEMS technology, the sensor position signal is instantaneous with no delays. It has a static linearity up to 0.05°. It can be mounted with selectable axis orientation. The sensor electronics are completely enclosed and protected by a hermetically sealed stainless-steel housing. For safety-critical applications, the sensor is available in a hermetically sealed stainless-steel housing with redundant output options.

For Free Info Visit http://info.hotims.com/65855-174

ABS Material

INEOS Styrolution, Frankfurt, Germany, offers a glass-fiber-filled ABS suitable for medical applications. Novodur HD M203FC G3 is certified against the relevant parts of ISO 10993 for biocompatibility. According to the company, the new grade of this material delivers a significantly increased stiffness in combination with a high flowability, making it ideal for demanding applications like medical spikes and applications requiring structural stability. The material comes with the company's Full Service HD package, which includes regulatory documents and up to 36 months notification of change (NOC).

For Free Info Visit http://info.hotims.com/65855-175

Low-Power Microcontroller

Microchip Technology, Chandler, AZ, has released a family of low-power microcontroller devices. The eXtreme Low Power (XLP) microcontrollers feature large memory in small packages, providing ample battery life for space-constrained applications. With the inclusion of several connectivity options, core independent peripherals, and feature-rich development boards, the PIC32MM GPM MCUs are well suited for portable medical devices. The devices provide power-saving options, such as sleep modes with current consumption as low as 650 nA with random access memory (RAM) retention, to greatly extend battery life in portable applications. They are available with up to 256 KB of error correction code (ECC) flash and 32 KB of RAM, providing ample space for application code and communication stacks.

For Free Info Visit http://info.hotims.com/65855-176

AC Facility Filter

Zero Surge, Frenchtown, NJ, has released a new AC facility filter. The FF2-5W-120-DIN facility filter is fully enclosed in a heavy-duty, magnetic shielded stainless-steel cabinet (IP 50). The 5-A, 120-V single-phase AC facility filter features a four-directional DIN adapter on the back that is spring loaded and easily glides and locks onto a 32–35 mm rail. It contains series mode wide voltage range technology that operates over a range of 85–175 V. The filter is certified to withstand a minimum of 10 years worst-case surge exposure without degradation or failure-filter technology. It also removes EMI/RFI noise disturbances from the power line.

For Free Info Visit http://info.hotims.com/65855-177

Dilators

Qosina, Ronkonkoma, NY, offers a selection of dilators available with and without tear-away introducer sheaths in various lengths, sizes, materials, and colors. The tear-away introducer sheaths with dilators offer a zero clearance dilator-to-sheath transition and are equipped with a unique locking mechanism on the hub. The sheaths are constructed of Teflon® for a smoother tear-away, or prescored polyethylene, which ensures consistent peel-away performance. Tear-away introducer sheaths and dilators with griplock hubs also have a zero clearance, a locking mechanism on the hub, and an ergonomically designed handle for easy removal. Valved tear-away introducer sheaths with dilators include tabs for more comfortable handling after device insertion, and the valve maintains a tight seal to help prevent air or fluid leakage.

For Free Info Visit http://info.hotims.com/65855-178

Single-Board Computer

Axiomtek, City of Industry, CA, has released a low-power Pico-ITX SBC. The PICO312, built with the Intel® Pentium® processor N4200 or Celeron® processor N3350, is designed to address the needs of fanless operation under temperatures from –20° to +70 °C. The SBC supports Intel® Gen9 graphics engine for high-definition with dual display configurations through one LVDS and a choice of VGA or HDMI. It features a full-sized PCI Express Mini Card slot in support of mSATA and a pair of expansion connectors with additional signals, including one PCIe x1 lane, one LPC, one DDI, four USB 3.0 ports, one SMBus, and one HD audio. The embedded SBC is suitable for video-intensive applications.

For Free Info Visit http://info.hotims.com/65855-180

Laminar Flow Cabinets

Air Science, Fort Myers, FL, has released a series of high-efficiency laminar flow cabinets designed to protect equipment and other contents of the work zone from particulates, for applications sensitive to such contamination. The Purair horizontal cabinets are available in 2, 3, 4, 5, 6, and 8 ft widths in standard and extra-tall heights for general applications. The hoods are shipped fully assembled. The rear wall of vertical flow cabinets is perforated to reduce work surface turbulence by removing some of the airflow to the rear. Horizontal flow cabinets are designed with a lip on the rear of the work surface to protect the ULPA filter from spills. The high-capacity air-handling system delivers flow velocity of 0.35–0.45 m/s or 70–90 fpm.

For Free Info Visit http://info.hotims.com/65855-179

Miniature Servo Motor Drive

Granite Devices, Tampere, Finland, has released a new industrial servo motor drive. A The 700-W IONI provides snap-on installation and built-in SIL2 safety functions in a 70 × 37 × 7 mm form factor. An improved high dynamic range torque control allows the motor drive to connect a range of motor variants to a single drive type. Through trajectory buffering and distributed clock synchronization, it can perform multi-axis synchronous motion control out of a non-real-time host, such as Windows PC with a USB or Ethernet connection. This has been achieved by the means of hardware side. The drive connects directly to the fully open C/C++/C# programmable SimpleMotion bus as well as traditional digital pulse train and analog controllers.

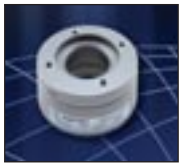
For Free Info Visit http://info.hotims.com/65855-181

Wireless Gages

Mahr Federal, Providence, RI, has expanded its line of wireless gaging products to include a range of depth gaging products. The Digital Depth Gage MarCal 30 EWR, MarCal Specialty Caliper 16 EWR, and Universal Caliper 16 EWR all provide wireless data transmission of depth probe measurements. The Digital Depth Gage Series, MarCal 16 EWR, includes several gages designed for a variety of depth gaging tasks, including measuring groove widths and distance between grooves. All of its depth gage and caliper products offer IP67 resistance to dust, coolants, and lubricants, and are easy to use with a high-contrast digital display, locking screw, zero reset function, and immediate measurement readout. The 16 EWR Digital Caliper line offers precise depth measurement via an integrated depth rod with measuring ranges of 0–6 or 8 in. (0–150 or 200 mm) and resolution to 0.0005 in. (0.01 mm).

For Free Info Visit http://info.hotims.com/65855-182

Spring-Engaged Tooth Brake



SEPAC, Elmira, NY, has designed an electromagnetic spring-engaged tooth (SETB) brake to deliver reliable, consistent operation within medical applications. The power-off brake offers large bore sizes, low backlash, and a high torque-to-size ratio. Backlash within the brake is less than 0.5°. Suitable for medical applications such as robotics, scanning equipment, and treatment tables, the brake features a high number of index positions, positive engagement, and a reliable coil. Custom voltages are available. The SETB is generally half the size of a friction-style brake with similar torque ratings.

For Free Info Visit http://info.hotims.com/65855-183

Strain Gages

Micro-Measurements, a Vishay Precision Group, Malvern, PA, has integrated its proprietary Advanced Sensors Technology into strain gage products. According to the company, Advanced Sensors Technology applies tangible specification and manufacturing process improvements. Further design improvements over traditional strain gage types include smaller and tighter grid-resistance tolerances, improved gage-to-gage repeatability, and enhanced measurement stability. The portfolio includes linear, shear, and circular gages, arranged as individual, half-bridge, and full-bridge configurations, in ranges from 350 Ω to 20 kΩ, with added flexibility in mounting options. The technology improves grid-to-grid tolerances and matching over traditional strain gage manufacturing techniques, enabling better sensor performance.

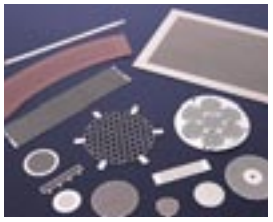
For Free Info Visit http://info.hotims.com/65855-187

Transducer

NK Technologies, San Jose, CA, has introduced a high-performance true RMS transducer for sensing voltage in single, three-phase, or DC installations. Housed in a 35-mm wide DIN rail mounting enclosure, the VTU-DIN measures from 0-15 to 0-600 V with an industry standard output proportional to connected voltage in AC circuits with sinusoidal or nonsinusoidal (variable frequency) applications or DC circuits. Standard outputs make the VTU-DIN reliable and easy to use with existing controllers, data loggers, and SCADA equipment. It effectively detects a wide range of conditions that may cause damage to the motor and/or soft starter components.

For Free Info Visit http://info.hotims.com/65855-189

Photo-Etched Screens and Filters



Tech-Etch, Plymouth, MA, photo etches custom screens, filters, and filter supports for medical devices and other uses. Photo etching enables designers to specify a straight hole or a tapered hole, which facilitates liquid filtration and back flow cleaning. Hole sizes range from 0.003 in. up. Unlike stamping, photo etching yields a burr-free product, resulting in cleaner, more efficient screens with greater material integrity. Photo-etched screens feature a tighter tolerance on hole sizes and greater dimensional stability than woven wire mesh, making them ideal in applications requiring frequent cleaning or in devices where there is mechanical contact. Unlike woven wire mesh screens, the fixed photo-etched openings do not change through use. These tight tolerance screens are primarily produced from stainless steel, but other materials, including polyimide, are available.

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Cloud CAM

MecSoft, Irvine, CA, has launched a beta program for its cloud-hosted, fully integrated CAM add-on application for Onshape's 3D CAD system. VisualCAMc is a production-level CAM app that is fully operated in the cloud. It requires no downloads or installs to local hardware. The company's computer-aided manufacturing (CAM) software is designed for custom manufacturing, rapid tooling, and mold making.

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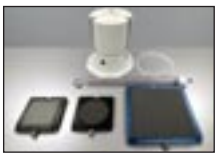

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Bio-Chem Fluidics, Inc.	1	www.biochemfluidics.com
Brentwood Medical	7	www.brentwoodindustries.com/medical
Clippard Instrument Laboratory	4	www.clippard.com
COMSOL, Inc.	5, 60	comsol.com
CPC - Colder Products Company	25	cpcworldwide.com/medical
Crystal IS	29	cisuvc.com/mdb2
Fluid Metering, Inc.	53	www.fmipump.com
Fluortek	9	Fluortek.com
Heatron, Inc.	46	www.Heatron.com
Hunter Products Inc.	59	www.hunterproducts.com
Indium Corporation of America	15, 53	www.indium.com/america
Interpower Corporation	33, 44	www.interpower.com
Master Bond Inc.	60	https://www.masterbond.com/tds/ep45htmed
mdi Consultants, Inc.	59	www.mdiconsultants.com
Medbio, Inc.	60	www.medbioinc.com
Medical Development Group	26	www.mdgboston.org
Medical Extrusion Technologies Inc.	57	www.MedicalExtrusion.com
MicroCare Corporation	Cover III	MicroCareMedical.com
MicroLumen Inc.	38-39	MicroLumen.com
Microspec Corporation	COV IA-COV IB	www.microspeccorporation.com
New England Wire Technologies	17, 45	www.newenglandwire.com
NewAge® Industries Inc.	60	http://www.newageindustries.com/sample-mdb9
NORDSON Medical	35	NordsonMEDICAL.com
Okay Industries	23	okayind.com
PhotoMachining, Inc.	60	www.photomachining.com
Renishaw Inc.	43	www.renishaw.com/vionic
Smalley	6	smalley.com/medical
Sterigenics International LLC	51	www.sterigenics.com
Steute Meditech, Inc.	COV IV	www.steutemeditech.com
Tech-Etch, Inc.	13	www.tech-etch.com
Teleflex Medical OEM	2	www.teleflexmedicaloem.com
The Lee Company	27	www.theleeco.com
TRUMPF Inc.	3, 60	www.us.trumpf.com
Unimed S.A.	31	www.unimed.ch
Watson-Marlow Fluid Technology Group	19	wmftg.com
Zeus, Inc.	11	www.zeusinc.com

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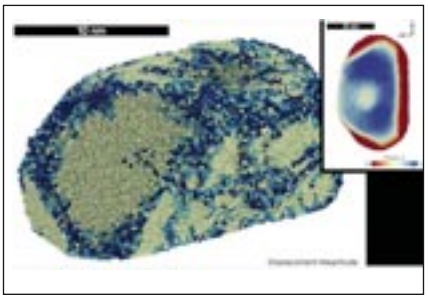
Shape Memory Gold Could Lead to Damage-Tolerant Devices

Technion-Israel Institute of Technology,
Haifa, Israel
http://www.technion.ac.il

Researchers from the Technion-Israel Institute of Technology and Germany have demonstrated for the first time the phenomena of shape memory and self-healing in gold microparticles. Achieved through defects-mediated diffusion in the particle, the discovery could one day lead to the development of micro- and nanorobots capable of self-repair, mechanically stable and damage-tolerant components and devices, and targeted drug delivery.

The study, published in the journal *Advanced Science,* was conducted by doctoral student Oleg Kovalenko and Dr. Leonid Klinger and led by Prof. Eugen Rabkin of the Technion Department of Materials Science and Engineering, together with Dr. Christian Brandl of Karlsruhe Institute of Technology, Germany (KIT).

The transformation of the austenite phase to the martensite can be activated by applying mechanical load to the material, or by cooling it down. The low-symmetry structure of the martensite allows the material to absorb considerable plastic strain by reorienting the distorted crystals of martensite according to the direction of the stress applied to it. Even after plastic deformation, the martensite crystals remember their parent austenite phase and are capable of restoring it in its original configuration. This happens if the material is heated up, causing the reverse martensite-austenite phase transformation and transforming the thermal energy into mechanical energy that restores the material to its original shape.



This is the first time the phenomenon of shape memory has been demonstrated in submicrometer particles of gold. (Credit: Technion-Israel Institute of Technology)

Prof. Rabkin's research group (from left): Ehud Almog, Nimrod Gazit, Oleg Kovalenko, Prof. Eugen Rabkin, and Dr. Leonid Klinger. (Credit: Technion-Israel Institute of Technology)

Until now, this shape memory effect has only been observed in very few metal alloys such as nitinol (Ni-Ti). These alloys are characterized by polymorphism — multiplicity of possible stable crystalline phases. This is the first time the phenomenon of shape memory has been demonstrated in submicrometer particles of gold. The researchers indented the gold particles with a sharp diamond tip controlled by an atomic force microscope (AFM). Annealing of the indented particles at a temperature of 600 °C (about 65 percent of the absolute melting temperature of gold) resulted in full healing of the damage and recovery of the particles' original shape prior to deformation.

According to Rabkin, the discovery of the shape memory effect in these particles is surprising for two reasons: "First, the particles' original shape was not perfect in terms of energy and thermodynamic equilibrium. Second, gold in its solid state is not characterized by polymorphism."

To understand the process in depth, the researchers investigated the atomic motion during indentation and heating, using atomistic molecular dynamic computer simulations. They demonstrated that the plastic deformation during the indentation process is mediated by nucleation and glide of dislocation half-loops (the dislocations are linear, one-dimensional defects in the crystal through which it undergoes plastic deformation). The loops that egress at the free surfaces form terraces and ledges on the flat facets of the particle, and these serve as guide rails, directing the diffusion of gold atoms back to the indented site during high-temperature anneal. Thus, the particle recovers its original shape.

Irreversible Process

Both plastic deformation and capillary-driven diffusion are classical examples of thermodynamically irreversible processes. It is remarkable that a combination of two irreversible processes can lead to damage recovery and reversible restoration of a particle shape.

Rabkin says that the self-healing and shape memory effect in metallic nano- and microparticles could be utilized for the design of mechanically stable and damage-tolerant components and devices at the submicrometer length scale.

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