Medical Wearables Solution Guide

A Quick & Easy Guide to Developing Wearable Medical Devices Utilizing Innovative Engineered Material and Thermal Solutions

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Overview

Boyd Corporation has been developing Medical solutions for decades for applications ranging from multi-layer advanced wound care to cooling for MRIs and Imaging Equipment. Medical Wearables is a fast growing market segment that requires Boyd's unique expertise in developing smaller, lighter, higher performing solutions for next generation applications. In this article, Boyd leverages this experience to develop a quick Guide to Engineered Materials and Thermal Solutions for optimized Medical Wearables. This guide covers technologies necessary to protect, seal, and cool these small, but vital devices while improving reliability, connectivity, accuracy, and user safety. The article also highlights how to best utilize these technologies to reduce weight and landed costs, as well as streamline the supply chain for the full spectrum of Medical Devices.

INTRODUCTION

Medical Wearable

There is a current global trend across most major industries where next generation devices are featuring faster processing, improved functionality, and higher performance than ever before. The Medical Device industry is no exception, especially for the disruptive, fast growing Medical Wearables segment where new and next generation devices require greater accuracy, connectivity, functionality, reliability, and ease of use. This requires improved, innovative technologies that meet incredibly strict design specifications for wearability such as size, weight, touch temperature and geometry.

Medical Wearables have expanded well beyond simple, traditional monitors and hearing aids to sophisticated patient monitoring with connected software, biosensors and smart trackers embedded in everything from bracelets and watches to clothing, glasses, and smart aids. These devices require integrated systems to meet customer expectations including guaranteed reliability and accuracy, comfort and ease of use, slim aesthetics, and real time results.

Wearable Medical Device Teardown

Medical Wearable devices can take many forms. Specific device design form will follow function needs, chiefly based on

electrical performance requirements of the sensors and wearability factors such as wear time, ease of application or removal, and skin sensitivity. These factors, along with unit cost, ease of manufacturing, regulatory and compliance concerns, as well as aesthetics will drive design and material selection.

This guide covers Engineered Material and Thermal Solutions that help make these new technologies possible for differentiated, wearable medical devices that perform better, are lighter weight, and more reliable.

WHY MATERIALS & THERMAL SOLUTIONS ARE REQUIRED

Wearable medical devices are subject to a wide range of environments and conditions, wear and tear from patient use, and potential interference from other electronics or motion. Engineered Materials combat these hazards and keep the device working at peak performance, playing a vital role in device performance and patient safety through accurate reporting. Engineered Material solutions include environmental sealing, materials to improve performance and comfort, protection from EMI and NVH, adhering to patient skin, and additional integrations to enable desired functionality and lifetime while saving on weight and space.

In addition to Engineered Materials, electronics with increased power and processing speeds or prolonged consumer usage in various environments and temperature extremes depend upon Thermal Solutions to spread, block, or shield heat, eliminate hot spots, or conduct waste heat away from sensitive electronics. This includes graphite and material conduction heat spreading, small board level heat sinks, and two phase cooling technology like vapor chambers and ultra-thin heat pipes.

By integrating multiple engineered materials and thermal technologies into efficient multi-function solutions, Boyd develops thinner, lighter, better performing products with less material waste, lower landed cost, and a streamlined supply chain.

ENGINEERED MATERIAL CONSIDERATIONS FOR MEDICAL WEARABLES

Gaskets & Sealing Solutions

Gaskets are flexible, resilient, and most often utilized to ruggedize devices and improve durability. They absorb shock and vibration to prevent electronic device damage, screen cracking and fluid and dust ingress. Many Medical Wearable devices incorporate an inner cushion gasket layer that protects delicate internal electrical assemblies and connections. Inner cushions can be a simple two-dimensional shape die-cut from a soft foam layer, or if three-dimensional features like pockets or cavities are needed, a thermoformed or molded foam component could be used.

Complex Gasket

Inner cushions can incorporate through-holes to allow light from board-mounted LEDs to illuminate the power button and logo through cover layers.

Combine gaskets with thermal spreading, electrical insulation, and static dissipative seals for safer, improved application performance. By integrating multiple engineered materials and thermal technologies into one efficient gasket solution, Boyd develops a streamlined, multi-functional component for greater assembly efficiency and simplified sourcing complexity.

Inner Cushion Layer of a Wearable Device Stack Up

Extremely high tolerances in unique, precise geometries are required due to the size and intricacy of the devices as well as Medical Standards. Innovative and streamlined converting methods and clean rooms ensure that gaskets, seals, and gasket assemblies meet and exceed these strict requirements.

Environmental Sealing & Protection

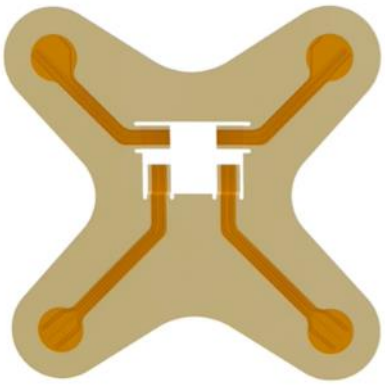
As these devices endure consistent use in varying environments, protective materials are necessary to ensure long life, durability, and reliability. Particle and Fluid Ingress is one of the most significant hazards from outdoor exposure and long term use as any dust or fluid can cause degradation, loss of reliability, or even device failure and this could cause harm to the user's wellbeing. Protective materials such as waterproofing, sealing input/output and charger ports, covers, meshes and surface protection are necessary to keep wearable devices sealed tight. Medical Wearable devices often incorporate a protective Cover Layer that can be selected based on breathability for long wear time or waterproofing to protect internal electrical components. For aesthetic performance, this layer could be a printable film or molded component to have distinctive shape or features.

Cover Layer developed based on application use.

Other hazards that can cause damage or impact performance are Shock, Noise and Vibration. These conditions can fatigue mechanical and bonded joints, strain electrical components to failure, or cause damage under transient impacts, generally reducing product reliability. These factors can also negatively impact the end customer experience through excessive vibratory sensation or excessive or unwanted noise. Integrating components that effectively absorb, damp or isolate energy transmitted through the product enables greater durability and smoother, more reliable performance to end users.

Electrical Conductivity, Insulation & Shielding

Medical Wearable devices often include trace layer electrical circuits to connect hydrogel electrodes contacting the skin to the PCB to conduct and capture patient signals and data. There are different ways to achieve this, such as a flexible copper trace incorporated into a flexible circuit, but one common method is to print the electrical trace to a support film using conductive inks. Conductive hydrogels are used as the electrically conducting medium to allow the biosensor or wearable device to work as intended. The specific hydrogel is chosen based on the nature of the application (sensing or stimulating) and other wearability factors.



Copper Trace Layer

To ensure proper electrical performance of the medical wearable device, it is also important to protect against the exterior environment; both to avoid electrical short circuit and to shield against electromagnetic noise that can interfere or damage sensitive electrical components. This generally involves the use of electrical insulation, as well as EMI/RFI shielding, absorption, and grounding techniques.

Electrical Insulation Example

Electrical insulation functions as an electrical barrier or shield and is required to prevent shorts, arcing or even ignition which can endanger the user, damage products, and impact product reliability. Electrical insulators can be made from high resistivity materials and converted into highly customized geometries and constructions to suit specific application needs.

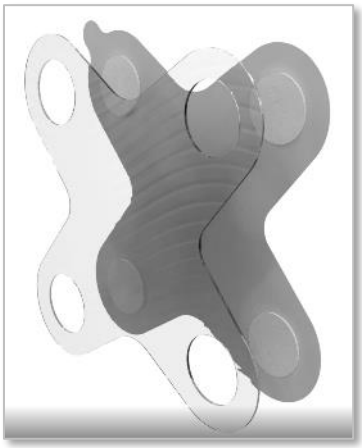
Electromagnetic interference (EMI) insulation and shielding is an equally crucial function of medical wearable device design. Caused by the proliferation of electromagnetic waves that come from a wide variety of both natural and artificial sources, including other electronic devices, EMI can cause issues with erratic performance and decreased accuracy. Ensure long term, consistent performance by absorbing or shielding EMI appropriately.

Medical Grade Skin-Contact Bonding & Adhesives

Adhesives are a cost-efficient way to introduce mechanical attachment and strength within the device as well as additional benefits such as vibration management in compressible foam tapes. Medical Grade Skin Contact Adhesives are utilized to attach or place the wearable devices and biosensors to the patient. The specific skin contact material is selected based on the needs of the application and could be made from a variety of skin-friendly materials. Application needs may include intended wear time, ease of removal and proximity to wound sites.

Skin-contact adhesives often incorporate a foam backing layer for additional comfort and flexibility. These are also often utilized with devices that require electrodes.

Delivery liners accompany skin contact adhesives to protect medical wearable adhesives from contaminants before application. Assembled medical wearable patches and biosensors are often presented on a medical grade delivery liner that can be designed to aid in healthcare provider application processes. An oversized liner or one with a pull tab can be used for easy handling when applying to the skin. A two-piece liner can be used, either split or with folded tabs like a typical bandage.



Delivery Liner over Skin Contact Material with Conductive Hydrogels

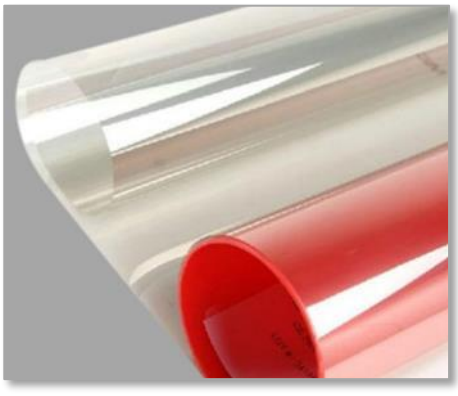
Acoustics

Next generation medical wearables that amplify sounds and provide notifications are offering improved tonality, control, and volume for better audibility and user experience. This is an important feature as notifications are often important to patients' health or wellbeing. Acoustic meshes are specialized micro-woven fabrics that offer waterproofing and dust protection while providing acoustic transparency in the audible frequency range.

Display

Medical Wearable Displays, when utilized, must be legible for users of all ages, accurate, and easy to use. Medical devices are susceptible to mechanical shock from being dropped, general wear and tear, and dust or water exposure; so Medical Wearable Displays must be durable and well-sealed.

Popular Display Solutions for Medical Wearables:



Light Enhancement Film

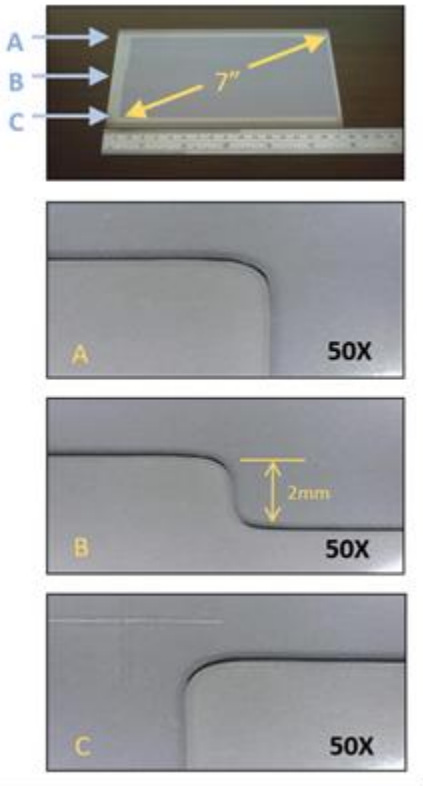
- **Anti-Glare & Security Films**
  Reduce display glare and reflection, improve screen legibility in diverse use environments with varying levels and sources of both natural and artificial light.

- **Brightness Enhancement Films**
  Ideal for backlights and viewing in dark environments. Integrate into a display backlight architecture to increase brightness, decrease weight, mitigate heat and improve power efficiency for Medical Wearable Displays.

- **Optically Clear Adhesives and Bezel Bonding**

  Improve mechanical strength with ultra-transparent adhesives that enable optically clear assemblies to transmit as much light as possible through optimal refraction and refractive index matching. Adhesives have high dimensional stability, low shrinkage, and resist whitening over time. Integrating layers with the right OCAs enable rugged, long lasting bonds in complex optically clear laminations.

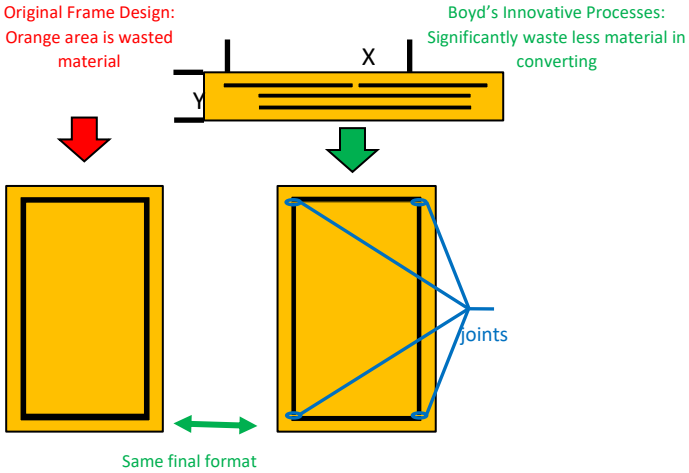
  OCAs also offer ingress protection and reduce the width required for bezels to maximize screen space, better waterproofing the display, protecting it against contaminants, and creating an overall better user experience. OCAs are often utilized with bezel bonding techniques and integrated medical wearable display gaskets for high performance, ultra-tight tolerance, streamlined touch display mounts.

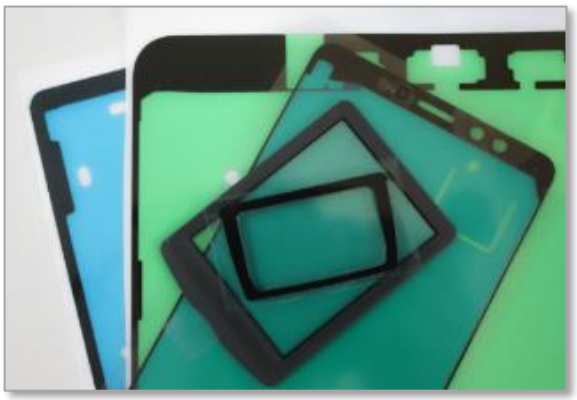


OCAs

- **Boyd Segmented Frames Processes**

  Segmented Frame Technology is a high precision, reel-to-reel manufacturing process that utilizes Boyd's proprietary high-speed production lines to eliminate waste, maximize material utilization, and optimize component cost. Material waste is eliminated by spacing and orienting release liners, bonding tapes, optical films, and optically clear adhesives in such a way that material is cut to maximize yield while components are assembled with zero-gap tolerances, assuring excellent quality and efficiency to drive down landed costs.




Segmented Frames for Multi-layer Solutions

THERMAL CONSIDERATIONS FOR MEDICAL WEARABLES

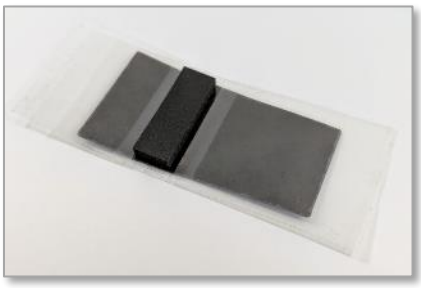
The rise in processing power, smart functionality, and connectivity of Medical Wearables generates more heat. This heat can cause high touch temperatures, device overheating and failure, and degradation in accuracy and performance.

Implement Heat Spreading to move heat quickly and efficiently away from sensitive components, dissipate heat more efficiently and prevent reaching critical temperatures. Heat Spreading methods are easily integrated with engineered materials for multi-functional display systems with streamlined supply chains and lower landed costs.

Heat Shields

Popular Thermal Solutions for Medical Wearables:

- **Graphite Pads & Films**
  For improved in-plane thermal conductivity with low mass and high heat transfer. They offer high performance and uniform heat spreading in ultra-thin, easy to integrate geometries.



Integrated Graphite Solution

- **Heat Pipes & Vapor Chambers**
  Superior heat spreading and long-term reliability in ultra-thin form factors. Copper and stainless steel vapor chambers at 0.4mm thickness offer 4X the thermal conductivity of graphite spreaders. For ultra-high performance applications, titanium vapor chambers at 0.4mm thickness offer 12 to 18X the thermal conductivity of graphite spreaders.

- **Flexible Heat Pipe Technology**
  Enable greater design flexibility and improved heat transfer in movable components or components that can be bent.

- **Thermal Interface Materials**
  Improve the interface between a heat source and the thermal management system through conduction cooling and heat spreading. They can also offer mechanical strength, vibration damping, and adhesion and can be used separately or integrated with other technologies.

Small Form Factor Heat Pipe Solution

- **Board Level Cooling**
  Cool PCBs, which handle processing and device control. PCBs can have a single or multiple heat sources and typically generate the most heat within the device.

- **Heat Shields**
  Stop radiant heat from transferring from hot components to sensitive surfaces, devices, and systems. These light, low profile, and flexible solutions are ideal for light weighting in minimal to zero clearance areas. They can also offer:
  - UV Resistance
  - Incombustible or Fire Resistance
  - Tear & Puncture Resistance
  - Flame Blocking
  - Easy Cleanability
  - Vapor & Fluid Blocking
  - Moisture, Corrosion, & Solvent Resistance

For more information on design engineering for Medical Wearables watch the Boyd/ 3M Webinar Collaboration on ENGINEERING360.

INTEGRATIONS & PROCESSES

By utilizing newer, advanced processes and integrated solutions, engineers can increase material utilization and reduce waste cost, simplify supply chain and end device assembly, and maximize reliable functionality for an overall total lower landed cost and enhanced patient experience. Medical Wearable applications require innovative manufacturing processes that enable extremely tight tolerances for precision assemblies and little to no waste of expensive, innovative, performance-enhancing materials. Clean room manufacturing, high quality control, and fast prototyping and design accelerate speed to market for high-volume, globally available production compliant with medical standards and regulations with lower overall cost.

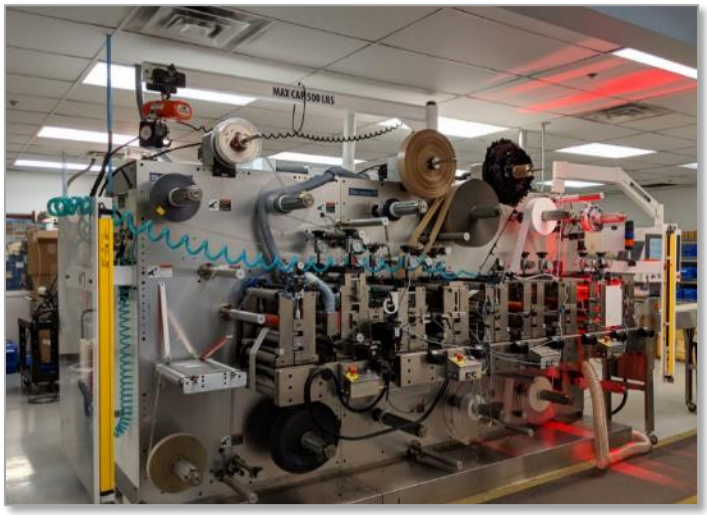
Boyd is an expert at evaluating a complete system design to identify complementary components with the potential to be manufactured and delivered to customers in a streamlined assembly. Boyd has collapsed as many as 12 unique, individual bill of material items into one streamlined component; helping to speed design, manufacturing and delivery cycles, improve quality and tolerance, and reduce device size, weight, supply chain complexity, and logistics costs. Specialized skills and processes like this and Boyd's Segmented Frame "zero gap" tolerance gaskets that reduce material waste help customers improve performance and better manage total cost.

Clean Room Rotary Die Cutting

For decades Boyd has fostered strategic partnerships with the world's leading medical material innovators, global suppliers, and design engineers. These partnerships, along with global manufacturing innovation and facilities, enable Boyd to stay at the forefront of Medical Wearable development and innovation. This has heavily contributed to one of the widest portfolios of Materials, Suppliers (including 3M and Nitto), dedicated processes, and global manufacturing for medical applications.

Multiple Integrated Components – One Pass Manufacturing

Boyd's advanced rotary die cut manufacturing in facilities that operate under ISO 13485 certified quality management systems is an industrial science that has refined a proprietary process to cut and assemble multiple material components that can feature a variety of raw materials and thicknesses with unique component configurations and functionality in one complex stack. Each input component is cut and introduced to the rotary production line using proprietary industrial design techniques and assembled with extremely tight tolerances in one pass through the manufacturing line. Innovation and complexity increase monthly with continuous research and development to advance what is achievable. Customers benefit from increased precision, faster turnaround, shorter lead times, higher performance, thinner solutions, and greater cost efficiency.



Advanced Rotary Die Cutting available globally in clean room environments.

Clean Room Manufacturing & Kitting

Manufacturing and assembling components for high quality medical applications require a clean and controlled environment. Sensitive components exposed to contaminants can cause catastrophic problems. Foreign Object Debris (FOD) increases adhesive and film assembly defects, which can cause lower yield rates. Boyd Corporation has FDA Registered facilities and is compliant with Current Good Manufacturing Practice regulations (CGMP) to ensure that products and components meet the exacting quality requirements and industry standards of our customers. Our clean room environments are regularly certified to internationally recognized standards, ranging from Class 100 to Class 100K to serve a variety of cleanliness needs.

Working Towards Lower Landed Costs & Supply Chain

Boyd has longstanding market leadership in advanced medical grade materials and a competitive advantage in medical design engineering, environmental protection, heat spreading, shielding, and high tolerance converting. Strong relationships with the world's leading medical material innovators and numerous existing vendor codes with leading medical organizations means that Boyd has established design partnerships and logistics to easily integrate into your value chain. Boyd's extensive material supply partnerships assure the earliest and continual access to the best performing, most technically advanced raw materials globally available. Boyd Corporation is often the global Preferred Converting Partner with these raw material innovators with relationships dating 50+ years and manufacturing processes and clean room environments optimized to handle and fabricate sensitive materials.

WHAT'S NEXT?

The market for Medical Wearables is growing and will continue to do so as the global population becomes more health conscious and innovation enables new functionality. As new products and brands enter the market, design and industry requirements will become more specific and marketplace differentiation will be key. Integrated material and thermal solutions are essential to industry growth and differentiation as they enable improved performance, simplified use, long-term reliability, and maximum durability, while being exceptionally light weight and offering high functionality and connectivity.

With decades of innovation expertise, experience, and supplier partnerships, coupled with the unique approach of integrating multiple technologies into a streamlined product, Boyd Corporation will continue to stay at the forefront of innovation and improved manufacturing for Medical Wearable device components with lower landed costs. If you are looking to solve current issues or tackle new challenges for the next generation, start by contacting Boyd Corporation to learn more about engineered materials, thermal solutions, customizations, and improved processes for Medical Wearables.

BOYD CORPORATION

To receive more information, please visit www.boydcorp.com.