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KEY CONSIDERATIONS TO ACHIEVE A **SUPERIOR** MEDICAL CONNECTOR DESIGN

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Our Approach

A connector designer certainly needs to understand the customer requirements for a new medical connector design. However, this is just the start of what gives the direction for a new custom connector. Additional considerations are the Contract Manufacturing Organization's capabilities, the competitors' offerings as well as the field use requirements for the medical device itself. All details combined will inform a complete custom connector design.

Know your customer & their design requirements

The most fundamental input is getting to know your customer and their requirements. When a customer asks for an "off-the-shelf" solution for a medical connector, the design engineer initially does not have details about current functionality gaps the customer would like to address with a new connector design. On the other hand, when you leave an 'off-the-shelf' option aside and the customer is open to a new custom-designed product, the design engineer can then probe for meaningful impact points. This can lead to a more cost-effective design option in the long run compared to an off-the-shelf connector.

Here are some important questions for the engineering team to ask the customer about key aspects that need to be considered. The answers will guide the team towards an effective connector design:

A) What was the previous connector solution?

B) What is the number of signals that need to be transferred across the connector?

C) What are the voltages and noise specifications?

D) What are the material constraints for these requirements?

A key factor for achieving outstanding results is for the connector design team to work in close collaboration with the customer's engineering team.

To identify some lesser-known aspects of a medical connector, engineers can evaluate further opportunities to enhance the connector:

A) Are there any advantages to physical size reduction of the connector?

B) Could adding features to the old solution like a simple alignment or locking feature enhance the connector?

C) Could consolidating multiple devices or cable assemblies into one interconnect platform work?

D) Are there any unneeded or unwanted design features that can be removed from the old connector solution that make the connector more cost-effective?

An advantage of Paragon Medical's Densyty® Interconnect System is the ability to handle high channel counts which makes it capable of consolidating multiple connectors into one. The solution is scalable up or down in channel count as well as customizable for sizes, locking mechanisms, and different contact types, making it a flexible solution for diverse design consolidation needs.

It is worth remembering that a purpose-built connector can reduce overall costs over the production lifespan of a product.

Fully understand your own manufacturing capabilities

Know exactly what you can manufacture and how. When a new project is being discussed in terms of what can be done, it is always nice to present new capabilities to the customer. However, being able to deliver those capabilities in production is every bit as important.

Design for manufacturability is key.

Thoroughly check what materials and services your manufacturing vendors support. Draw on manufacturing experience to simplify the assembly processing. Understand the trained techniques for manufacturing, and only include novel manufacturing approaches that have been thoroughly validated, directed by engineering, and gone through the prototype development process. Error-proof manufacturing techniques offer an assured process during production manufacturing.

Paragon Medical utilizes its state-of-the-art rapid prototyping capabilities. These are ideal for creating custom connector prototypes fast. If this involves a novel material or manufacturing technique, be sure to trial and test it before completing the design with this new feature incorporated.

A good example is the Densyty® connector design with card edge technology. The first connector with card edge contacts designed by Paragon Medical was executed via rapid prototyping prior to the full-scale Densyty® market launch.

Similarly, if the device is designed as a multiple use device, maybe the contact material can be changed from solid gold to a different metal alloy to be more cost effective.

However, we must fully understand this plan based on previous experience, otherwise a design experiment must be completed to prove suitability of use.

Another example where our extensive know-how has benefitted connector design is our expertise with fine wires, ranging from 46 to 50 AWG (American Wire Gage), which has resulted in the ability to reduce the overall connector size.

Understanding your manufacturing capabilities means knowing your facility's experts, the talents of the manufacturing associates, the manufacturing equipment, and the inspection capabilities.

For a typical project, product development might start with building and testing the first assemblies in the local manufacturing facility. Product validation may sail smoothly through the planned protocol for initial approvals. Then a desired transfer of manufacturing to a nearshore or global manufacturing site could hit a roadblock when a challenging skillset does not transfer well but is required for production. It is advisable to consider any required manufacturing talent skillsets during the connector design phase. This is especially critical, if a connector design includes potting and curing, and the manufacturing facility neither has a production team with adequate expertise nor the required environmental or safety standards for production.

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Study your competitors' products

Having an in-depth understanding of your competitors' connector services and product offerings is critical. Knowing the sizes and features of competitors' connectors will inform you about unique design opportunities for the connector application you are currently working on. This also includes materials. Once you know the material range offered by the competition, you can develop and offer a superior solution.

For example, the competition offers a 64-signal connector in a 1" x 2" metal housing that uses two flat head screws to secure the connection. In total, the connector weighs 12 ounces (340.2 grams). To manufacture this, the individual pins must be soldered onto the conductor wire and inserted into the connector. To offer a superior solution, you could design a polymer circular connector with 0.75" diameter that can be inserted and twist-locked in place with a single hand only weighing 10 ounces (283.5 grams).

Paragon Medical new card-edge technology connector Densyty® could be offered with bar soldering for increased manufacturability. If the newly designed connector can be offered with 25% cost savings, then that solution is a win-win for both the customer and the designer.

Check customer budget & final use constraints

Full understanding of the overall cost targets for the design and manufacture of a new medical device connector is essential. When customers communicate the overall medical device manufacturing cost, the connector solution is only a small part of the overall target budget.

Care must be taken to keep the design complexity and associated cost within manufacturing cost expectations, even if development budgets are high early in the project.

For a designer, few things are more frustrating than reaching a design review, being told to go back to the drawing board because the solution is not practical as it is too expensive. Designing a high-end connector solution for a standard or a generic requirement may sink a project after many hours of development have already been spent. So, avoid over-engineering!

Investigate how the customer's medical device will be used before you finish the design and prototyping process. When a new connector design is on the wish list to support a range of improvements for a new product generation, the given design criteria are not the most critical information to work with. Instead, deep dive into how the device will be used on a daily basis. Customer usage of previous versions of the same medical device needs to be well understood as the project progresses. When designers start on a blank canvas, they must insist on having access to the previous device version as well as the new prototype as soon as it is practical.

Knowing how the medical device will be used in the field as well as how the device will be acceptance tested is key to a better connector design. Experimenting with the previous version of the connector also informs the designer of any shortfalls and challenges that could possibly be rectified with a superior design solution.

In addition, it is necessary to determine the reliability requirements, such as failfree signal connectivity through the connector, which is a must.

Questions to ask are:

A) What will the minimum cycle count be?

B) Will the device be a disposable or reusable design?

Building a "critical to performance" and a "critical to quality" checklist will help drive design evaluations.

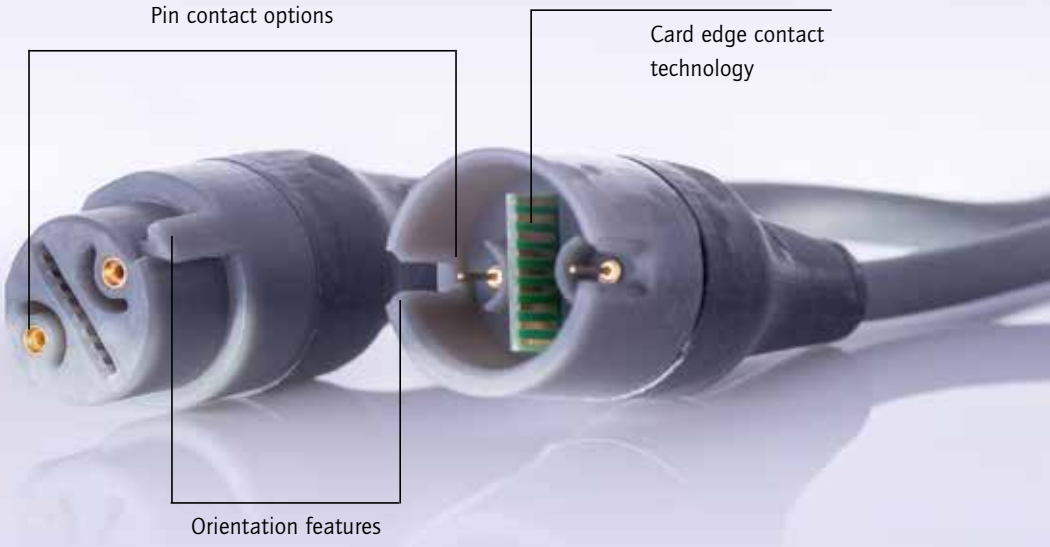
Fully embrace your company's and the customer's vision

Finally, make sure you understand your own company's vision for medical interconnect offerings. It is essential you know your company's technology roadmap for the future. You should determine whether ideas such as modular, expandable or replaceable components in a connector are part of the future or the company's vision. Design for manufacturability will always be a company mantra. Reduced component count is a focus for simplifying manufacturing processes. Ascertain whether there are plans for other innovative ideas.

In parallel, studying your customer's roadmap for the future will help align product design and acceptance during a design review. This can also determine whether there is a long-term benefit for vertical integration of manufacturing processes, currently outsourced with external vendors. These considerations could potentially lead to profitable facility upgrades and improvements.

If a new connector benefitted from incorporating an additional manufacturing technique, for example injection molding, first utilize a vendor for the prototype and pilot runs before installing and validating your own production capabilities.

Check if particular facilities are more suited for this capability-add in terms of space, skillset and set up. If labor fatigue is a factor with a current connector design, consider designing around automation; making the contact components and the housings feedable and manageable by automation.



Paragon Medical

Paragon Medical is a market leader in delivering optimal solutions for the medical device industry. With three leading brands Avicenna, Technical Services for Electronics (TSE), and Laserage, Paragon Medical has served the medical device industry for more than 40 years.

We have designed and developed a wide range of connectors addressing the needs of applications spanning from head to toe in the human anatomy. Examples of devices and applications we have designed connectors for include Imaging, Orthopedic Assist, IBP/NIBP, Pulse Oximetry, Cardiac Output, temperature and pressure monitoring, ECG, EKG, powered surgical tools, programming and recharging antennas, stimulation leads, electrophysiology catheters, pacemaker programming, AEDs, Intravascular Ultrasound, to pacing leads and assemblies.

Technical Services for Electronics (TSE)

Paragon Medical's specialized brand Technical Services for Electronics (TSE) has been designing custom interconnect solutions for 25+ years and is a market leader in custom medical connector design.

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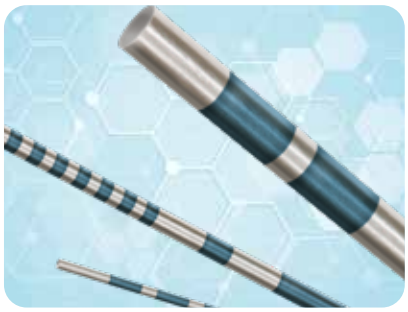
DENSYTY®

The DENSYTY® Interconnect System uses proven card edge technology to maximize contact density, performance and usability. The need for high contact density in a small form factor is increasing. New innovative medical devices that require high performance interconnects are being developed every day. Paragon Medical has developed high-density interconnect solutions that meet customers' needs and provide those customers with adaptability in an ever-changing market. DENSYTY® interconnect systems can be scaled or modified to fit the needs of many applications, and are tested to meet industry standards, providing confidence in the products connection.



ABOUT PARAGON MEDICAL

Paragon Medical is a business unit of AMETEK Inc., a leading global provider of industrial technology solutions serving a diverse set of attractive niche markets.

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