

Title slide

- Creganna Medical, part of TE Connectivity, has the largest and longest established design and development group for Minimally Invasive Medical devices.
- We partner with customers to bring their product concepts to life.
- We are a team of engineers for engineers.
- In 2018, a new design centre was established at our Plymouth facility in Minnesota, adding to our global network of design centres.

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- Minnesota is a world recognized and vibrant hub for medical device development within the US. Our new US design centre was established to meet the growing demand of customers throughout the US and within the MN region. Our engineers are now closer to your local R&D programs.
- The MN design centre is growing and currently consists of a team of 16 dedicated engineers. Our plans are to rapidly grow this headcount and our capability over the coming years.
- The centre operates as a centre of excellence – offering specialist design support for specific product applications.
 - For structural heart, we are a well-established partner to leading market players – we currently manufacture content for 2 of every 3 TAVRs performed globally.
 - For electrophysiology and advanced energy, our vision is to replicate this COE model with the intention to build a specialist team that can integrate advanced disparate technologies into a single medical device.
- Our design team are co-located at a large integrated facility with a proven track record in volume manufacturing. Our design team work hand-in-hand with our internal manufacturing partners both globally and locally. In fact, over ½ million devices shipping from our Plymouth site today had input from our local design and development team.
- Throughout the US, our combined skill base in contract product design and development totals to over 200 years specialist experience.

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- Our US model replicates a global contract design and development model that was first brought to market over 13 years ago.
- Today we comprise a number of centers across the globe – 2 in the US, 1 in Europe, supported by a TE center in Japan specialising in high density connector and PCBA design.
- All centers work hand-in-hand to provide a seamless service to customers, depending on specific requirements and projects.
- Our design and development model is proven. Globally:
 - We have delivered over 5,000 product concepts including over 50 FIH devices
 - We offer a combined bench totalling more than 950 year's experience with more than 150 engineers globally
 - We estimate that we have delivered more than \$1/4 BN in discrete product development programs, and are partners to leading brands in the industry

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Over the years we have learned what makes for a successful design partnership. This is how we know we can deliver success for you.

- It starts with people. We focus on offering a blend of requisite skills from mechanical, CAD and biomedical engineers to specialist regulatory professionals. Structured project management processes ensure optimum and predictable outcomes from these teams.
- Secondly, our work is executed within a professional design control process to verify and validate that design inputs meet design outputs and user needs match the final device. Over the years, we have optimized this process to achieve high performing designs that translate to efficiently manufactured products.
- Finally, we are more than a design partner. We are a manufacturing partner with proven wrap-around quality systems. We design for manufacture, understanding that investing \$1 in R&D provides 10 – 100 time more payback than investing \$1 in operational improvements. We design with the end in mind – not just a great product, but an efficiently manufactured product.
- Over the last 5 years, for products designed, approved and managed by Creganna we have experienced zero field complaints and zero recalls. These products are approved and regulated in over 35 countries worldwide.

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Our teams and leaders. Many are former customers. All are experienced innovators. All have delivered repeated success.

Point out key members for each facility – talk to backgrounds and former industry experience.

Key points:

- Engineers for engineers
- Product & industry experience
- Large scale product development program experience – joined from large customer companies
- Innovators

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- We are master product development specialists in our proven fields. We have honed the bulk of our collective experiences for access and delivery of MI therapies – delivery catheter, access systems, and vascular catheters. We are best known for these types of devices.
- However, we are now broadening that capability, particularly as part of TE Connectivity. Increasingly, we are doing more design work for endoscopic devices, advanced energy and surgical systems.
- Our customers are leading us on this journey. They are evolving. They ask that we evolve with them as they broaden reach, building and acquiring new product portfolios. We are responding in our design competencies.
- Our design supports and proven design process are core to your successful project.

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This image provides some insights into the types of products that we have successfully designed and developed on behalf of our customers.

Product – row one – working left to right:

- Transseptal crossing sheath for EP applications. 8.5F. Legal manufacturer on behalf of customer.
- Access sheath and dilator – TAVI. Legal manufacturer.
- Endoscopic Ultrasound needle – advanced visualization features and interchangeable deployment handle
- NOTES access device – for access to abdominal cavity via scope
- Intravascular biopsy device – vulnerable plaque detection, intravascular sample collection

Row two – working left to right

- Mitral guidewire – high strength & pre shaped guidewires, establish transseptal access, cross mitral valve and seat into ventricle to establish a stable access route for mitral valve repair/replacement therapies
- Structural heart balloon – annulus sizing and transseptal treatments
- Hi load steerable – articulating metal/braid delivery shaft, hi load for mitral delivery
- Access balloon – GI access balloon with depth markers
- Neurovascular microcatheters – access and delivery in small vasculature

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Our design center in Plymouth today is working on an extensive portfolio of devices within its core CoE focus fields.

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Structural Heart montage – key messages:

- Complete portfolio of solutions from access to delivery and closure
- Specialists – large bore, articulating shafts, high load devices, transseptal crossing devices
- Trusted partner to leading companies in the field across the full spectrum of valve replacement – access, sizing & delivery, valve repair, transeptal crossing, LAA delivery, femoral access & closure.

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Electrophysiology & Advanced Energy – key messages:

- Growth area – adding expertise
- Partner of choice for integration of advanced technologies into catheter/device for additional functionality – power, data, signal
- Solutions from proximal to distal – integrate our customers technologies