

The Characteristics of Innovative, Medical Devices

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It is not easy to design an innovative and successful product in any field of engineering. Medical device design is further complicated by strict regulations. Current engineering design methods provide help in designing a good product, but the designer lacks tools that help him or her create an innovative, commercially successful product. In this study, we analyzed 51 innovative, award-winning medical devices against their competition to identify what made those products stand out from the competition. The

method was focused on finding engineering-level characteristics that made the products successful and whether the characteristics of success in the medical device industry are similar to those of other industries. We used a set of innovation categories that have been shown to apply to mechanical engineering products. The results show that the most innovative medical devices were innovative in at least three categories. Overall, a majority (greater than 60%) of the award-winning medical devices exhibited enhanced user interactions, with a similar percentage displaying enhanced environmental interactions and architectural changes, compared with only 20% of devices offering an additional function. We conclude that designers of innovative medical devices need better design methods that extend beyond the functionality of the products.

Polymer Rigidity Control for Endoscopic Shaft Guide "PlastoLock": A Feasibility Study

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Flexible endoscopes are used for diagnostic and therapeutic interventions in the human body for their ability to be advanced through tortuous trajectories. However, this very same property causes difficulties as well. For example, during surgery a rigid shaft would be more beneficial since it provides more stability and allows for better surgical accuracy. In order to keep the flexibility and obtain rigidity when needed, a shaft guide with controllable rigidity could be used. In this article we introduce the PlastoLock concept, which uses thermoplastics that are reversibly switched

from rigid to compliant by changing their temperature from 5 °C to 43 °C. These materials are used to make a shaft that can be rendered flexible to follow the flexible endoscope and rigid to guide it. To find polymers that are suitable for the PlastoLock concept an extensive database and internet search was performed. The results suggest that many suitable materials are available or can be custom synthesized to meet the requirements. The thermoplastic polymer Purasorb[®] PLC 7015 was obtained and a dynamic mechanical analysis showed that it is suitable for the PlastoLock concept. A simple production test indicated that this material is suitable for prototyping by molding. Overall, the results in this article show that the PlastoLock concept can offer simple, scalable solutions for medical situations that desire stiffness at one instance and flexibility at another.