

## Design and Testing of a Three Fingered Flexural Laparoscopic Grasper

Harry O'Hanley, Matt Rosario, Yuanyu Chen, Audrey Maertens, and John Walton  
*Massachusetts Institute of Technology*

Jennifer Rosen  
*Boston Medical Center*

Laparoscopic surgery requires complex manipulation and movement of internal organs. Current laparoscopic devices succeed in offering surgeons remote access to internal organs but lack

the grasping degrees of freedom achieved by the human hand. Specifically, needle nose end effectors engage organs via pinching and can cause tissue perforation. To enhance surgical capacity, a three fingered laparoscopic device was designed, fabricated, and tested. Flexures are used to provide three points of articulation in each finger, while minimizing part count. Flexure joints are modeled as pseudorigid bodies and designed for manufacture with medical grade plastics. Articulation is achieved by tendonlike control cables. To integrate with current laparoscopic procedures, the device fits through a 12 mm trocar port. Furthermore, a handle was designed for this device to offer better control. Testing the device with organlike objects revealed an increased ability to grasp, move, and otherwise engage items.

## An Ontology Model for the Medical Device Product Development Process and Environment

Lourdes A. Medina and Gül E. Okudan Kremer  
*Pennsylvania State University*

Richard A. Wysk  
*North Carolina State University*

The development of medical devices is a complex problem from initial conception to final implementation and monitoring. The development process is critical, and attesting to this, the completeness of the process and the experience of the developers are identified as important factors for commercializing medical devices. Meanwhile, regulations, standards, and patents should also be considered in the development process. The Food and Drug

Administration (FDA) has been reported as the primary factor affecting companies' ability to develop new medical technology. The use of standards is voluntary; however, multiple benefits are attributed to their use. Patents are also necessary to protect the inventions employed in novel medical devices from being used/further developed by competitors. This paper addresses the complex nature of the medical device development process and its environment through development of an ontology model. The model describes the components of medical device development and their relationships, including the testing and approval environment that impacts this process. The final ontology model is the result from a document analysis (DA), completed in multiple iterations, and the verifications of source credibility, completeness, terminology, and redundancy. The comprehensiveness of the presented model should aid inexperienced designers understand and implement the development process more effectively.