

## A Problem Well Defined is Nearly Solved

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Solving problems is simple. Understanding which problems should be solved is immensely challenging. Medical device design projects frequently begin with a search for solutions rather than a clear appraisal of needs. Understanding clinical needs, user

needs, unmet needs and the differences between them is crucial. Through a process of filtering research into an array of needs the author prescribes a method to aid the designer in defining the overarching problem. This array can create a clear path to problem solutions while utilizing a methodology that fits in the context of a regulated design process. For medical device startups, design consulting firms, and corporate manufacturers, a clear understanding of the problem can mark the difference between a misguided solution and a solution that benefits physicians and patients.

## Preliminary Development and Engineering Evaluation of a Novel Cricothyrotomy Device

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Cricothyrotomy is one of the procedures used to ventilate upper airway blockage patients. The objectives of this paper are to examine the most regularly used cricothyrotomy devices, to suggest critical design specifications for improving the devices, and to

introduce a new cricothyrotomy device as well as perform an engineering evaluation of the devices' critical components. A review of the literature, manufacturer products and patents was performed to determine current cricothyrotomy devices in use. Four principal cricothyrotomy devices are currently in clinical use. From our review the Cook<sup>®</sup>, Melker device is the preferred method of clinicians but has acknowledged problems. Our group has developed a novel cricothyrotomy device, which addresses all design specifications and was shown to be very promising through engineering and in situ evaluations.