Gastrostomy tubes, or G-tubes, deliver food directly into a patient’s stomach when they cannot be fed orally. In the United States, there are over 566,000 G-tube placements annually, including 22,600 in children.

Existing G-tube devices are labeled as low-profile “buttons” that sit flush against the skin, or “non-button” devices that protrude significantly from the abdomen. They are fixed in the stomach using either a painful rigid internal bumper or an inflatable balloon. But all of these devices are susceptible to dislodgement by simple tugging or balloon failure, which can lead to significant pain and discomfort, tissue injury, and costly emergency procedures.

The Solution

University of Michigan team, James Geiger, M.D., Professor of Surgery, Executive Director of the University of Michigan Pediatric Device Consortium, and Saja Al-Dujaili, Ph.D., Research Associate, worked closely with Farokh Demehri, M.D., Tina Thomas, M.B.B.S., and Jonathon Campbell, M.Eng., to design the Buddy Button, a one-size-fits-all, low-profile G-tube that is customizable for each patient at bedside. The initial focus is on the pediatric population, but it can also be used for adult patients.

The Buddy Button has an innovative, non-balloon style fixation mechanism that reduces pain during insertion and prevents unintended dislodgements. Additionally, the internal fixation “bumper” mechanism is not inflated or under pressure, minimizing leaks and allowing for longer use (at least 6-8 months) between G-tube changes.
**Buddy Button is a novel device** that gives sick children a more comfortable and secure gastric feeding tube option.

**Significant Need**
Current G-tubes can be painful to insert, are highly susceptible to dislodgement, and can protrude uncomfortably from the stomach, especially in pediatric patients. The Buddy Button is a low-profile tube that improves patient comfort and reduces hospital expenses.

**Compelling Science**
An innovative, non-balloon style fixation mechanism reduces pain during insertion and prevents unintended dislodgements, allowing for longer use (at least 6-8 months) between G-tube changes.

**Competitive Advantage**
The Buddy Button offers painless insertion and removal and reduces the incidence of dislodgement. This lessens the medical, emotional, and financial stress on patients, caregivers, and clinicians. The one-size-fits-all feature lowers hospital inventory needs and increases cost savings.

**MTRAC Project Key Milestones**
- Obtain provisional patent
- Bench testing
- Develop functional prototypes
- Customer discovery
- Refine product
- Regulatory studies and FDA submission
- Licensing

**Overall Commercialization**
- Commercialization Strategy
  - Plan to license to existing G-tube manufacturer.

**Intellectual Property**
- Filed invention report with the U-M Office of Technology Transfer. Submitted provisional patent application.

**Product Launch Strategy**
To be determined by licensee.

**Engage Investors**
Seek further funding through venture capital, angel funds, and grants.

**Regulatory Pathway**
- Class II Medical Device, 510K pathway for FDA marketing approval.

**MTRAC funding is helping to reduce the technological and regulatory risks for the Buddy Button in order to achieve a license agreement with existing G-tube manufacturers and move this product to market. We appreciate the guidance and advice as we work to build a second prototype and manage regulatory consultation and filing.**

---

**FASTFORWARD**
research.med.umich.edu/mtrac 734-615-5060 ffmioffice@umich.edu