Application

01962 - The GEM Challenge 2015

02116 - Vesicostomy button for continent bladder urinary diversion

Collaborative awards with IEM

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Area of Specialty	Surgery/Urology		

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Information

PI Name (Last Name, First Name)	*Alagiri, Madhu*
CO-PI Name (Last name, First name)	
Project Title	*Vesicostomy button for continent bladder urinary diversion*
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PI Biosketch

File Name	Description	File Size
Alagiri Biosketch.pdf	*Alagiri Biosketch*	

Narrative

File Name	Description	File Size
Vesicostomy Button Narrative.pdf	*Vesicostomy Button Narrative*	

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Alagiri, Madhu	Professor of Surgery/Urology Vice-Chief, Pediatric Urology
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Columbia University, New York	B.A.	5/84	Computer Science
Temple University, Philadelphia	M.D.	5/89	Medicine
Temple University, Philadelphia		6/92	Surgery Residency
Temple University, Philadelphia		6/96	Urology Residency
U. of California, San Diego/Rady Children's		6/97	Ped Urology Fellowship

A. Personal Statement

I am a clinical professor of surgery at UCSD and have an active clinical and surgical practice based at Rady Children's Hospital. I am board certified in urology with added certification in pediatric urology. I have spent over twenty years treating urologic disease including managing neurogenic bladders and performing reconstructive surgery. Over this time, I have seen many novel therapies introduced to treat urologic disorders. Some of these treatment modalities have gone on to revolutionize the care of my patients and have sparked an interest in me to participate in the next wave of medical innovation.

B. Positions and Honors

Professional Positions:

1997-Present — University of California, San Diego
Clinical Professor of Surgery/Urology
Director: Pediatric Urology (1997-2009)

1997-Present — Children's Hospital and Health Center, San Diego
Senior Staff, Pediatric Urology
Vice Chief: Division of Pediatric Urology (2009-Present)

1997-2003 — VA Medical Center, La Jolla
Staff Physician, Surgery/Urology

2000-2009 — Scripps/Mercy Hospital Health Center
Staff Physician, Pediatric Urology

2000-2013 — Kaiser Permanente Medical Center
Staff Physician, Pediatric Urology

Professional Societies/Positions:

1996-Present	American Urologic Association
1997-2013	American Academy of Pediatrics
1997-Present	San Diego Urologic Society
1998-Present	American Urologic Association, Western Section
1999-Present	Expert Reviewer for *Urology*
1999-Present	Peer Reviewer for *Journal of Urology*

Sample of Pediatric Urology Publications

1. Powell CR, McAleer IM, Alagiri M, Kaplan GW: Comparison of Flaps Versus Grafts in Proximal Hypospadias Surgery. *J Urol*. 163: 1286-89, 2000.
2. Bernie JE, Alagiri M: The Tubeless Barcat: A Patient-Friendly Hypospadias Procedure. *Urology* 61: 1230-33, 2003.
3. Polepalle SK, Shabaik A, Alagiri M. Leydig cell tumor in a chid with spermatocytic maturation and no psuedoprecocious puberty. *Urology* 62(3): 551, Sep 2003.
4. Gabal-Shehab L and Alagiri M. Traumatic Adrenal Injuries*. J of Urol* 173: 1330 – 31, April 2005.
5. M Alagiri, S K Polepalle. Dietl's Crisis: An Under-Recognized Clinical Entity in the Pediatric Population. *Int Braz J Urol*. 2006; 32: 451-3.
6. Arsanjani A, Alagiri M. Identification of filling versus voiding reflux as predictor of clinical outcome*. Urology*. 2007 Aug; 70(2):351-4.
7. Nepple KG, Cooper CS, Alagiri M. Labial Adhesions. eMedicine from WebMD. Updated March 23, 2009.
8. Alagiri M: Diagnosis and Management of Megaureter, Ectopic Ureter, Reflux, and Ureterocele. *Urology Pearls of Wisdom*. 3rd Edition. Boston Medical Publishing Corp. Ed. David A. Levy. 2009.
9. Jeffrey M. Woldrich, Nicholas Holmes, Kerri Palazzi-Churas, Madhu Alagiri, Marvalyn DeCambre, George Kaplan, George Chiang. Comparison of Laparoendoscopic Single-Site, Conventional Laparoscopic, and Open Nephrectomy in a Pediatric Population. *Urology*. Jul 2011, Vol 78, No. 1: 74-77.

Vesicostomy button for continent bladder urinary diversion

Aim: To create a medical device (**vesicostomy button**) that can be percutaneously inserted into the bladder to allow for urine drainage in bladders that cannot properly empty. The device would be easy to replace by non-medical personnel. The device would be low profile and thus easily hidden. The device would be engineered to leak at a certain pressure to prevent over distention of the bladder and renal damage. The device would be coated or made of biocidal materials to prevent bacterial colonization and infection.

Rationale: Bladders that cannot spontaneously empty or empty inadequately are a relatively common affliction in both young and old patients. Adequate drainage of these defective bladders is important in preventing infection and renal damage. Present medical care relies on several options as described below:

1. Long-term urethral catheter – requires well-trained individuals for replacement and prone to infection, urethral erosion, and bladder stones.
2. Suprapubic tube – Requires a leg bag or other collection device, unsightly, prone to infections and stones.
3. Cutaneous stoma (vesicostomy) – requires a surgical procedure and long-term diapers and prone to chronic wetness, fungal infections and excoriation.
4. Continent catheterizable stoma - requires complex surgical reconstruction using bowel and is prone to malfunction requiring further surgery.
5. Intermittent catheterization - requires cooperation of the patient and training by the individual performing the procedure and is often painful.

Challenge/Need/ Significance: Over my career, I have used all the above treatment modalities for defective bladders. I, like many of my peers, have not found any of them to be perfect. However, if the **vesicostomy button** for continent bladder urinary diversion achieves its aims, it would effectively replace the first four treatment modalities and significantly improve how we manage this disorder.

Innovation: No device like this exists for the bladder.

Feasibility: The **vesicostomy button** for continent bladder urinary diversion could possibly follow the same trajectory as the gastrostomy feeding tube in general surgery. The gastrostomy tube is a percutaneous device placed in the stomach. It has replaced inferior treatment modalities and revolutionized the management of providing nutrition to special needs individuals. Currently, due to lack of other alternatives, pediatric urologists have started using gastrostomy feeding tubes to mimic what a **vesicostomy button** could potentially do. The MIC-

KEY gastrostomy feeding tube by Kimberly-Clark healthcare is what I use and can be looked up by potential collaborators interested in developing the **vesicostomy button**. The MIC-KEY feeding tube is not designed for the bladder and therefore, has limited success as a bladder drainage device. For example, it has an overly large lumen, it has no biocidal properties, and it has no pressure escape valve. Additionally, a MIC-KEY feeding tube used in the bladder has been mistaken for a stomach feeding tube, and food materials have accidentally been placed in the bladder.

Investigator Qualification: I am a clinical professor of surgery at UCSD and have an active clinical and surgical practice based at Rady Children's Hospital. I am board certified in urology with added certification in pediatric urology. I have spent over twenty years treating urologic disease including managing neurogenic bladders and performing reconstructive surgery. Over this time, I have seen many novel therapies introduced to treat urologic disorders. Some of these treatment modalities have gone on to revolutionize the care of my patients and have sparked an interest in me to participate in the next wave of medical innovation.