



SMOOTHFLOW

Shagun Gupta & Yalinie Kulandaivelu • 04.05.2016



We have a daughter, Janie, with short bowel syndrome who is dependent on home parenteral nutrition (HPN). When her feeding tube becomes clogged, both the feeding and our schedules come to an abrupt halt. Clogged tubes are time-consuming to unclog and expensive to replace. They interrupt her supply of nutrients and cause her discomfort. And it's discouraging for everyone in our home.

SHIRLEY HUANG MD, MOM

THE PROBLEM



45%

Incidence rates for feeding tube blockage or clogging are upwards of 45% over the lifetime of the tube.

Blumenstein et al., 2014

THE PROBLEM

100%

Disrupted feeds and medication

83%

Avoidable visits to the ER


50%

Need painful tube replacements

Increased nurse and physician
workload

Blumenstein et al., 2014

THE PROBLEM



“This is definitely
a problem for
us”

Holly Norgrove, RN
Silvana Oppedisano, RN
G-tube team @ The
SickKids Hospital

BACKGROUND

Feeding tube inserted through the wall of the stomach (percutaneous) or through the nose (nasal)

1

Short Term

- Nasogastric (NG)
- Nasojejunal (NJ)

2

Long Term

- Percutaneous gastric (G)
- Jejunal (J)
- Gastrojejunal (GJ)



MARKET

500,000

people relying on a feeding tube in the US

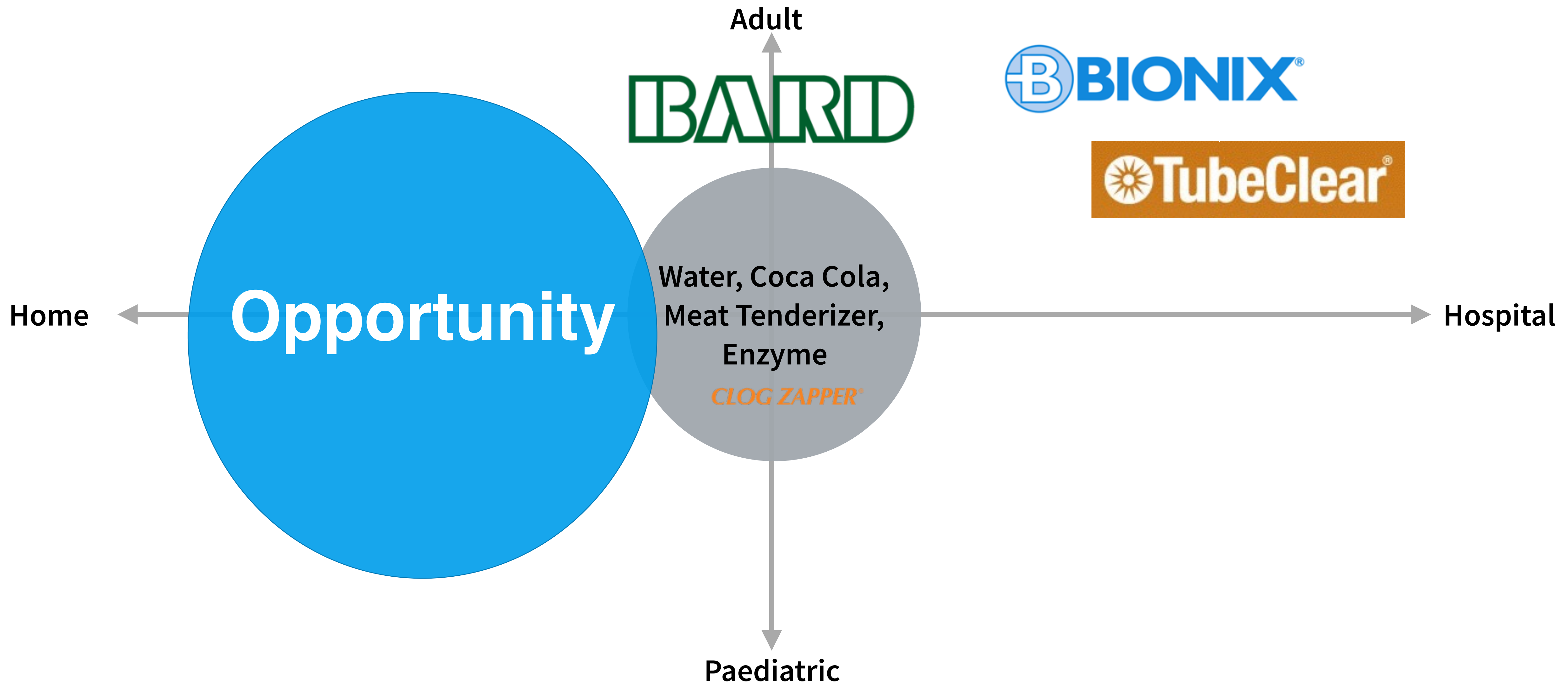
Kirby, 2011

MARKET OPPORTUNITY

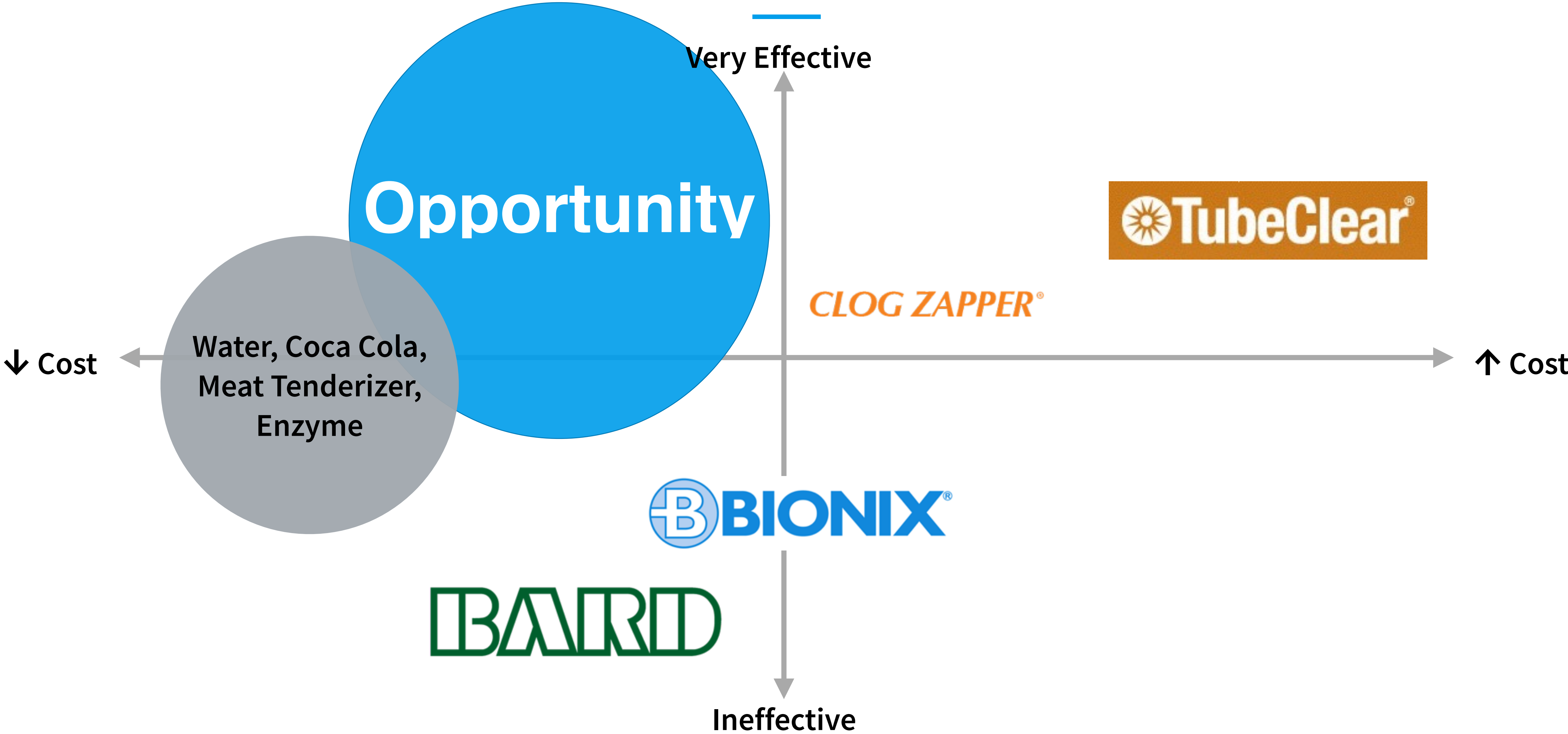
	Clogged Tubes	Unit Cost	Costs
Tubes Declogged	225,000	\$89	\$20,025,000
Tubes replaced	112,500	\$1,098	\$123,525,000
		Total	\$143,555,000

\$140+
million

MARKET LANDSCAPE



MARKET LANDSCAPE



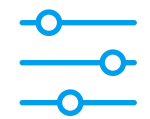
DESIGN REQUIREMENTS



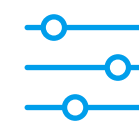
At Home Use



User Friendly



Highly Effective



**Compatible for G/GJ
tubes**



Cleans Tubes Quickly



Easy to Maintain



Low Cost



**Available in adult and
paediatric sizes**

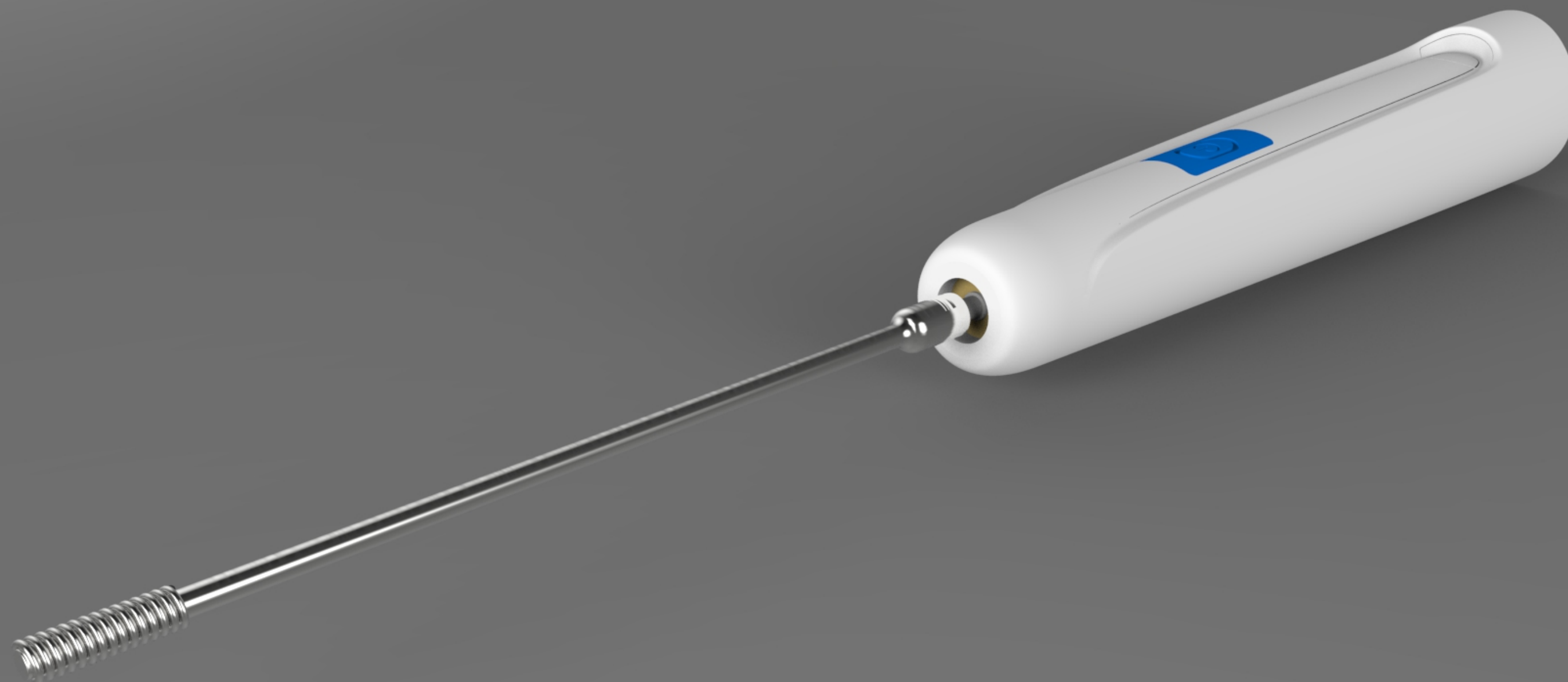


THE SOLUTION

SmoothFlow.

**The quick and easy way to clear your
feeding tube in the comfort of your HOME.**

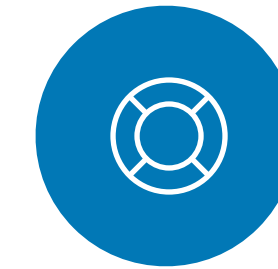
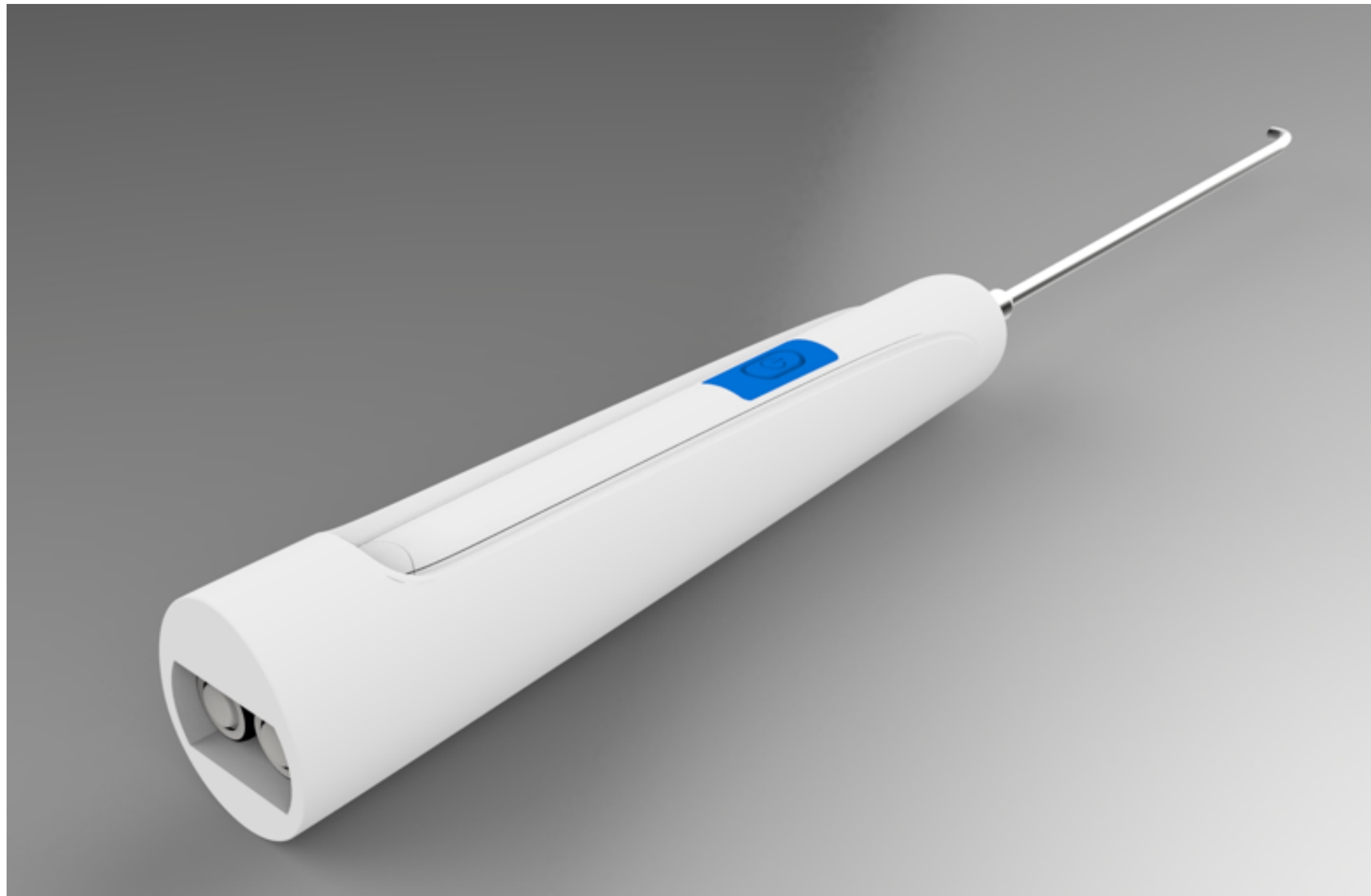
SmoothFlow.
It's the quick and easy
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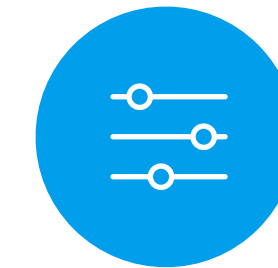
HOW IT WORKS



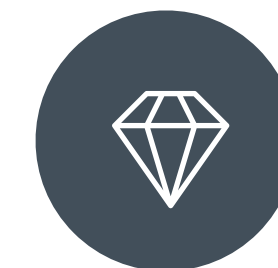
Why SmoothFlow ?



Quickly resume feeding & medication



Reduce visits to the ER

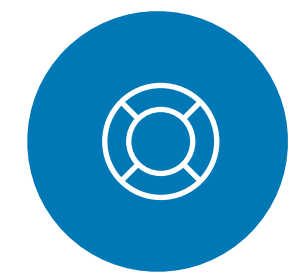


Reduce uncomfortable tube replacements



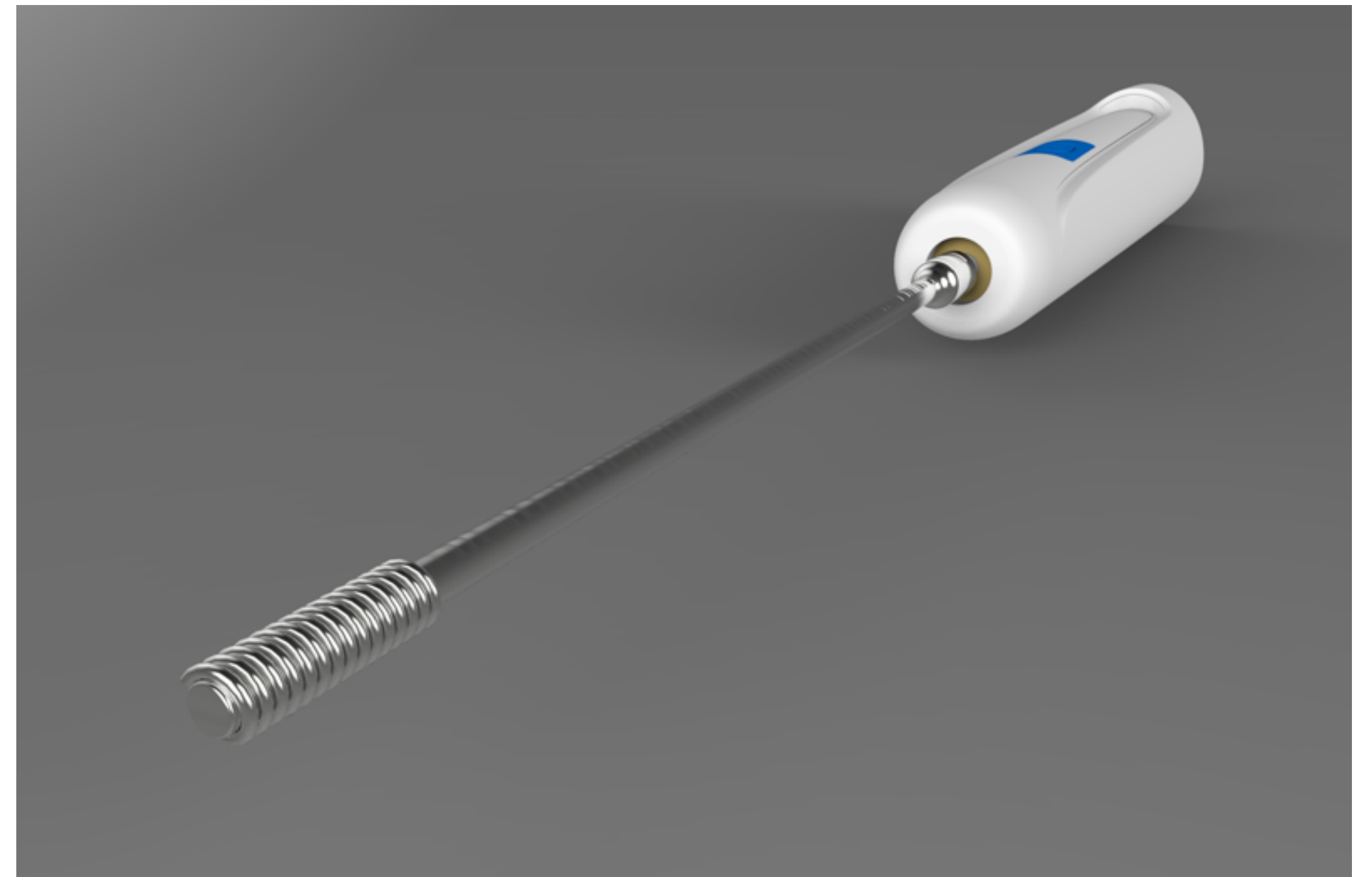
Able for all tube sizes 5Fr to 24Fr

Features



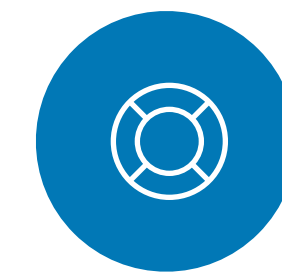
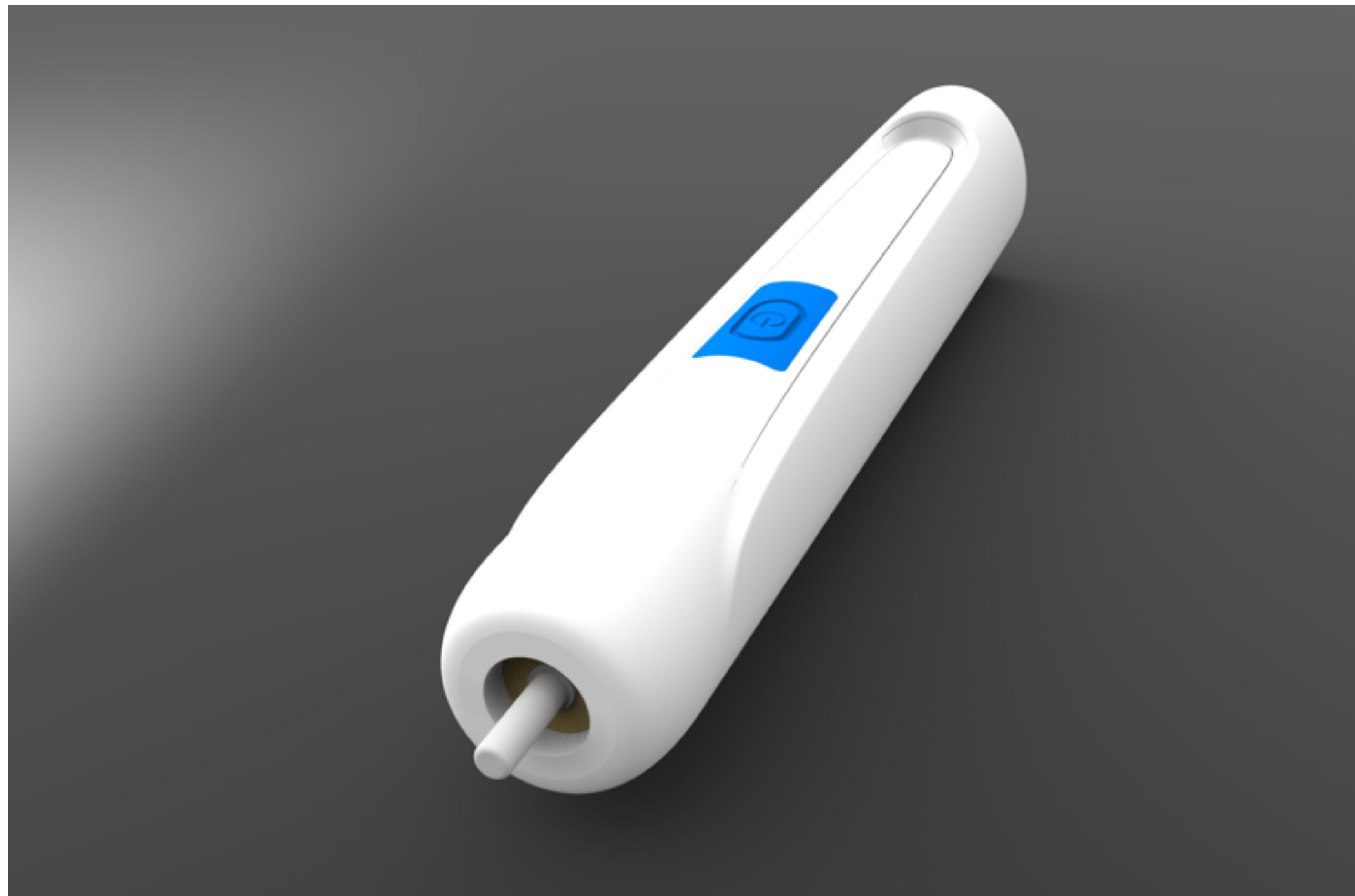
Device Stem

- detachable stem
- use and throw (single use)



Insert your subtitle text here

Desktop Features

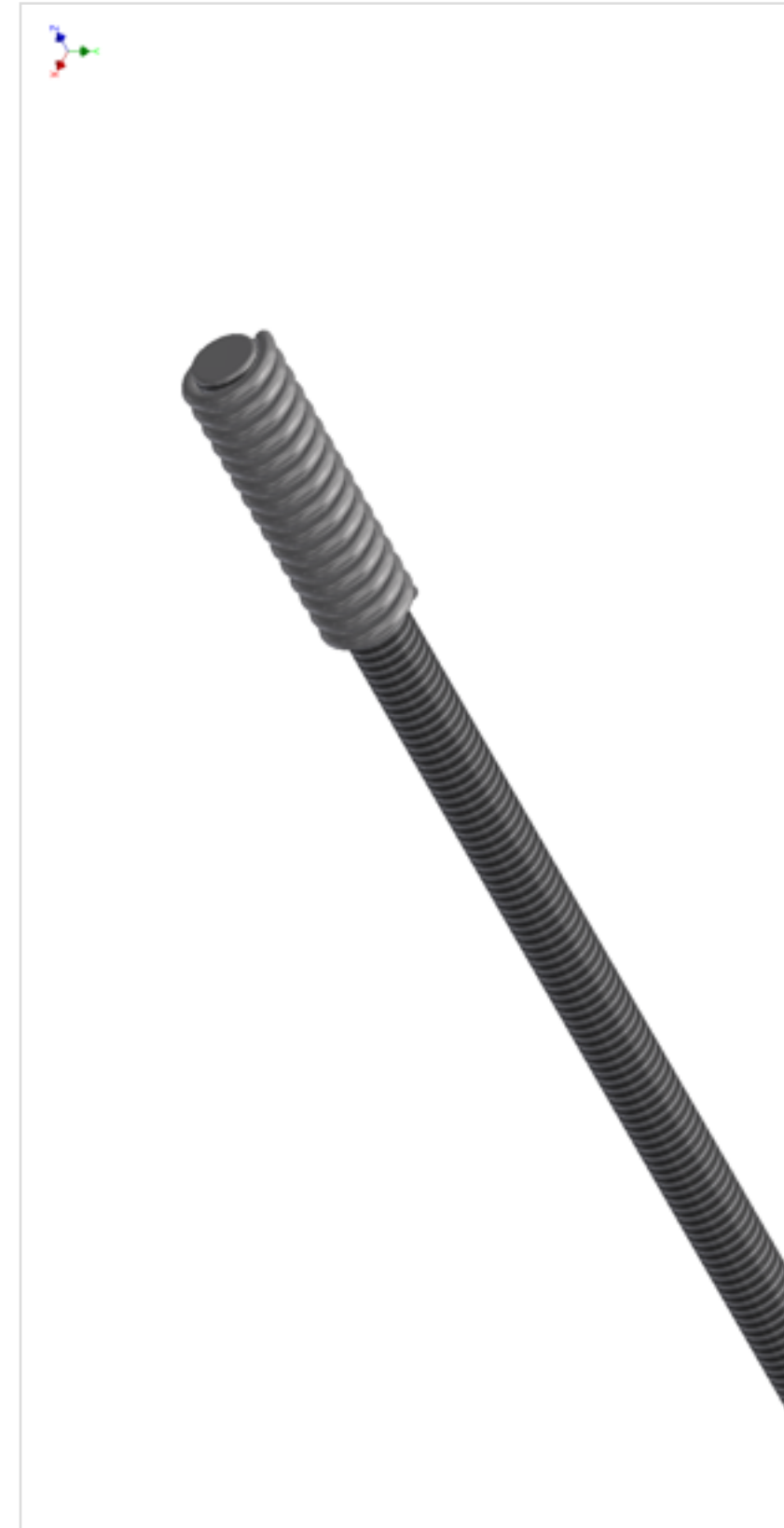


Device Base

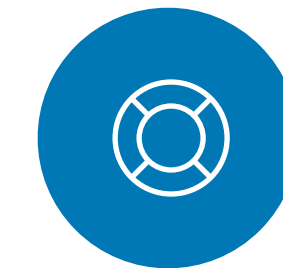
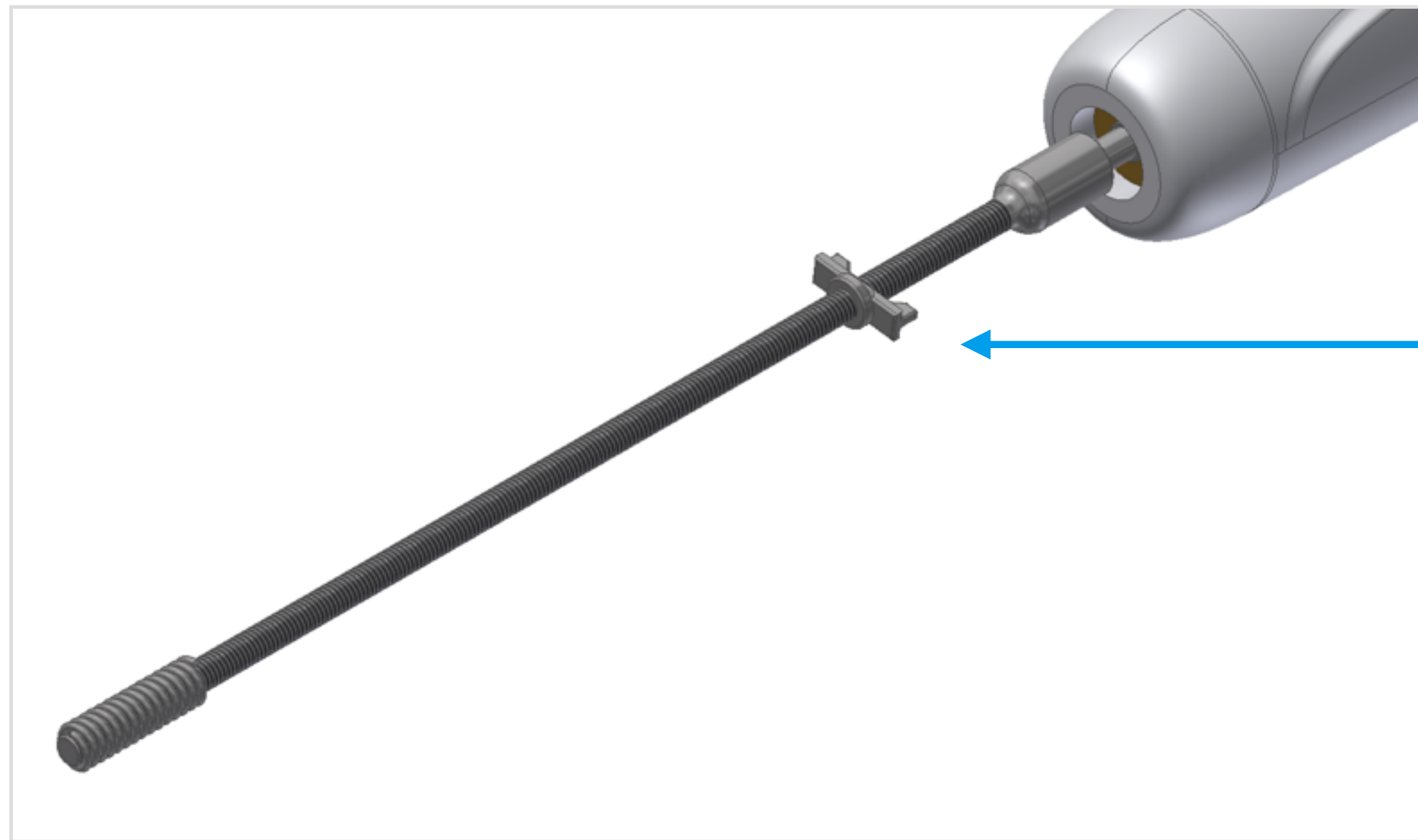
Reusable base

The Solution

Flexible nitinol core
allows stem to turn
corners



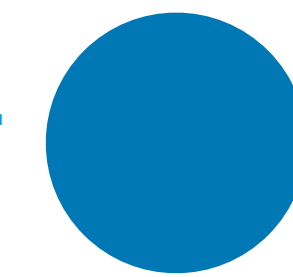
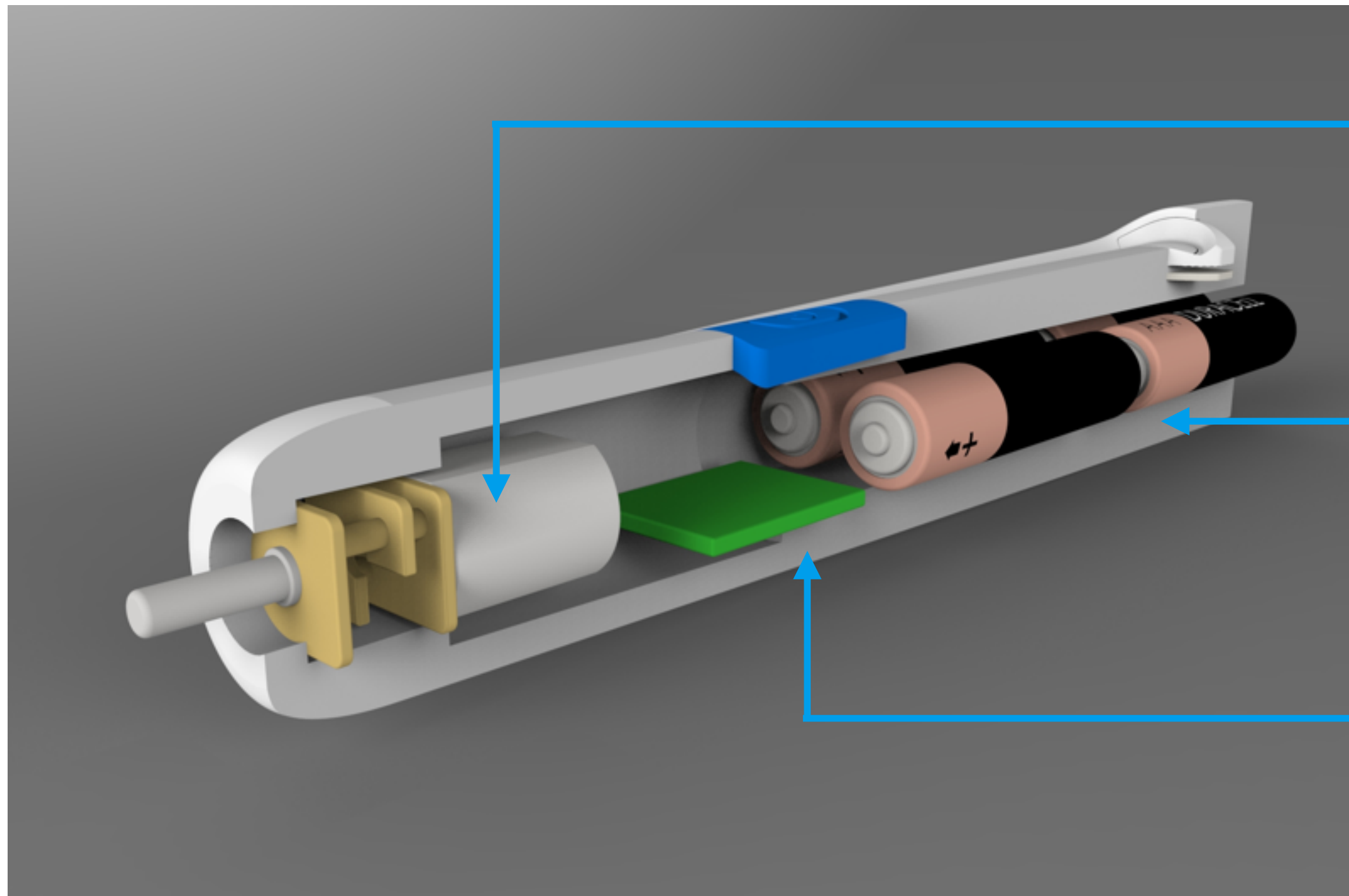
Features



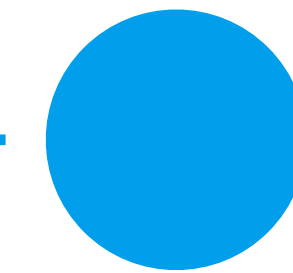
Device Safety

- Safety stopper allows you to control the length of stem inserted
- Length markings to indicate how far in body the device stem is

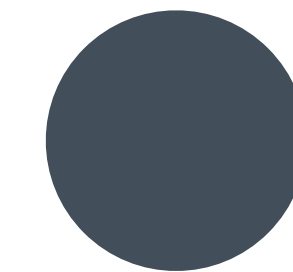
Features



High Torque Motor











AAA batteries x 4



PCB with safety mechanism

EVAULATION SUMMARY

	SmoothFlow	TubeClear	Tube Declogger	ClogZapper
Time to Clear	3 mins	5-30 mins	20 mins	30 - 60 mins
Effectiveness	  	  		
Cost	\$	\$\$\$\$	\$	\$\$\$

Based on self tested data. TubeClear data obtained from tubeclear.com

TESTIMONIALS

“There is great value in a simple, at-home device for patients and their families. Preventing clogs can reduce the amount of disruptions enteral feeding can cause in a family’s life from having to go to the hospital every time their child’s tube gets clogged. A lot of these families live quite far from the hospital itself, so we try to make every effort we can to show them how to effectively self-manage their child’s condition”

- Dr. John

“An at-home, mechanical device for clearing clogs is definitely beneficial for patients requiring PEG tubes who have had their tube for less than 6 weeks. Preventing a reinsertion before the tract fully heals can greatly reduce complications and any further problems in reinserting a feeding tube in this window of time.”

- Dr. Temple

TESTIMONIALS

“Disruption of feeding is a significant problem especially for pediatric patients who rely on their tube as their sole source of nutrition. A clog on Friday night may mean their tube won’t get unclogged or replaced until Monday. These children will have had their feeding disrupted and the discomfort of not receiving adequate amounts of nutrition of over 48 hours.”

- Dr John

“We try to avoid or reduce X-ray exposures as much as possible, a lot of these kids will need multiple replacement tubes throughout their childhood”

- Dr Temple

REGULATORY

- US
 - ▶ Two predicate devices → 510k pathway
 - ▶ Did not require clinical data
 - ▶ Class II device: Expect to pursue 510k

REGULATORY


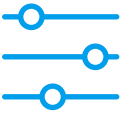


- Canada
 - ▶ Class II device
 - ▶ MDL application requires limited testing data
 - ▶ Identified relevant ISO standards

IP

- Freedom to Operate
- Not pursuing patent (cost to benefit ratio ↓)
- Aiming for public disclosure
- Trademark for name

BUSINESS MODEL

Business to Customer

-  Pharmacy
-  Online Wholesale
-  Need physician/advocacy group recommendation
-  OTC



COST STRUCTURE

- Model: Reusable base + Disposable Tips

	100 units	10,000 units
Base	\$10.50	\$6.50
Stem	\$0.379	\$0.306
Total	\$10.379	\$6.806

BUSINESS MODEL

COST STRUCTURE

	SmoothFlow
Material Costs	\$6.802
Manufacturing	\$9.68
Wholesale	\$14.52
Market Cost	\$30.00
PROFIT	\$150,000 with 10k devices

- Does not include multiple disposable tip income!!

BUISNESS MODEL

	SmoothFlow	TubeClear	Tube Declogger	ClogZapper
Cost	\$	\$\$\$\$	\$	\$\$

Stakeholder Analysis

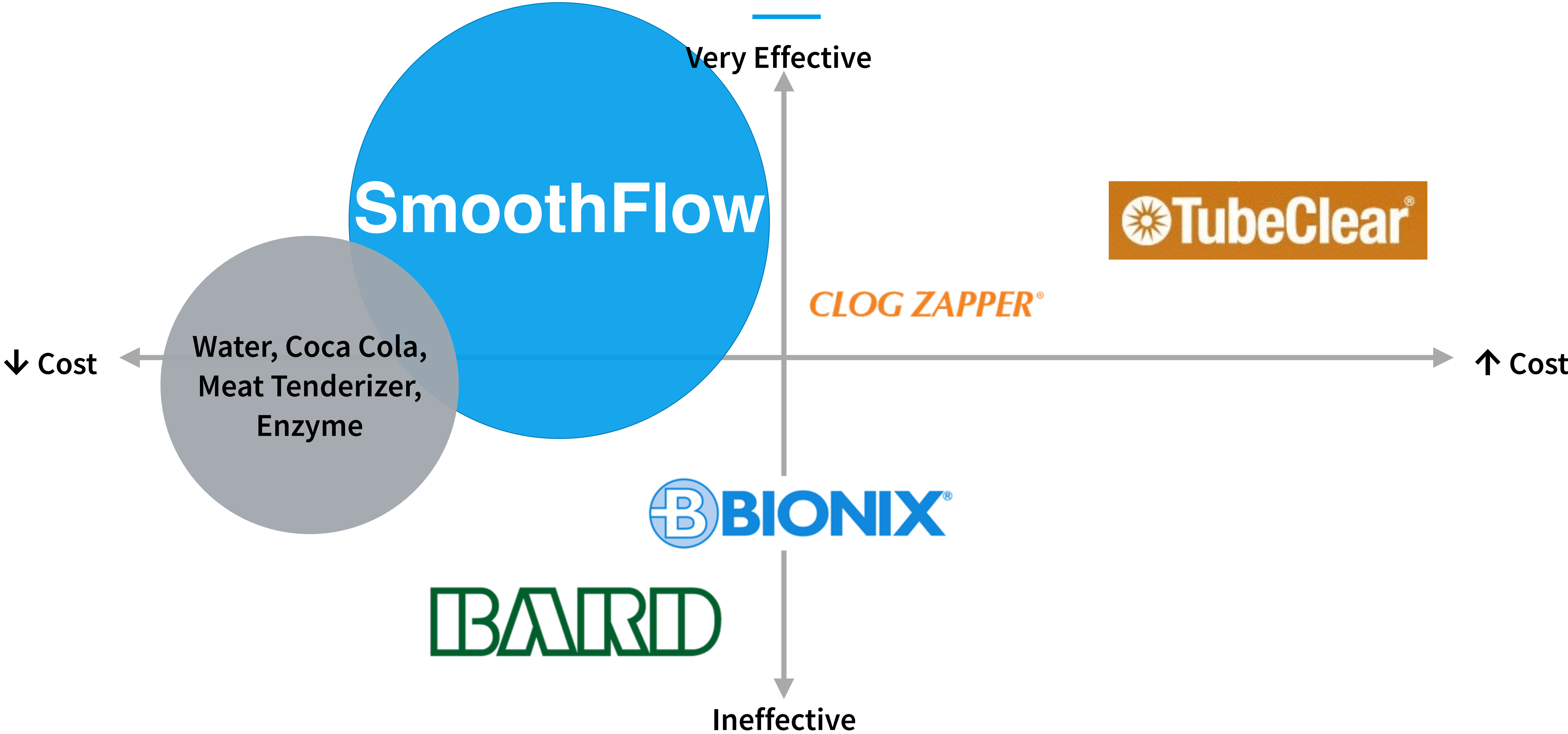
PATIENTS

- Less frustration
- Less ER visits > time off work
- Fewer X-rays
- Fewer replacement procedures
- Fewer feeding interruptions

HOSPITALS

- Lengthens tube life
- Reduced ER burden
- Less physician/nurse time wasted
- Less money wasted on tube unclogging and replacements

MARKET LANDSCAPE





Yalinie Kulandaivelu

Life Sciences, University of Toronto

Passionate about public health, social justice,
biomedical engineering

Shagun Gupta

Life Sciences, University of Toronto

Passionate about healthcare, data analytics,
biomedical engineering



NEXT STEPS

- Combine works-like and looks-like model
- Market Testing

ADVISORS

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DR. MICHAEL TEMPLE
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HARSH BHATT

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- [1] Blumenstein, Irina, et al. "Gastroenteric tube feeding: Techniques, problems and solutions" World J Gastroenterol. 20.26 (2014): 8505-8524.
- [2] Fisher, Charles, and Bethany Blalock. "Clogged Feeding Tubes: A Clinician's Thorn." Practical Gastroenterology (2014): 17.
- [3] Kirby, Donald. "Enteral and Parenteral Nutrition". American College of Gastroenterology Patient Education & Resource Centre. N.p., 2011. Web.
- [4] Phillips, Nicole M., and Rhonda Nay. "A systematic review of nursing administration of medication via enteral tubes in adults." Journal of clinical nursing 17.17 (2008): 2257- 2265.