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With their MASK-FREE Anesthesia Delivery System Designed for Children, PeDIA is Taking Some of the Trauma Out of Surgery

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"With all the previous options tried over the past century, 40% to 60% of children still display significant anxiety with placement of the anesthesia mask. PEDIA believes this is because all the past alternative approaches do not address the *central problem* of pediatric anxiety during induction of anesthesia. We believe, at the core, it is the claustrophobic, smelly anesthesia mask. PEDIA is a truly revolutionary, MASK-FREE anesthesia induction delivery system designed specifically for children. It is not just putting a Band-Aid on the problem. It is changing the entire paradigm." Diane Miller

CEOCFO: *Ms. Miller, what is PeDIA?*
Ms. Miller: PEDIA stands for PEDIAtric Device for Induction of Anesthesia. PEDIA is the only mask-free induction system for PEDIAtrics available on the market today. PEDIA is an FDA-cleared, latex-free, medical-grade whistling Balloon that helps to induce general anesthesia in children. The goal of PEDIA is to provide a less traumatic, stellar anesthesia experience for children, their parents and staff.

CEOCFO: *Has the industry been trying to make it easier?*
Ms. Miller: Absolutely. We've been trying to improve pediatric mask induction since its inception. In the early twentieth century we were putting all patients to sleep with intravenous needles. Of course, you do not need a big study to know that children do not like needles. In the 1930s, an anesthesia innovator took an adult anesthesia mask and made it child-size. They then used it as a vehicle to pass anesthesia gases through the mask so the children would breathe the anesthetic and go off to sleep. In theory that sounds so beautiful and simple but, in reality, it is neither. It did not take long for anesthesiologists to realize that children do not like the anesthesia mask either. Why is that? It is because you are taking a piece of claustrophobic-feeling plastic and filling it with a noxious-smelling gas. Anecdotally, children will tell you it makes them feel like they are suffocating.

Understandably, children will resist; they will turn their head away, push the mask away, verbally say no! Some will cry, some scream or kick. You will even have the children that are so scared that they just sit there, frozen in place, completely panic-stricken. Remember, the response to

stress is fight, flight or *freeze*. We sometimes confuse this freeze with cooperation. Cooperation and *calm* are not synonymous.

The resistance is countered by the operating room staff with brutane. *Brutane* not an official medical term but you would be hard-pressed to find an anesthesiologist who doesn't know what it means. Brutane is an anesthesia euphemism that basically means to apply 1/3 anesthesia and 2/3 brute force. If the child turns their head away, staff hold their head still. If they try to push or kick, staff hold their hands or legs down, sometimes gently and sometimes firmly. It can be quite traumatic for the patient being *brutaned*.

It is also traumatic for the staff because no one wants to do this to a child. If the parent is present, this causes concern. NO mother or father wants to witness their child struggling against the mask. At the very least, it's not a good experience for anyone.

CEOCFO: *I would think there would be some quality to the procedure itself if the patient is terribly unhappy the old way!*
Ms. Miller: There is an *old anesthesia wives' tale* that says *the way a child goes down is the way the come up*. If they have significant anxiety during induction, they have anxiety during emergence, waking up. If they wake up fighting, anesthesia providers then have to give more medication.

This mask placement anxiety can add to perioperative anxiety. Studies show anxiety before surgery, (including mask placement) is associated with increased post-operative pain, increased post-operative emerging agitation, and increased post-discharge maladaptive behavior changes such as aggression, regression, bedwetting, nightmares, and night terrors at home as well as mistrust of medical personnel. This, according to studies, can last 2 weeks, two months or more. For the *frequent flyers*, those children who frequent the operating room, it can last much longer. My little *veterans of the O.R.* definitely showed signs of post-traumatic stress symptoms for years.

The next time that child comes into the hospital, they will show signs of distress. Some of them do this whether they have had sedation before surgery or not, but that's another discussion altogether. I'd like to tell you about my little *Patient Z*. She was my inspiration. When I walked into Z's room, she took one look at me, put her hand in the air in a stop-right-there motion and started screaming "no mask, no mask, no mask!" That child screamed "no mask" all the way to the operating room and all the way through a brutane induction. I thought to myself, "We cannot keep doing this to her." After two years of surgery, she had developed post-traumatic stress symptoms to mask placement. I heard one of the nurses say, "Just blow up the balloon." She wasn't talking about the PEDIA. She was talking about a reservoir bag hanging from the anesthesia machine, in a place where Z couldn't see it, touch it, play with it and she knew it wasn't a balloon. But that gave me this BFO, this blinding flash of the obvious. I thought to myself, "If I promised her a balloon, why don't I just give her one?" And so, I did.

CEOCFO: *After your decision to do something, when did you realize you had a viable concept?*

Ms. Miller: Once I got past engineering, prototyping and hospital committees, I asked to take care of Z again. The same thing happened; she screamed all the way back to the O.R., fighting and screaming while staff tried to hold her down. This time, I filled up my PEDIA with anesthesia gases, walked up to her and said, "Z, do you want to play with my balloon?" She reached over, grabbed the balloon and, without any prompting from me, started breathing in and out through the balloon. After about 4-5 breaths, she got too sleepy to continue so I just switched over to the mask and finished induction.

The next month, when I saw Z again, I walked into her room and, this time, she started squealing "I want to go back and play with the balloon." I took her back and filled the PEDIA balloon with the anesthesia gases. When I went to hand it to her, Z snatched it out of my hand, literally pushed me away, looked me straight in the eye like only a confident four-year-old can do, and said "I can do it myself." And she did. She put the balloon in her mouth and started breathing the anesthesia gases, basically inducing herself. At that point, I decided every child deserved the option of going to sleep in this way: less trauma, more fun.

CEOCFO: ***What materials is the balloon?***
Ms. Miller: It is made out of medical-grade, stretchy, balloon-like material. It comes in three different colors so the child gets to choose their balloon as well as participate in their own induction. The aim is to give them choices to engender cooperation and return a little dignity to the process. It gives them a sense of control.
The whistle part is made with medical-grade plastic and it sounds like a child's party siren whistle. While they breathe in and out, the balloon slightly inflates and deflates and the whistle makes a nice sound. There is also a great animation—one in English and one in Spanish—found on the QR code on the label of each individually wrapped PEDIA. It's instructional, entertaining and just plain fun. The kids love it and it helps the providers explain the PEDIA to them.

CEOCFO: ***Where is PeDIA today in terms of development and commercialization?***
Ms. Miller: PEDIA has been FDA-cleared since 2018. We also have a full 20-year patent. I have done evaluations in the anesthesia community to make sure there was a want and need for this device, and the response was quite positive. I officially launched in January of 2022. Over the last year, I took on distributors, but I also sell directly. I am now in the throes of a huge market validation with a well-known national anesthesia medical device distributor. Those initial evaluations are going exceedingly well, spurring more evaluations and purchases. This company remarked how this response is unprecedented. There are also a couple of Group Purchasing Organizations and Integrated Delivery Networks that have shown interest.

CEOCFO: ***Are you seeking funding or investment?***
Ms. Miller: Not at this time. I went very slowly through the initial part of this process so I could fund it. I did this to maintain control over the product and selling practices. It had nothing to do with profits; it had to do with quality. I lived in the trenches of the operating room. I am also a *child whisperer*. I know what works and what does not work. I did not

want someone who was completely business-oriented and centered on profits to say "you must do this and that." I wanted to do what I thought was the best for the children, putting them first. The only way I could ensure that end product was to avoid giving any control over to an outside entity.

CEOCFO: *How do you deal with some of the frustration in knowing you have something that is so powerful but it takes a long time to get it into the mainstream?*
Ms. Miller: It was an exponential learning curve but I'm a quick study. And I've surrounded myself with trusted mentors. I am an anesthesia provider so I am used to having instant gratification: you give a medication and within 30 seconds, you see a result. I have learned over the years it does not work like that in business. Usually, when someone tells me a process is going to take a couple of months, I will multiple that by two or three because I know that's what happens. It's like business uses a different calendar! Again, there are entities and processes and people to whom I turn. I meditate every day and prayer is a big part of my life. I started a group called Medical Inventors and Innovators, which has about a thousand participants. There are probably a dozen people in that group who have become mentors and confidants to me, some more than others. I have three or four anesthesiologists and certified registered nurse anesthetists who really have my back. They are also medical device founders, so they *get me*. I can always just call or text one of them to discuss a problem or to talk me off the ledge!

I recently sat as a vendor at the American Society of Anesthesiology annual conference and, while I was there, competed and won their *Swimming with the Sharks* competition. Three out of four judges and the audience, made up of anesthesiologists, voted for PEDIA. The best part was I became a *minnow* (contestant) to my own Shark (an anesthesiologist and previous winner). He stays very close to me. Whenever I have a question, I also turn to him. He takes pride in guiding his little minnow.

So people, meditation, and doing the *next right thing*: That is how I deal with the frustration.

CEOCFO: *With so many new ideas in the medical arena, why does PEDIA stand out?*
Ms. Miller: PEDIA stands out because it solves a 100-year-old problem. It is not that anesthesia hasn't tried other modalities. We have tried everything from O.R. tours, parental presence at induction of anesthesia, hand-held devices, virtual reality, scented masks, etc.…the list just goes on. My very favorite study is about clown doctors, where clowns come into the operating room to help alleviate anxiety. I do not know a circulating nurse in this country that would allow that a clown in a sterile operating room, but that just shows how desperate we were to find a solution. With all the previous options tried over the past century, 40% to 60% of children still display significant anxiety with placement of the anesthesia mask. PEDIA believes this is because all the past alternative approaches do not address the *central problem* of pediatric anxiety during induction of anesthesia. We believe, at the core, it is the claustrophobic, smelly anesthesia mask. PEDIA is a truly revolutionary,

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