Necessity and Invention: New Mom Turns Entrepreneur

BY FABIA D’ARIENZO

“I developed this see-through surgical mask to address a glaring gap in communication accessibility that directly affects patient outcomes and patient satisfaction.”

– Dr. Anne McIntosh
When they wheeled her into the OR for an emergency C-section, it was as if four steel walls had come slamming down, cutting her off from any form of communication—and from any sense of control over her fate or that of her unborn child.

For Anne McIntosh, it was a terrifying moment. And it would shape her future.

The steel walls that left Anne powerless came in the form of conventional, white surgical masks intended to defend against infection. But for Anne, those opaque masks created a startling barrier.

Anne had developed hearing loss when she was a young infant—likely due to ototoxic antibiotics during an early surgery. She’d grown up relying on speechreading as a critically important tool for functioning in a hearing world. The masks made it impossible for her to comprehend what was being said, impeding her ability to quickly and easily follow verbal requests from the health care providers—and to sufficiently understand what was happening. Did the doctors and nurses know about her allergy to penicillin? What other time-sensitive information might they need?

Anne’s mind raced frantically. It was the first time she’d ever feared that a breakdown in communication might adversely affect the life of another human being—her child. She was beyond petrified.

Months of Preparation

Anne was a planner by nature and necessity. Knowing what to expect had become a useful coping mechanism that helped her effectively manage her severe-to-profound hearing loss. Importantly, planning gave her a reasonable sense of control and peace of mind. As a college professor with three degrees in communications, including a Ph.D. in communication sciences and disorders, advanced planning had always served her well.

So for months, Anne had researched the various stages, steps and procedures that were part of ensuring a healthy pregnancy. As a college professor with three degrees in communications, including a Ph.D. in communication sciences and disorders, advanced planning had always served her well.

When her water broke and she went into the hospital on that Friday night in 2001, Anne was well-informed. All was going according to expectations—for a while.

But after 25 hours, she was still in labor.

The obstetrician on call—not her regular doctor with whom she’d become so familiar over the last nine months—determined that a C-section was necessary.

Things began to move very quickly.

Luckily for Anne, when they rolled her into the OR, her husband was already there. And despite the sudden, extreme anxiety that rushed over her when she realized that her primary mode of communication wasn’t an option, she had the clarity of mind to verbally—and emphatically—hand over the reins to him. From there, Anne’s husband answered all the questions and made all the decisions for her. She could only hope that between the medical staff and her husband, they had all the information they needed.

Thankfully, the C-section went well for both mother and daughter. And within two days, all were home, celebrating the arrival and well-being of Sophia.

Taking Action

As the weeks and months passed, Anne reflected frequently on those crucial, anxiety-ridden moments in the OR. She wanted to spare others with hearing loss from such intense fear and helplessness. But she also believed that ensuring smooth communication for people with hearing loss could help avoid needless medical errors that threatened lives.

Her experience in the OR that night had become the impetus for action. Indeed, it set her on an entrepreneurial path.

Anne surmised that a see-through surgical mask could protect against infection while still allowing patients to see facial expressions and health care providers’ lips—which is essential for those who depend on speechreading. It was such a seemingly simple solution. Did something like it already exist?

After a good deal of research—and outreach within the health care and medical manufacturing industries—Anne confirmed two facts, she says:

1) The need for such a product existed. There even seemed to be a pent-up demand for this type of mask among health care providers.
2) There was no such mask on the market that had been approved by the Food and Drug Administration (FDA).

Anne started searching for collaborative partnerships. Specifically, she looked for a manufacturer that could help design her mask concept, see it through FDA regulatory approval, and mass produce it. She’d establish a C corporation to market the product.

After several months of searching, Anne identified Prestige Ameritech, the largest domestic surgical mask manufacturer in the U.S., which has a manufacturing plant in North Richland Hills, Texas.
After several meetings with Prestige Ameritech executives and attorneys, Anne and the manufacturer formed a business partnership. Anne founded Safe’N’Clear, Inc. in September 2012.

Together, they fine-tuned the design of a surgical mask with a clear, fog-resistant plastic window that kept the wearer’s mouth and facial expressions visible. Prestige Ameritech took the lead in the final design, production and FDA approval process.

It took about two years, but in December 2016, approval for ASTM F2100 Level 1 protection came. According to Safe’N’Clear, the mask has greater than 95% bacterial and particle filtration efficiency and is designed for use in operating rooms to protect both patient and health care workers from the transfer of microorganisms, body fluids and particulate materials.

Most significant, in winning regulatory approval, they made history. It was the first-ever FDA-approved medical mask with a clear window, Anne says. They were breaking down a dangerous communications barrier that had long existed in medical settings.

Manufacturing started almost immediately. And the Communicator Surgical Facemask with a Clear Window, marketed by Safe’N’Clear, hit the market within months. Hospitals were using it by March 2017.

Today, Safe’N’Clear ships to hospitals, medical clinics, medical and dental schools, dental clinics, assisted living centers, and nursing care facilities. Even health rooms at schools benefit from having this communication-friendly mask. HL

She believes that because the mask helps eliminate a social barrier—that is, people can still see the individual’s facial expressions—it’s useful in other settings as well. Anne gives a few examples of situations for which she believes the clear window mask can provide added benefit:

- school health rooms, where it could help put children of any hearing ability at ease
- for the general consumer, when flying or during periods of high cold and flu activity
- for oncology patients who need to wear a mask to protect themselves against infection
- for dental hygienists who want to make their clients more at ease during their six-month dental cleanings

Other see-through medical masks have come onto the market since the Communicator Surgical Facemask with a Clear Window by Safe’N’Clear was first introduced. For more information, see SafeNClear.com.

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