

Design of Medical Devices COVID-19 Response Session, June 9, 2020

Emergency Level 1 Gown Design & Production

Prof. Steven S. Saliterman, MD, FACP, Department of Biomedical Engineering



An Exciting Two Weeks in April...

- **Day 1, Friday, April 17, 2020**
 - Global shortages of PPE.
 - 17 BME students partnered with M Health Fairview Hospitals and Clinics to address an immediate dire shortage of healthcare provider level 1 gowns
 - Up to 10,000 gowns needed a day, up to 350,000 total!
 - Faced with escalating cases of COVID-19, the partnership considered procurement vs. design of gowns that could be mass produced quickly.

The *Gown for U* Team



Interview with Jennifer Brooks, Star Tribune. Not pictured are Dan Nguyen, Jasmine Nguyen, Ilsa Shobe and Jack Kotzenmacher.



- **Day 2, Saturday, April 18, 2020**

- Attempts to secure gowns from sellers locally and abroad were unsuccessful.
- Working groups were formed to design and produce gowns:
 - Design Team
 - Materials Team
 - FDA Team
 - Manufacturing Team
 - Organization and Archiving Team



- **Day 3, Sunday, April 19, 2020**

- The College of Design joined our efforts.
- The search began for a manufacturer of gown material and a “converter” – a company that takes the materials and produces gowns.

- **Day 4, Monday, April 20, 2020**

- Design meetings were held with M Health Minnesota.

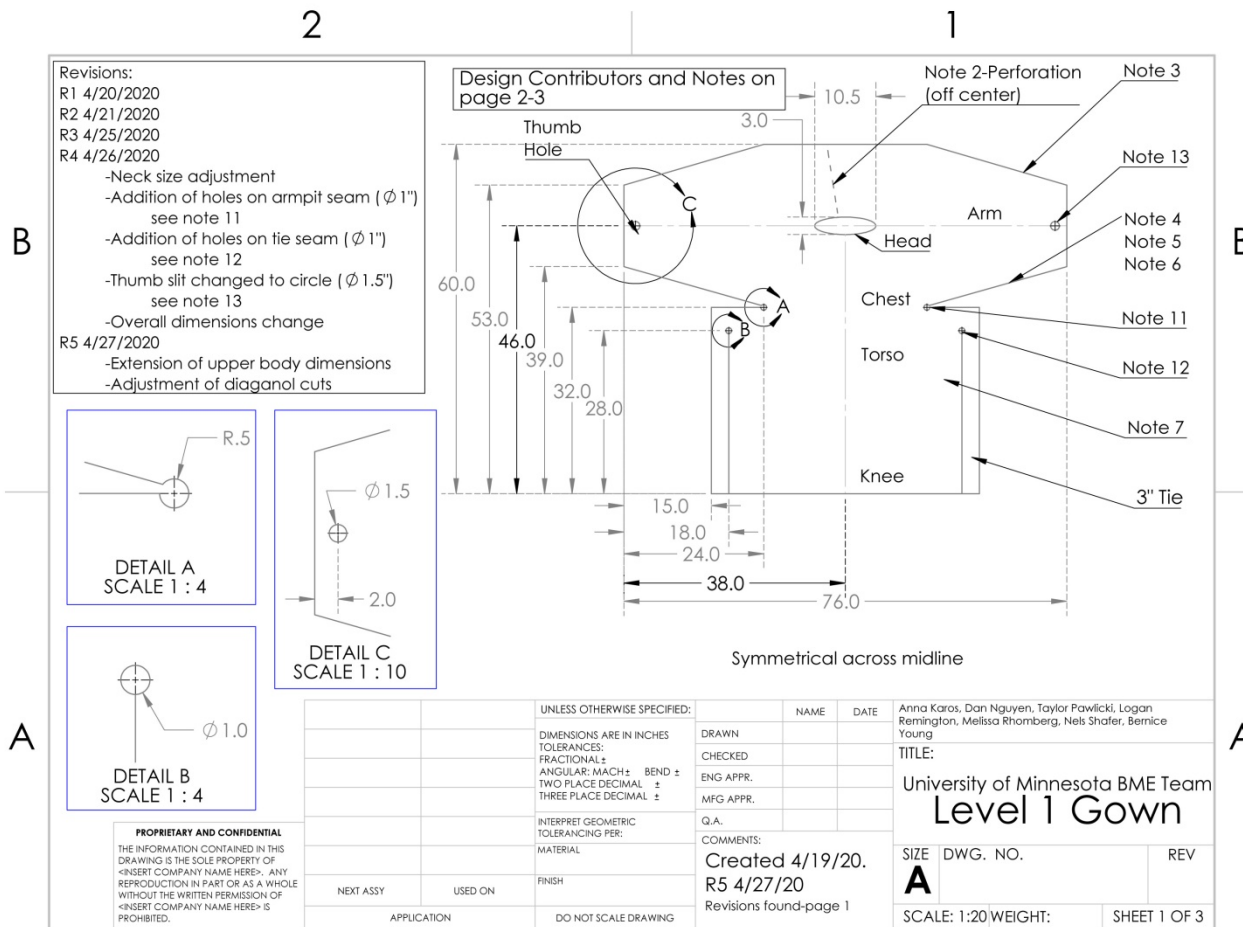
- Day 5, Tuesday, April 21, 2020

- The design group completed preliminary drawings, prototypes and photographs to show converters for quotations.



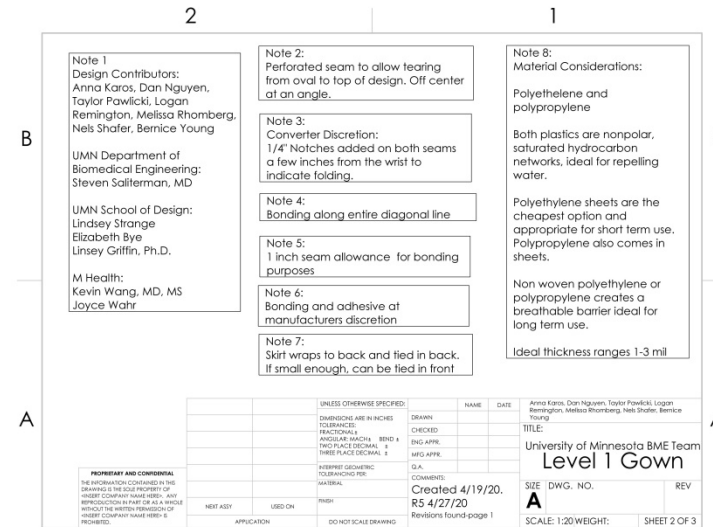
Nels Shafer, Student

Gown Design – Revision 5, 4/27/2020

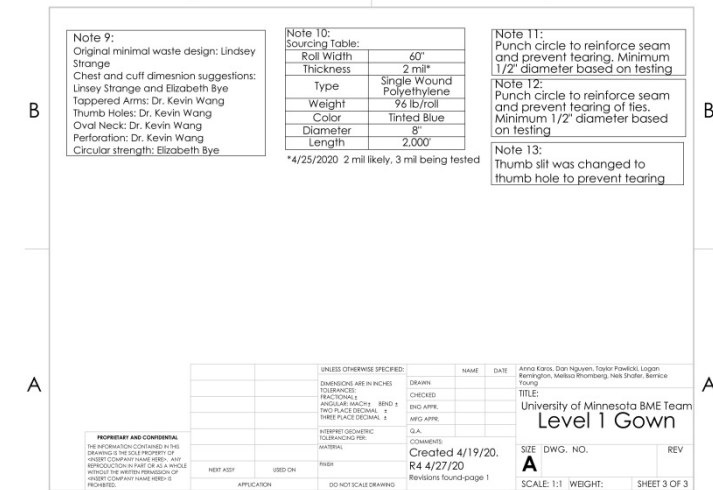


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Revisions continue – find the Technology Commercialization link on the last slide.



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- Days 6 – 12, April 22- 28, 2020

- High level meetings with M Health Fairview, including physicians, nurses and administrators were held.
- Criteria included design, availability, material, cost, production capacity, and reliability of delivery.
- Meetings were held on-site with presidents and managers of Polar Plastics and Red Fox Innovations to produce custom polyethylene material – blue tinted, antistatic, rolled for ease of manufacturing, and FDA certified.

Polar Plastics



Steve Anderson, Will Telken
and Eric Ave'Lallemant
(Click for Video)

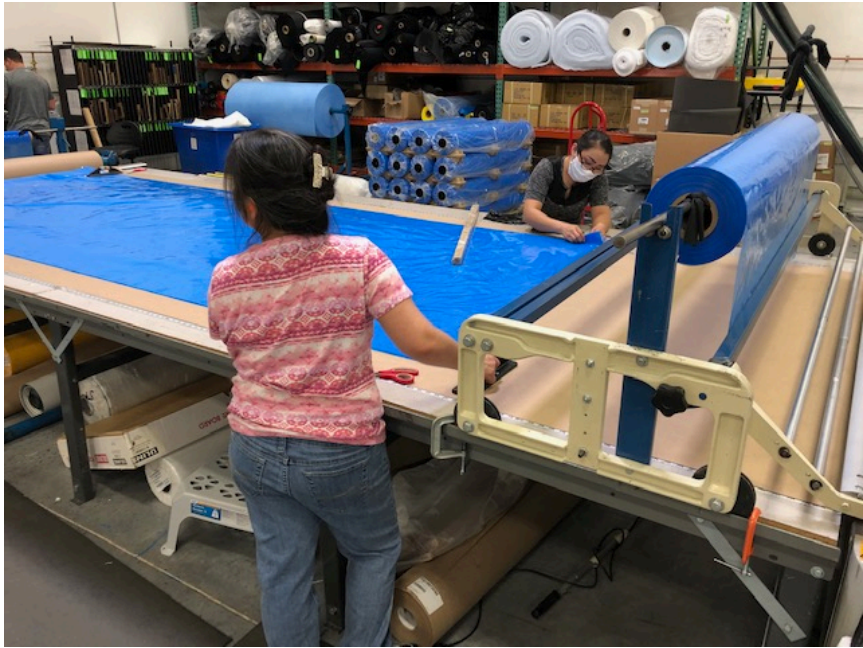


Polyethylene Film Production



- **Day 13, Wednesday, April 29, 2020**
 - Specifications for the materials and gown design were submitted to M Health Fairview to begin the purchase order process.
- **Day 14, Thursday, April 30, 2020**
 - Material was manufactured at Polar Plastics and delivered overnight to Red Fox Innovations.
- **Day 15, Friday, May 1, 2020**
 - Red Fox Innovations began production of gowns.

Red Fox Innovations Production Line



Pattern Cutting (Click for Video)



Bonding Sleeves



30,000 Gowns Delivered
as of 6/10/2020.

Finished Gowns



Nick Houkom, RN, Nurse Manager Pediatric CVICU & Teresa Cahill, RN, Nurse Manager Pediatric Emergency Department at M Health University of Minnesota Masonic Children's Hospital.

StarTribune May 10, 2020

A Gown for U: University of Minnesota students saved local hospitals from running out of PPE

A small group of students from the University of Minnesota just invented a new Class 1 medical device and got it into production. It took them two weeks.

MAY 10, 2020 — 2:17PM



Jennifer Brooks
@STIBROOKS

The next time it feels like the world will never get better and there's nothing anyone can do to make it better, remember this.

A small group of students from the University of Minnesota just invented a new Class 1 medical device and got it into production in time to save the university medical center and a children's hospital from running out of personal protective equipment.

It took them two weeks.

The University of Minnesota Medical Center and the University of Minnesota Masonic Children's Hospital were running through thousands and thousands of protective gowns each day. They tried to buy more, but the supply chain from China was broken and every other hospital was competing for the gowns that were left.

The solution was waiting in the last place they looked. The Department of Biomedical Engineering and 18 student volunteers from Prof. [Steven Saliterman's](#) biomedical engineering classes.

The M Health Fairview hospital system needed gowns that were affordable, disposable, one-size-fits-all, and safer than the garbage bags doctors and nurses have been forced to wear elsewhere.



STEVEN S. SALITERMAN - STAR TRIBUNE

A Gown for U. When local hospitals were at risk of running out of protective gowns, University of Minnesota Professor Steven Saliterman turned to his biomedical engineering students.

The students broke the big problem into small parts. During the first group call, Anna Karos started sketching and cutting out gown prototypes on Post-it notes. She led the design team.

"We prototyped with trash bags, with tablecloths, we picked up whatever plastic sheeting we could find at the stores," she said.

With each new design, they consulted with doctors and nurses, who offered suggestions or pointed out flaws but ended each meeting on the same note: "Whatever you have, it's OK. It's OK. We just need something." Instead of a trash bag with armholes, the students designed a gown with sleeves, wraparound ties at the waist and thumb holes, so the sleeves tuck neatly into gloves. The students gave up nights, weekends, free time and class time to work on the project. Nels Shafer divided his time between design work and his terminally ill grandmother, who was fascinated by the project. "She told me how happy and proud she was of this effort," said Shafer, who lost his grandmother to cancer shortly after the first gowns went into production. "I'm always going to remember that. My effort is dedicated to my grandmother."

The M Health Fairview hospital system needed gowns that were affordable, disposable, one-size-fits all, and safer than the garbage bags doctors and nurses have been forced to wear elsewhere.

Every manufacturer, medical supplier and PPE broker they approached told them no, or didn't return the call, or put them on a waiting list.

On April 17, the hospital reached out to Saliterman, who reached out to his students, who hopped on a Zoom call.

"If you can help at times like these, take the initiative," said Malcolm Pithawalla, who led the team of students that searched for an affordable source of raw material for the gowns. "People are in it together, and everybody wants to help each other out. What better way than to collaborate and solve a problem one step at a time?"

Fixing America's broken PPE supply chain wasn't a lesson students could learn from a textbook.

"Something like this, it's almost like a crash course," said Logan Remington. "I find it so much more useful than anything else that I've learned in college." Saliterman teaches classes on medical device prototyping, but his students have their entire senior year to come up with a medical device. Now deadlines were tighter and the stakes here were much higher. "We'll take it," Saliterman told Dr. Kevin Wang, the anesthesiologist who first reached out to him. "Give it to my students and we'll solve it."

While the design team worked on the gowns, the materials team, led by Sam Newell and John Liu, figured out what they should be made from and how. After dozens of calls and few takers, they found [Polar Plastics](#) in Oakdale. Not only did the company take the job, some of its clients offered to delay standing orders to give the hospital gowns priority. By the end of the next week, high-quality antistatic polyethylene film was [rolling off the assembly line](#), ready to be fabricated into gowns. Ten thousand gowns a day for the next six to eight weeks.



University of Minnesota student Anna Karos modeled one of the protective gowns she helped design. Students managed to get the gowns designed, approved by the FDA, and into production locally in the space of two weeks. Photo credit: Professor Steven Saliterman

Waiting to fabricate those gowns was [Red Fox Innovations](#) in Arden Hills, which took the job even though barely half its workforce has returned to work. "They told us, 'We need 350,000 gowns. Can you help?'" said Red Fox President Jon Boor Boor, who gets a lot of calls like that these days. This time, he said, his company [could help](#). One team of students sought regulations and guidance from the Food and Drug Administration to make sure the federal government had no objection to the gown project. Another team kept track of records, including the 700 e-mails exchanged during those two weeks. Production of the new "Gowns for U" began in earnest on May 1. Thanks poured in from the hospitals, from pediatric nurses who got to test the first prototypes, from administrators who will sleep a little easier at night. For team members like Peter Linden, the gown project brought a sense of purpose and comfort after weeks of dislocation and isolation. On campus, just seeing other students studying at the library or working in the labs made him feel "like you're part of a collective effort," he said.

"Being pulled out of that leaves a gap. This has helped fill it," Linden said. "Just to feel like you're on a team with people, trying to solve a legitimate problem in your community. It's been neat."

WCCO TV Minnovators May 14, 2020



MINNOVATORS



Protective Gown

6:45 53°
WCCO

WEATHER WATCHER

This block contains a graphic for the 'Protective Gown' segment. It features the 'MINNOVATORS' logo at the top. Below it is a photograph of a man and a woman wearing blue protective gowns and face masks, demonstrating the product. To the right of the photo is the text 'Protective Gown'. At the bottom right, there is a weather graphic showing '6:45 53°' and the 'WCCO' logo. At the bottom center, there is a 'WEATHER WATCHER' logo.



Downloads & Links

- [Gown for U Project Webpage](#)
- [Star Tribune Article May 10, 2020 \(PDF\)](#)
- [WCCO TV Minnovators May 14, 2020](#)
- [KDHL Radio 920 \(PDF\)](#)
- [College of Science & Engineering \(PDF\)](#)
- [Department of Biomedical Engineering \(PDF\)](#)
- [Institute for Engineering in Medicine \(PDF\)](#)
- [University of Minnesota Press Release \(PDF\)](#)
- [Design of Medical Devices COVID-19 Response Session June 9, 2020 \(PDF\)](#)
- [Office of Technology Commercialization - Open Access Licensing](#)
- [Prof. Steven S. Saliterman Teaching Website](#)