Tuff Cuff™ Technology

Solving leakage at the Glove-Gown Interface

Maine-Lee
technology group, LLC

The problem of problem leakage

Problem Leakage at the Glove-Gown Interface has been identified by Surgeons/ HCP and CDC/NIOSH as **a major weakness in surgical gowns**

Surgeons and HCP (Health Care Providers) have **acknowledged and published** the ongoing problem of fluid leaks at the glove-gown interface

The number of articles published on this issue **have grown significantly** from the period 1995 – 2009 vs 2009 – 2023

# of Publications Glove-Gown Interface

CDC/NIOSH - starting in 2015 - have published multiple articles to establish methodology and results studying the issue

CDC/NIOSH are striving to have recommendations to the FDA to update the existing guidance and specifications for surgical gowns by Q2 2027

“Protective clothing challenge - leaving no body unprotected”

RUN BY National Institute for Occupational Safety and Health NIOSH®

377 participants

WITH JUDGES FROM

NASA · National Institute for Occupational Safety and Health NIOSH® · CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

3rd place won by MLTG

SEPTEMBER 2022

- MLTG was **invited by the CDC** to participate in the challenge
- Tuff Cuff finished **3rd out of 377 participants**
- MLTG was the **only non-medical teaching hospital or medical entity** that placed in the top 5 winners

MLTG's solution

Tuff Cuff™ Technology

Solving leakage at the glove-gown interface

MLTG's patented* Tuff Cuff™ prevents leakage by creating tortuous paths for fluids

*US 12,041, 990 B2

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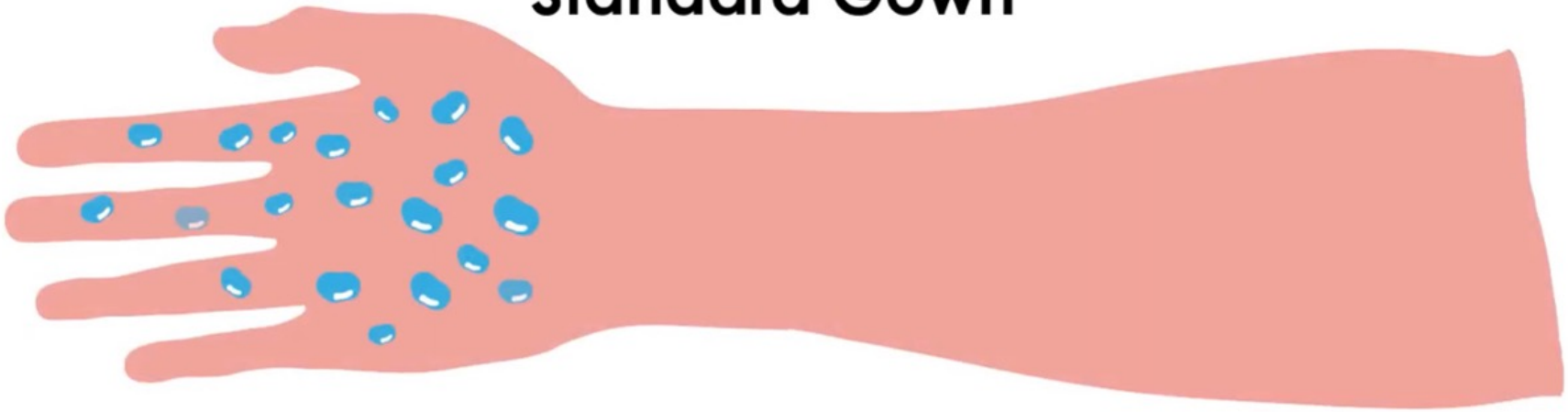
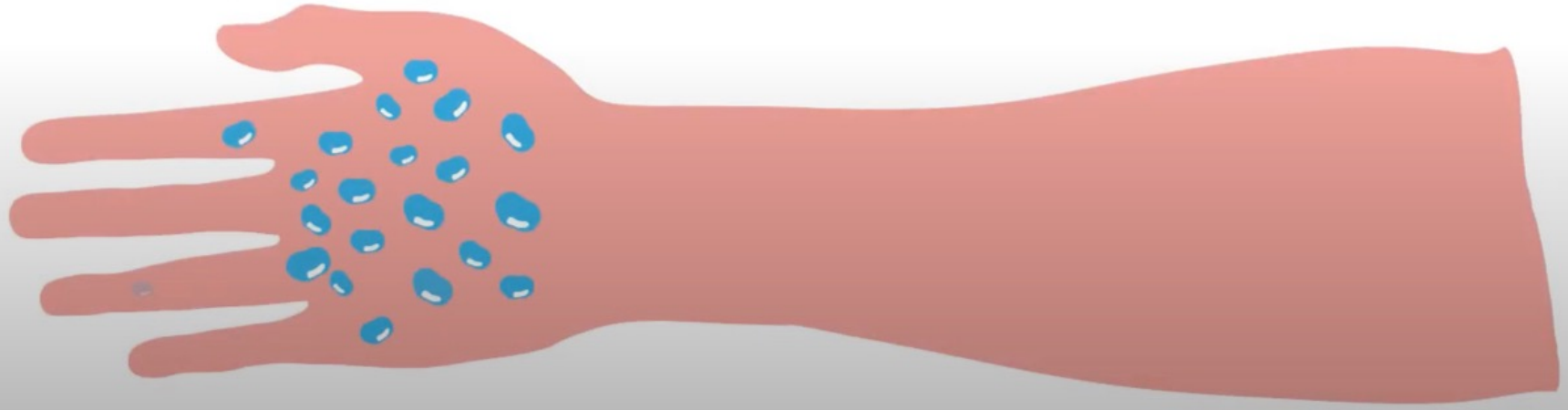
Standard Gown



Maine-Lee Tuff Cuff™ Solution Also Protect The Patients



Click here to play video:
https://www.youtube.com/watch?v=Q4JheLJqggA&t=12s

Seeing is believing

Click here to play video:
https://youtu.be/dw2DJjP2Twc

Independent Lab Testing using CDC/NIOSH Methodology w/Human Arm (Donn, Dunk and Doff)

Leakage Glove/Gown Interface, g

Control Predicate Gown w/o Tuff Cuff™	Predicate Gown w/ Tuff Cuff™
Leakage	No leakage
4.8,g	0,g

Maine-Lee, Vartest Laboratories, and CDC/NIOSH Collaborating on Improved Laboratory Testing

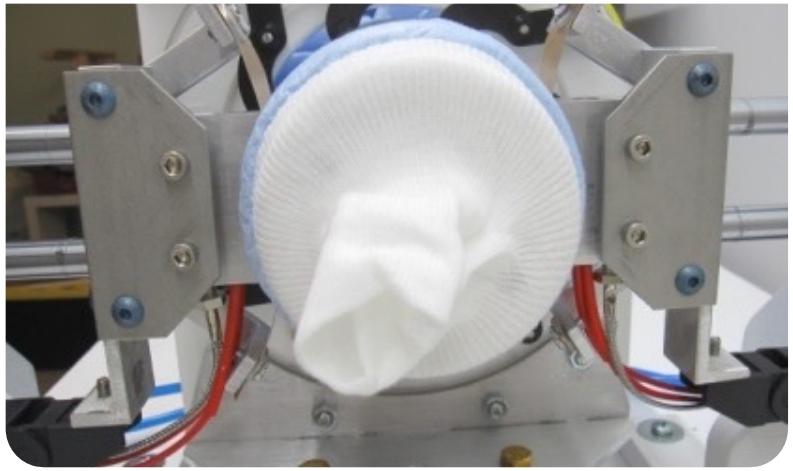
Methods to manufacturing

Current Gown Processes

Use automated methods of cutting the body and sleeves; however, the assembly processes still rely on **slow and manual based sewing processes** to assemble the cuffs, collars, and sleeves to the body

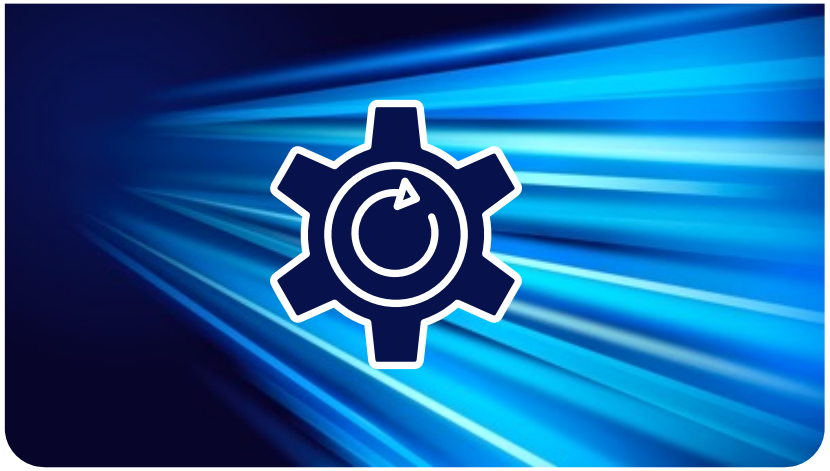
Tuff Cuff™ assembly module

MLTG has developed the patent pending* Tuff Cuff™ assembly module that can be used with a buyers premade sleeve or in a **semi-automated** process that makes the sleeve

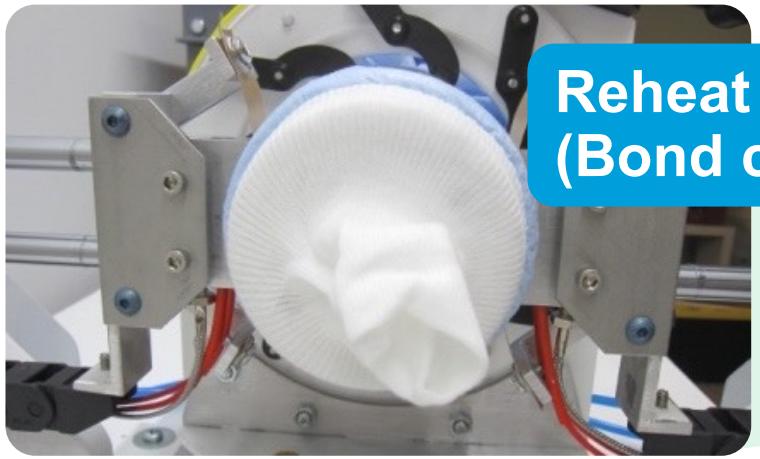


Continuous motion

The MLTG process and choice of cuff materials are **ready for the newly developed continuous motion higher speed machines recently being used for manufacturing** gowns developed by equipment manufacturer such as Curt G. Joa Inc.



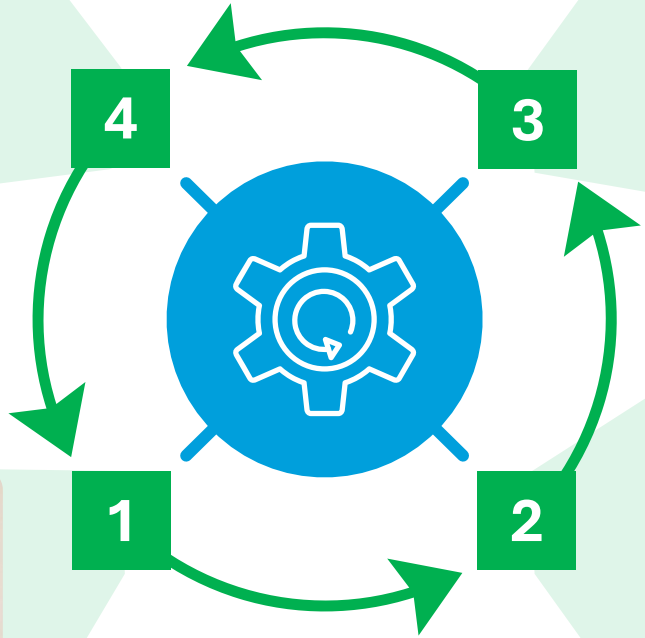
Tuff Cuff™ assembly modules have been built and are being used to manufacture gowns today for 510k



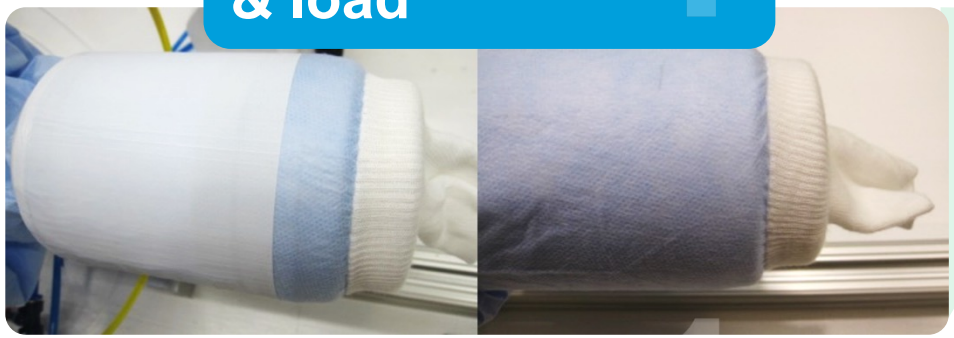
Reheat (Bond cuff) 4

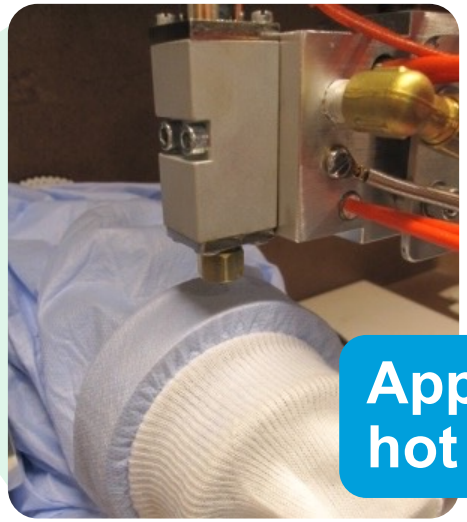
Apply Cuff 3

Cuff maker

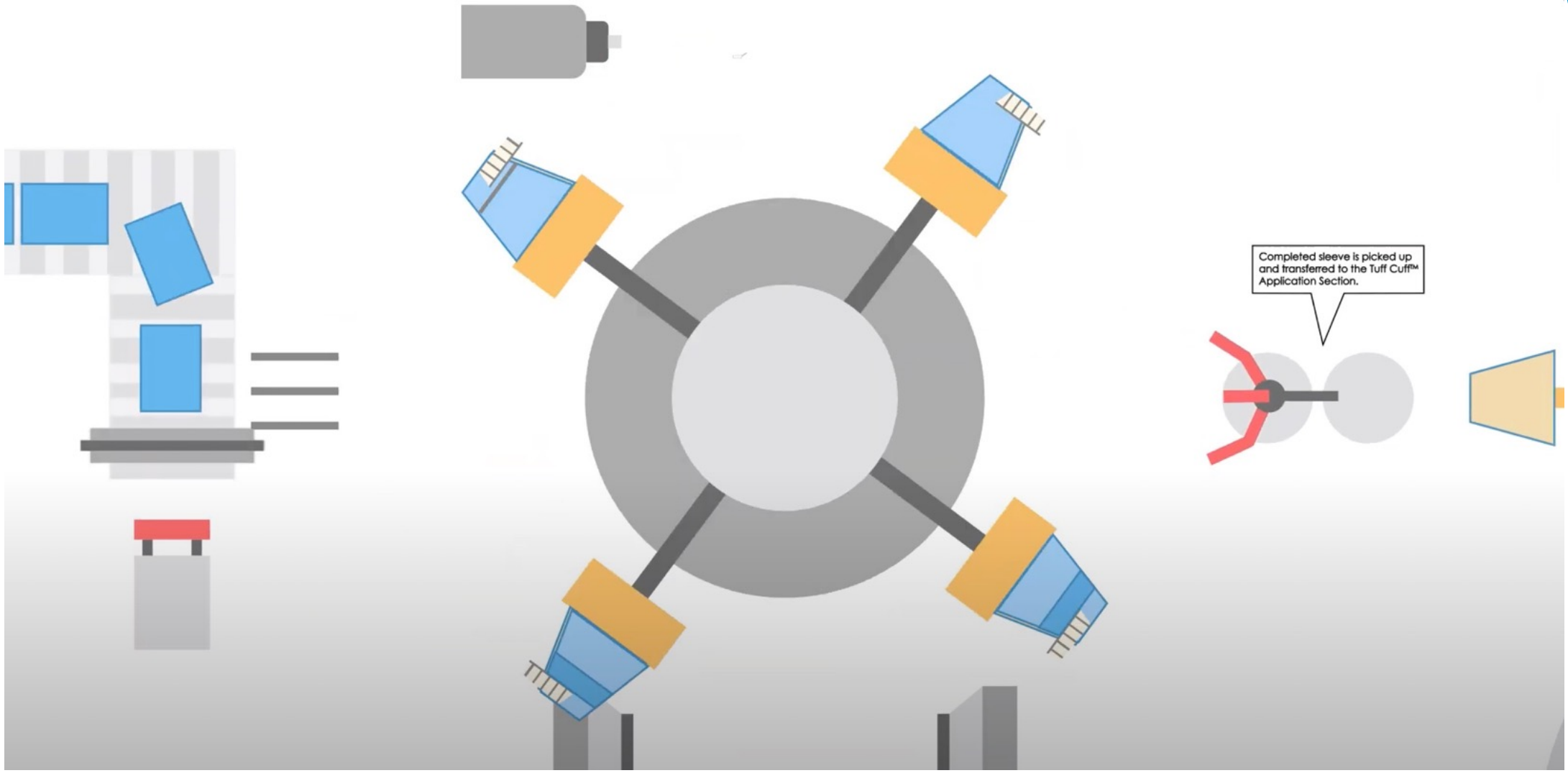


Sleeve unload & load 1



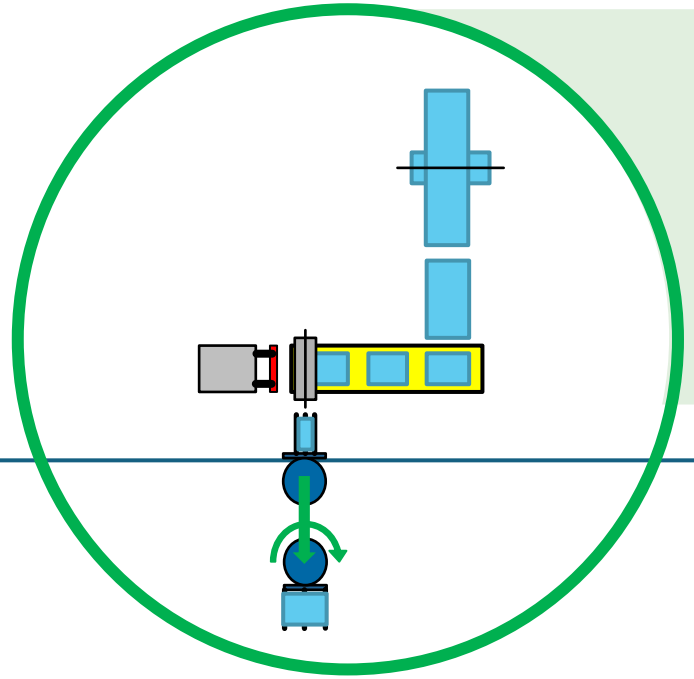


Apply hot melt 2



Click here to play video:
https://www.youtube.com/watch?v=2GU-4Tdzty4

Tuff Cuff™ Integration into Curt G. JOA high-speed gown machines would require a minor upgrade to add the cuff making step



Making the Tuff Cuff™ by either forming the ring and adding to the sleeve or placing the material flat prior to forming the sleeve

Commerical Gown Making Line

For additional details contact

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Estimated Cost of Making Assembled Sleeve US vs China

	Materials	Labor	Depreciation	$/Gown
Current Gown Sleeves **China***	$0.76	$0.24	$0	**$1**
MLTG-Gown Sleeves** **US**	$0.75	$0.42	$0.02	**$1.19**
MLTG-Gown Sleeves** **China**	$0.74	$0.18	$0.02	**$0.94**
MLTG-Gown High Speed **US****	$0.75	$0.12	$0.04	**$0.91**

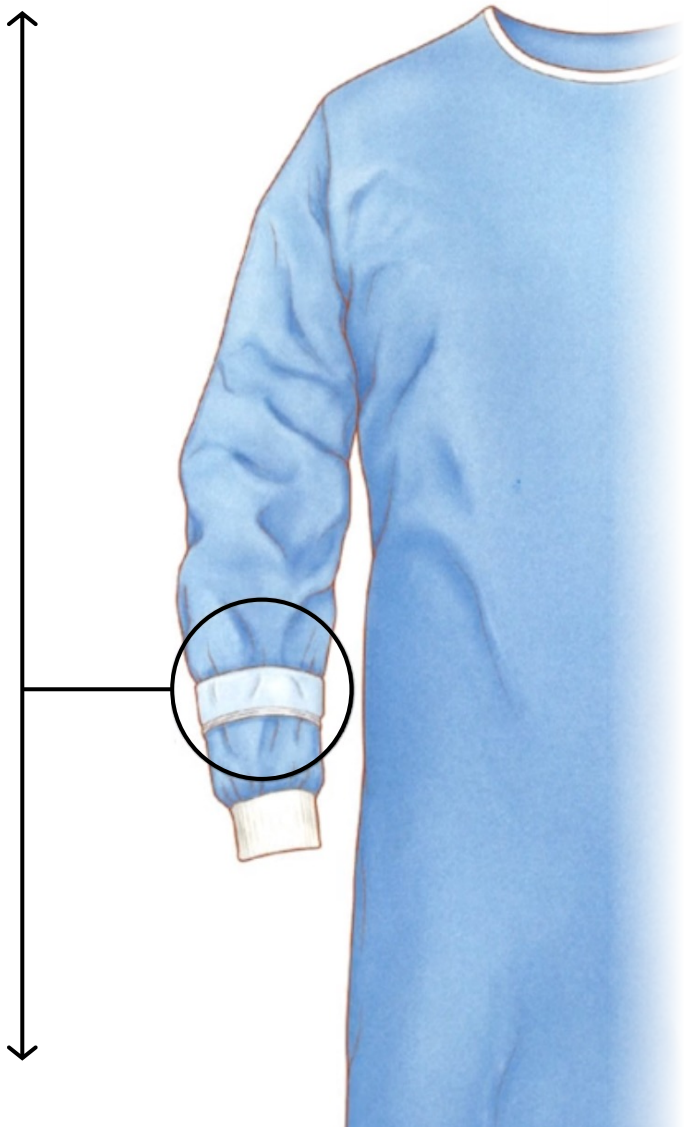
MLTG Gown and Assembly Process deployed in the US is still slightly above the cost to Import; however, the same process in China is a significant savings over gowns

MLTG Gown and Assembly For the first time has a process on high speed is now competitive and possibly savings over current Chinese made gowns automated gown making lines is competitive and possibly a savings vs. current China costs

*Current Gown = Knit Cuff | MLTG-Gown = thumbhole/No Knit Cuff** | X Works

Strong IP estate with Trademarks and Utility Patents

	Filing date	Issued
Tuff Cuff™ Common Law Trademark	● Aug 26, 2020	● Jul 23, 2024
US 12,041, 990 B2 Continuation in Part to PCT/US2020/048052	● Aug 26, 2020	● Jul 23, 2024
U.S. Patent Application No.: 18/760,702 Continuation of US 12, 041, 990	● Jul 01, 2024	○ TBD
U.S. Patent Application No.:18/762,518 Split into 3 Divisional Applications	● Jul 2, 2024	○ TBD
PCT International Application No. PCT/US24/36430	● Jul 1, 2024	○ TBD



Market size and facts

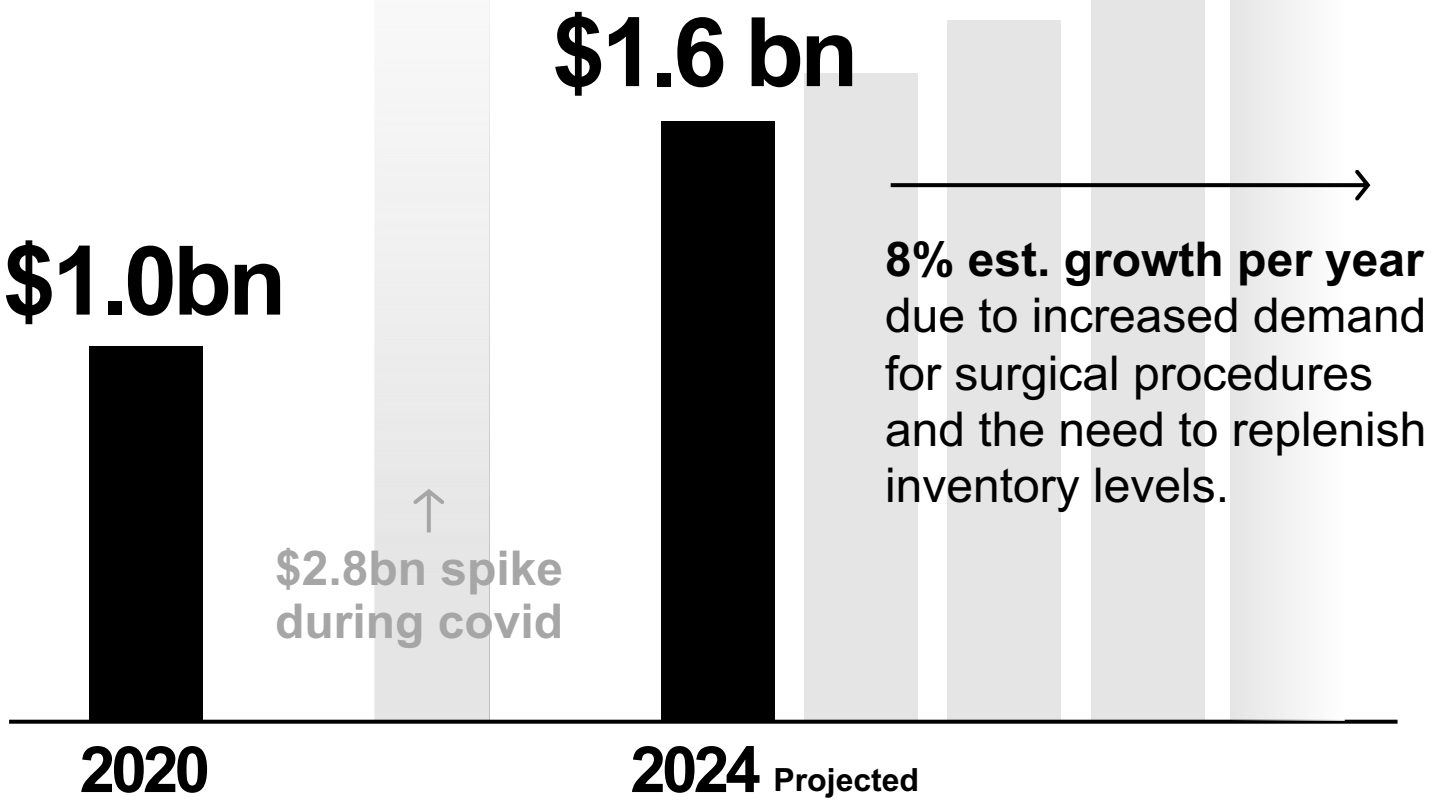
Current 2023 Total Gown **(surgical gowns + isolation gowns)** market is

$8 billion

90% Imports

(80% from China)

Surgical gown only market U.S. and Canada



Double these estimates for the global market

Regulatory status

Filed Pre-Submission 510K to the FDA to review

1	Classification	FDA agreed with the predicates proposed. De Novo application is not required
2	Testing plan and matrixes - FDA proposed expansion of testing	FDA proposed expansion of testing
3	**Performance claims and support**	**FDA agreed with label claims language of "improved glove-gown interface leakage protection" but required additional parameters be included in the laboratory claims support testing**

MLTG agreed to follow up with protocol.
Currently on schedule to be submitted in December 2024

Upon completion of the 510k will allow IP buyer of the technology to use the MLTG 510k to start sale in the US or use the 510k as a predicate to fast track additions/ changes if needed

FDA 510(k)

Key development milestones

1st Patent Approved Issued

July 23, 2024

510K Gown Production Completion

Oct 2024

510K Sterilization Validation, Testing & 510K Submission

Mar 2025

510K Approval

Jun 2025

1st Patent Continuation Filed

TBD

2nd Patent Filed

July 2nd

(Split into 3 Divisionals)

Maine-Lee Tuff Cuff™ checks all the boxes for a company purchase opportunity

- Proven performance superiority
- Solicited and recognized as a solution by the CDC, NIOSH, and NASA NTL
- Proven method of making
- IP protection
- Cost of goods parity or lower than industry benchmarks
- Sizable market
- 510k submission in progress
- Aligned with potential new FDA regulations for Glove-Gown interface requirements

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