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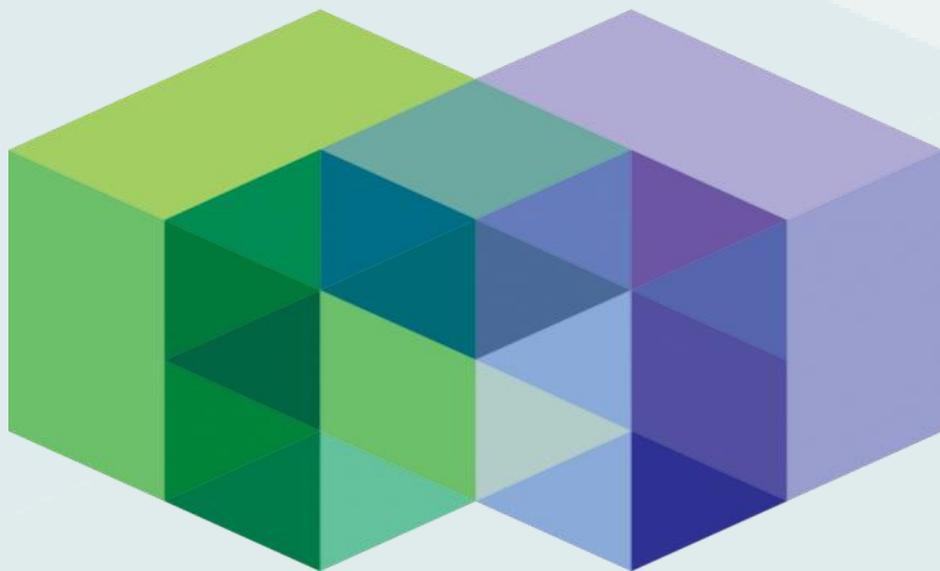
# **Innovative Treatment for Burn Patients and the Importance of Public-Private Collaboration in Drug Development**

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**Derek Naten, Vice President, Government Affairs and Patient Advocacy, Mallinckrodt**

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## Landscape of US Burn Injuries



~**500,000** burn injuries receive emergency treatment annually<sup>1</sup>

**40,000** require hospitalization<sup>1</sup>

~**86%** are thermal burn cases<sup>2</sup>

~**15,000** receive autografts during their hospital stay<sup>3,4</sup>



~**4500** people die as a result of burn injuries<sup>5</sup>

Older adults are an especially **vulnerable population** at increased risk of death<sup>6,7</sup>

Burns are the eighth leading cause of death in those 65 years or older<sup>7</sup>

Mortality rate rises with the **% TBSA burned**<sup>8</sup>

A 50% case fatality (LD50) occurs once burns are 60% to 70% TBSA<sup>8</sup>

**References:** 1. Burn Incidence Fact Sheet. American Burn Association. 2. Schaefer TJ, et al. Thermal burns. 2020. 3. Yu TC, et al. *Burns*. 2020;46(4):825-835. 4. McDermott KW, et al. Agency for Healthcare Research and Quality (US). 5. Burns. CDC website. 6. Spronk I, et al. *PLoS One*. 2018;13(5):e0197507. 7. Burn Injury Fact Sheet. American Burn Association. 8. Bitter CC, et al. *Wilderness Environ Med*. 2016;27(4):519-525.

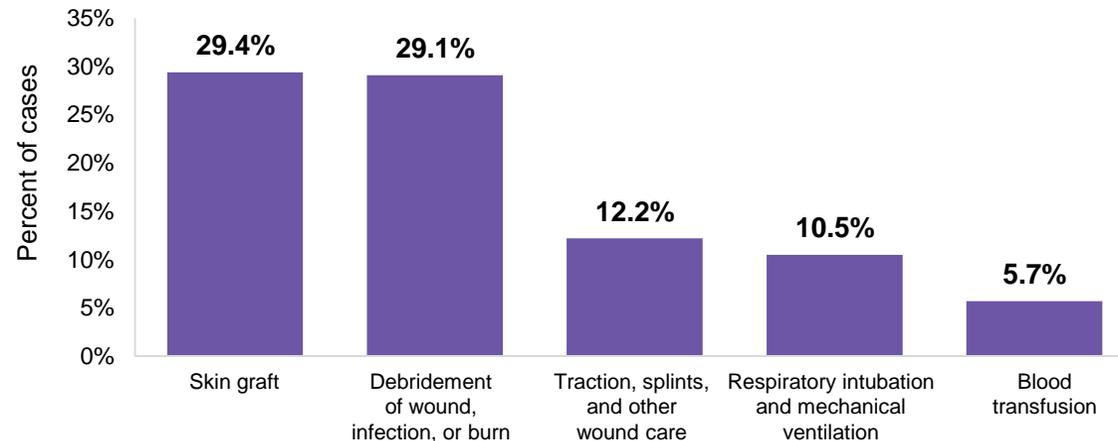
Please see Important Safety Information and full [Prescribing Information](https://www.stratagraft.com) at [StrataGraft.com](https://www.stratagraft.com).

# Burden of Burn Injuries in the US

Burn injuries can lead to several complications, with high short-term and long-term clinical burden.

## Interventions in burn-related hospitalization stays<sup>1</sup>

71% of inpatient stays had at least one of the following procedures:



Long-term care of burn injuries requires physical and rehabilitative therapy to maintain the range of movement and maximize functional ability in addition to the management of psychological distress

References: 1. McDermott KW, et al. Agency for Healthcare Research and Quality (US).

Please see Important Safety Information and full [Prescribing Information](#) at [StrataGraft.com](#).

# Economic Burden of Burn Injuries on the US Healthcare System

## Burn injuries are associated with substantial economic burden

-  The **mean total healthcare cost** per burn patient in high-income countries was **\$88,218 (range \$704-\$717,306; median \$44,024)**<sup>1</sup>
-  Direct medical costs represent only 10% of the total, which included costs due to **lost work productivity**, leading to additional economic burden<sup>1</sup>
-  Burn-related inpatient stays were **almost twice as long and more than double the cost** of non–burn-related inpatient stays<sup>2</sup>
  - Mean cost per day: \$24,000 vs \$10,700; mean hospital length of stay (LOS): 8.1 days vs 4.5 days

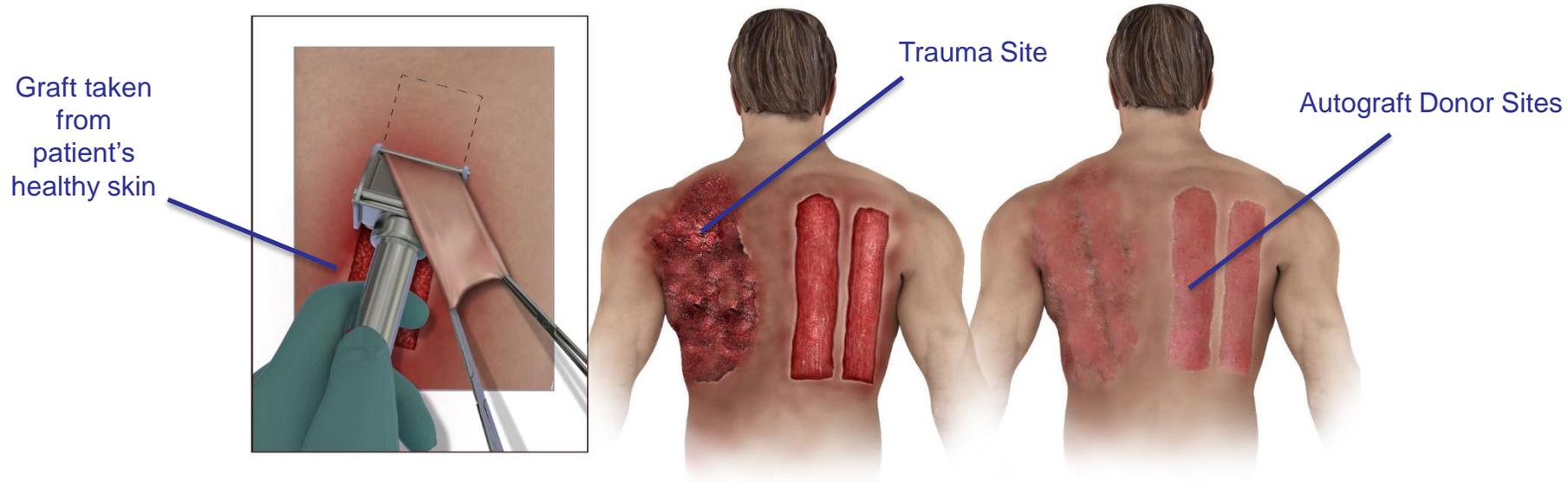
Abbreviation: HIRD, Health Insurance Responsibility Disclosure.

**References:** 1. Hop MJ, et al. *Wound Repair Regen.* 2014;22(4):436-450. 2. McDermott KW, et al. Agency for Healthcare Research and Quality (US).

Please see Important Safety Information on slide 6 and full [Prescribing Information](#) at [StrataGraft.com](#).

## Autografting: Current Standard of Care in Severe Burns

- Autologous skin grafting is a common practice in the treatment of severe burns
- Involves the excision of a sheet of healthy skin from an uninjured site (donor site) and transplantation to the wounded area on the same patient
- Creates a new, painful wound that is prone to infection, scarring, and long-term morbidity



# Autographing: Potential Outcomes



## Donor site complications

Area of wounded skin increased<sup>1</sup>

More pain<sup>1,2</sup>

Increased risk of infection<sup>1,3</sup>

Scarring and discoloration<sup>1,2</sup>

Possible compromised tissue function<sup>4</sup>



## Delayed healing

In older adults or patients whose wound-healing capabilities are compromised<sup>5</sup>



## Limited by donor site availability

In patients with burns of 50% to 60% of total body surface area (TBSA)<sup>6</sup>



## Disadvantages of reharvested donor sites

Can lead to prolonged hospitalization<sup>6</sup>

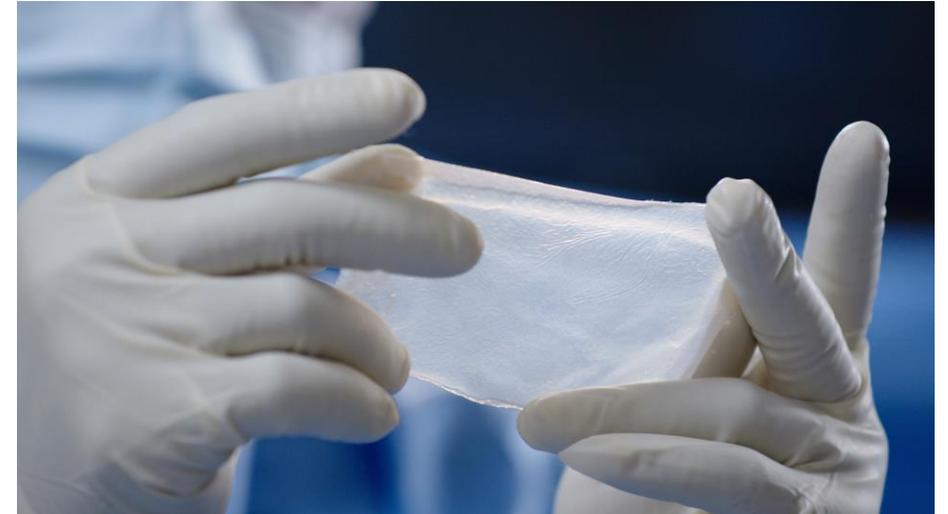
Decreased quality of the skin from reharvested sites<sup>6</sup>

**References:** 1. Sinha S, et al. *J Trauma Acute Care Surg.* 2017;83(5):954-964. 2. Burnett LN, et al. *Burns.* 2014;40(6):1097-1105. 3. Weber RS, et al. *Arch Otolaryngol Head Neck Surg.* 1995;121(10):1145-1149. 4. Serebrakian AT, et al. *Plast Reconstr Surg Glob Open.* 2018;6(9):e1928. 5. Osborne SN, et al. *Adv Skin Wound Care.* 2016;29(2):57-64. 6. Girard D, et al. *Tissue Eng Part B Rev.* 2017;23(1):59-82.

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# StrataGraft: Regenerative Product for the Treatment of Burns

- StrataGraft is a human cellular, bioengineered, regenerative skin construct
- Food and Drug Administration approved for the treatment of deep partial thickness (DPT) burns
- Product is rectangular 100 cm<sup>2</sup> format that is cryopreserved with an 18-month shelf life
- Product is handled, meshed, and applied similarly to an autograft; it contains both inner dermal and outer epidermal layers composed of well-characterized human cells<sup>1,2</sup>
- Product contains a dermal layer with human fibroblasts and an epidermal layer of fully-stratified NIKS epidermal keratinocytes – a continuous source of long-lived human epidermal progenitors – delivers viable cells to support the body's own ability to heal<sup>1,3</sup>



Initially discovered at the laboratory of Lynn Allen-Hoffman at the University of Wisconsin-Madison. Partnership at the state and federal level was critical to help bring StrataGraft to patients.

# StrataGraft vs. Autograft Treatment: Forearms



## StrataGraft Product Development History

Date	Activity
2000	Stratatech founded in University Research Park in Madison WI
2007	StrataGraft Phase I/II clinical study initiation
2012	Food and Drug Administration (FDA) awards Orphan Drug designation to StrataGraft
2013	Biomedical Advanced Research Product Development Authority (BARDA) initial funding award
2016	Stratatech Acquired by Mallinckrodt
2017	StrataGraft Phase III clinical initiation (deep partial thickness burns)
2017	FDA grants StrataGraft Regenerative Medicine Advanced Therapy (RMAT) status
2018	BARDA award additional funds to begin StrataGraft pediatric clinical trial
2019	StrataGraft Phase III enrolment completion
2020	Biological License Application submission
May 2021	FDA pre-approval inspection
June 2021	FDA approval of StrataGraft

# The Importance of FDA Designations and Development Pathways

## FDA Regenerative Medicine Advanced Therapy (RMAT) Designation Program

- A part of the [21<sup>st</sup> Century Cures Act](#) passed in December 2016
- This designation aims to help foster the development and approval of regenerative medicine products
- A drug is eligible for RMAT if it:
  - Is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
  - Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs
- RMAT designation allows for increased and earlier interaction with the FDA; and products may be eligible for priority review and accelerated approval by the FDA
- Following approval, allows for use of real-world clinical evidence (clinical studies, patient registries, electronic health records)

To date, FDA has publicly granted 53 RMAT designations; including for StrataGraft

## Orphan Drug Designation

- The [Orphan Drug Act](#) was passed in 1983 to facilitate the development of drugs for rare diseases in the United States
- Provides incentive to develop drugs in the rare and orphan disease space, including market exclusivity and tax credits
- Rare disease defined as one that affects under 200,000 patients
- Approximately 450 orphan drugs have been brought to market since the law took effect
- According to the National Organization for Rare Disorders (NORD) there are more than 7,000 rare diseases and more than 30 million Americans living with a rare disease

# The Importance of Public-Private Partnership: Federal Opportunities to Support Research and Development of New Treatments – the StrataGraft Example

## The National Institutes of Health

- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs encourage domestic small businesses to engage in research and development of new products
- Enables small businesses to explore their technological potential
- Stratatech received an SBIR grant critical to getting the technology started, and to develop more specialized skin constructs

## Defense Medical Research and Development Program

- The Defense Medical Research and Development Program/Military Infectious Disease Research Program (DMRDP/MIDRP) funding awards allow for the advancement of medical and scientific research to fill gaps by funding high impact, high risk and high gain projects
- Stratatech was awarded a DMRDP/MIDRP award for preclinical studies to test the ability of a novel antimicrobial skin tissue to promote wound healing and prevent infection in combat-related wounds

## The Biomedical Advanced Research and Development Authority

- The Biomedical Advanced Research and Development Authority's (BARDA) aim is to promote the advanced development of medical countermeasures
- StrataGraft received BARDA contracts for the development of skin grafts to protect health and safety during a radiological or nuclear emergency; and for pediatric studies of the use of the product

Opportunities for federal funding provide critical resources for the development of new products, particularly at the early stages of research, to help bring new treatment options to patients

## The Importance of Public-Private Partnership: Working at the State Level



- Initial discovery that led to the development of StrataGraft made in the laboratory of Dr. Lynn Allen-Hoffmann at University of Wisconsin-Madison
- Throughout StrataGraft research and development, have continued strong partnership with the State of Wisconsin (site leasing, legislator and policymaker engagement, facility inspection)
- Continued commitment to development of the product in its “home state”: 535 Science Drive in University Research Park
  - January 2015: Occupied by Stratatech
  - 2015/2016: Facility modified and renovated for manufacturing and quality control sterility testing
  - January 2017: Began clinical Manufacturing for Phase III
  - 2017/2018: Further expansion of the site for product development, including warehousing, storage, quality control labs, and office space



## Closing Thoughts



- Supporting scientific discovery is often a “home-grown” effort, with much of the basic research taking place at University laboratories across the country
- State legislators and policymakers can play a critical role in helping to support new discoveries and their development into treatments for patients – championing scientific development, state funded programs
- Pathways to accelerate the research and development of new medications and treatments for patients play a critical role, particularly when we talk about underserved or unmet disease areas

**Questions?**