

Science of Skin:

The challenges of adhering medical devices to skin

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3M Medical Materials & Technologies

3M Medical Solutions Division



3M at a glance

- \$1.7 billion invested in R&D
- 113,000 patents
- 101 straight years of dividends
- One of 30 companies on the Dow Jones Industrial Index
- Sales in ~200 countries
- \$31.7 billion in sales
- Five business groups
- 90,000 3M employees globally



*2016 figures

The 3M Carlton Science Center



3M Science.
Applied to Life.™



How do we apply science to solve problems and improve lives?



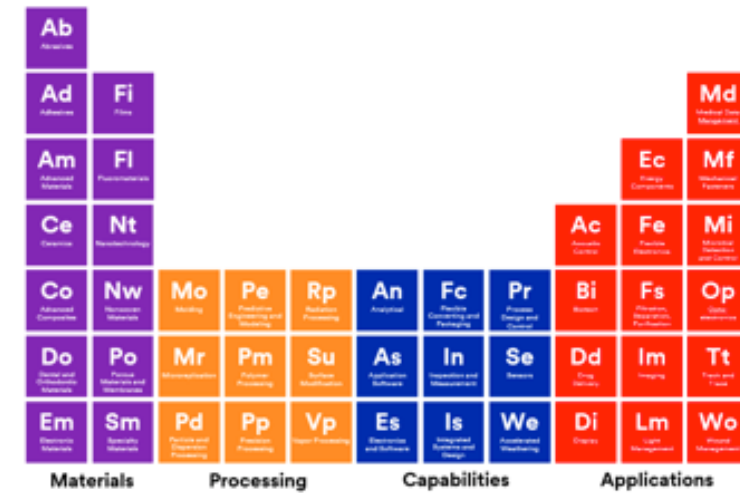
Our people and collaborative culture

+



Insights from customers and the market

+

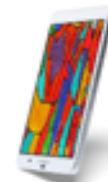


46 technology platforms

We apply individual technologies across our businesses...



Electronics & Energy



Industrial



Health Care



Safety & Graphics



Consumer



...and combine them in unique and creative ways

Ad Adhesives	Fi Films
Nt Nano-technology	Lm Light Management



High-performance window film

Ad Adhesives	Fi Films	Fc Flexible Converting and Packaging	Pm Polymer Processing
Nw Nonwoven Materials	Sm Specialty Materials	Su Surface Modification	Wo Wound Management



Medical dressings



Filtek™

Dental Adhesives,
Restoratives and Crowns



Ad Adhesives	Am Advanced Materials	Ce Ceramics	Nt Nano-technology	Co Advanced Composites
Do Dental and Ortho Materials	Pd Particle and Dispersion Processing	Su Surface Modification	Bi Biotech	

Our focus today

Medical device adhesive technology



A close-up photograph of human skin, showing texture and pores. A white geometric shape, resembling a stylized 'A' or a large triangle, is overlaid on the left side of the image. The text is positioned on the right side of the image.

The market need

Increased wear time for medical devices

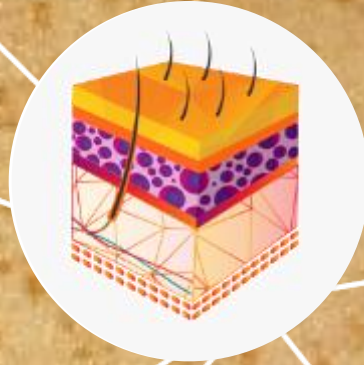
Medical devices are essential.
Can we make them more
convenient by increasing wear
time without compromising
skin safety?

Considerations for designing medical devices

- Will your desired wear time increase the risk of skin injuries?
- Have you selected the best adhesive options to trial for your medical device applications?
- Have you involved your adhesive partner early enough?
- Have you avoided design decisions and material choices that sub-optimize overall device performance?
- How do we extend our understanding of adhesive performance from the lab to the field?



**Before we talk adhesives,
we must first understand
the complexities of skin**



The Science of Skin

What do you know about skin?

1. According to the latest studies of dust in a modern home, what % is human skin?

- 80%
- 50%
- 20%

2. True or False – Humans (on average) have the same number of hair follicles as chimpanzees?

3. The average person in a desert environment, if fully hydrated, would sweat...

- ~ 1 liter per hour
- ~ 0.6 liter per hour
- ~ 0.3 liter per hour

4. True or False – Skin plays a critical role in the regulation of calcium uptake in our bones.

The science of skin

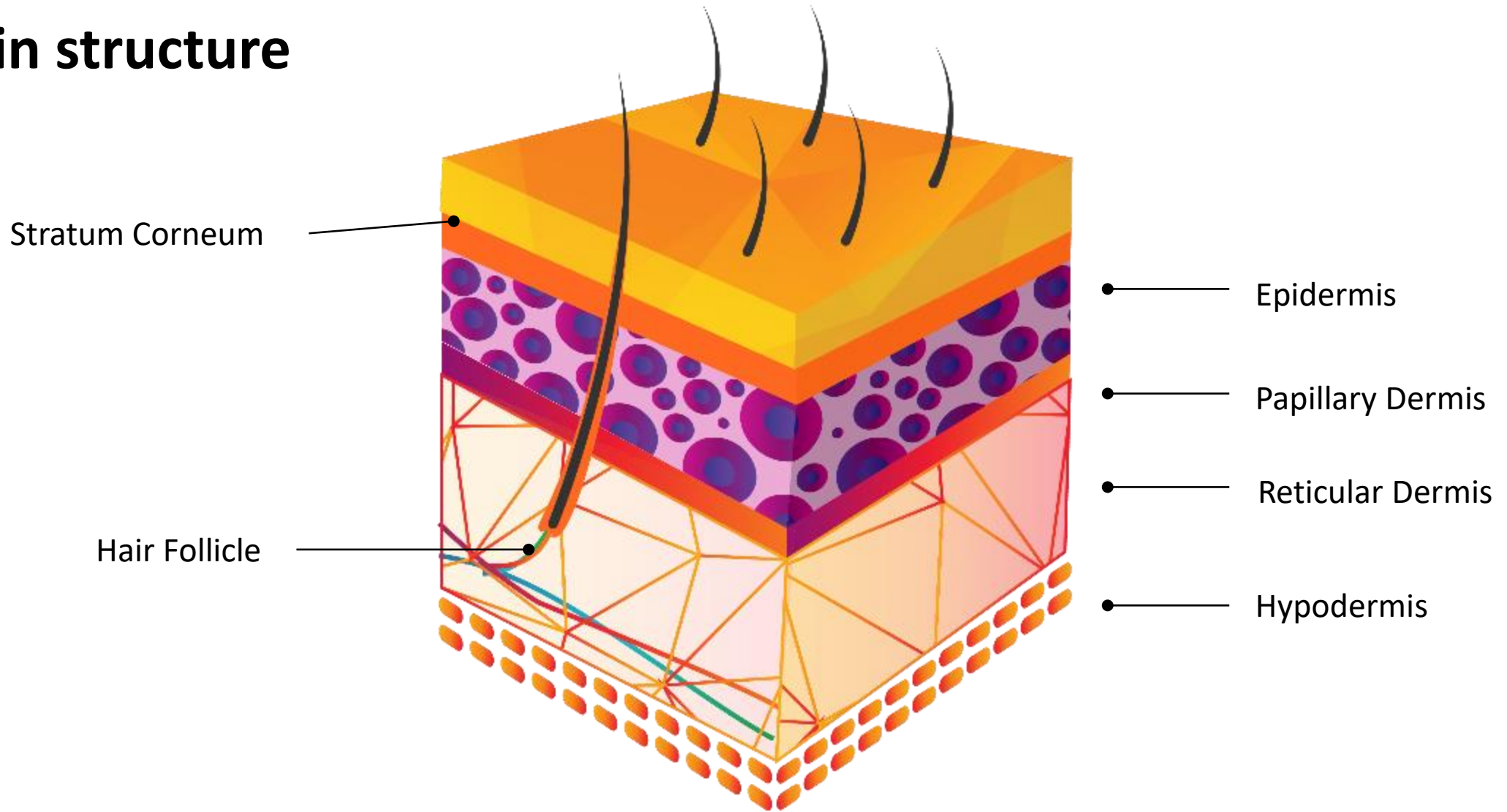
What do you think about when you think about skin?

- An elastic “organ” that covers our body
- Our interface to the world
- Physical, chemical, and microbial barrier
- Protection from the sun
- Our sense of touch relies on nerves embedded in our skin
- Contains receptors for heat, cold, pressure and pain sensations
- Self-repairing
- Supports regulation of our body temperature and phosphate/calcium



The science of skin

Skin structure



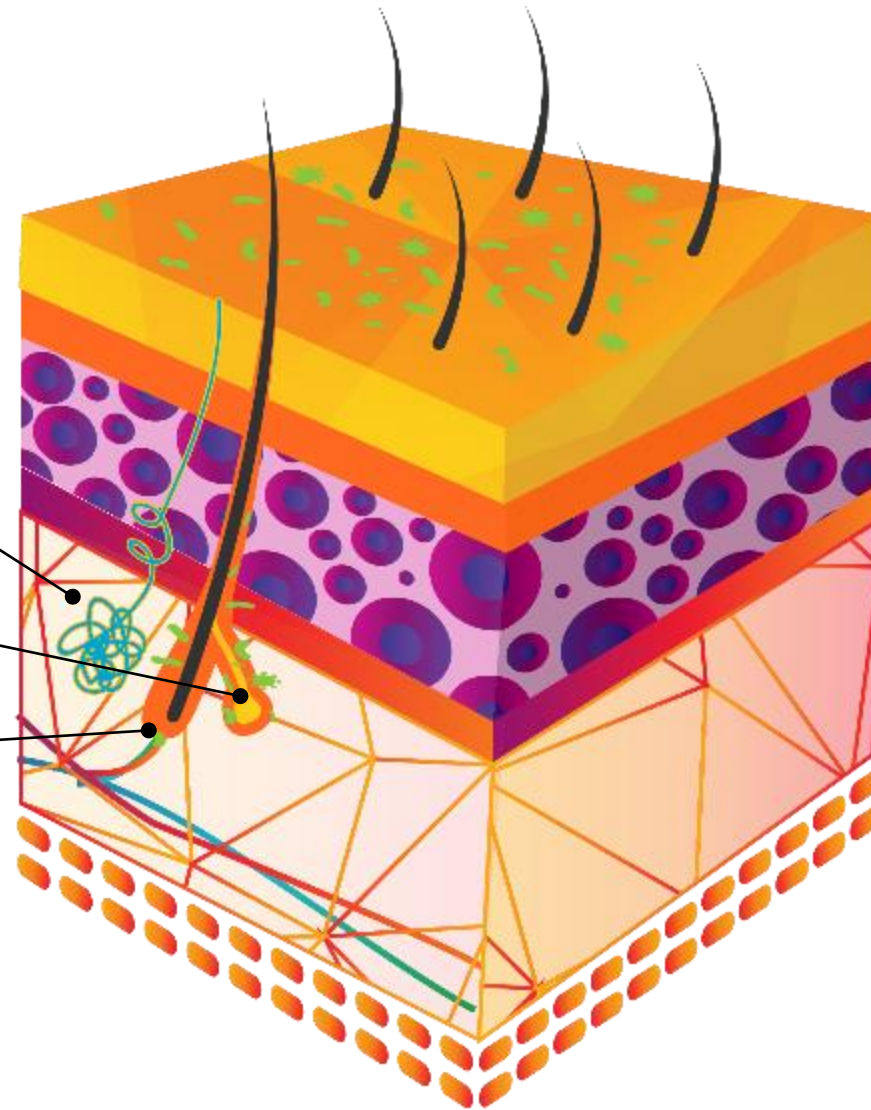
The science of skin

Microbiology of the skin

Apocrine Sweat Gland

Sebaceous Gland

Hair Follicle

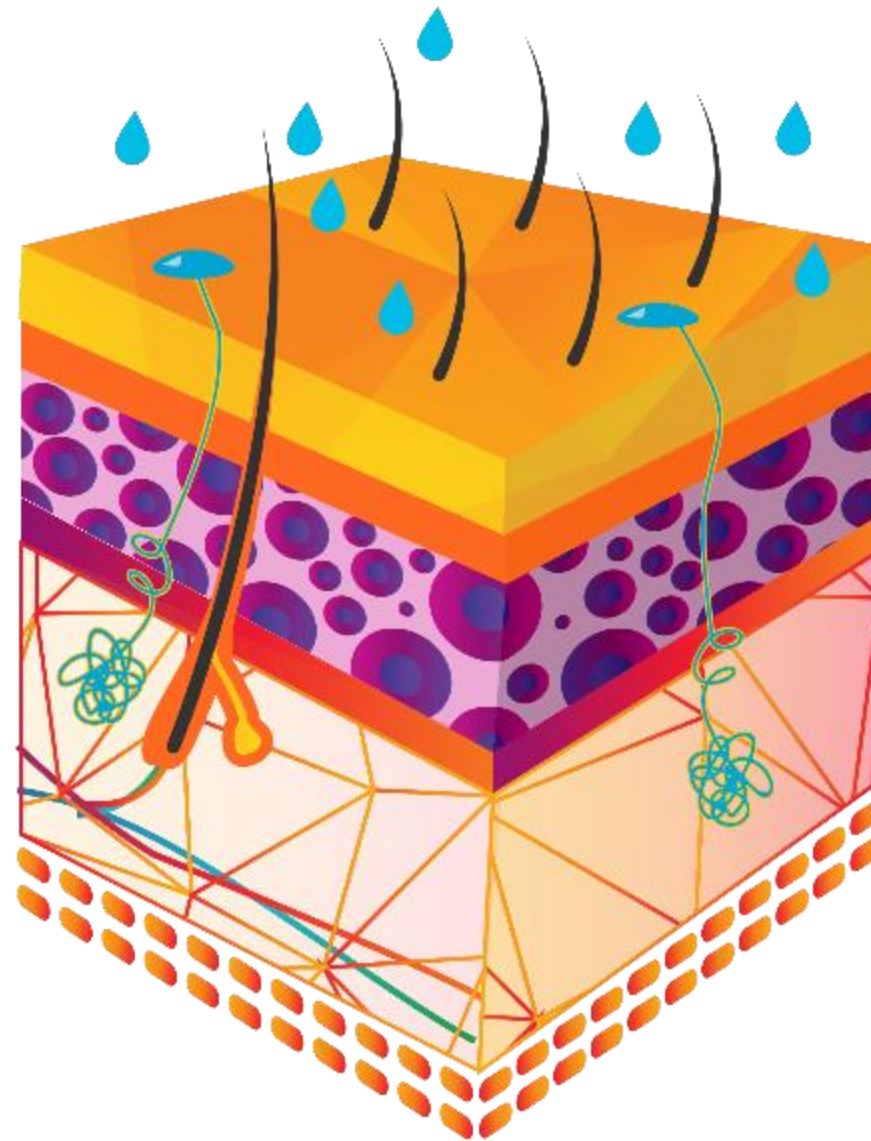


- 80% of the resident bacteria exist within the first 5 layers of the stratum corneum of the epidermis
- The remaining 20% of the resident bacteria are found in biofilms within the hair follicles and sebaceous glands
- Complete recolonization of surface bacteria can occur within 18 hours of antiseptic application

Ryder, MA. Catheter-Related Infections: It's All About Biofilm. Topics in Advanced Practice Nursing eJournal. 2005;5(3) ©2005 Medscape Posted 08/18/2005. <http://Medscape.com/viewarticle/508109>.

The science of skin

Moisture management is critical to epidermal function

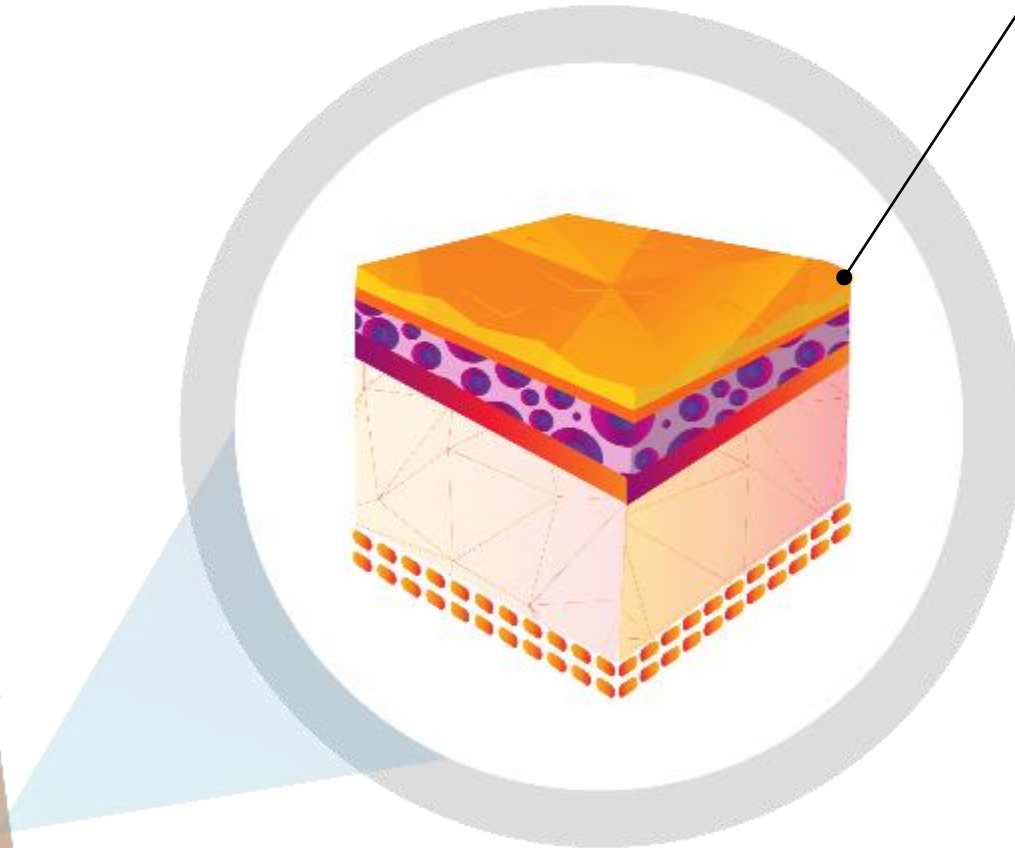


- 15% water — Flat, dead keratinized cells
- Cell death and keratinization
- Cell migration away from blood supply
- 70% water — Formation of new cells by cell division



The science of skin

Aging reduces skin functionality

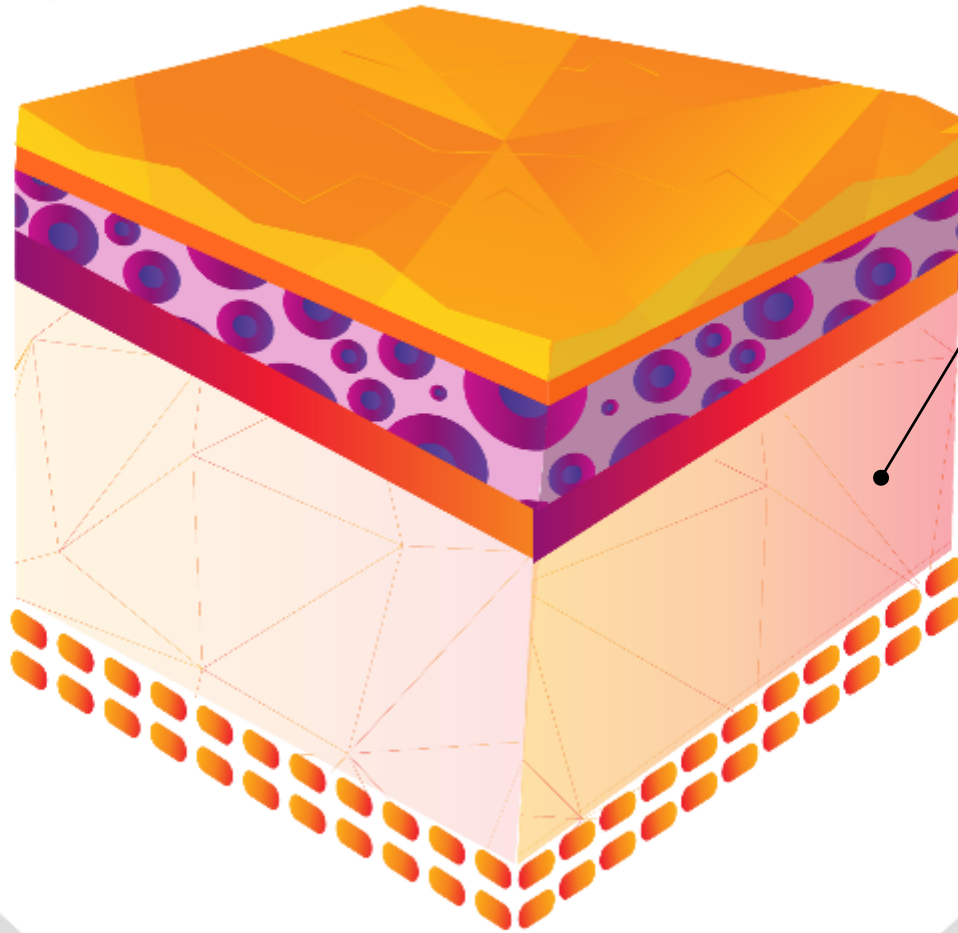


Epidermis

- Epidermis thins
- Increased TEWL
- Decreased SC lipids
- Decreased melanocytes
- Fewer functional dendritic cells
- Decreased cell turnover
- Decreased natural moisturizing factor

The science of skin

Aging reduces skin functionality

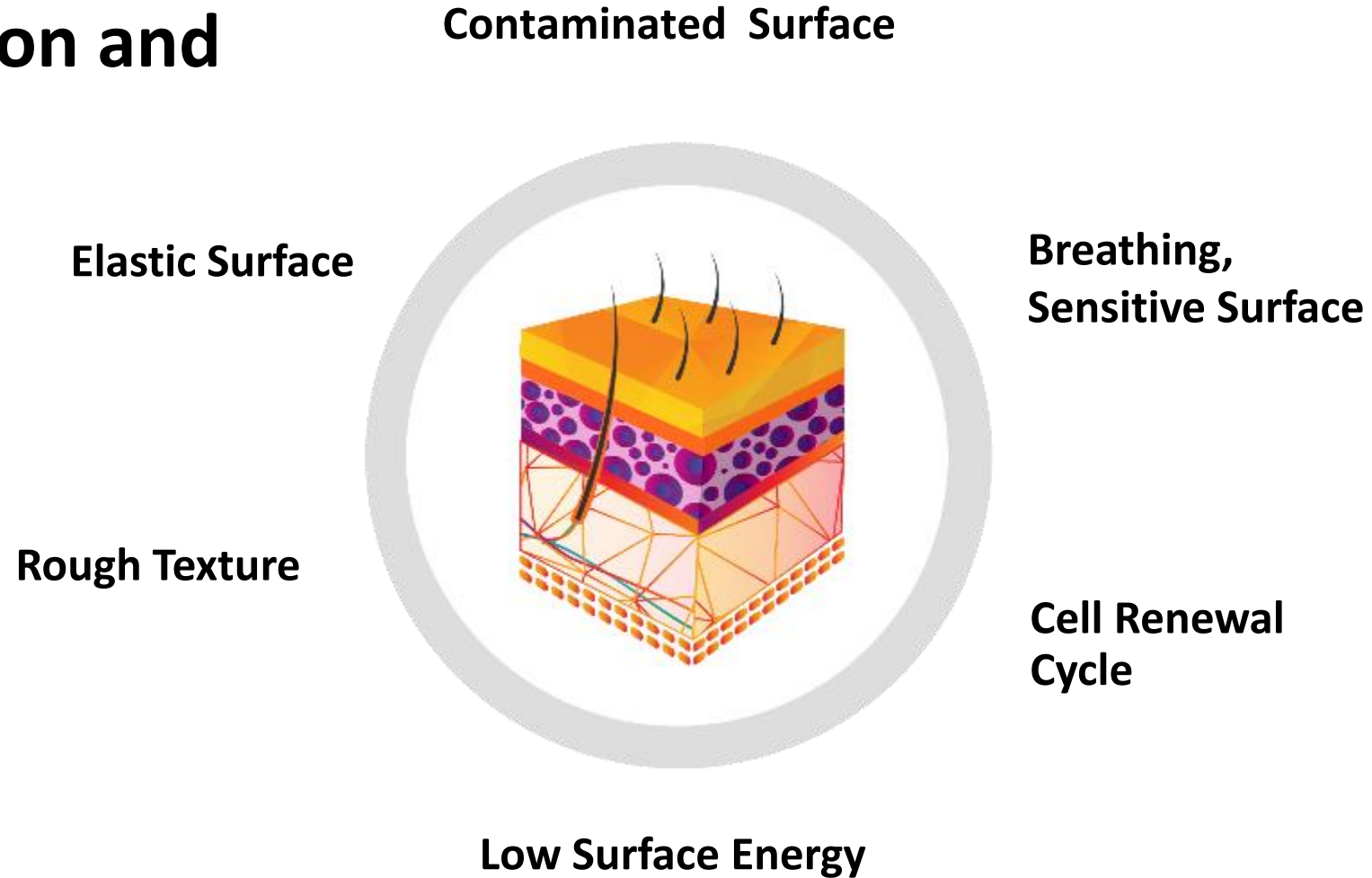


Dermis

- Reduced sebaceous gland activity
- Reduced collagen synthesis
- Collagen fibers stiffen
- Reduced elastin synthesis
- Shrinking collagen and elastin
- Increased MMP activity due to decreased MMP inhibitors
- Reduced hyaluronic acid synthesis
- Blood vessels become fragile
- Decreased sweat glands

The science of skin

Factors affecting skin adhesion and wear time





Medical adhesive tapes

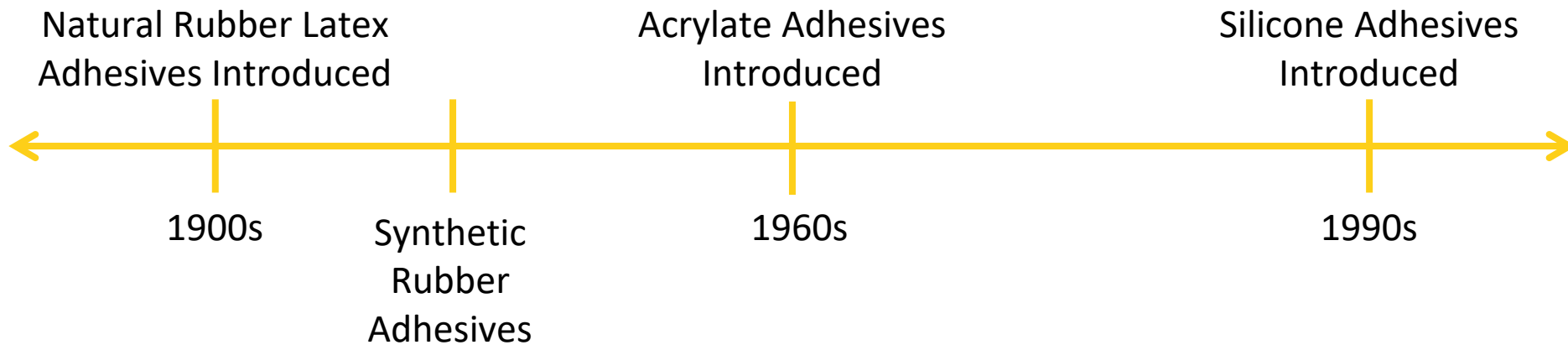
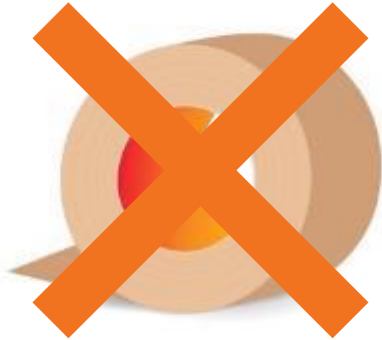
What is a medical adhesive tape?

- In the USA, medical adhesives, and the tape components created with them, should be produced under FDA current guidelines for Good Manufacturing Practices [cGMP]
- According to written operating standards that adhere to ISO:13485 Quality Management System guidelines
- In a clean facility that has dedicated validated equipment, supply chain traceability and is regularly audited for compliance to produce an adhesive tape that has been tested per ISO:10993 for biocompatibility and is shown to be safe for use on skin



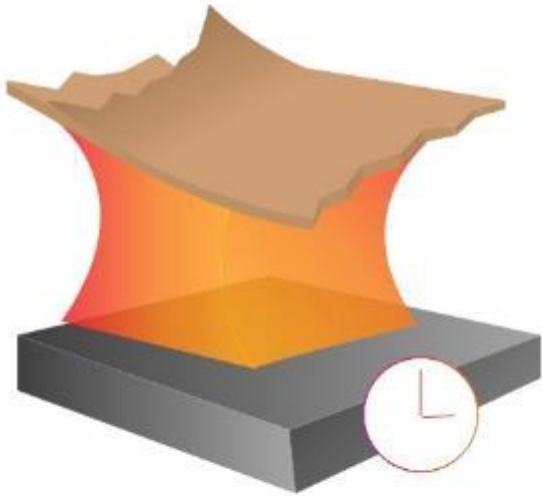
Medical adhesive tapes

Adhesives used in medical products

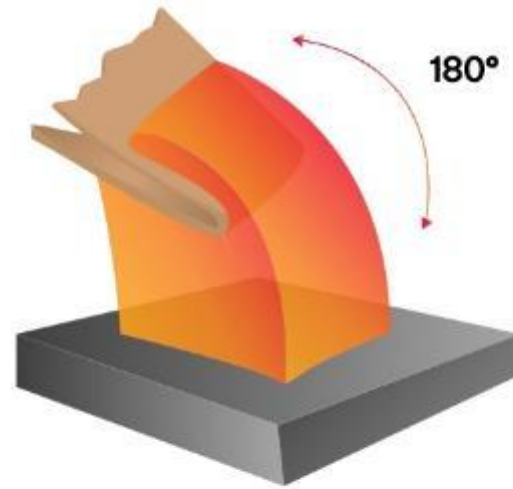


Medical adhesive tapes

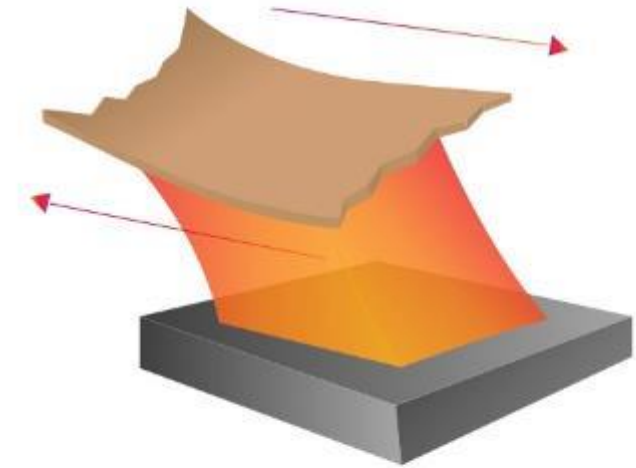
Peel strength measures (time dependent) adhesion



Tack



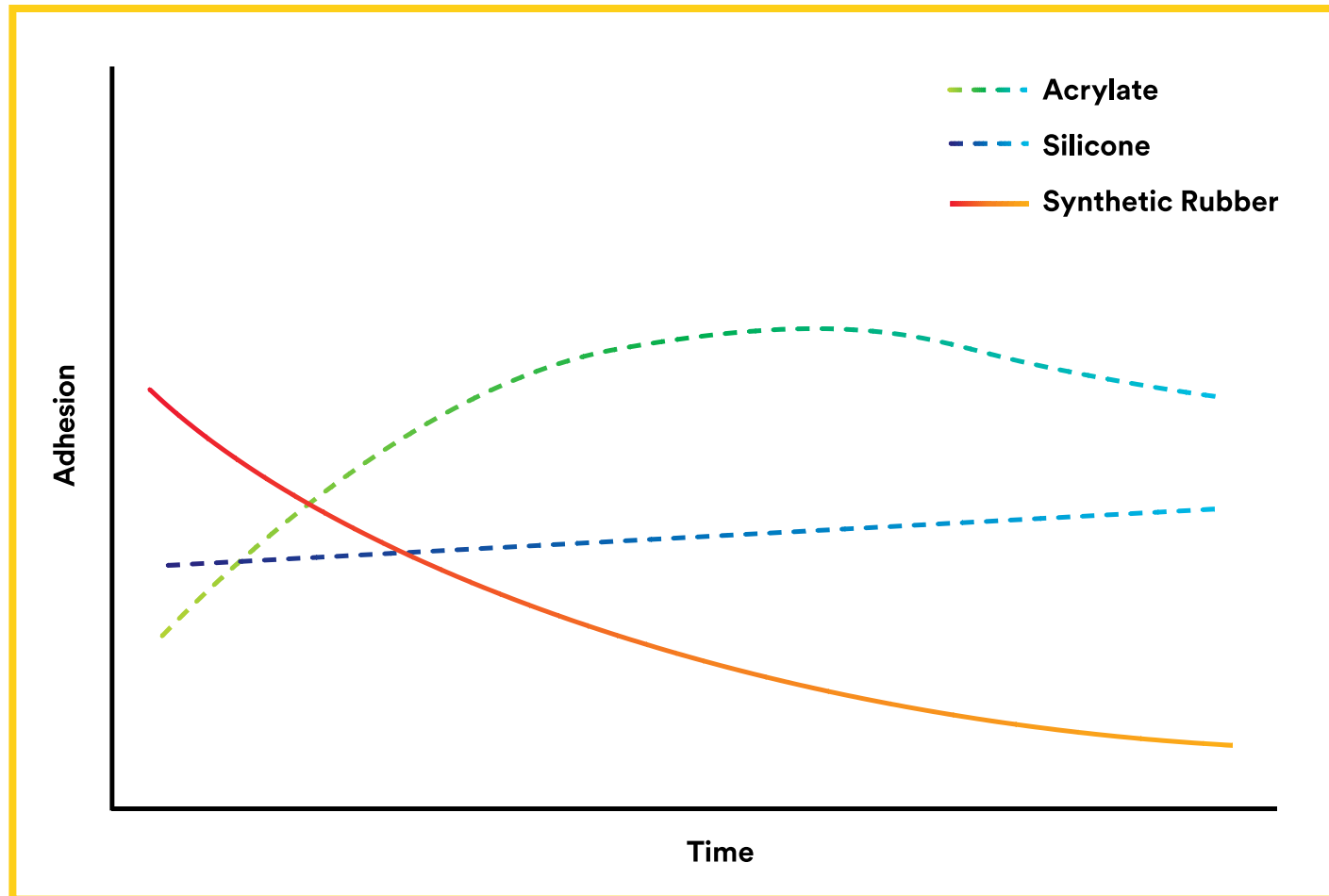
Adhesion



Shear

How various adhesives adhere to skin over time

General Skin Adhesion Profiles



Medical adhesive tapes

Avoiding skin injuries

A trade-off between adhesive performance and properties

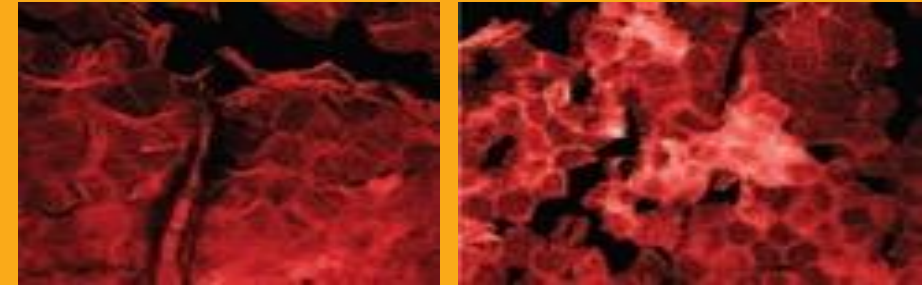


Acrylates demonstrate adhesion that increases over time

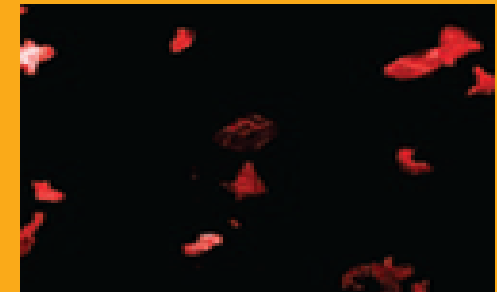


Traditional acrylates may pull on skin and hair when it's removed

Skin cell removal visualization



Acrylate Adhesives



Silicone Adhesive

A close-up photograph of a person's hand, showing the skin texture and the lines of the palm. A white geometric shape, resembling a stylized 'M' or a series of overlapping lines, is overlaid on the hand. The word 'MARSI' is written in white, bold, uppercase letters in the center of the hand.

MARSI

MARSI

Unintentional removal of skin layers is part of Medical Adhesive Related Skin Injury (MARSI)

Potential complications:

- Delayed healing
- Infection
- Hyperpigmentation
- Pain

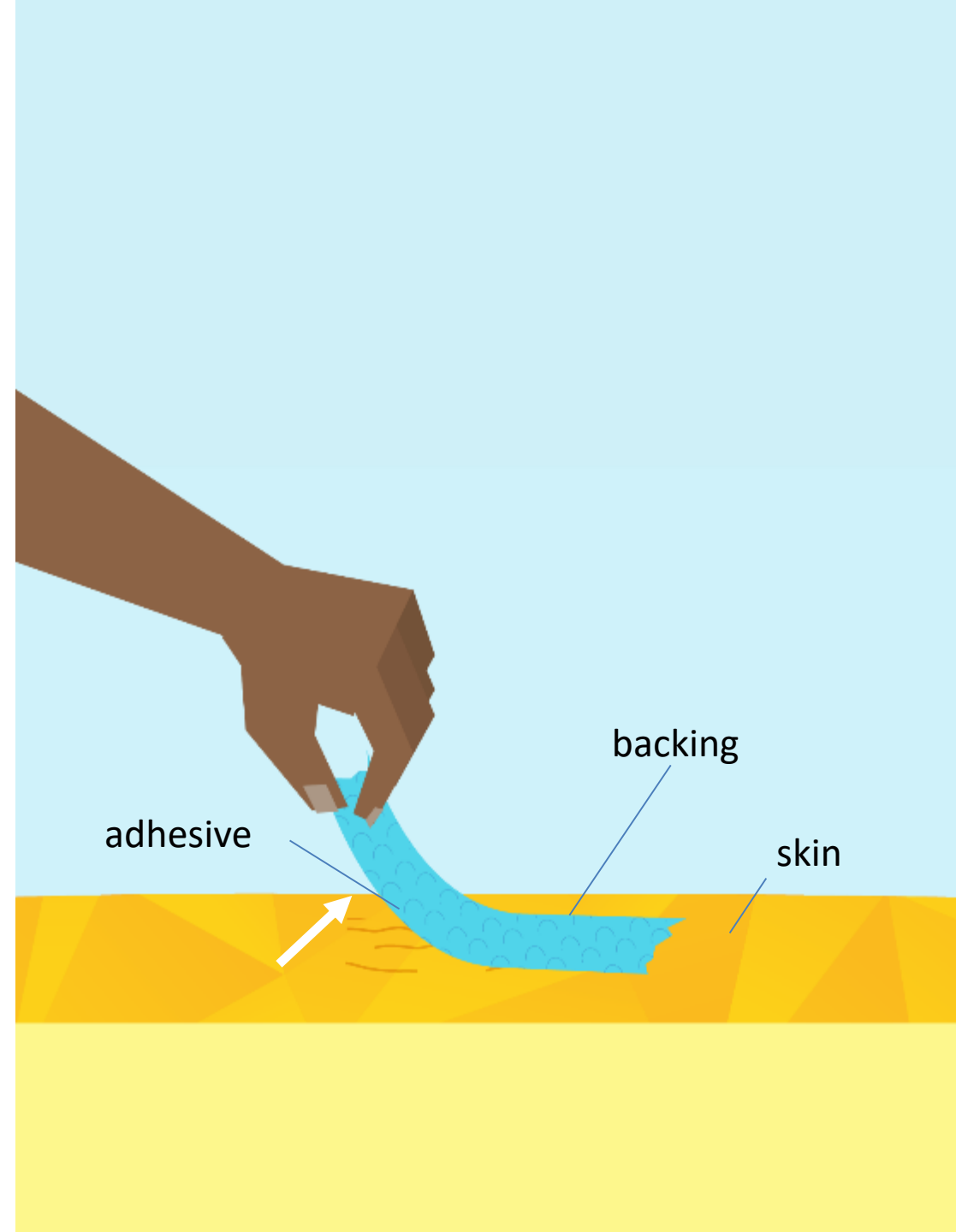
NOT THIS
MARCY



MARSI

How do medical adhesives cause skin injury?

Skin injury results when the skin-to-adhesive attachment is stronger than the skin-to-skin attachment

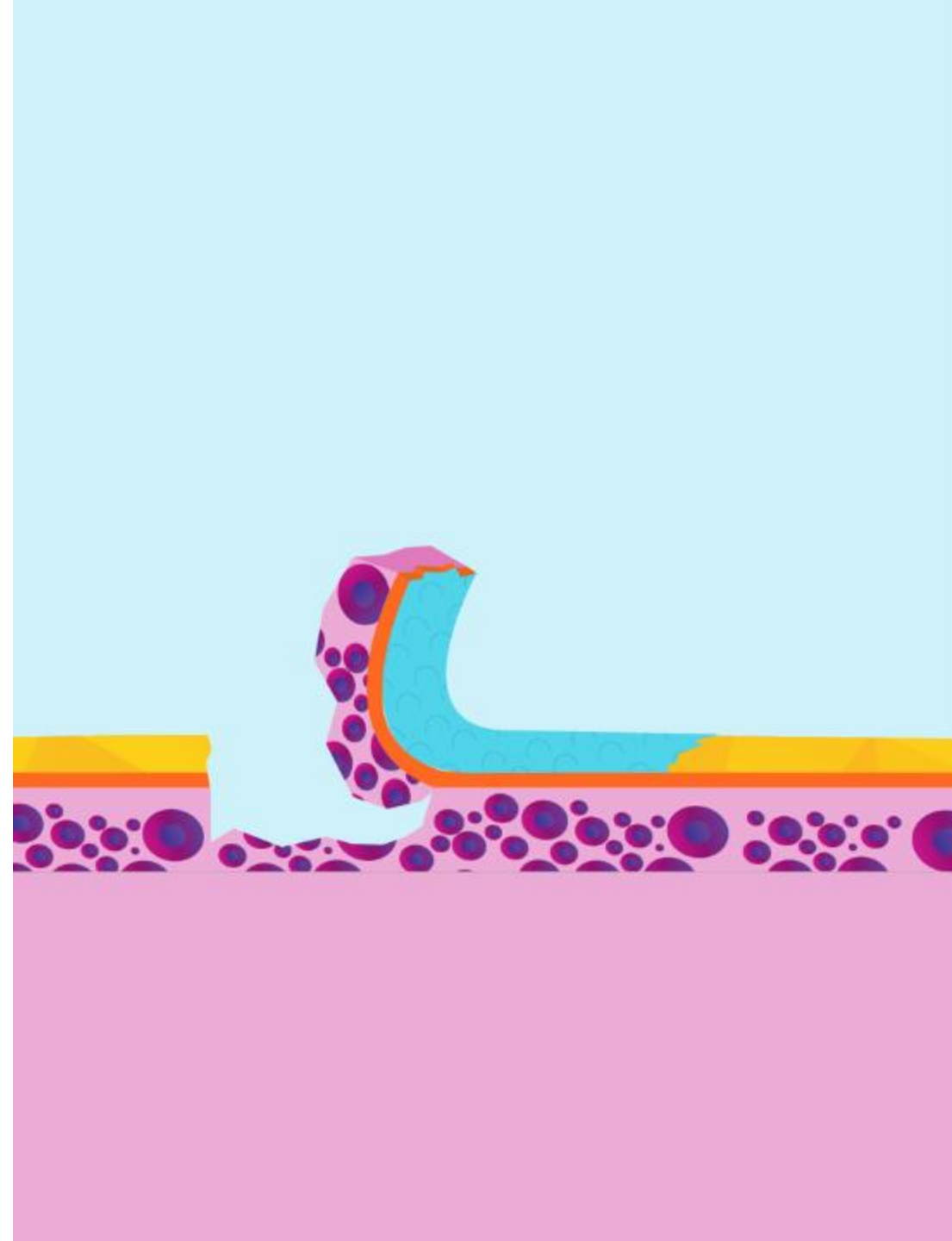


MARSI

Skin stripping

What is it?

- Mechanical injury caused by adhesives
- Epidermis detaches from itself or dermis
- Can involve few, many or all layers of epidermal cells
- Skin-adhesive attachment > skin-skin attachment
- Shiny skin is a classic “indicator” of skin stripping



MARSI

Potential patient safety concerns



Skin Stripping



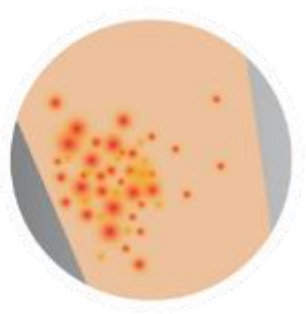
Skin Tear



Tension Injury or Blister



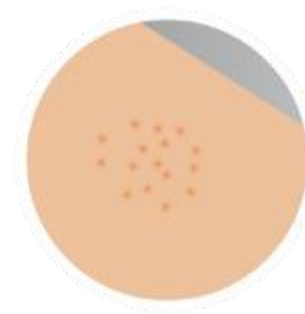
Maceration



Allergic Contact Dermatitis



Irritant Contact Dermatitis



Folliculitis

Risk factors



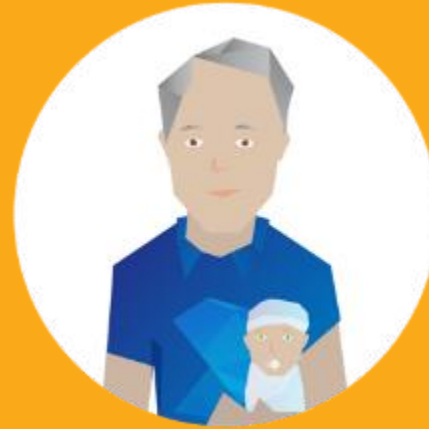
Underlying
illness



Skin changes
with sun
exposure



Immuno-
suppression



Extremes
of age



Choice of
adhesive



Finding the right adhesive

Adhering medical devices can be difficult.
**Let's find the right adhesive solutions
for your device.**

Select an option below to get started.



I want to hold device components
together



I want to stick a device to skin



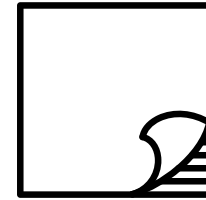
I want to overlay or cover my
device



I want to move fluid



I want to deliver an active
ingredient through the skin

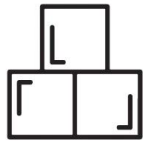


FindMyAdhesive.com

can help with adhesive selection

Adhering medical devices can be difficult.
**Let's find the right adhesive solutions
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Select an option below to get started.



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together



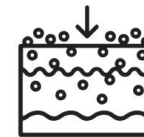
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3M Med Tech Adhesive Evaluations of Wear Time*

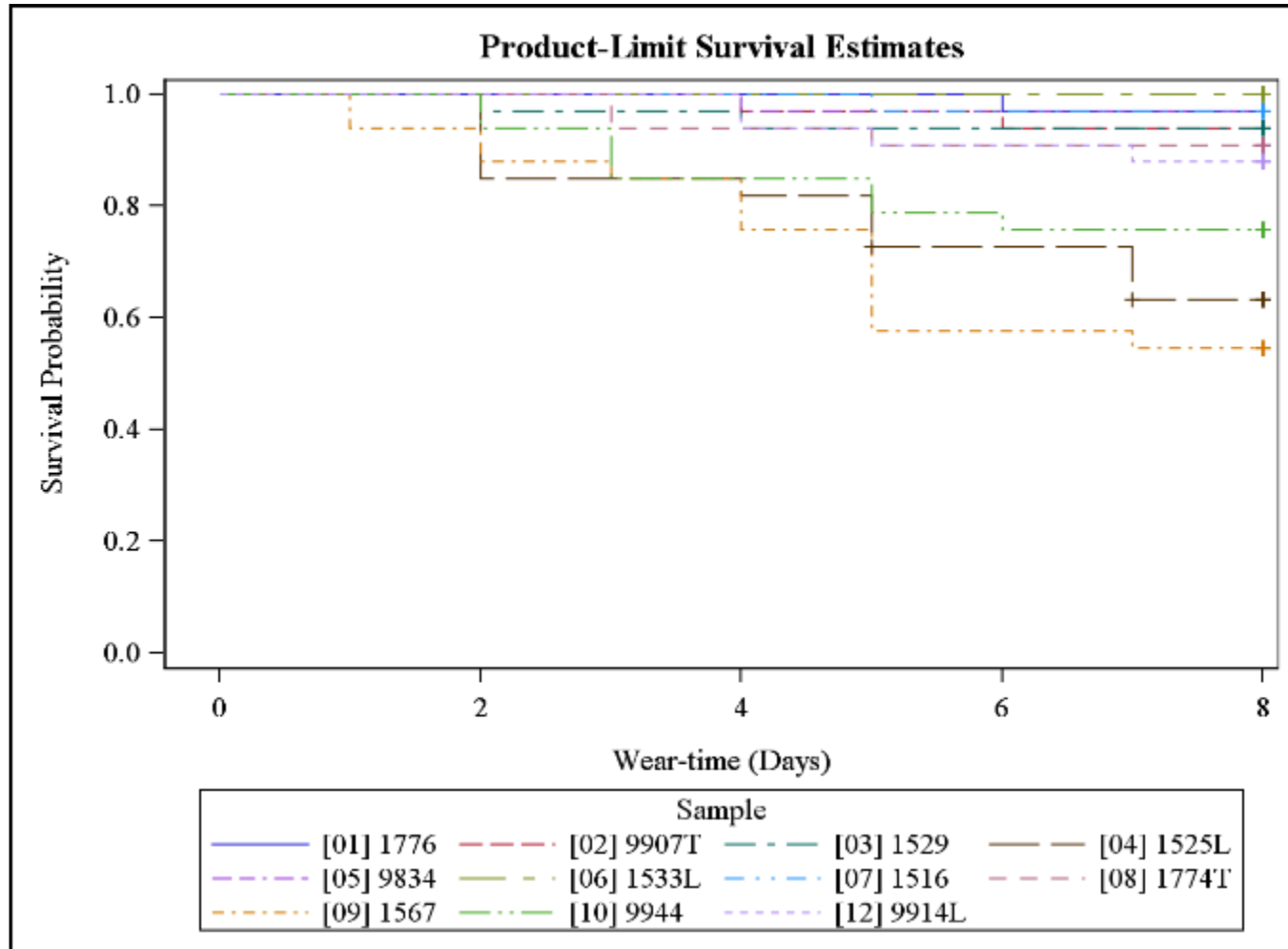
*Wear time results may vary, not a guarantee of performance

3M internal wear time studies

- Intended to screen wear time performance and skin health
- Wash to prep skin
- Clip excess hair
- 3 replicates typical
- Record activity



Wear Time Performance over 8 Days



- Target: >80% survival
- Showered, no hot tubs
- Active adults
- Recorded activity



8 day wear study*, select 3M Med Tech portfolio

Product ID	Description	% samples attached at 8 days
1533L	Single coated rayon nonwoven tape - acrylate adhesive	100.00%
1776	Single coated polyester nonwoven tape - acrylate adhesive	97.00%
9834	Single coated polyurethane tape - acrylate adhesive	97.00%
1516	Single coated polyester film tape - tackified acrylate adhesive	97.00%
9907T	Single coated elastic nonwoven blend tape - acrylate adhesive	93.90%
1529	Single coated rayon nonwoven tape - acrylate adhesive	93.90%
1774T	Single coated thin polyolefin foam tape - acrylate adhesive	90.90%
9914L	Single coated embossed nonwoven tape - acrylate adhesive	87.90%
9944	Single coated PU tape - tackified hydrocolloid adhesive	75.80%
1525L	Single coated polyethylene film tape - acrylate adhesive	63.60%
1567	Double coated polyester tape - synthetic rubber adhesive	54.50%

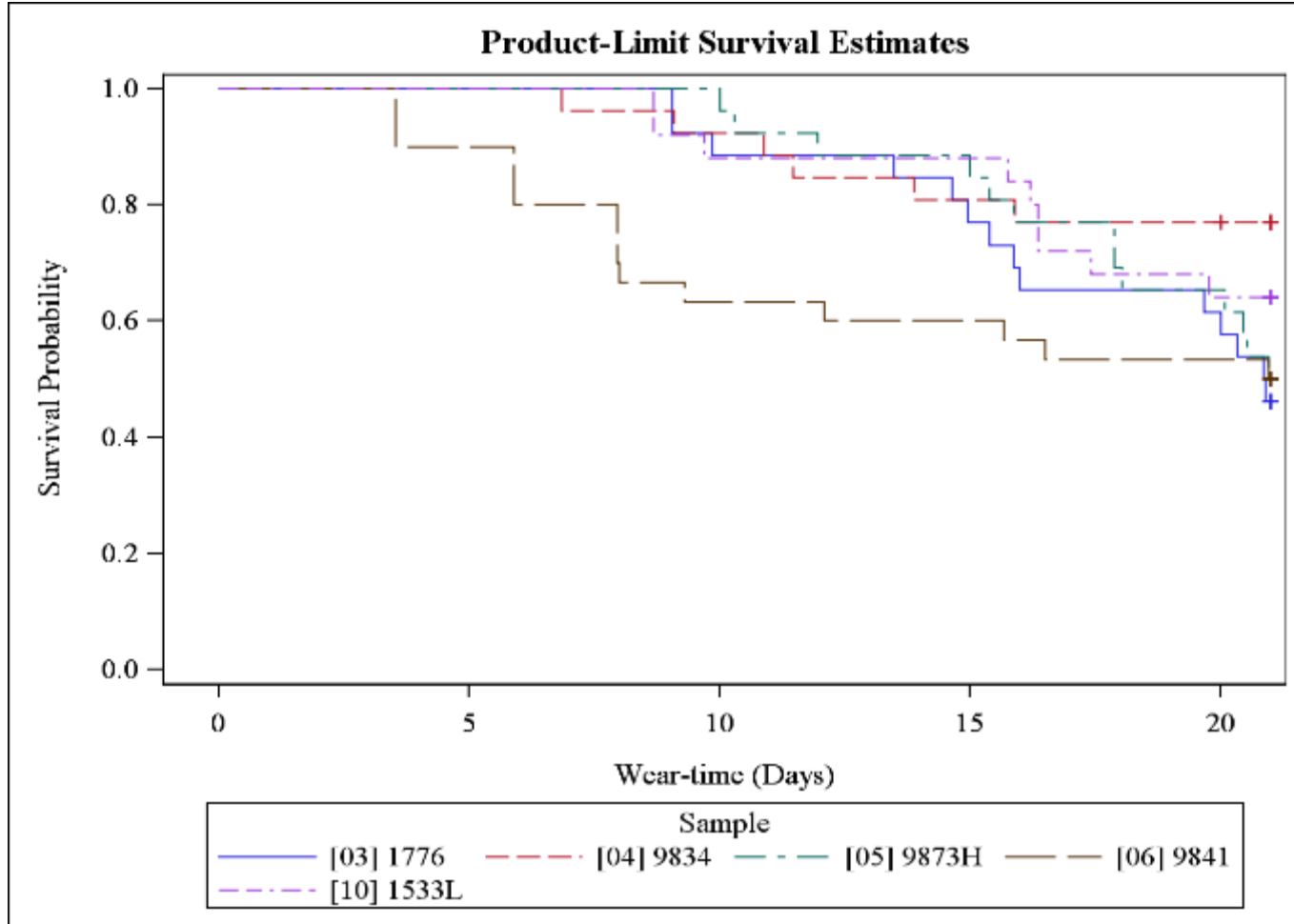
*Wear time results may vary, not a guarantee of performance

21 Day extended wear study

- Select 3M MedTech tapes based on best performers in the 8 day study
- Included experimental Gentle to Skin and long wear samples
- 3M employees
- Healthy Volunteers
- Wash to prep skin
- 3 replicates
- Record activity
- Tape only, no device

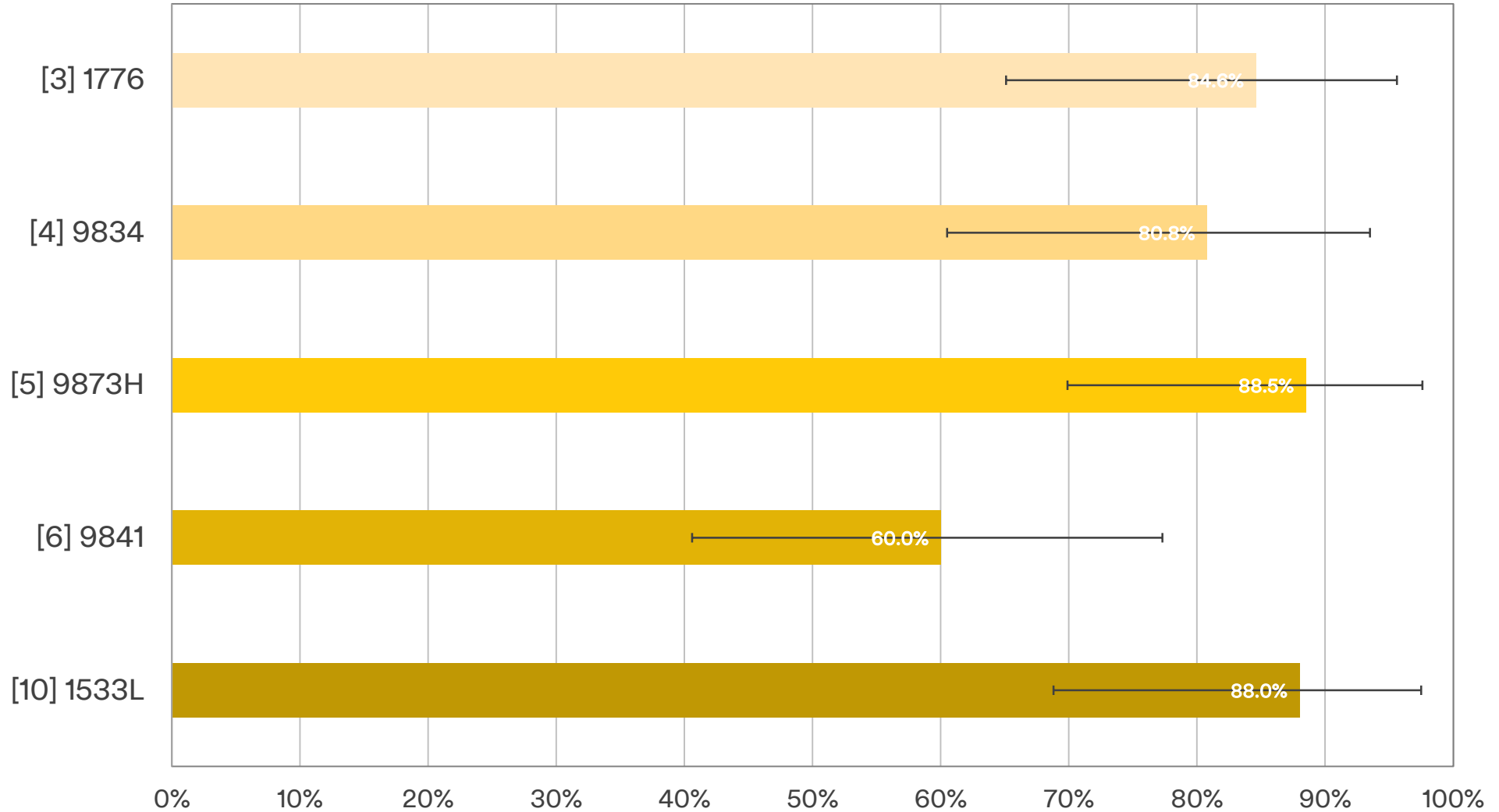


Wear Time Performance over 21 Days

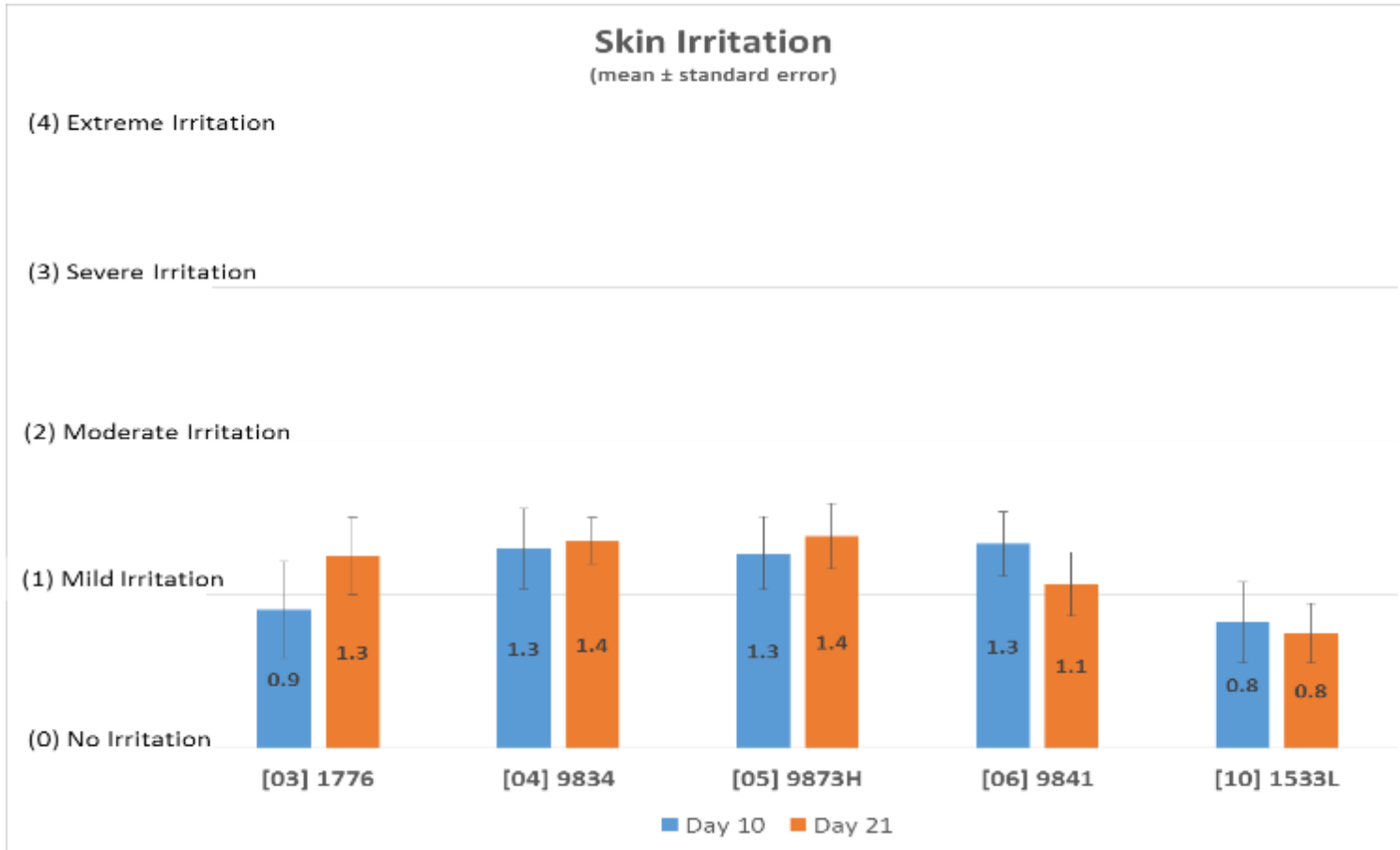


Proportion of Samples Intact at Day 14

(with 95% Confidence Intervals)



Evaluation of skin irritation at 10 and 21 days



The skin was graded following these guidelines:

0=No redness (of the skin)

1=Slight redness, barely perceptible

2=Definite redness

3=Severe redness (well defined) with edema

4=Extreme response with edema (swelling)



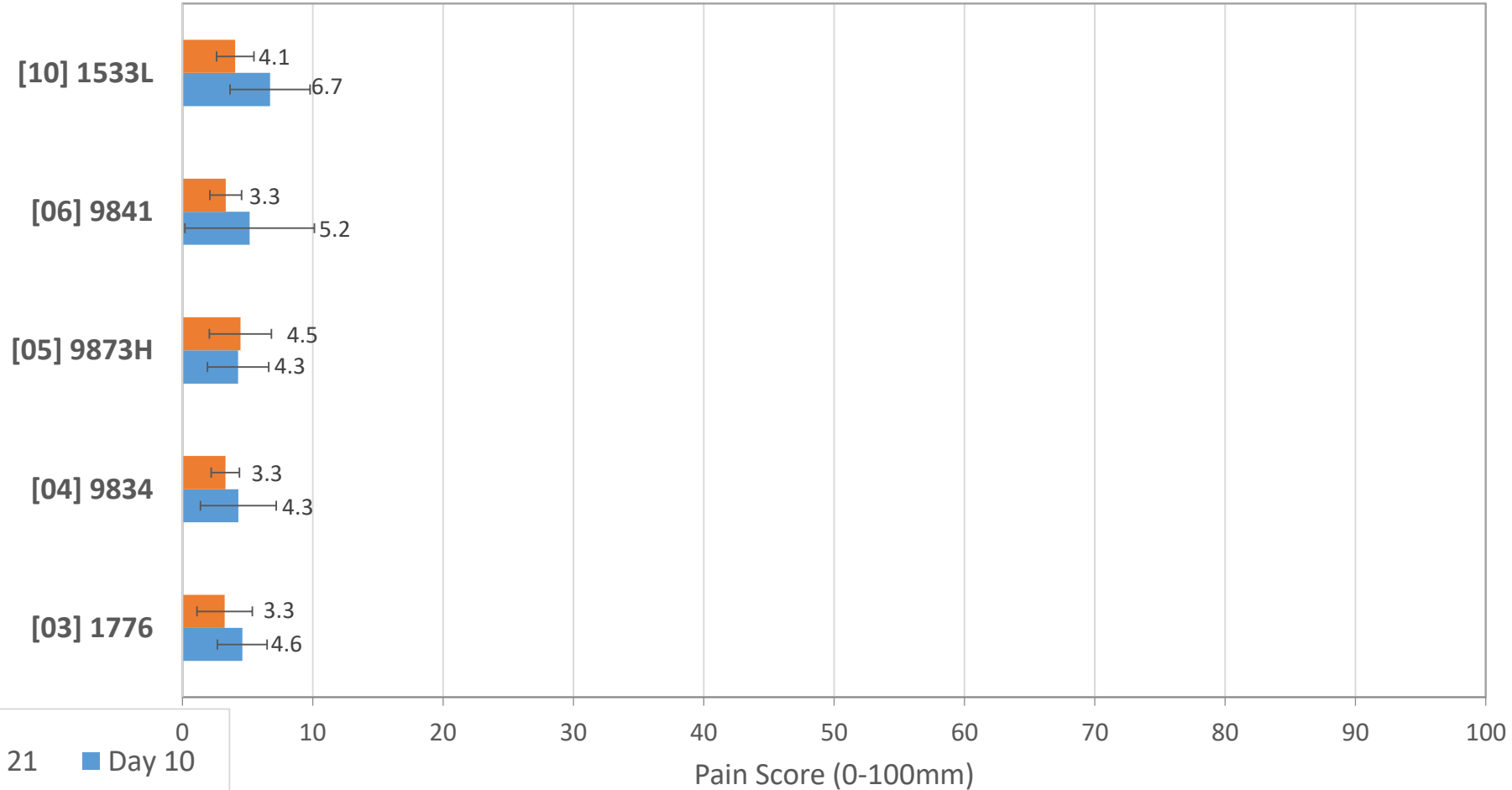
Pain response upon removal of tapes at 10 and 21 days

Pain Upon Removal

No pain zone: May have tugging or pulling sensation

(mean ± standard error)

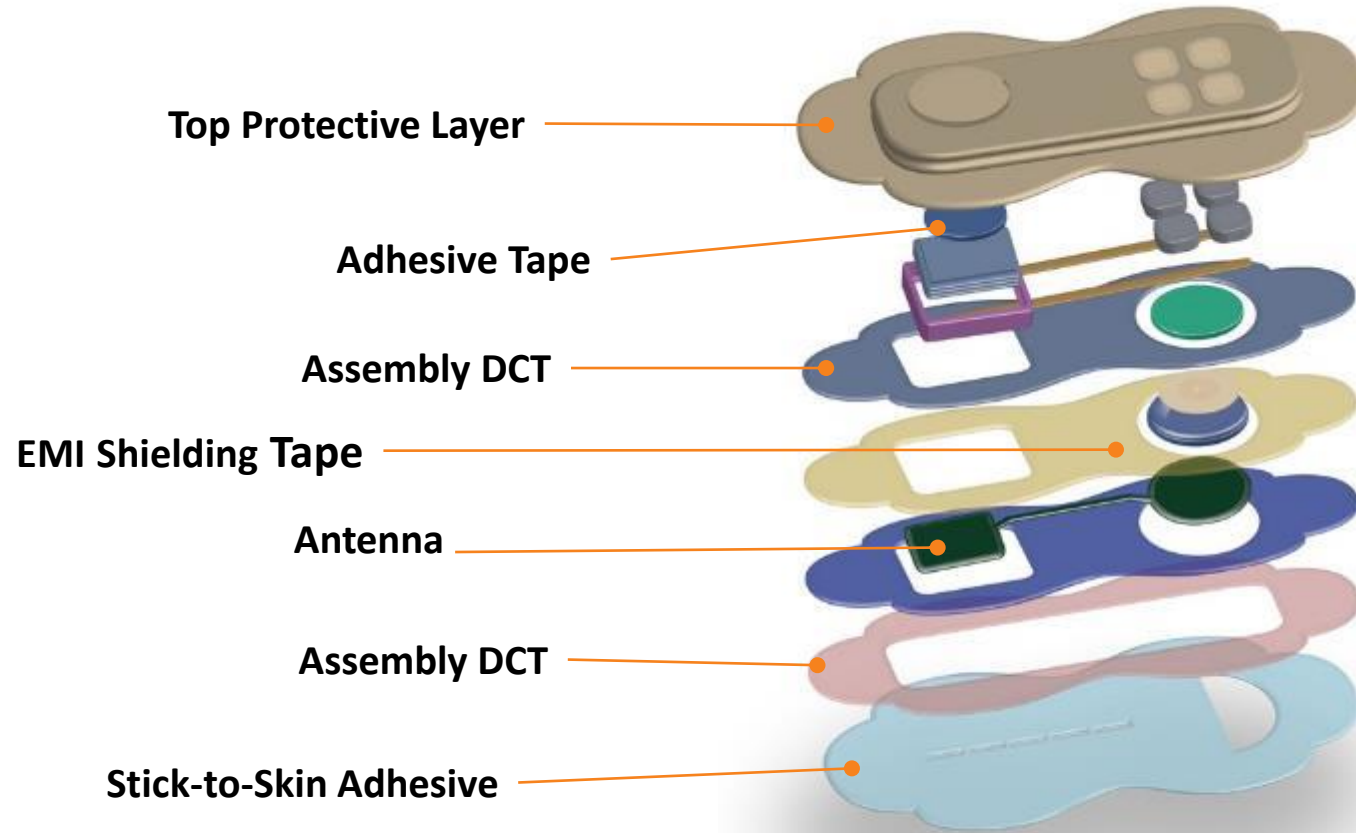
Very Painful





**Studies around adhesives in
wearable medical devices**

Typical structure of a medical device



Wear time study with occlusive device with and without a skirt (extended edge)

- Purpose to understand performance and skin health with device
- Device locations – abdomen and chest
- Experimental adhesives with polyurethane backing



Images of occlusive plate study



Lift score of "1"



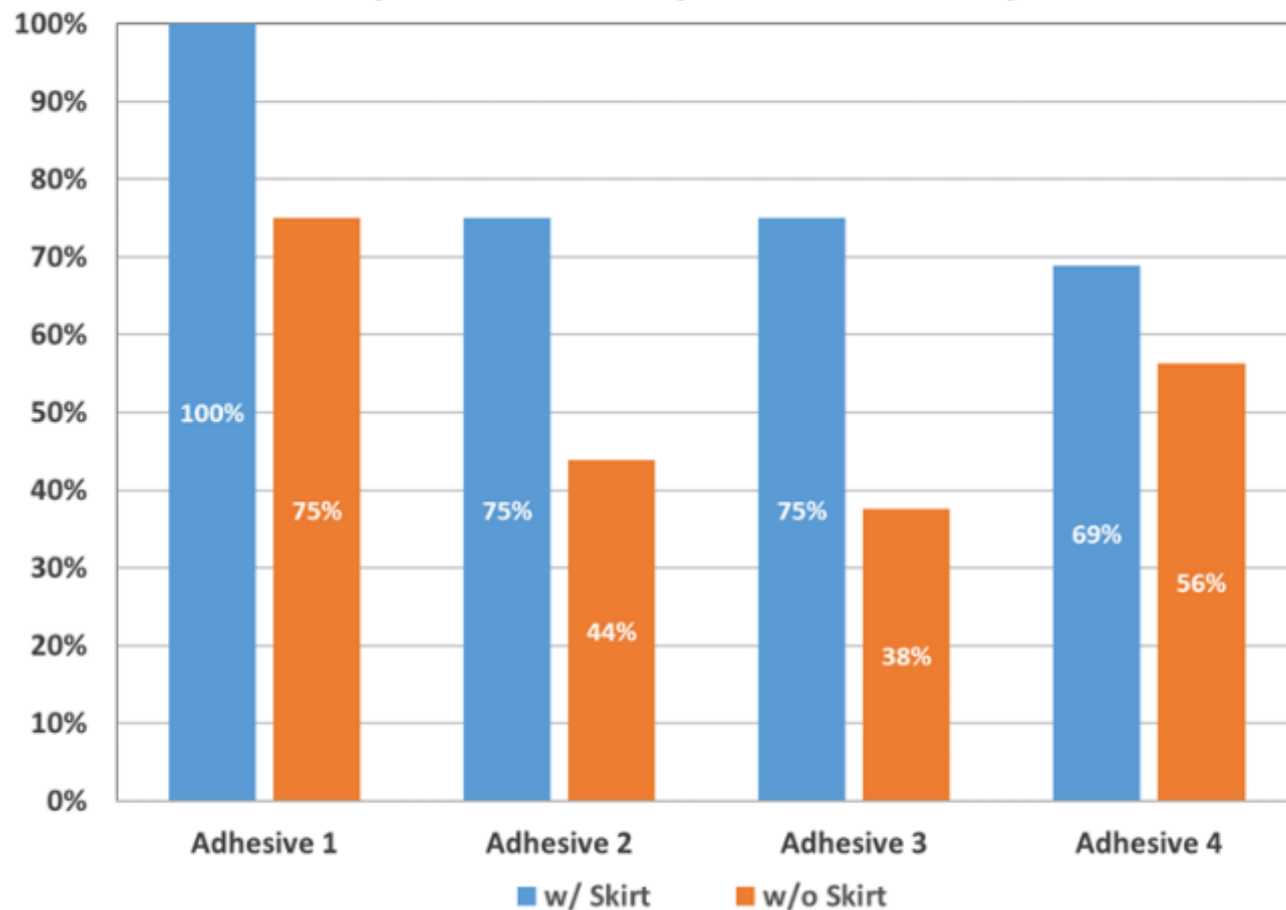
15 day - abdomen



15 day - chest

15 day wear time study with occlusive plates

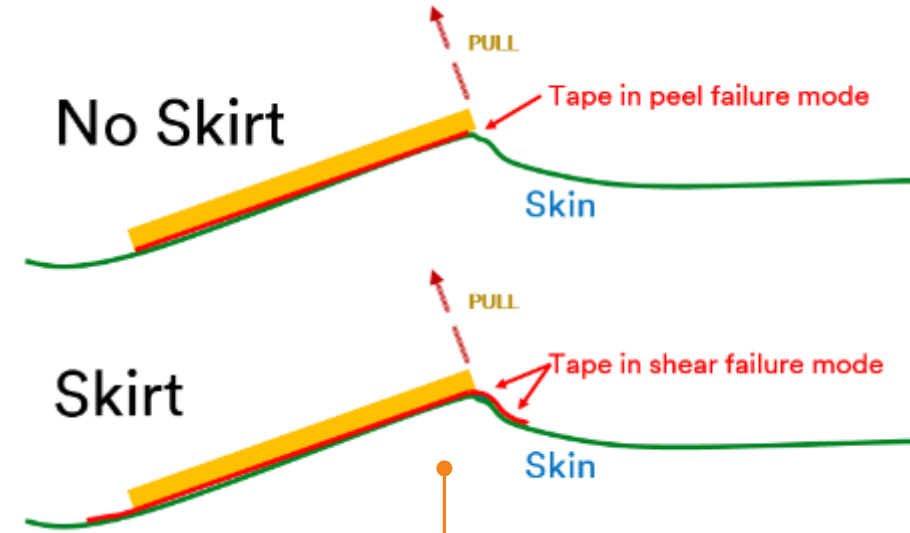
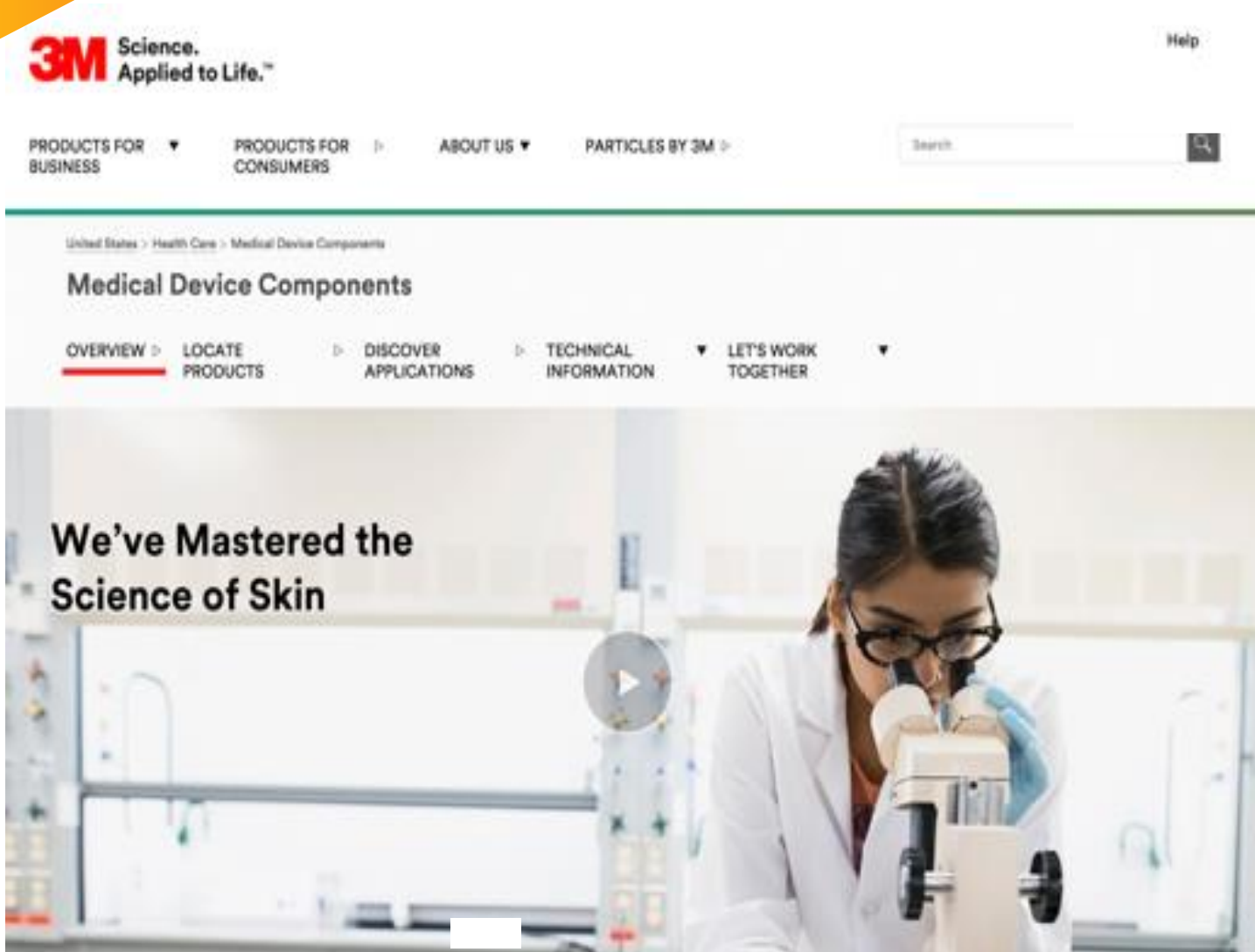
Proportion of Samples Intact at Day 15*



- 3M healthy volunteers
- Chest and abdomen
- No activity restrictions
 - Exception hot tubs/swimming
 - Recorded activity
- Normal showering
- Polycarbonate “device”
 - Footprint: 30mm x 46mm
 - Thickness: 3mm
 - Weight: 4 grams

* Adhesive 4 w/skirt failures were all at the device adhesive layer

Effect of skirt on wear time



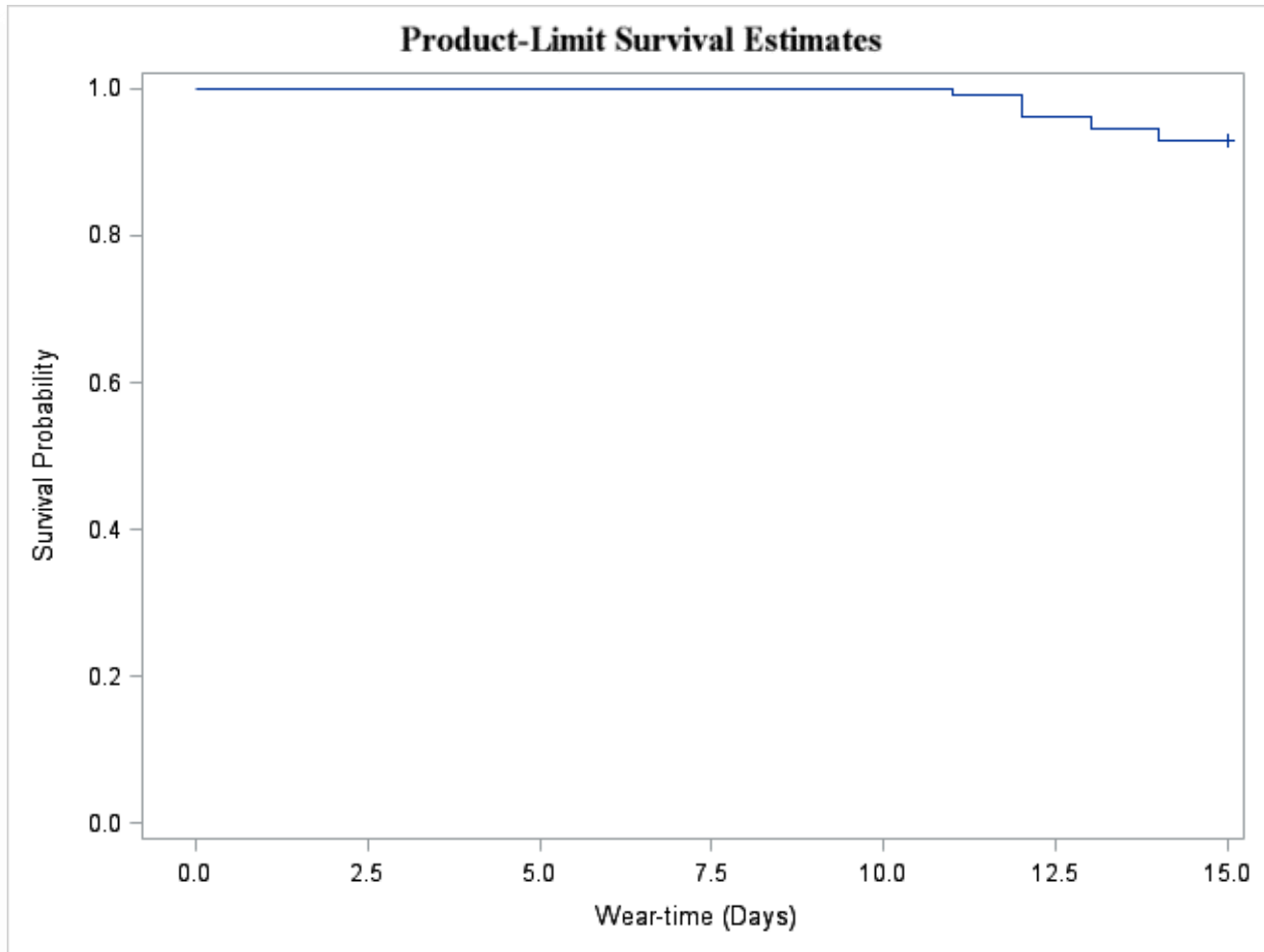
Hypothesis:
Skirt transforms failure
from peel to shear



3M™ 4076 Extended wear medical tape

- 16 - 3M healthy volunteers
- 8 devices/subject
- Average miles walked: 70 miles
- Activity tracked - only restriction hot tubs
 - # 5,6 & 11 were most active with highest recorded intensity minutes
 - #4,6 & 7 swam
 - #5 trained for and ran a 1/2 marathon
 - #11 ran daily
 - #12 harvested corn

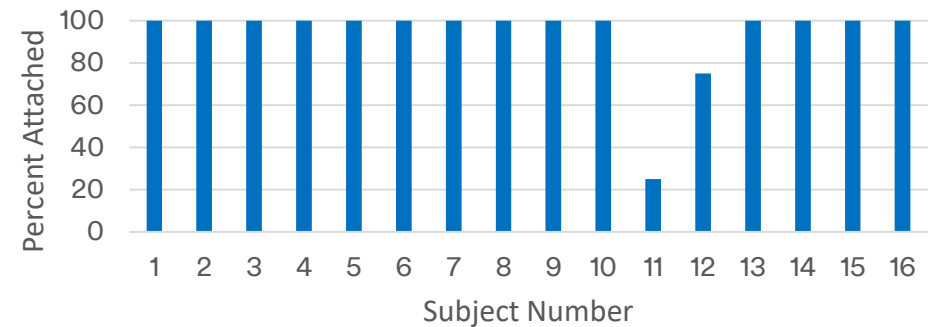
3M™ 4076 Extended wear medical tape



Day 14

- Polycarbonate “device”
Footprint: 30mm x 46mm
- Thickness: 3mm Weight:
4 grams
- 3M™ 9889 device
attachment

Percent of Devices Attached - Day 14
(3M™ 4076, Mock Device)



*Wear time results may vary, not a guarantee of performance

In summary

✓ Skin is a dynamic interface and highly individualized

✓ Think about tape/adhesives earlier in the design process

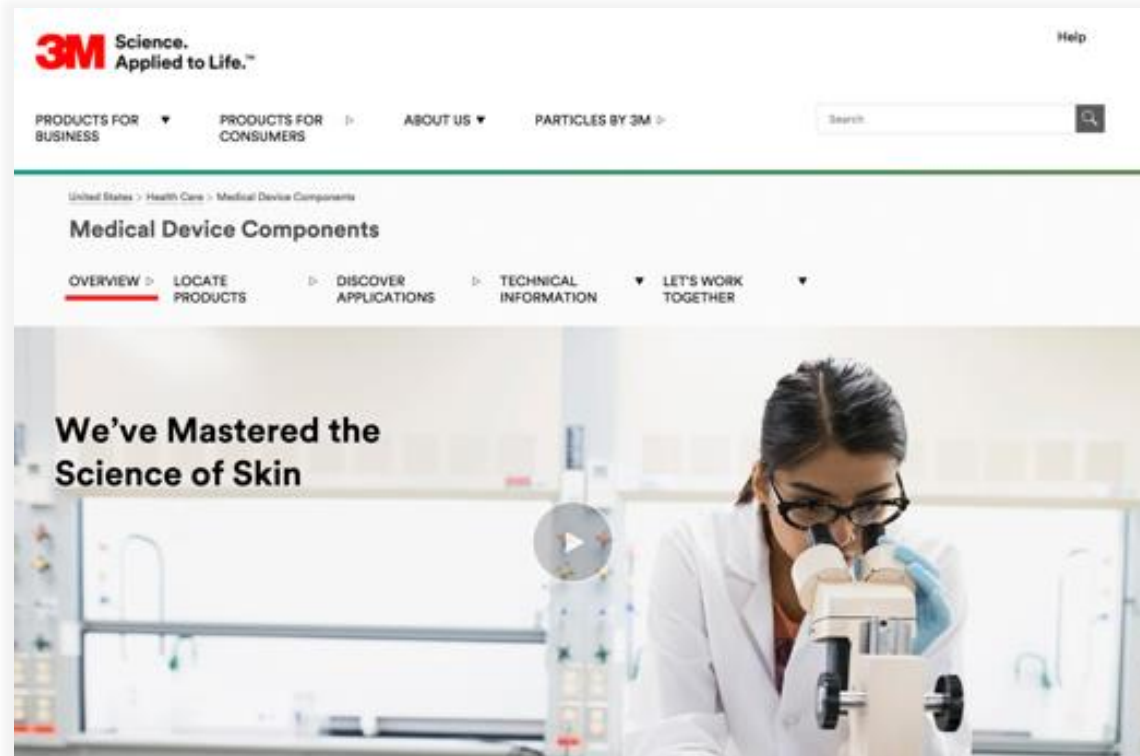
✓ Selecting the right adhesive is important to prevent MARSI

✓ An extended edge/skirt can improve wear time

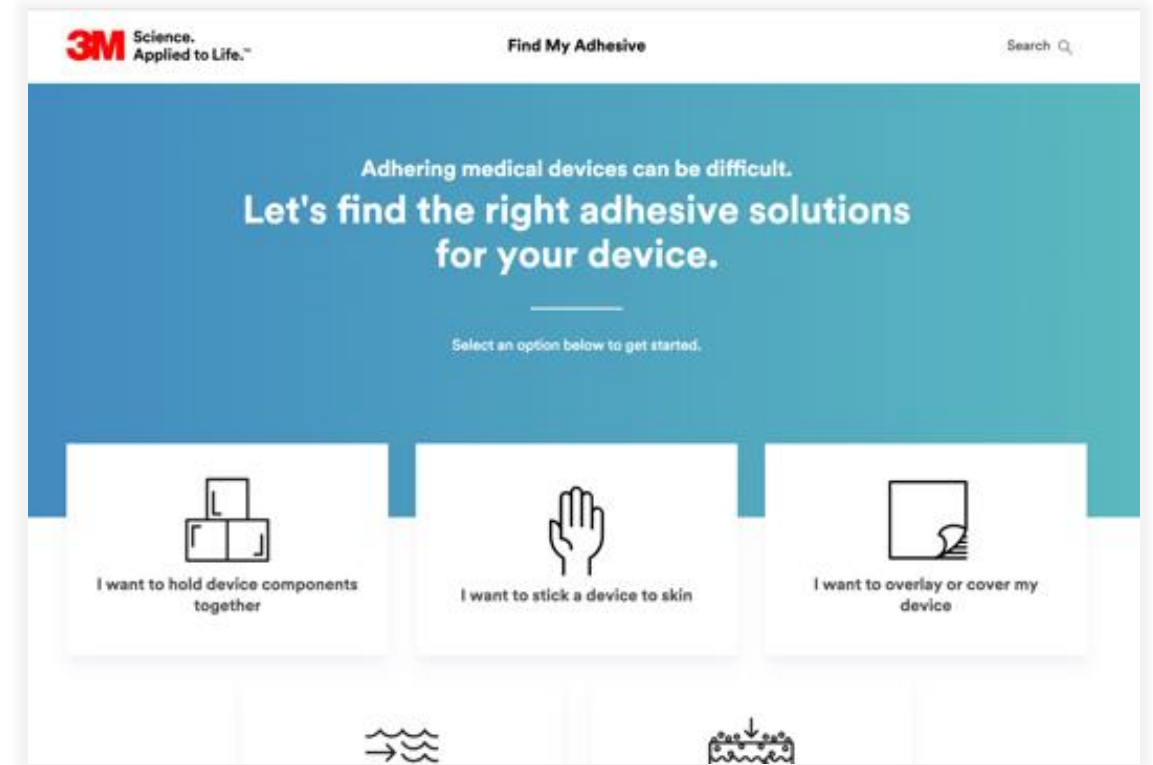
✓ Clinical wear time studies of the final product on target device users remain the most reliable predictor of performance

✓ 3M Med Tech tape constructions have demonstrated extended wear time*

3M Medical Materials & Technologies



▶ www.3M.com/MedTech



▶ www.Findmyadhesive.com

Thank you