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Science of Skin: A Medical Device Designer's Guide to the Pitfalls and Blind Alleys of Sticking to Skin.

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FAILURES ON SKIN

Skin is a challenging substrate[1] and the requirements an adhesive must fulfill to hold your device to it safely provide a myriad of opportunities to fail. The most obvious failure is, of course, your device falling off before the end of its mission, whether that was securing a drug delivery device for a few hours or a monitoring device for two weeks. A device falling off equals a patient not getting the treatment or collecting the data they need...and it leaves them thinking this failed while holding a device with your company's name on it, figuratively or literally.

If your device is as light as a feather you can use an adhesive whose bond builds with time (as many adhesives do). Of course, if your device has some heft 'quick stick', high initial adhesion, becomes a necessity. The need for high adhesion, whether to secure a weighty device immediately, or sticking to an active person for weeks, creates a range of challenges.

While sticking well enough to squishy, stretchy, sweaty, oily and sometimes-hairy skin that is continually shedding its outermost layer can be challenging. It is also disconcertingly easy to stick too well because the skin is also a living, breathing, sensitive organ. Even the toughest skin is more fragile than most substrates adhesive developers are asked to bond to, and the easily-damaged skin of the elderly or neonates gives even experienced developers pause. Many would argue that a device falling off because an adhesive didn't hold strongly enough is preferable to skin stripping caused by an adhesive sticking too well. Skin stripping involves pulling off the upper layers of skin, leaving moist, raw wounds.[2] (Figure 1)

Figure 1 Skin Stripping

Finding an adhesive that sticks well enough, long enough is only the first challenge. Imagine: Your device stayed securely attached for the prescribed time and removed without damaging the skin it was stuck to...

...but the skin is swollen and moist because the combination of device and tape trapped moisture against the skin. Known as maceration, (Figure 2) this swelling of the epidermis by trapped moisture weakens it, leaving it more prone to skin stripping and damage.[3] Maceration signals insufficient breathability (letting moisture out and oxygen in) beneath your device. Breathability

is affected by the adhesive's chemistry and its thickness, the material the backing is made of and its morphology (film or nonwoven), how that backing is bonded to your device, as well as the size and construction details of your device. Of course, trap enough moisture beneath the device and the adhesive will simply de-bond from the skin.

Figure 2 Maceration

...and you find a rash covering the exact footprint of the device. This contact dermatitis can be caused by a component of the stick to skin adhesive. (Figure 3) It's also possible for a component of the adhesive used to bond the device to the tape backing to diffuse through the stick to skin tape and induce redness and inflammation. Adhesives intended for use on the skin are generally cleaned of potential irritants more thoroughly than non-skin contacting adhesives, but the level of production by-products never actually reaches zero, and some people react to even the smallest amounts.[4] In addition, some components used to modify adhesive performance, such as tackifiers, need to be carefully screened for their potential to cause irritation. Sticking well enough, long enough without irritation is no easy feat; select your tape vendor carefully.

...and the skin underneath is darker than the surrounding skin. One cause of hyperpigmentation, the overproduction of melanin, is inflammation.[5] Keep the skin 'happy' with a breathable tape/

Figure 3 Irritant Contact Dermatitis

device combination and minimize the likelihood of this reaction.

...but the adhesive did not remove cleanly, leaving a sticky residue. Adhesives are formulated so their cohesive strength exceeds their potential adhesion so that they will remove cleanly. Exposure to skin oils, lotions, and bath products can soften adhesives and decrease their cohesive strength.[6]

FAILURES AWAY FROM SKIN

Several adhesive failures should never ruin a medical device developer's day, because guarding against them is part of tape

development. However, 'should never' equals 'eventually for someone' so consider: Tape developers test their products against every common combination of materials and processes, yet inevitably someone pairs a stick to skin tape with a device assembly tape that wasn't tested with that tape. When two adhesives are separated by only a tape backing, it's not a question of whether small molecules (residual monomer, plasticizers, tackifiers, contaminants) will diffuse from one adhesive to the other, it's only a question of how fast?[7] For example, you may find the tackifier of one adhesive diffusing into the backing of the other tape and causing it to wrinkle on the liner. Migration of components may also leave one adhesive tackier than you want and leave the other with sub-standard adhesion. Another example: a plasticizer key to the performance of one adhesive may cause the separation of the other adhesive from its backing, known as two bond failures.

Exposure to gamma and E-beam radiation, commonly used in the sterilization of medical devices, can significantly change the performance of adhesives.[8] Test device/tape combinations after the expected sterilization cycle as early in development as possible. Discovering a large drop in adhesion performance or an outsized increase in liner release values following sterilization late in the development cycle will induce headaches no one needs.
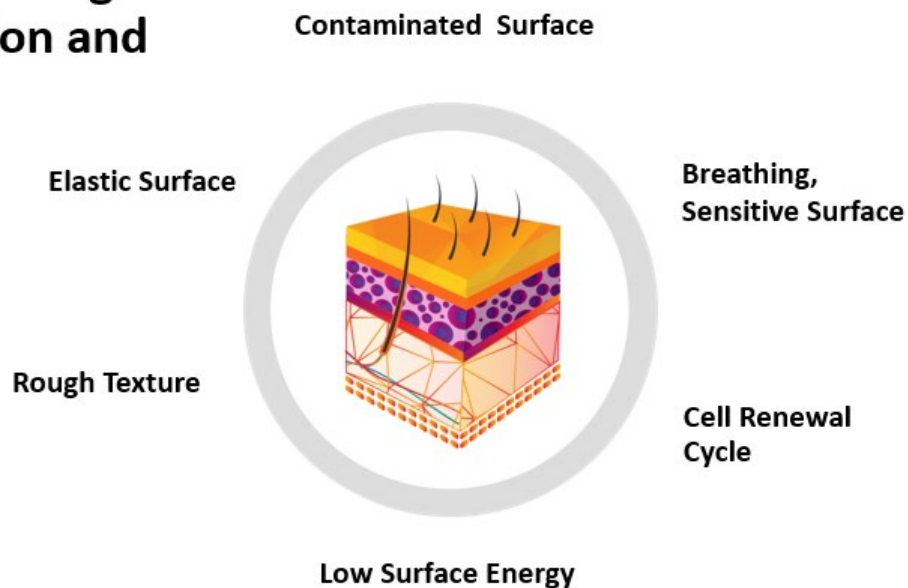
There is no shortage of potential pit falls in the selection of the right tape for your wearable device. Working with a guide versed in the landscape of challenges with the experience and tools to help you overcome them can save time, money and frustration.

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The science of skin

Factors affecting skin adhesion and wear time

Contaminated Surface

Elastic Surface

Breathing, Sensitive Surface

Rough Texture

Cell Renewal Cycle

Low Surface Energy

Skin is important. This elastic "organ" that covers our body, is our interface to the world. Skin is our physical, chemical, and microbial barrier that helps protect us from the sun; enables our sense of touch from the nerves embedded in our skin; and contains receptors for heat, cold, pressure and pain sensations. Our skin supports regulation of our body temperature and phosphate/calcium. Our skin is amazing when you think skin deeper.

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