

WHITE PAPER

PERSONAL CARE



“Diaper” backward spells “repaid”.

The benefits of
choosing the
right diaper
closure system.



**We’ve all heard the saying
“We enter the world in diapers and
we leave the world in diapers”.
But did we ever foresee an era
where that time spent in diapers
would make up such a large
part of our lives? And, more
importantly, of our health as well?**

About 258 worldwide births occur per minute, or 4.3 births every second¹. Of those more than 1 in 10 are born prematurely. The length of time that newborns spend in diapers has also doubled over the last 60 years². In the 1950s kids were potty trained and out of diapers by 18 months of age, but by 2001 however the average age had risen to 37 months.

On the other end of the spectrum, medical advances and overall health and living conditions have prolonged life and reduced prenatal and newborn mortality like never before. Human lifespans are currently increasing by approximately 3 years every generation, and there’s no sign of a slowdown in this trend³. This growing geriatric population, coupled with the growing cases of incontinence among men and women, are the major factors driving the growing demand for skin-friendly incontinence products.

**15
MILLION**
preterm babies
are born each year
11%
are preterm babies

The global baby diaper market is expected to reach € 78 billion by 2025, growing at a yearly increase of 6%⁴. The global adult incontinence market will even increase by 12.7% annually over the next 5 years⁵. Diaper manufacturers are faced with the ever-growing demand from existing and emerging economies such as China and India for affordable products that meet international hygiene and production standards.

With incontinence currently affecting over 50% of nursing home residents⁶, most of us have probably spent quite some time in diapers when we were young and could possibly be using incontinence products again during the twilight of our lives. However, not all diapers are created equal ...

Although disposable diapers and incontinence products offer far more benefits, hygiene, safety, and superior absorption being the main ones, but also comfort, confidence, independence and the ability to continue to participate in social activities, they do however come with some drawbacks. Dermatitis, more commonly known as “diaper” (or “nappy”) rash, for example is probably the most common medical condition associated with the use of these products, affecting up to 35% of infants during their first year⁷. Breakouts last about 6 days each month (which amounts to 20% of the time), involving 25% of the total surface area of the diapered skin. 40% of the diaper rash cases registered are moderate to severe⁸.

¹ https://www.indexmundi.com/world/birth_rate.html

² <http://www.allgov.com/news/unusual-news/why-do-american-children-spend-so-much-time-in-diapers-follow-the-money-130730?news=850709>

³ <https://medicalxpress.com/news/2018-11-lifespan-people.html>

⁴ <https://www.alliedmarketresearch.com/baby-diapers-market>

⁵ <https://www.grandviewresearch.com/industry-analysis/adult-diapers-market>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614622/>

⁷ <https://www.uptodate.com/contents/diaper-dermatitis>

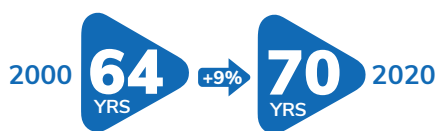
⁸ <https://www.sciencedirect.com/science/article/pii/S0273230017302830>



Newborns and elderly people suffer from an either incompletely formed or a deteriorating epidermis, respectively. This upper skin layer serves as an essential barrier, protecting us against infections from e.g. prolonged contact with stool and urine, and damage from e.g. the application and removal of diapers and tapes. Without that barrier we are defenseless against microbial attacks, extremely vulnerable to trauma due to improper selection of application of tapes, and at much greater risk of absorption of harmful substances and dehydration from loss of body water. Preterm newborns, during the first weeks of life, have an even less developed skin barrier and, therefore, are even more at risk. 50% of all newborn deaths are related to sepsis or other severe infections due to the infant's incompetent epidermal barrier!⁹

The problem of dermatitis and other skin conditions is not limited to just the patients. Nurses and caregivers with a fully functional epidermis, but who do come into contact with diapers, tapes and adhesives on a daily basis, may transfer bacteria and irritants to their patients' skin.

Thus, it is extremely important to know the skin-related mechanics and phenomena at play, in order to make well-informed decisions regarding which diapers and diaper closure systems to choose.



WE'VE ALL GOT SKIN IN THE GAME

Each second 4.3 babies are born worldwide¹⁰, which makes a total of 135.7 million babies per year. Of those, 15 million, or more than 11%, are born preterm (before 39 completed weeks of gestation), and their number is rising¹¹. Compared to babies born at or after 39 weeks of pregnancy, preterm infants are at a 20% greater risk of

complications and at a 50% greater risk for death within the first year of life¹². Besides birth-related problems and birth defects, infections cause most neonatal deaths¹³. In the late neonatal period, i.e. the first month after birth, the toll caused by conditions related to preterm babies' incomplete and incompetent epidermal barrier becomes even more apparent. Research has shown that half of all neonatal deaths are related to sepsis or other severe infections.



The world's population is also ageing. Virtually every country in the world is experiencing a rising number and proportion of elderly citizens. The current average life expectancy is 69 years (67 years for men and 71 years for women), already a 7% increase since 2000 (64 years)¹⁴! People aged 60 years or over make up the fastest growing population segment, growing faster than all younger age groups. There are currently more than 962 million elderly people (i.e. 65 years or older) worldwide, and this number is expected to more than double by 2050 and more than triple by 2100. This means that elderly people will make up 22% of the world's population by 2050, compared to 12% now¹⁵. There are currently 125 million people older than 80 worldwide. By 2050 this age group will increase to 434 million¹⁶. Based on these developments, it's clear to see that the burden of incontinence is expected to grow massively over the course of the next couple of decades, which should make its social and economic implications a top priority on the health and social policy agenda worldwide.

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

¹⁰ https://www.indexmundi.com/world/birth_rate.html

¹¹ <https://www.news-medical.net/news/20120503/15-million-preterm-babies-born-each-year-WHO-global-report.aspx>

¹² <https://www.verywellfamily.com/premature-birth-facts-and-statistics-2748469>

¹³ <https://www.who.int/news-room/fact-sheets/detail/newborns-reducing-mortality>

¹⁴ https://www.indexmundi.com/world/life_expectancy_at_birth.html

¹⁵ <https://www.who.int/news-room/fact-sheets/detail/ageing-and-health>

¹⁶ <http://www.uniindia.com/ageing-world-60-plus-to-outnumber-below-5-year-olds-by-2020-says-who/india/news/764265.html>

8.7%, or more than 423 million people worldwide, are faced with incontinence issues as early as 20 years of age¹⁷. The prevalence of the condition is 3 times higher in women than in men, affecting 12.4% of all women worldwide (or 303 million) and 5% of all men (or 121 million)¹⁸. Incontinence of course predominantly affects the elderly, with e.g. 50% of all nursing home residents dealing with incontinence on a daily basis, although not exclusively. From 40 years old onwards, between 30% and 60% of women are afflicted. Fecal incontinence furthermore occurs in up to 6% of those under 40.

Paired with this increasing burden of incontinence comes the need for a diverse and widespread support system in order to deal with it. Only 50.4% of all elderly people dealing with incontinence live independently at home. 41.5% do live at home, but require the care of others, be it family members or professional caregivers. 8.1% finally, reside in nursing homes and similar institutions, depending on the care of the in-house staff¹⁹. As a result, the caregivers treating these newborns and elderly people affected by dermatitis and other skin issues have a big role to play. Proper choice and use of diapers are crucial in preventing cross contamination between patients.

HEALTH IS ONLY SKIN-DEEP

Even at its thickest point our skin is only a few millimeters wide. And although you might not typically think of it that way, it's our largest and heaviest organ, making up about one seventh of our body weight²⁰.

It forms a vital physical barrier between our body and the environment. Through this barrier function it regulates our core body temperature, provides protection against UV, monitors our immune system, prevents the loss of bodily fluids, and last but not least, provides us with paramount protection against harmful external pathogens.

Depending on where it is on your body and the demands made on it, your skin varies in thickness. The thickness depends on age and sex too. Older people generally have thinner skin than younger people do, and men generally have thicker skin than women do.

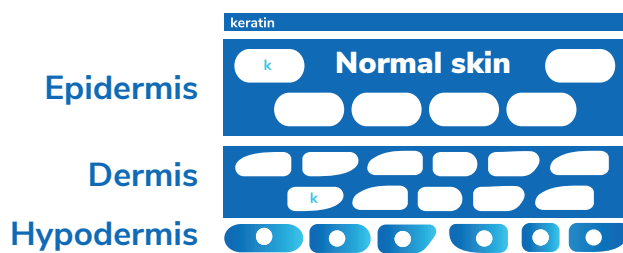
It is composed of multiple layers of cells and tissues, which are held to underlying structures by connective tissue. The deepest layer of skin can store water and fat for hydration and body temperature regulation. If skin is injured, the blood supply to the skin increases in order to deliver various substances from the underlying layers to the wound so it is better protected from infections and can heal faster. Later on, thanks to a continuous process of cell regeneration, new skin cells are produced in the bottom layers to replace the damaged skin layers on top.

¹⁷ <http://www.gfiforum.com/incontinence>

¹⁸ <http://www.gfiforum.com/Upload/43b34997-7408-4fa6-9547-72488e668060/1%20Milsom%20-%20Incontinence%20in%20numbers.pdf>

¹⁹ www.gfiforum.com/Upload/43b34997-7408-4fa6-9547-72488e668060/1%20Milsom%20-%20Incontinence%20in%20numbers.pdf

²⁰ <https://www.ncbi.nlm.nih.gov/books/NBK279255/>



To be able to do all of these things, skin consists of three different layers: the outer layer (epidermis), the middle layer (dermis) and the deepest layer (hypodermis).

The bottom layer or hypodermis connects the skin to the underlying bones and muscles. Its main functions are fat storage, insulation and cushioning in order to provide elasticity and thus protect the skin layers from trauma²¹.

The middle layer or dermis contains blood vessels, nerves, and other structures, such as hair follicles and sweat glands²². The dermis is made of two layers of connective tissue, the papillary and the reticular layer. The former provides the structural framework for the tissue and plays a crucial role in wound healing and immune responses²³, thanks to defensive cells that help fight bacteria or other infections that have breached the skin²⁴. The reticular layer is much denser and thicker, predominantly offering protection against trauma. It owes its name to its net-like (reticulated) appearance which is formed due to a tight meshwork of fibers. These fibers provide elasticity to the skin, allowing it to stretch in order to avoid tears and other trauma, as well as hydration, by bonding water to the skin.

The top layer or epidermis finally is comprised of 4 major layers, which are the basal, spinous, granular, and stratum corneum²⁵. The bottom or basal layer attaches the epidermis to the underlying dermis²⁶, providing a strong bond via the intertwining collagen fibers of layers. The spinous layer is composed of 8 to 10 layers of keratinocytes. As their name suggests these are keratin-producing cells, and their main purpose is to preserve against microbial, viral, fungal and parasitic invasion, as well as provide water-resistant properties²⁷. These vital keratinocytes originate in the basal layer. As new keratin-producing cells are formed, the existing ones are pushed superficially away into the layers above. The granular layer contains up to 5 layers of keratinocytes, which have become flatter and thicker caused by them being pushed out from the layers below. The large amounts of keratin produced accumulate as granules within the cells, giving the layer its grainy appearance and name.

The entire process of regeneration and migration of keratin-producing cells throughout the skin layers culminates with them being pushed outwards into the stratum corneum, the most superficial layer exposed to the outside environment²⁸. There are usually between 15 and 30 layers of keratinocytes in the stratum corneum. This dry layer of dead skin cells has a vital role as it helps prevent the penetration of microbes and the dehydration of underlying tissues. It also provides protection against abrasion for the more delicate, underlying layers. The entire layer is replaced during a period of about 4 weeks, as newly-formed keratinocytes are pushed up from the layers below, causing the top layer to be shed²⁹.

²¹ <https://opentextbc.ca/anatomyandphysiology/chapter/5-1-layers-of-the-skin/>

²² <https://www.ncbi.nlm.nih.gov/books/NBK279255/>

²³ <https://www.sciencedirect.com/topics/neuroscience/fibroblast>

²⁴ <https://www.sciencedirect.com/topics/neuroscience/phagocyte>

²⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

²⁶ https://www.physio-pedia.com/Integumentary_System

²⁷ <https://www.temposcience.com/blog/?p=410>

²⁸ <https://www.healthline.com/health/stratum-corneum>

²⁹ <https://opentextbc.ca/anatomyandphysiology/chapter/5-1-layers-of-the-skin/>

BABY STEPS TO GETTING OLDER

Our skin takes a beating from the moment we come into this world until we leave. Its characteristic features change from the time of birth to old age, as anatomical and physiological alterations, as well as exposure to sunlight and wind, leave skin dry, wrinkled, and flaccid. It's supposed to protect us against trauma, bacteria,

and chemicals. And it does, as long as it's capable to do so, which amounts to the majority of our lifespan. However, at the very beginning and the very end, we do need to provide some additional skin support, with emphasis on the proper choice and use of diapers.

Newborn skin, especially in preterm babies, is not yet fully developed, making it very sensitive, thin and fragile in the beginning. The skin of infants born at the lower limit of viability is gelatinous, easily injured when touched, and provides virtually no protection against loss of fluids or infection³⁰. Newborn skin contains less collagen than adults'. Collagen's main function is to sustain tendons, skin and cartilage. It is the matrix that gives structure to our cells, providing integrity, firmness and elasticity to the skin. A lack of collagen makes the skin less resistant against trauma³¹.

After birth our skin is subject to a gradual process of adaptation to the external environment. The immature epidermal barrier is still highly permeable, causing a substantial risk of toxicity from e.g. the percutaneous absorption of drugs. Preterm babies have decreased epidermal and stratum corneum thicknesses compared to those of a full-term baby³², about one third on average³³. Even a full term neonate's skin is only 60% of adult thickness³⁴.

Protection against water loss and prevention of substances and bacteria penetrating into the body rank as the most important functions of the skin's barrier function. Contact with, and improper use of diapers, is one of the main causes of skin barrier damage. The repeated removal of skin cells due to friction from diapers and abrasion from diaper tapes being attached and removed increases permeability and puts preterms and newborns at a very high risk of absorption of harmful chemicals and microbial infections through those wounds. These issues might possibly compromise the general health of the infant.

Skin hydration is the first issue where the newborn's incomplete skin functionalities come into play. In premature newborns the sweat glands have not completely formed. As a result the skin surface of newborns is rougher and dryer compared with older children. During the first month newborns' sweat glands start to develop, leading to an increase in skin hydration, and over the next 3 months the hydration of the stratum

³⁰ <https://www.ncbi.nlm.nih.gov/books/NBK11385/>

³¹ <https://my.clevelandclinic.org/health/articles/10978-skin>

³² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

³³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3439947/#B9>

³⁴ <https://www.woundsinternational.com/download/resource/6078>

³⁵ https://www.researchgate.net/publication/50851863_Children_and_newborn_skin_care_and_prevention

³⁶ <https://www.o-wm.com/content/impaird-skin-integrity-elderly>

³⁷ <https://www.ncbi.nlm.nih.gov/pubmed/26844894>

³⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>



Over time, the child's skin becomes more and more resistant, yet always less than the adult skin of adults. It was previously thought that the skin barrier function reached its maturity at about 34 weeks of gestation. However, recent data show that it continues to develop until 12 months after birth³⁵. Finally, as we grow older, we go through exactly the same process but in reverse order, as the ability of the epidermis to restore its impaired barrier declines with age³⁶.

corneum increases. Lipids, or fat cells, are the main mechanism used by the stratum corneum to preserve skin hydration³⁷. They prevent excessive water loss through the epidermis and prevent compounds from the environment permeating into layers below. The lipid content of newborn skin is lower, resulting in reduced water-holding capacity, making it more prone to water loss³⁸.



A second important difference between infant and mature skin lies in the acidity (pH) level. Once mixed with sweat, the oil (or sebum) secreted from the sebaceous glands (oil-producing glands found mainly in hair-covered areas), forms a very fine, slightly acidic film on the skin surface, commonly known as the “acid mantle”. This mantle acts as a barrier to bacteria, viruses and other potential contaminants that might penetrate the skin³⁹. Skin pH is the crucial factor for determining healthy bacteria present on the skin surface. A neutral pH is 7. Anything above that (7-14 pH) creates an alkaline environment, and anything below (0-7 pH) creates an acidic environment. An acidic skin surface is a good thing due to the fact that pathogenic bacteria (i.e. bacteria that can cause disease) thrive under alkaline conditions. Fully-functional healthy adult skin is acidic due to the presence of the acid mantle, and has a skin surface pH level of about 5.5⁴⁰. Infant, especially premature, skin pH levels are higher, up to about 7.5. This makes their skin surface alkaline and significantly reduces protection against harmful bacteria and microbial organisms.

From the time of delivery, newborns are exposed for the first time to different types of bacteria from a variety of sources. During the first days after birth, the function of the skin barrier changes and the evolving skin environment stimulates the growth of some bacteria and limits the growth of others. This process of composition of microflora residing on the skin surface continues to evolve over the first year of life.

Aging has a significant impact on the structure and function of the skin barrier. One of the most common problems in aging skin is the decreased ability of the epidermal barrier to prevent water loss⁴¹. A decrease in the production of lipids is the main culprit. Aging negatively affects the oil-producing sebaceous gland activity, resulting in the lowest skin surface lipids levels measured in people older than 70 years⁴². Without the natural moisturizing and isolating factors of sebum, lipids, and other natural oils the skin turns dry, causing irritation and other complications. Old age has its toll on the acidity level of the skin surface as well, which increases as we grow older. The increase in pH level means the skin is more susceptible to harmful bacteria because of the alkaline environment created by the loss of acidity. Aging finally also affects the skin peeling process of the stratum corneum, which has a significant role in maintaining moisture of the skin. As we grow older more time is required for epidermal cells to migrate from the lower layers up to the skin surface. As a consequence of this prolonged turnover time, the protective top layer of dead skin cells is thinner in older people, which in turn reduces protection from damage and creates a larger surface area for fluid loss⁴³.

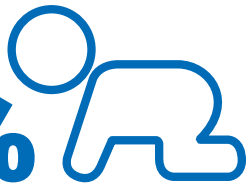
³⁹ <https://thenakedchemist.com/understanding-the-acid-mantle/>

⁴⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

⁴¹ <https://www.o-wm.com/content/impaired-skin-integrity-elderly>

⁴² <https://www.ncbi.nlm.nih.gov/pubmed/23113564>

⁴³ <https://www.o-wm.com/content/impaired-skin-integrity-elderly>

35% 
**Gets nappy rash
starting as early
as 1 week of age**

SAVE YOUR SKIN

One of the most common skin issues in newborns and elderly is dermatitis. Compromised skin barrier integrity is critical to its early onset and severity. There are 2 main variants: atopic and irritant dermatitis.

Atopic dermatitis (more commonly known as eczema) is an inflammatory skin condition that occurs in 15–20% of children worldwide⁴⁴. Symptoms include: dry skin; severe itching; red to brownish-gray patches (especially on the face and scalp in infants); small, raised bumps, which may leak fluid and crust over when scratched; thickened, cracked, scaly skin; and raw, sensitive, swollen skin due to scratching⁴⁵. It's common in children but can occur at any age. Atopic dermatitis is a chronic, long lasting disease that tends to flare up periodically. Alterations in skin barrier properties that lead to atopic dermatitis include: increased water loss through the epidermis; changes in skin surface pH; increased skin permeability; and increased bacterial colonization. Once the skin barrier is compromised, allergens, irritants, and other unwanted agents can penetrate the skin, leading to aggravation of symptoms associated with atopic dermatitis, such as asthma⁴⁶. No cure has been found for atopic dermatitis as of yet.

Irritant contact dermatitis refers to an inflammation of the skin caused by contact with a foreign substance. This can be e.g. any fabric or chemical substance. The rash will manifest immediately and be confined to the specific area that came into contact with the offending agent. The rash may appear as pink-to-red lesions, with sheets of skin hardening and scales and cracking appearing in areas of long-term exposure⁴⁷.

The most well-known variant or irritant dermatitis is diaper dermatitis or “diaper rash”, due to the fact that it's related to the use of diapers. It affects 35% of all babies during their first year, with symptoms starting as early as 1 week of age. The specific causes of nappy rash are⁴⁸:



Excessive moisture and heat buildup from prolonged use of diapers which causes skin irritation;



Friction caused by the diaper's fabric or adhesive tapes, which damages the skin barrier through chafing and rubbing;



Ammonia in trapped urine which causes inflammation;



Enzymes in stool which damage skin tissues they come in close contact with;



Dyes, perfumes, or materials in the diaper, which cause allergic reactions;



Potential secondary infection from bacteria or fungi;



Flare-ups of chronic skin conditions, such as psoriasis and eczema.

Keeping the diaper area clean and dry should resolve most diaper rashes within 4 to 7 days⁵⁰. However in severe cases the rash can spread to other parts of the body and can get significantly worse in case of bacterial infection, with symptoms such as pus-like drainages, yellowish-colored crusting, and fevers.

**FIRST
4 WEEKS
after birth
50%
DEATHS
are related to sepsis**

Infection is caused by the diaper negatively affecting the acid mantle's antimicrobial function. Due to chronic exposure to urine

and feces, diapered, neonatal skin shows a more neutral pH than uncovered skin⁵¹. This can cause harmful pathogens that grow at neutral pH and worsen existing diaper dermatitis, resulting in a vicious cycle where microbes continue to proliferate in an environment where the skin's antimicrobial barrier is being impaired. One should also take into account the fact that the area covered by diapers in newborns amounts to roughly 30% of their entire body⁵².

In the first 4 weeks after birth, about 50% of all deaths are related to sepsis or other severe infections due to the infant's incompetent epidermal barrier⁵³. The most serious manifestations of infections are commonly seen in preterm infants. As many as 65% of infants with birth weights of less than 1 kg have at least 1 infection during their initial hospitalization⁵⁴. These infections can include pneumonia, sepsis, and urinary tract infections. Newborns, preterms in particular, have difficulty

⁴⁴ <https://www.mayoclinic.org/diseases-conditions/atopic-dermatitis-eczema/symptoms-causes/syc-20353273>

⁴⁵ <https://www.mayoclinic.org/diseases-conditions/atopic-dermatitis-eczema/symptoms-causes/syc-20353273>

⁴⁶ <https://www.ncbi.nlm.nih.gov/pubmed/18034972>

⁴⁷ <https://www.skinsight.com/skin-conditions/infant/irritant-contact-dermatitis>

⁴⁸ <https://www.medicalnewstoday.com/articles/321857.php>

⁴⁹ <https://www.healthxchange.sg/children/baby-0-24-months/common-baby-skin-conditions-symptoms-causes>

⁵⁰ <https://www.webmd.com/children/diaper-rash#2>

⁵¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2688147/>

⁵² <https://www.sciencedirect.com/science/article/pii/S0273230017302830>

⁵³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

⁵⁴ <https://www.ncbi.nlm.nih.gov/books/NBK11385/>



confining infections to where they arise, frequently leading to abscesses and sepsis (i.e., a blood-borne infection). Sepsis is a serious medical condition, which can in turn spread to other parts of the body (resulting in, for example, meningitis, an infection of the membranes that surround the brain), and cause serious problems later in life. Neonates with birth weights of less than 1 kg who've had infections have been found to have more cognitive impairment and higher rates of cerebral palsy than those who did not have infections⁵⁵.

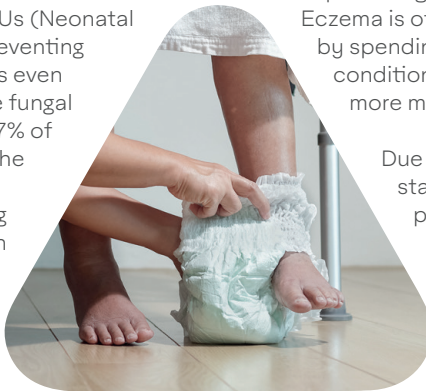
Because of the fact that infections are so commonplace in NICUs (Neonatal Intensive Care Units), preventing infections in newborns is even more important. Invasive fungal infections occur in 6 to 7% of infants in an NICU, and the rates of such infections increase with decreasing gestational age and birth weight. Candida is the most common fungal species that causes infections in preterm infants. It affects approximately 20% of infants with birth weights of less than 1 kg. In cases where the infection spreads throughout the body, the mortality rate increases to 30%⁵⁶.

At the other side of the age spectrum more than 70% of the older population deal with skin conditions, inducing dryness, irritation, and itching⁵⁷. Lifelong determining factors such as disease, diet, stress, hydration status, and the external environment, all cause alterations in skin barrier function and the ability of the epidermis to restore its impaired barrier. Physiological changes in aging skin such as altered lipid composition of the stratum corneum and decreased barrier ability to prevent epidermal water loss, decrease the skin's

ability to keep itself moist and hydrated.

Eczema is once again the most common affliction, occurring when skin moisture and oils are lost. Although any part of the body can be affected, this condition is found most commonly on the lower legs of older people. The affected skin is very dry and resembles cracked paving with fissures occurring between blocks of skin, or displays coin-shaped lesions that may develop into scales⁵⁸. These fissures allow environmental irritants to penetrate the skin and cause inflammation, further compromising the stratum corneum.

Eczema is often exacerbated by spending time in dry, warm conditions, all of which draw even more moisture from the skin.



Due to the bedridden state of some elderly people, as well as mental disorders that occur within this group, such as Alzheimer's disease, adult incontinence diapers have become an absolute necessity to safeguard the patient's

wellbeing and hygiene (as well as that of caregivers and fellow patients should he or she reside in a nursing home). However, their specific situation can potentially present aggravating risks. Conditions such as Alzheimer's disease affect their ability to remember to wash and go to the bathroom, making them totally dependent on others in that department. If left unattended, prolonged contact with dirty adult diapers leads to poorer genital hygiene, which worsens diaper rash and any subsequent infections. Because of their general frailness due to old age as well as preexisting medical conditions, infections can potentially quickly lead to life-threatening complications.

⁵⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593874/>

⁵⁶ <https://www.ncbi.nlm.nih.gov/books/NBK11385/>

⁵⁷ <https://www.o-wm.com/content/impaired-skin-integrity-elderly>

⁵⁸ <https://www.hindawi.com/journals/drj/2012/198789/>

The above clearly stresses the importance of keeping diaper rash at bay in both newborns and elderly. Wounds caused by friction and irritation due to the diaper material, and abrasions caused by application and removal of e.g. diaper tapes when coming into contact with the skin, can quickly lead to more severe conditions and even death. Protecting the skin integrity of both newborns and elderly starts by choosing and using the right diapers and diaper closure systems.

TALE OF THE TAPE

Use of tapes and adhesives on newborn and elderly skin needs to be avoided as much as possible. If and when they need to be used, e.g. during the often frequent medical procedures preterm babies are faced with. Attaching these adhesive tapes and subsequently removing them can lead to multiple skin tears in infants and elderly people, an issue commonly referred to as medical adhesive-related skin injury (MARSI).

Although diaper tapes typically aren't directly applied to the skin, unintentional contact during diaper changes is common. When this happens these diaper tapes can cause just as much (MARSI) damage as tapes and adhesives applied to the skin during regular medical procedures. Hence in addition to correct application and removal, the selection of diapers and in particular the safety of the diaper tape or any alternative closure system, necessitates particular care.

Diaper tapes are usually pressure-sensitive, which means that firm pressure applied to the surface of the tape or dressing will activate the adhesive by increasing the surface area contact⁵⁹. They do not require water, heat, or a solvent to activate the adhesion. They adhere to a variety of substrates when applied to most clean and dry surfaces. Over time, the adhesive will warm and flow to fill in gaps between the adhesive and the contact surface, increasing the strength of the bond. The length of time for this process differs among the various types of adhesive products. Some softer adhesives, such as silicone, have a lower surface tension and fill in these gaps quickly. Other adhesives, such as acrylates, act more slowly as adherence increases over time⁶⁰. The better and swifter this adherence between the tape and the diaper surface occurs, the stronger the bond. Hence there's less risk of skin damage because of the reduced need to remove and reapply the tapes, or change the diaper entirely because of this.

Pressure-sensitive adhesives (PSAs) are composed of a backing and an adhesive layer, which is protected by a silicone-coated release liner⁶¹. The type of backing and adhesive incorporated into the design determines the properties and performance. For example, tape backings may consist of paper, plastic, silk, soft nonwoven cloth, traditional cloth, or foam. Examples of types of adhesives used in tapes and dressings include acrylates, silicones, polyurethanes (plastics), and synthetic rubber⁶². PSAs offer an array of advantages, such as the possibility to use thinner and lighter materials whilst still providing adequate bonding and adhesion. Plus, they allow to bond two dissimilar materials or substrates together without incompatibility concerns.

⁵⁹ <https://www.sciencedirect.com/topics/engineering/pressure-sensitive-adhesive>

⁶⁰ <https://www.sciencedirect.com/topics/engineering/pressure-sensitive-adhesive>

⁶¹ <https://www.can-dotape.com/adhesive-tape-consultant/pressure-sensitive-adhesive-tape/>

⁶² <https://www.ncbi.nlm.nih.gov/pubmed/24022422>

MARSI
commonly referred
to as medical
**ADHESIVE-RELATED
SKIN INJURY**

Every year in the US alone, more than 1.5 million people suffer scarring and skin irritation from the incorrect choice and use of diapers and tapes, the majority of those being infants or elderly people⁶³. Skin tears are traumatic injuries that can result in partial or full separation of the skin's outer layers, be it separation of the epidermis from the dermis, or of both the epidermis and dermis from the underlying structures. They may result from friction, predominantly from contact with adult incontinence diapers, or the removal of tapes and adhesives, because the bond between tape and skin is stronger than the fragile bond between epidermal and dermal layers, causing the epidermal layer to be accidentally removed with the tape. In already fragile or vulnerable skin (e.g. in aged or very young skin), less force is required to cause these traumatic injuries, meaning that incidence of skin tears is often increased.

Due to the removal of skin cell layers of the stratum corneum when changing diapers or removing tapes, water loss at the site of adhesive application and removal elevates, further compromising hydration of an already incompetent skin barrier⁶⁴. Furthermore, due to the very thin skin of infants and elderly, skin tears and lesions might appear after removal. These tears can act as an entry point for absorption of drugs, harmful chemicals, and external agents and organisms, bypassing the little protection the now locally removed upper skin layer once provided. Diaper changes and use of tapes can also increase the pH level and subsequently the alkaline skin environment, further exacerbating the already deficient acid mantle of newborns and older people, making it easier for harmful bacteria to colonize the skin surface where tapes were used. In addition, repair of the skin after tissue injury requires a large consumption of energy. When the

skin is damaged evaporative heat loss and the skin trauma incurred, as well as immune response to combat the colonization and intrusion of harmful bacteria, put a lot of additional stress on the infant's already precarious intrinsic defensive capabilities.

The same can be said when looking at the problem skin tears pose for the elderly community. Patients with aged and fragile skin are at increased risk of skin tears, and the ageing of the worldwide population means that incidence is rising. They are at greater risk because of⁶⁵:

- Dry, thin, fragile skin;
- Certain medications such as anti-inflammatory agents, anticoagulants, or corticosteroids, that further thin the skin such as steroids;
- Bruising and discoloration of the skin, caused by leakage of blood into the subcutaneous tissue as a result of trauma to the underlying blood vessels;
- Preexisting dermatological conditions such as eczema, dermatitis, and ulcers;
- Poor nutrition and hydration;
- Chronic heart disease, renal failure, diabetes, and other conditions that compromise skin vascularity.

Not only are these wounds painful. They can potentially affect quality of life much more severely as we get older. Because of a frailer overall condition, skin tears may quickly cause infections, exacerbate preexisting health issues, and increase the likelihood of hospitalization, or prolong it.

⁶³ <http://news.mit.edu/2012/new-medical-tape-for-sensitive-skin-1029>

⁶⁴ <https://onlinelibrary.wiley.com/doi/full/10.1111/pde.13725>

⁶⁵ <https://multimedia.3m.com/mws/media/1190105O/understanding-and-guarding-against-marsi-brochure.pdf>

EVERY
YEAR IN US
1.5
MILLION
people suffer
scarring and skin irritation



The prevalence of skin tears due to the use of adhesives and tapes has led to mechanical diaper closure systems (generally hook-based systems) becoming the industry standard. Mechanical closure systems usually feature a soft, nonwoven fastening tape with a hook element, an adhesive layer and a release tape. The mechanical hook tape is designed to be applied on a loop-based landing zone, secured to the diaper's front⁶⁶.

Not all mechanical closure systems are created equally. There are obvious and subtle differences that affect performance. The vast choice in mechanical diaper closure systems is predominantly determined by the vast choice in materials used for the interaction between landing zone and fastening tape. The combination of materials used for these components influences everything from contamination resistance and performance to softness, comfort and cost of the closure system in the overall diaper design. The most economical choice consists of plastic adhesive-based closure tapes and landing zones. The downside here is that adhesive-based closures are still more vulnerable to contamination from baby oils and lotions than hook-based systems. They also lack the comfort and breathability that are paramount in avoiding diaper rash. Higher tier diaper closure systems use cloth-like material for increased comfort. The latest generation mechanical Hook-and-loop diaper closure systems address demands for softness, breathability and strong hold performance thanks to a specialized multilayer nonwoven construction. This construction enables the material to be processed on high speed diaper manufacturing lines and also to be repositioned and reclosed multiple times due to its high peel and shear performance.

Overall, mechanical closures provide a very reliable solution, are less sensitive to contamination from lotions, powders, and other common products used by caregivers, and allow the diaper to be opened and reliably closed, multiple times, without damaging the skin.

FIRST DO NO HARM

Spending time in a care facility as an infant or a senior, be it a hospital or a nursing home, brings about its own potential additional risks with regard to skincare and trauma. During the patient's stay he or she is subject to frequent diaper changes, which may require the frequent application and removal of tapes and adhesives, as well as regular manual handling by the caregivers.

All of these actions can cause or worsen irritation, friction and wounds. In a setting where patients with similar skin issues and lessened resistance are grouped this close together and where the risk of cross-contamination and infection is this high, the nurses and caregivers carry a very large part of the burden of keeping their patients' skin as healthy as possible.

8% of hospitalized infants are found to suffer tape-related wounds⁶⁷. Similarly in long-term care elderly patients, skin injury caused by application and removal of tapes is found in 15.5% of the nursing facility's residents⁶⁸. In 55% of cases where tape is applied to patients further wound treatments are needed⁶⁹. Despite these issues currently 62% of clinicians still indicate that their current tapes do not meet the needs of fragile skin patients⁷⁰!

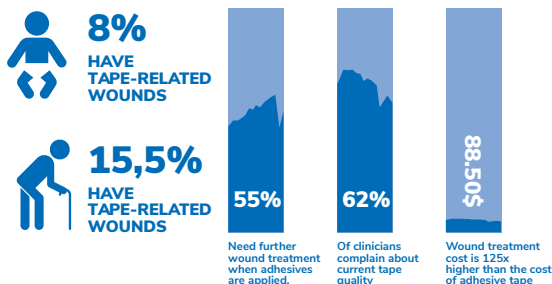
⁶⁶ https://www.nonwovens-industry.com/issues/2015-12-01/view_features/diaper-closure-systems-striking-the-right-balance-in-attributes/

⁶⁷ <https://www.ncbi.nlm.nih.gov/pubmed/24022422>

⁶⁸ <https://www.ncbi.nlm.nih.gov/pubmed/24022422>

⁶⁹ <https://www.semanticscholar.org/paper/Medical-adhesives-and-patient-safety%3A-state-of-the-McNichol-Lund/56d2cf40c16f0c641227ecd270911cc0a3deb06e>

⁷⁰ https://www.researchgate.net/publication/260875034_Evaluation_of_a_New_Silicone_Adhesive_Tape_among_Clinicians_Caring_for_Patients_with_Fragile_or_At-Risk_Skin



All this time spent on skin- and wound care inevitably comes at a considerable operating cost, as well as taking up valuable time that caregivers could be spending on other patients. Each treatment for the management of diaper- or tape-induced injury takes approximately 18 minutes of a nurse's time⁷¹. Nurses treat these injuries approximately 5 times a week, an average of 7.8 times per patient⁷². Skin injuries cost on average €78 (\$88.50) to treat. This issue is of increasing importance in nursing homes, hospitals, and other healthcare facilities, as it stands to reason that an aging population means a higher incidence of skin trauma, and corresponding treatment costs.

Nurses and caregivers play a vital role in keeping their patients and environment safe and healthy. Not only by making the correct choices when it comes to tapes and diapers and their application and removal, but just as important, by good hand hygiene. Unfortunately health care workers' compliance with hand hygiene is traditionally rather poor, with mean baseline rates ranging from 5% to 81%, and an overall average of only about 40%⁷³.

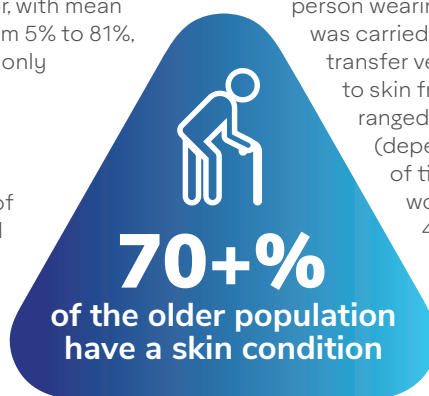
Several studies have documented increased contamination because of tapes, as well as bacterial growth, yeasts and fungi, beneath tapes applied to skin. This goes for both intentional application, e.g. during procedures, or unintentional contact, e.g. during diaper changes. In patients with already compromised skin this can easily lead to infection of the area⁷⁴. Medical adhesive products have been known to be potential reservoirs of pathogenic microorganisms for almost the past 50 years. For example, one study demonstrated that 74% (59 of 80 specimens) of tape samples collected at various areas in a hospital were found to be colonized by pathogenic bacteria⁷⁵. Another study documented that 52% (11 of 21 specimens) of partially used surgical adhesive tapes collected from 3 hospitals were all contaminated with multiresistant

organisms (methicillin-resistant *Staphylococcus aureus*)⁷⁶. None of the tape taken directly from unopened boxes had bacterial contamination.

But even if no single piece of tape intentionally or unintentionally touches the patient's skin, there's still the possibility of transfer of pathogens and bacteria e.g. via the process of changing diapers in case of insufficient hand hygiene.

The major components of the modern disposable diaper consist of 4 layers⁷⁷. The topsheet is the layer in direct contact with the baby's or adult's skin, and is composed of soft, porous polypropylene developed to transfer urine and other liquids quickly to the layers beneath. The acquisition layer is composed of modified cellulose and polyester, and facilitates the movement of liquid away from the skin to distribute it evenly to the diaper core. The absorbent layer consists of superabsorbent polymer gel that may be blended with cellulose and contained within a cellulose or a porous polymer nonwoven layer. Urine is locked and stored within this structure. The backsheet is the water-proof outer layer of the diaper, typically made of soft textured, cloth-like polypropylene laminated with a polyethylene film. Its function is to prevent liquid from leaking out of the diaper.

In a study to determine the possibility of transfer of substances present in these diaper parts to the skin of the person wearing it, a series of tests was carried out using lotion as a transfer vehicle. Direct transfer to skin from the topsheet ranged between 3.0 and 4.3% (depending on the amount of time the diaper was worn). This means that 4% of the initial amount of lotion present on the topsheet made its way to the skin surface. There was also indirect transfer from the diaper core parts that are not in direct contact with the skin. This can be attributed to the "re-wetting" of the skin when the lotion trapped in the diaper core resurfaces back to the topsheet under pressure via urine. This process was found to cause an additional 0.32 to 0.66% to be transferred to the skin. Thus, even without tapes or even caregivers' contaminated hands directly coming into contact with the skin, harmful substances, pathogens and bacteria can still make its way onto – and into – neonate or elderly skin, where it can wreak havoc, through contact with the topsheet when changing diapers.



⁷¹ <https://www.wounds-uk.com/journals/issue/33/article-details/hidden-costs-of-medical-tape-induced-skin-injuries>

⁷² <https://www.wounds-uk.com/journals/issue/50/article-details/clinician-perspectives-on-medical-adhesive-related-skin-injuries>

⁷³ <https://www.sciencedirect.com/science/article/pii/S0273230016302471>

⁷⁴ <https://www.ncbi.nlm.nih.gov/pubmed/1009007>

⁷⁵ <https://www.ncbi.nlm.nih.gov/pubmed/1519937>

⁷⁶ https://www.researchgate.net/publication/221758737_Adhesive_tape_in_the_health_care_setting_Another_high_risk_fomite

⁷⁷ https://www.technicaltextile.net/articles/overview-of-disposable-diaper-parts-and-their-purpose-3372?no_redirect=true

The inanimate environment in a care facility harbors large amounts of such harmful pathogens. Moreover, these can just as easily be acquired from a patient's body, just by touching normal, intact skin flora on unaffected areas of the patient's body. Hence caregivers should not only wash their hands between patients, but during the sequence of patient care as well, particularly when hands move from a microbiologically contaminated to a clean body site. Research regarding the contamination of health care workers' hands before and after direct patient contact, wound care, and handling patient secretions revealed that the number of bacteria recovered ranged from 0 to 300 colony-forming units⁷⁸. Furthermore, gloves do not provide complete protection against hand contamination. If not washed properly after the encounter with the patient the microorganisms will spread progressively over a short period of time due to the germs' capacity to survive on skin. Studies have demonstrated that multiresistant bacteria and viruses can survive at least 60 minutes on both gloved and ungloved fingertips⁷⁹.

It's clear to see that caregivers, be it in hospitals, nursing homes, or at home, carry a huge burden and responsibility for their patients' wellbeing. The following recommendations should be followed in order to preserve the frail skin of newborns and elderly people:

TAPES AND ADHESIVES:

SELECTION:

- Choose skin-friendly, hypoallergenic (causing fewer allergic reactions), antimicrobial, single-use pressure sensitive tape.
- Consider the application location on the body and the subsequent expected functions and characteristics of the tape first. Is the intended use gentle, or is a high adhesion required? What's the anticipated wear time, i.e. how long does the adhesive quality of the tape need to last? Where on the body will the tape be applied and for which purpose? Will it come into contact with the skin, and will that body part move and stretch a lot?

APPLICATION:

- Tape should be applied without tension (i.e. should not be pulled or stretched when applied) to clean, dry skin.
- Do not apply tape on wet skin surfaces.
- Body hair should be removed first.
- Do not use alcohol-based skin preparations, because they dry the skin.
- To protect at-risk skin, a pectin barrier film may be applied and allowed to dry first, before applying the tape.

- Minimize touching of adhesive during application.
- Smooth tape in place with gentle pressure.
- Avoid gaps and wrinkles.
- Tape should extend at least one-half inch beyond any dressing.
- Do not use any substances that increase the stickiness of adhesives, such as bonding agents.

REMOVAL:

- Whenever possible, avoid removing adhesives until at least 24 hours after application, in order for the adhesive to wear off and avoid removing the top layer of skin due to too high of an adhesive bond with the tape.
- Loosen edges of tape.
- Stabilize skin with one finger.
- Remove tape "low and slow" in direction of hair growth, keeping it close to the skin surface and pulled back over itself (removing tape at an angle will pull at the epidermis, increasing risk of tears).

DIAPERS⁸⁰:

SELECTION:

- Choose skin-friendly, hypoallergenic (causing fewer allergic reactions), antimicrobial, disposable, superabsorbent, and breathable diapers (the use of cloth diapers is associated with higher frequency of diaper dermatitis because they lack the absorbent qualities of disposable ones).

CHANGING:

- Always wash hands thoroughly before touching the patient or any of the diaper components in order to prevent infection.
- Frequent diaper changing (every 1–3 hours) is essential to prevent diaper dermatitis, as this reduces the amount of time the skin is in contact with moisture and irritants.
- Before putting on a new diaper, make sure that the skin is dry and clean.
- Avoid rubbing or friction during diaper changes.
- Ideally, an infant with irritant diaper dermatitis should be allowed periods of rest without a diaper, exposing the damaged skin to air.
- The diaper area should be gently cleansed with warm water and a small amount of a mild cleansing product with slightly acidic to neutral Ph.
- When applying the diaper, avoid tape adhering to the skin, because this can lead to irritation and infection.

⁷⁸ https://omniamedsso.com-systems.net/sso/check_site_login/site_id/15/login_type/2/ip_hash/fd07ea74e924420026f8dc4396cd6573

⁷⁹ <https://www.ncbi.nlm.nih.gov/pubmed/16087824>

⁸⁰ https://www.researchgate.net/publication/320266792_Diagnosis_and_management_of_diaper_dermatitis_in_infants_with_emphasis_on_skin_microbiota_in_the_diaper

HAND HYGIENE⁸¹:

SELECTION:

- Use a hand rub with hand sanitizer if hands appear clean.
- Use soap and water when hands are visibly soiled.

CRITICAL MOMENTS:

- Before and after having direct contact with patients.
- After removing gloves.
- Before handling an invasive device for patient care.
- After contact with body fluids or excretions, mucous membranes.
- If moving from a contaminated body site to a clean body site during procedures or examination.
- After contact with inanimate objects (including medical equipment).

HANDLING PATIENTS:

- Ensure adequate lighting and position small furniture to avoid unnecessary bumps or knocks.
- Upholster or pad sharp borders of furniture or bed surroundings with padding.
- Use appropriate aids when transferring patients and adopt good manual handling techniques.
- Always use a lifting device or slide sheet. Never use a bed sheet to move the patient as this can cause friction on the skin.

SKINCARE⁸²:

- Avoid the use of soap, which can dry the skin. Use pH-friendly solutions.
- Apply emollients to moisturize and rehydrate dry skin.
- Control moisture from incontinence.
- Place, fix and remove peripheral devices carefully.
- Use a barrier film or cream to protect vulnerable skin.

ISOLATING THE SOLUTION

Let's come back to the previous section's first recommendations when choosing tapes, adhesives and diapers: opt for skin-friendly, hypoallergenic, antimicrobial, disposable, superabsorbent, and breathable products. It's clear that this is the safest way to ensure that the products used will have the least chance of negative effects and preserve the essential skin barrier in babies and seniors as best as possible. Easier said than done, however. Unfortunately, many products intended for use on children have potentially toxic substances that are harmful to the skin of newborns. Even labels containing phrases such as "dermatologically tested" or "balanced pH" or "natural or organic ingredients" do not guarantee the safety of the ingredients.

Another issue one should be aware of is that there's a vital difference between baby diapers and adult incontinence products. Adult incontinence products (e.g. briefs and pads) are regulated as medical devices under the European Medical Devices regulation (MDR) and the US Food and Drugs Administration (FDA). Medical devices are considered to be specifically intended for medical purpose. Not all equipment used in a healthcare environment or used by a healthcare professional will be considered as a medical device however. Products that do not have such a specific medical purpose are not considered to be medical devices, even if they may be considered to be used for the prevention of disease as a secondary purpose. And therein lies the difference: baby diapers are not regarded as medical devices, whilst adult diapers are. This has a huge impact, because being classified as a medical device brings about a series of mandatory tests manufacturers have to pass in order to demonstrate that their products are safe for use, especially with regard to skin contact. Seeing as both baby and adult diapers basically have the same design and function, and baby diaper parts and tapes can come into contact with the patient's skin just as with adult diapers, this presents quite a predicament. Both newborns and elderly need additional protection in order to safeguard their skin just the same, but one group seems to get far better assurances than the other.

Medical devices are subject to testing under the international ISO 10993 guidelines. These guidelines require materials used in medical devices which come in contact with the body to be biocompatible, i.e. not have any toxic or injurious effects on biological systems. This is the only effective way of ensuring that a material, when it happens to come

⁸¹ <https://www.davidsonwashroom.com.au/hand-washing-procedures-steps-nurses/>

⁸² <https://studylib.net/doc/8211572/skin-tears-wounds-international>

into contact with the patient's body, not only performs its intended purpose but not causes any adverse (e.g. allergic) reactions for the patient either. These tests evaluate the interaction between a device or material and anything it comes into contact with in the patient's body, such as cells, tissue or body fluids .

Biocompatibility for medical devices consist of 3 tests: skin irritation, cytotoxicity and skin sensitization. Cytotoxicity tests serve to determine if device extracts or materials used in its production contain harmful extractable substances. Skin irritation tests evaluate if any substances or chemicals are released from the product which may produce irritation to the skin, mucous membranes, and eyes upon contact with the body. Lastly medical devices are tested for the presence of sensitizing chemicals or substances. Sensitization reactions typically occur after prolonged exposure to a substance that interacts with the body's immune system. Sensitization tests elicit immune responses such as redness and swelling .

So, when choosing adult diaper products, you're pretty much covered by these obligatory procedures. But how can you be absolutely sure the baby diapers you use as a parent or caregiver, or any tape or adhesive you use on a patient's body, not just the specific medical tape used during medical procedures, are 100% safe? Well, luckily there are quite some manufacturers who are well aware of this discrepancy, and who voluntarily submit all their baby diaper parts, tapes, and adhesives for the same ISO-10993 testing procedures.

Just as you, as a parent or a healthcare professional, should go above and beyond the call of duty when it comes to preserving your child, loved one, or patient's skin and consequently their overall health, you should choose manufacturers who do the same. Always look for ISO-certified products, whether they are medical devices or not, as this provides the best assurance that diapers, tapes and adhesives are absolutely safe for use on newborns and the elderly.

It might require some extra effort and investment, but that pales in comparison to the potential disastrous consequences to the people in your care, as well as skyrocketing overall costs and impact of infection spreading throughout the care facility.

Taking the time to choose the correct diapers and closure systems will be repaid in the long run.

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Performance
Tapes