LECZENIE RAN 2025; 22 (2): 46–79
DOI: 10.60075/lr.v22i2.103

Treatment of nipple wounds during breastfeeding. Position of the Center for Lactation Science and the Polish Wound Management Association

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Received: 15.05.2025; Accepted: 24.05.2025

Abstract

Nipple soreness and wounds are a common problem during lactation, especially in the first weeks after birth. These issues are associated with an increased risk of mastitis, poor weight gain in the newborn, formula supplementation, and premature cessation of breastfeeding. Prevention and early diagnosis are fundamental tasks for medical staff caring for both the mother and infant. The most common cause is the baby latching onto the breast too shallowly.

Therefore, improving the feeding technique is essential to prevent and treat nipple damage. With appropriate care, healing occurs quickly. However, in cases of hard-to-heal or infected nipple wounds, diagnostic and therapeutic measures should be taken immediately.

The position paper from the Center for Lactation Science (CLS) and the Polish Wound Management Association (PWMA) outlines practical guidelines for treating nipple wounds during lactation, considering their specific differences compared to wounds of other etiologies and in different locations. This study discusses issues related to wound infection development, the TIMERS strategy, and detailed guidelines for lactation care, essential for optimal healing.

The study proposes a classification of wounds into four categories: uninfected, at risk of infection, infected, and spreading infection from the wound to surrounding tissues. Each wound category includes appropriate therapeutic agents such as lavaseptics, antiseptics, and specialized dressings. The document also addresses indications for antibiotic therapy, the technique for taking a swab from the wound, and the most common errors in treating nipple wounds.

The described principles of treating nipple wounds are based on global and Polish consensuses in wound treatment and the many years of unique experience of Polish lactation consultants.

Key words: breastfeeding, sore nipples, nipple pain, nipple wound, nipple injury, damaged nipples, wound infection, antiseptics.

This document is intended exclusively for healthcare professionals, particularly physicians, midwives, and nurses who care for women and their infants during lactation. It will be particularly useful for lactation specialists.

Introduction

Nipple soreness and wounds are common issues among breastfeeding mothers. Studies from various countries show that 62–95% of women report such symptoms shortly after childbirth [1]. Pain occurs most frequently during the first week postpartum, with most women experiencing a reduction to mild discomfort within 7–10 days [2]. More than half of mothers with nipple pain also have visible nipple wounds or other skin changes [3]. Based on the number of births in 2024 (252,000) and the fact that 97% of women in Poland start breastfeeding [4], with 30% of them having nipple wounds, it can be estimated that over 73,000 breastfeeding mothers struggled with nipple wound problems.

In the study by Coca et al. [5], women with damaged nipples rated their pain intensity at an average of 6.2 points during the first week and 5.8 points later on, while women without visible damage rated it at an average of 2.7 points (on a numerical pain rating scale NRS or another scale ranging from 0 to 10 points, where mild pain is scored 1–3, moderate 4–6, and severe 7–10 points).

Nipple pain is one of the main reasons for formula feeding and premature breastfeeding cessation. In the USA, among mothers who stopped breastfeeding within the first month, one third cited nipple pain or wounds as the reason [3]. Nipple wounds are also a risk factor for mastitis [6]. The discomfort mothers experience multiple times a day when breastfeeding affects feeding quality, activity, mood, sleep, and increases the risk of depression. Disrupting the oxytocin reflex can reduce milk intake by the newborn [7].

Due to all the serious consequences of these issues, prevention is needed through educating mothers after childbirth about breastfeeding techniques, early detection of injuries, and implementing proper treatment. This responsibility lies with all healthcare professionals involved in maternal and child care, including midwives, nurses, doctors, and lactation consultants.

Distinctive features of nipple wounds compared to commonly occurring hard-to-heal wounds

A wound is a break in the continuity of the skin or the skin and the tissues beneath it. A wound of the nipple or areola usually occurs as a result of mechanical injury (pinching, pulling, rubbing, suction) caused by improper sucking technique or incorrect use of a breast pump.

Bite wounds occur as a result of being bitten by a teething infant.

Nipple wounds have several distinctive features compared to wounds of different etiology and locations. They occur in young, generally healthy women, in a well-vascularized and innervated area. Despite their usually small size of a few to several millimeters, they cause significant pain, and their healing is hindered by regular breastfeeding or expressing milk from the injured breast. Dressings must be removed every few hours before feeding, and medicinal agents must be wiped off the skin surface to ensure breastfeeding is safe for the baby. Sticky substances that are hard to wash off are not recommended.

The environment of a nipple wound is unique because it is shaped by the microbiome of the nipple skin, the milk ducts, the properties of breast milk, as well as the infant's oral microbiome and contact with saliva. A relationship has also been discovered between the mother's gut microbiota and her milk (the gut-breast pathway) [8].

The flora of the nipple skin is primarily composed of bacteria (commensal, symbiotic, probiotic), to a lesser extent fungi and viruses, and is integrated with the host's immune defense. Interestingly, this flora differs from the flora of the milk and the infant's stool. Dominant bacteria include *Staphylococcus* and *Streptococcus* species, as well as *Enterobacteriaceae*, *Corynebacterium*, *Propionibacterium*, *Bacteroides*, and others [9].

Any damage to the epidermis or dermis of the nipple (including micro-injuries) causes unfavorable changes in the microbiota composition, weakening the skin barrier and creating conditions for colonization by microorganisms of varying severity.

On the nipple, as the opening of a skin gland, commensal bacteria are present at higher concentrations than in other areas of the breast skin, so wound colonization occurs quickly. The mother's milk and its microbiome are important protective factors [3, 10]. Breast milk contains a variety of components with anti-inflammatory, immunomodulatory, antimicrobial, and healing-supportive properties, such as interleukins, lactoferrin, lactadhesin, lysozyme, SIgA (secretory IgA), antioxidants, growth factors, interferon, vitamin A, omega-3 and omega-6 fatty acids, mucin, and many others [11, 12].

Since the nipple is continuously exposed to milk with strong bacteriostatic properties, bacterial proliferation is more difficult in that area. It has been hypothesized that histatins (small molecular weight peptides secreted into the saliva of mammals) present

in the infant's saliva may support epidermal regeneration by stimulating migration of epidermal cells, fibroblasts, angiogenesis, and additionally destroying bacteria [13].

It is worth adding that breastfeeding from an injured breast, even if the wound is infected, does not pose a risk to the breastfed infant.

Causes and symptoms of nipple wounds

The most common cause of nipple pain and damage is shallow latch, improper sucking, or clenching of the breast with the gums, usually caused by incorrect positioning of the mother or newborn during feeding or improper latching technique [14, 15]. Nipple damage often occurs during breast engorgement due to difficulties in latching caused by swelling of the areola [14]. Some infants generate excessively high suction pressure, both baseline and peak, and mothers of these infants more frequently experience nipple pain [16]. A shortened tongue frenulum is rarely the cause of nipple pain, contrary to the current trend of diagnosing ankyloglossia. The problem of a shortened frenulum affects only about 7% of infants [17], while feeding problems affect nearly 50% of these children [18]. In her study, Geddes examined infants with ankyloglossia who produced either insufficient or excessive suction pressure or overly compressed the nipple; however, milk intake remained adequate, and the mothers did not report pain. The causes of nipple damage are summarized in Table 1 [19].

Nipple damage is usually located at the nipple tip, but sometimes fissures and cracks may appear on the nipple shaft, its base, or the areola. They vary in depth and extent, ranging from epidermal lesions to deeper skin damage. Table 2 presents the types of skin lesions observed in relation to nipple damage [20–22]. The appearance usually differs for each mother, yet Woolridge et al. [23] identified some similarities and proposed a classification of nipple injuries based on their causative mechanisms:

- compression damage – flattening of the nipple visible after removing the breast from the infant's mouth, longitudinal wounds at the nipple tip, fissures, crust referred to as positional streaks caused by incorrect positioning of the nipple-areola complex in the infant's mouth (Figs. 1, 2);
- suction injury – damage to the nipple tip characterized by redness, blisters, petechiae, and star-shaped cracks on the nipple tip, caused by generating high suction pressure in the infant's oral cavity (more often observed in mothers with low milk supply, impaired milk flow, or flat or inverted nipples).

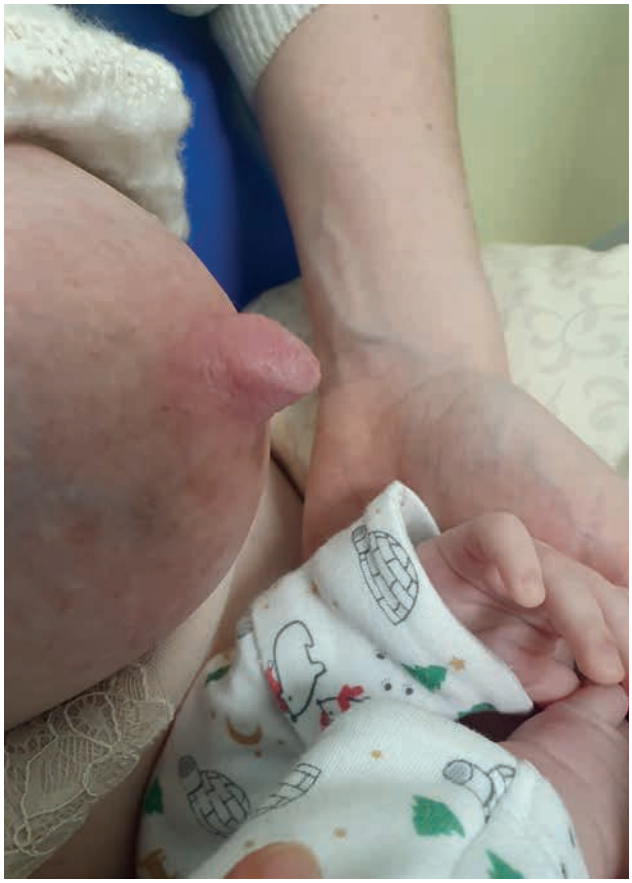

Figure 1. Compression flattening (positional stripe) of the nipple visible after feeding (photo by M. Żukowska-Rubik).

Table 1. Causes of nipple damage [19]

Maternal causes	Infant causes
Improper breastfeeding position, incorrect latching Tense/engorged areola during milk oversupply or breast engorgement Flat, inverted nipples, or other difficult-to-latch variants Improper detachment of the baby from the breast Inappropriate breast pump (lack of medical device certification) or improper use (excessive suction force, prolonged sessions, improperly sized flange)	Shallow latch during sucking Anatomical abnormalities of the oral cavity (short lingual frenulum, high-arched palate, significantly retracted jaw) Functional sucking disorders (abnormal oral reflex responses – excessive suction, biting, hyperactive gag reflex), compensatory behaviors Abnormal muscle tone, asymmetry, torticollis Restlessness, looking around, distraction – common in older infants Biting the breast by a teething infant

Treatment of nipple pain and wounds – a review of current literature

Due to the need to protect mothers and infants from complications such as mastitis [6] or premature cessation of breastfeeding, effective treatment of nipple pain and wounds has become a subject of interest for clinicians and researchers. In previously published studies, the effectiveness of various methods has been assessed. Nipple pain and damage are generally considered together under the term "sore nipples"; however, the severity of the problem differs significantly, and many authors advocate for more precise definitions when examining study groups [5].

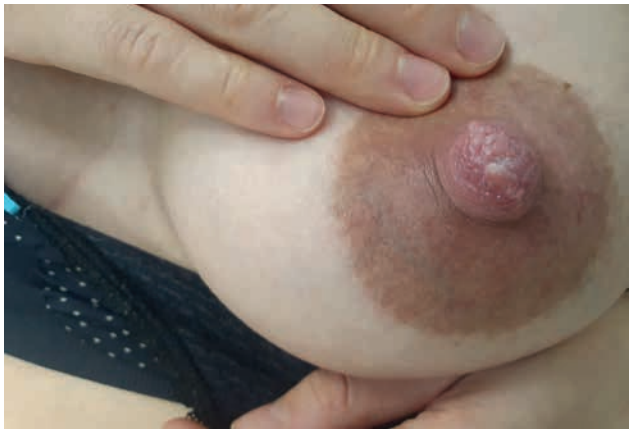

Figure 2. Positional stripe, slight epidermal damage along its course (photo by M. Żukowska-Rubik).

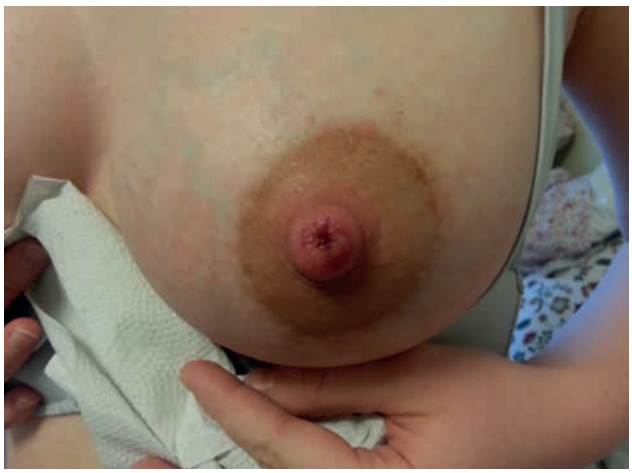

Figure 3. Crust in the centre of the nipple (photo by M. Żukowska-Rubik).

Breastfeeding technique and education

During breastfeeding, the nipple is positioned deeply in the infant's mouth, with the nipple tip reaching almost to the hard and soft palate junction (HSPJ), approximately 6 mm from the HSPJ. This positioning prevents excessive compression and pressing against the bony part of the palate while stimulating the sucking reflex through the nerve endings located in this area. The nipple tip, along with the final segment of the hard palate and the back of the tongue, participates in creating the suction pressure necessary for milk extraction [24].

A recently published systematic review found that biological breastfeeding (with the mother's body reclined, the baby positioned on her abdomen, and initiating breast latch independently) compared to traditional positions (cross-cradle, cradle, football, side-lying) reduced the risk of nipple pain and injuries. However, the study was criticized for the poor quality of the included research [25]. Bashiri did not observe any difference between the biological and cross-cradle positions regarding the frequency of nipple injuries [25]. Another study reported a higher risk of injuries when the infant's face was incorrectly positioned at the breast (lack of contact of the nose, chin, and both cheeks) and in cross-cradle and football positions compared to the cradle and lying positions [15]. The authors hypothesize that holding the infant by the anatomical structures of the head and neck restricts the freedom of cervical spine movements and the stabilizing function of the nuchal ligament, making it difficult for the baby to touch, smell, and taste to locate the nipple. It is also possible that this

Table 2. Types of skin changes observed in relation to nipple injuries [20–22]

Abrasion	A minor wound caused by the rubbing off of the epidermis (see Fig. 12A)
Erosion	Loss of the epidermis not exceeding the basement membrane, heals without scarring (see Fig. 13A)
Fissure, crack	A linear split of the epidermis (fissure) or epidermis and dermis (crack), heals with scarring (see Figs. 12B, 14A)
Ulceration	Loss of skin extending beyond the basement membrane, heals with scarring (see Fig. 14B)
Crust	Forms as a result of drying of exudate, pus, or blood on the surface of vesicles and blisters, erosions, ulcers, or wounds (Fig. 3)
Scar	A skin change usually resulting from damage to the dermis and replacement of the defect with fibrous connective tissue (Fig. 4)
Additionally, when describing skin lesions, it is essential to address the presence of exudate – its nature (serous, purulent) and the origin of the lesion, e.g., an erosion oozing serous fluid	

causes too shallow a breast latch, jaw dysfunction, and friction of the nipple against the hard palate.

A recently presented concept of conflicting vectors – the child's oral cavity and the breast axis – is associated with improper breastfeeding technique. According to the concept, unevenly distributed forces on the nipple surface cause stretching and pulling of the skin, leading to cytokine and histamine release, microvascular injuries, and consequently triggering an inflammatory response with interstitial swelling, nerve ending irritation, and pain. Repeated trauma results in damage (Figs. 5, 6) [3].

Education for mothers, technique guidance vs. different healing aids

The systematic review by Dennis (2014) [2] included four studies of good methodological quality involving 656 women, examining the effectiveness of nipple pain relief using expressed breast milk, a triple-component nipple ointment (mupirocin, miconazole, betamethasone), lanolin, protective shells, and hydrogel dressings. All mothers in the studies covered by the meta-analysis **received guidance on how to position the baby as part of routine care.** The results suggest that the absence of intervention or the use of expressed breast milk alone may be just as or more beneficial for short-term nipple pain relief compared to other methods. One of the key findings of this review is that, regardless of the treatment applied, nipple pain decreased to a mild level in most women approximately 7 to 10 days after childbirth, and mothers should be informed about this. In another large review, Niazi et al. [26] evaluated numerous interventions for nipple injuries. The primary measure taken for patients was also correcting the breastfeeding position.

Topical pharmacological agents for reducing pain, alongside other methods

Lanolin

A very popular remedy recommended to mothers is purified, hypoallergenic lanolin, cleansed of alcohols and pesticide residues. It is believed that the preparation creates a bacteriostatic barrier, maintains a moist environment, and accelerates healing. However, in the randomized study by Jackson and Dennis [1], lanolin showed no significant effectiveness in relieving nipple pain with visible nipple trauma in the early postpartum period, nor did it affect the duration of breastfeeding compared to routine care offered to mothers in the hospital after delivery. Mothers

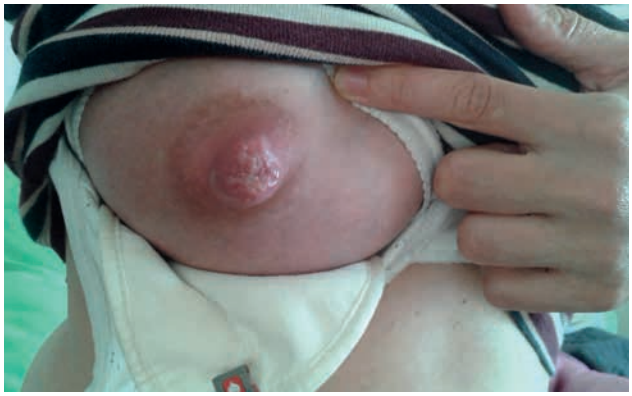

Figure 4. Scar covering the entire top of the nipple after an extensive wound (photo by M. Nehring-Gugulska).

Figure 5. Correct, latch, lower lip flanged, upper lip in neutral position, wide angle between lips, nose and chin in contact with breast (photo by M. Żukowska-Rubik).

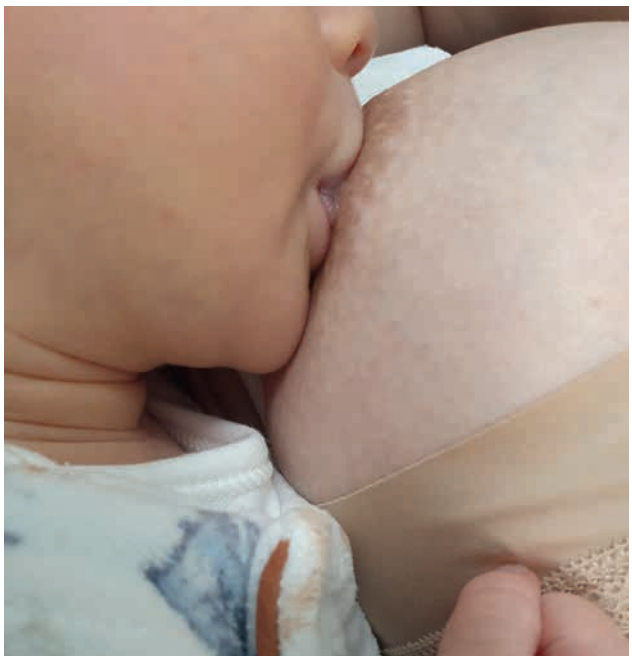

Figure 6. Abnormal, shallow sucking of the breast – tight corner of the mouth, angle of the lips only about 90 degrees, small part of the areola covered by the mouth (photo by M. Żukowska-Rubik).

using lanolin, however, reported greater satisfaction with the treatment. In another study, Vieira et al. [27] found that applying breast milk and protective shells to the nipples was more effective than lanolin in relieving pain. The use of lanolin on wounds raises concerns due to the risk of contact allergy. Lanolin preparations intended for nipple application are purified to remove alcohols, which reduces the risk of irritation; nevertheless, they should not be used on damaged skin or by patients with atopic dermatitis (AD) [28]. Most popular ointments and creams for nipple care during lactation have not been tested for effectiveness in relieving pain.

Various methods used in the treatment of nipple pain and damage

Among the studies included in the systematic review by Niazi et al. in 2018 [26], two examined the effect of mint on nipple cracking and pain; both had acceptable design and validation, and both demonstrated the effectiveness of menthol in the form of a gel or oil. The RCT by Lavergne [29] confirmed the effectiveness of using warm water or tea tree oil compresses in relieving nipple pain associated with irritation and damage early after birth (compresses were applied 4 times a day for 15 minutes over 5 days). Due to the small sample sizes in the studies mentioned above, strong recommendations regarding their use could not be made.

The use of low-level laser therapy had a significant effect on relieving nipple pain, but its high cost limits widespread adoption of this treatment. It is worth adding that besides the methods listed earlier, other treatments for nipple wounds have been tested, which often have a regional specificity. For example, there are reports on the use of extra virgin olive oil, turmeric extract, common yarrow, honey, aloe vera, a mixture of sesame, macadamia, and apricot oils, cream made from common purslane, and even phototherapy using wavelengths in the 360–1,000 nm range. It is difficult to draw definitive conclusions from these studies regarding the most effective treatment, and the results are sometimes contradictory.

Mechanical methods to prevent and treat nipple pain and damage

Protective shells

Sometimes it is beneficial to wear protective shells after feedings, which protect the nipples from contact with breast pads or clothing. The bra should be slightly looser in this case so that the shell does not compress the breast. However, it should be remembered that the environment inside the shell is moist, and continuous use leads to skin maceration (due to prolonged moisture exposure, the skin softens and peels off). Research results regarding the effectiveness of shells are inconclusive (Fig. 7).

Protective covers (nipple shields)

A nipple shield, a protective cover worn during feeding, reduces pain for some mothers. If pain cannot be reduced by improving feeding technique or decreasing areola tension, a nipple shield can be used for a limited time, especially in cases of strong suction (high negative pressure in the newborn's mouth) despite a deep latch [16, 30]. Use of a nipple shield may also be considered in anatomical or functional sucking disorders that do not improve immediately and where nipple wound healing progress is slow.

The impact of nipple shields on milk intake has been evaluated, but study results are inconclusive, so feeding progress and sucking efficiency must be closely monitored during shield use [29].

Moreover, it has been shown that if nipple shields are used by mothers without breastfeeding problems, it may negatively affect milk intake and nutritive sucking time; thus, nipple shields should only be recommended after careful consideration of indications [30]. The use of nipple shields has been associated with shorter breastfeeding duration, but not when supervised by lactation consultants [32, 33].

Nipple shields should be washed with detergent after each use and thermally disinfected once daily by immersion for 5–10 minutes in water at 90–100°C or in a special microwave sterilization bag. It is important to remember that lack of hygiene of the nipple shield and other equipment contacting the nipple skin increases the risk of wound infection (Fig. 8).

Figure 7. Protective shell with a wide opening (photo by M. Żukowska-Rubik).

Figure 8. Different types of nipple shields (photo by M. Żukowska-Rubik).

Consensuses regarding wound treatment in the context of nipple wounds

In the case of hard-to-heal or infected nipple wounds, improving breastfeeding technique, applying breast milk, or other methods described above will not be sufficient. Meanwhile, it is difficult to find reports on treating such wounds based on modern principles adopted in numerous consensus guidelines for wound treatment in surgery or dermatology, which discuss the use of classic lavaseptic solutions, surfactant-containing lavaseptic solutions, antiseptics, or specialized dressings [34–37]. Expert guidelines indeed concern a different type of wounds than nipple wounds, namely hard-to-heal wounds and ulcers associated with diabetic foot disease, leg ulcers, and pressure sores in typically elderly patients with multiple chronic health conditions. However, the action of lavaseptics and antiseptics is universal. These agents have been used in Poland for over a decade by lactation consultants to treat nipple wounds, showing good results in clinical observations, and the Center for Lactation Science includes them in their training protocols.

Hard-to-heal wounds

Until recently, the term chronic wounds was used to describe wounds that do not progress through the healing phases in an orderly and timely manner, with the healing process exceeding 6–8 weeks (ranging from 4 weeks to 3 months in various studies) [37]. Currently, a new definition according to Murphy is accepted, where instead of the term chronic wound, the term **hard-to-heal wound** is used. Any wound can be classified in this group, regardless of type or etiology. These are wounds in which factors that may impair healing exist and that do not respond to standard treatment. It has been documented that almost all contain biofilm (Fig. 9). The key moment for classifying a wound as hard-to-heal is the third day, when the wound shows increased exudate, fibrin at the wound base, and an increase in size despite ongoing treatment [39].

BIOFILM is a complex multispecies ecosystem of microorganisms enclosed in an extracellular polymeric substance – a matrix. It causes subclinical local wound infection. Within the biofilm, bacteria create a metabolically and immunologically different environment, making them resistant to antibiotics and antiseptics. Biofilm can regenerate within several hours, reaching maturity after 48–72 hours. Signs of biofilm formation include a large amount of dead tissue in the wound, shininess (glossiness), fibrinous coating, increased exudate, and unpleasant odor [35]. Counteracting biofilm proliferation involves mechanically removing the polymer matrix structure and preventing the regeneration of its mature form (Fig. 9).

In clinical observations, small nipple wounds typical in the first days after childbirth heal quickly within a few days after improving breastfeeding technique. This is supported by the bacteriostatic properties of breast milk, especially rich in bioactive factors in the first days postpartum. In a small study conducted by Nehring-Gugulska et al. in 2018 [38], the average healing time was 4.15 days, and pain

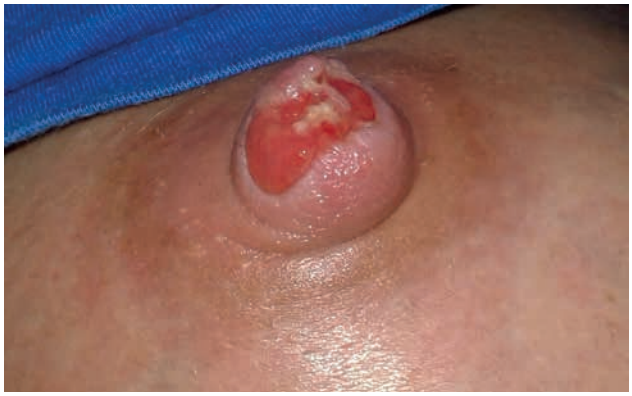

Figure 9. Deep wound involving the top and sides of the nipple, covered with biofilm, swelling of the wound edges, oozing of exudate, swelling of the nipple (photo by M. Nehring-Gugulska).

Source: Żukowska-Rubik M., Nehring-Gugulska M. Pathology of breast and nipple during lactation. In: Żukowska-Rubik M., Godyń-Myśliwy Z., Nehring-Gugulska M. *The Atlas of physiology and pathology of lactation.* 1st Edition. Medycyna Praktyczna, Krakow 2025, with consent.

resolution occurred after an average of 5.86 days. However, in clinical practice, lactation consultants often encounter nipple wounds that are hard to heal. This usually concerns extensive, deep wounds that are more prone to infection. Healing of such wounds typically takes 2–3 weeks, but sometimes even several months. It is important to remember that factors causing nipple damage can also impair its healing, such as sucking dysfunction.

Infection development in the wound

In nipple wounds, infection can develop through contact with microorganisms residing on the skin, transferred via the mother's hands, medical staff, or present in the infant's oral cavity. The most common pathogens are staphylococci, mainly methicillin-sensitive, rarely methicillin-resistant, enterococci, *Escherichia coli*, and other Gram-negative rods, streptococci [40].

Infection can spread to adjacent tissues, including breast skin, subcutaneous tissue, and the mammary gland, so it must be quickly diagnosed and treated. Infection is preceded by earlier phases of bacteria-host interaction, namely contamination and colonization (Table 3) [41–44].

Symptoms of nipple wound infection: significant increase in pain, nipple redness, swelling, warmth, swelling of wound edges, exudate – often purulent, presence of necrotic tissue [41], no healing progress despite proper breastfeeding technique and infant sucking function.

Wound management

The TIMERS strategy is used to describe wound management methods. Each letter in the acronym represents a component. Below are the individual components of the TIMERS strategy with comments regarding nipple wounds.

T – tissue debridement – wound cleaning

Lavaseptics are preparations used for washing the wound and remove physical, chemical and biological contaminants. Regular wound cleaning is essential for maintaining proper, uncomplicated healing. Classic lavaseptics include Ringer's solution and 0.9% NaCl. According to recent studies, 0.9% NaCl may increase the proliferation of mesothelial cells, disrupt the fibrinolysis system, and decrease interleukin-6 activity, thus adversely affecting tissue regeneration; therefore, other methods should be chosen. For this reason, regular use of 0.9% NaCl in the described procedures is increasingly being abandoned.

An ideal lavaseptic should contain a surfactant, which is a surface-active agent that, among other things, reduces surface tension and disrupts the biofilm. Examples of such substances include betaine, ethylhexylglycerin, and poloxamer. Lavaseptics can also contain antiseptic substances, such as octenidine dihydrochloride, at lower concentrations than those found in antiseptics. Hypochlorites (sodium hypochlorite and hypochlorous acid) are also used in lavaseptics, although they do not contain surfactants. The preparations can take the form of

Table 3. Stages of infection development in nipple wounds based on PTLR guidelines [35, 42]

Contamination	Microorganisms present in wound; pathogen proliferation (–); host immune response (–); healing delay (–)	No nipple swelling or redness, no swelling of wound edges, no exudate; healing occurs in typical time	RECOMMENDED: MONITORING
Colonization	Microorganisms present in wound; pathogen proliferation (+); host immune response (–); healing delay (–)	As above	
Local latent infection (critical colonization)	Pathogen proliferation (+++); host immune response (–); healing delay (+)	Bleeding, increasing exudate No healing progress	INTERVENTION NECESSARY
Local overt infection	Pathogen proliferation (+++); host immune response (+); healing delay (+)	Increased pain, swelling, nipple redness, swelling of wound edges, warmth around wound, exudate with unpleasant odor, no healing progress	
Spreading infection	Further pathogen proliferation, as above	Expanding redness and swelling around wound > 2 cm	
Spread of infection to surrounding tissues with a systemic response	Deterioration of general condition, fever, leukocytosis, increased C-reactive protein and procalcitonin levels	Pain, swelling, erythema, warmth of the breast or its part Differential diagnosis: skin and subcutaneous tissue infection – erysipelas, subcutaneous tissue infection – cellulitis [43], infection of breast gland structures [44]	

a washing liquid or gel. These substances should have a broad spectrum of activity, effectively penetrate biofilm structures, and should not induce bacterial resistance.

Nipple wounds – commentary: Nipple wounds can be mechanically cleaned with a stream of lavaseptic (spraying, rinsing), by wiping with a sterile gauze pad soaked in lavaseptic, or by using a dressing specifically designed for wound cleaning (a product made of monofilament fibers). If the wound contains fibrin, dried exudate, biofilm, or crust, it is beneficial to use a gauze soaked in lavaseptic or lavaseptic gel (applied for the duration recommended by the manufacturer) to moisten, soften the coating, and then gently clean with gauze. It is important to remember that all procedures should be performed gently because of the nipple's extensive sensory innervation.

Gao et al. described a surgical method for cleansing chronic lesions, keratotic buildups, and necrotic changes from the surface of the nipple in breastfeeding women. This method was applied when there was no improvement after two weeks of other treatments. After skin cleaning, about half of the patients experienced wound healing and pain resolution within a week, significantly more often than in the control group [45]. There are no reports on other methods of nipple wound cleaning, such as enzymatic or negative pressure therapy.

I – infection and inflammation control

To control infection and inflammation, antiseptics and dressings containing antibacterial substances are used. Sometimes, systemic antibiotic administration is necessary. Antiseptics should be used as long as there are clinical signs of local infection and discontinued when the symptoms subside, and the wound begins to heal. Antiseptics are substances with antiseptic properties; some are registered as medicines, while others as medical devices. Antiseptics exhibit bactericidal activity.

Nipple wounds – commentary: the choice of preparations depends on the wound category, as discussed below.

A gel containing an antiseptic substance, which can remain on the wound until the next feeding, can act as a dressing. The gel is applied in a thin layer, and it is advisable to use a secondary dressing, such as sterile gauze.

Lavaseptics and antiseptics are discussed in detail in Annex 2.

M – maintaining moisture balance in the wound

Specialist dressings have various properties, including providing a moist environment that promotes the proliferation and migration of epidermal cells [46]; some dressings have exudate-absorbing qualities and aim to reduce the risk of maceration of the skin around the wound; others contain antibacterial substances.

Depending on their structure, they can be divided into mesh, hydrogel, hydrocolloid, hydrofiber, foam, contact layer, and hydrogels with antibacterial substances.

Nipple wounds – commentary: A moist wound healing environment for nipple wounds, besides the mentioned benefits, reduces pain during breastfeeding by maintaining nipple skin elasticity and moisture. It also prevents crust formation, which, when disrupted during the next feeding, causes additional pain and damages the healing surface. It may be beneficial when the mother reports severe pain or the wound tends to dry out, sticking to the lactation pad or underwear. Annex 2 discusses dressings registered by manufacturers for use on nipples during lactation (Annex 2, Table I) and other types of specialist dressings that may be used for nipple wound treatment after considering the benefits and risks (Annex 2). Hydrocolloid and hydrofiber dressings adhere strongly to the wound and are unsuitable for nipple wounds.

E – protection of the wound edges and epidermization stimulation

To protect the skin from maceration, contact allergy, or irritation, it is recommended to use gentle cleansing agents with a slightly acidic pH, hypoallergenic moisturizing substances, petroleum jelly on the skin around the wound, active dressings, paraffin, epidermization-stimulating substances, and anti-inflammatory agents.

Nipple wounds – commentary: Nipple wounds are small enough that applying different substances to the wound and its edges is not feasible.

R – regeneration – supporting regenerative and repair processes

Nipple wounds – commentary: unless absolutely necessary, additional preparations from this group are not used. Due to good vascularization of the nipple, once appropriate conditions for wound healing are created through cleaning, maintaining a moist environment, and controlling infection, the wound begins to heal. An additional preparation is

an extra expense and requires washing off, which is inconvenient.

S – consideration of social factors related to the patient and their family

Specialized dressings

Many types of specialized dressings are available for both non-infected and infected wounds, including various dressings designed specifically for application on nipple wounds. Among antibacterial dressings, **silver ion-containing dressings** are frequently used in treating difficult-to-heal wounds. However, there are no conclusive studies on their effectiveness when applied to nipples in breastfeeding mothers and their safety for infants. One study investigated silver nipple shields that significantly reduced pain and accelerated healing on days 7 and 15 after application compared to standard nipple wound care (proper feeding technique, hygiene, milk application) [47]. Hale describes the use of silver-containing products applied locally, but not on nipples during lactation [48]. *In vitro* studies showed that silver nanoparticles have low absorption through intact skin (0.46 ng/cm^2) and damaged skin (2.32 ng/cm^2). It is unknown whether silver particles are absorbed through mucous membranes when an infant suckles a breast treated with such a product or how effective nipple cleaning before feeding would be. Animal studies indicate that colloidal silver may pass into breast milk. Although silver ions in sulfadiazine cream do not absorb through the skin, the exposure level of an infant suckling a treated breast is unknown. Silver sulfadiazine preparations are not recommended by PTLR for wound treatment.

There is no clear data regarding the topical use of silver or colloidal silver products in breastfeeding women. On the other hand, silver bioavailability via oral intake is below 10%, and silver toxicity occurs only with significant, prolonged exposure exceeding the liver's ability to eliminate it. Cases of argyria have been reported after the ingestion of several grams of the element. It seems that infant exposure from treating nipple wounds with silver-containing dressings or products would be minimal, but the lack of data necessitates caution.

Among antimicrobial dressings are those containing Manuka honey. Their use has not yet been studied in nipple wound healing. In vitro studies observed cytotoxic effects on human keratinocytes and skin fibroblasts [49]. Infants under 12 months should not consume honey. The absence of safety and efficacy data in breastfeeding mothers calls for caution.

Topical antibiotics

According to current microbiological knowledge of wounds, topical antibiotics should not be used routinely, but in selected clinical situations their use is acceptable. Topical antibiotics are applied in the treatment of local skin infections, especially on the basis of eczema or atopic dermatitis [50, 51], in ophthalmology, and for the prevention of surgical wound infections [52]. The most common applications include mupirocin, fusidic acid (which shows activity in deeper skin layers), aminoglycoside antibiotics, and others. Retapamulin and ozenoxacin are recommended for infections with MRSA strains [51].

In practice, lactation consultants use topical antibiotics for difficult-to-heal nipple wounds with good outcomes reported, but there are no studies confirming their efficacy for this indication [53]. In a small observation of 29 patients from the CLS study, topical antibiotics were used only for infected, extensive wounds and achieved better therapeutic effects than dressings without antibacterial substances; however, the sample size is too small to draw definitive conclusions [38]. If despite proper use of lavaseptics, antiseptics, or antibacterial dressings there is no progress in wound healing, the use of a topical antibiotic based on the obtained antibiogram may be justified. This is the last step before systemic antibiotic therapy, which is reserved for cases resistant to topical treatment or when infection spreads from the wound to surrounding breast tissue. Treating a small local wound infection with systemic antibiotics seems too aggressive, considering breastfeeding and the priority of topical treatments in the pharmacotherapy of lactating women [54]. However, topical antibiotics should not be used routinely as first-line treatment without indications based on an antibiogram. The use of antibacterial and antifungal agents, especially those available over the counter, without proper indications prolongs the wound healing process and causes suffering to mothers.

Substances not recommended for treating nipple wounds

- Povidone-iodine (absorption from the wound, accumulation in milk)
- Chlorhexidine (cytotoxicity)
- Peruvian balm
- Hydrogen peroxide (short action, does not eliminate microorganisms)

- Potassium permanganate (cytotoxicity)
- Rivanol (prolongs the viability of *Pseudomonas aeruginosa*, carcinogenic effect)
- Anesthesin
- Silver sulfadiazine (insufficient antimicrobial activity)
- Glucocorticosteroids (delay in healing; some preparations for skin lesions contain them, but their intended use according to the product's characteristics is different)

The most common mistakes in treating nipple wounds

- Lack of improvement in feeding technique
- Failure to ensure proper nipple-areola latch
- Failure to check correct use of lactation accessories
- Poor hand hygiene, feeding accessories, or milk expression equipment
- Reassuring that "it will go away on its own"
- Excessive airing of nipples after feeding
- Failure to recognize at risk of infection or infected wound
- Lack of antiseptic treatment in the above-mentioned wounds
- Continuing the same treatment without progress within a reasonable time
- Lack of swab with antibiogram and untargeted treatment
- Using gel or hydrogel dressings on infected wounds
- Using lanolin and other care products (e.g., ointments with vitamins) on infected wounds (unjustified, non-targeted treatment)
- Using steroids in wound treatment (delaying healing)
- Using antifungal agents (unjustified, non-targeted treatment)
- Using OTC topical antibiotics

Protocol for nipple wound management

Lactation consultation

Medical history taking

During the interview, it is necessary to determine how long the injuries have been present, whether the pain is easing or worsening, assess the pain intensity using the numerical rating scale (NRS), ask under what circumstances the pain is most severe, whether the mother has noticed any purulent discharge, what treatments have been applied, and what results these have brought. Information about previous care, hygiene of the breasts, hands, and lactation accessories is also important. Lack of healing progress may result from not following recommendations.

It is necessary to gather information about the health status of the mother and child, recent antibiotic use, and the presence of skin lesions in other areas.

Factors increasing the risk of wound infection

- Age over 35 yearss.
- Weakened immune system.
- Diabetes.
- Chronic diseases (kidney failure, heart failure).
- Malnutrition, obesity.
- Unhealthy lifestyle, tobacco smoking.
- Medications (glucocorticoids, insulin, cytostatic drugs, immunosuppressants).

Examination of the child

During the child's examination, special attention should be paid to muscle tone, symmetry of the face and body, presence of skin lesions, weight gain, anatomical structure of the oral cavity, condition of the mucous membranes, tongue mobility, and sucking function.

Breast examination

When examining the breasts, assess skin coloration, tissue consistency, presence of signs of inflammation in the gland or skin and subcutaneous tissue, and axillary lymph nodes. The shape of the nipples and the elasticity of the nipple-areola complex should be evaluated. The breast examination also serves to assess the condition of the nipples, the size and depth of the wound, shininess, swelling of the wound edges, the presence of erythema and swelling of the entire nipple, the spread of erythema and swelling around the nipple, or, conversely, signs of healing (Annex 1). If there are indications, a swab from the wound should be taken.

Assessment of the feeding process

A key element necessary for diagnosis is observing the feeding process, often involving improving the position of the mother or child and the way the child latches onto the breast. Experience shows that women can breastfeed even with fairly large wounds, as long as the pain level is tolerable (7–8/10 points). Often, technique adjustments are minor but significantly improve the way the baby latches onto the breast. Even an extensive wound may not be felt by

the mother during feeding if the nipple is placed sufficiently deep in the child's oral cavity.

A lactation consultation is conducted by a properly trained person to whom the mother and child should be referred (lactation consultant – doctor, midwife, nurse). The diagnosis is established based on the interview and examination, followed by selecting the appropriate treatment.

Causal treatment

The primary goal in treating nipple pain and damage is to eliminate the cause.

A small observational study conducted by CLS in 2018 found that nipple wounds were accompanied by an average pain intensity of 7.5/10, and 90% of mothers required breastfeeding technique correction, which relieved the pain. 10% of mothers required repeated instruction during a follow-up visit. Nipple wounds treated according to the applied protocol healed within 4.15 days, and the pain disappeared completely within just under 6 days [38].

Improving breastfeeding technique is the primary action that allows most injuries to heal quickly without the need for additional methods.

The feeding position should be comfortable and stable for both the mother and the child. The baby should be held close to the mother's body, with the head slightly tilted back, hands holding the breast from both sides, and the chin resting on the breast. Initially, the nipple is positioned at nose level, slightly raised, and directed toward the palate. When the baby tilts their head back and opens their mouth wide, the nipple is guided towards the palate. In reclined positions, when the baby lies on the mother, it can move its head forward and latch onto the breast independently. In other positions, the mother gently brings the baby close when the mouth opens wide (Figs. 10, 11).

If the areola is firm and engorged with milk, the mother should be advised to hand express a small amount of milk to reduce areola tension. Engorged breasts and a tense areola are primarily a problem during the first weeks after childbirth but can also occur in mothers with oversupply at any stage of lactation. For swelling of the breast and areola, the reverse pressure softening (RPS) technique is applied – manual drainage of the transudate fluid beneath the areola. **The nipple-areola complex should be flexible enough** to shape properly inside the infant's mouth. Instruction on proper breastfeeding techniques and hand expression should be given during the hospital stay. It is the hospital staff's duty to provide this training, as outlined in the Perinatal Care Organization Standard. However, many mothers still need help after leaving the hospital. They seek assistance from primary care midwives, but if it is insufficient, they turn to professional lactation consultants [56].

Figure 10. Correct position for feeding – mother in a reclined position, infant cuddled, stabilised on mother's stomach, arms around breast, head slightly tilted (photo by M. Żukowska-Rubik).

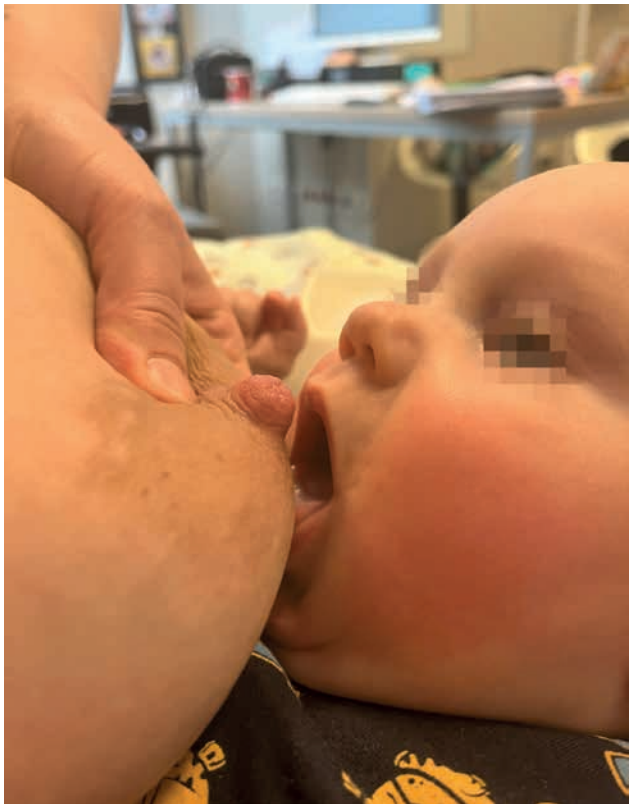

Figure 11. Asymmetric latch (photo by M. Nehring-Gugulska).

For newborns with oral cavity abnormalities, it is advisable to use specific feeding positions and manual assistance techniques, and working with an early intervention speech therapist can be helpful. In cases of anatomical or functional sucking disorders, the use

of a nipple shield may be considered. A restrictive tongue-tie should be clipped without delay. In cases of asymmetry or muscle tone disorders, parents should be advised on proper infant care principles, and in some situations, consultation with a neurologist or physiotherapist may be necessary.

For mothers who express milk using breast pumps, it is essential to check the suction strength and funnel size, considering that some pumps on the market are not registered as medical devices and may have uncontrolled suction strength, some lack replaceable funnels, and some mothers have not received assistance in selecting a flange suitable for their nipple type (diameter, elasticity). Sometimes, nipple size may change after a period of expressing milk. Some types of so-called shell pumps have opaque shells, preventing the mother from adequately controlling nipple positioning. It is also worth asking the mother how she ensures the hygiene of the equipment and correcting any mistakes. During the treatment of category 2, 3, and 4 wounds, enhanced equipment hygiene is recommended [57].

An integral part of the consultation is supporting the mother, showing understanding for her complaints, appreciating her commitment to breastfeeding, and encouraging her to persevere through the challenging wound-healing period.

Treatment – supporting healing, preventing infection, treating infection

At the time of the initial assessment, it is important to consider the type of wound based on the length of the medical history, the severity of local or both local and systemic symptoms, and whether any treatment has been applied so far – or if none has been given.

Recommendations for the mother must be simple and possible to perform repeatedly throughout the day – in accordance with the feeding schedule. Feeding involves the necessity of removing applied substances (which is troublesome and painful and concerns most preparations or dressings) and reapplying them after feeding. Moreover, these products are not cheap, must be financially accessible to the patient, and are usually needed for no longer than 1–3 weeks. Therefore, it is important to avoid using too many preparations. Dressings for breastfeeding women are not reimbursed because nipple wounds do not meet the criteria of chronic wounds as defined by the National Health Fund (NFZ).

It is important to monitor the course of treatment at short intervals and to change the strategy if necessary. The choice of treatment depending on the wound category is described in Table 4, Figures 12–15. Systemic antibiotic therapy is rarely necessary in the treatment of nipple wounds; indications are listed in Text box. The optimal approach is to select antibiotics according to the antibiogram obtained from a wound culture. In special cases, empirical treatment may be started – in such cases, first-generation cephalosporins are used, as the most common pathogen causing infection is methicillin-sensitive *Staphylococcus aureus* (MSSA).

It should be remembered that medicinal agents will act in combination with the previously described interventions, eliminating the causative factor of the injury.

Situations requiring systemic antibiotic treatment for infected nipple wounds

- Lack of improvement despite the proper implementation of all stages of local treatment
- Spread of infection to the areola
- Spread of infection to the skin of the breast, subcutaneous tissue, and glandular tissue
- Systemic infection symptoms

Table 5 lists antiseptic substances and their characteristics. Tables 6 and 7 describe the technique for collecting a swab from a nipple wound and skin lesions (Fig. 16). The indications for collecting a swab from a nipple wound or from the skin of the nipple and areola, as well as for collecting milk for culture in the case of mastitis, are presented in Text boxes.

Bite from a teething infant

Bites to the nipple or areola by a teething infant require prompt treatment. Management follows category three recommendations – a swab should be taken, the wound should be cleaned with a preparation containing a surfactant and antiseptic, a dressing with an antibacterial agent should be applied, and if healing does not occur within a few days, a broad-spectrum antibiotic or one based on an antibiogram should be administered. The substances of choice for a breastfeeding mother with a bite wound are sodium hypochlorite and hypochlorous acid, which can be used for wound irrigation. When used at low concentrations, hypochlorites offer high antimicrobial efficacy combined with safety, and are non-cytotoxic to healthy tissue. Additionally, hypochlorites have anti-inflammatory and antipruritic properties and are pH neutral (Fig. 17) [58, 59, 61].

Figure 18 presents example of infected niepple wound healing.

Table 4. Categories of nipple wounds, management, and selection of medicinal agents. Prepared by M. Żukowska-Rubik, M. Nehring-Gugulska

Nipple wound – assess the wound category	Treatment	Monitoring of treatment
Category 1. Uninfected Wounds: • superficial (epidermal abrasions, fissures, erosions) • small-sized – up to a few millimeters • newly formed (*contamination*)	• Recommend smearing with mother's milk after feedings, drying for several seconds • Additionally, if needed, use dressings without antibacterial substances between feedings (gel dressings, hydrogel dressings) or warm wet compresses with boiled water (4 times a day for 15 minutes over 5 days) after feedings – to maintain a moist healing environment and reduce pain	**Observation time:** signs of healing should appear within 4 days* **Improvement / wound is healing:** continue the above treatment until full healing **No improvement / wound is not healing:** verify if recommendations were properly applied, consider reclassification of the wound category
Category 2. At risk of infection **2A.** • Any wound in a woman with risk factors • Extensive wounds covering more than half of the nipple surface, wounds on the nipple shaft and at the base of the nipple • Deep wounds – ulcers, fissures (*colonization*) **2B.** • Hard-to-heal wounds – worrying symptoms appear – exudate, fibrin, the wound enlarges or no signs of healing within 4 days of observation (*increasing colonization*)	• For decolonization, prevention of biofilm formation, and cleansing, use a lavaseptic with added surfactant or hypochlorite – rinse the wound or apply a compress with a gauze soaked in the preparation after every feeding (the recommended time of application on the wound depends on the manufacturer[a]) • Use dressings without antibacterial substances to maintain proper moisture in the wound between feedings In the case of a wound showing signs of difficult healing • use a lavaseptic with added surfactant and an antiseptic substance[e] • consider dressings with antibacterial substances • consider taking a wound swab	**Observation time:** signs of healing should appear within 4 days* **Improvement/wound healing:** next check-up in 4 days, continue treatment until clear improvement in healing, then discontinue the antiseptic, maintain a dressing that ensures a moist healing environment **No improvement/wound not healing:** verify whether the recommendations were correctly applied, consider changing the category
Category 3. Infected **Significant increase in pain, redness, swelling, nipple warmth, swelling of the wound edges, exudate – often purulent, presence of necrotic tissue [41]** **Lack of healing progress despite no concerns regarding breastfeeding technique or sucking function in the newborn**	• Take a swab from the nipple wound • To remove biofilm and for cleansing, use a lavaseptic with added surfactant and an antiseptic[e] substance • Rinse the wound or apply a compress with gauze soaked in the preparation after each feeding (the recommended time of application on the wound depends on the manufacturer[a]) • Once a day, clean the wound using a moistened gauze to remove excessive exudate, biofilm, loose scabs, or fibrin (moisten the wound beforehand) • Use dressings containing antibacterial substances, a gel-based[b] product may be applied after feedings at least 3–4 times a day or after each feeding[c]; in case of skin maceration, reduce the amount or duration of application • Select a dressing suitable for the amount of exudate	**Observation time:** 4 days **Improvement:** follow-up in 4 days, continue treatment until the infection is under control**, and significant healing progress* is achieved. At that point, antiseptic use can be discontinued***, and a dressing that ensures a moist healing environment can be applied **No improvement/presence of infection symptoms/wound not healing:** • Verify whether the recommendations have been correctly implemented • Continue using the lavaseptic with surfactant and the antiseptic substance • Consider applying a topical antibiotic according to the antibiogram for 5–7 days[d] **Improvement / infection controlled / wound healing:** discontinue the antiseptic substance, stop the topical antibiotic, and apply a dressing that ensures a moist environment until complete healing **No improvement/presence of infection symptoms/wound not healing:** • Continue using the lavaseptic with surfactant, the antiseptic substance, and dressings containing an antibacterial agent • Administer a systemic antibiotic according to the antibiogram

Table 4. Categories of nipple wounds, management, and selection of medicinal agents (cont.)

Nipple wound – assess the wound category	Treatment	Monitoring of treatment
Category 4. Spread of infection to surrounding tissues Swelling and redness around the nipple (on the areola) > 2 cm erysipelas, cellulitis, infected mastitis Systemic infection symptoms (fever, chills, malaise, elevated inflammatory markers in laboratory tests)	• Local treatment as in category 3 (except for topical antibiotics) • If a wound swab was previously taken – administer systemic antibiotics based on the antibiogram • If no swab was taken – collect one and administer an empirically selected systemic antibiotic	**Observation time:** improvement should occur within 3 days of antibiotic treatment **Improvement/resolution of systemic symptoms, improvement of local condition:** continue antibiotic treatment according to established guidelines, and continue local treatment until significant wound healing improvement is achieved* **No improvement:** reassess treatment depending on the situation: • In the case of mastitis, collect milk for culture • If the antibiogram result from the wound swab is available – change the empirically chosen antibiotic to one based on the antibiogram • If no antibiogram is available – prescribe a broad-spectrum antibiotic

* Healing signs – reduced pain intensity, decrease in wound size and depth, epithelialization or granulation, closure of the wound from the edges.

** Infection control – reduction of pain intensity, decrease in exudate volume, subsidence of wound edge swelling, and reduction of nipple swelling and redness

*** Lack of improvement with antiseptic treatment within 2 weeks absolutely requires verification

[a] The recommended application time on the wound is provided by the manufacturer – refer to the appropriate documentation – in the case of drugs, the SmPC (Summary of Product Characteristics), and in the case of medical devices, the IFU (Instructions for Use of Medical Devices) (Annex 2, Table II).

[b] Primary dressings are applied directly to the wound. Some require the placement of a secondary dressing, which can be a sterile gauze pad. Sometimes it may be worth adding a secondary absorbent dressing depending on the exudate amount (e.g., foam dressing). Some dressings can function as both primary and secondary, e.g., foam dressings.

[c] Preparations and dressings should be washed off before the next feeding, except for antiseptic substances without a residual effect; it is essential to check the leaflet to see if the dressings intended for nipple application require washing.

[d] Routine treatment of wounds with topical antibiotics is not recommended; indications are limited to situations described in the article. The time given, based on experience, is sufficient for treating nipple wounds with topical antibiotics, in accordance with the SmPC of the products (usually 5–7 to 10 days). Longer treatment without signs of improvement is unjustified

[e] Antiseptic substances recommended depending on the clinical situation

	First-line	Second-line
Wounds at risk of infection	Polyhexanide (0.02%, 0.04%, 0.1%), octenidine 0.05%	Octenidine/phenoxyethanol 0.01%, hypochlorite
Infected wounds	Octenidine/phenoxyethanol 0.01%	Octenidine 0.05%, polyhexanide

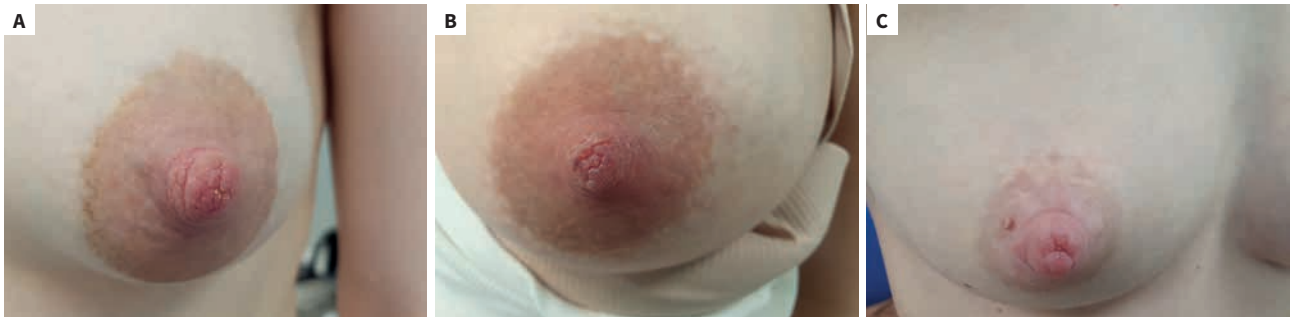

Figure 12. Category 1 of wounds: **A**) abrasion of the epidermis; **B**) fissure at the top of the nipple (9–13; **C**) healing fissure in the furrow of the nipple (in the 5–11 direction), without oozing, swelling of the wound edges (photos by M. Żukowska-Rubik).

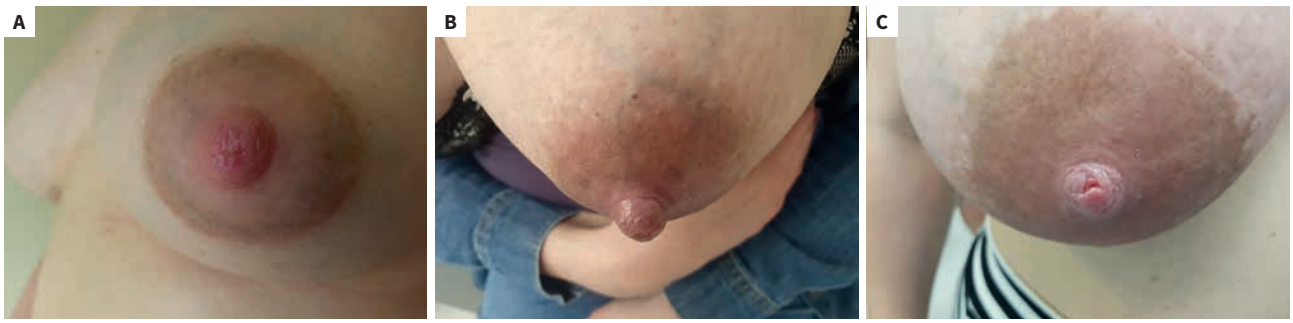

Figure 13. Category 2 of wounds: **A**) erosions on top; **B**) fissure surrounding more than half of the circumference of the nipple at the base, slight swelling and maceration of the wound edges, abrasion on the top; **C**) wound of small size, but exceeding the depth of the epidermis, without features of infection (photos by M. Żukowska-Rubik).

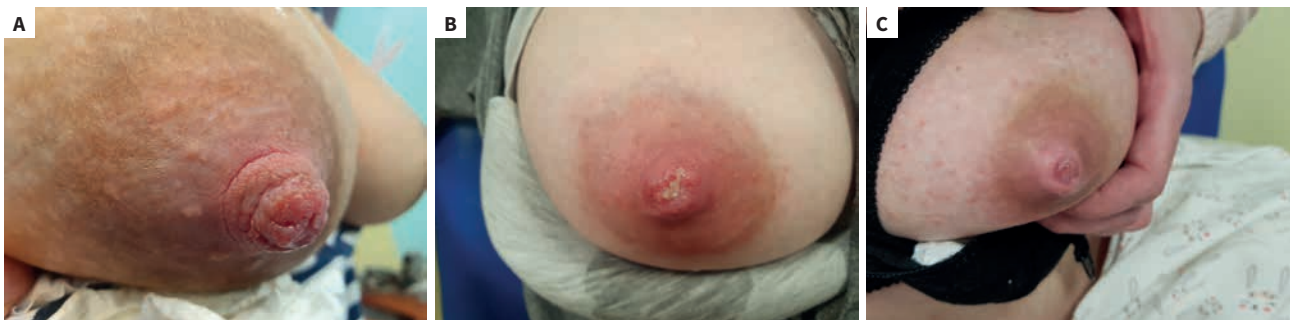

Figure 14. Category 3 of wounds: **A**) crack at the top (lower part of the top of the nipple) and around the shaft) ; **B**) ulceration at the top, covered with separating epidermis; **C**) extensive wound of the top of the nipple, partially covered with fibrin, oozing purulent secretion, heavily swollen wound edges and nipple, not healing for 2 weeks (photos by M. Żukowska-Rubik),

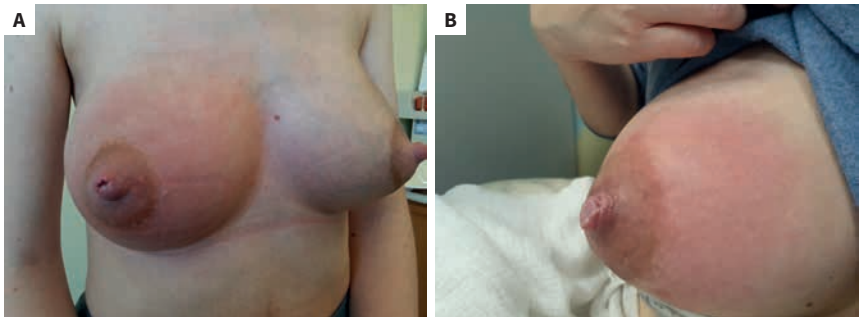

Figure 15. Category 4 of wounds: **A**) cellulitis – inflammation of the skin and subcutaneous tissue of the breast, infected deep wound on the nipple, swelling, redness of the nipple, oozing purulent secretion (photo by M. Żukowska-Rubik); **B**) Abscess as a complication of an untreated infected nipple-wound (photo by M. Żukowska-Rubik).

Table 5. A list of preparations containing antiseptic agents and their antimicrobial properties

Properties	Octenidine dihydrochloride 0.05%+ Ethylhexylglycerin	Polihexanide + betaine	Polihexanide + poloxamer	Hypochlorites [57–60]	Octenidine dihydrochloride 0.1% + phenoxyethanol 2%
Required contact time / time demonstrated in *in vitro* studies	Approx. 1–5 minutes / 60 seconds	15 minutes / 5–15 minutes	15 minutes / 5–15 minutes	15 minutes / 5–15 minutes	1 minute / 30 seconds
Residual effect	Yes	Yes	Yes	No	Yes
Sterility	Yes	Yes	No	No	No
Use in conjunction with silver-containing dressings	Possible	Possible	Possible	Possible	Possible
Development of resistant strains	No	No	No	No	No
Status	Medical device	Medical device	Medical device	Medical device	Medicinal product
Inhibition of healing	No	No	No	No	No
Deep wound, no drainage, eye [33]	No	No	No	Yes	No
Potentially higher risk of allergic reactions	No	Yes	Yes	No	No

Residual effect – the active substance remains on the skin; these products should be rinsed/removed from the nipple surface before breastfeeding/milk expression.

Among antiseptic agents, the following are registered as medicinal products: Octenisept (octenidine dihydrochloride), Braunol and Betadine (PVP-I) (PVP-I-containing preparations are not recommended during lactation). Other products have the status of medical devices (see Annex 2).

Table 6. Technique for taking a swab from a nipple wound [62, 63]

Swabbing technique (Fig. 16)	Comment
1. Prepare the following materials: • sterile transport medium • sterile gauze pads • saline ampoule • sterile gloves • referral for a swab to test for aerobic flora and, in some cases, also anaerobic flora (e.g., fistula, epibole, bite wound)	
2. Rinse the wound thoroughly with saline; wipe the wound with saline-soaked gauze if it is covered with exudate, biofilm, or scabs	• Cleaning the wound of exudate • Removal of ointments, creams, or gels applied by the patient from the wound surface • Reduction of the risk of collecting contaminating flora from the wound • Disinfecting the skin before sampling is not recommended, as it may lead to false-negative results
3. Assess the wound	• If dry, moisten the swab with saline; if moist, use a dry swab
4. Take a swab Levine technique – rotate the swab at the base of the wound, applying enough pressure to express fluid from the wound bed. The swab should be held perpendicular to the wound surface	• Avoid touching the surrounding skin with the swab • If a fistula or epibole is present, also collect material from that area
5. Place the swab in the transport medium, label it, and send it with the referral for analysis	
Comments • Swabs should be collected before feeding • The following are not recommended for microbiological analysis: pus, discharge from under a removed dressing, mucus from the wound bed, scabs, or material taken after applying an antiseptic [42]	

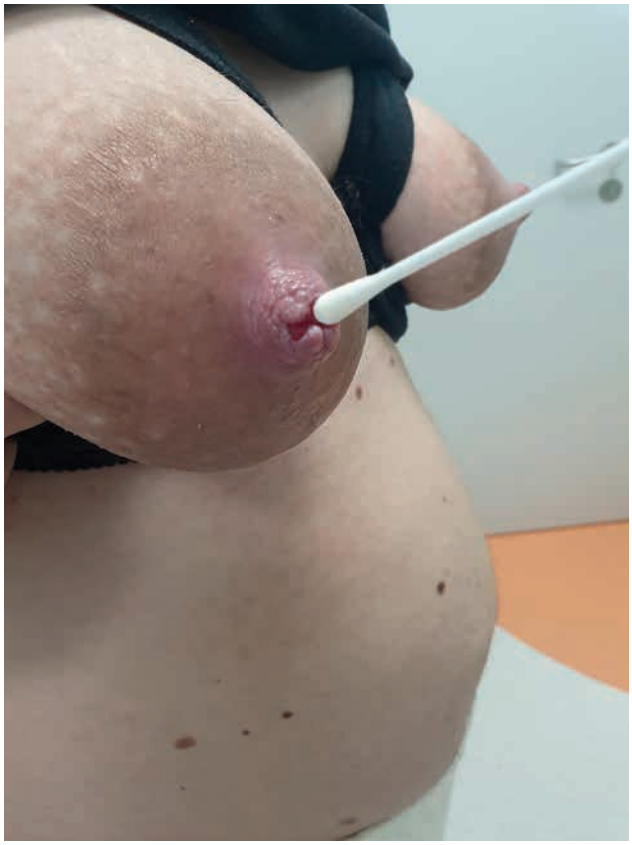

Figure 16. Wound swab collection using the Lewin method – culture tube positioned perpendicular to the wound, rolling motion with light pressure on the wound floor (photo by M. Żukowska-Rubik).

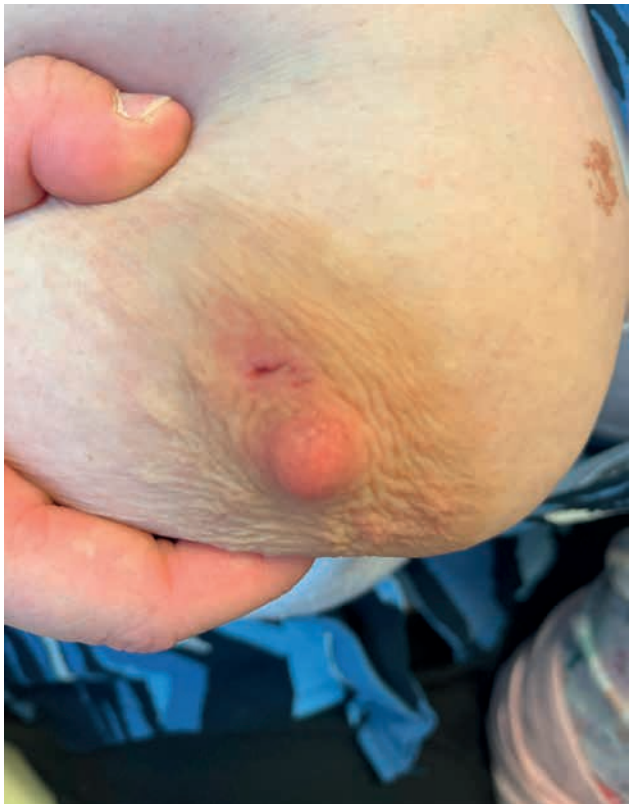

Figure 17. Bite wound of the areola (photo by M. Nehring-Gugulska).

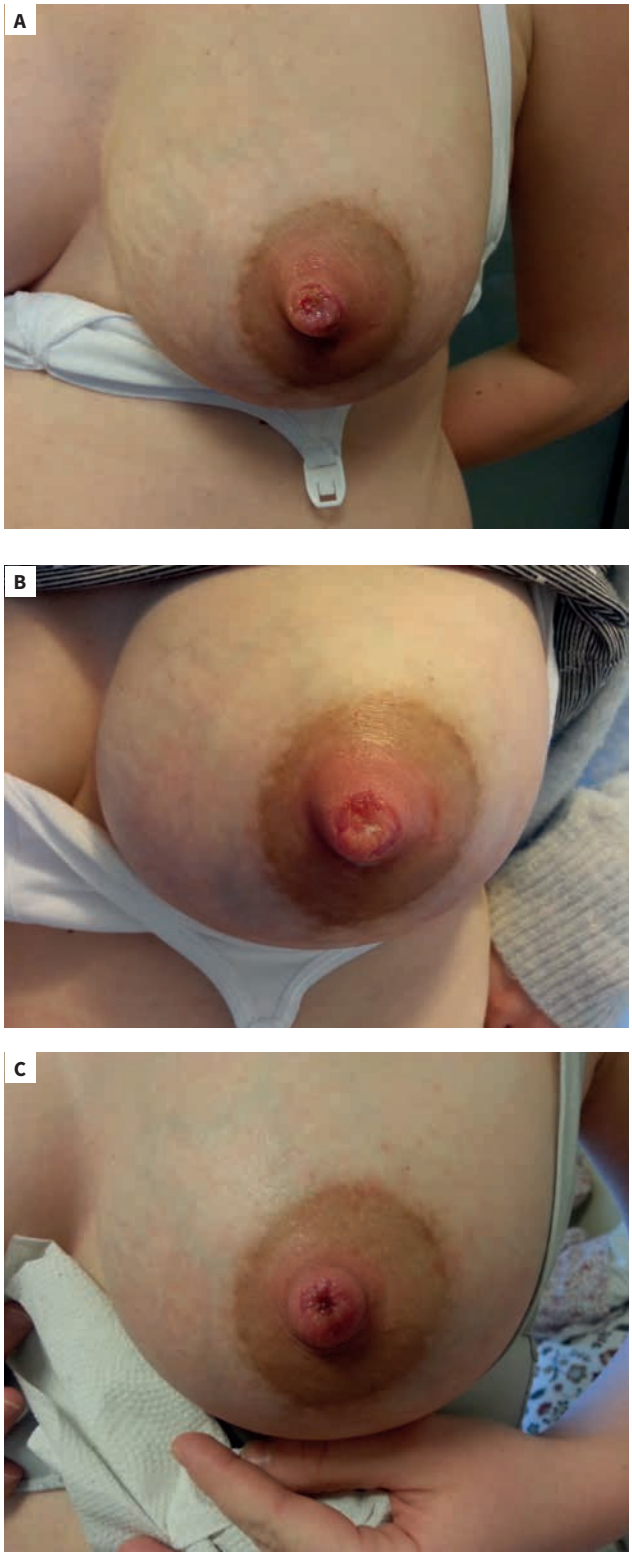

Figure 18. Example of healing. **A**) Course of healing of infected wound after application of lavaseptic with surfactant and antiseptic. Extensive nipple wound encompassing the entire top and deep in the centre, swelling of the wound edges, serous-purulent exudate observed on lactation pads. **B**) After a week, the wound begins to flatten out and become covered with epidermis, less exudate and edge swelling. **C**) After another week, there is a thin crust in the centre of the nipple and epithelialization around it (photos by M. Żukowska-Rubik).

Table 7. Swab collection techniques [62, 63]

Technique	Description	Comment
The Levine technique	The swab should be rotated in the wound with adequate pressure to express fluid from the wound bed; the swab for culture should be held perpendicular to the wound surface	• Recommended (higher effectiveness in obtaining a valid culture) • More painful for the patient
The Z-technique (zigzag)	A zigzag motion should be performed over the skin lesions while simultaneously rotating the swab between the fingers	• Better tolerated by patients • Recommended for collecting swabs from the nipple skin and areola • Not recommended for nipple wounds due to higher risk of contamination from bacteria at the wound edges

Indications for taking a swab from the nipple wound or skin of the nipple and areola include [57]
- Signs of wound infection
- Hard-to-heal wounds
- Persistent nipple pain despite improved latching technique
- Skin changes on the nipple or areola such as erythema, oozing, scaling, cracking

Indications for taking a breast milk sample for culture in cases of mastitis
- No improvement after 3 days of empirical antibiotic therapy
- Severe, septic course of mastitis
- Suspected nosocomial infection
- Recurrence of mastitis (symptoms reappearing in the same breast within 3 months of the last occurrence)
- Subacute mastitis
- Allergy to multiple antibiotics

The use of medicinal agents and breastfeeding

Medicinal agents applied to the nipple skin should be used after feeding the baby. Creams or ointments containing antibiotics should be applied before longer breaks in feeding, such as at night or before going for a walk. Antiseptics without residual effect do not need to be rinsed off before feeding, whereas other preparations should be rinsed off with preboiled water. To clean the breast before feeding when a cream or ointment has been applied, use expressed breast milk (squeezed onto a gauze pad) or a product with a slightly acidic pH. Similarly, the nipple surface should be cleaned after removing the dressing to minimise the infant's exposure to medicinal substances and, for example, mineral oils used as a base [64, 65].

Hygiene rules

During breastfeeding, especially when nipples are cracked or injured, hygiene rules must be followed:
- wash your hands before breastfeeding;
- wash your hands before dressing the wound;
- wash the breasts during your regular body hygiene routine (at least once a day), using water and a mild soap, or preferably a cleanser with a slightly acidic pH (syndet) [66]. The use of soaps or products containing antibacterial agents for washing the breasts is not recommended. Washing the breasts before each feeding is also not recommended;
- wash and thermally disinfect accessories that come into contact with the breast (nipple shields, breast pump parts) once a day, and after each use for category 2, 3, and 4 wounds (increased hygiene of lactation equipment). Thermal disinfection is done by soaking the equipment for 5–10 minutes in water at 90–100°C;
- frequent replacement of nursing pads;
- hand disinfection by medical staff prior to contact with the mother or infant;
- hand hygiene by family members before contact with the mother, infant, or nursing equipment

Pain management

The mother should be offered short-term analgesics, selecting the safest options for use during lactation (Hale's classification L1–2), such as paracetamol or NSAIDs (ibuprofen, ketoprofen, diclofenac). Another method of pain relief involves manual expression of milk before breastfeeding to stimulate the milk ejection reflex and trigger the analgesic effects of oxytocin in the central nervous system. Improving breastfeeding technique is of fundamental importance.

Temporary cessation of breastfeeding

Breastfeeding is safe for the infant but may be too painful for the mother. In such cases, a temporary

cessation of breastfeeding can be considered for several hours, up to several days, with regular expression of milk and feeding the infant with expressed milk until the wounds heal, provided that milk expression is less painful than breastfeeding, does not disrupt the wound, and ensures effective breast emptying.

General condition of the mother

Special attention should be given to women with a complicated medical history, in whom wound healing may be impaired and the risk of infection is higher than in the healthy population (see *Factors increasing the risk of wound infection* in Text box). Delayed wound healing is an indication to assess the mother's overall health and to perform additional tests, for example, to rule out anemia or abnormal blood glucose levels. Nutritional assessment is also necessary, as approximately half of Polish mothers follow elimination diets during lactation. They most commonly avoid dairy products, including eggs, as well as many other sources of energy, protein, and vitamins, allegedly to protect the infant from colic, allergies, and other conditions. Such nutrient-deficient diets may delay wound healing [67]. Malnutrition increases the risk of wound infection. According to recommendations, a patient with a chronic wound should receive 30–35 kcal/kg body weight/day (no less than 1,800 kcal) and an adequate amount of protein (1.5–2.5 g/kg body weight), carbohydrates (55–60%), and fats (20–25%).

Summary of treatment rules for nipple wounds in breastfeeding mothers

- Correction of breastfeeding technique and reduction of areolar tension before infant latch (if indicated)
- Appropriate interventions to improve the infant's sucking function when indicated (consultations with lactation consultants, speech therapists, physiotherapists, frenotomy)
- Selection/correction of the flange size and pump strength to ensure the mother's comfort during milk expression
- Hand, breast, and pump equipment hygiene
- Use of lavaseptics, antiseptic agents, specialized dressings, antibiotics as appropriate to the wound category
- Pain management; in exceptional cases, breastfeeding interruption for 1–2 days with continued milk expression and feeding expressed milk
- Proper maternal nutrition

TASKS – WHAT TREATMENT WOULD YOU APPLY?

- **Task 1 (Fig. 19):** Wound healing has not progressed for 3 weeks; at the nipple base, there is a fissure affecting most of the nipple's circumference, with varying depths, exuding discharge, and severe pain; the mother is close to stopping breastfeeding. So far, she has been applying breast milk to the wound after feedings and using hydrogel dressings. Breastfeeding technique is correct.
- **Task 2 (Fig. 20):** A deep wound present for one month involving the tip and sides of the nipple, covered with biofilm, swollen wound edges, oozing discharge, nipple swelling, and pain. The mother breastfeeds several times a day, but feeding is very painful, so she expresses milk more often. So far, she was recommended nursing creams, protective shells, and used an antiseptic for several days.

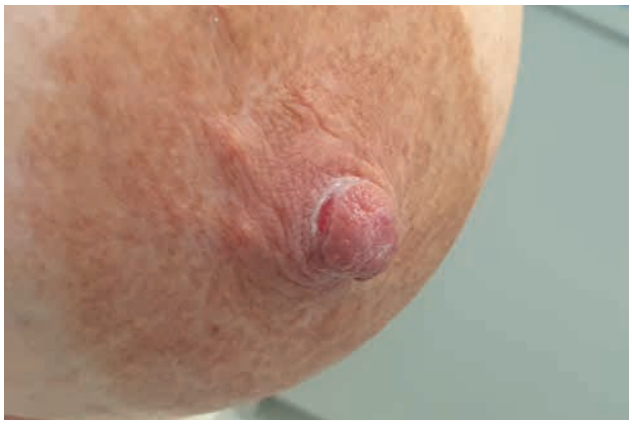

Figure 19. Task 1 – what treatment: wound at the nipple base covering most of the periphery of the nipple, of varying depth, with oozing exudate, no progress of healing for 3 weeks (photo by M. Żukowska-Rubik).

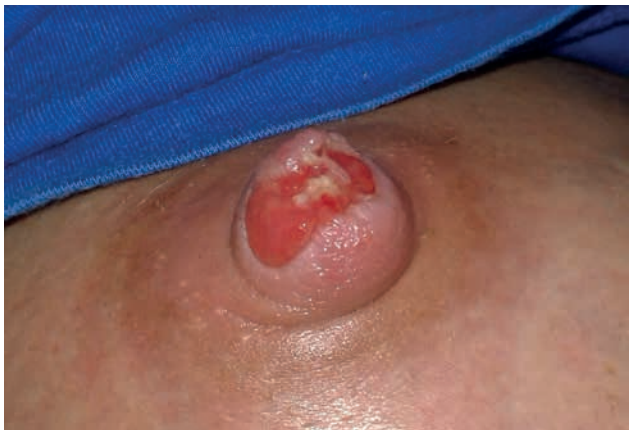

Figure 20. Task 2 – what treatment. Deep wound involving the top and sides of the nipple, covered with biofilm, swelling of the wound edges, oozing of exudate, swelling of the nipple (photo by M. Nehring-Gugulska).

Source: Żukowska-Rubik M., Nehring-Gugulska M. Pathology of breast and nipple during lactation. In: Żukowska-Rubik M., Godyń-Myśliwy Z., Nehring-Gugulska M. *The Atlas of physiology and pathology of lactation.* 1st Edition. Medycyna Praktyczna, Krakow 2025, with consent.

ASK:
When did the pain/damage begin? Pain intensity? Is it related to breastfeeding?
Breast hygiene? Previous treatments?
Depending on the situation – ask targeted questions related to the specific issue, e.g. expressing, teething.

EXAMINE:
Infant: Abnormal muscle tone, asymmetry? Skin infection?
Oral cavity – abnormal anatomy or function? Mucosal changes?
Mother: Appearance of lesions on nipples/areolas, signs of wound infection?
Shape and elasticity of the nipple–areola complex
Feeding: Poor technique or latch? Nipple being pulled in? Shallow latch, clamping, tugging?

DIAGNOSIS

MANAGEMENT – depending on the cause and nipple condition:
Improve feeding technique, latch of the nipple–areola complex, sucking function, method of milk expression
Consider: pain medication, nipple shields, protective shells, temporary pause in direct breastfeeding (regular expressing needed)
Wound or skin lesion swab – if infection is suspected
Refer the patient to a doctor – treatment of the wound according to the antibiogram, treatment of skin diseases or other problems
Refer the infant to a specialist if indicated (pediatrician, neurologist, speech therapist, physiotherapist, others)
Monitor breastfeeding and the child's weight gain

* Wash breasts with gentle soap during full-body hygiene, preferably with slightly acidic pH cleanser; wash hands before feeding; staff – clean and disinfected hands
** Apply breast milk after feeding, or products designed for use on nipples during lactation
*** Increased equipment hygiene – thermal disinfection before/after each use

Painful nipples without lesions – consider:
Early transient hypersensitivity – standard hygiene*, neutral care**
Raynaud's phenomenon – treat the underlying cause: dry heat, calcium channel blockers

Damaged nipples without signs of infection – standard hygiene*, breast milk, warm moist compresses, gel or hydrogel dressings if needed
Wounds at risk of infection – after feeding, cleanse using a lavaseptic containing a surfactant, consider an antiseptic and specialist dressings with antibacterial agents; increased equipment hygiene***

Erythematous, weeping, scaling changes on nipples/areolas – consider: eczema, bacterial, mixed or fungal infection, psoriasis, other skin irritation due to improper care
-- Causal treatment

Yellowish lump on nipple – consider:
plugged milk duct on the nipple, inflammatory bleb)
-- Causal treatment
Sebaceous cyst, sebaceous adenoma
-- Surgical treatment

Damaged nipples with signs of infection – standard hygiene*, elevated equipment hygiene*** + after feeding, cleanse wounds using a lavaseptic with a surfactant, use antiseptic agent and specialist antibacterial dressings; in severe cases topical antibiotic according to antibiogram; if infection spreads – systemic antibiotic

Blisters on nipple/areola skin – consider: excessive suction, nipple friction,
skin infection – herpes, shingles, impetigo
– Causal treatment

Unilateral lesion – erosion, oozing, crusting, scaling + prolonged symptoms, no improvement after treatment – consider Paget's disease
– refer to specialist

TARGETED QUESTIONS FOR SPECIFIC ISSUES	**Expressing** Suction strength Nipple placement in pump flange Flange size Session duration Equipment hygiene	**Blanching/Raynaud's phenomenon** Blanching, triphasic colour changes Cold sensitivity Tendency to have cold fingers Vasoconstrictive medications Illnesses of the mother Smoking	**Eczema** Cleaning agents Cosmetics Breast pads Medications and new foods (in the infant)	**Inflammatory bleb** Unilateral lesion White-yellow spot/ lump on nipple Stabbing, deep pain	**Dysbiosis** Nipple damage postpartum Antibiotics Incorrect care	**Fungal infection** Thrush Diaper rash Antibiotics Immunosuppressive drugs Diabetes

Figure 21. Algorithm – painful and damaged nipples - differentiation and management. Prepared by M. Żukowska-Rubik.

Differentiation of lesions located on the nipples

In breastfeeding mothers, injuries usually occur due to incorrect breastfeeding or breast pump use techniques. However, nipple lesions may also be caused by systemic diseases, e.g., viral infections (*Herpes simplex*, *Herpes zoster*, *Varicella zoster*), bacterial infections (syphilis, gonorrhea), or systemic conditions (psoriasis, ichthyosis, eczema, atopic dermatitis). Oncological vigilance is essential for lesions that do not heal within the expected time, and patients should be referred for diagnostics (e.g., Paget's disease of the breast). An algorithm on nipple pain and injury collects key information for managing painful and wounded nipples (Fig. 21). It briefly addresses other common lactation issues relevant to differentiating nipple pain causes.

Summary

Nipple wounds are a frequent problem, especially shortly after delivery, and one of the main reasons mothers prematurely stop breastfeeding. Knowledge of the basic principles of nipple wound treatment is essential for all healthcare workers caring for the mother or infant during lactation at various levels of the healthcare system and in different roles, including midwives, nurses, lactation consultants, gynecologists, neonatologists, pediatricians, and family doctors. Their expertise and cooperation serve public health. Improving breastfeeding technique and ensuring the nipple-areola complex is compliant enough to allow the infant to latch deeply are fundamental to treatment. It is important to frequently monitor the progress of wound healing to promptly respond to signs of emerging infection. In the study, the authors highlight when maternal milk, modern lavaseptics, antiseptic substances, or specialized dressings can be used for wound treatment depending on the wound category, taking into account the specific location of these wounds and the contact between the baby's oral cavity and the treated breast.

SOLUTION

- **Task 1 (Fig. 19):** Category 2B wound, hard to heal, the following should be recommended:
  - collect a wound swab for culture;
  - option 1 – cleansing after feeding with a lavaseptic containing surfactant and antiseptic; between feedings apply foam dressing;
  - option 2 – surfactant and antiseptic gel applied in a thin layer after feedings, left until the next feeding;
  - pain medication;
  - hygiene measures;
  - follow-up after 4 days.
- **Task 2 (Fig. 20):** Category 3 wound, the following should be recommended:
  - improve breastfeeding technique!
  - collect a wound swab for culture;
  - cleansing the wound with a surfactant-containing lavaseptic after breastfeeding/expressing, ideally in the form of a compress made from gauze soaked in the solution; a first-line antiseptic is optimal for infected wounds;
  - cleaning the wound surface of biofilm once daily;
  - between feedings, dressings containing antibacterial agents and monitoring of discharge;
  - pain medication;
  - hygiene (increased hygiene of expression equipment);
  - follow-up after 4 days.

Disclosures

Beata Mrozikiewicz-Rakowska: consultations and lectures for: Convatec, Hartmann, Schulke, Smith@Nephew, Urgo.
Monika Aleksy-Polipowska: consultations and lectures for: ConvaTec, Verco, Schulke, Urgo.
The other authors declare no conflict of interest.
This research received no external funding.
Approval of the Bioethics Committee was not required.

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Annex 1. General principles of wound assessment

Wound assessment

The wound assessment triangle is a fundamental tool, especially useful for beginners starting to manage wound care. Assessment is conducted as follows:

- wound bed,
- wound edges,
- surrounding skin.

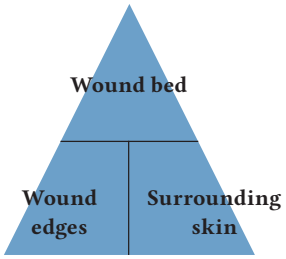

Figure I. The wound assessment triangle

Assessment of the wound bed

1. Tissue type.
2. Exudate.
3. Infection.

Assessment of wound edges

1. Maceration.
2. Dryness.
3. Epibole.

Assessment of surrounding skin

1. Maceration.
2. Excoriation.
3. Dry skin.
4. Hyperkeratosis.
5. Induration.
5. Eczematous lesions.

1. Tissue type

- Necrotic.
- Liquefactive necrosis.
- Granulating.
- Epithelializing.

2. Exudate

- Amount: none; small; moderate; large.
- Type: watery; dense; clear; cloudy; purulent; pink/red.

3. Infection

- Local: increased pain; erythema; swelling; localized warmth; increased exudate; friable granulation tissue; unpleasant odor; epibole.
- Spreading/systemic: intense erythema; fever; abscess/pus; wound dehiscence; cellulitis; general weakness; leukocytosis; lymphangitis.

Glossary

- **Dryness** – low moisture level preventing the formation and migration of cells necessary for new tissue growth. Keratinocytes become flat and flaky. The skin feels rough and peels.
- **Eczematous changes** – inflammatory condition characterized by itching, redness, and rash.
- **Epibole** – epidermal tissue building up inward into the wound rather than covering its entire surface. It may occur in wounds with an inflammatory basis, including those caused by tumors, and can result in delayed healing if appropriate measures are not taken.
- **Epithelializing** – pink tissue at the final healing stage, when epidermal cells appear on the wound surface.
- **Excoriation** – damage to the skin surface caused by repeated trauma such as scratching or abrasion
- **Exudate** – inflammatory fluid discharged from the wound; during a normal healing process, the amount of exudate increases in the inflammatory phase to cleanse the wound and maintain optimal moisture, which accelerates healing. In chronic wounds, exudate has a different biochemical composition, leading to the breakdown of protein structures in the wound and further tissue degradation.
- **Granulation** – new, red tissue and capillaries forming on the wound surface during healing.
- **Hyperkeratosis** – excessive thickening of the epidermis.
- **Induration** – thickened and hardened skin or soft tissue, especially in areas previously subjected to friction or pressure.
- **Infection** – the presence of bacteria and other microorganisms in sufficient quantities to damage tissue and impair healing. Clinical signs of infection may be absent in patients with immunosuppression, perfusion disorders, or chronic wounds.
- **Liquefactive necrosis** – yellow, fibrous tissue composed of fibers, pus, and protein material.
- **Maceration** – a process during which the tissues at the wound edge soften due to prolonged exposure to moisture from the wound exudate. The affected tissue is usually white in color.

- **Necrotic tissue (dead tissue)** – black, dead tissue containing dead cells and remnants of tissue resulting from the breakdown of dying cells.
- **Undermining** – tissue breakdown or ulceration spreading beneath the wound edge, resulting in a wound base wider than the skin surface opening.

Annex 2. List of lavaseptics, antiseptics, and specialized dressings

Lavaseptics, which may be sterile or non-sterile medical devices, are classified as products used for care, cleansing, washing, and rinsing of the skin or mucous membranes. They are used for wound cleansing and the removal of fibrin, clotted secretions, and scabs. They should be used according to recommendations, including prior to the application of the proper antiseptic.

Lavaseptics can be divided into those containing surfactants (substances that facilitate cleansing by reducing surface tension of secretions or bacterial biofilm on the wound surface) and those without surfactants. Some lavaseptics also contain antimicrobial substances in lower concentrations than antiseptics. Lavaseptics may come in liquid or gel form.

The use of soap and water for wound cleansing is not recommended due to the high, non-physiological pH of soap, which promotes tissue tension and dryness.

The preparations and dressings listed below are commercially available and have been described based on the IFU and SmPC, in accordance with the data available at the time of publication.

Group 1. Lavaseptics without surfactants

NaCl 0.9%

- Form: solution.
- Sterility: depends on the manufacturer and packaging.
- Notes Scientific literature reports the irritating effect of NaCl 0.9% on tissues.
- Suggested use: for short-term rinsing of the nipple.

Ringer's solution

- Form: solution.
- Sterility: depends on the manufacturer and packaging.
- Notes: none.
- Suggested use: for rinsing the nipple.

Solutions containing low concentrations of hypochlorous acid and/or sodium hypochlorite

The anti-inflammatory effects of hypochlorite solutions have been proven, and they are used in dermatology, e.g. in atopic dermatitis. Literature indicates their ability to reduce microbial load on tissue surfaces through rinsing. Research results on their antimicrobial activity are inconsistent due to the **lack of a residual effect**, as hypochlorites break down and deactivate. On the other hand, this also contributes to **their high safety profile**. Hypochlorites are substances with high oxidative potential, which is the main mechanism responsible for destroying microbial structures. Human cells are not sensitive to low concentrations of around 40/50 ppm, as they possess a natural detoxification mechanism. This results from the natural production of HOCl during the process of phagocytosis.

Microdacyn

- Form: solution. Medical device.
- Sterility: none – the manufacturer guarantees microbiological purity (statement available).
- Contraindications and safety measures: see IFU. Hypersensitivity to any component of the formulation. Do not ingest.
- Notes The manufacturer recommends a contact time of 15 minutes.
- Suggested use: for rinsing wounds on the nipple.

Granudacyn

- Form: solution. Medical device.
- Sterility: none; the manufacturer guarantees microbiological purity.
- Contraindications and safety measures: see IFU. Hypersensitivity to any component of the formulation. Do not ingest.

- Notes The manufacturer recommends a contact time of 15 minutes.
- Suggested use: for rinsing wounds on the nipple.

Granusept

- Form: solution. Medical device.
- Sterility: none; the manufacturer guarantees microbiological purity
- Contraindications and safety measures: see IFU. Hypersensitivity to any component of the formulation. Do not ingest.
- Notes The manufacturer recommends a contact time of 15 minutes.
- Suggested use: for rinsing wounds on the nipple.

Aquitox D

- Form: solution. Medical device.
- Sterility: none; the manufacturer guarantees microbiological purity.
- Contraindications and safety measures: see IFU. Hypersensitivity to any component of the formulation. Do not ingest.
- Notes The manufacturer recommends a contact time of 2 minutes.
- Suggested use: for rinsing wounds on the nipple.

Group 2. Lavaseptics containing surfactants

Octenilin® Wound Irrigation Solution

- Form: irrigation solution.
- Ingredients: octenidine, ethylhexylglycerin, glycerol.
- Surfactant: ethylhexylglycerin.
- Sterility: yes.
- Antimicrobial effect.
- Medical device. Studies show that the concentration of octenidine used in the medical product Octenilin exhibits bactericidal activity – reducing bacterial count by 5 log levels – against both Gram-positive and Gram-negative microorganisms as early as 15 seconds after exposure (incubated with exudate).
- Contraindications and safety measures: see IFU. The product is non-irritating, non-allergenic, painless to use, non-toxic to tissue, and does not hinder granulation or epithelial regeneration. The solution has good tissue tolerance. Octenilin® Wound Irrigation Solution, due to its low surface tension, provides excellent moisturizing and cleansing properties, even in hard-to-reach areas such as fissures, cracks, and the inside of wound pockets. For external use only on skin wounds. Interactions: Do not use in combination with anionic surfactants or other wound-cleaning agents such as soaps, ointments, oils, enzymes, etc., as this may adversely affect its preservation. Do not use in combination with PVP-iodine, as this may cause discolouration and reduce the antiseptic effect of PVP-iodine. If an allergy or suspected allergy to one or more ingredients is present, Octenilin® Wound Irrigation Solution must not be used. If unsure, consult your physician. To avoid potential tissue damage, Octenilin® Wound Irrigation Solution must not be applied to hyaline cartilage, eyes, ears, nose, bladder, or the abdominal cavity. Do not use for infusion or injection. Do not ingest. To prevent tissue injury, do not inject or apply the product under pressure into tissue. Proper drainage from wound cavities must always be ensured.
- Notes: Octenidine is not absorbed into the bloodstream, and the risk of its presence in breast milk is very low. Residual effect. Time of action – 1 minute.
- Suggested use: for rinsing nipple wounds to cleanse the area and reduce microbial burden. Due to the residual effect, rinsing before breastfeeding is recommended.

Prontosan® Wound Irrigation Solution

- IFU dated 22.04.2025 – Pregnancy and lactation There is no evidence of mutagenic or embryotoxic effects related to the ingredients of this product. However, due to the lack of adequate clinical studies and experience, Prontosan Wound Irrigation Solution should not be used in pregnant or breastfeeding women.

SutriSept® Płyn na rany [Wound cleansing fluid]

- Form: wound cleansing fluid.
- Ingredients: Water, poloxamer 188, polyhexamethylene biguanide (polyhexanide, PHMB) 0.1%.
- Surfactant: poloxamer 188.
- Sterility: no.
- Antimicrobial effect. Medical device.
- Contraindications and safety precautions (IFU): Polyhexanide is not absorbed into the systemic circulation, and the likelihood of it being excreted into breast milk is nearly zero. Due to the lack of clinical studies and experience in using the product in pregnant and breastfeeding women, the SutriSept® Wound cleansing fluid

should be used with caution, following a medical assessment.
- Newborns and infants: Due to insufficient clinical data for newborns and infants, the SutriSept® Wound cleansing fluid should only be used under strict medical supervision.
- To date, no adverse reactions have been reported for the SutriSept® Wound cleansing fluid, but rare cases (frequency less than 1 in 10,000) of anaphylactic shock caused by polyhexanide have been reported. The SutriSept® Wound cleansing fluid may cause allergic reactions such as itching (urticaria) and rash. Do not use the product in individuals with hypersensitivity to this substance. In very rare cases, a mild burning sensation may occur after applying the SutriSept® Wound cleansing fluid, but it subsides within a few minutes.
- The SutriSept® Wound cleansing fluid is compatible with all modern wound dressings.
- Do not use the SutriSept® Wound cleansing fluid in the following cases:
- it is not suitable for application to hyaline cartilage or for use in aseptic joint surgeries, in the middle or inner ear, or in the eyes. It must also not be applied to the central nervous system or the meninges. If used in combination with anionic surfactants, soaps, creams, oils, or enzymes, these substances must be thoroughly removed from the wound surface before applying the product.
- For external use on the skin only.
- The SutriSept® Wound cleansing fluid must not be administered via intravenous infusion or injection.
- Note: PHMB is not absorbed into the bloodstream, and it is unlikely to pass into breast milk. Residual effect. Time of application – 15 minutes.
- Suggested use: for rinsing nipple wounds to cleanse the area and reduce microbial burden. Due to the residual effect, rinsing afterwards is advised.

Group 3. Hydrogel with an antimicrobial agent

- To be used as a moisturising wound dressing.
- Medical device.
- Contraindications and safety precautions: same as for solutions.
- Warning. For external use only, under the supervision of a medical proffesional. No studies have been conducted in breastfeeding women. Apply to the nipple after breastfeeding. The product may remain on the wound surface until the next dressing change. Before feeding the baby, the gel must be thoroughly rinsed off the nipple, as hydrogels liquefy upon contact with water.
- Aquitox 0.03%
- Granudacyn 0.004%
- Microdacyn Hydrogel 0.006%

Hydrogels with added surfactant:
- Octenilin gel 0.05% (+ oxadermol)
- SutriSept gel 0.1% (+ poloxamer)

The percentage indicates the concentration of the antiseptic agent.

Group 4. Antiseptics

Octenisept® Spray

- Contains a surfactant – betaine.
- Composition: octenidine 0.1%, phenoxyethanol 2%, betaine.
- Medication for the disinfection of wounds, mucous membranes, and skin.
- Indication: for superficial wounds, especially in cases of infection or suspected colonisation with multidrug-resistant strains.
- Time of action – 1 min.
- To be used as a spray, swab, or compress for up to 5 minutes.
- Commonly used for everything from ulcers to acute wounds.
- Available in various forms: liquid, gel, cleansing emulsions, dressings.
- Octenidine has a high safety profile and can be used from the first day of life.
- It shows a broad-spectrum bactericidal effect against multidrug-resistant Gram-positive and Gram-negative bacteria, fungi, and yeasts.
- Compared to other substances, it has an effective bactericidal action even with a short contact time and low concentration, and remains active in the presence of protein load (exudate, blood) – 30 seconds.
- It has anti-inflammatory and immunomodulatory properties that support the healing process.
- It shows a residual effect.

Povidone-iodine (source: Braunol 7.5% skin solution, SmPC)

- Does not contain a surfactant.
- Medication.
- During pregnancy and breastfeeding, Braunol – like all iodine-based products – should only

be used under strict medical indication, and its use should be very limited. After use, assessment of the infant's thyroid function is recommended. If hypothyroidism is diagnosed, early hormone therapy should be initiated until normal thyroid function is restored. During breastfeeding, care should be taken to prevent accidental entry of Braunol into the child's mouth from the treated areas of the mother's body.

- Contraindications for the use of PVP-I include hypersensitivity to the active substance, toxic goiter, Hashimoto's disease, Duhring's disease, and peritoneal cavity irrigation.
- It passes into breast milk, and the concentration of iodides in breast milk increases to a greater extent than in blood serum.
- **Antiseptics containing povidone-iodine should not be used during pregnancy and breastfeeding.**
- **Due to potential side effects, it is not recommended for use on cracked or wounded nipples.**

Povidone-iodine (source: SmPC BETADINE, 100 mg/ml, skin solution)

- Does not contain a surfactant.
- Medication.
- The product may only be used after the second month of pregnancy and during breastfeeding if a thorough diagnosis has been made and there are strict indications for its use. In such cases, thyroid function in both mother and child should be monitored. The duration of treatment must be limited to the shortest possible time.
- Iodine crosses the placenta and is excreted in breast milk. Moreover, iodine reaches higher concentrations in breast milk than in serum. Povidone-iodine may cause transient hypothyroidism in the newborn.
- The infant must be strictly protected from ingesting the product!
- **Povidone-iodine should not be used during pregnancy and breastfeeding.**
- **Due to potential side effects, it is not recommended for use on cracked or wounded nipples.**

SPECIALIZED DRESSINGS

Table I. Classification and types of dressings registered by manufacturers for use in nipple pain and wounds

Brand	Name	Composition	Medical device status
Gel pads and dressings			
Ardo	Ardo Care Compresses	Water, pentylene glycol, xanthan gum, betaine, sodium hyaluronate, sodium anisate, lactic acid	Yes
Multi-Mam	Multi-Mam Compresses	Aloe leaf extract (2QR complex: patented bioactive polysaccharides), water, glycerine, xanthan gum, citric acid, caprylyl glycol, sodium benzoate, potassium sorbate, sodium hydroxide	Yes
Hydrogel pads and dressings			
Canpol babies	Soothing hydrogel breast pads with lanolin	Water, glycol, polymer, lanolin	Yes
Chicco	Hydrogel nipple compress – currently unavailable	Polyester, water, glycerol, polymer	Yes
Lansinoh	SOOTHIES® cooling gel pads	Plant-based glycerine, polymer, water	Yes
Medela	Hydrogel pads	Water, glycerol, polymer (sodium AMPs)	Yes
Foam dressings			
Ferris Mfg. Corp.	Nursicare	Polyurethane matrix, glycerine, surfactant: surfactant F-68; absorbent: starch copolymer	Yes

Specialist dressings whose use may be considered for nipple wounds, after weighing the benefits and risks

Specialist dressings are classified as medical devices. They should be used in accordance with the instructions for use, and under the supervision of a medical proffesional.

RECOMMENDATION: After removing the dressing, the wound and surrounding skin should be thoroughly cleansed. Follow the standard protocol for breast preparation before breastfeeding.

It is important to remember that nipple wounds during lactation differ in nature from other chronic or hard-to-heal wounds. When selecting a specialist dressing for these wounds, this distinction must be taken into account! Potential benefits of using dressings include the creation of a moist healing environment, absorption of exudate, antimicrobial action, and protection of the wound from external exposure. Potential drawbacks include the need to frequently remove the dressings for breastfeeding and to clean off any residue from the nipple surface, which may damage healing tissue and cause pain. Therefore, the benefits and risks must be assessed on a case-by-case basis.

The Annex includes examples of dressings available at the time of publication.

Group 1. Sterile hydrogel dressing

- Dressing indicated, among other uses, for the treatment of "abrasions and other superficial skin injuries"
- The Aqua-Gel® hydrogel dressing is a specialist dressing. It is composed of 91.5% pharmacopeia-grade water and natural and synthetic polymers that are permanently cross-linked using an electron beam. These polymers form a network that provides the dressing with a stable structure.
- Thanks to its hydrogel structure, the dressing has a soothing and analgesic effect, improving patient comfort.
- It supports autolytic wound debridement.
- The dressing is hypoallergenic and non-sensitising. Its ingredients are fully biocompatible.
- The dressing's transparency is an advantage during treatment, allowing for continuous monitoring of the wound and early detection of any adverse changes.
- Important: prolonged use of a sterile hydrogel dressing may lead to maceration of the skin surrounding the wound.
- The frequency of dressing changes depends on the amount of wound exudate.
- When changing the dressing, the wound should be rinsed with a wound decontamination solution; the manufacturer recommends, for example, Microdacyn.

Group 2. Mesh dressings

Main characteristics:

1. Do not contain antimicrobial agents.
2. Sterile.
3. Protect the wound from drying out while allowing free exudate transfer to the secondary dressing.
4. Require a secondary dressing, such as a sterile gauze pad, high-absorbency dressing, polyurethane foam, and fixation with adhesive tape or clothing.
5. The dressings form a breathable protective barrier.
6. They enable unrestricted drainage of exudate to the secondary dressing.
7. Intended for superficial wounds without signs of infection!

Mesh dressing impregnated with neutral ointment

- A mesh dressing that does not contain any active substances. (GRASSOLIND).

Mesh dressing impregnated with paraffin

- Paraffin dressing. Made of sterile gauze coated with white paraffin. It is compatible with ointments, including those containing antibiotics. Made from high-quality cotton gauze providing effective wound protection. (JELONET).
- Gauze dressing impregnated with paraffin. Helps maintain proper wound moisture, prevents drying and maceration of the wound edges. The neutral properties of paraffin allow the dressing to be used in combination with other products containing medicinal substances or antiseptic agents. (PARAFFINET).

Mesh dressing – various structures

- Thin, hydrophobic tulle mesh dressing, impregnated with a neutral, non-active, and non-allergenic ointment. Ensures good ventilation. (ATRAUMAN). Made from smooth viscose knit impregnated with an oil-in-water emulsion; mesh size 1×1 mm to prevent ingrowth of granulation tissue. It is a contact layer dressing with moisturizing and emollient effects that prevents adherence to the wound surface. (ADAPTIC).

- A hydrogel dressing in the form of a polyester fiber tulle mesh impregnated with a coating mass consisting of a polymer matrix. This is a flexible fixing mass that allows flexible shaping. Additional components include petrolatum and hydrocolloid. (LOMATUELL PRO).
- A non-adherent dressing made of tulle mesh impregnated with a polymer matrix containing fat and hydrocolloid. In contact with wound fluids, hydrocolloid particles form a gel, which, together with petrolatum, creates an amphiphilic layer (hydro-lipo-flow). This promotes wound healing and prevents adhesion to the wound. The dressings are sterile and individually packed. (LOMATUELL® PRO).

Group 2. Mesh dressings containing antimicrobial substances

Features

- They contain antimicrobial agents, mainly silver particles.
- Recommended for wounds showing signs of infection or at risk of infection.
- The mesh form allows cutting the dressing to fit the wound size, ensuring efficient use and reducing the risk of maceration of the skin surrounding the wound.
- + same as in Group 1

Antibacterial dressing with neutral ointment containing metallic silver

- A low-cytotoxicity dressing with metallic silver for infected wounds or those at risk of infection. Recommended as a complementary treatment for infected wounds or wounds exposed to contamination.
- Based on research, the manufacturer recommends it for use against Gram-negative and Gram-positive bacteria, including strains of *Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis, Klebsiella pneumoniae, Pseudomonas aeruginosa, Escherichia coli*, and *Bacillus subtilis*.
- The dressing's carrier material consists of a hydrophobic polyamide mesh impregnated with an ointment containing plant-derived fatty acids. The ointment cares for the wound edges and maintains their elasticity. This specialist dressing contains no vaseline or other paraffin-based components, preventing adherence to the wound and allowing painless removal. (ATRAUMAN AG).

Antibacterial dressing impregnated with silver salts, made using lipid-coloid technology

- A dressing impregnated with silver salts. It contains a healing matrix with silver, made of polyester mesh impregnated with hydrophilic particles (carboxymethylcellulose), vaseline, cohesive polymers, and silver salts.
- Bactericidal efficacy against bacteria (*Pseudomonas aeruginosa, Staphylococcus aureus*).
- Suitable for deep and fissure wounds.
- Indicated for treatment of wounds with risk or signs of local bacterial infection with small amounts of exudate. (UrgoTul Ag/Silver).

Dressing with nanocrystalline silver

- Exhibits bactericidal activity. The dressing is intended for the treatment of superficial, hard-to-heal wounds with a tendency to exude, as well as wounds located in areas difficult to dress.
- The nanocrystalline silver coating releases silver ions. Polyethylene mesh with a high-density weave. Low adhesion facilitates easy dressing removal.
- Recommended for infected as well as infection-prone superficial and deep wounds. (ACTICOAT FLEX 3).

Dressing with ionic silver (1.2%), made using hydrofiber™ technology. antibiofilm dressing – contains ethylenediaminetetraacetic acid (EDTA) and benzethonium chloride (BEC)

- It consists of two layers made from sodium carboxymethylcellulose fibers, reinforced with stitching. It is created using the More Than Silver™ and Hydrofiber™ technologies.
- **Recommended for wounds with moderate and/or heavy exudate and biofilm formation.**
- Forms a coherent gel when in contact with exudate. This creates an ideal environment supporting the wound healing process. Thanks to Hydrofiber™ technology, the dressing locks excess exudate, bacteria, and biofilm within its structure.
- For deep wounds, fill only up to 80% of the wound cavity with the dressing. This is due to the dressing's properties, which initially contract slightly upon contact with exudate during gel formation, then expand to fill the empty space.
- It requires the use of a secondary dressing. (AQUACEL AG +EXTRA).

Group 3. Foam dressings without antimicrobial substances

Features

1. Allow the skin to breathe.
2. Protect the wound from drying out, absorb exudate through various mechanisms – depending on the structure of the dressing.
3. Intended for superficial wounds **without signs of infection!**
4. Versions available – adhesive and non-adhesive. NON-ADHESIVE versions must not be cut.
5. Can be used as primary dressings (for shallow wounds, e.g. abrasions) or as secondary ones, to cover e.g. a mesh dressing with an antimicrobial substance.
6. All foam dressings have cushioning properties.
7. They are waterproof, transparent, and flexible, which increases user comfort.
8. They do not stick to the wound, making dressing changes painless.
9. They protect the wound from the entry of bacteria and microorganisms.
10. They help maintain an optimal environment for wound healing.

Multilayer foam dressing for exuding wounds

- Foam dressing with a wound contact layer made using Hydrofiber™ technology. Thanks to its absorbent properties and the use of silicone adhesives, the dressing is well suited for treating wounds of various etiologies.
- It is composed of a waterproof, highly breathable polyurethane outer film, a soft absorbent foam layer, a Hydrofiber™ wound contact layer, and a gentle silicone adhesive (in the adhesive version).
- The outer polyurethane layer makes the dressing waterproof, which protects the wound from viruses and bacteria, while allowing the patient to wash without removing the dressing.
- Thanks to the outer polyurethane film, the wound environment maintains an optimal moisture level, with any excess moisture being evaporated.
- The dressing absorbs and retains exudate in its structure, reducing the risk of skin maceration.
- Hydrofiber™ technology also helps reduce the level of active matrix metalloproteinases in chronic wounds and stimulates angiogenesis, which greatly benefits the healing process. (AQUACEL FOAM).

Foam dressing

- Dressing made of a three-layer construction consisting of:
- a perforated wound-contact layer that allows even sticky exudate to pass into the dressing,
- a hydrocellular core that absorbs and retains fluid in its microscopic structure,
- a breathable outer surface that allows excess moisture to evaporate from the dressing, while serving as a tight barrier against bacteria and foreign matter.
- This dressing is suitable for exudate absorption and for treating partial- or full-thickness wounds.
- Dressings **should not be used** with oxidising agents such as hypochlorite solutions or hydrogen peroxide, as these may break down the absorbent hydrocellular component of the dressing. (ALLEVYN).

Foam dressing with Safetac® soft silicone contact layer

- It is soft and conformable to the surrounding skin
- The dressing has a unique pain-minimising contact layer made of Safetac® soft silicone. Clinical studies show that dressings with Safetac® technology minimise wound and skin damage during removal. By sealing the wound edges, they help prevent maceration. Because they do not damage the wound or surrounding skin, pain during dressing changes is minimised. For shallow wounds with low to moderate exudate. (MEPILEX).

Foam dressing for low exudate wounds – 3-layer structure

- The dressing consists of an outer polyurethane layer that is waterproof and provides effective protection against bacteria and viruses, while allowing optimal moisture evaporation from the wound environment. The middle layer is a thin, flexible, and soft foam that absorbs exudate and maintains a moist wound environment conducive to healing. The adhesive contact layer is made of silicone. The silicone layer is gentle and skin-friendly, allowing safe and painless application, removal, and repositioning.
- Its soft and elastic design allows it to adapt effortlessly to different areas of the body. The dressing effectively protects, secures, and cares for low-exudate wounds. (Foam Lite™ ConvaTec).

Foam dressing with silicone – Kliniderm®

- Soft, conformable, and absorbent polyurethane foam dressing with a silicone contact layer. This layer protects the surrounding skin and reduces pain during dressing changes. Exudate is retained inside the dressing, while the outer layer allows for free gas exchange.
- Suitable for superficial wounds. (Kliniderm Foam Silicone).

Foam dressing with contact layer made using TLC technology

- Contact dressing intended for clean wounds with slight exudate, especially during granulation and epithelialization stages. (UrgoTul Absorb).

Group 4. Foam dressings with antimicrobial substances

Polyurethane dressing containing 0.5% PHMB and 0.1% B-panthenol

- The dressing consists of a polyurethane foam core with an open-cell structure. The foam core absorbs and retains exudate, reducing maceration of the surrounding skin. The antimicrobial agent PHMB (polyhexamethylene biguanide) reduces and prevents bacterial growth in the wound and dressing. B-Panthenol moisturises and improves skin hydration. The dressing also features a breathable outer polyurethane layer that allows internal moisture transfer while being resistant to external bacteria and water, thus maintaining a moist wound environment.
- It can be used as a primary or secondary dressing. (KLINIDERM FOAM PHMB).

Antibacterial foam dressing with a Safetac® silicone contact layer

- Antibacterial foam dressing for wounds with low to moderate exudate.
- The dressing gently adheres to the skin thanks to the unique Safetac® silicone contact layer, which reduces pain. This significantly lessens the pain experienced by patients during dressing changes.
- It exhibits rapid and long-lasting antibacterial activity.
- In vitro studies have shown that the silver foam dressing can inactivate wound pathogens (bacteria and fungi) within 30 minutes. According to international consensus, antibacterial action is essential and key to reducing biological contamination in infected wounds. The dressing acts as an antibacterial barrier where there is a high risk of infection or reinfection. (Mepilex Ag).

Multilayer foam dressing with silver ions

- The dressing is suitable for shallow wounds that are infected or suspected of infection, with moderate to heavy exudate.
- The dressing can be used as either a primary or secondary dressing.
- Thanks to the presence of silver ions, the dressing is effective against a wide range of microorganisms, including MRSA, VRE, and other antibiotic-resistant strains.
- Thanks to Hydrofiber technology, the dressing can also be used on heavily exuding wounds. When in contact with wound exudate, the dressing's contact layer transforms into a cohesive gel, allowing it to conform closely to the wound surface and fill empty spaces where bacteria might grow.
- The dressing also supports the removal of necrotic tissue (autolytic debridement), without damaging healthy tissue. It also reduces the risk of cross-infection during dressing changes by retaining exudate and its harmful components within the dressing. (AQUACEL® Ag Foam).

Definition of a Medical Device according to the Medical Devices Act

According to **Article 2(1) of the Polish Act of 7 April 2022 on Medical Devices** (Journal of Laws 2022, item 974):

A **medical device** is a tool, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used on humans for medical purposes such as:

- diagnosing, preventing, monitoring, treating or alleviating disease,
- diagnosing, monitoring, treating, alleviating or compensating for injury or disability,
- examining, replacing or modifying the anatomy or a physiological process,
- controlling conception.

Additionally:

- A medical device **does not achieve its principal intended action by pharmacological, immunological or metabolic means**, but its function may be **assisted** by such means.

The differences between a medical device and a medicinal product

Definition and mechanism of action

- A **medical device** works through **mechanical, physical or electronic means** – e.g., implants, syringes, diagnostic equipment, dressings. It may contain pharmacological substances, but these are not its main mechanism of action.
- A **medicinal product** acts on the human body through **pharmacological, immunological or metabolic means** – e.g., antibiotics, vaccines, painkillers.

Regulations

- **Medical devices** are governed by **Regulation (EU) 2017/745 (MDR).**
- **Medicinal products** are regulated by the **Pharmaceutical Law** and **Regulation (EU) 2001/83/EC.**
- **Assessment and marketing authorization**
- **Medical devices** require a conformity assessment and CE certification, often involving a notified body.
- **Medicinal products** must undergo clinical trials and receive marketing authorization from bodies such as the **EMA (European Medicines Agency)** or **URPL (Polish Office for Registration of Medicinal Products)**.
- In summary: **a medical device is not a drug**, although some products (e.g., inhalers with medication) may combine characteristics of both categories.
- The definition of a **biocidal product** can be found in the **Act of 9 October 2015 on Biocidal Products** (Journal of Laws 2022, item 2178).

Definition of a biocidal product

According to **Article 2(1)(1)** of this Act:

A **biocidal product** is "a substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing, or generating one or more active substances, intended to destroy, deter, render harmless, prevent the action of, or otherwise control harmful organisms by means other than purely physical or mechanical action".

This definition aligns with and implements **Regulation (EU) 528/2012** into national law.

Table II. Differences between a medicinal product, a medical device and a biocidal product

Feature	Medicinal product	Medical device	Biocidal product
Purpose	Treatment, prevention of diseases, diagnosis or modification of body functions	Diagnosis, prevention, monitoring, treatment or alleviation of diseases and injuries	Destruction, deterrence, neutralization of harmful organisms
Mechanism of action	Pharmacological, immunological or metabolic agents that affect the human body	**Physical, mechanical or electronic action** (possibly supported by pharmacological means)	**Chemical or biological action** against microorganisms (e.g. bacteria, viruses, fungi)
Examples	Antibiotics, vaccines, painkillers	Syringes, implants, CT scanners, contact lenses, medical software	Disinfectants, insecticides, anti-mould agents
Regulations	**Pharmaceutical Law** (Journal of Laws 2022, item 2301)	**Medical Devices Act of 7 April 2022** (Journal of Laws 2022, item 974)	**Biocidal Products Act of 9 October 2015** (Journal of Laws 2022, item 2178)