Toward the Optimal Use of Negative Pressure Wound Therapy for the Treatment of Complex Wounds

Recommendations for Clinical Practice
(Extract from the report)

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Toward the optimal use of negative pressure wound therapy for the treatment of complex wounds

The health technology assessment report, the systematic review, and the context and process for the development of the recommendations are available at www.inesss.qc.ca.

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Acronyms

CTX	contextualization
EK	experiential knowledge
EO	expert opinion
HTA	health technology assessment
INESSS	Institut national d'excellence en santé et en services sociaux
LE	level of evidence
NPWT	Negative Pressure Wound Therapy
RCP	recommendations for clinical practice
SD	scientific data
SR	systematic review
WP	wound pathophysiology

Definitions

Complex wound: A wound that does not heal according to the normal healing process or that requires advanced medical care (as defined in current documents produced by the Institut national d'excellence en santé et en services sociaux (INESSS).

Debridement: The process of cleaning a traumatic or infected wound through the excision of damaged, necrotic, or infected tissue to expose healthy surrounding tissue.

Dehiscence: Spontaneous opening of an organ or tissue lysis, which leaves the tissue or organ exposed.

Diabetic foot and diabetic foot ulcers: A result of neuropathy and angiopathy in diabetic patients. As the foot is insensitive to pain and poorly vascularized, there is a high risk of infection; therefore, any minor injury must be treated immediately, as it may lead to complications and, ultimately, amputation of the foot.

Exeresis (or ablation): A surgical procedure performed to remove, in whole or in part, a natural, pathological, or foreign element from the body.

Granulation tissue: New connective tissue composed of fibroblasts stimulated to multiply by growth factor and released by macrophages, endothelial cells, and fibroblasts. This healthy tissue forms during the normal healing process. It is bright red and shiny, with a granular appearance, and fills and covers the wound cavity.

Healing by primary intention: Occurs in surgical wounds or surgically sutured traumatic wounds.

Healing by secondary intention: Occurs in wounds that cannot be surgically closed, as they involve a significant loss of tissue or show evidence of edema or infection. Therefore, the wounds are left open and close on their own through a "natural" process.

Healing by tertiary intention: Occurs when the size of the wound has decreased sufficiently through the natural process, or when the edema or infection has been brought under control, thus allowing the wound to be surgically closed or covered using either skin flaps or split-thickness skin grafts.

Hypergranulation: The formation of excess granulation tissue that exceeds the amount needed to replace the wound's tissue deficit. It is fragile, friable tissue that bleeds easily and prevents wound healing.

Leg ulcer: A persistent leg wound caused by impaired circulation. There are four types of leg ulcers: venous, arterial, combined, and arteriolocapillary.

Original prescriber: A professional, either a physician or a nurse, authorized to prescribe negative pressure wound therapy (NPWT) in virtue of the regulations established by the Collège des médecins du Québec. The original prescriber makes a decision regarding NPWT, reassesses the relevance of continuing NPWT, and renews the original prescription with the collaboration of a dedicated interprofessional team or a wound care specialist who is recognized and authorized by the establishment (as defined in current documents produced by INESSS).

Pressure ulcer: Injury to the skin and underlying tissue usually occurring over a bony prominence as a result of pressure, or pressure in combination with shear or friction.

Quality of life: Quality of life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad-ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationship to salient features of their environment.

Re-epithelialization: Formation of new epithelium as a result of the healing process.

Skin flap: A portion of skin, subcutaneous cellular tissue, or muscle detached from a healthy part of the body to cover a wound.

RECOMMENDATIONS FOR CLINICAL PRACTICE

Context

Complex wounds place a great burden on patients, health care providers, and Canada's health care system as a whole. They can have a significant impact on the quality of life of patients who are affected, and on the health care professionals involved, who often feel powerless when treatment fails.

Among the available therapeutic options that help close this type of wound is negative pressure wound therapy (NPWT). In recent years, a number of regions in Quebec have created NPWT technology parks to meet increasing demand by clinicians. Given that the technology is relatively expensive compared to standard dressings, that there are no practice guidelines in Quebec, and that the number of individuals likely to develop complex wounds is on the increase, the risks of suboptimal use and an increase in costs are foreseen. It is in this context that the Direction générale des services de santé et médecine universitaire of the Ministère de la Santé et Services sociaux's (MSSS) appointed the Institut national d'excellence en santé et en services sociaux (INESSS) to undertake work to develop guidelines for and harmonize clinical practice.

The set of recommendations, which are included in an **optimal use guide** intended for health care professionals, are available on the INESSS website.

Major issues

The decision to use NPWT largely depends on therapeutic intention, which varies according to the nature and complexity of the wound and the characteristics of the patient. Therefore, to benefit from the use of this technology and to ensure that it is safe, the contraindications and risk factors specific to the patient should be taken into consideration as soon as the decision to use NPWT has been made, in the same way as factors that impede healing. If the clinical objectives are not met within the prescribed time frame, the use of NPWT must be reassessed to determine the relevance of continuing or discontinuing treatment.

Current data do not provide enough evidence to predict which patients would be more effectively treated with NPWT than with standard treatment. The duration of the healing process varies from one individual to another, mainly as a function of age, nutritional deficiencies or excesses, medical history, and medication. The healing process also appears to be affected by the nature, size, depth, site, and level of contamination of the wound.

Moreover, although this technology might be the best option for a particular wound and patient when it is applied in a hospital, it might not be when it is applied at home or in another health care facility. Various winning conditions are therefore required to ensure the successful and safe use of NPWT, not only in relation to the wounds and patients as whole people (e.g., their specific characteristics, medical history, environment, and social network), but also in relation to the health care settings and the available resources.

For this reason, training the health care professionals who make decisions concerning the use of NPWT and the assessment of wounds is of crucial importance in ensuring the safety of the technology and obtaining the expected benefits from its use.

Development of recommendations

The method used to develop recommendations for clinical practice (RCP) made it possible, through a systematic and transparent approach, to assess the quality of the evidence and weigh the advantages and disadvantages, while taking the Quebec context into consideration.

The recommendations developed by INESSS are based on current knowledge of wound pathophysiology (WP) and on the analysis of scientific data (SD) on various complex wounds taken from randomized controlled trials (RTCs). The recommendations are also based on the analysis of other types of research designs assessed by the authors of the guidelines consulted SD, as well as on the best clinical practice guidelines, the context (contextualization [CTX]) for the organization of wound care in Quebec, and the experiential knowledge (EK) of various experts and clinicians who collaborated with the Institut. When scientific proof is insufficient, the recommendations are based on expert opinion (EO), which features the EK of Quebec and international experts.

An adaptation of the recommendations may be required, depending on the conditions specific to each clinical setting and on the distribution of tasks among the various health care professionals.

DECISION-MAKING REGARDING THE USE OF NPWT

Interprofessional collaboration

INESSS recommends that:

- **the original prescriber collaborate with** a dedicated interprofessional team or a wound care specialist, recognized and authorized by the health care facility, to carry out a comprehensive assessment of the client and of the wound prior to starting NPWT (EO based on CTX, RCP, and EK).
- **a dedicated team or** a wound care specialist **be** clearly identified and readily available for the original prescriber and/or the attending physician, who may have to monitor the use of NPWT when the patient is discharged from the hospital (EO based on CTX, RCP, and EK).
- **the dedicated interprofessional team be composed of at least** one physician with complex wound care expertise and a wound care nurse. The team may also include a nutritionist, a physiotherapist, and an occupational therapist (EO based on CTX, RCP, and EK).

Justifications:

- A complex wound is a wound that does not heal normally and that requires advanced care. The identification and management of the causes of impaired healing are key factors in caring for patients with complex wounds.
- Health care professionals are bound by ethical requirements to act within the scope of their knowledge and abilities.
- Certain wound care activities are occupation-specific, while others are shared among various health care professionals (nurses, physiotherapists, and occupational therapists).
- Several therapeutic options may be considered to treat complex wounds that do not heal within a predictable amount of time. The interprofessional approach is used to identify the advantages and disadvantages of various available therapeutic options, including NPWT, which helps to determine the best approach for patients that is aligned with the clinical objectives.
- Tests for compliance for the required organizational practices on skin and wound care released by Accreditation Canada in 2014 require that organizations providing home care services use an interprofessional and collaborative approach to assess clients who need skin and wound care. The formation of dedicated teams allows the requirements of this set of required organizational practices to be met.
- Resource availability varies according to health care setting and region. It is the responsibility of health care facilities to identify professionals who meet their standards of care and who are authorized to assess complex wounds and apply NPWT in their facilities.

Training and knowledge

INESSS recommends the following:

Health care professionals consulted for an EO must have received the appropriate training and have up-to-date knowledge of the healing process, wound chronicity, the care required to manage complex wounds, and the therapeutic options (EO based on CTX, WP, RCP, and EK).

Justifications:

- Various winning conditions are required to ensure the success and safe use of NPWT— not only in relation to the wound and patient as a whole, but also in relation to the health care setting and available resources.
- In virtue of the ethical requirements to be complied with, the autonomy of health care professionals — with respect to wound treatment — is dependent on their knowledge and skills in the field, the complexity of the wound, the patient's state of health, and the use of prescription drugs.
- The healing process is a complex and dynamic phenomenon in which the inflammatory (debridement), proliferation (formation of granulation tissue), re-epithelialization (wound closure), and remodelling (scarring) phases follow one another.
- Various **exogenous and endogenous factors** may interfere with wound healing and lead to a predisposition to their recurrence.
- Factors related to patients' environments, their support networks, and their physical, psychological, and neurocognitive states may initiate the development of chronic wounds that become more complex with time.
- Complications arising from NPWT are rare events that generally occur in long-term care facilities or at home and are caused by the injudicious use of the technology, which includes not always taking patient-specific characteristics into account.
- Considering the limitations of NPWT and the uncertainty as to which patients will respond best to treatment, a discussion with patients and their families is essential for avoiding unrealistic expectations and for informing them of any adverse effects and possible complications; this would enable them to make informed decisions freely regarding this therapeutic choice.

Steps in the decision-making process

INESSS recommends the following steps:

First, "potential" NPWT candidates must be carefully selected based on their specific characteristics and on wound-related factors, while taking into account their values and preferences. This step is fundamental in identifying the risk factors that affect wound healing potential and the safety of the procedure (EO based on CTX, SD, WP, RCP, and EK).

Second, for NPWT to be considered as a treatment option, the complex wound must belong to one of the following two categories (EO based on CTX, SD, WP, RCP, and EK):

- Healing does not occur within the expected time frame, **despite the appropriate management of the risk factors that interfere** with the healing process.
- The size or depth of the wound must be reduced to allow the wound to be surgically closed or covered, or to promote healing by secondary intention.

Third, clinically realistic objectives must be defined according to the complex wound to be treated — for which NPWT may be indicated (its evolution and complexity) — i.e., the characteristics of the patient, the technology's mechanism of action, the healing process, and the method recommended to close the wound (healing by secondary intention, surgical closure, surgical coverage) (EO based on CTX, SD, WP, RCP, and EK).

Caution
Considering the costs associated with the technology, patients with a history of treatment non-adherence should not receive this therapy at home (EO based on CTX and EK).

Justifications:

- The healing process is a complex and dynamic phenomenon in which the inflammatory (debridement), proliferation (formation of granulation tissue), re-epithelialization (wound closure), and remodelling (scarring) phases follow one another.
- Various exogenous and endogenous factors may interfere with wound healing and lead to a predisposition to their recurrence.
- The mechanisms of action of NPWT are not yet clearly defined. According to experts in the field, and manufacturers, this technology reduces exudate, promotes angiogenesis, and stimulates the formation of granulation tissue.
- The assessment of the scientific results related to the clinical objectives, and their application on a larger scale for all complex wounds, are limited by various parameters inherent to the design of the RCTs.
- The clinical objectives pursued for the use of NPWT vary according to the type of complex wound (indications). The choice to begin NPWT to treat a complex wound must be aligned with the clinical objective(s) set.

CLINICAL OBJECTIVES

The clinical objectives pursued for the use of NPWT (EO based on SD, RCP, and EK) are the following:

- accelerate the formation of healthy granulation tissue
- reduce time to wound closure
- drain exudate and reduce perilesional edema
- reduce wound size in preparation for surgical closure (e.g., sutures, staples) or coverage (e.g., split-thickness skin grafts, skin flaps)
- prevent the separation of wound edges in the case of wound dehiscence
- serve as a temporary dressing prior to an additional surgical procedure.

Caution

- NPWT is not a substitute for debridement (EO based on WP, RCP, and EK).
- NPWT must not be used to attain complete wound closure (EO based on SD, WP, RCP, and EK).

Justifications:

- These clinical objectives are based on the RCPs, systematic reviews (SRs), clinical studies, and EK of the various stakeholders consulted.
- Several of these objectives are indicators measured in primary studies to assess the efficacy of NPWTcompared with a comparator treatment (e.g., wound size reduction, time for wound closure or coverage by healthy granulation tissue prior to surgical closure or surgical coverage, prevention of complications).

INDICATIONS

The precautionary principle is relevant to the decision-making process for NPWT use, as the levels of evidence for the various indications are generally weak. Moreover, clinical studies comparing the efficacy of NPWT are usually designed to obtain evidence on a general population and then apply it to individuals. In practice, however, response to treatment varies with each individual and type of wound. The indications supported by INESSS take into account the available level of evidence(LE), the clinical objectives for each indication, the risk factors, and the EK of the various stakeholders consulted. When there is insufficient scientific evidence, the recommendations are based on EO, which comprises mostly the EK of Quebec and international experts. The relationship between the indications supported by INESSS and the clinical objectives is shown in a **table** on page 13 of this document. The **complete report and SR** are available on the INESSS website.

Chronic wounds

The following are some of the indications for which NPWT can be a treatment option:

NPWT can be used to promote healing by secondary intention of a chronic wound resulting from a surgical closure or surgical coverage (reconstructive surgery) in the following situations:

- non-ischemic diabetic foot ulcer **associated with** significant tissue loss, after any bone or soft tissue infection has been treated and after the debridement of necrotic tissue and off-loading of the ulcer (based on $SD^{\text{moderate LE}}$, WP, RCP, and EK)
- arterial or mixed ulcer **after** an assessment of the potential for revascularization (based on $SD^{\text{low LE}}$, WP, RCP, and EK)
- stage III or stage IV pressure ulcer **after** pressure has been off-loaded from the wound and any bone or soft tissue infection has been treated (based on $SD^{\text{low LE}}$, WP, RCP, and EK).

Caution

- NPWT is not a viable option in the case of venous ulcers, which require compressive therapy to promote venous return, a reduction in exudate and re-epithelialization (EO based on SD, WP, and EK).
- NPWT must not be used to attain complete wound closure (EO based on SD, WP, RCP, and EK).

Justifications:

- A wound that does not heal according to the normal healing process, or is arrested in one of the phases of the healing process, becomes a chronic wound.
- According to the classification proposed by the Association québécoise d'établissements de santé et de services sociaux (in 2006, acute wounds include burns, tears, traumatic wounds, incisions, excisions, surgical debridement, split-thickness skin graft s, and skin flaps. A chronic wound is generally considered to be an acute wound resulting from debridement performed according to established best practices.
- Results from studies with a comparator group indicate that the NPWT group often shows fewer adverse effects than the control group. When serious adverse effects are reported, one cannot rule out handling errors or attribute these incidents to the use of NPWT. Regarding pain, the data indicate that the level of pressure applied might affect the intensity of the pain patients feel during treatment. Continuous pressure would help alleviate it.
- Complications arising from NPWT are rare events that generally occur in long-term care facilities or at home and are caused by the injudicious use of the technology, which includes not always taking patient-specific characteristics into account.

According to the EK of the stakeholders consulted, NPWT does not perform miracles; however, if used properly for the right patient, with the appropriate clinical objectives and in a timely manner, and by trained health care professionals, it can be of benefit with respect to the different targeted indicators.

Diabetic foot ulcers

- There is a moderate LE that NPWT was more effective than conventional treatment in promoting the closure of foot ulcers and post-operative wounds in diabetic patients included in the original controlled trials, particularly for factors interfering with wound healing. The primary objective is to allow the ulcer to heal by secondary intention or to reduce it sufficiently for surgical coverage. There is a very low LE showing NPWT's advantage in reducing the size of diabetic foot ulcers.
- There is a low LE that NPWT further prevents complications in diabetic foot ulcers or in acute wounds after amputation in diabetic patients.
- There is a low LE of NPWT's advantage regarding the quality of life of diabetic patients with foot ulcers.

Stage III and stage IV pressure ulcers

- There is a low LE that NPWT promotes the formation of granulation tissue in stage III and stage IV pressure ulcers **under generally optimal conditions.** These types of wounds often are included in RCTs involving various types of chronic wounds. The clinical objective of using NPWT on these types of complex wounds is to promote the formation of healthy granulation tissue, which is necessary for successful split-thickness skin grafting, or to reduce wound size sufficiently for surgical closure.
- There is insufficient evidence that NPWT can further reduce the size of pressure ulcers, prevent complications, improve quality of life, or limit resource use.

Leg ulcers

- There is a low LE showing NPWT's efficacy on leg ulcers **exclusively** (leg ulcers often are included in RCTs involving various types of chronic wounds). The clinical objective of using NPWT on these types of complex wounds is to promote the formation of healthy granulation tissue, which is necessary for successful split-thickness skin grafting. Its use should follow an assessment of the potential for revascularization and should never be considered an alternative to revascularization.
- There is a very low LE that NPWT can further reduce the size of these ulcers, prevent complications, improve quality of life, or limit resource use.

Split-thickness skin grafts for acute wound closure (surgical coverage)

- Split-thickness skin grafts are relatively common procedures used for patients requiring reconstructive surgery for burns, open fractures, and post-operative wounds, or to cover acute or chronic wounds when conditions are optimal.
- There is a moderate LE that NPWT led to a higher incidence of split-thickness skin graft take on acute wounds in some patients included in the original controlled studies notably for factors interfering with the healing process, particularly by improving the condition of the wound bed and by securing the graft.

Acute wounds

The following are some indications for which NPWT can be a treatment option:

NPWT can be used to secure and maintain a split-thickness skin graft on an acute wound (based on $SD^{\text{moderate LE}}$, WP, RCP, and EK).

NPWT can be used to prepare the wound bed for a split thickness skin graft on an acute wound (based on $SD^{\text{moderate LE}}$, WP, RCP, and EK).

NPWT can be used to promote healing by secondary intention in an acute wound resulting from a surgical closure or surgical coverage (reconstructive surgery) in the following situations:

- a traumatic wound that cannot be sutured and that is associated with significant and/or deep tissue loss without infection; or after treatment, if necessary (based on $SD^{\text{low LE}}$, WP, RCP, and EK)
- a surgical resection associated with significant and/or deep tissue loss; without infection or after treatment, if necessary (EO based on WP, RCP, and EK; the available SD were taken from mixed methods studies without subgroup analysis; for this reason, it is impossible to determine the LE specific to this type of wound)
- dehiscence of an extensive surgical wound and/or an adverse situation — when surgical closure is impossible (EO based on WP, RCP, and EK; the available SD were taken from mixed methods studies without subgroup analysis; for this reason, it is impossible to determine the LE specific to this type of wound).

NPWT can be used in preparation for surgical closure or surgical coverage (reconstructive surgery) of an acute wound in the following situations:

- open wound of the abdomen or thorax (based on $SD^{\text{low LE}}$, WP, RCP, and EK)
- surgical wound associated with a high risk of dehiscence (EO based on WP, RCP, and EK).

NPWT can be used to secure and maintain skin flaps (EO based on RCP and EK).

Caution

- NPWT must not be used to attain complete closure of an acute wound (EO based on SD, WP, RCP, and EK).

Justifications:

- Acute wounds are wounds for which there are no factors that interfere with wound healing. They may or may not be surgical in origin. These types of wounds generally close after a few days or within three to four weeks at most, depending on their sizes and depths. Based on the extent of the damages done to the skin, the wounds may be considered simple or complex. According to the classification proposed by the AQESSS in 2006, acute wounds include burns, tears, traumatic wounds, incisions, excisions, surgical debridement, split-thickness skin grafts, and skin flaps. Initially acute surgical wounds that worsen as a result of infection, dehiscence, or evisceration become chronic wounds.
- Results from studies with a comparator group indicate that the NPWT group often shows fewer adverse effects than the control group. When serious adverse effects are reported in the literature, one cannot rule out handling errors or attribute these incidents to the use of NPWT. The data indicate that the level of pressure applied might affect the intensity of the pain patients feel during treatment. Continuous pressure would help alleviate the pain.
- Complications arising from NPWT are rare events that generally occur in long-term care facilities or at

home and are caused by the injudicious use of the technology, which includes not always taking patient-specific characteristics into account.

Traumatic wounds — soft tissues

- Few studies compare the efficacy of NPWT with a comparator for the treatment of traumatic soft tissue wounds (these types of wounds are often included in RCTs involving various types of acute wounds). The objectives of NPWT for traumatic soft tissue wounds are, for example, to promote the formation of healthy granulation tissue to rapidly proceed to surgical closure or coverage, promote healing by secondary intention, or temporarily close the wound between debridement sessions.
- There is insufficient evidence that NPWT further reduces the size of these wounds, prevents complications, improves quality of life, or limits resource use.

Traumatic wounds — open fractures

- There is a low LE of NPWT's advantage in treating traumatic wounds from open fractures. The objective is to temporarily close the wounds in preparation for surgical coverage or to reduce the complexity of the wounds by promoting the formation of healthy granulation tissue.
- There is a very low LE of NPWT's greater impact on preventing complications and on the quality of life of patients with traumatic wounds from open fractures.

Open abdomen

- The main indicator of interest for open abdominal wounds is NPWT's capacity to serve as a temporary dressing in preparation for an additional surgical procedure. Hence, these types of wounds do not lend themselves as well to RCTs, and the available data are taken from study specifications with lower levels of evidence that are nevertheless in favour of NPWT. Depending on the stage of the wounds, the clinical objectives are the protection of the organs and the prevention of complications (e.g., infection, formation of adhesions), the treatment of edema, temporary wound closure in preparation for an additional surgical coverage procedure, and preparation of the wound bed for a split-thickness skin graft.

Split-thickness skin grafts

- Split-thickness skin grafts are relatively common procedures used in patients requiring reconstructive surgery for burns, open fractures, and post-operative wounds, or to cover acute or chronic wounds when conditions are optimal.
- There is a moderate LE that NPWT led to a higher incidence of split-thickness skin grafts take on acute wounds in some patients included in the original controlled studies, notably for factors interfering with the healing process, particularly by improving the condition of the wound bed and by securing the graft.
- There is a very low LE that NPWT reduces recovery time for split-thickness skin grafts.
- There is a low LE of NPWT's greater impact on the prevention of complications, resource use, and quality of life following split-thickness skin grafts on acute wounds.
- There is insufficient evidence of NPWT's efficacy on skin flaps. As the application of skin flaps requires several debridement sessions to remove necrotic tissue, some international experts agree that the wounds are considered to be traumatic (soft tissue) after debridement, and that the same objectives as those previously mentioned for these types of wounds may be established.

CONTRAINDICATIONS

The following are some of the absolute contraindications adopted by INESSS:

- Significant amount of necrotic tissue (bed sores or moist necrotic tissue)
- Uncontrolled anticoagulant therapy
- Active bleeding
- Untreated active deep infections (e.g., osteomyelitis)
- Patient in shock (e.g., septic, hypovolemic, cardiogenic)
- Wounds on tumour sites that are not excised
- Unprotected vital organs and structures (e.g., arteries, veins, nerves)
- Unstable open fractures
- Non-enteric and unexplored fistulas
- Allergy to any of the material used in the procedure
- Any atypical wound without an established diagnosis (e.g., pyoderma gangrenosum, neoplasia, metastasis, vasculitis, etc.).

The following are some of the relative contraindications adopted by INESSS:

- Patients at high risk of bleeding
- Arterial insufficiency of non-revascularized lower limbs
- Social, medical (e.g., cognitive impairment), or psychological factors preventing treatment adherence or safety.

Justifications:

- These contraindications are based on the monographs of the various available technologies, the regulatory agencies, the health technology assessment (HTA) agencies, the SRs, the clinical studies, and the EK of the various stakeholders consulted.

MOST COMMON ADVERSE EFFECTS AND COMPLICATIONS

PARAMETERS OF THE INTERVENTION OR IMPROPER USE	QUALITY OF LIFE	COMPLICATIONS DUE TO UNCONTROLLED RISK FACTORS

· Local bleeding (e.g., tubulation or dressing with coagulated blood), hematoma
· Blisters
· Seroma
· Development of a skin allergy
· Fistula
· Maceration of surrounding skin
· Dermatitis (infectious or inflammatory)
· Severe infection associated, or not, with the presence of forgotten pieces of sponge or gauze
· Pressure wound caused by the device[a]
	· Pain:
	  · when dressing is removed
	  · while the device is in operation
	· Noise (particularly disturbing at night)
	· Permanent dependence on the device
	· Limited mobility
	· Difficulty of use
	· Stress or anxiety
	· Odours
	· May be detrimental to one's social life and affect self-esteem
		· Secondary infection
		· Heavy bleeding
		· Septicemia
		· Hypovolemic shock
		· Risk of cardiac arrest when there is an excessive loss of electrolytes
		· Mortality

[a] Based on the clinical experience of members of the INESSS committee of experts.

Justifications:

- Based on the monographs of the various available technologies, regulatory agencies, HTA agencies, SRs, clinical studies, and the EK of the various stakeholders consulted.

DETERMINING THE TECHNICAL PARAMETERS

INESSS recommends:

- **Considering the following factors when choosing the device:** availability, cost, ease of use, health care setting, adverse effects, and the differences between the technologies regarding dressing types, pressure, and mode. Certain parameters related to patients should also be taken into account during the decision-making process (EO based on WP, RCP, and EK).
- **Basing the choice of dressing on** the nature of the wound, the technology available in the facility and when the patient is being transferred, the experience of the wound care specialist, and the patient's sensitivity to pain (EO based on SD, WP, RCP, and EK).
- **Generally using a pressure of** –80 mmHg to –125 mmHg to treat acute or chronic complex wounds (EO based on SD, RCP, and EK).
- **Using intermittent pressure for a wound in an area of low sensitivity (e.g., diabetic foot) and continuous pressure,** in the following situations (EO based on SD, RCP, and EK):
  - the patient is at an increased risk of bleeding
  - it is a high exudate wound, recent skin flap, or graft
  - for wounds with acute enteric fistulas
  - in unstable body structures
  - for a perianal wound
  - for a patient with increased sensitivity to pain.

Justifications:

- These parameters are based on the monographs of the various available technologies, regulatory agencies, HTA agencies, clinical studies, SRs, and EK of the various stakeholders consulted.
- Clinical studies use pressure levels of –80 mmHg to –125 mmHg, depending on the type of wound under consideration and the technology being used (in-house versus commercial NPWT).
- It is the responsibility of the clinician to determine which level of pressure and mode to use. Collaboration with a dedicated interprofessional team or a wound care specialist expertise is recommended.
- There is insufficient evidence showing the difference in efficacy between the two types of interfaces (dressings). The choice of dressing should be based on the nature of the wound, the technology available in the facility and when the patient is being transferred, the experience of a wound care specialists, and the patient's sensitivity to pain. Collaboration with a dedicated interprofessional team or a wound care specialist is recommended.

STARTING NPWT AND PRECAUTIONS FOR USE

INESSS recommends:

- **Starting NPWT in collaboration with** a dedicated interprofessional team or a wound care specialist, recognized and authorized by the health care facility (EO based on CTX, RCP, and EK).
- **Ensuring that the prescription and treatment plan are clear and comprehensive, and that they provide at least the following information** (EO based on RCP and EK):
  - the general objectives and clinical criteria of the treatment
  - the estimated time to achieve the established clinical objectives
  - the treatment plan revision date
  - the recommended choice of device
  - the technical parameters related to the NPWT system (pressure, intensity, mode, type of dressing)
  - the parameters to assess during the follow-up and the frequency of dressing changes.

Caution

- The patient and caregiver must be informed of the technical aspects of the intervention, particularly when NPWT is given at home (EO based on RCP and EK).
- Lack of a firm commitment from the patient to closely follow instructions concerning the use of NPWT may constitute a criterion not to initiate therapy (EO based on RCP and EK).

Justifications:

- To ensure optimal use and the safety of the intervention, and to facilitate the work of the professionals who will monitor the patient and the wound, the instructions of the original prescriber must be clear.
- Several documents specify the elements to be included in the ordinance to foster communication among health care professionals, such as the general objectives and clinical criteria targeted by the treatment, the estimated time to attain the clinical objectives, the choice of device, and the technical and monitoring parameters. The stakeholders consulted suggested also including the revision date for the treatment plan.

Precautions to be taken prior to setting up the device and during dressing changes (EO based on RCP and EK):

- Ensure that standard precautions for infection control are observed for all patients and that they adhere to the protocol pre-established by the facility, regardless of the diagnosis or presumed infection status.
- Ensure that the wound bed is free of debris and necrotic tissue.
- In the event of a laparotomy, avoid contact between the digestive tract and the NPWT system to prevent the formation of a gastrointestinal fistula.
- Position the tubing so as to prevent the formation of pressure ulcers.
- Minimize the risks associated with dressing changes by:
  - noting the number of dressing pieces placed in the wound on the cover dressing
  - avoiding cutting sponges, foam dressings, or gauze directly over the wound
  - properly cleaning the wound bed and performing a thorough examination
  - ensuring that the wound is filled to skin level (that is, placing a sufficient number of sponges or compresses in the wound without compacting) once NPWT has begun
- Never leave a dressing in place for a prolonged period of time without the active use of the pump. Refer to the manufacturers' product monographs to adjust the time frames according to the dressing and device used.
- Avoid interrupting NPWT during treatment, insofar as possible, to optimize its effect.
- To ensure continuity of care, the NPWT device — or at least the dressing used with the device intended for home care — should be set up at the nursing unit, prior to the patient's discharge from the hospital.

Reasons:

- These precautions are according to the monographs of the various available technologies, regulatory agencies, HTA agencies, SRs, clinical studies, and the EK of the various stakeholders consulted.
- Necessary precautions are generally taken in clinical studies to ensure the successful outcome of the studies and to avoid complications.

DRESSING CHANGES AND PARAMETERS TO ASSESS

INESSS recommends the following:

- **Change the dressings every 48 to 72 hours depending** on the condition of the wound and on the volume of exudate. Frequency can vary, especially in the presence of infection or if NPWT is used before or after surgical coverage (EO based on SD, RCP, and EK).
- **Strictly monitor** the wound, surrounding tissue, and the patient, once a week (EO based on RCP and EK).
- **Assess the following parameters** (EO based on SD, WP, RCP, and EK):
  - the patient's general state of health, complications, adverse effects, and treatment adherence
  - the progression of granulation (wound size, quality, appearance and percentage of granulation tissue, absence/presence of necrotic tissue), the drainage of exudate (quantity and appearance), the presence of infection, the state of the wound edges, and the presence of odour after the wound has been cleaned
  - the appearance of the surrounding tissue (edema, redness, sign of infection, allergic reaction to dressing, maceration).

Caution

- The health care professionals who APPLY NPWT must have the requisite skills to use the technology, recognize any signs of complications, and take appropriate action, if necessary (EO based on CTX, RCP, and EK).
- The health care professionals who ASSESS wounds undergoing NPWT must have relevant and up-to-date skills to assess wound progression — including the formation of granulation tissue —, recognize any signs of complications, and take appropriate action, if necessary (EO based on CTX, RCP, and EK).
- Patients and/or their caregivers, as well as the nursing staff, must be well-informed to ensure that they recognize certain signs that can pose a risk to the patients. They should also be informed of the technical aspects of NPWT (EO based on CTX, RCP, and EK).

Justifications:

- These justifications are in accord with the monographs of the various available technologies, regulatory agencies, HTA agencies, clinical studies, SRs, and the EK of the various stakeholders consulted.
- In clinical studies, dressings are usually changed every 48 to 72 hours, with the exception of dressings for split-thickness skin grafts, which are generally kept in place for a few days before they are removed.
- All health care professionals must take into account the operating framework established by their practice settings and comply with internal standards of care and protocols.
- To ensure optimal use, the safety of the intervention, the achievement of the clinical objectives, and timely cessation must be considered.

MONITORING, DURATION, AND RENEWAL OF NPWT

INESSS recommends that:

- **the maximum duration** of the original prescription should be 30 days (EO based on SD, WP, RCP, and EK);
- **a medical reassessment should be carried out by the original prescriber, in collaboration with** the team or a wound care specialist, two weeks after the start of treatment (EO based on RCP and EK);
- **a renewal of the original prescription should be carried out only** if a reassessment was done beforehand by a team or a wound care specialist (EO based on RCP and EK).

Caution

Reconsider the use of NPWT if anticoagulant therapy has to be initiated in order to respect therapeutic priorities (EO based on RCP and EK).

Justifications:

- These justifications are in accord with the monographs of the various available technologies and the pathophysiology of the wounds, regulatory agencies, HTA agencies, SRs, clinical studies, and the EK of the various stakeholders consulted.
- Clinical studies usually are strictly monitored to ensure the successful outcome of the studies and to prevent complications. Although the duration of NPWT varies with each patient, depending on the type of wound, it rarely exceeds 30 days. However, follow-up may last longer.
- To ensure optimal use, the safety of the intervention, the achievement of the clinical objectives, and timely cessation should be considered.

CRITERIA FOR CESSATION

INESSS recommends discontinuing NPWT (EO based on SD, WP, RCP, and EK):

- as soon as healthy granulation tissue covers the wound and before it reaches the edges of the wound
- as soon as the clinical objectives have been met
- if there is evidence of necrotic tissue, hypergranulation, or stagnation; or if the wound is not progressing favourably after two weeks of NPWT
- in the absence of any benefits related to the health care objectives and the pre-established clinical criteria
- in a situation in which the use of NPWT is not appropriate (e.g., negative pressure is difficult to maintain because of the location of the wound)
- if there is no health care team or professional authorized to change the dressings
- if a complication occurs that threatens the patient's life
- if moderately severe adverse events occur, namely:
  - excessive bleeding
  - severe wound or periwound infection
  - intense pain
  - an allergic reaction following application
- when patients and/or their caregivers do not adhere to the treatment.

Justifications:

- These justifications are in accord with the monographs of the various available technologies, the pathophysiology of the wounds, regulatory agencies, HTA agencies, systematic reviews, clinical studies, and the EK of the various stakeholders consulted.
- These should be considered to ensure an optimal, effective, and safe use.

RELATIONSHIP BETWEEN THE CLINICAL OBJECTIVES OF NPWT USE, THE INDICATIONS, AND THE LEVEL OF EVIDENCE

CLINICAL INDICATIONS	OBJECTIVES OF NPWT USE							
	Accelerate the formation of healthy granulation tissue	**Reduce wound closure time**	**Reduce** wound size in preparation for surgical closure or coverage	**Drain** exudate and reduce perilesional edema	**Prevent** retraction of wound edges in case of surgical wound dehiscence	**Serve as** a temporary dressing prior to additional or reconstructive surgery	**Prevent complications**	**Limit** resource use
CHRONIC WOUNDS								
Non-ischemic diabetic foot ulcer associated with significant loss of tissue, after the treatment of a bone or soft tissue infection, if necessary, and after debridement and off-loading of the ulcer	[Karatepe et al., 2011; Nain et al., 2011; Dalla Paola et al., 2010; Sepulveda, 2009]	[Karatepe et al., 2011; Nain et al., 2011; Dalla Paola et al., 2010; Sepulveda, 2009, Blume et al., 2008; Armstrong and Lavery, 2005; Etöz et al, 2004]	[Nain et al, 2011; Novinscaket et al, 2010; Blume et al., 2008; Akbari et al., 2007; Armstrong and Lavery, 2005; Etöz et al, 2004]	[Vig et al., 2011; HAS, 2010]	NR	[Vig et al., 2011; HAS, 2010]	[Nain et al., 2011; Dalla Paola et al., 2010]	[Dalla Paola et al., 2010]
Arterial or mixed ulcer after the assessment of the potential for revascularization	[Vig et al., 2011; HAS, 2010]	[Vig et al., 2011; HAS, 2010]	[Vig et al., 2011; HAS, 2010]	[Vig et al., 2011; HAS, 2010]	NR	[Vig et al., 2011; HAS, 2010]	Ø	Ø
Stage III or stage IV pressure ulcer after the removal of pressure from the wound site and the management of any bone or soft tissue infection, if necessary	[Ashby et al., 2012; Vig et al., 2011; HAS, 2010]	[Ashby et al., 2012; Vig et al., 2011; HAS, 2010]	[Vig et al., 2011; HAS, 2010]	[HAS, 2010]	NR	[Vig et al., 2011; HAS, 2010]	Ø	[Ashby et al., 2012; Vig et al., 2011]
ACUTE WOUNDS								
Surgical Procedure								
Surgical resection associated with significant and/or deep tissue loss without infection, or after treatment, if necessary	[Krug et al., 2011; HAS, 2010]	Ø	[HAS, 2010]	[HAS, 2010]	NR	[Krug et al., 2011; HAS, 2010]	Ø	Ø
Dehiscence of extensive surgical wound and/or adverse event (surgical closure impossible)	[HAS, 2010]	[HAS, 2010]	[HAS, 2010]	[HAS, 2010]	[HAS, 2010]	Ø	Ø	Ø
Surgical wound with a high risk of dehiscence (i.e., any wound requiring a complex approach)							[Pachowsky, 2012]	Ø
Open wound of the abdomen or thorax	NR	NR	NR	[Bruhin et al., 2014]	NR	[Bruhin et al., 2014]	[Bruhin et al., 2014]	[HAS, 2010]
Traumatic Open Fracture								
Traumatic wound that cannot be sutured and that is associated with significant and/or deep tissue loss without infection, or after treatment, if necessary	[Rasool et al., 2013; Krug et al., 2011; Stannard, 2009]	[Rasool et al., 2013; Krug et al., 2011; Stannard, 2009]	[Krug et al., 2011; HAS, 2010]	[Krug et al., 2011; HAS, 2010]	NR	[Krug et al., 2011; HAS, 2010]	[Stannard, 2009]	Ø

Reconstructive Surgery								
Just prior to a split-thickness skin graft	[Saaiq, 2010]	Ø	*	Ø	NR	NR	[Saaiq, 2010]	[Saaiq, 2010]
Following a split-thickness skin graft	Llanos et al., 2006	[Petkar et al., 2012; Krug et al., 2011; Petkar et al., 2011; Dalla Paola et al., 2010; Llanos et al., 2006; Moisidis et al., 2004]	NR	[Krug et al., 2011]	NR	NR	[Chio, 2010]	[Petkar et al., 2012; Llanos et al., 2006]
Following a skin flap procedure	[Krug et al., 2011]	NR	[Krug et al., 2011]	[Krug et al., 2011]	NR	[Krug et al., 2011]	Ø	Ø

Ø = no studies identified; NR = not relevant; = moderate level of evidence (Level 1, with moderate risk of bias); = low level of evidence (Level 1, with high risk of bias);
= assessment of the evidence by the authors of the BPR consulted (Levels of evidence 1 to 3); = expert opinion; *Consult the data on other types of wounds for which surgical coverage is intended.

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