

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

PRINCIPLES OF WOUND CARE MANAGEMENT

-

TOPIVAC NPWT APPLICATIONS

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This presentation is prepared to highlight wound care management, market and financial analysis of negative pressure wound and burn treatment devices and consumables considering different wound types.

TOPIVAC NPWT devices and consumables are defined and illustrated with details to tutor how to operate and treat the wounds with different wound care methods.

Data given in this presentation is gathered from reputable clinics, research centers, clinic protocols and practices in the market.

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CLASSIFICATION OF WOUNDS

CLASSIFICATION OF WOUNDS

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CLASSIFICATION OF WOUNDS

Wounds may be classified by several methods; their aetiology, location, type of injury or presenting symptoms, wound depth and tissue loss or clinical appearance of the wound.

General wounds are classified as being:

- **Superficial:** loss of epidermis only
- **Partial thickness:** involve the epidermis and dermis
- **Full thickness:** involve the dermis, subcutaneous fat and sometimes bone



SUPERFICIAL

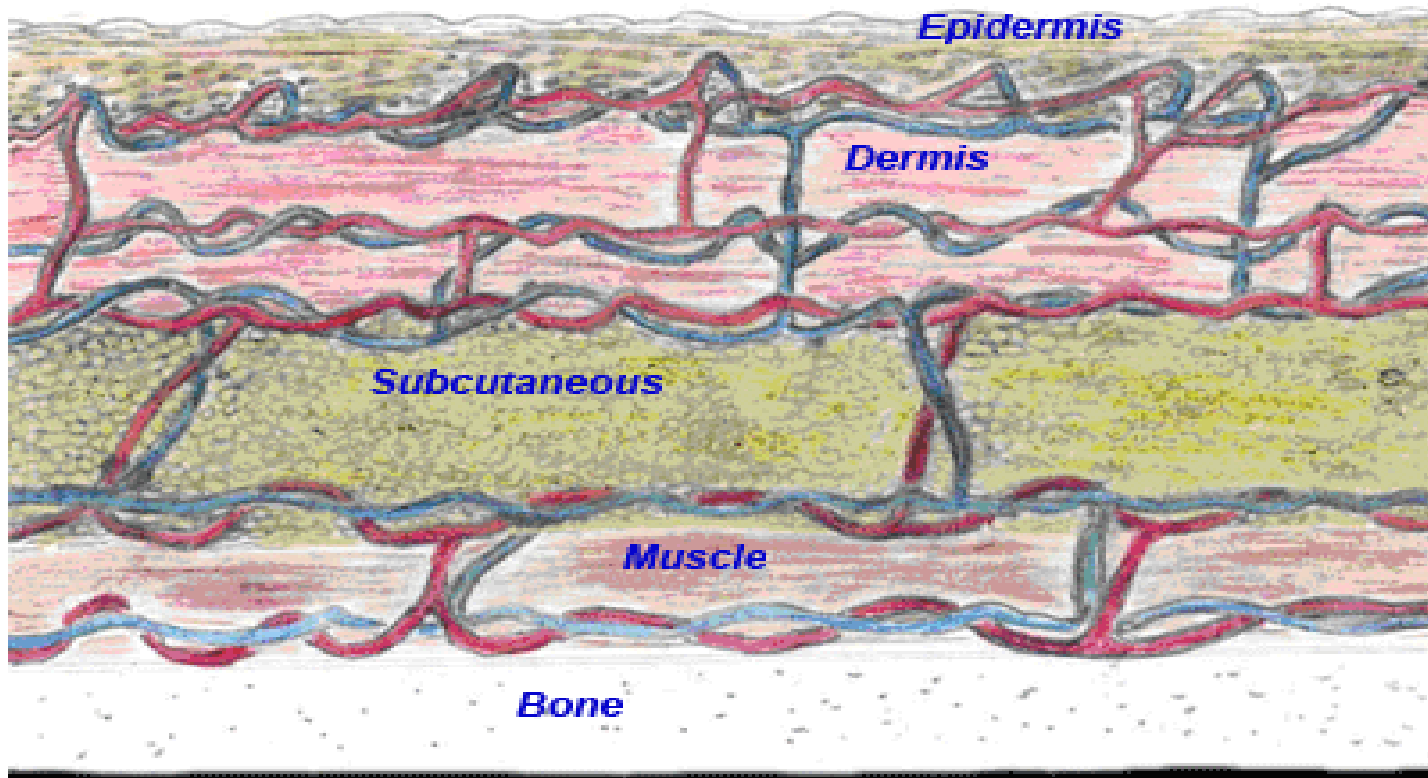
PARTIAL
THICKNESS

FULL
THICKNESS

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- **Superficial:** loss of epidermis only
- **Partial thickness:** involve the epidermis and dermis
- **Full thickness:** involve the dermis, subcutaneous fat and sometimes bone



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WOUND BED



WOUND BED

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WOUND BED

- **Granulating:** Healthy red tissue which is deposited during the repair process, presents as pinkish/red colored moist tissue and comprises of newly formed collagen, elastin and capillary networks. The tissue is well vascularized and bleeds easily.
- **Epithelializing:** Process by which the wound surface is covered by new epithelium, this begins when the wound has filled with granulation tissue. The tissue is pink, almost white, and only occurs on top of healthy granulation tissue.
- **Sloughy:** The presence of devitalized yellowish tissue. Is formed by an accumulation of dead cells. Must not be confused with pus.
- **Necrotic:** Wound containing dead tissue. It may appear hard dry and black. Dead connective tissue may appear grey. The presence of dead tissue in a wound prevents healing.
- **Hypergranulating:** Granulation tissue grows above the wound margin. This occurs when the proliferative phase of healing is prolonged usually as a result of bacterial imbalance or irritant force.

GRANULATING

HYPERGRANULATING

NECROTIC

EPITHELIALIZING

SLOUGHY

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WOUND CARE TOPICAL
VACUUM
TREATMENT
UNIT

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WOUND BED

FACTORS DELAYING WOUND HEALING:

- **Malnutrition**- Inadequate supply of protein, carbohydrates, fatty acids, and trace elements essential for all phases of wound healing.
- **Reduced Blood supply** - Cardiovascular disorders and Ischemia.
- **Medication** - Non-steroidal anti inflammatory drugs and Corticosteroids.
- **Chemotherapy** - Suppresses the immune system and inflammatory response.
- **Radiotherapy** - Increases production of free radical which damage cells.
- **Psychological** - Stress and lack of sleep- increase risk of infection and delayed healing.
- **Obesity** - Decreases tissue perfusion.
- **Infection** -Prolong inflammatory phase, use vital nutrients, impair epithelialisation and release toxins.

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WOUND BED

FACTORS DELAYING WOUND HEALING:

- **Reduced Wound Temperature** - Prolonged dressing changes or use of cold cleansing products.
- **Underlying Disease** - Diabetes Mellitus and Autoimmune disorders.
- **Maceration** - excess wound exudates or contact with bodily fluids reduces wound tensile strength.
- **Inappropriate Wound Management.**
- **Patient Compliance.**
- **Unrelieved Pressure.**
- **Immobility.**
- **Substance Abuse** - Including alcohol and cigarette smoke.

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TYPES OF WOUNDS

**TYPES OF
WOUNDS**

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TYPES OF WOUNDS

Depending on the healing time of a wound, it can be classified as **acute or chronic**.

Those classified as **acute** wounds heal uneventfully in the predicted amount of time.

Those classified as **chronic** wounds take a longer time to heal and might have some complications.



ACUTE



CHRONIC

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TYPES OF WOUND

Wounds can be **open** or **closed**.

Open wounds are wounds with exposed underlying tissue and/or organs that are open to the outside environment.

Closed wounds have damage that occurs without exposing the underlying tissue and organs.



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TYPES OF WOUND

OPEN WOUND



CLOSE WOUND



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TYPES OF WOUND

Another way to classify wounds is to determine if the wound is **clean** or **contaminated**.

Clean wounds have no foreign materials or debris inside.

Contaminated wounds or infected wounds might have exudate, dirt, fragments of the causative agent, bacteria or other foreign materials.



CLEAN



INFECTED

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TYPES OF WOUND

CLEAN WOUND



INFECTED WOUND



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TYPES OF WOUND

Short-term, **open wounds** are often described in 5 categories, based on the mechanism and appearance of a skin injury.

➤ **INCISION**

- Refers to a clean cut in the skin caused by a sharp object.
- A surgical incision is another common example.



INCISION

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TYPES OF WOUND

➤ LACERATION

- refers to an injury caused by tissue tearing.
- Similar to gaped wounds.



LACERATION

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TYPES OF WOUND

➤ ABRASION

- Abrasions occur when the skin is scraped off due to rubbing against a rough surface.



ABRASION

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TYPES OF WOUND

➤ AVULSION

- known as de-gloving, is a serious injury in which the skin is torn from the tissues beneath it.
- The mechanism of skin avulsion typically involves the skin catching on an object while the involved body part is in motion.



AVULSION

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TYPES OF WOUND

➤ PUNCTURE

- Refers when a sharp, slender object penetrates the skin and possibly the underlying tissues, depending on the length of the object.



PUNCTURE

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TYPES OF WOUND



ULCERS

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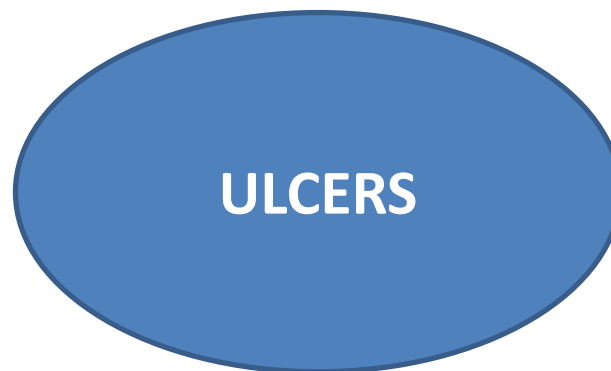
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TYPES OF WOUND

➤ **ULCERS**

- A lesion that is eroding away the skin or mucous membrane. Ulcers can have various causes, depending on their location. Ulcers on the skin are usually due to irritation, as in the case of bedsores, and may become inflamed and/or infected as they grow.

- VENOUS STASIS ULCERS
- NEUROPATHIC / DIABETIC ULCERS
- ARTERIAL ULCERS
- PRESSURE ULCERS
- TRAUMATIC ULCERS
- POST-SURGICAL ULCERS



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TYPES OF WOUND

Venous stasis ulcers are damage and skin loss on the legs due to problems with the underlying veins.

They're usually found below the knee on the inner part of the leg. They're shallow and red but may be covered in yellow tissue.



**VENOUS STASIS
ULCERS**

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TYPES OF WOUND

Also known as **diabetic ulcers**, **neuropathic ulcers** can actually affect anyone who has impaired sensation in their feet due to neurologic disorders or Hansen disease.

They usually occur on the foot, most commonly on pressure points that are prone to blisters.

Diabetic ulcers are typically caused by prolonged pressure or trauma to the foot.



**NEUROPATHIC /
DIABETIC ULCERS**

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TYPES OF WOUND

Most people who suffer from **arterial ulcers** have cardiac or cerebrovascular disease.

These foot wounds are deep, sometimes exposing tendons, and usually located on bony prominences, the heel or between toes.



ARTERIAL ULCERS

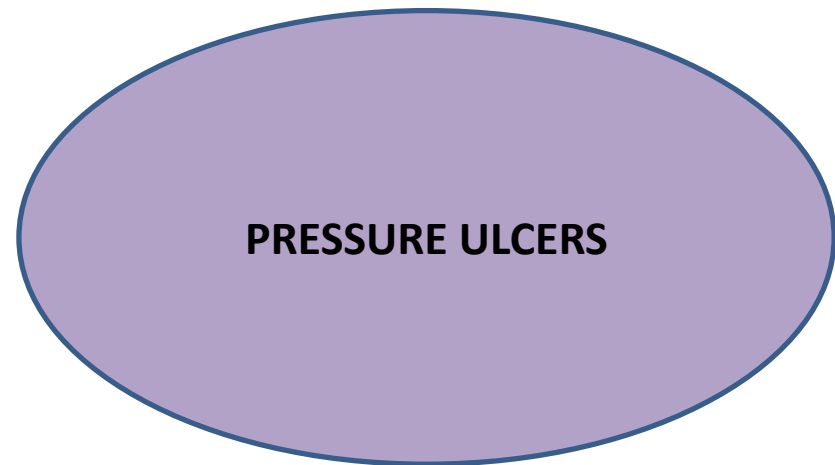
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TYPES OF WOUND

Pressure ulcers are most common in patients with limited mobility and occur on body parts that have prolonged pressure applied to them such as the hips, tailbone and heels.

Skin pressure limits blood flow to the area and the skin eventually dies.



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TYPES OF WOUND

Trauma or injury to the body may cause a loss of tissue layers and may result in damage to or loss of body parts or organs.

Traumatic injuries involving the oral cavity may typically lead to the formation of surface ulcerations.



TRAUMATIC ULCERS

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TYPES OF WOUND

Wound infections are a common complication of surgery.

Watch for any signs of these common wounds including redness around a surgical wound in the days following surgery.

You may also notice redness or streaking in surrounding tissues, throbbing or intense pain, pus or collection of fluids around the surgical site, a strong, unpleasant odor, and a mild to moderate fever.



POST SURGICAL ULCERS

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TYPES OF WOUND

Infectious wounds whether it is bacterial, fungal or viral, if the cause of the infection is not treated with the proper medication, the wound will not heal properly in the expected time.



INFECTIOUS WOUNDS

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TYPES OF WOUND

Ischemic wounds; means that the wound area is not getting sufficient blood supply. Limiting the blood supply, and the oxygen and nutrients it carries, can delay the healing process or even prevent it.

Ischemic ulcers can occur when there is poor blood flow in your legs. Ischemic means reduced blood flow to an area of the body.

Poor blood flow causes cells to die and damages tissue. Most ischemic ulcers occur on the feet and legs. These types of wounds can be slow to heal.



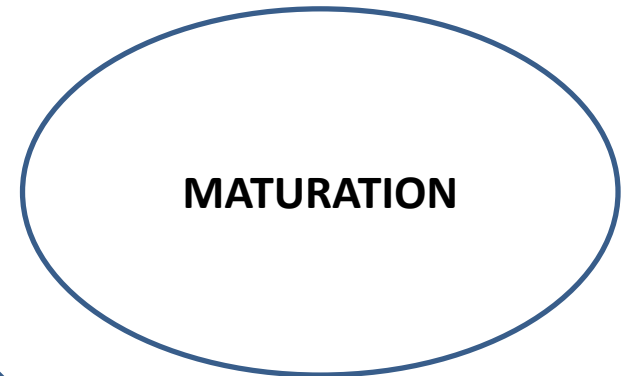
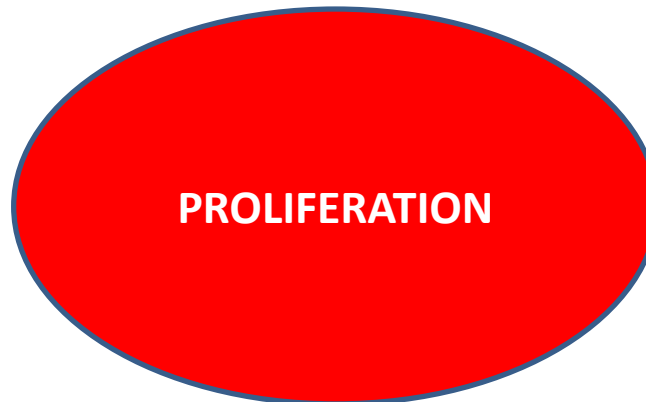
ISCHEMIC ULCERS

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PHASES OF WOUND HEALING

- **INFLAMMANTORY PHASE**
- **PROLIFERATION PHASE**
- **MATURATION PHASE**



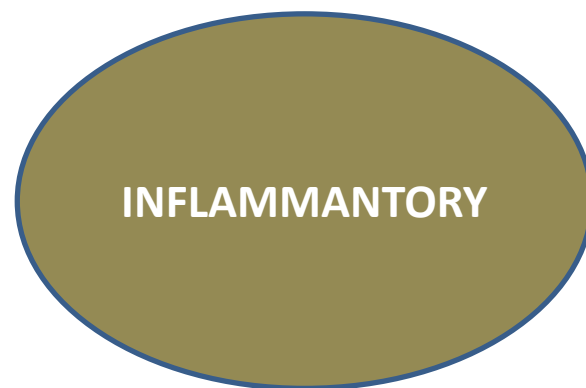
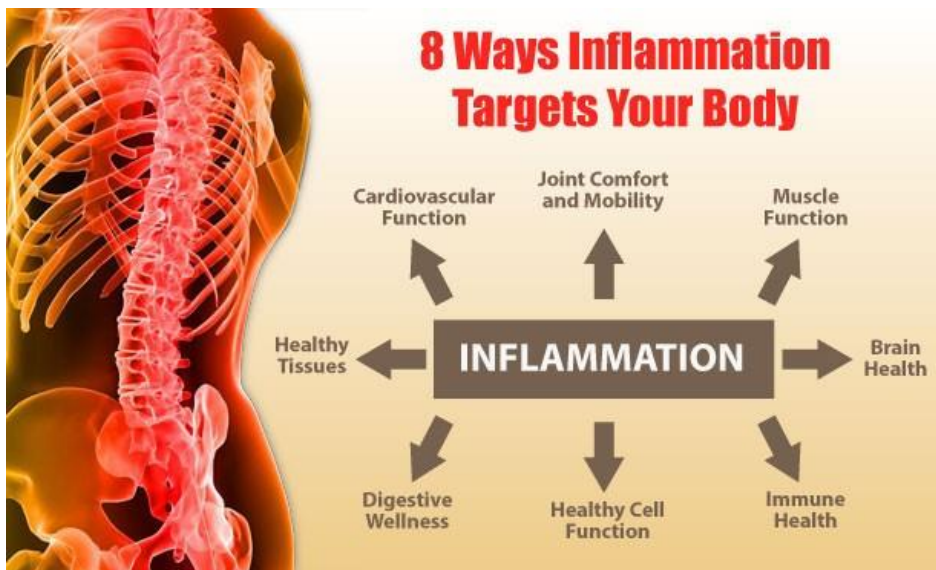
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PHASES OF WOUND HEALING

The **inflammatory phase** is the body's natural response to injury. After initial wounding, the blood vessels in the wound bed contract and a clot is formed.

Once haemostasis has been achieved, blood vessels then dilate to allow essential cells; antibodies, white blood cells, growth factors, enzymes and nutrients to reach the wounded area.



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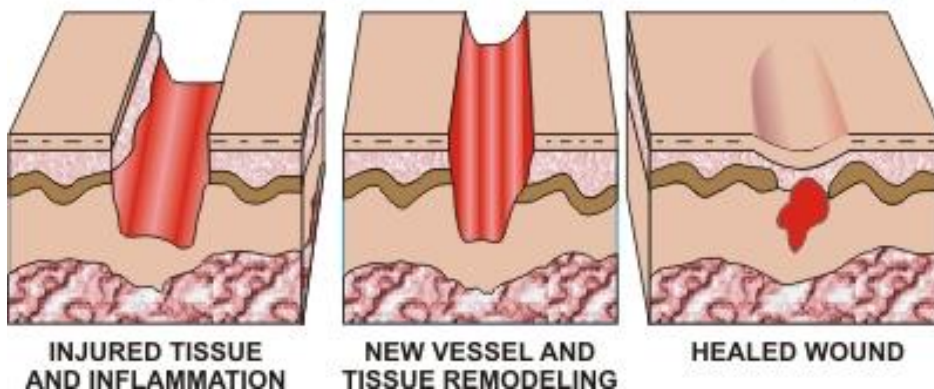
PHASES OF WOUND HEALING

During **proliferation**, the wound is 'rebuilt' with new granulation tissue which is comprised of collagen and extracellular matrix and into which a new network of blood vessels develop, a process known as 'angiogenesis'.

Healthy granulation tissue is dependent upon the fibroblast receiving sufficient levels of oxygen and nutrients supplied by the blood vessels.

Healthy granulation tissue is granular and uneven in texture; it does not bleed easily and is pink / red in colour.

Natural Phases of Wound Healing



PROLIFERATION

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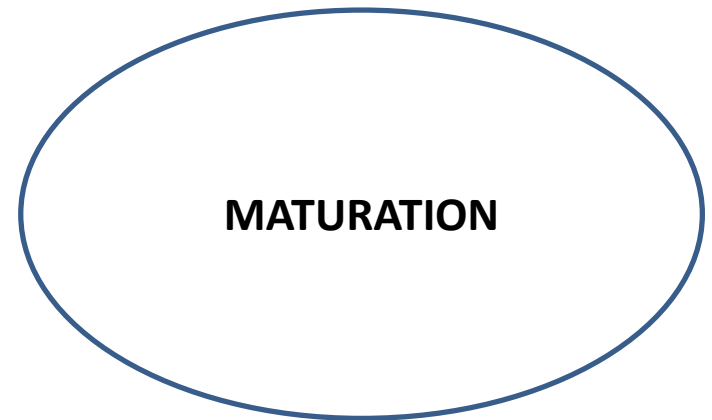
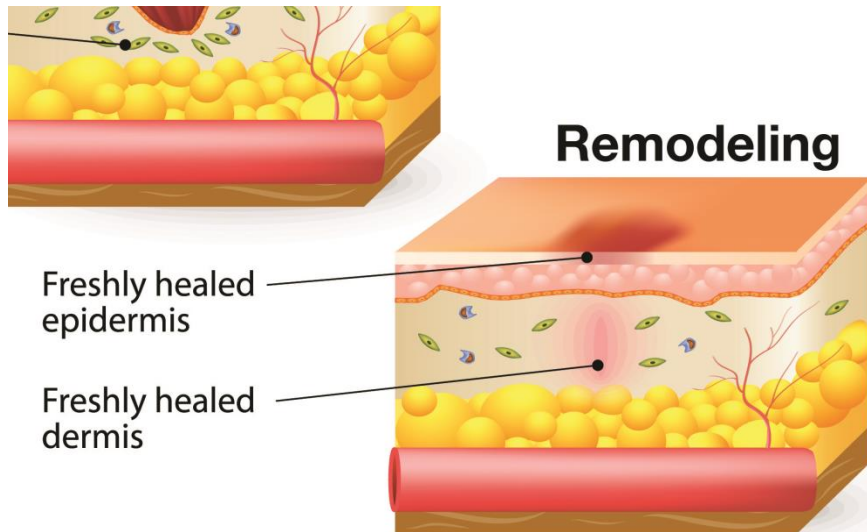
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PHASES OF WOUND HEALING

Maturation is the final phase and occurs once the wound has closed.

This phase involves remodelling of collagen from type III to type I.

Cellular activity reduces and the number of blood vessels in the wounded area regress and decrease.



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WOUND MANAGEMENT



WOUND
MANAGEMENT

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WOUND MANAGEMENT

The definition of **wound management** is mainly;

The process of returning to health; the restoration of structure and function of injured or diseased tissues. The healing processes include blood clotting, tissue mending, scarring and bone healing.



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WOUND MANAGEMENT

To ensure proper healing, the wound bed needs to be well vascularized, free of devitalized tissue, clear of infection, and moist.

Wound dressings should eliminate dead space, control exudate, prevent bacterial over growth, ensure proper fluid balance, be cost-efficient, and be manageable for the patient and/or nursing staff.

Wounds that demonstrate progressive healing as evidenced by granulation tissue and epithelialization can undergo closure or coverage.

All wounds are colonized with microbes; however, not all wounds are infected.



**CONTROL
EXUDATE**



DEAD SPACE



PROPER FLUID



**PREVENT
BACTERIAL
GROWTH**

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WOUND MANAGEMENT

WOUND MANAGEMENT PURPOSE:

- To promote wound granulation and healing ,
- To prevent undue contamination of wound,
- To decrease purulent wound drainage (dressing material absorbs the drainage),
- To provide dry environment (moist environment facilitates growth and multiplication of micro-organisms),
- To immobilize and support the wound,
- To apply medication to the wound,
- To provide comfort,
- To promote aesthetic sense.

**CONTROL
EXUDATE**

DEAD SPACE

PROPER FLUID

**PREVENT
BACTERIAL
GROWTH**

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VACUUM
TREATMENT
UNIT
WOUND CARE

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WOUND MANAGEMENT

TYPES OF DRESSING:

- Transparent adhesive films,
- Hydrocolloids,
- Collagens,
- Hydrogels,
- Exudate absorbers,
- Polyurethane foams,
- Lubricating sprays of emollients,
- Enzymatic debrides,
- Non-adherent dressings,
- Gauze dressings.

**CONTROL
EXUDATE**

DEAD SPACE

PROPER FLUID

**PREVENT
BACTERIAL
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INFECTION CONTROL

FACTS AND ADVISES:

All open wounds are colonised.

Bacteriological culture is indicated only if clinical signs of infection are present or if infection control issues need to be considered.

The classic signs of infection are heat, redness, swelling, and pain.

Additional signs of wound infection include **increased exudate, delayed healing, contact bleeding, odour, and abnormal granulation tissue.**

Treatment with antimicrobials should be guided by microbiological results and local resistance patterns.



**CONTROL
EXUDATE**



DEAD SPACE



PROPER FLUID



**PREVENT
BACTERIAL
GROWTH**

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INFECTION CONTROL

INFECTION CONTROL

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INFECTION CONTROL

Never close infected wounds.

Systematically perform wound toilet and surgical debridement.

Continue the cycle of surgical debridement and saline irrigation until the wound is completely clean.

Do not close(e.g Grafting) contaminated wounds and clean wounds that are more than six hours old.

To prevent wound infection:

- Restore breathing and blood circulation as soon as possible after injury.
- Warm the victim and at the earliest opportunity provide high-energy nutrition and pain relief.
- Perform wound toilet and debridement as soon as possible.
- Give antibiotic prophylaxis to victims with deep wounds and other indications.
- Antibiotics do not reach the source of the wound infection.
- Use of topical antibiotics and washing wounds with antibiotic solutions are not recommended.

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PATIENT ASSESSMENT

PATIENTS ASSESSMENTS TO UNDERTAKE:

- Life style,
- Ability to care for self,
- Mobility,
- Caregiver support,
- Reimbursement status,
- Psychosocial,
- Nutritional status,
- Blood test.



PATIENT ASSESSMENT

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TRENDS ON WOUND MANAGEMENT

- SILVER DRESSINGS
- ADVANCED DRESSINGS
- BIO-SYNTHETICS AND TISSUE ENGINEERING
- SKIN SUBSTITUTES
- GROWTH FACTORS AND BIOLOGICAL WOUND PRODUCTS
- HYPERBARIC OXYGEN THERAPY
- OZONE GAS THERAPY
- ELECTROSTIMULATION / TENS THERAPY
- NEGATIVE PRESSURE WOUND AND BURN THERAPY

WOUND
MANAGEMENT

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TRENDS ON WOUND MANAGEMENT

SILVER DRESSINGS:

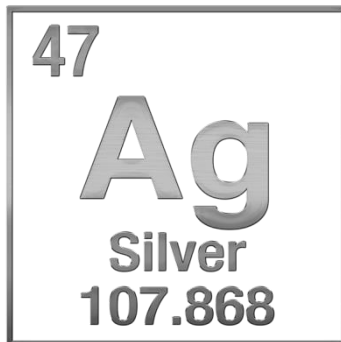
The use of silver to prevent and treat infection is both one of the earliest forms of wound care.

Silver has a very broad spectrum of microbial coverage, including yeast, fungi, mould, and even antibiotic-resistant bacteria.

Silver concentrations lethal to bacteria can also cause damage to healthy cells. In vitro studies on silver nitrate show a negative impact on fibroblasts.

Overall silver is a very effective modality for prevention or treatment of infection over a wide variety of bacteria, viruses, fungi, and moulds, with few side effects.

Though there are some reports of developing resistance, with continued appropriate use it should remain effective against even multi-antibiotic-resistant microorganisms.



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TRENDS ON WOUND MANAGEMENT

ADVANCED DRESSINGS:

Plain gauze certainly has its place as it is inexpensive, readily available, and appropriate for a large number of wounds. Impregnated gauze improves upon this by adding zinc, iodine, or petrolatum to help prevent desiccation and provide non-adherent coverage.

New wound understanding and technology have produced advanced products that help the body achieve the ideal moist, warm, protected wound healing environment.



**ADVANCED
DRESSINGS**

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TRENDS ON WOUND MANAGEMENT

ADVANCED DRESSINGS:

Gauze	Inexpensive; readily available	Availability issues in US	Papain/urea
Impregnated gauze	Nonadherent; preserves moisture	Selective debridement	Collagenase
Antimicrobial dressings	Hydrogels	Hydrofibers	Absorbent dressings
Antibacterial ointments	Reapply often to maintain moisture	Absorbs moderate exudate	Foam
Iodine based	Absorbent; not for use with thyroid disorders	Absorbs minimal exudate	Occlusive; allows exchange of gasses
Silver based	Many forms; broad spectrum; low resistance	Absorbs heavy exudate	Not for exudative or infected wounds
Autolytic debridement	Hydrogels	Absorbs heavy exudate	Rehydrates to soften dry wounds
Films	Chemical debridement	Alginates	Hydrocolloids

**ADVANCED
DRESSINGS**

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WOUND CARE
TOPICAL VACUUM TREATMENT UNIT

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TRENDS ON WOUND MANAGEMENT

IDEAL DRESSING:

- Provides moisture,
- Provides thermal insulation,
- Removes excess exudates and toxins,
- Protects from trauma and infection,
- Facilitates debridement of necrotic tissue,
- No trauma with removal.



**IDEAL
DRESSING**

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TRENDS ON WOUND MANAGEMENT

BIO-SYNTHETICS AND TISSUE ENGINEERING:

Systems and Synthetic Biology is a relatively new field in biomedical research.

It focuses on engineering new or modified signalling proteins to create desired signalling pathways in the cell.

Every living cell is an extremely complex machine expressing thousands of different proteins.

Due to superb regulation, many cells, such as photoreceptors and other neurons in vertebrates, can live for decades.

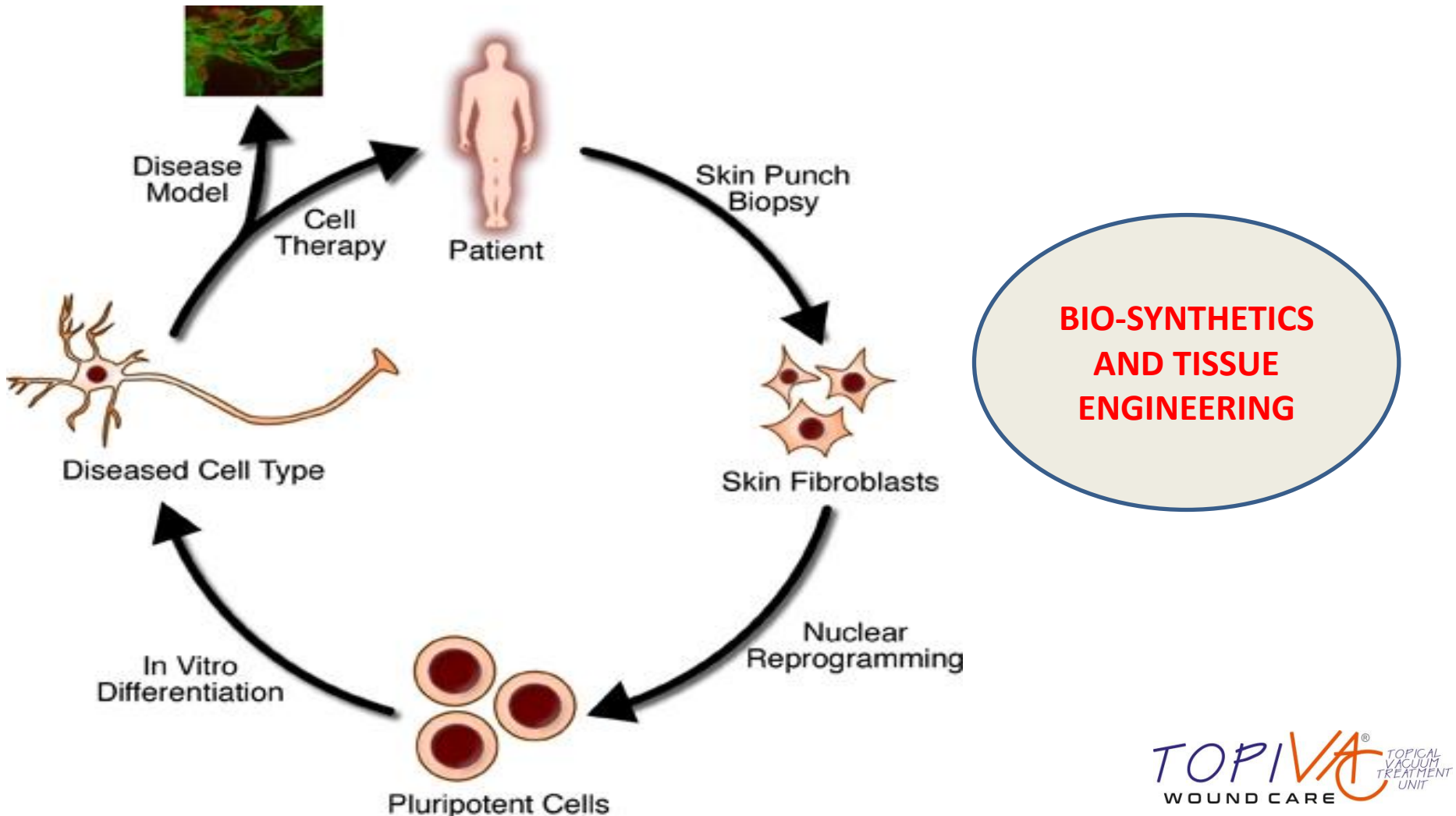
Cells can also self-reproduce by division, where both daughter cells are perfectly viable.

**BIO-SYNTHETICS
AND TISSUE
ENGINEERING**

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TRENDS ON WOUND MANAGEMENT



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TRENDS ON WOUND MANAGEMENT

BIO-SYNTHETICS AND TISSUE ENGINEERING:

Tissue engineering integrates biological components, such as cells and growth factors, with engineering principles and synthetic materials.

Substitute tissues can be produced by first seeding human cells onto scaffolds, which may be made from collagen or from a biodegradable polymer.

Examples of tissues that are candidates for tissue engineering include skin, cartilage, heart, and bone.

**BIO-SYNTHETICS
AND TISSUE
ENGINEERING**

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TRENDS ON WOUND MANAGEMENT

SKIN SUBSTITUTES:

Skin substitutes are used to aid in wound closure, control associated pain and replace the skin function to promote healing of the wound.

A skin substitute can be either temporary or permanent.

Synthetic substitutes, formed from synthesized materials that are made on demand with specific characteristics required in each case.

Permanent skin substitutes are used to replace the full thickness of skin layers and improve the quality of skin at the wound or burn sites permanently.



SKIN SUBSTITUTES

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TRENDS ON WOUND MANAGEMENT

SKIN SUBSTITUTES:



SYNTHETIC SKIN
SUBSTITUTES

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TRENDS ON WOUND MANAGEMENT

SKIN SUBSTITUTES:



**PERMANENT SKIN
SUBSTITUTES**

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TRENDS ON WOUND MANAGEMENT

GROWTH FACTORS AND BIOLOGICAL WOUND PRODUCTS:

Platelet derived growth factor (PDGF) plays a role in each stage of the wound healing process.

PDGF is released from de-granulating platelets upon injury and is present in wound fluid.

PDGF stimulates mitogenicity and chemotaxis of neutrophils, macrophages, fibroblasts, and smooth muscle cells to the wound site aiding the initiation of the inflammatory response.

**GROWTH FACTORS AND
BIOLOGICAL WOUND
PRODUCTS**

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TRENDS ON WOUND MANAGEMENT

- **Epidermal growth factor (EGF)** is secreted by the platelets and macrophages and stimulates proliferation of fibroblasts, the cells that produce collagen. EGF may reduce the healing time of wounds when applied topically.
- **Keratinocyte growth factor (KGF)** promotes the growth of cells known as keratinocytes, cells that secrete a protein called keratin.
- **Transforming growth factors (TGFs)** are a group of substances with different properties. TGF-a stimulates growth and migration of keratinocytes and fibroblasts in the affected area. TGF-b1 and TGF-b2 have been shown to promote the growth of new blood vessels (angiogenesis), ensuring adequate blood supply to the healing wound.
- **Vascular endothelial growth factor (VEGF)** is a growth factor that promotes angiogenesis.
- **Platelet-derived growth factor (PDGF)** is a growth factor secreted by the platelets, which attracts fibroblasts and macrophages to the area of injured tissue.

GROWTH FACTORS
AND BIOLOGICAL
WOUND PRODUCTS

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

HYPERBARIC OXYGEN THERAPY:

Hyperbaric oxygen therapy involves breathing pure oxygen in a pressurized room or tube.

Conditions treated with **hyperbaric oxygen therapy** include serious infections, bubbles of air in your blood vessels, and wounds that won't heal as a result of diabetes or radiation injury.

In a **hyperbaric oxygen therapy** chamber, the air pressure is increased to three times higher than normal air pressure.

Under these conditions, your lungs can gather more oxygen than would be possible breathing pure oxygen at normal air pressure.

Your blood carries this oxygen throughout your body.

This helps fight bacteria and stimulate the release of substances called growth factors and stem cells, which promote healing.



HYPERBARIC
OXYGEN THERAPY

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

HYPERBARIC OXYGEN THERAPY:



HYPERBARIC
OXYGEN THERAPY

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TRENDS ON WOUND MANAGEMENT

OXYGEN THERAPY:

Body tissues need adequate supply of oxygen to function.

When tissue is injured, it requires even more oxygen to survive. Oxygen therapy increases the amount of oxygen on your blood can carry.

In wound healing, **hypoxia** is an insufficient supply of oxygen which prevents normal healing process.

When **hypoxia** extends beyond the local wound environment the effects of ischemia-reperfusion injury can be seen.

Soft tissue and bone infections are frequently accompanied by localized areas of tissue **hypoxia** caused by the inflammatory processes accompanying infection and by subsequent vascular thrombosis.



OXYGEN THERAPY

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OXYGEN THERAPY:

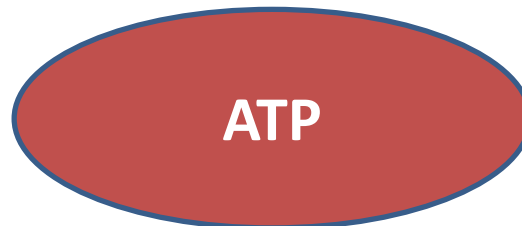
FUNCTION OF ATP (Adenosine triphosphate):

Mitochondrial respiration is responsible for more than %90 of oxygen consumption in humans.

Cells utilize oxygen as the final electron acceptor in the aerobic metabolism of glucose to generate **ATP** which fuels most active cellular processes such as during wound healing.

Increased energy demand of the healing tissue leads to a hyper metabolic state wherein additional energy is generated from oxidative metabolism increasing the oxygen demand of the healing tissue.

ATP thus, generated powers tissue repair.



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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OXYGEN THERAPY:

Vascular complications commonly associated with problematic wounds are primarily responsible for wound **ischemia**.

Limitations in the ability of the vasculature of deliver oxygen rich blood to the wound tissue leads to, among other consequences, **hypoxia**.

Hypoxia is a reduction in oxygen delivery below tissue demand, whereas **ischemia** is a lack of perfusion, characterized not only by hypoxia but also by insufficient nutrient supply.



ISCHIMIA



HYPOXIA

TOPIVAC

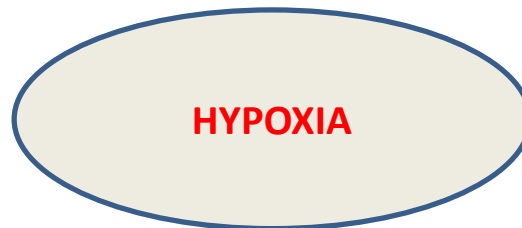
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OXYGEN THERAPY:

MAJOR FACTORS OF HYPOXIA:

- Peripheral vascular diseases garroting oxygen supply,
- Increased oxygen demand of the healing tissue,
- Generation of reactive oxygen species by way of respiratory burst and for redox signaling.
- Arterial Hypoxia.



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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OXYGEN THERAPY:

OXYGEN THERAPY IS REQUIRED FOR THE FOLLOWING CONDITIONS:

- Anemia, severe,
- Brain abscess,
- Bubbles of air in your blood vessels,
- Burn,
- Decompression sickness,
- Carbon monoxide poisoning,
- Crushing injury,
- Gangrene,
- Infection of skin or bone that causes tissue death,
- Non-healing wounds, such as diabetic foot ulcers,
- Radiation injury,
- Skin graft or skin flap at risk of tissue death.



HYPERBARIC
OXYGEN THERAPY

OXYGEN THERAPY

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TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:



OZONE GAS THERAPY

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

Ozone (O₃) is three molecules of oxygen combined together.

The goal of an **ozone treatment** is to force oxygen into the cells of the body.

Ozone enters the mitochondria of the cells, repairing it (the energy production of the cell) and helps decrease fatigue and better utilize oxygen in the cells.

This has been shown to treat a variety of chronic illnesses.



OZONE GAS
THERAPY

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

It has been proven that cancer and disease grow very poorly in oxygenated tissue.

Ozone triggers the white blood cells to start producing antibodies which will prevent the immune system from attacking healthy cells.

Ozone helps to reduce oxidation of the cells promoting natural antioxidant properties and decreases the level of acidity in the body.



OZONE GAS
THERAPY

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

METHODS OF OZONE GAS APPLICATIONS:

- IV TREATMENTS: Intravenous - Transfusion
- INSUFFLATIONS: Breathing
- LIMB BAGGING / CUPPING: Ozone Bag
- OZONATED SALINE: Debridement
- MAJOR AUTOHEMOTHERAPY: Similar to IV
- SINUS INSUFFLATION:
- EAR INSUFFLATION:
- RECTAL INSUFFLATION:
- BLADDER INSUFFLATION:
- VAGINAL INSUFFLATION:



OZONE GAS
THERAPY

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

Medical grade ozone is a mixture of pure O₂ and O₃ in the ratio of 0.1% to 5% of O₃ and %95 to %99.5 O₂.

The half life of **O₃** is 40 minutes at 20 C degree.

Ozone therapy is the non-surgical alternative form of the medical treatment in which amount of oxygen in the body is increased by administrating O₃ via different routes.

OZONE GAS
THERAPY

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
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TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

Ozone therapy may help to reduce clogging of blood cells, detoxify the liver, decrease uric acid in the body, improves circulation and oxygen supply, kill viruses, fungi, bacteria and also increase the activity of ATP.

European generators give the ozone concentration in terms of microgram/ml and the range 1-100 is sufficient for medical use.

A green oval with a dark blue border, containing the text "OZONE GAS THERAPY" in white, bold, uppercase letters.

OZONE GAS
THERAPY

The logo for TOPIVAC, featuring the word "TOPIVAC" in a stylized font with a registered trademark symbol. Below it, the words "WOUND CARE" are written in a smaller, sans-serif font. To the right of "TOPIVAC", the words "TOPICAL VACUUM TREATMENT UNIT" are written in a smaller, sans-serif font, arranged vertically.

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WOUND CARE
TOPICAL
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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

BENEFITS:

- **Ozone** increases availability and delivery of Oxygen, Glucose, and ATP within the Ischemic Tissue.
- **Ozone** enhances implantation of bone marrow stem cells at the site of lesion, which can provide angiogenesis, Neovascularization and Tissue Regeneration.
- **Ozone** activates neurohormonal reaction responsible for improving quality of life.
- **Ozone** induces up-regulation of expression of antioxidant enzymes and hence Oxygenize and extends preconditioning benefits.

OZONE GAS
THERAPY

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OZONE GAS THERAPY:

BENEFITS:

Medical Ozone Gas activates the red blood cell to release the oxygen into surrounding tissue and cells;

- Improved oxygen release,
- Increased flexibility,
- Improved blood circulation,
- Increase in ATP production.

OZONE GAS
THERAPY

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TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

BENEFITS:

- **Ozone** stimulates the production of white blood cells, which are necessary to fight infection.
- **Ozone** increases oxygen and hemoglobin disassociation, thus increasing the delivery of oxygen from the blood to the cells.
- **Ozone** inhibits the growth of new tissues like tumors.
- **Ozone** increases red blood cell membranes distensibility, thus enhancing their flexibility and effectiveness.
- **Ozone** increases anti-oxidant enzyme system, which scavenges excess free radicals in the body.

OZONE GAS
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OZONE GAS THERAPY:

4 PRIMARY WAYS TO APPLY MEDICAL OZONE GAS:

- Autohemotherapy, which involves removing about one half pint of blood from the patient, adding **ozone** and **oxygen** to the blood, and infusing the blood back to the patient.
- Rectal insufflation, in which ozone and oxygen are administered as a rectal enema. The **ozone/oxygen** mixture is then absorbed through the large intestine.
- **Ozone** Bagging which involves having an airtight bag placed around the area to be treated. A mixture of **ozone** and **oxygen** are pumped into the bag and absorbed through the skin.
- **Ozone** is also used externally in the form of ozonized olive or sunflower oil.

OZONE GAS
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OZONE GAS THERAPY:

OZONE THERAPY CAN BE USED IN THE FOLLOWING MEDICAL SPECIALTIES:

Gerontology	Infectiology	Orthopedics
Gastroenterology	Hepatology	Rheumatology
Dentistry	Gynecology	Stomatology
Dermatology	Intensive Therapy	Pneumology
Cosmetology	Neurology	Urology
Cardiology	Oncology	Angiology

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THERAPY**

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TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

OZONE GAS IN PRACTICE :

Ozone therapy was found its way into medical practice in Germany. Ozone/Oxygen mixture had been used in vascular surgery, stomatology and geriatrics.

Italian ozone therapists focused their activity on medical cosmetology.

Specialized ozone therapeutic clinics are operated in Switzerland and other countries of West Europe.

Cuba is well-known for its Ozone Research Centers.

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OZONE GAS THERAPY:

Ozone can destroy practically all kinds of bacteria, viruses, fungi and protozoa.

Gram-Positive bacteria and capsular viruses having a lipid bio-layer are particularly sensitive to oxidation.

The therapeutic ozone concentrations provides bactericidal effect which indirectly activates the non-specific defense system as well as components of cellular and humoral immunity.

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OZONE GAS THERAPY:

Anti-inflammatory effect is revealed in ozone capacity to oxidize the compounds containing double bonds, the arachidonic acid and its derivatives – prostalandins, in particular.

These biologically active substances participate in the development and sustaining the inflammatory process. Besides, ozone regulates metabolic reactions in tissues at the place of inflammation and resolves pH.

Detoxication effect of ozone is revealed in correction and activation of metabolic processes in the hepatic and renal tissues, thus, ensuring their main function of neutralization and evacuation of the toxic compounds from the organs.

A green oval with a dark blue border, containing the text "OZONE GAS THERAPY" in white, bold, uppercase letters.

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OZONE GAS THERAPY:

ACTIVATION OF OXYGEN-DEPENDENT PROCESSES:

Ozone gas causes the increase in the content of free and dissolved blood oxygen with rapid intensification of enzymes that catalyze aerobic oxidation of carbohydrates, lipids and proteins with formation of ATP energy substrate.

The great importance of this process is the mitochondrion activation of H-ATP-ase, responsible for conjugation of respiratory processes and oxidative phosphorylation, resulting in ATP synthesis.



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TRENDS ON WOUND MANAGEMENT

OZONE AERATED BAGS:

The method has proved to be highly efficient in the treatment of trophic ulcers, purulent sluggish wounds, bed sores, painful cicatrices, burns and defects caused by sequestrations of irradiated surficial and subcutaneous tumors.

Before the procedure the affected leg is damped with water or saline and then bag is put on and hermetically sealed. The bag is filled with gas mixture until the excessive pressure is reached. Then a destructor is switched on. The aerating is done for 15-20 minutes.

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TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

Treatment times vary depending on the wound type.

Typically range from 10-30 minutes of application time.

In this method, the ozone kills any bacteria, viruses, fungus or molds infecting the open wound, increase blood flow on the wound, and stimulates the healing process.

75 to 90 microgram/liter is undertaken as sterilizer.

20 to 30 microgram/liter is undertaken as medical grade and healing the wounds.

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OZONE GAS THERAPY:

Principally, ozone is applied complementary to a corresponding basic therapy.

Diabetes, Type II diabetes, chronic inflammatory diseases such as inflammatory vascular disease, in particular diabetic angiopathia, chronic hepatitis forms, and chronic intestinal conditions belong to the classic indications within the low-dose ozone concept.

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OZONE GAS THERAPY:

TOPICAL APPLICATION FORM OF OZONE GAS:

- Instillation by Ozonized water under vacuum,
- Application of Ozone gas under vacuum,
- Ozone cream,

Topical application of O₃/O₂ gas mixtures, from ozone-treated water or Ozone Gas or Ozone cream and beyond, a wound healing effect is produced, which is being used to an increasingly successful extent :

- External ulcers,
- Burns, superinfected wounds,
- Skin lesions,
- Local infections.

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OZONE GAS THERAPY:

OZONIZED WATER:

In topical applications, the use of ozonized water is present in water in molecular form as O_3 , presenting a physical solution.

When using de-ionized water and a high quality ozone generator, a maximum saturation of approximate 20 microgram ozone per ml of water at room temperature can be obtained.

It reacts immediately on skin contact, has a longer influence than cream.

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OZONE GAS THERAPY:

OZONIZED WATER INDICATIONS:

- Local infections,
- Ulcus cruris,
- Decubitus ulcers,
- Mycosis, mycotic infections,
- Herpes simplex and herpes zoster,
- Burns,
- Intraoperative rinsing,
- Surgery scars,
- Edemas of traumatic or bacterial origin.

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OZONE GAS THERAPY:

TOPICAL TREATMENT OF OZONE BAGGING:

Transcutaneous (ozone gas immersion) is a method of deep topical infections.

After moisturizing the extremity to be treated or the area over the organ concerned, direct O₃ gas immersion is applied inside a sealed ozone resistant bag, or in a slight vacuum using a special- low pressure boot or under a low pressure cup.

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OZONE GAS THERAPY:

TOPICAL TREATMENT OF OZONE BAGGING INDICATORS:

- Skin lesions,
- Burns,
- Superinfected wounds,
- Diabetic foot,
- Phlegmons,
- Large-surface,
- Open and deep chronic ulcers,
- Possibly infected and decubitus ulcers.

OZONE GAS
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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

OZONE GAS THERAPY:

TOPICAL TREATMENT OF OZONE BAGGING APPLICATION:

BURN STAGE 1 AND 2 :

- Moisturizing by ozonized water / de-ionized water,
- 10-20 min of gas application.

OZONE GAS
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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

CONTRA-INDICATIONS TO OZONE THERAPY:

- All cases with blood coagulation failure,
- Bleeding organs,
- Thrombocytopenia,
- Ozone allergy,
- Hemorrhagic or apoplectic stroke,
- Ozone intolerance.

**OZONE GAS
THERAPY**

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

ELECTROSTIMULATION / TENS THERAPY:



**ELECTROSTIMULATION/TENS
THERAPY**

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

ELECTROSTIMULATION / TENS THERAPY:

TENS stands for Transcutaneous Electrical Nerve Stimulation.

TENS is a therapy that uses low-voltage electrical current for pain relief in physiotherapy.

TENS is a method of electrical stimulation which primarily aims to provide a degree of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system.

The stimulating pulses help prevent pain signals from reaching the brain. Tens devices also help stimulate your body to produce higher levels of its own natural painkillers, called "Endorphins".

**ELECTROSTIMULATION/TENS
THERAPY**

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
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TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):



VACUUM ASSISTED CLOSURING

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TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

Negative pressure wound therapy is a medical procedure in which a vacuum dressing is used to enhance and promote wound healing in acute, chronic and burn wounds before skin grafting.

The therapy involves using a sealed wound dressing attached to a pump to create a negative pressure environment in the wound.

Applying continued vacuum helps to increase blood flow to the area and draw out excess fluid from the wound.

Depending on the wound type or location, the vacuum can either be applied continuously or intermittently.

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

Dealing with wounds is a matter of knowledge and experience.

Different etiologies such as trauma and infection may lead to acute and chronic wounds.

Management of these wounds differs according to the size of wound and the type of structures exposed and the **co-morbid condition** of the patients.



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TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

NPWT was developed to aid wound healing and is increasingly used prophylactically to prevent wound complications, including SSIs (Surgical Site Infections).

NPWT had been used by Wim Fleischmann and his colleagues in 1998. they proved the blood flow was **increased 4 times than normal** flow thanks to negative pressure application.



INCREASING BLOOD
FLOW FOUR TIMES



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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

NPWT applications are used to treat acute & chronic wounds. The main aims of the application are;

- Keeping the wound bed clean until surgery,
- Reducing the exudate and infection on the wound bed,
- Increasing the blood flow of the wound bed,
- Increasing the granulation of the wound bed to influence success of wound closing .

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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

Types of wounds can benefit from negative pressure wound therapy such as:

- Diabetic ulcers,
- Venous ulcers,
- Arterial ulcers,
- Pressure ulcers,
- First and second degree burns,
- Chronic wounds,
- Wounds with large amounts of exudate,
- Surgical and acute wounds at high risk for infection.

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

APPLICATION PROCESS:

The dressing used for negative pressure wound therapy starts with sterile open-cell foam that is cut to size and packed into the wound.

This foam acts as a sort of filter to keep any large particles (such as blood clots or dead, sloughed off tissue) from clogging the vacuum system.

Once packed with foam, the wound is covered with an occlusive dressing, typically made of polyurethane.



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THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

APPLICATION PROCESS:

A pump is attached to the occlusive dressing and once negative pressure is applied, a vacuum environment is created.

The pump can be programmed by a health care professional for strength of suction, amount of time it is to be applied and if it is to be intermittent or continuous.

A canister on the pump collects drainage and exudate is drawn away from the wound site.

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

BENEFITS:

- Optimizes blood flow in wound bed,
- Helps granulations in wound bed,
- Decreases local tissue swelling,
- Removes exudate and relevant excessive fluid,
- Decreases number of bacteria,
- Increasing cell division thanks to intermittent function,

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

BENEFITS:

- Earlier hospital discharge,
- Fewer wound dressing changes,
- Less need for surgery,
- Savings in nursing costs,
- Enable transfer from hospital to lower-cost health care setting,
- Improved quality of life.

VACUUM ASSISTED CLOSURING

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

BENEFITS:

- Increased local blood flow via enhancement of capillary blood flow
- Increased angiogenesis with profuse granulation formation
- Increased number of active fibro blasts and macrophages
- Enhanced epithelial cell migration
- Decreased bio-burden, bacterial toxins, and subsequent cessation/delay of healing and decreased tensile strength of the wound.

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

BENEFITS:

- Decreased harmful , chronic wound fluid and by-products and subsequent senescent cells and tissue damage,
- Decompressed excess interstitial fluid with subsequent decreased per wound induration, inelasticity, and micro vascular occlusion,
- Reduced number of dressing changes and subsequent decreased damage to delicate new tissue, pain, desiccation, and exposure to nosocomial infection,
- Provision of a moist, norm thermic wound environment that allows more efficient epithelization, growth factor synthesis and availability, and overall wound healing potential.

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TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

BENEFITS:

- Provision of mechanical approximation of wound edges,
- Promotion of viscoelastic flow and distraction histogenesis due to tissue stretch and stimulation of the cytoskeleton with subsequent enhanced mitosis,
- Decreased shear forces to the graft during inosculation via uniform wound bed immobilization,
- Decreased seroma/hematoma of grafts and flaps,
- Limitation of zone of injury after acute orthopedic trauma,
- Splinting effect (sternal, abdominal).

VACUUM ASSISTED CLOSURING

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

WORKING FUNTIONS:

Vacuum assisted closing can be applied between -70 to 150 mmhg on wound bed in terms of two working functions:

- INTERMITTENT NEGATIVE PRESSURE THERAPY
- CONTINUOUS NEGATIVE PRESSURE THERAPY



INTERMITTENT



CONTINUOUS

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

WORKING FUNTIONS:

INTERMITTENT THERAPY:

This type of treatment refers to application of negative pressure on wound bed alternating the vacuum value at a certain period of time.

The application would last between 12 to 72 hours by applying a high level of vacuum (e.g. -125mmhg) for 2 minutes and lower level of vacuum (e.g. -70mmhg) for 2 minutes repeating until sessions are completed.

This type of treatment was proved by clinical study that the blood flow and granulation were increased at the optimum level of application.

INTERMITTENT

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

WORKING FUNTIONS:

CONTINOUS THERAPY:

This type of treatment refers to application of negative pressure on wound bed at a certain set value of vacuum degree.

The application would last between 12 to 72 hours by applying a constant vacuum value (e.g - 125mmhg)



CONTINUOUS

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TRENDS ON WOUND MANAGEMENT

NEGATIVE PRESSURE WOUND THERAPY (VAC):

GENERAL VAC APPLICATION FACTS:

- Decreasing application cost as one in third,
- Decreasing length of stay of patient at hospital as %60,
- Decreasing the cost of hospitalization as %30.
- Decreasing amputation chances,
- Faster closing wound bed and areas,
- Wound bed readiness for grafting and flapping applications.

CONTINUOUS

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

MARKET FACTS:



STATISTICAL DATA

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

MARKET FACTS:

- 20 billion US \$ yearly spending on wound care market,
- 422 Million diabetic patient in the world (WHO 2014)
- 1.2 Million mortality record in 2012 (WHO)
- 2.2 Million mortality due to high glucose rate (WHO)
- Conventional NPWT device rental cost 488\$-623\$,
- Dressing cost per application 86\$-110\$,
- Portable NPWT 198\$
- Use of NPWT increased from %51 to %73,
- The percentage of leg ulcers that utilized compression increased from %60 to %90,
- Daily dressing changes reduced from %39 to %19,
- Healing increased from 39 weeks to 29 weeks (2009-2011)

* Data acquired from a private survey company along with WHO studies. (www.o-wm.com)

**STATISTICAL
DATA**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

FACTS:

SOME OF THE FACTORS CONTRIBUTING TO THE GROWTH OF THE MARKET ARE:

- Increase in the aging population,
- Rise in chronic wounds and ulcers,
- Increase in diabetes population,
- Increase in the number of surgeries,
- Rise in the number of government initiatives towards prevention of injuries,
- Rapid rise in technological advancements.

**STATISTICAL
DATA**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

FACTS:

SOME FACTORS LIMITING THE GROWTH OF THE MARKET ARE:

- Expensive procedures,
- Reluctance in acceptance of new technologies,
- Lack of proper reimbursement policies.

**STATISTICAL
DATA**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

FACTS:

TOTAL WOUND COSTS PROPORTION:

- %20 Dressing,
- %40 Nurse,
- %40 hospitalization.

* The given proportions are general approach of cost estimations.

**STATISTICAL
DATA**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

BURDEN / STATISTICAL DATA FACTS

INNOVATION IN WOUND CARE:

PROCESS INNOVATION :

- PROTOCOLS,
- STUDIES,
- CLINICAL RESULTS,

PRODUCT INNOVATION:

- INNOVATIVE MEDICAL DEVICES AND CONSUMABLES



PROCESS

PRODUCT

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

WHO STATEMENT FOR TARGET BY 2030

“As part of the 2030 Agenda for Sustainable Development, Member States have set an ambitious target to reduce premature mortality from NCDs – including Diabetes- by one third; achieve universal health coverage; and provide access to affordable essential medicines – all by 2030.”

Dr. Margaret Chan
Director – General
WHO



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

WHO STATEMENT FOR TARGET BY 2030

Diabetes is a serious, chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.

Diabetes is an important public health problem, one of four priority non-communicable diseases targeted for action by world leaders.



DIABETES

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

WHO STATEMENT FOR TARGET BY 2030

TYPE I:

- Requires insulin injections for survival.

TYPE II:

- Where the body cannot properly use the insulin it produces.



TYPE I



TYPE II

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

WHO STATEMENT FOR TARGET BY 2030

MANAGING DIABETES:

- Blood glucose control,
- Through a combination of diet,
- Physical activity,
- Medication if necessary,
- Control of blood pressure and lipids to reduce cardiovascular risk.

MANAGING DIABETES

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

In the market, most of the producers are offering Vacuum application and Vacuum assisted instillation applications.

**HOWEVER, TOPIVAC NPWT IS NOT ONLY OFFERING A VACUUM APPLICATION. IT IS OFFERING
COMBINATION OF TREATMENT THERAPIES.**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

OUR NPWT PRODUCTS

TOPIVAC[®] TOPICAL
VACUUM
TREATMENT
UNIT
WOUND CARE



TOPIVAC[®] TOPICAL
VACUUM
TREATMENT
UNIT
WOUND CARE

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

OUR NPWT PRODUCTS



TOPISET - CONSUMABLES

TOPIVAC®
WOUND CARE
TOPICAL VACUUM
TREATMENT
UNIT

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

TOPIVAC IS FEATURING COMBINATION OF DIFFERENT TREATMENT METHODS:

1. The healthcare giver would choose to apply vacuum therapy.
2. Vacuum therapy can also be combined with moisturizing during application.
3. The debridement can be done under vacuum by the device when Vacuum and Irrigation/Instillation application chosen.
4. TOPIVAC can work as Hyperbaric Oxygen treatment by applying Oxygen/Ozone gas under vacuum.
5. By Gas Therapy, the applicator can practice the bagging method.

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

TOPIVAC IS FEATURING COMBINATION OF DIFFERENT TREATMENT METHODS:



THERAPY SELECTION MENU

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

HISTORY of TOPIVAC NPWT:

- ✓ TOPIVAC was developed in 2011.
- ✓ R&D studies and clinical protocols have been finalized in 2014.
- ✓ First product launch had been made in 2014 in Turkey.
- ✓ Global market launch had been made in 2016 at ARAB HEALTH SHOW (DUBAI).

HISTORY OF TOPIVAC

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

TOPIVAC NPWT enables to apply the following treatments:

- CONVETIONAL VACUUM THERAPY,
- VACUUM & MOISTURIZING THERAPY (De-ionized / Oxygenated / Ozonized Water)
- VACUUM & INSTILLATION THERAPY (De-ionized / Oxygenated / Ozonized Water)
- VACUUM & GAS THERAPY (Oxygen / Ozone)
- GAS THERAPY (Oxygen / Ozone)
- ELECTROSTIMULATION / TENS THERAPY.
- VAC + MOISTURIZING + INSTILLATION + GAS + TENS THERAPY AT ONE SESSION.

**TREATMENT
SELECTION**

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

IN THE FOLLOWING CONTENTS DESCRIBE THE EACH OF THE TREATMENT APPLIED BY TOPIVAC



MEDIUM CLINIC V4



MEDIUM V2



HAND DIGITAL IRRIGATION



HAND CLASSIC



TOPI MOBILE
DISPOSABLE DEVICES

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPI MOBILE DISPOSABLE NPWT VACUUM ASSISTED WOUND CARE THERAPY DEVICES & SETS

(Home Care Devices)

TOPI A100 Classic NPWT Device:



- Used for rapid healing of the wound in wound treatments such as;
Diabetic Foot Wounds, Bedsore, Chronic Wound, Non-Healing Wound, Burn Wound, Infected Wounds, etc.
- Operates under vacuum of **-75 mmHg, -100 mmHg, -125 mmHg.**
- Draws exudate from the wound centre. Increases granulation. Fastens wound healings.
- Provides ease of use without expert help.

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPI MOBILE DISPOSABLE NPWT VACUUM ASSISTED WOUND CARE THERAPY DEVICES & SETS

(Home Care Devices)

TOPI A100 Mobile Disposable CLASSIC NPWT Vacuum-Assisted Wound Care Treatment Device and Dressing Set includes 1 protocol and 5 dressing treatment sterile products.



- **Topi A100 Set Components:**

- 1 Topi A100 Mobile Disposable CLASSIC NPWT Vacuum-Assisted Wound Care Treatment Device
- 5 pcs Dressing Foam Set (100 * 100 mm)
- 5 pcs 75 cc Canister
- 1 pcs Extension Hose
- 1 pcs (30 * 40 cm) Drape
- 1 pcs Device Carry Bag

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPI MOBILE DISPOSABLE NPWT VACUUM ASSISTED WOUND CARE THERAPY DEVICES & SETS

(Home Care Devices)

TOPI A200 Incision NPWT Device:



- Used in advanced incision management such as;
Chest and Plastic Surgery Wounds, Orthopedic Surgery Wounds, Cardiothoracic Surgery Wounds, Vascular Surgery Wounds, Obstetric and Gynecological Surgery Wounds, Cesarean Section Wounds, etc.
- Operates under vacuum of **-35 mmHg, -50 mmHg, -65 mmHg.**
- Has high healing performance in surgical incision wounds.
- Provides ease of use without expert help.
- Draws exudate from the wound centre. Increases granulation. Fastens wound healings.

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPI MOBILE DISPOSABLE NPWT VACUUM ASSISTED WOUND CARE THERAPY DEVICES & SETS

(Home Care Devices)

TOPI A200 Mobile Disposable INCISION NPWT Vacuum-Assisted Wound Care Treatment Device and Dressing Set includes 1 protocol and 5 dressing treatment sterile products.



- Topi A200 Set Components:

- 1 pcs Topi A200 Mobile Disposable INCISION NPWT Vacuum-Assisted Wound Care Treatment Device
- 5 pcs Incision Dressing Foam Set (45 * 220 mm)
- 5 pcs 75 cc Canister
- 1 pcs Extension Hose
- 1 pcs Device Carry Bag
- 1 pcs (30 * 40 cm) Drape

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND performs the followings:



- Conventional Vacuum Therapy NPWT,
- Intermittent Vacuum Therapy,
- Continuous Vacuum Therapy,
- Canister (1000 ml),
- Polyurethane Sponge.
- Touch Screen Full Colored Display/ Membrane Buttons.

TOPIVAC

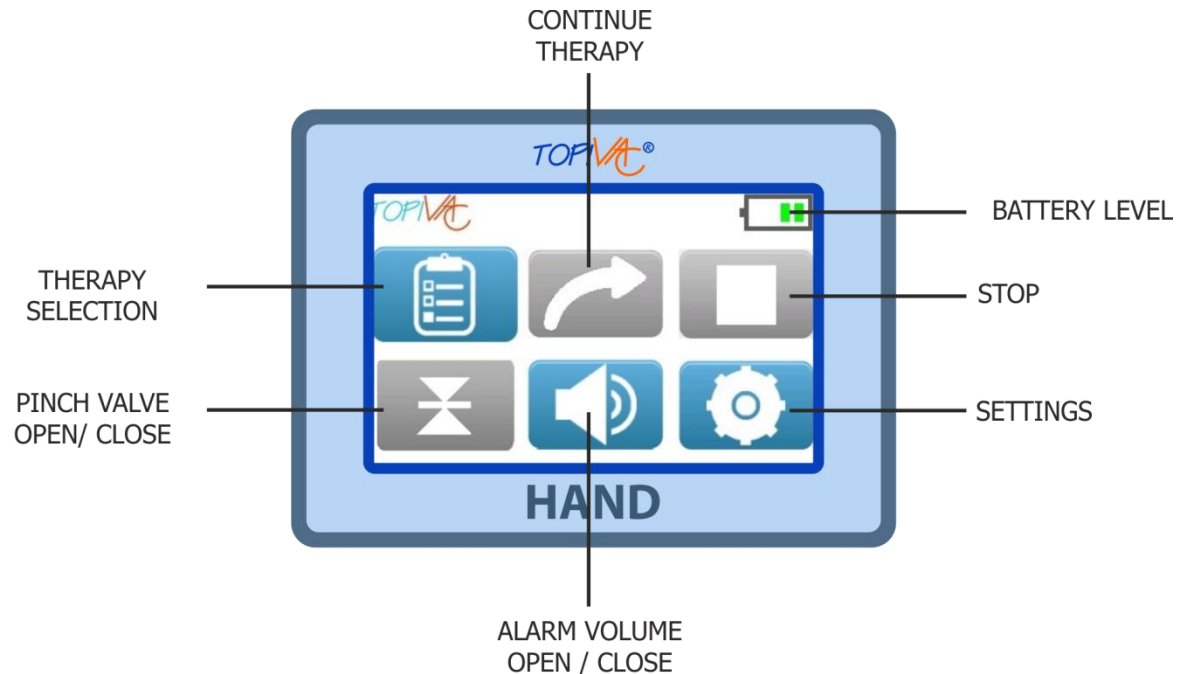
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

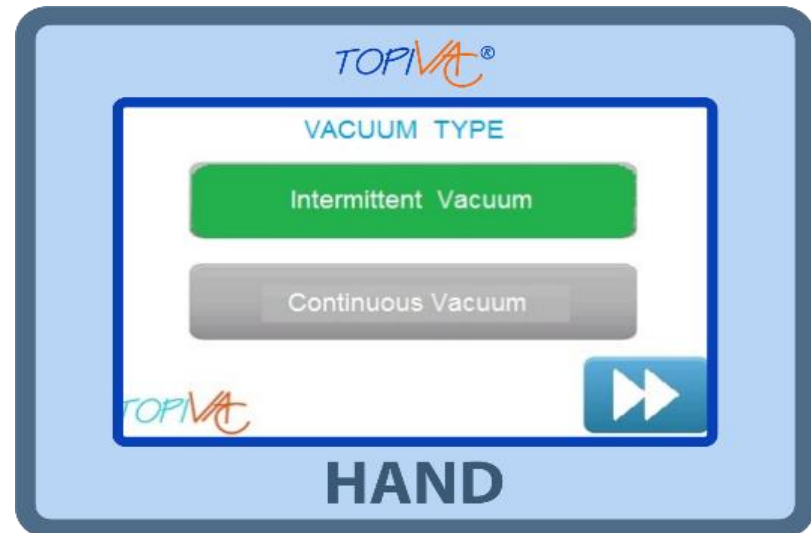
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

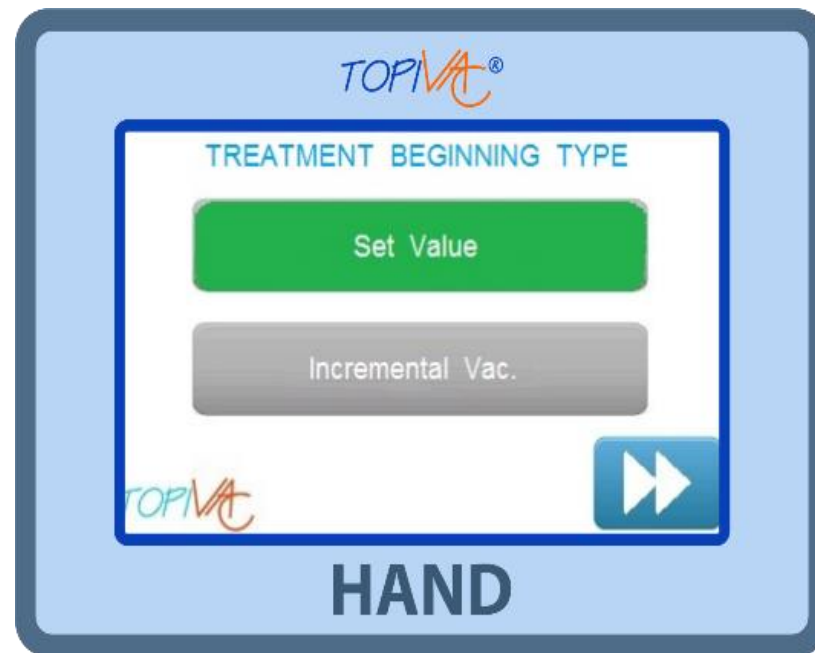
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

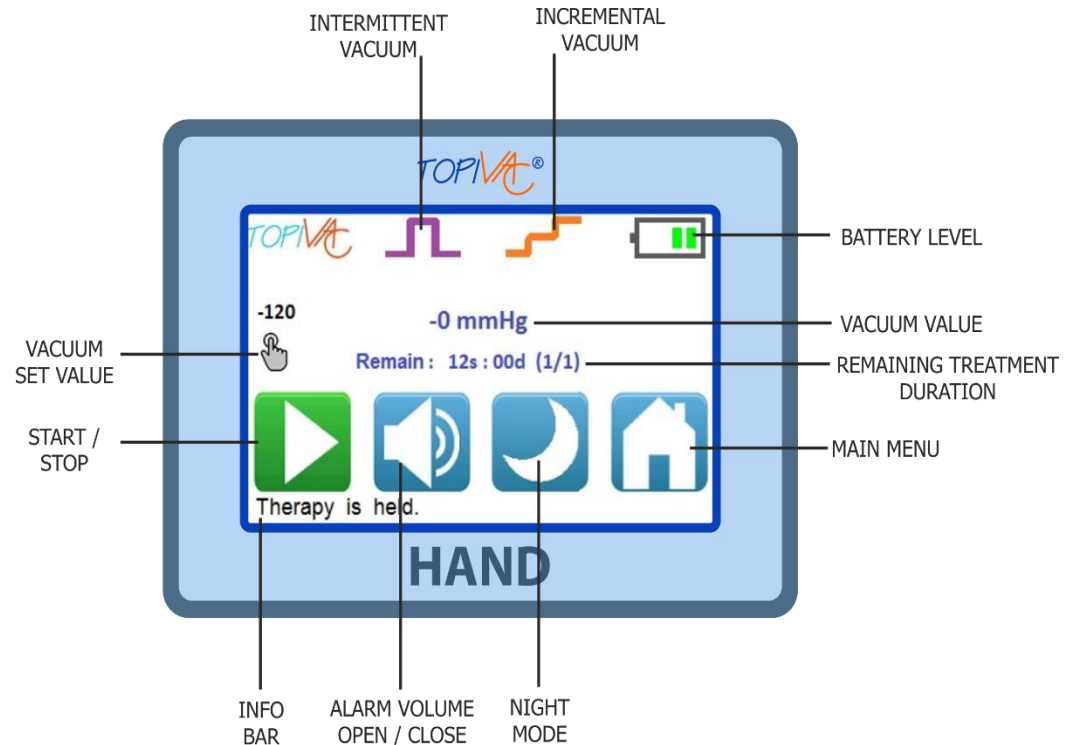
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC HAND NPWT PRODUCT DESCRIPTION

TOPIVAC HAND DASHBOARD AND STEPS OF TREATMENT



TOPIVAC HAND



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

MEDIUM V1



MEDIUM V2



MEDIUM V3



MEDIUM CLINIC



SPECIFICATIONS

- ✓ Conventional NPWT
- ✓ Moisturizing
- ✓ Instillation

SPECIFICATIONS

- ✓ Conventional NPWT
- ✓ Moisturizing
- ✓ Instillation
- ✓ O2 Instillation
- ✓ O2 Gas Therapy

SPECIFICATIONS

- ✓ Conventional NPWT
- ✓ Moisturizing
- ✓ Instillation
- ✓ Electro / Tens
- ✓ O2 / O3 Instillation
- ✓ O2 /O3 Gas Therapy

SPECIFICATIONS

- ✓ Conventional NPTW
- ✓ Moisturizing
- ✓ O2 / O3 Instillation
- ✓ Electro / Tens
- ✓ O2 / O3 Gas Therapy
- ✓ *Compatible with OzonBag for burn treatment

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

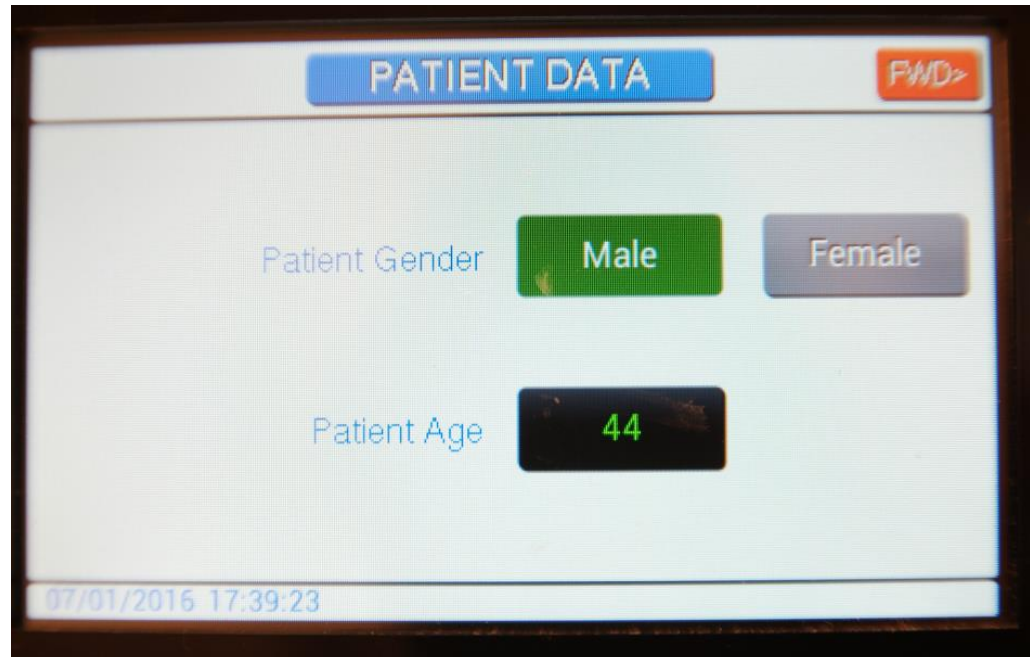
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

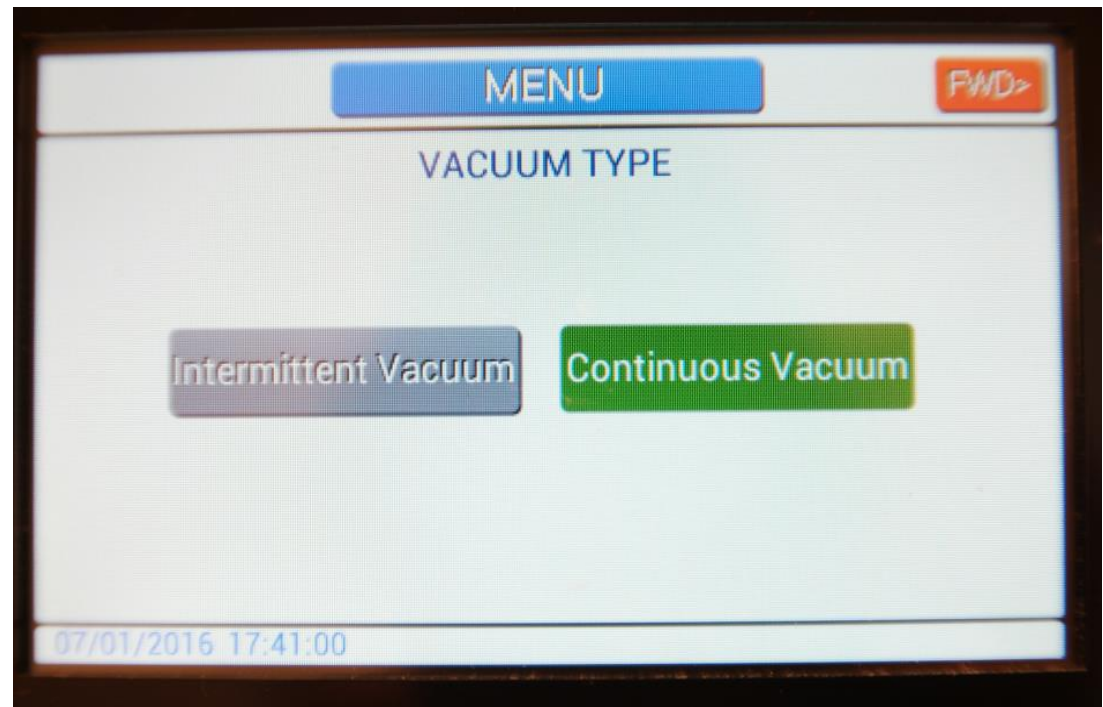
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

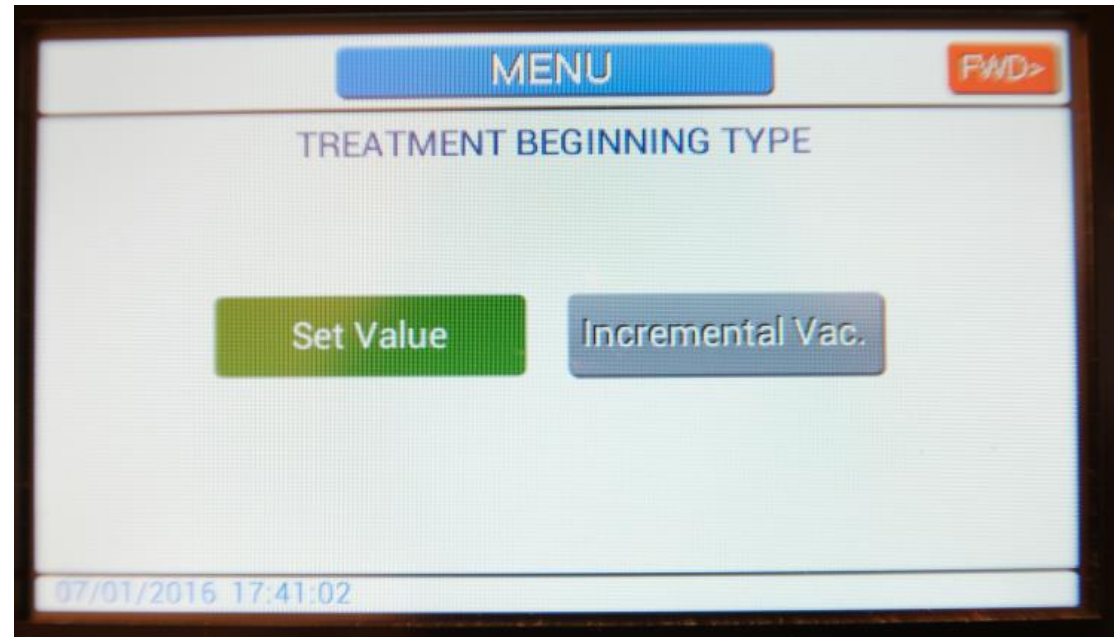
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

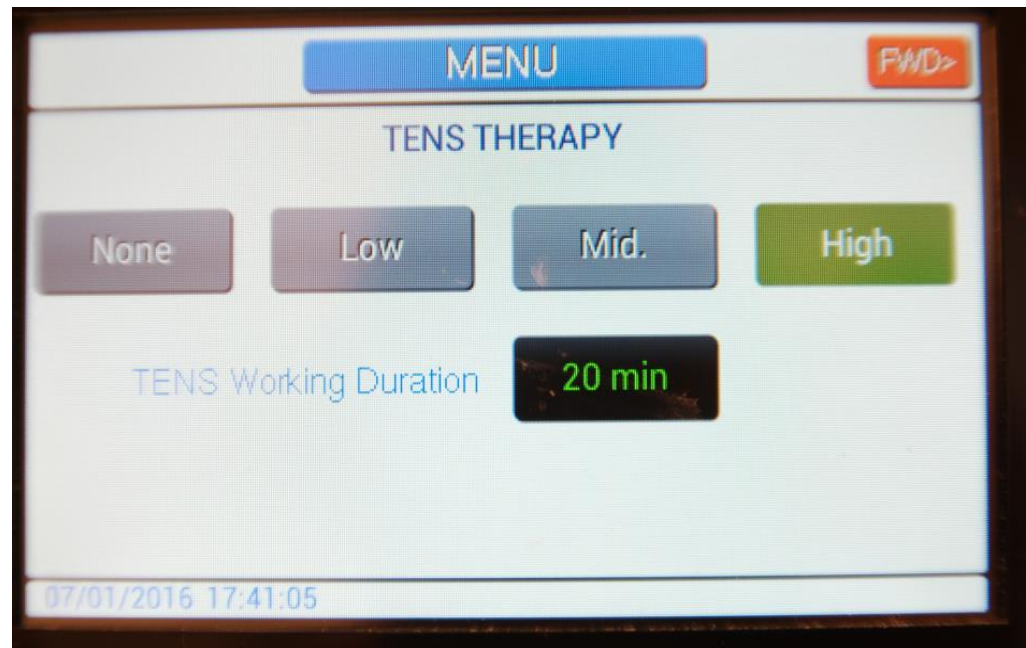
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

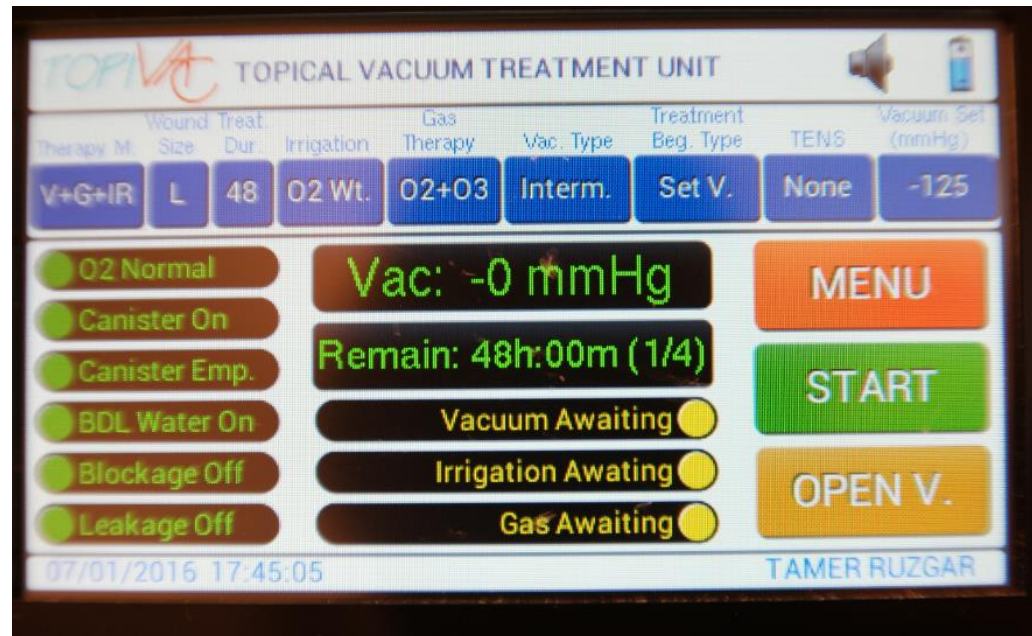
NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC MEDIUM NPWT PRODUCT DESCRIPTION

TOPIVAC MEDIUM DASHBOARD AND STEPS OF TREATMENT:



TOPIVAC MEDIUM



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC PRO NPWT PRODUCT DESCRIPTION

TOPIVAC CLINIC V4 SPECIFICATIONS



TOPIVAC CLINIC V4

- ✓ Conventional Negative Pressure Vacuum Therapy
- ✓ Moisturizing
- ✓ O2 / O3 Instillation
- ✓ Electro / Tens
- ✓ O2 / O3 Gas Therapy

*Compatible with OzonBag for burn treatment.

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

TOPISET



TOPISET

Box set of required consumables:

- ✓ CANISTER
- ✓ MULTICASE
- ✓ DRESSING
- ✓ DE-IONIZED WATER
- ✓ DRESSING KIT
- ✓ HAZARDOUS BAG
- ✓ OXYGEN HOSE
- ✓ ELECTROTENS CABLE
- ✓ ELECTRODE

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

CANISTER

- ✓ 1000 ML Canister – Collection Cup
- ✓ It is required for all of the treatment processes.

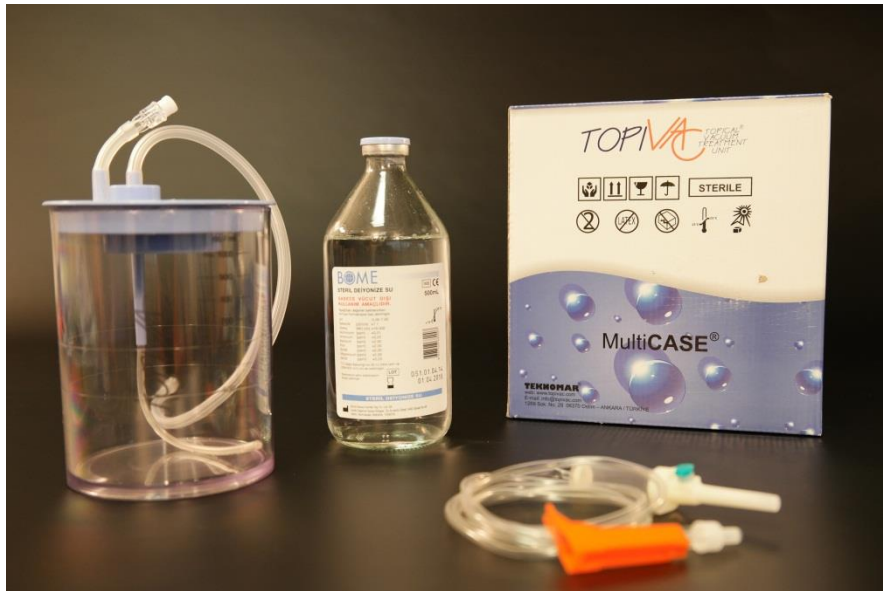


CANISTER

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



MultiCASE

MULTICASE

- ✓ 1000 MI MultiCase–MultiFunctional Irrigation Cup
- ✓ It is required for instillation and Moisturizing Therapies.
- ✓ MultiCase is coming with 500 ml. De-ionized water and infusion kit.

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



DRESSINGS

DRESSINGS













- ✓ SINGLE TUBE VACUUM DRESSINGS,
- ✓ DOUBLE TUBE VACUUM & INSTILLATION DRESSINGS
- ✓ MULTIDRESS DRESSINGS

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

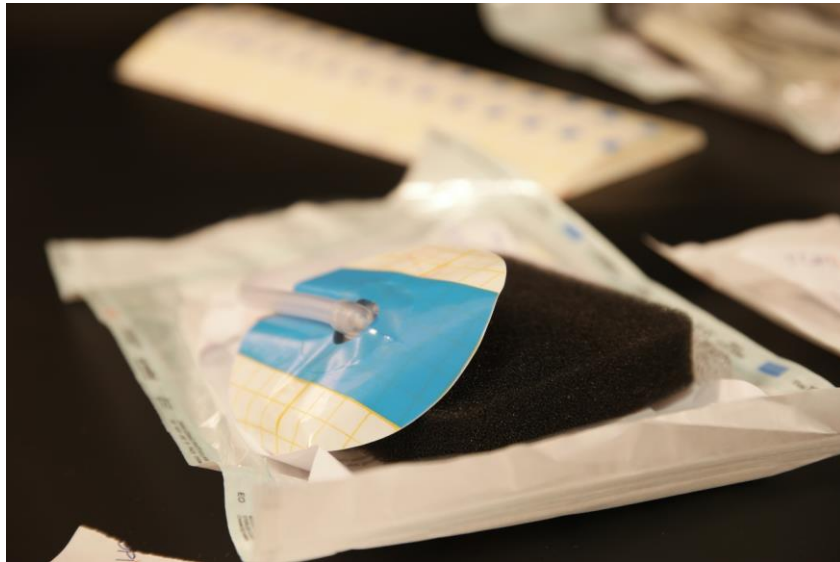
PRODUCT DESCRIPTION

SPONGE SIZES			
PRODUCT – SIZES	DESCRIPTION	PRODUCT – SIZES	DESCRIPTION
R 10 cm		20x30 cm	
10x10 cm		30x30 cm	
6x15 cm		25x45 cm	
13x20 cm		10x10 cm for SMALL MULTIDRESS	
20x20 cm		13x20 cm for MEDIUM MULTIDRESS	
15x30 cm		20x30 cm for LARGE MULTIDRESS	

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



SINGLE TUBE

SINGLE TUBE DRESSING

- ✓ SINGLE TUBE VACUUM DRESSING,
- ✓ SPONGE
- ✓ DRAPE
- ✓ RULER
- ✓ INSTRUCTIONS
- ✓ MEDICAL CLEANING KIT
- ✓ TRAC PAD

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



SINGLE TUBE

SINGLE TUBE DRESSING

- ✓ SINGLE TUBE VACUUM DRESSING,
- ✓ SPONGE
- ✓ DRAPE
- ✓ RULER
- ✓ INSTRUCTIONS
- ✓ MEDICAL CLEANING KIT
- ✓ TRAC PAD

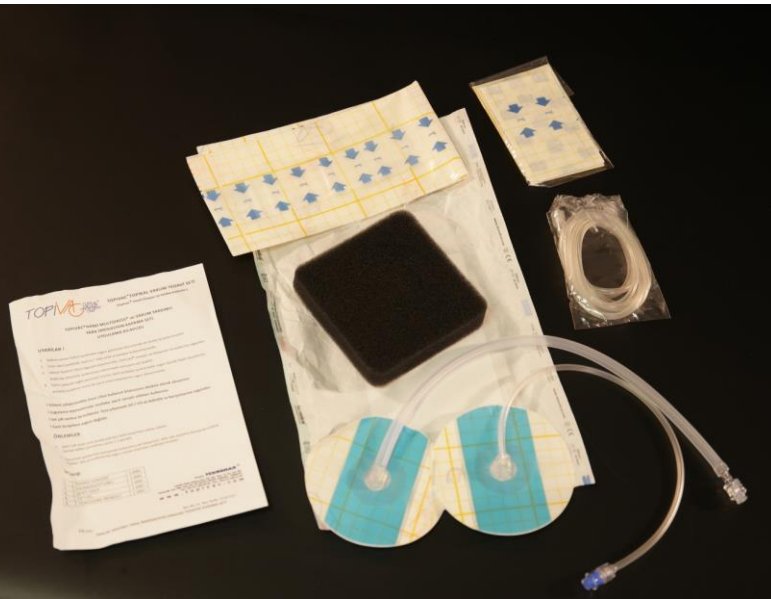
TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

DOUBLE TUBE DRESSING

- ✓ DOUBLE TUBE VACUUM DRESSING
- ✓ INSTILLATION HOSE
- ✓ PINCH VALVE CONNECTOR
- ✓ SPONGE
- ✓ DRAPE
- ✓ RULER
- ✓ INSTRUCTIONS
- ✓ MEDICAL CLEANING KIT
- ✓ TRAC PAD



DOUBLE TUBE

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

DOUBLE TUBE DRESSING



DOUBLE TUBE

- ✓ DOUBLE TUBE VACUUM DRESSING
- ✓ INSTILLATION HOSE
- ✓ PINCH VALVE CONNECTOR
- ✓ SPONGE
- ✓ DRAPE
- ✓ RULER
- ✓ INSTRUCTIONS
- ✓ MEDICAL CLEANING KIT
- ✓ TRAC PAD

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

MULTIDRESS

- ✓ MULTIDRESS
- ✓ INSTILLATION HOSE
- ✓ PINCH VALVE CONNECTOR
- ✓ SPONGE
- ✓ DRAPE
- ✓ RULER
- ✓ INSTRUCTIONS
- ✓ MEDICAL CLEANING KIT

MULTIDRESS

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



Y CONNECTOR

Y CONNECTOR

Required for the followings:

- ✓ INSTILLATION WITH OXYGENATED WATER,
- ✓ INSTILLATION WITH OZONIZED WATER,
- ✓ VACUUM + IRRIGATION THERAPY
- ✓ VACUUM + IRRIGATION + GAS THERAPY

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION

ELECTROTENS CABLE

Required for the following:

- ✓ ELECTROSTIMULATION / TENS THERAPY



TENS CABLE

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT PRODUCT DESCRIPTION



OZONE BAG

OZONE BAG

Required for the following:

- ✓ GAS THERAPY
- ✓ HAND
- ✓ ARM
- ✓ LEG
- ✓ FULL BODY PARTS

TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT

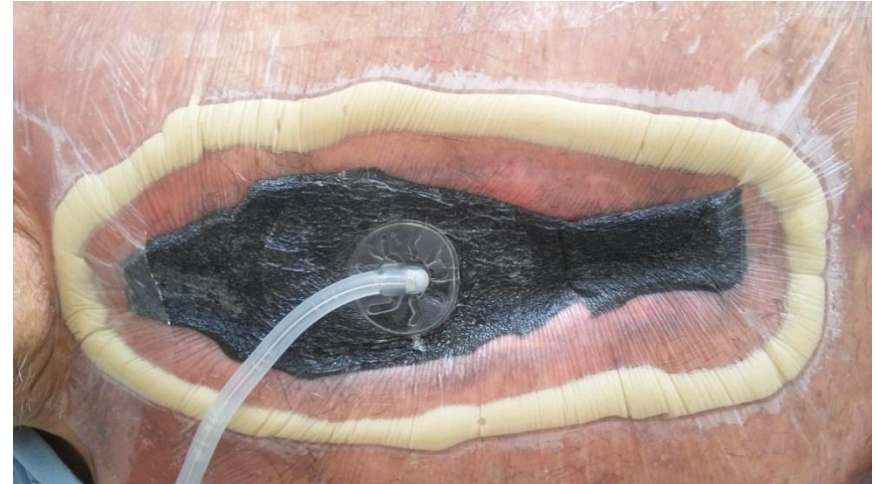


TOPIVAC

NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

TOPIVAC NPWT

THERAPY APPLICATIONS & WOUND MANAGEMENT



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NEGATIVE PRESSURE WOUND & BURN TREATMENT THERAPY DEVICE

TOPIVAC NPWT CERTIFICATES



CERTIFICATE



AMEDUS MEDİKAL UYGULAMALAR SAĞLIK SANAYİ VE TİCARET LTD. ŞTİ.

OSTİM ORGANİZE SANAYİ BÖLGESİ MAHALLESİ 100. YIL BULVARI NO: 99/34
YENİMAHALLE - ANKARA - TÜRKİYE

Production and Packaging Services in Sterile Clean Room Conditions, Design and
Development, Production, Installation, Technical Services of Tropical Vacuum
Treatment Device, Burn-Wound Care Consumables and Medical Consumables

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.9.2"

Certificate No : M 11627
Initial Certification Date : 31 May 2021
Certification Date : 31 May 2021
Expiration Date : 30 May 2024

General Manager



Kiwa Belgelendirme Hizmetleri A.Ş.
TİOBB 9. Cadde No. 15 Tepeören Tuzla
İstanbul / Türkiye

Tel: +90 216 593 25 75
Faks: +90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.

Last Modified: 31 May 2021 - R 00



CERTIFICATE



AT Sertifikası

Tam Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-II Bölüm 3

Sertifika Numarası: 1984-MDD-21-831

Aşağıda bahsi geçen kuruluşun tam kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-II (Bölüm 4 muaf tutularak) gereksinimlerine göre yapıldığını beyan ederiz. Tam kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

AMEDUS MEDİKAL UYGULAMALAR SAĞLIK
SANAYİ VE TİCARET LTD. ŞTİ.

Ostim Organize Sanayi Bölgesi Mahallesi 100. Yıl Bulvarı No: 99/34
Yenimahalle / Ankara, Türkiye

Ürün: Topikal Vakum Tedavi Cihazı

Tipler: Careoxi, Topivac

Model Numarası: Hand T-NPWT, Hand T-NPWT Irrigation, MEDIUM (V1, V2, V3, Clinic V4),
TOPI T-NPWT Klasik A100, TOPI T-NPWT İnsizyon A200

Ürün: Topikal Vakum Tedavi Seti

Tipleri: Careoxi, Topivac

Model Numarası: Topiset, Multidress, Multicase, Canister, Ozon Bag

Ürün: Canister Toplama Kabi

Tipleri: Careoxi / Topivac

Topivac Modelleri: TPVCA1000, TOPIVAC TPVCA1000, TOPISET TPVCA1000, MULTIDRESS
TPVCA1000, TPVCAS00, TOPIVAC TPVCAS00, TOPISET TPVCAS00, MULTIDRESS TPVCAS00,
CANISTER 1000ml, CANISTER 75ml

Careoxi Modelleri: CTPVCA1000, CAREOXI CTPVCA1000, TOPISET CTPVCA1000, MULTIDRESS
CTPVCA1000, CTPVCAS00, CAREOXI CTPVCAS00, TOPISET CTPVCAS00, MULTIDRESS
CTPVCA500, CANISTER 1000ml, CANISTER 75ml

Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile
tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No: M.6151.01

Son Geçerlilik Tarihi: 27 Mayıs 2024

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği Ek II'ye uygun olarak metrolojik
aletlere sahip cihazların uygunluğu ile ilgili üretim yönleri ve steril şartların güvence altına
alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle ilgili olan kalite sistemini
denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek II'deki şartları karşıladığını tespit
etmiştir.

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış
kuruluş olup kimlik numarası 1984'tür.

Muhtesem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

22 Mayıs 2021, İstanbul, Türkiye

Kiwa Belgelendirme Hizmetleri A.Ş.
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WOUND CARE
TOPICAL
VACUUM
TREATMENT
UNIT

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NEGATIVE PRESSURE WOUND & BURN TREATMENT
THERAPY DEVICE

PRINCIPLES OF WOUND CARE MANAGEMENT

-

TOPIVAC NPWT APPLICATIONS

CONTACT:

Amedus® Medikal Uygulamalar Sağlık San. Tic. Ltd. Şti.

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PRINCIPLES OF WOUND CARE MANAGEMENT

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TOPIVAC NPWT APPLICATIONS

*Prepared by TAMER RUZGAR
August 2021*