

TOPIVAC

NEGATIVE PRESSURE TOPICAL VACUUM
WOUND CARE THERAPY DEVICES & SETS



is a non-invasive, developed wound treatment method that has proven itself in wound healing. These conventional vacuum-assisted negative pressure treatment units & wound dressing are needed to apply controlled negative pressure (subatmospheric) to the wounded area. It is an active system that supports healing in difficultto-heal open wounds (eg. acute, traumatic, or chronic), <u>Accelerates</u> burns, diabetic/pressure ulcers. tissue microcapillary circulation healina with increasing applying controlled local negative by pressure.

TOPI disposable group is designed for the end user & home care, while the Hand and Medium group devices offer more complex treatment systems. Professional models also include wound irrigation, gas therapy with oxygen and ozone, moistening and electrostimulation treatment methods. By applying all these treatments with a single device, obstacles to the normal healing process of the tissue are removed; complications, hospitalization period and cost are reduced. Prevents tissue dryness by providing the sterile and moist environment necessary to preserve tissue functions in the wound, and removes exudate and toxic substances from the wound bed without drying the wound centre.

Briefly, TopiVac is an advanced technology treatment system that allows the healing of burn tissue and open wounds quickly and under appropriate conditions, away from the risk of infection.

Models;

Mobile Disposable Classic Vacuum
Assisted NPWT Wound Care
Therapy Device and Dressing Set

-TOPI A100 Classic

-TOPI A200 Incision

Topical Vacuum Therapy Devices

-HAND T-NPWT Classic

-HAND T-NPWT Digital Irrigation

-MEDIUM V2

-MEDIUM CLINIC / V4

Topical Vacuum Therapy Sets (Consumables)

-MultiDRESS

-Closure Foams

-MultiCASE

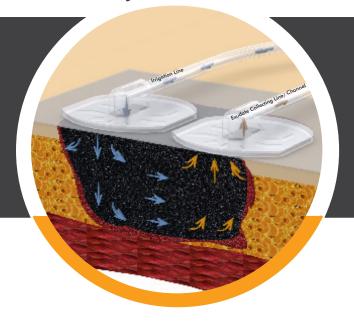
-Canister

-Ozone Bag

-TopiSET

TOPIVAC TOPICAL VACUUM THERAPY UNITS

Working Principle











Pressure / Bedsore Wound



Caesarean Section Wounds



Incision Wounds



Venous Ulcer



Infected Wounds



Burn Wound



Cardiothoracic & Vascular
Surgical Wounds



Obstetric & Gynaecological Surgery Wounds



Orthopaedic
Surgery Wounds

WHICH WOUND TREATMENTS IS IT USED?



It's a negative pressure wound treatment with a single treatment protocol, designed for single patient use. The negative pressure wound closure system accelerates tissue healing by increasing microcapillary circulation. The device and dressing set operate in harmony and integration with each other.

The system is an active wound treatment system that maximizes patient treatment comfort. Its compact and ergonomic mobile structure (the size of a mobile phone) offers patients quality life and comfort of movement without restricting their daily lives and mobility during wound treatment processes.

While it heals wounds quickly and effectively, reduces the need for expert personnel with its ease of application and provides ease of home wound care and mobility to patients. Reduces hospitalizations, lowers treatment costs and provides more efficient and widespread delivery of health services.

NPWT WOUND THERAPY DEVICES & SET



TOPI A100 continuously draws exudate from the wound via a special dressing set applied to the wounded area specially produced for the device; provide equal distribution of negative pressure to the wounded area. Heal the wound by forming granulation.

TOPI A100

MOBILE DISPOSABLE CLASSIC NPWT VACUUM ASSISTED WOUND CARE THERAPY DEVICE



-125 mmHg

_100 mmHa

.15 mm H9

- Diabetic foot wound,
- Pressure / bedsore wound,
- Chronic wound,
- Non- healing wound,
- Burn wound,
- Infected wounds

Used for rapid healing of all kinds of wounds up to 100 cm² with the approval of the physician.



Advanced Wound Management



TOPI A200 continuously draw exudate from the wound via a special dressing set applied to the wounded area specially produced for the device; provide equal distribution of negative pressure to the wounded area.

Unlike the A100, the A200 is designed for use postoperative incision wounds. Vacuum values are lower and with its special medical foam specific for incision wounds, keeps the incision edges together without damaging the sutures, provides rapid healing of the wound and helps to prevent scarring aesthetically.

-50 mmHg



TOPI A200

MOBILE DISPOSABLE INCISION NPWT
VACUUM ASSISTED WOUND CARE
THERAPY DEVICE

- Incision wounds,
- Chest and plastic surgery wounds,
- Orthopaedic surgery wounds,
- Cardiothoracic surgical wounds,
- Vascular surgical wounds,
- Obstetric & gynaecological surgery wounds,
- Caesarean section wounds and similar wounds

Used by physicians after surgery to reduce the risk of hospital infection, to prevent the wound from becoming infected, to heal the wound quickly and to prevent scarring.

TOPI Mobile Disposable NPWT Vacuum Assisted Wound Care Therapy Set

TOPI Mobile Disposable NPWT Vacuum Assisted Wound Care Therapy Set

Includes 1 Protocol and 5 Dressing Treatment Sterile Products.

■ 1 TOPI Mobile Disposable NPWT Vacuum Assisted

Wound Care Therapy Device (TOPI A100 or TOPI A200)

- 5 Pcs Dressing Foam Set (Classic or Incision)
- 5 Pcs 75 cc Canister
- 1 Pcs Extension Hose
- 1 Pcs Extra 30x40 cm Drape
- 1 Pcs Device Carry Bag
- 1 Pcs User Manuel





TOPI A100 Classic NPWT Vacuum Assisted Wound Care Therapy Device



Classic Dressing Foam Set 10*10 cm Dressing Foam 1 Pcs Trackpad 1 Pcs 30x40 cm Drape 1 Pcs Ruler



30*40 cm Drape



Extension Hose



TOPI A200 Incision NPWT Vacuum Assisted Wound Care Therapy Device



Incision Dressing Foam Set 4,5*22 cm Dressing Foam 1 Pcs Trackpad 1 Pcs 30x40 cm Drape

1 Pcs Ruler



75 cc Canister



Device Carry Bag



- Ease of starting and ending treatment with one button.

- High security with visual & audible warning system. (Instant alert during vacuum leak, full canister and low battery)

User Friendly

- Zero cross-contamination risk.
- Zero cost for preventive maintenance.
- Canister-based system for effective exudate management.
- A small lightweight design that is easy to wear or hang on the body, can be hidden under clothes, helps you continue your social life uninterrupted without anyone noticing.
- Thanks to its innovative design that allows silent operation during therapy, does not disturb you even in your sleep.
- Uninterrupted treatment thanks to efficient battery usage.



Ease of Use Without Expert Personnel

- Adaptable from hospital to long-term care, outpatient settings or home care.



Skin Friendly

- Optimum breathability for the patient's healthy skin while maintaining a vacuum environment for the wound.
- Special foam system used for sucking exudates and any wound fluids by creating a hygiene environment in the wound.



A Movement Comfort

- Special dressing set provides a strong adhesive bond to maintain an active lifestyle while keeping the dressing intact during treatment.
- Quality life and comfort of movement with its compact mobile structure.

Beyond That Is The Patient Comfort...



More Than Vacuum Therapy

TopiVac Hand Classic & Hand Digital Irrigation Vacuum Assisted (NPWT) Wound Closure Therapy Devices

It is an active system that applies controlled local negative pressure that supports healing in noninvasive acute and chronic wounds.

It continuously draws exudate (wound fluid) from the wound by means of a special sponge (foam) dressing set (TopiVac MultiDRESS) specially produced for the device applied to the wounded area. Provides that the negative pressure is evenly distributed over the wounded area. Heals the wound by forming granulation. The negative pressure wound closure system accelerates tissue healing by increasing microcapillary circulation.

Hand T-NPWT Digital Irrigation Device; on the other hand, provides the removal of exudate and necrotic materials from the wound bed by irrigating the wound together with the closure sets, as a support of VAC treatment.



TREATMENT METHODS	CLASSIC CLASSIC	HAND T-NPWT DIGITAL IRRIGATION STATE OF THE PROPERTIES OF THE PRO		
Intermittent & Increasing Vacuum Therapy	+	+		
Classic Negative Pressure Vacuum Therapy	+	+		
Irrigation Under Vacuum	-	+		
Moistening	-	+		

WHAT'S THE TOPIVAC TOPICAL HYBRID WOUND THERAPY SYSTEM?

- TopiVac Professional Hybrid NPWT Devices are Topical Vacuum, Ozone, Oxygen Treatment Applied, Irrigation, Electrostimulation, Vacuum Assisted, Wound and Burn Treatment Devices.
- Professional type wound care devices, which have a complex system and treatment method unlike the known vacuum assisted wound closure dressings, are available in two different models.
- Increases the patient's quality of life and reduces treatment costs. Heals wounds faster and more effectively than conventional vacuum assisted devices used in the market. Enables clinical studies for physicians.
- The devices allow you to apply the right treatment to the patient in the fastest way, depending on the type of wound or burn, thanks to the easy-to-use main and intermediate menu. Its user-friendly software where you can apply ready-made prescriptions provides the fastest application of the most accurate treatment specific to the patient and the wound.
- Easy to carry thanks to its ergonomic structure. It is made of, cleanable, antibacterial material suitable for use in services and intensive care. It is a complex system and form of treatment, unlike known vacuum-assisted closure dressings.

TREATMENT METHODS	WEDIOW NAME OF THE PARTY OF THE	WEDICW Name Can VI
Intermittent & Increasing Vacuum	+	+
Conventional NPWT	+	+
Moistening	+	+
O ₂ Instillation / Irrigation	+ \	+
O ₃ Instillation / Irrigation		
O ₂ Gas Therapy	+	+
O ₃ Gas Therapy	-	+
Electro / Tens		+ ====

PROFESSIONAL CLINIC TYPE

HYBRID TOPICAL GAS VACUUM ASSISTED
WOUND THERAPY DEVICES

MEDIUM V2

Medium V2 Topical Vacuum Oxygen
Therapy Applied, Irrigation, Wound and
Burn Treatment Device, unlike conventional
vacuum assisted closure dressings, is a
complex system and form of treatment.
Enables both oxygen gas therapy and
irrigation and moistening with oxygenated
bidistillated water to the wound under
vacuum. Thus, accelerates the healing
process with the oxygen gives to the wound
bed. Provides the revival of organic functions
and the activation of the immune system at
the cellular level.

Diffuses the oxygen it gives to the wound bed directly to the cell, thanks to special wound closure sets, and accelerates the healing process at the cellular level, prevents the reproduction of bacteria and microorganisms and helps to strengthen the leukocyte activation in the wound area. With this respect, it is much more effective than the classical VAC system and offers rapid recovery.

MEDIUM CLINIC V4 HYBRID WOUND THERAPY DEVICE

Medium Clinic V4 Topical Vacuum Wound and Burn Therapy Device is a system that has oxygen & ozone gas therapy, moistening, wound irrigation with both oxygen & ozone and with any medicine of the physician's choice, also tens therapy (electrostimulation).

Consists of an advanced device and wound closure sets that can be used in the treatment of burn wounds and all kinds of open wounds, both to create a classic vacuum to provide subatmospheric pressure on the wound and to create negative pressure on the closure set, and to create the oxygen, ozone and moisture required for the rapid healing of the wound. All functions are performed under vacuum.

This complex system is the first and only in the world, and has been proven to provide much faster wound healing than conventional VAC treatment.

- Accelerates the healing process with the oxygen it gives to the wound bed,
- Thanks to ozone gas, destroys the infection and prevents re-infection,
- Thanks to its electrostimulation feature, which is based on activating the skin, subcutaneous tissues and deep muscle groups with high-frequency electrical impulses, accelerates the healing process in the wound and muscle tissue and reduces pain.

50% - 70% Faster Healing in Wound



TOPIVAC DEVICE FUNCTION COMPARISON TABLE

TREATMENT METHODS	Vacuum	Intermittent & Increasing Vacuum	Wound Irrigation	Irrigation Type	Moistening	Gas Therapy	Tens
ORDER NO: 110188 110188	+	-	-	-	-	-	-
ORDER NO: 110164 110164 10164	+	-	-		-	-	
ORDER NO. 12236 D. 12	+	+	-		-	-	-
ORDER NO: 12229 12229 12229	+	+	+	Bidistillated Water	+	-	-
ORDER NO. 12212 12	+	+	+	Bidistillated Water With O ₂	+	O ₂	
OR DER NO: 12205	+	+	+	O ₂ & O ₃ Bidistillated Water	+	O ₂ & O ₃	+

TOPICAL VACUUM THERAPY SETS

MULTIDRESS

MultiDRESS is a dressing set with a special sponge (foam) applied to the wounded area, specially produced for the device, and provides equal distribution of negative pressure to the wounded area. Accelerates tissue healing by forming granulation and helps the wound to heal.

The sets are diversified in size and shape. There is a wide range of sizes and shapes available. However, according to the purposes of use; our MultiDRESS sets are classified in 3 different groups as single ventouse, double ventouse and incision.

Our single ventouse sets; only suitable for use in conventional vacuum assisted therapy. (There is also an abdominal model.)

Our double ventouse sets; are suitable for use in wound irrigation device models. Used in O_2/O_3 gassing and irrigation treatment as well as classic vacuum therapy.

Our incision sets; are suitable for use in incision wound treatments after surgical operations.

MultiDress Ingredients Information



Medical Foam Medical Drape

1 pcs vacuum hose 35 cm

1 pcs irrigation hose 35 cm*

1 pcs irrigation hose 145 cm*

1 pcs trackpad (+1*)

EO sterilization package

Patient chart

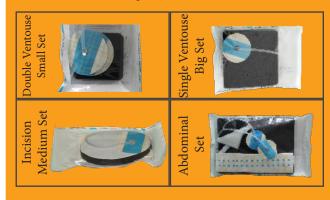
User manual

*Used with devices with irrigation function.

Example image is the small set with double ventouse.

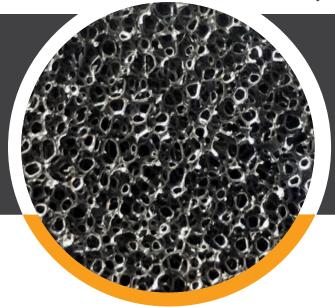
Sets cannot be used alone in wound treatment. However, if they are used together with the related TopiVac brand devices, used for topical vacuum wound treatment.

Sample Models;



All MultiDRESS sets and components are EO sterile and biocompatibility tests have been carried out.

Optimal Breathability



Medical Foam

- Helps the formation of granulation in the wound.
- Provides the wound exudate to be absorbed.
- It is hydrophobic, soft and porous.
- Has high durability and flexibility.
- Allows the passage of gas and does not stick to the wound.
- They fit perfectly when placed in the wound centre.
- Accelerates the healing process at the cellular level by delivering the oxygen and ozone given to the wound bed under negative pressure with the device to the wound without damaging the tissue and directly diffusing it into the cell.
- Together with the device, inhibits the growth of anaerobic bacteria and helps to strengthen the leukocyte activation in the wound area.
- Not interact chemically with ozone gas and oxygen.

Medical Drape

- It is a component that is placed on the wound and foam, to fix the foam and to enable the active device to vacuum, cut the contact of the wounded surface with the air and provide a negative pressure environment.
- Provides a strong and flexible adhesive bond to maintain an active lifestyle while keeping the dressing intact.
- Acts as a good barrier against bacteria.
- While it is providing soft and safe adhesion to the wound circumference and healthy skin, reduces pain during dressing changes.
- Resistant to sweat and liquids.
- Has the feature of staying on the skin for a long time.



It is the cup used to transfer the irrigation liquid to the patient for irrigation and gas treatment. Has device and patient connections and is used as a mix generator in the O_2/O_3 gassing & irrigation treatment function. Also enables putting medicine in the irrigation liquid. (The bidistillated, oxygenated, ozonized or medicated water to be used should be applied with a doctor's prescription and control.) Irrigation hose and collecting hose are separate from each other, eliminating the risk of infection and crosscontamination. It is EO sterile.



Absorbs the exudate from the wound with a vacuum-assisted device and traps it inside. While the integrated filter system inside the device prevents the passage of liquid into the device, the special chemical component (gel) in the unit prevents the spread of odour to the external environment. The solidifying gel in each collecting set prevents the movement of the collected waste liquid and increases the safety of the environment. The collecting sets are integrally connected with the vacuum device. The luer-lock spout allows an easy and safe connection with the closure on the wound. It is EO sterile. It is available in 3 different sizes; 500 ml, 1000 ml to be used in Hand and Medium models, and 75 ml to be used in Topi models.





OZONEBAG

Used in ozone therapy application of Medium Clinic V4 devices to provide tightness for effective dressing and to trap ozone inside. No contact with the wound and intact skin. Foot & leg – Hand & arm and Body models are available. It is EO sterile.

TOPISET



Topiset is an integrated wound care treatment set used in the TopiVac Medium Clinic V4 model, which enables the application of all hybrid treatments. With this set, O_2/O_3 gas therapy, TENS therapy, vacuum therapy and wound irrigation with O_2/O_3 bidistilled water are all combined.

TOPIVAC MULTIDRESS - CLOSURE SET

MULTIDRESS CLASSIC CLOSURE SET

(Suitable for devices without irrigation function)
(Single Ventouse &Tubing)

	ORDER NO	REF NO
Single Ventouse Small 1010	12007	ATPVSSF1010
Single Ventouse Medium 1320	12014	ATPVSMF1320
Single Ventouse Large 2020	12021	ATPVSLF2020
Single Ventouse (Abdominal)	10324	ATPVSAF

MULTIDRESS IRRIGATION CLOSURE SET

(Suitable for devices with irrigation function) (Double Ventouse&Tubing)

		ORDER NO	REF NO
100 Market - 1553 (100 Market) 100 Market (10	Double Ventouse Small 1010	11963	ATPVHMDS1010
	Double Ventouse Medium 1320	11970	ATPVHMDM1320
	Double Ventouse Large 2020	11987	ATPVHMDL2020

TOPIVAC MULTIDRESS - CLOSURE SET

MULTIDRESS (Incision Wound Closure Set)(Single Ventouse&Tubing)			
ORDER NO REF N			
	Vacuum Assisted Spiral Small Incision Closure Set	12038	ATPVISF
	Vacuum Assisted Spiral Medium Incision Closure Set	12045	ATPVIMF
	Vacuum Assisted Spiral Large Incision Closure Set	12052	ATPVILF

MULTICASE IRRIGATION CUP (Suitable for use with Medium V4, V2, Hand Irrigation Devices) ORDER NO Multicase Irrigation Cup (500 ml) Multicase Irrigation Cup (500 ml) Multicase Irrigation Cup 1000 ml 11956 ATPVMPR

CANISTER COLLECTING UNIT

(Suitable for use with Medium and Hand Devices)

		ORDER NO	REF NO
100 100 100 100 100 100 100 100 100 100	Canister 1000 ml Collecting Unit	12090	ATPVCA1000
	Canister 500 ml Collecting Unit	12106	ATPVCA500

Topical Hybrid Electrotens Wound Closure and Dressing Sets

Including 1 Canister, 1 Multicase, 1 MultiDRESS (Double Ventouse&Tubing) and other pieces which necessary for ozone & tens therapy (Suitable for use with Medium V4)

		ORDER NO	REF NO
	Topical Vacuum Wound Instillation Therapy Tens Combined Therapy Set Small 1010	11444	ATPVST1010
TOPING	Topical Vacuum Wound Instillation Therapy Tens Combined Therapy Set Medium 1320	11475	ATPVST1320
	Topical Vacuum Wound Instillation Therapy Tens Combined Therapy Set Large 2020	11482	ATPVST2020

OZONE BAG

(Used in ozone therapy application of Medium V4 devices)



	ORDER NO	REF NO
Hand & Arm	10430	ATPVSO3EM
Foot & Leg	10461	ATPVSO3AM
Body	10492	ATPVSO3BM

OZONE BAG

(Used in ozone therapy application of Medium V4 devices)

(Used in ozone therapy application of Medium V4 devices)				
		ORDER NO	REF NO	
The famely is except to the same of the sa	Dressing Multiplexer Y Connector	10683	ATPVSYKO	
The state of the s	Medical Drape	10171	ATPVSDRP3	
	Electrode Pad	12168		
	Electrotens Cable	12175		
	Peristaltic Pump Hade (for Incission Function)	12182		

BIOCOMPATIBILITY TEST REPORTS

TOPICAL VACUUM THERAPY SET

(MultiDRESS, MultiCASE, Canister, Ozone Bag, TopiSET)*

- Acute Systemic Toxicity Test (ISO 10993-11)
- Skin Irritation Test (ISO 10993-10)
- Skin Sensitization Test (ISO 10993-10)
- Genotoxicity Assay (In Vitro Micronucleus Test, OECD 487)
- Genotoxicity Test (Mutation Test-Ames Test, OECD 471)
- In Vitro Cytotoxicity Assays (ISO 10993-5)
- Implantation Test (ISO 10993-6) (1-6 Weeks) Rabbit
- Pyrogenicity Test
- Subacute Systemic Toxicity Test (ISO 10993-11)
- Bioburden (Aerobic, Mold And Yeast) Assay (ISO 11737-1)
- Bioburden (Anaerobe) Assay (ISO 11737-1)
- Sterility Test (ISO 11737-2)
- Residue Test (Ethylene Chlorohydrin) (ISO 10993-7)
- Residue Test (Ethylene Oxide) (ISO 10993-7)

ELECTRICAL MEDICAL EQUIPMENT TEST REPORTS

TOPI

- EN 60601-1:2006
- EN 60601-1-2:2015
- EN 60601-1-6:2010/A1:2015
- EN 60601-1-8:2007/A11:2017
- EN 60601-1-11:2015

HAND & MEDIUM

- EN 60601-1:2006
- EN 60601-1-2:2015
- EN 60601-1-6:2010/A1:2015

The device is used together with the sets, with a doctor's prescription, only for patients who have been deemed suitable for treatment by the doctor.

Wound Therapy with Vacuum + Gas+ Moistening

Before Treatment





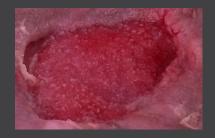


Wound Therapy with Vacuum + Gas+ Irrigation

Before Treatment

After 8 Sessions





Wound Therapy with Vacuum + Gas+ Irrigation + TENS

Before Treatment

After 10 Sessions





Wound Therapy with Vacuum + Gas+ Irrigation

Before Treatment

After 10 Sessions





Ozone Therapy with TopiVac Under the Foam

Before Treatment



After 6 Hours



Under Vacuum O_2 (Oxygen) + O_3 (Ozone) Vacuum Therapy

Before Treatment



After 6 Sessions



Vacuum + O_2 Gas + Wound Irrigation Therapy with O_2 Bidistillated Water

Before Treatment



After 36 Days



Vacuum + O^2 Gas + Wound Irrigation Therapy with O_3 Bidistillated Water

Before Treatment







Vacuum + Wound Therapy with Ozone Gas

Before Treatment



In treatment



After 3 Sessions



