


TOPICAL VACUUM TREATMENT SETS

(MultiDress/ MultiCASE/ Canister/ OzoneBag/ TopiSET)




Technical Specifications / DataSheet


TOPIVAC CLASSIC VACUUM ASSISTED WOUND CLOSURE DRESSING SET

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110331	Single Ventouse Small 1010	TOPIVAC	MULTIDRESS	ATPVSSF1010
	8683161110348	Single Ventouse Small R10	TOPIVAC	MULTIDRESS	ATPVSSFR10
	8683161110355	Single Ventouse Small 615	TOPIVAC	MULTIDRESS	ATPVHK615
	8683161110362	Single Ventouse Medium 1320	TOPIVAC	MULTIDRESS	ATPVSMF1320
	8683161110379	Single Ventouse Large 2020	TOPIVAC	MULTIDRESS	ATPVSLF2020
	8683161110386	Single Ventouse Large 1530	TOPIVAC	MULTIDRESS	ATPVSLF1530
	8683161110393	Single Ventouse Large 2030	TOPIVAC	MULTIDRESS	ATPVSLF2030
	8683161110409	Single Ventouse Large 3030	TOPIVAC	MULTIDRESS	ATPVSLF3030
	8683161110416	Single Ventouse Large 2545	TOPIVAC	MULTIDRESS	ATPVSLF2545
8683161110324	Single Ventouse Abdominal	TOPIVAC	MULTIDRESS	ATPVSAF	
8683161110638	Single Ventouse Set Custom	TOPIVAC	MULTIDRESS	ATPVSCU	


TOPIVAC IRRIGATION WOUND CLOSURE DRESSING SETS

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110232	Double Ventouse Small 1010	TOPIVAC	MULTIDRESS	ATPVHMDS1010
	8683161110249	Double Ventouse Small R10	TOPIVAC	MULTIDRESS	ATPVHMDSR10
	8683161110256	Double Ventouse Small 615	TOPIVAC	MULTIDRESS	ATPVHMDS615
	8683161110263	Double Ventouse Medium 1320	TOPIVAC	MULTIDRESS	ATPVHMMDM1320
	8683161110270	Double Ventouse Large 2020	TOPIVAC	MULTIDRESS	ATPVHMMDL2020
	8683161110287	Double Ventouse Large 1530	TOPIVAC	MULTIDRESS	ATPVHMMDL1530
	8683161110294	Double Ventouse Large 2030	TOPIVAC	MULTIDRESS	ATPVHK2030
	8683161110300	Double Ventouse Large 3030	TOPIVAC	MULTIDRESS	ATPVHMMDL3030
	8683161110317	Double Ventouse Large 2545	TOPIVAC	MULTIDRESS	ATPVHMMDL2545
8683161110645	Double Ventouse Set Custom	TOPIVAC	MULTIDRESS	ATPVHCU	


VACUUM ASSISTED INCISION WOUND CLOSURE DRESSING SETS

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110591	Vacuum Assisted Spiral Small Incision Closure Set	TOPIVAC	MULTIDRESS	ATPVISF
	8683161110607	Vacuum Assisted Spiral Medium Incision Closure Set	TOPIVAC	MULTIDRESS	ATPVIMF
	8683161110614	Vacuum Assisted Spiral Large Incision Closure Set	TOPIVAC	MULTIDRESS	ATPVILF


MULTICASE IRRIGATION CUP

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110195	MULTICASE IRRIGATION CUP 1000 ml + OXYGENATED WATER SET (500 ML)	TOPIVAC	MULTICASE	ATPVMCOK
	8683161110201	MULTICASE IRRIGATION CUP 1000 ml + OZONATED WATER SET (500 ML)	TOPIVAC	MULTICASE	ATPVMCOZ
	8683161110218	MULTICASE IRRIGATION CUP 1000 ml + BIDISTILLATED WATER SET (500 ML)	TOPIVAC	MULTICASE	ATPVMCBS
8683161110225	MULTICASE IRRIGATION CUP 1000 ml	TOPIVAC	MULTICASE	TPVMPR	


CANISTER COLLECTING UNIT

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110652	TOPI CANISTER COLLECTING UNIT WITH GEL (75ml)	TOPIVAC	CANISTER75ml	CANISTER75ml
	8683161110669	CANISTER 1000 ml COLLECTING UNIT (WITH GEL)	TOPIVAC	TOPIVAC TPVCA1000	ATPVCA1000
8683161110676	CANISTER 500 ml COLLECTING UNIT	TOPIVAC	TOPIVAC TPVCA500	ATPVCA500	

OZONEBAG

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161110423	OzoneBag Small Hand / Arm	TOPIVAC	OZONEBAG	ATPVSO3ES
	8683161110430	OzoneBag Medium Hand / Arm	TOPIVAC	OZONEBAG	ATPVSO3EM
	8683161110447	OzoneBag Large Hand / Arm	TOPIVAC	OZONEBAG	ATPVSO3EL
	8683161110454	Ozonebag Small Foot / Leg	TOPIVAC	OZONEBAG	ATPVSO3AS
	8683161110461	Ozonebag Medium Foot / Leg	TOPIVAC	OZONEBAG	ATPVSO3AM
	8683161110478	Ozonebag Large Foot / Leg	TOPIVAC	OZONEBAG	ATPVSO3AL
	8683161110485	Ozonebag Small Body	TOPIVAC	OZONEBAG	ATPVSO3BS
	8683161110492	Ozonebag Medium Body	TOPIVAC	OZONEBAG	ATPVSO3BM
	8683161110508	Ozonebag Large Body	TOPIVAC	OZONEBAG	ATPVSO3BL
	8683161110515	Ozone BAG Body OZONE / O2 GAS VAC THERAPY SET Small	TOPIVAC	OZONEBAG	AT.P.V.G.01.3.1
	8683161110522	Ozone BAG Body OZONE / O2 GAS VAC THERAPY SET Medium	TOPIVAC	OZONEBAG	AT.P.V.G.01.3.2
	8683161110539	Ozone BAG Body OZONE / O2 GAS VAC THERAPY SET Large	TOPIVAC	OZONEBAG	AT.P.V.G.01.3.3
8683161110546	Ozone BAG Body OZONE / O2 GAS VAC THERAPY SET The Largest	TOPIVAC	OZONEBAG	AT.P.V.G.01.3.4	
8683161110553	Ozone BAG Body OZONE / O2 GAS VAC THERAPY SET Custom Size	TOPIVAC	OZONEBAG	AT.P.V.G.01.3.5	

TOPIVAC TOPISET TOPICAL HYBRID E-TENS WOUND CLOSURE DRESSING SETS

	BARCODE NO	PRODUCT NAME	BRAND	MODEL	REF NO
	8683161111420	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET CUSTOM SIZE	TOPIVAC	TOPISET	ATPVSTC
	8683161111437	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET SACRAL S	TOPIVAC	TOPISET	ATPVSTS
	8683161111444	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Small 1010	TOPIVAC	TOPISET	ATPVST1010
	8683161111451	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Small R10	TOPIVAC	TOPISET	ATPVSTR10
	8683161111468	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Small 615	TOPIVAC	TOPISET	ATPVST615

8683161111475	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Medium 1320	TOPIVAC	TOPISET	ATPVST1320
8683161111482	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Large 2020	TOPIVAC	TOPISET	ATPVST2020
8683161111499	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Large 1530	TOPIVAC	TOPISET	ATPVST1530
8683161111505	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Large 2030	TOPIVAC	TOPISET	ATPVST2030
8683161111512	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Large 3030	TOPIVAC	TOPISET	ATPVST3030
8683161111529	TOPICAL VACUUM WOUND INSTILLATION TREATMENT WITH TENS COMBINE THERAPY SET Large 2545	TOPIVAC	TOPISET	ATPVST2545
8683161110683	ABDOMINAL Y-CONNECTOR	TOPIVAC	TOPISET	ATPVSYKO

TECHNICAL SPECIFICATIONS

BRAND	TopiVac
Product Name	Topical Vacuum Therapy Set (Wound Closure Set)
Model	TopiSET / MultiDress / MultiCASE / Canister / OzoneBag
Manufacturer	AMEDUS MEDİKAL UYGULAMALAR SAĞLIK SAN. TİC. LTD. ŞTİ.
Wound Closure Set Class	Class IIb (Sterile)
Collecting Unit (Canister) Class*	Class Is & Im (Sterile)
Device Compatibility	TopiVac Brand NPWT Topical Vacuum Therapy Devices
Usage	Disposable
Sterile Packaging Type	EO Sterilization Package
Sterilization Type	Ethylene Oxide (EO)
Sterile Shelf Life	24 Months

Maximum Usage Time in the Patient	72 Hours	
Dressing Kit	One Set for Each Treatment Session	
DEPH Content	DEHP Type Chemical Free	
Documents	ISO 9001:2015, ISO 13485:2016, 93/42/EEC – CE Certificate	
	Domestic Goods Certificate, TUR Technological Product Experience Certificate, Certificate of Free Sale	
Product Test & Analyses	Packaging Robustness Test	
	Packaging Leakage Test	
	Real Aging Tests	
	Bioburden (Aerobic, Mould 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)	
	BIOCOMPATIBILITY TESTS	Genotoxicity Assay (In Vitro Micronucleus Test, OECD 487)
		Genotoxicity Test (Mutation Test-Ames Test, OECD 471)
		Pyrogenicity Test
		In Vitro Cytotoxicity Assays (ISO 10993-5)
		Implantation Test (ISO 10993-6) (1-6 Weeks) Rabbit
		Skin Irritation Test (ISO 10993-10)
		Skin Sensitization Test (ISO 10993-10)
		Subacute Systemic Toxicity Test (ISO 10993-11)
		Acute Systemic Toxicity Test (ISO 10993-11)
Product Origin	TR	
GTIP Number	90.18.90.93.00.00	

Wound Closure Set GMDN Code	61145
Collecting Unit (Canister) GMDN*	47404

* Class and GMDN information provided separately for the Canister is only valid when the Canister is sold individually.

DEVICE PACKAGE SPECIFICATIONS

PRODUCT NAME	NUMBER OF PRODUCTS INSIDE A BOX (PIECE)	BOX DIMENSIONS (CM)	BOX WEIGHT (KG)
Small / Medium Closure Set	20	34 x 38 x 32	2.1
Large Closure Set	20	34 x 48 x 32	2.3
Collecting Unit (Canister)	10	39 x 56 x 23	5.1
MultiCase (O₂ / O₃ Irrigation and Collecting Cartridge)	5	36 x 42 x 23	6.9
Abdominal (Abdomen Closure Set)	10	38 x 48 x 32	2.4
TopiSET With Tens Combine Therapy Set	3	39 x 55 x 25	7.15

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