



MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

FATİH MAH. 1142 SOK. NO: 35 SARNIÇ GAZİEMİR - İZMİR - TURKEY

SURGICAL COVERS AND DRAPES PRODUCTS, IV FLOW REGULATOR PRODUCTS, KARMAN CANNULA PRODUCTS, ENDOSCOPY MOUTHPIECE PRODUCTS, MUCUS ASPIRATION COLLECTION CONTAINER PRODUCTS, VALVE URINE BAG PRODUCTS, ARTROCOPY SETS PRODUCTS, VALVE EMESIS BAG PRODUCTS, SURGICAL HAND BRUSHES, FILTERED MOUTHPIECE PRODUCTS, SMEAR BRUSHES, AMNIOTIC POUCH PERFORATOR, PARACON TUBE, SKIN MARKING SET, UMBILICAL CORD CLAMP, ARTERIAL CANNULA, EXTENSION LINE, ENDOMETRIAL SUCTION CURETTE, PHOTOTHERAPY EYE BAND (Y-BAND) PRODUCTS, STERILE LUER CONNECTOR CAP (STOPPER) PRODUCTION, PACKAGING OF INTENSIVE CARE PRODUCTS, STERILIZATION, STORAGE, DISTRIBUTION AND COMPLY WITH EN ISO 11135 STANDARD ETHYLENE OXIDE ACCORDING TO THE STANDARD OF ETHYLENE OXIDE STERILIZATION SERVICES STERILIZATION SERVICES

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"

"7.5.3" "7.5.4" "7.5.9.2"

Certificate No	: M 11326
Initial Certification Date	: 03 October 2019
Certification Date	: 15 November 2022
Expiration Date	: 14 November 2025

General Manager



Kiwa Belgelendirme Hizmetleri A.Ş. ITOSB 9. Cadde No. 15 Tepeören Tuzla Istanbul / Turkey

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

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





EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-682

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

Medbar Tıbbi Malzemeler Turizm San. Ve Tic. A.Ş.

Fatih Mah. 1142 Sokak Sarnıç No:35 Gaziemir - İzmir - Turkey

Products: IV Flow Controller, Extension Line, Karman Cannula and Karman Cannula Injector, Arthroscopy Set, Spirometer Filtered Mouthpiece, Skin Marking Set, Mucous Aspirator, Valve Urine Bag, Valve Emesis Bag, Surgical Covers and Drapes, Endoscopy Mouthpiece, Smear Brushes, Amniotic Pouch Perforator, Umbilical Cord Clamp, Sterile Luer Connector Cap (Stopper), Arterial Cannula, Endometrial Suction Curette, Phototherapy Eye Band (Y-Band)

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5746.03
Date of first issue:	13 July 2020
Date of last issue:	11 May 2021
Revision Number:	01
Expiry Date:	27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements for Class Im devices and with securing and maintaining sterile conditions in accordance with MDD Annex V for Class Is devices covered by this certificate and found that the quality system meets the applicable requirements in MDD Annex V.

Muhteşem Gökhan Yücel Head of Notified Body

11 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş. ITOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey Tel.: +90 216 593 25 75, Fax: +90 216 593 25 74 Web: www.kiwa.com.tr, e-mail: posta@kiwa.com.tr



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Enclosure of the EC Certificate: Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V Certificate Number: 1984-MDD-20-682, Revision Number: 01 Concerned medical devices;

Product Name Types IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free) IV Flow Controller Cylindrical IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free) Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm-120cm- 150cm) Extension Line Pressure Resistant Extension Line (30cm- 50cm- 60cm- 75cm-90cm- 100cm- 120cm- 150cm) Karman Cannula (No: 3, 4, 5, 6, 7, 8, 9, 10,12) Single Valve Manual Vacuum Aspirator Set. Double Valve Karman Cannula and Karman Cannula Manual Vacuum Aspirator Set, Single Valve Manual Vacuum Injector Aspirator, Double Valve Manual Vacuum Aspirator Non-Sterile Single Valve Manual Vacuum Aspirator, Non-Sterile Double Valve Manual Vacuum Aspirator Y-Tur Set, Y-Tur Set With Pump Arthroscopy Set Small (26mm, 30mm, 33mm) Small With Latch (26mm, 30mm, 33mm) Spirometer Filtered Mouthpiece Big (30mm, 33mm) Big With Latch (30mm, 33mm) Skin Marking Set, Thin Tipped Skin Marking Set Skin Marking Set Mucous Aspirator (15ml, 25ml, 40ml, 100ml) Mucous Aspirator Mucous Aspirator With Hose (40ml) Valve Urine Bag White, With Discharge Valve Emesis Bag Transparent, White Microscope Drape, Camera Cover, Cardboard Camera Cover, Telescopic Camera Cover, Circled Camera Cover, Accordion Surgical Covers and Drapes Folded Camera Cover, Probe Cover, Endoscopy Bag, Scopy Cover, C Arm Scopy Cover, Fluoroscopy Cover, Light Handle Cover Endoscopy Mouthpiece Smear Brushes Brush, Spatula Amniotic Pouch Perforator Umbilical Cord Clamp Sterile Luer Connector Cap (Stopper) Arterial Cannula 18G, 20G, 22G Endometrial Suction Curette, Endometrial Suction Curette With **Endometrial Suction Curette** Syringe Phototherapy Eye Band (Y-Band) Small, Medium, Large

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel Head of Notified Body

11 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş. ITOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey Tel.: +90 216 593 25 75, Fax: +90 216 593 25 74 Web: www.kiwa.com.tr, e-mail: posta@kiwa.com.tr



Cardboard **Camera Cover**















medbar®

CARDBOARD CAMERA COVER

TECHNICAL DATA SHEET

Intended Use

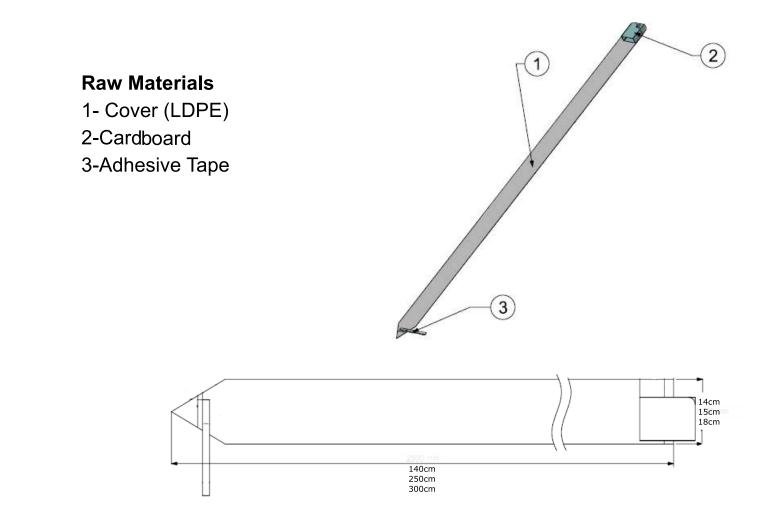
Camera Cover is used for isolating non-sterile surgery camera cables that are utilized in the sterile operating room. For endoscopic and arthroscopic procedures. The fiber optic cable of the device is protected by the sterile camera cover in order to remove any risk of contamination. At the same time, the camera cover protects the device from liquid damage during the procedures, therefore prolonging the life of your equipment.

Components of product

Medbar brand Cardboard Camera Cover consists of 3 parts: cardboard, cover and adhesive tape.

Manufacturing Methods

Main manufacturing processes for Cardboard Camera Cover consists of nylon production, cutting-sticking, folding, packaging, parcelling and EO sterilization.





Quality and Legislation

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.

- Manufactured under ISO 13485 Quality Management System Standard.
- Notifed Body: KİWA TURKEY (1984)
- EC Certification No:1984-MDD-20-682
- GMDN Code: 37450

Biocompability

- Biological evaluation of Carboard Camera Cover done according to ISO 10993-1.

- The products do not incorporate a substance of a human blood derivative, animal orginated tissues, phthalates, medicinal product, radioactive materials and electromagnetic waves.

-Latex free.

Sterilization

- Carboard Camera Cover is sterilized with Ethylene oxide. Validated for ISO 11135 standard.

Shelf Life

-5 years.



REF NO	PRODUCT NAME

202 15	Cardboard Camera Cover 14x140 cm
202 01	Cardboard Camera Cover 14x250 cm
202 25	Cardboard Camera Cover 14x300 cm
202 10	Cardboard Camera Cover 15x250 cm
202 17	Cardboard Camera Cover 18x250 cm
202 27	Cardboard Camera Cover 18x300 cm

FEATURES

• Centralized hanger hole.

- Telescopically folded.
- Single layer thickness = 40 micron.
- Eight layer folding allows shorter cover
- length Easier and faster to pass camera.Compatible with all camera models.
- Compatible with all camera models.





EC DECLARATION OF CONFORMITY

Manufacturer	: Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş. 1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey Phone: +90 232 2816003 Fax: +90 232 2816648
Intended Use	: Camera covers are sterile medical devices used to keep the environment sterile by covering the video camera cable or probe in cases where operations will be performed with a video camera in a sterile environment in hospitals.
GMDN Code	: 37450 - Camera cover, single-use
Classification	: Class I sterile
Classification Route	: Annex V
Classification Rule	: Rule 1

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and relative Medical Device Regulations. All supporting documentation is retained under the premises of the manufacturer.

We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Standards

:	TS EN 13795-1	TS EN ISO 15223-1	TS EN 1041	TS EN ISO 13485/AC
	ASTM F 88, 1886, 1929,	TS EN ISO 10993-1, 4, 5,	TS EN ISO 14644-1, 2,	TS EN ISO 11135
	1980	7, 10, 11,18	3, 4, 5	TS EN 62366-1
	TS EN ISO 11138-1, 2	TS EN ISO 11140-1	TS EN ISO 11607-1, 2	TS EN ISO 11737-1, 2
	TS EN ISO 22610	TS EN 868-5	TS EN ISO 14971/D1	TS EN 1779/A1
	TS EN ISO 14161	TS EN ISO 80369-7	TS EN 1895	

Notified Body Information	:	Kiwa Certification Services A.Ş. (NB 1984) İTOSB 9. Cad No.15 Tepeören Tuzla- Istanbul-Turkey
Certification No	:	1984-MDD-20-682
Certification Date	:	13.07.2020
Issue Place	:	Izmir/ Turkey
Issue Place	:	13.07.2020
Signature	:	Armağan Yalgın

(Quality Management Rep.)

TIBBI MALZEHELER TUR, SAN, VE TIC. A.S. Tath Mah. 1147/Solar No. 35 John Galemin - Ruiki Tet 0237 ZBI (45) (2023) (2017) Fair (2023 2016) 668

Products:	Constantia No	0. 05/30/914080013 Gaziemir V.D. 613 089 8649	
Brand	Barcode	Ref	Product Name
MEDBAR	8698881910024	202 01	Cardboard Camera Cover 14x250cm
MEDBAR	8698881913117	202 15	Cardboard Camera Cover 14x140 cm
MEDBAR	8698881913933	202 27	Cardboard Camera Cover 18x300 cm
MEDBAR	8698881913162	202 25	Cardboard Camera Cover 14x300 cm
MEDBAR	8698881911922	202 05	Cardboard Camera Cover with Double Clips 14x250cm
MEDBAR	8698881912851	202 10	Cardboard Camera Cover 15x250
MEDBAR	8698881913124	202 16	Cardboard Camera Cover 15x300 cm
MEDBAR	8698881913131	202 17	Cardboard Camera Cover 18x250cm
MEDBAR	8698881912417	202 07	Cardboard Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881912936	202 28	Cardboard Camera Cover with Elastic Tip 14x140 cm
MEDBAR	8698881912943	202 29	Cardboard Camera Cover with Elastic Tip 15x300cm
MEDBAR	8698881912950	202 37	Cardboard Camera Cover with Elastic Tip 14x300cm

Medbar Tibbi Malzemeler Turizm San ve Tic. A.Ş.

35+ yıllık deneytmente ile hep daha iyisi için çalışıyoruz...







m	ed	b	ar"

MEDBAR	8698881912981	202 30	Cardboard Camera Cover with Elastic Tip 18x300cm
MEDBAR	8698881912967	202 19	Cardboard Camera Cover with Elastic Tip 15x250 cm
MEDBAR	8698881912974	202 20	Cardboard Camera Cover with Elastic Tip 18x250 cm
MEDBAR	8698881914848	202-07WE	Cardboard Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881914855	202-37WE	Cardboard Camera Cover with Elastic Tip 14x300cm
MEDBAR	8698881914862	202-20WE	Cardboard Camera Cover with Elastic Tip 18x250cm
MEDBAR	8698881914879	202-30WE	Cardboard Camera Cover with Elastic Tip 18x300cm
MEDBAR	8698881914251	202 38	Cardboard Camera Cover 14x250 cm 100 micron Reverse Tipped
MEDBAR	8698881914268	202 39	Cardboard Camera Cover 18x250 cm 100 micron Reverse Tipped
MEDBAR	8698881914565	202 41	Cardboard Camera Cover 14x250cm Closed System with Lens
MEDBAR	8698881914800	202 43	Cardboard Camera Cover 18x250cm Closed System with Lens
MEDBAR	8698881914770	202 OGPC	Circled Ring Camera Cover Closed System 15x250cm (OptiGuard Pro Coupler)
MEDBAR	8698881914763	202 OGPA	Circled Ring Camera Cover Closed System Advanced 15x250 cm (OptiGuard Pro ArthrO)
MEDBAR	8698881914794	202 17 OGPC	Cardboard Camera Cover Closed System 18x250 cm (OptiGuard Pro Coupler) Promecon
MEDBAR	8698881914787	202 17 OGPA	Cardboard Camera Cover Closed System 18x250 cm (OptiGuard Pro ArthrO) Promecon
MEDBAR	8698881912899	202 03	Camera Cover Delta Teleskopic (Sterile)
MEDBAR	8698881912271	202 06	Telescopic Camera Cover 14x250 cm
MEDBAR	8698881913148	202 23	Telescopic Camera Cover 14x300 cm
MEDBAR	8698881913155	202 24	Telescopic Camera Cover 14x140 cm
MEDBAR	8698881913179	202 11	Telescopic Camera Cover 15x250 cm
MEDBAR	8698881913186	202 12	Telescopic Camera Cover 15x300 cm
MEDBAR	8698881913193	202 13	Telescopic Camera Cover 18x250 cm
MEDBAR	8698881913209	202 14	Telescopic Camera Cover 18x300 cm
MEDBAR	8698881913230	202 32	Telescopic Camera Cover with Elastic Tip 14x140 cm
MEDBAR	8698881913247	202 33	Telescopic Camera Cover with Elastic Tip 14x250 cm
MEDBAR	8698881913254	202 34	Telescopic Camera Cover with Elastic Tip 14x300 cm
MEDBAR	8698881913032	202 35	Telescopic Camera Cover with Elastic Tip 18x250 cm
MEDBAR	8698881913261	202 36	Telescopic Camera Cover with Elastic Tip 18x300 cm
MEDBAR	8698881914749	202-33WE	Telescopic Camera Cover 14x250 cm White Elastic Tip
MEDBAR	8698881914824	202-34WE	Telescopic Camera Cover 14x300 cm White Elastic Tip
MEDBAR	8698881914756	202-35WE	Telescopic Camera Cover 18x250 cm White Elastic Tip
MEDBAR	8698881914831	202-36WE	Telescopic Camera Cover 18x300 cm White Elastic Tip
MEDBAR	8698881913216	202 21	Accordion Folded Camera Cover 14x250 cm
MEDBAR	8698881913223	202 22	Accordion Folded Camera Cover 14x300 cm
MEDBAR	8698881912684	202 09	Circled Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881912998	202 31	Circled Camera Cover with Elastic Tip 15x250cm
MEDBAR	8698881914886	202-09WE	Circled Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881911045	202 02	Circled Camera Cover 14x250cm
MEDBAR	8698881914619	202 42	Circled Camera Cover with Perforated Tip
MEDBAR	8698881914817	202 44	Circled Camera Cover 15x250cm Closed System with Lens
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TD.02-UB.02(Rev2-13.07.2020)EN



Medbar Tibbi Malzemeler Turizm San ve Tic. A.Ş.

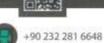


www.medbar.com.tr info@medbar.com.tr



35+ yıllık deneytminiz ile hep daha iyisi için çalışıyoruz.





medbar®

Mucous Aspirators



Mucous Aspirators

Intended Use

- Mucous Aspirator is used by professional users generally for taking mucous sample for diagnosis and treatment of respiratory tract diseases.
- Mucous Aspirator is a sterile and disposable device with transient use.
- It is intended for single use.
- Mucous Aspirator is manufactured as: 15 ml, 25 ml, 40 ml and 100 ml.

Components of The Product

Medbar brand Mucous Aspirator consists of :

- A chamber,
- A double-entry cap,
- A cap with no entry,
- A cap on connector,
- A conical connector,
- Two connection hose.

Manufacturing Methods

Main manufacturing processes of Mucous Aspirator consists of :

- Injection,
- Hose production,
- Assembly,
- Packaging,
- Parcelling,
- EO sterilization.

Product Features of Mucous Aspirator

- Compatible with all suction catheters between 4-20 ch.
- Sticker for patient information included.
- An additional cap is provided free of charge.
- Sterilized disposable device with transient use.
- Our Tracheal aspiration set with tube consists f a 40 ml gruduated chamber with a double-entry cap, a conical connector and hose. (Hose Length 12 cm)

Product Features of Mucous Aspirator with Tube

- After the procedure the container can be easily sealed via the use of the tube.
- Compatible with all suction catheters between 4-20 ch.
- Sticker for patient information included.
- An additional cap is provided free of charge.
- Up to 40 ml of aspiraton capacity.

Product Features of Mucous Aspirator with Catheter

- Connecting suction tube 30cm long with female suction connection port.
- 53 cm long, 10 Fr Suction Catheter.
- Size of inside bore diameter 4-5 mm.
- 25ml Bottle Trap.
- Leak Proof Design.





Mucous Aspirators

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class IIa medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notifed Body: UDEM Ltd. AŞ. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43947

Sterilization

- Mucous Aspirator is sterilized with Ethylene oxide.
- Validated for ISO 11135 standard.

Shelf Life

• 5 years.

Biocompability

- Biological evaluation of Mucous Aspirator done according to ISO 10993-1.
- Tests for in vitro cytotoxicity done according to ISO 10993-5.
- Tests for irritation and skin sensitization done according to ISO 10993-10.
- The products do not incorporate a substance of a human blood derivative, animal orginated tissues, phthalates, medicinal product, latex, radioactive materials and electromagnetic waves.

Usage Technics

- Mucous Aspirator Sorter/Catheter and aspirator are used by professional users to collect mucous samples from the upper respiratory tracts in the diagnosis and treatment of respiratory tract diseases.
- The aspiration probe is inserted into the body through the natural body openings such as the nostril, the oral cavity, or through the tracheal aspiration opening through the larynx.
- The other outlet hose on the mucous collection container to which the aspiration probe is connected to the vacuum device to collect the mucous sample in the container.
- The process time is shorter than one hour.
- The mucous collecting container is a non-invasive device because it does not enter the body.

Indications

Mucous Aspirator is used in conjuction with a nasogastric probe to acquire mucous sample in the diagnosis and treatment of respiratory tract diseases.

Complications

- Irritation,
- Sensitization,
- Cross-contamination.

Warnings

- Mucous collection cups are designed for one-time use for a single patient.
- The integrity of sterile pouch should be checked prior to use.
- After taking the product out from the pouch, it should be used immediately.
- Should be thrown to biohazard trash after usage.
- Shouldn't be reused without sterilization.
- It is strictly not appropriate and not recommended to use outside of medical usage and on third person.

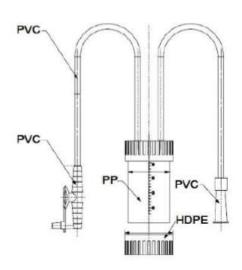
Instructions For Use

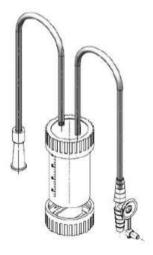
- Attach another aspiration probe/catheter to the aspiration device.
- Send the aspiration catheter nasal or tracheal cavity.
- Proceed the suction process.
- Gently withdraw the aspiration catheter with a motion once the suction finished.
- Wash catheter with 2.0 ml VTM; abstain from sucking; to seal the mucous suction tube, tie the arm itself.
- After the sample collection, deliver the sample to the laboratory immediately for viral testing and viral antigen detection.

Mucous Aspirator 25 ml

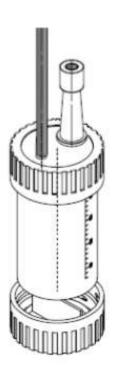
Technical Drawing

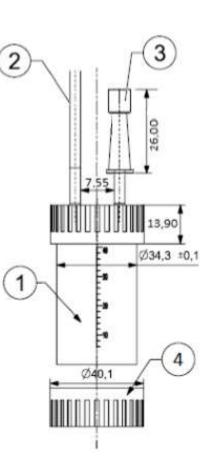


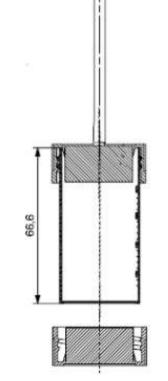




Mucous Aspirator 40 ml Closed System Technical Drawing







- 1- Polystyrene (GPPS)
- 2- PVC
- 3- PVC
- 4- HDPE

Mucous Aspirators



40 ml



305 01

REF NO	PRODUCT NAME	STERILIZATION	PACKAGING
229 01	Mucous Aspirator 40 ml	EO	150 pcs / outer box (9 KG)
229 02	Mucous Aspirator 25 ml	EO	250 pcs / outer box (7 KG)
229 03	Mucous Aspirator 100 ml	EO	100 pcs / outer box (6,70 KG)
229 04	Mucous Aspirator 15 ml	EO	150 pcs / outer box (9 KG)
229 06	Mucous Aspirator 25 ml 10 Fr Catheter	r EO	250 pcs / outer box (8 KG)
305 01	Mucous Aspirator with Tube	EO	100 pcs / outer box (6 KG)



Medbar Tıbbi Malzemeler Turizm San. Tic. A.Ş. 1142 Sk. No:35 Sarnıç Gaziemir-İzmir/Turkey T: +90 232 2816003 - F: +90 232 2816648 www.medbar.com.tr - info@medbar.com.tr



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EC DECLARATION OF CONFORMITY

Manufacturer

: Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş. 1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey Phone: +90 232 2816003 Fax: +90 232 2816648

Products

Brand	Barcode	Ref	Product Name	Product Photo
MEDBAR	8698881910857	229 01	Mucous Collection Container (40 ml)	J.P.
MEDBAR	8698881911311	229 02	Mucous Collection Container (25 ml)	Ċ,
MEDBAR	8698881911533	229 03	Mucous Collection Container (100 ml)	A Contraction
MEDBAR	8698881912431	229 04	Mucous Collection Container (15 ml)	ţ,
MEDBAR	8698881912905	305 01	Mucous Collection Container with Hose (40 ml)	

Intended Use

: The sterile medical devices used to collect mucus drawn between the aspirator device used to collect mucus from the upper respiratory tract and nasal catheter in the diagnosis and treatment of respiratory diseases.

		diseases.
GMDN Code	:	43947- Mechanical positive pressure airway secretion-clearing device
Classification	:	Class IIa
Classification Route	:	Annex V
Classification Rule	:	Rule 2

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and relative Medical Device Regulations. All supporting documentation is retained under the premises of the manufacturer.

We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Standards	:	TS EN 556-1	TS EN ISO 15223-1	TS EN 1041	TS EN ISO 13485/AC
		ASTM F 88, 1886, 1929, 1980		TS EN 1779/A1	TS EN ISO 11135
		TS EN ISO 11138-1, 2	TS EN ISO 11140-1	TS EN ISO 11607-1, 2	TS EN ISO 11737-1, 2
		TS EN ISO 1135-4	TS EN 868-5	TS EN ISO 14971/D1	TS EN 1895
		TS EN ISO 14161	TS ISO 2859-1/A1	TS EN ISO 14644-1, 2, 3, 4, 5	
		TS EN ISO 10993-1, 4, 5, 7,	, 10, 11,18	TS EN 62366-1	
Notified Body	:	Kiwa Certification Service	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Information		ITOSB 9. Cad No.15 Tepe	ören Tuzla- Istanbul-Turk	еу	
Certification No	:	1984-MDD-20-682			
Certification Date	:	13.07.2020			
Issue Place	:	Izmir/ Turkey			
Issue Place	:	13.07.2020			
Signature	:	Armağan Yalgın			
		(Quality Managemer	nt Rep.)		
		TIBEI MALZEMELLE TUR. SAN. VE T	1C. A.Ş.		

TD.17-UB.01(Rev3-13.07.2020)EN

Fatih Mah. 1142/5 Tel: 0232 281 69 0

Medbar Tibbi Malzemeler Turizm San ve Tic. A.Ş.





35+ yıllık deneytminiz ile hep daka iyisi için çalışıyoruz.













BIOCIDAL

SURGICAL HANDBRUSH

Impregnated Surgical Hand Brush

- -Egonomic brush design (48*79*34mm).
- -Easy peeling package.
- -With or wihout rasp options.
- -For external usage.

Cholerhexidine gluconate or Povidone Iodine options. -20ml disinfectant

Quality

-Manufactured with ISO 13485:2012 QM Standard. -Biocidal Licensed.(Impregnated) -Sterile handbrush is not classified as medical device according to European Commisson.

Biocompatibility

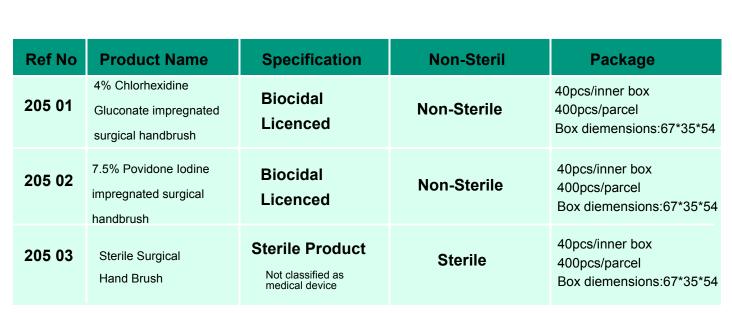
-Latex-Free

Shelf Life

-2 years (Impregnated)-5 yeras (Sterile)









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Intended Use

Limb Holders are used for fastening the patient's hands and feet having a surgery or confined to bed who might hurt himself or environment unconsciously. Limb Holders are sterile disposable devices with single use.

Indications

Limb Holders are used for fastening the patient's hands and feet where lying, to prevent a possible damage may be caused by patient unconsciously.

Quality and Legistion

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.

- Manufactured under EN ISO 13485:2012 Quality Management System Standard.
- Notifed Body: UDEM Ltd. AŞ. (2292)
- EC Certification No: M.2016.106.7000

Biocompability

- Biological evaluation of Limb Holders done according to ISO 10993-1.

- The products do not incorporate a substance of a human blood derivative, animal orginated tissues, phthalates, medicinal product, latex, radioactive materials and electromagnetic waves. **Sterilization**

- Limb Holders are sterilized with Ethylene oxide. Validated for ISO 11135 standard.



REF NO	PRODUCT NAME	FEATURES	STERILIZATION	PACKAGING UNITS
23801	Limb Holder	• Adult Hand.	ETO	25 pcs / inner bag 250 pcs / outer box Box Dimensions (cm): 43*37*56 Box Weight: 7,00 kg
23802	Limb Holder	• Adult Foot.	ETO	25 pcs / inner bag 250 pcs / outer box Box Dimensions (cm): 43*37*56 Box Weight: 7,60 kg
23803	Limb Holder	• Kids.	ETO	100 pcs / inner bag 500 pcs / outer box Box Dimensions (cm): 39*43*41 Box Weight: 6,50 kg
23804	Limb Holder	• Baby.	ETO	100 pcs / inner bag 500 pcs / outer box Box Dimensions (cm): 39*43*41 Box Weight: 6,50 kg





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Microscope Drape

Intended Use

• Nowadays lots of surgery is made by surgical microscopes. During these procedures the risk of contamination from microscope to patient with open wound and to the media is high. Microscope cover is used for isolating nonsterile surgery microscopes which is taken into the sterile area during the surgical procedures and kept in. Microscope cover's centre is placed on the microscope's objective and its special ends are placed on the binoculer. The cover is fixed to the microscope via stickers and belts on the cover.

Components of Product

Medbar Brand Microscope Drape consists of:

- Microscope cover film,
- A lens,
- A Lens center,
- 6 double-sided tape(small)
- A small blue arrow sticker,
- A small blue right hand sticker,
- A small blue left hand sticker,3 tear here sticker,
- 3 green belt,
- A double-sided tape (larger).
- In some models (204-01, 204-03, 204-05) there are
- Inner and Outer ring parts around the lens centre.
- Microscope cover (204-04) only consists of cover.

Product Features

- Specially folded for easy application.
- Super transparent lens system.
- Adhesive straps secure the drape safely in place.
- Accessories are easy to use when the drape is in place.
- Compatible with Carl Zeiss, Leica and Moller-Wedel operating microscope models.
- More than 50 different sizes available.
 - Customized sizes are available upon request.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as class I sterile medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM Ltd. Şti. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 12535

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Biocompatibility

- Biologic evaluation of Microscope Drape is done according to ISO 10993-1.
- The products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, radioactive materials and electromagnetic waves.
- Latex-free.

Shelf Life

• 5 years.

Manufacturing Methos

Main manufacturing processes for Microscope Drape are consists of

- Nylon production,
- Injection
- Assemble,
- Cutting-Stickking,
- Folding,
- Packaging,
- Parcelling and
- EO sterilization.

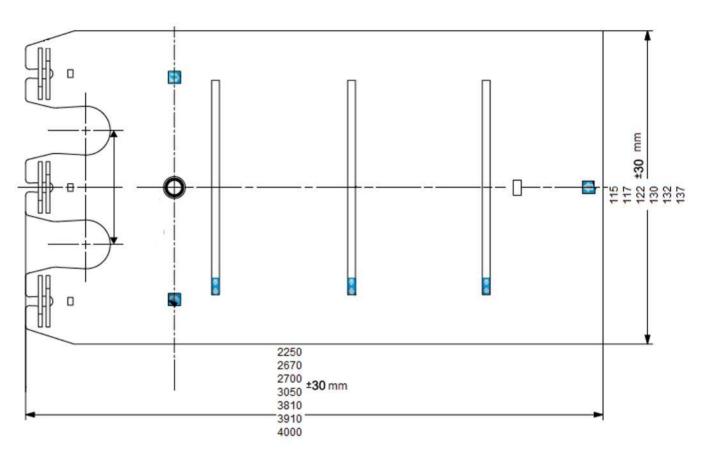
Compatible Devices

- Microscope Drape 48 mm (Straight Lens) (Zeiss)
- Microscope Drape 65 mm (Straight Lens) (Zeiss, Moller-Wedel)
- Microscope Drape 68 mm (Straight Lens) (Leica)



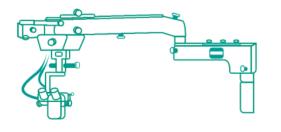






Microscope Drape

Instructions For Use



Prepare Microscope by clamping all cables securely. Adjust tension of knobs.



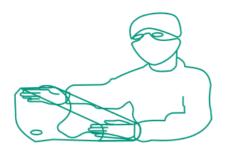
2

Unfold drape, lens cover facing down and away from you, label up.

3

Microscope Drape

Instructions For Use

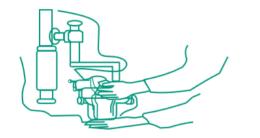


3

With hands placed inside center fold, from pouch opening.



Feed drape over furthest protruding microscope components, continue unfolding drape over balance of microscope equipment.



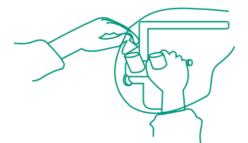
- 5
- Attach lens/light covers, applying upward pressure with palm of hand.





Δ

Extend balance of drape over microscope arm, gather up extra width with straps. 6



7

Tighten excess material around eyepieces. Just before procedure remove top.

4

Microscope Drape

Microscope Drape Versions

Microscope Drape

REF NO	PRODUCT NAME	STERILIZATION
204 01	Microscope Drape (48 mm Straight Lens)	EO
204 02	Microscope Drape (65 mm Sloped Lens)	EO
204 03	Microscope Drape (68 mm Straight Lens)	EO
204 07	Microscope Drape (65 mm Straight Lens)	EO
204 37	Microscope Drape with Handle Protection 48 mm 122x225 cm	EO
204 11	Microscope Drape with Handle Protection 65 mm 122x225 cm	EO
204 16	Microscope Drape with Handle Protection 65 mm 122x225 cm Slope	ed EO
204 23	Microscope Drape with Handle Protection 68 mm 122x225 cm	EO



Microscope Drape

Microscope Drape Versions

Microscope Drape

REF NO	PRODUCT NAME	STERILIZATION
291 17	Microscope Drape 65 mm 115x225 cm (Slopped Lens)	EO
291 14	Microscope Drape 65 mm 115x300 cm (Slopped Lens)	EO
291 18	Microscope Drape 65 mm 117x163 cm (Slopped Lens)	EO
291 19	Microscope Drape 65 mm 117x203 cm (Slopped Lens)	EO
291 20	Microscope Drape 65 mm 117x225 cm (Slopped Lens)	EO
291 21	Microscope Drape 65 mm 117x267 cm (Slopped Lens)	EO
204 06	Microscope Drape 65 mm 117x305 cm (Slopped Lens)	EO
204 74	Microscope Drape 65 mm 122x210 cm (Slopped Lens)	EO
204 02	Microscope Drape 65 mm 122x225cm (Slopped Lens)	EO
204 75	Microscope Drape 65 mm 122x260 cm (Slopped Lens)	EO
204 09	Microscope Drape 65 mm 122x300cm (Slopped Lens)	EO
291 22	Microscope Drape 65 mm 132x225 cm (Slopped Lens)	EO
204 47	Microscope Drape 65 mm 132x267 cm (Slopped Lens)	EO
204 48	Microscope Drape 65 mm 132x305 cm (Slopped Lens)	EO
204 45	Microscope Drape 65 mm 132x381cm (Slopped Lens)	EO
204 49	Microscope Drape 65 mm 132x391 cm (Slopped Lens)	EO
204 41	Microscope Drape 65mm 132x400 cm (Slopped Lens)	EO
204 50	Microscope Drape 65 mm 137x267 cm (Slopped Lens)	EO
204 51	Microscope Drape 65 mm 137x305 cm (Slopped Lens)	EO
204 43	Microscope Drape 65 mm 137x381cm (Slopped Lens)	EO
204 52	Microscope Drape 65 mm 137x391cm (Slopped Lens)	EO
204 53	Microscope Drape 65 mm 137x400 cm (Slopped Lens)	EO

6

Microscope Drape

Microscope Drape Versions

Microscope Drape

REF NO	PRODUCT NAME	STERILIZATION
204 74	Microscope Drape 65 mm WxL 95x215 cm (Straight Lens)	EO
291 16	Microscope Drape 65 mm WxL 115x225 cm (Straight Lens)	EO
204 30	Microscope Drape 65 mm WxL 117x225 cm (Straight Lens)	EO
204 38	Microscope Drape 65mm WxL 117x270 cm (Straight Lens)	EO
204 07	Microscope Drape 65 mm WxL 122x225 cm (Straight Lens)	EO
204 33	Microscope Drape 65 mm WxL 130x225 cm (Straight Lens)	EO

REF NO	PRODUCT NAME	STERILIZATION
204 37	Microscope Drape with Handle Protection 48 mm 122x225 cm	EO
204 11	Microscope Drape with Handle Protection 65 mm 122x225 cm	EO
204 16	Microscope Drape with Handle Protection 65 mm 122x225 cm Slope	EO
204 23	Microscope Drape with Handle Protection 68 mm 122x225 cm	EO

REF NO	PRODUCT NAME	STERILIZATION
204 27	Microscope Drape 48 mm 115x225 cm	EO
204 29	Microscope Drape 48 mm 117x225 cm	EO
204 70	Microscope Drape 48 mm 117x267 cm Straight Lens	EO
204 01	Microscope Drape 48 mm 122x225 cm Straight Lens	EO
204 32	Microscope Drape 48 mm 130x225 cm	EO

Bonnet Microscope Drape

Intended Use

- Bonnet Microscope Drape is used for isolating the contamination source to prevent risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- Bonnet Microscope Drape is sterile and disposable medical devices with transient use.
- The drapes are intended for single use.
- Main peformance indicators for Bonnet Microscope Drapes are sterility to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.

Product Features

- Elastic seamed cover tip
- 65 mm sloped super transparent lens system.
- 70 micron nylon thickness.

Components Of The Product

- Nylon
- A double-sided tape
- Lens
- Lens center
- Sewing elastic

Quality

- Manufactured under ISO 13485:2016 Quality Management System standard.
- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Notifed Body: UDEM Ltd. Şti. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Biocompability

- Biologic evaluation of Microscope Drape is done according to ISO 10993-1.
- The products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, radioactive
 materials and electromagnetic waves.
- Latex-free.

Sterilization

- Sterilized with Ethylene Oxide.
- Validated with ISO 11135 standard.

Shelf Life

• 5 years.

REF NO	PRODUCT NAME	STERILIZATION
293 03	Bonnet Microscope Drape 65 mm Sloped 40x34 cm (Small)	EO
293 04	Bonnet Microscope Drape 65 mm Sloped 76x60 cm (Small)	EO





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Microscope Handle Protector

Intended Use

• Used for sterile protection of Operating Microscope handles.

Components of Product

Medbar Brand Microscope Handle Protector consists of:

- Polyethylene Nylon,
- Velcro,
- Fabric.

Product Features

- Ideal for sterile protection of Operating Microscope handles.
- Oval Tip and Triangular Tip options are available.
- 2 units per sterile pouch.
- Each protector has 2 pieces of Velcro Tape for easy application.
- Sold seperately, or together with our Microscope Drapes.
- Universally comptaible every surgical microscope's handle part.

Quality

- CE certificated.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM Ltd. Şti. (2292)

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life

• 5 years.



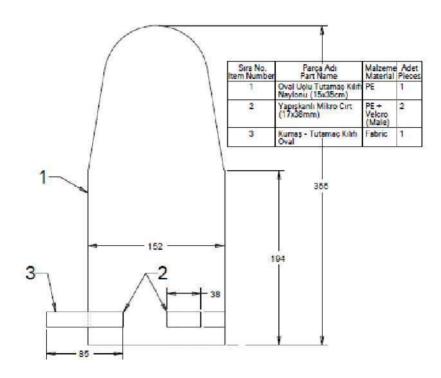


REF NO	PRODUCT NAME	
293 01	Microscope Handle Protector Conical Tip 15 x 36 cm	
293 02	Microscope Handle Protector Triangular Tip 14 x 31 cm	

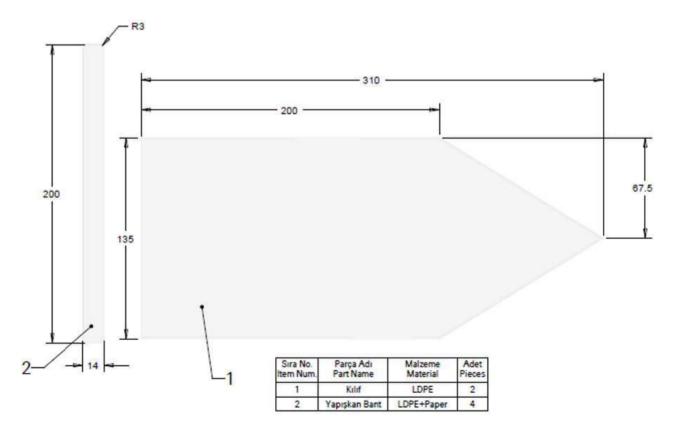
Microscope Handle Protector

Technical Drawing

Microscope Handle Protector Conical Tip



Microscope Handle Protector Triangular Tip



Intended Use

Camera Cover is used for isolating nonsterile surgery camera cables which is taken into the sterile area during the surgical procedures and kept in. Especially in endoscopic, arthroscopic and etc. surgeries, the probe cable which cannot be sterilized is passed through the sterile camera cover thus contamination risk from cables to the media and patient is removed. At the same time the device protects the cables from liquids dispersed into the media during the process. The cable of the camera is passed through the Camera Cover easily. The cover is kept stationary by linking to a cable or a probe with a strip which is on the cover.

Components of The Product

Medbar brand Cardboard Video Camera Cover (202 01) consists of 3 parts:

Cardboard, Cover and Adhesive tape.

Product Features

Centralized hanger hall. Telescopically folded. Single layer thickness is 40 micron. Eight layer folding allows the cover to pass over the camera easier and faster. Compatible with all endoscopic cameras. Different sizes available.



Quality

CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device. Manufactured under ISO 13485 Quality Management System standard. Notified Body: UDEM LTD A.Ş. (2292) EC Certification No: M.2016.106.7000 GMDN Code: 37450

Biocompability

- Biologic evaluation of Cardboard Camera Cover done according to ISO 10993-1.
- Manufactured under ISO 13485 Quality Management System standard.
- The products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, radioactive materials and electromagnetic waves.

Sterilization

• Sterilized with Ethylene Oxide. Validated for ISO 11135 standard.

Shelf Life

5 years.

REF NO	PRODUCT NAME	STERILIZATION	PACKAGING UNIT
202-15	Cardboard Camera Cover 14x140 cm	EO	50 pcs inner box
202-01	Cardboard Camera Cover 14x250 cm	EO	400 pcs outerbox
202-25	Cardboard Camera Cover 14x300 cm	EO	Box Dimensions:
202-16	Cardboard Camera Cover 18x300 cm	EO	38*47*43 cm
202-17	Cardboard Camera Cover 18x250 cm	EO	



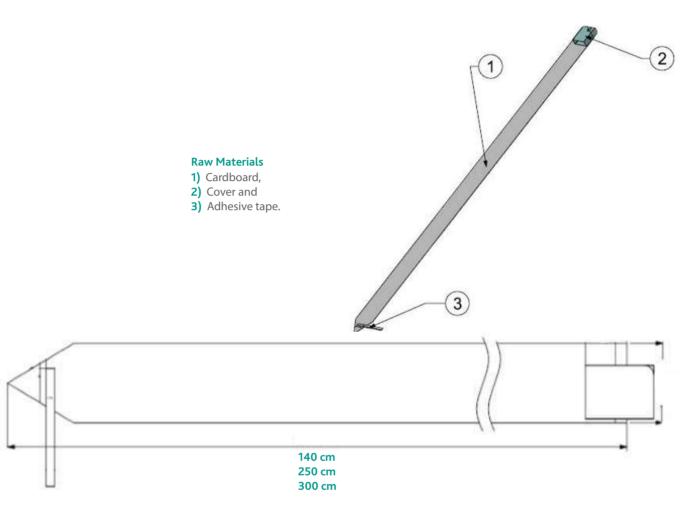


11

Cardboard Camera Cover

Technical Drawing





Manufacturing Method

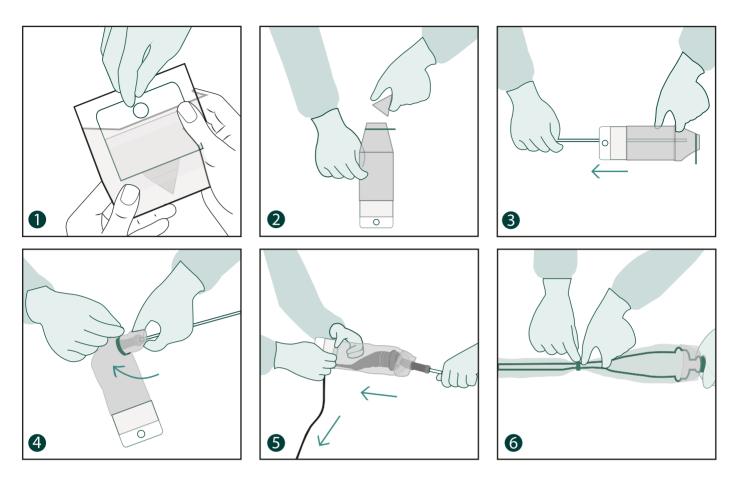
Main manufacturing processes for Cardboard Camera Cover are consists of

- Nylon production,
- Cutting-stickking,
- Folding,
- Packaging,
- Parcelling and
- EO sterilization.

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Cardboard Camera Cover

Instructions For Use



- 1 Peel up individual pouch and remove the cover from it.
- 2 Insert endoscope through rigid applicator of folded drape and triangle cut tip up to its camera connecton side.
- 3 Wrap the portion of drape that covers camera connection side of endoscope with adhesive tape pre-atached to the triangle cut tip of a film.
- 4 Partially remove endoscope out and connect camera device to the endoscope.
- 5 Make assistant to pull and apply protective cover onto the remaining cabling of a camera device.
- 6 In case if there is an extra adhesive tape, wrap around the portion of drape where cabling connects to the camera device.

Cardboard Camera Cover with Elastic Tip

Product Features

- Specially designed elastic tip provides easy application.
- Telescopically folded.
- Single layer thickness is 40 micron.
- Eight layer folding allows the cover to pass over the camera easier and faster.
- Compatible with all endoscopic camera models.
- Different sizes available upon request.

Quality

- Manufactured under ISO 13485 Quality Management System standard.
- CE certified.

Biocompability

• Latex free.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life

• 5 years.

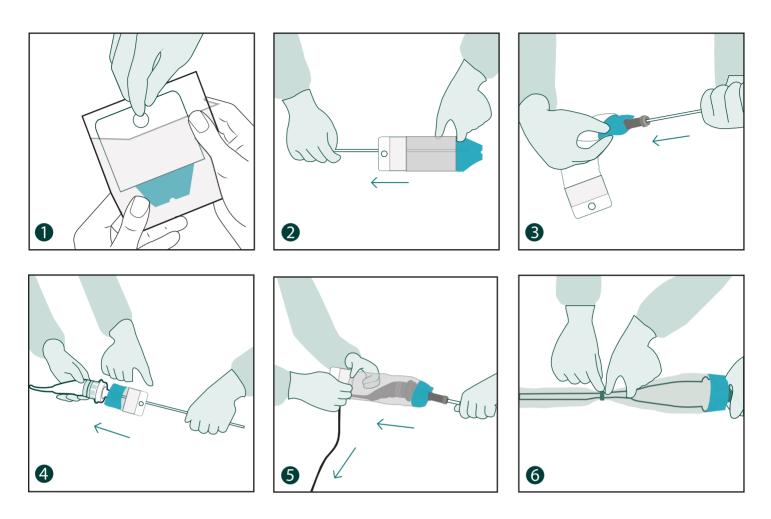
REF NO	PRODUCT NAME	STERILIZATION	PACKAGING UNIT
202-28	Cardboard Camera Cover with Elastic Tip 14x140 o	cm EO	50 pcs inner box
202-07	Cardboard Camera Cover with Elastic Tip 14x250 o	cm EO	400 pcs outerbox
202-37	Cardboard Camera Cover with Elastic Tip 14x300	cm EO	Box Dimensions:
202-20	Cardboard Camera Cover with Elastic Tip 18x250 o	cm EO	38*47*43 cm
202-30	Cardboard Camera Cover with Elastic Tip 18x250 o	cm EO	



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Cardboard Camera Cover with Elastic Tip

Instructions For Use



- 1 Peel up individual pouch and remove the cover from it.
- 2 Insert endoscope through cardboard applicator of folded drape and hole on elastic tip up to its camera connection side.
- 3 Wrap the portion of drape that covers camera connection side of endoscope with adhesive tape pre-atached to the triangle cut tip of a film.
- 4 Partially remove endoscope out and connect camera device to the endoscope.
- 5 Make assistant to pull and apply protective cover onto the remaining cabling of a camera device.
- 6 In case if there is an extra adhesive tape, wrap around the portion of drape where cabling connects to the camera device.

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Telescopic Folded Camera Cover

Intended Use

- Camera cover is used for isolating nonsterile surgery camera cables which is taken into the sterile area during the surgical procedures and kept in.
- Especially in endoscopic, arthroscopic and etc. surgeries, the probe cable which can not be sterilized is passed through the sterile camera cover thus contamination risk from cables to the media and patient is removed.
- At the same time the device protects the cables from liquids dispersed into the media during the process.
- The cable of the camera is passed through the Camera Cover easily. The cover is kept stationaryby linking to a cable or a probe with a strip which is on the cover.

Component of the Products

- Cover,
- Adhesive tape.

Manufacturing Methods

- Main manufacturing processes for camera cover are consists of
- Nylon production,
- Cutting-stickking,
- Folding,
- Packaging,
- Parcelling and
- EO sterilization

Quality

- Manufactured under ISO 13485 Quality Management System standard.
- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I steril medical device.
- Manufactured under ISO 13485 Quality Management System Standard.
- Notified Body: UDEM Ltd. A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 37450

Biocompability

- Biological evaluation of Camera Cover done according to ISO 10993-1.
- The products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, radioactive
 materials and electromagnetix waves.
- Latex free.

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life

• 5 years.

REF NO	PRODUCT NAME	STERILIZATION
202 06	Telescopic Camera Cover 14x250 cm	EO
202 23	Telescopic Camera Cover 14x300 cm	EO
202 24	Telescopic Camera Cover 14x140 cm	EO
202 11	Telescopic Camera Cover 15x250 cm	EO
202 12	Telescopic Camera Cover 15x300 cm	EO
202 13	Telescopic Camera Cover 18x250 cm	EO
202 14	Telescopic Camera Cover 18x300 cm	EO



Accordion Folded Camera Cover

Intended Use

- Accordion Folded Camera Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- Accordion Folded Camera Cover is sterile and disposable medical device with transient use.
- The device is intended for single use.
- Main performance indicators for Accordion Folded Camera Cover are sterility, to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.

Product Features

- 14 x 250 cm and 14 x 300 cm flexible tip.
- Perfectly folded for fast application.
- Has bigger mid-hole than any other camera cover in the market.

Quality

- Manufactured under ISO 13485 Quality Management System standard.
- CE marked.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life

• 5 years.



REF NO	PRODUCT NAME	STERILIZATION
202 21	Concertina/Accordion Folded Camera Cover WxL 14x250cm	EO
202 22	Concertina/Accordion Folded Camera Cover WxL 14x300cm	EO



Circled Ring Camera Cover

Product Features

- 14x250 cm perforated tip.
- Perfectly folded for fast application.
- Has bigger mid-hole than any other Camera Cover in the market.
- Easy to fix adhesive straps.
 Extra strap provided with each product.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485:2012 Quality Management System standard.

Biocompability

• Latex free.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life

5 years.

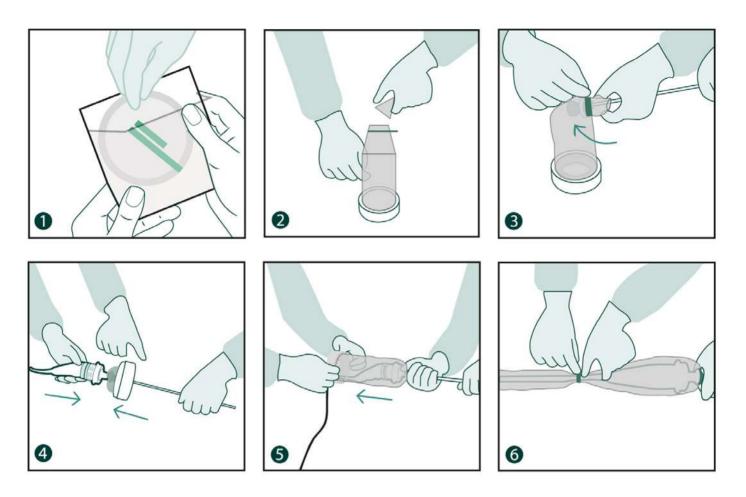
REF NO	PRODUCT NAME	STERILIZATION	PACKAGING UNIT
			125 pcs outerbox
			Box Dimensions:
202-02	Circled Ring Camera Cover	EO	38*47*43 cm
			Box Weight
			8.00 KG





Circled Ring Camera Cover

Instructions For Use



- 1 Peel up individual pouch and remove the cover from it.
- 2 Insert endoscope through rigid applicator of folded drape and triangle cut tip up to its camera connecton side.
- 3 Wrap the portion of drape that covers camera connecton side of endoscope with adhesive tape pre-atached to the triangle cut tip of a flm.
- 4 Partially remove endoscope out and connect camera device to the endoscope.
- 5 Make assistant to pull and apply protective cover onto the remaining cabling of a camera device.
- 6 In case if there is an extra adhesive tape, wrap around the portion of drape where cabling connects to the camera device.

Circled Ring Camera Cover with Elastic Tip

Product Features

- Centralized hanger hole.
- Telescopically folded.
- Single layer thickness is 40 micron.
- Eight layer folding allows short cover length. Easier and faster to pass camera.
- Allows easy application and fixation on to device.
- Compatible with all camera models.

Quality

- Manufactured under ISO 13485:2012 Quality Management System standard.
- CE certified.

Biocompability

• Latex free.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life

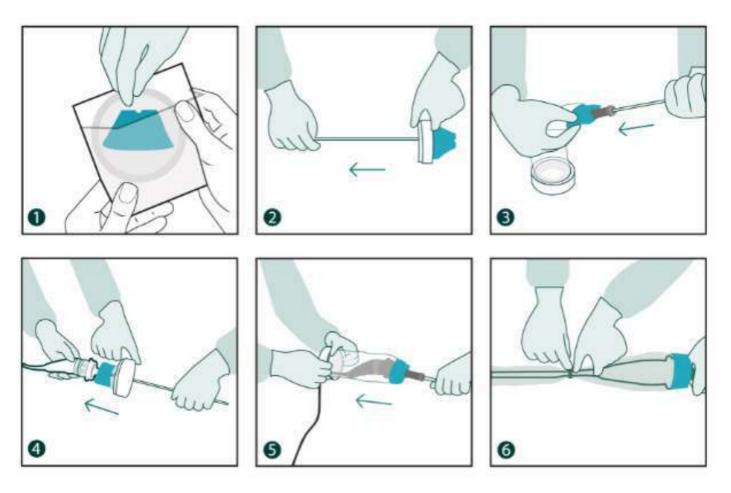
5 years.

REF NO	PRODUCT NAME S	TERILIZATION	PACKAGING UNIT
			125 pcs outerbox
			Box Dimensions:
202-09	Circled Ring Camera Cover with Elastic Tip (14x250 cm)	EO	45*50*38 cm
			Box Weight
			8.10 KG



Circled Ring Camera Cover with Elastic Tip

Instructions For Use



- 1 Peel up individual pouch and remove the cover from it.
- 2 Insert endoscope through rigid applicator of folded drape and triangle cut tip up to its camera connecton side.
- 3 Adjust properly elastic piece on tip of the portion of drape that covers camera connection side of endoscope.
- 4 Partially remove endoscope out and connect camera device to the endoscope.
- 5 Make assistant to pull and apply protective cover onto the remaining cabling of a camera device.
- 6 In case if there is an extra adhesive tape, wrap around the portion of drape where cabling connects to the camera device.

C-Arm Drape with Clips

Intended Use

- C-Arm Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- C-Arm Covers are sterile and disposable medical devices with transient use.
- The devices are intended for single use.
- Main performance indicators for C-Arm Covers are sterility, to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.

Components of The Product

Medbar brand C-Arm Drape with Clips consists of :

- 2 piece scopy/floroscopy drapes,
- One Drape with 6 clips.

Product Features

- Specially folded for easy application.
- Easy to use directional sticker labels for correct application.
- Two durable straps to properly secure the device to the machine.
- More than different sizes available.
- Customized sizes are available upon request.



Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485:2012 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life

REF NO	PRODUCT NAME	STERILIZATION	CLIPS
227-04	C-Arm Drape 75*90 cm (Big)	EO	16*13*13 cm
227-08	C-Arm Drape 75*75 cm (Medium)	EO	13*10*10 cm
227-11	C-Arm Drape 75*75 cm (Small)	EO	13*7*10 cm

C-Arm Cover with Clips Technical Drawing

C-Arm Cover with Clips



23

C-Arm Uniprotection Cover

Intended Use

- C-Arm Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- C-Arm Covers are sterile and disposable medical devices with transient use.
- The devices are intended for single use.
- Main performance indicators for C-Arm Covers are sterility, to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.

Components of The Product

Medbar brand C-Arm Uniprotection Drape consists of 5 parts:

- Cover,
- Belt,
- Assembly Side Label,
- Left Hand Sticker,
- Rigth Hand Sticker.

Product Features

- Specially folded for easy application.
- Easy to use directional sticker labels for correct application.
- Two durable straps to properly secure the device to the machine.
- More than different sizes available.
- Customized sizes are available upon request.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485:2012 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Sterilization

• Sterilized with Ethylene Oxide. Validated for ISO 11135 standard.

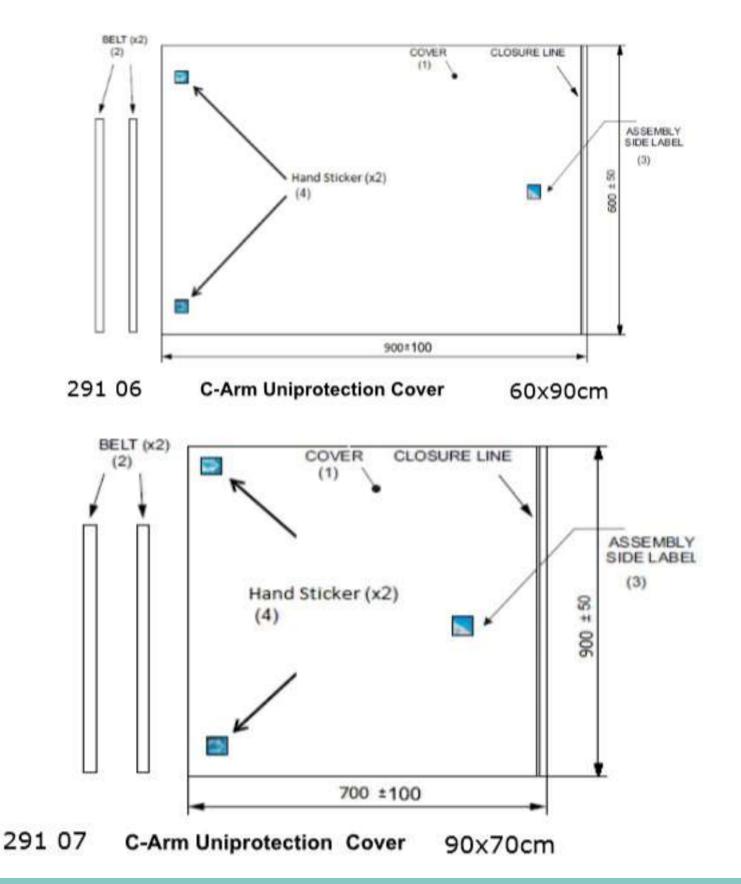
Shelf Life





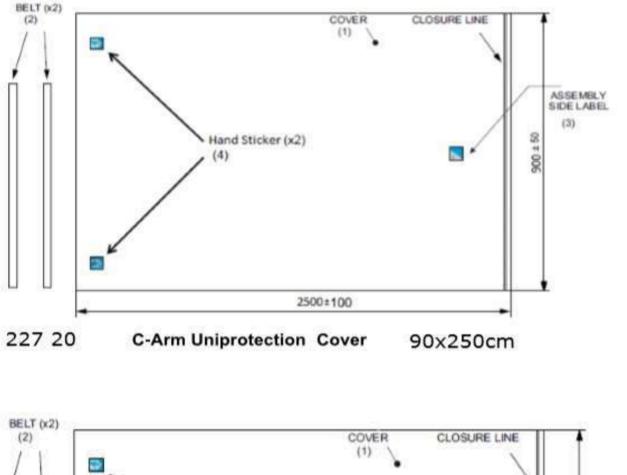
REF NO	PRODUCT NAME	STERILIZATION	PACKAGING UNIT
291-06	C-Arm Uniprotection 60x90 cm	EO	50 pcs inner box
291-07	C-Arm Uniprotection 90x70 cm	EO	400 pcs outerbox
291-08	C-Arm Uniprotection 100x170 cm	EO	Box Dimensions:
227-20	C-Arm Uniprotection 90x250 cm	EO	38*47*43 cm
227-21	C-Arm Uniprotection 90x275 cm	EO	

C-Arm Uniprotection Cover Technical Drawing

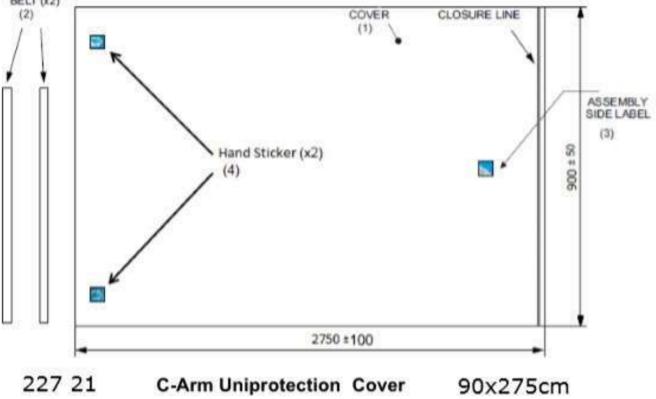


C-Arm Uniprotection Cover

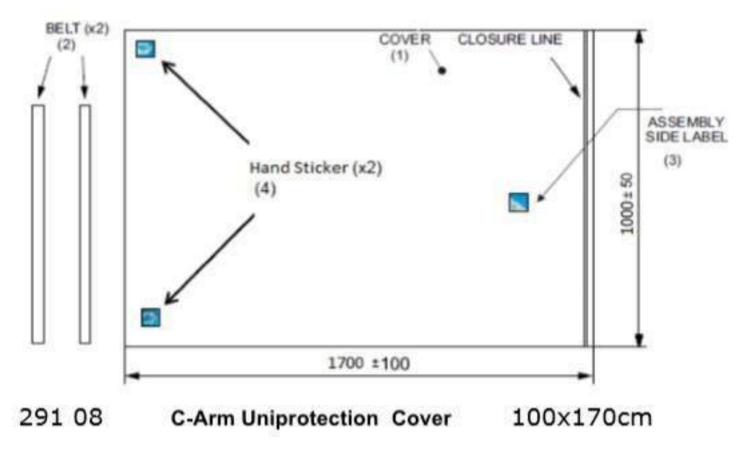
C-Arm Uniprotection Cover Technical Drawing



C-Arm Uniprotection Cover



C-Arm Uniprotection Cover Technical Drawing



C-Arm Uniprotection Cover

Raw Materials

Raw Materials of C-Arm Uniprotection Cover are consists of

- Cover,
- Belt,
- Assembly Side Label ,
- Left Hand Sticker,
- Right Hand Sticker.

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Mini C-Arm Uniprotection Cover

Intended Use

- Mini C-Arm Cover is used for isolating the contamination source to prevent risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- Mini C-Arm Covers sterile and disposable medical devices with transient use.
- The covers are intended for single use.
- Main peformance indicators for Mini C-Arm Covers are sterility to cover the device without preventing device use and to provide sterile media b preventing the contamination from the device to media.

Quality

- Manufactured under ISO 13485:2016 Quality Management System standard.
- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Notifed Body: UDEM Ltd. Şti. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Biocompability

• The Mini C-Arm Covers do not incorporate a substance of a human blood derivate, animal orginated tissues, phthalates, medicinal product, radioactive materials and electromagnetic waves.

Sterilization

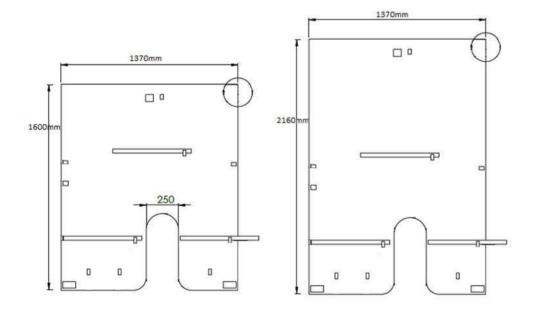
- Sterilized with Ethylene Oxide.
- Validated with ISO 11135 standard.

Shelf Life

• 5 years.

Technical Drawing





F	REF NO	PRODUCT NAME	STERILIZATION
22	27 33	Mini C-Arm Drape 137x160cm	EO
22	27 34	Mini C-Arm Drape 137x216cm	EO

28

C-Arm Set Stringbow

Intended Use

- C-Arm Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or personel during the surgical operations from contamination.
- C-Arm Covers are sterile and disposable medical devices with transient use.
- The devices are intended for single use.
- Main performance indicators for C-Arm Covers are sterility, to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.

Components of The Product

Medbar brand C-Arm Set Stringbow with Clips consists of :

- 2 piece scopy/floroscopy drapes,
- One drape for the c-arm .

Product Features

- Specially folded for easy application.
- Easy to use directional sticker labels for correct application.
- Latex-free, transparent, one-side closed c-arm drape with 40 micron thickness.
- Latex-free, transparent, fluoroscopy or scopy drape with tired open side.
- More than different sizes available.
- Customized sizes are available upon request.



Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485:2012 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life





REF NO	PRODUCT NAME ST	ERILIZATION
227 30	3 piece C-arm Set (Stringbow) 30x195cm 1x Scopy 65cm, 1x Scopy 75cm)	EO
227 31	3 piece C-arm Set (Stringbow) 30x195 cm (Fluoroscopy Drape 75x75 cm: 2x)	EO
227 36	3 piece C-arm Set (Stringbow) 30x208 cm (Fluoroscopy Drape 75x75 cm: 2x)	EO
227 37	3 piece C-arm Set (Stringbow) 30x208 cm (1x Fluoroscopy Drape 80x75 cm & 1x Fluoroscopy Drape 65x65 cm)	EO
227 35	3 piece C-arm Set (Stringbow) 40x190 cm (Fluoroscopy Drape 75x75 cm: 2x)	EO

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Fitted C-Arm Universal Cover

Intended Use

- C-Arm Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or per during the surgical operations from contamination.
- C-Arm Covers are sterile and disposable medical devices with transient use.
- The devices are intended for single use.
- Main performance indicators for C-Arm Covers are sterility, to cover the device without preventing device use and to provide sterile media b preventing the contamination from the device to media.

Components of The Product

Medbar brand Fitted C-Arm Uniprotection Cover consists of :

- Polyethylene nylon.
- Directional handpan sticker.
- Green strap.
- Sterile pouch.

Product Features

- Straps for easy application.
- Easy to use directional sticker labels for correct application.
- Latex-free, transparent, one-side closed c-arm drape with 40 micron thickness.
- Folded closed side teemed inside.
- More than different sizes available.
- Customized sizes are available upon request.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as Class I sterile medical device.
- Manufactured under ISO 13485:2012 Quality Management System standard.
- Notified Body: UDEM LTD A.Ş. (2292)
- EC Certification No: M.2016.106.7000
- GMDN Code: 43970

Sterilization

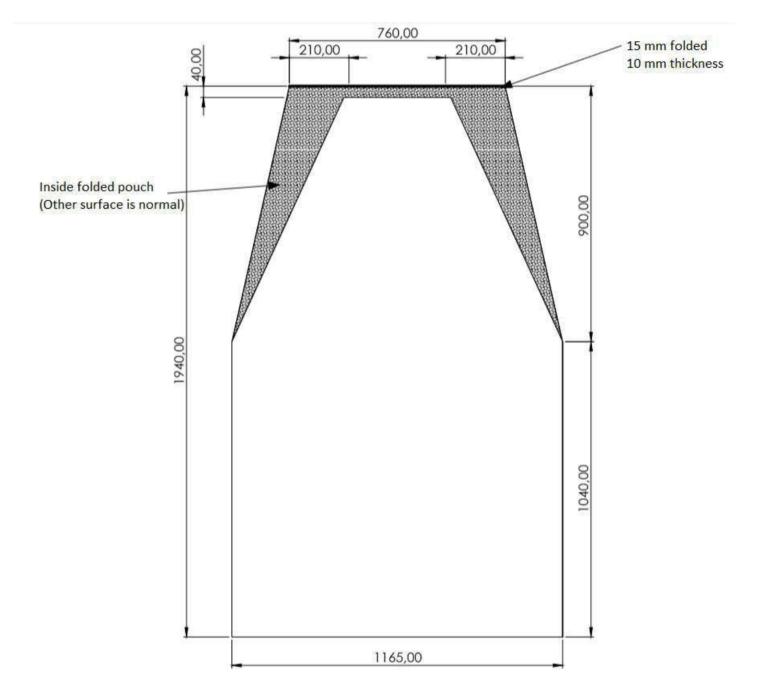
- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Shelf Life

REF NO	PRODUCT NAME	STERILIZATION
227-29	Fitted C-Arm Uniprotection Cover 75+42x200cm	EO
227-38	Fitted C-Arm Uniprotection Cover 75+42x220cm	EO



Fitted C-Arm Universal Cover Technical Drawing



Fitted C-Arm Universal Cover

31

Universal Light Handle Cover

Intended Use

• Universal light handle cover is used not to get contaminated while the operator is turning the light during the operation.

Component of the Products

- Sponge
- Polyethylene cover

Manufacturing Methods

- Main manufacturing processes for camera cover are consists of
- Nylon production,
- Cutting-stickking,
- Folding,
- Packaging,
- Parcelling and
- EO sterilization

Quality

Manufactured under ISO 13485 Quality Management System standard.

• CE certified. Biocompability

Latex free.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life



REF NO	PRODUCT NAME	STERILIZATION
307 01	Universal Sponge Light Handle Cover Long	EO
307 02	Universal Sponge Light Handle Cover Short	EO
307 04	Universal Sponge Light Handle Cover 44x149x152	EO



32

Plastic Ring Light Handle Cover

Intended Use

• Universal light handle cover is used not to get contaminated while the operator is turning the light during the operation.

Component of the Products

- Plastic ring,
- Polyethylene cover.

Manufacturing Methods

- Main manufacturing processes for plastic ring light cover are consists of
- Nylon production,
- Cutting-stickking,
- Folding,
- Packaging,
- Parcelling and
- EO sterilization

Product Features

- Consists of Low Density Polyethylene (LDPE) film and two inter-connected plastic rings.
- The total length of the product is 165 mm.
- Compatible with all sizes of different operating room light handles.
- The inner ring has specially designed teeth to grip the light handle and prevent it from falling.

Quality

- Manufactured under ISO 13485 Quality Management System standard.
- CE certified is done according to ISO 13485 Quality System Standard.
- GMDN Code: 45021

Biocompability

• Latex free.

Sterilization

• Sterilized with Ethylene Oxide.

Shelf Life

• 5 years.

Instructions For Use

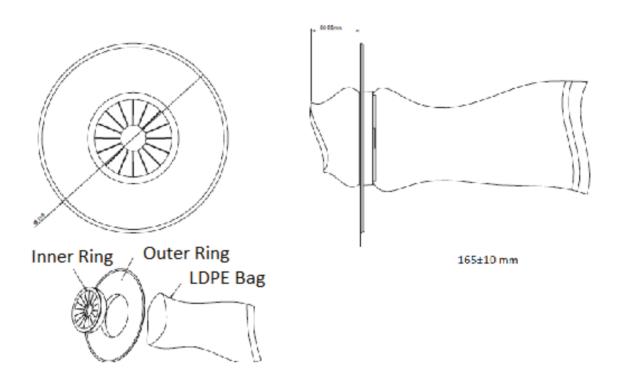
- Take the product off from the package.
- Replace the light handle cover's plastic part upwards to the handle part

REF NO	PRODUCT NAME	STERILIZATION
308 01	Plastic Ring Light Handle Cover Short	EO
308 02	Plastic Ring Light Handle Cover Long	EO



Technical Drawing

Plastic Ring Light Handle Cover



Scopy Drape

Intended Use

• Drape used with viewing, observation, or examination medical equipment to maintain a sterile field and prevent contamination during surgical procedures.

Product Features

- Ref. 227 01: 65 cm standard diameter. (More than 10 different sizes available.)
- Transparent: Does not inhibit the functioning of the device during use.
- Customized sizes are available upon request.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as class I sterile medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM Ltd. Şti. (2292)
- EC Certification No: M.2016.106.7000

Sterilization

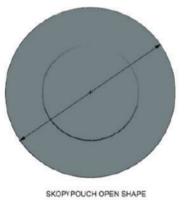
- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Biocompatibility

• Latex-free.

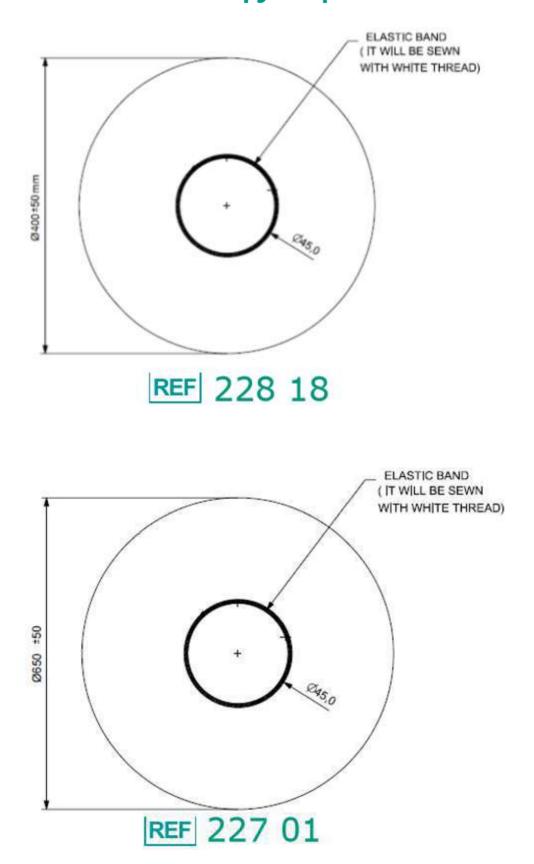
Shelf Life





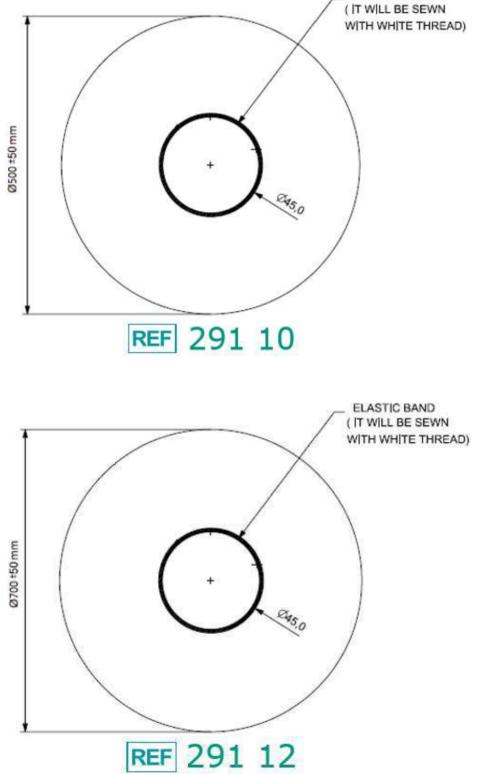
RE	FNO	PRODUCT NAME S	TERILIZATION
22	7 01	Scopy Drape 65 cm	EO
29	1 10	Scopy Drape 50 cm	EO
29	1 11	Scopy Drape 60 cm	EO

Scopy Drape



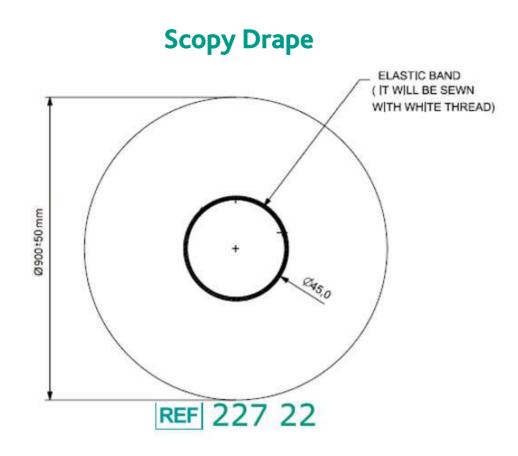
ELASTIC BAND

Scopy Drape

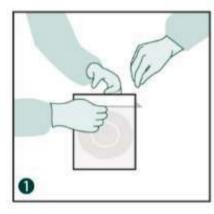


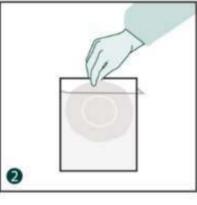
Scopy Drape ELASTIC BAND (IT WILL BE SEWN WITH WHITE THREAD) Ø550±50mm \$45.0 REF 227 07 ELASTIC BAND (IT WILL BE SEWN WITH WHITE THREAD) Ø800±50mm Ø45,0 REF 291 13

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Instructions For Use







- 1 Peel up individual pouch.
- 2 Remove the cover from the pouch.
- 3 Put the cover onto the related equipment.

Fluoroscopy Drape

Intended Use

• Drape used with viewing, observation, or examination medical equipment to maintain a sterile field and prevent contamination during surgical procedures.

Product Features

- Ref: 222 01: 90x60 cm standard size (more than 15 different sizes available).
- Compatible with all devices.
- Customized sizes are available.
- 60 microns double year.
- Manufactured from Polyethylene (PE).
- Transparent: Does not inhibit the functioning of the device during use.

Quality

- CE marked according to 93/42/EEC Medical Device Directive and classified as class I sterile medical device.
- Manufactured under ISO 13485 Quality Management System standard.
- Notified Body: UDEM Ltd. Şti. (2292)
- EC Certification No: M.2016.106.7000

Sterilization

- Sterilized with Ethylene Oxide.
- Validated for ISO 11135 standard.

Biocompatibility

- Biological evaluation of Microscope Drape done according to ISO 10993-1.
- The products do not incorporate a substance of a human blood derivative, animal orginated tissues, phthalates, medicinal product, latex, radioactive materials and electromagnetic waves.
- Latex-free.

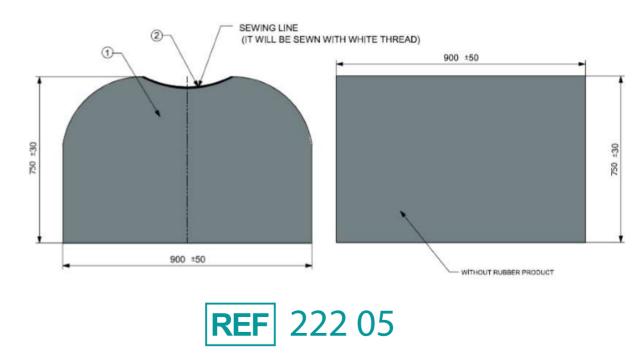
Shelf Life

• 5 years.

Fluoroscopy Drape

Technical Drawing

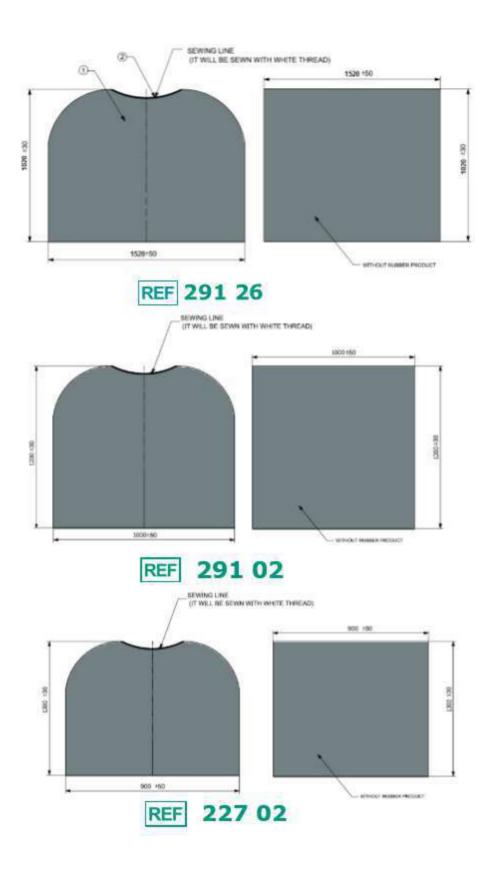
Fluoroscopy Drape

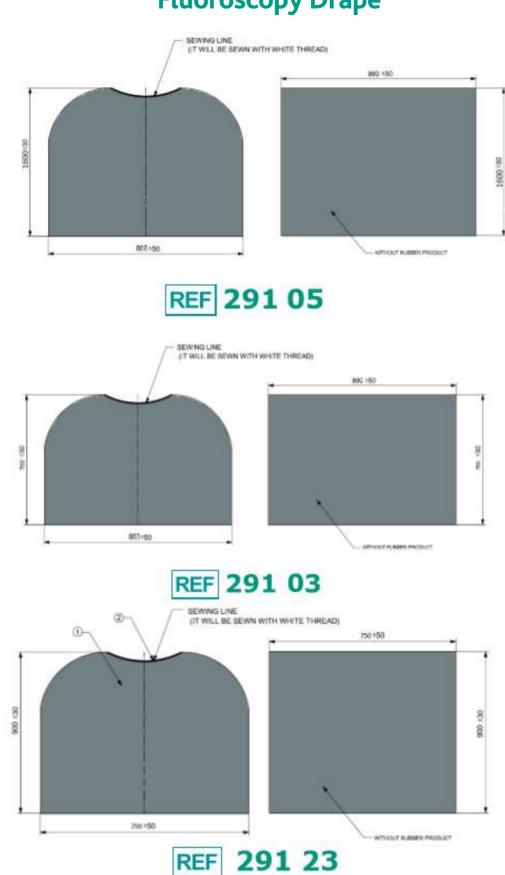




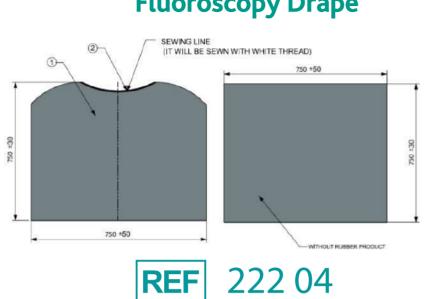
Technical Drawing





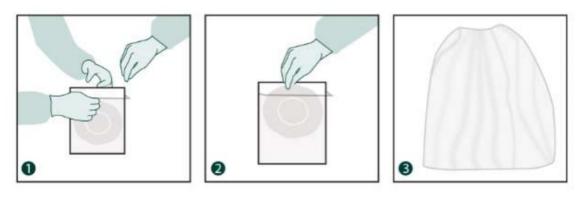


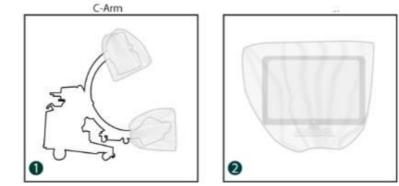
Fluoroscopy Drape



Fluoroscopy Drape

Instructions For Use





- 1 Peel up individual pouch.
- 2 Remove the cover from the pouch.
- 3 Put the cover onto the related equipment.

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Fluoroscopy Drape

Fluoroscopy Drape Versions

Fluoroscopy Drape

REF NO	PRODUCT NAME	STERILIZATION
222 02	Fluoroscopy Drape Hooded	EO
222 03	Fluoroscopy Drape 60x120 cm	EO
227 05	Fluoroscopy Drape 70x80cm	EO
222 08	Fluoroscopy Drape 75x60cm	EO
222 04	Fluoroscopy Drape 75x75cm	EO
222 05	Fluoroscopy Drape 75x90 cm	EO
222 06	Fluoroscopy Drape 80x60 cm	EO
291 03	Fluoroscopy Drape 80x70 cm	EO
222 07	Fluoroscopy Drape 80x100 cm	EO
291 04	Fluoroscopy Drape 80x145 cm	EO
291 05	Fluoroscopy Drape 80x160 cm	EO
222 01	Fluoroscopy Drape 90x60cm	EO
291 23	Fluoroscopy Drape 90x75 cm	EO
227 02	Fluoroscopy Drape 90x130 cm	EO
291 30	Fluoroscopy Drape 91x91 cm	EO
29124	Fluoroscopy Drape 100x80 cm	EO
291 01	Fluoroscopy Drape 100x90 cm	EO
291 25	Fluoroscopy Drape 100x110 cm	EO
291 02	Fluoroscopy Drape 100x120 cm	EO
291 26	Fluoroscopy Drape 102x152 cm	EO
291 28	Fluoroscopy Drape 116x116 cm	EO
291 27	Fluoroscopy Drape 125x125 cm	EO
291 29	Fluoroscopy Drape 180x160 cm	EO



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