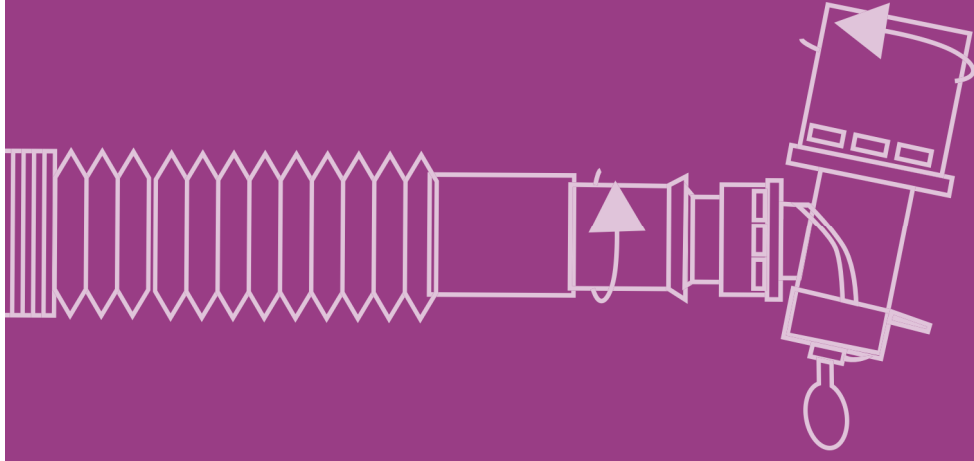




Catheter Mounts

altech[®]

a Medtronic Company

Catheter Mounts

Altech range of catheter mounts includes a wide choice of smoothbore PVC and extendible configurations

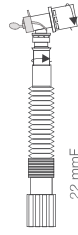
- Smoothbore products provide low resistance to flow while external coil reduces kinks and blockages. Besides they prevent fluid build up reducing risks of bacterial growth thanks ti smooth inner surface.

- Extendible PP product provides a lightweight and flexible solution and allows clinician to adjust the position of the catheter mount
- 360 degree double swivel connector increases ease of use
- Double cap helps to maintain PEEP during suctioning or bronchoscopy.
- Luer lock port for gas sampling
- 15M or 22F adapters available

Catheter Mounts

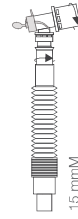


CATHETER MOUNT EXTENDIBLE



22 mmF

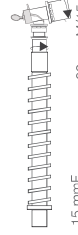
Dead space (ml): Close: 25, Open: 40



15 mmM

22 mmM/15mmF
Dead space (ml): Close: 25, Open: 40

CATHETER MOUNT SMOOTH BORE



15 mmF

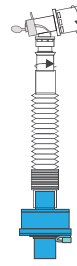
Dead space (ml): 30



22 mmF

22 mmM/15mmF
Dead space (ml): 30

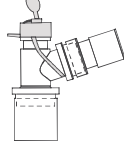
CATHETER MOUNT & FILTER



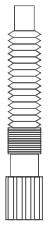
22 mmF

Dead space (ml): Close: 103, Open: 117

CATHETER MOUNTS



15 mmM/22 mmF



22 mmF



15 mmM/22 mmF

EXTENDIBLE TUBE

CODE: 67300	CODE: 66300	CODE: AL-10000
QTY/Box: 50	PVC-FREE CODE: P66300	QTY/Box: 100
Dead space (ml): Close: 22, Open: 37	QTY/Box: 50	Dead space (ml): 3

SMOOTH BORE TUBE

CODE: 67300	CODE: 66300	CODE: AL-10000
QTY/Box: 50	PVC-FREE CODE: P66300	QTY/Box: 100
Dead space (ml): Close: 22, Open: 37	QTY/Box: 50	Dead space (ml): 3

SWIVEL CATHETER MOUNT

CODE: 67300	CODE: 66300	CODE: AL-10000
QTY/Box: 50	PVC-FREE CODE: P66300	QTY/Box: 100
Dead space (ml): Close: 22, Open: 37	QTY/Box: 50	Dead space (ml): 3

CATHETER MOUNT SMOOTH BORE

Smoothbore

Length	Code	Qty/Box
15 cm/6"	AL-22300	50
15 cm/6" (PVC-free)	AL-P22300	50



22 mmF

22 mmM/15 mmF

Dead space (ml): 30



22 mmF

22 mmM/15 mmF

Dead space (ml): 30

Smoothbore

Length	Code	Qty/Box
15 cm/6"	AL-12300	50
15 cm/6" (PVC-free)	AL-P12300	50



22 mmF

22 mmM/15mmF

Dead space (ml): 30



22 mmF

22 mmM/15mmF

Dead space (ml): 30

CATHETER MOUNT SMOOTH BORE

Smoothbore

Length	Code	Qty/Box
15 cm/6"	AL-22300	50
15 cm/6" (PVC-free)	AL-P22300	50



22 mmF

22 mmM/15 mmF

Dead space (ml): 30



22 mmF

22 mmM/15 mmF

Dead space (ml): 30

Smoothbore

Length	Code	Qty/Box
15 cm/6"	AL-12300	50
15 cm/6" (PVC-free)	AL-P12300	50



22 mmF

22 mmM/15mmF

Dead space (ml): 30



22 mmF

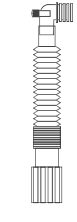
22 mmM/15mmF

Dead space (ml): 30

CATHETER MOUNT EXTENDIBLE

Extendible

Length	Code	Qty/Box
15 cm/6"	AL-27300	50



22 mmF

22 mmM/15 mmF

Dead space (ml): Close: 25, Open: 40

	AL-10000.V001 CATHETER MOUNT (ALTECH) ÜRÜN SPESİFİKASYONU AL-10000.V001 CATHETER MOUNT (ALTECH) PRODUCT SPECIFICATION Doküman No / Document No: PSAL-10000.V001
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1. ÜRÜN TANIMI / *PRODUCT IDENTIFICATION*

AL-10000.V001 CATHETER MOUNT (ALTECH)

1.1. Ürün Sınıfı / *Product Class*

Class 2A

1.2. Uygulanan Standartlar / *Applicable Standards*

EN ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes

ISO 5356-1 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets

EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

TS EN ISO 5367 Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications

ISO 10993-1 Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process

2. KULLANIM AMACI VE FONKSİYONEL TANIMI / *INTENDED USE AND FUNCTIONAL DESCRIPTION*

Kateter bağlantısı hastaya hava ve/veya anestezi gaz veren solunum/anestezi sistemlerinin bir parçası olarak kullanılır. Solunum gazlarının solunum sistemi ile mekanik olarak ventile edilen bir hastaya ait hasta arabirimi (örn. Endotrakeal tüp, maske) arasında iletimi için kullanılan solunum devresi hava yolu konektörüdür. Solunum/anestezi makinesine bağlı olan ve mekanik olarak solutulan hasta ile ventilasyon/anestezi devresi arasına bağlanır. Solunum gazlarının solunum sistemi ile mekanik olarak ventile edilen bir hastaya ait hasta arabirimi (örn. Endotrakeal tüp, maske) arasında iletimi için kullanılır. Çekme etkisini azaltarak solunum/anestezi devresi ve hasta mobilitesine katkıda bulunur. Üzerinde bulunan portlara göre gaz örnekleme, aspirasyon, bronkoskopi gibi prosedürlerde kateterizasyon kolaylığı sağlar.

The catheter mounts are used as part of breathing / anesthesia systems that deliver air and / or anesthetic gas to the patient. Breathing circuit airway connector used for the transmission of respiratory gases between the respiratory device system and the patient interface of a mechanically ventilated patient (eg, endotracheal tube, mask). It is connected between the mechanically inhaled patient connected to the breathing / anesthesia machine and the ventilation / anesthesia circuit. It is used for the delivery of respiratory gases between the respiratory device system and the patient interface of a mechanically ventilated patient (eg endotracheal tube, mask). It contributes to the breathing / anesthesia circuit and patient mobility by reducing the pulling effect. It provides ease of catheterization according to the ports on it in procedures such as gas sampling, aspiration, and bronchoscopy.

3. ÜRETİCİ / *MANUFACTURER*

Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

	AL-10000.V001 CATHETER MOUNT (ALTECH) ÜRÜN SPESİFİKASYONU AL-10000.V001 CATHETER MOUNT (ALTECH) PRODUCT SPECIFICATION Doküman No / Document No: PSAL-10000.V001
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4. ÜRETİM / PRODUCTION

4.1. Ürün hammaddeleri ve çizimi / Product raw materials and drawing

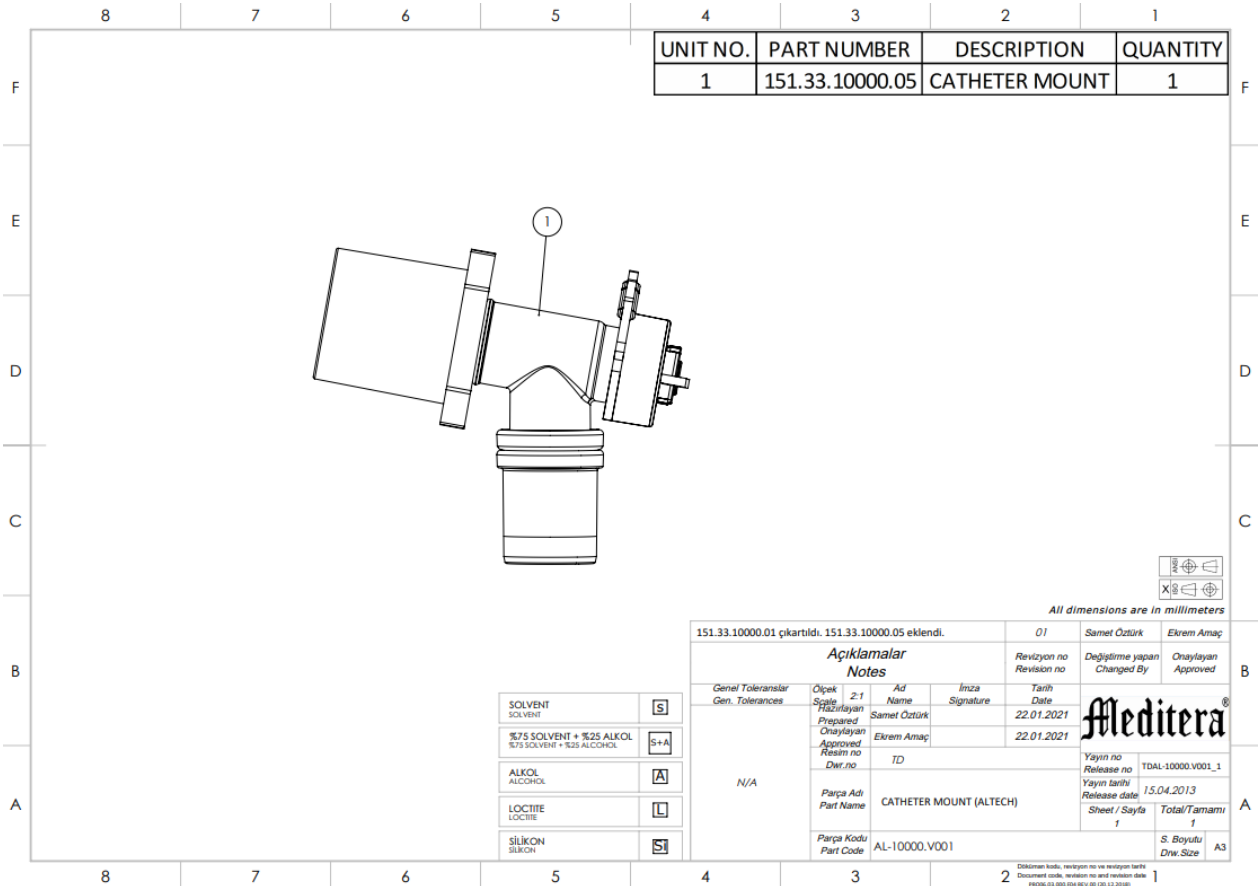
Komponent Parça Numarası <i>Component PN</i>	Komponent Tanımı <i>Component Description</i>	Miktar <i>Qty</i>	Ölçüm Birimi <i>UoM</i>
151.33.10000.05	CATHETER MOUNT	1,00	Adet / Pc

4.2. Kullanım Kılavuzu ve Etiketleme / IFU and Labeling

Parça Adı <i>Part name</i>	Üretici kodu <i>Manufacturer code</i>
CATHETER MOUNT IFU	150.02.305

Etiket <i>Label</i>	Ürün Etiket Kodu <i>Product Label Code</i>	Koli Etiket Kodu <i>Box Label Code</i>
	AW.04.ALT.AL.0659-REV.06	AW.04.ALT.AL.0643-REV.07

4.3. Teknik Çizim / Technical Drawing



5. BİYUYUMLULUK / BIOCOMPATIBILITY

Bu ürün ISO 10993-1 standardına göre biyoyumludur.

This product is biocompatible according to ISO 10993-1.

6. ÜRETİM ALANI / PRODUCTION ENVIROMENT

Bu ürün, EN ISO 14644-1 “Temiz odalar ve bu odalarda birlikte kontrol edilen ortamlar - Bölüm 1: Hava Temizliğinin Sınıflandırılması” standardına göre valide edilen ve takip edilen Sınıf 8 temiz odalarda, ISO 13485 ve MDD 93/42/EEC gerekliliklerine göre üretilmiştir.

This product is produced according to the requirements of ISO 13485 and MDD 93/42/EEC in a validated and monitored Class 8 cleanroom according to the EN ISO 14644-1 “Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness”.

7. STERİLİZASYON / STERILIZATION

Bu ürünler müşteriye sterilize olmamış biçimde sağlanır. Eğer bu ürünler müşteri tarafından sterilize edilirse Meditera bu durumda oluşabilecek herhangi bir şikayetten dolayı sorumlu tutulamaz.

This products are supplied non sterile to the customer. Meditera cannot be hold responsible for any claims regarding sterility if these products are sterilized by customer.

8. RAF ÖMRÜ VE SAKLAMA KOŞULLARI / SHELF-LIFE AND STORAGE CONDITIONS

Normal koşullar altında saklanması durumunda (orijinal ambalajında kuru ve oda sıcaklığında), ürün raf ömrü 5 (Beş) yıldır. Son kullanma tarihi etiket üzerinde yazılıdır.

The shelf-life of this product is 5 (five) years if the product is stored under normal conditions(room temterature, dry and original packaging). Expiration date is printed on the packaging label.

9. UYARILAR / WARNINGS

Tekrar kullanmayınız, yeniden işlemeyiniz veya tekrar steril etmeyiniz. Tekrar kullanım, yeniden işleme veya tekrar steril etme üründe yapısal değişikliğe sebep olabilir ve/veya hastada yaralanmaya, hastalığa veya ölüme yol açabilir. Tekrar kullanım, yeniden işleme veya tekrar steril etme üründeki kontaminasyon riski yaratabilir ve/veya hastada enfeksiyona yada çapraz enfeksiyona, bununla sınırlı olmamak kaydıyla bulaşıcı hastalıkların bir hastadan başka birine yayılmasına sebep olabilir. Üründe yaşanan kontaminasyon yaralanmaya, hastalığa veya hastanın ölümüne sebep olabilir.

Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to the transmission of infectious disease(s) from one patient to another .Contamination of the device may lead to injury, illness or death of the patient.