Aseptic Pharmacy Medical Device & Consumables

Product Brochure



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s April 2nd - check back for updates • STOP PRESS • New Proc

Contacting AMD **Aseptic Medical Devices**

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ENQUIRIES

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Packs call for a combination of ptic procedure s/components which do exist within AMD's standard vation of products. At this It is worth considering a

Consumables

Range The AMD range of le prov

Syringes & Closure Devices

AMD Vented Vial

Access Devices

AMD Custom

Needles & Filter Devices A comprehens es and filtration all form atted fo

UNIQUE & INNOVATIVE PROD

Sterile Alcohol & Wipes AMD supply the R dical range poricides a

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Pouches & Sealers AMD stan

CUSTOMER CARE/ORDERING

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Batch specific Certificates of Conformity and Irradiation are obtainable online at AMD's website: www.asepticmedical.com (log in required).



Visit our new website: www.asepticmedical.com



Introduction

AMD manufacture and provide medical devices in a format designed exclusively for one application, namely the production of aseptically manufactured parenterals.

It is the aim of AMD to ensure devices utilised in the manufacture of drugs are:

- The best devices for the application and are made available to all scales of manufacturing
- Optimally packaged for ease of QC, use and transfer into Isolators or LAF
- Supported by industry leading validation and qualification

Packed devices and combinations are available from individual units right through to packs large enough to support bulk aseptic manufacture. All goods are manufactured in AMD's dedicated ISO Class 7 Cleanroom.





AMD provides optimised medical device transfer sets and accessories which include:

- Syringes
- Syringe Caps
- Needles
- Filters & Filter Needles
- Linked Devices
- Vial Access Devices
- Customised Procedure Packs

At the heart of the products is one of our core areas of expertise: packaging.

AMD Packaging is made available in PeroxyClear and PeroxyMet making pre-use QC of the contents rapid and accurate.

Our pouches are manufactured in cleanroom facilities on site.

AMD Pouches are qualified and validated for gamma sterilisation and compatible with VHP, Alcohol and Hypochlorite/Hypochlorous Acid transfer processes.

AMD aims to supply all products in validated primary medical device pouches which are then placed in two further sterile barrier pouches within our cleanroom. This ensures compliance with current guidance and significantly improves the transfer time of devices into the manufacturing area.

FACILITIES

For over 40 years, Riverside Medical Packaging has established itself at the forefront of the healthcare industry. We have increasingly developed intelligent and innovative solutions to satisfy the demanding requirements for producing, packaging and sterilising single use medical devices. Riverside's state of the art 86,000 sq ft manufacturing facility has been tailor-made specifically for the manufacture of medical packaging and products. It house's Twelve Cleanrooms (three Class 8 and nine Class 7), each being either process or product specific. Manufactured products and packed devices are 100% inspected. In addition they may be subjected to quality checks which are customer or product specific.

All orders received pass through our stringent contract review procedure to ensure that exact customer requirements are met. The company holds UKCA and CE accreditation for Class I sterile devices and a number of Class IIa medical devices.



C Key and Information

C KEY

lcon	Description
	Triple Packed All our pouched devices are supplied with 3 sterile barrier pouches, meeting both the current guidance and enabling a more rapid transfer of devices.
	VHP Triple Cycle VHP Impermeable. AMD's pouches are constructed from a unique alcohol, VHP and sporicide impermeable crystal clear film which is suitable for all transfer methods.
S S	Certification Batch specific Certificates of Conformity and Irradiation are supplied with goods and obtainable online at www.asepticmedical.com (contact AMD customer care to receive a login and password on amd@asepticmedical.com)
R	Sterile Sterilised item.
	Ordering Information Product coding. Denotes pouched products are manufactured and packaged to UK Conformity
	Quantity per Pouch Quality Mark Assessment
	5 Constant Standards.
	S05A25T 🕄 📀
	S05A10T CO Denotes pouched devices are manufactured and packaged to conform to CE Standards.

INFORMATION

This catalogue has been designed to make choosing your devices as simple as possible. To aid you, we have divided the items into these categories:

CE/UKCA Marked Items

All of the items listed below are CE/UKCA marked items throughout the catalogue:

- Custom Packs
- Syringes
- Linked Devices
- Linked Devices
- Vial Access
- NeedlesFiltration
- Caps & Connectors

Sterile Pharmacy Consumables

Consumables

Hardware

CUSTOMISED PACKS

AMD specialises in customised packs to meet aseptic procedural needs.

If there is a combination or quantity of components you do not see offered in this catalogue, please see page 7 for more details or contact us to discuss your requirements.



O AMD Iconography Explained

AMD has provided a simple icon set on packaging to enable the user to instantly recognise:

- What the product is
- How many there are
- Are the contents pre-joined together

MEDICAL DEVICES

NON-MEDICAL DEVICES

Icons	Description	Icons	Description
	Combi-Stopper		Black Permanent
1ml	BD Syringe 1ml, other sizes shown in text	PERMANENT	Marker Pen
21 G	21 Gauge Needle, other gauges shown in text		
5µ 19 G	5 Micron Filter Needle 19 Gauge	BALLPOINT	Black Ballpoint Pen
5μ	5 Micron Filter Straw		1
CODAN	Codan Universal Vented Vial Access Device with 0.2µm Vent Filter		
CODAN 5µ	Codan Universal Vented Vial Access Device with 0.2µm Vent Filter and 5µm Liquid Filter		
•	Two-Way Fluid Adapter		

C EXAMPLE OF A FINAL POUCH LABEL

A Unique Device Identification (UDI) for medical devices is standard on AMD labels in the form of 2D GS1 labelling.



Aseptic Medical Devices



AMD Pouches

Formatted for Aseptic Pharmacy AMD Sterile Transfer Sets & Accessories

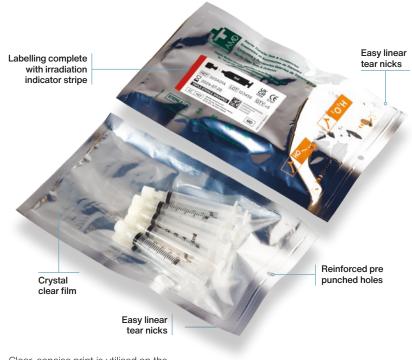
The best packaging solution for all transfer methods.

Aseptic Medical Devices' pouches have been designed with aseptic user requirements in mind. The pouch is constructed from a unique Alcohol, VHP and Sporicide impermeable crystal clear film which is suitable for all transfer methods.

By utilising two variants of this laminate film - a metalised film (PeroxyMet) and visually clear film (PeroxyClear) in the AMD pouch construction, it has allowed the creation of a pouch that makes 'in process' inspection simpler and more efficient. Our pouches are manufactured in cleanrooms.

The metalised film half of the pouch provides a high visual background contrast, so that small and semi-translucent devices may easily be inspected through the optically neutral transparent panel.

The pouch incorporates reinforced prepunched holes at the welded end, removing any need for additional steps prior to loading into a VHP gassing port.



Clear, concise print is utilised on the metalised panel, along with pre-cut 'easy linear tear' system making opening with the gloved hand straight forward without the need for scissors.

C AMD POUCHES & PACKAGING

Products are presented in AMD's Triple Wrap Sterile System. This comprises of 3 sterile barrier pouches designed to exceed the stringent requirements of today's transfer process. The secondary and tertiary pouches are fully validated sterile barriers. AMD's innovative design features have also been carried over on to these layers, with easy tear opening resulting in a simplification of the transfer process with greater quality assurance.



Product is always packed into polythene lined cartons to further separate goods from any sources of particulate and contamination. Each carton is completed with labels and irradiation indicators.

Each carton also contains a detachable self adhesive 'transcription' labels for each pouch - placed inside the polythene liner.

These mini labels replicate the contents' product code, its batch number and expiry date, enabling swift physical transfer of critical information to the customer's own batch documentation should they wish. Products are then placed into outer shippers, again labelled and with an irradiation indicator.

The Certificate of Conformity and Irradiation for every batch is generated and uploaded to the AMD website where all customers with a login can search and download the appropriate certificate.

If you are a customer and wish to receive a unique login to use this service, please contact: **amd@asepticmedical.com**



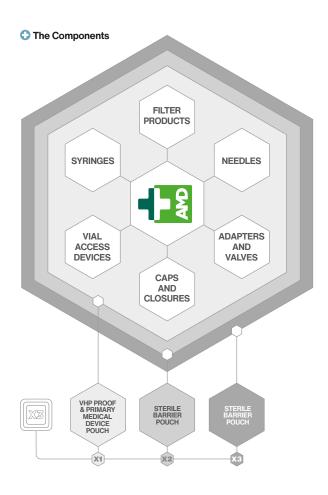


Aseptic Medical Devices



Customised Procedure Packs

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A UNIQUE AMD SERVICE

Many times an aseptic procedure may call for a combination of devices/components which do not exist within AMD's standard configuration of products. At this point it is worth considering a bespoke approach. In the aseptic preparation and transfer of drug formulations, users of the necessary medical devices may have a 'wish list' of the ideal number of components required.

AMD works with users, to create a pack unique to their procedures. The aim of these packs is to support the recognised traditional method of transfer.

The customised procedure pack approach can help support the release of staff time, increase productivity and aid with capacity planning.

This approach can assist by:

- Improve speed of manufacture and efficiency
- Save significant time for recording and checking individual components
- Simplifying the transfer process and reduces variance of the transfer process between operators
- Reduction in use of wipes and spray
- Increased quality assurance
- Ease of accessibility whilst gloved or when working in an isolator
- Reduction in manipulations during the manufacturing process, as many components can be 'linked'
- Increased protection of the fluid pathway
- Removing all paper from the process
- Having the exact number of devices required for a procedure
- Reduction in waste stream

Aseptic Medical Devices



Custom Packs



C Traditional Transfer Process



C AMD Triple Wrap Transfer Process



There have been numerous studies that show the savings made and risk reduction by utilising Custom Procedure Packs. Imagine not having to Spray & Wipe each individual component before transferring to the next area.

How easy would it be knowing that the exact component and quantity are contained within a Triple Sterile Pouch System. Aseptic Medical Devices has qualified and validated all components that are used within Procedure Packs. This allows the end user to "mix and match" components to suit their requirements. Added to this we are able to link devices where required meaning less manipulations by the end user and less risk during your production process.

- Qualified and Validated Components
- Triple Sterile Wrapped
- Non-Sterile evaluation sample upon request



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OBD Syringe Range

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ORDERING INFORMATION

BD Syri	nges			Certificati			
Size	Description	5	10	25	30	CE	Ϋ́
01ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A01A	S10A01A	S25A01A	POA	0	0
03ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A03A	S10A03A	S25A03A	POA	0	0
05ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A05A	S10A05A	S25A05A	POA	0	Ø
10ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A10A	S10A10A	S25A10A	POA	0	Ø
20ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A20A	S10A20A	S25A20A	POA	0	Ø
30ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A30A	S10A30A	POA	S30A30A	0	Ø
50ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A50A	S10A50A	S25A50A	POA	0	0

PRODUCT INFORMATION

Aseptic Medical Devices offer a standard range of BD syringes, selected for their suitability for gamma sterilisation and compatibility with existing manufacturing procedures.

The whole range of products is CE marked and certified under ISO 13485.

AMD are always able to offer bespoke pack solutions such as different quantities per pouch or combinations of devices to meet specific procedure requirements bringing flexibility and scalability to any manufacturing process.

All syringe tips have a Luer Lock tip protector fitted to maintain the fluid pathway integrity.

BD 01ml syringe is made from polycarbonate and has been qualified separately to the rest of the sizes which are manufactured from a gamma stable polypropylene. The sterile transfer sets utilise Aseptic Medical Devices' own specialist pouch: PeroxyMet/PeroxyClear - a purpose designed pouch for aseptic area use the pouch is alcohol, VHP and oxidising sporicide impermeable, yet transparent with a contrasting background for easy pre-use QC.

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K P R

O B Braun Syringe Range

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ORDERING INFORMATION

B Brau	un Syringes	Quantity	Certif	ication	
Size	Description	5	10	CE	Ϋ́
01ml	B Braun Injekt [®] Luer Slip Syringe Fitted with Natural Coloured Stopper	S05A01I	S10A01I	0	Ø
02ml	B Braun Injekt [®] Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A02I	S10A02I	0	0
05ml	B Braun Injekt [®] Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A05I	S10A05I	0	0
10ml	B Braun Injekt [®] Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A10I	S10A10I	0	0
20ml	B Braun Injekt [®] Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A20I	S10A20I	0	0

PRODUCT INFORMATION

B Braun Injekt[®] syringes are a 2-piece syringe made from polypropylene/ polyethylene. AMD offer both Luer Lock and Luer Slip variations of the syringe. The barrel is highly transparent with contrasting black graduations. They are supplied with a green plunger and the barrel incorporates a plunger back stop. Injekt[®] syringes are latex, PVC and silicone oil free. The 01ml Injekt-F[®] syringe is a concentric Luer Slip tip with a fine graduation also benefiting from all the same features of the standard Injekt[®] syringe range.

All syringes are supplied with the fluid pathway protected and in the standard pack sizes. These syringes are also available for inclusion in custom procedure packs.



Aseptic Medical Devices



O BD Syringes fitted with Needles

Formatted for Aseptic Pharmacy AMD Sterile Transfer Sets & Accessories



C ORDERING INFORMATION

Syringes fitted with Need	lles					Quantity p	per Pouch		Certification		
Needle Type	Gauge	Length	Syringe Size	Description	5	10	20	25	CE	۲Ķ	
BD Blunt Fill	18 Gauge	38mm (1.5")	01ml	BD Luer Lock Syringe	L05A01R	POA	POA	POA	0	0	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	01ml	BD Luer Lock Syringe	L05A01P	POA	POA	POA	0	Ø	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	03ml	BD Luer Lock Syringe	L05A03P	POA	POA	POA	0	0	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	10ml	BD Luer Lock Syringe	L05A10P	L10A10P	POA	POA	0	0	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	20ml	BD Luer Lock Syringe	L05A20P	POA	L20A20P	POA	0	0	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	30ml	BD Luer Lock Syringe	POA	POA	L20A30P	POA	0	0	
Regular Bevelled Needle	19 Gauge	38mm (1.5")	50ml	BD Luer Lock Syringe	L05A50P	L10A50P	POA	POA	0	0	
Regular Bevelled Needle	21 Gauge	38mm (1.5")	01ml	BD Luer Lock Syringe	POA	L10A01S	POA	L25A01S	0	0	
Regular Bevelled Needle	21 Gauge	38mm (1.5")	03ml	BD Luer Lock Syringe	L05A03S	L10A03S	POA	POA	0	0	
Regular Bevelled Needle	21 Gauge	38mm (1.5")	05ml	BD Luer Lock Syringe	L05A05S	L10A05S	POA	L25A05S	0	0	
Regular Bevelled Needle	21 Gauge	38mm (1.5")	10ml	BD Luer Lock Syringe	L05A10S	L10A10S	POA	POA	0	0	
BD Braun Sterican	21 Gauge	50mm (2")	05ml	BD Luer Lock Syringe	L05A05V	L10A05V	POA	POA	0	0	
BD Braun Sterican	21 Gauge	50mm (2")	10ml	BD Luer Lock Syringe	L05A10V	L10A10V	POA	POA	0	0	
Regular Bevelled Needle	23 Gauge	32mm (1.25")	01ml	BD Luer Lock Syringe	L05A01N	POA	POA	POA	0	0	
Regular Bevelled Needle	23 Gauge	32mm (1.25")	03ml	BD Luer Lock Syringe	L05A03N	L10A03N	POA	POA	0	0	
Regular Bevelled Needle	23 Gauge	32mm (1.25")	05ml	BD Luer Lock Syringe	L05A05N	L10A05N	POA	POA	0	0	
Regular Bevelled Needle	23 Gauge	32mm (1.25")	10ml	BD Luer Lock Syringe	L05A10N	L10A10N	POA	POA	0	0	

PRODUCT INFORMATION

Aseptic Medical Devices offer a range of BD syringe sizes pre-fitted with needles. These devices are selected for their suitability for gamma sterilisation and compatibility with existing manufacturing procedures. The whole range of products is CE marked and certified under ISO 13485. AMD are always able to offer bespoke pack solutions such as different quantities per pouch or combinations of devices to meet specific procedure requirements bringing flexibility and scalability to any manufacturing process. All syringes in this range are pre-fitted with sheathed needles to reduce in situ assembly. The linked devices are orientated within their packing for rapid and easy aseptic removal.

The sterile transfer sets utilise triple packing using Aseptic Medical Devices' own specialist pouch: PeroxyMet / PeroxyClear.

Aseptic Medical Devices







O AMD Vented Vial Access Devices

Formatted for Aseptic Pharmacy AMD Sterile Transfer Sets & Accessories



ORDERING INFORMATION

BD SmartSite [™] supplied in the below combinations					Quantity per Pouch			
Description	Vial Size	Closed Pathway	Aeration and Venting Filter	5	10	25	CE	ĽΚ
AMD Vented Vial Access Device	Universal	No	Hydrophobic 0.2µm Filter	P05A10R	P10A10R	P25A10R	0	0
AMD Vented Vial Access Device fitted with BD SmartSite™	Universal	Yes	Hydrophobic 0.2µm Filter	P05A20R	P10A20R	P25A20R	0	0

PRODUCT INFORMATION

The AMD vented vial access device works with standard Luer Lock syringes providing a system that allows safe access to vials.

The AMD vented vial access device includes a 0.2 micron hydrophobic airvent filter that neutralises vial pressure, minimising aerosols from rubber stoppered multi-dose vials where aerosolising of hazardous material is a potential risk. The AMD vented vial access device is also available fitted with The SmartSite[™] needle-free valve enabling multiple connections and closes off the fluid pathway in to the vial upon disconnecting of a syringe.

Ergonomically designed and easy to grip, this vented vial access device is a universal device and can be used on varying vial sizes. It incorporates a cut away section in the spike to allow drawing from just above the bung offering a needle-free, non-coring, penetrating spike.

A variety of pouched quantities exist, the table above shows the possible permutations all of which are CE marked.

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O BD SmartSite™ Vented Vial Access Devices

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ORDERING INFORMATION

BD Smartsite [™] Vented Vial Access Devices	Quantity	Certification					
Description	Vial Size	Closed Pathway	Aeration and Venting Filter	5	10	C€	胀
BD SmartSite [™] Vented Vial Access Device	Universal	Yes	Hydrophobic 0.2µm Filter	P05A00A	P10A00A	Ø	0
BD SmartSite [™] Vented Vial Access Device	13mm	Yes	Hydrophobic 0.2µm Filter	P05A13A	P10A13A	Ø	0
BD SmartSite [™] Vented Vial Access Device	20mm	Yes	Hydrophobic 0.2µm Filter	P05A20A	P10A20A	Ø	0

O PRODUCT INFORMATION

The SmartSite[™] vented vial access device works with all Luer Lock syringes enabling needle-free drug transfer from vial to syringe. The SmartSite[™] needle-free valve enables multiple connections and the novel shrouded spike design ensures easy attachment and superior vial connection security with standard 13mm and 20mm vials. The Universal spike option allows use with all vial sizes.

The 0.2 micron hydrophobic air-venting filter neutralises vial pressure, minimising aerosols and surface contamination.

Aseptic Medical Devices





Codan Vented Universal Vial Access Devices

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ORDERING INFORMATION

Codan Vented Universal Vial Access Devices					Quantity per Pouch					Certification	
Description	Vial Size	Closed Pathway	Aeration and Venting Filter	Fluid Filter	5	10	25	50	C€	۲Ķ	
Codan Spike	Universal	No	Hydrophobic 0.2µm Filter	-	P05A01C	P10A01C	P25A01C	P50A01C	0	0	
Codan Spike	Universal	No	Hydrophobic 0.2µm Filter	5µm Filter	P05A05C	POA	P25A05C	POA	0	0	

PRODUCT INFORMATION

The Codan vial access device works with standard Luer Lock syringes providing a system that allows safe access to vials.

In both designs the 0.2 micron hydrophobic air-vent filter neutralises vial pressure, minimising aerosols from rubber stoppered multi-dose vials where aerosolising of hazardous material is a potential risk. Additionally they are easy to grip and are universal (all of these vial access devices can be used on varying vial sizes). They offer a needle free non-coring penetrating spike.

Two versions are offered in AMD's VHP Triple packaging configuration. A variety of pouched quantities exists, the table above shows the possible permutations all of which are CE marked.

Aseptic Medical Devices

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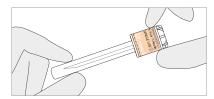




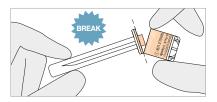
C Encapsulated Needles for Syringe Filling

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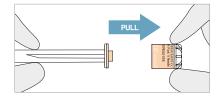
How to access the hub of the Encapsulated Needle



1. Grip needle case at both ends



2. Make a slight breaking movement (at the perforation) on both ends



3. Pull the cap from the needle



ORDERING INFORMATION

Needles - Pouched & Double Outer Wrapped	Quantity per Pouch					Certification		
Description	Gauge	5	10	25	50	100	C€	۲Ķ
Encapsulated Needle - 38mm (1.5") in Length	18 Gauge	N05A18T	N10A18T	N25A18T	N50A18T	N00A18T	0	Ø
Encapsulated Needle - 38mm (1.5") in Length	19 Gauge	N05A19T	N10A19T	N25A19T	N50A19A	N00A19T	0	Ø
Encapsulated Needle - 38mm (1.5") in Length	21 Gauge	N05A21T	N10A21T	N25A21T	N50A21T	POA	Ø	Ø
Encapsulated Needle - 32mm (1.25") in Length	23 Gauge	N05A23T	N10A23T	N25A23T	N50A23T	POA	0	0

PRODUCT INFORMATION

AMD selected this needle for aseptic transfer of liquids as it is specifically designed to allow insertion into a secondary packaging. Each needle is individually encapsulated in an ergonomically shaped, colour-coded hard cap and case. This format ensures safety and compliance with good aseptic technique. Riverside are the legal manufacturer of this product and take full responsibility for its safety and performance. The CE mark 0197 and reference to Terumo Europe as legal manufacturer present on the individual needles should be disregarded.

Aseptic Medical Devices







Capped Needles for Syringe Filling

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ORDERING INFORMATION

Needles (Capped)			Quantity per Pouch				
Description	Gauge	5	10	25	50	CE	ΓŔ
BD Nokor Needle 18G x 1.5" Capped	18 Gauge	N05A18G	N10A18G	POA	POA	0	Ø
Blunt Needle - 38mm (1.5") in Length	18 Gauge	N05A18B	N10A18B	N25A18B	N50A18B	0	Ø
Regular Bevelled Needle - 38mm (1.5") in Length	18 Gauge	N05A18C	N10A18C	N25A18C	N50A18C	0	Ø
Regular Bevelled Needle - 25mm (1") in Length	19 Gauge	N05A19D	N10A19D	N25A19D	N50A19D	0	Ø
Regular Bevelled Needle - 38mm (1.5") in Length	19 Gauge	N05A19E	N10A19E	N25A19E	N50A19E	0	Ø
Regular Bevelled Needle - 50mm (2") in Length	19 Gauge	N05A19F	N10A19F	N25A19F	N50A19F	0	Ø
Regular Bevelled Needle - 38mm (1.5") in Length	21 Gauge	N05A21J	N10A21J	N25A21J	N50A21J	0	Ø
Regular Bevelled Needle - 32mm (1.25") in Length	23 Gauge	N05A23A	N10A23A	N25A23A	N50A23A	0	Ø

C PRODUCT INFORMATION

Aseptic Medical Devices offer a wide range of needles which are individually capped for easy manipulation and aseptic transfer of liquids, the needles are presented with no paper blister present. All versions of this range utilise triple packing using Aseptic Medical Devices' own specialist pouch: PeroxyMet / PeroxyClear.

All are available in quantities per pouch from 5 through to 50 – please refer to the ordering information.



Aseptic Medical Devices



Filter Needles

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ORDERING INFORMATION

Filter Needles	a	Certification				
Description	Gauge	5	10	25	C€	К
BD Blunt Needle with 5µm Filter - 38mm (1.5") in Length (Capped)	18 Gauge	F05A06B	F10A06B	POA	0	Ø
B Braun Needle with 5µm Filter - 38mm (1.5") in Length (Capped)	19 Gauge	F05A01X	F10A01X	F25A01X	0	0

PRODUCT INFORMATION

Filter Needle - BD Blunt

5 micron filter in a female Luer Lock connector with an 18 Gauge x 1.5 inch (38mm) needle, which has a blunt tip 45° bevel to avoid coring. Components do not contain DEHP or natural rubber latex. Uniquely available via AMD in paper free packaging and fluid pathway protected with a white Luer Lock cap.

Filter Needle - B Braun

5 micron filter in a female Luer Lock connector with 19 Gauge x 1.5 inch (38mm) needle, which is a thin wall needle for withdrawal or injection of medication from a rubber-stoppered vial. Components do not contain DEHP or natural rubber latex. Uniquely available via AMD in paper free packaging and fluid pathway protected with a white Luer Lock cap.

Aseptic Medical Devices







C Linked Devices - Multi-Access Port featuring BD SmartSite™

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ORDERING INFORMATION

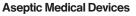
BD Smartsite [™] supplied in	the below co	mbinations		Quantity	Certification		
Needle Type	edle Type Gauge Length Description		3	5	CE	딶	
BD Blunt Fill	18 Gauge	38mm (1.5")	No filter	L03A96R	L05A96R	0	0
Regular Bevelled Needle	19 Gauge	38mm (1.5")	No filter	L03A96P	L05A96P	Ø	Ø
Regular Bevelled Needle	19 Gauge	38mm (1.5")	5µm CA membrane 28mm diameter	L03A97P	L05A97P	0	Ø
Regular Bevelled Needle	19 Gauge	38mm (1.5")	0.2µm SFCA membrane 28mm diameter	L03A99P	L05A99P	0	Ø
Regular Bevelled Needle	21 Gauge	38mm (1.5")	0.2µm SFCA membrane 28mm diameter	L03A99S	L05A99S	0	Ø

PRODUCT INFORMATION

The BD SmartSite[™] needle free 2-way non-drip valve works with standard Luer Lock syringes. The SmartSite[™] needle-free valve enables multiple connections and when disconnected from the syringe can withhold 45 psi of back pressure. In order to solve a wide range of aseptic transfer issues AMD have linked this device to both Sartorius filters and/or needles and protected the tip of the SmartSite[™] with a pin-less cap to simplify aseptic removal from AMD's triple wrap packaging.

OPTIONS

This linked set of devices can be provided in a wide range of combinations including needle gauge and length and also with or without filters - $0.2\mu m$, $0.45\mu m$ and $5\mu m$ are offered as options, and in a variety of pouched quantities.









• Filter Straws

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C Filter Straw - B Braun



Filter Straws in OEM Blister		Quantity per Pouch		Certification		
Description	Length	5	10	20	C€	Ϋ́
B Braun 5µm Filter Straw	4.5cm / 1.75"	F05A01A	F10A01A	POA	0	0
B Braun 5µm Filter Straw	10cm / 4"	F05A04A	F10A04A	POA	0	0

PRODUCT INFORMATION

Filter straws are ideal for fluid aspiration from glass ampoules. To ensure full protection along the full length of the straw, the original manufacturer's blister packaging has been removed and the straws are placed in a small plastic bag to reduce the risk of contamination by a gloved hand whilst removing one from an open pouch.

Filter Straw - B Braun

A 5 micron filter in female Luer Lock connector in ABS (uncapped) with a PVC tube of either 10cm or 4.5cm length. Components do not contain DEHP or latex.

Aseptic Medical Devices





O Syringe Filter Devices

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ORDERING INFORMATION

Syringe Filters - Capped both ends - VHP pouched and double outer wrapped					Quantity per Pouch	Certification	
Description	Pore Size	SmartSite Valve Included	Application	Membrane Material	5	Œ	ĽŔ
28mm Diameter Syringe Filters - Female Luer Lock Inlet, Male Luer Lock Outlet	0.2µm	No	Sterilising Grade	SFCA*	F05A02A	0	0
	0.2µm	No	Sterilising Grade	PES**	F05A02P	0	Ø
	0.45µm	No	Bioburden Reduction	SFCA*	F05A45A	Ø	Ø
	5.0µm	No	Particulate Removal	CA***	F05A05A	Ø	Ø
28mm Diameter Syringe Filters with SmartSite Valve Upstream - Female Luer Lock Inlet, Male Luer Lock Outlet	5.0µm	Yes	Particulate Removal	CA***	F05A05B	0	0

* SFCA - Surfactant-free Cellulose Acetate - low protein binding

** PES - Polyethersulfone - low protein binding, high flow *** CA - Cellulose Acetate

PRODUCT INFORMATION

Many parenteral formulations require a final filtration step in their manufacture. To make this step straightforward and rapid, AMD have qualified Sartorius syringe filtration devices both on their own and also prelinked to the BD SmartSite™ valve.

The BD SmartSite[™] needle free 2-way, non-drip valve works with standard Luer Lock syringes. The SmartSite[™] needle-free valve enables multiple connections and when disconnected from the syringe can withhold 45 psi of back pressure. Both ends of the device(s) are protected by caps.

Filter pore sizes are made available in 0.2 micron for sterilisation of fluids, 0.45 micron for bioburden management and 5 micron for particulate control.

The surfactant free cellulose acetate (SFCA) membrane is suitable for all applications including biological therapeutics (low protein binding). The Polyethersulphone (PES) membrane is also suitable for low protein binding applications and offers a higher flow rate. Pre-testing is recommended to establish protein binding levels under dynamic filtration conditions.

Aseptic Production Formatting

Each device is fitted with a pin-less Luer Lock cap to protect the surface of the SmartSite[™] simplifying aseptic handling and manipulation.

Aseptic Medical Devices





Two-Way Fluid Connector

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Sterilisation process may cause the product to change colour.

ORDERING INFORMATION

Two-Way Fluid Connector	Quantity per Pouch			Certification		
Description	5	10	25	CE	쏞	
Two-way fluid connector/adapter (female to female) fully capped	Z05A02C	Z10A02C	Z25A02C	0	0	

C PRODUCT INFORMATION

Aseptic Medical Devices offer a fully capped, two-way fluid connector format exclusively for aseptic manipulation. This Luer-lock connector is in femalefemale format and constructed from polycarbonate.

Easy to grip and hold, the adapter is ideal for changing Luer gender or connecting two male devices together e.g. syringe to syringe. The two-way adapter is provided capped at both ends to ensure fluid pathway integrity and ease of manipulation. All packs of this product are CE marked.

AMD are always able to offer bespoke pack solutions such as different quantities per pouch or combinations of devices to meet specific procedure requirements bringing flexibility and scalability to any manufacturing process. The sterile transfer sets utilise triple packing using Aseptic Medical Devices' own specialist pouch: PeroxyMet / PeroxyClear.

Aseptic Medical Devices

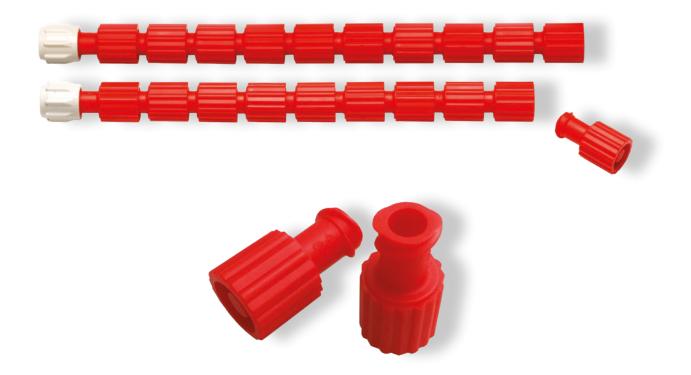






O Syringe Closure Combi-Stoppers

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ORDERING INFORMATION

AMD Closure Combi-Stoppers (Red) Triple Outer Wrapped		Quantity per Pouch				
Description	5	10	25	50	C€	К
AMD Closure Combi-Stopper (red) in Rods	C05A01A	C10A01A	C25A01A	C50A01A	0	Ø

PRODUCT INFORMATION

Formatted for Aseptic Manipulation

Pre-connected in 'rods' - ensuring the fluid pathway of the Luer connector is always protected by the next combi-stopper, making individual removal, one at a time, safe and secure. NB - as a safety measure the final discardable white cap will not connect to a syringe.

CLOSURE QUALIFICATION

Shelf Life

The AMD Red Combi-stopper has been both CE marked and qualified for a 3 year shelf-life post gamma sterilisation.

Dye Intrusion Testing

Structural integrity as a syringe closure was qualified on all BD Syringe sizes via dye intrusion testing in accordance with the 'yellow cover document'.

Biological Challenge Testing

Biological impermeability confirmed (100% integrity) via total immersion integrity qualification (90 day challenge) using B. diminuta.

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O AMD Mini Cap

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ORDERING INFORMATION

AMD Mini Cap	Qu	Certification		
Description	5	10	25	딵
AMD Mini Cap	C05A03R	C10A03R	POA	0

O PRODUCT INFORMATION

The AMD Mini Cap is a small luer lock syringe cap. It has been designed so the external dimensions of the cap are approximately the same size as the luer lock ring on a syringe, allowing the cap to be used with syringe shields used in Radiopharmacy. The cap is made from polypropylene supplied sterile, in Aseptic Medical Devices standard triple sterile wrapped. Please see the table above for the options available.

Aseptic Medical Devices



O AMD Syringe Clamshells



ORDERING INFORMATION

AMD Single Use Clamshells						
Size	Description	Qty per Carton	Product Code			
S	Small Syringe Clamshell	430	X10R01S			
L	Large Syringe Clamshell	150	X10R01L			

C PRODUCT INFORMATION

The AMD Syringe Clamshell is designed to allow safe storage and transportation of prefilled syringes. Two sizes of clamshell are available that covers 01ml to 05ml and 20ml to 50ml capped syringes and can be used with any fill volume of the syringe to be placed inside. Manufactured from clear R-PET.

Supplied non-sterile and in a carton lined with a PE Food Grade Bag. Please see the above table for further information.

ASEPTIC MEDICAL DEVICES

Aseptic Medical Devices

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Consumables



O AMD Isolator Cleaning Tool and Bonnet

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ORDERING INFORMATION

AMD Isolator Cleaning Tool and Bonnet				
Description	Product Code			
AMD Isolator Cleaning Bonnet, Individually Pouched (carton of 25)	X70A25R			
AMD Isolator Cleaning Bonnet, Individually Pouched (carton of 50)	X70A50R			
AMD Isolator Cleaning Tool	X70B01R			

PRODUCT INFORMATION

AMD's Isolator Cleaning Tool and Cleaning Bonnets are specifically designed for isolator, laminar flow cabinet cleaning and other cleanroom areas where access is restricted.

CLEANING TOOL

The triangular head shape of the cleaning tool allows for improved access in tight corners ensuring areas are cleaned effectively and efficiently.

- Fully autoclavable
- Made from 316 stainless steel with
 aluminium handle for optimum reach
- Easy to use, lightweight and manoeuvrable

CLEANING BONNET

Designed to be used with the cleaning tool for efficient cleaning of environments that are critical to the quality of compounded products. The presentation of a dry absorbent bonnet allows for customers to use their preferred biological agents and cleaning solutions.

- Single use disposable low particulate bonnets are manufactured from a 2 ply polyester blend material
- Elastic sewn edge enables a secure fit on
- the isolator cleaning tool head during use
 Supplied triple sterile wrapped and packed within a class 7 cleanroom sterilised by gamma irradiation
- AMD's unique packaging ensures easy opening, even when wearing gloves





O AMD Sterile Dry Wipe

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Single Wipe Triple wrapped

ORDERING INFORMATION

AMD Sterile Dry Wipes		Quantity per Pouch				
Size	Description	1	3	10		
9" x 9" (23cm x 23cm)	AMD Sterile Dry Wipe	W60A01A	W60A03A	W60A10A		

CHARACTERISTICS

$65 \text{gr} \pm 5 \text{g/m}^2$
0.28 ± 0.02 mm
350 mL/m ²
3 years
Store at room temperature, in a cool and dry place

CONTAMINATION CHARACTERISTICS

• 3 Wipes Triple wrapped

Release Analysis Trough Test IEST-RP-CC004.3	Specifications	Typical Value
NVR (IPA)	< 0.9 mg/g	0.671 mg/g
NVR (DIW)	< 0.8 mg/g	0.114 mg/g
lons Concentration (IC) Cl- Na+	< 30 ppm < 50 ppm	10.696 ppm 46.618 ppm
Liquid Particle Counting (LPC) \geq 0.5µm	< 500 (x10 ⁶ particles/m ²)	200 (x10 ⁶ particles/m ²)
Fibre release ≥ 100µm	< 500 fibres/cm ²	200 fibres/cm ²

PRODUCT INFORMATION

AMD sterile dry wipes are made with a hydroentangled, non-woven blend of polyester/cellulose (45% polyester and 55% cellulose) to form an extremely robust and absorbent material, ideal to be used as part of cleanroom sanitising and cleaning regimes of isolators, LAF cabinets, general cleanroom surfaces, spill control and device cleaning. The cleanroom compatible material combines the absorbent properties of a natural fibre, with the strength of a synthetic fibre and are absent of chemical binders.

Dry Wipes are packed in AMD's ISO 7 Cleanroom. They are supplied ready folded in a Triple Sterile Wrap format meaning a simple transfer process into your Cleanroom and reduced risk of contamination. This product is sterilised by gamma irradiation at a minimum of 25kGy. Available in several packaging configurations from an individually packaged wipe to economic multi-pack of 3 wipes.

All batches are cleanroom processed with lot number traceability and certificates of conformity and irradiation.

Aseptic Medical Devices





Individual Sachet IPA 70% Wipe

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ORDERING INFORMATION

Individual Sachet IPA 70% Wipe		Quantity per Pouch			
Description	Size	5	10	25	
AMD Sterile Wipe with 70% IPA	200mm x 120mm	W05A02A	W10A02A	W25A02A	

PRODUCT INFORMATION

In the course of aseptic manufacturing, there are small surfaces which require cleaning. To enable this activity in LAF cabinets and isolators AMD's range of small sterile wipes has been developed to meet this need.



ORDERING INFORMATION

Individual Sachet IPA 70% Wipe		Quantity per Pouch			
Description	Size	5	10	25	
B Braun Alcohol Wipes with 70% IPA	30mm x 65mm	W05A03B	W10A03B	W25A03B	

PRODUCT INFORMATION

B Braun Alcohol Pads are 30mm x 65mm and folded in half to fit the individual sealed foil pouch. The non-linting wipe is impregnated with 70% IPA.

Aseptic Medical Devices





Clinical Waste Bins

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ORDERING INFORMATION

Clinical Waste Bins	
Description	Part No.
1 Litre Cyto sharps Bin (Purple Lid) with lid attached, Sterile Triple Wrapped	B01A01P
2.5 Litre Cyto sharps Bin (Purple Lid) with lid unattached, Sterile Triple Wrapped	B01C02P
5 Litre Cyto sharps Bin (Purple Lid) with lid unattached, Sterile Triple Wrapped	B01C05P
7 Litre Cyto sharps Bin (Purple Lid) with lid unattached, Sterile Triple Wrapped	B01C07P
0.6 Litre sharps Bin (Yellow Lid) with lid attached, Sterile Triple Wrapped	B01C00Y
1 Litre sharps Bin (Yellow Lid) with lid attached, Sterile Triple Wrapped	B01C01Y
2.5 Litre sharps Bin (Yellow Lid) with lid unattached, Sterile Triple Wrapped	B01C02Y
5 Litre sharps Bin (Yellow Lid) with lid unattached, Sterile Triple Wrapped	B01C05Y
7 Litre sharps Bin (Yellow Lid) with lid unattached, Sterile Triple Wrapped	B01C07Y

O PRODUCT INFORMATION

Clinical waste bins are supplied sterile triple wrapped, ready for easy transfer into a controlled area. Apart from the 1 litre bins, lids are supplied detached (the lid is contained within primary pouch next to the bin).

Bins are manufactured under BS EN ISO 23907 - Sharps Injury Protection. AMD offer sterile cleanroom compatible triple-packed bins of 1 Litre, 2.5 Litre, 5 Litre and 7 Litre volumes and in two types, dependant on waste stream material.

Yellow Lid

For sharps including those contaminated with medicines other than those that are cytotoxic and cytostatic.

Purple Lid

For sharps including those contaminated with cytotoxic and cytostatic medicines.

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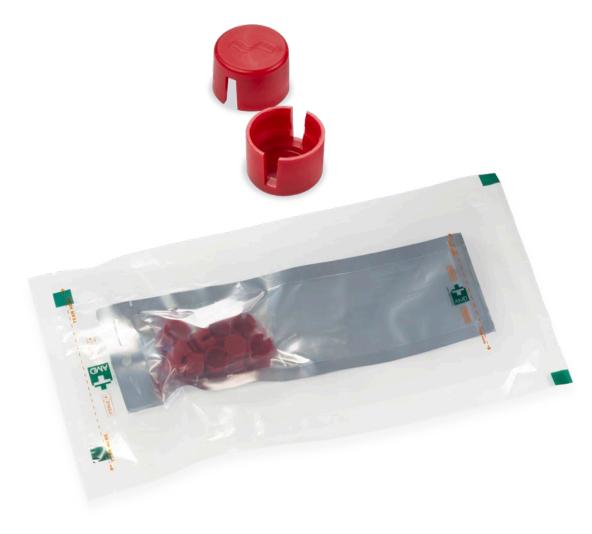
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• Fresenius Free Flex Caps (Red)

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ORDERING INFORMATION

Fresenius Free Flex Caps	Qty per Pouch	
Description	5	10
Fresenius Free Flex Caps (Red)	C05A01B	C10A01B

C PRODUCT INFORMATION

The free flex port cap is manufactured by Fresenius Kabi for use with Freeflex additive port and supplied in Aseptic Medical Devices standard triple sterile wrapped. Please see the above table for the options available.

Aseptic Medical Devices



Consumables



• Waste Bags

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ORDERING INFORMATION

Waste Bags	Quantity per Pouch		
Description	5	10	20
Sterile Polyethylene Zip Lock Bag 152mm x 228mm	POA	Z10B05W	POA
Sterile Polyethylene Zip Lock Bag 210mm x 297mm	POA	Z10B10W	POA
Sterile Polyethylene Zip Lock Bag 300mm x 405mm	Z05B20W	Z10B20W	Z20B20W
Large Transfer Waste Bags 600mm x 900mm	POA	X10A30A	POA

C PRODUCT INFORMATION

In the course of aseptic manufacture a significant non-sharps waste stream can be generated. For ease of removal from LAF cabinets or VHP isolators, AMD has developed a range of sterile polyethylene 'Zip Lock' waste bags and also provide a much larger sterile (non zip lock) bag for use in outer preparation areas. These products are carefully folded and placed into triple packing using Aseptic Medical Devices' own specialist pouch: PeroxyMet/PeroxyClear.



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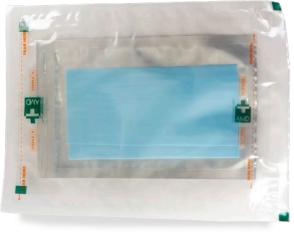


• Sterile Preparation Mats

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260mm x 200mm



ORDERING INFORMATION

Sterile Preparation Mat		
Description	Pack of 1	
Sterile Preparation Spill Mat (260mm x 200mm)	Z01A01A	
Sterile Preparation Spill Mat, full sized (270mm x 410mm)	Z01A02A	

PRODUCT INFORMATION

is very low linting

The AMD cleanroom sterile preparation mats have following properties:

- Suitable for use in up to ISO 5 areas as it

- Latex free
- High liquid holding capacity, porous top layer, bonded reservoir layer and impermeable back layer

There are two mat sizes available:

- Small 260mm x 200mm -
- folded into one third
 Large 270mm x 410mm folded in half

The mats are folded into our pouches, one mat per pouch, and each pouch is double outer wrapped.

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• Sterile Kwill (Luer Slip)

Formatted for Aseptic Pharmacy AMD Sterile Triple Wrapped Consumables

ORDERING INFORMATION

Sterile Kwill (Luer Slip)		Quantity per Pouch	
Description Length		5	11
Kwill (Luer Slip)	127mm	Z05A01K	Z11A01K



PRODUCT INFORMATION

Sterile Luer Slip Kwill for drawing up of liquids, syrups and other viscous solutions, when attached to a syringe. It is virtually transparent and will not kink when in use. The Kwill is 127mm in length, with an external diameter of 4.95mm and bore diameter of 3.94mm.

Each Kwill is individually packed within the primary pouch, this is to reduce the risk of contamination by a gloved hand whilst removing one from an open pouch.

Aseptic Medical Devices





O Sterile Cleanroom Pens

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Fine Tip



🗘 Ultra Fine Tip



ORDERING INFORMATION

Sterile Cleanroom Pens	
Description	Pack of 1
Ball point Pen, Black Ink	X01A10J
Permanent marker pen (Ultra fine Tip)	X01A10K
Permanent marker pen (fine Tip) Black	X01A10L
Permanent marker pen (fine Tip) Blue	X01A10M
Ball Point Pen, Blue Ink	X01A10N

PRODUCT INFORMATION

AMD have made available two types of cleanroom compatible pens:

- Permanent Marker Pens
- Ballpoint Pens

Each is suited to ISO 5 GMP cleanroom use and are offered individually packaged and gamma sterilised in AMD VHP and alcohol impermeable pouches, with double outer wraps. All are batch coded and provided with a Certificate of Conformity.

Permanent Marker Pens

Writes indelibly on paper and most plastics:

- Black or blue ink available in Fine Tip
- Ultra Fine Tip in black

Ballpoint Pens

Simple ballpoint style

Black or Blue ink available

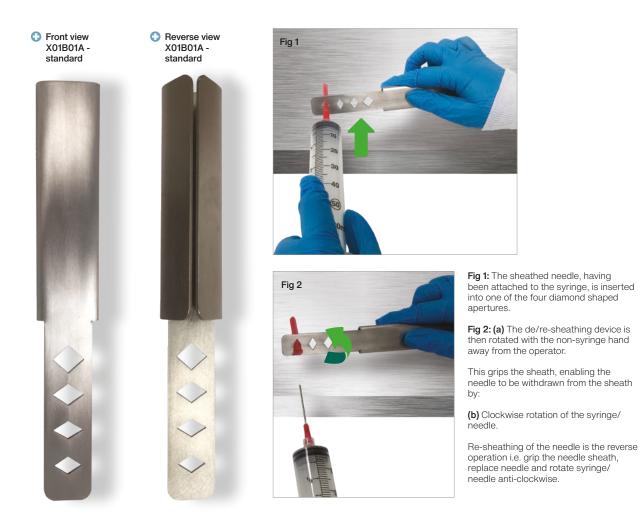
Utilising triple packing using Aseptic Medical Devices' own specialist pouch: PeroxyMet / PeroxyClear.



Aseptic Medical Devices

O AMD Stainless Steel (316L) Needle De-sheath/Re-sheath Device

Parts Nos. X01B01A (Standard)



ORDERING INFORMATION

AMD Stainless Steel 316L	
Description	AMD Part No.
AMD Stainless steel (316L) de/re sheathing device - standard design (non-sterile)	X01B01A

PRODUCT INFORMATION

Designed and manufactured by AMD this device is manufactured from 316L stainless steel in once piece. This allows pharmacy operators to more safely remove and replace needle sheaths freeing the operator from close proximity to the needle. Suitable for left and right handed use. Product is supplied ultrasonically cleanroom cleaned, non-sterile in a polyethylene bag. Registered design No. 4040973.

Aseptic Medical Devices



Shawseal TS2 Pneumatic Pouch Sealer

AMD Hardware







Standard Seal Profiles

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C Above and below - examples of the broad textured seal produced by the Shawseal.

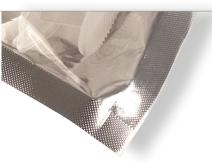
C TECHNICAL SPECIFICATION

Α

Model Number	W	D	н	Max Seal Width
PPS300-TS2	375mm	260mm	140mm	320mm
PPS400-TS2	475mm	260mm	140mm	420mm
PPS500-TS2	575mm	260mm	140mm	520mm
PPS Stand	460mm	460mm	900mm	Not applicable

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PRODUCT INFORMATION

On the TS2, seal temperature, pressure and dwell time settings can all be altered. Operation will not be allowed until the setpoints have been reached. Settings can only be varied via a PIN-protected screen, giving an added layer of security to the operation.

Within the touchscreen interface are a number of useful tools including batch and master counters and a 'calibration due' and 'calibration expired' notification as well as the ability to 'data-log' every seal actuation. Once activated, the seal temperature, pressure and dwell time are logged along with a time and machine serial number stamp. This data can then be exported out as a spreadsheet allowing the TS2 and its sealing process to be comprehensively and reliably validated.

There are a wide choice of options available offering bespoke customisation to individual requirements. The units are finished in stainless steel or powder coated making them ideal for cleanroom or laboratory settings. Three sizes of unit are available starting with the Shawseal PPS300-TS2 which can accommodate sealing widths up to 320mm. For widths up to 420 / 520mm Shawseal PPS400-TS2 AND PPS500-TS2 are the solution. Units can be supplied for bench mounting or complete with stand.

Please note: Shawseal TS2 sealers are not suitable for use with polythene bags.

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O Notes

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