



Aseptic Pharmacy Medical Device & Consumables

Product Brochure





+ Contacting AMD Aseptic Medical Devices

+ OFFICE ADDRESS




-  Newmarket Drive, Derby DE24 8SW
-  www.asepticmedical.com

+ ENQUIRIES


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+ 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 houses 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.

+ Key and Information

+ KEY

Icon	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.
	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)
	Sterile Sterilised item.

Ordering Information

Product coding.

Quantity per Pouch	Quality Mark	
5		
S05A25T		
S05A10T		

Denotes pouched products are manufactured and packaged to **UK Conformity Assessment Standards.**

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
- Vial Access
- Needles
- Filtration
- 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.

+ 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

Icons	Description
	Combi-Stopper
	BD Syringe 1ml, other sizes shown in text
	21 Gauge Needle, other gauges shown in text
	5 Micron Filter Needle 19 Gauge
	5 Micron Filter Straw
	Codan Universal Vented Vial Access Device with 0.2µm Vent Filter
	Codan Universal Vented Vial Access Device with 0.2µm Vent Filter and 5µm Liquid Filter
	Two-Way Fluid Adapter

+ NON-MEDICAL DEVICES

Icons	Description
	Black Permanent Marker Pen
	Black Ballpoint Pen

+ 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.



The label features a red vertical bar on the left. At the top, it shows icons for a combi-stopper and a 1ml syringe. To the right are UKCA 0086 and CE 2797 marks. Below these are fields for REF S05A01A, LOT 123456, and QTY x5. A date field shows 2024-07-28. A QR code is present with the UDI (01)05060466650299 (240)S05A01A (17)240728 (10)123456. A 'TRIPLE STERILE WRAPPED' banner is below the QR code. At the bottom, it lists EC REP Meddev Solutions Ltd, River House, Home Avenue, Newry, BT34 2DL, Northern Ireland, and an MD mark. A vertical label on the right edge reads 'AMD-OUT Issue 5'.

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+ AMD Pouches

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AMD Sterile Transfer Sets & Accessories

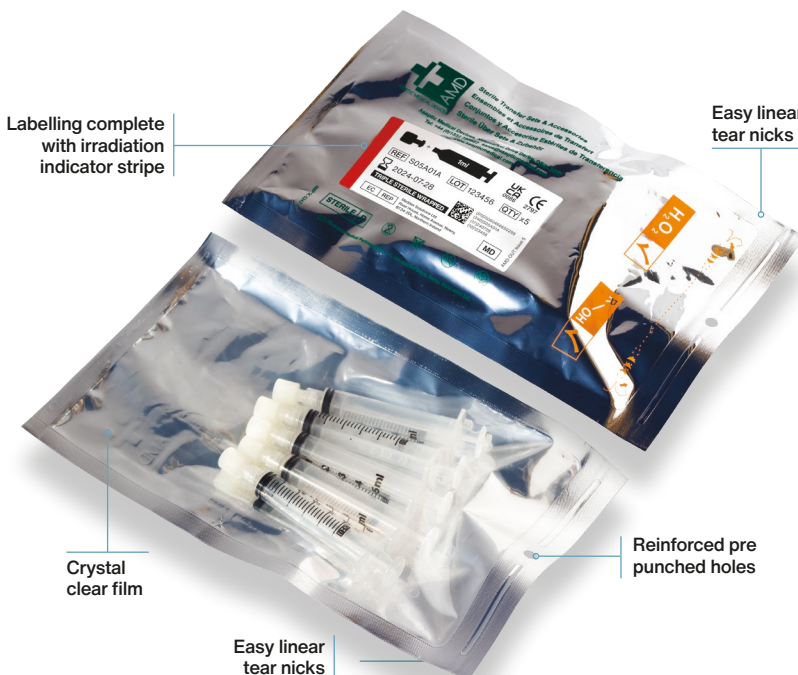
The best packaging solution for all transfer methods.

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-transparent devices may easily be inspected through the optically neutral transparent panel.

The pouch incorporates reinforced pre-punched 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.

+ 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

Transcription Label Size

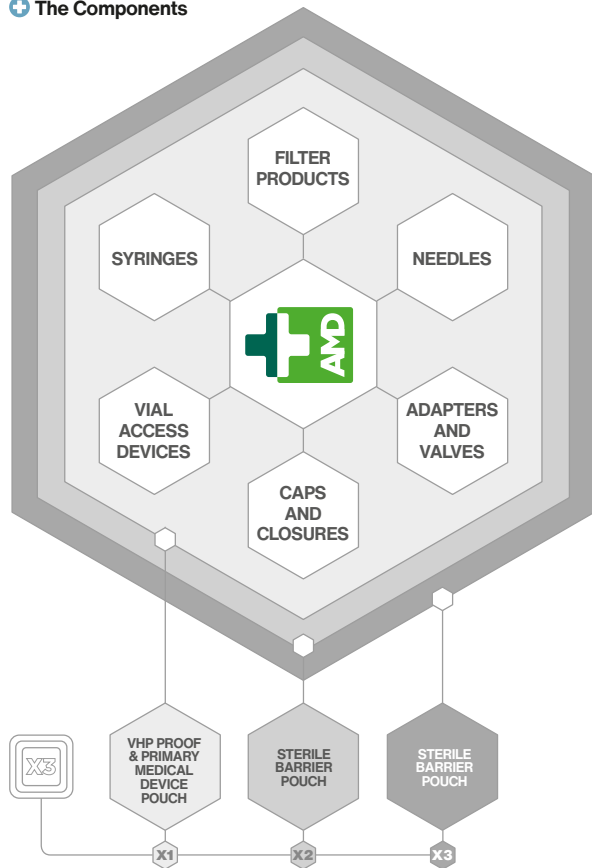




+ Customised Procedure Packs

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AMD Sterile Transfer Sets & Accessories

+ The Components



+ 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

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+ Traditional Transfer Process



Approximately
20 Minutes



OR

+ AMD Triple Wrap Transfer Process



2 Minutes



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**



+ BD Syringe Range

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AMD Sterile Transfer Sets & Accessories

BD Syringe Range



+ ORDERING INFORMATION

BD Syringes		Quantity per Pouch				Certification	
Size	Description	5	10	25	30	CE	UKCA
01ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A01A	S10A01A	S25A01A	POA	✓	✓
03ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A03A	S10A03A	S25A03A	POA	✓	✓
05ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A05A	S10A05A	S25A05A	POA	✓	✓
10ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A10A	S10A10A	S25A10A	POA	✓	✓
20ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A20A	S10A20A	S25A20A	POA	✓	✓
30ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A30A	S10A30A	POA	S30A30A	✓	✓
50ml	BD Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A50A	S10A50A	S25A50A	POA	✓	✓

+ 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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+ B Braun Syringe Range

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AMD Sterile Transfer Sets & Accessories



B Braun Syringe Range

+ ORDERING INFORMATION

B Braun Syringes		Quantity per Pouch		Certification	
Size	Description	5	10	CE	UK
01ml	B Braun Injekt® Luer Slip Syringe Fitted with Natural Coloured Stopper	S05A01I	S10A01I	✓	✓
02ml	B Braun Injekt® Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A02I	S10A02I	✓	✓
05ml	B Braun Injekt® Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A05I	S10A05I	✓	✓
10ml	B Braun Injekt® Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A10I	S10A10I	✓	✓
20ml	B Braun Injekt® Luer Lock Syringe Fitted with Natural Coloured Stopper	S05A20I	S10A20I	✓	✓

+ 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.

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+ BD Syringes fitted with Needles

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AMD Sterile Transfer Sets & Accessories

+ 5ml BD Syringe with 23 Gauge needle attached



+ 10ml BD Syringe with 21 Gauge needle attached



+ ORDERING INFORMATION

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

+ 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.

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+ AMD Vented Vial Access Devices

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 AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

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

+ 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 air-vent 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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+ BD SmartSite™ Vented Vial Access Devices

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AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

BD Smartsite™ Vented Vial Access Devices				Quantity per Pouch		Certification	
Description	Vial Size	Closed Pathway	Aeration and Venting Filter	5	10	CE	UK CA
BD SmartSite™ Vented Vial Access Device	Universal	Yes	Hydrophobic 0.2µm Filter	P05A00A	P10A00A	✓	✓
BD SmartSite™ Vented Vial Access Device	13mm	Yes	Hydrophobic 0.2µm Filter	P05A13A	P10A13A	✓	✓
BD SmartSite™ Vented Vial Access Device	20mm	Yes	Hydrophobic 0.2µm Filter	P05A20A	P10A20A	✓	✓

+ 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.

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+ Codan Vented Universal Vial Access Devices

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+ Codan 0.2µm hydrophobic vent only spike



+ Codan 0.2µm hydrophobic vent spike with 5µm liquid filter



+ 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	CE	UKPS
Codan Spike	Universal	No	Hydrophobic 0.2µm Filter	-	P05A01C	P10A01C	P25A01C	P50A01C	✓	✓
Codan Spike	Universal	No	Hydrophobic 0.2µm Filter	5µm Filter	P05A05C	POA	P25A05C	POA	✓	✓

+ 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.

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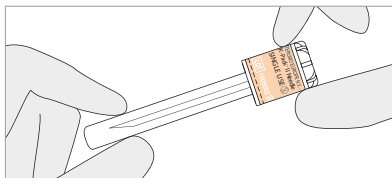


+ Encapsulated Needles for Syringe Filling

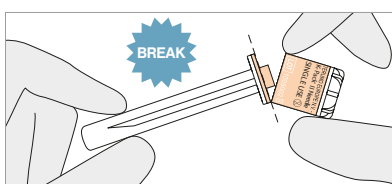
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AMD Sterile Transfer Sets & Accessories

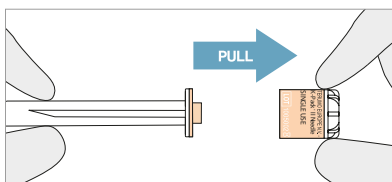
How to access the hub of the Encapsulated Needle



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	CE	UKCA
Encapsulated Needle - 38mm (1.5") in Length	18 Gauge	N05A18T	N10A18T	N25A18T	N50A18T	N00A18T	✓	✓
Encapsulated Needle - 38mm (1.5") in Length	19 Gauge	N05A19T	N10A19T	N25A19T	N50A19A	N00A19T	✓	✓
Encapsulated Needle - 38mm (1.5") in Length	21 Gauge	N05A21T	N10A21T	N25A21T	N50A21T	POA	✓	✓
Encapsulated Needle - 32mm (1.25") in Length	23 Gauge	N05A23T	N10A23T	N25A23T	N50A23T	POA	✓	✓

+ 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.

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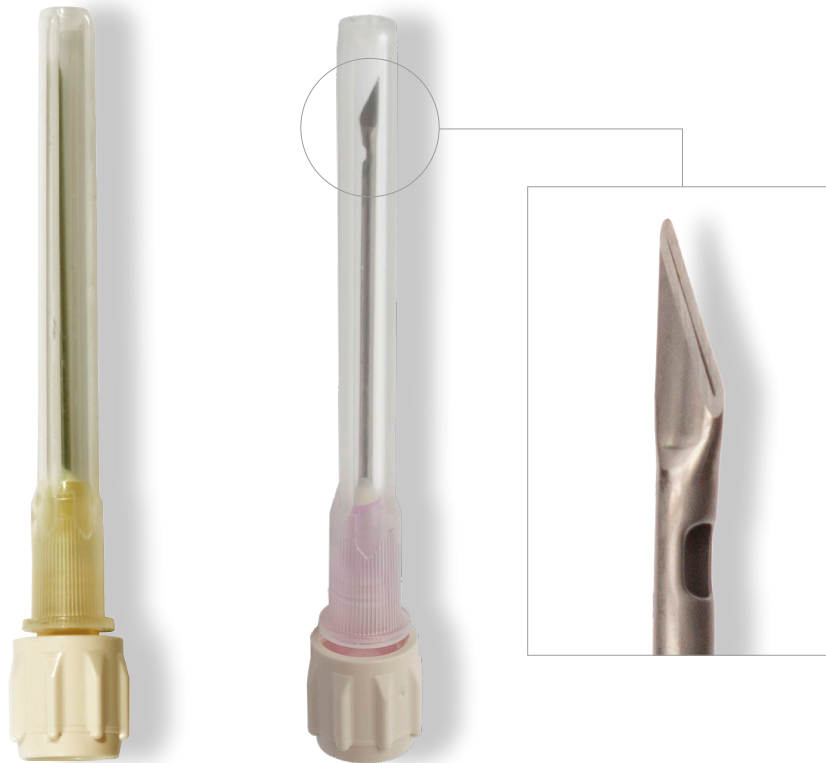
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+ Capped Needles for Syringe Filling

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AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

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

+ 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.

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+ Filter Needles

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AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

Filter Needles		Quantity per Pouch			Certification	
Description	Gauge	5	10	25	CE	UKCA
BD Blunt Needle with 5µm Filter - 38mm (1.5") in Length (Capped)	18 Gauge	F05A06B	F10A06B	POA	✓	✓
B Braun Needle with 5µm Filter - 38mm (1.5") in Length (Capped)	19 Gauge	F05A01X	F10A01X	F25A01X	✓	✓

+ 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.

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

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+ Example 1
18 Gauge blunt needle linked to BD SmartSite™ with pin-less cap protector.



+ Example 2
19 Gauge BD needle linked to 0.45µm filter and BD SmartSite™ valve (pin-less cap protected).



+ ORDERING INFORMATION

BD Smartsite™ supplied in the below combinations				Quantity per Pouch		Certification	
Needle Type	Gauge	Length	Description	3	5	CE	UK CA
BD Blunt Fill	18 Gauge	38mm (1.5")	No filter	L03A96R	L05A96R	✓	✓
Regular Bevelled Needle	19 Gauge	38mm (1.5")	No filter	L03A96P	L05A96P	✓	✓
Regular Bevelled Needle	19 Gauge	38mm (1.5")	5µm CA membrane 28mm diameter	L03A97P	L05A97P	✓	✓
Regular Bevelled Needle	19 Gauge	38mm (1.5")	0.2µm SFCA membrane 28mm diameter	L03A99P	L05A99P	✓	✓
Regular Bevelled Needle	21 Gauge	38mm (1.5")	0.2µm SFCA membrane 28mm diameter	L03A99S	L05A99S	✓	✓

+ 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 withstand 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 - 0.2µm, 0.45µm and 5µm are offered as options, and in a variety of pouched quantities.

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+ Filter Straws

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AMD Sterile Transfer Sets & Accessories

+ Filter Straw - B Braun



+ ORDERING INFORMATION

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

+ 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.

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+ Syringe Filter Devices

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AMD Sterile Transfer Sets & Accessories



+ 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	CE	UK RA
28mm Diameter Syringe Filters - Female Luer Lock Inlet, Male Luer Lock Outlet	0.2µm	No	Sterilising Grade	SFCA*	F05A02A	✓	✓
	0.2µm	No	Sterilising Grade	PES**	F05A02P	✓	✓
	0.45µm	No	Bioburden Reduction	SFCA*	F05A45A	✓	✓
	5.0µm	No	Particulate Removal	CA***	F05A05A	✓	✓
28mm Diameter Syringe Filters with SmartSite Valve Upstream - Female Luer Lock Inlet, Male Luer Lock Outlet	5.0µm	Yes	Particulate Removal	CA***	F05A05B	✓	✓

* 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 pre-linked 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.



+ Two-Way Fluid Connector

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AMD Sterile Transfer Sets & Accessories



Sterilisation process may cause the product to change colour.

+ ORDERING INFORMATION

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

+ PRODUCT INFORMATION

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

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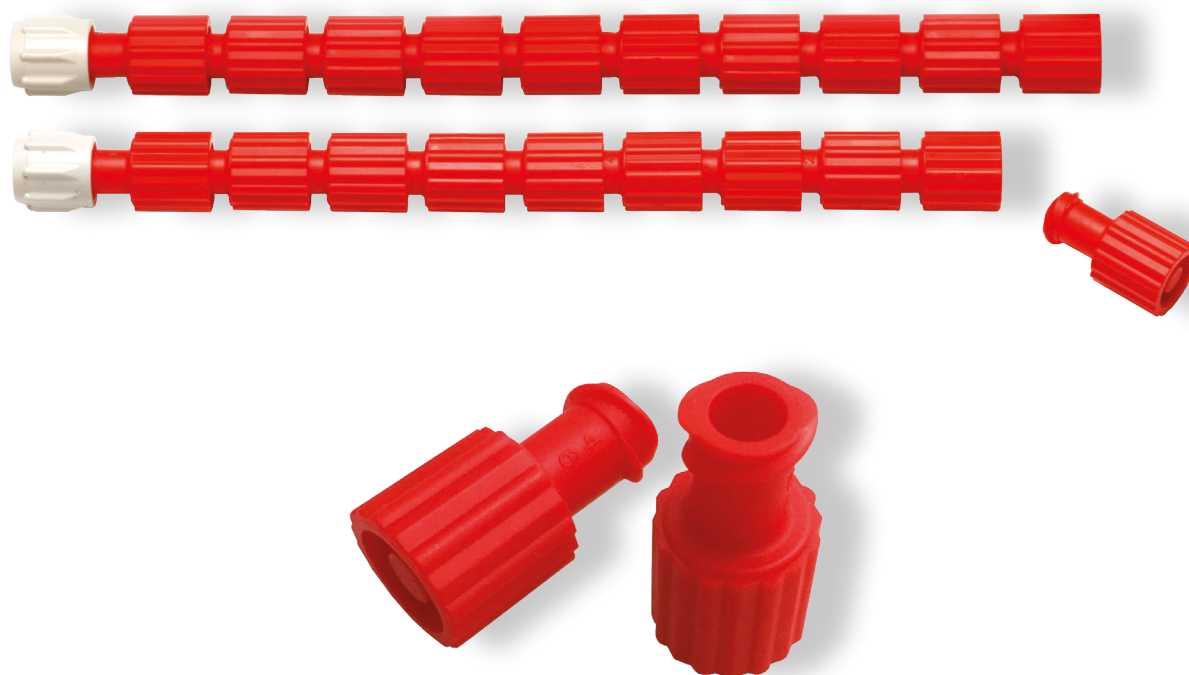




+ Syringe Closure Combi-Stoppers

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AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

AMD Closure Combi-Stoppers (Red) Triple Outer Wrapped	Quantity per Pouch				Certification	
Description	5	10	25	50	CE	UK
AMD Closure Combi-Stopper (red) in Rods	C05A01A	C10A01A	C25A01A	C50A01A	✓	✓

+ 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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+ AMD Mini Cap

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 AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

AMD Mini Cap	Quantity per Pouch			Certification
	5	10	25	
Description				UK CA
AMD Mini Cap	C05A03R	C10A03R	POA	✓

+ 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.

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+ AMD Syringe Clamshells



For syringes from
01ml to 05ml

For syringes from
20ml to 50ml

+ 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

+ 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.

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+ AMD Isolator Cleaning Tool and Bonnet

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AMD Sterile Triple Wrapped Consumables



+ 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



+ AMD Sterile Dry Wipe

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AMD Sterile Triple Wrapped Consumables



+ Single Wipe
Triple wrapped



+ 3 Wipes
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

Weight	65 gr ± 5 g/m ²
Thickness	0.28 ± 0.02 mm
Absorption capacity	350 mL/m ²
Shelf life	3 years
Storage conditions	Store at room temperature, in a cool and dry place

+ CONTAMINATION CHARACTERISTICS

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
Ions Concentration (IC) Cl- Na+	< 30 ppm < 50 ppm	10.696 ppm 46.618 ppm
Liquid Particle Counting (LPC) ≥ 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.

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+ Individual Sachet IPA 70% Wipe

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AMD Sterile Triple Wrapped Consumables



+ 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.

+ B Braun Wipe

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AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

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

+ 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.

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+ Clinical Waste Bins

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AMD Sterile Triple Wrapped Consumables

+ Full Yellow Bin Range



+ Example Yellow Bin - 1 Litre



+ Full Cyto Bin Range



+ Example Cyto Bin - 1 Litre



+ 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

+ 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

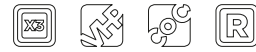
For sharps including those contaminated with cytotoxic and cytostatic medicines.

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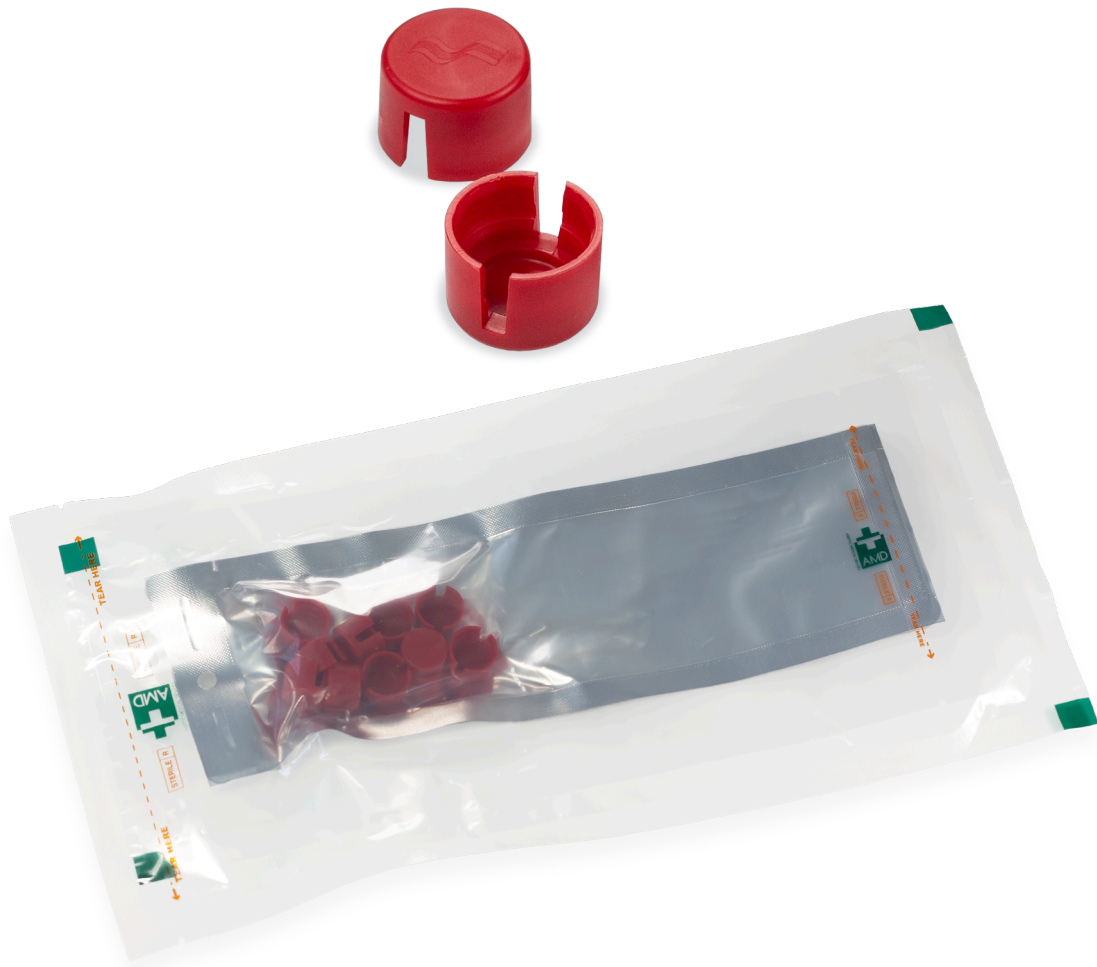
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+ Fresenius Free Flex Caps (Red)

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 AMD Sterile Transfer Sets & Accessories



+ ORDERING INFORMATION

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

+ 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.

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+ Waste Bags

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AMD Sterile Triple Wrapped Consumables



+ ORDERING INFORMATION

Waste Bags	Quantity per Pouch		
	5	10	20
Description			
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

+ 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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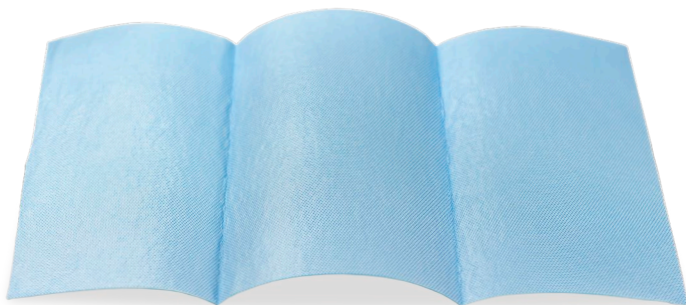
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+ Sterile Preparation Mats

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AMD Sterile Triple Wrapped Consumables



260mm x 200mm



+ ORDERING INFORMATION

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

There are two mat sizes available:

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

+ PRODUCT INFORMATION

The AMD cleanroom sterile preparation mats have following properties:

- Suitable for use in up to ISO 5 areas as it is very low linting
- Latex free
- High liquid holding capacity, porous top layer, bonded reservoir layer and impermeable back layer

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



+ Sterile Kwill (Luer Slip)

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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.

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+ Sterile Cleanroom Pens

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AMD Sterile Triple Wrapped Consumables



+ 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.

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

Parts Nos. X01B01A (Standard)

+ Front view
X01B01A -
standard



+ Reverse view
X01B01A -
standard

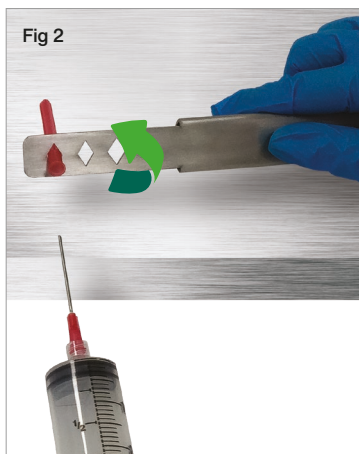
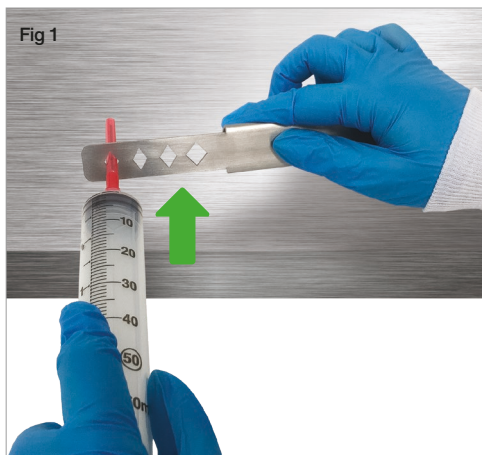


Fig 1: The sheathed needle, having been attached to the syringe, is inserted into one of the four diamond shaped apertures.

Fig 2: (a) The de/re-sheathing device is then rotated with the non-syringe hand away from the operator.

This grips the sheath, enabling the needle to be withdrawn from the sheath by:

(b) Clockwise rotation of the syringe/needle.

Re-sheathing of the needle is the reverse operation i.e. grip the needle sheath, replace needle and rotate syringe/needle anti-clockwise.

+ 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

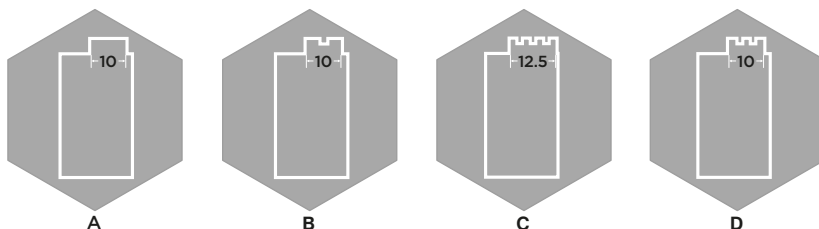
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+ Shawseal TS2 Pneumatic Pouch Sealer

AMD Hardware



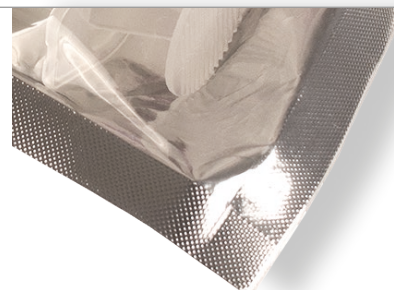
+ Standard Seal Profiles



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

+ TECHNICAL SPECIFICATION

Model Number	W	D	H	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



+ PRODUCT INFORMATION

On the TS2, seal temperature, pressure and dwell time settings can all be altered. Operation will not be allowed until the set-points 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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