



VIGTIGT: SIKKERHEDSINFORMATION – MDS-21-4072

Infusionssæt til

Alaris™-pumper (GP, VP, CC, GW/GW800, SE, IVAC 590-serien) (Appendiks 1)

Gravitations-infusionssæt & konnektorer (Appendiks 2)

Type af foranstaltning: Fjernelse af produkt

11-03-2021

Til: Klinisk personale, Risk Managers, biomedicinsk personale

Dette brev indeholder vigtig information, der kræver **omgående** handling.

Kære Kunde

BD foretager en sikkerhedsmæssig korrigerende foranstaltning for at fjerne alle varepartier af distribuerede:

- **Infusionssæt til Alaris™-pumper (GP, VP, CC, GW/GW800 and SE, IVAC 590-serien) og**
- **Gravitations-infusionssæt og konnektorer.**

Se appendiks 1 og 2 for en komplet liste over alle berørte produktvarenumre (REFs). Repræsentative billeder af produkterne kan ses i tabel 1 og 2 herunder.



Beskrivelse af problemet

BD har fra en tredjepartsleverandør af steriliseringsydelse fået underretning om, at de bevidst har forfalsket optegnelser over steriliseringsprocessen relateret til behandlingen af BD-produkter.






BD igangsatte øjeblikkeligt en undersøgelse og har konstateret, at BD ikke kan garantere steriliteten af de produkter, der er nævnt i de vedlagte appendikser. Vi fjerner derfor produkterne fra markedet.

Omfanget af denne fjernelse af produkter inkluderer også ikke-udløbne partier af de distribuerede SKU'er nævnt i appendikserne. BD har et on-line-redskab, der kan hjælpe i identifikationen af berørte lot-numre bd.com/MDS-21-4072

Tabel 1: Repræsentative eksempler på infusionsæt til Alaris™-pumper (GP, VP, CC, GW/GW800 og SE), IVAC 590-serien

	Produkt	Formål	Alternativ
	Infusionspumpe til stort volumen	Præcis IV-infusion og -transfusion på afdelinger, operationsstuer og intensivafdelinger	Ingen alternative sæt – se klinisk forslag herunder
	Sprøjtepumpesæt med in-line-trykovervågning	Præcis IV-infusion og -transfusion på afdelinger, operationsstuer og intensivafdelinger	Ingen alternative sæt – se klinisk forslag herunder

Tabel 2: Repræsentative eksempler på gravitationssæt og konnektorer

	Produkt	Formål	Alternativ
	Primære og sekundære administrationssæt	IV-administration af væsker og lægemidler	Andre ikke-dedikerede BD IV-sæt eller konkurrerende sortiment. Kontakt jeres lokale repræsentant
	Transfusionssæt	Blodtransfusioner	Andre BD transfusionsæt eller konkurrerende sortiment. Kontakt jeres lokale repræsentant
	Flervejs onkologi-sæt	Infusion af onkologiske lægemidler	Andre BD onkologisæt eller konkurrerende sortiment. Kontakt jeres lokale repræsentant
	SmartSite™-nålefri konnektor	Nålefri konnektor, der giver kateteradgang til infusion	Anden BD konnektor-teknologi eller konkurrerende sortiment. Kontakt jeres lokale repræsentant
	Adgangsordninger til hætteglas og poser	Nålefri adgang til hætteglas og poser med beskyttelse mod farlige lægemidler	Kontakt jeres lokale repræsentant

Klinisk påvirkning:

Anvendelsen af ikke-sterile produkter i et klinisk miljø kan føre til en øget infektionsrisiko, der vil kunne medføre alvorlig skade eller livstruende tilstand.

BD har ikke identificeret nogen indrapporteringer af utilsigtede hændelser eller alvorlig patientskade, der kan associeres med denne sikkerhedsmæssige korrigerende foranstaltning. Der kræves ingen særlig patientopfølgning, hvis produktet allerede har været anvendt.



Råd til klinisk personale:

1. Stop anvendelse af alle berørte lot-numre i jeres besiddelse.
2. Indtil BD genoptager forsendelse, anbefales det at:
 - a. Kontakt jeres lokale BD-repræsentant for at tale om mulige produktalternativer.
 - b. Hvor der ikke kan findes produktalternativer, overvej generelle tiltag for at garantere infusionskontinuitet, fx:

For brugere af Alaris™ CC Plus:

- i) Spørg jeres lokale repræsentant og teknisk support om muligheden for midlertidigt at omstille jeres pumpe til "*Semi-dedicated*"-tilstand (muliggør pumpefunktion kun i ml/h og uden in-line-trykovervågning) og bruge standard forlængersæt som alternativ.
- ii) Kræves der filtrering, kan der anvendes add-on-filtre (0,22-/1,2µm-filtre).
- iii) Grundet begrænset beholdning af forlængersæt med trykplade, vil in-line trykmålinger måske ikke være mulige. Derfor anbefaler vi at anvende en trykplade på EN pumpe, den tættest på patienten, således at denne kan overvåge in-line-trykket på alle pumper i systemet (dvs. multi-infusionsopsætning).

For brugere af Alaris™ GP Plus & Alaris™ SE & Alaris™ IVAC 590-serien:

- i) Overvej anvendelse af sprøjtepumper til høj risiko lægemidler, der kræver kontinuerlig infusion (inklusive vægtbaserede lægemidler) eller gravitationsalternativer, hvis det er klinisk tilladeligt.
- ii) Anvend enhver tilgængelig alternativ pumpe.
- iii) Overvej anvendelse af gravitations infusion til infusioner af stort volumen, der ikke kræver højpræcision eller er vægtbaserede.
- iv) Når der indgives parenteral ernæring, kemoterapi eller andre infusioner, der kræver infusionssæt med filtre (0,2 eller 1,2 µm), kan det overvejes at anvende add-on in-line-filtre ved gravitations-infusioner (med eller uden flow-rate-regulatorer).
- v) Overvej anvendelse af slanger med IV-flow-rate-regulatorer med integreret kalibreret skala (fx RATE FLOW-regulator, DIAL-A-FLOW), kan anvendes til at regulere flow-rate i stedet for rulleklemmen.

For brugere af Alaris™ VP Plus og GW/GW800:

- i) Da der ikke findes erstatningsalternativer til pumpesæt, kan gravitations infusion være den eneste mulighed, ellers anvend enhver tilgængelig alternativ pumpe.
- ii) Overvej anvendelse af sprøjtepumper til høj risiko lægemidler, der kræver kontinuerlig infusion (inklusive vægtbaserede lægemidler). Anbefalingerne af sæt herunder er måske ikke identiske med de sæt I har anvendt, men vil matche de essentielle kliniske krav.
- iii) Overvej anvendelse af gravitations infusion til infusioner af stort volumen, der ikke kræver højpræcision eller er vægtbaserede.
- iv) Når der indgives parenteral ernæring, kemoterapi eller andre infusioner, der kræver infusionssæt med filtre (0,2 eller 1,2 µm), kan det overvejes at anvende add-on in-line-filtre ved gravitations-infusioner (med eller uden flow-rate-regulatorer).
- v) Overvej anvendelse af slanger med IV-flow-rate-regulatorer med integreret kalibreret skala (fx RATE FLOW-regulator, DIAL-A-FLOW), kan anvendes til at regulere flow-rate i stedet for rulleklemmen.

- c. Overvej alternativer til jeres behov for infusionsbehandlinger i overensstemmelse med enten nationale eller lokale retningslinjer eller retningslinjer fra **ISMP (Institute for Safe Medication Practices)**, et institut tilknyttet ECRI), alternative infusionsbehandlingsmuligheder i tilfælde af leveringsproblemer af IV-engangsudstyr:
- i. **Omstilling fra IV til oral.** Hospitaler bør skifte patienter fra IV-behandling til oral behandling, så hurtigt som muligt. Dette skal overvejes for alle egnede patienter, der kan synke og som opfylder andre definerede kriterier (fx feberfri), inklusive patienter på akutafdelingen og langtidsplejefaciliteter tilknyttet sundhedssektoren.
 - ii. **Anvend bolus-injektion i stedet for infusion.** Administrering af lægemidler ved bolus-injektion i stedet for som sekundær infusion, bør også overvejes, hvor muligt. Hospitals-specifikke retningslinjer for bolus-injektion, såvel som ISMP-retningslinjerne *Safe Practice Guidelines for Adult IV Push Medications*, skal konsulteres, inden dette alternativ overvejes.
 - iii. **Potentiel mulighed for gravitations-infusion.** Eksempler kan omfatte IV-hydrering, nogle IV-antibiotika, ikke- høj risiko lægemidler og andre lægemidler, der vil kunne være egnede til gravitations-infusion ved vurdering under ordinerings og indgivelse. For at måle flow-rate i ml/h ved gravitations-infusion, er det nødvendigt at vide, hvor mange dråber per ml administrationssættet leverer (fx 10, 15, 20, 60 dråber pr ml). Antallet af dråber kontrolleres af rulleklemmen (klemme til kontrol af gravitations-flow).
 - iv. **Andre alternativer.** Andre alternativer for typer af infusionsudstyr bør overvejes ved mangel på infusionspumper, så som volumetrisk burette, elastomerisk udstyr og andre ikke-elektroniske rate-controllers.

Kilde: ISMP (april 2020). Tilgængelig på <https://ismp.org/resources/planning-anticipated-shortage-smart-infusion-pumps-and-dedicated-administration-sets>

Det, I skal gøre nu:

1. Del denne sikkerhedsinformation til alle i jeres organisation, der bør informeres.
 - o Hvis produktet er videredistribueret, beder vi jer identificere til hvem og fremsende denne sikkerhedsinformation til dem med det samme.
2. Brug BD online-redskabet bd.com/MDS-21-4072 til at identificere lot-numre i jeres lagerliste, der er berørt af denne tilbagekaldelse af produkter.
 - o **BEMÆRK:** Hvis I ikke kan tilgå online-redskabet, beder vi jer kontakte jeres lokale BD-repræsentant.
3. Tilbagehold og destruer alle dele af de berørte lot-numre, og udfyld tilbagemeldingsformularen på side 6, og returner den til bdnordicsfieldaction@bd.com til levering af erstatningsprodukter **snarest muligt, men ikke senere end 16. april 2021.**

Korrigerende foranstaltninger foretaget af BD

BD arbejder på at finde en anden sterilisationsmulighed til disse produkter.



Kontaktperson

Hvis I har spørgsmål til dette, beder vi jer kontakte jeres lokale BD-repræsentant eller det lokale BD-kontor på tlf. + 45 43 43 45 66 eller e-mail bddenmark@bd.com

Vi bekræfter, at de relevante regulatoriske myndigheder er blevet informeret om disse foranstaltninger.

BD er fokuseret på at forbedre sundhed på verdensplan. Vores primære mål er patientsikkerhed og brugersikkerhed samt at levere kvalitetsprodukter til jer. Vi undskylder for de ulemper, denne situation måtte forårsage, og takker jer på forhånd for at hjælpe BD med at håndtere denne situation, så hurtigt og effektivt som muligt.

Med venlig hilsen

A handwritten signature in blue ink that reads 'Klaus Hoerauf'.

Prof. Dr. Klaus Hoerauf, Vice
President Medical Affairs, EMEA
Region
BD Switzerland Sàrl

A handwritten signature in blue ink that reads 'Idal Beer'.

Idal Beer, MD
Vice President Medical Affairs,
Medication Management
Solutions

A handwritten signature in blue ink that reads 'Lorna Darrock'.

Lorna Darrock
Senior Manager, Post Market Quality,
BDX EMEA



Formular til kundetilbage melding – MDS-21-4072

Infusionssæt til Alaris™-pumper (GP, VP, CC, GW/GW800 and SE, IVAC 590-serien)
& gravitationssæt & konnektorer

Læs dette sammen med sikkerhedsinformation MDS-21-4072, og returner formularen udfyldt og underskrevet hurtigst muligt og **ikke senere end 16. april 2021** til bdnordicsfieldaction@bd.com

- **Jeg bekræfter at have læst og forstået denne sikkerhedsinformation, og at alle de anbefalede foranstaltninger er blevet implementeret som krævet.**

Sæt kryds i den relevante boks herunder

Vi har ingen af de berørte produkter, nævnt i appendiks 1 & 2, i vores besiddelse.

ELLER

Vi har enheder af de berørte produkter, nævnt i appendiks 1 & 2, i vores besiddelse, og jeg bekræfter, at følgende enheder er blevet destrueret/returneret til gengæld for erstatningsprodukt, som indikeret herunder (*Vær opmærksom på, at der vil kunne opleves forsinkelser for erstatningsprodukter alt efter produkttilgængelighed*).

SKU	Lot-nummer	Antal destrueret	SKU	Lot-nummer	Antal destrueret

Kunde-/virksomhedsnavn:	
Afdeling (hvis relevant):	
Adresse:	
Postnummer:	By:
Navn på kontaktperson:	
Jobtitel:	
Telefonnummer på kontaktperson:	E-mailadresse på kontaktperson:
Underskrift:	Dato:

Denne formular skal returneres til BD, før denne foranstaltning kan anses for gennemført hos jer.



Appendix 1: Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series)

All products listed in Appendix 1, manufactured by BD Switzerland Sàrl, Terre Bonne Park – A4, Route de Crassier 17, Eysins, Switzerland unless otherwise indicated.

Product Catalogue (REFs)	Product Name
Infusion Sets for Alaris™ CC Syringe Pump	
G30402M	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ 701/711/770/P7000 Pumps. EXTENSION SET.
G30453V	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ P7000 Pumps. EXTENSION SET. LIGHT RESISTANT. LOW SORBING (PE/PVC)
G30653V	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ P7000 Pumps. EXTENSION SET. LIGHT RESISTANT.
Infusion Sets for Alaris™ GP Volumetric Pump	
60593	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
60643	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.
60693	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
60793	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
60894	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.
60895	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.
60903	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
60980	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.
60093E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
60123E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 1.2 µm FILTER.
60173E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
60393E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION / BLOOD SET. 200 µm FILTER.
60693E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
60793E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
60950E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
60951E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
60952E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.
60953V	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 µm FILTER.
63200NYB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. NO FILTER.
63401EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63402BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63420EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63423BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63477EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.
Infusion Sets for Alaris™ GW Volumetric Pump	
273-001V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.



273-002V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.
273-003V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.
273-007V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. TRANSFUSION/BLOOD SET. 200 µm FILTER.
273-008EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free Valve. Alaris™ GW 800 Volumetric Pump. TRANSFUSION/BLOOD SET. 200 µm FILTER.
273-009V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 1.2µm FILTER.
273-022V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 0.2µm FILTER.
273-043V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LIGHT RESISTANT. ANTI-SIPHON VALVE. 15 µm FILTER.
273-053V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LOW SORBING. ANTI-SIPHON VALVE. 15 µm FILTER.
273-080EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LOW SORBING. ANTI-SIPHON VALVE. 15 µm FILTER.
273-103EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. BURETTE SET. ANTI-SIPHON VALVE. NO FILTER.
273-303EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. BURETTE SET. ANTI-SIPHON VALVE. NO FILTER.
273-304V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. 15 µm FILTER.
273-950EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
273-951EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
273-952EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. 15 µm FILTER.
273-954EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. 15 µm FILTER.
273-004V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. 15 µm FILTER.
273-005V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. NO FILTER.
0000TG00074	GW Calibration tubing
Infusion Sets for Alaris™ VP Volumetric Pump	
70096	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW PRIMING VOLUME. 15 µm FILTER.
70593	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
70641	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW PRIMING VOLUME. LIGHT RESISTANT. 15 µm FILTER.
70643	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.
70895	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.
70896	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.
70953	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 µm FILTER.
70033V	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 0.2 µm FILTER.
70093E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
70103E	Burette Set. No Filter. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. BURETTE SET. NO FILTER.
70123E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. LIGHT RESISTANT. 1.2 µm FILTER.
70125E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. UNVENTED. 1.2 µm FILTER.



70693E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
70793E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
70950E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
70951E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
70952E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.
70954E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.
70955E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. 2 SPIKE. VENTED. 15 µm FILTER.

Infusion Sets for Alaris™ SE Volumetric Pump

71980B	Alaris™ SE Pump. Transfusion/Blood Set.200 µm Filter.
72001EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72013EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. No Filter.
72024EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72304B	Alaris™ SE Pump. Infusion Set. 15 µm Filter.
72504EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72643EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. Light Resistant. 15 µm Filter.
72953B	Alaris™ SE Pump. Infusion Set. Low Sorbing. 15 µm Filter.
MF72950EB	Multi-infusion set. Oncology. Vented. 15 µm Filter.
MF72951EB	Multi-infusion set. Oncology. Vented. 15 µm Filter.
MF72952EB	Multi-infusion set. Oncology. Low Sorbing (TPU/EVA). Light Resistant. Vented. 15 µm Filter.
MF72954EB	Multi-infusion set. Oncology. Low Sorbing (TPU/EVA). Light Resistant. Vented. 15 µm Filter.

Infusion Sets for Alaris™ IVAC™ 590 Pump Volumetric Pump

G59073	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59123E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 1.2 µm FILTER.
G59173E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ needle-free system. INFUSION SET. NO FILTER.
G59293E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59593F	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
G59693FE	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
G59793	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59793E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
G59953V	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. LOW SORBING. 15 µm FILTER.
G59593	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59643	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.
G59693	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59693E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.



Appendix 2: Gravity IV sets & connectors

All product listed in Appendix 2, manufactured by BD Switzerland Sàrl, Terre Bonne Park – A4, Route de Crassier 17, Eysins, Switzerland unless otherwise indicated

Product Catalogue (REFs)	Product Name
Needle-free connectors stand-alone	
2000E7D	SmartSite™ Needle-Free Valve
ARD Sets	
388000	BD Gravity IV Set with Anti-Run Dry (ARD) technology and Auto Prime. Infusion Set. Vented.
388002	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented.
388004	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. Micro Infusion Set. Vented.
388006	BD Gravity IV set with Anti-Run Dry (ARD) Technology and AutoPrime. SmartSite™ Needle-free System. Micro Infusion Set. Vented.
388010	BD Gravity Burette Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. 150ml Micro Burette Set.
388013	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented.
388015	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented.
388017	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented. 0.2µm Filter.
388018	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented. 1.2µm Filter.
388019	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented.
388020	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented. 0.2µm Filter.
388021	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented. 1.2µm Filter.
388050	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. Back Check Valve. Infusion Set. Vented. Back Check Valve.
388051	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. BACK CHECK VALVE – SMARTSITE™ NEEDLE-FREE SYSTEM.
388053	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. INFUSION SET. VENTED. Gravity flow only.
388125	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. INFUSION SET. VENTED. Gravity flow only.
388126	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. BACK CHECK VALVE – SMARTSITE™ NEEDLE-FREE SYSTEM.
388136	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. 3WAY STOPCOCK. INFUSION SET. VENTED. Gravity flow only.
R87 Sets – Gravity/Pressure Rated Sets <i>Legal Manufacturer: Becton Dickinson Infusion Therapy AB, Florettgatan 29C PO Box 631, Helsingborg, Sweden.</i>	
396350	R87P Luer-Lock IG-P
396351	R87P Luer-Lock IG-P
396353	R87 RLS Luer-Lock IG-P
396354	R87P Luer-Lock IG-P
396357	R87 RLS Luer-Lock IG-P
396361	R87 G Precision Luer-Lock IG-G
396363	R87 V Luer-Lock IG-P
396368	R87 V Luer-Lock IG-P
396370	R87 G Precision Luer-Lock IG-G
396373	R87 V Luer-Lock IG-P
396377	R87 V Luer-Lock IG-P
396392	R87 G Precision Luer-Lock IG-G
Gravity infusion sets	



02008366189	Alaris™ Products. INFUSION SET. LOW SORBING. UNVENTED. 15 µm FILTER.
02008374189	Infusion set unvented. 15µm Filter
02008382189	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.
03500100208	Alaris™ Products. INFUSION SET. VENTED. 15 µm FILTER.
MF2309EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
MF2310EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. LOW SORBING (TPU/EVA) VENTED. 15 µm FILTER.
MF2311EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 0.2 µm FILTER.
03500304407	Alaris Products, Infusion Sets 15 µm Filter
03501410184	Universal Infusions set fur Druckinfusion
03508105208	Alaris™ Products. INFUSION SET. VENTED. 15 µm FILTER.
03508117442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508239442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508239448	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508240442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508241442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508242442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15µm FILTER.
03508317319	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 0.2 µm FILTER.
03508318429	Alaris™ Products. INFUSION SET. VENTED. 15 µm FILTER.
03508364318	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15 µm FILTER.
03508370319	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 0.2 µm FILTER.
03508411318	Alaris™ Products. INFUSION SET. LIGHT RESISTANT. LOW SORBING. VENTED. 15 µm FILTER.
03508422208	Infusion set, Light resistant. Vented. 15 µm Filter
03508367318	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15 µm FILTER.
Gravity blood sets	
12310100356	Transfusion/Blood Set. Unvented. 200 µm Filter.
12310100403	Transfusion set 200µm
12310105356	Transfusion/Blood Set. Unvented. 200 µm Filter.
12318381356	Transfusion/Blood Set. Unvented. 200 µm Filter.
12360100357	Transfusion/Blood Set. Vented. 200 µm Filter.
Secondary Sets	
MF2300EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. LOW SORBING (TPU/EVA) LIGHT RESISTANT. VENTED. BACK CHECK VALVE.
MF2301EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE.
MF2302EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE. 0.2 µm FILTER.
MF2303EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. BACK CHECK VALVE. FLOW CONTROLLER.
MF2304EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. MALE TO MALE. BACK CHECK VALVE.
04108362X10	Multi-way Connecting Set.
72946NE	Secondary Set. Oncology. Vented. Light Resistant.
72946NEX10	Secondary Set. Oncology. Vented. Light Resistant.
72947NE	Secondary Set. Oncology. Unvented. Light Resistant. Back Check Valve.
72948NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72949NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72950NE	Secondary Set. Oncology. Unvented. Light Resistant. Back Check Valve.
72951NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72951NEX10	Secondary Set. Oncology. Unvented. Back Check Valve.
72961NE	Secondary Set. Oncology. Vented. Back Check Valve.
72978NE	Secondary Set. Oncology. Vented. 0.2 µm Filter.
72979NE	Secondary Set. Oncology. Vented. 0.2 µm Filter.
72981NE	Secondary Set. Oncology. Vented. Back Check Valve.
72987NE	Secondary Set. Oncology. Light Resistant. Vented. Back Check Valve.
72988NE	Secondary Set. Oncology. Vented. Back Check Valve. 0.2 µm Filter.



Secondary Sets: Legal Manufacturer: Becton Dickinson and Company Limited, Pottery Road, Co. Dublin, Dun Laoghaire, Ireland

515302	SECONDARY SET (C61)
Flow controller sets	
03508060270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508067270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508068307	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15µm FILTER.
03508073270	Alaris™ Products. INFUSION SET. LOW SORBING. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508077270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508078270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508079270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508080404	Alaris™ Products. SmartSite™ Needle-free System. MULTI-INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508083440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508084440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508085440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
04108060270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108064270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108073270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108074270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108078411	Alaris™ Products. SmartSite™ Needle-free System. EXTENSION SET. FLOW CONTROLLER.
Accessories and add-ons	
2305E	Multi-way Connecting Set
2306E	Multi-way Connecting Set
04108341419	Multi-way Connecting Set.
04108362418	Multi-way Connecting Set.
MF22250EV	Alaris™ Products. SmartSite™ Needle-free System. BAG ACCESS DEVICE. VENTED.
04302243317	BD CHECK VALVE
04302260452	Anti-siphon valve
397015	FloPro
04000380192	Alaris™ Products. TRANSFER DEVICE
04002040071	Alaris Products Transfer Device
04302434353	Protection cap for female luer lock
04302398353	Injection site cap
TIVA Sets	
500-002V	Alaris™ Products. TIVA 2 WAY SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.
500-003V	Alaris™ Products. TIVA 3 WAY SET. ANTI-SIPHON VALVES. BACK CHECK VALVE.
500-012V	Alaris™ Products. TIVA 2 WAY EXTENSION SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.
500-013V	Alaris™ Products. TIVA 3 WAY EXTENSION SET. ANTI-SIPHON VALVES. BACK CHECK VALVE.
Administration & Catheter Extension Sets	
G40020B	Alaris™ Products. EXTENSION SET
G40320V	Alaris™ Products. EXTENSION SET. LIGHT RESISTANT.
500-021EV	Alaris™ Products. SmartSite™ Needle-free System. 2 WAY EXTENSION SET WITH CLAMPS
500-031EV	Alaris™ Products. SmartSite™ Needle-free System. 3 WAY EXTENSION SET WITH CLAMPS
MF22203EV	Extension Set. Back Check Valve.
MF22280EV	Extension Set. 3-Way Stopcock
MF22283EV	Extension Set. 3-Way Stopcock
MF22284EV	Extension Set. 3-Way Stopcock
04301433200	Alaris Products™. 4-WAY STOPCOCK
04301462200	Alaris Products™. 4-WAY STOPCOCK
04301463200	Alaris Products™. 4-WAY STOPCOCK
04103215162	Extension Set
04103220162	Extension Set
04100002162	Alaris Products Extension set
04100006162	Extension Set



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04100008162	Extension Set
04100010162	Extension Set
04100015162	Extension Set
04100020162	Extension Set
04100135162	Alaris™ Products. EXTENSION SET. Gravity flow only.
04100146162	Alaris™ Products. EXTENSION SET. Gravity flow only.
04100215162	Extension Set
04100401162	Extension Set. 4-way Stopcock.
04100403162	Extension Set. 4-way Stopcock.
04100405162	Extension Set. 4-way Stopcock.
04100410162	Extension Set. 4-way Stopcock.
04100415162	Extension Set. 4-way Stopcock.