

BD StatLock™ Catheter Stabilization DevicesBD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.comTDS number: 095 – Rev. 01
2022-October**1. General Information****1.1 Intended use**

Catheter stabilization devices are indicated for use as a stabilization device for compatible medical tubes and catheters. Multiple pad and retainer designs are available

1.2 General description

The StatLock™ Stabilization Device consists of a sterile, natural rubber latex-free, adhesive backed anchor pad containing plastic posts that secure onto the catheter with a locking clamp. The catheter sits above the pad, so unlike tape, there is no catheter between the adhesive surface and the skin to act as a wedge that may undermine adherence.

Serial No	StatLock Family
1	PICC
2	Arterial
3	CVC
4	Epidural
5	Dialysis
6	IV
7	Universal

1. PICC Family:

BD Catalog Number	BD Product Description
PIC0220CE	StatLock PICC Plus, Crescent Tricot Pad, Sliding Post Retainer
VPPCSPCE	StatLock PICC Plus, Crescent Foam Pad, Sliding Post Retainer
VPPDFPCE	StatLock PICC Plus, Crescent Foam Pad, Fixed Post Retainer
VPPPSPCE	StatLock PICC Plus, Pediatric, Teddy Bear Foam Pad, Sliding Post Retainer
NN0200	StatLock PICC Neonate, Poster Retainer
VNN2	StatLock Neonate II

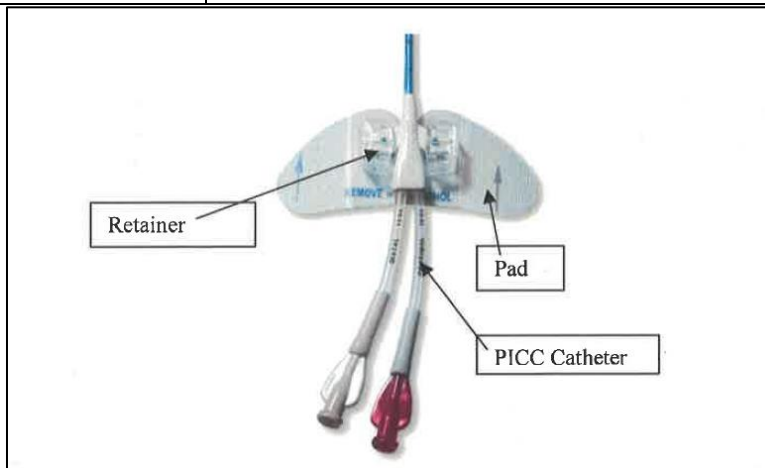


Figure 1 PICC StatLock example device

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2. Arterial Family:

BD Catalog Number	BD Product Description
ART0222CE	StatLock Arterial Plus Crescent Tricot Pad, Clamshell Retainer
ART0422	StatLock Arteril Ultra, Tricot Pad
ART0420CE	StatLock Arterial Select, Tricot Pad
ART0421	StatLock Arterial Select, Tricot Pad with Extension Set
ART0423	StatLock For Arrow Arterial Catheters with Tricot Pad
ART0320	StatLock Adhesive Well Pad for BE Arterial Catheters
ART0321	StatLock for Vygon Arterial Catheters

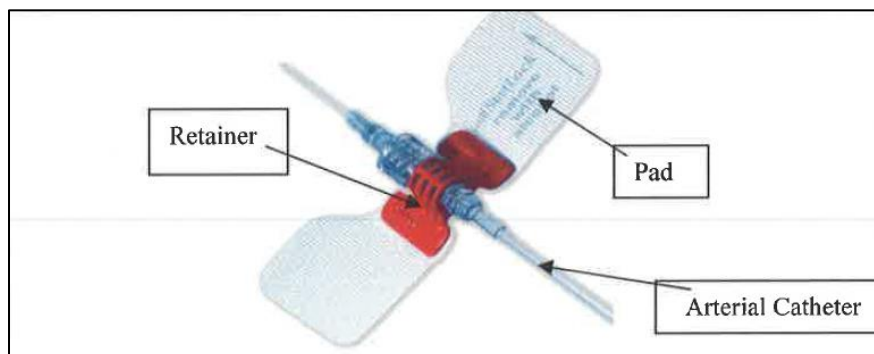


Figure 2 Arterial StatLock example device

3. CVC Family

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BD Catalog Number	BD Product Description
CV0220CE	StatLock CV Plus, Crescent Tricot Pad, Sliding Post Retainer and Pigtail Clip
CV0224CE	StatLock CV Plus, Butterfly Tricot Pad, sliding Post Retainer
CV0226CE	StatLock CV Plus, Crescent Tricot Pad, Sliding Post Retainer and Pigtail Clip
VCDCE	StatLock CV, Butterfly Foam Pad, Posted Retainer with Clip
VCDPP	StatLock CV Plus, Pediatric, Teddy Bear Foam Pad, Sliding Post Retainer
VCDTCE	StatLock CV, Pediatric, Teddy Bear foam Pad, Posted Retainer with Clip
CV0321	StatLock CV Ultra, Tricot Pad, Posted retainer with Tethered Locking Caps

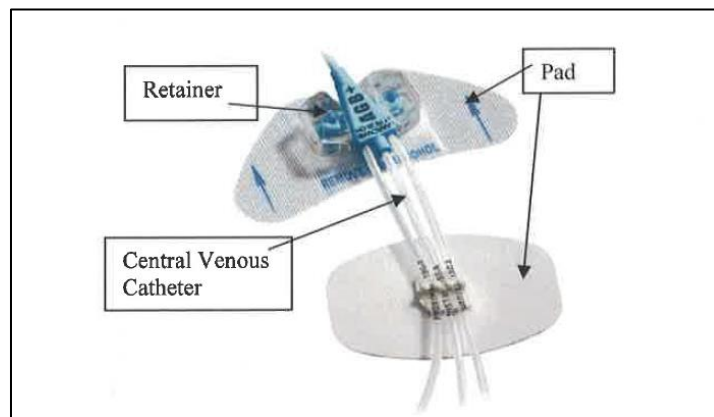


Figure 3 CVC StatLock example device

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4. Epidural Family

BD Catalog Number	BD Product Description
VEDC	StatLock Epidural Crescent Foam Pad with Serpentine Clip
VEDCAML6	StatLock, Butterfly Foam Pad, For Arrow Epidural Catheters with Extension Set
VEDCML6CE	StatLock Epidural, Butterfly Foam Pad, with Extension Set
VEDML6	StatLock Epidural, Butterfly Foam Pad, with Extension Set

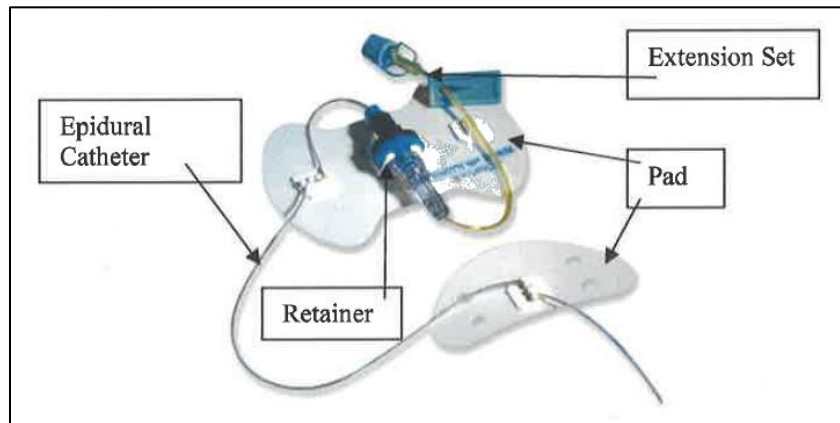


Figure 4 Epidural StatLock example device

5. Foley/Dialysis Family

BD Catalog Number	BD Product Description
DI0120CE	StatLock Dialysis, Butterfly Tricot Pad, Clamshell Retainer
VDS2	StatLock Dialysis II, Butterfly Foam Pad, Two Connector Retainers

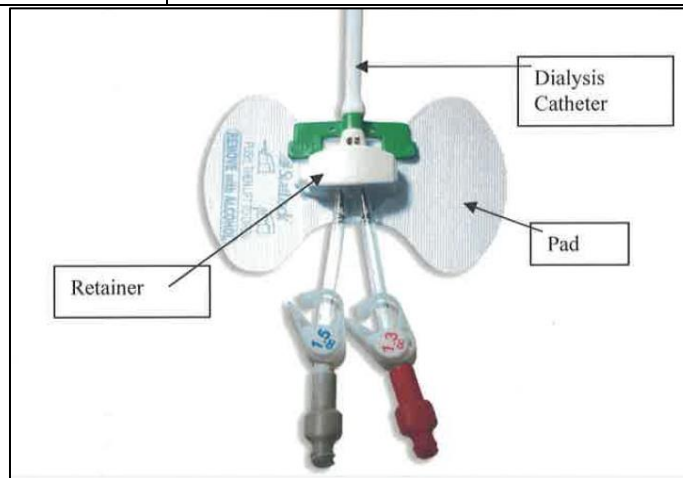


Figure 5 Dialysis StatLock example device

6. IV Family:

BD Catalog Number	BD Product Description
IV0221CE	StatLock IV Plus, Trapezoidal Pad, Clamshell Retainer with Micro Extension Set
IV0225	StatLock IV Plus, Trapezoidal Pad, Clamshell Retainer with Macro Extension Set
IV0500	StatLock IV Ultra, Pediatric
IV0520CE	StatLock IV Ultra
IV0521CE	StatLock IV Select
IV0602CE	StatLock IV Elite for BBraun Vasofix Catheters
IV0621CE	StatLock Adhesive Wall Pad for Winged Catheters
VIFP4	StatLock Adhesive Well Pad for BD Intima Closed IV Catheter Systems
SLP001CE	StatLock Pro

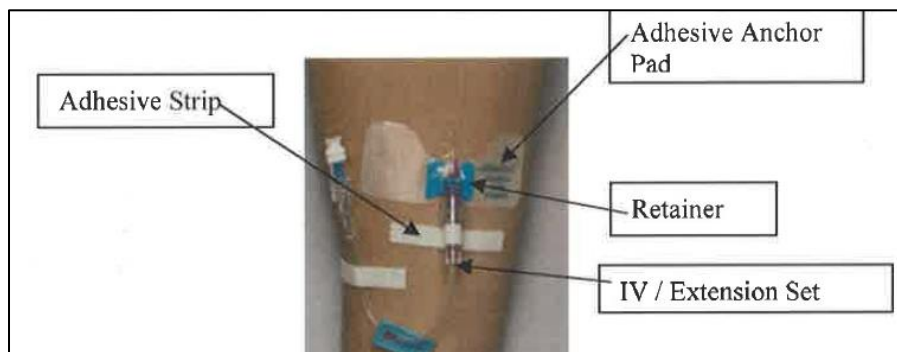


Figure 6 IV StatLock example device

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7. Universal Family:

BD Catalog Number	BD Product Description
VUPD1012CE	StatLock Universal Plus, Butterfly Tricot Pad, (10-12 F) Medium Clamp
VUPD1214CE	StatLock Universal Plus, Butterfly Tricot Pad, (12-14 F) Large Clamp
VUPD1416CE	StatLock Universal Plus, Butterfly Tricot Pad, (14-16 F) Extra Large Clamp
VUPD68CE	StatLock Universal Plus, Butterfly Tricot Pad, (6-8.5 F) Small Clamp
MP0120	StatLock Multi-Purpose, Butterfly Tricot Pad, 5 In. Filament Retainer

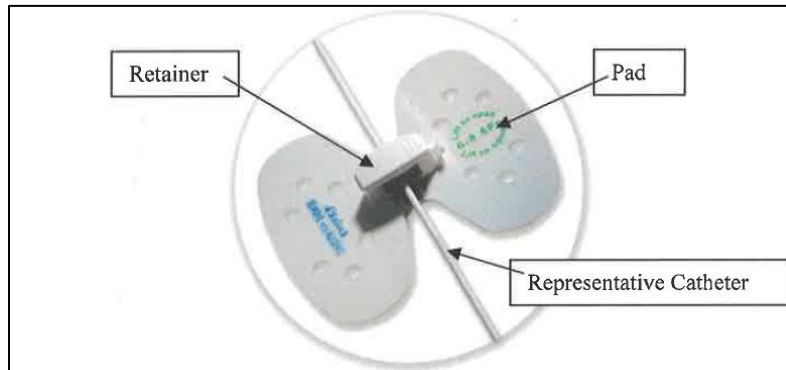


Figure 7 IV StatLock example device

Further features:

N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
IV0500	<p>Address: Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States</p> <p>ISO 13485 Certificate No.: MDSAP 676596</p>	<p>CE certified with BSI Group (2797) Certificate No.: 551349</p>	<p>Address: BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States</p> <p>ISO 13485 Certificate No.: MDSAP 676596</p>	<p>Authorized Representative: Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland</p>
IV0520CE				
IV0602CE				
IV0621CE				
VIFP4				
SLP001CE				
PIC0220CE				
VPPCSPCE				
VPPDFPCE				
VPPPSPCE				
CV0220CE				
CV0224CE				
CV0226CE				
VCDCE				
VCDPP				
VCDTCE				
CV0321				
ART0422				
ART0423				
ART0320				
ART0321				
DI0120CE				
VDS2				
VEDC				
VUPD1012CE				
VUPD1214CE				
VUPD1416CE				
VUPD68CE				
MP0120				
NN0200				
VNN2				

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BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
IV0221CE	Address: Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States ISO 13485 Certificate No.: MDSAP 676596	CE certified with BSI Group (2797) Certificate No.: 551333	Address: BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States ISO 13485 Certificate No.: MDSAP 676596	Authorized Representative: Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
IV0225				
IV0521CE				
ART0222CE				
ART0420CE				
ART0421				
VEDCAML6				
VEDCML6CE				
VEDML6				

1.4 Materials

Universal Family		
SKUs: VUPD68CE, VUPD1012CE, VUPD1214CE, VUPD1416CE, and MP0120		
Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
HARDENER	Hardener for Print Pad Ink	Incidental Skin Contact
INK BLUE	Reflex Blue Ink	Incidental Skin Contact
JZ PAD BUTTERFLY TRICOT	Acrylic adhesive coated Tricot woven polyester, hydrocolloid adhesive and liner	Primary Skin Contact
JZ PAD PREPRINTED	Acrylic adhesive coated Tricot woven polyester, hydrocolloid adhesive and liner	Primary Skin Contact
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> Substrate: 1/32" White Volara Foam; Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; Release Liner: 60# SCK Liner; Substrate: Polyester Film 	Primary Skin Contact

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PAD JZ FOAM .375x3.5 IN	Liner; Substrate: Polyester Film	Packaging
PAD PRINTING INT	Pad Printing Ink Orange # 021C	Incidental Skin Contact
PAD PRINTING INT	Pad Printing Ink Yellow #142C	Incidental Skin Contact
PAD PRINTING INT	Pad Printing Ink Green # 354C	Incidental Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
PRIMER LOCTITE 7951	Organic Amine in Solvent (perfluorocarbon and co-solvent)	Incidental Skin Contact
SIMI RETAINER	Nylon, Zytel ST801 or equivalent	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SL CLAMP UNIVERSAL PLUS	Exxon Mobil PP 9074Med REF, Insert GLS Krayton #G2706 – Blue colorant, Chroma #PC54434B, 60 gr/10lbs or equivalent	Incidental Skin Contact
SL CLAMP UNIVERSAL PLUS	Exxon Mobil PP 9074Med REF, Insert GLS Krayton #G2706 – Orange colorant, Chroma #PC36312A, 60 gr/10lbs or equivalent	Incidental Skin Contact
SL CLAMP UNIVERSAL PLUS	Clamp #17143 Exxon Mobil PP 9074Med REF, Insert GLS Krayton #G2706 – Yellow colorant, Chroma # PC43323A, 4% mix ratio or equivalent	Incidental Skin Contact
SL CLAMP UNIVERSAL PLUS	Exxon Mobil PP 9074Med REF, Insert GLS Krayton #G2706 – Green colorant, Chroma #PC62251, 30 gr/10lbs or equivalent	Incidental Skin Contact
THINNER	Thinner for pad printing ink	Incidental Skin Contact

CVC Family		
SKUs: CV0220CE, CV0240CE, CV0260CE, VCDCE, VCDPP, VCDTCE, and CV0321		
Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
ASI CYANOACRYLATE	Thinner for pad printing ink	Incidental Skin Contact
FREKOTE 770NC	Chemical type: Solvent based polymer	Incidental Skin Contact

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HARDENER	Hardener for Print Pad Ink	Incidental Skin Contact
INK BLUE	Reflex Blue Ink	Incidental Skin Contact
LINER	Liner; Substrate: Polyester Film	Packaging
LINER	Liner, Statlock, Diaphoretic 4.5" ; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed)	Packaging
LINER	Liner, Statlock, Diaphoretic 2.5"; Polyethylene Coated 53# BL Kraft, Loparex # 10769 (Not-Printed)	Packaging
PAD	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> • Substrate: 1/32" White Volara Foam; • Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; • Release Liner: 60# SCK • Liner; Substrate: Polyester Film 	Primary Skin Contact
PICC CLAMP PLUS	K-Resin KR03E (Molded styrene butadiene resin housing with molded polycarbonate resin posts)	Incidental Skin Contact
PICC CLAMP PLUS	K-Resin KR03E (Molded styrene butadiene resin housing with molded polycarbonate resin posts)	Incidental Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
PRIMER LOCTITE 7701	Regrind Material 50% as maximum	Incidental Skin Contact
SERPENTINE CLIP	Molded polycarbonate resin; Lexan 144R-801 White	Incidental Skin Contact
SIMI PAD DIAPH BUTTERFLY	Foam 108 GSM 6.625" <u>Subcomponents:</u> <ul style="list-style-type: none"> • Substrate: 1/32" White Volara Foam; 	Primary Skin Contact

	<ul style="list-style-type: none"> Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; Release Liner: 60# SCK Liner, Statlock, Diaphoretic 4.5" ; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed) Liner, Statlock, Diaphoretic 2.5"; Polyethylene Coated 53# BL Kraft, Loparex # 10769 (Not-Printed) 	
SIMI PAD JZ TRICOT	Acrylic adhesive coated Tricot woven polyester, hydrocolloid adhesive and liner	Primary Skin Contact
SIMI RETAINER POSTED	K-Resin Phillips KR-03 or equivalent. / Color White A3650C.	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SL CLAMP UNIVERSAL 2	Polycarbonate L1225L with 4% Green Conc. GRN ACC 70130 or equivalent.	Incidental Skin Contact
SLIDING POST STATLOCK	Resin - Polycarbonate, SABIC Lexan 144R - 112. Colorant -FCC81559-PC2, 4% mix ratio. Blue PMS 2925C Regrind Material 50% as maximum	Incidental Skin Contact
SLIDING POST STATLOCK	Resin - Polycarbonate, SABIC Lexan 144R - 112. Colorant -FCC81559-PC2, 4% mix ratio. Blue PMS 2925C Regrind Material 50% as maximum Blue PMS 2925C Blue PMS 2925C	Incidental Skin Contact
THINNER	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact

Epidural Family		
SKUs: VEDC, VEDCAML6, VEDCML6CE, and VEDML6		
Component	Material	Body Contact

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ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
BONDING SOLVENT CYCLOHEX	Cyclohexane and methylene chloride (50/50 mix)	Incidental Skin Contact
FREKOTE 770NC	Chemical type: Solvent based polymer	Incidental Skin Contact
HARDENER	Hardener for Print Pad Ink	Incidental Skin Contact
HEX LOCK HUB	PolyCarbonate (PC)	Primary Skin Contact
INK BLUE	Reflex Blue Ink	Incidental Skin Contact
JZ PAD DIAPH STANDARD	<p>Foam 108 GSM 9.375";</p> <p><u>Subcomponents:</u></p> <ul style="list-style-type: none"> • Substrate: White Volara Foam; • Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; • Release Liner: 60# SCK <p>Liner, Statlock, Diaphoretic 4"; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed)</p> <p>Liner, Statlock, Diaphoretic 8"; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed)</p>	Primary Skin Contact
LINER	Liner, StatLock, Diaphoretic; Polyethylene Coated 53# Kraft, Rexam #10769 (Non-Printed)	Packaging
MALE LUER .088 W/HEX	PolyCarbonate (PC)*	Primary Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
SERPENTINE CLIP	Molded polycarbonate resin; Lexan 144R-801 White	Incidental Skin Contact
SIMI PAD DIAPH CRESCENT	<p>Foam 108 GSM 6.625"</p> <p><u>Subcomponents:</u></p> <ul style="list-style-type: none"> • Substrate: 1/32" White Volara Foam; • Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; • Release Liner: 60# SCK • Liner, Statlock, Diaphoretic 4.5" ; Polyethylene Coated 	Primary Skin Contact

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	53# Kraft, Loparex #10769 (Non-Printed) Liner, Statlock, Diaphoretic 2.5"; Polyethylene Coated 53# BL Kraft, Loparex # 10769 (Not-Printed)	
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SIMI TUBE CLIP .093	Polycarbonate, Lexan 144R 801 White or Equivalent	Primary Skin Contact
SL FEMALE DUST CAP	High density Polyethylene (HDPE)	Packaging
SL FEMALE LUER LOCK ADAPTER	High density Polyethylene (HDPE) Chevron HID 9012.	Primary Skin Contact
SL RETAINER 0 DEGREE	Polycarbonate, Lexan 144R 801 White or equivalent.	Incidental Skin Contact
SL SLIDE CLAMP .093 IN	Low density Polyethylene (LDPE 20 DUPONT/ACC20579P LT).	Primary Skin Contact
THINNER	Thinner for pad printing ink	Incidental Skin Contact
TUBING .088 x 5.00 IN	DOA PVC (Non-DEHP)	Primary Skin Contact
VENTED MALE LUER LOCK CAP	DOA PVC (Non-DEHP)	Packaging

Foley/Dialysis Family		
SKUs: DI0120CE and VDS2		
Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
GLUE DOT SUPER HIG TACK	Permanent synthetic rubber-based pressure sensitive super high tack medium profile glue dot	Incidental Skin Contact
HARDENER	Hardener for Print Pad Ink	Incidental Skin Contact

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INK BLUE	Reflex Blue Ink	Incidental Skin Contact
JZ PAD BUTTERFLY TRICOT	Acrylic adhesive coated Tricot woven polyester, hydrocolloid adhesive and liner	Primary Skin Contact
LINER	Liner; Substrate: Polyester Film	Packaging
LINER	Liner, StatLock, Diaphoretic 4"; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed)	Packaging
LINER	Liner, Statlock, Diaphoretic 8"; Polyethylene Coated 53# Kraft, Loparex #10769 (Non-Printed)	Packaging
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> Substrate: 1/32" White Volara Foam; Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; Release Liner: 60# SCK Liner; Substrate: Polyester Film 	Primary Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
PRIMER LOCTITE 7951	Organic Amine in Solvent (perfluorocarbon and co-solvent)	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SL CLAMP DYALISIS EXXON	Exxon Mobil PP 9074Med Polypropylene Copolymer, Ferco Color Standard White, Colorant FCC-10001-PP-1, 10 % Exxon Mobil Exact 3024 Plastomer	Incidental Skin Contact
THINNER	Thinner for pad printing ink	Incidental Skin Contact

IV Family

SKUs: IV0221CE, IV0225, IV0500, IV0520CE, IV0521CE, IV0602CE, IV0621CE, VIFP4, and SLP001CE

Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact

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BONDING SOLVENT CYCLOHEX	Cyclohexane and methylene chloride (50/50 mix)	Incidental Skin Contact
HEX LOCK HUB	PolyCarbonate (PC)	Primary Skin Contact
JZ PAD PREPRINTED TRICOT	Acrylic adhesive coated Tricot woven polyester and liner	Primary Skin Contact
LINER	Liner; Substrate: Polyester Film	Packaging
LINER	Polyethylene, PET liner	Packaging
MALE LUER .088 W/HEX	PolyCarbonate (PC)	Primary Skin Contact
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> • Substrate: 1/32" White Volara Foam; • Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; • Release Liner: 60# SCK Liner; Substrate: Polyester Film	Primary Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
PRIMER LOCTITE 7951	Organic Amine in Solvent (perfluorocarbon and co-solvent)	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SL CLAMP IV PLUS BLUE	Exxon Mobil PP 9074Med Polypropylene Copolymer, Ferco Blue Color Additive FCC-81534, 10 % Exxon Mobil Exact 3024.	Incidental Skin Contact
SL FEMALE DUST CAP	High density Polyethylene (HDPE) Chevron HID 9012.	Packaging
SL SLIDE CLAMP .093 IN	High density Polyethylene (HDPE).	Primary Skin Contact
TUBING .088 X 5.00 IN	DOA PVC (Non-DEHP).	Primary Skin Contact
VENTED MALE LUER LOCK CAP	Low density Polyethylene (LDPE 20 DUPONT/ACC20579P LT).	Packaging

ARTERIAL Family		
SKUs: ART0222CE, ART0422, ART0420CE, ART0421, ART0423, ART0320, and ART0321		
Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
BONDING SOLVENT CYCLOHEX	cyclohexane and methylene chloride (50/50 mix)	Incidental Skin Contact
HEX LOCK HUB	PolyCarbonate (PC)	Primary Skin Contact
MALE LUER .158 W/HEX	Bayer Makrolon RX 2530-451118 (RM2400708)	Primary Skin Contact
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> • Substrate: 1/32" White Volara Foam; • Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; • Release Liner: 60# SCK Liner; Substrate: Polyester Film	Primary Skin Contact
PRIMER LOCTITE 7701	Chemical type: aliphatic amine in solvent (heptane)	Incidental Skin Contact
PRIMER LOCTITE 7951	Organic Amine in Solvent (perfluorocarbon and co-solvent)	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SL CLAMP IV PLUS RED	Exxon Mobil PP 9074Med Polypropylene Copolymer, Ferco Red Color Additive FCC-91123 (PMS#200M), 10 % Exxon Mobil Exact 3024.	Incidental Skin Contact
SL FEMALE DUST CAP	High density Polyethylene (HDPE) Chevron HID 9012.	Packaging
SL FEMALE LUER LOCK ADAPTER	Copolyester	Primary Skin Contact
SLIDE CLAMP .093 IN RED	High density polyethylene (HDPE).	Primary Skin Contact
TUBING 0.110/7.00 IN	DOA PVC (Non-DEHP).	Primary Skin Contact
TUBING 0.158/0.110 IN	DOA PVC (Non-DEHP).	Primary Skin Contact

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VENTED MALE LUER LOCK CAP	Low density Polyethylene (LDPE 20 DUPONT/ACC20579P LT).	Packaging
LINER	Liner; Substrate: Polyester Film	Packaging
PAD TRICOT CRESCENT	Acrylic adhesive coated Tricot woven polyester, hydrocolloid adhesive and liner	Primary Skin Contact
RETAINER	Molded polypropylene resin	Incidental Skin Contact

PICC Family		
SKUs: PIC0220CE, VPPCSPCE, VPPDFPCE, VPPPSPCE, NN0200, VNN2		
Component	Material	Body Contact
ASI CYANOACRYLATE	Adhesive Cyanoacrylate	Incidental Skin Contact
LINER	Liner; Substrate: Polyester Film	Packaging
PAD JZ FOAM .375x3.5 IN	Foam Tape, White, 8.5"; <u>Subcomponents:</u> <ul style="list-style-type: none"> Substrate: 1/32" White Volara Foam; Adhesive: Cytec Gelva GMS 788 Acrylic Adhesive; Release Liner: 60# SCK Liner; Substrate: Polyester Film	Primary Skin Contact
PAD JZ TRICOT NOTCHED	Acrylic adhesive coated closed-cell polyethylene foam and liner	Primary Skin Contact
PICC CLAMP PLUS	K-Resin KR03E (Molded styrene butadiene resin housing with molded polycarbonate resin posts)	Incidental Skin Contact
SIMI SKIN PREP STERILE	Sterile skin protectant prep pad, latex free, (Acetyl tributyl citrate, butyl ester of PVM/MA copolymer, isopropanol)	Primary Skin Contact
SLIDING POST STATLOCK	Resin - Polycarbonate, SABIC Lexan 144R - 112. Colorant - FCC81559-PC2, 4% mix ratio. Blue PMS 2925C Regrind Material 50% as maximum	Incidental Skin Contact

1.5 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers, BD has not identified any phthalates in the article and packaging with the product in an individual concentration above 0.1% (w/w).
BPA	Based on our ongoing data collection efforts and/or information received from our suppliers, BD has identified BPA only in the article of the product. It is a building block of the raw material Makrolon 2458 added. The article falls under incidental skin contact and BD has not found testing to evaluate levels of this chemical necessary in this product.
Substances of animal origin BSE/TSE	Based on our ongoing data collection efforts and/or information received from our suppliers, BD has not identified any intentionally incorporated animal tissue or animal derived materials in the article and packaging with the product. We have not conducted any tests for animal-derived materials in the products.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers, the articles and packaging with the product are not made with natural rubber latex.
Heavy metals	Based on our ongoing data collection efforts and/or information received by our suppliers, the product (device and packaging) conforms to the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004)
PVC	The product has not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to this product.

1.6 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging of BD StatLock™ Stabilization Device, in an individual concentration above 0.1% weight by weight (w/w), which

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have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on July 2019 according to Art. 59 (1.10) of the Regulation (EC) N° 1907/2006 (REACH)

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

The StatLock™ stabilization device is sterilized by Ethylene Oxide in a validated sterilization cycle following established sterilization procedures. The sterilization cycle is validated per ISO-11135 (Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices). The Ethylene Oxide sterilization residuals remaining in the device are within the limits specified in ISO 10993-7 (Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals).

1.9 Shelf life and storage conditions

The StatLock™ stabilization device shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time. The StatLock™ Pro stabilization device has a shelf life of 3 years.

Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the appendix 8 - Essential Requirements Checklist of the Technical file (TF-EU-STAT-01 Rev 6) linked to the CE certificate number 551349:

Harmonized Standards	
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity.
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
EN ISO 11607-2:2006	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation requirements for forming, sealing and assembly processes.
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices.
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 14155:2011	EN ISO 14155:2011
EN 62366:2008	Medical Devices – Application of Usability Engineering to Medical Devices, Edition 1.0
EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Test for irritation and skin Sensitization.
EN 1041:2008	Information supplied by the manufacturer of medical devices.

Note:

The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

The following StatLock™ Catheter Stabilization Devices are **Class I** medical device in accordance with **Annex IX, Rule 1** of the Medical Device Directive 93/42/EEC which states “All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies”. The rationale for the classification is based on intended use, duration of contact, and invasiveness of the product. This device meets the definition as stated in Annex IX, Rule 1 by StatLock Stabilization Devices without extension set(s) are intended to secure catheters or medical tubes to patients. Product is intended to “contact intact skin only.”

StatLock SKU	Family
IV0500	IV
IV0520CE	IV
IV0602CE	IV
IV0621CE	IV
VIFP4	IV
SLP001CE	IV
PIC0220CE	PICC
VPPCSPCE	PICC
VPPDFPCE	PICC
VPPPSPCE	PICC
CV0220CE	CVC
CV0224CE	CVC
CV0226CE	CVC
VCDCE	CVC
VCDPP	CVC
VCDTCE	CVC
CV0321	CVC
ART0422	ARTERIAL
ART0423	ARTERIAL
ART0320	ARTERIAL
ART0321	ARTERIAL
DI0120CE	Foley/Dialysis
VDS2	Foley/Dialysis
VEDC	Epidural
VUPD1012CE	Universal
VUPD1214CE	Universal

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StatLock SKU	Family
VUPD1416CE	Universal
VUPD68CE	Universal
MP0120	Universal
NN0200	PICC
VNN2	PICC

The following StatLock™ Catheter Stabilization devices are **Class II a** medical device in accordance with **Annex IX, Rule 1** of the Medical Device Directive 93/42/EEC which states "All non-invasive devices are in Class II, unless one of the rules set out hereinafter applies". The rationale for the classification is based on intended use, duration of contact, and invasiveness of the product. This device meets the definition as stated in Annex IX, Rule 1 by StatLock Devices without extension set(s) are intended to secure catheters or medical tubes to patients. Product is intended to "contact intact skin only."

StatLock SKU	Family
IV0221CE	IV
IV0225	IV
IV0521CE	IV
ART0222CE	ARTERIAL
ART0420CE	ARTERIAL
ART0421	ARTERIAL
VEDCAML6	Epidural
VEDCML6CE	Epidural
VEDML6	Epidural

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), StatLock™ Device is referenced as follows:

GMDN code	StatLock SKU
12170	IV0221CE
12170	IV0225
56631	IV0500
56631	IV0520CE
12170	IV0521CE
56631	IV0602CE
56631	IV0621CE
56631	VIFP4
56631	SLP001CE
56631	PIC0220CE
56631	VPPCSPCE
56631	VPPDFPCE
56631	VPPPSPCE
56631	CV0220CE
56631	CV0224CE
56631	CV0226CE
56631	VCDCE
56631	VCDPP
56631	VCDTCE
56631	CV0321
12170	ART0222CE
56631	ART0422
12170	ART0420CE
12170	ART0421
56631	ART0423
56631	ART0320
56631	ART0321
56631	DI0120CE
56631	VDS2
34916	VEDC
12170	VEDCAML6
12170	VEDCML6CE

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GMDN code	StatLock SKU
12170	VEDML6
56630	VUPD1012CE
56630	VUPD1214CE
56630	VUPD1416CE
56630	VUPD68CE
56630	MP0120
56631	NN0200
56631	VNN2

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs"*) is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (QTY)	Shelf Box (QTY)	Shipping Case (QTY)	IFU Insert N/A / Yes / No*
<u>PIC0220CE</u>	<u>StatLock PICC Plus, Crescent Tricot Pad, Sliding Post Retainer</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VPPCSPCE</u>	<u>StatLock PICC Plus, Crescent Foam Pad, Sliding Post Retainer</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VPPDFPCE</u>	<u>StatLock PICC Plus, Crescent Foam Pad, Fixed Post Retainer</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VPPPSPCE</u>	<u>StatLock PICC Plus, Pediatric, Teddy Bear Foam Pad, Sliding Post Retainer</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>NN0200</u>	<u>StatLock PICC Neonate, Poster Retainer</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VNN2</u>	<u>StatLock Neonate II</u>	<u>Pouch (FFS)</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>ART0222CE</u>	<u>StatLock Arterial Plus Crescent Tricot Pad, Clamshell Retainer</u>	<u>Pouch (FFS)</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>ART0422</u>	<u>StatLock Arteril Ultra, Tricot Pad</u>	<u>Pouch (FFS)</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>ART0420CE</u>	<u>StatLock Arterial Select, Tricot Pad</u>	<u>Pouch (FFS)</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>ART0421</u>	<u>StatLock Arterial Select, Tricot Pad with Extension Set</u>	<u>Pouch (FFS)</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>ART0423</u>	<u>StatLock For Arrow Arterial Catheters with Tricot Pad</u>	<u>Pouch (FFS)</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>ART0320</u>	<u>StatLock Adhesive Well Pad for BE Arterial Catheters</u>	<u>Pouch (FFS)</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>ART0321</u>	<u>StatLock for Vygon Arterial Catheters</u>	<u>Pouch (FFS)</u>	<u>50</u>	<u>500</u>	<u>Yes</u>

BD Catalog Number	BD Product Description	Primary Packaging (QTY)	Shelf Box (QTY)	Shipping Case (QTY)	IFU Insert N/A / Yes / No*
<u>CV0220CE</u>	<u>StatLock CV Plus, Crescent Tricot Pad, Sliding Post Retainer and Pigtail Clip</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>CV0224CE</u>	<u>StatLock CV Plus, Butterfly Tricot Pad, sliding Post Retainer</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>CV0226CE</u>	<u>StatLock CV Plus, Crescent Tricot Pad, Sliding Post Retainer and Pigtail Clip</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VCDCE</u>	<u>StatLock CV, Butterfly Foam Pad, Posted Retainer with Clip</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VCDPP</u>	<u>StatLock CV Plus, Pediatric, Teddy Bear Foam Pad, Sliding Post Retainer</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VCDTCE</u>	<u>StatLock CV, Pediatric, Teddy Bear foam Pad, Posted Retainer with Clip</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>CV0321</u>	<u>StatLock CV Ultra, Tricot Pad, Posted retainer with Tethered Locking Caps</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VEDC</u>	<u>StatLock Epidural Crescent Foam Pad with Serpentine Clip</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VEDCAML6</u>	<u>StatLock, Butterfly Foam Pad, For Arrow Epidural Catheters with Extension Set</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VEDCML6CE</u>	<u>StatLock Epidural, Butterfly Foam Pad, with Extension Set</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VEDML6</u>	<u>StatLock Epidural, Butterfly Foam Pad, with Extension Set</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>

BD Catalog Number	BD Product Description	Primary Packaging (QTY)	Shelf Box (QTY)	Shipping Case (QTY)	IFU Insert N/A / Yes / No*
<u>DI0120CE</u>	<u>StatLock Dialysis, Butterfly Tricot Pad, Clamshell Retainer</u>	<u>Pouch (FFS)</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VDS2</u>	<u>StatLock Dialysis II, Butterfly Foam Pad, Two Connector Retainers</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>IV0221CE</u>	<u>StatLock IV Plus, Trapezoidal Pad, Clamshell Retainer with Micro Extension Set</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>IV0225</u>	<u>StatLock IV Plus, Trapezoidal Pad, Clamshell Retainer with Macro Extension Set</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>IV0500</u>	<u>StatLock IV Ultra, Pediatric</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>IV0520CE</u>	<u>StatLock IV Ultra</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>IV0521CE</u>	<u>StatLock IV Select</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>IV0602CE</u>	<u>StatLock IV Elite for Bbraun Vasofix Catheters</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>IV0621CE</u>	<u>StatLock Adhesive Wall Pad for Winged Catheters</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VIFP4</u>	<u>StatLock Adhesive Well Pad for BD Intima Closed IV Catheter Systems</u>	<u>Pouch</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>SLP001CE</u>	<u>StatLock Pro</u>	<u>Pouch (FFS)</u>	<u>50</u>	<u>500</u>	<u>Yes</u>
<u>VUPD1012CE</u>	<u>StatLock Universal Plus, Butterfly Tricot Pad, (10-12 F) Medium Clamp</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VUPD1214CE</u>	<u>StatLock Universal Plus, Butterfly Tricot Pad, (12-14 F) Large Clamp</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>VUPD1416CE</u>	<u>StatLock Universal Plus, Butterfly Tricot Pad, (14-16 F) Extra Large Clamp</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>

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<u>VUPD68CE</u>	<u>StatLock Universal Plus, Butterfly Tricot Pad, (6-8.5 F) Small Clamp</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>
<u>MP0120</u>	<u>StatLock Multi-Purpose, Butterfly Tricot Pad, 5 In. Filament Retainer</u>	<u>Pouch</u>	<u>25</u>	<u>250</u>	<u>Yes</u>

2.2Packaging material

Universal Family	
Component	Material
DFU(IFU)	Paper
Bag	Polyethylene
Label	Acrylic adhesive coated paper
Box	Corrugated Kraft

2.3 Examples of labeling

StatLock® Stabilization Device (Arterial Select, Pediatric, Tricot Pad) with Extension Set

Catheter Stabilization Device

Stabilisateur de cathéter
 Gerät zur Stabilisierung von Kathetern
 Dispositivo di stabilizzazione del catetere
 Dispositivo de estabilización de catéter
 Stabilisatiehulpmiddel voor katheter
 Dispositivo de estabilização do cateter
 Συσκευή Στερέωσης Καθετήρα
 Stabiliseringsanordning til kateter
 Kateterstabiliseringsenhet
 Katetrin stabilointilaitte
 Przyrząd stabilizujący cewnik
 Katéter stabilizáló eszköz
 Prostředek pro stabilizaci katétru
 Kateter Stabilizasyon Cihazı
 カテーテル安定装置

01)10801741081344
 (17)200228
 (10)TEST1234

REF ART0401
 Catalog Number

LOT TEST1234
 Lot Number

2020-02-28
 Use By

Assembled in Mexico

Arterial Select Pediatric

25
Quantity

Do not use if package is damaged

Do not reuse

CE 2797

STERILE EO
Sterilized using ethylene oxide

Attention, see instructions for use

Do not resterilize

This product and packaging does not contain natural rubber latex or DCP

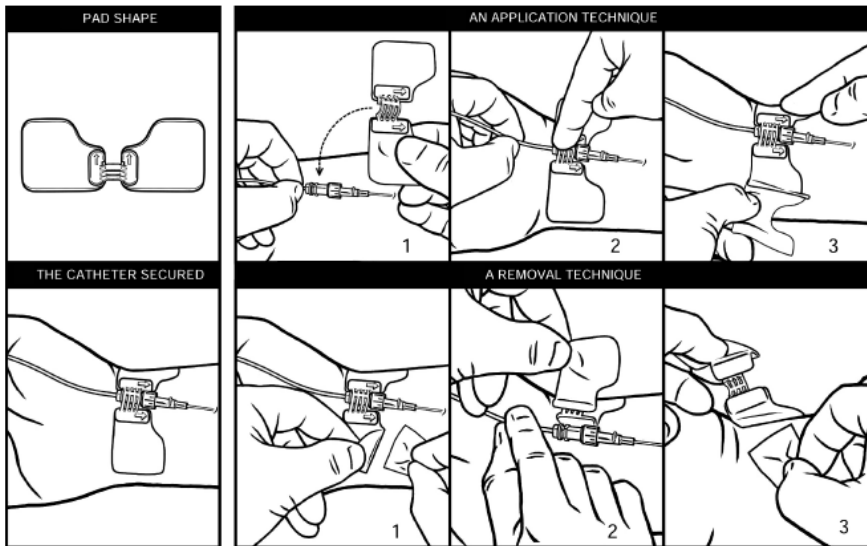
Non pyrogenic Fluid Path

Rx Only

The Greendot

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Manufacturer:
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 Salt Lake City, UT 84116 USA
 800-463-5555, 801-522-5000
www.bardaccess.com | www.statlock.com



REVISION	CHANGE SUMMARY
01	Initial release

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