BD® Connecta™ Stopcocks without Extension Tubing

Sterile, single-use

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

Product codes:
394600, 394601, 394602, 394605

TDS number: V201-029 – Rev. 03
Veeva Vault number: BD-132080
2024-August

1. General Information

1.1 Intended purpose

Connecta™ Stopcocks are used to administer fluids or medication through one or two different ports via an Intravenous (IV) cannula or extension tube. The ports can be used to sample blood or for haemodynamic monitoring. When used with IV lipid nutritional products, the stopcock device can be used for up to 24 hours.

1.2 Intended User

Intended to be used by healthcare professionals experienced in infusion therapy.

1.3 General Medical Devices description

The **Connecta™ Stopcock** is a stopcock with two ports and a rotating lever to control fluid direction through the device.
The device consists of a clear housing with two ISO female luer fittings protected with a plug, and one ISO male luer lock fitting with protective cover. The housing has a rotating tap to control fluid flow through the device. Connecta™ Stopcock devices have a 360° "ON" directed tap. The devices are available in a variety of colours.
The product is packaged in a Polyethylene (PE) -coated Polyamide (PA) -blister, which is sealed with a paper lid. The products are sterilised by E-beam.

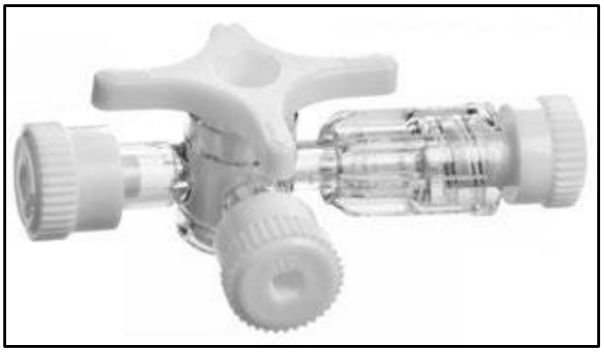


Figure 1: Connecta™ Stopcock – 3 Way with "ON" directed tap

BD Catalogue Number	BD Product Description	Directed tap	Luer Lock	Priming Volume (mL)	Flushing volume (ml)	Gravity Flow Rate		Maximum Pressure Limit Setting
						B-port (mL)	C-port (ml)	
394600	Connecta™ Stopcock – 3 Way – White	"ON" (360°)	Rotating	0.22	0.04	415.0	490.0	45 psi (310 kPa)
394601	Connecta™ Stopcock – 3 Way – White, with coloured pegs							
394602	Connecta™ Stopcock – 3 Way – Blue							
394605	Connecta™ Stopcock – 3 Way – Red							

Note: Please check BD catalogue number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalogue Number.

1.4 Certification

BD Catalogue Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body (acronym)	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative
394600, 394601, 394602, 394605	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland ISO 13485:2016 Certificate No.: MD 71300	CE Certified with BSI (Notified body number 2797) Certification number: MDR 745680	Becton Dickinson Infusion Therapy Systems Inc., S. A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales, Sonora, C.P. 84048 Mexico ISO 13485:2016 Certificate No.: FM 673986	Becton Dickinson Ireland Limited Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland

1.5 UDI-DI and Basic UDI-DI

BD Catalogue Number	UDI-DI		Basic UDI-DI
394600	Unit	(01)00382903946006	038290DXQVBQHQJJ
	Shelf	(01)30382903946007	
	Carton	(01)50382903946001	
394601	Unit	(01)00382903946013	
	Shelf	(01)30382903946014	
	Carton	(01)50382903946018	
394602	Unit	(01)00382903946020	
	Shelf	(01)30382903946021	
	Carton	(01)50382903946025	
394605	Unit	(01)00382903946051	
	Shelf	(01)30382903946052	
	Carton	(01)50382903946056	

1.6 Materials

Component	Component Raw Material
1 – Stopcock Housing	Polycarbonate
2 – Lubricant	Polydimethylsiloxane
3 – Tap	Polyethylene (with White, Blue or Red colouring)
4 – BD Plug	Polypropylene
5 – Protection Cap	Polyethylene
6 – Nut Rotating Luer Lock	Polycarbonate

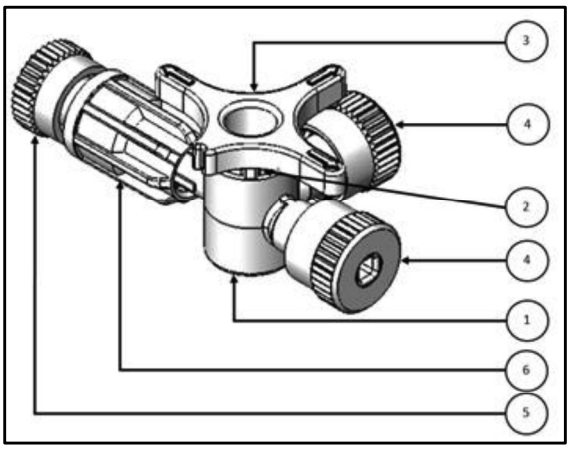


Figure 2: Connecta™ Stopcock – 3 Way with "ON" directed tap key functional components

1.7 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
DEHP/Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 July 2024, BD has not identified any: 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzendicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS# 68648-93-1), Benzyl butyl phthalate (BBP) (CAS# 85-68-7), Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), Dibutyl phthalate (DBP) (CAS# 84-74-2), Diisobutyl phthalate (DIBP) (CAS# 84-69-5), Diisopentyl phthalate (DIPP) (CAS# 605-50-5), Dipentyl phthalate (DPP) (CAS# 131-18-0), N-pentyl-isopentyl phthalate (CAS# 776297-69-9), or Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7 in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% (w/w).

Material	Comment
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 July 2024, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced abo
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 July 2024, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). There are polycarbonate components in these products. Bisphenol A (BPA), CAS# 80-05-7, is an organic compound that is a chemical building block for polycarbonate. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labelling for California Prop 65 is needed. No REACH SVHC declaration is required.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acid and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2020 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, and EU No 722/2012).
Blood Derivatives	The medical devices referenced above have not been designed nor intentionally manufactured with human or animal blood or blood derivatives, and thus EU Directive 2002/98/EC is out of scope.
Polyvinyl chloride (PVC)	The medical devices and packaging referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.
Class 1A and 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) & Endocrine-Disrupting (ED) Substances	BD has been collecting data on Class 1A and Class 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) & Endocrine-disrupting (ED) chemicals to meet Medical Device Regulations (MDR) 2017/745 and 2017/746. Based on the information received from our suppliers as per 18 July 2024, we have not been made aware of any Class 1A or Class 1B CMR, or ED substances in the components that are invasive, (re)administer medicines, body liquids or other substances, including gases, to/from the body at concentrations greater than 0.1% w/w. This includes ED substances covered by Article 5(3) of Regulation EU 528/2012.

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 July 2024, BD has not identified any chemicals in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 14 June 2023 according to Art. 59 (1,10) of the Regulation (EC) No. 1907/2006 (REACH).

1.9 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.10 Sterilisation method

Connecta™ Stopcocks are placed on the market in sterile form.
Sterilisation method: **E-beam radiation**. Do not re-sterilise.

1.11 Shelf life and storage conditions

Connecta™ Stopcocks shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
Based on the test results of the real-time aging and accelerated aging test reports, Connecta™ Stopcocks stability and shelf-life of **3 years** are conformed.

1.12 Applied Standards

As per Technical File:

Standard reference number	Title
Quality Standards	
EN ISO 13485:2016	Medical devices – Quality management Systems – Requirements for Regulatory purposes
Risk Management Standards	
EN ISO 14971:2019+A11: 2021	Medical Device – Application of risk management to Medical Devices
Biocompatibility Standards	
EN ISO 10993-1:2009/AC:2010 (ISO 10993-1:2018, Corrected Version 10/2018)	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2:2006 (ISO 10993-2:2006)	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-3:2014 (ISO 10993-3:2014)	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017 (ISO 10993-4:2017)	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016 (ISO 10993-6:2016)	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008/AC:2009 (ISO 10993-7:2008/ COR 1:2009/AM 1:2019)	Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilisation residuals
EN ISO 10993-9:2009 (ISO 10993-9:2019)	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-10:2013 (ISO 10993-10:2010)	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation
EN ISO 10993-11:2018 (ISO 10993-11:2017)	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012 (ISO 10993-12:2012)	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Standard reference number	Title
EN ISO 10993-13:2010 (ISO 10993-13:2010)	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-14:2009 (ISO 10993-14:2001)	Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics
EN ISO 10993-15:2009 (ISO 10993-15:2019)	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
EN ISO 10993-16:2017 (ISO 10993-16:2017)	Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables
EN ISO 10993-17:2009 (ISO 10993-17:2002)	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009 (ISO 10993-18:2020)	Biological evaluation of medical devices – Part 18: Chemical characterisation of materials
Labelling Standards	
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – General requirements
Packaging Standards	
ISO 11607-1:2019	Packaging for terminally sterilised medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilised medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
Sterilisation Standards	
EN ISO 11135:2014	Sterilisation of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilisation process for medical devices
EN ISO 11137-1:2015	Sterilisation of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices
EN ISO 11137-2:2015	Sterilisation of Health Care Products – Radiation – Part 2: Establishing the sterilisation dose
EN ISO 11737-1:2018	Sterilisation of Medical Devices – Microbiological Methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilisation of Medical Devices – Microbiological Methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process
EN 556-1:2001	Sterilisation of Medical Devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilised medical devices
Device Specific Standards	
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
Usability Engineering Standard	
IEC/EN 62366-1:2015	Medical Devices – Application of usability engineering to medical devices
Environmental Standard	
EN ISO 14644-1:2015	Clean rooms and associated controlled environments – Part 1: Classification of – cleanliness by particle concentration
Other Standard	
EN ISO 22442-1:2015	Medical devices utilising animal tissues and their derivatives – Part 1: Application of risk management
Other Guidelines	
EMA 410/01	Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products

Standard reference number	Title
MEDDEV 2.7/1 Rev04	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC
MDCG 2020-6	(EU) 2017/745 Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
MDCG 2021-24	Guidance on classification of medical devices
Other Regulations	
(EU) 2017/745	Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC hereafter referred to as EU MDR
EU 2021/2226	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices

Note: The above standards reflect the status at the time of drafting this document.

1.13 Classification

Connecta™ Stopcocks are **Class IIa** medical devices as per Annex VIII, Rule 2 of MDR (EU) 2017/745, no other rules apply.

1.14 Medical Device Nomenclature

GMDN Code: 32172
GMDN Term: Infusion Stopcocks
EMDN Code: A0703
EMDN Description: Stopcocks

1.15 Manufacturing practices

The entire manufacturing and testing processes are following the 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.
- BD reserves the right to use the internal change control procedure to change raw material suppliers and production process.

1.16 Other information

- Material Data Safety sheets are not required for this product.
- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch 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.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert
394600, 394601, 394602, 394605	Connecta™ Stopcocks – 3 Way with "ON" directed tap	1	100	500	Yes

2.2 Packaging material

BD Catalogue Number	Component	Material
394600, 394601, 394602, 394605	Unit Pack	Foil PE/PA
		Reinforced lacquered paper without TiO2
	Dispenser Box	SBS Medium Density
	Shipper Box	Corrugated "C" Flute

2.3 Recycled material in packaging

BD Product Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
394600, 394601, 394602, 394605	100%	55%

Based on our ongoing data collection and/or information received from our suppliers, the secondary and tertiary portions of the packaging of the medical devices referenced above are recyclable (at least partially) according to EN 13430:2004.

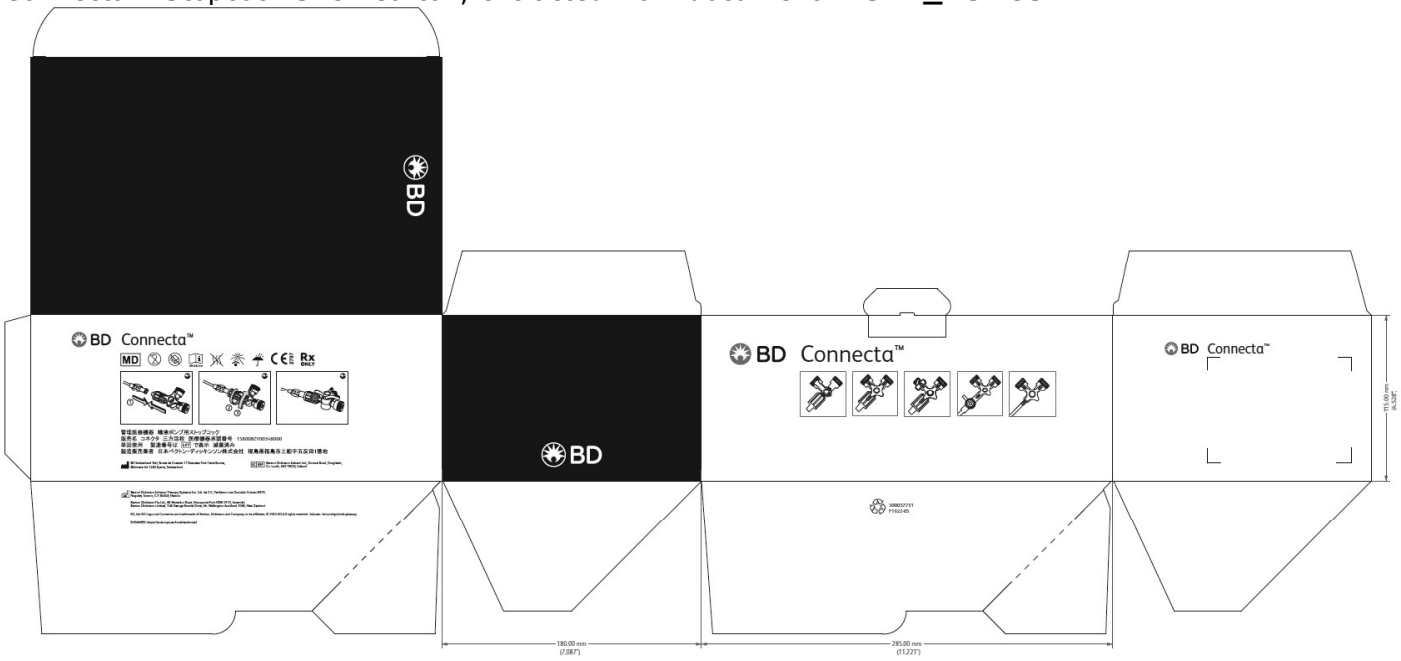
2.4 Examples of labelling

Connecta™ Stopcock Unit label, extracted from document **H0579_Rev.07** (example for product *394601*):

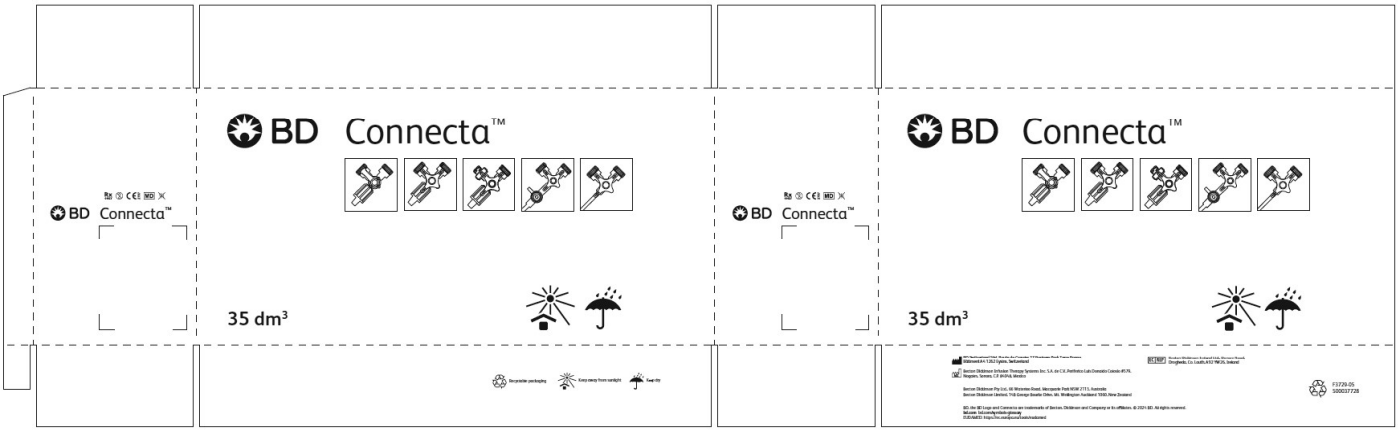
Connecta™ Stopcock Shelf Label, extracted from document **D16627_Rev.07** (example for product *394601*):

Connecta™ Stopcock Case Label, extracted from document **D16626_Rev.07** (example for product *394601*):

Connecta™ Stopcock Shelf Carton, extracted from document **F1922_Rev.05**:

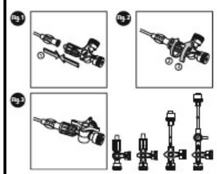


Connecta™ Stopcock Case Carton, extracted from document **F3729_Rev.05**:



Connecta™ Stopcock part of IFU (English parts only), extracted from document **D16535_Rev.05**:

BD Connecta™



STERILE R CE 2797 Rx ONLY

en - Stopcock • Stopcock with Extension Tube • Stopcock with Extension Tube and Injection Valve

DEVICE DESCRIPTION:
- The BD Connecta™ is a stopcock with two ports and a rotating lever to control fluid direction through the device.
- The BD Connecta™ with extension tubing is a stopcock with flexible tubing attached with two ports and a rotating lever to control fluid direction through the device. One configuration has an injection port included.

INTENDED PURPOSE:
BD Connecta™ Stopcocks are used to administer fluids or medication through one or two different ports via an IV cannula or extension tube. The ports can be used to sample blood or for hemodynamic monitoring. When used with IV lipid nutritional products, the stopcock device can be used for up to 24 hours

INTENDED USER:
Intended to be used by healthcare professionals experienced in infusion therapy.

INTENDED PATIENT POPULATION:
Adults, pediatrics and neonates.

WARNINGS:
- Intended for single patient use only. Reuse and/or repackaging may compromise the safety and efficacy of the device which may lead to device failure, and/or patient injury, illness, or infection.
- Failure to properly prime the device can result in air embolism.
- Ensure all connections are secure and injection ports are closed before and after each use. Disconnections or loose connections can result in air embolism, blood loss, blood or drug exposure, and infection due to leakage.
- DO NOT use if protective cap(s) are not in place, device or packaging is damaged or opened, contains any foreign material or the expiration date has passed.
- When using the product, avoid over-threading. Excessive threading may damage the integrity of the product.
- Do not use alcohol or other disinfectants on open luers to prevent potential cracking of the device and potential of alcohol intrusion into the fluid path. Maintain fluid path sterility by using Aseptic Non-Touch Technique, sterile caps and/or Needle-free connectors.
- Do not leave open packages or discarded devices within the patient's reach to prevent ingestion of the device or its components. Ingestion of the device or its components may pose a choking hazard.
- DO NOT use with power injectors. Doing so may result in leakage and/or failure of the device.
- DO NOT use with non-ISO luer connectors or luer connections with visible defects. Doing so may result in leakage and/or failure of the device.

PRECAUTIONS:
- Follow all instructions, contraindications, warnings, and precautions for all infusates, IV pumps, IV sets, and IV extension sets used with this device, as specified by its manufacturer.
- Follow recognized standards and institution policies on securement of vascular access devices and extension sets to reduce the risk of accidental catheter dislodgment.
- Trace lines before connection. Verify the line being connected to the BD Connecta™ stopcock is the appropriate Intravenous therapy line.
- If using a hypodermic needle to inject through a rubber membrane cap, use the shortest possible needle length to avoid damaging the stopcock.
- Contact with some organic solvents, infusion solutions and high pH value substances can also create internal stress and cause the stopcock material to crack.
- Luer slip connections should not be left unattended due to a potential risk for disconnection.
- Use of excessive force during connection can over stress stopcock ports, particularly when lubricious infusates, such as fat emulsions, are present.
- This device can be used for up to 72 hours or every 24 hours when administering lipid emulsions and should be changed accordingly.
- Follow recognized standards for blood sampling to reduce the risk of mechanical hemolysis.

INSTRUCTIONS FOR USE: Use Aseptic Non Touch Technique (ANTT)
1. Remove device from packaging.
2. Check that protection plugs are tight.
3. Remove the protective cap(s) from distal end(s)
4. Prime the device per facility protocol.
5. Connect the BD Connecta™ Stopcock's male port to a female luer connector by inserting the luer into the hub and rotate clockwise until a secure connection is made. Do not overtighten.
6. Initiate infusion, aspiration, or hemodynamic monitoring by rotating lever to desired position.
   Note: Rotate the handle to the appropriate position to get the desired fluid path.
   a. The molded "off" on handle indicates a closed port preventing flow of fluid.
   b. For other lever configurations, each lever indicates open channels of fluid flow and the short lever indicates the "off" position.
7. Close off the BD Connecta™ Stopcock prior to disconnecting from the device to minimize reflux of blood. Cover all luers after use.
8. Flushing should be performed prior to and after each medication administration, hemodynamic monitoring and/or blood sampling.
9. Handle and dispose this device in accordance with local and/or other governing regulations for medical device and/or biohazardous waste disposal.

GENERAL GUIDELINES:
- Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.
- DEHP or natural rubber latex are not part of the material formulation.

BD Switzerland Sàrl, Route de Crassier 17 Business Park Terre-Bonne, Bâtiment A4 1262 Eysins, Switzerland
EC REP Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland
Becton Dickinson Distribution Center NV, Laagstraat 57, 9140 Temse, Belgium
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V., Periferico Luis Donaldo Colosio #579, Nogales, Sonora, C.P. 84048, Mexico
Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417 USA
Becton Dickinson de México, Monte Pelvoux No. 111, Pisos 8, 9 y PH, Colonia Lomas de Chapultepec. México, D.F. 11000
Becton Dickinson India Private Ltd, 5th Floor, Signature Tower II, South City 1, Gurgaon - 122001, Haryana, India
Becton Dickinson & Company, 2 International Business Park Road, #08-08 The Strategy, Singapore 609930
Becton Dickinson Pty Ltd., 66 Waterloo Road, Macquarie Park NSW 2113, Australia
Becton Dickinson Limited, 14B George Bourke Drive, Mt. Wellington Auckland 1060, New Zealand
Becton Dickinson Philippines, Inc., 19th Floor High Street South Corporate Plaza Tower 1, 26th Street corner 9th Avenue, Bonifacio Global City, 1634 Taguig City, Philippines

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EUDAMED: //https://ec.europa.eu/tools/eudamed

500037734 D16535-05 (2024-03)

Do not resterilize
Do not re-use
UDI Unique device identifier
REF Catalogue number
LOT Batch code
Importer
Manufacturer
Keep dry
Use-by date
STERILE R Sterilized using irradiation
Keep away from sunlight
Non-pyrogenic
Date of manufacture
Country of manufacture
Do not use if package is damaged and consult instructions for use
EC REP Authorized representative in the European Community/European Union

en–Open Here es–Abrir aquí pt–Abrir aqui fr–Ouvrir ici de–Hier öffnen it–Aprire qui nl–Hier openen sv–Öppna här da–Åbn her fi–Avaa tästä el–Ανοίξτε εδώ no–Åpnes her pl–Otwórz tutaj sl–Odprite tukaj sk–Otvoriť tu et–Avada siit hu–Itt nyissa fel cs–Zde otevřít tr–Buradan açın ru–Открывать здесь hr–Ovdje otvoriti ro–Deschideți aici bg–Отворете тук uk–Відкрити тут ko–여기에서 열기

en–Consult instruction for use or Consult electronic instruction for use es–Consultar las instrucciones de uso o las instrucciones de uso electrónicas pt–Consulte as instruções de utilização ou as instruções eletrónicas de utilização fr–Consulter la notice d'utilisation ou consulter la notice d'utilisation électronique de–Gebrauchsanweisung oder elektronische Gebrauchsanweisung beachten it–Consultare le istruzioni per l'uso in formato cartaceo o elettronico nl–Raadpleeg de gebruiksaanwijzing of de digitale gebruiksaanwijzing sv–Se bruksanvisningen eller konsultera den elektroniska bruksanvisningen da–Se brugsanvisningen eller den elektroniske brugsanvisning fi–Perehdy käyttöohjeisiin tai sähköisiin käyttöohjeisiin el–Συμβουλευτείτε τις οδηγίες χρήσης ή συμβουλευτείτε τις ηλεκτρονικές οδηγίες χρήσης no–Se bruksanvisningen eller den elektroniske bruksanvisningen pl–Należy zapoznać się z instrukcją używania lub z elektroniczną instrukcją używania sl–Glejte navodila za uporabo ali elektronska navodila za uporabo. sk–Preštudujte si pokyny na používanie alebo elektronickú formu pokynov na používanie et–Vaadake kasutusjuhendist või elektroonilisest kasutusjuhendist hu–Nézze meg a használati utasításban vagy az elektronikus használati utasításban cs–Přečtěte si návod k použití nebo si přečtěte elektronický návod k použití tr–Kullanım talimatına veya elektronik kullanım talimatına başvurun ru–Обратитесь к инструкции по применению или к электронной инструкции по применению hr–Pogledajte upute za uporabu ili pogledajte elektroničke upute za uporabu ro–Consultați instrucțiunile de utilizare sau instrucțiunile de utilizare în format electronic bg–Направете справка в инструкциите за употреба или в електронните инструкции за употреба uk–Ознайомтеся з інструкціями із застосування або ознайомтеся з електронними інструкціями із застосування ko–取扱説明書またはその電子版を参照してください

MD en–Medical Device es–Producto sanitario pt–Dispositivo Médico fr–Dispositif médical de–Medizinisches Gerät it–Dispositivo medico nl–Medisch hulpmiddel sv–Medicinteknisk produkt da–Medicinsk udstyr fi–Lääkinnällinen laite el–Ιατροτεχνολογικό προϊόν no–Medisinsk utstyr pl–Wyrób medyczny sl–Medicinski pripomoček sk–Zdravotnícka pomôcka et–Meditsiiniseade hu–Orvostechnikai eszköz cs–Zdravotnický prostředek tr–Tıbbi Cihaz ru–Медицинское устройство hr–Medicinski uređaj ro–Dispozitiv medical bg–Медицинско изделие uk–Медичний пристрій ko–医疗器械

en–Single sterile barrier system es–Sistema de barrera estéril única pt–Sistema de barreira estéril único fr–Système de barrière stérile simple de–Einzelnes Sterilschutzsystem it–Sistema a singola barriera sterile nl–Toepassing van een enkelvoudige steriele barrière sv–Enkelt sterilbarriärsystem da–Enkelt sterilt barrieresystem fi–Yksinkertainen sterilli suojajärjestelmä el–Σύστημα μονού στείρου φραγμού no–System med steril enkeltbarriere pl–System pojedynczej bariery sterylnej sl–Sistem enojne sterilne pregrade sk–Systém s jednou sterilnou bariérou et–Ühe steriilse barjääriga süsteem hu–Egyszeres steril izolálószár-rendszer cs–Systém jedné sterilní bariéry tr–Tek steril bariyer sistemi ru–Единая барьерная система для стерилизации hr–Sustav jednostruke sterilne barijere ro–Sistem de barieră sterilă unică bg–Система с единична стерилна бариера uk–Система з єдиним стерильним бар'єром ko–单层无菌阻隔包装

en–Recyclable packaging es–Embalaje reciclable pt–Embalagem reciclável fr–Emballage recyclable de–Wiederverwendbare Verpackung it–Materiali di confezionamento riciclabili nl–Recyclebare verpakking sv–Återanvändbar förpackning da–Genanvendelig emballage fi–Kierrätettävä pakkaus el–Ανακυκλώσιμη συσκευασία no–Resirkulerbar pakning pl–Opakowanie nadające się do recyklingu sl–Embalaža, ki jo je mogoče reciklirati sk–Recyklovateľný obal et–Taasringluspakend hu–Újrahasznosítható csomagolás cs–Recyklovatelný obal tr–Geri dönüşümlü ambalaj ru–Упаковка пригодна для вторичной переработки hr–Pakiranje se može reciklirati ro–Ambalaj reciclabil bg–Рециклируема опаковка kk–Қаптамасын қайта өңдеуге болады ko–可回收 包装

en–Inside Diameter es–Diámetro interior pt–Diâmetro interno fr–Diamètre intérieur de–Innendurchmesser it–Diametro interno nl–Binnendiameter sv–Diameter inside da–Indvendig diameter fi–Sisäläpimitta el–Εσωτερική διάμετρος no–Innvendig diameter pl–Średnica wewnętrzna sl–Notranji premer sk–Vnútorný priemer et–Siseläbimõõt hu–Belső átmérő cs–Vnitřní průměr tr–İç Çap ru–Внутренний диаметр hr–Unutarnji promjer ro–Diametru interior bg–Вътрешен диаметър uk–Внутрішній діаметр ko–내경

en–Ukrainian conformity mark es–Marca de conformidad ucraniana pt–Marca de conformidade ucraniana fr–Marque de conformité ukrainienne de–Ukrainisches Konformitätszeichen it–Marchio di conformità ucraino nl–Oekraïens conformiteitsmerkteken sv–Märkning om överensstämmelse för Ukraina da–Ukrainsk overensstemmelsesmærke fi–Ukrainalainen vaatimustenmukaisuusmerkintä el–Ουκρανικό σήμα συμμόρφωσης no–Ukrainsk samsvarsmerke pl–Ukraiński znak zgodności sl–Oznaka skladnosti za Ukrajino sk–Ukrajinská značka zhody et–Ukraina vastavustähis hu–Ukrán megfelelőségi jelölés cs–Ukrajinská značka shody tr–Ukrayna uyumluluk işareti ru–Украинский знак соответствия hr–Oznaka usklađenosti za Ukrajinu ro–Marcaj de conformitate ucrainean bg–Украинска маркировка за съответствие uk–Український знак відповідності ko–우크라이나 적합성 마크

REVISION	CHANGE SUMMARY
01 (April 2019)	Initial release according to new template
02 (May 2020)	Label extracts updated
03 (August 2024)	General TDS revision according to new template *EMEA-SOP039-F1_Rev.01* and new MDR requirements, as per *ISD-STED-002_Rev.02/Ver.B*: - Keep codes *394600*, *394601*, *394602*, *394605* from Revision 2