

Document Number: EMEA-SOP039-F1	Rev. Lev.: 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

BD® Connecta™ Stopcock with Extension Tube

Sterile, Single-use

Product codes: 394926, 394951, 394961, 394982, 394983, 394995, 394997

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

BD® Connecta™ Stopcock with Extension Tube and Injection Valve

Sterile, Single-use

Product codes: 394936, 394945, 394971

BD® Connecta™ Stopcock

Sterile, Single-use

Product codes: 394600, 394601, 394602, 394605

TDS number: V201-033 Rev. 03
Veeva Vault number: BD-146323
2025-April

1. General Information

1.1 Intended purpose

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 lipid nutritional products, the Connecta™ device can be used for up to 24 hours.

Risk of re-use statement: Connecta™ Stopcock is intended for single use only. Reuse and/or repackaging may compromise the safety and efficacy of the set, which may lead to device failure, and/or patient injury, infection, or illness.

1.2 Intended User

Connecta™ Stopcock is intended to be used by healthcare professionals who are 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. The Connecta™ Stopcock devices here referenced (394600, 394601, 394602, 394605) have a 360° "ON" directed tap. The devices are available in a variety of colours.

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The product is packaged in a Polyethylene (PE)-coated Polyamide (PA)-blister, which is sealed with a paper lid. The products are sterilized by E-beam.



Figure 1: Connecta™ Stopcock (with ON directed tap)

The **Connecta™ Stopcock with Extension Tubing** and **Connecta™ Stopcock with extension tube and injection valve** is a stopcock with flexible tubing attached with two ports and a rotating lever to control fluid direction through the device. **Connecta™ Stopcock with extension tube and injection valve** has an injection port included.

The distal end of the tubing is fitted with an ISO male luer lock (with protective cover) which has either a fixed or a spin nut. The stopcock consists of a clear housing with two ISO female luer fittings protected with a plug. The housing has a 360° "ON" directed rotating tap. The extension tubes are available in multiple lengths and sizes. Certain configurations include an injection valve.

The product is packaged in a PE-coated PA-blister, which is sealed with a paper lid. The products are sterilized by E-beam.



Figure 2 - Connecta™ Stopcock with extension tube



Figure 3 - Connecta™ Stopcock with extension tube and injection valve

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BD Catalogue Number	BD Product Description	Total Length (cm)	Tube Length (cm)	Priming Volume (mL)	Tube inner diameter (mm)	Tube outer diameter (mm)
394600	Connecta™ Stopcock White	5	NA	0.21	NA	NA
394601	Connecta™ Stopcock White with colored pegs	5	NA	0.21	NA	NA
394602	Connecta™ Stopcock Blue	5	NA	0.21	NA	NA
394605	Connecta™ Stopcock Red	5	NA	0.21	NA	NA
394926	Connecta™ Stopcock with Extension Tube – 30cm	30	25	1.5	2.60	3.20
394936	Connecta™ Stopcock with Extension Tube and Injection Valve – 30cm	30	25	1.5	2.60	3.20
394945	Connecta™ Stopcock with Extension Tube and Injection Valve – 16cm	16	7	0.76	2.60	3.20
394951	Connecta™ Stopcock with Extension Tube – 54cm	54	50	2.8	2.60	3.20
394961	Connecta™ Stopcock with Extension Tube – 105cm	105	100	6	2.60	3.20
394971	Connecta™ Stopcock with Extension Tube and Injection Valve – 105cm	105	100	6	2.60	3.20
394982	Connecta™ Stopcock with Extension Tube – 21cm (low volume)	21	15	0.43	2.25	2.80
394983	Connecta™ Stopcock with Extension Tube – 35cm (low volume)	35	30	0.58	2.25	2.80
394995	Connecta™ Stopcock with Extension Tube – 16cm (White)	16	10	0.78	2.60	3.20
394997	Connecta™ Stopcock with Extension Tube – 16cm (Blue)	16	10	0.78	2.60	3.20

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BD Catalogue Number	BD Product Description	Directed tap	Flushing volume (mL)	Gravity Flow Rate	
				B-port (mL)	C-port (mL)
394600	Connecta™ Stopcock White	"ON" (360°)	0.04	415.0	490.0
394601	Connecta™ Stopcock White with colored pegs				
394602	Connecta™ Stopcock Blue				
394605	Connecta™ Stopcock Red				

BD Catalogue Number	BD Product Description	Macro/ Microbore	Luer Lock	Lipid resistance	Pressure Resistance
394600	Connecta™ Stopcock White	NA	Rotating	Yes (24h)	5 bar 72psi (500kPa)
394601	Connecta™ Stopcock White with colored pegs	NA	Rotating	Yes (24h)	5 bar 72psi (500kPa)
394602	Connecta™ Stopcock Blue	NA	Rotating	Yes (24h)	5 bar 72psi (500kPa)
394605	Connecta™ Stopcock Red	NA	Rotating	Yes (24h)	5 bar 72psi (500kPa)
394926	Connecta™ Stopcock with Extension Tube – 30cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394936	Connecta™ Stopcock with Extension Tube and Injection Valve – 30cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394945	Connecta™ Stopcock with Extension Tube and Injection Valve – 16cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394951	Connecta™ Stopcock with Extension Tube – 54cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394961	Connecta™ Stopcock with Extension Tube – 105cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394971	Connecta™ Stopcock with Extension Tube and Injection Valve – 105cm	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394982	Connecta™ Stopcock with Extension Tube – 21cm (low volume)	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394983	Connecta™ Stopcock with Extension Tube – 35cm (low volume)	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)
394995	Connecta™ Stopcock with Extension Tube – 16cm (White)	Macro bore	Fixed	Yes (24h)	5 bar 72psi (500kPa)

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BD Catalogue Number	BD Product Description	Macro/ Microbore	Luer Lock	Lipid resistance	Pressure Resistance
394997	Connecta™ Stopcock with Extension Tube – 16cm (Blue)	Macrobore	Fixed	Yes (24h)	5 bar 72psi (500kPa)

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/UKCA Certificate Number and Notified Body Acronym and Number	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
394600, 394601, 394602, 394605, 394926, 394936, 394945, 394951, 394961, 394971, 394982, 394983, 394995, 394997,	<u>Name and Address:</u> BD Switzerland Sàrl Route de Crassier 17, Business Park Terre- Bonne, Batiment A4, 1262 Eysins, Switzerland <u>ISO 13485 Certificate</u> <u>No.:</u> MD 71300	<u>CE certified</u> with BSI (2797) MDR Certificate No.: 745680 <u>UKCA certified:</u> N/A	<u>Name and Address:</u> Becton Dickinson Infusion Therapy Systems Inc., S. A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales, Sonora, C.P. 84048, Mexico <u>ISO 13485 Certificate</u> <u>No.:</u> FM 673986	<u>Name and Address:</u> EC Representative: 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	Case	50382903946001	038290DXQVBQHQJJ
	Each	00382903946006	
	Shelfpack	30382903946007	
394601	Case	50382903946018	
	Each	00382903946013	
	Shelfpack	30382903946014	
394602	Case	50382903946025	
	Each	00382903946020	
	Shelfpack	30382903946021	
394605	Case	50382903946056	
	Each	00382903946051	
	Shelfpack	30382903946052	
394995	Case	50382903949958	038290JSEISQNUEM

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BD Catalogue Number	UDI-DI		Basic UDI-DI
	Each	00382903949953	038290DOVABTMT9P
	Shelfpack	30382903949954	
394997	Case	50382903949972	
	Each	00382903949977	
	Shelfpack	30382903949978	
	Case	50382903949262	
394926	Each	00382903949267	
	Shelfpack	30382903949268	
394951	Case	50382903949514	
	Each	00382903949519	
	Shelfpack	30382903949510	
	Case	50382903949613	
394961	Each	00382903949618	
	Shelfpack	30382903949619	
394982	Case	50382903949828	
	Each	00382903949823	
	Shelfpack	30382903949824	
	Case	50382903949835	
394983	Each	00382903949830	
	Shelfpack	30382903949831	
394936	Case	50382903949361	
	Each	00382903949366	
	Shelfpack	30382903949367	
	Case	50382903949453	
394945	Each	00382903949458	
	Shelfpack	30382903949459	
394971	Case	50382903949712	
	Each	00382903949717	
	Shelfpack	30382903949718	

1.6 Materials

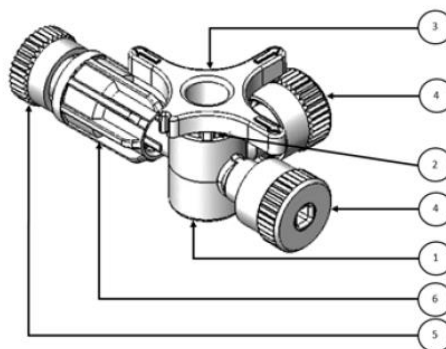


Figure 4 - Key Functional Components for Connecta™ Stopcock with ON directed tap

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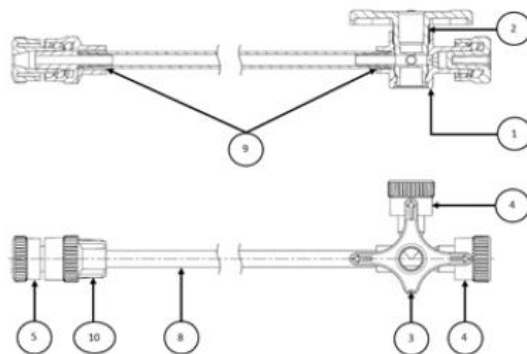


Figure 5 - Key Functional Components for Connecta™ Stopcock with extension tube

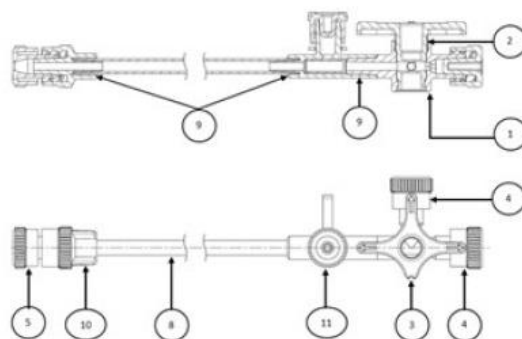


Figure 6 - Key Functional Components for Connecta™ Stopcock with extension tube and injection valve

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BD Catalogue Number	Component Identifier	Component	Material
394600, 394601, 394602, 394605, 394926, 394936, 394945, 394951, 394961, 394971, 394982, 394983, 394995, 394997,	1	Stopcock Housing	Polycarbonate
	2	Lubricant	Polydimethylsiloxane
	3	Tap	Polyethylene
		Tap Colorant	Red, white, blue
	4	BD Plug	Polypropylene
		BD Plug Colorant	White
	5	Protection Cap	Polyethylene
		Protection Cap Colorant	White
	6	Nut Rotating Luer Lock	Polycarbonate
	8	Extension Tube	Polyvinylchloride
	9	Adhesive	Acrylic
	10	Luer Lock Fitting	Polycarbonate
	11	Injection Valve Housing	Polycarbonate
	Not shown	Primer	Acrylic
Not shown	Peg	Polyethylene	
Not shown	Peg colorant	Red, blue	

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
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 March 2025, 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.

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Material	Comment
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 March 2025, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A (BPA)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 March 2025, 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 labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Heavy Metals in Packaging	Based on our ongoing data collection efforts and/or information received by our suppliers as per 18 March 2025, the products (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).
Polyvinyl chloride (PVC)	For SKUs 394600, 394601, 394602, 394605, 395214, 395215: The medical devices 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. For SKUs 394926, 394936, 394945, 394951, 394961, 394971, 394982, 394983, 394995, 394997: The extension tubing of medical devices referenced above have been designed and manufactured with PVC raw material.
RoHS directive, heavy metals, brominated flame retardants	It is BD's view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive. Based on our ongoing data collection efforts and/or information received from our suppliers as of 18 March 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products.
Animal Derivatives	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).
Class 1A and 1B Carcinogenic, Mutagenic and	Based on our ongoing data collection efforts and/or information received from our suppliers as per 18 March 2025, no CLP (EC 1272/2008) Class 1A or Class 1B CMR, or ED substances are intentionally part of the components that are invasive,

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Reprotoxic (CMR) & Endocrine-Disrupting (ED) Substances (euMDR Annex I Sections 10.4.1a and 10.4.1b)	(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 March 2025, 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 23 January 2024 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 series - Biological Evaluation of Medical Devices.

1.10 Sterilisation method

Products included in this document are sterilized by E-beam (irradiation).

1.11 Shelf life and storage conditions

The **Connecta™ Stopcocks'** shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

The **Connecta™ Stopcocks** have a shelf life of 3 years.

BD recommends to store in a dry and warm place, not exposed to strong light.

Use-life:

The devices can be engaged up to 24 hours when used with lipid nutritional products and 72 hours when used with other fluids.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title	Standard Applied (Full or Partial)
Quality Standard		
BS EN ISO 13485:2016+A11:2021	Medical Devices – Quality management systems – Requirements for regulatory purposes	Full

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Risk Management Standard		
EN ISO 14971:2019/ A11 :2021 (ISO 14971:2019)	Medical Devices – Application of risk management to medical devices	Full
Biocompatibility Standards		
EN ISO 10993-1:2020 (ISO 10993-1:2018, Corrected Version 10/2018)	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-2:2022 (ISO 10993-2:2022)	Biological evaluation of medical devices - Part 2: Animal welfare requirements	Full
EN ISO 10993-4:2017 (ISO 10993-4:2017)	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Full
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Full
EN ISO 10993-7:2008/A1:2022 (ISO 10993-7:2008/ COR 1:2009/ AM 1:2019)	Biological evaluation of medical device – Part 7: Ethylene oxide sterilization residuals	Full
EN ISO 10993-10:2023 (ISO 10993-10:2021)	Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Full
EN ISO 10993-11:2018 (ISO 10993-11:2017)	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-12:2021 (ISO 10993-12:2021)	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full
EN ISO 10993-17:2023 (ISO 10993-17:2023)	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	Full
EN ISO 10993 18:2020/ AM 1:2023 (ISO 10993-18:2020/AM 1:2022)	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process	Full
EN ISO 10993-23:2021 (ISO 10993-23:2021)	Biological evaluation of medical devices – Part 23: Test for irritation	Full
Labelling Standards		
EN ISO 20417:2021	Medical Devices - Information to be supplied by the manufacturer	Full
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Full
Packaging Standards		
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
Sterilization Standards		
EN 556-1:2001/AC:2006	Sterilization of Medical Devices –Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices	Full
EN ISO 11737-1:2018 +A1:2021 (ISO 11737-1:2018+A1:2021)	Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of a population of microorganisms on products - Amendment 1	Full
EN ISO 11737-2:2020 (ISO 11737-2:2019)	Sterilization of Health Care Products – Microbiological Methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Full

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BS EN ISO 11135:2014 +A1:2019 (ISO 11135:2014 +A1:2018)	Sterilization of Health Care Products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1	Full
EN ISO 11137-1:2015 (ISO 11137-1:2015)	Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Full
EN ISO 11137-2:2015 (ISO 11137-2:2015)	Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose	Full
Device Specific Standards		
BS EN ISO 80369-7:2021 (ISO 80369-7:2021)	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications	Full
BS EN ISO 8536-9:2015 (ISO 8536-9:2015)	Infusion equipment for medical use – Part 9: Fluid lines for single use with pressure infusion equipment	Full
BS EN ISO 8536-10:2015 (ISO 8536-10:2015)	Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment	Full
Cleanroom Specific Standards		
ISO 14644-1:2015	Clean rooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	Full
ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations	Full
Usability Engineering Standard		
IEC/EN 62366-1:2015/AMD 1:2020	Medical devices - Part 1: Application of usability engineering to medical devices - Amendment 1	Full
Other Standards		
EN ISO 22442-1:2020 (ISO 22442-1:2020)	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	Full
USP 788	Particulate matter in injections	Full
USP 27	Pyrogen Levels	Full
ISO 14001:2015	Environmental management systems	Full
Other Guidelines		
EMA 410/01	Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Full
MEDDEV 2.7/1 Rev04	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC	Full
MDCG 2020-6	Regulation (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	Full
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies	Full
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies	Full
MDCG 2021-24	Guidance on Classification of medical device	Full
Other Regulations		

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(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	Full
(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.	Full*
(EC) No 1272/2008	Regulation (EC) No 1272/2008 of The European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	Full
(EU) 528/2012	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	Full
EU Regulation 2011/696/EU	Commission Recommendation of 18 October 2011 on the definition of nanomaterial	Full

* As the instructions for use will be provided in electronic form in addition to instructions for use in paper form, only compliance with Article 9 of 2021/2226 is required.

Note:

The above standards reflect the status at time of document release.

1.13 Classification

MDR (EU) 2017/745 Risk Classification and Rationale (based on Annex VIII, Rule 2):

Risk classification: **Class IIa**

Justification: Connecta™ Stopcocks are non-invasive devices, intended for short term use. Connecta™ Stopcock devices are intended for channeling blood, medication or nutrition for the purpose of eventual infusion, administration or introduction into the human body. Connecta™ Stopcock devices can be connected to an active device such as a pump.

1.14 Medical Device Nomenclature

GMDN Code: 32172

GMDN Term: Infusion Stopcocks

EMDN code: A0703

EMDN Term: 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.

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- 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.

1.16 Other information

- 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 intended for channeling blood, medication or nutrition for the purpose of eventual infusion, administration or introduction into the human body.
- Good Manufacturing Practices as defined by the EU Pharmaceutical is not applicable for Medical Devices.
- The Connecta™ Stopcocks are not intended to be used in accordance with the provisions on personal protective equipment (PPE), therefore Council Directive 89/686/EEC is not applicable.
- The Connecta™ Stopcocks are not machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and, therefore, the essential health and safety requirements set out in Annex I of Directive 2006/42/EC are not applicable.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
394600	Connecta™ Stopcock White	1	100	500	Yes
394601	Connecta™ Stopcock White with colored pegs	1	100	500	Yes
394602	Connecta™ Stopcock Blue	1	100	500	Yes
394605	Connecta™ Stopcock Red	1	100	500	Yes
394926	Connecta™ Stopcock with Extension Tube - 30cm	1	20	100	Yes
394936	Connecta™ Stopcock with Extension Tube and Injection Valve - 30cm	1	20	100	Yes
394945	Connecta™ Stopcock with Extension Tube and Injection Valve - 16cm	1	50	250	Yes
394951	Connecta™ Stopcock with Extension Tube - 54cm	1	20	100	Yes
394961	Connecta™ Stopcock with Extension Tube - 105cm	1	20	100	Yes

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BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
394971	Connecta™ Stopcock with Extension Tube and Injection Valve – 105cm	1	20	100	Yes
394982	Connecta™ Stopcock with Extension Tube – 21cm (low volume)	1	50	250	Yes
394983	Connecta™ Stopcock with Extension Tube – 35cm (low volume)	1	50	250	Yes
394995	Connecta™ Stopcock with Extension Tube – 16cm (White)	1	50	250	Yes
394997	Connecta™ Stopcock with Extension Tube – 16cm (Blue)	1	50	250	Yes

*"No": IFU may be available but not as an insert.

2.2 Packaging materials

BD Catalogue Number	Component	Material
394926, 394936, 394945, 394951, 394961, 394971, 394982, 394983, 394995, 394997,	Unit Pack	30652 Amcor Film
		Reinforced lacquered paper without TiO2
	Dispenser Box	styrene-butadiene-styrene (SBS) Medium Density
	Shipper Box	Corrugated "C" Flute
394600, 394601, 394602, 394605	Unit Pack	Foil Polyethylene/Polyamide
		Reinforced lacquered paper without TiO2
	Dispenser Box	SBS Medium Density
	Shipper Box	Corrugated "C" Flute

2.3 Recycled materials in packaging

-Recyclability of Packaging: 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.

Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities and some portions of the package may not be recyclable.

-Recycled Content:

BD Catalogue Number	Packaging Type	Packaging Recycled content	Recyclability
394600, 394601, 394602, 394605, 394926, 394936, 394945, 394951, 394961, 394971, 394982, 394983, 394995, 394997	Primary Packaging: Multilayer laminate plastic and paper	0%	Two materials – designed to be peeled apart.
			Paper is recyclable
		Multilayer laminate is recyclable through monomer recovery recycling methods	
	Secondary Packaging: Shelf Carton	Unknown	Cardboard is recyclable
	Tertiary Packaging: Case Carton	Unknown	Corrugated box is recyclable

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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):



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

REF 394601 360° ↻

BD Connecta™ **STERILE R** - 0.21 mL

en-Stopcock es-Llave de paso pt-Torneira fr-Robinet d'arrêt de-Absperhahn
 it-Rubinetto nl-Afsluitkraan sv-Infusionskran da-Stophane fi-Sulkukhana
 el-Καύουλα διαγύου ποίης no-Stoppeskran pl-Kurek sl-Zaporni ventil
 sk-Zastavovací kohútik et-Sulgurkraan hu-Érőcsap cs-Úzovíradí kohout
 tr-Stopkok ru-Сторонний кран hr-Zaporni ventil ro-Ventil de oprire
 bg-Спирателен кран uk-Краник ko-스들크

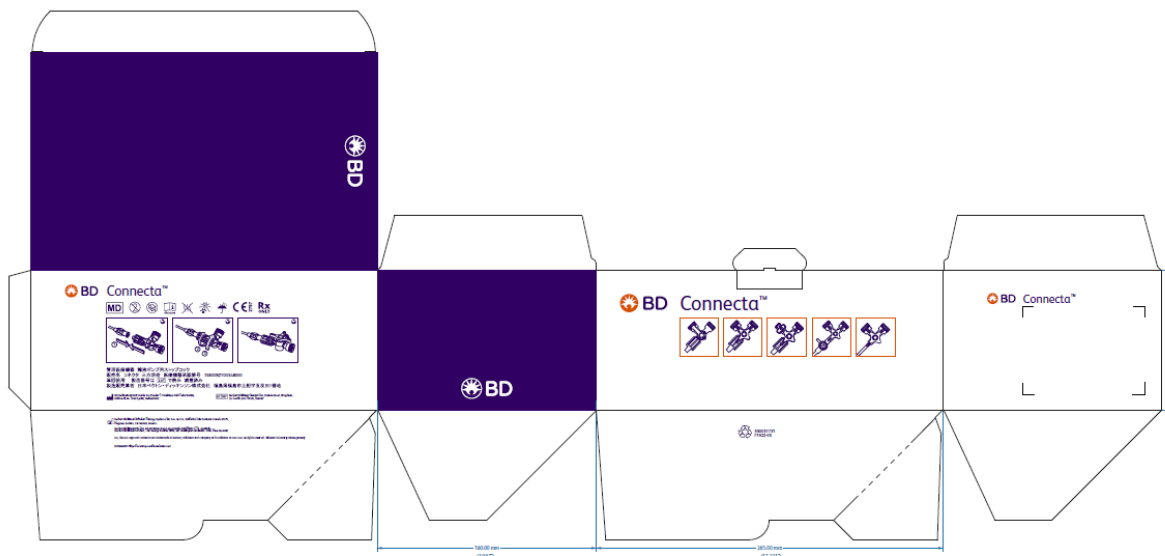
QTY: 500 UATR.115


 (01)50382903946018


 (11)YYMMDD(17)YYMMDD(10)1234567

 YYYY-MM-DD  YYYY-MM-DD **LOT** 1234567
 D16626-07

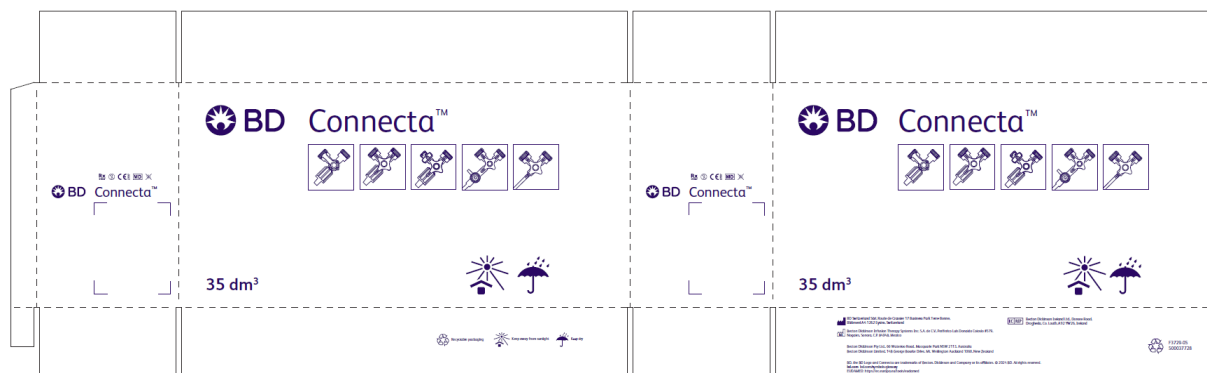
Connecta™ Stopcock Shelf Carton, extracted from document **F1922_Rev.05**:



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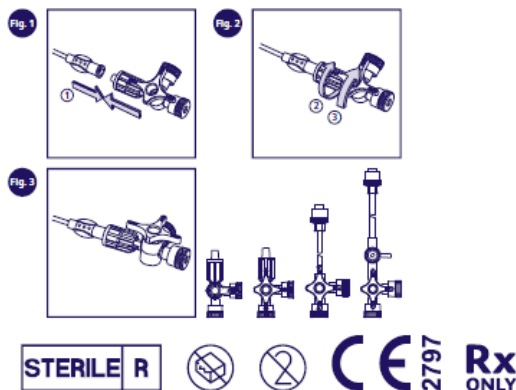
Connecta™ Stopcock Case Carton, extracted from document **F3729_Rev.05**:



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

For the whole document, where other languages are included, please refer to: eifu.bd.com



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.

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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.

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Made in Mexico

bd.com bd.com/symbols-glossary eifu.bd.com

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

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500037734 D16535-05 (2024-03)



Do not re-sterilize



Do not re-use



Unique device identifier



Catalogue number



Batch code



Importer



Manufacturer



Keep dry



Use-by date



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





Authorized representative in the European Community/European Union


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 **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**-Otvorít tu **et**-Avada siit **hu**-Itt nyissa fel **cs**-Zde otevřít **tr**-Buradan aç **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

 **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**-Meditsiiniisead **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**-의료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 steril barrieriesystem **fi**-Yksinkertainen steriili 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 izolálóeszköz **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**-Taasringuspakend **hu**-Újrahasznosítható csomagolás **cs**-Recyklovatelný obal **tr**-Geril dönüştürümlü 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 insida **da**-Indvendig diameter **fi**-Sisäläpimitä **el**-Εσωτερική διάμετρος **no**-Innvendig diameter **pl**-Średnica wewnętrzna **sl**-Notranji premer **sk**-Vnútorňý 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 samsvarsmærke **pl**-Ukraiński znak zgodności **sl**-Oznaka skladnosti za Ukrajinu **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 uskladenosti za Ukrajinu **ro**-Marcaj de conformitate ucrainean **bg**-Украинска маркировка за съответствие **uk**-Український знак відповідності **ko**-우크라이나 적합성 마크

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REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	<ul style="list-style-type: none">- Product picture added. Correction of Product description for 394983 and additional information added for Low Volume Extension tube.- Updated label extracts.
03	<ul style="list-style-type: none">- Update to current template TDS template EMEA-SOP039-F1 Rev.02 based on Technical Documentation ISD-STED-002/latest updated in November 2024- Addition of BD Catalogue Numbers: 394600, 394601, 394602, 394605, 394936, 394945, 394971, 395214, 395215- Removal of BD catalogue numbers: 394995, 394997, 394926, 394951, 394961, 394982, 394983- It supersedes TDS V201-029 and V201-034- Update of section 1.7 (Materials of concern)