BD PureHub™ Disinfection Cap
Sterile
306598, 306599

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TDS number: V201-002 – Rev. 01
2020-June

1. General Information

1.1 Intended use

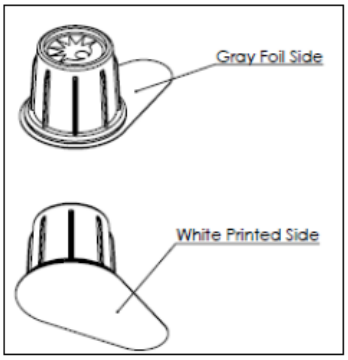
BD PureHub™ Disinfecting Cap are intended to be used as a disinfecting device for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses.

1.2 General description

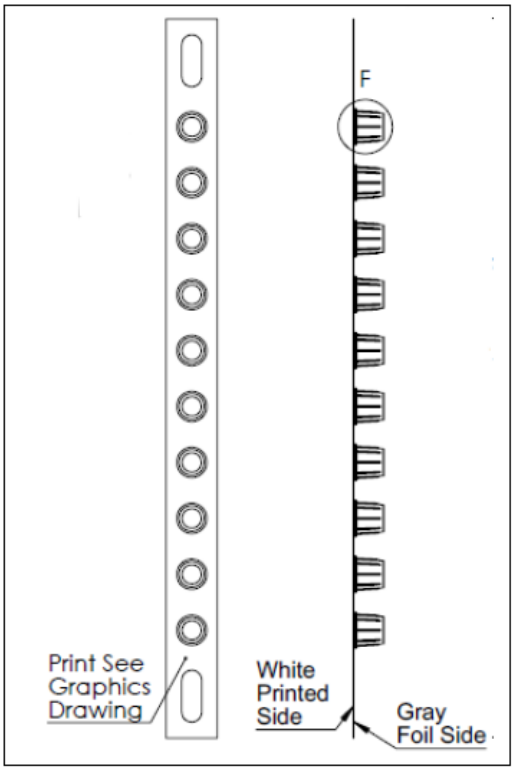
BD PureHub™ Disinfecting Cap is comprised of a threaded plastic cap containing a porous pad pre-saturated with 70% Isopropyl Alcohol and sealed with a multilayer foil film.
BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed. The effectiveness of BD PureHub™ Disinfecting Cap was tested in vitro against the following microorganisms: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata* and *Candida albicans*. BD PureHub™ Disinfecting Cap reduced the number of microorganisms by greater than 4-log.

BD Catalog Number	BD Product Description	Compatibility when connected to other medical devices
306598	BD PureHub™ Disinfecting Cap Single	Female Luer connector of needleless connector
306599	BD PureHub™ Disinfecting Cap Strip	Female Luer connector of needleless connector

Bulk Configuration:



Strip configuration:



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)
306598 306599	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI Certificate No.: 252.1127	BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.:MD19.2143	Becton Dickinson France SAS 11 rue Aristide Bergès ZI des Iles - BP 4 38801 Le-Pont-de-Claix France

1.4 Materials

Component	Material
Cap	Polyethylene
Sponge	Polyester
IPA	The sponge is impregnated with USP grade 70% Isopropyl Alcohol (other names: 2-Propanol or Propan-2-ol)
Foil Lid (multilayer)	Polyester, aluminum foil and thermal adhesive

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 as per 26 May 2020, BD has not identified any • 1,2-Benzendicarboxylic 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), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentylphthalate (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% weight by weight (w/w). Furthermore, these products are not designed to contain any phthalates.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 26 May 2020, the articles with the product numbers referenced above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 26 May 2020, 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. It is not a building block of any of the raw materials utilized and is not intentionally added. BD has not done any testing to evaluate levels of this chemical in these products.
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 tallow-derived materials have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN 22442-1 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, as recognized by MEDDEV 2.4/1, 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 and EU No 722/2012).
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 products.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 26 May 2020, 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 15 January 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

Sterilization method: **Gamma irradiation** as per EN ISO 11137 – "Sterilization of health care products – Radiation"
Guaranteed sterile until opening.

1.9 Shelf life and storage conditions

The BD PureHub™ shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD PureHub™ references 306598 and 306599 have a shelf life of 3 years.
Store in dry and controlled temperature between 2 - 25°C and not exposed to strong light.

1.10 Standard

As per extract from the Declaration of Conformity:

Harmonized Standards	
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 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 62366:2008	Medical devices. Application of usability engineering to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2002 /amd.1:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-17:2009	Biological Evaluation of Medical Devices Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterisation of materials
EN 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
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11737-1:2006	Sterilization of medical devices – Microbial 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 validation of a sterilization process
ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
Non-Harmonized Standards	
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO TS 13004:2013	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD
ASTM D4169:2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D3078-02:2013	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM F1980:2011	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2825:2015	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery

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

BD PureHub™ is classified as a **Class IIa** medical device under rule 15 of Annex IX of the Council Directive 93/42/EEC, as amended.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD PureHub™ is referenced as follows:
GMDN Code: 61141
GMDN Term: Vascular catheter disinfection cap

1.13 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.

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.
- Instruction for Use is available for these catalog numbers.

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*
306598	BD PureHub™ Disinfecting Cap Single	1	300	3000	Yes
306599	BD PureHub™ Disinfecting Cap Strip	1	300	4500	Yes

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

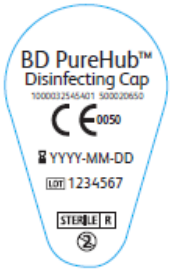
2.2 Packaging material

Component	Material
Unit Pack	Composed of White print mat, Polyester, Aluminum foil and Rayopeel thermal adhesive. The Peel Film is heat sealed to the Cap Housing flange
Shelf Box	Corrugated carton
Shipping Case	Corrugated carton
IFU	50 lb. white paper IFU is delivered as insert in shelf carton

2.3 Examples of labeling

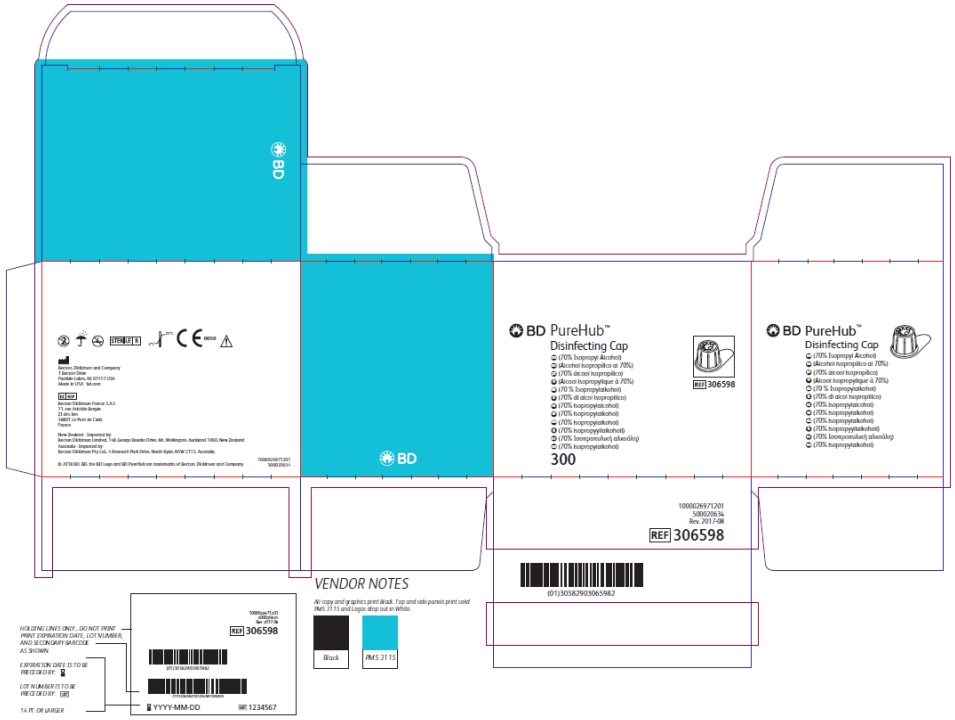
Labels: According to European Medical Device directive, labels are multilingual (English, Spanish, Portuguese, French, German, Italian, Dutch, Swedish, Danish, Finnish, Greek and Norwegian)

Primary Packaging Label (Top Web) extracted from document 10000325454 related to reference 306598:

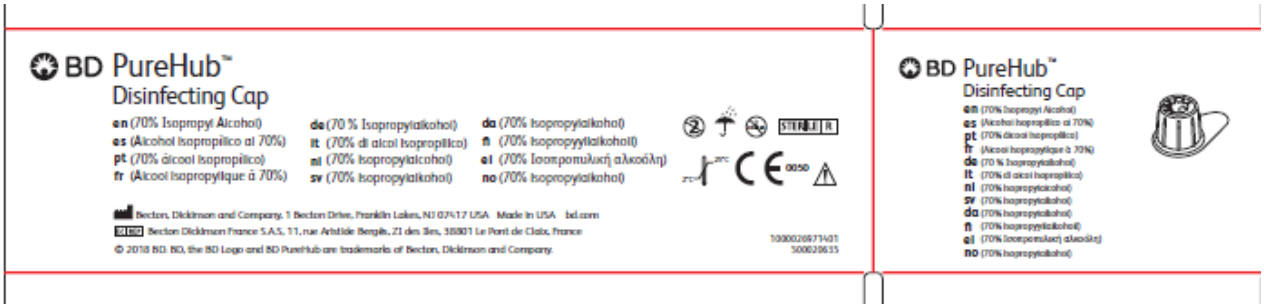


Primary Packaging Label (Top Web) extracted from document 10000294886 related to reference 306599:

Shelf Box extracted from document 10000269712 related to reference 306598:



Shipping Case extracted from document 10000269714 related to reference 306598:

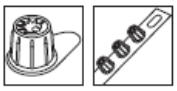


Case Label extracted from document 10000295078 related to reference 306598:

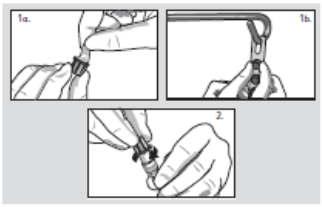
IFU extract (English language) from document 10000269705 related to reference 306598 and 306599:

BD PureHub™

Disinfecting Cap (70% Isopropyl Alcohol)



- BD PureHub™ Disinfecting Cap (70% Isopropyl Alcohol)
- Tapón desinfectante BD PureHub™ (Alcohol isopropílico al 70 %)
- Tampa protetora BD PureHub™ (70% álcool isopropílico)
- Capuchon de désinfection BD PureHub™ (Alcool isopropylique à 70%)
- BD PureHub™ Desinfektionskappe (70 % Isopropylalkohol)
- Cappuccio disinfettante BD PureHub™ (70% di alcol isopropilico)



Becton, Dickinson and Company
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Franklin Lakes, NJ 07417 USA
Made in USA bd.com

EC REP

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ZI des Ilas
38801 Le Pont de Claix
France

10000269705
500038507
Rev. 2019-04

ENGLISH

Intended Use:
BD PureHub™ Disinfecting Caps are intended to be used as a disinfecting device for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses.

Description:
BD PureHub™ Disinfecting Cap is comprised of a threaded plastic cap containing a porous pad pre-saturated with 70% Isopropyl Alcohol, and sealed with a multilayer foil film.

BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed.

The effectiveness of BD PureHub™ Disinfecting Cap was tested in vitro against the following microorganisms: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata and Candida albicans*. BD PureHub™ Disinfecting Cap reduced the number of microorganisms by greater than 4 log.

This product is not made with natural rubber latex or plasticizer Diethylhexyl Phthalate (DEHP).

CAUTIONS:
1. Do not use if product is open or damaged.
2. Verify the expiration date on the product label. Do not use if product has expired.
3. Do Not Re-Sterilize.
4. After removing the foil film, visually inspect the contents of the cap and do not use if it appears dry or contains particulate matter.
5. Do not place cap on a sterile field or aseptic area.
6. Do Not Reuse. For Single Use Only. Re-use may lead to infection or other illness / injury.
7. For use only on needle-free luer connectors.
8. Always follow hospital protocol for disinfection of needle-free luer connectors.
9. Store at controlled temperature (2-25°C).
10. The safety of 70% Isopropyl Alcohol caps has not yet been directly established in clinical use scenarios with neonates.

WARNING: Potential choking hazard.
WARNING: Keep out of reach of children. In case of accidental ingestion, seek medical help or consult a poison control center immediately.
WARNING: 70% Isopropyl Alcohol is not considered sporicidal and may not prevent Central Line Associated Blood Stream Infection arising from bacterial spores (e.g., Bacillus spp., Clostridia).

Instructions:
1. Peel the foil film from the BD PureHub™ Disinfecting Cap.
2. Apply cap to needle-free luer connector by pushing and twisting.
3. Ensure that the cap is securely attached to the connector.
4. The BD PureHub™ Disinfecting Cap must remain on the needle-free luer connector for a minimum of one (1) minute and may remain on for up to seven (7) days.
5. Always place a new disinfecting cap on the needle-free luer connector after completing a line access procedure.
6. Discard cap after removal.

How Supplied:
BD PureHub™ Disinfecting Caps are provided in shelf boxes in the following configurations:

Reorder No. 306598 Singles (300 units)
Reorder No. 306599 IV Pole Strips (300 units/30 strips of 10)

ESPAÑOL

Uso previsto:
Los tapones desinfectantes BD PureHub™ están diseñados para usarse como un dispositivo desinfectante para los conectores Luer intercambiables sin aguja antes del acceso o para actuar como una barrera física entre los accesos de las líneas.

Descripción:
El tapón desinfectante BD PureHub™ consta de un tapón plástico roscado que contiene una almohadilla porosa previamente saturada con alcohol isopropílico al 70 %, y sellado con una lámina de aluminio de varias capas.

El tapón desinfectante BD PureHub™ desinfectará el conector Luer sin aguja un (1) minuto después de la aplicación y actuará como una barrera física por hasta siete (7) días, si no se quita.

La eficacia de los tapones desinfectantes BD PureHub™ se probó de manera in vitro contra los siguientes microorganismos: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata y Candida albicans*. Se comprobó que el tapón desinfectante BD PureHub™ tuvo una reducción del número de microorganismos mayor a 4 log.

Este producto no está fabricado con látex de caucho natural o ftalato dietilhexil (DEHP).

PRECAUCIONES:
1. No utilice el producto si está abierto o dañado.
2. Verifique la fecha de vencimiento en la etiqueta del producto. No utilice el producto si está vencido.
3. No reesterilice el producto.
4. Después de quitar la lámina de aluminio, inspeccione visualmente el contenido de los tapones y no los utilice si parecen estar secos o tienen alguna partícula.
5. No coloque el tapón en un campo estéril o un área aséptica.
6. No reutilizar el producto. Está indicado para un solo uso. La reutilización puede ocasionar infecciones u otras enfermedades/lesiones.
7. Únicamente puede utilizarse con conectores Luer sin aguja.
8. Siga siempre el protocolo del hospital para la desinfección de los conectores Luer sin aguja.
9. Almacene el producto a temperatura controlada (de 2 °C a 25 °C)
10. La seguridad de las tapas con alcohol isopropílico al 70% aún no se ha establecido directamente en situaciones de uso clínico con recién nacidos.

ADVERTENCIA: posible peligro de atragantamiento.
ADVERTENCIA: mantenga el producto fuera del alcance de los niños. En caso de ingesta accidental, acuda a un médico o consulte con un centro de control de envenenamiento de inmediato.
ADVERTENCIA: El alcohol isopropílico al 70% no se considera esporicida y es posible que no evite la infección del torrente sanguíneo asociado al catéter venoso central derivada de esporas bacterianas (p. ej., Bacillus spp., clostridios).

Instrucciones:
1. Quite la lámina de aluminio del tapón desinfectante BD PureHub™
2. Aplique el tapón al conector Luer sin aguja empujando y retorciendo.
3. Asegúrese de que la tapa está correctamente acoplada al conector.
4. El tapón desinfectante BD PureHub™ debe permanecer en el conector Luer sin aguja por al menos un (1) minuto y puede permanecer colocado por hasta siete (7) días.
5. Siempre coloque un tapón desinfectante en el conector Luer sin aguja después de después de completar un procedimiento de acceso a la vía.
6. Deseche el tapón después de quitarlo.

Presentación:
Los tapones desinfectantes BD PureHub™ se proporcionan en cajas con las siguientes configuraciones:

N.° de nuevo pedido de 306598 individuales (300 unidades)
N.° de nuevo pedido de 306599 Soporte para IV (300 unidades/30 de 10)

PORTUGUÊS

Utilização pretendida:
As tampas protetoras BD PureHub™ destinam-se a uma utilização como dispositivo desinfetante para conectores luer sem agulha esterilizáveis previamente ao acesso e para atuar como barreira física entre os acessos da linha.

Descrição:
A tampa protetora BD PureHub™ inclui uma tampa plástica de rosca com um suporte poroso pré-saturado com álcool isopropílico de 70%, e vedado com uma película metálica multicamadas.

A tampa protetora BD PureHub™ irá desinfetar o conector luer sem agulha um (1) minuto após a aplicação e atua como uma barreira física até sete (7) dias, se não for removida.

A eficácia da tampa protetora BD PureHub™ foi testada in vitro contra os seguintes micro-organismos: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata e Candida albicans*. A tampa protetora BD PureHub™ apresentou uma redução do número de micro-organismos superior a 4 log.

Este produto não é feito com látex de borracha natural nem com ftalato de bis(2-etil-hexilo) (DEHP).

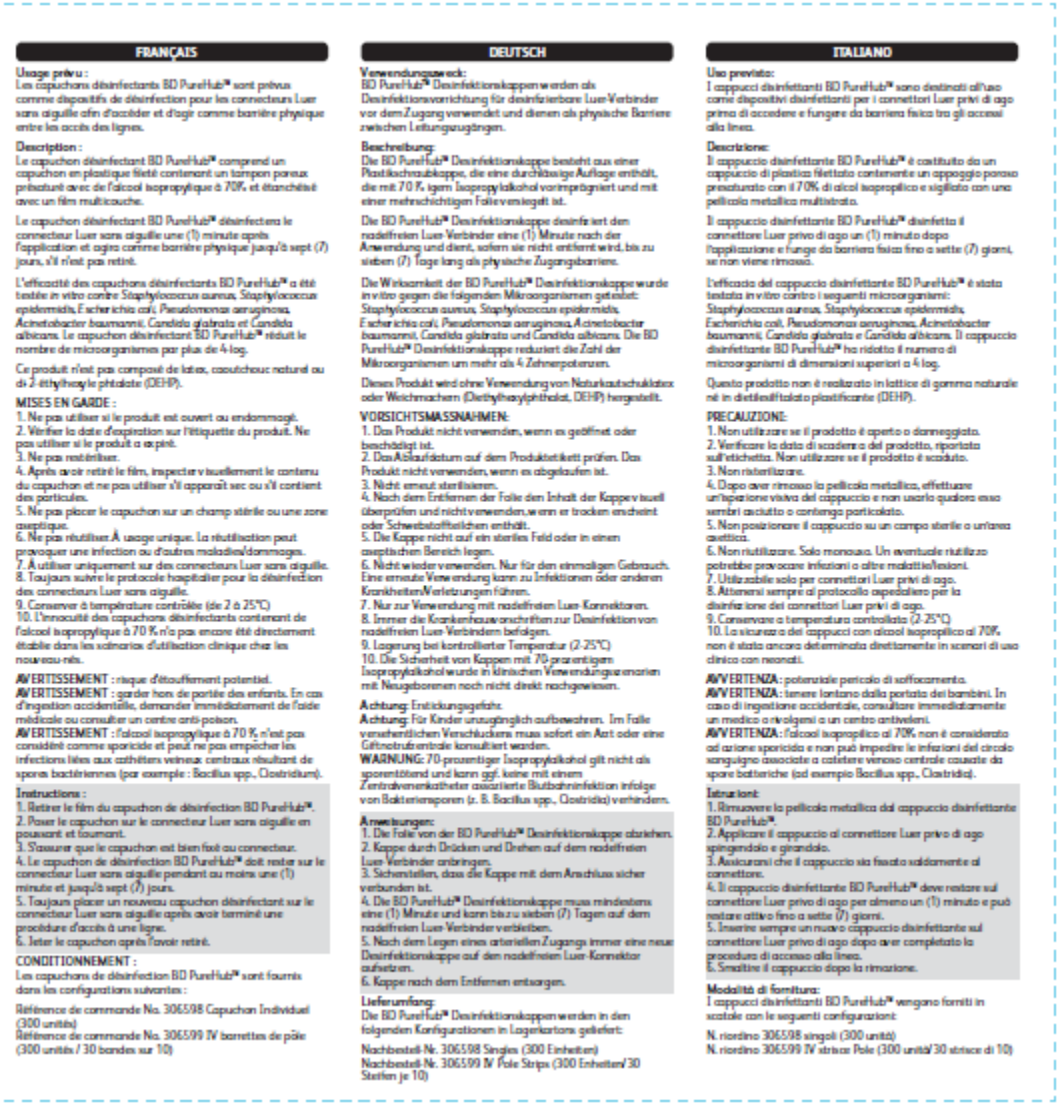
PRECAUÇÕES:
1. Não utilize se o produto estiver aberto ou danificado.
2. Verifique a data de validade no etiqueta do produto. Não utilize se o produto estiver fora de validade.
3. Não esterilize de novo.
4. Após a remoção da película metálica, deve inspecionar visualmente o conteúdo da tampa e não utilize se parecer seco ou contiver partículas.
5. Não coloque a tampa numa área esterilizada ou asséptica.
6. Não reutilize. Para utilização única apenas. A reutilização pode provocar infeção ou outra doença/outro ferimento.
7. Apenas deverá ser utilizado para conectores luer sem agulha.
8. Cumpra sempre o protocolo do hospital relativamente à desinfeção de conetores luer sem agulha.
9. Armazenar a temperatura controlada (2-25 °C)
10. Ainda não foi provado garantir diretamente a segurança das tampas do álcool isopropílico a 70% em crianças de utilização clínica com recém-nascidos.

AVISO: Potencial perigo de asfixia.
AVISO: Manter afastado do alcance das crianças. No caso de ingestão acidental, procurar imediatamente assistência médica ou um centro de controlo de envenenamentos.
AVISO: O álcool isopropílico a 70% não é considerado esporicida e poderá não evitar infeções da corrente sanguínea associadas a cateter venoso central, decorrentes de esporos bacterianos (por ex., Bacillus spp., Clostridia).

Instruções:
1. Retire a película metálica da tampa protetora BD PureHub™.
2. Coloque a tampa no conetor luer sem agulha pressionando e rosqueando.
3. Certifique-se de que a tampa está firmemente fixada ao conector.
4. A tampa protetora BD PureHub™ deve permanecer no conector luer sem agulha, durante um (1) minuto, no mínimo, e pode manter-se durante um período de sete (7) dias.
5. Coloque sempre uma tampa protetora no conector luer sem agulha após concluir um procedimento de acesso da linha.
6. Elimine a tampa após remoção.

Apresentação:
As tampas protetoras BD PureHub™ são fornecidas em embalagens nas seguintes configurações:

N.° de reposição 306598 (individual (300 unidades)
N.° de reposição 306599 Tiras para suporte IV (300 unidades/30 tiras de 10)



FRANÇAIS

Usage prévu :
Les capuchons désinfectants BD PureHub™ sont prévus comme dispositifs de désinfection pour les connecteurs Luer sans aiguille afin d'accéder et d'agir comme barrière physique entre les accès des lignes.

Description :
Le capuchon désinfectant BD PureHub™ comprend un capuchon en plastique fileté contenant un tampon poreux prétraité avec de l'alcool isopropylique à 70%, et étanchéisé avec un film multicouche.

Le capuchon désinfectant BD PureHub™ désinfectera le connecteur Luer sans aiguille une (1) minute après l'application et agira comme barrière physique jusqu'à sept (7) jours, s'il n'est pas retiré.

L'efficacité des capuchons désinfectants BD PureHub™ a été testée *in vitro* contre *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata* et *Candida albicans*. Le capuchon désinfectant BD PureHub™ réduit le nombre de microorganismes par plus de 4-log.

Ce produit n'est pas composé de latex, caoutchouc naturel ou di 2-éthylhexyle phtalate (DEHP).

MISES EN GARDE :
1. Ne pas utiliser si le produit est ouvert ou endommagé.
2. Vérifier la date d'expiration sur l'étiquette du produit. Ne pas utiliser si le produit a expiré.
3. Ne pas restériliser.
4. Après avoir retiré le film, inspecter visuellement le contenu du capuchon et ne pas utiliser s'il apparaît sec ou s'il contient des particules.
5. Ne pas placer le capuchon sur un champ stérile ou une zone aseptique.
6. Ne pas réutiliser. À usage unique. La réutilisation peut provoquer une infection ou d'autres maladies/dommages.
7. À utiliser uniquement sur des connecteurs Luer sans aiguille.
8. Toujours suivre le protocole hospitalier pour la désinfection des connecteurs Luer sans aiguille.
9. Conserver à température contrôlée (de 2 à 25°C).
10. L'innocuité des capuchons désinfectants contenant de l'alcool isopropylique à 70 % n'a pas encore été directement établie dans les scénarios d'utilisation clinique chez les nouveau-nés.

AVERTISSEMENT : risque d'étouffement potentiel.
AVERTISSEMENT : garder hors de portée des enfants. En cas d'ingestion accidentelle, demander immédiatement de l'aide médicale ou consulter un centre anti-poison.
AVERTISSEMENT : l'alcool isopropylique à 70 % n'est pas considéré comme sporicide et peut ne pas empêcher les infections liées aux cathéters veineux centraux résultant de spores bactériennes (par exemple : Bacillus spp., Clostridium).

Instructions :
1. Retirer le film du capuchon de désinfection BD PureHub™.
2. Poser le capuchon sur le connecteur Luer sans aiguille en poussant et tournant.
3. S'assurer que le capuchon est bien fixé au connecteur.
4. Le capuchon de désinfection BD PureHub™ doit rester sur le connecteur Luer sans aiguille pendant au moins une (1) minute et jusqu'à sept (7) jours.
5. Toujours placer un nouveau capuchon désinfectant sur le connecteur Luer sans aiguille après avoir terminé une procédure d'accès à une ligne.
6. Jeter le capuchon après l'avoir retiré.

CONDITIONNEMENT :
Les capuchons de désinfection BD PureHub™ sont fournis dans les configurations suivantes :

Référence de commande No. 306598 Capuchon Individuel (300 unités)
Référence de commande No. 306599 IV barrettes de pôle (300 unités / 30 bandes sur 10)

DEUTSCH

Verwendungszweck:
BD PureHub™ Desinfektionskappen werden als Desinfektionsvorrichtung für desinfizierbare Luer-Verbinder vor dem Zugang verwendet und dienen als physische Barriere zwischen Leitungszugängen.

Beschreibung:
Die BD PureHub™ Desinfektionskappe besteht aus einer Plastikschraubkappe, die eine durchlässige Auflage enthält, die mit 70 % igem Isopropylalkohol vorimprägniert und mit einer mehrschichtigen Folie versiegelt ist.

Die BD PureHub™ Desinfektionskappe desinfiziert den nadelfreien Luer-Verbinder eine (1) Minute nach der Anwendung und dient, sofern sie nicht entfernt wird, bis zu sieben (7) Tage lang als physische Zugangsbarriere.

Die Wirksamkeit der BD PureHub™ Desinfektionskappe wurde *in vitro* gegen die folgenden Mikroorganismen getestet: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata* und *Candida albicans*. Die BD PureHub™ Desinfektionskappe reduziert die Zahl der Mikroorganismen um mehr als 4 Zehnerpotenzen.

Dieses Produkt wird ohne Verwendung von Naturkautschuklatex oder Weichmachern (Diethylhexylphthalat, DEHP) hergestellt.

VORSICHTSMASSNAHMEN:
1. Das Produkt nicht verwenden, wenn es geöffnet oder beschädigt ist.
2. Das Ablaufdatum auf dem Produktetikett prüfen. Das Produkt nicht verwenden, wenn es abgelaufen ist.
3. Nicht erneut sterilisieren.
4. Nach dem Entfernen der Folie den Inhalt der Kappe visuell überprüfen und nicht verwenden, wenn er trocken erscheint oder Schwebstoffpartikeln enthält.
5. Die Kappe nicht auf ein steriles Feld oder in einen aseptischen Bereich legen.
6. Nicht wieder verwenden. Nur für den einmaligen Gebrauch. Eine erneute Verwendung kann zu Infektionen oder anderen Krankheiten/Verletzungen führen.
7. Nur zur Verwendung mit nadelfreien Luer-Konnektoren.
8. Immer die Krankenhausvorschriften zur Desinfektion von nadelfreien Luer-Verbindern befolgen.
9. Lagerung bei kontrollierter Temperatur (2-25°C).
10. Die Sicherheit von Kappen mit 70-prozentigem Isopropylalkohol wurde in klinischen Verwendungsszenarien mit Neugeborenen noch nicht direkt nachgewiesen.

Achtung: Entzündungsgefahr.
Achtung: Für Kinder unzugänglich aufbewahren. Im Falle versehentlichen Verschluckens muss sofort ein Arzt oder eine Giftnotrufzentrale konsultiert werden.
WARNUNG: 70-prozentiger Isopropylalkohol gilt nicht als sporentötend und kann ggf. keine mit einem Zentralvenenkatheter assoziierte Blutbahninfektion infolge von Bakteriensporen (z. B. Bacillus spp., Clostridia) verhindern.

Anweisungen:
1. Die Folie von der BD PureHub™ Desinfektionskappe abziehen.
2. Kappe durch Drücken und Drehen auf dem nadelfreien Luer-Verbinder anbringen.
3. Sicherstellen, dass die Kappe mit dem Anschluss sicher verbunden ist.
4. Die BD PureHub™ Desinfektionskappe muss mindestens eine (1) Minute und kann bis zu sieben (7) Tagen auf dem nadelfreien Luer-Verbinder verbleiben.
5. Nach dem Legen eines arteriellen Zugangs immer eine neue Desinfektionskappe auf den nadelfreien Luer-Konnektor aufsetzen.
6. Kappe nach dem Entfernen entsorgen.

Lieferumfang:
Die BD PureHub™ Desinfektionskappen werden in den folgenden Konfigurationen in Lagerkartons geliefert:

Nachbestell-Nr. 306598 Singles (300 Einheiten)
Nachbestell-Nr. 306599 IV Pole Strips (300 Einheiten/30 Streifen je 10)

ITALIANO

Uso previsto:
I cappucci disinfettanti BD PureHub™ sono destinati all'uso come dispositivi disinfettanti per i connettori Luer privi di ago prima di accedere e fungere da barriera fisica tra gli accessi alla linea.

Descrizione:
Il cappuccio disinfettante BD PureHub™ è costituito da un cappuccio di plastica filettato contenente un appoggio poroso preisaturato con il 70% di alcol isopropilico e sigillato con una pellicola metallica multistrato.

Il cappuccio disinfettante BD PureHub™ disinfetta il connettore Luer privo di ago un (1) minuto dopo l'applicazione e funge da barriera fisica fino a sette (7) giorni, se non viene rimosso.

L'efficacia del cappuccio disinfettante BD PureHub™ è stata testata *in vitro* contro i seguenti microorganismi: *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Acinetobacter baumannii, Candida glabrata* e *Candida albicans*. Il cappuccio disinfettante BD PureHub™ ha ridotto il numero di microorganismi di dimensioni superiori a 4 log.

Questo prodotto non è realizzato in lattice di gomma naturale né in dietilesilftalato plastificante (DEHP).

PRECAUZIONI:
1. Non utilizzare se il prodotto è aperto o danneggiato.
2. Verificare la data di scadenza del prodotto, riportata sull'etichetta. Non utilizzare se il prodotto è scaduto.
3. Non risterilizzare.
4. Dopo aver rimosso la pellicola metallica, effettuare un'ispezione visiva del cappuccio e non usarlo qualora esso sembri asciutto o contenga particolato.
5. Non posizionare il cappuccio su un campo sterile o un'area asettica.
6. Non riutilizzare. Solo monouso. Un eventuale riutilizzo potrebbe provocare infezioni o altre malattie/lesioni.
7. Utilizzabile solo per connettori Luer privi di ago.
8. Attenersi sempre al protocollo ospedaliero per la disinfezione dei connettori Luer privi di ago.
9. Conservare a temperatura controllata (2-25°C).
10. La sicurezza dei cappucci con alcool isopropilico al 70% non è stata ancora determinata direttamente in scenari di uso clinico con neonati.

AVVERTENZA: potenziale pericolo di soffocamento.
AVVERTENZA: tenere lontano dalla portata dei bambini. In caso di ingestione accidentale, consultare immediatamente un medico o rivolgersi a un centro antiveleni.
AVVERTENZA: l'alcool isopropilico al 70% non è considerato ad azione sporicida e non può impedire le infezioni del circolo sanguigno associate a catetere venoso centrale causate da spore batteriche (ad esempio Bacillus spp., Clostridia).

Istruzioni:
1. Rimuovere la pellicola metallica dal cappuccio disinfettante BD PureHub™.
2. Applicare il cappuccio al connettore Luer privo di ago spingendolo e girandolo.
3. Assicurarsi che il cappuccio sia fissato saldamente al connettore.
4. Il cappuccio disinfettante BD PureHub™ deve restare sul connettore Luer privo di ago per almeno un (1) minuto e può restare attivo fino a sette (7) giorni.
5. Inserire sempre un nuovo cappuccio disinfettante sul connettore Luer privo di ago dopo aver completato la procedura di accesso alla linea.
6. Smaltire il cappuccio dopo la rimozione.

Modalità di fornitura:
I cappucci disinfettanti BD PureHub™ vengono forniti in scatole con le seguenti configurazioni:

N. riordino 306598 singoli (300 unità)
N. riordino 306599 IV strisce Pole (300 unità/ 30 strisce di 10)

REVISION	CHANGE SUMMARY
01	Initial release according to new template *Addition of a new catalog number: 306599 and new product design (PureHub Strip)*