BD Spinal Needles, Sterile

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TDS number: V201-012 – Rev. 01
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1. General Information

1.1 Intended use

The BD™ Spinal Needle is a sterile, sharp bevel-edged, hollow tubular metal instrument designed to deliver anaesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord). It is typically fenestrated, spring-tipped, and used for short-term administration; it is typically made of metal and plastic materials. This is a single-use device.

The Non-Luer Spinal Needles are for use with BD Non-Luer Devices.

1.2 General description

Spinal needles are medical devices used for specific therapeutic or diagnostic medical procedures, such as delivering anaesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord) for spinal anesthesia (total or partial loss of feeling or sensation), analgesia (absence of pain), and lumbar punctures for collecting cerebral spinal fluid (CSF).

Performed by either an Anesthesiologist or Certified Registered Nurse Anesthetist, spinal anesthesia and analgesia involves inserting local anesthetics or narcotics into the spinal space by locating the subarachnoid or spinal space with a spinal needle. The spinal needle consists of two important components: the needle and the stylet. The needle consists of a hollow stainless-steel needle with a plastic or metal hub at one end of the needle and a specific point style configured at the opposing end. The stylet is solid steel or a solid plastic needle with a plastic hub. The stylet is fitted to the inside of the spinal needle and the two hubs are oriented by way of a small key and notch feature. The key also indicates the position of the bevel for both the spinal needle and the stylet. The bevel designs are matched to allow the stylet to fill the open end of the spinal needle when the stylet is securely placed within the needle for use.

BD Whitacre Spinal Needle

BD Quincke Spinal Needle

BD Catalog Number	BD Product Description	Gauge Size	Length (Inch)	Length (mm)	Color Code	Introducer dimension
BD Quincke Spinal Needles						
405248	SPINAL NEEDLE 18GA 3.50 IN	18	3.50	90	Pink	N/A
405247	SPINAL NEEDLE 18GA 3.00 IN	18	3.00	75	Pink	N/A
405249	SPINAL NEEDLE 19GA 3.00 IN	19	3.00	75	Cream	N/A
405250	SPINAL NEEDLE 19GA 3.50 IN	19	3.50	90	Cream	N/A
405251	SPINAL NEEDLE 20GA 1.50 IN	20	1.50	38	Yellow	N/A
405252	SPINAL NEEDLE 20GA 3.00 IN	20	3.00	75	Yellow	N/A
405253	SPINAL NEEDLE 20GA 3.50 IN	20	3.50	90	Yellow	N/A
405254	SPINAL NEEDLE 22GA 1.50 IN	22	1.50	38	Black	N/A
405255	SPINAL NEEDLE 22GA 3.00 IN	22	3.00	75	Black	N/A
405244	SPINAL NEEDLE 22GA 2-1/2IN	22	2.50	63	Black	N/A
405256	SPINAL NEEDLE 22GA 3.50 IN	22	3.50	90	Black	N/A
405240	SPINAL NEEDLE THIN WALL 23GA 3-1/21N	23	3.50	90	Turquoise	N/A
405246	SPINAL NEEDLE 25GA 3IN	25	3.00	75	Orange	N/A
405257	SPINAL NEEDLE 25GA 3.50 IN	25	3.50	90	Orange	N/A
405258	SPINAL NEEDLE 26GA 3.50 IN	26	3.50	90	Bronze	N/A
405259	SPINAL NEEDLE 27GA 3.50 IN	27	3.50	90	Grey	N/A
405084	SPINAL SET 25GA 3-1/21N	25	3.50	90	Orange	20G 1.25IN
405065	SPINAL SET 26GA 3-1/21N	26	3.50	90	Bronze	20G 1.25IN
405069	SPINAL SET 27GA 3-1/21N	27	3.50	90	Grey	22G 1.25IN
405148	NEEDLE SPINAL S/SU 22GA 5IN QUINCKE	22	5.00	127	Black	N/A
405149	NEEDLE SPINAL S/SU 22GA 7IN QUINCKE	22	7.00	178	Black	N/A
405211	NEEDLE SPINAL S/SU 20GA 6IN QUINCKE	20	6.00	152	Yellow	N/A
405234	NEEDLE SP S/SU 25GA 4-11/16IN QUINCKE	25	4.69	119	Blue	N/A
408360	NEEDLE SPINAL S/SU 18GA 6IN QUINCKE	18	6.00	152	Pink	N/A
BD Whitacre Spinal Needles						
401995	WHITACRE 22GA 3-1/2IN	22	3.50	90	Black	N/A
405104	WHITACRE 24GA 3-1/2IN	24	3.50	90	Purple	N/A
402050	WHITACRE 25GA 3-1/2IN	25	3.50	90	Blue	N/A
402051	WHITACRE 27GA 3-1/2IN	27	3.50	90	Grey	N/A
405076	WHITACRE SET 25GA 3-1/2IN	25	3.50	90	Blue	20G 1.25IN
405111	Whitacre 27GA 4-1/16	27	4.06	103	Grey	N/A
405075	WHITACRE SET 27GA 3-1/2IN	27	3.50	90	Grey	22G 1.25IN
405112	WHITACRE SET 25 GA 4-1/16	25	4.06	103	Blue	20G 1.25IN
405113	WHITACRE SET 27 GA 4-1/16	27	4.06	103	Grey	22G 1.25IN
409442	NEEDLE SP S/SU 25GA 4-11/16IN WHITACRE	25	4.69	119	Blue	N/A
409443	NEEDLE SP S/SU 27GA 4-11/16IN WHITACRE	27	4.69	119	Grey	N/A
BD Introducers						
405260	SPINAL NEEDLE 20GA 1.25 IN	20	1.25	32	Natural	N/A
405261	SPINAL NEEDLE 22GA 1.25 IN	22	1.25	32	Natural	N/A

BD Neonatal Spinal Needle						
405243	SPINAL NEEDLE NEONATAL LUMBAR 25GA 1IN	25	1.00	25	Blue	N/A
405245	SPINAL NEEDLE NEONATAL LUMBAR 25GA 2IN	25	2.00	51	Blue	N/A

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

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)
405248 405247 405249 405250 405251 405252 405253 405254 405255 405244* 405256 405240 405246 405257 405258 405259 405243* 405245* 405084 405065 405069	**Address:** Becton Dickinson, S.A. Camino de Valdeoliva, s/n 28750 San Augustin del Guadalix Madrid **ISO 13485** Certificate No.: 2012 07 0013 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0005 CP Coupled with: 2010 02 0701 ET	**Address:** Becton Dickinson, S.A. Camino de Valdeoliva, s/n 28750 San Augustin del Guadalix Madrid **ISO 13485** Certificate No.: 2012 07 0013 EN **SKU with *,** the assembly is done in: BD Caribe, LTD. Road 31 km 24.3 P.O. Box 4010 Juncos, Puerto Rico 00777-4010 **ISO 13485** Certificate No.: MD19.1805	N/A
401995 405104* 402050 402051 405076 405111* 405075 405112* 405113*		CE certified with AEMPS (0318) Certificate No.: 95 06 0005 CP Coupled with: 2010 02 0700 ET		
405260 405261	**Address:** Becton Dickinson, S.A. Camino de Valdeoliva, s/n 28750 San Augustin del Guadalix Madrid **ISO 13485** Certificate No.: 2012 07 0013 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0005 CP	**Address:** Becton Dickinson, S.A. Camino de Valdeoliva, s/n 28750 San Augustin del Guadalix Madrid **ISO 13485** Certificate No.: 2012 07 0013 EN	N/A

Note: As this are class III devices, there is one CE certificate and one EC type examination certificate.

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)
405148 405149 405211 405234 408360 409442 409443	**Address:** Becton Dickinson and Co. 1 Becton Drive Franklin Lakes New Jersey 07417 **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.797 Coupled with AEMPS (0318) Certificate No.: 2010 02 0698 ET 2010 02 0699 ET	BD Caribe, LTD. Road 31 km 24.3 P.O. Box 4010 Juncos, Puerto Rico 00777-4010	**ISO 13485** Certificate No.: MD19.1805 Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium

Note: As this are class III devices, there is one CE certificate and one EC type examination certificate.

1.4 Materials

- For Spinal Needles:

	Component	Material
Needle	Cannula	Stainless steel
	Hub	Polypropylene
	Shield	Polypropylene
Stylet	Wire	Stainless steel
	Handle	Polypropylene + Colorant

- For Introducers Needles (SKU 405260 and 405261):

Component	Material
Hub	Polypropylene
Cannula	Stainless steel
Shield	Polypropylene

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 30 January 2019, BD has not identified any • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS#84-69-5), • Benzylbutyl phthalate (BBP) (CAS# 85-68-7), • Bis(2-methoxyethyl phthalate) (DMEP) (CAS#117-82-8), • Diisopentylphthalate (DIPP) (CAS#605-50-5), • Dipentyl phthalate (DPP) (CAS#131-18-0), • Di-n-hexyl phthalate (DnHP) (CAS#84-75-3), or • N-pentyl-isopentylphthalate (CAS# 776297-69-9) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 30 January 2019, the articles with the Product Numbers 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 30 January 2019, 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). BD has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the articles with the Product Number(s) 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.

Material	Comment
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 animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. 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, tallow processed in accordance with the aforementioned standards and guidelines is 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 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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 30 January 2019, BD has not identified any chemicals in the articles and packaging of BD Spinal Needles and Introducers, 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 27 June 2018 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

Etylene oxide Sterilization: validated per EN ISO 11135 *(Sterilization of Healthcare Products – Ethylene Oxide*).

1.9 Shelf life and storage conditions

The BD Spinal Needles and introducers shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Spinal Needles and introducers have a shelf life of 5 years.
Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity linked to CE certificate number 95 06 0006 CP and 2010 02 0701 ET:

Harmonized 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
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993 series	Biological evaluation of medical devices
EN ISO 11138-2:2009	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 13485:2016 /AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006 /AC:2009	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
EN 20594-1:1993 /AC:1996 /A1:1997	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
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
Non-Harmonized Standards	
UNE-EN ISO 11135:2015	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 9626:1995 /A1:2001	Stainless steel needle tubing for the manufacture of medical devices

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

1.11 Classification

Spinal needles are Class III Medical Devices as per Annex IX, Chapter III, Section 2.2 Rule 6 of the Medical Device Directive 93/42/EEC as amended with 2007/47/EC – OJL 247, 21/09/2007.

Introducers for Spinal needles (SKU 405260 and 405261) are classified as a Class IIa medical device under the rule 6 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 Spinal Needle and Introducers are referenced as follows:

- BD Spinal Needles:

GMDN Code: 35212
GMDN Term: Spinal Anesthesia Needle, Single Use

- BD Introducers for Spinal Needles (SKU 405260 and 405261):

GMDN Code: 45018
GMDN Term: Non-implantable needle guide, single-use

1.13 Good Manufacturing practices

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

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

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* 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 Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
BD Quincke Spinal Needles					
405248	SPINAL NEEDLE 18GA 3.50 IN	1	25	200	Yes
405247	SPINAL NEEDLE 18GA 3.00 IN	1	25	200	Yes
405249	SPINAL NEEDLE 19GA 3.00 IN	1	25	200	Yes
405250	SPINAL NEEDLE 19GA 3.50 IN	1	25	200	Yes
405251	SPINAL NEEDLE 20GA 1.50 IN	1	25	200	Yes
405252	SPINAL NEEDLE 20GA 3.00 IN	1	25	200	Yes
405253	SPINAL NEEDLE 20GA 3.50 IN	1	25	200	Yes
405254	SPINAL NEEDLE 22GA 1.50 IN	1	25	200	Yes
405255	SPINAL NEEDLE 22GA 3.00 IN	1	25	200	Yes
405244	SPINAL NEEDLE 22GA 2-1/2IN	1	25	200	Yes
405256	SPINAL NEEDLE 22GA 3.50 IN	1	25	200	Yes
405240	SPINAL NEEDLE THIN WALL 23GA 3-1/21N	1	25	200	Yes
405246	SPINAL NEEDLE 25GA 3IN	1	25	200	Yes
405257	SPINAL NEEDLE 25GA 3.50 IN	1	25	200	Yes
405258	SPINAL NEEDLE 26GA 3.50 IN	1	25	200	Yes
405259	SPINAL NEEDLE 27GA 3.50 IN	1	25	200	Yes
405084	SPINAL SET 25GA 3-1/21N	1	25	200	Yes
405065	SPINAL SET 26GA 3-1/21N	1	25	200	Yes
405069	SPINAL SET 27GA 3-1/21N	1	25	200	Yes
405148	NEEDLE SPINAL S/SU 22GA 5IN QUINCKE	1	10	50	Yes
405149	NEEDLE SPINAL S/SU 22GA 7IN QUINCKE	1	10	50	Yes
405211	NEEDLE SPINAL S/SU 20GA 6IN QUINCKE	1	10	50	Yes
405234	NEEDLE SP S/SU 25GA 4-11/16IN QUINCKE	1	10	50	Yes
408360	NEEDLE SPINAL S/SU 18GA 6IN QUINCKE	1	10	50	Yes
BD Whitacre Spinal Needles					
401995	WHITACRE 22GA 3-1/2IN	1	25	200	Yes
405104	WHITACRE 24GA 3-1/2IN	1	25	200	Yes
402050	WHITACRE 25GA 3-1/2IN	1	25	200	Yes
402051	WHITACRE 27GA 3-1/2IN	1	25	200	Yes
405076	WHITACRE SET 25GA 3-1/2IN	1	25	200	Yes
405111	Whitacre 27GA 4-1/16	1	25	200	Yes
405075	WHITACRE SET 27GA 3-1/2IN	1	25	200	Yes
405112	WHITACRE SET 25 GA 4-1/16	1	25	200	Yes
405113	WHITACRE SET 27 GA 4-1/16	1	25	200	Yes
409442	NEEDLE SP S/SU 25GA 4-11/16IN WHITACRE	1	10	50	Yes
409443	NEEDLE SP S/SU 27GA 4-11/16IN WHITACRE	1	10	50	Yes

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
BD Introducers					
405260	SPINAL NEEDLE 20GA 1.25 IN	1	25	200	Yes
405261	SPINAL NEEDLE 22GA 1.25 IN	1	25	200	Yes

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
BD Neonatal Spinal Needle					
405243	SPINAL NEEDLE NEONATAL LUMBAR 25GA 1IN	1	25	200	Yes
405245	SPINAL NEEDLE NEONATAL LUMBAR 25GA 2IN	1	25	200	Yes

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

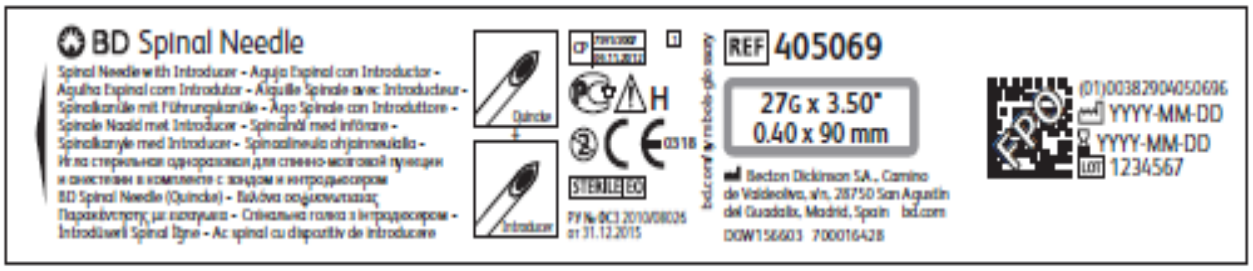
2.2 Packaging material

Component	Material
Unit Pack	Film (Polypropylene + Polyethylene) + TYVEK
Shelf Box	Cardboard
Shipping Case	Carton
IFU	Paper

2.3 Examples of labeling

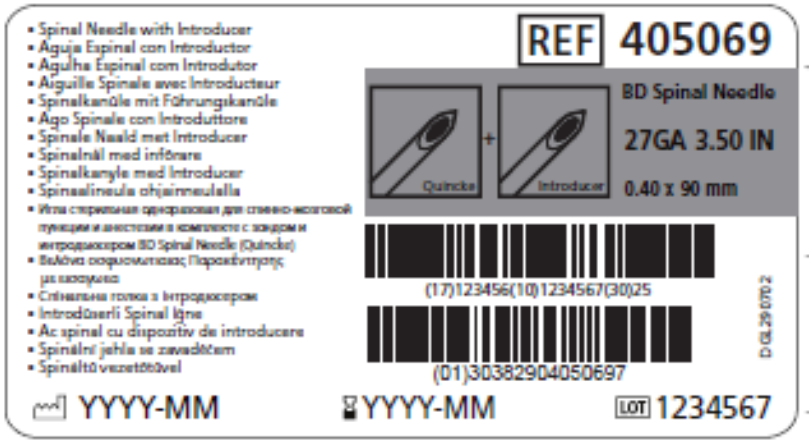
Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document DGW1566 related to reference 405069:

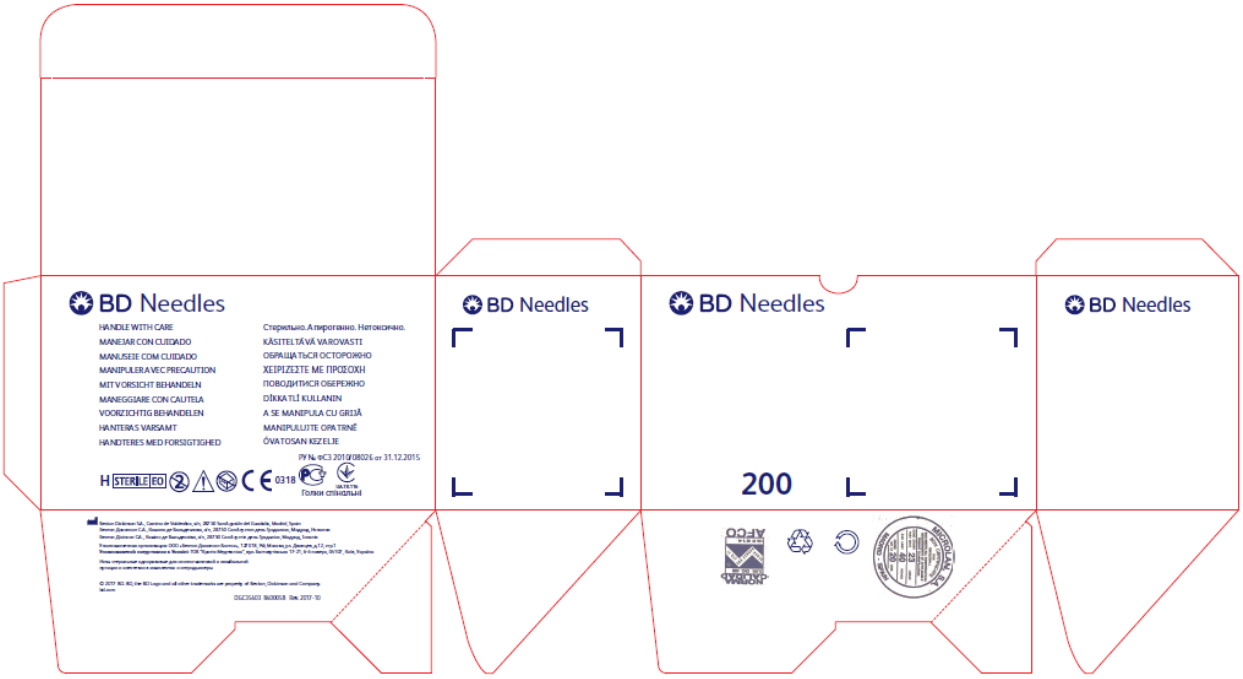


Shelf Box extracted from document DGF596 related to reference 405069:

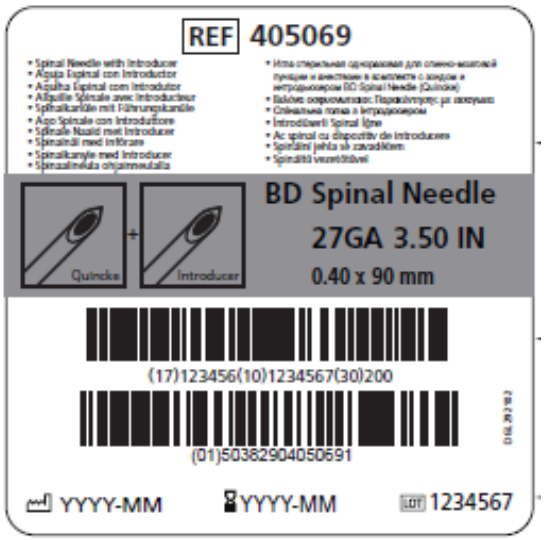
Shelf Label extracted from document DGL2907 related to reference 405069:



Shipping Case extracted from document DGC354 related to reference 405069:



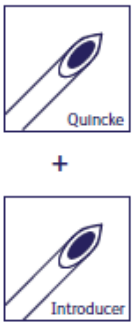
Case Label extracted from document DGL2921 related to reference 405069:



IFU insert extracted from document DGP158 related to reference 405069:

BD Spinal Needle

- Spinal Needle with Introducer
- Aguja Espinal con Introductor
- Agulha Espinal com Introdutor
- Aiguille Spinale avec Introducteur
- Spinalkanüle mit Führungskanüle
- Ago Spinale con Introduttore
- Spinale Naald met Introducer
- Spinalnål med införare
- Spinalkanyle med Introducer
- Spinaalineula ohjainneulalla
- Спинальная игла с интродьюсером
- Βελόνα οσφυονωτιαιας Παρακ ντησης με εισαγωεα
- Igła podpajęczynówkowa z igłą prowadzącą
- Spináltű vezetőtűvel
- Spinální jehla se zavaděčem
- Spinálna ihla so zavádzačom
- Spinalna igla z vodilom
- Spinaalnõel koos sisestusseadmega
- Spinalinė adata su įvediklių
- Muguras smadzeņu punkcijas adata ar ievaditāju
- Spinalnål med innføringshylse
- İntrodüserli Spinal İğne
- إبرة نخاعية مع مدخل
- Спинална игла с интродюсер
- Spinalna igla s uvodnikom
- Жұлын пункциясына арналған, интродьюсермен жиынтықталған ине
- Ac spinal cu dispozitiv de introducere
- Spinalna igla sa uvodnikom
- Спінальна голка з інтродюсером
- Игла стерильная одноразовая для спинно-мозговой пункции и анестезии в комплекте с зондом и интродьюсером BD Spinal Needle (Quincke)



en

OBSERVE UNIVERSAL PRECAUTIONS ON ALL PATIENTS
REPORT NEEDLE STICKS IMMEDIATELY AND FOLLOW ESTABLISHED PROTOCOL.
- Percutaneous puncture with a contaminated needle may lead to serious illness such as hepatitis, HIV (AIDS), or other infectious diseases.
- Resheathing needles is hazardous.
NON-PYROGENIC - STERILE:
Unless package has been opened or damaged.
DO NOT RESTERILIZE.
As with any spinal procedure, to help avoid needle breakage, DO NOT ATTEMPT TO STRAIGHTEN A BENT NEEDLE.
Care should be taken to avoid needle damage. Repeated repositioning may increase the risk of needle breakage. Observe needle carefully during procedures.
Remove spinal needle and introducer needle together. Replace with a new needle.
ENSURE SYRINGE IS SEATED FIRMLY IN NEEDLE HUB.
To be used by properly qualified and trained health professionals.
CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
Re-use may lead to infection or other illness/injury.

REVISION	CHANGE SUMMARY
01	Initial release according to new template