

III Sterilizasyon tipi için primer ambalaja bakınız. İthalatçı Firma: B. Braun Medical Dış Ticaret A.Ş., Maslak Mah., Sümer Sok., No: 4/5-4 Sarıyer - İstanbul

IV „柏期“ 標準麻醉用穿刺針 „B. Braun“ Needles for Spinal Anaesthesia 製造廠地址: 如原廠標示 製造日期及有效期限或保存期限: 如原廠標示 製造廠名稱:

(O) B. Braun Medical Industries AG (P) B. Braun Medical Industries Sdn. Bhd. 製造廠地址: (O) Carl-Brann-Strasse 1, 34212 Melsungen, Germany (P) Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia 廠商名稱: 台灣柏朗股份有限公司 臺灣地址: 臺南市松山區健康路152號9樓

CE 0123 0620 12410799 U.A. TR. 630 B. Braun Melsungen AG 34209 Melsungen Germany www.bbraun.com

**GB Instructions for use**

**Materials used**  
Stainless steel, nickel plated brass, polycarbonate, polypropylene, epoxy resin

**Indications**  
- Lumbar puncture (diagnosis)  
- Spinal anesthesia (injection of local anesthetics into the subarachnoid space for diagnosis, operative procedures and pain management).

**Contraindications**  
The recognized contraindications for spinal anesthesia and lumbar puncture must be observed. Be aware of:  
• blood coagulation disorders  
• skin infection at or near the puncture / injection site  
• sepsis  
• History of hypersensitivity to local anesthetic or any of the materials employed is known

• Patient refusal  
• Severe untreated hypovolemia  
• Increased intracranial pressure  
Spinal anesthesia should not be performed in patients with the following conditions:  
• severe decompensated hypovolemia  
• shock  
• acute cerebral or spinal cord disease  
• increased intracranial pressure  
• existing infection at the injection site

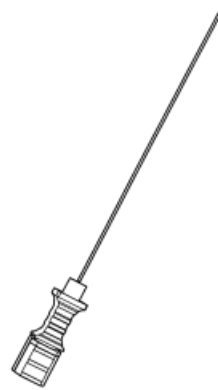
**Warning**  
Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/

or limited functionality of the device may lead to injury, illness or death of the patient. Do not use if packaging is damaged. Do not re-sterilize. The needle might bend and eventually break when applying too strong forces during advancement. The tip of the needle becomes blunt or can even split after bone contact. Needles with damaged tip increase the risk of post dural puncture headache due to an extended perforation of the dura mater.

**Duration of use**  
Spinal needles are used for a few minutes for diagnostic puncture (lumbar puncture) or for the injection of drugs into the subarachnoid space (spinal anesthesia) and are withdrawn from the patient immediately after completion of the procedure.

**Instructions for use**  
Lumbar puncture/spinal anesthesia  
**Aseptic conditions are required.**  
1. Orient the patient according to his/her condition and/or the planned puncture/injection site. Choose between lateral, sitting or prone position. Locate the midline and follow it during injection. Try to minimize lumbar lordosis.  
2. Select a suitable spinal needle and use an Introducer Needle for spinal needles less than

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25 G diameter. Check emergency equipment (intubation kit, drugs) and ensure continuous monitoring of the patient.  
3. Disinfect puncture site.  
4. Inject 1–1.5 cc of local anesthetic into the skin at the selected puncture site of the spinal needle to anesthetize the tissue and the supraspinous and intraspinal ligaments.  
5. The guiding needle is introduced into the puncture site until reaching the interspinous ligament. The guiding needle is fixed with thumb and index finger of the left hand (for right-hand user).  
6. The spinal needle including the stylet is advanced through the guiding needle. The typical "dural click" occurs when the ligamentum flavum has been passed and the subarachnoid space has been reached.  
**Warning**  
If any resistance is felt during advancement of the spinal needle carefully correct the orientation of the needle but never apply strong forces in order to overcome the obstacles.  
7. Remove the stylet from the spinal needle. Carefully check the occurrence of cerebrospinal fluid which can slightly be contaminated by blood but must never be pure blood.

- Lumbar puncture procedure - (take liquor for diagnosis, withdraw spinal needle, cover the puncture site with sterile plaster).  
8. - Spinal anesthesia - Before and shortly after injection of the local anesthetic withdraw liquid from the subarachnoid space. Inject the drug as described in the manufacturer's instructions.  
**Note**  
- The local anesthetic must never be injected without the evidence of cerebrospinal fluid.  
- If pure blood is flowing instead of cerebrospinal fluid withdraw the needle and re-try at a different intervertebral space.  
- If no cerebrospinal fluid is flowing back rotate the needle to all four quadrants and carefully aspirate until cerebrospinal fluid is visible. If this procedure does not show any backflow of cerebrospinal fluid repeat the spinal puncture using a different needle direction.  
- If paresthesia occurs after reaching the subarachnoid space the needle must be slightly withdrawn.  
- If paresthesia occurs during injection the needle must be repositioned

**B BRAUN**

	Do not re-use	Consult instruction for use	Batch number	Sterilized using ethylene oxide
DE	Nicht wiederverwenden	Gebrauchsanweisung beachten	Chargennummer	Sterilisiert mit Ethylenoxid
BG	Да не се използва повторно	Вижте инструкциите за употреба	Партиден номер	Стерилизирано с етиленов оксид
CN	禁止重复使用	阅读使用说明	批号	使用环氧乙烷灭菌
CZ	Nepoužívat opětovně	Čtěte návod k použití	Kód dávky	Sterilizováno ethylenoxidem
DK	Må ikke genbruges	Læs brugsanvisningen	Lot-nr.	Steriliseret med ethylenoxid
EE	Mitte kordukasutada	Vt kasutusjuhendit	Partinumber	Steriliseeritud etüleenoksiidiga
ES	No reutilizable	Consulte las Instrucciones de uso	Código de lote	esterilización por O <sub>2</sub>
FI	Ei saa käyttää uudelleen	Katso käyttöohje	Eränumero	Steriloitu etyleenioksidilla
FR	Ne pas réutiliser	Consulter le mode d'emploi	Numéro de lot	Stérilisation à l'oxyde d'éthylène
GR	Να μην επαναχρησιμοποιηθεί	Συμβουλευτείτε τις οδηγίες χρήσης	Αριθμός παρτίδας	αποστειρωμένο με αιθυλενοξειδίο
HR	Nemojte ponovno upotrebljavati	Pogledajte upute za uporabu	Broj serije	Sterilizirano etilen-oksikom
HU	Ne használja fel újra	Nézze meg a használati utasítást	Sorozat száma	Etilén-oxidál sterilizálva
ID	Jangan gunakan kembali	Baca petunjuk penggunaan	Nomor batch	Disterilkan menggunakan etilena oksida
IT	Non riutilizzare	Consultare le istruzioni per l'uso	Numero di lotto	Sterilizzato con ossido di etilene
KR	의류기기와, 일회용 재사용금지	사용법 참조	로트 번호	멸균 EO
KZ	Қайта пайдаланбаңыз	Пайдалану нұсқалығын қараңыз	Топтам нөмірі	Этиленоксидпен зарарсыздандырылған

Use-by date	Manufacturer	Date of manufacture	Do not use if package is damaged	Caution
Verwendbar bis	Hersteller	Herstellungsdatum	Bei beschädigter Verpackung nicht verwenden	Achtung
Срок на годност	Производитель	Дата на производство	Не употребявайте, ако опаковката е повредена	Внимание
有效期限	製造商	生产日期	若包装损坏, 请勿使用	警告
Použití do data	Výrobce	Datum výroby	Nepoužívat, jestliže je balení poškozeno	Pozor (výstraha)
Anvendtes inden	Producent	Fremstillingsdato	Produktet må ikke anvendes, hvis emballagen er beskadiget	Forsigtig!
Kasutada kuni:	Tootja	Tootmiskuupäev	Mitte kasutada, kui pakend on kahjustatud.	Ettevaatust
Fecha de caducidad	Fabricante	Fecha de fabricación	No utilizar si el envase está dañado	Precaución
Vimeinen käyttöpäivä	Valmistaja	Valmistuspäivä	Ei saa käyttää, jos pakkaus on vahingoittunut	Huomio
Date limite d'utilisation	Fabricant	Date de fabrication	Ne pas utiliser si l'emballage est endommagé	Attention
Ανάλυση έως	Κατασκευαστής	Ημερομηνία κατασκευής	Μην χρησιμοποιείτε το προϊόν αν η συσκευασία είναι φθαρμένη	Προσοχή
Upotrijebiti do	Proizvođač	Datum proizvodnje	Ne koristiti ako je pakiranje oštećeno	Oprez
Savattossági idő	Öváltó	Öváltási dátum	Ne használja, ha a csomagolás sérült	Figyelem!
Gunakan sebelum	Produsen	Tanggal produksi	Jangan gunakan jika kemasan rusak	Perhatian
Da utilizzare entro	Produttore	Data di produzione	Non utilizzare se la confezione è danneggiata	Attenzione
유효 기간	제조업체	제조일	포장이 손상된 경우 사용하지 마십시오.	주의
Пайдалану мерзани	Өндүрүшчү	Жасалган шагартыптан кунү	Орпактын зарым кепес корданбаныз	Абайлаңыз