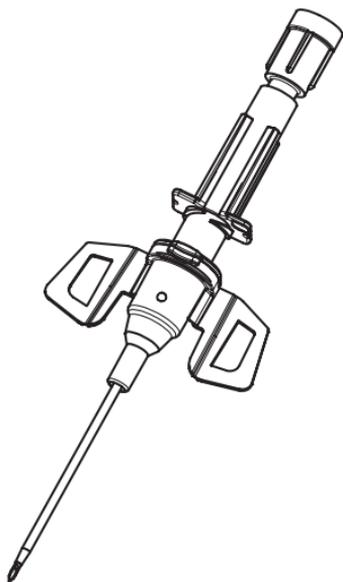


Introcan Safety[®] 3

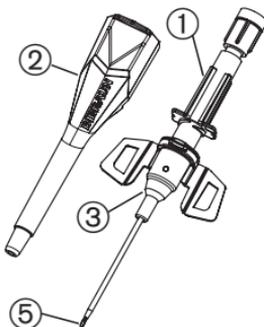


B | BRAUN

LLDorder 6029 - grunewald 221544

- en** Fig. 1: Before needle removal
de Abb. 1: Vor dem Entfernen der Kanüle
bg Фиг. 1: Преди изваждане на иглата
cs Obr. 1: Před vytažením jehly
da Fig. 1: Inden fjernelse af kanylen
el Σχ. 1: Πριν από την αφαίρεση της βελόνας
es Fig. 1: antes de la extracción de la aguja
et Joon 1: Enne nõela eemaldamist
fi Kuva 1: Ennen neulan poistamista
fr Fig. 1 : Avant le retrait de l'aiguille
hr Slika 1: prije vađenja igle
hu 1. ábra: A tű eltávolítása előtt
it Fig. 1: Prima della rimozione dell'ago
lt 1 pav.: prieš nuimant adatą
lv 1. att. Pirms adatas noņemšanas
nl Afb. 1: Voor verwijderen van de naald
no Fig. 1: Før fjerning av nål
pl Ryc. 1: Przed wyjęciem igły
pt Fig. 1: Antes da remoção da agulha
pt BR Fig. 1: Antes da remoção da agulha
ro Fig. 1: înainte de scoaterea acului
ru Рис. 1. До извлечения иглы
sk Obr. 1: Pred vyťahnutím ihly
sl Slika 1: Pred odstranitvijo igle

- sr** Sl. 1: Pre uklanjanja igle
sv Fig. 1: Innan nålen tas bort
tr Şek. 1: İğneyi çıkarmadan önce
vi Hình 1: Trước khi tháo kim
zh 图 1: 撤出针芯之前

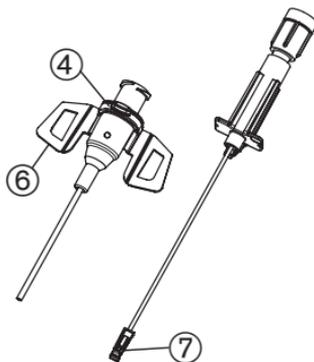


- en** ① Flashback Chamber, ② Protective Guard,
 ③ Catheter Hub, ④ Push-Off Plate,
 ⑤ Needle Bevel, ⑥ Stabilization Platform,
 ⑦ Passive Safety Shield
de ① Blutrückflusskammer, ② Schutzkappe,
 ③ Katheteransatz, ④ Schiebesteg,
 ⑤ Kanülenschliff, ⑥ Fixierflügel,
 ⑦ Passiver Sicherheitsmechanismus
bg ① Камера за аспириране, ② Предпазител,
 ③ Катетърно съединение, ④ Избутваща пла-
 стина, ⑤ Скосяване на иглата, ⑥ Стабилизираща
 платформа, ⑦ Пасивен предпазен механизъм

- cs** ① Komůrka zpětného toku krve, ② Ochranný
 kryt, ③ Konec katétru, ④ Posuvná destička,
 ⑤ Hrot jehly, ⑥ Fixační křídélka,
 ⑦ Pasivní bezpečnostní kryt
da ① Flashback-kammer, ② Beskyttelseskappe,
 ③ Katetermuffe, ④ Frigørelsesplade, ⑤ Skråspids,
 ⑥ Stabiliseringsgreb, ⑦ Passivt sikkerhedsskjold
el ① Θάλαμος επιστροφής, ② Προστατευτικό κάλυμμα,
 ③ Πλήμνη καθετήρα, ④ Περιβλήμα προώθησης,
 ⑤ Λοξοτομή βελόνας, ⑥ Σύστημα σταθεροποίησης,
 ⑦ Προστατευτικός μηχανισμός παθητικής
 ασφάλειας

- en** Fig. 2: After needle removal
de Abb. 2: Nach dem Entfernen der Kanüle
bg Фиг. 2: След изваждане на иглата
cs Obr. 2: Po vytažení jehly
da Fig. 2: Efter fjernelse af kanylen
el Σχ. 2: Μετά την αφαίρεση της βελόνας
es Fig. 2: después de la extracción de la aguja
et Joon. 2: Pärast nõela eemaldamist
fi Kuva 2: Neulan poistamisen jälkeen
fr Fig. 2 : Après le retrait de l'aiguille
hr Slika 2: nakon vađenja igle
hu 2. ábra: A tű eltávolítása után
it Fig. 2: Dopo la rimozione dell'ago
lt 2 pav.: nuėmus adatą
lv 2. att. Pēc adatas noņemšanas
nl Afb. 2: Na verwijderen van de naald
no Fig. 2: Etter fjerning av nål
pl Ryc. 2: Po wyjęciu igły
pt Fig. 2: Após a remoção da agulha
pt BR Fig. 2: Depois da remoção da agulha
ro Fig. 2: după scoaterea acului
ru Рис. 2. После извлечения иглы
sk Obr. 2: Po vyťahnutí ihly
sl Slika 2: Po odstranitvi igle

- sr** Sl. 2: Posle uklanjanja igle
sv Fig. 2: Nålen borttagen
tr Şek. 2: İğneyi çıkardıktan sonra
vi Hình 2: Sau khi tháo kim
zh 图 2: 撤出针芯之后



- es** ① Cámara de retorno, ② Cubierta protectora, ③ Conector del catéter, ④ Placa de empuje, ⑤ Bisel de la aguja, ⑥ Plataforma de estabilización, ⑦ Protector de seguridad pasiva

- et** ① Tagasilaskekamber, ② Kaitsekate, ③ Kateetri jaotur, ④ Mahalükkamisplaat, ⑤ Nõela kaldenurk, ⑥ Stabiiliseerimisalus, ⑦ Passiivne ohutustoke

- fi** ① Takaisinvirtauskammio, ② Suoja, ③ Kateetriin keskiosa, ④ Työntölevy, ⑤ Neulan viiste, ⑥ Vakautussiveike, ⑦ Passiivinen neulansuojus

- fr** ① Chambre de reflux, ② Couvre-aiguille, ③ Embout du cathéter, ④ Onglet de poussée, ⑤ Biseau, ⑥ Ailettes de stabilisation, ⑦ Protection de sécurité passive

- hr** ① Komora za povrat, ② štitnik, ③ čvorište katetera, ④ pločica za guranje, ⑤ kosa ploha igle, ⑥ stabilizacijska platforma, ⑦ pasivnom sigurnosnom zaštitom

- hu** ① Visszaáramlási kamra, ② Védőtok, ③ Katéterdugó, ④ Kónusz, ⑤ Metszett tőgyek, ⑥ Rögzítő szárny, ⑦ Önmagától aktiválódó biztonsági védőelem

- it** ① Camera di refluxo, ② Custodia protettivo, ③ Connettore del catetere, ④ Linguetta d'avanzamento, ⑤ Smussatura dell'ago, ⑥ Alette di stabilizzazione, ⑦ Protezione di sicurezza passiva
- lt** ① Grįžimo kamera, ② apsauga, ③ kateterio įvorė, ④ nustumiamo plokštelė, ⑤ adatos kampainis, ⑥ stabilizavimo platforma, ⑦ Savaimis užsidengiantis apsauginis dangtelis
- lv** ① Asins uztvērējs, ② Aizsargs, ③ Katetra uzgalis, ④ Fiksēšanas plāksnīte, ⑤ Adata ar slīpējumu, ⑥ Atbalsta pamatne, ⑦ Pasīvas drošības adatas aizsargs
- nl** ① Terugslagkamer, ② Beschermende rand, ③ Katheterhub, ④ Afschuiplaat, ⑤ Geslepen naaldpunt, ⑥ Stabilisatieplatform, ⑦ Passief veiligheidsmechanisme
- no** ① Flashback-kammer, ② Beskyttelsesplate, ③ Kateter-koblingspunkt, ④ Avskyningsplate, ⑤ Nåleskråkant, ⑥ Stabiliseringsplattform, ⑦ Passiv sikkerhetsskjerm
- pl** ① Komora kontrolna, ② Nasadka ochronna, ③ Gniazdo kaniuli, ④ Płytką typu push-off, ⑤ Ostrze igły, ⑥ Platforma stabilizująca, ⑦ Pasywna osłona
- pt** ① Câmara de refluxo, ② Capa protectora, ③ Conexão do cateter, ④ Placa de separação, ⑤ Bisel da agulha, ⑥ Plataforma de estabilização, ⑦ Dispositivo de protecção passivo

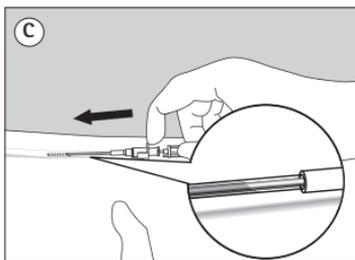
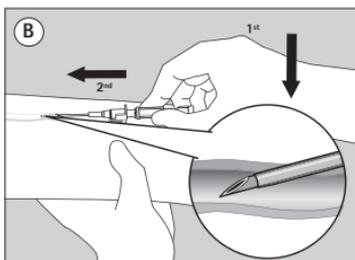
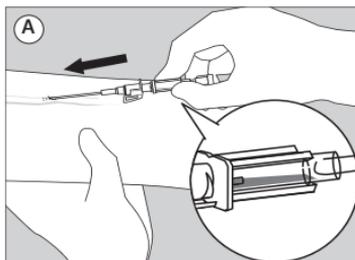
- pt BR** ① Câmara de visualização do refluxo, ② Capa protetora, ③ Canhão do cateter, ④ Aleta de inserção, ⑤ Bisel da agulha, ⑥ Plataforma de estabilização "asas", ⑦ Tampa de segurança
- ro** ① Cameră de reflux, ② Capac protector, ③ Amboul cateterului, ④ Grip de fixare, ⑤ Bizou ac, ⑥ Aripioare de fixare, ⑦ Dispozitiv de siguranță pasiv
- ru** ① Камера обратного тока крови, ② Защитный колпачок, ③ Павильон катетера, ④ Устройство открывания мембраны, ⑤ Игла-проводник, ⑥ Стабилизационная платформа, ⑦ Пассивный защитный экран
- sk** ① Komôrka na sledovanie toku krvi, ② Ochranný kryt, ③ Prípojka katétra, ④ Posuvná platnička, ⑤ Hrot ihly, ⑥ Fixačné krídeltká, ⑦ Pasivný bezpečnostný mechanizmus
- sl** ① Nastavek kanile, ② Zaščita, ③ Priključek za kateter, ④ Potisna ploščica, ⑤ Poševna konica igle, ⑥ Platforma za stabilizacijo, ⑦ Pasivni varnostni ščitnik
- sr** ① Povratna komora ② Štitnik, ③ Čvorište katetera, ④ Potisna ploča, ⑤ Vrh igle, ⑥ Stabilizaciona platforma, ⑦ Pasivni bezbednosni štit
- sv** ① Backflödeskammare, ② Skyddskåpa, ③ Katetermittstycke, ④ Tryckplatta, ⑤ Nålavfasning, ⑥ Stabiliseringsplattform, ⑦ Passiv säkerhetsskold

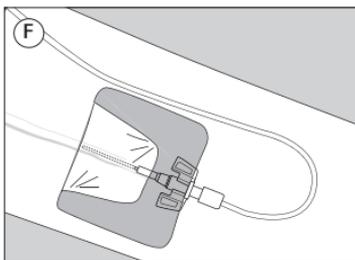
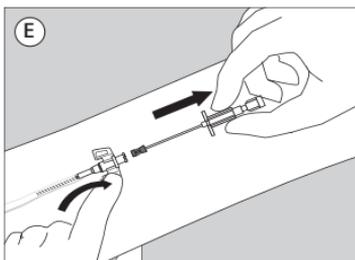
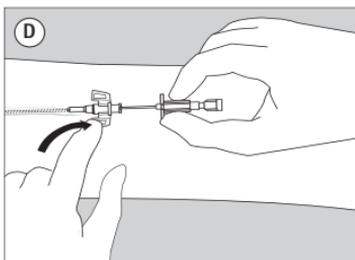
tr ① Kan tutucu ve Odacığı, ② Koruyucu Parça, ③ Kateter Göbeđi, ④ Basma Plakası, ⑤ İğne ucu, ⑥ Sabitleme Platformu, ⑦ Pasif Emniyet Kilidi

vi ① Đầu bảo, ② Bộ phận bảo vệ, ③ Trục ống thông, ④ Tấm dầy tháo kim, ⑤ Măt vát của kim, ⑥ Tấm cố định, ⑦ Đầu bảo vệ an toàn

zh ① 回血密封腔, ② 保护鞘, ③ 针座, ④ 推送板, ⑤ 针尖斜面, ⑥ 固定翼, ⑦ 被动式针头护罩

en Directions:
de Anwendungshinweise:
bg Указания:
cs Postup:
da Anvisninger:
el Οδηγίες:
es Instrucciones:
et Juhised:
fi Ohjeet:
fr Instructions :
hr Upute:
hu Leírás:
it Istruzioni:
lt Nurodymai:
lv Norādījumi
nl Instructies:
no Instruksjoner:
pl Wskazówki:
pt Instruções de uso:
pt BR Instruções:
ro Instrucțiuni:
ru Указания:
sk Pokyny:
sl Navodila:
sr Uputstva:
sv Anvisningar:
tr Talimatlar:
vi Hướng dẫn:
zh 说明:





en Instructions for use

Description

The Introcan Safety® 3 Closed IV Catheter is an indwelling peripheral catheter to obtain intravascular and subcutaneous tissue access for short-term use. It is designed to:

- Minimize inadvertent needlestick injuries with a passive safety shield
- Improve catheter stability with an integrated stabilization platform designed to minimize movement within the vessel
- Control the flow of blood from the catheter hub after needle removal and during subsequent (dis-) connections of Luer access devices, helping to reduce blood exposure.

The Introcan Safety® 3 Closed IV Catheter can be used with Luer access devices which are in compliance with ISO 80369-7.

This device is intended for single use only. It is provided sterile and non-pyrogenic.

Materials Used

- PUR, PP, ABS, Chrome-Nickel steel, POM, Elastomer
- FEP, PP, ABS, Chrome-Nickel steel, POM, Elastomer

Components are not made with natural rubber latex, PVC, or DEHP.

Indication

- The Introcan Safety® 3 Closed IV Catheter is inserted into a patient's vascular system for short term use to
 - sample venous or arterial blood,
 - monitor blood pressure, or
 - administer infusion solutions, blood products or pharmaceuticals (e.g. in or without carrier solutions) according to the SPC of the drug/solution.

- The Introcan Safety® 3 Closed IV Catheter is also indicated for subcutaneous infusion therapies according to the SPC of the drug/ solution.
- The 14–24 gauge catheters may be used with power injectors set at a maximum pressure of 325 psi and a recommended maximum flow rate. Use Luer lock connection only. See table below for recommended maximum flow rates when using a power injector. Testing performed at room temperature (22°C / 72°F). Warming contrast media per manufacturers' recommendations can reduce the pressure necessary to achieve recommended flow rates.

	Contrast Media [mPa*s]	Flow Rate (ml/sec)
24 Gauge*	2.3	5.0
	27.5	2.5
22 Gauge*	2.3	8.0
	27.5	3.5
20 Gauge*	2.3	10.5
	27.5	4.0
18 Gauge*	2.3	14.0
	27.5	5.0
16 Gauge*	2.3	15.5
	27.5	5.5
14 Gauge*	2.3	16.5
	27.5	5.5

* applicable to all lengths

The above are flow rates tested in a laboratory setting and are the maximum flow rates our IV catheters are able to achieve and do not constitute guarantees, warranties, or predictions regarding the outcome of your matter. In any case, it is the responsibility of the user to accommodate the flow rates to each patient's condition and/ or therapy needed.

Patient Population & Intended User

The catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the procedure being performed, the solution being infused and duration of therapy.

The catheter is intended to be used by qualified Healthcare Professionals who are trained on the use of peripheral IV catheters according to national regulations.

Contraindications

- The Introcan Safety® 3 Closed IV Catheter should not be used in patients with known hypersensitivity to any of the materials employed.
- The Introcan Safety® 3 Closed IV Catheter is not intended to be used to facilitate the placement of vascular access devices such as guidewires, indwelling central venous catheters (CVC), peripherally inserted central catheters (PICC) and midline catheters into the vascular system.

Precautions & Warnings

- Observe standard precautions on all patients. Aseptic technique, proper skin preparation, and continued protection of the insertion site are essential.
- When placing or maintaining any IV Catheter, standard precautions must be adhered in accordance with Centers for Disease Control and Prevention / Occupational Safety and Health Administration (CDC / OSHA) standards for blood-borne pathogens to avoid the risk of exposure to contaminated blood.
- Use only if packaging is intact. This device is sterile unless packaging has been opened or damaged.
- Do not re-use. 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.

- In the case of an unsuccessful IV Catheter placement attempt, remove the needle first to activate safety mechanism, then remove catheter from patient and discard both.
- Never reinsert the needle inside the catheter once the needle has been partially or completely withdrawn as it may pierce and/or sever the catheter.
- Do not attempt to bypass the safety mechanism.
- In the unlikely event that the safety mechanism has not been triggered/activated, keep the tip of the needle away from the body and fingers at all times and immediately dispose the IV Catheter into a suitable sharp-proof container. Care must be taken to avoid needlestick injuries.
- Report needlestick injuries immediately and follow established institutional protocols
- Use of only ISO Luer slip and Luer lock connectors ensures proper functioning.
- Luer Slip connections should not be left unattended due to potential of disconnection.
- Extreme care should be taken not to damage, pierce, cut or sever the catheter. Therefore, do not bend the catheter and/or needle during insertion, advancement, or removal of the needle.
- Do not use scissors or sharp instruments at or near the insertion site.
- If blood is present, flush device according to institutional protocol.
- Always clearly mark arterial lines to avoid inadvertent injection.
- Verify adequate collateral circulation prior to arterial puncture.
- Patency of catheter must be assured immediately before power injecting.
- Measures should be taken to avoid kinking or obstructing the catheter system during power injection to avoid product failure.

- Prior to use with power injectors, ensure that secure connection exists between the catheter and power injector. Use Luer Lock connection only.
- In the event of occlusion or lack of patency, power injector pressure-limiting function may not prevent catheter failure and/or infiltration.
- Monitor tightness of all connections during the whole infusion procedure.

Residual Risks & Side Effects

- General risks related to IV Catheters: infiltration, extravasation, leakage, air embolism, phlebitis, thrombophlebitis, thrombosis, catheter-related bloodstream infection, local infection, inflammation, catheter occlusion, catheter fracture or clot formation.
- Risks of arterial catheterization include injury to adjacent structures during insertion, infection, vascular spasm and thrombotic or embolic complications that may result in occlusion of the artery causing ischemia.
- Non-ischemic complications of arterial catheterization, or even repeated attempts at catheterization, include bleeding, pseudo aneurysms, arteriovenous fistulae, nerve palsy, infection and injury to the tendon sheaths and adjacent structures during insertion.
- Risks related to subcutaneous infusion therapies:
 - systemic side effects: acute cardiac failure and hyponatremia
 - local side effects: edema, inflammation, bleeding, cellulitis, erythema and pain.

Application

Use aseptic technique. Do not rotate catheter hub prior to insertion.

1. Gather all necessary items for insertion and stabilization procedure.
2. Select and disinfect per institutional protocol.
3. Apply tourniquet.
4. Flex stabilization wings before returning them to horizontal position. Remove protective guard

in a straight outward motion. Inspect device and confirm catheter hub is properly seated on flashback chamber.

5. Anchor the vessel with gentle skin traction and access vessel. Observe blood return in flashback chamber to confirm successful vessel entry (see figure A).
6. Lower and advance the entire catheter and needle unit slightly to ensure catheter tip is in vessel (see figure B).
7. Using the push-off plate, advance catheter off the needle (approximately 1/8" or 3mm). You can observe blood return between the needle and catheter to confirm catheter is in the vessel (see figure C). After confirmation, continue advancing catheter off the needle and into vessel.
8. Release tourniquet.
9. Gently press the stabilization platform to the skin to stabilize the catheter (see figure D). Withdraw the needle straight out with a controlled and continuous motion (minimize rotation or bending of the needle). The metal safety shield will automatically attach to the needle tip as the needle tip exits the catheter hub (see figure E). Blood flow from catheter hub is restricted after needle is removed.
10. Dispose of the shielded needle immediately into a sharps-proof container.
11. Immediately connect the infusion line or accessory device and cover the puncture site with a sterile and transparent dressing (see figure F) per institutional protocol.
12. After removal, dispose catheter according to local guidelines and/ or institutional protocols.

Duration of Use

- Duration of use is dependent on the applied therapy according to the SPC of the drug/ solutions and should follow the national guidelines and/or hospital protocols.

- The insertion site should be checked frequently and at regular intervals. The catheter should be removed in event of local or systemic signs of infection.

Disposal

Disposal according to local guidelines and/ or institutional protocols.

If, during the use of this product or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.



en	Do not re-use
de	Nicht wiederverwenden
bg	Да не се използва повторно
cs	Nepoužívat opětvorně
da	Må ikke genbruges
el	Να μην επαναχρησιμοποιείται
es	No reutilizable
et	Mitte kordvukasutada
fi	Ei saa käyttää uudelleen
fr	Ne pas réutiliser
hr	Nemojte ponovno upotrebljavati
hu	Ne használja fel újra
it	Non riutilizzare
lt	Negalima naudoti kartotinai
lv	Neizmantot atkārtoti
nl	Niet opnieuw gebruiken
no	Skal ikke gjenbrukes
pl	Nie używać ponownie
pt	Não reutilizar
pt	Não reutilizar
BR	
ro	A nu se reutiliza
ru	Не использовать повторно
sk	Opätovne nepoužívať
sl	Samo za enkratno uporabo
sr	Ne koristiti ponovo
sv	Får ej återanvändas
tr	Yeniden kullanmayınız
vi	Không tái sử dụng
zh	不得二次使用



Caution
Achtung
Внимание
Pozor (výstraha)
Forsigtig
Προσοχή
Atención
Ettevaatust
Huomio
Attention
Oprez
Figyelem!
Attenzione
Atsargiai
UZMANĪBU!
Let op
Viktig
Uwaga
Cuidado
Cuidado
Atenție
Внимание!
Varovanie
Previdno
Oprez
Obs
Dikkat
Thận trọng
警告



Consult instruction for use
Gebrauchsanweisung beachten
Вижте инструкциите за употреба
Čtěte návod k použití
Læs brugsanvisningen
Συμβουλευτείτε τις οδηγίες χρήσης
Consulte las instrucciones de uso
Vt kasutusjuhendit
Katso käyttöohje
Consulter les instructions d'utilisation
Pogledajte upute za uporabu
Nézze meg a használati utasítást
Consultare le istruzioni per l'uso
Žr. naudojimo instrukcijas
Lasit lietošanas instrukciju
Raadpleeg gebruikersinformatie
Se i bruksanvisningen
Przed użyciem należy zapoznać się z instrukcją
Consulte as instruções de utilização
Consulte as instruções de uso
Consultați instrucțiunile de utilizare
См. руководство по эксплуатации
Pozri návod na použitie
Glejte navodila za uporabo
Pogledajte uputstvo za upotrebu
Se bruksanvisningen
Kullanma kılavuzuna bakınız
Tham khảo hướng dẫn sử dụng
查阅使用说明

REF**LOT**

en	Catalog number	Batch number	Green dot
de	Artikelnummer	Chargennummer	Grüner Punkt
bg	Каталожен номер	Партиден номер	Зелена точка
cs	Katalogové číslo	Kód dávky	Zelený bod
da	Katalognummer	Batchnummer	Grøn prik
el	Αριθμός καταλόγου	Αριθμός παρτίδας	Πράσινη κουκκίδα
es	Número de catálogo	Número de lote	Punto verde
et	Katalooginumber	Partiinumber	Roheline punkt
fi	Luettelonumero	Eränumero	Vihreä piste
fr	Numéro de référence	Numéro de lot	Point vert
hr	Kataloški broj	Broj serije	Zelena točka
hu	Katalógusszám	Gyártási sorozat száma	Zöld pont
it	Numero di catalogo	Numero di lotto	Punto Verde
lt	Katalogo numeris	Partijos numeris	Žalias taškas
lv	Kataloga numurs	Partijas numurs	Zaļš punkts
nl	Artikelnummer	Lotnummer	Groene Punt- logo
no	Artikkelnummer	Batch/LOT-nummer	Grønn prikk
pl	Numer katalogowy	Numer serii	Zielony punkt
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pt	Número de catálogo	Número do lote	Ponto verde
BR	Número de catálogo	Número do lote	Ponto verde
ro	Număr de catalog	Lot nr.	Punct verde
ru	Номер по каталогу	Номер серии	Зелёная точка
sk	Katalógové číslo	Číslo šarže	Zelený bod
sl	Kataloška številka	Številka serije	Zelena pika
sr	Kataloški broj	Broj partije	Zelena tačka
sv	Katalognummer	Batchnummer	Green dot
tr	Katalog numarası	Parti kodu	Yeşil nokta
vi	Mã số sản phẩm	Số lô	Chấm màu xanh lá cây
zh	产品编号	批号	绿点标志

				
en	Use-by date	Manufacturer	Date of manufacture	
de	Verwendbar bis	Hersteller	Herstellungsdatum	
bg	Срок на годност	Производител	Дата на производство	
cs	Použit do data	Výrobce	Datum výroby	
da	Anvendes inden	Producent	Fremstillingsdato	
el	Ανάλωση έως	Κατασκευαστής	Ημερομηνία κατασκευής	
es	Fecha de caducidad	Fabricante	Fecha de fabricación	
et	Kasutada kuni:	Tootja	Tootmiskuupäev	
fi	Viimeinen käyttöpäivä	Valmistaja	Valmistuspäivä	
fr	Date limite d'utilisation	Fabricant	Date de fabrication	
hr	Rok uporabe	Proizvođač	Datum proizvodnje	
hu	Szavatossági idő	Gyártó	Gyártási dátum	
it	Da utilizzarsi entro	Produttore	Data di produzione	
lt	Tinka iki datos	Gamintojas	Pagaminimo data	
lv	Derīguma termiņš	Ražotājs	Izgatavošanas datums	
nl	Houdbaarheidsdatum	Fabrikant	Productiedatum	
no	Holdbarhetsdato	Produsent	Produksjonsdato	
pl	Data przydatności do użycia	Wytwórca	Data produkcji	
pt	Prazo de validade	Fabricante	Data de fabrico	
pt	Usar até	Fabricante	Data de fabricação	
BR				
ro	Data de expirare	Fabricantul	Data fabricației	
ru	Использовать до	Производитель	Дата изготовления	
sk	Použiteľné do	Výrobca	Dátum výroby	
sl	Rok uporabnosti	Izdelovalec	Datum izdelave	
sr	Rok trajanja	Proizvođač	Datum proizvodnje	
sv	Används före	Tillverkare	Tillverkningsdatum	
tr	Son kullanım tarihi	Üretici	Üretim tarihi	
vi	Hạn sử dụng	Nhà sản xuất	Ngày sản xuất	
zh	有效期	制造商	生产日期	



en	Country of manufacture	Do not use if package is damaged
de	Herstellungsland	Bei beschädigter Verpackung nicht verwenden
bg	Страна на производство	Не употребявайте, ако опаковката е повредена
cs	Země výroby	Nepoužívat, jestliže je balení poškozeno
da	Fremstillingsland	Må ikke anvendes, hvis pakningen er beskadiget
el	Χώρα κατασκευής	Μην χρησιμοποιείτε το προϊόν εάν η συσκευασία είναι φθαρμένη
es	País de fabricación	No utilizar si el envase está dañado
et	Tootmisriik	Mitte kasutada, kui pakend on kahjustatud.
fi	Valmistusmaa	Ei saa käyttää, jos pakkaus on vahingoittunut
fr	Pays de fabrication	Ne pas utiliser si l'emballage est abîmé
hr	Država proizvođnje	Nemojte upotrebljavati ako je pakiranje oštećeno
hu	Gyártó ország	Ne használja, ha a csomagolás sérült
it	Paese di produzione	Non utilizzare se la confezione è danneggiata
lt	Pagaminimo šalis	Nenaudoti, jei pakuotė sugadinta
lv	Ražotājvalsts	Nelietojiet, ja iepakojums ir bojāts
nl	Land van productie	Niet gebruiken wanneer de verpakking beschadigd is
no	Produksjonland	Skal ikke brukes hvis pakningen er skadet.
pl	Kraj produkcji	Nie stosować, jeśli opakowanie jest uszkodzone
pt	País de fabrico	Não utilizar se a embalagem estiver danificada
pt	País de fabricação	Não utilizar se o pacote estiver danificado
BR		
ro	Țara de fabricație	A nu se utiliza dacă ambalajul este deteriorat
ru	Страна изготовления	Не используйте при повреждении упаковки
sk	Krajina výroby	Nepoužívať, ak je obal poškodený
sl	Država izdelave	Prepovedana uporaba, če je ovojnina poškodovana
sr	Zemlja proizvodnje	Nemojte koristiti ako je pakovanje oštećeno
sv	Tillverkningsland	Använd inte produkten om förpackningen är skadad
tr	Üretildiği ülke	Ambalajı hasar görmüşse kullanmayınız
vi	Quốc gia sản xuất	Không sử dụng nếu bao bì bị hư hỏng
zh	制造国家	若包装破损切勿使用

STERILEEO

en	Sterilized using ethylene oxide	Single sterile barrier system
de	Sterilisiert mit Ethylenoxid	Einfachsterilbarrieresystem
bg	Стерилизирано с етиленов оксид	Единична стерилна преградна система
cs	Sterilizováno ethylenoxidem	Systém jedné sterilní bariéry
da	Steriliseret med ethylenoxid	Enkelt sterilt barrieresystem
el	αποστειρωμένο με αιθυλενοξειδίο	Σύστημα μονού φραγμού αποστείρωσης
es	Esterilizado con óxido de etileno	Sistema de barrera estéril único
et	Steriliseeritud etüleenoksiidiga	Ühekordse steriilsusbarjääri süsteem
fi	Steriloitu etyleenioksidilla	Yksinkertainen steriiliyden varmistusjärjestelmä
fr	Sterilisation à l'oxyde d'éthylène	Système de barrière stérile simple
hr	Sterilizirano etilen-oksidom	Sustav jednostruke sterilne barijere
hu	Étilén-oxiddal sterilizálva	Egyszeres sterilgát-rendszer
it	Sterilizzato con ossido di etilene	Sistema a barriera sterile singola
lt	Sterilizuota etileno oksidu	Viengubo steriliojo barjero sistema
lv	Sterilizēts, izmantojot etilēnoksidu	Viena sterila barjeras sistēma
nl	Gesteriliseerd met ethyleenoxide	Enkelvoudig steriel barriersysteem
no	Sterilisert med bruk av etylenoksid	Enkelt sterilisert barrieresystem
pl	Wysterylizowano tlenkiem etylenu	Pojedynczy system bariery sterylnej
pt	Esterilizado por óxido de etileno	Sistema de barreira estéril único
pt	Esterilizado com óxido de etileno	Sistema de barreira estéril única
BR		
ro	Sterilizat cu etilenoxid	Sistem cu barieră sterilă unică
ru	Стерилизовано этиленоксидом	Одиная стерильная барьерная система
sk	Sterilizované použitím etylénoxidu	Systém jednej sterilnej bariéry
sl	Sterilizirano z etilenoksidom	Sistem enojne sterilne pregrade
sr	Sterilisano etilen oksidom	Sistem sa jednom sterilnom barijerom
sv	Sterilisering med etylenoxid	Enkelt steriliserat barriärsystem
tr	Etilen oksit kullanılarak sterilize edilmiştir	Tek steril bariyer sistemi
vi	Tiệt trùng bằng ethylene oxide	Hệ thống bảo vệ vô khuẩn
zh	使用环氧乙烷灭菌	单重无菌屏障系统



en	Single sterile barrier system with protective packaging outside	Non-pyrogenic
de	Einfachsterilbarrieresystem mit Schutzverpackung außen	Pyrogenfrei
bg	Единична стерилна преградна система със защитна външна опаковка	Непирогенно
cs	Systém jedné sterilní bariéry s vnějším ochranným obalem	Apyrogenní
da	Enkelt sterilt barrieresystem med udvendig beskyttelsesemballage	Ikke-pyrogen
el	Σύστημα μονού φραγμού αποστείρωσης με προστατευτική συσκευασία εξωτερικά	Μη πυρετογόνο
es	Sistema de barrera estéril único con embalaje protector en el exterior	No pirogénico
et	Ühekordse steriilsusbarjääri süsteem kaitsva väliisapakendiga	Mittepürogeenne
fi	Kertakäyttöinen steriiliyden takaava järjestelmä, suojaava ulkopakkaus	Pyrogeeniton
fr	Système de barrière stérile simple avec emballage de protection à l'extérieur	Apyrogène
hr	Sustav jednostruke sterilne barijere s vanjskim zaštitnim pakiranjem	Nepirogeno
hu	Kivülről védőcsomagolással ellátott egyszeres sterilgát-rendszer	Nem pirogén
it	Sistema a barriera sterile singola con confezione protettiva esterna	Apirogeno
lt	Viengubo steriliojo barjero sistema su išorine apsaugine pakuote	Nepirogeninis
lv	Viena sterila barjeras sistēma ar aizsargiepakojumu	Nepirogēns
nl	Steriel barriersysteem met beschermende verpakking voor eenmalig gebruik	Niet-pyrogeen
no	Enkelt sterilt barrieresystem med beskyttende utvendig emballasje	Ikke-pyrogen
pl	Pojedynczy system bariery sterylnej z zewnętrznym opakowaniem ochronnym	Wyrób apirogeny
pt	Sistema de barreira estéril único com embalagem exterior de protecção	Isento de pirogénios
pt BR	Sistema de barreira estéril única com embalagem de proteção externa	Não pirogênico
ro	Sistem cu barieră sterilă unică cu ambalaj de protecție exterior	Apirogen
ru	Одиная стерильная барьерная система с защитной наружной упаковкой	Апирогенно
sk	Systém bariéry na uchovanie sterility s vonkajším ochranným obalom	Nepyrogeenne
sl	Sistem enojne sterilne pregrade z zunanjo zaščitno ovojnino	Apirogeno
sr	Sistem sa jednom sterilnom barijerom sa spoljašnjom zaštitnom ambalažom	Nepirogeno
sv	Enkelt sterilt barriärsystem med skyddsförpackning på utsidan	Pyrogenfri
tr	Dişında koruyucu ambalaj olan tek steril bariyer sistemi	Pirojenik değildir
vi	Hệ thống bảo vệ vô khuẩn có bao bì bảo vệ bên ngoài	Không sinh nhiệt
zh	带外部保护性包装的单重无菌屏障系统	无热原



en	Does not contain or no presence of natural rubber latex
de	Enthält nicht oder keine Anwesenheit von Naturkautschuklatex
bg	Не съдържа и няма следи от латекс от естествен каучук
cs	Neobsahuje nebo není přítomen latex z přírodního kaučuku
da	Indeholder ikke (eller ingen tilstedeværelse af) naturgummilætex
el	Δεν περιέχει ή υπάρχει λάτεξ από φυσικό καουτσόκ
es	No contiene ni presenta trazas de látex de caucho natural
et	Ei sisalda looduslikku kummilateksi ega selle osakesi
fi	Ei sisällä luonnonkumilateksia.
fr	Ne contient pas (ou absence) de latex de caoutchouc naturel
hr	Ne sadrži ili nije prisutan prirodni gumeni lateks
hu	Összetevőként nem tartalmazza vagy nincs benne természetes gumi latex
it	Non contiene o nessuna presenza di lattice di gomma naturale
lt	Sudėtyje nėra natūralios gumos latekso ar jo požymių
lv	Nesatur vai tajā nav dabiskā kaučuka lateksa
nl	Bevat geen (of geen aanwezigheid van) latex
no	Inneholder ikke (eller ingen tilstedeværelse av) naturgummilætex
pl	Nie zawiera lateksu z kauczuku naturalnego
pt	Não contém ou não apresenta vestígios de látex de borracha natural
pt	Não contém ou inexistência de látex de borracha natural
BR	
ro	Nu conține și nu include latex din cauciuc natural
ru	Не содержит латекс
sk	Neobsahuje ani nie je prítomný latex z prírodného kaučuku
sl	Ne vsebuje lateksa iz naravnega kavčuka in ni prisoten
sr	Ne sadrži prirodni gumeni lateks i on nije prisutan
sv	Innehåller inte (eller ingen förekomst av) naturgummilætex
tr	Doğal kauçuk lateks içermez ya da yoktur
vi	Không có chứa hoặc không có sự hiện diện của latex thiên nhiên
zh	不含或不存在天然橡胶乳胶



en	Does not contain or no presence of DEHP
de	Enthält nicht oder keine Anwesenheit von DEHP
bg	Не съдържа и няма следи от DEHP
cs	Neobsahuje nebo není přítomen DEHP
da	Indeholder ikke (eller ingen tilstedeværelse af) DEHP
el	Δεν περιέχει ή υπάρχει DEHP
es	No contiene ni presenta trazas de DEHP
et	Ei sisalda DEHP-d ega selle osakesi
fi	Ei sisällä DEHP:tä.
fr	Ne contient pas (ou absence) de DEHP
hr	Ne sadrži ili nije prisutan DEHP
hu	Összetevőként nem tartalmazza vagy nincs benne DEHP
it	Non contiene o nessuna presenza di DEHP
lt	Sudėtyje nėra DEHP medžiagos ar jos požymių
lv	Nesatur vai tajā nav DEHP
nl	Bevat geen (of geen aanwezigheid van) DEHP
no	Inneholder ikke (eller ingen tilstedeværelse av) DEHP
pl	Nie zawiera DEHP
pt	Não contém ou não apresenta vestígios de DEHP
pt	Não contém ou inexistência de DEHP
BR	
ro	Nu conține și nu include DEHP
ru	Не содержит ДЭГФ
sk	Neobsahuje ani nie je prítomný DEHP
sl	Ne vsebuje DEHP ali je prisoten
sr	Ne sadrži DEHP i on nije prisutan
sv	Innehåller inte (eller ingen förekomst av) DEHP
tr	DEHP içermez ya da yoktur
vi	Không chứa hoặc không có sự hiện diện của DEHP
zh	不含或不存在 DEHP



en	Does not contain or no presence of PVC
de	Enthält nicht oder keine Anwesenheit von PVC
bg	Не съдържа и няма следи на PVC
cs	Neobsahuje nebo není přítomen PVC
da	Indeholder ikke (eller ingen tilstedeværelse af) PVC
el	Δεν περιέχει ή υπάρχει PVC
es	No contiene ni presenta trazas de PVC
et	Ei sisalda PVC-d ega selle osakesi
fi	Ei sisällä PVC:tä.
fr	Ne contient pas (ou absence) de PVC
hr	Ne sadrži ili nije prisutan PVC
hu	Összetevőként nem tartalmazza vagy nincs benne PVC
it	Non contiene o nessuna presenza di PVC
lt	Sudėtyje nėra PVC medžiagos ar jos požymių
lv	Nesatur vai tajā nav PVC
nl	Bevat geen (of geen aanwezigheid van) PVC
no	Inneholder ikke (eller ingen tilstedeværelse av) PVC
pl	Nie zawiera PVC
pt	Não contém ou não apresenta vestígios de PVC
pt	Não contém ou inexistência de PVC
BR	
ro	Nu conține și nu include PVC
ru	Не содержит ПВХ
sk	Neobsahuje ani nie je prítomné PVC
sl	Ne vsebuje PVC-ja in ni prisoten
sv	Innehåller inte (eller ingen förekomst av) PVC
sr	Ne sadrži PVC i on nije prisutan
tr	PVC içermez ya da yoktur
vi	Không chứa hoặc không có sự hiện diện của PVC
zh	不含或不存在 PVC

MD

Medical Device
Medizinprodukt
Медицинско изделие
Zdravotnický prostředek
Medicinsk udstyr
Ιατροτεχνολογικό προϊόν
Dispositivo médico
Meditsiiniseade
Lääkinnällinen laite
Dispositif médical
Medicinski proizvod
Orvostechikai eszköz
Dispositivo medico
Medicinos priemonė
Medicinska ierīce
Medisch hulpmiddel
Medisinsk utstyr
Urządzenie medyczne
Dispositivo médico
Dispositivo médico
Dispozitiv medical
Медицинское изделие
Zdravotnícka pomôcka
Medicinski pripomoček
Medicinteknisk produkt
Medicinski uređaj
Tibbi Cihaz
Thiết bị y tế
医疗器械



en	Keep away from sunlight
de	Von Sonnenlicht fernhalten
bg	Да се пази от слънчева светлина
cs	Chránit před slunečním zářením
da	Må ikke opbevares i sollys
el	Να διατηρείται μακριά από το ηλιακό φως
es	No exponer a la luz solar
et	Hoida päikesevalguse eest
fi	Suojattava auringolta
fr	Tenir à l'abri des rayons solaires
hr	Držati podalje od sunčeve svjetlosti
hu	Napfénytől védve tartandó
it	Tenere lontano dalla luce solare
lt	Saugoti nuo saulės šviesos
lv	Neturēt saulē
nl	Buiten direct zonlicht bewaren
no	Beskyttes mot sollys
pl	Chronić przed światłem słonecznym
pt	Manter ao abrigo da luz solar
pt	Manter protegido da luz do sol
BR	
ro	A se feri de lumina solară
ru	Не допускать воздействия солнечного света
sk	Chránit pred slnkom
sl	Ne izpostavljajte sončni svetlobi
sv	Skydda mot solljus
sr	Držati dalje od sunčeve svetlosti
tr	Güneşten uzak tutunuz
vi	Tránh ánh sáng mặt trời
zh	避免日晒



Keep dry
Trocken aufbewahren
Съхранявайте на сухо
Chránit před vlhkem
Opbevares tørt
Να διατηρείται στεγνό
Mantener seco
Hoida kuivas
Säilytä kuivassa
Garder au sec
Čuvati na suhom
Százazon tartandó
Conservare al riparo dall'umidità
Laikyti sausoje vietoje
Sargāt-no-mitruma
Droog houden
Oppbevares tørt
Przechowywać w suchym miejscu
Manter em local seco
Mantenha seco
A se pāstra uscat
Беречь от влаги
Uchovávať v suchu
Hranite na suhem
Förvaras torrt
Čuvati suvim
Kuru tutunuz
Giữ khô ráo
保持干燥



en	Passive Safety Shield
de	Passiver Sicherheitsmechanismus
bg	Пасивен предпазен механизъм
cs	Passivní bezpečnostní kryt
da	Passivt sikkerhedsskjold
el	Προστατευτικός μηχανισμός παθητικής ασφάλειας
es	Protector de seguridad pasiva
et	Passiivne ohutustoke
fi	Passiivinen neulansuojus
fr	Protection de securite passive
hr	pasivnom sigurnosnom zaštitom
hu	Onmagatol aktualodo biztonsagi vedőelem
it	Protezione di sicurezza passiva
lt	Savaime užsidengiantis apsauginis dangtelis
lv	Passīvas drošības adatas aizsargs
nl	Passief veiligheidsmechanisme
no	Passiv sikkerhetsskjerm
pl	Pasywna osłona
pt	Dispositivo de proteccao passivo
pt	Tampa de segurancia
ro	Dispozitiv de siguranță pasiv
ru	Пассивный защитный экран
sk	Passivny bezpečnostny mechanizmus
sl	Passivni varnostni ščitnik
sr	Passivni bezbednosni štit
sv	Passiv sakerhetsskold
tr	Passif Emniyet Kilidi
vi	Đầu bảo vệ an toàn
zh	被动式针头护罩



en	Blood Control Septum
de	Membran zur Reduzierung von Blutaustritt
bg	Мембрана за спиране на кръвотечението
cs	Septum pro kontrolu krve
da	Septum til blodkontrol
el	Διάφραγμα ελέγχου αίματος
es	Tabique de control de sangre
et	Veretõkke vahesein
fi	Verenvirtauksen rajoitin
fr	Septum de contrôle du reflux sanguin
hr	Pregrada za kontrolu krvi
hu	Véráramlás-szabályozó szeptum
it	Setto di controllo del sangue
lt	Kraujavimo kontrolės pertvara
lv	Uzmava, lai kontrolētu asins plūsmu
nl	Bloedcontrole-septum
no	Blodkontrollseptum
pl	Zastawka do kontroli krwawienia
pt	Septo de controlo sanguíneo
pt	Septo de Controle Sanguíneo
BR	
ro	Sept de control al sângelui
ru	Перегородка для контроля кровотока
sk	Priehradka na kontrolu krvi
sl	Pregrada za uravnavanje pretoka krvi
sr	Septum za kontrolu krvarenja
sv	Funktion för blodflödeskontroll
tr	Kan Kontrol Bölmesi
vi	Vách ngăn kiểm soát máu
zh	血液控制隔膜

-
- AU** For sterilization type see primary packaging
B. Braun Australia Pty. Ltd.
Level 5, 7 – 9 Irvine Place
Bella Vista NSW 2153
Australia
- BR** Cateter Intravascular Fechado com Dispositivo de Segurança - Estéril - Esterilizado por Óxido de Etileno - Proibido Reprocessar - Importado e Distribuído por: Laboratórios B|Braun S/A., Av. Eugênio Borges, 1092 e Av. Jequitibá, 09-Arsenal, São Gonçalo – RJ – Brasil, CEP.: 24751-000, Farm. Resp.: Sônia M. Q. de Azevedo, CRF-RJ n° 4260, C.N.P.J. 31.673.254/0001-02 SAC: 0800-0227286 - Fabricado por: B. Braun Medical Industries Sdn. Bhd., Bayan Lepas Free Industrial Zone, 11900 Penang, Malásia, Consulte a embalagem para ver o número de registro.
- CA** Distributed by: **B. Braun Medical Inc.**
Bethlehem, PA USA 18018-3524
- CN** 产品标准: 见标签
注册号: 见标签
规格、型号: 见标签
生产地址: Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia
售后服务单位:
贝朗医疗(上海)
国际贸易有限公司
上海市外高桥保税区港澳路285号S,P及Q部分
邮编: 200131
- CO** Importado por B Braun Medical SA.
Calle 44 N° 8-08/31 Bogotá.
- ID** Imported by:
PT. B. Braun Medical Indonesia
Jakarta-Indonesia
-

KZ Адрес организации принимающей претензии от потребителей по качеству продукции (товара) на территории Республики Казахстан/Организация на территории Республики Казахстан, ответственная за пострегистрационное наблюдение за безопасностью лекарственного средства:
ТОО «Б.Браун Медикал Казахстан»
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Тел.: 8 (727) 2200002
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TR Sterilizasyon tipi için primer ambalaja bakınız.
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