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Rx Only

STERILE EO

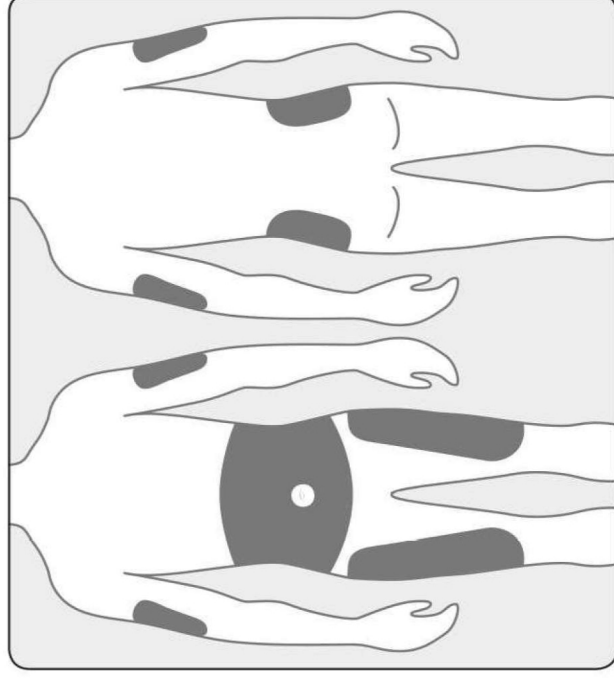


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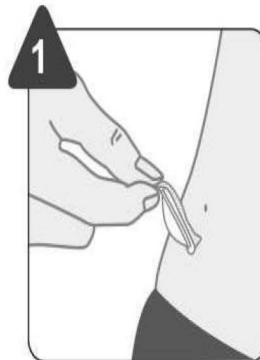
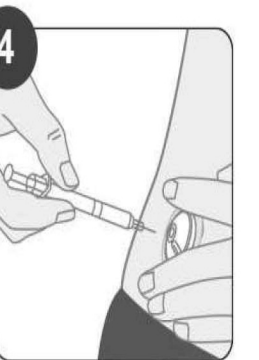
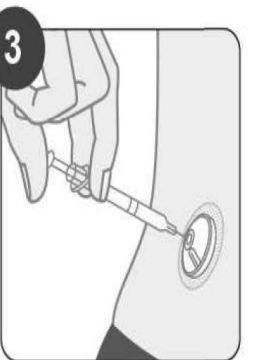
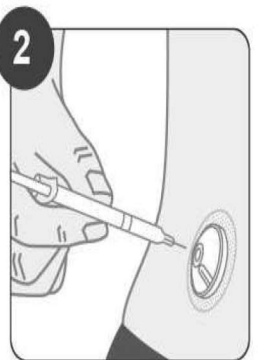
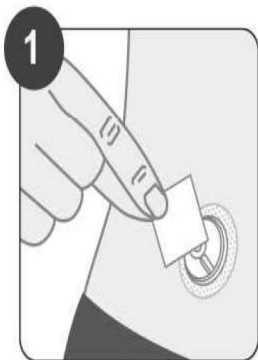
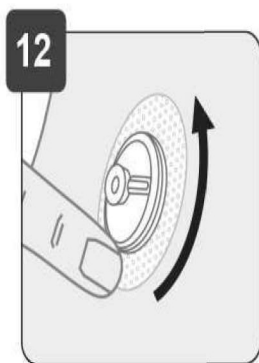
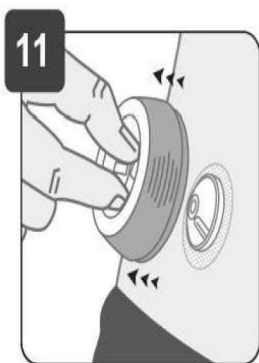
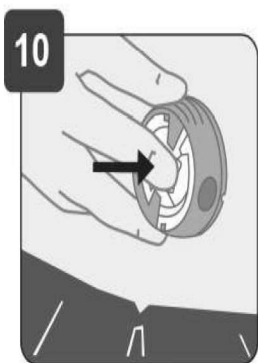
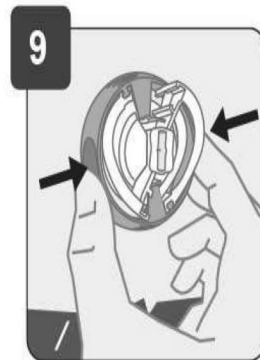
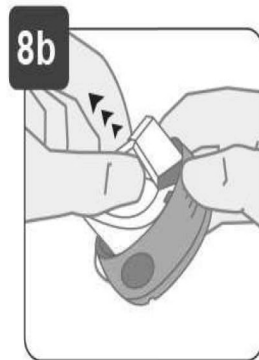
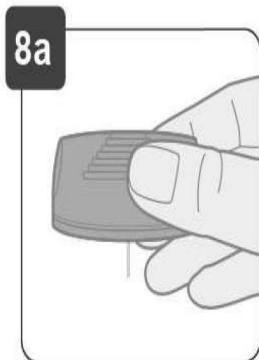
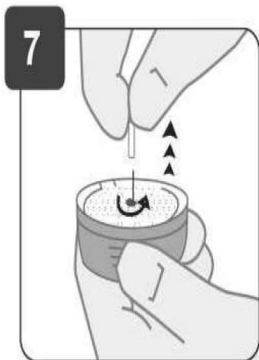
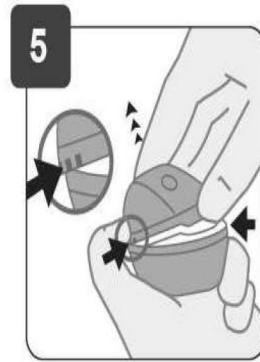
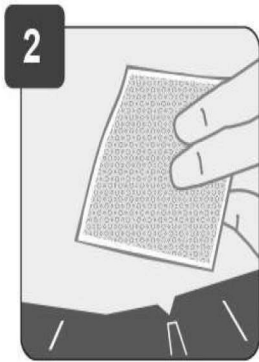
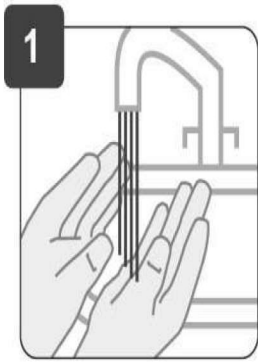
EN	Insertion Sites
FR	Sites d'insertion
DE	Einführstellen
ES	Zonas de inserción
NL	Inbrengplaatsen
IT	Siti di inserimento
NO	Innstikksteder
FI	Asetuskohdat
SV	Appliceringsställen
DA	Indstikssteder
PT	Locais de inserção
SL	Mesta vstavitve

CS	Mista zavedeni
HU	Bevezetési helyek
PL	Miejsca wprowadzenia
TR	Giriş Bölgeleri
SK	Miesta zavedenia
EL	Σημεία εισαγωγής
RU	Места введения
ZH	植入部位
AR	مواقع الإدخال
HE	נקודות החדרה

i-Port Advance™

Injection port • Port d'injection • Injektionsport
Aplicador de inyecciones • Injectiepoort
Accesso per iniezioni sottocutanea • Injektionsport
Injektionsportti • Injektionsport • Injektionsport
Porta de injeção • Injekcijski nastavak
Injekční port • Injekciós bemenet
Port iniekcijny • Enjeksiyon portu
Injekčný port • Θύρα έγχυσης
Инъекционный порт • 注射端口
منفذ الحقن • פתח הזרקה

**See Symbols Glossary Inside the
Instructions for Use**



Indications for Use

The i-Port Advance™ injection port is indicated for patients who administer or receive multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device may remain in place for up to 72 hours to accommodate multiple injections without the discomfort of additional needle sticks. The i-Port Advance injection port may be used on a wide range of patients, including adults and children.

Product Description

The i-Port Advance injection port is a subcutaneous injection port, which combines the injection port with an aid for insertion. The injection port is an integrated part of the inserter. Two injection port models are available: a 6 mm or 9 mm cannula length. The i-Port Advance injection port is a sterile unit, delivered assembled for one time, single-patient use.

Contraindications

- **Do not** use the same i-Port Advance injection port for longer than 72 hours.
- **Do not** attempt to reapply the i-Port Advance injection port after use.
- The i-Port Advance injection port is neither intended nor indicated for use with blood or blood products.
- **Do not** use the i-Port Advance injection port for any purpose other than the indications specified by your healthcare professional.
- **Do not** use needles with a gauge smaller than 28 or greater than 32. Doing so may damage the septum and may cause incorrect medication delivery.
- **Do not** use a needle longer than 5/16 in. (8 mm) when injecting into the i-Port Advance injection port. Longer needles may damage the device causing unnecessary punctures of the skin, or tearing or puncturing of the soft cannula, which may result in unpredictable medication delivery.
- **Do not** use a needle shorter than 3/16 in. (5 mm) when injecting into the i-Port Advance injection port. Shorter needles may not pass through the port septum, which may prevent the medication from properly entering the body.

Warnings and Precautions

- The i-Port Advance injection port is only sterile and non-pyrogenic if the insertion device is unopened or undamaged. **Do not** use if the package is already open or is damaged, or if the protective liner has fallen off. Ensure the sterility by checking the sterile paper and tamper-proof seal.
- Carefully read through instructions prior to using the i-Port Advance injection port. Failure to follow instructions may result in pain or injury.
- If the i-Port Advance injection port is not securely placed in the inserter with the needle pointing straight ahead prior to insertion, pain or injury may occur.
- Be sure that the needle guard is removed before insertion.
- **Do not** use if introducer needle is bent or broken.
- **Do not** inject multiple medications contraindicated for subcutaneous administration into the same site.
- The i-Port Advance injection port is a one time, single-patient use device. Reuse of the port may damage the cannula in the device and increases the risk of the tape becoming loose. Reuse of the port may result in infection or site irritation and inaccurate medication delivery.
- Incorrect medication absorption, infection, or site irritation may result from improper application to the body or maintenance of the i-Port Advance injection port insertion site, or both. If the insertion site becomes irritated or inflamed, remove and discard the device and apply a new device to a different location on the body.
- The soft cannula may crimp or bend when applying or while wearing. A crimped or bent cannula may limit or prevent medication delivery through the i-Port Advance injection port. You should remove and discard the device immediately if you suspect a crimped or bent cannula. Indications that your i-Port Advance injection port has a crimped or bent cannula include:
 - difficulty pressing down on the plunger of the syringe when injecting
 - injected medication escaping from the device onto the top of the septum
 - injected medication leaking onto the skin or saturating the tape
 - moisture present inside the transparent body of the device

- Make sure that the soft cannula does not extend beyond the introducer needle. If it does, do not use the device. This may result in improper insertion, causing a bent cannula and incorrect medication delivery.
- **Do not** reinsert the introducer needle into the i-Port Advance injection port. Reinsertion could cause puncturing or tearing of the soft cannula which would result in unpredictable medication delivery or injury.
- Replace the i-Port Advance injection port if the tape becomes loose or is displaced from its original site. Since the cannula is soft, it may not cause pain if it slips out, and this may occur without you noticing it. The soft cannula must always be completely inserted to receive the full amount of medication from the injection.
- Refer to your healthcare professional for instructions about site rotation. Improper site rotation can result in incorrect medication delivery, infection or site irritation.
- Wash your hands, and swab skin with alcohol or similar disinfectant where you intend to apply the i-Port Advance injection port. Let skin surface dry completely prior to applying the device to the disinfected area.
- Ensure the septum is clean before every use (use purified water).
- **Do not** put perfumes or deodorants on the i-Port Advance injection port as these may affect the integrity of the device.
- **Do not** inject into the i-Port Advance injection port through clothing.
- Never point the loaded inserter toward any body part where insertion is not desired.
- Store the i-Port Advance injection port at room temperature. **Do not** store or leave the device in direct sunlight.
- Avoid applying the i-Port Advance injection port to sites that contain scar tissue, lipodystrophy, or stretch marks. Avoid sites that are constrained by clothing or accessories, or that are subjected to rigorous movement during exercise. Avoid sites that are under a belt or on the waistline.
- **Do not** inject more than 75 times through a single device.

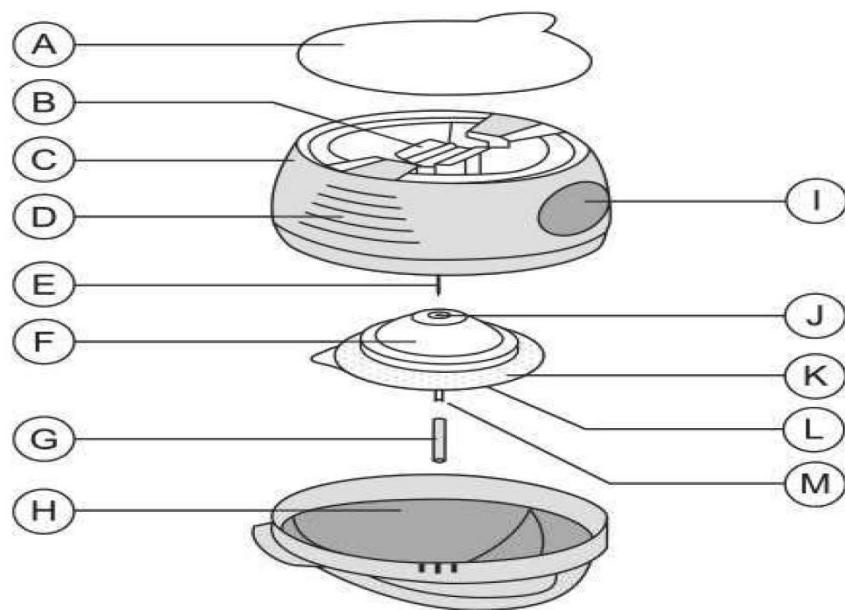
- The i-Port Advance injection port may have up to 2.60 μL or 0.26 units of medication that remain in the port. This can delay or prevent your medication from entering your body. Consult with the healthcare professional of your prescribed medication to determine if this impacts your therapy management.

Recommendations

- Refer to your healthcare professional for instructions about insertion site rotation.
- Test your blood glucose per your healthcare professional's instructions to ensure that insulin delivery at the insertion site is appropriate.
- Test blood glucose 1 to 3 hours after using the i-Port Advance injection port to ensure insulin delivery performs as anticipated, and measure your blood glucose on a regular basis as specified by your healthcare professional.
- Avoid applying and using a new i-Port Advance injection port prior to bedtime unless you can check your blood glucose 1 to 3 hours after injection.
- In the case of an unexplained high blood glucose reading, remove and discard the i-Port Advance injection port and apply a new device to a different location on the body since the soft cannula could be dislodged, crimped or partially clogged. Continue to monitor blood glucose readings to ensure insulin is absorbed. Should suggested actions not provide a resolution to the problem or should your blood glucose remain high, contact your physician or healthcare professional.
- Contact your healthcare professional if your symptoms do not match test results and you have followed all of the instructions in this manual.
- Consult with your healthcare professional if you have any questions or concerns regarding diabetes management.

Instructions for Use

i-Port Advance™ injection port



- | | |
|------------------------|------------------------|
| (A) Sterile liner | (H) Lid |
| (B) Center of inserter | (I) Round indentations |
| (C) Inserter | (J) Septum |
| (D) Finger grips | (K) Tape |
| (E) Introducer needle | (L) Protective liner |
| (F) Injection port | (M) Soft cannula |
| (G) Needle guard | |

Insertion

Unfold the front cover of this booklet to view images that are numbered to the steps below.

- 1** Wash your hands with soap and water. Select an insertion site on a recommended area (shown in gray).
- 2** Clean the insertion site with a disinfectant. Be sure the area is dry before inserting i-Port Advance injection port. If needed, remove hair around the insertion site to prevent improper attachment of the tape to the skin. Contact a healthcare professional if you have any questions regarding proper insertion site cleaning.
- 3** Pull the red tab and remove the seal.
- 4** Remove the sterile liner.
- 5** Securely hold the inserter and remove the lid.
- 6** Remove the protective liner from the tape.

- 7** Twist and remove needle guard from introducer needle.
- 8a** Place your fingers on the finger grips and hold the inserter so that the introducer needle is facing down or away from the body.
- 8b** With your other hand, pull up on the center of the inserter until it is locked in an upright position.
- 9** Place the inserter against your skin and place your fingers on the round indentations. Squeeze both round indentations at the same time to insert the injection port.
- 10** Press down on the center of the inserter to secure the injection port to your skin.
- 11** Grip the center of the inserter and gently pull to remove the inserter from the injection port.
- 12** Smooth down the tape to secure it to your skin.
- 13** Put the lid back and dispose of the inserter according to local requirements.

Using the i-Port Advance injection port

- 1** Clean the septum with purified water before each use.
- 2** Puncture the septum using an injection needle.
- 3** Slowly inject medication into the injection port.
- 4** Remove the injection needle.

Removal

- 1** Grip the edge of the tape and pull upward to remove the injection port from your skin.
- 2** Dispose of the device as biohazard waste in compliance with local and national requirements.

i-Port Advance is registered in U.S. Patent and Trademark Office 940M12078-012 20140127
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(EN) Do Not Reuse
(FR) Ne pas réutiliser
(DE) Nicht wiederverwenden
(ES) No reutilizar
(NL) Niet opnieuw gebruiken
(IT) Non riutilizzare

(NO) Skal ikke brukes flere ganger
(FI) Älä käyttää uudelleen
(SV) Får ej återanvändas
(DA) Må ikke genbruges
(PT) Não reutilizar
(SL) Ne uporabljajte znova



(EN) Caution
(FR) Attention
(DE) Vorsicht
(ES) Precaución
(NL) Let op
(IT) Attenzione

(NO) Forsiktig
(FI) Varoitus
(SV) Försiktighet
(DA) Forsigtig
(PT) Atenção
(SL) Pozor

STERILE EO

(EN) Method of Sterilization:
Ethylene Oxide
(FR) Méthode de stérilisation :
oxyde d'éthylène
(DE) Sterilisierungsverfahren:
Ethylenoxid
(ES) Método de esterilización:
óxido de etileno
(NL) Sterilisatiemethode:
ethyleenoxide
(IT) Metodo di sterilizzazione:
ossido di etilene

(NO) Steriliseringsmetode: etylenoksid
(FI) Sterilointimenetelmä:
etyleenioksidi
(SV) Steriliseringsmetod: Etylenoxid
(DA) Steriliseringsmetode: etylenoxid
(PT) Método de esterilização:
óxido de etileno
(SL) Način sterilizacije: etilenoksid



(EN) Use by (YYYY-MM-DD)
(FR) À utiliser avant le (AAAA-MM-JJ)
(DE) Mindestens haltbar bis
(JJJJ-MM-TT)
(ES) No utilizar después de
(DD-MM-AAAA)
(NL) Gebruik vóór (YYYY-MM-DD)
(IT) Utilizzare entro (AAAA-MM-GG)

(NO) Siste forbruksdag (dd.mm.åååå)
(FI) Käytettävä ennen (VVVV-KK-PP)
(SV) Används senast (AAAA-MM-DD)
(DA) Anvendes inden (AAAA-MM-DD)
(PT) Não utilizar depois de
(AAAA-MM-DD)
(SL) Rok uporabnosti (LLLL-MM-DD)

REF

(EN) Model Number
(FR) Numéro de modèle
(DE) Modellnummer
(ES) Número de modelo
(NL) Modelnummer
(IT) Numero di modello

(NO) Modellnummer
(FI) Mallinnumero
(SV) Modellnummer
(DA) Modelnummer
(PT) Número do modelo
(SL) Številka modela



(EN) Manufacturer
(FR) Fabricant
(DE) Hersteller
(ES) Fabricante
(NL) Fabrikant
(IT) Fabbricante

(NO) Produsent
(FI) Valmistaja
(SV) Tillverkare
(DA) Fabrikant
(PT) Fabricante
(SL) Izdelovalec

LOT

(EN) Batch Code
(FR) Numéro de lot
(DE) Chargenbezeichnung
(ES) Número de lote
(NL) Partijnummer
(IT) Codice del lotto

(NO) Batch-kode
(FI) Eräkoodi
(SV) Lotnummer
(DA) Partikode
(PT) Código de lote
(SL) Serijska številka



(EN) Replace Every 3 Days
(FR) À remplacer tous les 3 jours
(DE) Alle 3 Tage austauschen
(ES) Sustituir cada 3 días
(NL) Om de 3 dagen vervangen
(IT) Sostituire ogni 3 giorni

(NO) Byttes hver 3. dag
(FI) Vaihda 3 päivän välein
(SV) Byt ut var 3:e dag
(DA) Udskift hver 3. dag
(PT) Substitua a cada 3 dias
(SL) Zamenjajte vsake 3 dni



(EN) Consult Instructions for Use
(FR) Consulter le mode d'emploi
(DE) Gebrauchsanweisung beachten
(ES) Consultar las instrucciones de uso
(NL) Raadpleeg gebruiksaanwijzing
(IT) Consultare le istruzioni per l'uso

(NO) Se bruksanvisningen
(FI) Katso käyttöohjeet
(SV) Se bruksanvisningen
(DA) Se brugsanvisningen
(PT) Consultar instruções de utilização
(SL) Glejte Navodila za uporabo



(EN) Latex Free
(FR) Ne contient pas de latex
(DE) Latexfrei
(ES) Sin látex
(NL) Latexvrij
(IT) Senza lattice

(NO) Lateksfri
(FI) Lateksiton
(SV) Latexfri
(DA) Latexfri
(PT) Não contém látex
(SL) Ne vsebuje lateksa



EN Nonpyrogenic
FR Apyrogène
DE Pyrogenfrei
ES Apirógeno
NL Niet-pyrogeen
IT Non pirogeno

NO Pyrogenfri
FI Pyrogeeniton
SV Icke-pyrogen
DA Ikke-pyrogen
PT Apirogénico
SL Apirogeno



EN Open Here
FR Ouvrir ici
DE Hier öffnen
ES Abrir aquí
NL Hier openen
IT Aprire qui

NO Åpnes her
FI Avaa tästä
SV Öppna här
DA Åbnes her
PT Abrir aqui
SL Odprite tukaj



EN Recycle
FR Recyclage
DE Recyclbar
ES Reciclar
NL Recyclen
IT Riciclare

NO Kan resirkuleres
FI Kierrätä
SV Kan återanvändas
DA Genbrug
PT Reciclar
SL Za reciklažo

R_x Only

EN Rx - prescription required, does not apply in all geographies
FR Rx - ordonnance requise, ne s'applique pas à tous les pays
DE Rx - Verschreibungspflichtig, gilt nicht für alle geografischen Gebiete
ES Rx: Solo con receta, no es de aplicación en todas las regiones geográficas
NL Rx - uitsluitend op voorschrift, niet in alle landen van toepassing
IT Rx - richiesta prescrizione medica; non si applica a tutti i Paesi

NO Rx – reseptbelagt, gjelder ikke i alle områder
FI Rx – edellyttää lääkärin määräystä, ei koske kaikkia maantieteellisiä alueita
SV Rx – receptbelagd, gäller inte i alla geografiska områden
DA Rx - kun på recept, gælder ikke alle geografiske områder
PT O requisito de prescrição médica não se aplica a todos os locais geográficos.
SL Rx - samo na recept, ne velja na vseh geografskih območjih

CS Nepyrogení
HU Nem pirogén
PL Niepirogenny
TR Pirojenik Değildir
SK Nepyroženne
EL Μη πυρετογόνο

RU Апирогенно
ZH 无热原
AR لا ينتج عنه ارتفاع في درجة الحرارة
HE אינו פירוגני

CS Zde otevřete
HU Itt nyílik
PL Otwierać tutaj
TR Buradan Açın
SK Tu otvorit'
EL Ανοίξτε εδώ

RU Открывать здесь
ZH 撕开此处
AR افتح هنا
HE לפתוח

CS Recyklace
HU Újrahasznosítható
PL Produkt podlegający recyklingowi
TR Geri dönüştürüm
SK Recyklovateľné
EL Ανακυκλώστε

RU Переработка
ZH 回收利用
AR إعادة التدوير
HE מיחזור

CS Rx - na lékařský předpis,
neplatí ve všech zemích
HU Rx - kizárólag orvosi rendelvényre -
nem vonatkozik minden földrajzi
régióra
PL Rx – wymagana recepta; nie ma
zastosowania we wszystkich
strefach geograficznych
TR Rx - reçete gereklidir; tüm
coğrafi bölgelerde geçerli değildir
SK Iba na predpis – nevztáhuje sa to
na všetky krajiny a oblasti

RU Rx - требуется назначение врача,
применяется не во всех регионах
ZH Rx - 必须有处方, 并非
无论何地都适用
AR Rx - الوصفة الطبية مطلوبة, غير
منطبق في جميع المناطق الجغرافية
HE דרוש מרשם, לא
תקף בכל המדינות

How to order:

iPort Advance is available from Health-Care Equipment

WWW.HCE-UK.COM ☎ +44(0)1784 220 400 ✉ sales@hce-uk.com



HELPFUL TIPS

- Use i-Port Advance with both pens and syringes between 3/16-5/16" (5mm-8mm)
- A single port can be used to inject rapid- and long-acting insulin as long as you wait 60 minutes between injections and always inject rapid-acting insulin first.¹
- After 72 hours of wear or 75 injections, whichever comes first, replace i-Port Advance and rotate sites.

Medtronic

PRODUCT SUPPORT
01923 205167

¹Blevins T, Shwartz SL, Bode B et al. A study assessing an injection port for administration of insulin. *Diabetes Spectr.* 2008;21(3):197-202