ENGLISH Instructions for Use

DESCRIPTION:
The PleuraFlow® Active Clearance Technology™ (ACT™) System incorporates a Clearance Apparatus intended to prevent clogging and occlusion of PleuraFlow Chest Tubes used for pleural and mediastinal drainage after cardiothoracic surgery and trauma.

The primary components of the System are the PleuraFlow Chest Tube and the PleuraFlow Clearance Apparatus. (FIG. 1) The PleuraFlow Chest Tube is a silicone chest tube. It is connected to a Clearance Apparatus, which is connected to the tubing from the drainage canister. (FIG. 3) The PleuraFlow Clearance Apparatus consists of a Guide Tube with a Clearance Wire and Loop that is advanced into the PleuraFlow Chest Tube using a magnetic Shuttle Guide. When indicated, the Clearance Wire and Loop is advanced and retracted within the PleuraFlow Chest Tube to proactively prevent or break up and clear any tube obstructions or clogging to keep the tube patent. Components of the PleuraFlow System are not made with natural rubber latex.

The device is inserted through the skin adjacent to open surgical incision. The proximal end of the drain is positioned within the operative site prior to repair of the incision. The device's distal end is attached to an appropriate suction source in order to allow efflux of bloody, serosanguinous, chylous, purulent fluid, and/or other fluids from the operative site that could impair surgical wound healing. The device is indicated for use in cardiothoracic surgical procedures.

INDICATIONS:
The PleuraFlow System is indicated for use during cardiothoracic surgical procedures and chest trauma. Its Active Clearance Technology proactively removes clots formed inside the chest tube to prevent or minimize chest tube occlusion with clot. A patent chest tube enables evacuation of blood and fluid from the operative site after closure of the surgical wound and reduces retained blood.

In the United States the product is indicated for adult and pediatric patients including infant, preadolescent and adolescent patients under clinical settings.

In the European Community the product is indicated for adult and pediatric patients including infants ranging in age from six months old to 18 years old under clinical settings (See Table 1 for additional information).

CONTRAINDICATIONS:
The PleuraFlow System is contraindicated for patients with a history of intolerance to implantable silicone materials.

This device should not be used in proximity to an MRI.

SET UP INSTRUCTIONS
Prior to Placement:
• Check the package for damage before opening.

To open the package:
• Open the Pouch and deliver the contents to the sterile field using aseptic technique.

• Inspect thoroughly, assuring that it is not kinked or otherwise damaged. If there is any damage, replace with a new device.

Inserting the PleuraFlow System
• Insert the PleuraFlow Chest Tube into the pleural or mediastinal space according to standard methods.

When a median sternotomy approach is used it is recommended that at least one PleuraFlow System is used in the anterior mediastinum as the majority of postoperative bleeding occurs in this location.

WARNING: The Chest Tube is not intended for direct contact with the central circulatory system.

Care should be taken to ensure the path of the PleuraFlow Chest Tube is as straight as possible to minimize the resistance of the Clearance Wire and Loop inside the Chest Tube. In some instances, excessive curvature and tortuosity may result in activating the Magnetic Safety Release.

• Secure the PleuraFlow Chest Tube according to standard methods.

• Take care not to constrict the PleuraFlow Chest Tube when securing in place, which may restrict the movement of the Clearance Wire and Loop.

• After insertion, when trimming the PleuraFlow Chest Tube, cut the Chest Tube precisely where indicated by the labeling that indicates "CUT". (FIG. 2)

WARNING: Do not attempt to cut the PleuraFlow Chest Tube shorter than indicated by the "CUT" indicator close to the distal end. Never cut the proximal end (the end having eyelets/drain holes) of the PleuraFlow Chest Tube. This could result in the Clearance Wire and Loop extending beyond the tip of the Chest Tube, which could potentially damage internal structures.

Connect the Clearance Apparatus between the PleuraFlow Chest Tube and the drainage tubing (FIG. 3)
• Connect the chest tube to the chest barb, advance tubing all the way onto barb.

• Once the PleuraFlow Clearance Apparatus is connected to the PleuraFlow Chest Tube, advance the external Shuttle Guide toward the proximal barb and Chest Tube. This will advance the Clearance Wire and Loop into the proximal end of the Chest Tube. (FIG. 4)

• Click the Shuttle Guide into the proximal barb housing to park the Clearance Wire and Loop in the proximal end of the Chest Tube.

• Connect the drain barb adapter of the Clearance Apparatus to the drainage tubing that goes to the drainage canister, advance tubing all the way onto barb.

• Secure all connections per hospital protocol.

• Connect the drainage canister to the suction source.
  • Maximum vacuum: -40 cmH_2O

• If a Y-connection is indicated, ensure the Y-junction is placed distal to the Clearance Apparatus. Additional drainage tubing may be used to compensate for length discrepancies.

POST INSERTION INSTRUCTIONS
• Confirm tip position of the PleuraFlow Chest Tube according to institution protocol. Although the PleuraFlow Chest Tube material contains a radiopaque stripe to aid in the radiographic visualization of the PleuraFlow Chest Tube, the Clearance Wire and Loop may be left in place to improve radiographic visualization.

USE OF THE CLEARANCE APPARATUS
• Only a qualified healthcare practitioner should operate the device.

• When it is indicated to clear the PleuraFlow Chest Tube, the Shuttle Guide is disengaged from the proximal connector, and moved down the Clearance Apparatus, away from the patient and toward the drainage canister tubing. (FIG. 5)

• The Clearance Apparatus should be actuated often in the setting of thick output, such as clotting blood, to ensure the chest tube is patent.
  • It is recommend that the device is actuated to clear the PleuraFlow Chest Tube every 15 minutes during the first 8 hours after placement when bleeding is typically more common, then every 30 minutes for the next 16 hours, then every hour thereafter.
  • The device should be actuated as needed in addition to these baseline requirements.
  • This should be repeated as often as necessary to keep the tube patent and free of any occlusions.

• Each time the Clearance Apparatus is actuated to clear the PleuraFlow Chest Tube; the Clearance Apparatus should be inspected for any clot or occluding material accumulating on the Clearance Wire and Loop.
  • If obstructive clot is forming on the Clearance Wire and Loop, steps should be taken to dislodge the clot or fibrinous material stuck to the wire.
  • If this cannot be cleared from the wire and is obstructing drainage, the Clearance Wire and Loop should be parked outside the PleuraFlow Chest Tube, in the Clearance Apparatus, by moving the Shuttle Guide to the distal portion of the Clearance Apparatus and leaving it outside of the Chest Tube.

• Traditional methods of chest tube clearance can be carried out at any time, as long as the Clearance Wire and Loop is fully retracted outside of the PleuraFlow Chest Tube.

• When not in use, the Shuttle Guide should be parked by clicking it to the proximal barb, thereby parking the Clearance Wire and Loop in the proximal end of the PleuraFlow Chest Tube. (FIG. 6)

• The Clearance Apparatus should be removed within 5 days or once the bleeding and clotting have ceased, whichever is sooner. This can be done by retracting the Clearance Wire into the Guide Tube and removing the PleuraFlow Chest Tube and the Clearance Apparatus together, if clinically indicated. Alternatively, the Clearance Wire can be retracted into the Guide Tube and the Clearance Apparatus removed, leaving the Chest Tube connected directly to the drainage tubing. The chest tube can then be left in place until removal is clinically indicated up to two weeks from insertion.

TROUBLE SHOOTING
• If an obstructive clot appears on the Clearance Wire and Loop, steps should be taken to dislodge the clot into the larger diameter Guide Tube.
  • Gently squeeze the wire through the PleuraFlow Chest Tube or Guide Tube while advancing the Clearance Wire and Loop to clear off clots.
  • Rapidly run the wire back and forth to dislodge any clot while taking care not to squeeze the Clearance Loop.
  • Flick or tap the PleuraFlow Chest Tube and Guide Tube.
  • Gently tap the Shuttle Guide against the distal connector.
  • If clot remains adherent to the Clearance Wire and Loop, withdraw it from the PleuraFlow Chest Tube and leave in the Guide Tube.
  • If further tube clearance is needed, you may attach a new Clearance Apparatus into the existing PleuraFlow Chest Tube using standard techniques.
  • If necessary, the Clearance Apparatus can be removed and the PleuraFlow Chest Tube can be connected to the drainage tubing in the standard fashion.
  • Never move the Clearance Wire and Loop against resistance without careful assessment of cause.
  • If cause cannot be determined, move the Clearance Wire and Loop out of the PleuraFlow Chest Tube and leave it in the Guide Tube.
  • Movement against resistance may result in damage to the PleuraFlow Chest Tube, which could allow the Clearance Wire and Loop to extend outside the Chest Tube.
  • If the internal and external magnets become uncoupled, advance or retract the Shuttle Guide over the internal magnet to recouple. Retaining elements set on the internal magnets will keep the internal magnets and wire from exiting the Guide Tube, thus encouraging recoupling of the magnets. If after several attempts the magnets remain uncoupled, the PleuraFlow Clearance Apparatus may be disconnected from the PleuraFlow Chest Tube. The Chest Tube may then be connected to the drainage tubing and canister in the standard fashion.
  • If decoupling occurs when the Clearance Wire and Loop are in proximity to the parked position continue using the device if:
    - it is not possible to click the Shuttle Guide into the proximal barb housing to park the Clearance Wire and Loop in the proximal end of the Chest Tube, and;
    - There is no resistance to wire movement inside the chest tube distally to the point of decoupling.

PLEURAFLOW SYSTEM (CHEST TUBE AND CLEARANCE APPARATUS) REMOVAL
• Retract the Clearance Wire into the Guide Tube.
• Remove old dressing, sutures and/or tape.
• Grasp the PleuraFlow Chest Tube near the insertion site; using a slow, steady motion, remove the Chest Tube from the incision.
• Apply occlusive dressing after removal.

CAUTION: Care should be taken during Chest Tube removal from the patient to avoid damaging the Chest Tube. Withdrawal against excessive resistance may result in Chest Tube damage and patient injury.

SUGGESTED PLEURAFLOW CHEST TUBE MAINTENANCE
• The PleuraFlow Chest Tube should be maintained in accordance with standard institutional protocols. Suggested PleuraFlow Chest Tube maintenance is as follows:
  • Dressing Changes: Assess the dressing in the first 24 hours for accumulation of blood, fluid, or moisture beneath the dressing.
  • Cleaning Exit Site: Maintain according to institution protocol.

COMPATIBILITY
•The PleuraFlow System is only compatible with PleuraFlow Chest Tubes. Compatibility with other drainage tubes has not been established.
• The PleuraFlow System is compatible with any drainage canister system.
• Refer to product label for device dimensions.

DURATION OF USE
• Maximum for PleuraFlow Chest Tube use is 2 weeks.
• Maximum for Clearance Apparatus is 5 days.
• If the PleuraFlow Chest Tube is still needed, but the Clearance Apparatus is not, the Clearance Apparatus can be removed and discarded, and the Chest Tube left in place. Always retract the Clearance Wire and Loop into the Guide Tube prior to removing the Clearance Apparatus. The Chest Tube may then be connected to the drainage tubing and canister in the standard fashion.

WARNINGS
• Do not reuse. Discard after one use. Caution: The characteristics of this device have been verified for single-use ONLY. Any attempt to re-process this device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.
• PleuraFlow Chest Tubes should not be clamped except when changing the drainage canister or removing the Clearance Apparatus. Withdraw the Clearance Wire and Loop prior to clamping.
• The PleuraFlow Chest Tube should not be clamped when the Clearance Wire and Loop is advanced in the Chest Tube, as this could result in damage.
• Use only the supplied PleuraFlow Chest Tube.
• Cut the PleuraFlow Chest Tube only as indicated by the "CUT" mark on the distal end. Cutting it shorter can result in the Clearance Wire and Loop extending beyond the tip of the Chest Tube. (FIG. 2). Do not cut the proximal end (the end having eyelets/drain holes) of the PleuraFlow Chest Tube.
• Never advance the Clearance Wire and Loop against resistance without careful assessment of cause. If cause cannot be determined, withdraw the Clearance Wire and Loop into the Guide Tube or replace the PleuraFlow Chest Tube. Movement against resistance may result in damage to the PleuraFlow Chest Tube, which could allow the Clearance Wire and Loop to extend outside the PleuraFlow Chest Tube.
• Dispose of the used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product presents a potential biohazard.
• Do not place the Shuttle Guide within 6 inches of an implanted pulse generator, such as pacemakers or implantable defibrillators.
• The PleuraFlow Clearance Apparatus should be removed if in proximity to an MRI.

PRECAUTIONS
• Carefully read and follow instructions prior to using this device.
• Insertion or removal of this device is only to be done by qualified health professionals.
• Follow aseptic techniques when inserting or removing the PleuraFlow System.
• The device must be used prior to the expiration date.

COMPLICATIONS
Inserting the PleuraFlow Chest Tube and utilizing the Clearance Apparatus may result in any of the following complications:

- Pneumothorax
- Pericardial tamponade
- Infection
- Exposure to body fluids
- Empyema
- Leakage
- Hypotension subsequent to drainage
- Skin irritation or infection
- Splenic or hepatic laceration
- Re-expansion pulmonary edema
- Occlusion
- Pain
- Hemothorax
- Chest tube malposition
- Accidental Chest Tube dislodgement or removal
- Tumor seeding
- Chest tube erosion through skin

HOW SUPPLIED
The PleuraFlow System is provided sterile and will remain so as long as the package is unopened and undamaged. Do not resterilize.

STORAGE
Handle with care. The System should be stored in an area with good ventilation under good conditions that protect it from extremes of temperature and humidity.

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
The Instructions for Use do not override clinical practice by qualified individuals.

ATTENTION: for European Community users

Table 1. Correlation of pediatric ages and range of chest tube sizes that may be used

Pediatric Subpopulation by age	PleuraFlow Chest Tube Model (effective drainage length*)
6 months	PF-20 SEDL, PF-20
1-2 years	PF-20 SEDL, PF-20, PF-24
2-7 years	PF-20 SEDL, PF-20, PF-24, PF-28
8-18 years	PF-20 SEDL, PF-20, PF-24, PF-28, PF-32

* The Effective Drainage Length (EDL) is the length of the chest tube having eyelets. The EDL of Models PF-20, PF-24, PF-28 and PF-32 is 10.2 cm with 6 eyelets. Model PF-20 SEDL has a short EDL measuring 5.1cm with 4 eyelets.

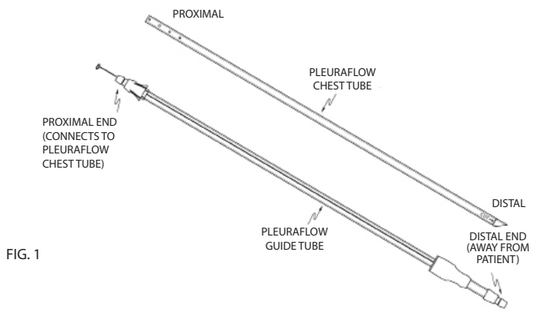

FIG. 1

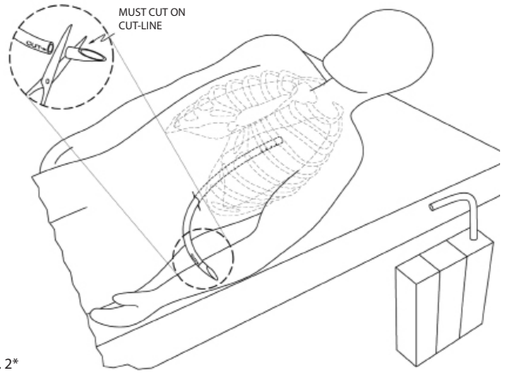

FIG. 2*

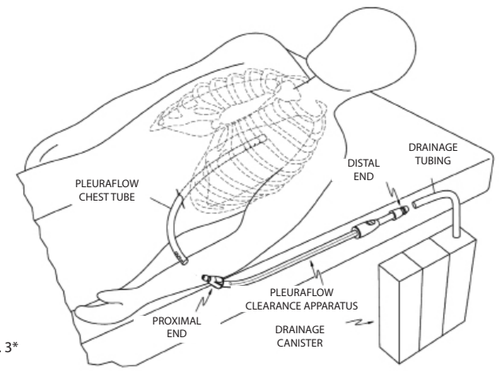

FIG. 3*

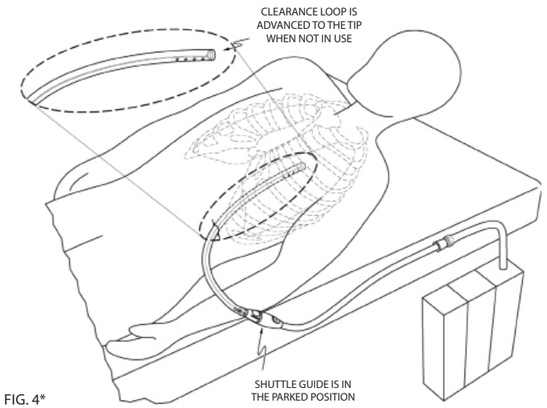

FIG. 4*

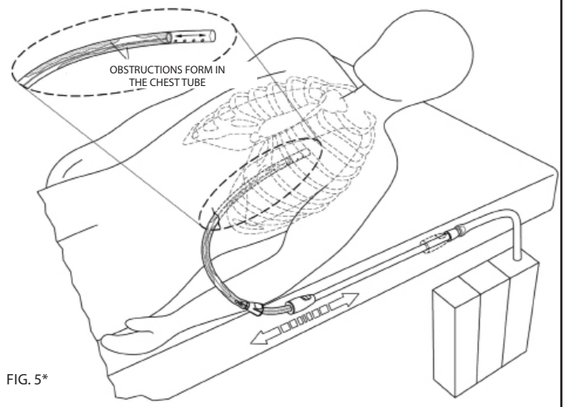

FIG. 5*

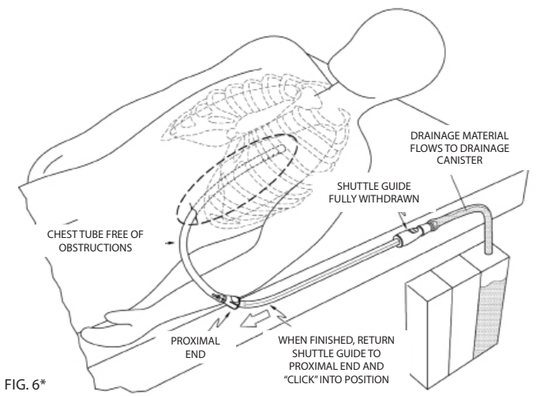

FIG. 6*

*Note: Artist rendering does not reflect the actual placement of the Chest Tube inside the chest. The diagram is for illustrative purposes only. See "Inserting the PleuraFlow System" above.

The PleuraFlow® System
For Single Use Only
Made in the U.S.A.

PLEURAFLOW
ACTIVE CLEARANCE TECHNOLOGY

ENGLISH
The PleuraFlow® System
For Single Use Only
Made in the U.S.A.

DEUTSCH
Das PleuraFlow® System
Nur für den Einmalgebrauch
Hergestellt in den U.S.A.

ESPAÑOL
Sistema PleuraFlow®
Para un solo uso
Fabricado en EE. UU.

ΕΛΛΗΝΙΚΑ
Το σύστημα PleuraFlow®
Για μία μόνο χρήση
Κατασκευάζεται στις Η.Π.Α.

FRANÇAIS
Le système PleuraFlow®
A usage unique seulement
Fabriqué aux Etats-Unis

HRVATSKI
Sustav PleuraFlow®
Isključivo za jednokratnu uporabu
Proizvedeno u SAD-u

ITALIANO
Il Sistema PleuraFlow®
Sistema monouso
Fabbricato negli Stati Uniti

NEDERLANDS
Het PleuraFlow® -systeem
Uitsluitend voor eenmalig gebruik
Geproduceerd in de Verenigde Staten

PORTUGUÊS
Sistema PleuraFlow®
Apenas para utilizaÇão única.
Fabricado nos E.U.A.

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Sistemul PleuraFlow®
Exclusiv de unică folosință
Fabricat în S.U.A.

SLOVENSKI
Sistem PleuraFlow®
Samo za enkratno uporabo
Izdelano v ZDA

SVENSKA
PleuraFlow® -systemet
Endast för engångsbruk
Tillverkad i USA.

فارسی
PleuraFlow® سیستم
فقط برای یک بار استفاده
تولید شده در ایالات متحده آمریکا

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℞ ONLY

CE 0050

Do not reuse; Nicht wiederverwenden; No reutilizar; Μην επαναχρησιμοποιείτε; Ne pas réutiliser; Nemojte ponovo upotrebljavati; Non riutilizzare; Niet opnieuw gebruiken; Não reutilizar; A nu se reutiliza ; Ni za ponovno uporabo; Får ej återanvändas; دوباره استفاده نکنید.

Use by; Zu verwenden bis; Fecha de caducidad; Ημερομηνία λήξης Utiliser avant le; Upotrijebiti do; Utilizzare entro il; Houdbaar tot; Prazo de validade; A se utiliza până la; Uporabno do; Används före; تاریخ مصرف

LOT
Batch code; Chargencode; Código de lote; Κωδικός παρτίδας; Code de lot; Šifra serije; Codice lotto; Code van de partij; Código do lote; Cod de lot ; Številka serije; Batchkod; کد سری ساخت

STERILE EO
Sterilization using ethylene oxide
Sterilisation mit Ethylenoxid
Esterilizado utilizando óxido de etileno
Αποστείρωση με χρήση οξειδίου του αιθυλενίου
Méthode de stérilisation utilisant de l'oxyde d'éthylène
Sterilizacija etilen oksidom
Sterilizzazione con ossido di etilene
Gesteriliseerd met behulp van ethyleenoxide
Esterilização com óxido de etileno
Sterilizat cu oxid de etilenă
Sterilizirano z etilenoksidom
Steriliserad med etylenoxid
استریل سازی با استفاده از اتیلن اکسید

2 Sterilize
Do not resterilize; Nicht erneut sterilisieren; No reesterilizar; Μην επαναποστειρώνετε; Ne pas restériliser; Nemojte ponovo sterilizirati; Non risterilizzare; Niet opnieuw steriliseren; Não voltar a esterilizar; A nu se resteriliza; Ne sterilizirajte ponovno; Får ej resteriliseras; دوباره استریل نکنید

Manufacturer; Hersteller; Fabricante; Κατασκευαστής; Fabricant; Proizvođač; Produttore; Fabrikant; Fabricante; Producător; Izdelovalec; Tillverkare; تولیدکننده

Consult Instructions for Use; Gebrauchsanweisung heranziehen; Consúltense las instrucciones de uso; Συμβουλευτείτε τις οδηγίες χρήσης Consulter la notice d'utilisation; Proučite upute za uporabu; Consultare le istruzioni per l'uso; Raadpleeg de gebruiksaanwijzing; Consultar as instruções de utilização; Consultați instrucțiunile de utilizare; Preberite navodila za uporabo; Se bruksanvisningen; به دستورالعمل های استفاده رجوع کنید

REF
Catalog number; Katalognummer; Número de catálogo; Αριθμός καταλόγου; Référence du catalogue; Broj kataloga; Numero di catalogo; Catalogusnummer; Número de catálogo; Număr de catalog; Kataloška številka; Katalognummer; شماره کاتالوگ

MR
MR unsafe; Nicht MR-sicher; No utilizar en resonancia magnética; Μη ασφαλές για μαγνητική τομογραφία; Incompatible avec la résonance magnétique; Nije sigurno za MR snimanje; Non adatto per Risonanza Magnetica; MR-onveilig; Não seguro para uso em Ressonância Magnética; Nesigur RM; Ni varno za uporabo pri magnetni resonanci; Ej MR kompatibel; MR غیر ایمن با

Contents; Inhalt; Contenido; Περιεχόμενα; Contenu; Sadržaj; Sommario; Inhoud; Conteúdo; Conținut; Vsebina; Innehåll; محتویات

Do not use if package is damaged
Bei beschädigtem Paket nicht verwenden
No utilizar si el envase está dañado
Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά
Ne pas utiliser si l'emballage est endommagé
Nemojte koristiti ako je pakiranje oštećeno
Non utilizzare se la confezione appare danneggiata
Niet gebruiken indien de verpakking beschadigd is
Não usar se a embalagem estiver danificada
A nu se utiliza dacă ambalajul este deteriorat
Ne uporabljajte, če je ovojnina poškodovana
Får ej användas om förpackningen är skadad
اگر بسته بندی آسیب دیده است استفاده نکنید

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
WARNUNG
Die Gesetze der USA gestatten den Verkauf dieses Geräts nur an Ärzte oder deren Auftraggeber.
PRECAUCIÓN
Las leyes federales de Estados Unidos restringen la venta de este dispositivo a médicos o por prescripción facultativa.
ΠΡΟΣΟΧΗ
Η Ομοσπονδιακή Νομοθεσία (των Η.Π.Α.) επιτρέπει την πώληση αυτής της συσκευής μόνο σε ιατρό ή κατόπιν εντολής ιατρού
ATTENTION
La loi fédérale (États-Unis) restreint la vente de ce dispositif aux médecins ou sur leur prescription.
OPREZ
Prema saveznom zakonu (SAD-a), ovaj naprava može se kupiti samo od liječnika ili na njegovu preporuku.
ATTENZIONE
la legge federale degli Stati Uniti limita la vendita di questo prodotto al solo personale medico o sotto la loro richiesta.
LET OP
Op grond van de federale wetgeving van de Verenigde Staten mag dit product uitsluitend door of op voorschrift van een arts worden verkocht
ATENÇÃO
As Leis Federais dos EUA restringem a venda deste dispositivo pelo médico ou mediante receita médica.
ATENȚIE
Legea federală (S.U.A.) restricționează vânzarea acestui aparat de către sau la comanda unui medic
POZOR
Ameriška zvezna zakonodaja omejuje prodajo te naprave na zdravnika ali po njegovem naročilu
VAR FÖRSIKTIG!
Enligt federal (USA) lag får denna anordning endast säljas av eller på ordination av läkare.
احتیاط
فروش یا سفارش این محصول بر طبق قوانین فدرال (ایالات متحده آمریکا) صرفاً توسط پزشکان مجاز می باشد

℞ ONLY

The Instructions for Use do not override clinical practice by qualified individuals.
Die Gebrauchsanweisung setzt die klinische Praxis durch qualifiziertes Personal nicht außer Kraft.
Las instrucciones de uso no se anteponen a la práctica clínica por profesionales cualificados.
Οι οδηγίες χρήσης δεν υπερισχύουν της κλινικής πρακτικής από καταρτισμένα άτομα.
La notice d'utilisation ne l'emporte pas sur les pratiques cliniques par des personnes qualifiées.
Upute za uporabu ne prevladavaju nad kliničkom praksom kvalificiranih osoba.
Le istruzioni per l'uso non hanno la precedenza sulla pratica clinica del personale qualificato.
De Gebruiksaanwijzing heeft geen voorrang boven de klinische praktijk door gekwalificeerde zorgverleners.
As instruções de utilização não substituem a prática clínica por profissionais qualificados.
Instrucțiunile de utilizare nu anulează practica clinică a persoanelor calificate.
Navodila za uporabo nimajo prednosti pred kliničnimi izkušnjami usposobljenih posameznikov.
Bruksanvisningen är inte avsedd att åsidosätta klinisk praxis som utövas av kvalificerad personal.
دستورالعمل های استفاده جایگزین شیوه های حرفه ای کلینیکی مورد استفاده افراد واجد شرایط نمی باشند.