ELECTRONIC INSTRUCTIONS FOR USE — EIFU

Pruitt F3® Carotid Shunt

Ref: Model # 2011-10M, 2012-10M, 2013-10M (Outlying) | Model # 2011-12M, 2012-12M (Inlying) | Rev: D | 12/25

Manufacturer: LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803, USA

For Healthcare Professionals Only

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1. Device Description & Manufacturer

Introduction

The Pruitt F3® Carotid Shunt is designed to serve as an artificial passage connecting two blood vessels, allowing blood flow from one vessel to another. This is accomplished by using a clear, plastic, sterile conduit that is held in place by a stabilization technique on both ends of the conduit.

Product Description

The Pruitt F3 Carotid Shunt (the Shunt) is a multi-lumen device with balloons at both the distal (internal carotid) and proximal (common carotid) ends of the shunt. The balloons, when inflated independently, act as a stabilization mechanism to maintain the position of the Shunt when it is placed within the common and internal carotid arteries. An external safety balloon located on the inflation arm leading to the distal (internal carotid) balloon acts as a mechanism to relieve pressure on the internal carotid balloon in the event it inflates above optimal size and pressure. The external safety balloon feature reduces the possibility of balloon over-inflation and resultant vessel damage.

The Pruitt F3 Carotid Shunt has features to aid the user during shunt insertion and balloon inflation. The inflation path of the proximal (common carotid) balloon is color-coded. Sterile saline is injected from the blue stopcock, through the blue lumen and into the blue common carotid balloon. The sleeve of the external safety balloon is yellow, to increase its visibility. Depth markings on the shunt body are for reference during insertion.

Manufacturer

LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803, USA

2. Intended Purpose

Indication

The Pruitt F3 Carotid Shunts are indicated to facilitate carotid endarterectomy procedures for the treatment of carotid artery disease.

Intended Use/ Purpose

The Pruitt F3 Carotid Shunt is intended to act as a temporary conduit to allow for blood flow between the common and internal carotid arteries during endarterectomy procedures.

Intended User

The Pruitt F3 Carotid Shunt is a surgical tool intended for use by experienced vascular surgeons trained in the procedures for which they are intended.

Patient Population

Patients of any gender, age or ethnicity undergoing carotid endarterectomies.

Part of the Body Contacted

The Pruitt F3 Carotid Shunt will come in contact with the common and internal carotid arteries.

Clinical Condition

Carotid artery disease

Clinical Benefits

The clinical benefits associated with the use of the Pruitt F3 Carotid shunts include reduced risk of stroke and

increased survival, comparable to rates observed in similar devices and no shunting.

3. Contraindications

1. The Shunt is a temporary device and should not be implanted.
2. The Shunt is not indicated for use in embolectomy, thrombectomy, or vessel dilation.

4. Warnings and Precautions

Warnings

1. Do not reuse. Do not resterilize. For single use only.
2. Do not use air or gas to inflate the balloons. Inflate the balloons with sterile saline.
3. Do not inflate the internal carotid balloon to any greater volume than is necessary to obstruct blood flow for the internal carotid artery. DO NOT EXCEED the recommended maximum balloon liquid capacity (see Specifications).
4. Exercise caution when encountering extremely diseased vessels. Arterial rupture or balloon failure due to sharp calcified plaque may occur. The possibility of balloon rupture must be taken into account when considering the risks involved in the endarterectomy procedure.
5. Deflate the balloons prior to Shunt removal. Avoid using excessive force to push or pull the Shunt against resistance.

Precautions

1. Inspect the product and package prior to use and do not use if there is any evidence that the package or the Shunt has been damaged.
2. The Shunt should be used only by qualified physicians thoroughly familiar with cardiovascular surgical procedures involving the carotid artery.
3. Pretest the Shunt according to the pretest procedure prior to patient use to ensure the lumen is free of obstructions and the balloons are functional.
4. Aspirate the balloons prior to inflation.
5. Place internal carotid balloon into internal carotid artery and common carotid balloon in common carotid artery.
6. If the Shunt is not properly maintained in position through balloon stabilization, it may migrate within the internal carotid artery, potentially scuffing the intima.
7. Avoid extended or excessive exposure to fluorescent light, heat, sunlight, or chemical fumes to reduce balloon degradation. Excessive handling during insertion, and/or plaque and other deposits within the blood vessel, may damage the balloon and increase the possibility of balloon rupture.
8. Do not grasp the balloon with instruments at any time to avoid damage to the latex.
9. When applying atraumatic clamps to the shunt body, do so carefully to avoid damage to the shunt lumens and joints. Avoid directly clamping over the joints.
10. Make secure connections between the syringe and the hub to avoid introduction of air.
11. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

5. Instructions for Use

How Supplied

The Shunt is supplied sterile and nonpyrogenic. The sterility of the package is assured as long as it is unopened and undamaged.

Procedure

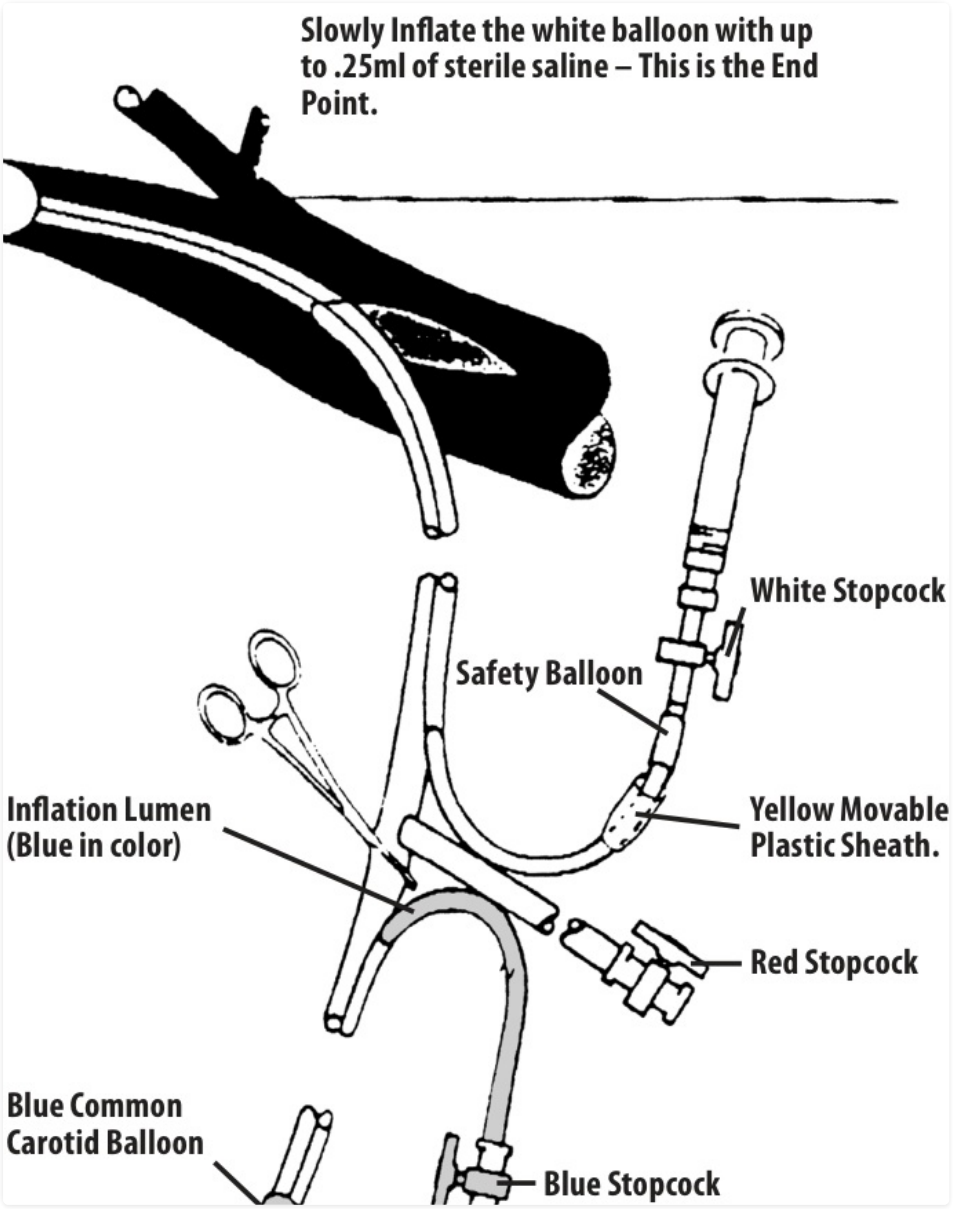
> *IMPORTANT: A variety of surgical techniques may be used when using the Shunts; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient. Specific surgical techniques are left to the discretion of the surgeon.*

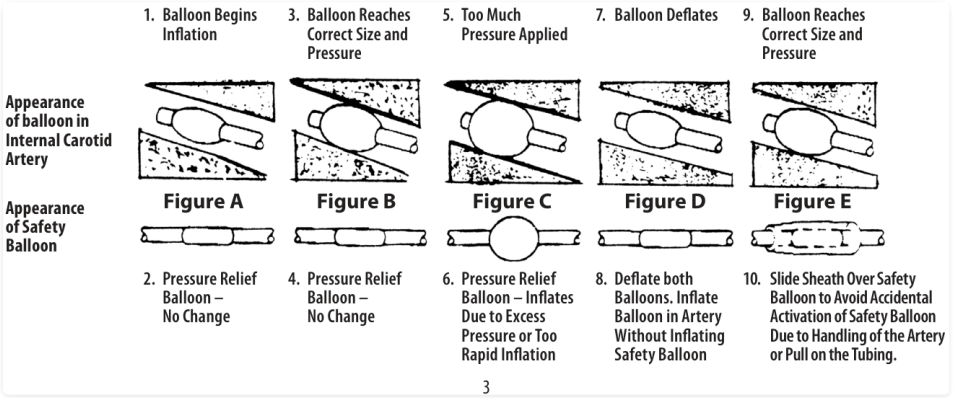
Balloon Pretest Procedure (Perform Before Patient Use)

1. Inflate both balloons up to the maximum recommended volumes with sterile saline and inspect for leaks. If there is any evidence of leaks around the balloons or if either balloon will not remain inflated, do not use the product.

> *NOTE: The common carotid balloon is designed to inflate partially to minimize pressure on the common carotid artery while maintaining position.*

2. Ensure that the movable sleeve hangs loosely on the infusion area of the distal (internal carotid) lumen and DOES NOT cover the external safety balloon as it will render the safety balloon inoperable and subject the internal carotid artery to possible injury by over-inflation of the internal carotid balloon.
3. In order to properly deflate the balloon(s), remove the syringe and open the stopcock. The balloon(s) should then deflate unaided.
4. Before patient use, aspirate the balloons completely prior to inflation of the balloons.





T-Port Pretest (Perform Before Patient Use)

1. Place a gloved finger over the opening near the common carotid (large blue balloon) end and inject sterile saline through the T-Port stopcock. Fluid should flow through the opening near the internal carotid (small balloon) end.
2. Place a gloved finger over the internal carotid (small balloon) end and inject sterile saline through the T-Port stopcock. Fluid should flow through the opening near the common carotid (large blue balloon) end.
3. Do not use the Shunt if fluid does not flow through both openings.

Procedure for T-Port Models 2011-10M, 2011-12M, 2012-10M, 2012-12M, 2013-10M

1. Expose the carotid artery and perform the arteriotomy in the usual manner.
2. Place a clamp on the proximal (common carotid) end of the Shunt before the T-Port.
3. Place the distal (internal carotid) end of the Shunt into the internal carotid artery.

4. Attach a 3 ml syringe to the white stopcock and SLOWLY inflate the internal carotid artery balloon with up to 0.25 ml of sterile saline (Figure A).
5. As inflation progresses, carefully observe back-bleeding from the internal carotid artery around the Shunt. The back-bleeding will diminish as the balloon expands. When the balloon is inflated sufficiently to occlude the artery, back-bleeding around the shunt will stop, there will be a feeling of slight resistance to further inflation and/or there will be a slight distention of the external safety balloon. This is the end-point: STOP INFLATION IMMEDIATELY AT THIS POINT. The external safety balloon should not be inflated (Figure B).
6. Close the white stopcock and slide the movable sleeve over the external safety balloon. This will prevent reflux from the internal carotid balloon into the external safety balloon and prevent subsequent loss of vessel occlusion (Figure E).

> *NOTE: The internal carotid balloon may accidentally become dislodged from its position by over-inflation, handling of the artery, or pulling on the Shunt. This may result in spontaneous decompression of the internal carotid balloon with reflux into the external safety balloon and loss of occlusion in the artery. Placement of the sleeve or sheath over the external safety balloon prevents this potential problem.*

> *IMPORTANT: Should the internal carotid balloon be over-inflated, causing the external safety balloon to inflate (Figure C), BOTH balloons must be deflated. After both balloons have been deflated (Figure D), SLOWLY inflate the internal carotid artery balloon with up to 0.25 ml of sterile saline without inflating the external safety balloon (Figure B).*

7. Open the T-Port stopcock and allow blood to back-bleed through the T-Port of the shunt observing for air bubbles and/or atheromatous debris.
8. When no debris or bubbles are noted, close the T-Port stopcock and move the clamp from the proximal (blue common carotid) end to the distal (internal carotid) end of the Shunt beyond the T-Port.
9. Place the proximal (blue common carotid) end of the Shunt into the common carotid artery.
10. Attach a 3 ml syringe to the blue stopcock and slowly inflate the blue common carotid artery balloon with up to 1.5 ml of sterile saline. Close the blue stopcock.
11. Remove the clamp from the common carotid artery, open the T-Port stopcock and allow blood to flow through the T-Port of the Shunt observing for air bubbles and/or atheromatous debris.
12. When no debris or bubbles are noted, close the T-Port stopcock and remove the clamp on the distal (internal carotid) end of the Shunt. Proceed with the procedure.
13. When the endarterectomy is completed, deflate the balloons, remove the Shunt and close the arteriotomy in the usual manner.

6. Adverse Effects and Complications

Adverse Events

As with all cardiovascular procedures involving the carotid arteries, complications may occur during or following carotid endarterectomy. These may include, but are not limited to:

- stroke
- transient ischemic attack
- neurologic complications
- embolization of blood clots, areteriosclerotic plaque, or air
- hypertension or hypotension
- infection (not observed in any cases but measured in literature)*
- intimal disruption
- arterial dissection
- vessel perforation and rupture
- hemorrhage
- arterial thrombosis
- aneurysms
- arterial spasm
- mortality
- newly developed ischemia
- Intimal flap*
- Reperfusion injury* (could encompass intimal disruption and arterial dissection)
- Postoperative neurological impairment*
- Nerve palsy
- Myocardial infarction
- Embolization*

7. Technical Specifications

Model	Description	Usable Length	Diameter	Common Inflation Lumen Markings	Safety Balloon Sheath Color
2011-10M	Pruitt F3 Carotid Shunt with T-port (Outlying)	31 cm	10 French (3.4 mm)	Blue Lumen	Yellow
2011-12M	Pruitt F3 Carotid Shunt with T-port (Inlying)	15 cm	10 French (3.4 mm)	Blue Lumen	Yellow
2012-10M	Pruitt F3 Carotid Shunt with T-Port (Outlying)	31 cm	9 French (3.0 mm)	Blue Lumen	Yellow
2012-12M	Pruitt F3 Carotid Shunt with T-Port (Inlying)	15 cm	9 French (3.0 mm)	Blue Lumen	Yellow
2013-10M	Pruitt F3 Carotid Shunt with T-Port (Outlying)	31 cm	8 French (2.7 mm)	Blue Lumen	Yellow

	Stopcock Color	Balloon Maximum Liquid Capacity	Balloon Diameter at Maximum Liquid Capacity
Common Carotid Balloon	Blue	1.5 ml	14 mm
Internal Carotid Balloon	White	.25 ml	8 mm
T-Port	Red	N/A	N/A

Storage Shelf Life

The shelf life is indicated by the USE BY date on the package label. The USE BY date printed on each label is NOT a sterility date. The USE BY date is based on the normal life expectancy of the natural rubber latex balloon when properly stored. The use of the shunt beyond the expiration date is not recommended because of potential balloon deterioration. LeMaitre Vascular, Inc. does not make provisions for replacing or reprocessing expired product.

Since natural rubber latex is affected by environmental conditions, proper storage procedures must be practiced to achieve optimum shelf life. The product should be stored in a cool dark area, not to exceed 30°C, away from fluorescent lights, sunlight, and chemical fumes to prevent premature deterioration of the rubber balloon. Proper stock rotation should be practiced.

Resterilization/Re-use

This device is single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only.

Safe Handling and Disposal

This device is single-use and disposable device. Do not implant. Please return the used device only at the time that the device has not performed as intended or the device is related to an adverse event. In other situations, the device should not be returned but disposed according to local regulations.

If serious medical incidents should arise during use of this medical device, users should notify both LeMaitre Vascular and the Competent Authority of the country where the user is located.

This product contains no sharps, heavy metals or radioisotopes, and is not infectious or pathogenic. No special requirements for disposal are evident. Please consult local regulations to verify proper disposal.

Cleaning:

1. Devices considered necessary to return should be cleaned using one of the following:
   - a) Sodium hypochlorite solution (500-600 mg/l), or
   - b) Peracetic acid solution with subsequent ultrasonic treatment
2. Devices should then be decontaminated with either: a) 70% solutions of ethanol or isopropanol for a minimum of 3 hours or,
   - b) Ethylene oxide gas
3. Devices should be completely dried prior to packaging.

Packaging:

1. Cleaned devices should be sealed and packed in a manner that minimizes potential for breakage, contamination of the environment or exposure to those handling such packages during transit. For devices capable of penetrating or cutting skin or packaging material, the primary packaging must be capable of maintaining the product without puncture of the packaging under normal conditions of transport.
2. The sealed primary container should be placed inside watertight secondary packaging. The secondary packaging should be labelled with an itemized list of the contents of the primary receptacle. Cleaning methods should be detailed if possible.
3. Both primary and secondary packaging of cleaned, decontaminated single-use disposable devices should be labelled with an ISO 7000-0659 Biohazard symbol.
4. Primary and secondary packaging must then be packaged inside an outer package, which must be a rigid, fiberboard

box. The outer shipping container must be provided with sufficient cushioning material to prevent movement between the secondary and outer containers.

5. Shipping paper and content marking for the outer shipping container are not required.
6. Packages prepared in the above manner may be shipped to:
   LeMaitre Vascular Attn: Complaint Lab 63 Second Avenue Burlington, MA 01803, USA

Summary of Safety and Clinical Performance

To view the Pruitt F3 Shunt Summary of Safety and Clinical Performance document, please visit www.lemaitre.com/sscp

Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information.

If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

References

1. Dainko EA. Complications of the use of the Fogarty Balloon. Catheter Arch Surgery, 105:79-82, 1972.
2. Cranley JJ, Krause ES, Strausser CC, Hafner A, Complication With the Use of the Fogarty Balloon Catheter for Arterial Embolectomy J. Cardiovas Surgery, Volume 10, September-October 1969. Pp. 407-409.
3. Debakey M. Gooto A. The Living Heart. 1977, pp. 144-153
4. A Foster JH et al, Arterial Injuries Secondary to Use of the Fogarty Catheter Arr Surgery, 171: 971-978, 1970.
5. Ochlert WH. A Complication of the Fogarty Arterial Embolectomy Catheter AM Heart J, 84:484-486, 1972.
6. Pruitt JC. 1009 Consecutive Carotid Endarterectornies Local Anesthesia, EEG, and Selective Shunting with Pruitt-Inahara Carotid Shunt Contemporary Surgery, Vol. 23, Sept 1983.
7. Pruitt JC, Morales RE. Carotid Endarterectomy: A Report of 7,854 Procedures Using Local Anesthesia, Electroencephalographic Monitoring, Occlusion Catheters and the Pruitt-Inahara Carotid Shunt Surgical Technology International IV, 1995.

8. Symbols

Symbol Legend

English	Symbol Legend	Distributed By	Outer Diameter	Usable Length	Syringe included	UK Responsible Person	
Deutsch	Symbol-Legende	Vertrieb	Außendurchmesser	Nutzbare Länge	Spritze im Lieferumfang enthalten	Verantwortliche Person im Vereinigten Königreich	S V
Français	Légende des symboles	Distribué par	Diamètre externe	Longueur utile	Seringue inclue	Personne responsable au Royaume-Uni	R S
Italiano	Legenda	Distribuito da	Diametro esterno	Lunghezza utile	Siringa inclusa	Persona responsabile nel Regno Unito	ra sv
Español	Leyenda	Distribuido por	Diámetro externo	Longitud utilizable	Jeringa incluida	Responsable del Reino Unido	R su
Português	Legenda dos símbolos	Distribuído por	Diâmetro externo	Comprimento Utilizável	Seringa incluída	Pessoa responsável no Reino Unido	re su

English	Symbol Legend	Distributed By	Outer Diameter	Usable Length	Syringe included	UK Responsible Person	
Dansk	Symbolforklaring	Distribuert af	Udvendig diameter	Anvendelig længde	Medfølgende sprøjte	Ansvarlig person i Storbritannien	s re
Svenska	Symbolförklaringar	Distribueras av	Ytterdiameter	Arbetslängd	Spruta medföljer	Ansvarig person i Storbritannien	s re
Nederlands	Legenda	Distributeur	Buitendiameter	Bruikbare lengte	Spuit meegeleverd	Verantwoordelijke persoon voor het VK	Z ve
Ελληνικά	Υπόμνημα συμβόλων	Διανέμεται από	Εξωτερική Διάμετρος	Χρησιμοποιήσιμο Μήκος	Περιλαμβάνεται σύριγγα	Υπεύθυνος στο Ηνωμένο Βασίλειο	Α τη
Suomi	Symbolin kuvateksti	Jakelija	Ulkohalkaisija	Käyttöpituus	Ruisku sisältyy pakkaukseen	Vastuuhenkilö Isossa-Britanniassa	S
Türkçe	Sembol Açıklaması	Dağıtıcı	Dış Çap	Kullanılabilir Uzunluk	Şırınga dahil	Birleşik Krallık'ta Sorumlu Kişi	İs
norsk	Symbolforklaring	Distribuert av	Ytre diameter	Brukbar lengde	Sprøyte inkludert	Ansvarlig person i Storbritannia	S re
Česky	Vysvětlivky symbolů	Distributor	Vnější průměr	Použitelná délka	Včetně stříkačky	Odpovědná osoba v České republice	Š za
slovenčina	Opis symbolov	Distribútor	Vonkajší priemer	Použiteľná dĺžka	Striekačka je súčasťou balenia	Zodpovedná osoba vo Veľkej Británii	Z Š
Magyar	Szimbólumok jelentése	Forgalmazó:	Külső átmérő	Hasznos hossz	Fecskendőt tartalmaz	A Nagy-Britanniában felelős személy	S
Polski	Legenda symboli	Dystrybutor	Średnica zewnętrzna	Długość użytkowa	Dołączona strzykawka	Osoba odpowiedzialna w Wielkiej Brytanii	P S
eesti	Sümbolite selgitus	Turustaja	Välisläbimõõt	Kasutatav pikkus	Komplektis on süstal	Vastutav isik Ühendkuningriigis	Es
latviešu valodā	Simbolu skaidrojums	Izplatītājs	Ārējais diametrs	Izmantojamais garums	Komplektā iekļautā šļirce	Atbildīgā persona Apvienotajā Karalistē	P
lietuvių k.	Simbolių paaiškinimas	Platintojas	Išorinis skersmuo	Naudojamas ilgis	Pridedamas švirkštas	JK atsakingas asmuo	A Š
română	Legenda simbolurilor utilizate	Distribuită de	Diametru exterior	Lungimea utilizabilă	Seringa inclusă	Persoana responsabilă din Regatul Unit	R el
srpski	Legenda simbola	Distributer	Spoljni prečnik	Upotrebljiva dužina	Špric uključen	Odgovorno lice u Ujedinjenom Kraljevstvu	P Š
Български	Легенда на символите	Разпространявано от	Външен диаметър	Използваема дължина	Включена спринцовка	Отговорно лице в Обединеното кралство	П Ш