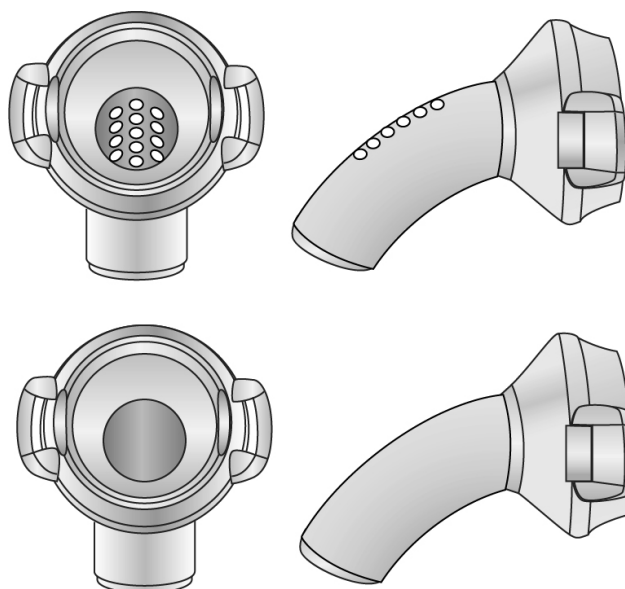


# INHEALTH

## TECHNOLOGIES®

### Blom-Singer® StomaSoft™ Laryngectomy Tube



#### USER Instructions for Use

Udhëzime përdorimi për PËRDORUESIN / تعليمات المستخدم الخاصة بالاستخدام / Инструкции за употреба за ПОТРЕБИТЕЛЯ / UPUTE za korištenje / Návod k použití pro UŽIVATELE / BRUGER brugsanvisning / Gebruiksaanwijzing voor de GEBRUIKER / KASUTAJA kasutusjuhend / KÄYTTÄJÄN käyttöohjeet / Instructions d'utilisation destinées à l'UTILISATEUR / Gebrauchsanweisung für BENUTZER / ΧΡΗΣΤΗΣ, οδηγίες χρήσης / הוראות שימוש למשתמש / HASZNÁLATI utasítás / Leiðbeiningar fyrir NOTENDUR / Istruzioni per l'uso destinate all'UTENTE / 사용자 사용 지침 / Lietošanas instrukcijas LIETOTĀJAM / Naudojimo instrukcija NAUDOTOJUI / BRUKER Bruksanvisning / Instrukcja użytkowania dla UŻYTKOWNIKA / Instruções de uso para o USUÁRIO / Instruções de utilização para o UTILIZADOR / Instrucțiuni de utilizare pentru UTILIZATOR / ПОЛЬЗОВАТЕЛЬСКИЕ инструкции по применению / Uputstvo za upotrebu za KORISNIKA / Návod na použitie pre POUŽÍVATEĽA / Instrucciones para el USUARIO / ANVÄNDARE, bruksanvisning / KULLANICI Kullanım Talimatları

**Blom-Singer®**

voice restoration systems

37889-01A Effective October 2018 / Në fuqi nga tetori 2018 / 2018 ييسري هذا اعتبارًا من أكتوبر / В сила от октомври 2018 г. / Stupa na snagu u listopadu 2018. / V platnosti od října 2018 / Træder i kraft oktober 2018 / Met ingang van oktober 2018 / Jõustus 2018. aasta oktoobrikuus / Voimassa lokakuusta 2018 alkaen / Date d'entrée en vigueur : octobre 2018 / Gültig ab Oktober 2018 / Με ισχύ από τον Οκτώβριο του 2018 / 2018 בתוקף מאוקטובר. / Érvényes: 2018 októberétől / Gilda frá október 2018 / Valido da ottobre 2018 / 2018년 10월 발효 / Spēkā no 2018. gada oktobra / Įsigalioja 2018 m. spalio mėn. / Gjelder fra oktober 2018 / Wchodzi w życie w październiku 2018 r. / Em vigor a partir de outubro de 2018 / Válido a partir de outubro de 2018 / Cu intrare în vigoare din octombrie 2018 / Вступает в силу с октября 2018 г. / Stupa na snagu u oktobru 2018. / Platný od októbra 2018 / Efectivo a partir de octubre de 2018 / Gäller från oktober 2018 / Ekim 2018'de Yürürlüğe Girdi

**Blom-Singer®** and **InHealth Technologies®** are registered trademarks of **Freudenberg Medical, LLC**.

Copyright © 2018 Freudenberg Medical, LLC. All rights reserved.

## TABLE OF CONTENTS

Tabela e përmbajtjes / جدول المحتويات / Съдържание / Sadržaj / Obsah / Indholdsfortegnelse / Inhoud / Sisukord / Sisällysluettelo / Sommaire / Inhaltsverzeichnis / Πίνακας περιεχομένων / תוכן עניינים / Tartalomjegyzék / Efnisyfirlit / Sommario / 목차 / Saturs / Turinys / Innholdsfortegnelse / Spis treści / Índice / Índice / Cuprins / Содержание / Sadržaj / Obsah / Índice / Innehållsförteckning / İçindekiler

<b>ENG</b>	Laryngectomy Tube	4	<b>ITA</b>	Tubo per laringectomia	52
<b>SQI</b>	Tubi i laringektomisë	7	<b>KOR</b>	후두절개술 튜브	55
10	الأنبوب المخصص لحالات استئصال الحنجرة	<b>ARA</b>	<b>LAV</b>	Laringektomijas caurulīte	58
<b>BUL</b>	Тръба за ларингектомия	13	<b>LIT</b>	Laringektomijos vamzdelis	61
<b>HRV</b>	Cijev za laringektomiju	16	<b>NOR</b>	Laryngektomislange	64
<b>CZE</b>	Kanyla pro laryngektomii	19	<b>POL</b>	Rurka laryngektomijna	67
<b>DAN</b>	Laryngektomitube	22	<b>PTB</b>	Tubo de laringectomia	70
<b>NLD</b>	Laryngectomiecanule	25	<b>PTE</b>	Tubo de laringectomia	73
<b>EST</b>	Larüngotoomiatoru	28	<b>RON</b>	Tub pentru laringectomie	76
<b>FIN</b>	Laryngektomiaputki	31	<b>RUS</b>	Ларингэктомическая канюля	79
<b>FRA</b>	Tube de laryngectomie	34	<b>SRP</b>	Tubus za laringektomiju	82
<b>DEU</b>	Laryngektomietubus	37	<b>SLK</b>	Laryngektomická trubica	85
<b>ELL</b>	Σωλήνας λαρυγγεκτομής	40	<b>SPA</b>	Tubo de laringectomía	88
43	צינורית לרינגקטומיה	<b>HEB</b>	<b>SWE</b>	Laryngektomikanyl	91
<b>HUN</b>	Laringektómiás tubus	46	<b>TUR</b>	Larenjektomi Tüpü	94
<b>ISL</b>	Barkakýlisnámsslanga	49			

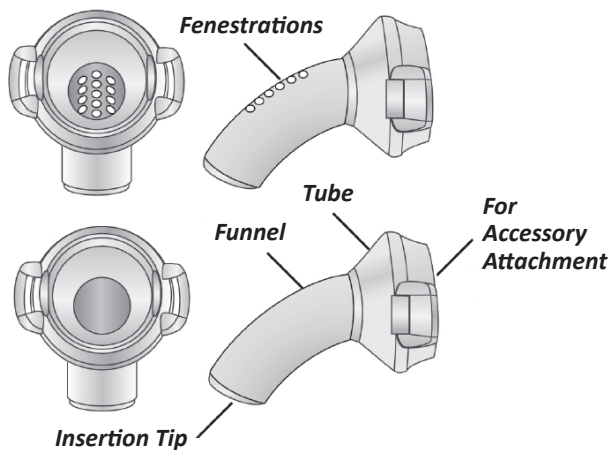
## ENGLISH

### DEVICE DESCRIPTION

The Laryngectomy Tube (Tube) is a flexible silicone tube that is available in many sizes. It comes in both fenestrated and non-fenestrated models.

### INDICATIONS FOR USE

The Tube is designed for use by a single patient to maintain tracheostoma patency after laryngectomy and allow attachment of stoma accessories.



### CONTRAINDICATIONS

The Tube should only be used by people that have been trained on its use. It is not meant for use in radiation therapy. The Tube should not be used when experiencing inflammation, infection, bleeding, discharge, or coughing. The Tube is not meant for use with mechanical ventilators.

### CAUTIONS

**R**Only CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

### PRECAUTIONS



Wash hands with soap and water prior to handling the Tube.

Only use a lint-free cloth or tissue to dry the Tube to avoid getting lint into the airway.

Do not use solvent or petroleum-based products for cleaning or lubricating the Tube. These materials may damage the Tube.

Only Blom-Singer® stoma accessories can be used with the Tube. Use of other accessories may result in complications.

### WARNINGS



Never insert any cleaning device into the laryngectomy tube while the tube is positioned in the neck. Always clean the device after it has been removed.

The Tube is for single patient use only and must not be shared between patients. Infection can occur with shared use which could lead to illness or serious injury.

Inspect the Tube before each use for physical damage, such as cracks or tears, and do not use if damaged. If physical damage is found, contact InHealth Technologies Product Complaints.

Modifications should not be attempted to the Tube.

### POTENTIAL COMPLICATIONS

Complications that require potential removal of the Tube, cleaning, and/or medical treatment include but are not limited to: stoma contamination/infection, accidental inhalation of an inappropriately sized Tube into the airway, structural failure from excessive usage and/or cleaning, and obstruction of the Tube by mucus.

## INSTRUCTIONS FOR USE

Please refer to the diagrams at the back of this instruction manual.

### How to Insert the Laryngectomy Tube

1. Inspect the Tube before each use for physical damage, such as cracks or tears. Do not use if damaged.
2. Wash hands with soap and water.
3. Stand in front of a mirror with a bright light shining directly on the stoma. See **Diagram 1**.
4. Apply a small amount of medical grade, water-soluble lubricant to the rim of the stoma to help with insertion. See **Diagram 2**.
5. In some cases, it may be necessary to slightly fold or compress the insertion tip of the Tube to conform to the contour of the trachea. See **Diagram 3**.
6. Insert the insertion tip of the Tube to the lower rim of the stoma and insert completely into the stoma until its larger funnel shaped end rests against the stoma. See **Diagram 4**.

### How to Remove the Laryngectomy Tube

1. Wash hands with soap and water.
2. Stand in front of a mirror with bright light shining directly on the Tube in the stoma. See **Diagram 5**.
3. If using a tube holder, untie or cut the holder straps. See **Diagram 6**.
4. Remove the Tube from the stoma. See **Diagram 7**.

### How to Attach Optional Laryngectomy Tube Holder (sold separately)

1. Secure the Tube around the neck by inserting the straps into the openings in the side of the Tube such that the tabs on the straps point away from the Tube.
2. Pass the straps around the back of the neck and tie to secure. The straps should be loose enough to permit one finger width between the backside of the straps and the surface of the neck. After adjusting the straps to a comfortable tension, the excess strap may be removed. See **Diagram 8**.

### How to Attach or Remove an Accessory Device

1. To insert an accessory device, grasp the top of the accessory device and press onto the top of the Tube until fully seated. See **Diagram 9**.
2. To remove an accessory device, hold the top of the Tube and grasp the exposed portion of the accessory device. Starting at one end, pull until free of the Tube. See **Diagram 10**.

### How to Clean and Disinfect the Laryngectomy Tube

1. Rinse the Tube under warm running tap water. See **Diagram 11**.
2. Soak the Tube in hot water (122-140°F / 50-60°C) containing at least two drops of dish soap per 8 oz. (235mL) of water for at least 15 minutes. See **Diagram 12**.
3. Remove the Tube from the soap and water solution and rinse under warm running tap water. Gently clean the inside and outside of the Tube with a cleaning foam swab available from InHealth Technologies. Do not use cotton swabs to clean the Tube as fibers may be left behind. See **Diagram 13**.
4. If the Tube is fenestrated, clean the fenestrations in a similar manner using the Blom-Singer Cleaning Brush. See **Diagram 14**.
5. Disinfect the Tube by soaking in a 3% hydrogen peroxide solution overnight. See **Diagram 15**.
6. Rinse thoroughly under running tap water and air dry. See **Diagram 16**.

## DISPOSAL INSTRUCTIONS

The Tube is not biodegradable and can be contaminated when used. Carefully dispose of the Tube per local guidelines.

## ORDERING INFORMATION

Online Ordering **www.inhealth.com**  
 USA InHealth Technologies  
 1110 Mark Avenue  
 Carpinteria, CA 93013-2918  
 Customer Service: +1-800-477-5969  
 Fax: +1-888-371-1530  
**Email: order@inhealth.com**












International Contact InHealth Technologies Customer Service at +1-805-684-9337 for local distributor contact.

## PRODUCT COMPLAINTS

If you are dissatisfied with the Blom-Singer® StomaSoft™ Laryngectomy Tube or have any questions, please contact **productcomplaints@inhealth.com**.

Telephone: +1-800-477-5969  
 Fax: +1-888-371-1530

## SYMBOL GLOSSARY

SYMBOL	SYMBOL DEFINITION	SYMBOL	SYMBOL DEFINITION
	Manufacturer		Caution: Read all warnings and precautions in the instructions for use.
	CE Marking		Caution: Federal law restricts this device to sale by or on the order of a physician (USA).
	Authorized representative in the European community		Do not use if package is damaged.
	Catalog number		Contents (number sign # represents number of units inside)
	Batch code		Consult Instructions for Use
	Use-by date		

## SİPARİŞ BİLGİLERİ

Online Sipariş [www.inhealth.com](http://www.inhealth.com)

ABD  
InHealth Technologies  
1110 Mark Avenue  
Carpinteria, CA 93013-2918

Müşteri Hizmetleri: +1-800-477-5969

Faks: +1-888-371-1530

E-posta: [order@inhealth.com](mailto:order@inhealth.com)

Uluslararası Yerel distribütör iletişimi için +1-805-684-9337 numaralı telefondan  
InHealth Technologies Müşteri Hizmetleri ile iletişime geçin.

## ÜRÜN ŞİKAYETLERİ

Blom-Singer® StomaSoft™ Larenjektomi tüpünden memnun değilseniz veya sorularınız varsa lütfen [productcomplaints@inhealth.com](mailto:productcomplaints@inhealth.com) üzerinden irtibata geçin.

Telefon: +1-800-477-5969

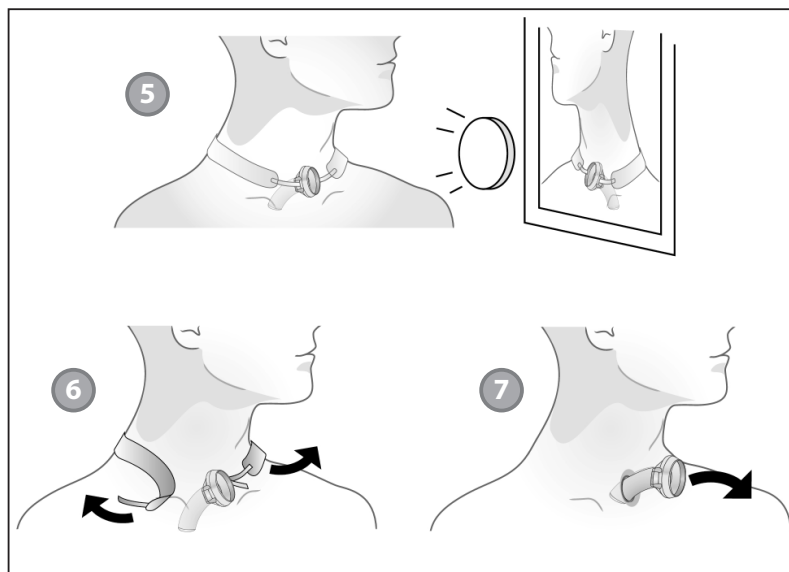
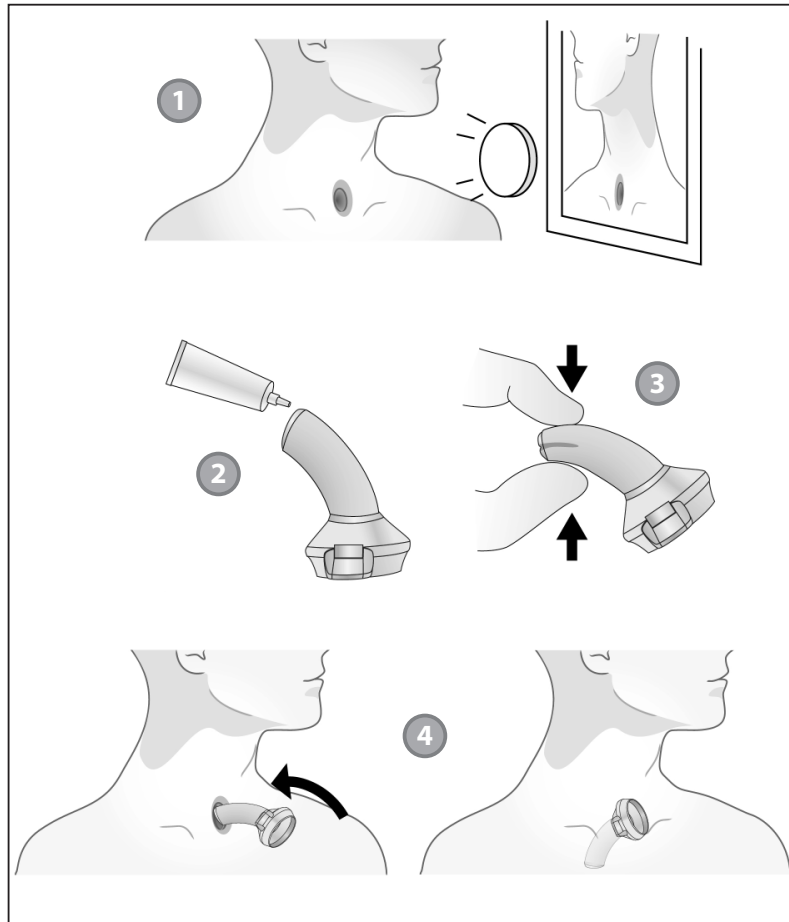
Faks: +1-888-371-1530

## SEMBOL SÖZLÜĞÜ

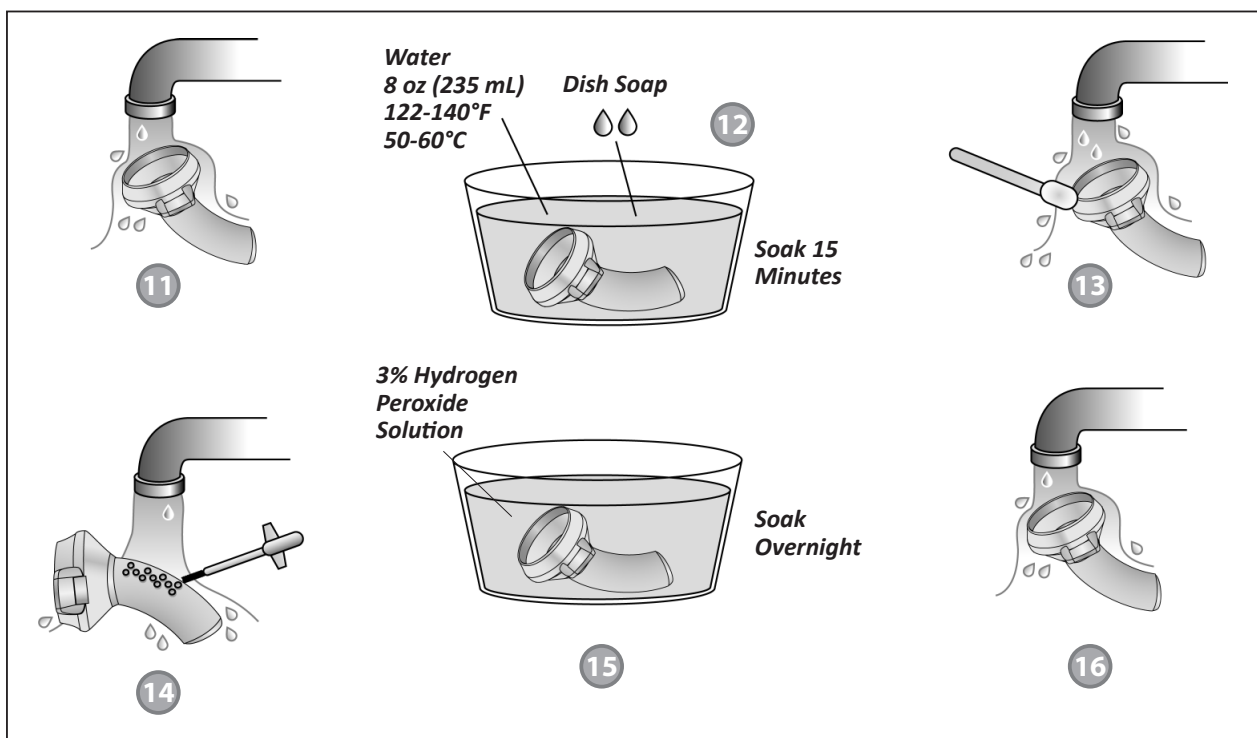
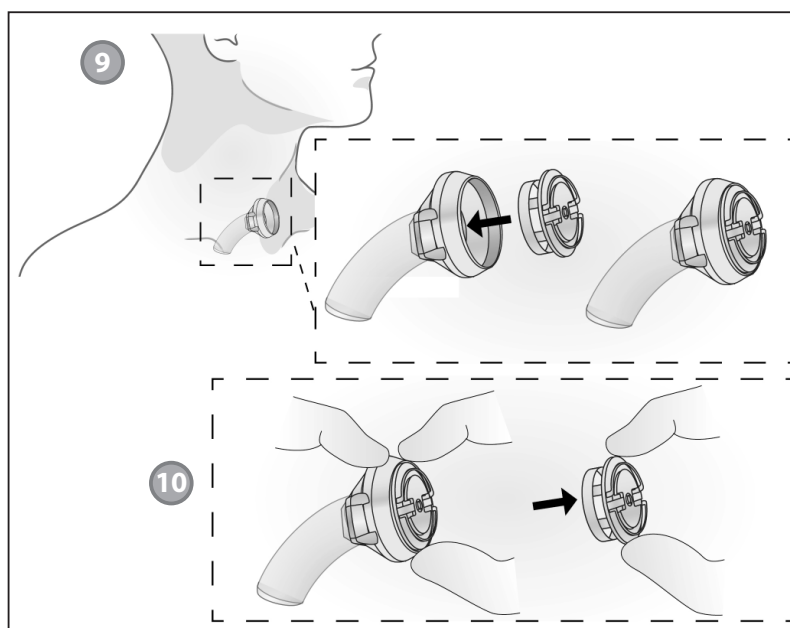
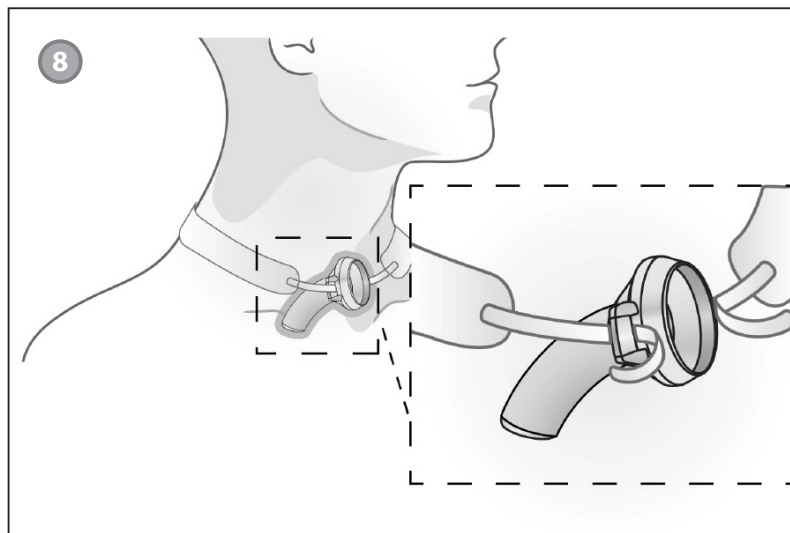
SEMBOL	SEMBOL AÇIKLAMASI	SEMBOL	SEMBOL AÇIKLAMASI
	Üretici		Dikkat: Kullanım talimatlarındaki tüm uyarı ve önlemleri okuyun.
	CE İşareti		Dikkat: Federal kanun uyarınca bu cihaz yalnızca hekim tarafından veya hekim talimatıyla satılabilir (ABD).
	Avrupa topluluğu yetkili temsilcisi		Ambalaj zarar görmüş ise kullanmayın.
	Katalog numarası		İçindekiler (# numara simgesi, içindeki birim sayısını gösterir)
	Parti kodu		Kullanım Talimatlarına bakın
	Son kullanma tarihi		

**DIAGRAMS**

Diagramet / الرسوم التوضيحية / Схеми / Dijagrami / Schémata / Diagrammer / Afbeeldingen / Diagrammid / Kaaviot / Diagrammes / Abbildungen / Διαγράμματα / תרשימים / Ábrák / Skýringarmyndir / Diagrammi / 그림 / Diagrammas / Diagramos / Diagrammer / Schematy / Diagramas / Diagramas / Diagrame / Схемы / Crteži / Grafické znázornenia / Diagramas / Diagram / Diyagramlar







# INHEALTH

## TECHNOLOGIES®

---

### UNITED STATES

1110 Mark Avenue  
Carpinteria, CA 93013-2918 USA  
Toll-Free: 800.477.5969  
Toll-Free Fax: 888.371.1530

### INTERNATIONAL

Tel: +1.805.684.9337  
Fax: +1.805.684.8594  
E-mail: [order@inhealth.com](mailto:order@inhealth.com)

### ORDER ONLINE

[www.inhealth.com](http://www.inhealth.com)



**Freudenberg Medical, LLC**  
1110 Mark Avenue  
Carpinteria, CA 93013-2918  
USA  
[www.inhealth.com](http://www.inhealth.com)



**EMERGO EUROPE**  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands