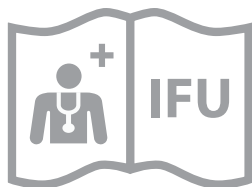


PROVOX Dilator



Rx ONLY

MD



Provox Dilator REF 8341

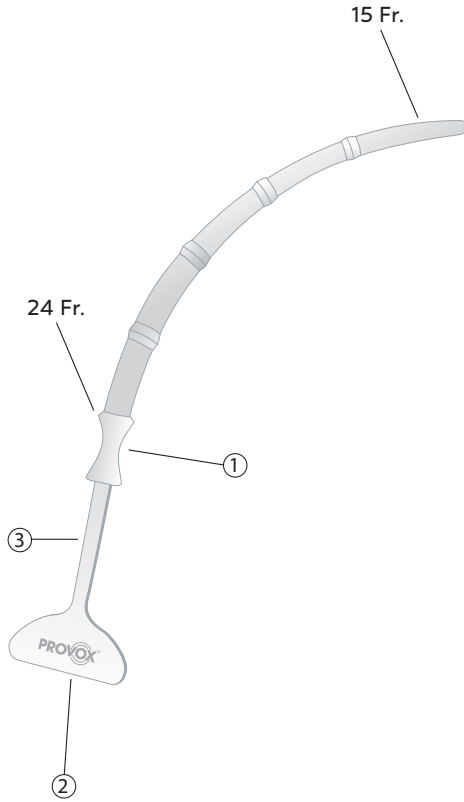


Figure 1

Prescription Information

CAUTION: United States Federal law restricts this device to sale, distribution, and use by or on order of a physician or a licensed practitioner. The availability of this product without prescription outside the United States may vary from country to country.

Disclaimer

Atos Medical offers no warranty—neither expressed nor implied—to the purchaser hereunder as to the lifetime of the product delivered, which may vary with individual use and biological conditions. Furthermore, Atos Medical offers no warranty of merchantability or fitness of the product for any particular purpose.

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1. Intended Use

The Provox Dilator is intended to dilate or stent the tracheoesophageal puncture in laryngectomized patients.

Intended User Group

Provox Dilator is intended for use in a clinical setting, by healthcare professionals trained in rehabilitation of laryngectomized patients, in adult (18+ years) laryngectomized patients who use a voice prosthesis.

2. Contraindications

The device is not intended to be used for puncture dilation at the time of surgical creation of the puncture.

3. Description of the Device

Provox Dilator is a single-use, disposable device used for dilating or stenting a tracheoesophageal (TE) puncture. Provox Dilator is a stepwise tapered, about 140 mm (5.5 in.) long solid curved rod made of medical grade silicone. The diameter is 15 Fr at the tip and increases to 24 Fr. At the end of each diameter step, i.e. 18, 20, and 22 Fr respectively, a small retention collar is present that is designed to prevent the dilator from sliding back to a thinner section. The dilator has a safety strap with medallion that can be taped to the neck to keep the dilator in place and is designed to reduce the risk of accidental aspiration of the device.

For dilating the TE puncture, the tip of the dilator is inserted into the open TE puncture and slowly progressed forward and down into the esophagus, until the desired diameter of the TE puncture is reached. The gradual increase in the diameter of the device gradually dilates the TE puncture to facilitate the subsequent insertion of the voice prosthesis.

For stenting the TE puncture, the tip of the dilator is inserted into the open TE puncture and slowly progressed forward and down into the esophagus, until it reaches the desired diameter for blocking the TE puncture. The presence of the dilator keeps the TE puncture open and prevents esophageal contents from entering the trachea.

Information

The products are intended to be stored in the box until removed for use, as the box protects the products and the label on the box contains important information like batch code, use-by date, and a unique barcode.

4. Warnings

- Do not reuse Provox Dilator in another patient. Reuse in another patient may cause cross-contamination which may lead to serious infection.
- Do not use the device if it shows any sign of structural damage.
- Allergic reactions against the lubricant/anaesthetic gel may occur. Read the instructions for use accompanying the lubricant. Always ask the patient about allergic history.

5. Precautions

- Do not use any kind of oil or ointment for product care or during the procedure. Oil based lubricants (e.g. Vaseline) may weaken, damage, or destroy the device or may enter your trachea and lungs, which can result in severe coughing and/or lipoid pneumonia.
- Patients on anticoagulant therapy or with bleeding disorders should be carefully evaluated for the risk of hemorrhage prior to dilation of the TE puncture.
- Make sure that the position chosen on the dilator is adequate for the TE puncture. Over-dilatation may result in leakage around the voice prosthesis.
- Never use excessive force to insert or remove the dilator from the TE puncture, as this may cause bleeding or a false route.
- Do not use a contaminated dilator. Contaminated dilators may cause infection and inflammation.
- It is advisable to lubricate the dilator. Use only water-soluble lubricants in an appropriate amount.
- Do not use the dilator for too long a period of time as this may damage the esophagus wall.
- Never remove the medallion from the device. The medallion is of the utmost importance for safety. It helps to reduce the risk of the device accidentally falling into the trachea.
- Do not reuse and do not reprocess the device by any method. Intended for single use only. Reuse may cause contamination and/or damage to the device.
- Carefully assess the suitability of the device for patients with small tracheostomas. The device takes up space in the tracheostoma and may affect the patient's ability to breathe.

- Bleeding from the TE puncture during insertion may occur. The risk of bleeding can be reduced by inserting the dilator gently and slowly. Allow sufficient time for each section to dilate the TE puncture and do not force the dilator through the TE puncture to move to the next section.

Side-Effects

Possible side-effects of using Provox Dilator are coughing, gagging, and discomfort when the device is inserted, in situ, and/or removed from the TE puncture. Minor bleeding may occur due to the dilatation of the tissues of the TE puncture. Users with smaller sized tracheostomas may temporarily experience increased breathing resistance when the device is in situ as it occupies space within the tracheostoma. Users may also experience irritation and/or discomfort from the safety strap and medallion.

6. How to Use

6.1 Preparation

Always handle the dilator with clean gloves and avoid touching parts of it that will enter the TE puncture. Check the integrity of the safety strap (see Figure 1:3) by holding the device handle (see Figure 1:1) and slightly pulling the medallion (see Figure 1:2). Discard the device if it shows any signs of damage.

Prior to use, it is advisable to lubricate the dilator with some water-soluble lubricant/anaesthetic gel. To lubricate the dilator, put a small amount of gel on a clean surface (e.g. a gauze) and slide the tip of the dilator through the gel so that the tip is covered with a thin layer of gel.

Recommended Water-Soluble Lubricants

K-Y Jelly
Surgilube
Xylocaine (Lidocaine) Jelly*

*Local anesthetic.

6.2 Operating Instructions

To dilate

1. Remove the voice prosthesis from the TE puncture.
2. To dilate the TE puncture, probe the TE puncture with the tapered tip of the dilator, its curvatures directed downwards, and gently insert the device until a slight resistance from the TE puncture can be felt.
3. Hold the dilator in this position for the desired amount of time and then slowly and gently continue progressing, section by section, until the desired TE puncture diameter has been reached. The waiting time needed for each section can vary from case to case. Carefully tape the medallion to the skin during the waiting time.
4. Once the dilator has been in the final position for the desired amount of time, gently pull the rod—not the medallion—for removal and insert the Provox voice prosthesis using its standard procedure.

To stent

1. Remove the voice prosthesis from the TE puncture.
2. To stent the TE puncture, probe the TE puncture with the tapered tip of the dilator, its curvature directed downwards, and gently insert the device until it reaches the desired diameter for stenting the TE puncture. The presence of the dilator keeps the TE puncture open and prevents esophageal contents from entering the trachea.
3. Carefully tape the medallion to the skin whilst the device is in situ.
4. Once the dilator has been in position for the desired amount of time, gently pull the rod—not the medallion—for removal and insert the Provox voice prosthesis using its standard procedure.

7. How Supplied

The device is manufactured in a cleanroom and supplied non-sterile.

8. Device Lifetime and Disposal

Provox Dilator is a single-use device and shall be discarded after each use.

Always follow medical practice and national requirements regarding biohazards when disposing of a used medical device.

9. Reporting

Please note that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the national authority of the country in which the user and/or patient resides.



Do not re-use; Nur zum Einmalgebrauch; Niet hergebruiken; Ne pas réutiliser; No riutilizar; No reutilizar; Não reutilizar; Áternavánd ej; Má ikke genanvendes; Skal ikke gjenbrukes; Ei uudelleenkäytettävä; Má ekki endurnýta; Mitte taaskasutada; Neizmantot atkārtoti; Pakartotinaī nenaudoti; Nepouzívejte opakovaně; Ne használja fel újra; Nepoužívejte opakovane; Ne uporabljajte ponovno; Nie używać ponownie; A nu se reutiliza; Nemojte ponovno upotrebljavati; Ne koristiti ponovo; Μην επαναχρησιμοποιείτε; He izpolzujte povtorno; Tekrar kullannamayni; არ გამოყენებთ ხელახლა; Մեկանգամյա օգտագործման համար; Yeniden istifade etmeyin; He podlezhit povtornomu ispolzovaniyu; Jangan gunakan ulang; Jangan guna semula; 再利用不可; 재사용하지 마십시오; 請勿重複使用; 请勿重复使用;

يجب عدم إعادة الاستخدام; אינו מיועד לשימוש חוזר



Non-sterile; Unsteril; Niet steriel; Non stérile; Non sterile; No estéril; Não estéril; Osteril; Ikke-steril; Usteril; Steriloomaton; Osæft; Mittesterilne; Nesterils; Nesterilu; Nesterilni; Nem steril; Nesterilné; Nesterilno; Produktnejalowy; Produs nesteril; Nesterilino; Nijeststerilno; Μη αποστειρωμένο; Нестерильно; Steril degildir; არასტერილური; Աստերիլ; Qeyri-steril; Нестерильно; Tidak steril; Tidaksteril; 非滅菌; 무균 아님; 未滅菌; 非无菌;

غير معقم; לא מעוקר



Keep away from sunlight and keep dry; Vor Sonnenlicht und Feuchtigkeit schützen; Niet blootstellen aan zonlicht, droog bewaren; Maintenir à l'abri de la lumière directe du soleil et de l'humidité; Tenere all'asciutto e al riparo dalla luce del sole; Mantener seco y alejado de la luz solar; Manter afastado da luz solar e da chuva; Håll borta från solljus och håll torr; Holdes bort fra sollys og holdes tør; Unngå direkte sollys, holdes tørt; Säilytetävä kuivassa paikassa suojassa auringonvalolta; Geymið fjarri sólarljósi og haldið þurru; Hoida kuivas ja eemal päikesevalgusest; Sargāt no saules stariem un mitruma; Saugoti nuo saulės šviesos ir laikyti sausai; Chraňte před slunečním zářením a udržujte v suchu; Tartsa a napfénytől távol, és tartsa szárazon; Chráňte pred slnečným žiarením a uchovávaťe v suchu; Shranjujte na suhem in ne izpostavljajte sončni svetlobi; Chronić przed światłem słonecznym i przechowywać w suchym miejscu; A se feri de lumina soarelui și a se menține uscat; Cuvajte na suhom mjestu i podalje od Sunčeve svjetlosti; Držati dalje od sunčeve svetlosti i čuvati na suvom; Φυλάσσετε μακριά από το ηλιακό φως και διατηρείτε τη συσκευή στεγνή; Держте далече от слнчева светлина и съхранявайте на сухо място; Güneş ışığından uzakta ve kuru tutun; შეინახეთ მზისგან დაცულ ადგილას და მშრალ მდგომარეობაში; Հնուս պահեք արևի ճառագայթներից և պահեք չոր տևողում; Gün ışığından uzakda ve quru saxlayın; Бергите от воздействия прямых солнечных лучей и влаги; Hindarkan dari sinar matahari dan simpan di tempat yang kering; Jauhkan dari cahaya matahari dan pastikan sentiasa kering; 直射日光および湿気禁止; 직사광선이 닿지 않게 하고 건조한 상태로 유지하십시오; 避免日照並保持乾燥; 避免日照和保持干燥;

يجب الحفاظ على المنتج جافاً وبعيداً عن أشعة الشمس; יש להרחיק מאור השמש ולאחסן במקום יבש



Caution, consult instructions for use; Vorsicht, Gebrauchsanweisung beachten; Let op: Raadpleeg de gebruiksaanwijzingen; Mise en garde, consulter le mode d'emploi; Attenzione, consultare le istruzioni per l'uso; Precaución, consultar instrucciones de uso; Cuidado, consultar as instruções de utilização; Varning, läs instruktion; Forsiktig, se brugsanvisning; Forsiktig, se bruksanvisningen; Varoitus, katso käyttöohjeet; Varűd, lesiűd notkunarleiűbeinngarmar; Ettevaatust, tutvuge kasutusjuhendiga; Uzmanību! Izlasiet lietošanas norādījumus; Dmesio, skaityti naudojimo instrukcija; Upozornění, viz návod k použití; Figyelem, tájékozdójon a használati útmutatóból; Pozor, riadte za návodom na použitie; Pozor; glejte navodila za uporabo; Uwaga, należy zapoznać się z instrukcją obsługi; Atentie! Consultați instrucțiunile de utilizare; Pozor: proučite upute za upotrebu; Oprez, konsultovati uputstvo za upotrebu; Προσοχή, συμβουλευτείτε τις οδηγίες χρήσης; Внимание, консултирайте се с инструкциите за употреба; Dikkat, kullannadan önce talimatları inceleyin; გაფრთხილებდა, მოთხოვრეთ გამოყენების ინსტრუქციას; Оւշադրութիւն, հետևեք օգտագործման հրահանգներին; Хəbərdarlıq, istifadə qaydalarını oxuyun; Предостережение, обратитесь к инструкциям по применению; Perhatian, baca petunjuk penggunaan; Berhati-hati, rujuk arahan penggunaan; 注意,取扱説明書を参照; 주의, 사용 지침을 참조하십시오; 注意事項, 參閱使用說明; 小心, 參閱使用说明书;

تنبیه، راجع تعليمات الاستخدام; זהירות, יש לעיין בהוראות השימוש

Rx ONLY

Prescription;

MD

Medical Device; Medizinprodukt; Medisch hulpmiddel; Dispositif médical; Dispositivo medico; Productio sanitario; Dispositivo médico; Mediceitknisk produkt; Medicinsk udstyr; Medicinsk udstyr; Lääkinällinen laite; Läkningateki; Meditsiiniseade; Mediciniska ierçe; Medicinos priemonė; Zdravotnický prostředek; Orvostechnikai eszköz; Zdravotnicka pomůcka; Medicinski pripomoček; Wyród medyczny; Dispozitiv medical; Medicinski proizvod; Медицинско средство; Ιατροτεχνολογικό προϊόν; Медицинскоизделие; Tibbi cihaz; სამედიცინო მოწყობილობა; Tibbi Avadanlıq; Медицинское изделие; Peralatan Medis; Peranti Perubatan; 医療機器; 의료 장치; 醫療裝置; 医疗器械;

جهاز طبي; התקן רפואי



Instructions for use intended for clinician; Gebrauchsanweisung für Ärzte; Gebruiksaanwijzing voor de arts; Mode d'emploi destiné au praticien; Istruzioni per l'uso previsto per il medico; Instrucciones de uso destinadas al médico; Instruções de utilização destinadas a profissionais de saúde; Bruksanvisning avsedd för läkaren; Brugsanvisning tiltenkt kliniker; Bruksanvisning beregnet på lege; Lääkärille tarkoitettu käyttöohjeet; Notkunarleiðbeiningar fyrir lækni; Kasutusjuhend meditsiinitõõtjale; Årstem paredzēti lietošanas norādījumi; Gedytojui skirta naudojimo instrukcija; Návod k použití určený pro klinického lékaře; Használati útmutató az orvosnak; Návod na použitie určený pre lekára; Navodila za uporabo, namenjena zdravstvenemu delavcu; Instrukcija użycia przeznaczona dla lekarza; Instrucţiuni de utilizare destinate medicului; Upute za upotrebu namijenjene kliničkim djelatnicima; Uputstvo za upotrebu namenjeno lekaru; Οδηγίες χρήσης για τον ιατρό; Инструкции за употреба, предназначени за лекаря; Klinisyen için kullanılm talimatları; Գծրայցեցեթոն օննժրայլցիցեթո ղյօթօնտցեթո; Oqumաqrնման հրահանգներ նախատեսված բժշկի համար; Həkim üçün nəzərdə tutulmuş istifadə qaydaları; Инструкции по применению предназначены для врача; Petunjuk penggunaan khusus untuk tenaga medis; Arahan penggunaan untuk klinisian; 醫師用的取扱説明書; 의사 사용 지침; 臨床醫生專用使用說明; 适用于临床医生的使用说明书;

تعليمات الاستخدام المخصصة للطبيب הוראות שימוש לרופא



Triman symbol and Infotri for France; Triman-Logo und Infotri für Frankreich; Triman- en Info-tri-symbool voor Frankrijk; Signalétique Triman et info-tri pour la France; Logo Triman e Infotri per la Francia; Símbolo Triman e Infotri para Francia; Símbolo Triman e Infotri para a França; Triman-symbol och Infotri for Frankrike; Triman-symbol og Infotri for Frankrig; Triman-symbol og Info-Tri for Frankrike; Triman-symbolji ja Infotri-ohjeet Ranskaa varten; Triman tákn og Infotri fyrir Frakkland; Trimani símbol ja Infotri Prantsusmaal; Triman simbols un Infotri Francijai; Prancūzijai skirtas „Triman“ simbolis ir „Infotri“; Symbol Triman a Infotri pro Francii; Triman szimbólum és Infotri Franciaország esetében; Symbol Triman a Infotri pre Francúzsko; Symbol Triman in Infotri za Francijo; Symbol Triman i Infotri dla Francji; Simbolul Triman și Infotri pentru Franța; Simbol Triman i oznaka Infotri za Francusku; Símboli Triman i Infotri za Francusku; Σύμβολο Triman και Infotri για τη Γαλλία; Символ Triman и Infotri за Франция; Fransa için Triman sembolü ve Infotri; Թրոմանին սիմբոլը և ինֆոտրիան Գրանցիայի համար; Triman simbolu və Fransa üçün Infotri; Символ Triman и Infotri для Франции; Simbol Triman dan Infotri untuk Prancis; Simbol Triman dan Infotri untuk Perancis; フランスのTriman 記号とInfotri; 프랑스용 Triman 기호 및 Infotri; 法國 Triman 標誌和分類中心; 法國 Triman 标志和分类信息;

رمز Infotri و Triman لأجل فرنسا ممل Infotri-و Triman עבור צרפת



Recycling guidelines; Recycling-Richtlinien; Recycling richtlijnen; Consignes de recyclage; Linee guida per il riciclo; Directrices de reciclado; Orientações relativas à reciclagem; Riktlinjer för återvinning; Retningslinjer for genanvendelse; Retningslinjer for resirkulering; Kierrätysohjeet; Leiðbeiningar um endurnýnnslu; Ringlussevötu juhised; Reciclėsšanas vadlinijas; Perdribimo rekomendacijos; Pokyny pro recyklači; Újrahasznosítási útmutató; Usmernenia týkajúce sa recyklácie; Smernice za recikliranje; Wytzeczne dotyczące recyklingu; Indicații privind reciclarea; Smjernice za recikliranje; Smernice za reciklažu; Κατευθυντήριες γραμμές σχετικά με την ανακύκλωση; Указания за рециклиране; Geri dönişüm yönergeləri; გადამუშავების გაიდლაინები; վերամշակման ուղեցույց; Тэкар emal üçün atilma təlimatları; Рекомендации по переработке отходов; Panduan mendaur ulang; Garis panduan kitar semula; リサイクルガイドライン; 재활용 지침; 回收指引; 回收指南;

إرشادات إعادة التدوير; הנחיות מיחזור

XXXX, NN
YYYY-MM-DD

XXXX, NN = Reference number, Version number; Referenznummer, Versionsnummer; referentienummer, versienummer; Numéro de référence, numéro de version; Numero di riferimento, numero di versione; Número de referencia Número de versión; Número de referência, Número da versão; Referensnummer, Versionsnummer; Referencenummer, versionsnummer; Referansnummer, Versjonsnummer; viitenumero, versionumero; Tilvisunarnúmer, Útgáfunúmer; viitenumber, versiooinumber; atsauces numurs, versijas numurs; nuorodos numeris, versijos numeris; referenční číslo, Číslo verze; hivatkozási szám, verziószám; referenčné číslo, číslo verzie; Referenčna številka, Številka različice; Numer katalogowy, Numer wersji; Numărul de referință, numărul versiunii; referentni broj, broj verzije; referentni broj, broj verzije; referentni broj, broj verzije; Αριθμός αναφοράς, Αριθμός έκδοσης; Референтен номер, Номер на версията; Referans numarası, Sürüm numarası; ՆԱՅՆՈՒԹՅԱՆ ԵՐԺՇԵՐԻ, ՅԵՐՆՆՈՍ ԵՐԺՇԵՐԻ; <ղնան համարը, Συμπληρωή ή αριθμός; İstinad nömrəsi, Versiya nömrəsi; справочный номер, номер версии; Nomor referensi, Nomor versi; Nombor rujukan, Nombor versi; 参照番号、バージョン番号; 참조 번호, 버전 번호; 參考編號・版本號碼; 参考编号, 版本号;

الرقم المرجعي، رقم الإصدار; מספר סימוכין, מספר גרסה

YYYY-MM-DD = Date of issue; Ausstellungsdatum; datum van uitgifte; Date d'émission; Data di emissione; Fecha de expedición; Data de emissão; Utfärdandedatum; Udstedelsesdato; Udgivelsesdato; julkaisupäivä; Útgáfudagur; väljaandmise kuupäev; izdošanas datums; leidimo data; Datum vydání; a kiadás dátuma; dátum vydania; Datum izdaje; Data wydania; Data emiterii; Datum izdavanja; datum izdavanja; datum izdavanja; Ημερομηνία έκδοσης; Дата на издаване; Verilme tarihi; გამომცემის თარიღი; Թողարկման ամսաթիվ; Buraxılma tarixi; дата выпуска; Tanggal penerbitan; Tarikh dikeluarkan; 発行日; 발행일; 發行日期; 发布日期;

תאריך הנפקה; تاريخ الإصدار

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Atos

atosmedical.com



Atos Medical AB
Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00 • info@atosmedical.com
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