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TRACOE®
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TRACOE® *vario* Tracheostomy Tubes with Low-Pressure Cuff and Minimally Traumatic Insertion System

TRACOE® *vario* Tracheostomiekanülen mit Cuff und minimal-traumatischem Einführsystem

REF 450-P, REF 451-P, REF 460-P, REF 461-P, REF 470-P, REF 471-P

EN Instructions for Use	**HR** Upute za uporabu
DE Gebrauchsanweisung	**SL** Navodila za uporabo
FR Instructions d'utilisation	**CS** Návod k použití
IT Istruzioni d'uso	**RO** Instrucțiuni
ES Instrucciones de uso	**TR** Kullanma talimatı
PT Instruções de uso	**RU** инструкция по применению
DA Brugsanvisning	**PL** Instrukcja używania
FI Käyttöohje	**EL** Οδηγίες χρήσης
NO Bruksanvisning	**KO** 사용 설명서
HU Használati utasítás	**ZH** 用于新生儿
SV Bruksanvisning	**HE** הוראות לשימוש
NL Gebruiksaanwijzing	**AR** دليل اسعمال

TRACOE®

TRACOE medical GmbH
Reichelsheimer Straße 1 / 3, 55268 Nieder-Olm / Germany
Tel.: +49 6136 9169-0, Fax: +49 6136 9169-200
info@tracoe.com, www.tracoe.com

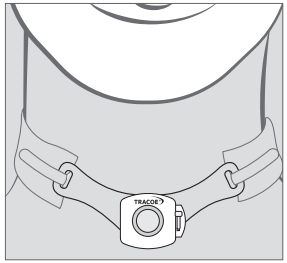


Image 2

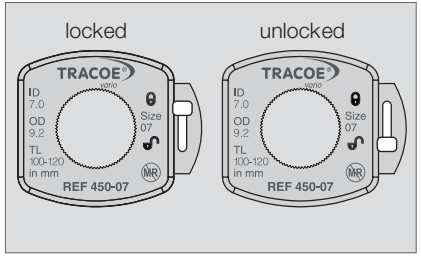


Image 3

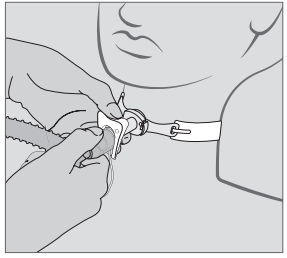


Image 4

Image 5

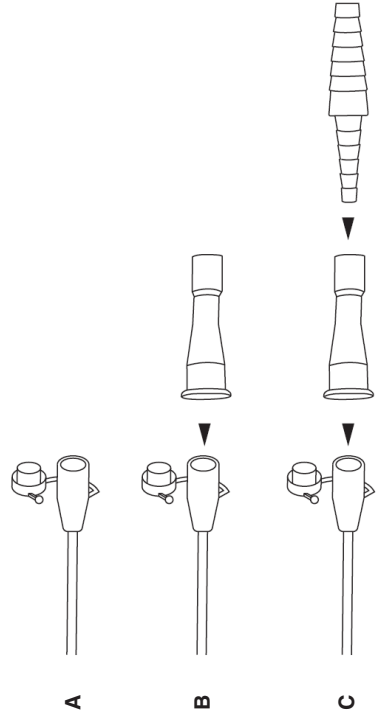
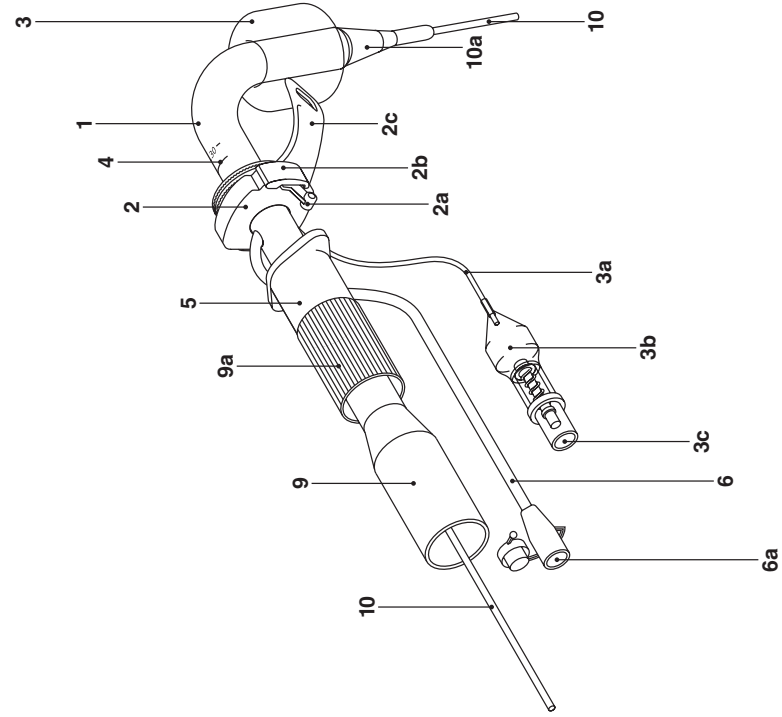
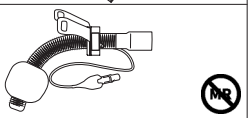
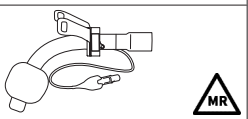
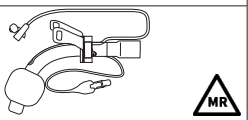
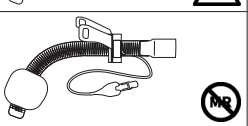
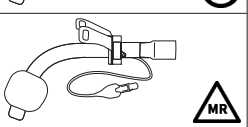
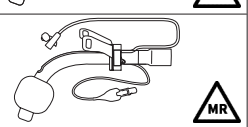
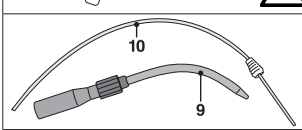


Image 1



	REF 450-P	REF 460-P	REF 470-P	REF 451-P	REF 461-P	REF 471-P
	1	–	–	–	–	–
	–	1	–	–	–	–
	–	–	1	–	–	–
	–	–	–	1	–	–
	–	–	–	–	1	–
	–	–	–	–	–	1
	1	1	1	1	1	1
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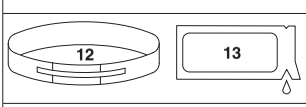
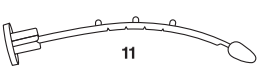
	1	1	1	1	1	1
	1	1	1	1	1	1

EN / Warning. Please read Instructions for Use · **DE /** Achtung. Gebrauchsanweisung beachten · **FR /** Attention. Respecter le mode d'emploi · **IT /** Attenzione. Consultare le istruzioni per l'uso · **ES /** Atención. Siga las instrucciones de uso · **PT /** Atenção. Ter atenção às instruções de utilização · **DA /** Vigtigt: Følg brugsanvisningen · **FI /** Huomio. Noudata käyttöohjetta · **NO /** OBS. Følg bruksanvisningen · **HU /** Figyelem. Olvassa el a használati útmutatót · **SV /** OBS! Se bruksanvisningen. · **NL /** Let op. Rekening houden met de gebruiks-aanwijzing · **HR /** Upozorenje. Pridržavajte se uputa za uporabu. · **SL /** Pozor. Upoštevajte navodila za uporabo · **CS /** Pozor. Respektujte návod k použití · **RO /** Atenție. Respectați instrucțiunile de utilizare · **TR /** Dikkat. Kullanma talimatına dikkat ediniz · **RU /** Внимание! Соблюдать инструкцию по применению · **PL /** Ostrzeżenie. Zajrzyj do instrukcji używania. · **EL /** Προσοχή. Ακολουθήστε τις οδηγίες χρήσης · **KO /** 주의. 사용 설명서를 준수하십시오. · **ZH /** 注意。注意使用说明书 **AR /** تنبيه. يجب مراعاة دليل الاستعمال · **HE /** אזהרה. עקוב אחר הוראות השימוש

MD **EN /** Medical Device · **DE /** Medizinprodukt · **FR /** Dispositif médical · **IT /** Dispositivo medico · **ES /** Dispositivo médico · **PT /** Dispositivo médico · **DA /** Medicinsk udstyr · **FI /** Lääkinnällinen laite · **NO /** Medisinsk enhet · **HU /** Orvosi eszköz · **SV /** Medicinteknisk produkt · **NL /** Medisch hulpmiddel · **HR /** Medicinski proizvod · **SL /** Medicinski pripomoček · **CS /** Zdravotnický prostředek · **RO /** Dispozitiv medical · **TR /** Tıbbi cihaz · **RU /** Медицинское изделие · **PL /** Wyrób medyczny · **EL /** Ιατροτεχνολογικό προϊόν · **KO /** 의료 기기 · **ZH /** 医疗器械 **AR /** جهاز طبي · **HE /** מכשור רפואי

℞ ONLY **EN /** Federal (USA) law restricts this device to the sale by or on the order of a physician · **ES /** Siguiendo las leyes federales estadounidenses, la venta de este dispositivo está sometida a prescripción medica

REF **EN /** Item number · **DE /** Artikelnummer · **FR /** Référence · **IT /** Codice prodotto · **ES /** Número de artículo · **PT /** Número do artigo · **DA /** Artikelnummer · **FI /** Tuotenumero · **NO /** Artikkelnummer · **HU /** Cikkszám · **SV /** Katalognummer · **NL /** Artikelnummer · **HR /** Broj artikla · **SL /** Številka artikla · **CS /** Číslo výrobku · **RO /** Numărul de articol · **TR /** Ürün numarası · **RU /** Номер артикула · **PL /** Numer katalogowy · **EL /** Αριθμός είδους · **KO /** 품목 번호 · **ZH /** 产品编号 **AR /** رقم السلعة · **HE /** מק"ט

LOT **EN /** Batch code · **DE /** Chargencode · **FR /** Code de lot · **IT /** Numero di lotto · **ES /** Código de lote · **PT /** Código do lote · **DA /** Batchkode · **FI /** Eräkoodi · **NO /** Chargekode · **HU /** Tételkód · **SV /** Satsnummer · **NL /** Lotcode · **HR /** Oznaka serije · **SL /** Koda šarže · **CS /** Kód šarže · **RO /** Cod serie de producţie · **TR /** Parti kodu · **RU /** Код партии · **PL /** Kod partii · **EL /** Κωδικός παρτίδας · **KO /** 생산 단위 · **ZH /** 批次编码 **AR /** رمز الشحن · **HE /** קוד אצווה

EN / Manufacturer · **DE /** Hersteller · **FR /** Fabricant · **IT /** Produttore · **ES /** Fabricante · **PT /** Fabricante · **DA /** Producent · **FI /** Valmistaja · **NO /** Produsent · **HU /** Gyártó · **SV /** Tillverkare · **NL /** Fabrikant · **HR /** Proizvođač · **SL /** Proizvajalec · **CS /** Výrobce · **RO /** Producător · **TR /** Üretici · **RU /** Производитель · **PL /** Wytwórca · **EL /** Κατασκευαστής · **KO /** 제조사 · **ZH /** 生产商 **AR /** الشركة المُصنّعة · **HE /** יצרן

EN / Date of manufacture · **DE /** Herstellungsdatum · **FR /** Date de fabrication · **IT /** Data di produzione · **ES /** Fecha de fabricación · **PT /** Data de fabricação · **DA /** Produktionsdato · **FI /** Valmistuspäivä · **NO /** Produksjonsdato · **HU /** Gyártási dátum · **SV /** Tillverkningsdatum · **NL /** Fabricagedatum · **HR /** Datum proizvodnje · **SL /** Datum proizvodnje · **CS /** Datum výroby · **RO /** Data fabricaţiei · **TR /** Üretim tarihi · **RU /** Дата изготовления · **PL /** Data produkcji · **EL /** Ημερομηνία κατασκευής · **KO /** 제조일 · **ZH /** 生产日期 · **AR /** تاريخ التصنيع · **HE /** תאריך ייצור

EN / Use by date · **DE /** Verwendbar bis · **FR /** Utilisable jusqu'au · **IT /** Utilizzare entro il · **ES /** Fecha de caducidad · **PT /** Utilizável até · **DA /** Anvendes inden · **FI /** Käytettävä ennen · **NO /** Kan brukes til · **HU /** Felhasználhatóság dátuma · **SV /** Används före – utgångsdatum · **NL /** Bruikbaar tot · **HR /** Upotrebljivo do · **SL /** Uporabno do · **CS /** Použitelné do · **RO /** Data expirării · **TR /** Son kullanma tarihi · **RU /** Срок годности · **PL /** Użyć do daty · **EL /** Χρήση έως · **KO /** 유통기한 · **ZH /** 保质期至 **AR /** قابل للاستخدام حتى · **HE /** לשימוש עד

STERILE EO **EN /** Sterilised with Ethylene oxide · **DE /** Sterilisiert mit Ethylenoxid · **FR /** Stérilisé à l'oxyde d'éthylène · **IT /** Sterilizzato con ossido di etilene · **ES /** Esterilización con óxido de etileno · **PT /** Esterilização com óxido de etileno · **DA /** Sterilisation med ethylenoxid · **FI /** Steriloitu etyleenioksidilla · **NO /** Sterilisering med etylenoksid · **HU /** Sterilizáció etilénoxiddal · **SV /** Sterilisering med etylenoksid · **NL /** Sterilisatie met ethyleenoxide · **HR /** Sterilizirano etilen oksidom · **SL /** Sterilizirano z etilenoksidom · **CS /** Sterilizováno ethylenoxidem · **RO /** Sterilizat cu oxid etilenic · **TR /** Etilenoksit ile sterilize edilmiştir · **RU /** Стерилизовано оксидом этилена · **PL /** Sterylizowany tlenkiem etylenu · **EL /** Αποστείρωση με αιθυλενοξείδιο · **KO /** 에틸렌으로소독살균되었습니다 · **ZH /** 乙撑氧 (Ethylene oxide) 灭菌 **AR /** معقم.ممادة أوكسيد الأثيلين · **HE /** עבר עיקור בתחמוצת אתילן

2 STERILIZE **EN /** Do not resterilise · **DE /** Nicht erneut sterilisieren · **FR /** Ne pas restériliser · **IT /** Non risterilizzare · **ES /** No esterilizar de nuevo · **PT /** Não esterilizar de novo · **DA /** Må ikke resteriliseres · **FI /** Ei saa steriloida uudelleen · **NO /** Ikke sterilisert på nytt · **HU /** Tilos újrasterilizálni · **SV /** Får ej återsteriliseras · **NL /** Niet opnieuw steriliseren · **HR /** Nemojte ponovno sterilizirati. · **SL /** Ne sterilizirajte znova · **CS /** Znovu nesterilizujte · **RO /** Nu se sterilizează din nou · **TR /** Tekrar sterilize etmeyiniz · **RU /** Не стерилизовать повторно · **PL /** Nie resterylizować · **EL /** Αποστειρωμένο με ακτινοβολία · **KO /** 방사선으로 멸균처리됨 · **ZH /** 经辐射消毒 **AR /** معقمة بالعلاج الإشعاعي · **HE /** אין לעקר מחדש

EN / Do not reuse · **DE /** Nicht wiederverwenden · **FR /** Ne pas réutiliser · **IT /** Non riutilizzare · **ES /** No reutilizar · **PT /** Não reutilizar · **DA /** Må ikke genanvendes · **FI /** Ei saa käyttää uudelleen · **NO /** Må ikke benyttes igjen · **HU /** Tilos újra felhasználni · **SV /** Endast för engångsbruk · **NL /** Niet opnieuw gebruiken · **HR /** Ne koristite ponovno. · **SL /** Ne uporabljajte znova · **CS /** Znovu nepoužívejte · **RO /** Nu se reutilizează · **TR /** Tekrar kullanmayınız · **RU /** Не использовать повторно · **PL /** Nie używać powtórnie · **EL /** Μην επαναχρησιμοποιείτε · **KO /** 재사용하지 마십시오. · **ZH /** 不得回收利用 **AR /** يُمنَع إعادة استخدامها مرة أخرى · **HE /** לא לשימוש חוזר

EN / Single sterile barrier system with protective packaging outside · **DE /** Einzel-Sterilbarrieresystem mit äußerer Schutzverpackung · **FR /** Système de barrière stérile unique avec emballage protecteur extérieur · **IT /** Sistema di barriera sterile singola con imballaggio protettivo esterno · **ES /** Sistema de barrera estéril sencillo con embalaje externo protector · **PT /** Sistema de barreira estéril simples com embalagem protetora no exterior · **DA /** System med enkelt steril barriere og beskyttende emballage udvendigt · **FI /** Yksi steriili estojärjestelmä ja suojapakkaus ulkopuolella · **NO /** Enkelt sterilt barrieresystem med beskyttende utvendig emballasje · **HU /** Szimpla steril zárórendszer külső

védőcsomagolással · **SV /** Enskilt sterilbarriärsystem med skyddsförpackning utanför · **NL /** Enkelvoudig steriel barrièresysteem met beschermende verpakking aan de buitenkant · **HR /** Sustav jedne sterilne obloge sa zaštitnom vanjskom ambalažom · **SL /** Enojni sterilni pregradni sistem z zunanjo zaščitno embalažo · **CS /** Systém sterilní bariéry s vnějším ochranným obalem · **RO /** Sistem cu o singură barieră sterilă, cu ambalaj de protecție la exterior · **TR /** Dıştan koruyucu ambalajlı tek steril bariyer sistemi · **RU / Единая система защиты стерильности с защитной упаковкой снаружи · PL /** System pojedynczej bariery sterylnej z zewnętrznym opakowaniem ochronnym · **EL / Σύστημα μονού στείρου φραγμού με προστατευτική συσκευασία εξωτερικά · KO /** 외부 보호 포장이 있는 단일 멸균 장벽 시스템 · **ZH /** 带外层保护包装的单套无菌屏障系统 **/ HE** מערכת חסימה סטרילית בודדת, כולל אריזת מגן חיצונית **/ AR** نظام حاجز مُعقم أحادي بتغليف واقٍ خارجي

EN / Single sterile barrier system · **DE /** Einzel-Sterilbarrieresystem · **FR /** Système de barrière stérile unique · **IT /** Sistema di barriera sterile singola · **ES /** Sistema de barrera estéril sencillo · **PT /** Sistema de barreira estéril simples · **DA /** System med enkelt steril barriere · **FI /** Yksi steriili estojärjestelmä · **NO /** Enkelt sterilt barrieresystem · **HU /** Szimpla steril zárórendszer · **SV /** Enskilt sterilbarriärsystem · **NL /** Enkelvoudig steriel barrièresysteem · **HR /** Sustav jedne sterilne obloge · **SL /** Enojni sterilni pregradni sistem · **CS /** Systém sterilní bariéry · **RO /** Sistem cu o singură barieră sterilă · **TR /** Tek steril bariyer sistemi · **RU / Единая система защиты стерильности · PL /** System pojedynczej bariery sterylnej · **EL / Σύστημα μονού στείρου φραγμού · KO /** 단일 멸균 장벽 시스템 · **ZH /** 单套无菌屏障系统 · **HE /** מערכת חסימה סטרילית בודדת **/ AR** نظام حاجز مُعقم أحادي

EN / Store in a dry place · **DE /** Trocken aufbewahren · **FR /** Conserver au sec · **IT /** Conservare in luogo asciutto · **ES /** Conservar en un lugar seco · **PT /** Guardar em local seco · **DA /** Opbevares tørt · **FI /** Säilytettävä kuivassa · **NO /** Oppbevares på et tørt sted · **HU /** Száraz helyen tárolandó · **SV /** Förvaras torrt · **NL /** Droog bewaren · **HR /** Čuvajte na suhom mjestu. · **SL /** Hranite na suhem · **CS /** Uchovávejte v suchu · **RO /** A se păstra la loc uscat · **TR /** Kuru şekilde saklayınız · **RU / Хранить в сухом месте · PL /** Chronić przed wilgocią · **EL / Να φυλάσσεται σε ξηρό μέρος · KO /** 건조한 곳에 보관하십시오. · **ZH /** 需保存于干燥处 · **HE /** נא לאחסן במקום יבש **/ AR** يجب الحفاظ عليها جافة

EN / Temperature limits · **DE /** Temperaturbegrenzung · **FR /** Limitation de température · **IT /** Limite di temperatura · **ES /** Límite de temperatura · **PT /** Limitação da temperatura · **DA /** Temperaturbegrænsning · **FI /** Lämpötilarajat · **NO /** Temperaturbegrensning · **HU /** Hőmérsékleti tartomány · **SV /** Tillåtet temperaturområde · **NL /** Temperatuurbegrenzing · **HR /** Ograničenje temperature · **SL /** Omejitev temperature · **CS /** Omezení teploty · **RO /** Limitare a temperaturii · **TR /** Sıcaklık sınırlaması · **RU / Ограничение температуры · PL /** Dopuszczalna temperatura · **EL / Όριο θερμοκρασίας · KO /** 온도 제한 · **ZH /** 温度限值范围 **/ AR** حد درجة الحرارة · **HE /** הגבלת טמפרטורה

EN / Protect from sunlight · **DE /** Von Sonnenlicht fernhalten · **FR /** Protéger de l'ensoleillement · **IT /** Non esporre alla luce del sole · **ES /** Mantener alejado de la luz solar · **PT /** Manter afastado da luz solar · **DA /** Beskyttes mod sollys · **FI /** Säilytettävä auringonvalolta suojattuna · **NO /** Må holdes unna sollys · **HU /** Napfénytől távol tartandó · **SV /** Skyddas från solljus · **NL /** Beschermen tegen zonlicht · **HR /** Držite podalje od sunčeve svjetlosti. · **SL /** Varujte pred sončno svetlobo · **CS /** Chraňte před slunečním světlem · **RO /** A se feri de razele solare · **TR /** Güneş ışığından uzak tutunuz · **RU / Беречь от солнечных лучей · PL /** Trzymać z dala od światła słonecznego · **EL / Να φυλάσσεται μακριά από το φως του ήλιου · KO /** 직사광선에 노출되지 않도록 하십시오. · **ZH /** 避免阳光直射 · **HE /** נא להרחיק מאור **/ AR** يجب إبقاؤها بعيدة عن أشعة الشمس

EN / Not made with phthalates (e.g. DEHP) · **DE /** Phthalat-frei (z. B. DEHP) · **FR /** Sans phtalates (par ex. DEHP) · **IT /** Senza ftalati (per es. DEHP) · **ES /** Sin ftalatos (p. ej. DEHP) · **PT /** Sem ftalatos (por ex. DEHP) · **DA /** Phthalat-fri (f.eks. DEHP) · **FI /** Ftalaatition (esim. DEHP) · **NO /** Ftalatfritt (f.eks. DEHP) · **HU /** Ftalátmentes (pl. DEHP) · **SV /** Ftalatfri (t. ex. DEHP) · **NL /** Niet gefabriceerd met ftalaten (bijv. DEHP) · **HR /** Ne sadrži ftalate (npr. DEHP) · **SL /** Brez ftalatov (npr. DEHP) · **CS /** Bez obsahu ftalátů (např. DEHP) · **RO /** Nu conține ftalați (de ex. DEHP) · **TR /** Ftalat içermez (örn. DEHP) · **RU / Не содержит фталатов (например, DEHP) · PL /** Nie zawiera ftalanów (np. DEHP) · **EL / Δεν περιέχει φθαλικές ενώσεις (π.χ. DEHP) · KO /** (디에탈헥실프탈레이트) 포함 · **ZH /** 不含邻苯二甲酸盐 **(DEHP) / AR** خالٍ من مادة الفثالات · **HE /** פתאלטים ללא (למשל, DEHP)

EN / Not made with Natural Rubber latex · **DE /** Nicht mit natürlichem Latex hergestellt · **FR /** Non fabriqué avec du latex naturel · **IT /** Non realizzato con lattice naturale · **ES /** No elaborado con látex natural · **PT /** Não fabricado com látex natural · **DA /** Ikke fremstillet med naturligt latex · **FI /** Ei valmistettu luonnonlateksista · **NO /** Ikke produsert med naturlig latex · **HU /** Nem természetes latexből készült · **SV /** Tillverkad utan användning av naturlig latex · **NL /** Niet gefabriceerd met natuurlijk latex · **HR /** Nije proizvedeno s prirodnim lateksom. · **SL /** Ni izdelano z naravnim lateksom · **CS /** Není vyrobeno z přírodního latexu · **RO /** Nu este produs cu latex natural · **TR /** Doğal lateksle üretilmemiştir · **RU / Не содержит натурального латекса · PL /** Nie zawiera lateksu kauczuku naturalnego · **EL / Δεν είναι κατασκευασμένο με φυσικό λάτεξ · KO /** 천연 라텍스로 만들지 않음 · **ZH /** 制作过程未添加天然乳胶 · **AR /** غير مصنوعة من مادة اللاتكس الطبيعية · **HE /** טבעי לטקס ללא יוצר

EN / MR conditional · **DE /** Bedingt MRT-sicher · **FR /** IRM compatible sous conditions · **IT /** A compatibilità RM condizionata · **ES /** Condicional para RM · **PT /** Condicional para RM · **DA /** MR-betinget · **FI /** Soveltuu magneettikuvaukseen tietyin ehdoin · **NO /** MR-betinget · **HU /** MR feltételes · **SV /** MR-villkorlig · **NL /** MR-voorwaardelijk · **HR /** Uvjetno sigurno za upotrebu s MR-om · **SL /** MR pogojno · **CS /** MR přípustné za určitých podmínek · **RO /** Sigur pentru RM în anumite condiții · **TR /** MR koşullu · **RU / MPT-совместимо · PL /** Warunkowo bezpieczny w środowisku rezonansu magnetycznego · **EL / Ασφαλές για χρήση σε περιβάλλον μαγνητικού συντονισμού υπό προϋποθέσεις · KO /** MR 조건부 · **ZH /** 特定条件下磁共振安全 · **AR /** آمن بشروط في مجال الرنين المغناطيسي · **HE /** מותנה MR

EN / MR unsafe · **DE /** Nicht MRT-sicher · **FR /** IRM non compatible · **IT /** Non compatibile con la RM · **ES /** No seguro para RM · **PT /** Inseguro para RM · **DA /** MR-usikker · **FI /** Ei sovellu magneettikuvaukseen · **NO /** MR-usikker · **HU /** MR veszélyes · **SV /** MR-farlig · **NL /** MR-onveilig · **HR /** Nije sigurno za upotrebu s MR-om · **SL /** MR nevarno · **CS /** MR nebezpečné · **RO /** Nesigur pentru RM · **TR /** MR güvenli değil · **RU / Небезопасно при использовании в присутствии оборудования для МРТ · PL /** Niebezpieczny w środowisku rezonansu magnetycznego · **EL / Μη ασφαλές για χρήση σε περιβάλλον μαγνητικού συντονισμού · KO /** MR 비안전 · **ZH /** 磁共振不安全 · **AR /** غير آمن في مجال الرنين المغناطيسي · **HE /** לא בטיחותי בתנאי MR

EN / Do not use device if packaging is damaged · **DE /** Bei beschädigter Verpackung nicht verwenden · **FR /** Ne pas utiliser en cas d'emballage endommagé · **IT /** Non utilizzare se la confezione è danneggiata · **ES /** No utilizar si el envase está dañado · **PT /** Não utilizar em caso de embalagem danificada · **DA /** Må ikke anvendes, hvis emballagen er beskadiget · **FI /** Älä käytä, jos pakkaus on vahingoittunut · **NO /** Må ikke benyttes hvis emballasjen er skadet · **HU /** Tilos felhasználni, ha a csomagolás sérült · **SV /** Används inte om förpackningen är skadad · **NL /** Niet gebruiken bij beschadigde verpakking · **HR /** Proizvod ne koristite ako je pakiranje oštećeno. · **SL /** Ne uporabljajte, če je embalaža poškodovana · **CS /** Nepoužívat při zjištění poškození obalu · **RO /** Nepoužívat při zjištění poškození obalu · **TR /** Ambalajı hasarlıysa kullanmayınız · **RU / Не использовать, если целостность упаковки нарушена · PL /** Nie używać, jeżeli opakowanie jest uszkodzone · **EL / Να μην χρησιμοποιείτε σε περίπτωση που η συσκευασία έχει υποστεί ζημιά · KO /** 포장이 손상된 경우 사용하지 마십시오. · **ZH /** 如包装破损，不得使用 · **AR /** مُنع الاستخدام في حالة تلف العبوة · **HE /** אין להשתמש אם האריזה פגומה

EN / Pull-out image pages · **DE /** Ausklappbare Bildseiten · **FR /** Pages d'illustration dépliables · **IT /** Pagine grafiche ripiegabili · **ES /** Páginas del anverso desplegables · **PT /** Páginas ilustrativas desdobráveis · **DA /** Billedsider, der kan foldes ud · **FI /** Avattavat kuvasivu · **NO /** Utbrettbare sider med illustrasjoner · **HU /** Kihajtható lapok · **SV /** Utvikbara bildsidor · **NL /** Uitklapbare fotopagina's · **HR /** Otklopive stranice sa slikama · **SL /** Zložljive strani s slikami · **CS /** Výklopné stránky s obrázky · **RO /** Pagini pliante cu ilustrații · **TR /** Açılabilen resimli sayfalar · **RU / Вкладки с иллюстрациями · PL /** Rozkładane strony z ilustracjami · **EL / Αναπτυσσόμενες σελίδες εικόνων · KO /** 접이식 그림 페이지 · **ZH /** 可折叠图片页 · **AR /** صفحات مصوّرة قابلة للطي · **HE /** דפי תמונות מתקפלים

EN / Packaging Content · **DE /** Packungsinhalt · **FR /** Contenu de l'emballage · **IT /** Contenuto della confezione · **ES /** Contenido del envase · **PT /** Conteúdo da embalagem · **DA /** Pakningsindhold · **FI /** Pakkauksen sisältö · **NO /** Pakningsinnhold · **HU /** A csomag tartalma · **SV /** Förpackningens innehåll · **NL /** Inhoud verpakking · **HR /** Sadržaj pakiranja · **SL /** Vsebina embalaže · **CS /** Obsah balení · **RO /** Conținutul ambalajului · **TR /** Paket içeriği · **RU / содержимость упаковки · PL /** Zawartość opakowania · **EL / Περιεχόμενο συσκευασίας · KO /** 포장이 손상된 경우 사용하지 마십시오 · **ZH /** 包装内容 · **AR /** محتويات العبوة · **HE /** תכולת אריזה

EN / Peel here. · **DE /** Hier öffnen. · **FR /** Ouvrir ici. · **IT /** Strappare qui. · **ES /** Abra aquí · **PT /** Descolar aqui. · **DA /** Åbn her. · **FI /** Repäise tästä. · **NO /** Åpne her. · **HU /** Itt nyílik. · **SV /** Öppnas här. · **NL /** Hier openen. · **HR /** Otvoriti ovdje. · **SL /** Odprite tukaj. · **CS /** Zde otevřít. · **RO /** Deschideți aici. · **TR /** Buradan açın. · **RU /** Вскрывать здесь. · **PL /** Tu otwierać. · **EL /** Ανοίξτε εδώ. · **KO /** 여기를 벗기시오 · **ZH /** 从此处撕开 · **HE /** לפתוח כאן. · **AR /** افتح هنا.

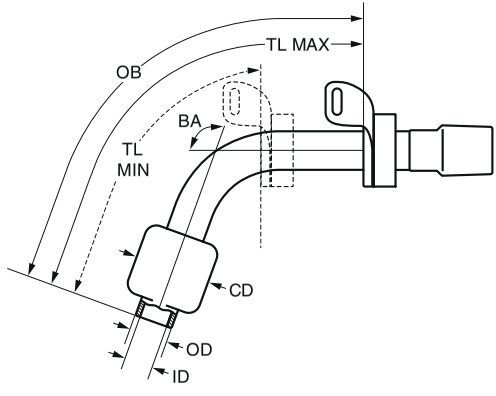
EN / Locked neck flange fixation · **DE /** Feststellhebel des Schildes geschlossen · **FR /** Fixation verrouillée de la plaque de la canule · **IT /** Fissaggio della flangia con collo bloccato · **ES /** Fijación de la placa del cuello bloqueada · **PT /** Fixação por placa para o pescoço bloqueada · **DA /** Fiksering af halsflange låst · **FI /** Kaulalaippa lukitussa asennossa · **NO /** Låst hylsehalsfiksering · **HU /** Zárt karima rögzítés · **SV /** Fixering av låst kanylsköld · **NL /** Schildfixatie vergrendeld · **HR /** Fiksiranje zabravljene prirubnice · **SL /** Zaklenjena fiksacija vratne prirobnice · **CS /** Uzamčený fixační límec · **RO /** Fixarea flanșei în poziția de blocare a gâtului · **TR /** Kilitli boyun plakası fiksasyonu · **RU /** Замкнутый фиксатор фланца · **PL /** Zablokowane mocowanie kołnierza szyjnego · **EL /** Πλάκα σωλήνα ασφαλισμένη · **KO /** 잠긴 넥 플랜지 고정부 · **ZH /** 颈法兰盘固定装置已锁紧 · **HE /** קיבוע אוגן צוואר נעול · **AR /** عنصر تثبيت الطرف العنقي مقفول

EN / Unlocked neck flange fixation · **DE /** Feststellhebel des Schildes geöffnet · **FR /** Fixation déverrouillée de la plaque de la canule · **IT /** Fissaggio della flangia con collo sbloccato · **ES /** Fijación de la placa del cuello desbloqueada · **PT /** Fixação por placa para o pescoço desbloqueada · **DA /** Fiksering af halsflange ikke låst · **FI /** Kaulalaippa avatussa asennossa · **NO /** Ulåst hylsehalsfiksering · **HU /** Nyitott karima rögzítés · **SV /** Fixering av olåst kanylsköld · **NL /** Schildfixatie ontgrendeld · **HR /** Fiksiranje nezabravljene prirubnice · **SL /** Odklenjena fiksacija vratne prirobnice · **CS /** Odemčený fixační límec · **RO /** Fixarea flanșei în poziția de deblocare a gâtului · **TR /** Kilitlenmemiş boyun plakası fiksasyonu · **RU /** Разомкнутый фиксатор фланца · **PL /** Odblokowane mocowanie kołnierza szyjnego · **EL /** Πλάκα σωλήνα απασφαλισμένη · **KO /** 잠금 해제된 넥 플랜지 고정부 · **ZH /** 颈法兰盘固定装置已解锁 · **HE /** קיבוע אוגן צוואר לא נעול · **AR /** عنصر تثبيت الطرف العنقي مفتوح

Size Table

Size	ID	OD	OB	CD	BA	REF 450-P	REF 460-P	REF 470-P
	mm	mm	mm	mm	Θ°	TL (min-max) mm	TL (min-max) mm	TL (min-max) mm
07	7.0	9.7	86	23.0	100	53.0 – 68.0	54.0 – 69.0	
08	8.0	11.2	97	28.0	100	64.0 – 84.0	65.0 – 85.0	63.0 - 83.0
09	9.0	12.3	106	30.0	100	66.0 – 93.0	64.0 – 91.0	64.0 - 91.0

Size	ID	OD	OB	CD	BW	REF 451-P	REF 461-P	REF 471-P
	mm	mm	mm	mm	Θ°	TL (min-max) mm	TL (min-max) mm	TL (min-max) mm
07	7.0	9.7	110.0	23.0	100	65.0 – 98.0	64.5 – 97.5	
08	8.0	11.2	128.0	28.0	100	76.0 – 116.0	73.5 – 113.5	73.0 – 113.0
09	9.0	12.3	134.0	30.0	100	73.5 – 118.5	78.0 – 123.0	73.5 – 118.5



Instructions for Use for TRACOE vario Tracheostomy Tubes and Minimally Traumatic Insertion System

Note: Please read the instructions for use carefully. They are part of the described product and must be available at all times. For your patients' and your own safety, please follow instructions below.

The illustrations to which the text refers can be found at the beginning of these instructions. The numbers indicate product components and refer to the respective illustrations of the product. Symbols and icons used with the product are explained in sections "General Description" and "Functional Description".

1. Intended Use and Indications for Use

TRACOE *vario* tracheostomy tubes with minimally traumatic insertion system are indicated for providing tracheal access for airway management especially to those patients with unusual anatomy or patients with thick necks. It may be used for up to 29 days.

Patient Population: The product is intended for adults and adolescents (adolescent age range: 12 - 21 years according to medical judgement)

The product is intended for mechanically ventilated and self breathing patients in hospitals, pre-hospitals (EMS), extended care facilities, outpatient clinics.

Intended User: The product can be used by medical staff trained in tracheostomy care or individuals trained by professionals.

Indications: This medical device is indicated for cases where access to the respiratory tract is required by means of a tracheostomy. With its high-volume-low-pressure (HVLP) cuff the sealing of the trachea can be achieved to separate the upper airways from the lower respiratory tract to prevent airflow. Therefore, it allows efficient ventilation and prevents influx of subglottic secretions into the lung. The minimally traumatic insertion system is intended to facilitate insertion of the tracheostomy tube into newly created or sensitive stomas using the Seldinger technique. It can be used either during percutaneous dilation tracheostomy or when the tube is changed.

TRACOE *vario* XL models (REF 451-P, REF 461-P and REF 471-P) are indicated wherever the standard tube length is insufficient, or when it is necessary to move the low-pressure cuff towards caudal (e.g. with stenosis).

TRACOE *vario* extract tracheostomy tubes with subglottic suction line and cuff (REF 470-P and REF 471-P) are predominantly used for patients producing large amounts of secretions and for whom suctioning of the subglottic space is indicated.
The extract tracheostomy tube models can also be used for Above Cuff Vocalisation (ACV).

Single Patient Use and Useful Life: Multiple use of the tracheostomy tube by one and the same patient is possible within the intended useful life.

TRACOE *vario* tracheostomy tubes should not be used for more than 29 days beginning from the first opening of the sterile barrier. This maximum period of use also includes all times, during which the tracheostomy tube is not used.

Caution:
A pro-longed use of more than 29 days may result in material safety and biocompatibility issues.

2. General Description

The tracheostomy tube is made of PVC and provides an artificial airway to the lower respiratory tract.

The product consists of a tracheostomy tube, a minimally traumatic insertion system that consists of inserter and guiding catheter with silicone sleeve, an obturator, a fabric neck strap, and lubricating gel which are supplied together within a sterile bag. Adaptors are only delivered for models with subglottic suctioning system.

The tracheostomy tubes are available in different diameters and lengths. The models are provided with the cuff deflated. The appropriate diameter and length of the tube is to be determined by the physician.

The tracheostomy tube is radiopaque, either because of the incorporated metal spiral reinforcement (REF 450-P, 451-P) or because of the radiopaque stripe in clear models (REF 460-P, 461-P, 470-P, 471-P).

The MRI conditions vary due to the product specifications and are described in chapter “MRI Safety Information”.

Products can be used in combination with medical devices, which are approved for invasive ventilation through a tracheostoma and are connected via a standard 15 mm connector. Products with subglottic suction can be used with products, which are approved for subglottic suction connected via a Luer connector.

This product is supplied with an information card, including two detachable labels, which contain product specific details. These labels will facilitate reordering and can be attached to the patient record.

Fold out pages: The image 1 represents the most complex tracheostomy tube model.

1	tube	6	suction line
2	adjustable neck flange	6a	suction line port with female standard Luer connector
2a	lever	9	inserter
2b	push button with spring element	9a	handle with screwing function
2c	wings with eyelets	10	guiding catheter
3	HVLP cuff	10a	silicone sleeve
3a	inflation line	11	obturator
3b	pilot balloon with check valve	12	neck strap
3c	female standard Luer connector	13	lubricant gel
4	scale for axial orientation	14	adaptors
5	standard 15mm connector		

(1) Tracheostomy Tube:

- All tubes are curved and feature a smooth, round tip at the distal end (inside the patient).
- The tracheostomy tube (**1**) has a scale for axial orientation (**2d**) behind the 15 mm connector (**5**) indicating the position of the tube relative to the adjustable neck flange (**2**). This scale has no measuring function.
- REF 450-P, 451-P: The tube has a radio-opaque metal spiral-reinforcement.
- REF 460-P, 461-P, 470-P, 471-P: The tube is clear and has a radiopaque stripe.
- TRACOE *vario* tracheostomy tubes with suction line (REF 470-P, and REF 471-P) allow intermittent suctioning of secretions of the subglottic space.
- The standardized 15 mm connector (**5**) is permanently attached to the tube and is intended for connecting the tracheostomy tube to external devices with female standardized 15 mm connectors e.g. connection to mechanical ventilation, HME, speaking valve.

(2) Adjustable Neck Flange

- With the adjustable neck flange (**2**) the insertion depth of the tracheostomy tube can be adapted to the patient’s needs.
- The flange includes two flexible wings with eyelets (**2c**) for attachment of the neck strap (**12**). The wings can be rotated within a range of about 60° to 180°. This permits universal adjustment to the most common neck anatomies.
- The product code (REF), clinical size (size), internal diameter (ID), external diameter (OD), and length range (TL) of the tube are all indicated on the neck flange. The cuff resting diameter (CD) and size are displayed on the pilot balloon (**3b**) where appropriate.

(6) High-Volume-Low-Pressure (HVLP) Cuff:

- The HVLP-cuff (**3**) is located on the distal end of the tracheostomy tube and directly connected to its e inflation line (**3a**).
- The proximal end of the inflation line includes a pilot balloon (**3b**), with incorporated self-sealing check valve and a female Luer connector (**3c**).
- The HVLP-cuff is inflated with air only.

(8) Subglottic Suction Line:

- TRACOE *vario* tracheostomy tubes with subglottic suction line (**6**) contain a channel integrated into the wall of tube that ends with an aperture immediately above the cuff.
- The suction line ends with a standard female Luer connector (**6a**) as port for connection with external accessories for subglottic

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suctioning or the air or oxygen supply for ACV. In case of subglottic suctioning, additionally, adaptors (**14**) can be used for connection.

- The subglottic suctioning port (**6a**) can be closed by using the attached cap.

(9-10 a) Minimally Traumatic Insertion System

- The combination of inserter (**9**) and guiding catheter (**10**) with silicone sleeve (**10a**) constitute the minimally traumatic insertion system.
- The silicone sleeve enables a smooth transition between the conical end of the inserter and the distal end of the tube. This facilitates the insertion of the tube into the trachea and reduces the risk of false insertion or injuries to the trachea, e.g. fracture of the tracheal rings.

(11) Obturator:

- If a stoma channel is stable, the re-insertion with Seldinger technique may not be necessary. Then, the standard non-perforated obturator (**11**), with its smooth, round, conical tip at the distal end can be used for tracheostomy tube re-insertion during the useful life of the product.

(12) Neck Strap:

- The neck strap (**12**) is a soft strip of padded fabric that wraps around the patient's neck.
- The ends of the strap include hook-and-loop fasteners that are inserted through the eyelets of the neck flange to secure the tracheostomy tube in position.
- The frequency of change should be determined by the physician or caretaker.

(13) Lubricating Gel

- The lubricating gel (**13**) facilitates insertion by reducing the friction resistance of the tracheostomy tube, minimally traumatic insertion system, and/or obturator during insertion.
- The lubricating gel contains following ingredients: pure water (>80%), polypropylene glycol 300 (<10%), polypropylene glycol 1450 (<10%), glycerine (<1%), carbomer (<1%), sodium hydroxide (<0.5%), methylparaben (<0.03%), propylparaben (<0.03%).

Supplementary Products:

- Products, which can be used in combination with the described one are listed in section "Supplementary Products".

3. MRI Safety Information

TRACOE vario models REF 450-P and 451-P are classified as "MR unsafe" because of their metal spiral reinforcement and therefore cannot be used in MRI.

A patient with clear models REF 460-P, 470-P, 461-P and REF 471-P can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 T.
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m).
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and a maximum whole head specific absorption rate (SAR) of 3.2W/kg.
- Quadrature driven transmit body coil only.
- The neck flange must be secured in place with the neck strap.
- The check valve must be secured to the skin with medical tape, away from the area of MR diagnostic interest.

In non-clinical testing, the image artifact, caused by the check valve, extends (radially) up to 107 mm from the check valve when imaged with a gradient echo pulse sequence and a 1.5 T MR system, and up to 113 mm when imaged with a spin echo pulse sequence in a 3.0 T MR system. Therefore, it is recommended to tape the check valve to the patient's skin away from the area of interest.

Warning:

When used in MR imaging:

- Securely fasten the tube, with a metal-free neck strap, to prevent possible movement while in the MR environment.
- Securely affix the check valve away from the area of interest with standard medical tape to prevent movement within the MR environment.
- MR image quality may be compromised if the area of interest is close to the position of the inflation valve.

4. Contraindications

- Spiral-reinforced models are MR unsafe and must not be used for MRI.
- The tracheostomy tube cannot be used in conjunction with heat emitting devices, e.g. laser. There is a risk of fire, also toxic gases may form, and the tube may get damaged.
- Not suitable for patients with spasms, which may result in excessive axial forces > 15 N (e.g. neurological spasticity).
- Neonates, infants, and children.

When using ACV:

- Patients with fresh stoma (less than 7 days after stoma creation).
- Obstructions in the upper airways that inhibit the airflow and therefore inhibit speaking.
- Obstructions may lead to pressure rise in the trachea and therefore cause a risk of emphysema.
- Patients with surgical emphysema or infections of the tracheal tissue.

5. General Precautions

- When the product is used together with other medical devices, follow their respective instructions for use. Contact the manufacturer if there are any questions, or if assistance is required.
- Safety precautions must be taken in case of complications during the described procedures, so that the physician can provide ventilation without delay by alternative airways, (e.g. trans laryngeal intubation, laryngeal mask).
- The product should be inspected for integrity and function prior to use/insertion. If the product is damaged, it should be replaced with a new product.
- It is strongly recommended that a ready-to-use spare device is available nearby.
- The sterile packaging should be inspected for damage prior to opening. If the packaging is damaged or has been unintentionally opened, the device should not be used.
- A disconnect wedge for 15 mm connectors should remain at the patient's bedside and be available to assist in the disconnection of external devices, e.g. mechanical ventilation.
- Always hold the tracheostomy tube at the base of the 15 mm connector when connecting to or disconnecting from external devices.
- Do not move the adjustable neck flange along the tube without unlocking it.
- Lubricating gel might inhibit the locking mechanism of the adjustable neck flange. Ensure that the lubricating gel is applied only on the areas described in chapter "Preparing the Tracheostomy Tube".
- Optimum oxygen levels must be established in the patient before cannulation or re-cannulation.
- The cuff pressure can change, if laughing gas is used as an anesthetic.
- All parts of the cuff inflation system must be free from strain and kinking during measurement of the cuff pressure, otherwise the manometer may show incorrect pressure values.

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- Ensure that all allowed objects for inflating the cuff are clean (free of dust, visible particles, and contaminants). Obstacles may result in deflation of the cuff filling system which will reduce efficiency of ventilation or protection from aspiration.
- To avoid damage to the cuff and improve ease of insertion, always ensure that the cuff is completely deflated prior to insertion and shift the cuff material towards the neck flange.
- Do not move the neck-flange with excessive force against the stop near the 15 mm connector. Otherwise the inflating line of the cuff might get damaged.
- Water inside the Cuff: All HVLP cuffs have a certain degree of permeability to water vapor. Therefore, condensed water vapor may accumulate inside the cuff. If larger quantities of water may inadvertently get into the inflation line, this may lead to improper cuff pressure measurement, cuff pressure adjustment, and cuff deflation. If this is the case, the tracheostomy tube has to be replaced.
- During subglottic suctioning, ensure that negative pressure is not too extensive, and not applied for an extended period. This can avoid drying out of the subglottic area. Use intermitted suction. The suction line might get blocked due to accumulated and/or dried secretions inside the suction line or by drawing tracheal mucosa. If the suction line becomes blocked, follow instruction in chapter 8.4. Closing the cap after suction reduces the drying-out effect.
- Improper storage conditions may result in product or sterile barrier damage.

6. Warnings

- Do not use this product if the sterile packaging has been compromised/damaged, e.g. open edges, holes in packaging etc.
- Refurbishing (including re-sterilisation) is not allowed, this may influence the material and function of the product. The product is single use only.
- Modifications of TRACOE products are not allowed. TRACOE will not be responsible for modified products.
- After removing the insertion system, ensure that the silicone sleeve is still located on the guiding catheter. If this is not the case, the radiopaque silicone sleeve must immediately be removed, i.e. from the tube or airways.
- For first insertion the ventilation with the endotracheal tube has to be stopped immediately when the tracheostomy tube is blocked: danger of emphysema.
- Ensure that the cuff is not punctured by instruments or sharp cartilage ridges.

- Use only water-soluble lubricating gel, as oil-based gel may damage the tube.
- To prevent an increase in air resistance, ensure that the tube does not become obstructed when applying lubricating gel to the obturator tip.
- Check the position and function of the tube following insertion. Incorrect placement may result in permanent damage to the tracheal mucosa or increased air resistance.
- Do not move or shift the tube once it is in position, as this may damage the stoma / trachea or lead to insufficient ventilation.
- For correct orientation of the tube and adjustable neck flange, it is essential, that the scale on the tube faces upwards (cranial) so the distal end of the tube is oriented caudal. The writing on the neck flange has to be readable in frontal view (TRACOE logo towards patient's chin; see Image 2).
- Long-term and excessive cuff pressure above 30 cmH2O (≈ 22 mm Hg) poses a risk of permanent damage to the trachea.
- Only fill the cuff with air. Do not fill the cuff with liquids as this would lead to cuff pressure peaks above 30 cmH2O.
- Insufficient filling (below 20 cmH2O) of the cuff could result in an increased risk of aspiration, which may result in the worst case in VAP (ventilator associated pneumonia).
- To prevent damage to the stoma or trachea, ensure that the cuff is completely deflated (empty) prior to insertion or removal of the tube. If it is not possible to deflate the cuff, cut the inflation line with a pair of scissors and remove the air. In this event, the product is defective and must be replaced.
- During air travel alteration of the cuff pressure may occur. Therefore, ensure permanent cuff pressure control.
- Before deflating the cuff ensure that the patient`s upper respiratory tract is unobstructed. When applicable, clear the upper respiratory tract of any secretions through suction or patient coughing.
- Make sure that the correct Luer connectors are used for filling the cuff and suctioning.
- The regular suctioning of the tube is recommended to prevent any subtle increase in air resistance.
- Use only suction catheters to clear the secretions from the patient`s respiratory tract and the tracheostomy tube. Instruments may wedge in the tube and restrict ventilation.
- Regularly check that all connections are secure to prevent an inadvertent disconnection of the tube from external equipment and ensure efficient ventilation.
- Keep the 15 mm connector clean and dry.
- Do not use non-authorized tools to detach 15 mm connector,

because this might deform the 15 mm connector.
- Occlusion caps/speaking valves must only be used with an unblocked cuff – danger of suffocation.

7. Adverse Reactions

Typical adverse effects of tracheostomy tubes use include: pressure points, stenosis, and skin irritation (e.g. due to moisture), granulation tissue, increased salivation, and swallowing difficulties. In case of an adverse event please contact a medical professional immediately.
The lubricating gel must not be used if the patient is allergic or hypersensitive to any ingredients described. In case of using ACV, typical adverse effects include increased secretion, coughing, nausea, or laryngeal drying out due to the restoration of the functionality of the upper respiratory tract (cleaning / tasting / speaking).

8. Functional Description

Caution:

- It is strongly recommended that a ready-to-use spare device is kept at the patient's bedside.
- Safety precautions must be taken in case of complications during the described procedures, so that the physician can provide ventilation without delay by alternative airways, (e.g. trans laryngeal intubation, laryngeal mask).

8.1 Preparation

This is a sterile device, which enables the usage in an aseptic environment.
The size of the tube to be used and appropriate length should be determined by a physician.
The following functions must be checked immediately prior to use. If the cuff leaks during use, replace the tube and contact TRACOE Customer Service. If the device fails the initial inspection, repeat the procedure with a new device. Do not discard the device, and follow instructions provided in section "Returns and Complaints".

A, when using the Minimally Traumatic Insertion System

1. Inspect the sterile packaging to ensure it is secure, undamaged and all components are present.
2. Open the package and inspect the device for damages prior to use.
3. Verify that the tube is free of obstruction, the material is not brittle or torn and that the cuff is intact, the inflating or suction lines are not kinked, there are no tears or cuts, the connection between the tube and the neck flange is stable.

4. Check the HVLP- cuff for leakage by inflating with a hand-held manometer, to a pressure of 50 cmH2O (≈ 36.78 mm Hg). Watch the filled cuff for 1 minute to detect leakage by pressure decrease / cuff deflation. If the cuff is leak tight, remove all of the air with a syringe. Shift the cuff material towards the neck flange to facilitate its sliding through the stoma.
5. For adjustment of the flange ensure, that the orange lever (**2a**) at the right-hand side of the flange is open (lower position “unlocked”, see locking symbol on flange). Press the button with spring element (**2b**), and move the flange along the tube. Release the push button when the flange is in the envisaged position. Push the locking lever upwards (“locked” position) to fix the flange in place (see Image 3).

Caution:

- Do not move the neck flange with excessive force against the stop near the 15mm connector. Otherwise the inflating line of the cuff might get damaged.
- For correct orientation of the tube and adjustable neck flange, it is essential, that the scale on the tube faces upwards (cranial) so the distal end of the tube is oriented caudal. The writing on the neck flange has to be readable in frontal view (TRACOE logo towards patient’s chin; see Image 2).

6. Check the rotating function of the neck-flange wings and place both wings in a position that will be most comfortable for the patient.
7. Check if the pre-assembled silicone sleeve (**10a**) smoothly bridges the gap between the conical end of the inserter and the distal end of the tube. If a gap is visible, the connection can be tightened by carefully rotating the handle of the inserter (**9a**).
8. Check if the Seldinger wire (not included) which will be used, fits smoothly inside the guiding catheter (**10**) of the minimally traumatic inserter.
9. The silicone sleeve and the end of the tracheostomy tube are then lubricated with the lubricant gel supplied.
10. If appropriate, the neck strap can already be attached to allow quick fixation after insertion of the tube.

B, when using the obturator for re-insertion

Follow steps 1-6 as described above in and proceed as follows:
11. In case the obturator enclosed to the tracheostomy tube will be used, ensure that it can be easily moved in and out of the tube.
12. Ensure the envisaged suction catheter can be easily inserted through the tube.
13. Place the obturator in the tracheostomy tube.

14. Apply a thin film of lubricant gel to the protruding part of the obturator and the lower part of the tube including the cuff.
15. If appropriate, the neck strap can already be attached to allow quick fixation after insertion of the tube.

8.2 Preparing the Patient

Ensure that the patient is optimally pre-oxygenated immediately before insertion or re-insertion.
To facilitate insertion, slightly overextend the patient`s neck, if possible.

8.3 Inserting the Tube

A, with the Minimally Traumatic Insertion System

For initial insertion after tracheostomy, the following steps must be carried out subject to bronchoscopic monitoring:
1. The tracheotomised patient has been prepared for cannulation and a Seldinger wire has been inserted in the stoma canal.
2. Insert the Seldinger wire into the guiding catheter (which is mounted in inserter and tube) without pulling the Seldinger wire out of the trachea.
3. Place the proximal end of the white guiding catheter at the marking of the Seldinger wire.
4. Insert the tube together with inserter (1+9+10) and Seldinger wire through the tracheostoma into the trachea. Take care that tube, handle, guiding catheter, and Seldinger wire stay aligned by fixation with one hand. Any displacement may result in a gap in diameter between the silicone sleeve and tube and therefore difficult or impossible insertion.
5. Push the tube forward until the neck flange has reached skin level.
6. Then, the inserter and guiding catheter together with the Seldinger wire is pulled out while the tracheostomy tube remains in the trachea. Therefore, secure the tube with one hand and withdraw the minimally traumatic inserter, guiding catheter, and Seldinger wire.

Caution:

- After removing the inserter, ensure that the silicone sleeve is still located on the guiding catheter. If this is not the case, the radiopaque silicone sleeve must immediately be removed, i.e. from the tube or airways.

B, with the Obturator

The obturator is non-perforated and cannot be used in combination with a Seldinger wire.

1. Prepare tube and patient as described before (chapter “Preparation” and “Preparation the Patient”)
2. When inserting the tube into the tracheostoma hold the tube at the flange, and press the obturator firmly against the 15 mm connector.
3. Push the tube forward until the neck flange has reached skin level.
4. Remove the obturator immediately after insertion.

8.4 Following Tube Insertion

1. Check if the airway through the tube is unobstructed and if necessary, adjust the position of the tracheostomy tube (e.g. using a bronchoscope) and the neck flange, if necessary. The correct position of the flange of TRACOE *vario* tracheostomy tubes must be checked regularly.
2. Connect the 15 mm connector of the tracheostomy tube with the respiratory system, if ventilation is required.
3. If appropriate: Inflate the cuff of the tracheostomy tube with air through the Luer connector located at the pilot balloon.
4. If needed, the wings of the flange can be re-adjusted.
5. Secure the tube in place with the neck strap.
6. It is recommended that a dressing is placed between the tracheostoma and the adjustable flange in order to prevent irritation of the skin underneath the flange.
7. Re-check the cuff pressure in order to make sure that the cuff has not been damaged during the insertion.

8.5 Inflating the Cuff

Option 1: Instead of a standard syringe we recommend the use of a hand-held cuff pressure monitor. Adjust the cuff pressure to the individual ventilation therapy and check it at regular intervals. Typically, the pressure should be between 20 cmH2O (≈ 15 mm Hg) and 30 cmH2O (≈ 22 mm Hg).

Option 2: Use a TRACOE smart Cuff Manager to maintain the cuff pressure within the range of 20 to 30 cmH2O through passive control. Attach the male Luer of the TRACOE smart Cuff Manager to the female Luer of the check valve of the tracheostomy tube. Inflate the TRACOE smart Cuff Manager using a standard syringe according to the respective IFU.

Caution:

- When repositioning the patient, while in bed, ensure that the patient does not lie on the pilot balloon, as this could increase the cuff pressure and potentially damage the trachea.

8.6 Connecting/Disconnecting External Equipment

To connect to external equipment or accessories (e.g. ventilator) firmly hold the base of the 15 mm connector and gently push the connection end of the external device until it is securely attached to the tracheostomy tube.

Please make sure, that the connection is secure but also can be easily disconnected at a later time. In case of difficult disconnection use a standardized disconnect wedge (not supplied) to uncouple the tracheostomy tube from external equipment or accessories (see Image 4).

Caution:

- Do not use unnecessary force on the tracheostomy tube when connecting to or disconnecting from external devices. This may result in damage of the tracheostomy tube and/or displacement / decannulation.

8.7 Subglottic Suction

1. Remove the cap of the connector to perform intermittent suctioning with a syringe with male Luer connector.
2. An active suction device can be connected using the adaptors (**14**) (see image 5).
3. If the suction line becomes blocked, it can be cleared by blowing air through it or cleaning with 2 to 3 ml sterile saline solution while the cuff should remain sufficiently blocked (risk of aspiration).
4. Reseal the Luer connector with the cap after subglottic suctioning.

8.8 Above Cuff Vocalisation

Caution:

- ACV can be carried out by experienced professional personnel.

ACV is used in order to improve the patient’s quality of life. Therefore, it has to be adjusted to the individual patient’s needs and abilities. It is substantial that the patient is instructed to and involved in every step of ACV to ensure good cooperation and results during application.
Before using ACV ensure that the patient is wearing a tracheostomy tube with permanently inflated cuff and does not tolerate cuff deflation. If needed, air can be humidified before inflation through the subglottic suction line to prevent laryngeal drying out.

1. Explain the planned procedure to the patient. Indicate possible adverse reactions and clarify questions of the patient.

2. Verify that the upper airways are not obstructed.
3. Clear the subglottic space from secretions using subglottic suctioning.
4. Connect the adjustable air or oxygen supply via a fingertip connector to the Luer connector of the subglottic suction line. Alternatively, other devices for interruption of the permanent airflow may be used (e.g. Y-connector).
5. Inflate air slowly into the upper airways of the patient starting with 1 l/min and slowly rise to a typical flow rate of 3-6 l/min depending on patients' needs. To reduce laryngeal drying out, flow rates must not exceed 12 l/min. Use the fingertip connector to limit the time of flow given. This timeframe should be adapted to the exhaling rhythm. Adjust airflow and time within the comfort zone of the patient.
6. Monitor patient's reaction and adjust parameters (flow and time of airflow) as necessary.
7. Turn off the air flow and disconnect the equipment used.

Caution:

- The airflow through the upper airways may irritate the patient or may lead to increased secretion, coughing, or nausea.
- If the voice sounds gruff, repeat subglottic suction to clear the airway.
- Adjust the duration of a single ACV session to the capabilities/endurance of the patient.
- Use short episodes of ACV to prevent drying of the laryngeal mucosa.
- Regularly monitor patients with tracheostomies by educated staff.

8.9 Deflating the Cuff

Before deflating the cuff, ensure that as little secretions as possible enter the lower respiratory tract, e.g. by subglottic suctioning. For deflation attach a syringe (with the plunger pushed in) to the female Luer connector of the check valve. Pull the plunger back until all air is removed from the cuff. The cuff must be completely deflated (empty) prior to removal.

8.10 Removing the Tube

1. Slightly overextend the patient`s neck, if possible.
2. Unblock the cuff (see chapter "Deflating the Cuff").
3. Firmly hold the base of the 15 mm connector and gently pull the tracheostomy tube from the stoma.

If necessary, suctioning of secretions through the tube may be helpful to prevent infiltration into the lower respiratory tract.
4. Following removal, the tube should be cleaned as soon as possible to prevent encrustation of fluids.
5. If the product is damaged, do not reuse the tube. Please inform TRACOE Customer Service about the REF and LOT number. Do not discard the tube and follow instruction in chapter "Returns".

9. Care and Cleaning

Cleaning of the tracheostomy tube and obturator is intended to remove any bodily fluids or encrustation that may inhibit its clinical use.
Please take care to hold the tube after cleaning at the 15 mm connector and the obturator at its handle.
The following instruction for manual cleaning applies to all TRACOE *vario* models and sizes:
1. To clean the tube and obturator, rinse the devices separately under lukewarm (40 °C/104 °F) water of minimum drinking water quality until they are visibly clean and free of encrustations.
2. Particular attention should be taken to ensure the inside of the tube and the suction line is thoroughly rinsed.
3. For removal of residual debris brushes or swabs can be used.
4. Alternatively, the TRACOE tube clean cleaning kits can be used in accordance to their respective instructions for use.
5. After cleaning, rinse the tube with tap water or distilled water.
6. Place the tube and obturator on a clean dry towel and air-dry in an area free of airborne contaminants.
7. The tube and obturator are considered dry when there is no visual evidence of residual water. Please check, that the inner of the cuff is dry, too.
8. Finally, a visual and functional inspection prior to re-insertion should be performed to verify that the tube and the obturator are not damaged (also see chapter "Preparation").

Caution:

- The tracheostomy tube should be cleaned immediately after removal from the stoma to prevent drying of soil and contaminants.
- When cleaning, take care not to damage the cuff or the inflating line.
- The frequency of cleaning must be defined by the physician but must not exceed the allowed frequency.
- Maximum allowed cleaning frequency is once a day, otherwise biocompatibility and material stability could be impaired.
- The tubes must never be cleaned using agents or procedures which are not specified in this instruction.

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- The device is single patient use, therefore, the tube must be returned to the same patient.
- Failure to clean the device properly can result in damage to the tube, an increase in air resistance due to obstructions, or irritation/inflammation of the tracheal stoma.
- Since the upper respiratory tract is never free from microorganisms - even in healthy individuals – we do not recommend the use of disinfectants.
- The minimally traumatic inserter, guiding catheter, and Seldinger wire are single-use and not allowed to be cleaned and reused.

10. Storage

a) Store the factory delivered tracheostomy tubes in their original packaging according to the conditions displayed on the packaging.
b) Store cleaned tracheostomy tubes in a clean covered container, in a clean and dry location, and away from sunlight. Re-insert as soon as possible. Improper storage conditions may result in tube damage or contamination. Do not store the cleaned devices for more than 29 days from first use.

11. Packaging

The product is provided sterile (with ethylene oxide) which allows application under sterile conditions. TRACOE tracheostomy tubes do not require a sterile environment during normal use or cleaning.

12. Disposal

Used products are to be disposed of in accordance with the valid national regulations, waste management plans, or clinical procedures governing biohazardous waste materials, e.g. the direct disposal in a tear- and moisture-resistant and secure bag or container, which is routed to the local waste disposal system for contaminated medical products.
For further recommendations, contact your hygiene officer in health facilities or the local waste management for homecare use.

13. Returns and Complaints

Returned products, that have been used, will only be accepted, if TRACOE has agreed to the return and a completed decontamination certificate and complaint report is enclosed. These forms are available either directly from TRACOE medical, or via the website www.tracoe.com.

If the device is involved in a reportable incident, as defined in local medical device legislation, please contact TRACOE medical (complaints@tracoe.com), and the appropriate regulatory body in the country of use.

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14. Supplementary Products

TRACOE *vario* Tracheostomy Tubes with minimally traumatic insertion system are also available as TRACOE experc Set (REF 420 – REF 425) in combination with TRACOE experc Dilation Set (REF 520).

The TRACOE *percutan* Seldinger Guide Wire is part of the above-mentioned sets. It is also available separately with guiding catheter (REF 517) or without guiding catheter (REF 518).

14.1 Recommended Products

- Syringes with standard male Luer connector
- Cuff pressure monitors for HVLP-cuffs with standard male Luer connector (e.g. TRACOE cuff pressure monitor REF 720)
- TRACOE smart Cuff Manager (REF 730-5)
- TRACOE lubricating gel (REF 677) and other sterile water-soluble lubricating gels for tracheostomy applications
- neck straps (e.g. REF 903-F, REF 903-E, and REF 903-D)
- Disconnecting wedges for tracheostomy / endotracheal tubes with 15 mm connectors
- TRACOE *technic* connection tubes including Luer connector with integrated check valve
- Humid Moist Exchangers (HME) with a standard male 15 mm connector

14.2 Optional Products:

- Speaking valves and occlusion caps with a standard male 15 mm connector.
- TRACOE tube clean cleaning kit (REF 930-A / -B), including TRACOE tube clean cleaning powder (REF 932)
- TRACOE tube clean cleaning kit (REF 931-A / -B), including TRACOE tube clean cleaning liquid (REF 933)
- TRACOE cleaning swabs, and TRACOE brushes
- TRACOE shower guard
- dressings and compresses
- TRACOE protective bibs (REF 919-A, -B, -C)
- TRACOE protective scarves (REF 921-A to -E)
- TRACOE protective roll-necks (REF 923-A to -G)

15. General Terms and Conditions

The sale, delivery and return of all TRACOE products shall be affected exclusively on the basis of the valid General Terms and Conditions (GTC), which are available either from TRACOE medical GmbH or on our website at www.tracoe.com.