AORTIC PERFUSION CANNULA
Instructions for Use

Directory

English (EN)

AORTIC PERFUSION CANNULA

Instructions for Use

CAUTION: Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician.

DESCRIPTION

Edwards Lifesciences aortic perfusion cannulae terminate in a connector acceptance of 3/8" (9.5 mm) or 1/4" (6.3 mm). The catalog identifies models that are supplied with a 3/8" (9.5 mm), 1/4" (6.3 mm) connector, or vent plug. Cannulae are available in wire-reinforced and non-reinforced product codes with a wide variety of tip styles, including the EZ Glide tip.

Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

INDICATIONS FOR USE

Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (≤6 hours) cardiopulmonary bypass procedures.

Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

CONTRAINDICATIONS FOR USE

This device is not intended for use other than as indicated and should not be used when any physical impairment would contraindicate its use.

WARNINGS AND PRECAUTIONS

Supplied sterile and non-pyrogenic in undamaged package. Do not use if device shows signs of damage (i.e., cuts, kinks, crushed areas, leakage), or if package is damaged or open as this may indicate compromised sterility and/or product damage.

FOR SINGLE USE ONLY. This device is designed, intended, and distributed for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE THIS DEVICE. There are no data to support the sterility, non-pyrogenicity, and functionality of the device after reprocessing. Such action could lead to illness or an adverse event, as the device may not function as originally intended.

Products are known to contain phthalates, which may be found in device materials containing plasticizers such as DEHP and BBP. High exposure to such phthalates during medical treatments in children and pregnant or nursing women may raise a concern. A review of available data and literature supports the conclusion that the benefits outweigh the overall residual risk.

This device is intended for short-term use only (≤6 hours). There are no data to support the function and performance of the device beyond six hours of use.

DO NOT PRECOOL the EZ Glide cannula in an ice bath prior to use. Precooling can cause the tip to become brittle and prone to damage.

Orient curved tip of the cannula to direct flow away from the aortic valve. Improper orientation may lead to patient harm or excessive line pressures. Cannula with a curved tip will have a printed orientation line on the cannula body; do not use if line is missing or illegible.

Ensure that the vessel used is of adequate size to allow sufficient perfusion distal to the cannula after insertion.

When using small diameter cannulae, do not exceed the maximum pressure limit while increasing flow. A rapid pressure rise may result.

Keep the vent plug dry prior to use. The porous vent plug is designed to vent air when dry and may not function as intended if wet.

Line pressure exceeding acceptable clinical limits may result from incorrect cannula tip position and/or restricted tip patency. Confirm proper placement to minimize risk of injury.

Wire-reinforced cannulae should be clamped in the non-reinforced section located at the connector end since clamping of the reinforced section may produce permanent cannula deformation, thereby impeding flow through the cannula and risking puncture or tearing of the cannula.

Ensure proper levels of anticoagulant therapy are maintained prior to insertion of the cannula and throughout cardiopulmonary bypass, to reduce the risk of complications due to thrombus formation on or within the cannula, and in the blood stream.

If increased resistance is felt at any time upon insertion or removal of the cannula, stop and investigate the cause before continuing. Inability to easily advance or remove these devices may indicate vascular disease or injury. Closely examine the device position within the vessel using fluoroscopy and/or ultrasound imaging prior to proceeding.

Avoid over-insertion of the cannula to reduce risk of cannula impingement against the vessel walls which may lead to excessive line pressures and vessel damage.

Securely tie-band the connector to cannula junction prior to initiating bypass to protect against tubing slippage.

Monitor vessel patency and hemostasis after removal of cannula to avoid possible injury and/or blood loss.

Prior to initiating cardiopulmonary bypass, completely expel air from the system. Failure to eliminate air from the system could result in an air embolus.

Proper surgical procedures and techniques are the responsibility of the medical professional. Described procedures are provided for informational purposes only. Each physician must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.

Dispose of used product in accordance with established hospital protocols for biohazards to minimize risk of exposure.

DIRECTIONS FOR USE

Note: If suture ring assembly is required prior to aortic cannulation, remove suture ring from pouch and slide over cannula tip to desired location.

WARNING: When using small diameter cannulae, do not exceed the maximum pressure limit while increasing flow. A rapid pressure rise may result.

1. Using standard surgical technique, place cannula so that proper perfusion can take place.
2. For cannulae marked with an orientation line, tip direction is indicated by referencing the orientation mark on the cannula body in relationship to the direction of flow as it exits the cannula tip. Orient the curved tip so the flow is directed superiorly, away from the aortic valve.
3. If supplied, the white porous vent plug is designed to fit securely into the back of the lumen of aortic perfusion cannulae without a pre-attached connector. For cannulae with a pre-attached connector, the red vent cap is designed to fit securely around the connector barb. Use the appropriate porous vent plug or vent cap to ensure proper function.
4. Products that state "quick venting cap" on the label (EZQ) contain a vent cap designed to allow venting while wet. This cap may leak blood while venting.
5. Secure cannula. Connect to circuit tubing and securely tie-band all line connections.
6. Upon completion of procedure, remove cannula and repair aortotomy. Graphs of Pressure-Flow relationships are provided at the end of these instructions. Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Made in Mexico

Français (FR) French

CANULE DE PERFUSION AORTIQUE

Mode d'emploi

DESCRIPTION

L'extrémité des canules de perfusion aortique Edwards Lifesciences accepte des raccords de 9,5 mm (3/8 po) ou 6,3 mm (1/4 po). Le catalogue indique les modèles fournis avec un bouchon de ventilation ou un raccord de 9,5 mm (3/8 po) ou 6,3 mm (1/4 po). Les canules sont disponibles en codes produit avec ou sans renfort, avec une large variété d'embouts, notamment EZ Glide.

Chaque dispositif Edwards Lifesciences est conditionné de manière stérile et apyrogène dans une pochette hermétique pelable.

INDICATIONS

Les canules de perfusion aortique sont indiquées pour la perfusion de l'aorte au cours d'interventions rapides (d'une durée inférieure ou égale à 6 heures) de circulation extracorporelle.

EP0043

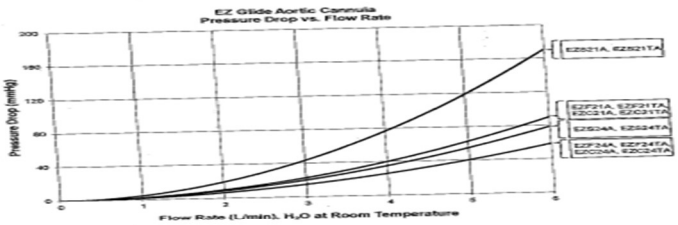

CHART LEGEND - LÉGENDE DU GRAPHIQUE - ZEICHENERKLÄRUNG - SIGNIFICADO DEL CUADRO - LEGENDA DEL GRAFICO - LEGENDA TABEL - DIAGRAMFORKLARING - DIAGRAMFÖRKLARING - ΥΠΟΜΝΗΜΑ ΓΡΑΦΗΜΑΤΩΝ - LEGENDA DA TABELA DIAGRAMMAS SKAIDROJIMS - GRAFIK AÇIKLAMALARI - УСЛОВНЫЕ ОБОЗНАЧЕНИЯ ДИАГРАММЫ - LEGENDA GRAFIKONA

EN	EZ Glide Aortic Cannula Pressure Drop vs. Flow Rate	Pressure Drop (mmHg)	Flow Rate (L/min), H_2O at Room Temperature
FR	Canule aortique EZ Glide Rapport baisse de pression-débit	Baisse de pression (mmHg)	Débit (L/min), H_2O à température ambiante
DE	EZ Glide Aortenkanüle Druckabfall im Vergleich zur Flussrate	Druckabfall (mmHg)	Flussrate (l/min), H_2O bei Zimmertemperatur
ES	Cánula aórtica EZ Glide Caída de presión en comparación con flujo	Caída de presión (mmHg)	Flujo (l/min), H_2O a temperatura ambiente
IT	Cannula aortica EZ Glide Riduzione della pressione in funzione della portata	Riduzione della pressione (mmHg)	Portata (L/min), H_2O a temperatura ambiente
NL	EZ Glide aortische canule Drukafname vs. stroomsnelheid	Drukafname (mmHg)	Stroomsnelheid (l/min), H_2O bij kamertemperatuur
DA	EZ Glide aortakanyle Trykfald vs. flowhastighed	Trykfald (mmHg)	Flowhastighed (L/min), H_2O ved stuetemperatur
SV	EZ Glide kanyl, aorta Tryckfall gentemot flödeshastighet	Tryckfall (mmHg)	Flödeshastighet (L/min), H_2O vid rumstemperatur
EL	Αορτική κάνουλα EZ Glide Πτώση πίεσης προς ρυθμό ροής	Πτώση πίεσης (mmHg)	Ρυθμός ροής (l/λεπτό), H_2O σε θερμοκρασία δωματίου
PT	Cânula Aórtica EZ Glide Queda de pressão vs. Taxa de fluxo	Queda de pressão (mmHg)	Taxa de fluxo (L/min), H_2O à temperatura ambiente
CS	Aortální kanyla EZ Glide Pokles tlaku vs. průtok	Pokles tlaku (mmHg)	Průtok (l/min), H_2O při pokojové teplotě
HU	EZ Glide aortakanül Nyomásesés az áramlási sebesség függvényében	Nyomásesés (Hgmm)	Áramlási sebesség (l/perc), H_2O szobahőmérsékleten
PL	Kaniula aortalna z końcówką EZ Glide — spadek ciśnienia a szybkość przepływu	Spadek ciśnienia (mmHg)	Szybkość przepływu (l/min), H_2O w temperaturze pokojowej
SK	Aortálna kanyla EZ Glide Pokles tlaku vs. prietok	Pokles tlaku (mmHg)	Prietok (l/min), H_2O pri izbovej teplote
NO	EZ Glide aortisk kanyle Trykkfall vs. strømningshastighet	Trykkfall (mmHg)	Strømningshastighet (l/min), H_2O ved romtemperatur
FI	EZ Glide -aorttakanyyli Paineen lasku suhteessa virtausnopeuteen	Paineen lasku (mmHg)	Virtausnopeus (l/min), H_2O huoneenlämpötilassa
BG	Аортна канюла EZ Glide Спад на налягането спрямо скорост на потока	Спад на налягането (mmHg)	Скорост на потока (L/min), H_2O при стайна температура
RO	Canulă aortică EZ Glide Scădere de presiune vs. debit	Scădere de presiune (mmHg)	Debit (l/min), H_2O la temperatura camerei
ET	EZ Glide aordikanüül Rõhulangus vs voolukiirus	Rõhulangus (mmHg)	VooluKiirus (l/min), H_2O toatemperatuuril
LT	„EZ Glide" aortinė kanulė Spaudimo kritimas, palyginti su srauto greičiu	Spaudimo kritimas (mmHg)	Srauto greitis (l/min), H_2O esant kambario temperatūrai
LV	EZ Glide aortas kanula Spiediena kritums pret plūsmas ātrumu	Spiediena kritums (mmHg)	Plūsmas ātrums (l/min), H_2O istabas temperatūrā
TR	EZ Glide Aort Kanülü Basınç Düşüşü Ile Akış Hızı Karşılaştırması	Basınç Düşüşü (mmHg)	Akış Hızı (L/dk), H_2O, Oda Sıcaklığında
RU	Аортальная канюля EZ Glide Падение давления и скорость потока	Падение давления (мм рт. ст.)	Скорость потока (л/мин), H_2O при комнатной температуре
RS	EZ Glide aortna kanila Pad pritiska prema brzini protoka	Pad pritiska (mmHg)	Brzina protoka (l/min), H_2O na sobnoj temperaturi