intubation stylet

sterile

features

- made of PVC-coated aluminium
- special material for both stiffness and pliability
- intended for use during difficult intubation
- size and diameter markings
- soft distal tip
- single-use
- phthalate-free
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

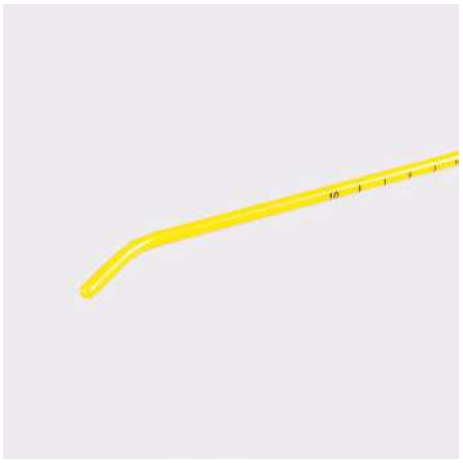
indication

- allows you to give the endotracheal tube the right curvature
- introduced to the endotracheal tube facilitates intubation in routine and difficult cases, when the laryngeal inlet is not visible

REF	size	diameter	length	tube size	intermediate packaging	bulk packaging
PRI-06	6 Fr	2,0 mm	310 mm (±10)	from 2,0 to 4,0	20 pcs	20 x 20 pcs
PRI-10	10 Fr	3,3 mm	390 mm (±10)	from 4,5 to 6,5	20 pcs	20 x 20 pcs
PRI-14	14 Fr	4,7 mm	390 mm (±10)	from 7,0 to 10,0	20 pcs	20 x 20 pcs

tracheal tube introducer

curved, sterile



features

- made of medical grade low density polyethylene
- curved and rounded tip enables safe intubation without damaging the soft tissues
- optimum flexibility and rigidity facilitate correct insertion and safe removal of the introducer after intubation
- imprint of the size, diameter and manufacturer's name on the device
- bright yellow body for increased visibility of the introducer in the tracheal tube canal
- clear, easy to read graduation every 1 cm
- available in three sizes and lengths
- single-use
- PVC free
- latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- for use during difficult intubation procedures
- as an aid to facilitate the insertion of the endotracheal tube during standard intubation

bulk packaging:
20 x 10 pcs

REF	size	diameter O.D.	total length	tube size	graduation	intermediate packaging
PTIZ-06-535	6 Fr	2,0 mm	535 mm	from 2,0 to 4,0	10 – 45 mm	10 pcs
PTIZ-10-600	10 Fr	3,3 mm	600 mm	from 4,5 to 6,0	10 – 50 mm	10 pcs
PTIZ-10-800	10 Fr	3,3 mm	800 mm	from 4,5 to 6,0	10 – 60 mm	10 pcs
PTIZ-15-600	15 Fr	5,0 mm	600 mm	from 6,5 to 10,0	10 – 50 mm	10 pcs
PTIZ-15-800	15 Fr	5,0 mm	800 mm	from 6,5 to 10,0	10 – 60 mm	10 pcs

endotracheal tube

uncuffed, sterile

features

- made of flexible PVC
- radiopaque line over the entire tube length
- equipped with lateral Murphy eye
- graduated every 1 cm
- double depth marker to control the position of the tube
- tube size marked in 3 places (on the connector and in two places on the tube body)
- detachable connector with an outer diameter of 15 mm
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- for both oral and nasal intubation
- inserted into the trachea to prevent airway obstruction and respiratory failure

REF	size	intermediate packaging
RIB-20	I.D. (mm) 2.0	20 pcs
RIB-25	I.D. (mm) 2.5	20 pcs
RIB-30	I.D. (mm) 3.0	20 pcs
RIB-35	I.D. (mm) 3.5	20 pcs
RIB-40	I.D. (mm) 4.0	20 pcs
RIB-45	I.D. (mm) 4.5	20 pcs
RIB-50	I.D. (mm) 5.0	20 pcs
RIB-55	I.D. (mm) 5.5	20 pcs
RIB-60	I.D. (mm) 6.0	20 pcs
RIB-65	I.D. (mm) 6.5	20 pcs
RIB-70	I.D. (mm) 7.0	20 pcs
RIB-75	I.D. (mm) 7.5	20 pcs
RIB-80	I.D. (mm) 8.0	20 pcs
RIB-85	I.D. (mm) 8.5	20 pcs
RIB-90	I.D. (mm) 9.0	20 pcs
RIB-95	I.D. (mm) 9.5	20 pcs
RIB-100	I.D. (mm) 10.0	20 pcs

bulk packaging:
10 x 20 pcs

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139535 0001

Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs
  (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges
  (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls
  (with or without X-ray thread)
- Sterile and non-sterile gauze rolls
  (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
  (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 2/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 3/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 4/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannulla fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 5/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity: Production

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023663-1

Organization: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Scope: Design and development, manufacture and distribution of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes.
Manufacture and distribution of sterile and non-sterile disposable medical devices and non-sterile reusable medical devices.
Distribution of in-vitro medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the above mentioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Rafał Byczkowski
TR LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02