

Naudojimui su indukciniai pakrovėjais 8546LE1, Bateriniai įdėklais Xenon 8546A, Bateriniai įdėklais LED 8546LD1, pakraunamais bateriniais įdėklais LED 8549LD ir šaltos šviesos laringoskopais.
p. 3.1.

P-GRIP™ Handles for **Cold Light Laryngoscope Blades**

Standard Handles

Šaltos šviesos laringoskopų mentelės.
p. 6.

NEW
Baterinis įdėklas, pakraunamas, ilgis 12 cm, ličio jonų baterinis įdėklas, kraunamas indukcinio pakrovėjo.
p. 3.2.

8546

Handle Sleeve, with green silicone coating, ISO 7376, **autoclavable**, standard P-GRIP™ handle, for use with **Inductive Charging Unit 8546 LE1, Battery Insert Xenon 8546 A, Battery Insert LED 8546 LD1, rechargeable, Battery Insert Set LED 8549 LD and cold light laryngoscopes**

8546 LD1

Battery Insert, rechargeable, length 12 cm, for Handle Sleeve 8546, with high-power-LED, > 56 lm / > 100 klx, **lithium-ion battery insert**, burning time 240 min at 100% brightness, **charging via Inductive Charging Unit 8546 LE**

8549 LDX

Battery Insert Set LED, length 12 cm, with high-power LED, > 56 lm / >100 klx, burning time at 100% brightness > 120 min, for use with Handle Sleeve 8546 and cold light laryngoscopes including:

Battery Insert, high-power LED
2x **Battery**, Mignon-cell, LR 06, 1.5 V
Cap



8546



8546 LD1



8549 LDX

Slim Handles

NEW

8547

Handle Sleeve, with green silicone coating, ISO 7376, **autoclavable**, slender P-GRIP™ handle, for use with battery insert set LED, slim 8547 LDX, battery inserts Xenon, slim 8547 A, 8547 B and cold light laryngoscopes

8547 BK

Battery Insert Xenon, slim, rechargeable, length 12 cm, charging via Inductive Charging Unit 8546 LE/LE1 including:
Xenon Lamp

8547 LDX

Battery Insert Set LED, slim, length 12 cm, with high-power LED, burning time > 120 min at 100% brightness, for use with Handle Sleeve 8547 and cold light laryngoscopes including:

Battery
Cap



8547



8547 BK

NEW



8547 LDX

- High-performance LED with extremely bright light
- Battery lasts 5 hours after each charge
- **Over 5,000 reprocessing cycles**
- Battery life with over 1,000 charge cycles
- Inductive charging unit specially adapted to the new handle

Daugiau nei 5000
apruošimo ciklų.
p. 1.1.

Aukštos kokybės nerūdijančio plieno
mentelės (Macintosh 3 ir 4).
p. 4.

High-quality stainless steel
blade (MACINTOSH
3 and 4)

LED power with
100,000 Lux

Handle manufactured in
one piece from stainless
steel

Rankena pagaminta iš
vieno nerūdijančio plieno
gabalo.
p. 3.3.

Non-slip surface

Neslystantis paviršius.
p. 3.3.

Rechargeable or
battery-powered

It is recommended to check the suitability of the product for the intended procedure prior to use.

EC-DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG

Device Name
Produkt Name **Handle Sleeve, 12 cm**

Model Number(s)
Modell Nummer(n) **8546**

Classification
Klassifizierung Class I per Annex IX, Rule 4 of Council Directive 93/42/EEC
Klasse I gemäß Anhang IX, Regel 4 der Richtlinie 93/42/EWG des Rates

Rankenos mova, 12 cm.
p. 3.2.

We herewith declare under our sole responsibility that the device mentioned above meets the Essential Requirements as defined in Annex I MDD 93/42/EEC.
Wir erklären hiermit unter alleiniger Verantwortung, dass das oben genannte Produkt die Grundlegenden Anforderungen gemäß Anhang I MDD 93/42/EWG erfüllt.

This Declaration of Conformity is issued according to Annex VII Council Directive 93/42/EEC for Medical Devices (*for class I devices*).
Diese Konformitätserklärung ist erstellt gemäß Anhang VII Richtlinie 93/42/EWG des Rates über Medizinprodukte (*für Klasse I Produkte*).

Full list of applied standards, directives and laws (12-C2.3F013-LOAS-RA) on request.
Vollständige Liste angewandter Normen, Richtlinien und Gesetze (12-C2.3F013-LOAS-RA) auf Anfrage.

This Declaration is valid until: 2018-07-16
Diese Erklärung ist gültig bis: 2018-07-16



Karl Storz GmbH & Co. KG
Mittelstraße 8
78532 Tuttlingen
Germany

Tuttlingen, 23 August 2013

i.d.

Anatol Montagna
-International Director Global
Regulatory Affairs-
Authorized Person

*This declaration loses all validity if Karl Storz GmbH & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by Karl Storz GmbH & Co. KG was made at the device mentioned above.
Diese Erklärung verliert ihre Gültigkeit sobald Karl Storz GmbH & Co. KG Produktänderungen durchführt, welche die Konformität mit den Grundlegenden Anforderungen beeinflusst oder eine Änderung jeglicher Art ohne Freigabe durch die Karl Storz GmbH & Co. KG am oben genannten Produkt durchgeführt wird.*

8.10 Verpackungssysteme

Es dürfen nur genormte und zugelassene Verpackungsmaterialien und -systeme eingesetzt werden (EN 868 Teil 2-10, EN ISO 11607 Teil 1 + 2, DIN 58953).

8.11 Sterilisation

Die Abläufe sowie die prozessrelevanten Parameter der einzelnen validierten Verfahren sind in der Anleitung „Reinigung, Desinfektion, Pflege und Sterilisation von KARL STORZ Instrumenten“ detailliert beschrieben. Die Wahl des Verfahrens muss unter Berücksichtigung der jeweiligen nationalen Anforderungen und in Absprache mit den Geräteherstellern erfolgen.

Folgende Verfahren zur Sterilisation wurden von KARL STORZ für dieses Medizinprodukt validiert und freigegeben:

- Dampfsterilisation im fraktionierten Vorvakuumverfahren

Das Medizinprodukt (Handgriffhülse und Laryngoskopspatel sowie Fiberglas-Lichtträger bei TAKE-APART® Kaltlicht-Laryngoskopspateln) im fraktionierten Vorvakuumverfahren (DIN EN ISO 17665-1) bei 134 °C – 137 °C mit einer Mindesteinwirkzeit von 4 bis maximal 18 Minuten sterilisiert werden. Diese Verfahren sind nur für thermostabile Instrumente geeignet.

HINWEIS: Gefettete Komponenten sind zerlegt der Sterilisation zuzuführen, damit die Dampfdurchdringung sichergestellt ist.

- Wasserstoffperoxid (H₂O₂)-Sterilisation – ASP
- STERRAD®

! WARNUNG: Medizinprodukte müssen im zerlegten Zustand sterilisiert werden.

! WARNUNG: Bitte beachten Sie, dass es Einschränkungen gibt, was in den verschiedenen STERRAD® Sterilisationssystemen sterilisiert werden kann, basierend auf Material.

! VORSICHT: Detaillierte Informationen sind dem Benutzerhandbuch des jeweiligen Gerätes zu entnehmen.

i HINWEIS: Anhand des „STERRAD® Sterility Guide“ kann sichergestellt werden, ob das jeweilige Medizinprodukt in den unterschiedlichen STERRAD® Geräten sterilisierbar ist.

i HINWEIS: An gefetteten und geölte Oberflächen ist die Sterilisation nicht möglich.

8.10 Packaging systems

Only standardized and approved packaging materials or systems may be used (EN 868 Parts 2-10, EN ISO 11607 Parts 1 + 2, DIN 58953).

8.11 Sterilization

The procedures as well as the process-relevant parameters for the individually validated methods are described in detail in the manual 'Cleaning, Disinfection, Care and Sterilization of KARL STORZ Instruments'. The method must be selected taking into account the respective national requirements and in consultation with the device manufacturers.

The following sterilization methods have been validated and approved by KARL STORZ for this medical device:

- Steam sterilization using the fractionated prevacuum procedure

The medical device (handle sleeve and laryngoscope blade as well as fiberoptic light carrier on TAKE-APART® coldlight laryngoscope blades) must be sterilized using a fractionated prevacuum procedure (DIN EN ISO 17665-1) at 134 °C – 137 °C with a minimum exposure time of 4 minutes and maximum of 18 minutes. This procedure is only suitable for thermostable instruments.

i NOTE: Greased components must be disassembled for sterilization, so that steam penetration is ensured.

- Hydrogen peroxide (H₂O₂) sterilization – ASP
- STERRAD®

! WARNUNG: Medical devices must be dismantled for sterilization.

! WARNUNG: Please note that there are restrictions concerning the instruments which can be sterilized in the different STERRAD® sterilization systems in respect of material.

! CAUTION: For more detailed information, please consult the user handbook of the respective device.

i NOTE: Refer to the 'STERRAD® Sterility Guide' to ensure that the medical device concerned can be sterilized using the different STERRAD® devices.

i NOTE: Lubricated and oiled surfaces cannot be sterilized.

8.10 Sistemas de embalaje

Solamente deben utilizarse materiales y sistemas de embalaje normalizados y homologados (EN 868 partes 2-10, EN ISO 11607 partes 1 + 2, DIN 58953).

8.11 Esterilización

Los procesos, así como los parámetros relevantes de los mismos, de cada uno de los procedimientos validados se describen detalladamente en la Instrucción "Limpieza, desinfección, conservación y esterilización

Medicinos įrenginys (rankenos mova ir laringoskopo mentelė, taip pat ir fibrooptinis šviesolaidis Take Apart šaltos šviesos laringoskopo mentelės turi būti sterilizuojamas, naudojant frakcionoto prevakuomo procedūrą (DIN EN ISO 17665-1) 134+137 laipsn. C temperatūroje.

p. 1.

Estimice el producto médico (el casquillo del mango, la espátula para laringoscopio y el portaluz de fibra de vidrio de las espátulas para laringoscopio de luz fría TAKE-APART®) por el procedimiento de prevacío fraccionado (DIN EN ISO 17665-1) a 134 °C – 137 °C durante un tiempo mínimo de aplicación de 4 y un máximo de 18 minutos. Estos procedimientos solo son adecuados para instrumentos termoestables.

i NOTA: Los componentes engrasados deben esterilizarse desmontados para asegurar la penetración del vapor.

- Esterilización con peróxido de hidrógeno (H₂O₂) – ASP
- STERRAD®

! CUIDADO: Los productos médicos han de esterilizarse desmontados.

! CUIDADO: Tenga en cuenta que las posibilidades de esterilización de instrumentos en los diferentes sistemas STERRAD® están sujetas a limitaciones dependiendo del material.

! ADVERTENCIA: En el Manual del usuario del aparato correspondiente puede consultar información detallada al respecto.

i NOTA: Consulte la guía "STERRAD® Sterility Guide" para comprobar si el producto médico correspondiente puede ser esterilizado en los diferentes aparatos STERRAD®.

i NOTA: Las superficies engrasadas y lubricadas con aceite no son aptas para la esterilización.

Akumuliatoriniai įdėklai su LED šviesos šaltiniais šaltos šviesos laringoskopų mentelėms.
p. 6.1.



Battery Inserts with LED Light Source

For cold light laryngoscope blades

Special Features:

Šviesus LED, daugiau nei 56lm / >100000 lux.
p. 6.2., p. 6.3.

- Very bright LED of more than 56 lm / >100,000 Lux
- Standard LED inserts available with rechargeable Li-ion or disposable batteries
- LED with a service life of more than 50,000 hours; no need to replace lamp
- Depending on the battery charge, burning time up to 240 min at 100% brightness
- Rechargeable lithium-ion batteries with 1,000 charging cycles

LED tarnavimo laikas daugiau nei 50000 valandų nekeičiant lemputės;
p. 6.4.
Priklausomai nuo akumuliatoriaus pakrovimo, 100% šviesumu, veikimo laikas siekia
240 min.
p. 7.2.
Įkraunamas ličio jonų akumuliatorius.
p. 7.1.



Handles with LED Light Source

for Cold Light Laryngoscope Blades



Absoliučiai balta šviesa dėka LED technologijos (5500 K) p. 2.2.

Special Features:

- Rechargeable lithium-ion batteries
- Extremely bright LED of more than 50 lm/> 100 klx
- **Absolute white light due to LED technology (5500 K)**
- Small handle with photo battery
- Special lens system allows optimal light adjustment at the blade connector
- LED provides a lifetime of more than 50,000 hours
- Burning time up to 240 min at 100% brightness
- Charging via inductive technology
- ISO 7376 compatible



8546



8546 LD1



8549 LDX



8548



8548 LDX1

8546 **Handle Sleeve**, ISO 7376, **autoclavable**, length 12 cm, for use with Battery Inserts 8546 A, 8546 LD, 8549 LD and cold light laryngoscopes

8546 LD1 **Battery Insert, rechargeable**, length 12 cm, for Handle Sleeve 8546, **with high-power LED**, 56 lm/> 100 klx, lithium-ion battery insert, burning time at 100% brightness 240 min, charging via Inductive Charging Unit 8546 LE (see page 31)

NEW 8549 LDX **Battery Insert Set LED**, length 12 cm, for Handle Sleeve 8546 and cold light laryngoscopes, **with high-power LED**, > 56 lm/ >100 klx, burning time at 100% brightness > 120 min including:
Battery Insert, high-power LED
 2x **Battery**, Mignon-Cell, LR 06, 1.5 V
Cap

8548 **Handle Sleeve**, ISO 7376, length 6 cm, **autoclavable**, for use with Battery Insert Set 8548 LDX

8548 LDX1 **Battery Insert Set**, length 6 cm, for Handle Sleeve 8548, **with high-power LED**, > 56 lm/> 100 klx, burning time at 100% brightness > 120 min including:
Battery Insert, high-power LED
Photo Battery, CR 123 A
Cap

Components/Spare Parts see chapter 7

Indukcinių baterijų pakrovėjas
Pakraunamų laringoskopų rankenoms
p. 2.1.

Inductive Battery Charger

For rechargeable laryngoscope handles



Special Features:

- Modified with larger inner diameter for the new P-GRIP™ handles
- No open contacts due to inductive technology
- No corrosion or contact problems
- No voltage peaks extends the lifespan of the rechargeable batteries
- **Batteries can be charged with or without handles – sterile packaging**
- For use with LED or rechargeable Xenon handles
- Compatible with previous rechargeable battery models

Baterijos gali būti kraunamos su arba
be rankenų - sterilioje pakuotėje
p. 8.2.

ISO Standard (applies to blades and handles):

- KARL STORZ laryngoscopes comply with ISO Standard 7376
- Ensures compatibility of any handles and blades with this standard

Green P-GRIP™ handle



Blade marked with a green dot



All handles with black cap have rechargeable Li-ion batteries
All handles with green cap have disposable batteries

Inductive Battery Charger

For rechargeable laryngoscope handles



Special Features:

- Modified with larger inner diameter for the new P-GRIP™ handles
- **No open contacts due to inductive technology**
- No corrosion or contact problems
- No voltage peaks extends the lifespan of the rechargeable batteries
- **Batteries can be charged with or without handles – sterile packaging**
- For use with LED or rechargeable Xenon handles
- Compatible with previous rechargeable battery models

Jokių atvirų kontaktų dėka indukcinės technologijos p. 2.1.

Baterijos gali būti kraunamos su arba be rankenų - sterilioje pakuotėje p. 8.2.

ISO Standard (applies to blades and handles):

- KARL STORZ laryngoscopes comply with ISO Standard 7376
- Ensures compatibility of any handles and blades with this standard

Green P-GRIP™ handle



Blade marked with a green dot



All handles with black cap have rechargeable Li-ion batteries
All handles with green cap have disposable batteries

Technische Daten

Versorgungsspannung

100 VAC ... 240 VAC, 50 ... 60 Hz, 0,4 A

Netzanschluss

Netzanschlussadapter für EU/UK/USA/AUS

Kabel Länge: 2 m

Statusanzeige durch LED

Steckernetzteil
grün: betriebsbereit, Netzspannung

Induktyvaus pakrovimo stotelė.
Paruošta naudojimui kiekviena iš dviejų
pakrovimo skyrių.
p. 8.1.

Lager:
-20 °C ... +45 °C / 10 % ... 85 % rel. Feuchte
nicht kondensierend
Betrieb:
0 °C ... +40 °C / 30 % ... 70 % rel. Feuchte
nicht kondensierend

Maße

Steckernetzteil
ca. (87 x 52 x 33) mm
(ohne Netzanschlussadapter)
Ladestation
ca. (120 x 60 x 77) mm

Gewicht

Steckernetzteil
ca. 130 g
Ladestation
ca. 300 g

Technical Data

Supply voltage

100 VAC ... 240 VAC, 50 ... 60 Hz, 0,4 A

Power supply

Power supply adaptor for EU/UK/USA/AUS

Cable Length: 2 m

LED status display

AC adaptor
green: ready for use, line voltage
present

Inductive charging station
green: ready for use
for each of the 2 charging compartments
green: the battery is completely charged
orange: recharging in progress.

Ambient conditions

Storage:
-20°C ... +45°C / 10% ... 85% rel. humidity
non-condensing
operation:
0°C ... +40°C / 30% ... 70% rel. humidity
non-condensing

Dimensions

AC adaptor
approx. (87 x 52 x 33) mm
(without power supply adaptor)
Charging station
approx. (120 x 60 x 77) mm

Weight

AC adaptor
approx. 130 g
Charging station
approx. 300 g

Datos técnicos

Tensión de alimentación

100 V CA ... 240 V CA, 50 ... 60 Hz, 0,4 A

Conexión a la red

Adaptador de conexión a la red para UE/GB/
EE.UU./AUS

Cable longitud: 2 m

Indicador de estado por diodo luminoso

Adaptador de alimentación enchufable
verde: listo para el servicio, tensión de red
disponible

Estación de carga por inducción
verde: lista para el servicio
para cada uno de los 2 compartimientos
verde: la pila está totalmente cargada
naranja: recarga en curso

Clima

Almacenamiento:
-20 °C ... +45 °C / 10 % ... 85 % hum. relat.
sin condensación
Servicio:
0 °C ... +40 °C / 30 % ... 70 % hum. relat.
sin condensación

Dimensiones

Adaptador de alimentación enchufable
aprox. (87 x 52 x 33) mm
(sin adaptador de conexión a la red)
Estación de carga
aprox. (120 x 60 x 77) mm

Peso

Adaptador de alimentación enchufable
aprox. 130 g
Estación de carga
aprox. 300 g

MACINTOSH Laryngoscope Blades

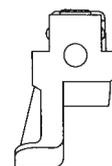
Fiber Optic Light Carrier Incorporated

autoclavable

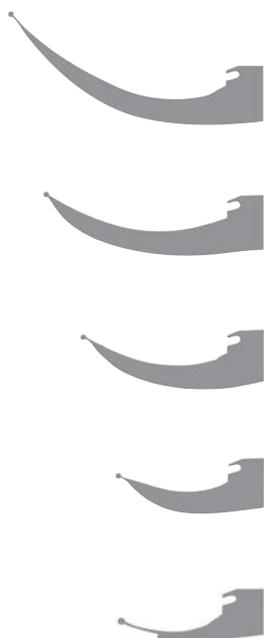


Macintosh laringoskopų mentelės su integruotu šviesolaidžiu. p. 4.1., p. 4.2.

8546
8546 LD1
8549 LDX



8541 AA - E



8541 AA MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 5

Macintosh laringoskopo mentelė, dydis 4. p. 2.3., p. 5.

8541 A **MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 4**

Macintosh laringoskopo mentelė, dydis 3. p. 2.2., p. 5.

8541 B **MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 3**

8541 C MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 2

8541 D MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 1

8541 E MACINTOSH Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 0

Miller laringoskopų mentelės su integruotu šviesolaidžiu. p. 5.1.

MILLER Laryngoscope Blades

Fiber Optic Light Carrier Incorporated

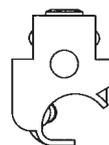
autoclavable

Integruotas fibrooptinis šviesolaidis. p. 5.2.

8546
8546 LD1
8549 LDX



8537 A-E



8537 A MILLER Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 4

Miller laringoskopo mentelė, dydis 3. p. 2.4., p. 5.

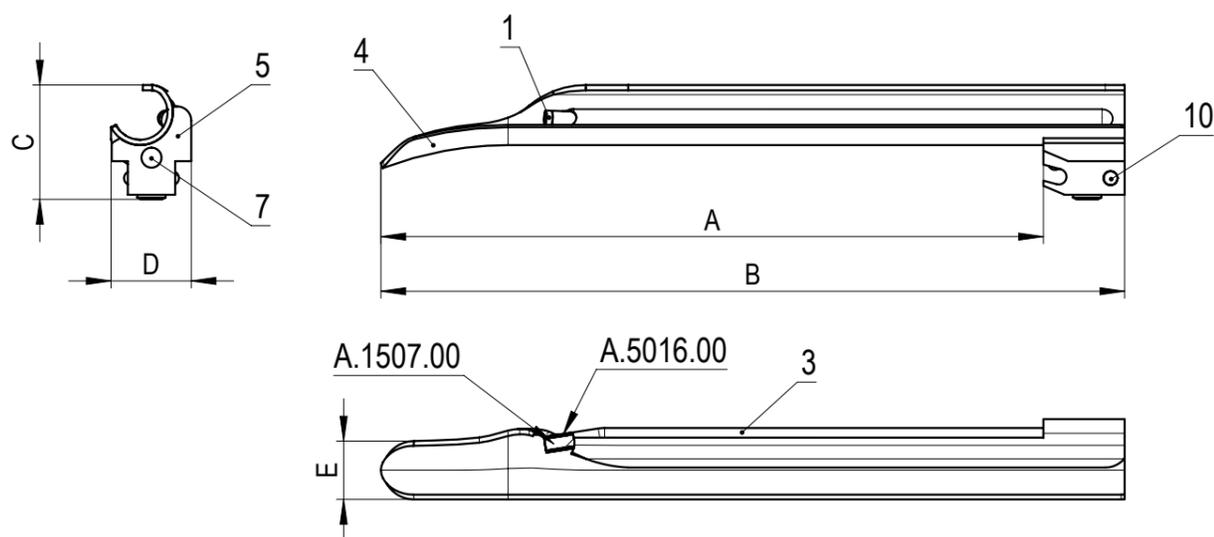
8537 B **MILLER Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 3**

8537 C MILLER Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 2

8537 D MILLER Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 1

8537 E MILLER Laryngoscope Blade, cold light, fiber optic light carrier incorporated, size 0

Engineering drawing:



part-number (BC)	A	B	C	D	E
8537A	187,5	210,5	32,6	22,7	16,5
8537B	169,5	192,5	31,1	22,5	13,0
8537C	130,5	153,5	29,8	22,5	14,0
8537D	79,5	102,5	28,5	22,5	11,0
8537E	55,5	78,5	28,5	22,5	11,5

Specific properties:

Total length	see table (BC)
Working length	see table
Outer diameter	N/A (BC)
Inner diameter	N/A
Color code	Green
Direction of view	N/A
Field of view	N/A

Vertraulich / Confidential

General properties:

Insulation	No	electr. connector	No
Use	Placement of endotracheal tubes		
Medical field	Anesthesia	Product status	
Typical application	Intubation		
Sterilization	autoclaveable	Date	22.12.2016
Version: BC	Changed:	Releaser:	Page 1 of 2

Medžiaga:
1.4305, 1.4301
p. 5.3.

POS.-NR.	Material	Treatment (BB)
1	1.4305	chrome surface
3	1.4301	chrome surface
4	1.4301	chrome surface
5	1.4305	chrome surface
7	PPSU GREEN	
10	1.3541 (BC)	

Vertraulich / Confidential