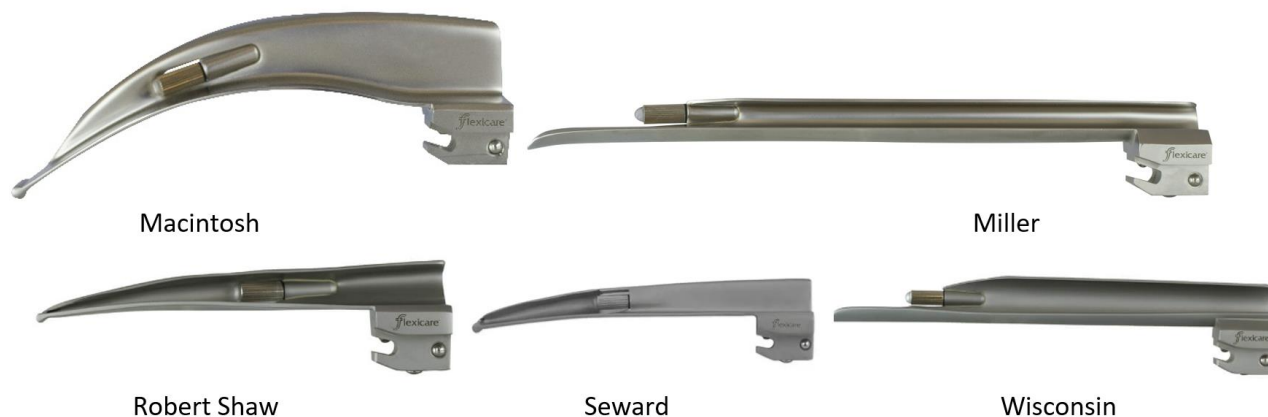


Reusable Laryngoscopes – Fibre Optic and Conventional

Product Data Sheet

PRODUCT: Reusable Laryngoscopes – Fibre Optic and Conventional

Conventional Blades:



Fibre Optic Blades:



Handles:



DESCRIPTION / FUNCTION

Conventional Blades

Flexicare's reusable conventional blades are designed to be connected to conventional laryngoscope handles. The blade has a light bulb incorporated approximately 1/3 of the distance from the tip. The light bulb screws into position and is powered via an integral line that transfers powers from the batteries located within the handle.

Fibre Optic Blades

Flexicare's reusable fibre optic laryngoscope blades are designed to be connected to fibre optic laryngoscope handles where the bulb is situated. The light is transferred to the proximal tip of the blade via a fibre optic bundle, so the light is transmitted without heat, eliminating the risk of thermal damage to the patient's tissues within the oral cavity.

Blade Types

The fibre optic or conventional blades, together with a handle are intended for use in laryngoscopy to obtain an illuminated view of the vocal cords and glottis by insertion into the oral cavity to manipulate the tongue and/or epiglottis. Laryngoscopy may be performed to facilitate tracheal intubation for patient ventilation or for procedures on the larynx or other parts of the upper tracheobronchial tree in both pre-hospital and hospital settings.

There are a variety of styles of blades available from Flexicare.

- **Macintosh** – curved blade allows tip to be guided to the epiglottic vallecula for direct visualisation of the glottis whilst holding the tongue to the side for direct vision of intubation.
- **Miller** – straight blade with shallow curved tip provides greater control in patients with a larger epiglottis, such as paediatric patients.
- **Flexible** – based on the Macintosh blade but has a hinged tip operated by a lever mechanism. This elevates the epiglottis while reducing the amount of force required.
- **Robert Shaw (Speciality Blade)** – designed for infants and neonates as they feature a gentle, shallow blade curvature to lift the epiglottis indirectly.
- **Seward (Speciality Blade)** – designed originally as an infant blade for asphyxia neonatorum. Can also be used for paediatric patients.
- **Wisconsin (Speciality Blade)** – designed for neonatal and infant use as it provides an improved view and greater control of the epiglottis with a subtly wider distal end than a standard miller blade.

Handles

Flexicare offers Conventional and Fibre Optic Reusable Laryngoscope Handles (Halogen and LED). Flexicare's Reusable Laryngoscope Handles are supplied as a standard size, a mini/penlight size (with a smaller diameter), and stubby size (which is shorter), to suit all patients and users. Also, the handles are available knurled (rough) or satin (smooth), depending on user preference.

All handles conform to the appropriate ISO standards for laryngoscope blades and handles. Flexicare's Conventional Reusable Laryngoscope Handles can be connected to both reusable and single use Conventional Blades, where the bulb is situated in the blade. Flexicare's Fibre Optic Reusable Laryngoscope Handles contain a bulb and these can be connected to reusable and single use Fibre Optic Blades. Fibre Optic Handles are marked green for easy identification.

All handles are provided non-sterile and designed to be disassembled and autoclaved prior to patient use.

Conventional and Halogen handles are bipolar, allowing the Laryngoscope to function irrespective of the way the batteries are inserted. All handles can be opened at both ends to remove swollen batteries with ease.

PRECAUTIONS, WARNINGS & CAUTIONS**Blades**

- Do not use if packaging is open or damaged.
- Consult Instructions for Use.
- Do not point the light guide directly in the eye while in operation. The light output can cause severe eye discomfort.
- Test the function of the blade after sterilisation, prior to use.
- Ensure blades are used with correct handles.
- After use, this product is contaminated waste and may be a potential biohazard. Handle and dispose of in accordance with hospital policy, applicable local guidelines and regulations and manufacturer reprocessing instructions.

Handles

- Use pre-approved packaging designed for use with your sterilisation equipment.
- Follow all manufacturer's instructions.
- Prior to sterilisation, ensure the handle and blade are completely dry and visibly clean. If contaminants are visible, repeat the decontamination/ cleaning procedure.
- Always wear appropriate PPE and handle devices and materials with care.
- If the device will be unused for prolonged periods, remove the batteries prior to storing.
- Always check the condition of the batteries by switching on the light source before commencing clinical procedure.
- Avoid using mineral acids and abrasive agents.
- DO NOT use sterilising agents with caustic ingredients, such as surgical scrub solutions, peroxide solutions, bleaches, or povidone-iodine solutions.
- DO NOT sterilise along with sub-standard stainless steel instruments as this may cause severe damage.
- No part of the process should exceed 138°C.
- Ultrasonic cleaning and flush autoclaving is not recommended.

SPECIFICATION / KEY FEATURES

- Fully autoclavable, ensuring long term usage.
- High quality stainless steel.
- Rounded edges to reduce the risk of tissue damage.
- Conform to ISO 7376.
- Suitable for multiple patients, can be autoclaved.
- Latex free.
- DEHP free.

REPROCESSING PARAMETERS

Please adhere to the following laryngoscope autoclave parameters:

- Temperature – 134-138°C
- Pressure – 2.25bar
- Cycle Time – 3 minutes

Other forms of sterilisation may be available such as Ortho-phthalaldehyde (OPA) soak and Ethylene Oxide ($\leq 65^{\circ}\text{C}$). These are suitable only if used in accordance with the manufacturer's instructions. If in doubt, consult the manufacturer.

PRODUCT RANGE & PART NUMBERS**Fibre Optic Blades**

Product Code	Product Description
040-831	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 1
040-832	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 2
040-833	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 3

Product Code	Product Description
040-834	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 4
040-835	Reusable Fibre Optic Laryngoscope Blade Flexible McCoy Type Size 3
040-836	Reusable Fibre Optic Laryngoscope Blade Flexible McCoy Type Size 4
040-840	Reusable Fibre Optic Laryngoscope Blade Oxy Miller Size 00
040-841	Reusable Fibre Optic Laryngoscope Blade Oxy Miller Size 0
040-849	Reusable Fibre Optic Laryngoscope Blade Miller Size 00
040-850	Reusable Fibre Optic Laryngoscope Blade Miller Size 0
040-851	Reusable Fibre Optic Laryngoscope Blade Miller Size 1
040-852	Reusable Fibre Optic Laryngoscope Blade Miller Size 2
040-853	Reusable Fibre Optic Laryngoscope Blade Miller Size 3
040-854	Reusable Fibre Optic Laryngoscope Blade Miller Size 4
040-930	Reusable Fibre Optic Laryngoscope Blade Robertshaw Size 0
040-931	Reusable Fibre Optic Laryngoscope Blade Robertshaw Size 1
040-951	Reusable Fibre Optic Laryngoscope Blade Seward Size 1
040-952	Reusable Fibre Optic Laryngoscope Blade Seward Size 2
040-920	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 0
040-921	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 1
040-922	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 2
040-923	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 3
040-924	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 4
040-911	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 1
040-911U	IntegraBlade Reusable Fiber Optic Blade Mac 1
040-912	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 2
040-912U	IntegraBlade Reusable Fiber Optic Blade Mac 2
040-913	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 3
040-913U	IntegraBlade Reusable Fiber Optic Blade Mac 3
040-914	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 4
040-914U	IntegraBlade Reusable Fiber Optic Blade Mac 4
040-980	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 0
040-980N	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 00
040-980NU	IntegraBlade Reusable Fiber Optic Blade Miller 00
040-980U	IntegraBlade Reusable Fiber Optic Blade Miller 0
040-981	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 1
040-981U	IntegraBlade Reusable Fiber Optic Blade Miller 1
040-982	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 2
040-983	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 3
040-983U	IntegraBlade Reusable Fiber Optic Blade Miller 3
040-984	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 4
040-984U	IntegraBlade Reusable Fiber Optic Blade Miller 4

Conventional Blades

Product Code	Product Description
040-110	Reusable Conventional Laryngoscope Blade Macintosh Size 1
040-111	Reusable Conventional Laryngoscope Blade Macintosh Size 2
040-112	Reusable Conventional Laryngoscope Blade Macintosh Size 3
040-113	Reusable Conventional Laryngoscope Blade Macintosh Size 4
040-126	Reusable Conventional Laryngoscope Blade Oxy Macintosh Size 0
040-127	Reusable Conventional Laryngoscope Blade Oxy Macintosh Size 00
040-128	Reusable Conventional Laryngoscope Blade Oxy Macintosh Size 0

040-129	Reusable Conventional Laryngoscope Blade Miller Size 00
040-130	Reusable Conventional Laryngoscope Blade Miller Size 0
040-131	Reusable Conventional Laryngoscope Blade Miller Size 1
040-132	Reusable Conventional Laryngoscope Blade Miller Size 2
040-133	Reusable Conventional Laryngoscope Blade Miller Size 3
040-134	Reusable Conventional Laryngoscope Blade Miller Size 4
040-230	Reusable Conventional Laryngoscope Blade Robertshaw Size 0
040-231	Reusable Conventional Laryngoscope Blade Robertshaw Size 1
040-261	Reusable Conventional Laryngoscope Blade Seward Size 1
040-262	Reusable Conventional Laryngoscope Blade Seward Size 2
040-250	Reusable Conventional Laryngoscope Blade Wisconsin Size 0
040-251	Reusable Conventional Laryngoscope Blade Wisconsin Size 1
040-252	Reusable Conventional Laryngoscope Blade Wisconsin Size 2
040-253	Reusable Conventional Laryngoscope Blade Wisconsin Size 3
040-254	Reusable Conventional Laryngoscope Blade Wisconsin Size 4

Handles

Product Code	Product Description	Battery
Fibre Optic LED		
040-813	BritePro Max Reusable LED Fibre Laryngoscope Handle Knurled Finish	2x C
040-814	BritePro Max Reusable LED Fibre Mini Laryngoscope Handle Knurled Finish	2x AA
040-815	BritePro Max Reusable LED Fibre Stubby Laryngoscope Handle Knurled Finish	CR 123
041-813	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Standard Handle	-
041-814	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Mini Handle	-
041-815	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Stubby Handle	-
Fibre Optic Halogen		
040-811	Reusable Fibre Optic Laryngoscope Handle Knurled Finish	2x C
040-812	Reusable Fibre Optic Mini Laryngoscope Handle Knurled Finish	2x AA
040-821	Reusable Fibre Optic Laryngoscope Handle Satin Finish	2x C
040-822	Reusable Fibre Optic Mini Laryngoscope Handle Satin Finish	2x AA
040-823	Reusable Fibre Optic Stubby Laryngoscope Handle Knurled Finish	2x AA
040-824	Reusable Fibre Optic Stubby Laryngoscope Handle Satin Finish	2x AA
041-601	Halogen Bulb For Use with Fibre Optic Handles	-
041-606	Halogen Bulbs For Use with Fibre Optic Handles Pack Of 6	-
Conventional		
040-021	Reusable Conventional Laryngoscope Handle Knurled Finish	2x C
040-022	Reusable Conventional Mini Laryngoscope Handle Knurled Finish	2x AA
040-023	Reusable Conventional Stubby Laryngoscope Handle Knurled Finish	2x AA
040-011	Reusable Conventional Laryngoscope Handle Satin Finish	2x C
040-012	Reusable Conventional Mini Laryngoscope Handle Satin Finish	2x AA
040-013	Reusable Conventional Stubby Laryngoscope Handle Satin Finish	2x AA
041-401	Small Krypton Bulb For Use with Standard Miller Blade Sizes 00 0 and 1	-
041-402	Standard Krypton Bulb For Use with Standard Blades	-

Box Sets

Product Code	Product Description
040-837	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Size 3
040-838	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Size 4
040-839	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Sizes 3 + 4
040-859	Box Set Laryngoscope BritePro Max Led Handle with Oxy Miller Sizes 00 0 and Integra Mac Blade 1 2
040-860	Box Set Fibre Optic Laryngoscope Kit A
040-861	Box Set Fibre Optic Laryngoscope Kit B
040-862	Box Set Fibre Optic Laryngoscope Kit D
040-985	Box Set Laryngoscope Fibre Optic Laryngoscope Handle with Integra Macintosh Blades Sizes 1 2 3 and 4
040-985MAX	Box Set BritePro Max Led Fibre Optic Laryngoscope Kit A
040-986MAX	Box Set BritePro Max Led Fibre Optic Laryngoscope Kit B

MATERIALS**Fibre Optic Blades**

Component	Material
Blade	Stainless Steel
Locking Block	Stainless Steel
F/O Light Guide	Glass
Light Guide Sheath	Stainless Steel
Locking Bearing	Stainless Steel

Conventional Blades

Component	Material
Blade	Stainless Steel
Locking Block	Stainless Steel
Wire Carrier Tube	Stainless Steel
Bulb Holder	Stainless Steel
Contact Pin	Brass
Ball Bearing	Stainless Steel
Springs	Stainless Steel

Handles

Component	Material
Head	Chromium Plated Brass
Green Band	Silicone
Light Source	Chromium Plated Brass, Polypropylene (PP)
Body	Chromium Plated Brass
Spring	Steel
Cap	Chromium Plated Brass

LATEX CONTENT

Flexicare's Reusable Laryngoscopes Handles and Blades do not contain natural rubber latex.

DEHP CONTENT

Flexicare's Reusable Laryngoscopes Handles and Blades do not contain phthalate DEHP.

PRODUCT USE

Flexicare's reusable fibre optic blades can be reused. To be cleaned and sterilised in accordance with hospital policy, applicable local guidelines and regulations and manufacturer reprocessing instructions.

STERILITY

Flexicare's Reusable Laryngoscopes Handles and Blades are supplied non-sterile.

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

These devices do not have a shelf life or life time.

DISPOSAL CONSIDERATIONS

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Primary – *Box*