

# PROACT

## PROACT Disposable MR Conditional Laryngoscope Blades



### INTENDED USE

- The MRHPC Laryngoscope Blade, when connected to a compatible handle, is used to illuminate the oropharynx and trachea to assist with endotracheal intubation or allow examination of the oral cavity.
- Designed for use inside Magnetic Resonance Environment (See conditions in yellow below)
- Compatible with ISO 7376:2020 compliant handles.

### WARNINGS

- Tracheal intubation requires specialist training. Only competent trained personnel should use this device.
- PROACT Medical advocates that intubation is only attempted with a full alternate plan in place for the event of difficult intubation due to equipment failure or physiological complications. This should include the availability of back-up devices and alternative means of ensuring ventilation.
- Reuse of medical devices intended for single use has associated dangers of cross-patient infection and may compromise the integrity, functionality or clinical efficacy of the device.
- In the event that one of these devices is involved in a serious clinical incident, please report to your local competent authority.

### PRE-USE CHECKS

- Check device for completeness, sharp edges, damage, flaws or loose components.
- Engage and disengage the laryngoscope twice to confirm operation. Ensure consistent light when force is exerted on the blade tip in all directions.

### INSTRUCTIONS FOR USE

- Select appropriate sized device for patient.
- To switch on, pull blade up and lock into position (see handle IFU for more details)
- Examine / intubate trachea following current accepted medical guidelines.

### PROACT DISPOSABLE MR CONDITIONAL LARYNGOSCOPE BLADES

Part Number	Style	Size	Blade Length (mm)	Blade Width (mm)
MRHPCMIL00 ①	Miller	00	43	11.5
MRHPCMIL0 ②	Miller	0	56	11.5
MRHPCMIL1 ③	Miller	1	80	11.5
MRHPCMIL2 ④	Miller	2	133	13.5
MRHPCMIL3 ⑤	Miller	3	171	15.0
MRHPCMAC1 ⑥	Macintosh	1	70	10.0
MRHPCMAC2 ⑦	Macintosh	2	90	12.0
MRHPCMAC3 ⑧	Macintosh	3	110	12.0
MRHPCMAC4 ⑨	Macintosh	4	133	15.0



Independent Laboratory based Non-clinical testing of the worst case positioning & application in relation to the MR Magnetic Field have demonstrated that MRGSHB01 and MRHPCXXX are MR conditional, and the PROACT Medical Ltd therefore deem that these products can be MR scanned safely under the following MRI conditions:

Static magnetic field of up to and including 3 Tesla  
 Spatial gradient field of up to and including 2250 Gauss/cm  
 Maximum whole body averaged specific absorption rate (SAR) of 2.68 W/kg for 15 minutes of scanning.



LATEX FREE



SINGLE USE



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# PROACT Disposable MR Conditional Handle with Batteries



## INTENDED USE

- The laryngoscope handle, when connected to a compatible blade, is used to illuminate the oropharynx and trachea to assist with endotracheal intubation or allow examination of the oral cavity.
- Only use with PROACT MRHPC MR Conditional Laryngoscope Blades
- These laryngoscope handles are supplied with x2 Reusable MR Conditional Lithium Ion Batteries (MRBATT01). Each providing greater than 100 minutes of illumination.
- Designed for use inside Magnetic Resonance Environment (See conditions in yellow below)
- ONLY use PROACT (MRBATT01) lithium ion batteries supplied, do not use any other batteries.

## WARNINGS

- Tracheal intubation requires specialist training. Only competent trained personnel should use this device.
- PROACT Medical advocate that intubation is only attempted with a full alternate plan in place for the event of difficult intubation due to equipment failure or physiological complications. This should include the availability of back-up devices and alternative means of ensuring ventilation.
- Batteries should be recycled after use in accordance with local regulations
- Batteries should not be incinerated or heated above 100 degrees celcius.
- Care should be taken not to pierce or deform batteries and damaged batteries should be handled with care.
- Reuse of medical devices intended for single use has associated dangers of cross-patient infection and may compromise the integrity, functionality or clinical efficacy of the device
- In the event that one of these devices is involved in a serious clinical incident, please report it to your local competent authority.

## PRE-USE CHECKS

- Check device for completeness, sharp edges, damage, flaws or loose components.
- Engage and disengage laryngoscope twice prior to use to confirm operation, ensure consistent light when force is exerted on blade tip in all directions.

## PROACT DISPOSABLE MR CONDITIONAL HANDLE WITH BATTERIES

Part Number	Size	Batteries Supplied	Dimensions
MRGSHB01 ①	Adult	x2 MRBATT01	144 x 29mm
MRBATT01 ②	Battery Insert	N/A	To fit MRGSHB01

Independent Laboratory based Non-clinical testing of the worst case positioning & application in relation to the MR Magnetic Field have demonstrated that MRGSHB01 and MRHPCXXX are MR conditional, and the PROACT Medical Ltd therefore deem that these products can be MR scanned safely under the following MRI conditions:  
 Static magnetic field of up to and including 3 Tesla  
 Spatial gradient field of up to and including 2250 Gauss/cm  
 Maximum whole body averaged specific absorption rate (SAR) of 2.68 W/kg for 15 minutes of scanning.



## INSTRUCTIONS FOR USE

- Select appropriately sized device for patient.
- To switch on, pull blade up and lock into position.
- Light will activate automatically.
- Examine / intubate trachea following current accepted medical guidelines.
- The lithium ion battery is designed to be removed in a way that prevents contact with any contaminated gloves or surfaces
- Remove the lithium ion battery by unscrewing the bottom cap and allowing the battery to gently slide out of the handle on to a clean surface. Ready for re-use.

## CLEANING INSTRUCTIONS

The PROACT Disposable MR Conditional Laryngoscope Handle is a single use device. Do not reprocess.

Should the battery become lightly contaminated it can be cleaned using a 70% alcohol wipe. If in doubt discard the battery.

## WARRANTY

PROACT Medical Ltd offer an out-of-box warranty for the PROACT Disposable MR Conditional Laryngoscope Handle, for a single clinical application.

- The Reusable MR Conditional Laryngoscope Lithium Battery (MRBATT01) has a shelf life of two years from the date of manufacture. The use-by-date is printed onto the device packaging. The warranty for MRBATT01 covers greater than 100 minutes of illumination or four reuses, five times in total (whichever is sooner).



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