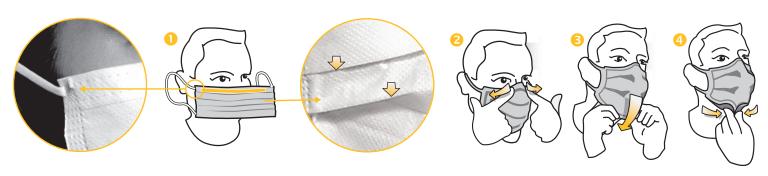
INSTRUCTIONS FOR USE

Personal Protection



Surgical Earloop Face Masks

How to Properly Wear Your Crosstex Face Mask:



Step **4** for SecureFit™ Masks only

Ref.#'s GCLBL, GCLPK, GCBL*, GCPK*, GCAPTPK*, GCIBLSF, GCILVSF, GCIPKSF, GCIBL, GCIGR, GCILV, GCIPK, GCISA, GCITE, GCITZ, GCITQ, GCIBL100, GCIBL300, GCICXB, GCICXS, GCICXZ, GCICXT, GCIPWB, GCIPWS, GCIPWZ, GCIPWT, GCICXBSF, GCIPWBSF, GPLUSBL, GPLUSKA, GPLUSPK, GPLUSWHSF, GCPBLSF, GCPLVSF, GCPPKSF, GCPBL, GCPLV, GCPPK, GCPYE, GCPBL100, GCABL*, GCAPK*, GCFCXSSF, GCFCXSFSF, GCPWSSF, GCFCXUSF, GCFCXSF, GCPWS, GCFCXU, GCFCX, GCPW

Intended Use:

Crosstex[™] Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device and provided non-sterile.

Indications for Use:

Crosstex[™] Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device and provided non-sterile.

Contra-Indications:

Do not re-use, this is a single-use disposable device.

Do not use near flammable anesthesia gases.

Compliance:

US-FDA 510K cleared class II medical device Surgical Mask.

US-FDA Regulation: 21 cfr 878.4040.

Meets fluid barrier protection per ASTM F2100 standards.

Meets applicable ISO 10993 Biocompatibility testing requirements.

Meets Class 1 Flammability Spread per 16 cfr 1610.

Devices are manufactured in compliance with 21 cfr Part 820 and ISO 1385:2016 quality systems.



Crosstex International, Inc. 6789 W. Henrietta Road, Rush, NY 14543 USA 585.359.0130 | 631.582.6777 | crosstex.com









Made in USA unless otherwise noted. *Made outside of the USA. EARLOOPMASK-IFU / REV D - 07/2021 Not made with natural rubber latex.



& Definitions Symbols Use:
Consult electronic instructions for use
Catalog number
Single use only Do not re-use
Non-sterile
Manufacturer
Unique Device Identifier
Manufacturing lot number
Date of manufacture
Medical Device
Approved for European Union, notified body
European Union Representative

