

READ INSTRUCTIONS BEFORE USE!

PRODUCT DESCRIPTION

Face visors are personal protective equipment devices that are used for protection of the facial area and associated mucous membranes (eyes, nose, mouth) from splashes, sprays, and spatter of body fluids. Face visors provide a barrier to acutely-expelled aerosols of body fluids and protect a large area of the face.

INTENDED USE

The Innovia Face Visor is intended to provide top, side, and front face protection from aerosols and to minimise airborne cross-contamination.

This protective Face Visor is manufactured for COVID-protection only. This protective Face Visor is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19.

WARNINGS AND PRECAUTIONS

- **DO NOT RE-USE OR RE-STERILIZE THIS DEVICE.** It is designed for **A SINGLE-USE**.
- **THIS PRODUCT SHALL NOT BE USED FOR MORE THAN ONE SHIFT**
- This device is supplied clean but is **NON-STERILE**. The instructions on cleaning the device provided below should be followed prior to use.
- It is recommended that this device is used as part of a PPE regimen
- Care should be taken when putting on and taking off the device to prevent contamination.
- Care should be taken if it is necessary to adjust the visor during use, as this may lead to contamination.
- The use of a face visor in combination with goggles can lead to poor peripheral vision. Care should be taken when selecting goggles to ensure that vision is not adversely affected, when used in combination.
- Ensure that the visor conforms to the face/head and that the visor does not slip whilst in use.
- Check before use that the visor will not become detached from the headband.
- It is generally recommended that for added protection (and depending upon circumstances), PPE should be worn by HCP on entry into patient rooms or care areas.
- After use, the visor should be carefully removed without contaminating the eyes, mucous membranes or clothing with potentially infectious materials and discarded.
- The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.
- Dispose of this device after use in accordance with standard hospital protocol.

INSTRUCTIONS FOR USE

Following cleaning follow hospital approved protocol for putting the device on in conjunction with other PPE.










Put on the visor, taking care to ensure that it is secure and correctly fitted.

To remove, handle via the head band. The visor should be carefully removed without contaminating the eyes, mucous membranes or clothing with potentially infectious materials and discarded.

CLEANING

This device is non-sterile and should be wiped down with an anti-bacterial wipe prior to use.

GRAPHICAL SYMBOLS USE ON LABELLING

								
Lot Number	Consult Instructions for Use	Catalogue Number	Non-sterile	Manufacturer	Date of Manufacture	Caution	Do not use if product is opened or damaged and consult instructions for use	Do Not Re-use

INCIDENT REPORTING

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE-USE ONLY DEVICES

1. Single-use devices have not been validated for re-use.
2. If you re-use a device you may be held Legally Liable for the safe performance.
3. Cross-contamination and infection risks to patients. Including transmission of:
 - CJD & Variant CJD.
 - Prion Diseases.
 - Bacterial Endotoxins.
 - Hepatitis B & Hepatitis C.
 - Risks posed by HIV and AIDS
 Note : Reprocessing may not remove all viable micro-organisms. Abnormal proteins associated with prion diseases eg. Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease, have been identified in corneal tissue and are very resistant to all conventional methods of decontamination.
4. Device failure through material fatigue or degradation caused by initial use and design:
 - Materials may degrade, becoming unacceptable when compared to original manufacturing criteria
5. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

This product meets the following

Regulation (EU) 2016/425 of the European Parliament and of the Council

BSI's PPE for Healthcare Professionals 2020/403 – Eyewear Technical Specification

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