U.S. FOOD & DRUG ADMINISTRATION

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Protective Barrier Enclosures

U.S Food and Drug Administration (FDA)

October 13, 2020

Protective Barrier Enclosures (PBEs)- Product classification definition

- **Protective Barrier Enclosure-**
  A transparent device designed to cover a patient's head and upper body and incorporates one or more ports through which the health care provider's (HCP) hands are passed to perform medical procedures, and provides an extra layer of barrier protection in addition to personal protective equipment (PPE).
- Procode: **QLD**
- **Protective Barrier Enclosure with Negative Pressure-**
  A barrier device with negative pressure which partially or fully covers a patient to prevent HCP exposure to pathogenic biological airborne particulates. These barrier devices include ports for medical care and/or procedures.
- Procode: **QLE**

Intended Use

Emergency Use Authorizations (EUAs) for PBE with negative pressure have been authorized only for in-hospital use for:

- Airway management
- Respiratory treatments
- Direct transport to a different level of care within a hospital
- With nurse or physician in attendance monitoring:
  - Electrocardiogram (EKG)
  - Mixed venous oxygen saturation (SvO2)
  - End tidal carbon dioxide (EtCO2)
  - Temperature
- Increasing negative pressure treatment areas in a hospital
- Increasing contagious patient isolation areas in a hospital

Resources

Revocation of Umbrella EUA for Protective Barrier Enclosures:

https://www.fda.gov/media/141415/download

Protective Barrier Enclosures Without Negative Pressure Used During the COVID-19 Pandemic May Increase Risk to Patients and Health Care Providers - Letter to Health Care Providers:

https://www.fda.gov/medical-devices/letters-health-care-providers/protective-barrier-enclosures-without-negative-pressure-used-during-covid-19-pandemic-may-increase

List of Authorized PBE EUAs:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

MDRs: Adverse Event Reporting for Medical Devices Under Emergency Use Authorization (EUA) or Discussed in COVID-19-Related Guidance Documents: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/adverse-event-reporting-medical-devices-under-emergency-use-authorization-eua-or-discussed-covid-19

QUESTIONS?

Webinar Resources

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will be available at:

www.fda.gov/training/cdrhlearn

Under Heading: Specialty Technical Topics and Sub-heading

Personal Protective Equipment (PPE)

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