

# Argen 3D Printed Headbands

## Personal Protective Equipment (PPE)

3D Printed headbands for protective shields.

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### Headband Details

The 3D printed headband uses a tan material in a solid, open gap design. The design has three circular protrusions on the front to hang the shield in place and hooks on the sides to fasten the strap. Instructions for assembly with shield and strap are available upon request.

### Re-Use of the Headband

Feedback from physicians and infection control groups suggests that the headband product is suitable for reuse with appropriate cleaning in between uses. Each hospital should determine appropriate use / reuse protocols based on a review of the product by the hospital's Infection Control group.

### Cleaning the Headband

Headbands delivered to facilities should be considered non-sterile. Consult the CDC for guidance on disinfectants known to be effective against COVID-19.

The following materials are not compatible with the headband and should not be used to clean the headband:

- Hydrogen peroxide vapor sterilization
- Autoclave
- Soaking in isopropanol or other organic solvents

### Regulatory Status

In the United States, face shields are considered Class I 510(k) exempt products by the Federal Drug Administration (FDA). Based on current FDA guidance, these face shields do not require FDA clearance.

Per the FDA guidance:

- These products are not “surgical masks” or “full face respirators.”
- These products are not recommended for use:
  - In any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids may be expected;
  - Use in a clinical setting where the infection risk level through inhalation exposure is high (without the use of a primary barrier such as a N95 or surgical mask);
  - Use in the presence of a high intensity heat source or flammable gas.
- The product does not make any claims of particulate filtration or possession of antibacterial or anti-viral properties.