

FACT SHEET FOR PATIENTS

Emergency Use of ISOCUBE SS and ISOCUBE ONE

May 4, 2021

**Coronavirus
Disease 2019
(COVID-19)**

You are being given this Fact Sheet because your healthcare provider (HCP) intends to place you in an ISOCUBE SS or ISOCUBE ONE device (collectively ISOCUBE).

ISOCUBE is intended to be used by HCPs as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of patients with suspected or confirmed diagnosis of coronavirus disease 2019 (COVID-19) when performing certain medical procedures, such as placing a breathing tube in your trachea to support your breathing and providing breathing treatments, or during patient transport within a hospital setting during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the risks and benefits of using ISOCUBE for preventing the spread of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For up-to-date information on COVID-19, please visit the Center for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) Webpage:

<https://www.cdc.gov/COVID19>

What is the COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is ISOCUBE?

ISOCUBE SS and ISOCUBE ONE are negative pressure chambers that attach to a standard hospital or surgical bed or stretchers that use a transparent covering and frame which extends around your head, neck, and shoulders and is draped & secured over your torso. Both devices use a single-use, clear, negative pressure isolette chamber that is discarded between uses. The ISOCUBE SS stainless-steel base and rail system is sanitized between uses. The ISOCUBE ONE frame is single use and completely discarded along with the negative pressure isolette chamber between uses.

Four integrated gloved access holes are built into the chamber to allow for HCP to have access to you while you remain isolated. ISOCUBE provides a negative pressure environment around you using vacuum and oxygen to help protect the HCP from pathogenic biological airborne particulates.

ISOCUBE is limited to use in a hospital setting, including for patient transport for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician.

You have the option to refuse this device. If you choose to decline use of this device, you should discuss any alternative options or questions/concerns with your healthcare provider.

How does ISOCUBE work?

Suction is connected to the ISOCUBE to create negative pressure and air flow. You will always receive supplemental oxygen while you are in the ISOCUBE device. Negative pressure inside the enclosure should help keep pathogenic biological airborne particulates from sneezes, coughs, and talking inside the enclosure. This should reduce the risk to HCP of becoming infected.

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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What are the known and potential benefits and risks with ISOCUBE?

Known and Potential Benefits

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates, as an added layer of protection.
- May allow a potentially safer method for HCP to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates.

Known and Potential Risks

- Device malfunction may lead to oxygen deprivation for you and cause you injury.
- Failure of the device may also increase the risk of possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of people in the surrounding area.
- Allergic reaction to ISOCUBE materials.
- Failure of the device to work properly may lead to inadequate oxygen levels in the bloodstream for you causing a condition known as hypoxia or elevated carbon dioxide levels in the blood stream in a condition known as hypercarbia.
- Accidental device folding or blockage of air-ports may result in harm to you
- Delayed emergency removal of the device may also result in harm to you

Is ISOCUBE FDA-approved or cleared?

No, ISOCUBE is not U.S. Food & Drug Administration (FDA)-approved or cleared. The FDA has authorized this use of ISOCUBE through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The EUA is supported by the Secretary of Health and Human Service declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

ISOCUBE under this EUA, has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available, showing that it is reasonable to believe that the product may be effective in protecting HCP when performing certain respiratory treatments during the COVID-19 pandemic, and the known and potential benefits outweigh the known and potential risks for such use.

The EUA for ISOCUBE is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or authorization is revoked (after which the products may no longer be used).

What are the approved alternatives?

There are no approved available alternative devices as added protection for HCPs. FDA has issued EUAs for similar products that can be found at:

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

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