May 4, 2021

Pete Prados
Chief Operations Officer
Prep Tech, LLC
1614 Wolf Circle
Lake Charles, LA 70605
337-739-5850
pete@preptechmed.com

Dear Mr. Prados:

This letter is in response to your request on behalf of Prep Tech, LLC, that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the ISOCUBE SS and ISOCUBE ONE[1] (hereafter "ISOCUBE") by healthcare providers (HCP)[2] 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 hospitalized patients with suspected or confirmed diagnosis of coronavirus disease 2019 (COVID-19), at the time of definitive airway management, or when performing air-way related medical procedures,[3] or during certain transport[4] of such patients, during the COVID-19 pandemic.[5]

---

[1] ISOCUBE SS is a multi-use base and rail system. ISOCUBE ONE is a single-use base and rail system. Both systems have a single-use, clear, negative pressure plastic sheet chamber and attach to a standard hospital or surgical bed, or stretchers, and extend around the patient's head, neck, and shoulders. Access holes with four (4) integrated gloves, are built into the chamber to allow for isolated patient access. The negative pressure environment is generated via wall-mounted hospital vacuum lines or 1-2 negative pressure pumps equipped with in-line high-efficiency particulate air (HEPA) filter(s). The ISOCUBE is not intended to replace the need for PPE or room sanitation and disinfection procedures. If end-tidal CO2 monitoring is not available, the maximum duration of use is 30 minutes with inline blower fan on and under direct observation.

[2] For this EUA, HCP refers to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or health professionals that have a role in using such a device.

[3] Non-transport use of the ISOCUBE is only authorized for emergency use during definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure/bi-level positive airway pressure [CPAP/BiPAP] mask use, airway suctioning, percussion and postural drainage).

[4] Use of the ISOCUBE during patient transport is only authorized for emergency use within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO2% (oxygen saturation), End tidal carbon dioxide (EtCO2), if available, throughout transport. The patient should always have supplemental oxygen during all authorized uses of the ISOCUBE. If the patient needs to be transported, the HCP may follow removal instructions, and either transport the patient without the hood as they would transport patients via standard protocol. Limit the duration of transport to 30 minutes if end-tidal CO2 monitoring is not available with inline blower fan on and under direct observation.

[5] During the public health emergency, it would not be feasible to require HCP to limit the ISOCUBE use for patients

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[6] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[7]

There are no FDA-approved or -cleared devices for use as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates from patients during the COVID-19 pandemic. The ISOCUBE is not approved or cleared for marketing in the U.S. The use of the ISOCUBE may provide a greater level of protection for HCP during high-risk procedures involving manipulation of the airway, such as endotracheal intubations and in non-invasive respiratory care (such as high-flow nasal cannula oxygen, nebulizers and CPAP/ BiPAP), and during certain patient transport. Based on FDA's review of bench performance testing of particulate clearance, HCP to patient communication, internal environment, and HEPA filter performance, and when evaluating the safety and usability of the ISOCUBE when used over a patient's upper body, and a usability study with anticipated users of the ISOCUBE, FDA has concluded that the ISOCUBE may be effective, and that the known and potential benefits outweigh the known and potential risks, when the ISOCUBE is used as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed cases of COVID-19, as described below.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the ISOCUBE, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the ISOCUBE, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

---

with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

[6] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020).

[7] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 17335 (March 27, 2020).

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that ISOCUBE may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of patients with suspected or confirmed diagnosis of COVID-19[8] and that the known and potential benefits of ISOCUBE for such use outweigh its known and potential risks; and,

3. There is no adequate, approved, and available alternative to the emergency use of the ISOCUBE.[9]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of ISOCUBE by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19[10] at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or CPAP/BiPAP mask use, airway suctioning, percussion and postural drainage), or during certain patient transport. When being used for transport of such patients, ISOCUBE is limited to use within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air flow must be ensured. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2%, and $EtCO_2$, if available, throughout transport. If end-tidal CO_2 monitoring is not available, then the use of the ISOCUBE must be limited to no longer than 30 minutes with air flow fan on and under direct observation. For all authorized uses, the patient should always have supplemental oxygen during use of ISOCUBE. The ISOCUBE is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

This product should be removed from the patient if it impedes the ability to perform the standard of care, or if there is difficulty visualizing or identifying anatomic landmarks, or if it impedes the ability to intubate the patient after the first try.

ISOCUBE is not authorized for use on:

- Patients needing emergent endotracheal intubation with severe hypoxemia;
- Patients with anticipated or known history of difficult airway;
- Patients with communication disorders that might interfere with clinical care;
- Patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes;
- Children under 45 pounds (lbs.);
- Patients with anticipated or known history of claustrophobia;

[8] Refer to footnote 5.
[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[10] Refer to footnote 5.

- Bariatric patients;
- Patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure;
- Patients in elderly care centers (non-hospital environment); or,
- Patients in ambulance transport.

Authorized Product

ISOCUBE SS is a multi-use detachable stainless steel base and rail system, which is sanitized between uses. ISOCUBE ONE is a single-use collapsible rigid coated-steel frame base and rail system. Both systems have a single-use, clear, negative pressure plastic sheet chamber (comprised of a transparent plastic isolette barrier enclosure and detachable drape), and attach to a standard hospital or surgical bed, or stretchers, and extend around the patient's head, neck, and shoulders. Access holes with four (4) integrated gloves, are built into the chamber to allow for isolated patient access. The negative pressure environment is generated via wall-mounted hospital vacuum lines or 1-2 wall-mounted or portable negative pressure pumps equipped with in-line high- efficiency particulate air (HEPA) filter(s) (able to filter 0.3 μm particulates or smaller) which are connected to a vacuum port located in the lower right corner of the device. A wall-mounted or portable supplemental oxygen line should be connected to a port located in the lower right corner of the device. During transport of patients, ISOCUBE maintains negative pressure via portable vacuum pump(s) with in-line HEPA filter(s), and oxygenation is supplied via a portable medical oxygen tank. Each system is assembled by HCP following the instructions for use applicable to each device model. Once assembled, device use steps are the same for both devices. The difference between ISOCUBE SS and ISOCUBE ONE is their frames. The clear plastic isolettes used on both units are exact in size, shape, and features. An ISOCUBE SS isolette can be used on an ISOCUBE ONE frame. The slight difference is an external "sleeve" found on two sides of an ISOCUBE SS isolette used for attachment to the stainless-steel rails of ISOCUBE SS on the exterior of the isolette.

The ISOCUBE requires the following components that are not included:

- Portable or wall-mounted vacuum source (if using portable vacuum pump(s), an inline HEPA filter is required for each pump);
- Portable or wall-mounted oxygen.
- Healthcare facility standard oxygen line;
- Healthcare facility standard suction hose lines (minimum 1/4 inch inner diameter)
- A blanket for the patient;
- Endo-tracheal tube;
- O_2 mask;
- Nasal Cannula.

The above described ISOCUBE is authorized to be accompanied with the "Instructions for Healthcare Providers and Facilities: ISOCUBE™ SS Device" and "Instructions for Healthcare Providers and Facilities: ISOCUBE™ ONE Device" (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices), together with the following product-specific

information pertaining to the emergency use, which is required to be made available to HCP and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of ISOCUBE™ SS and ISOCUBE™ ONE
- Fact Sheet for Patients: Emergency Use of ISOCUBE™ SS and ISOCUBE™ ONE

The above described product, when accompanied with the "Instructions for Healthcare Providers and Facilities: ISOCUBE Device" and the two Fact Sheets (identified above, and collectively referred to as "authorized labeling") is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the ISOCUBE when used and labeled consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ISOCUBE may be effective as described within, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized ISOCUBE, as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the ISOCUBE under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under section 564(b)(1) of the Act, the ISOCUBE is authorized to be used and distributed as set forth in this EUA.

III. Waiver of Certain FDA Requirements

Under section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under section 520(f)(1) of the Act. FDA waives all such requirements, including the quality system requirements under 21 CFR Part 820.

IV. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

Prep Tech, LLC, as Sponsor of Authorized Product

A. Prep Tech, LLC may request changes to this EUA for the ISOCUBE, including changes to the authorized labeling. Any requests for changes to this EUA must be submitted to the Office of Health Technology 4 (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation. [11]

B. Prep Tech, LLC must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. Compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

C. Prep Tech, LLC must have a process in place for reporting adverse events in accordance with 21 CFR Part 803. Prep Tech, LLC must report any adverse events of which it becomes aware to FDA in accordance with 21 CFR Part 803. Prep Tech, LLC must establish a process to collect adverse event information from healthcare facility customers.

D. Prep Tech, LLC must notify FDA of any authorized distributor(s)[12] of the ISOCUBE, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Prep Tech, LLC, and any Authorized Distributor(s)

E. Prep Tech, LLC and authorized distributors must distribute ISOCUBE with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using ISOCUBE.

F. Prep Tech, LLC and authorized distributors must make the authorized labeling available on their websites.

G. Authorized distributors must make Prep Tech, LLC aware of any adverse events of

[11] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) expiration dating extensions; (5) changes to manufacturing processes, including tests or other authorized components of manufacturing; (6) new conditions of authorization to require data collection or study; (7) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. For changes of the type listed in (6) or (7), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

[12] "Authorized Distributor(s)" are identified by the sponsor in an EUA submission as an entity allowed to distribute the device.

which they become aware.

H. Through a process of inventory control, Prep Tech, LLC and authorized distributors must maintain records of the healthcare facilities to which they distribute ISOCUBE and the number of products they distribute.

I. Prep Tech, LLC and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Prep Tech, LLC, any Authorized Distributor(s), and Healthcare Facilities

J. Prep Tech, LLC, any authorized distributor(s), and healthcare facilities must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

K. Healthcare facilities using ISOCUBE must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

L. Healthcare facilities using ISOCUBE must make Prep Tech, LLC and FDA aware of any adverse events pursuant to 21 CFR Part 803.

M. Healthcare facilities must ensure HCP are adequately equipped, trained, and capable of using ISOCUBE.

N. Healthcare facilities must maintain records of ISOCUBE usage.

Conditions Related to Printed Materials, Advertising and Promotion

O. All descriptive printed matter, advertising, and promotional materials, relating to the use of ISOCUBE shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (q)(1) and (r) of the Act and FDA implementing regulations.

P. No descriptive printed matter, advertising, or promotional materials relating to the use of ISOCUBE may represent or suggest that such products are safe or effective for the prevention or treatment of COVID-19.

Q. All descriptive printed matter, advertising, and promotional materials relating to the use of ISOCUBE shall state that:

- ISOCUBE has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for use by HCP as an extra layer of barrier

protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing any airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic; and,

- The emergency use of the ISOCUBE has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.05.04 14:26:07 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures