July 24, 2020

Eric Mair, M.D.
Chief Medical Officer
IkonX, Inc.
1628 Linwood St.
San Diego, CA 92103

Dear Dr. Mair:

This letter is in response to your request on behalf of IkonX, Inc. that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the Airway Dome[1] 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 isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing airway-related medical procedures[3] or during certain transport[4] of such patients during the COVID-19 pandemic.

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

[1] The Airway Dome is a single-use negative pressure covering which is placed around the head, neck, and shoulders of the patient. Access apertures, sealed by non-latex gloves, are built into the dome and allow for isolated patient access. The negative pressure environment is generated via a portable suction or negative pressure pumps equipped with in-line HEPA filters or via the wall-mounted vacuum lines. The Airway Dome is not intended to replace the need for PPE.

[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] Authorized non-transport use of Airway Dome is only for 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] Authorized use of the Airway Dome during patient transport is only 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), SpO_2% (oxygen saturation), End tidal carbon dioxide ($EtCO_2$), if available, throughout transport. For all authorized uses, the patient should always have supplemental oxygen during use of the Airway Dome.

causes COVID-19.[5] 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.[6]

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 use of the Airway Dome 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 to test leaks and CO_2 levels during use of the dome, FDA has concluded that the Airway Dome may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE by providing isolation of hospitalized patients with suspected or confirmed diagnosis 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 Airway Dome, 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 Airway Dome, 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;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Airway Dome 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, when performing airway-related medical procedures or during certain transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the Airway Dome for such use outweigh its known and potential risks; and,

[5] 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).
[6] 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).

3. There is no adequate, approved, and available alternative to the emergency use of the Airway Dome.[7]

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 the Airway Dome by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by isolating patients with known or suspected COVID-19, at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), 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, the Airway Dome 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. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO_2%, and $EtCO_2$, if available, throughout transport. For all authorized uses, the patient should always have supplemental oxygen during use of the Airway Dome.

The Airway Dome is not authorized for emergent endotracheal intubation with severe hypoxemia and is not authorized for use on:

- 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; or
- Children under 45 pounds (lbs).

Authorized Airway Dome

The Airway Dome is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates by providing isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19 at the time of definitive airway management, when performing any airway-related medical procedures or during certain patient transport; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

The Airway Dome is a single-use, transparent, negative pressure covering extending around the patient's head, neck, and shoulders. Two pairs of access apertures, sealed by non-latex gloves, are built into the dome and allow for isolated patient access by HCP. The negative pressure environment is generated via a portable suction or negative pressure pumps equipped with in-line HEPA filters or via the wall-mounted vacuum lines. The Airway Dome is authorized for use with supplemental oxygen, hospital vacuum lines, as well as portable vacuum pumps with in-line HEPA filters.

[7] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The Airway Dome is comprised of a collapsible dome frame, transparent polyethylene vinyl acetate (PEVA) covering, two pairs of access apertures sealed with latex-free gloves, a "Pass-Through Pouch" bag for transporting supplies or equipment into and out of the dome, air ports with viral filters, and guarded vacuum ports. The PEVA covering is secured onto the patient's chest using skin-safe adhesive tape. The device also comes with an accessory kit containing anesthesia circuit tube, end-tidal CO_2 extension monitor line, O_2 extension line for nasal cannulas and O_2 mask, and two "Y" suction connectors. All components of the Airway Dome are intended to be single-use and should be disposed after use.

The Airway Dome requires the following components that are not included as part of the Airway Dome system:

- Skin-safe adhesive tape;
- Portable or wall mounted vacuum pump with an in-line HEPA filter or healthcare facility wall-mounted suction;
- Portable or wall-mounted medical air or oxygen;
- Anesthesia ventilator or bag valve mask;
- In-line suction HEPA filter;
- Anesthesia circuit viral filter;
- In-line suction on/off valve;
- End-tidal CO_2 line;
- Suction tubing;
- Endo-tracheal tube;
- O_2 mask; and
- Nasal Cannula.

The Airway Dome is authorized for use as described in the Scope of Authorization (Section II). During transport of patients, the Airway Dome maintains negative pressure via portable self-contained, suction or negative pressure pumps equipped with HEPA filters.

The above described Airway Dome is authorized to be accompanied with the "Instructions for Healthcare Facilities: Assembly and disposal of Airway Dome," and "Instructions for Healthcare Personnel (HCP): Use of the Airway Dome" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), 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 the Airway Dome
- Fact Sheet for Patients: Emergency Use of the Airway Dome

The above described product, when accompanied with the Instructions for Healthcare Facilities and Instructions for Healthcare Personnel and the two Fact Sheets (identified above, and collectively referred to as "authorized labeling") is authorized to be distributed and administered 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 Airway Dome 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 Airway Dome may be effective as described within, when used consistent 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 Airway Dome, 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 Airway Dome 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 Airway Dome 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:

IkonX, Inc., as Sponsor of Authorized Product

A. IkonX, Inc. will make the authorized labeling available with the Airway Dome. IkonX, Inc. may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 4 (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

B. IkonX, Inc. may request changes to the Scope of Authorization (Section II in this letter)

of the Airway Dome. Such requests will be made by IkonX, Inc., in consultation with OHT4/OPEQ/CDRH, and require concurrence of the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and OHT4/OPEQ/CDRH.

C. IkonX, Inc. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT4/OPEQ/CDRH.

D. IkonX, Inc. 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.

E. IkonX, Inc. must have a process in place for reporting adverse events pursuant to 21 CFR Part 803. Adverse events of which IkonX, Inc. becomes aware will be reported to FDA. IkonX, Inc. will establish a process to collect adverse event information from healthcare facility customers.

F. IkonX, Inc. will notify FDA of any authorized distributor(s)[8] of the Airway Dome, 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.

IkonX, Inc. and any Authorized Distributor(s)

G. IkonX, Inc. and authorized distributors will distribute the Airway Dome with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the Airway Dome.

H. IkonX, Inc. and authorized distributors will make authorized labeling available on their websites.

I. Authorized distributors will make IkonX, Inc. aware of any adverse events of which they become aware.

J. Through a process of inventory control, IkonX, Inc. and authorized distributors will maintain records of the healthcare facilities to which they distribute the Airway Dome and the number of each product they distribute.

K. IkonX, Inc. 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.

IkonX, Inc., any Authorized Distributor(s), and Healthcare Facilities

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

L. IkonX, Inc., any authorized distributor(s), and healthcare facilities will 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

M. Healthcare facilities using the Airway Dome must make available to patients the accompanying Patient Fact Sheet and make available to HCP the accompanying Healthcare Provider Fact Sheet.

N. Healthcare facilities using the Airway Dome must make IkonX, Inc. and FDA aware of any adverse events pursuant to 21 CFR Part 803.

O. Healthcare facilities will ensure HCP are adequately equipped, trained, capable to use the Airway Dome, and will maintain records of device usage.

Conditions Related to Printed Materials, Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional material, relating to the use of the Airway Dome, shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Q. No descriptive printed matter, including advertising or promotional material, relating to the use of the Airway Dome, may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

R. All descriptive printed matter, including advertising and promotional materials, relating to the use of the Airway Dome shall clearly and conspicuously state that:

- The Airway Dome has neither been cleared or approved 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 isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing any airway-related medical procedures or during certain transport of such patients during the COVID-19 pandemic;

- The Airway Dome has been authorized for emergency use by FDA under an EUA; and,

- The Airway Dome 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures