

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of SCONE™

April 12, 2021

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the SCONE™. This device is authorized for use by healthcare providers (HCP) 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, or when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

All patients who are treated with the SCONE™ should receive the Fact Sheet for Patients: Emergency Use of the SCONE™.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Center for Disease Control and Prevention (CDC) webpage for the most up to date information (<https://www.cdc.gov/COVID19>).

What do I need to know about the emergency use of SCONE™?

- SCONE™ is authorized for patient transport within a hospital setting for temporary transfer only for 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), oxygen saturation (SpO₂%), End tidal carbon dioxide (EtCO₂), if available, throughout transport.

- Authorized non-transport use of SCONE™ is only for 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).
- SCONE™ can be used longer than 30 minutes only if constant monitoring of vital signs is maintained and only for as long as required to complete the indicated procedures. If End-Tidal CO₂ monitoring is not possible, then use of the SCONE™ is limited to a maximum of 30 minutes with negative pressure suction on and under direct observation, while ECG/EKG and SpO₂% must be monitored at all times.
- SCONE™ is intended to be used by HCP in a hospital setting.
- SCONE™ is not intended to replace PPE or room sanitation and disinfection procedures.
- Inspect SCONE™ prior to use. Any wear/tear of the chamber or other signs of degradation on the SCONE™ must promptly be reported to SCONE™ Medical Solutions Inc. The healthcare facility must not use on patients, and must dispose of, such a SCONE™.
- When using SCONE™ on a patient:
 - Direct observation is required at all times
 - Use portable or wall-mounted oxygen.
 - When using SCONE™, patients should always be receiving supplemental oxygen.
 - Use continuous pulse oximetry and end-tidal CO₂ monitoring, if available.
 - Ensure all connections are tightly secured and checked frequently.
 - Position the patient in a temperature-controlled environment to avoid hyper- and hypothermia.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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- Ensure the suction is connected to vacuum source that has either a High-Efficiency Particulate Air (HEPA) filter (0.1 µm particulates or better) or the vacuum is part of a hospital wall suction system that evacuates the vacuumed air safely to the environment per institution's building codes and regulations.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for HCP is available at the CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is SCONE™?

SCONE™ is a single-use, clear, negative pressure chamber that attaches to a standard hospital or surgical bed or stretchers and extends around the patient's head, neck, and shoulders. Access holes, sealed by vinyl access covers, are built into the chamber to allow for isolated patient access. The negative pressure environment is generated via wall-mounted hospital vacuum lines or negative pressure pumps equipped with in-line high-efficiency particulate air (HEPA) filters. SCONE™ acts as an added layer of physical barrier in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates,

SCONE™ will be available to HCP and healthcare facilities.

SCONE™ is comprised of the following components:

- Collapsible rigid frame
- Transparent plastic overlay
- Four arm access holes with flaps that hinge on the plastic overlay
- Two ports made of barbed fitting on one side for connecting hospital suction lines to either wall-

mounted vacuum pump(s) or portable vacuum pump(s) with in-line HEPA filter(s)

- One port made of barbed fitting on one side for connecting hospital wall-mounted or portable oxygen line

SCONE™ requires the following which is not provided:

- Wall-mounted vacuum pump(s) or portable vacuum pump(s) with in-line HEPA filter(s) (0.3 µm or better filtration)
- Healthcare facility standard suction hose lines (Minimum 1/4" suction tubing)
- Nasal Cannula
- Portable or wall-mounted oxygen
- Healthcare facility standard oxygen line (Standard 3/16" oxygen tubing)
- A blanket for the patient;
- Endo-tracheal tube
- O₂ mask

All components of SCONE™ are intended to be single-use and should be discarded after use. During transport of patients, the SCONE™ maintains negative pressure via portable vacuum pump(s) with in-line HEPA filter(s), and oxygenation is supplied via a portable medical oxygen tank.

Contraindications

SCONE™ is not intended for use on:

- Patients needing emergent endotracheal intubation with severe hypoxemia
- Patients with anticipated or known history of difficult airway
- Patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- Patients with communication disorders that might interfere with clinical care
- Children under 45 lbs.
- Patients with anticipated or known history of claustrophobia
- Patients with communication disorders that might interfere with clinical care
- Bariatric patients
- Patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure

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- Patients in elderly care centers (non-hospital environment)
- Patients in ambulance transport

Warnings and Cautions

- Flammability of SCONE™ has not been tested. No interventions that could create a spark or be a flammable source should be used within the SCONE™.
- Remove SCONE™ and use standard of care 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.
- Prolonged use of the SCONE™ may induce hypercarbia in a spontaneously breathing patient. In spontaneously breathing patients, SCONE™ should only be used with medical air flow and suction both on and working, under direct observation, and with end-tidal CO₂ monitoring, if available.
- Patients with diminished hearing or communication disorders may have difficulty understanding the provider while inside the SCONE™.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/ or confined space anxiety
- Use of SCONE™ for patient transport must only occur 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 assured. All patients should be on supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (Sp-O₂) levels, vital signs, EKG, and End-tidal CO₂, if available, during transport.
- Accidental device folding or blockage of air-ports may result in patient injury
- Delayed emergency removal of the device may result in patient injury

What are the known and potential benefits and risks of using SCONE™?

Known and Potential Benefits

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

Known and Potential Risks

- Device malfunction may lead to hypoxia of the patient, patient injury and possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.
- Device malfunction may lead to hypercarbia in a spontaneously breathing patient.
- Device may interfere with procedures conducted on the patient.
- Accidental device folding or blockage of air-ports may result in patient injury
- Delayed emergency removal of the device may result in patient injury
- Patient may have an allergic reaction to device materials.

What is an EUA?

The United States Food & Drug Administration (FDA) has made the emergency use of SCONE™ available under an emergency access mechanism called an EUA.

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

The authorized use of SCONE™ 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, or available alternatives. In addition, the FDA decision is based on the totality of

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scientific evidence available showing that it is reasonable to believe that the device that meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

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

What are the approved available alternatives?

There are no approved available alternative devices. FDA has issued EUAs for other similar products that can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Where can I go for updates and more information?

CDC websites:

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

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on Personal Protective Equipment:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Manufacturer Information

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