Medtronic News

Per FDA Guidance, Medtronic Temporarily Modifies Several Cardiopulmonary Product Indications for Longer Duration Use in ECMO Therapy to Address COVID-19

DUBLIN, May 29, 2020 (GLOBE NEWSWIRE) -- During this critical time, Medtronic remains committed to our strategy of delivering critical care products — designed and indicated for Extracorporeal Membrane Oxygenation (ECMO) — to treat patients around the world. Following guidance issued by the U.S. Food and Drug Administration (FDA) on April 6, 2020, several Medtronic cardiopulmonary technologies are now permitted to temporarily be used in the U.S. for ECMO therapy greater than six hours.

Under this new guidance the FDA is allowing temporary limited modifications to the indications of certain FDA-cleared or FDA-approved cardiopulmonary devices without prior submission of premarket notification. These modifications are allowed, considering the public health emergency, when they do not create an undue risk. This limited indication modification for ECMO therapy greater than six hours has not been cleared or approved by the FDA and is in effect only for the duration of the public health emergency related to COVID-19 as declared by the Department of Health and Human Services (HHS).

The devices listed below are currently FDA-cleared for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

In accordance with the new FDA guidance, the devices listed below can now be used for longer than 6 hours in an ECMO circuit to treat patients who are experiencing acute respiratory/cardiopulmonary failure during the COVID-19 Public Health Emergency*.

- Bio-Console™ 560 Extracorporeal Blood Pumping Console with Accessories
    - Autoclamp
    - Bubble Detector (adult)
    - Bubble Detector (pediatric)
    - External Drive Motor for Affinity™ CP Centrifugal Blood Pump
    - Emergency Hand Crank for Affinity™ CP Centrifugal Blood Pump
    - TX50 Adult Flow Transducer
        - Adult Bio-Probe™ Flow Probe**
        - Adult Bio-Pump Flow Probe™ with Cortiva™ BioActive Surface**
        - Adult Bio-Pump Flow™ Probe with Trillium Biosurface***
    - TX50P Pediatric Flow Transducer
        - Pediatric Bio-Probe™ Flow Probe**
        - Pediatric Bio-Probe™ Flow Probe with Cortiva™ BioActive Surface**
        - Pediatric Bio-Pump™ Flow Probe with Trillium Biosurface***
- Affinity™ CP Adapter
- Affinity™ Centrifugal Blood Pumps:**
    - Affinity™ CP Centrifugal Blood Pump**
    - Affinity™ CP Centrifugal Blood Pump with Cortiva BioActive Surface**
    - Affinity™ CP Centrifugal Blood Pump with Balance Biosurface**

The special supplement to the products' Instructions for Use (IFU) can be found on the Medtronic website for U.S. eManuals. This special supplement contains information on:

- Available data on design characteristics and use conditions related to ECMO
- Performance and durability testing summary
- Potential risks related to the use of the device for ECMO
- Clinical signs or observations that require device change-out

Extracorporeal membrane oxygenation (ECMO) is a life supporting therapy. People who need ECMO have a severe and life-threatening illness that stops their heart or lungs from working properly. ECMO therapy temporarily replaces the function of the heart and/or lungs by pumping blood from the patient's body to an oxygenator that provides long term physiological gas exchange (oxygen and carbon-dioxide transfer).

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**Other part numbers that include these devices in other configurations are also covered*
**Also available in tubing packs
*** Only available in tubing packs

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