TEG® 5000 System

Instructions for Use Addendum

Using the TEG 5000 Hemostasis System for Hospitalized Patients Suspected of a COVID-19 Associated Coagulopathy

129427-US(AA)
January 2021

HAEMONETICS®

Publication Information

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Reader comments

Any comments or suggestions regarding this publication are welcomed and should be forwarded to the attention of:

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Introduction

What is the Purpose of this Addendum?

The *Instructions for Use Addendum* provides information that highlights changes to the TEG® 5000 System to allow use with hospitalized patients suspected of a COVID-19 associated coagulopathy. It is intended as a supplement to the following TEG 5000 manuals and package inserts:

- TEG® 5000 User Manual (06-510-US)
- TEG® 5000 Kaolin Reagent insert (118468-MULTI)
- TEG® 5000 Heparinase Cups and Pins insert (118469-MULTI)
- TEG® 5000 RapidTEG insert (118473-MULTI)
- TEG® 5000 Functional Fibrinogen insert (118474-MULTI)
- TEG® 5000 PlateletMapping Assay insert (118472-MULTI)

The information in this addendum is based on the FDA guidance document, *Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (“Coagulation Systems”).

For questions regarding testing and COVID-19, contact HaemoneticsMedInfo@Haemonetics.com.

Attention: *The information in this addendum is valid only for the duration of the COVID-19 public health emergency as declared by the Secretary of Health and Human Services.*

Attention: *Use this addendum in conjunction with the TEG 5000 User Manual (06-510-US).*

Precautions

- **All test results generated by the TEG 5000 Hemostasis System are adjunctive (supporting) and should not be solely or primarily relied upon to diagnose or treat COVID-19 associated coagulopathy.**
- **Use universal precautions for handling potentially biohazardous material when using the TEG 5000 device.** All parts of the TEG analyzer system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Although the TEG analyzer does not present a significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly handle, clean, and disinfect the equipment as appropriate.Haemonetics recommends that institutions follow CDC guidance to protect against COVID-19 infection.
- The TEG 5000 Hemostasis System is not indicated for the diagnosis of COVID-19.
- All results from the TEG 5000 Hemostasis System are intended to be interpreted by a licensed healthcare provider with appropriate training.

Pipettes

Only appropriately calibrated pipettes should be used per the instructions outlined in the TEG 5000 reagent package inserts.

Interfering Substances

Specific to the extended intended population described in this addendum, the TEG 5000 Hemostasis System has not been evaluated for interference from substances such as, but not limited to, the following:

- Antiphospholipid antibodies
- Bamlanivimab
- Baricitinib and remdesivir, separately or in combination
- Casirivimab and imdevimab, separately or in combination
- Convalescent plasma

Additional Labeling for Modified Devices

Device Modifications

There are **no** changes to the functionality of the TEG 5000 system, which is made up of the following components:

- TEG 5000 analyzer
- TEG Analytical Software (TAS)
- Disposables
- Reagents

Installation and Qualification Testing

There are **no** changes to the recommended installation and qualification testing for the TEG 5000 system. Refer to the *TEG 5000 User Manual* (06-510-US) and *TEG 5000 Validation Guide* (06-505-US) for installation and qualification instructions.

Post-Installation Activities

There are **no** changes to the recommended post-installation, calibration, testing, and maintenance activities for the TEG 5000 system. Refer to the *TEG 5000 User Manual* (06-510-US) for post-installation activities.

Indications for Use

As supported by the FDA *Coagulations Systems* guidance document, the indications for use for the TEG 5000 System is expanded beyond the cleared indications to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

The following section outlines the FDA-cleared indications for use and the allowed use for the applicable components of the TEG 5000 Hemostasis System.

TEG 5000 Hemostasis Analyzer System

FDA-Cleared Indications for Use

Indications for Use: The TEG Thrombelastograph Coagulation Analyzer TEG 5000 Series is a non-invasive diagnostic instrument designed to monitor and analyze the coagulation state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG analyzer is indicated for use with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Intended Use: The TEG 5000 Series Analyzer is intended to be used to provide a quantitative and qualitative indication of the coagulation state of a blood sample by monitoring, measuring, analyzing and reporting coagulation parameter information. The TEG analyzer records the kinetic changes in a sample of whole blood, plasma or platelet rich plasma as the sample clots, retracts and/or lyses (breaks apart).

Results from the TEG analyzer should not be the sole basis for a patient diagnosis; TEG results should be considered along with a clinical assessment of the patient's condition and other coagulation laboratory tests. For Professional Use Only.

Allowed Use

The TEG 5000 Hemostasis System is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 5000 Kaolin Reagent

FDA-Cleared Indications for Use

The TEG 5000 Thrombelastograph Hemostasis Analyzer System is a non-invasive diagnostic instrument designed to monitor and analyze the hematological state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG Hemostasis System is indicated for use with adult patients where an evaluation of their blood hemostatic properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Allowed Use

The TEG 5000 Hemostasis System is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 5000 Heparinase Cups and Pins

FDA-Cleared Indications for Use

The TEG 5000 Thrombelastograph Hemostasis Analyzer System is a non-invasive diagnostic instrument designed to monitor and analyze the hematological state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG Hemostasis System is indicated for use with adult patients where an evaluation of their blood hemostatic properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Allowed Use

The TEG 5000 Hemostasis System is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 5000 RapidTEG Reagent

FDA-Cleared Indications for Use

The RapidTEG™ TEG-ACT test is a quantitative in vitro diagnostic test intended to monitor heparin anticoagulation in adult patients. It is intended for use with the TEG® 5000 Thrombelastograph® Hemostasis Analyzer System.

The TEG Hemostasis System is a non-invasive diagnostic instrument designed to monitor and analyze the hematological state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG Hemostasis System is indicated for use with adult patients where an evaluation of their blood hemostatic properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Allowed Use

The RapidTEG TEG-ACT test, used with the TEG 5000 Hemostasis System, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 5000 Functional Fibrinogen Reagent

FDA-Cleared Indications for Use

The TEG 5000 Thrombelastograph Hemostasis Analyzer System is a non-invasive diagnostic instrument designed to monitor and analyze the hematological state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG Hemostasis System is indicated for use with adult patients where an evaluation of their blood hemostatic properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Allowed Use

The TEG 5000 Hemostasis System is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.

TEG 5000 PlateletMapping Assay

FDA-Cleared Indications for Use

For application with the TEG 5000 Thrombelastograph Hemostasis Analyzer System to assess platelet function in patients who have received platelet inhibiting drugs such as aspirin, clopidogrel, abciximab, tirofiban, or eptifibatide.

The TEG Hemostasis System is a non-invasive diagnostic instrument designed to monitor and analyze the hematological state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG Hemostasis System is indicated for use with adult patients where an evaluation of their blood hemostatic properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

Allowed Use

The TEG 5000 PlateletMapping Assay, used with the TEG 5000 Hemostasis System, is intended to provide supporting and adjunctive diagnostic information to facilitate patient management recommendations to the healthcare professional for the treatment of COVID-19 or co-existing conditions in hospitalized patients suspected of a COVID-19 associated coagulopathy.