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INTRODUCTION

Preface

This manual contains information needed to properly and safely use the HeartMate 3 Mini Apical Cuff Kit. New users should read this document in its entirety before using the Mini Apical Cuff Kit. For experienced practitioners, this manual may serve as a reference. As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. Use of the HeartMate 3 Mini Apical Cuff Kit should be performed only by physicians who have received Thoratec training. Device malfunction may necessitate emergency treatment, therefore, patients should not be more than two hours from a healthcare facility that has trained personnel who are capable of treating a HeartMate 3 patient. Device Tracking and Reporting Requirements - any device malfunctions must be reported to Thoratec by the implanting center.

Understanding Warnings and Cautions

In this manual, warnings and cautions that are relevant to a specific procedure or piece of equipment appear at the start of each applicable section. Warnings refer to actions or hazardous conditions that could cause serious injury or death if not avoided. Ignoring a warning can cause sudden and serious injury, life-threatening harm, or death for the user or patient.

WARNING !

Warnings appear in the manual in this format.

Cautions refer to actions or potentially unsafe conditions that may cause injury to a patient or user, damage the equipment, or affect how the system works. Ignoring a caution can cause the patient or user injury, or result in equipment failure or sub-optimal system operation. Although important for maximum safety and optimal system function, usually cautions do not refer to life-threatening risks.

CAUTION !

Cautions appear in the manual in this format.
OVERVIEW

The HeartMate 3 Mini Apical Cuff Kit Instructions for Use (IFU) provides important information on securing the Mini Apical Cuff to the heart. For additional information regarding the HeartMate 3 Left Ventricular Assist System, refer to the HeartMate 3 Left Ventricular Assist System Instruc-
tions for Use.

Package Contents

The HeartMate 3 Mini Apical Cuff Kit package contains
- HeartMate 3 Mini Apical Cuff
- HeartMate 3 Apical Cuff Holder
- Instructions for Use for HeartMate 3 Mini Apical Cuff Kit

The HeartMate 3 Mini Apical Cuff Kit is supplied sterile and for single use only. Store components in a cool, dry place. The system is packaged for safe transportation and effective use in an operating room under sterile conditions.

Description

The HeartMate 3 Mini Apical Cuff Kit consists of the Mini Apical Cuff and the Apical Cuff Holder. The Mini Apical Cuff consists of a compliant felt ring attached to a metal ring. The felt ring is utilized to suture the Mini Apical Cuff to the heart. The metal ring locks with the HeartMate 3 LVAD to secure it to the heart. Radial and circumferential black lines are present on the felt to aid in placement of sutures.

The Apical Cuff Holder consists of a plastic handle for a comfortable grip that is connected to a circular disk that interfaces with an Apical Cuff. A silicone o-ring is present at this interface for a hemostatic connection with the Apical
Cuff. The Apical Cuff Holder has a central hollow vent that is connected to a luer port at the top for de-airing.
WARNING!

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using the HeartMate 3 Mini Apical Cuff Kit system. Read this entire manual before attempting implantation of the Left Ventricular Assist Device or before caring for HeartMate 3 patients. Completion of the Thoratec Corporation HeartMate 3 Surgical Training Program and the HeartMate 3 Mini Apical Cuff Surgical Training Program are also required prior to use.

- Understanding the operating and safety aspects of the HeartMate 3 Mini Apical Cuff Kit is critical for safe and successful use.

- Do not modify this device without authorization from Thoratec Corporation.

- HeartMate 3 Mini Apical Cuff Kit is compatible only with the HeartMate 3 Left Ventricular Assist System.

- Do not use the HeartMate 3 Mini Apical Cuff Kit if the sterile packaging is damaged or open.

- Ensure the HeartMate 3 Mini Apical Cuff Kit is not damaged prior to use.

- Do not use the HeartMate 3 Mini Apical Cuff Kit if it has been dropped. The Mini Apical Cuff Kit is for single use only. Do not attempt to re-sterilize as this may damage the device and impair its functionality and/or degrade its safety.

- Do not reuse any items. If any items are dropped they cannot be flash sterilized and a new kit must be opened.

- Only personnel using sterile technique should make contact with the sterilized kit accessories.
Indications
For the HeartMate 3 Left Ventricular Assist System Indications for Use, please refer to the HeartMate 3 Instructions for Use.

The HeartMate 3 Mini Apical Cuff Kit is intended for use with the HeartMate 3 Left Ventricular Assist System (LVAS). The Mini Apical Cuff is intended to be sutured onto the heart to secure the HeartMate 3 Left Ventricular Assist Device to the heart. It is to be used as an alternative to the HeartMate 3 Apical Cuff when it is required to have more compact suture placement, such as patients with small hearts with increased curvature. The Apical Cuff Holder provides a means to stabilize and manipulate the Mini Apical Cuff during suturing and to check for hemostasis of the tissue-cuff interface.

Contraindications
The use of the HeartMate 3 Mini Apical Cuff Kit is contraindicated in patients who are contraindicated for HeartMate 3 Left Ventricular Assist System (LVAS) therapy.

Compatibility
The HeartMate 3 Mini Apical Cuff Kit can be used with both the HeartMate 3 Coring Tool and the HeartMate 3 Coring Knife. The HeartMate 3 Mini Apical Cuff Kit should not be

CAUTION!

- Clinical procedures should be conducted under the direction of the prescribing physician (Authorized Personnel) only.
- Do not try to repair the Mini Apical Cuff Kit system components. If components need service, contact the appropriate Thoratec personnel.
- Notify the appropriate Thoratec personnel if there is a change in how the device works, sounds, or feels.
- Do not use the HeartMate 3 Mini Apical Cuff Kit system after the “Use by” date specified on the package label.
used with the HeartMate II LVAS. The Apical Cuff Holder can be used with all HeartMate 3 compatible Apical Cuffs.

**Adverse Events**

The following adverse events may be associated with the use of the Mini Apical Cuff Kit. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first as it is a non-reversible complication:

- Death
- Bleeding (perioperative or late)
- Local infection
- Local ischemia
- Cardiac arrhythmia
- Stroke
- Peripheral thromboembolic event
- Neurologic dysfunction
- Hemolysis
- Hepatic dysfunction
- Sepsis
- Respiratory Failure
SURGICAL PROCEDURES

<table>
<thead>
<tr>
<th>CAUTION !</th>
</tr>
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<tbody>
<tr>
<td>• When sewing the Mini Apical Cuff to the exterior of the heart, the felt surface should have a flat or convex shape. This is so that the pump and Slide Lock mechanism can engage the metal ring on the Mini Apical Cuff.</td>
</tr>
<tr>
<td>• When sewing the Mini Apical Cuff to the exterior of the heart, the sutures should <strong>not</strong> create a protrusions of the myocardial tissue that would prevent the LVAD from fully approximating a flat/convex Mini Apical Cuff.</td>
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<tr>
<td>• The suture knots should <strong>not</strong> interfere with the connection.</td>
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<tr>
<td>• If a sealing agent is used on or near the Mini Apical Cuff, it should <strong>not</strong> interfere with the Slide Lock mechanism.</td>
</tr>
<tr>
<td>• If the Slide Lock mechanism on the HeartMate 3 LVAD fails to engage, do <strong>not</strong> make further attempts to engage until retracting the Slide Lock mechanism. Evidence of the Slide Lock mechanism failing to engage will be either visual evidence of the yellow “wings,” or a tactile feel of three ridges versus one. The Slide Lock will <strong>not</strong> engage the Mini Apical Cuff unless initially fully retracted.</td>
</tr>
<tr>
<td>• If difficulty persists when engaging the Slide Lock mechanism, the LVAD should be removed from the Mini Apical Cuff to visualize what might be preventing the connection.</td>
</tr>
<tr>
<td>• The Mini Apical Cuff must be affixed to the Left Ventricle only by the Sew-Then-Cut method. Using the Cut-Then-Sew method may lead to challenges with engaging the Slide Lock mechanism.</td>
</tr>
<tr>
<td>• The Mini Apical Cuff must be affixed to the Left Ventricle only by the prescribed technique in this document to avoid challenges with engaging the Slide Lock mechanism.</td>
</tr>
<tr>
<td>• Components of the system that are supplied sterile are intended for single use only and should <strong>not</strong> be reused or re-sterilized. Do <strong>not</strong> use sterile components if sterile packaging is compromised. Contact Thoratec for a Return Authorization number.</td>
</tr>
</tbody>
</table>
Thoratec-Supplied Equipment

Included in this package:
- HeartMate 3 Mini Apical Cuff
- HeartMate 3 Apical Cuff Holder
- Instructions for Use for HeartMate 3 Mini Apical Cuff Kit

Supplied separately:
- HeartMate 3 Left Ventricular Assist System Implant Kit
  - See the HeartMate 3 Left Ventricular Assist System Instructions for Use for detailed information regarding this kit.
- HeartMate 3 Coring Tool (optional)
  - See HeartMate 3 Coring Tool Instructions for Use for detailed information regarding this kit.

Unpacking the Mini Apical Cuff Kit

Thoratec Corporation ships the HeartMate 3 Mini Apical Cuff Kit in a cardboard box. Both the Mini Apical Cuff and Cuff Holder are packaged in this cardboard box in sterile Tyvek® pouches. You will need to remove all of the Tyvek® pouches from the cardboard box.

**WARNING !**

- Do not reuse any items. If any items are dropped, a new kit must be opened.
- Only personnel using sterile techniques should touch the sterilized Mini Apical Cuff Kit.
- Do not use the device if it appears to be damaged in any way.
- Do not subject patients implanted with the HeartMate 3 Left Ventricular Assist System (including the Mini Apical Cuff) to Magnetic Resonance Imaging (MR) as the device contains Ferromagnetic components. MRI can cause Pump failure or patient injury.

**Note:** The operating room has several sterile fields. Use care when unpacking these items, as all of them must be placed in the sterile field.

To unpack the Mini Apical Cuff and Cuff Holder:

1. Peel back to open the outer Tyvek® pouch of the Mini Apical Cuff.
2. Remove the inner Tyvek® pouch from the outer pouch and place it in the sterile work area.

3. Open the inner Tyvek® pouch and remove the Mini Apical Cuff.

4. Place the Mini Apical Cuff in the sterile work area.

5. Repeat steps 1-5 for the Apical Cuff Holder.

**Preparing the Mini Apical Cuff and Apical Cuff Holder**

1. Engage the Cuff Holder to the Mini Apical Cuff by inserting the bottom part of the Cuff Holder into the metal ring of the Mini Apical Cuff.

   **Note:** One side of the Mini Apical Cuff is printed and should be facing the handle. The blank side of the Cuff goes onto the heart.

   **Note:** A silicone o-ring is present in the groove in the bottom part of the Cuff Holder and some resistance may be felt during insertion.

2. Visually confirm that the Cuff Holder is fully seated in the metal ring of the Mini Apical Cuff.

3. Confirm that the luer cap on the Apical Cuff Holding Tool (ACHT) is fully tightened to avoid unintentional blood loss from the tool.

4. Place the assembly in a sterile area until it is time to suture the Mini Apical Cuff on the heart.
DIRECTIONS FOR USE

Note: Prepare the patient and HeartMate 3 LVAS based on instructions provided in the HeartMate 3 IFU.

Note: The Mini Apical Cuff Kit should only be used in a Sew-Then-Cut method, and secured to the heart using the prescribed suturing technique.

Securing Mini Apical Cuff to Ventricle

CAUTION!

- The Mini Apical Cuff should be affixed to the Left Ventricle only by the Sew-Then-Cut method. Using the Cut-Then-Sew method may lead to challenges with engaging the Slide Lock mechanism.
- The Mini Apical Cuff should be affixed to the Left Ventricle only by the prescribed technique in this document to avoid challenges with engaging the Slide Lock mechanism.
- The pledgets should be placed no more than one and a half centimeters from the edge of the felt on the Mini Apical Cuff. Placing the pledgets at larger distances may lead to challenges with engaging the Slide Lock mechanism.

1. Choose the LVAD cannulation site.
   a. Identify the LVAD cannulation site slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery.
   b. With the Mini Apical Cuff loaded on the Cuff Holder, mark the outer diameter of the Mini Apical Cuff on the left ventricle.

2. Complete the following steps to anchor the Mini Apical Cuff at the chosen LVAD cannulation site:
   a. Place pledgeted sutures in the myocardium approximately 1 cm from the edge of where the felt will sit on the heart.
   b. Apply corresponding suture to the felt ring of the Mini Apical Cuff to achieve a horizontal mattress suture, targeting their placement on or inside the black circumferential line marked on the Mini Apical Cuff felt.
   c. Place a minimum of four horizontal mattress sutures around the periphery of the Mini Apical Cuff. It is recommended that the four sutures be
placed at the locations of the four radial black markings on the felt.

\[ 
\text{Note: Hold on to the Mini Apical Cuff when detaching the Apical Cuff Holder to avoid applying the disengagement force to the sutured connection to the heart.} 
\]

3. Complete the following steps to secure the myocardium around the felt cuff:
   a. Secure a running suture around the periphery of the felt ring. Target placement on or inside the circumferential black line marked on the felt ring.
b. Ensure that the bites of the running sutures are sufficiently close to each other to achieve hemostasis.

Note: This will help ensure that a hemostatic connection between the Mini Apical Cuff and the heart tissue, for which uninterrupted apposition between the myocardial tissue and the Mini Apical Cuff felt is required.

c. Inspect the area to ensure that the Mini Apical Cuff and surrounding tissue produces no interference that would prevent the LVAD from approximating the Mini Apical Cuff.

If a sealing agent (e.g. BioGlue®) is used on or near the Mini Apical Cuff, ensure that it does not interfere with the Slide Lock mechanism.

4. Core the left ventricle.
   a. Align the orientation of the Coring Knife toward the mitral valve.
b. Take care to avoid orienting the inlet towards the interventricular septum. Pump function will be compromised in the presence of inlet obstruction.

c. Apply the cutting edge to the epicardium, and maintain pressure while rotating the knife in one direction until the ventricular cavity is entered.

5. Remove the core and inspect the ventricular chamber for mural thrombi and crossing trabeculae, addressing both as needed.

Confirming Hemostasis

After coring the implant site, complete the following steps to check the hemostasis of the anastomosis of the Mini Apical Cuff.

1. Push the Apical Cuff Holder onto the Mini Apical Cuff to re-engage to the Apical Cuff Holder. Ensure that the luer cap is tightened to the Apical Cuff Holder port.

2. Fill the left ventricle with blood by increasing volume going to the heart and reduce that going to the cardiopulmonary bypass (CPB) machine.

3. Remove the luer cap to allow air in the ventricle to escape from the luer port on top of the Apical Cuff Holder.

4. Once the ventricle is cleared of air and some bleed through is observed, close the luer port completely to prevent further bleeding.

**WARNING !**

It is important to remove the air in the ventricle to avoid air escaping from the ventricle and causing air embolism.

5. Check the anastomosis for bleeding. If any bleeding is observed, place additional sutures until bleeding is sufficiently addressed.

6. Once hemostasis is verified, re-initiate cardiopulmonary bypass.
7. Disconnect the handle by gently pulling on the Cuff Holder.

CAUTION!

It is important to check the hemostasis before installing the pump as it may be difficult to place additional sutures in the Mini Apical Cuff once the pump is installed.

**Note:** Hold on to the Mini Apical Cuff when detaching the Apical Cuff Holder to avoid applying the disengagement force to the sutured connection to the heart.

**Inserting the Pump in the Ventricle**

Carefully perform the following steps to ensure proper placement of the Pump and Inflow Cannula:

1. Remove glove tip.
2. Retract the Slide Lock so that it is in the fully opened position as far as it will go.
3. Insert the Inflow Cannula into the opening within the cuff.
4. Rotate the Pump so that the Outflow Graft is directed to the midline of the thorax, and the Pump Cable is oriented toward the midline.
5. When the Inflow is inserted into the ventricle, ensure that the thread protector is secure and the luer fitting is tight to prevent air entrapment.
6. Push the Slide Lock on the Pump inward to engage and lock the Pump into position.
7. Gently pull on the Slide Lock to ensure that it is properly engaged.
8. Inspect the entire circumference of the pump-cuff junction to ensure that the LVAD is properly seated. The Slide Lock, with the exception of the tab, will be fully inserted and no “yellow zone” will be visible.
9. If the Slide Lock mechanism on the HeartMate 3 LVAD fails to engage, complete the following steps:
a. Do **not** make further attempts to engage until retracting the Slide Lock mechanism. Evidence of the Slide Lock mechanism failing to engage will be either visual evidence of the yellow “wings,” or a tactile feel of three ridges versus one.

b. If difficulty persists, remove the LVAD from the Apical Cuff to visualize what might be preventing the connection.

10. If the yellow zone is visible, fully retract the Slide Lock and repeat Steps 4–6.
### SYMBOLS

Description of Labeling Symbols

**General Symbols**

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