Heart Failure Treatment Options:
Frequently Asked Questions

1. Q: What is heart failure?
   A: Heart failure is a widespread condition that develops when the heart muscle weakens and is unable to pump sufficient amounts of blood throughout the body. Heart failure is a chronic condition that worsens over time and is typically caused by persistent high blood pressure, heart attack, valve disease and other forms of heart disease or birth defects. Left untreated, the lack of adequate blood flow causes the organs to progressively fail, resulting in numerous medical complications that erode a person’s quality of life and often leads to death.

   Heart failure can involve both sides of the heart or be localized to the left or right side. The left ventricle, which supplies oxygenated blood to the body, accounts for approximately 80 percent of all heart failure cases.

2. Q: How common is heart failure?
   A: According to the American Heart Association (AHA) and the Heart Failure Society of America (HFSA), approximately five million Americans are living with heart failure, and 550,000 new cases are diagnosed each year. In the United States, the number of deaths from this condition has more than doubled since 1979, averaging 250,000 annually.

3. Q: What are the different stages of heart failure?
   A: The New York Heart Association (NYHA) created a classification system to help physicians determine the best course of therapy for their patients. This system compares symptoms to daily activities and the patient’s quality of life.

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea (shortness of breath).</td>
</tr>
<tr>
<td>(Mild)</td>
<td></td>
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<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.</td>
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<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation or dyspnea.</td>
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<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</td>
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</table>

4. Q: How is heart failure treated?
   A: Symptoms of advanced-stage heart failure are generally managed with the use of medications, including diuretics, angiotensin converting enzyme (ACE) inhibitors, beta-blockers and digoxin combined with strict diet and exercise programs. For many, a heart transplant is necessary for survival, but advanced-stage heart failure sufferers are frequently ineligible for transplant because of age or other extenuating health reasons. Between 2,000 and 2,500 Americans receive a heart transplant each year, while another 25,000-50,000 Americans die waiting for a donor heart to become available.

   Recent guidelines from the American College of Cardiology (ACC) and the AHA recommend that physicians consider ventricular assist devices (VADs) as a treatment option for advanced-stage patients and those with refractory heart failure who might be eligible for specialized advanced treatment, including transplantation.

5. Q: What are VADs?
   A: Ventricular Assist Devices are mechanical pumps that are implanted alongside a patient’s own heart and designed to assist the heart's pumping function to restore hemodynamic function, or the flow of oxygenated blood throughout the body.

6. Q: What is the HeartMate II® Left Ventricular Assist System (LVAS)?
   A: The HeartMate II LVAS is a miniaturized heart assist device designed to restore hemodynamic function by pumping oxygenated blood throughout the body. The HeartMate II LVAS uses a single rotating part to pump up to 10 liters of blood per minute, the full output of a healthy heart. The HeartMate II is designed to provide long-term cardiac support for patients who have advanced-stage heart failure.

7. Q: Which patients might be helped by this device?
   A: The HeartMate II LVAS is FDA-approved for Bridge-to-Transplantation (BTT). It is still under investigation for Destination Therapy* (DT). A BTT indication allows the HeartMate II to be used for temporary support to restore adequate
hemodynamics while a patient is waiting for heart transplant. A DT indication* would allow the HeartMate II to be used for long-term or permanent support for advanced-stage heart failure patients who are not eligible for heart transplantation.

8. Q: How does the HeartMate II differ from other heart assist pumps?
A: The HeartMate II LVAS provides blood flow to the body through the circulatory system on a continuous basis with only one moving part. The HeartMate II is designed to have a much longer functional life than the previous generation of devices and to operate more simply and quietly. It is also smaller and designed to be easier to implant than the previous generation of devices.

9. Q: What is REMATCH?
A: REMATCH, which stands for the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH), was a landmark clinical trial that demonstrated VADs could be implanted for DT in patients ineligible for a transplant. The trial indicated a significant increase in patient survival and quality of life for VAD patients in comparison to patients who were treated only with medical management.

10. Q: What is the HeartMate II Pivotal Clinical Trial?
A: The Thoratec® HeartMate II Left Ventricular Assist System (LVAS) pivotal clinical trial incorporates a number of unique elements, including the use of the device for both Bridge-to- Transplantation (BTT) and Destination Therapy (DT). This is the first time the FDA has approved a clinical trial with both indications in one protocol.

BTT Study - The BTT pivotal clinical trial was a non-randomized trial in which all subjects received the HeartMate II LVAS and was compared to an objective performance criterion (OPC). Study enrollment ended with FDA approval in April 2008.

DT Study* - The DT pivotal clinical trial is a prospective, randomized evaluation of the HeartMate II LVAS. Patients will be randomly assigned to treatment with the HeartMate® XVE LVAS (control group) or to treatment with the HeartMate II LVAS. The DT arm of the study involves 200 total patients at up to 40 sites in its primary cohort, randomizing the HeartMate II LVAS to the HeartMate XVE LVAS on a 2-1 basis, respectively.

11. Q: How many patients are currently in the trial?
A: The HeartMate II LVAS pivotal clinical trial was approved by FDA on Feb. 18, 2005, and has been enrolling patients at a record pace. As of early 2008, there were over 365 pilot and pivotal trial patients who had been supported for a year or longer, with 50 of them supported for two years or more. The trial continues to enroll additional patients under a Continued Access Protocol (CAP) approval for the Destination Therapy arm. As of April 24, 2009,
enrollment in the DT arm reached 733 patients. In total, more than 1,000 patients have been enrolled in the pivotal trial, by far the largest VAD study ever conducted.

In April 2009, Thoratec filed a PMA Supplement to provide data on adjunctive cohorts totaling an additional 409 patients, including those who had originally been supported by an XVE who elected to receive a HeartMate II based on the need for device replacement.

In May 2009, Thoratec received FDA approval for a new 30-patient CAP.

12. Q: What criteria did patients need to meet in order to be considered for trial enrollment?
   A: Enrollment for BTT was limited to advanced-stage heart failure patients who were on the heart transplant list and who met certain criteria. The DT arm* includes patients who were not candidates for heart transplantation due to age or other health conditions. Most candidates are classified as NYHA Class IV. The criteria of the trial allowed the DT arm to enroll some late-stage NYHA Class IIIIB heart failure patients.

13. Q: Which centers are participating in the HeartMate II trial?
   A: There are more than 100 centers in the U.S. and Canada that are participating in the trial. A complete list is below:

ALABAMA

University of Alabama Health System
1802 6th Avenue South
Birmingham, AL 35249
(205) 934-4011
www.health.uab.edu

ARIZONA

Mayo Clinic Hospital Scottsdale
5777 East Mayo Boulevard
Phoenix, AZ 85054
(480) 301-8200
www.mayoclinic.org/scottsdale

UMC Tucson
1501 N.Campbell Avenue
Tucson, AZ 85724
(520) 694-6455
www.umcarizona.org

ARKANSAS

Baptist Little Rock
9501 Lile Drive
Little Rock, AR 72205
(501) 690-8784
www.baptist-health.com
CALIFORNIA

Cedars Sinai
8700 Beverly Boulevard
Los Angeles, CA 90048
(310) 467-0441
www.cedars-sinai.edu

UCLA
Ronald Regan Medical Center
757 Westwood Plaza
Los Angeles, CA 90095
(310) 825-9111
www.uclahealth.org

Sutter Health
5151 F Street
Sacramento, CA 95819
(916) 396-9402
www.sutterhealth.org

Sharp Memorial Hospital
7901 Frost Street
San Diego, CA 92123
(858) 939-3831
www.sharp.com

California Pacific Medical Center
2333 Buchanan Street
San Francisco, CA 94115
(415) 600-1050
www.cPMC.org

UCSF Medical Center
513 Parnassus Avenue
San Francisco, CA 94143
(415) 353-3786
www.ucsfhealth.org

CONNECTICUT

Hartford Hospital
80 Seymour Street
Hartford, CT 06102
(860) 545-5000
www.harthosp.org

Yale
New Haven Hospital
20 York Street
New Haven, CT 06510
(203) 688-4242
www.ynhh.org

COLORADO

University of Colorado Hospital
4200 E 9th Avenue, # C310
Denver, CO 80220
(303) 315-8527
www.uch.edu
DISTRICT OF COLUMBIA

Washington Hospital Center
110 Irving Street
Washington, DC 20010
(202) 877-7321
www.whcenter.org

FLORIDA

Shands Health Care
1600 SW Archer Road
Gainesville, FL 32608
(800) 749-7424
www.shands.org

Mayo Clinic Hospital Jacksonville
4203 Belfort Road
Jacksonville, FL 32216
(904) 296-5215
www.mayoclinic.org

Jackson Memorial Hospital
1611 NW 12th Avenue
Miami, FL 33136
(305) 585-1111
www.jhsmiami.org

Tampa General Hospital
2 Columbia Drive
Tampa, FL 33606
(813) 844-7137
www.tgh.org

GEORGIA

Emory Healthcare
1364 Clifton Road NE
Atlanta, GA 30322
(404) 712-2000
www.emoryhealthcare.org

Saint Joseph’s Hospital
5665 Peachtree Dunwoody Road, N.E.
Atlanta, GA 30342
(678) 843-5757
www.stjosephsatlanta.org

ILLINOIS

Northwestern Memorial Hospital
201 East Huron
Chicago, IL 60611
(312) 695-3121
www.nmh.org

Rush University Medical Center
1653 W. Congress Parkway
Chicago, IL 60612
(312) 942-5000
www.rush.edu
University of Chicago Medical Center
5841 South Maryland Avenue
Chicago, IL 60637
(773) 702-2500
www.uchospitals.edu

Loyola Medicine
2160 S. First Ave.
Maywood, IL 60153
(888) LUHS-888
loyolamedicine.org

Advocate Christ Medical Center
4400 West 95th Street
Oak Lawn, IL 60453
(708) 684-7044
www.advocatehealth.com

OSF Saint Francis Medical Center
530 NE Glen Oak Avenue
Peoria, IL 61637
(309) 655-2000
www.osfsaintfrancis.org

INDIANA

Lutheran Heart Center
7950 W. Jefferson Boulevard
Fort Wayne, IN 46804
(260) 435-7434
www.lutheranheartcenter.com

St. Vincent Hospital
8333 Naab Road
Indianapolis, IN 46260
(317) 338-2721
www.stvincent.org

The Clarian Cardiovascular Center
1801 N. Senate Boulevard
Indianapolis, IN 46202
(800) 347-9054
www.clarian.org

IOWA

University of Iowa, Hospitals & Clinics
200 Hawkins Drive
Iowa City, IA 52242
(319) 356-1028
www.uihealthcare.com

KENTUCKY

University of Kentucky Medical Center
900 South Limestone
Lexington, KY 40536
(859) 323-6494
www.mc.uky.edu

Jewish Hospital and St. Mary’s Healthcare
201 Abraham Flexner Way
MICHIGAN

University of Michigan Health System
1500 E. Medical Center Drive
Ann Arbor, MI 48109
(734) 647-2894
www.med.umich.edu

Henry Ford Health System
2799 W. Grand Boulevard
Detroit, MI 48202
(313) 916-2695
www.henryford.com

Spectrum Health
Meijer Heart Center
100 Michigan St. NE
Grand Rapids, MI 49503
(866) 989-7999
www.spectrum-health.org

MINNESOTA

Abbott Northwestern
Allina Hospitals & Clinics
2925 Chicago Avenue
Minneapolis, MN 55407
(612) 262-5000
www.abbottnorthwestern.com

Fairview-University Medical Center
2450 Riverside Avenue
Minneapolis, MN 55454
(612) 624-6401
www.fairviewtransplant.org

Mayo Clinic
200 First Street SW
Rochester, MN 55905
(507) 284-3994
www.mayoclinic.org/rochester

MISSOURI

St. Luke's Hospital of Kansas City
4320 Wornall Road
Kansas City, MO 64111
(816) 931-3312
www.saintlukeshealthsystem.org

Barnes-Jewish Hospital
4921 Parkview Place
St Louis, MO 63110
(314) 747-3000
www.barnesjewish.org
NEBRASKA

The Nebraska Medical Center
42nd and Dewey
Omaha, NE 68198
(402) 559-2000
www.nebraskamed.com

NEW JERSEY

Saint Barnabas Heart Center at Newark Beth Israel
201 Lyons Avenue
Newark, NJ 07112
(973) 926-7213
www.saintbarnabas.com

NEW YORK

Montefiore Medical Center
3400 Bainbridge Avenue
Bronx, NY 10467
(718) 920-6500
www.montefiore.org

Cornell
520 East 70th Street
New York, NY 10021
1-877-CORNELL
www.med.cornell.edu

Mount Sinai
One Gustave L. Levy Place
New York, NY 10029
(800) 637-4624
www.mountsinai.org

New York Presbyterian Hospital / Columbia
177 Fort Washington Avenue
New York, NY 10032
(212) 305-6003
www.columbiasurgery.org

Strong Memorial Hospital
Strong Heart & Vascular Center
601 Elwood Avenue
Rochester, NY 14642
(585) 275-6964
www.mystrongheart.com

Stony Brook University Medical Center
Nicolls Road and Health Sciences Drive Intersection
Stony Brook, NY 11794
(631) 444-4000
www.stonybrookmedicalcenter.org

Westchester County Medical Center
95 Grasslands Rd
Valhalla, NY 10595
(914) 493-7000
www.worldclassmedicine.com
NORTH CAROLINA

University of North Carolina Hospitals
101 Manning Drive
Chapel Hill, NC 27514
(919) 843-5214
www.unccardiology.org

Carolinas Medical Center
1000 Blythe Boulevard
Charlotte, NC 28203
(704) 355-2000
www.carolinasmedicalcenter.org

Duke University Medical Center
200 Trent Drive
Durham, NC 27710
(919) 681-5816
cardio.surgery.duke.edu

OHIO

Cleveland Clinic
9500 Euclid Avenue
Cleveland, OH 44195
(216) 444-2200
my.clevelandclinic.org

Ohio State University Medical Center
410 West 10th Avenue
Columbus, OH 43210
(888) 293-7677
www.medicalcenter.osu.edu

OKLAHOMA

Integris Baptist Medical Center
3300 Northwest Expressway
Oklahoma City, OK 73112
(405) 945-4952
www.integris-health.com

Pennsylvania

Penn State University - Hershey Medical Center
500 University Drive
Hershey, PA 17033
(717) 531-8407
www.pennstatehershey.org

Lancaster General
555 N Duke St,
Lancaster, PA 17604
(717) 544-5511
www.lancastergeneral.org

Hahnemann University Hospital
230 N Broad Street
Philadelphia, PA 19102
(215) 762-7000
www.hahnemannhospital.com
Penn Presbyterian Medical Center  
51 N. 39th Street  
Philadelphia, PA 19104  
(215) 662-8000  
www.pennhealth.com/presby/  

Temple University Hospital  
3401 N. Broad Street  
Philadelphia, PA 19140  
(215) 707-2000  
tuh.templehealth.org  

Thomas Jefferson University Hospital  
1025 Walnut Street  
Philadelphia, PA 19107  
(215) 955-6996  
www.jeffersonhospital.org  

University of Pennsylvania Health System  
3400 Spruce Street  
Philadelphia, PA 19104  
(215) 615-0800  
www.pennhealth.com  

Allegheny General Hospital  
320 E. North Avenue  
Pittsburgh, PA 15212  
(412) 359-6739  
www.mcginniscvi.org  

University of Pittsburgh Medical Center  
200 Lothrop Street  
Pittsburgh, PA 15213  
(412) 647-5800  
www.upmc.com  

SOUTH CAROLINA  

MUSC  
179 Ashley Avenue, MSC 001  
Charleston, SC 29425  
(834) 792-9259  
www.musc.edu  

TENNESSEE  

Cardiovascular Surgery Clinic  
6029 Walnut Grove Rd.  
Memphis, TN 38120  
(901) 747-3066  
cvsclinic.com  

St. Thomas Hospital  
4220 Harding Road  
Nashville, TN 37205  
(615) 222-2111  
www.stthomas.sths.com
Vanderbilt Medical Center
1211 Medical Center Drive
Nashville, TN 37232
(615) 322-5000
www.mc.vanderbilt.edu

TEXAS

Seton Medical Center
1301 West 38th Street
Austin, TX 78705
(512) 681-0500
www.seton.net

Baylor University Medical Center
621 N. Hall Street
Dallas, TX 75226
(214) 841-2000
www.baylorhealth.com

Medical City Hospital
7777 Forest Lane
Dallas, TX 75230
(972) 566-5700
www.medicalcityhospital.com

UT Southwestern Medical Center
5939 Harry Hines Boulevard
Dallas, TX 75390
(214) 645-7544
www.utsouthwestern.org

Methodist Hospital (Houston)
6560 Fannin #1860
Houston, TX 77030
(713) 798-1927
www.methodisthealth.com

Texas Childrens Hospital
6621 Fannin
Houston, TX 77030
(832) 826-1917
www.texaschildrens.org

Texas Heart Institute
6770 Bertner Avenue
Houston, TX 77030
(832) 355-9021
www.texasheartinstitute.org

Methodist Specialty and Transplant Hospital
8026 Floyd Curl Drive
San Antonio, TX 79229
(210) 575-8485
sahealth.com

UTAH

Intermountain Medical Center
5121 S. Cottonwood Street
Salt Lake City, UT 84157
(801) 507-4785
www.uahp.com
University of Utah Health Care
50 North Medical Drive
Salt Lake City, UT 84132
(801) 581-2121
healthcare.utah.edu

VIRGINIA

University of Virginia
University of Virginia Medical Center
1215 Lee Street
Charlottesville, VA 22908
(434) 924-0211
www.healthsystem.virginia.edu

Inova Fairfax Hospital
3300 Gallows Road
Falls Church, VA 22042
(703) 776-7075
www.inova.org

Sentara Norfolk General Hospital
600 Gresham Drive
Norfolk, VA 23507
(757) 388-3000
www.sentara.com

Maguire VA Hospital
1202 Broad Rock Blvd
Richmond, VA 23239
(804) 675-5000
www.richmond.va.gov

WASHINGTON

University of Washington Medical Center
1959 NE Pacific Street
Seattle, WA 98195
(206) 598-4300
www.uwmedicine.org

Sacred Heart Medical Center
101 W 8th Avenue
Spokane, WA 99204
(509) 623-7575
www.shmc.org

Tacoma General Hospital
315 Martin Luther King Jr Way
Tacoma, WA 98405
(253) 403-1000
www.multicare.org

WISCONSIN

University of Wisconsin Hospital and Clinics
600 Highland Avenue
Madison, WI 53792
(608) 263-1530
www.uwhealth.org
14. Q: Does insurance reimburse the HeartMate II for Bridge to Transplantation?
   A: Now that the US Food and Drug Administration (FDA) has approved the
   HeartMate II for BTT, implantation for that indication is covered for virtually all
   payers, public or private. For Medicare, implantation of VADs has been
   covered since the late-1990s under their National Coverage Determination for
   VADs used as BTT. The codes for implantation of this device remain the same
   as the HeartMate XVE or the Thoratec IVAD device. Existing private payer
   policies for BTT will cover the HeartMate II as well as any other approved
   VAD.

15. Q: Does insurance reimburse the HeartMate II under the clinical trial for
   Destination Therapy?
A. For the continuing DT arm of the category B IDE clinical trial, coverage is clear at all of our treating centers; all of the Medicare contractors cover the HeartMate II clinical trial. However, once a hospital treats the number of patients in the initial approval letter, they must submit a request for continued coverage to their Medicare contractor.

Private payers have their own patient-benefit-specific guidelines regarding coverage and payment for investigational devices. Payers such as United Health Care, Aetna, Cigna and multiple Blue Cross Blue Shield plans have approved patients in the trial. More than 90 percent of private payer cases have determined that the HeartMate II is coverable, but all private payers make those decisions on a case-by-case basis.

16. Q: Where can I find clinical information about VADs?
   A: Clinical information on Thoratec’s ventricular assist devices is available in the Medical Professionals section of the Thoratec Web site at www.thoratec.com.

* CAUTION: The HeartMate II for Destination Therapy is an investigational device limited by under Federal U.S.A. law to investigational use.

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