



T H O R A T E C[®]
C O R P O R A T I O N

FOR USE ANYTIME

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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 American (HFSA), more than five million Americans are living with heart failure, and 600,000 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.

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea (shortness of breath).

Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

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) and 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 allows 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 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 was the first time the FDA 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 was a prospective, randomized evaluation of the HeartMate II LVAS. Patients were 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 initially involved 200 patients in its primary cohort at 38 sites, randomizing the HeartMate II LVAS to the HeartMate XVE LVAS on a 2-1 basis, respectively. The objective of the DT arm of the trial was to determine the safety and efficacy of the HeartMate II LVAS as DT in advanced heart failure patients who did not qualify for cardiac transplantation.

10. Q: How many patients were enrolled in the trial?

A: As of July 24, 2009, enrollment in the DT arm reached 795 patients. In total, 1,149 patients have been enrolled in the pivotal trial, by far the largest VAD study ever conducted. FDA Approval of HeartMate II for Destination Therapy was announced on January 20, 2010.

11. 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 included patients who were not candidates for heart transplantation due to age or other health conditions. Most candidates were classified as NYHA Class IV.

The criteria of the trial allowed the DT arm to enroll some late-stage NYHA Class IIIB heart failure patients.

12. Q: Does insurance reimburse the HeartMate II for Bridge to Transplantation and Destination Therapy?

A: The majority of private payors cover LVAD procedures when performed according to the FDA-approved indications. Multiple private payers, including Blue Cross plans, Aetna, Cigna, Humana, Optum Health Group, have published positive coverage decisions related to Thoratec products. The Centers for Medicare & Medicaid Services (“CMS”) covers any procedures using Thoratec VADs for FDA-approved indications, including reimbursement for the use of the Left Ventricular Assist System for Destination Therapy at Joint Commission certified centers.

13. Q: Where can I find clinical information about VADs?

A: Clinical information on Thoratec’s ventricular assist devices is available in the “VAD Trials and Outcomes” section at www.thoratec.com.

14. Q: Which centers currently offer HeartMate II?

A: There are more than 100 HeartMate II centers in North America. A list of centers 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

USC University Hospital
1500 San Pablo Street
Los Angeles, CA 90033
(888) 770-5700
www.uscuniversityhospital.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

Orlando Regional Medical Center
1414 Kuhl Avenue
Orlando, FL 32806
(321) 843-7000
www.orlandohealth.com

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
Suite 1200
Louisville, KY 40202
(502) 583-8383
www.ucsamd.com

LOUISIANA

Ochsner Medical Center
Heart and Vascular Institute
1514 Jefferson Hwy
New Orleans, LA 70121
1-866-OCHSNER
www.ochsner.org/services/heart_vascular

Tulane Medical Center
1415 Tulane Ave
New Orleans, LA 70112
(504) 988-5800
www.tuhc.com

MAINE

Maine Medical Center
818 Congress Street
Portland, ME 04102
(207) 773-8161
www.mmc.org

MARYLAND

The Johns Hopkins Hospital
600 North Wolfe Street
Baltimore, MD 21287
(410) 955-2800
www.hopkinshospital.org

University of Maryland Medical Center
22 South Greene Street
Baltimore, MD 21201
(800) 492-5538
www.umm.edu

MASSACHUSETTS

Brigham and Women's Hospital

15 Francis Street
Boston, MA 02115
(617) 732-7678
www.brighamandwomens.org

Massachusetts General Hospital

MGH Heart Failure and Transplant Service
55 Fruit Street
Boston, MA 02114
(517) 726-9554
www.massgeneral.org

Tufts-New England Medical Center

750 Washington Street
Boston, MA 02111
(617) 636-6137
www.tufts-nemc.org

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 JERESY

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

Wake Forest University Baptist Medical Center
300 S. Hawthorne Road South
Winston Salem, NC 27103-2732
(336) 716-2011
www.wfubmc.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

OREGON

Providence Portland Medical Center

4805 NE Glisan Street
Portland, OR 97213
(503) 215-1111
www.providence.org/Oregon/facilities/hospitals/providence_portland

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

St. Lukes Medical Center

2900 W. Oklahoma Avenue
Milwaukee, WI 53215
(414) 649-5410
www.stlukesmedcenter.com

CANADA

St. Paul's – Vancouver

1081 Burrard Street
Vancouver, BC V6Z 1Y6
(604) 682-2344
www.providencehealthcare.org

Queen Elizabeth II / Capital Health

Halifax Infirmery
1796 Summer Street
Halifax, NS B3H 3A7
(902) 473-2700
www.cdha.nshealth.ca

St. Boniface General Hospital

409 Tache Avenue
Winnipeg MB R2H 2A6
(204) 233-8563
www.sbgh.mc.ca

Ottawa Hospital

1053 Carling Ave
Ottawa, ON K1Y 4E9
(613) 722-7000
www.ottawahospital.on.ca

Toronto General Hospital

4N-464, Toronto General Hospital
200 Elizabeth Street
Toronto, ON M5G 2C4
(416) 340-3562
www.uhn.ca

Montréal Heart Institute

5000 rue Bélanger
Montréal, QC H1T 1C8
(514) 376-3330
www.icm-mhi.org

Royal Victoria Hospital

687 Pine Ave West
Montréal, QC H3A 1A1
(514) 842-1231
www.rvh.on.ca

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