

# Use of Cold and Compression Therapy With Total Knee Replacement Patients

**This study is currently recruiting participants.**

Verified by CoolSystems, Inc., October 2009

First Received: July 7, 2008 Last Updated: October 7, 2009 [History of Changes](#)

<b>Sponsor:</b>	<b>CoolSystems, Inc.</b>
<b>Information provided by:</b>	CoolSystems, Inc.
<b>ClinicalTrials.gov Identifier:</b>	NCT00712816

## ► Purpose

The purpose of the study is to evaluate the effectiveness of a device that delivers cold and intermittent compression as compared to ice and compressive wraps on patients who have undergone knee replacement.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Osteoarthritis Total Knee Arthroplasty	Device: Game Ready Injury Treatment System (CoolSystems Inc.) Other: Ice with compressive bandages	Phase IV

Study Type:      Interventional

Study Design:    Treatment, Randomized, Single Blind (Outcomes Assessor), Parallel  
Assignment, Efficacy Study

Official Title:    Investigating the Use of a Cryopneumatic Therapy Device in Primary  
Total Knee Arthroplasty Patients

## Resource links provided by NLM:

[MedlinePlus](#) related topics: [Knee Replacement](#) [Osteoarthritis](#)

[U.S. FDA Resources](#)

## Further study details as provided by CoolSystems, Inc.:

Primary Outcome Measures:

- Physical function performance [ Time Frame: 2 weeks postoperative, 6 weeks postoperative, 6 months postoperative ] [ Designated as safety issue: No ]
- Time to reach defined physical therapy milestones [ Time Frame: 2 weeks postoperative, 6 weeks postoperative, 6 months postoperative ] [ Designated as safety issue: No ]

Estimated Enrollment: 224

Study Start Date: July 2008

Estimated Study Completion Date: June 2010

Estimated Primary Completion Date: January 2010 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
A: Experimental	Device: Game Ready Injury Treatment System (CoolSystems Inc.) Cold with intermittent compression postoperatively for 2 weeks
B: Active Comparator	Other: Ice with compressive bandages Cold with static compression postoperatively for 2 weeks

### Detailed Description:

The use of cryotherapy with compression for orthopedic postoperative recovery has not been fully investigated. A new device has been developed that combines cold and intermittent pneumatic compression in a single system. A well-controlled clinical study evaluating the clinical effectiveness of cryotherapy with compression in an orthopedic postoperative application is the subject of this protocol. Patients diagnosed with osteoarthritis of the knee and scheduled for primary total knee arthroplasty procedure will be invited to participate in this study.

### ► Eligibility

Ages Eligible for Study: 18 Years to 85 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

### Criteria

#### Inclusion Criteria:

- At least 18 but no more than 85 years of age
- Body Mass Index not greater than 40
- Diagnosis of osteoarthritis of the knee

- Medically cleared for total knee replacement surgery
- Physically and mentally able and willing to participate in and follow the study protocol and schedule
- Able and willing to have all postoperative physical therapy visits in a physical therapy clinic associated with the research site
- Signed informed consent document for the study

Exclusion Criteria:

- Rheumatoid arthritis
- Severe pitting edema in the ipsilateral limb
- History of thrombophlebitis in lower extremities
- An active systemic disease such as AIDS, HIV, hepatitis, etc.
- Is immunologically suppressed or has received or is receiving steroids at any dose daily for more than one month within the last 12 months
- Is pregnant or planning to become pregnant during the study period
- Any condition that would contraindicate using the Game Ready
- Currently enrolled in another clinical trial that could affect outcome of this study
- Previously enrolled in this study

**▶ Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00712816

**Locations**

**United States, Hawaii**

Tripler Army Medical Center Honolulu, Hawaii, United States, 96859 Contact: J. Scott Reid, MD 808-433-3182 Principal Investigator: Gregory Lee, MD	<b>Recruiting</b>
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**United States, Illinois**

Central DuPage Hospital Winfield, Illinois, United States, 60190 Contact: Linda Abella, RN, BSN, ONC 630-933-6807 <a href="mailto:Linda.Abella@cdh.org">Linda.Abella@cdh.org</a> Principal Investigator: Scott Sporer, MD	<b>Recruiting</b>
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**United States, Indiana**

Orthopaedic Research Foundation Indianapolis, Indiana, United States, 46278 Contact: Darrell Whinnery, BS 317-802-2000	<b>Recruiting</b>
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[dwhinnery@orthoindy.com](mailto:dwhinnery@orthoindy.com)

Principal Investigator: Joseph Randolph, MD

### United States, Maine

Eastern Maine Medical Center

Bangor, Maine, United States, 04401

Contact: Denise Michaud 207-973-7175

Principal Investigator: John Bradford, MD

Recruiting

[dmichaud@emh.org](mailto:dmichaud@emh.org)

### United States, New York

Hospital for Special Surgery

New York, New York, United States, 10021

Contact: Basem Aziz, MD 212-606-1128

Principal Investigator: Edwin Su, MD

Recruiting

[azizb@hss.edu](mailto:azizb@hss.edu)

### United States, Ohio

Cleveland Clinic

Cleveland, Ohio, United States, 44195

Contact: Alison Klika 216-444-4954

Principal Investigator: Wael Barsoum, MD

Recruiting

[klikaa@ccf.org](mailto:klikaa@ccf.org)

### United States, Texas

Brooke Army Medical Center

Fort Sam Houston, Texas, United States, 78234

Contact: Socorro Garcia, RN 210-916-2368

[socorro.garcia1@us.army.mil](mailto:socorro.garcia1@us.army.mil)

Principal Investigator: Tad Gerlinger, MD

Recruiting

Sports Medicine Associates of San Antonio

San Antonio, Texas, United States, 78240

Contact: Lisa Rodriguez 210-949-0807

[lrodriguez@endeavorclinicaltrials.com](mailto:lrodriguez@endeavorclinicaltrials.com)

Principal Investigator: David Schmidt, MD

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### United States, Washington

Madigan Army Medical Center

Tacoma, Washington, United States, 98431

Contact: Erinn Morris, RN, MN 253-968-6590

[erinn.morris@us.army.mil](mailto:erinn.morris@us.army.mil)

Principal Investigator: Edward Arrington, MD

Recruiting

### Sponsors and Collaborators

CoolSystems, Inc.

► **More Information**

No publications provided

Responsible Party: CoolSystems, Inc. ( Marianne Baldwin )

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Health Authority: United States: Institutional Review Board

Keywords provided by CoolSystems, Inc.:

osteoarthritis  
total knee arthroplasty  
cryotherapy

Additional relevant MeSH terms:

Musculoskeletal Diseases  
Osteoarthritis  
Joint Diseases  
Arthritis  
Rheumatic Diseases

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