

Lymphedema Isn't a Secret Anymore.



L-Dex[®]

Introducing an Advanced Tool for Aiding in the Clinical Assessment of Unilateral Lymphedema of the Arm and Leg in Women, and the Leg in Men.

Today, most lymphedema is not diagnosed until it is visually apparent. By this point, fibrotic changes and lipid deposition caused by protein rich extracellular fluid stasis have already begun. But now there is hope for early detection and treatment. L-Dex[®] from ImpediMed is the first FDA-cleared medical technology for aiding in the clinical assessment of unilateral lymphedema of the arm and leg in women, and the leg in men. Now there is a new way to help protect your patient's quality of life following cancer.

New Data Demonstrates Early Diagnosis and Treatment Effective in Controlling Lymphedema

In spite of recent advances, lymphedema remains a significant problem—even with the adoption of more conservative cancer treatments. Although new techniques such as sentinel lymph node biopsy have demonstrated some improvement, incidence rates of lymphedema ranging from 4–17% are still cited in the literature for breast cancer patients^{2,3,4,5,6,7,8} and from 5–67% for pelvic cancer patients.^{16,17,18,19}

BREAST CANCER

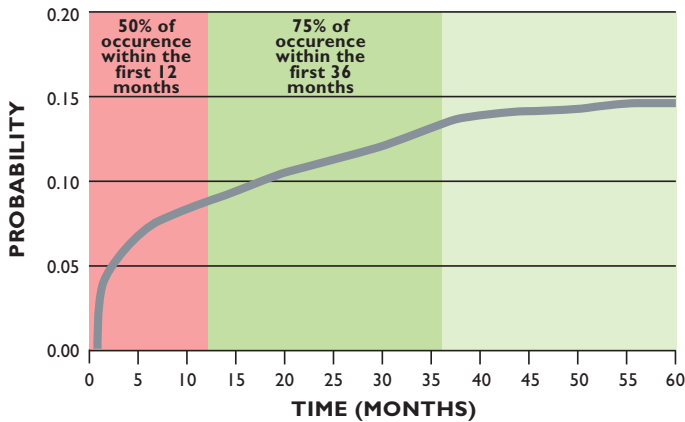
24–49%
after mastectomy¹
4–28%
after lumpectomy¹
4–17%
after sentinel lymph
node biopsy and
radiation therapy^{2,3,4,5,6,7,8}

PELVIC CANCER

41%
after cervical cancer¹⁶
5–10%
after endometrial
cancer^{17,18}
60–67%
after vulvar cancer¹⁹

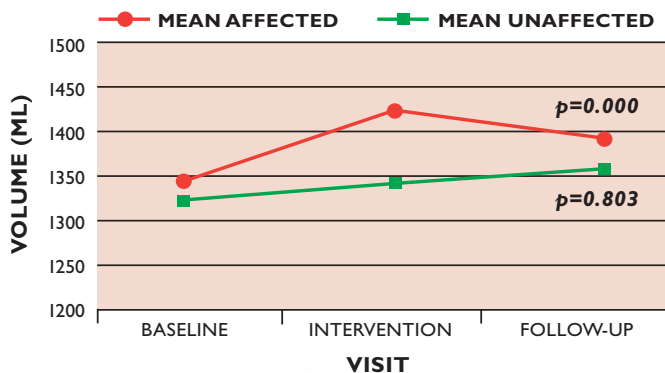


When Do Patients Develop Lymphedema?²⁰



Cumulative data indicates rapid advancement of lymphedema.

NIH Study Confirms the Importance of Early Assessment and Intervention



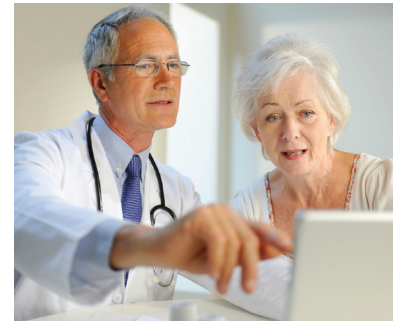
New data from a five year, prospective NIH study demonstrate that it is possible to prevent the progression of lymphedema in patients at risk.¹⁰ This research supports the findings of lymphedema researchers around the globe.^{11,12,13} In addition, there is a growing international consensus among professional organizations in support of the prospective (pre-surgical) assessment of newly diagnosed cancer patients to identify and manage those patients at high risk for lymphedema.^{14,15}

Establishing a Pre-surgical Baseline

Pre-surgical baselines establish what is “normal” for your patient in terms of fluid levels in their arms or legs. Periodic post-operative clinical assessment can detect significant changes from pre-surgical levels. An off-the-shelf compression garment has been demonstrated to be an effective intervention. In the NIH study, all women diagnosed with subclinical lymphedema returned to their pre-surgical baseline arm volume after an average of 4.4 weeks.^{9,10} None (0%) progressed to a Stage 2 or Stage 3 lymphedema.

Keeping Score for Your Patients: The Lymphedema Index (L-Dex)

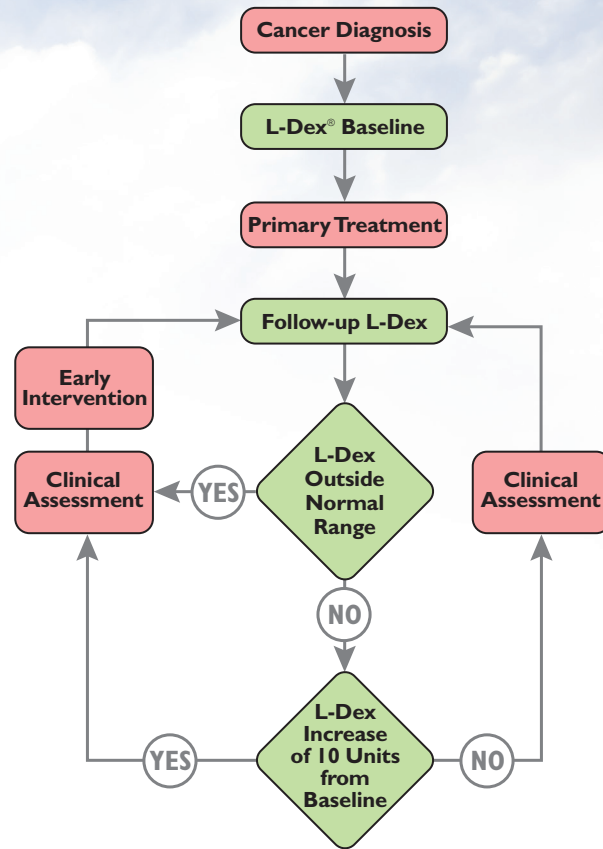
ImpediMed's L-Dex technology utilizes bioimpedance spectroscopy to measure the characteristics of current flow changes through the extracellular fluid in the patient's limb. These changes can assist the surgeon and oncologist in clinically assessing patients for the early signs of lymphedema.



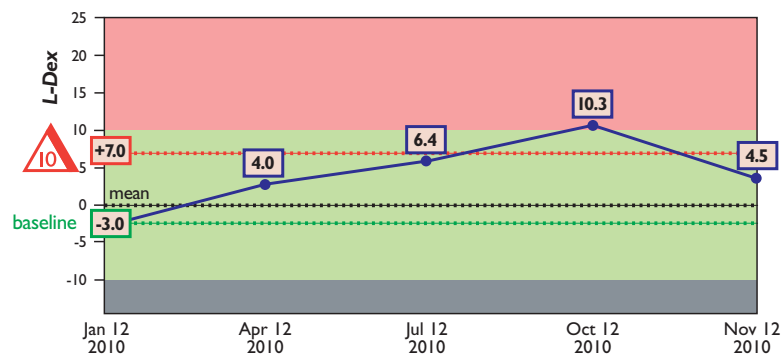
L-Dex is a simple, noninvasive measurement of extracellular fluid conductivity, performed in your office.

- The L-Dex score is specific for extracellular fluid.
- As fluid accumulates in the affected limb, L-Dex values increase on this scale.
- The device provides an immediate result and is provided with software for tracking changes in the patient's L-Dex values over time.

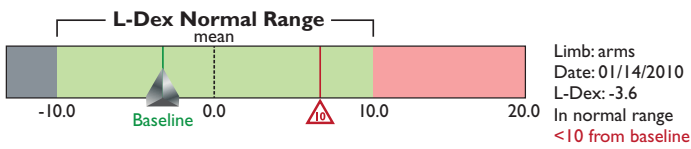
A New Paradigm for Lymphedema Management



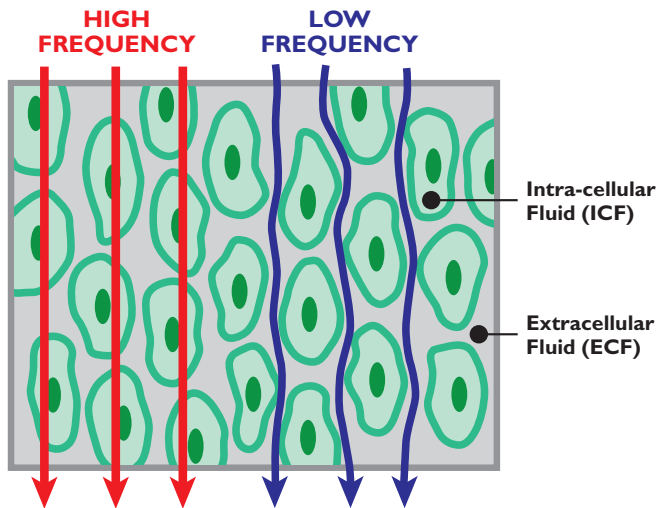
Pre-operative assessment, prospective surveillance and early intervention may have prevented the onset of irreversible Lymphedema in this cohort of 43 patients.^{9,10}



This image demonstrates the concept of a Delta 10 shift from a pre-surgical baseline of -3 L-Dex units. The orange "Delta 10" line is shown for demonstration purposes only to allow the reader to more easily visualize the Delta 10 concept.



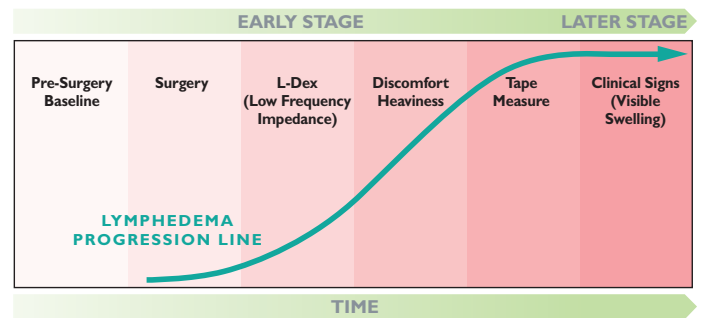
L-Dex values that lie outside the normal range may indicate the early signs of lymphedema. Values that have changed +10 L-Dex units from baseline may also indicate early lymphedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphedema by a medical provider.



A New Level of Confidence for Everyone

L-Dex technology is creating a new paradigm for all parties involved with lymphedema management.

- Physicians can now reduce the severity of lymphedema and its physiological and psychological impact.
- Patients can return to the quality of life they enjoyed prior to their cancer treatment knowing their physician can clinically assess and treat the early signs of lymphedema.
- Health insurance providers benefit from reduced costs and a preventative approach to an otherwise chronic, lifelong condition with significant medical risks.



The Four Stages of Unilateral Lymphedema*†



STAGE 0



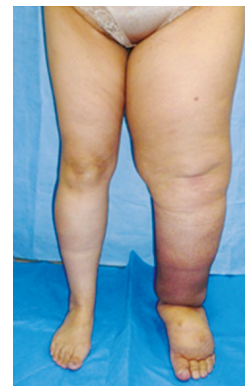
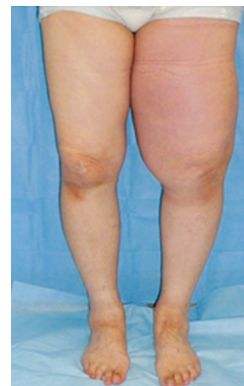
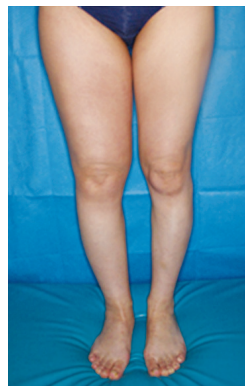
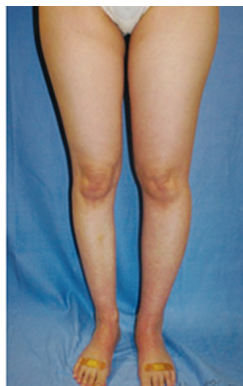
STAGE I



STAGE II



STAGE III



REFERENCES

1. Warren A, Brorson H, Borud L, and Slavin S, Lymphedema: A Comprehensive Review, *Annals of Plastic Surgery* Volume 59, Number 4, 2007.
2. Francis WP, Abghari P, Du W, Rymal C, Suna M, Kosir MA. Improving surgical outcomes: standardizing the reporting of incidence and severity of acute lymphedema after sentinel lymph node biopsy and axillary lymph node dissection. *Am J Surg* 2006;192(5):636-9. Available from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=17071198 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=17071198>.
3. Armer J, Fu MR, Wainstock JM, Zagar E, Jacobs LK. Lymphedema following breast cancer treatment, including sentinel lymph node biopsy. *Lymphology* 2004;37(2):73-91. Available from PM:15328760.
4. Leidenius M, Leivonen M, Vironen J, von Smitten K. The consequences of long-time arm morbidity in node-negative breast cancer patients with sentinel node biopsy or axillary clearance. *J. Surg. Oncol.* 2005;92(1):23-31. Available from PM:16180231.
5. Langer I, Guller U, Berclaz G, Koechli OR, Schauer G, Fehr MK, et al. Morbidity of sentinel lymph node biopsy (SLN) alone versus SLN and completion axillary lymph node dissection after breast cancer surgery: a prospective Swiss multicenter study on 659 patients. *Ann Surg* 2007;245(3):452-61. Available from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=17435553 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=17435553>.
6. Clark B, Sitzia J, Harlow W. Incidence and risk of arm oedema following treatment for breast cancer: a three-year follow-up study. *QJM.* 2005;98(5):343-48. Available from PM:15820971.
7. Umberto Veronesi, M.D., Giovanni Paganelli, M.D., Giuseppe Viale, F.R.C.Path., Alberto Luini, M.D., Stefano Zurrada, M.D., Viviana Galimberti, M.D., Mattia Intra, M.D., Paolo Veronesi, M.D., Chris Robertson, Ph.D., Patrick Maisonneuve, Eng., Giuseppe Renne, M.D., Concetta De Cicco, M.D., Francesca De Lucia, M.D. and Roberto Gennari, M.D.: A Randomized Comparison of Sentinel-Node Biopsy with Routine Axillary Dissection in Breast Cancer. *N Engl J Med* Volume 349;6:546-553 August 7, 2003.
8. Haid et al: Morbidity of Breast Cancer Patients Following Complete Axillary Dissection or Sentinel Node Biopsy Only: A Comparative Evaluation. *Breast Cancer Research and Treatment* Volume 73, Number 1 / May, 2002.
9. Gergich N, Pfalzer L, Soballe P, Washington F, and McGarvey C: "Preoperative Assessment Improves early Diagnosis and Treatment of Lymphedema" Poster, Society of Surgical Oncology, Washington DC, 15-18 Mar 2007.[Poster] <http://www.wcpt.org/abstracts2007/Abstracts/29-05.htm>.
10. Gergich N, Pfalzer L, McGarvey C, Springer B., Gerber L, Soballe P. Preoperative assessment Enables the Early Diagnosis and Successful Treatment of Lymphedema: *Cancer* Volume 112, Issue 12, Pages 2809-2819, 15 June 2008. <http://www3.interscience.wiley.com/cgi-bin/abstract/118821880/ABSTRACT>.
11. Armer JM, Stewart BR. A comparison of four diagnostic criteria for lymphedema in a post-breast cancer population. *Lymphat Res Biol* 2005;3(4):208-17. Available from http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=16379589 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=16379589>.
12. Robyn C. Box, Hildegard M. Reul-Hirche, Joanne E. Bullock-Saxton and Colin M. Furnival: Physiotherapy after breast cancer surgery: results of a randomized study to minimise lymphoedema. *Breast Cancer Research and Treatment* 75:51-64, 2002.
13. Johansson K, Ohlsson K, Ingvar C, Albertsson M, Ekdahl C. Factors associated with the development of arm lymphedema following breast cancer treatment: a match pair case-control study. *Lymphology* 2002;35(2):59-71. Available from PM:1208105.
14. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. *Lymphology* 2003;36(2):84-91.
15. Harris, Susan R., Hugi, Maria R., Olivotto, Ivo A., Levine, Mark Clinical practice guidelines for the care and treatment of breast cancer: 11. *Lymphedema CMAJ* 2001 164: 191-199.
16. Werngren-Elgstrom M, Lidman D. Lymphedema of the lower extremities after surgery and radiotherapy for cancer of the cervix. *Scand J Plast Reconstr Surg Hand Surg* 1994;28:289-93.
17. Nunns D, Williamson K, Swaney L, et al. The morbidity of surgery and adjuvant radiotherapy in the management of endometrial carcinoma. *Int J Gynecol Cancer* 2000;10:233-8.
18. Fujiwara K, Kigawa J, Hasegawa K, et al. Effect of simple omentoplasty and omentopexy in the prevention of complications after pelvic lymphadenectomy. *Int J Gynecol Cancer* 2003;13:61-6.
19. Carlson J, Kauderer J, Walker J, Gold M, O'Malley D, Tuller E, Clarke-Pearson D. Phase III trial of Tisseel to reduce lymphedema after inguinal lymph node dissection: a Gynecologic Oncology Group study. The 38th Annual Meeting on Women's Cancer. March 3-7, 2007. San Diego, CA. Abstract #228.
20. Herd-Smith et al: Prognostic factors for lymphedema after primary treatment of breast carcinoma. *Cancer* Vol 92, 7, 1783-1787, 2001.

*Arm photos courtesy of Dr. Charles McGarvey and Guenter Klose.

†Leg photos from Mihara M, Hara H, Hayashi Y, Narushima M, et al. (2012) Pathological Steps of Cancer-Related Lymphedema: Histological Changes in the Collecting Lymphatic Vessels after Lymphadenectomy. *PLoS ONE* 7(7): e41126. doi:10.1371/journal.pone.0041126 <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0041126>.



www.impedimed.com | www.L-Dex.com

ImpediMed Inc.
5900 Pasteur Court, Suite 125, Carlsbad, CA 92008
Toll Free: +1-877-247-0111 Email: info@impedimed.com

ImpediMed and L-Dex are registered trademarks of ImpediMed, Limited. ©2014 ImpediMed, Limited.