

**FOR IMMEDIATE RELEASE**

**Contact:**

Intact Medical Corporation  
Christopher Bleck, President and CEO  
508-655-7820

Rx Communications Group  
Pat Garrison (media) 917-322-2567  
Judith Sylk-Siegel (media) 917-322-2164

**INTACT MEDICAL CORPORATION ANNOUNCES INITIATION OF U.S. MULTI-CENTER PERCUTANEOUS EXCISION CLINICAL TRIAL (I-PET)**

**NATICK, MA, June 26, 2006** – Researchers today will begin a large, multi-center, multi-disciplinary clinical study designed to determine whether women at high risk of developing breast cancer can avoid an open surgical biopsy by demonstrating that a definitive diagnosis can be made from a tissue sample collected with the minimally-invasive *Intact*<sup>™</sup> Breast Lesion Excision System (BLES).

The study, sponsored by privately-held Intact Medical Corporation, will investigate the effectiveness of the *Intact* BLES in identifying women who have been diagnosed with atypical ductal hyperplasia (ADH) – abnormal, yet benign cells in the breast that increase their risk of cancer. The *Intact* BLES is an image-guided biopsy procedure in which a slender wand is inserted through a small incision in the breast to remove an intact sample of suspicious tissue for histopathological analysis. The procedure is performed under local anesthesia in a physician’s office or other outpatient setting. After capture, the small incision is closed with a bandage and requires no stitches.

A study in the *New England Journal of Medicine*<sup>1</sup> cited a four-fold increase in the risk of breast cancer in women with ADH. While the majority of patients with these high-risk lesions do not develop breast cancer, current guidelines call for careful monitoring.<sup>2</sup>

“Thousands of women each year are diagnosed with ADH and other high-risk breast lesions that are benign,” said Christopher Bleck, President and Chief Executive Officer of Intact Medical Corporation. “However, the increased risk of breast cancer in these women requires careful monitoring, frequent mammograms and multiple biopsies. This prospective, multi-site, study, the first of its kind, is designed to prove the *Intact* BLES is an effective alternative to open surgical biopsy for patients with high-risk breast lesions. Standard core needle biopsy, which cuts and shreds tissue, makes full pathological assessment impossible, making a secondary procedure mandatory for these high-risk breast lesions. With the *Intact*<sup>™</sup> BLES, physicians and pathologists will soon have a proven, highly accurate alternative for clinical assessment of such lesions.”

Clinical studies in more than 1,500 patients have shown that the **Intact** BLES effectively simulates surgical biopsy by completely excising a lesion intact. The system avoids fragmenting of the lesion, while retaining its architectural integrity in a surgical-quality sample. As a result, the **Intact** BLES permits the pathologist to accurately evaluate the full extent of the lesion, negating the need for confirmatory surgical excision of many high-risk breast lesions.

The **I-PET** trial will enroll approximately 4,000 women, aged 18 and over, at up to 40 centers throughout the U.S. To participate in the trial, patients must have had an imaged abnormality found via a mammogram or sonogram, which warrants a biopsy for further diagnosis. The objective of the trial is to confirm that surgical intervention can be avoided by using the **Intact** BLES for a definitive diagnosis of the most prominent high-risk breast lesion, ADH.

#### **About Intact Medical Corporation**

Founded in 1998, and based in Natick, Massachusetts, Intact Medical Corporation is a privately held company focused on the design, development and marketing of innovative, minimally invasive systems for the volumetric excision of tissue for diagnostic and therapeutic applications in select cancer markets. The Company's lead product, the **Intact** Breast Lesion Excision System, received market clearance from the Food and Drug Administration in June 2001. Initial products are targeted at breast biopsy and the excision of benign lesions, potentially obviating the need for open surgical excisions. In August 2005, the company received expanded approval for the System, allowing its use to obtain tissue samples for histologic examination with partial or complete removal of an imaged abnormality, or partial removal of a palpable abnormality that has been classified as benign.

1. Hartman LC, Sellers TA, et. Al. Benign breast disease and the risk of breast cancer. NEJM;353:229-237.
2. US Department of Health and Human Services, National Institutes of Health. Understanding Breast Changes: A Health Guide for All Women.

For more details on the Company, visit [www.intactmedical.com](http://www.intactmedical.com)

###