



Theraclion, a leader in the non-invasive ablation of small tumors, uses ultrasound for the first time to successfully treat breast fibroadenomas in two patients

- ✓ *A non-invasive, non-scarring alternative with no side effects*
- ✓ *The two patients have been successfully treated in Bulgaria*

Paris, November 29, 2011 - [Theraclion](#) is an innovative start-up developing the TH-One system for the non-invasive ablation of small tumors (thyroid nodules, parathyroid gland pathologies and breast fibroadenomas). It today announced the first ever successful treatments of two breast fibroadenoma patients (in Bulgaria) using its high-intensity, focused ultrasounds (HIFU) technology¹. A second study on the treatment of breast fibroadenoma (this time in France) has just been launched.

With six months' hindsight, it is clear that the treatment of the first patients included in the Bulgarian clinical trial (initiated in spring 2011) has been a success. The fibroadenomas have shrunk in volume by 64%. The lump has become softer on palpation and the patients are totally satisfied with the outcomes.



"In view of the excellent results already obtained in Bulgaria in this first study in patients with breast fibroadenomas, we have decided to launch a new clinical trial in France. This will enable us to gather more data and accelerate the adoption of our technology and the TH-One treatment system. Our solution is a true alternative for women keen to avoid surgery for the treatment of their benign tumors", stated Theraclion's Marketing Director David Del Bourgo.

"When my physician suggested ultrasound treatment, I decided to try it because as a young woman, I did not want to risk having a scar on my breast. Six months after the ultrasound treatment, the lump is much smaller - I can hardly feel it and I am totally satisfied", emphasized 27-year-old Marina² (treated in May 2011 in the Bulgarian study).

"I have always been very scared of surgery - particularly the general anesthesia and the risk of having a scar on the breast. Six months after the treatment, I am very pleased with the result because the lump is much smaller and doesn't bother me anymore", commented 22-year-old Roza³ (treated in May 2011 in the Bulgarian study).

¹ High Intensity Focused Ultrasound

² not her real name

³ not her real name

"The results obtained here are very promising. I saw a remarkable difference in the size of the fibroadenomas, both clinically and in an ultrasound examination. They can barely be felt by palpation and the two patients are very satisfied", commented Professor Roussanka Kovatcheva (Sofia University Medical Center), who performed the HIFU treatments in May of this year.

A second prospective, multicenter study has just been launched in France. It plans to include 20 patients over a 6-month period and will be performed at two prestigious investigating centers in Paris and Lille. The trial's objective is to confirm the efficiency of HIFU use in the treatment of breast fibroadenomas. This will be demonstrated by a reduction in the fibroadenoma's size and (for some patients) by histological analysis. Positive study results would prove the potential for ablating a fibroadenoma without having to resort to surgery – thus avoiding general anesthesia and the trauma of scarring. HIFU treatments are performed in a single session under sedation and on an outpatient basis. They last for about 30 to 40 minutes, depending on the size of the fibroadenoma.

"Theraclion's technology meets needs in fibroadenoma treatment and constitutes an innovative, relevant alternative for patients seeking relief from their fibroadenoma without having to undergo surgery", commented Professor Michel Cosson, Professor of Gynecology and Obstetrics at Jeanne de Flandres Hospital (Lille University Medical Center).

Breast fibroadenoma is the most common benign breast tumor. 10% of women will develop a fibroadenoma at some point in their lifetime. In the United States, fibroadenomas account for around half of the 1.6 million breast biopsies performed each year⁴. In France, several tens of thousands of fibroadenomas are detected each year. This pathology can be observed at any age but mainly concerns women under 30. The fibroadenoma is generally detected by palpation. However, the fibroadenoma can be asymptomatic and may only be detected after a mammography or an ultrasound examination. Detection of a nodule in the breast will prompt cytopuncture or a microbiopsy. If the analysis reveals a fibroadenoma, the physician and the patient will decide on the best course of action: regular monitoring or (if the fibroadenoma is bothersome, growing in size or causing anxiety) ablation. The benign nature of the fibroadenoma means that both the patient and physician may consider that surgery is not an appropriate option. The HIFU may be a well-matched response to this problem.

Theraclion's solution

The medical instrument developed by Theraclion (the TH-One) uses HIFU technology. A focused, high-intensity ultrasound beam (like sunlight through a magnifying glass) and rapidly heats a defined area. The cells in the targeted tumor are destroyed without any need to make a scalpel incision on the skin. The breast fibroadenoma can be treated on an outpatient basis.

The TH-One is unique in that it combines ultrasound imaging and HIFU treatment systems in the same compact, mobile machine. In addition to this ease of use, the TH-One offers an excellent image quality, millimeter-scale shot accuracy and an integrated cooling device for the patient's safety.

This type of technology constitutes a novel system for specialists and patients.

⁴ Reference: <http://www.mammotome.com/Mammotome/Breast-Biopsy/Biopsy-ResultsDiagnosis/AboutManaging-Fibroadenomas>

About Theraclion

The Paris-based medtech company Theraclion (incorporated in 2004) specializes in the non-invasive ablation of small targets such as thyroid nodules, parathyroid gland pathologies and (in the near future) breast fibroadenoma. The company has developed a technology platform (TH-One) that combines ultrasound imaging with high-intensity focused ultrasound therapy. After 20 years of cutting-edge research and development, this non-invasive “surgery” enables the very accurate destruction of small areas of tissue delimited by the physician. More than 80 patients have already been treated with this device and the results are very promising. To date, Theraclion has raised €8.6 million from its longstanding investor Truffle Capital and has received significant public funding (€2.3 million from the OSEO innovation agency and €6.9 million as part of the OSEO-ISI TUCE research project). Theraclion is primarily responding to the needs of clinics and hospitals in Europe, the United States and Asia. For more information on Theraclion, visit <http://www.theraclion.com>

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