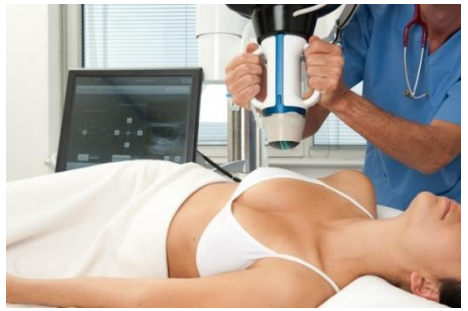
Theraclion
THE SOUND THERAPY

# *Non invasive ultrasound therapy for breast fibroadenomas and thyroid nodules*



## Echotherapy with ECHOPULSE®

# Theraclion at a glance


French company **expert in echotherapy**
Specialist in ultrasound-guided high intensity focused ultrasound

**Public company since 2014**
Created in 2004
ISO 13485:2003 certified

Theraclion's product: the **Echopulse®**
- Class IIb device, according to the council directive 93/42/EEC
- **CE mark for thyroid nodules and breast fibroadenomas treatment**

20 employees among which 70% dedicated to R&D
**International medical and scientific committee support**

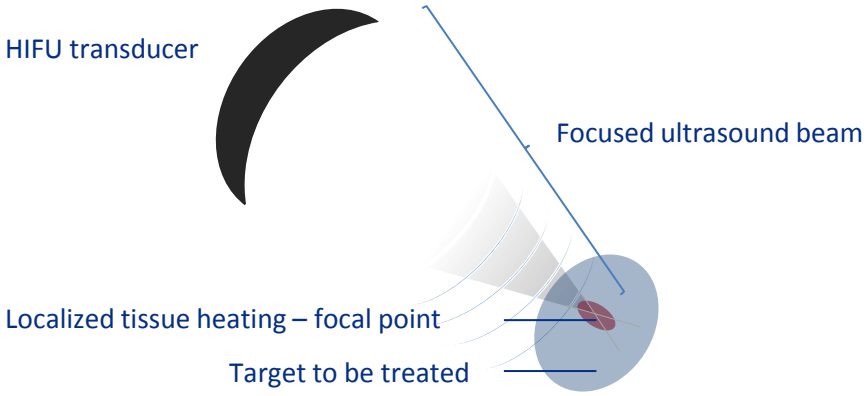
# Echotherapy: an alternative to surgery

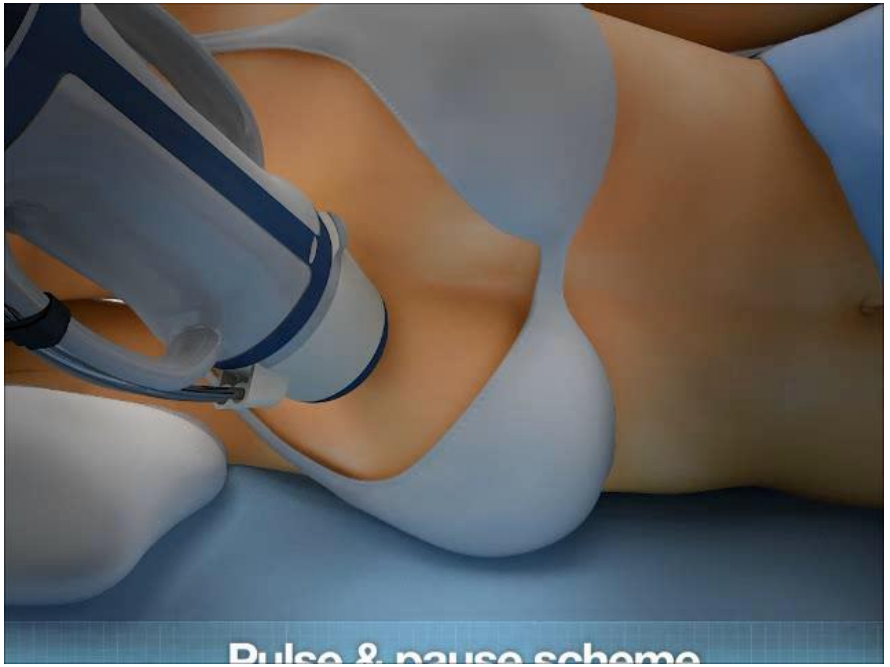
## Surgery

## Echotherapy

# Echotherapy: an alternative to surgery

**Echotherapy**: therapy using **high intensity focused ultrasound under ultrasound guidance**




**High Intensity Focused Ultrasound or HIFU**

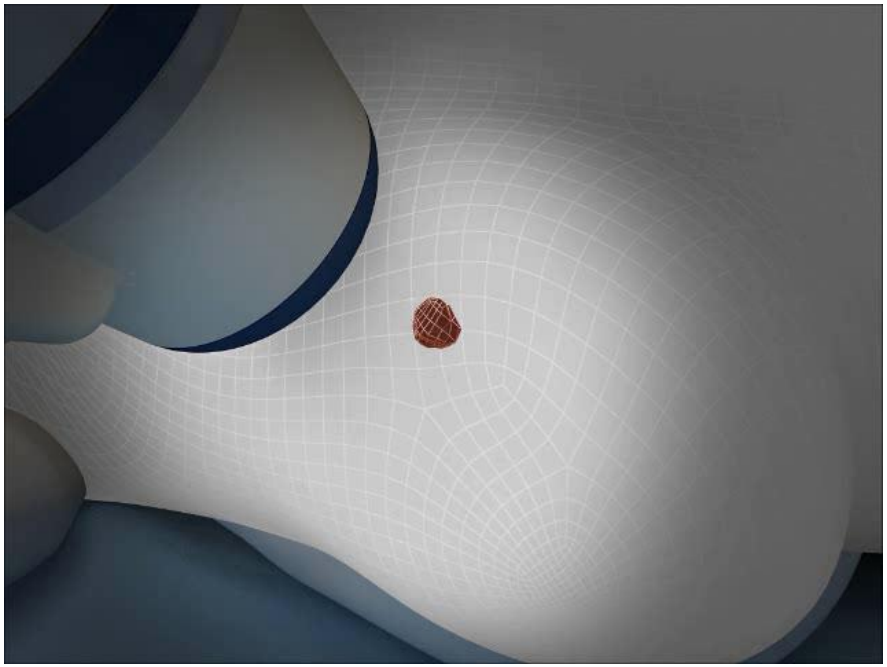
High energy sound waves focused to deliver a large amount of energy in a confined space similar to sunrays through a magnifying glass

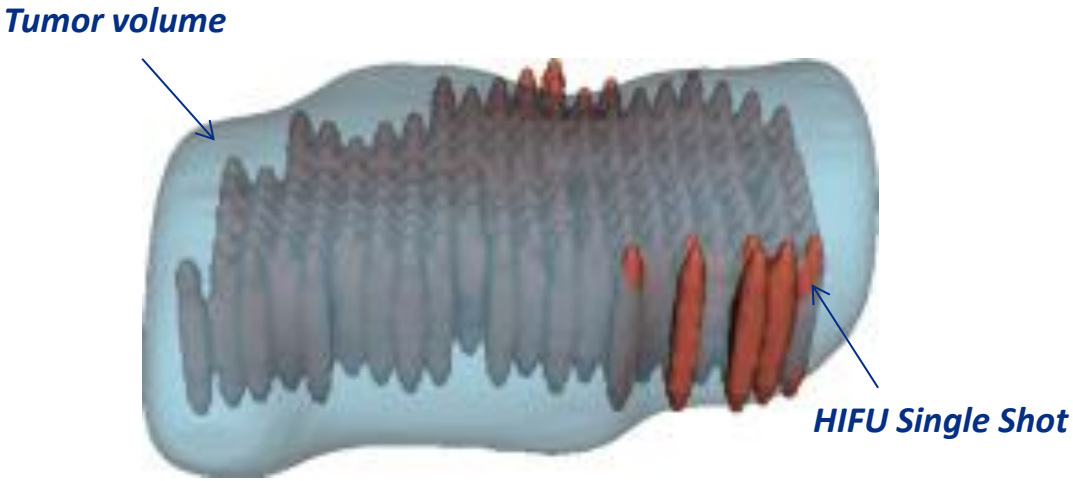
HIFU principle: Tissue heating (85°C) inducing tissue necrosis at the focal point

# Echotherapy: an alternative to surgery

**Echotherapy**: therapy using **high intensity focused ultrasound under ultrasound guidance**

- Sequential treatment made of HIFU Pulse
- Very high focal point accuracy
- Millimetric lesion: 2 x 2 X 9 mm






***3D Planning & Visualization***

# The Echopulse®: a unique technology for echotherapy

## Echopulse®

## Visualization and treatment head

Robotized head

Cooling and coupling system

Ultrasound imaging probe

HIFU transducer

## A unique combination of innovations…

1. Very high focal-spot accuracy
2. Smart patented cooling system
3. Compact, mobile, ergonomic and multi-indications device
4. A smart interface for treatment management

# The Echopulse®: a unique positioning

| |  Theraclion THE SOUND THERAPY HIFU |  RF*/ Laser/ Cryoablation |  Vacuum biopsy |  Surgery |
|---|---|---|---|---|
| **Non-invasiveness** | ✓✓✓✓ | ✓ | ✓ | ✗ |
| **Ease of use/ operator independency** | ✓✓✓ | ✓ | ✓ | ✗ |
| **Low post-operation risks** | ✓✓✓ | ✓✓ | ✓✓ | ✓ |
| **Recuperation time** | ✓✓✓ | ✓✓ | ✓✓ | ✗ |
| **Overall treatment duration** | ✓ | ✓✓ | ✓✓ | ✓ |

**Echotherapy by Echopulse® offers an improved quality of care**

Safety – Efficacy - Scarless

# The Echopulse®: addressing two important markets

| | | **Prevalence** | **Incidence** (EMEA) |
|---|---|---|---|
| **Breast fibroadenoma** |  | **10 %**<br>**Of women will develop a fibroadenoma over the course of their life** | **610,000**<br>**new cases per year** |
| **CE mark obtained for 2 pathologies** | | | |
| **Thyroid nodules** |  | **About 5%**<br>**of the population have palpable nodules** | **911,000**<br>**new cases per year** |

# Proven efficacy and safety on breast fibroadenoma

*Clinical studies in France and Bulgaria*

## Clinical results (51 fibroadenomas treated)

**Efficacy**

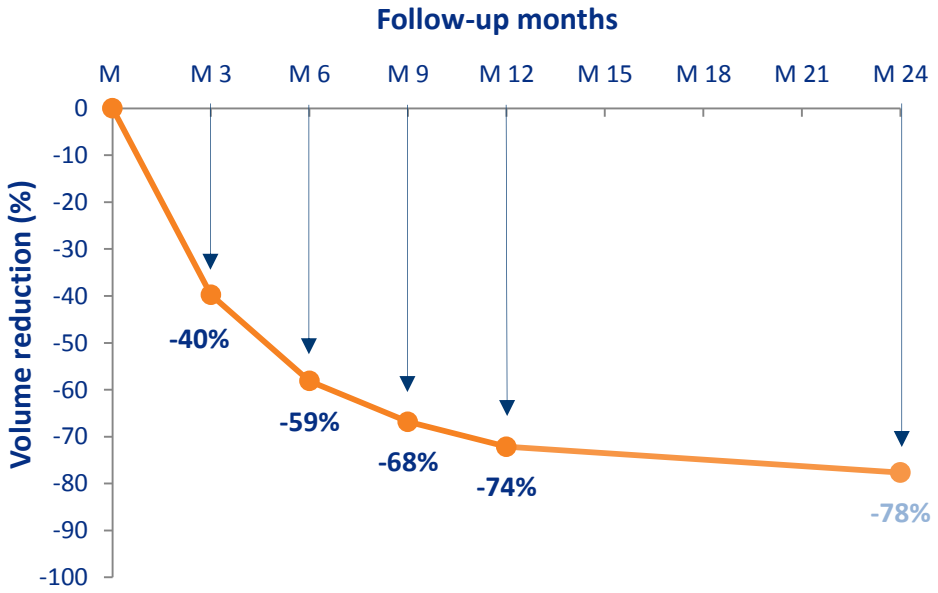
- 100% patients satisfied by echotherapy
- Rapid disappearance of symptoms
- Major average volume reduction in all patients

**Safety**

- Excellent tolerance
- No side effects

## Mean volume reduction over time (% vs. months)

| Volume reduction (%) n=number of pts | 2mo. n=46 | 4mo. n=43 | 6mo. n=48 | 9mo. n=25 | 12mo. n=46 | 24mo. n=24 |
|---|---|---|---|---|---|---|
| Mean (%) | -33% | -47% | -60% | -66% | -74% | -78% |
| Standard deviation (%) | 19% | 22% | 18% | 13% | 15% | 13% |

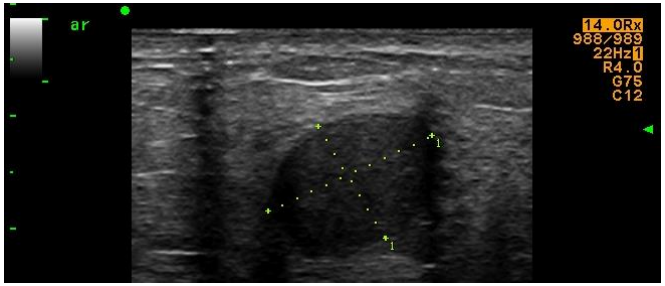



*Source: "Ultrasound-guided High-Intensity-Focused-Ultrasound (HIFU) treatment of breast fibroadenoma" par les Professeurs R. Kovatcheva, J. Stoinov, J.N. Guglielmina, B. Seror, M. Abehsera – Internal data.*

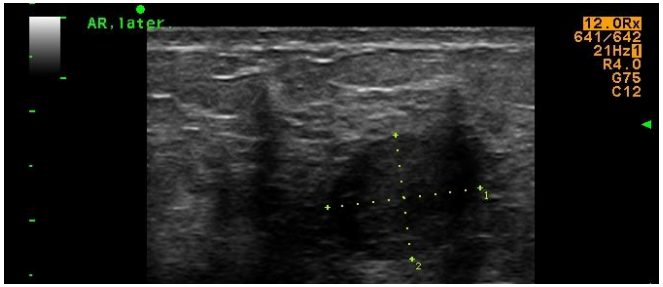
# Proven efficacy on breast fibroadenoma

**Case of a 18yo patient**

**Before HIFU (1.39cc)**

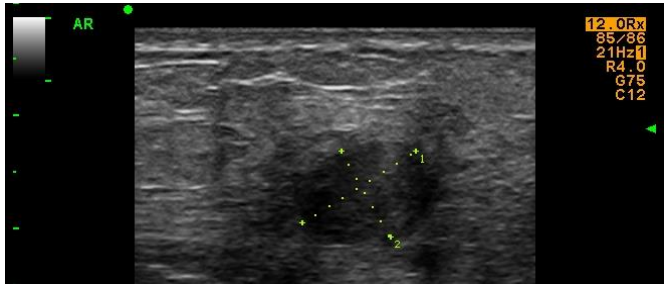



**1 month after HIFU (1.07 cc)**



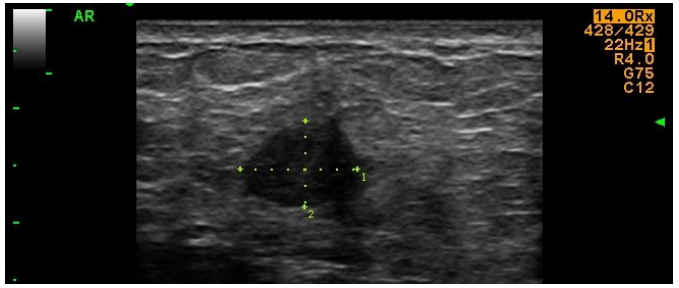

**- 23%**

**2 months after HIFU (0.59 cc)**




**- 57%**

**3 months after HIFU (0.34 cc)**



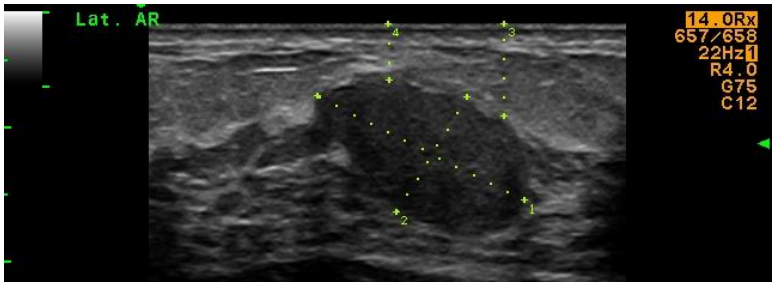

**- 76%**

*Source: "Ultrasound-guided High-Intensity-Focused-Ultrasound (HIFU) treatment of breast fibroadenoma" par les Professeurs R. Kovatcheva, J. Stoinov, J.N. Guglielmina, B. Seror, M. Abehsera – Internal data.*

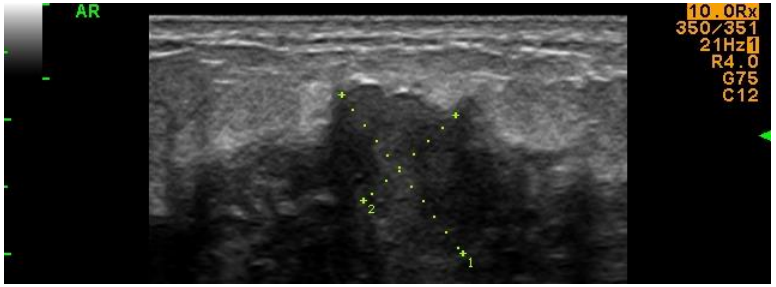
# Proven efficacy on breast fibroadenoma

**Case of a 16yo patient**

**Before HIFU (2.00cc)**

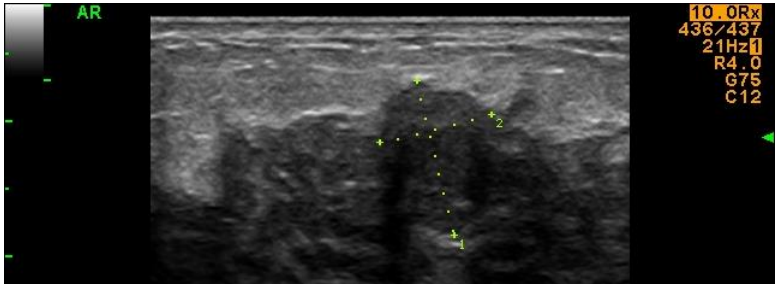



**2 months after HIFU (1.29 cc)**



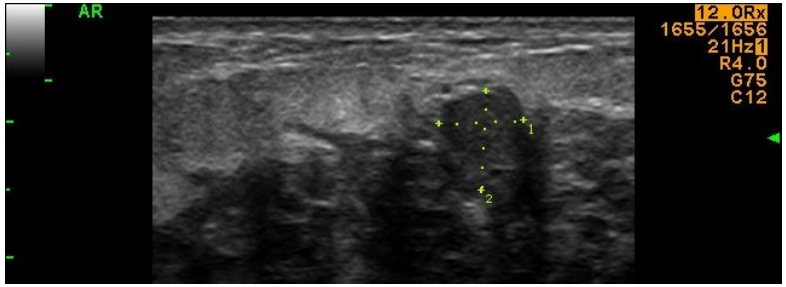

**- 36%**

**4 months after HIFU (0.74 cc)**




**- 63%**

**6 months after HIFU (0.35 cc)**

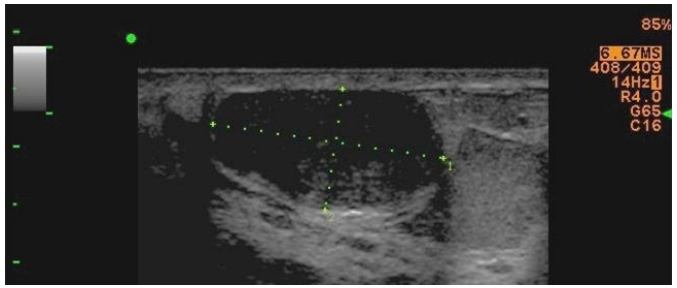



**- 82%**

*Source: "Ultrasound-guided High-Intensity-Focused-Ultrasound (HIFU) treatment of breast fibroadenoma" par les Professeurs R. Kovatcheva, J. Stoinov, J.N. Guglielmina, B. Seror, M. Abehsera – Internal data.*

# Proven efficacy on breast fibroadenoma

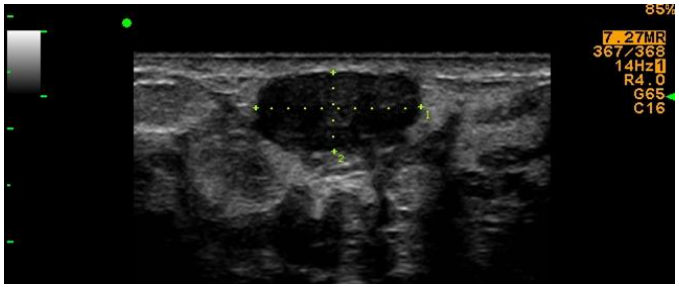
**Before HIFU (1.87 cc)**




**Case of a 27yo patient**

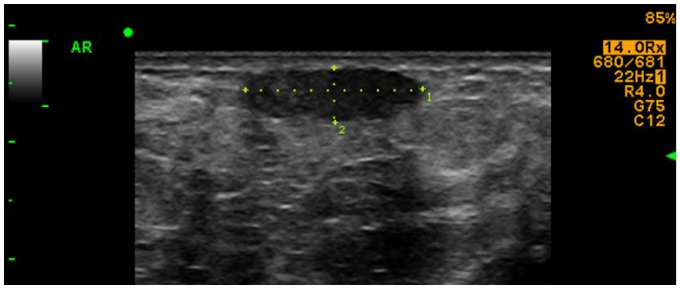
Pregnancy after echotherapy session

**3 months after HIFU (1.04 cc)**



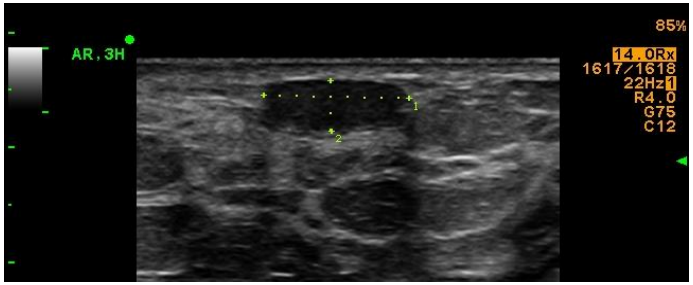

**- 45%**

**12 months after HIFU (0.50 cc)**




**- 73%**

**24 months after HIFU (0.40 cc)**



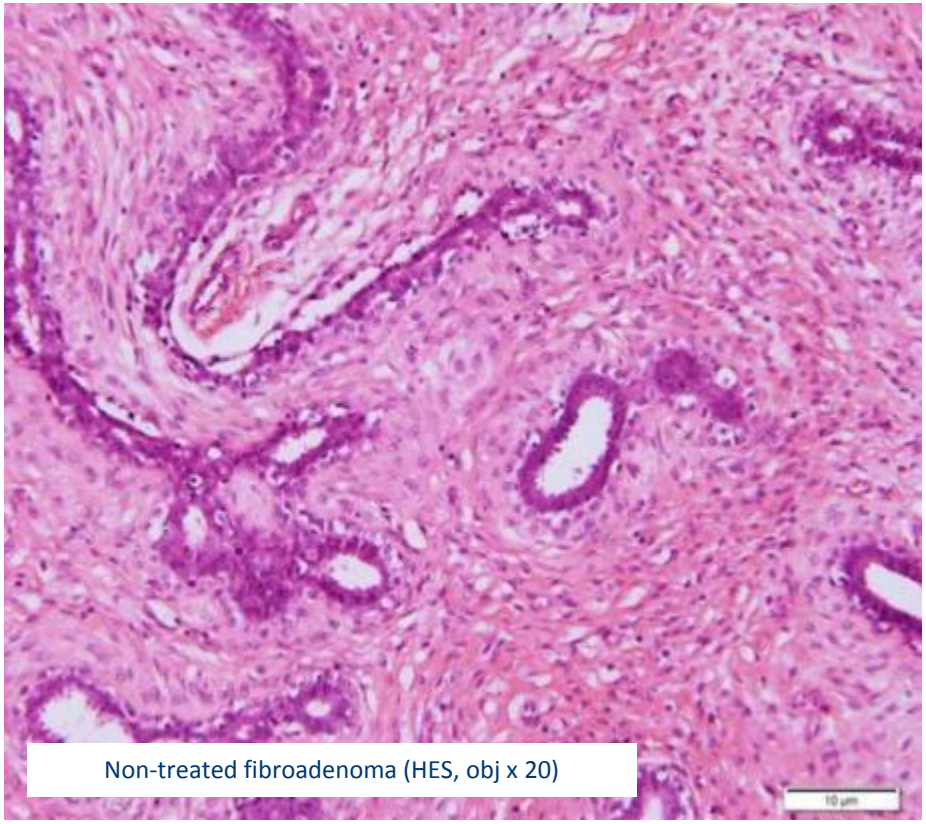

**- 79%**

*Source: "Ultrasound-guided High-Intensity-Focused-Ultrasound (HIFU) treatment of breast fibroadenoma" par les Professeurs R. Kovatcheva, J. Stoinov, J.N. Guglielmina, B. Seror, M. Abehsera – Internal data.*

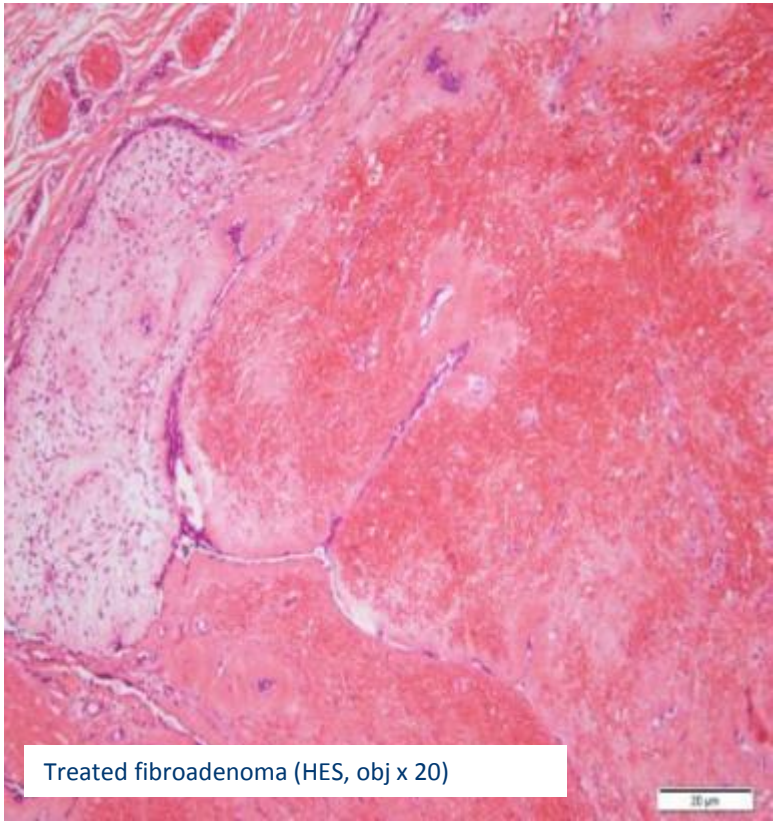
# Proven efficacy on breast fibroadenoma

## Histological tissue comparison

Before and after HIFU treatment



Non-treated fibroadenoma (HES, obj x 20)



Treated fibroadenoma (HES, obj x 20)

**Successful tissue necrosis through echotherapy**

*Source: "Ultrasound-guided High-Intensity-Focused-Ultrasound (HIFU) treatment of breast fibroadenoma" par les Professeurs R. Kovatcheva, J. Stoinov, J.N. Guglielmina, B. Seror, M. Abehsera – Internal data.*

# Proven efficacy and safety on thyroid nodules

*Clinical registry in Bulgaria*

## Clinical results (20 thyroid nodules treated)

**Efficacy**

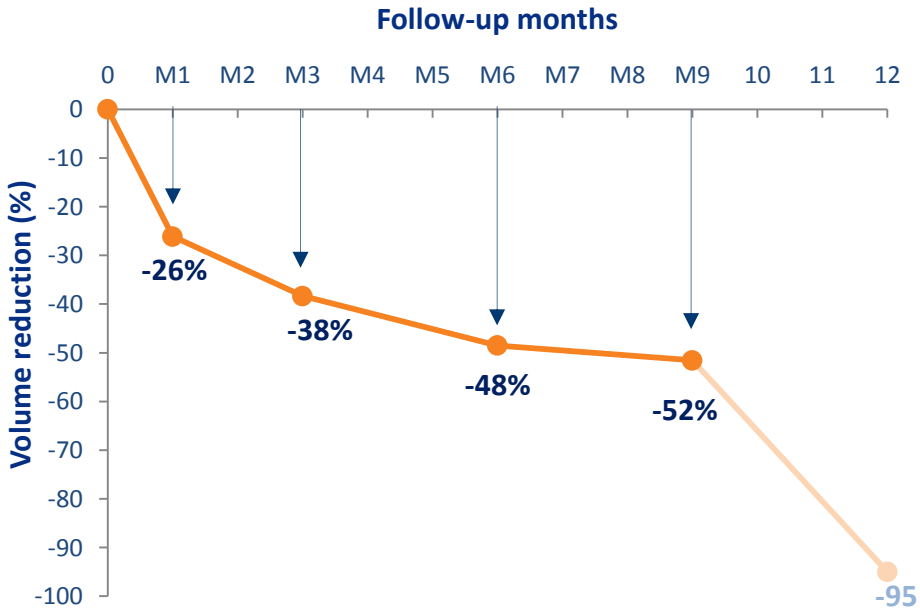
- Fast volume reduction in all patients

**Safety**

- Excellent tolerance
- No modification of the voice
- Normal laryngoscopy after echotherapy

## Mean volume reduction over time (% vs. months)

| Volume reduction (%) n=number of pts | 1mo. n=20 | 3mo. n=20 | 6mo. n=16 | 9mo. n=10 | 12mo. n=2 |
|---|---|---|---|---|---|
| Mean (%) | -26% | -38% | -48% | -52% | -95% |
| Standard deviation (%) | 17% | 21% | 24% | 28% | 0 |

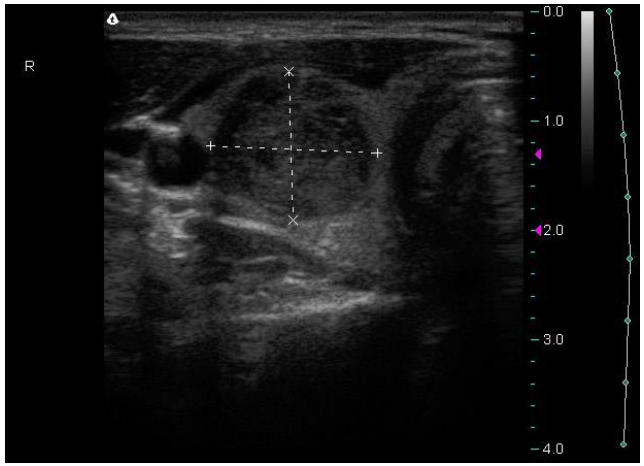



*Source: Prospective Non-Controlled Study of HIFU in Patients with Non-Malignant Thyroid Nodules – Theraclion internal data.*

# Proven efficacy on thyroid nodules

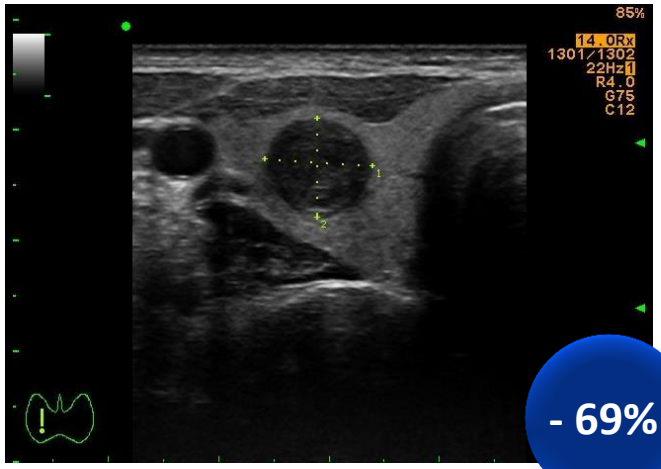
## Case of a 42yo patient

### Before HIFU (1.92 cc)




distance +: 1.53 cm
distance x: 1.36 cm

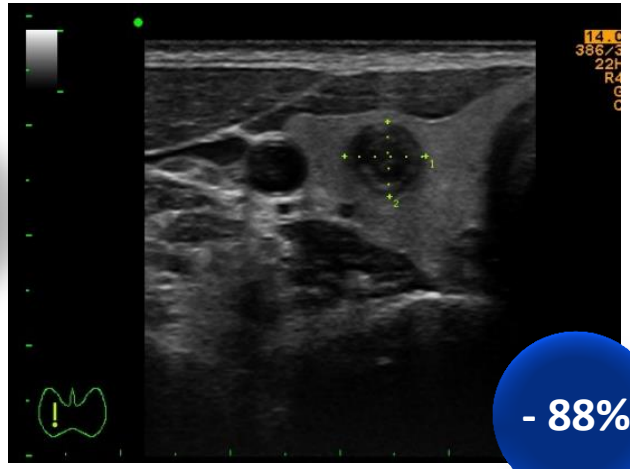
### 2 months after HIFU (0.59 cc)




- 69%

distance 1: 0.98 cm
distance 2: 0.88 cm

### 3 months after HIFU (0.23 cc)



- 88%

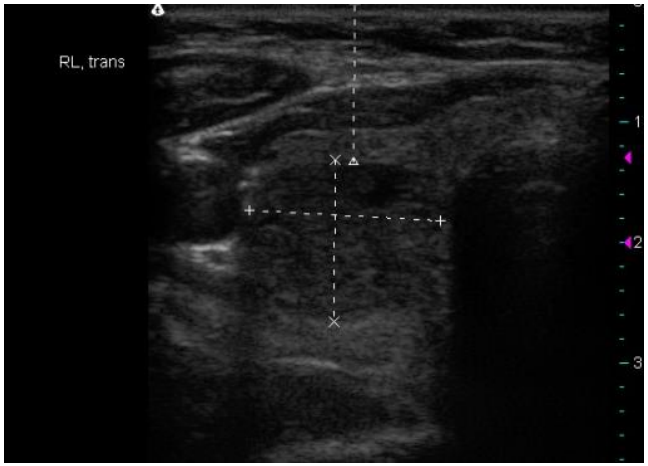
distance 1: 0.74 cm
distance 2: 0.68 cm

*Source: Prospective Non-Controlled Study of HIFU in Patients with Non-Malignant Thyroid Nodules – Theraclion internal data.*

# Proven efficacy on thyroid nodules

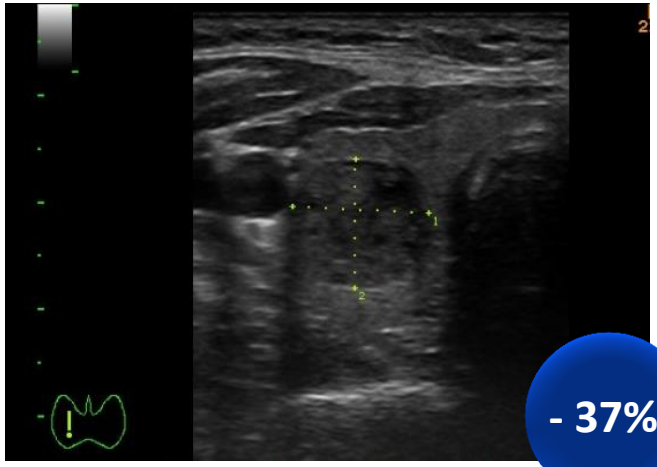
## Case of a 61yo patient

### Before HIFU (2.12 cc)




distance +: 1.59 cm
distance x: 1.34 cm

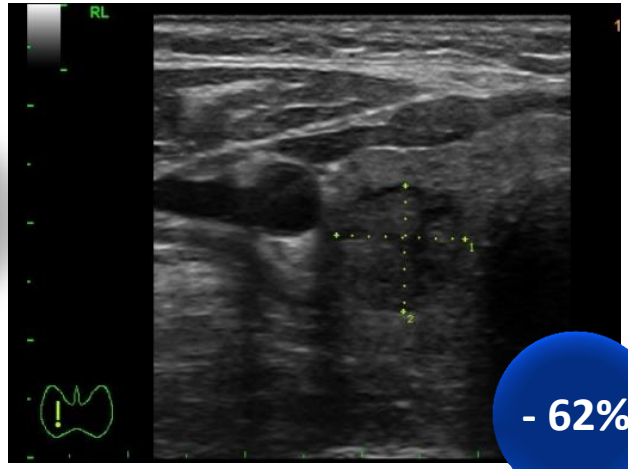
### 1 month after HIFU (1.33 cc)



- 37%

distance 1: 1.28 cm
distance 2: 1.21 cm

### 3 months after HIFU (0.80 cc)




- 62%

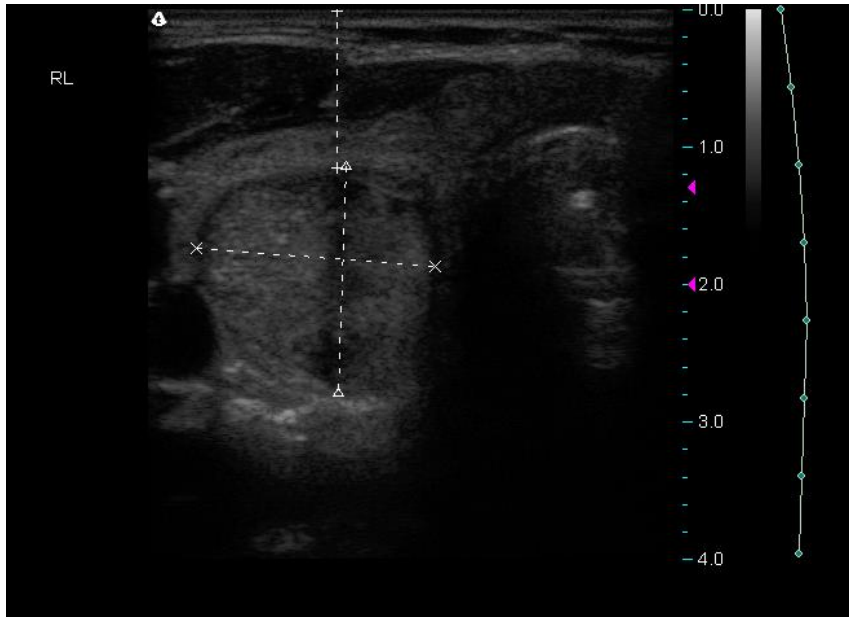
distance 1: 1.10 cm
distance 2: 1.07 cm

*Source: Prospective Non-Controlled Study of HIFU in Patients with Non-Malignant Thyroid Nodules – Theraclion internal data.*

# Proven efficacy on thyroid nodules

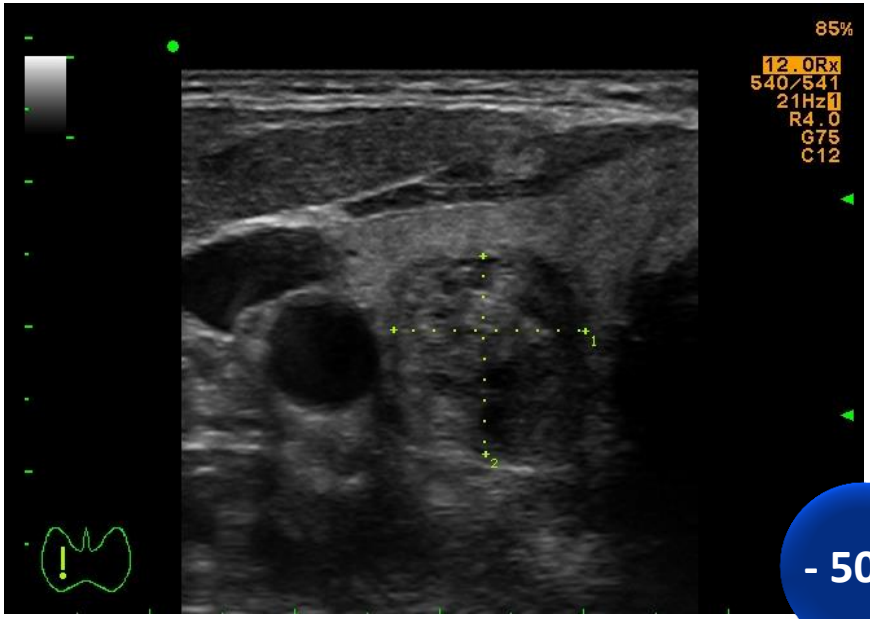
## Case of a 62yo patient

### Before HIFU (3.70 cc)




distance +: 1.59 cm
distance x: 1.34 cm

### 1 month after HIFU (1.84 cc)




distance 1: 1.28 cm
distance 2: 1.21 cm

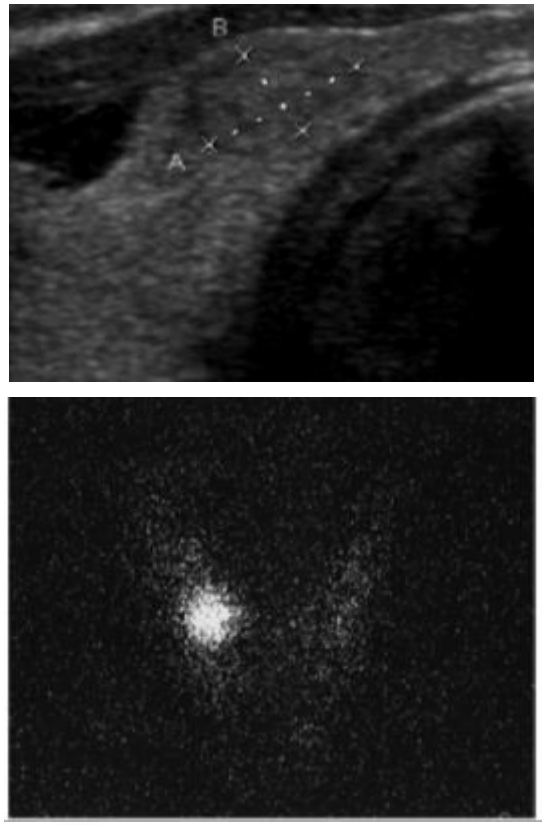
**- 50%**

*Source: Prospective Non-Controlled Study of HIFU in Patients with Non-Malignant Thyroid Nodules – Theraclion internal data.*

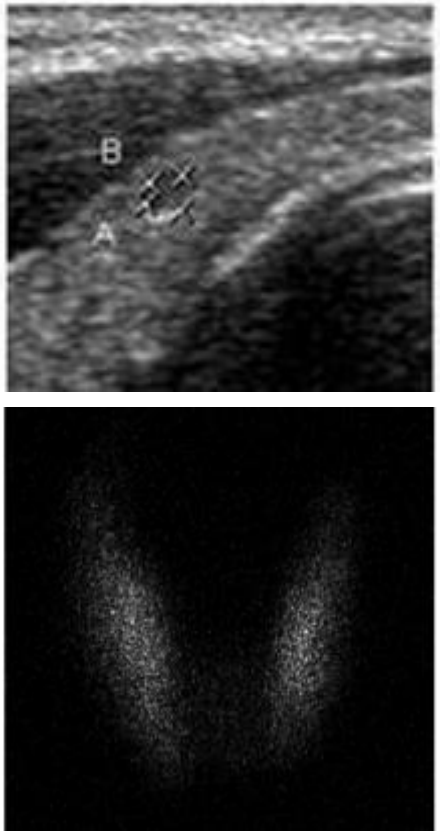
# Proven efficacy on thyroid nodules

## Case of a 26yo patient with a toxic thyroid nodule

**Before HIFU session**




**After HIFU session**




**Recovery of extranodular iodine uptake**
**Nodule size reduction**

*Source: Minimally Invasive Ablation of a Toxic Thyroid Nodule by High-Intensity Focused Ultrasound. Esnault et al. Am J Neuroradiol Nov-Dec 2010; 31:1967– 68*

# Patient’s quality of life improvement

**Study realized 6 months after treatment – 26 patients**

| | No | Yes |
|---|---|---|
| Do you feel more comfortable in your daily activities? | 0% | 100% |
| Would you undergo the treatment again if you had to? | 0% | 100% |
| Would you recommend this treatment? | 0% | 100% |

# A leading scientific reputation

## Publications in leading scientific journals

Localized Ablation of Thyroid Tissue by High-Intensity Focused Ultrasound: Improvement of Noninvasive Tissue Necrosis Methods

Olivier Esnault,[1] Brigitte Franc,[2] and Jean-Yves Chapelon[3]



Minimally Invasive Ablation of a Toxic Thyroid Nodule by High-Intensity Focused Ultrasound

High-Intensity Focused Ultrasound Ablation of Thyroid Nodules: First Human Feasibility Study



High-Intensity Focused Ultrasound for Localized Thyroid Tissue Ablation: Preliminary Experimental Animal Study

Olivier Esnault,[1] Brigitte Franc,[2] Jean-Paul Monteil,[1] and Jean-Yves Chapelon[3]

Thyroid

AJNR AMERICAN JOURNAL OF NEURORADIOLOGY

## International events and congresses

60èmes JFR 2012
Journées Françaises de Radiologie Diagnostique et Interventionnelle

INRiM ISTITUTO NAZIONALE DI RICERCA METROLOGICA

CHICAGO
THE AMERICAN SOCIETY OF BREAST SURGEONS
14th Annual Meeting
May 1–5, 2013

European Congress of Radiology
ECR 2014

European Society of Gynecology

European Thyroid Association
ETA

2nd International Congress of Breast Disease Centers 2012
PARIS 2012
CENTRES DU SEIN: L'ETAT DE L'ART
Jeudi 9 Février & Vendredi 10 Février 2012
Lieu : Pavillon Dauphine - Place du Maréchal de Lattre de Tassigny - 75116 Paris

Acquis & Limites

34èmes journées
DE LA SOCIÉTÉ FRANÇAISE DE
SÉNOLOGIE
ET DE PATHOLOGIE MAMMAIRE

JFR 2013
Diagnostique & Interventionnelle
jfr2013.radiologie.fr

FOCUSED ULTRASOUND FOUNDATION

European Society of Endocrinology
the European hormone society
ECE2014
3 - 7 May 2014
Wrocław, Poland

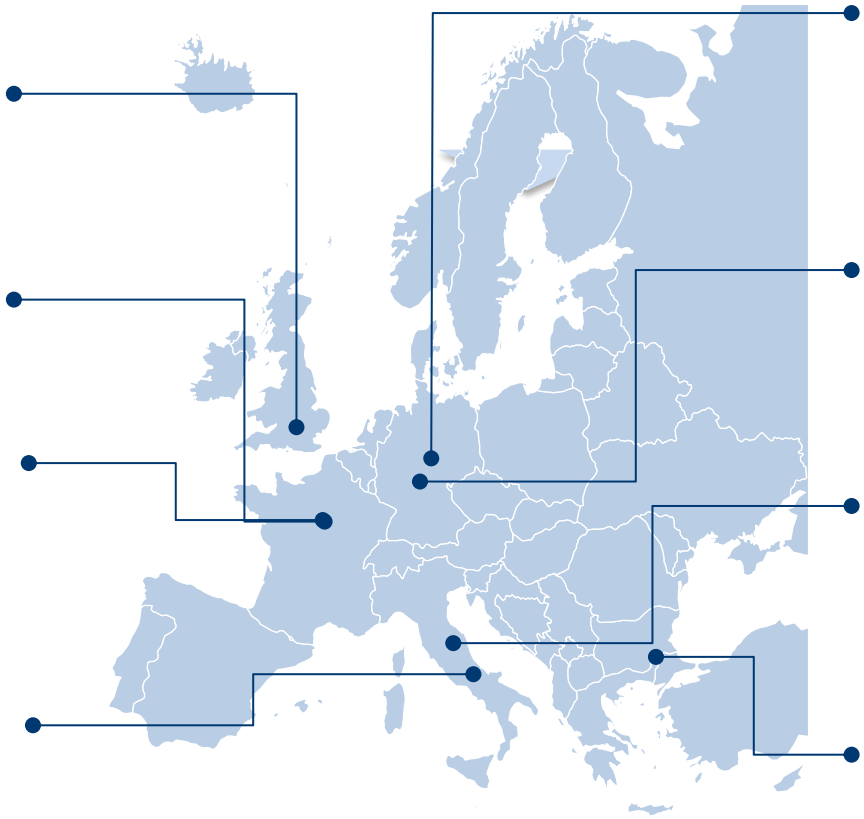
# Treatment centers

**London. King's College**. Nov 2013
- Prof. Douek
- Breast surgeon

**American Hospital of Paris.** 2011
- Dr. Abehsera
- Radiologist

**Hôpital des Diaconesses**. 2014
- Prof. Villet
- Breast Surgeon

**Umberto I Hospital.** Nov 2013
- Prof. Catalano
- Interventional radiologist



**University Hospital Tübingen.** Nov 2013
- Dr. Hahn
- Breast surgeon

**Marien Hospital Bottrop. Feb** 2013
- Dr. Kolberg
- Gynecologist

**Arcispedale - IRCCS Hospital**. 2014
- Dr. Valcavi
- Endocrinologist

**University Hospital Sofia.** 2009-2013
*(center involved during clinical trials)*
- Prof. Kovatcheva
- Endocrinologist

# Strong support from *"Key Opinion Leaders"*

## Marc Abehsera

Radiologist – American Hospital of Paris

*"In the HIFU treatment of breast fibroadenoma, first results are encouraging for an outpatient technique very well tolerated with significant fibroadenomas volume reductions."*

## Hans-Christian Kolberg

Chief of the Department of Obstetrics and Gynecology - Marienhospital Bottrop – Germany

*"We are pleased now, based on our experience with this new brand, to offer women with benign mass in the chest a new high quality and non surgical method. The successful clinical trials and uses in three important French hospitals testify for the high therapeutic value of Echopulse."*

## Roussanka Kovatcheva

Professor of endocrinology - University Hospital of Endocrinology of Sofia – Bulgaria

*" In my opinion, it is a very good method. Patients are interested because it allows them to avoid a surgical intervention for this benign pathology."*

# Significant benefits for all stakeholders

## For the patient

- No surgery, no general anesthesia, no infection risk, no scar, painless during and after the treatment
- 1 hour and half ambulatory procedure, local anesthesia, immediate recovery, back to work

## For the hospitals and practitioners

- Low cost : no use of a surgical sterilized suite, only one operator, no infection risk … less legal and financial risk
- More revenues: innovative pioneer, demand consolidation
- Change management … less hospital stays, more technology

## For the healthcare system

- Direct expenses lower than current standard
- No indirect expenses… No paid recovery time opposite to standard surgery. Back to work immediately after the procedure

Breast fibroadenoma

Thyroid nodules

# Discover more about echotherapy on Youtube

ECHOPULSE

Echotherapy for Breast Fibroadenoma
Echotherapy for Thyroid Nodules
TV reportage on echotherapy

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