Ultrasound dedicated to medical application

Shockwaves and High Intensity Focused Ultrasound for the non invasive treatment of kidney stones and Prostate cancer

Emmanuel Blanc
Development Director
Leader in Minimal Invasive Therapies

Founded in 1979, EDAP TMS is a leader in the development, production, marketing and distribution of minimally invasive medical devices for the treatment of urological diseases.

Revenues ~25 Millions €
Headquarters in LYON, France
150 employees
Global Presence

Strong presence across Europe, the Middle East & Asia through subsidiaries, branches and distributors
Tradition and Success in Innovation

Sonolith® i-move, 2010

Sonolith® Praktis Plus, 2006
Sonolith® Vision, 2001
Sonolith® Praktis, 1997

Sonolith® 4000, 1993
Sonolith® 4000+, 1995

Prototype Ablatherm®, 1993

Ablatherm® Imager Intégral, 2005
Ablatherm® Maxis, 2000

Sonolith® i-sys, 2007

LT01, 1985
LT01 Plus, 1990

Laser Pulsolith, 1988
Multilase 2100, 1991

Sonolith® 3000, 1989
Sonolith® 2000, 1985

LT02, 1991
LT02X, 1996

Prostatron®, 1991
Prostatron Maxis, 1995
Prostatron Praktis, 1997

Pyrotech, 1990


Bringing New Horizons to Therapy
The Key to Success: “Golden Triangle”:

Public laboratory/ Public hospital/ Manufacturer

Inserm

Hôpitaux de Lyon

Scientific research

Manufacturing, marketing and commercialization

Clinical validation

Bringing New Horizons to Therapy
Product Ranges

HIFU
(High Intensity Focused Ultrasound)
minimally-invasive treatment for localized prostate cancer

ESWL
(Extracorporeal ShockWave Lithotripsy)
non-invasive treatment for kidney stone

27 countries
210 centres
20,000 treatments

36 countries
500 systems
Gold standard for urinary stones

60% to 70% of urinary track stones indicated and treated through ESWL worldwide

Urinary stones diagnosed by X-Ray or Ultrasound 1

Stones blasted thanks to beam of shockwaves directed onto the stone through skin and tissue 2

No pain

No anesthetic required

Ambulatory treatment
Electroconductive technology

Exclusive technology based on a patented reusable electrode including a highly conductive solution for:

- A more precise spark origin and
- A more accurate focal point
- A better stability and power of the electrical discharge during whole electrode lifetime.
Stone fragmentation depends on shock waves technology
(i.e. Max positive /negative pressure, Focal volume, energy etc …)
Ablatherm HIFU: Prostate cancer treatment

By focussing high energy ultrasound waves, a temperature of up to 90 degrees Celsius is produced at the focal point inducing:

⇒ Coagulation necrosis
⇒ immediate & irreversible tissue destruction
Ablatherm®-HIFU: Equivalent Efficacy with Lower Morbidity

Range of published 5-year disease free Rates*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Surgery</th>
<th>EBRT 100%</th>
<th>Cryo</th>
<th>Brachy</th>
<th>HIFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-year</td>
<td>94%</td>
<td>83% average</td>
<td>92%</td>
<td>97%</td>
<td>86%</td>
</tr>
<tr>
<td>Disease Free</td>
<td>72%</td>
<td>70% average</td>
<td>61%</td>
<td>63%</td>
<td>79%</td>
</tr>
<tr>
<td>Rate</td>
<td>40%</td>
<td></td>
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</tr>
</tbody>
</table>

- Proven high efficacy and equivalent to traditional treatments
- Provides most consistent outcomes of any therapy thanks to robotic guidance

Range of Published Morbidity Rates*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Incontinence</th>
<th>Impotence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>49%</td>
<td>91%</td>
</tr>
<tr>
<td>Radiation</td>
<td>15%</td>
<td>63%</td>
</tr>
<tr>
<td>HIFU</td>
<td>5%</td>
<td>13%</td>
</tr>
</tbody>
</table>

- Incontinence and impotence post treatment significantly impact quality of life
- HIFU’s low rates translate into “Quality of Life Preservation”

*Data sources on file
Ablatherm®-HIFU 10-year Market Validation

- WW market: ~700,000 new cases/year and growing
- Ablatherm-HIFU Medical community acceptance
  - > 25,000 treatments performed to date
  - > 250 WW trained sites
  - > 100 publications and posters
- Approved and marketed in several countries
  - E.U., Canada, Mexico, Brazil, Argentina, Russia, Australia, New Zealand, SE Asia
  - Recommended localized Pca standard of care by AFU and AURO
  - Reimbursed in Germany, Italy and U.K.
- Clinically accepted treatment protocols
  - Primary therapy
  - Salvage after radiation failure
- Geographic expansion: U.S. PMA in progress
  - Enrollment phase completed: June 2010
  - 2 years follow-up phase
  - IDE submission expected mid-2012

Total WW Ablatherm-HIFU Treatments
Ablatherm®-HIFU: Growth Strategy

- **Competitive Advantages**

  - Non-invasive, preserves patients quality of life
  - Non operator dependent - stable results
  - Flexible and repeatable

- **Market Segmentation**

  - Primary Care Patients: major and most competitive segment
  - EBRT Failures: growing market, unique curative capability for HIFU
  - **Focal Therapy**: new trend, HIFU best positioned option
• Trend to **Focal Therapy** (as for kidney & breast cancer)
  ✓ Targeted approach utilizing enhanced imaging (MRI / US)
  ✓ Offers the best balance between efficacy and adverse event
  ✓ Controlled approach for early, low-risk disease

⇒ **Major alternative to radical treatment for early stage prostate cancer**
HIFU for other applications:

Curative treatment of cancers:
- Liver
- Breast
- Cervical and uterine fibroids
- Renal
- Thyroid cancer

Palliative treatment of cancers:
- Bone
- Pancreas

Benign applications:
- Glaucoma
- ....
Thank you!