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TECHNOLOGY FOR UROLOGY -

Dedicated to providing urologists worldwide with innovative high-technology devices.

Direx, partnered with Initia, marks 25 years of high technology innovation during which we have offered advanced and unique therapeutic technologies in urology. Since the groundbreaking introduction in 1986 of the world’s first modular and compact SWL system, further innovations by the company include:

• Linear Shockwave Therapy (LSWT) for Erectile Dysfunction
• Dual-head shockwave lithotripsy
• Transurethral RF bipolar treatment for BPH and prostate disease
• Stationary patient SWL with Integra, incorporating In-line On-line fluoroscopy
• Holmium lasers for lithotripsy with unique “Protect” technology

To-date, thousands of such urological devices have been installed in over 70 countries worldwide. These units are supported by a group of direct distribution companies, as well as a network of independent distribution partners, who have extended experience with our devices.
Erectile Function Renovation

Low intensity shockwaves have been shown to induce revascularization and treat a variety of soft-tissue conditions. Recent demonstration of erectile dysfunction (ED) treatment expands the applicability to vascular ED treatment and improvement of penile hemodynamics.

ED treatment geometry requires a dedicated device and associated protocols for matching the associated clinical and operational needs.

Renova uniquely meets the challenging requirements of:
- Linear waves focusing for efficient penile coverage
- Improved crura coupling by transperineal attachment
- High frequency and quantity of shockwaves

Historical progression of sample applications:
- 2000: Gutherson et al. (Germany): in vitro revascularization (ref. 1)
- 2004: Nishida et al. (Japan): clinical cardiac revascularization (ref. 2)
- 2011: Wang et al. (Taiwan): clinical wound healing (ref. 3)
- 2010-2012: Vardi et al. (Israel): clinical ED application (ref. 4)
- 2013: DirexGroup: dedicated second generation ED device (Renova)

Comparing respective devices of 1st and 2nd generation

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Technology</td>
<td></td>
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</tr>
<tr>
<td>Shockwave method</td>
<td>Electrohydraulic</td>
<td>Electromagnetic</td>
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<tr>
<td>Shockwave focus</td>
<td>Pointy</td>
<td>Linear</td>
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<tr>
<td>Shockwaves frequency</td>
<td>up to 120/minute</td>
<td>up to 600/minute</td>
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<td>Application</td>
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<td>Organ coverage</td>
<td>discrete points</td>
<td>Linear segments</td>
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<tr>
<td>Crura coverage</td>
<td>1 point</td>
<td>linear segment</td>
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<tr>
<td>Coupling to crura</td>
<td>Via lower abdomen</td>
<td>Via perineum</td>
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<tr>
<td>Majority of shocks to</td>
<td>Shaft</td>
<td>Crura</td>
</tr>
<tr>
<td>Utilization</td>
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<td></td>
</tr>
<tr>
<td>Penis holding</td>
<td>Physician</td>
<td>Mechanical scaffold</td>
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<tr>
<td>Transducer Holding</td>
<td>Physician</td>
<td>Articulated Arm</td>
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<tr>
<td>Number of sessions</td>
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<tr>
<td>Shockwaves per session</td>
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<td>Down to 6.83 minutes</td>
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<tr>
<td>Shockwaves duration</td>
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<td>Down to 8.33 minutes</td>
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<td>Internet</td>
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References: