

## **Experiences with the Sonablate HIFU-System for the Treatment of Localized PC**

### **Clinical Data Overview**

PC treatments world-wide using the Sonablate<sup>®</sup>: > **2.000 patients**

PC treatments with the Sonablate<sup>®</sup> 200: **85 patients**

PC treatments with the Sonablate<sup>®</sup> 500: > **1.915 patients**

#### Clinical data Japanese study Sonablate<sup>®</sup> 200 and Sonablate<sup>®</sup> 500

Since 1999 N=345, N= 181 min. follow-up 12 months with mean follow-up 18 months (4-68)

basic PSA mean = 9,76 ng/ml (3,39-89.6)

negative biopsy = 91%

CR following ASTRO-guidelines =

pre-PSA <10 ng/ml = 94%

pre-PSA <20 ng/ml but >10 ng/ml = 75%

pre-PSA >20 ng/ml = 35%

#### Clinical Data US Feasibility Study Sonablate<sup>®</sup> 500:

N=20, follow up 18 months, basic PSA <10.0ng/ml, mean Gleason was 6.18

Mean Pre-treatment PSA is 5.36, 30 days is 1.68, 90 days is 0.87, and 180 days is 0.44ng/ml.

68% PSA <1 after initial treatment, 100% <1 after 2. Treatment.

No rectal injuries with initial treatment, 1 after re-treatment; no incontinence, all patients discharged overnight from hospital, and a 30% retreatment rate after 18 months follow up.