



B I N D E X

Osteoporosis Diagnostics

*Reduction in fractures from Osteoporosis with  
revolutionary point-of-care screening*

# Bone Index Ltd.

- One of the most promising Life Science Start-up Company in Scandinavia 2014 (Nordic Star).
- One of Europe's top new manufacturers of medical devices 2015 (Healthtech Summit).
- Based on 30+ years of bone studies (ISO 13485).



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CTO, PhD, Founder



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Jussi Holopainen  
Chairman of Board, Partner



# Osteoporosis and Diagnostics



**Elli, 83 years old**



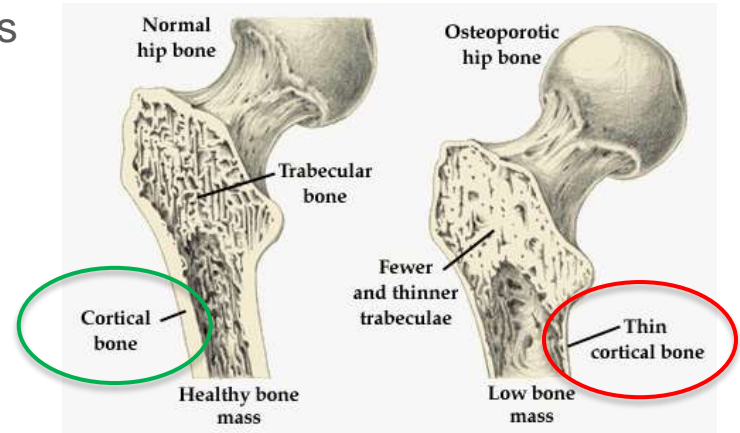
**NO access (75%)!**

**Costs from fractures:  
€40 billion (EU)<sup>1</sup>  
\$20 billion (US)<sup>2</sup>  
£2 billion (UK)<sup>3</sup>**

- 1) Tarantino, U. ym., Aging Clin Exp Res 19:7-11; 2007
- 2) National Osteoporosis Foundation
- 3) Direct medical costs, NICE guidelines [CG146], 2012.

# Osteoporosis

- Bone mass has decreased and the structure has changed
  - ➡ Fracture risk has increased!
- **In UK, there are about 3 million osteoporotic patients<sup>1</sup>.**
- Worldwide, 200 million osteoporotic patients<sup>2</sup>.



**Fracture risk × 11!!**

1) NHS, 2016

2) Tarantino, U. ym., Aging Clin Exp Res 19:7-11; 2007

# Bindex<sup>®</sup> - Radical improvement with access!



At primary care / retail clinic



At home by nurse

## Bindex<sup>®</sup> point-of-care!

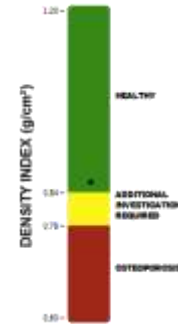


FDA  
Cleared

CE



Strong IPR

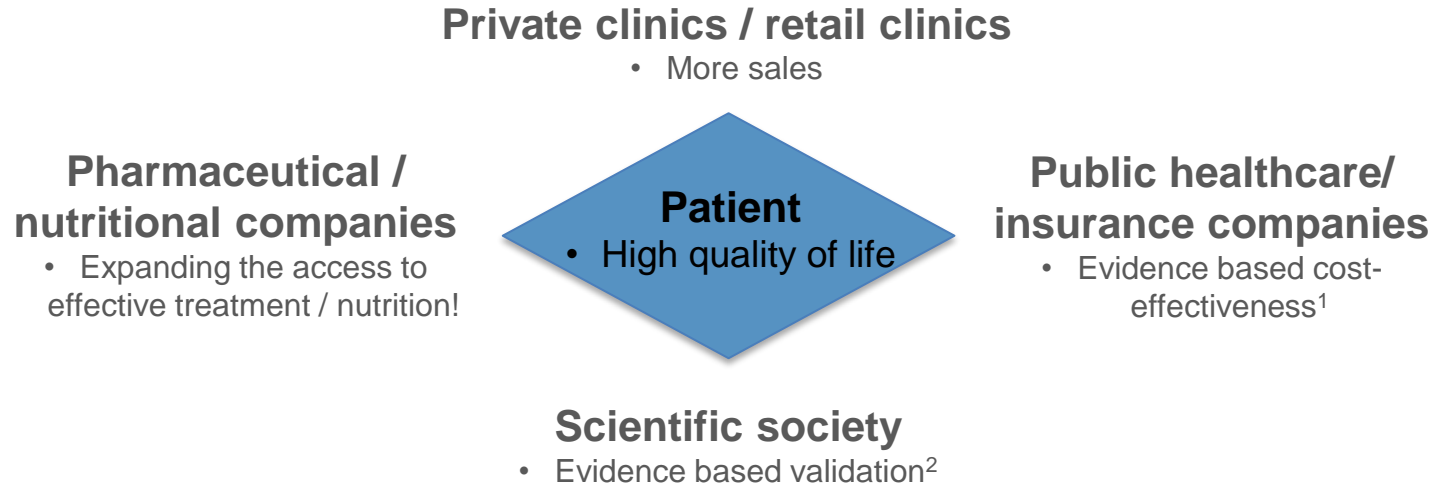


70%  
can be diagnosed  
(green/red)!<sup>1,2</sup>

1) Karjalainen J. et al., Osteoporosis International, 2016.

2) Karjalainen J. et al., World Congress of Osteoporosis, Malaga, 2016.

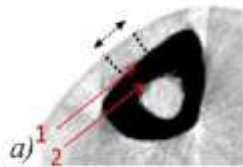
# Benefits for..



1) Asseburg C. et al., IOF-ECCEO, 2013

2) Karjalainen J. et al., Osteoporosis International, 2016

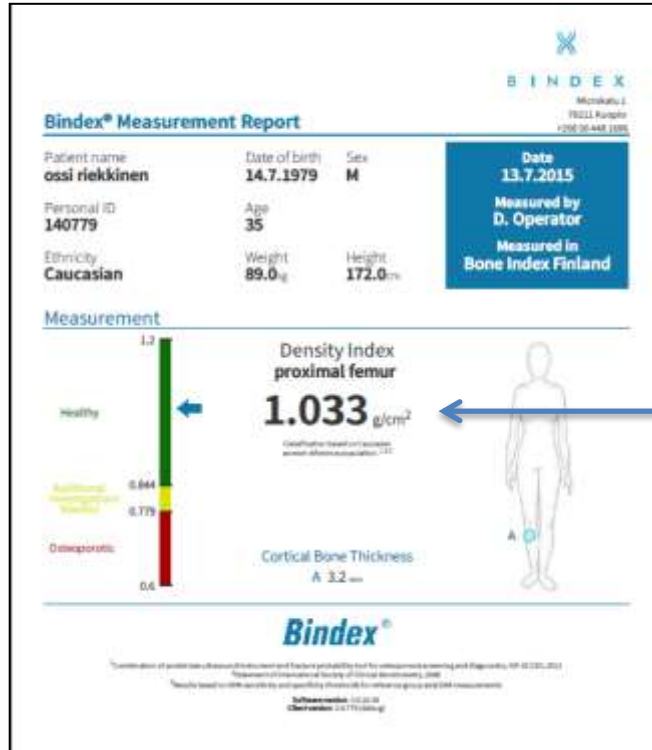
# Bindex<sup>®</sup>



- Density Index<sup>1</sup>:
  - The thickness of cortical bone.
  - Age, weight and height.
- Density Index is the estimation for hip bone mineral density measured with DXA (see validation).

1) Karjalainen J. et al., Osteoporosis International, 2012.

# Bindex®

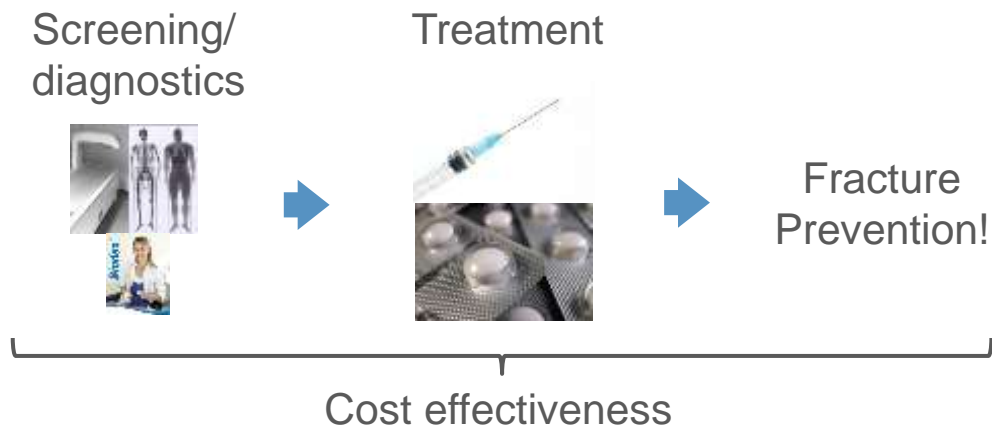


- Density Index as a numeric value in colour bar.
- If the Density Index is in the red area, treatment is recommended<sup>1,2</sup>.

1) Hans D. et al., J Clin Densitom, 2008, 2) Patel et al., National Osteoporosis Society practical guide, 2011



# The diagnostics and treatment



- **90% sensitivity/specificity thresholds against DXA are needed!**<sup>1,2</sup>

1) Hans D. et al., J Clin Densitom, 2008,  
2) Patel et al., National Osteoporosis Society practical guide, 2011

# Evidence based

## Clinical Validation of Bindex<sup>®</sup> for osteoporosis diagnostics

- **Bindex validation study in Kuopio, Finland (Bindex vs. DXA)<sup>1</sup>:**
  - A total of 445 females<sup>2</sup>
  - 70% of women were diagnosed with Bindex (green/red value).
  - 30% were referred for DXA (yellow value).
  - Sensitivity and specificity in osteoporosis diagnostics was 90%.
- **Multicentral study in 9 research sites in US and Finland (pooled data, Bindex vs. DXA)<sup>3</sup>:**
  - A total of 1830 females<sup>2</sup>.
  - 30% needed DXA (yellow value).
  - Sensitivity and specificity in osteoporosis diagnostics was 90% and 87%, respectively.

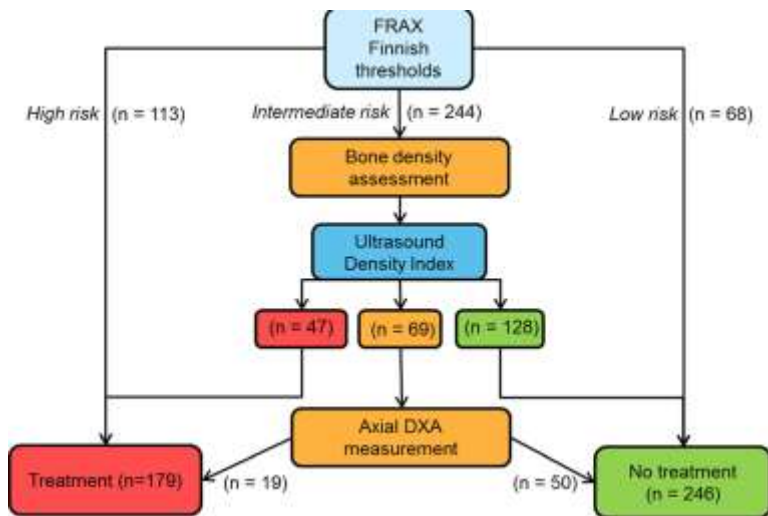
1) Karjalainen J. et al., Osteoporosis International, 2016.

2) Over 50 years old Caucasian women with osteoporosis suspicion.

3) Karjalainen J. et al., World Congress of Osteoporosis, Malaga, 2016.

# Evidence based

## Clinical Validation of Bindex<sup>®</sup>, treatment desions (FRAX<sup>®</sup> + Bindex<sup>®</sup>)



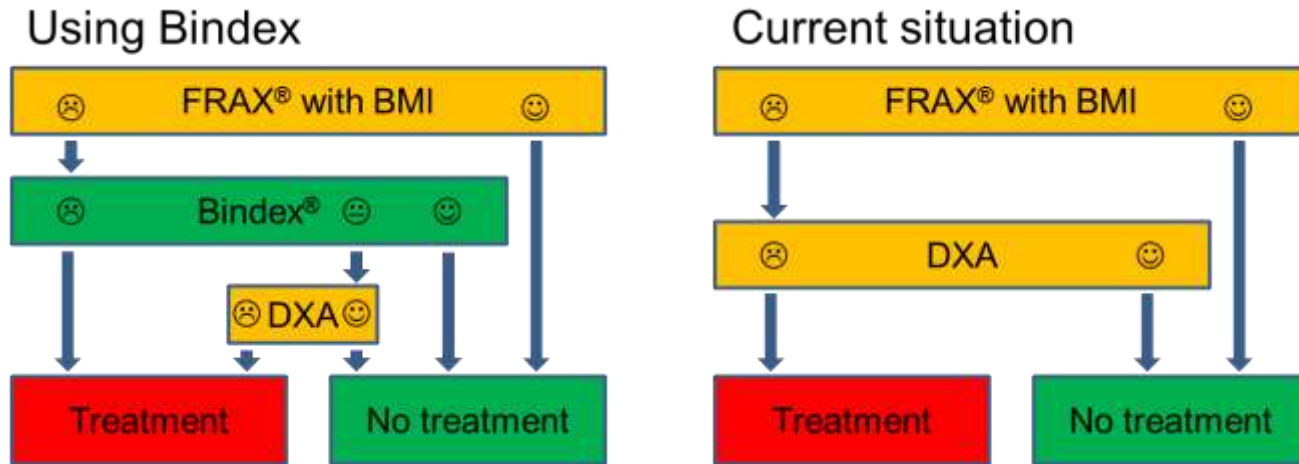
- A total of 425 over 50 years old women with osteoporosis suspicion<sup>1</sup>.
- Sensitivity and specificity for treatment desions<sup>2</sup> is 85% and 79%, respectively. **Only 16% of patients need DXA investigation.**
- Without Bindex<sup>®</sup> 57% of patients would be referred for DXA investigation.

1) Karjalainen J. et al., Osteoporosis International, 2016.

2) FRAX<sup>®</sup> with BMD suggest treatment or patient has osteoporosis with DXA.

# Evidence based

Cost effectiveness of case finding strategies in Finland<sup>1</sup>



The average screening cost saved with Bindex® technique is 230€<sup>1</sup>

1) Asseburg C. (2013), ECCEO13-IOF, Italy

# Evidence based

## Cost effectiveness of case finding strategies in Finland<sup>1</sup>

- Women (BMI  $24 \text{ kg/m}^2$ ) aged 65 years with previous fracture and 75 or 85 years with and without previous fracture.
- Based on FRAX<sup>®</sup>, all should be investigated with DXA.
- **Bindex<sup>®</sup> strategy is highly cost effective even with 50-100€ screening cost<sup>2</sup>!**

 **Simplify the process is the key!!**

1) Asseburg C. (2013), ECCEO13-IOF, Italy

2) Incremental cost-effectiveness ratio, ICER 107 - 493k€ vs. the threshold 50k€

# Trump vs. Clinton, US future

- Testing 180,000 additional risk group patients ➡ Over \$15M Medicare savings<sup>1</sup>.
- Clinical need for 52 million BMD testing<sup>2</sup> vs. 2 million (real life).
- If BMD testing (Bindex<sup>®</sup>) is done only for 25 million risk group patients:

➡ **At least \$2.2 billion net savings over three years!**

➡ ***It is your decision!***

1) <http://www.prnewswire.com/news-releases/increasing-bone-mineral-density-testing-for-osteoporosis-by-only-10-percent-could-save-medicare-over-15-million-76490592.html>

2) Based on the size of US population, NOF guidelines and the approximations of Bone Index

# Bindex<sup>®</sup> - Summary

- **Will:** reduce the number of osteoporotic fractures by 1M<sup>1</sup>.
- **Offers:** improved quality of life for families at a lower cost.
- **Will be:** the most preferred osteoporosis partner.



1) Based on IOF statistics of global osteoporotic fractures, 10% out of yearly numbers

# Thank you!

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