Cancer depth assessment using Optical Coherence Tomography



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### We've built the next generation cancer discovery tech that will drastically improve cancer treatment and care

It's a minimally invasive imaging catheter that allows doctors to see cancerous tissue otherwise hidden within the organ walls.

With our device doctors will be able to discover bladder, colon, lung and prostate cancer already at the 1st consult, in real time.



# We focus on the bladder cancer first because that's where the need is the biggest



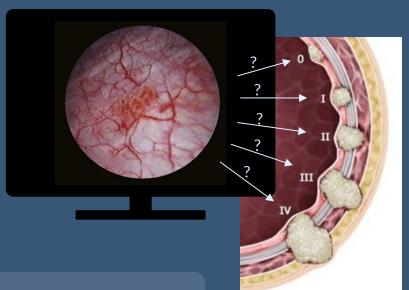
This year alone, more than **500.000** people will be diagnosed, **160.000** will not survive

Out of all cancers, bladder cancer is the most taxing on the health system due to life-long follow-ups and unnecessary surgeries



## Urologists today simply can not see the structure of the bladder wall to determine the stage of cancer

They can only see the surface through the camera



Bladder Cancer Staging System (TNM Classification)

**Stage 0:** Cancer cells found on the inner surface of the bladder.

**Stage I:** Cancer cells have penetrated the inner lining of the bladder but not muscle.

#### Muscle-invasive stages

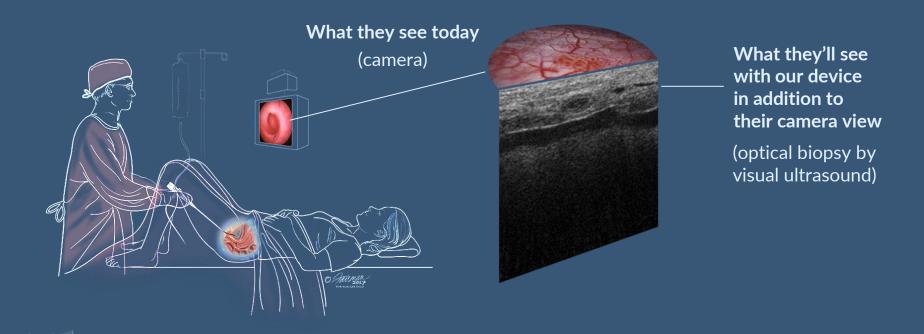
**Stage II:** Cancer cells have spread into the muscle layer.

**Stage III:** Cancer cells have spread beyond the bladder and into the outer layer.

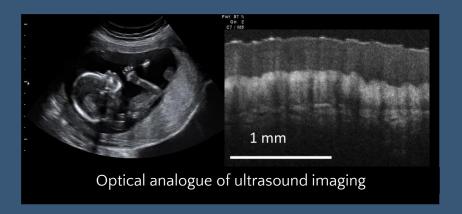
**Stage IV:** Cancer cells have spread towards the abdominal or pelvic wall.

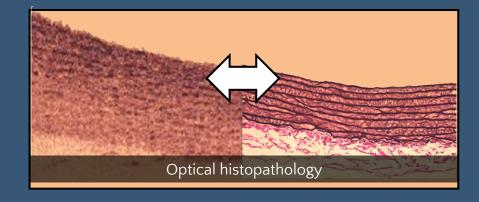
MRI/CT techniques are unusable due to low resolution (1mm while the entire bladder wall is 2mm thick)

### With our product urologists will be able to see into the depth of the bladder wall instead of just looking at the surface



### **Optical coherence tomography**





### With image guided therapy, we expect to prevent 1 in 2 TURBT surgeries and spare 1 in 5 bladders







### 1 in 5 bladders can be spared

No one wants to carry a bag to collect urine everywhere they go because the doctor wasn't sure enough. Not to mention resurgeries, lifelong checkups, skin irritations, infections.

### 1 in 2 TURBT surgeries can be prevented

Besides being painful for the patient and costly for the health system, those unnecessary surgeries come with a risk of complications and death

### 3 in 10 lives can be saved

In the long term, enabling faster diagnosis of muscle-invasive bladder cancer can result in saving 3 out of 10 lives



## Our OCT base and disposable catheters are used as compatible add-ons to standard hospital equipment



#### Scinvivo OCT Base

will be parked in the room, comes as a turn-key solution with our software and interface

#### **Scinvivo catheters**

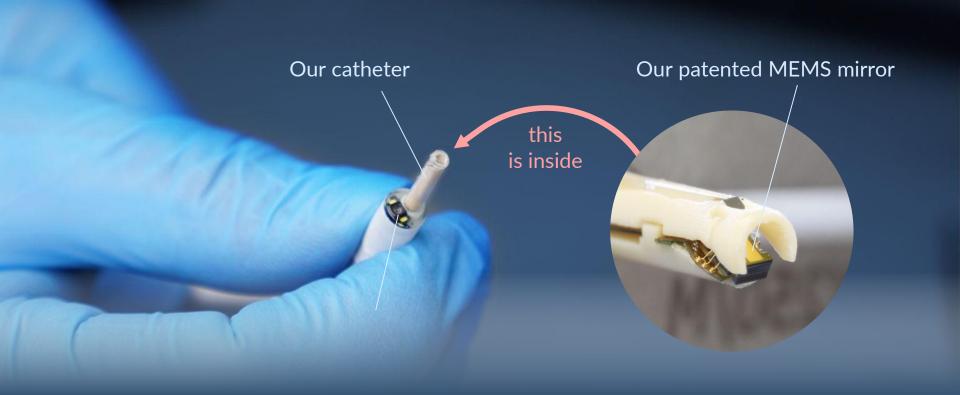
also in the room, sterile and disposable (we take them back for our sustainability program)

#### Standard cystoscope

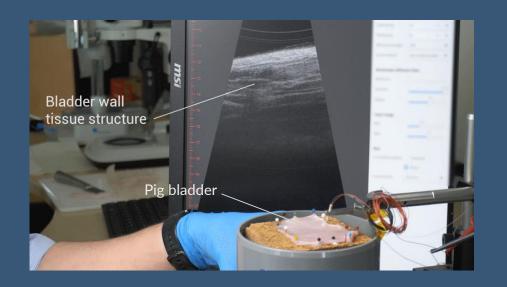
Standard, available at hospitals

not only is it available at the hospital but it's already ideally positioned in patient's body at the moment Scinvivo is needed

## We managed to make our catheter so small that it fits within the working channel of a standard cystoscope



## After seeing our working demo, 10 out of 10 urologists want to participate in our early adopter program!



"The bladder wall appears to be clearly visible and it's even possible to see the lumina of blood vessels!"

Dr. Pascal Stijns, uroloog St. Antonius hospital

Click to see our 20-second video:

https://youtu.be/luD4SgnXX18

#### **OCT** catheter game changer in BC diagnostics

Technology		Resolution	Penetration depth	Field of View	Sensitivity/ specificity	Notification	Companies
	ост	<mark>✓</mark> 10-50μm	<b>✓</b> 1-3mm	mm	<b>1</b> 00%/89%	Can be combined with other technologies	Scinvivo & partners
6	Traditional Cystoscopy	<b>X</b> mm-cm	X None	✓ Wide field	<b>※</b> 70%/70%	Currently most used technique	Olympus (JP) Karl Stotz (DE) Cogentin Medical (NL)
	Photodynamic Diagnostics (PDD)	<b>X</b> mm-cm	X None	✓ Wide field	<b>※</b> 97%/59%	Potential toxic contrast agent needed	Karl Stotz (DE)
Name of the last o		<b>X</b> mm-cm	X None	✓ Wide field	94%/85%	High costs (€60.000 – €90,000)	Olympus (JP)
War war and a second se	Confocal Light Endomicroscopy (CLE)	1-5μm	120μm	<b>Χ</b> <600μm	94%/85%	Potential toxic contrast agent needed	Mauna Kea (FR) Stryker (USA)
		<mark>Χ</mark> μm-mm	10-20 cm	<b>✓</b> Wide field	<b>✓</b> 84%/91%	High costs	Siemens (DE) Philips (NL)
	Ultrasound (US)	<b>✓</b> ~70μm	<b>✓</b> Cm range	<b>✓</b> Wide field	X No differentiation between Ta/T1 tumors	No detection of bladder tumors < 4mm; impossible to see front of bladder	Exact Imaging (US)

Only OCT provides the needed depth information.

A game changer in combination with the standard Cystoscopy.



#### Proven advantage of OCT for BC diagnostics

OCT in-vivo studies of Bladder Cancer										
Source	#lesions	Sensitivity	Specificity	False negative rate	False positive rate					
Manyak et al.	87	100%	89%	0%	11%					
Lerner et al.	38	Superficial: 90%. Muscle invasive 100%.	Superficial: 88% Muscle invasive: 80%	Superficial: 10%  Muscle invasive: 6%	Superficial: 11%  Muscle invasive: 10%					
Ren et al.	68	94.4%	81.3%	5.6%	18.7%					
Karl et al.	102	100%	65%*	0%	35%					

- > Standard cystoscopy: sensitivity = 70%, specificity = 70%; FNV = 30%; FPV = 30%
- > Studies have been performed with catheter from Imalux (not on the market anymore):
  - smaller field of view (<2 mm, Scinvivo: 5mm)</p>
  - lower image acquisition rate (8 Hz, Scinvivo: 800 Hz)
  - > Slightly, but significant larger diameter (2.7 mm, Scinvivo: 2.45 mm)



<sup>\*</sup> The high rate of drop-outs in our study, lesions in which biopsy and scanning area could not be matched sufficiently using later video-analysis, can be explained by the need to change the cystosope sheath and biopsy sheath between each lesion within the bladder. To

#### **Outlook**

- We performed a dry run, to test our system in the Amsterdam UMC
- First in vivo clinical trials ready to start!
- We're looking for collaborations:
  - O Clinical trials
  - O Technical development

