

# SENSOFAR

MEDICAL

Solution for  
the inspection  
of contoured  
stents and heart  
valve frames





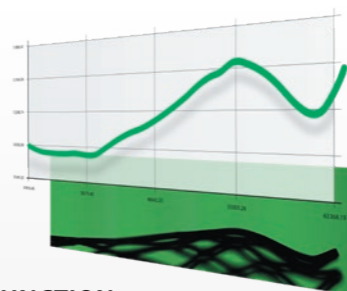
# Inspection system for the new generation of implantable devices



Q vix pivot is the outcome of Sensofar Medical's dilated experience in stent inspection technologies, taking a leap forward in the inspection of non-cylindrical (contoured) devices and overcoming the limitations to cylindrical geometries.

## INSPECTION OF CONTOURED SHAPES

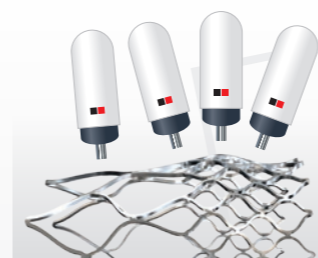
Q vix pivot has been designed as a simple solution for a complex challenge: the automated inspection of non-cylindrical stents and contoured heart valve frames.



### FUNCTION PROFILE

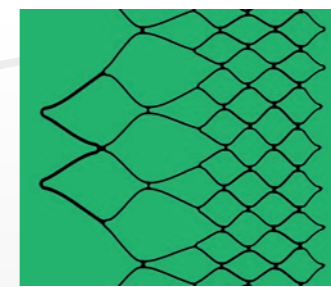
The automatic detection of the shape of the device, obtained by the measurement of the contoured profile of the device, allows an accurate characterization of the shape setting process.

Thanks to a pivoting sensor head, with Q vix pivot it is possible to rapidly inspect non-cylindrical devices, providing immediate dimensional results on any strut in the device without complex programming.



### LET US DO THE HARD JOB

Q vix pivot automatically computes the optimal sensor head positions needed to complete the inspection of the contoured shape with no additional programming required from the user.



### AUTOMATED INSPECTION, IMMEDIATE RESULTS

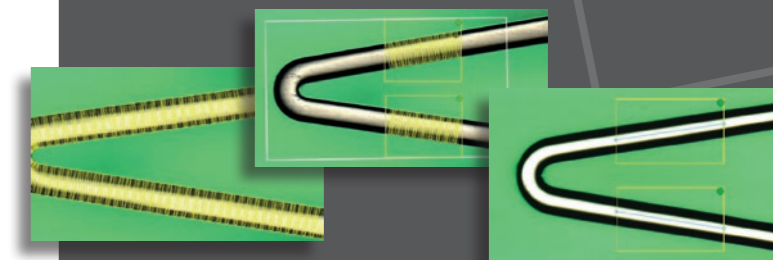
As a result, all acquired images are combined in a single, completely focused image containing the whole surface of the device. Dimensional measurements are automatically performed on the image completing the full inspection in a matter of seconds.

## Software

### SensoINSPECT

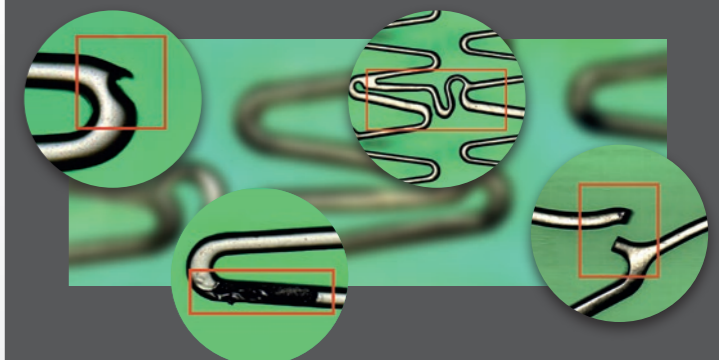
#### DIMENSIONAL INSPECTION

Sensofar's powerful software SensoINSPECT automatically detects the measurement positions and provides accurate results of dimensional measurements.



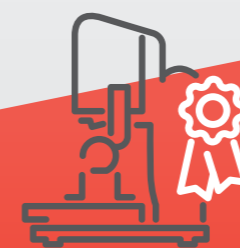
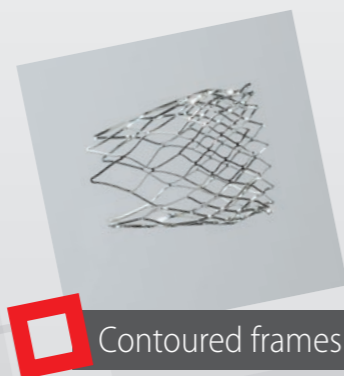
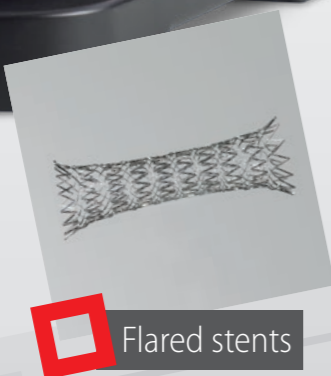
#### VISUAL INSPECTION

Automatic detection of fractures, cutting defects and surface defects.



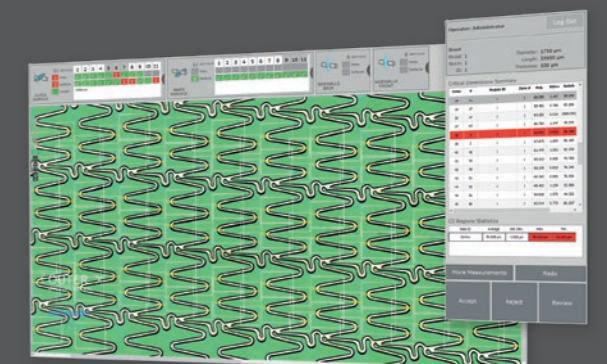
#### TRACEABLE RESULTS

After the automatic inspection performed by means of flexible inspection routines, results are automatically exported, locally or remotely. All results are traceable to the measurement point, and images of the detected irregularities can be saved together with the report.



### 21CFR PART11 COMPLIANT

SensoINSPECT software is CFR21 part 11 compliant, and all results exported in production are digitally signed to guarantee data integrity.





# System Specifications

Stent type	Laser cut, braided, welded.
Stent material	Metal (Nitinol, other metallic alloys), polymer
Stent OD <sup>[1]</sup>	1 - 32 mm (up to 40mm with 5X)
Stent length	Up to 185mm
Camera	Color 2044 x 1084 effective pixels
Frame rate	50 fps (array), 3000 fps (linear)
Z scan linear stage range	50 mm
Rotation stage	360°, 1.5µrad resolution
Head tilt angle range	-45° to +45°
Overall positioning accuracy	Better than ±1µm
Illumination system	Flexible illumination setup (up to 7 independent LED light sources)
Nosepiece	5 position fully motorized
Imaging modes	Live, unrolled (FoV and section), extended focus
Inspection capabilities	Outer surface, inner surface, lateral surfaces, edges (grazing illumination)

CD measurement repeatability	Better than ±1% rms (typical $\sigma$ figures lower than 1µm)
CD measurement accuracy	Better than ±3% PV (typical $\sigma$ figures lower than 3µm)
Surface inspection	Automatic defect detection
3D modes	Surface topography, roughness, thickness of transparent coatings
3D measurement technique	CSI (Coherence Scanning Interferometry)
Assisted concept	Decision Accept / Reject made by the operator
Computer	HP platform
Operating system	Microsoft Windows, 64bit
Electrical requirements	Line voltage 100-240V AC; frequency 50/60Hz single phase
Power consumption	Lower than 100W
Weight	75 Kg (vibration isolation table not included, 37Kg)
Working conditions	Temperature 18°C to 25°C; Humidity < 80% RH

## Imaging Objectives

## 3D Objectives

MAG	2X	5X	10X	10XDI	20XDI	50XDI
Numerical aperture	0,055	0,14	0,28	0,3	0,4	0,55
Working distance (mm)	34	41	34	7,4	4,7	3,4
Horizontal FoV (mm)	9	3,6	1,8	1,8	0,9	0,36
Spatial sampling (µm) <sup>[2]</sup>	4,4	1,76	0,88	0,88	0,44	0,18
Optical resolution (µm) <sup>[3]</sup>	2,77	1,09	0,54	0,51	0,38	0,28
Unrolled acq. rate (mm <sup>2</sup> /s) <sup>[4]</sup>	120	20				
Vertical resolution (nm) <sup>[5]</sup>				1	1	1

## Dimensions units: mm (in)

Weight: 75 kg (165 lbs)



**1** Maximum stent OD for on-axis inspection of inner surface at 45 degree head tilt is 17.5mm. **2** Pixel size on the imaged surface **3** L&S: Line and Space (500nm wavelength) **4** Frame rate 3000 fps **5** Vibration isolation table is required

# SENSOFAR

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