

Normative reference

EN 12006-3:

Non-active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices.

# STENT

## FATIGUE

Basic information about mechanical testing of stents is provided by DIN-EN 12006-3. Going more into the details, neither the normative reference itself nor the quoted literature provide sufficient information about the tests to be performed.

At this point it is useful to become aware of the test purpose: The implant should provide safety against mechanical failure in-vivo. It therefore is required to simulate the environment in-vivo as close as possible.

First of all, the implant is loaded by the vessel. The load level changes periodically according to the blood pressure. In contrast to the general opinion, the maximum load occurs at the minimum blood pressure.

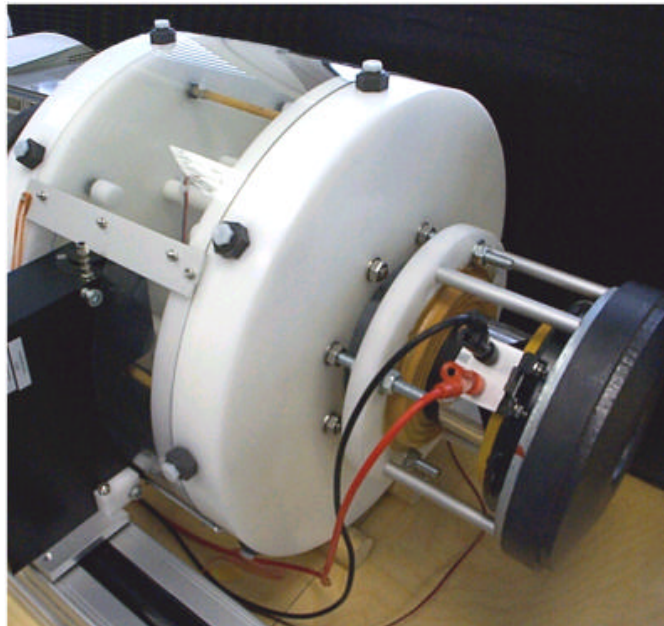
According to the principles explained, first experimental setups performed tests using rubber tubes with implanted stents subjected to the systolic and diastolic blood pressure. Two disadvantages of those systems are obvious: First of all, the material properties of the tube directly influence the mechanical loading of the stent. In addition, the test frequency is limited by the viscoelastic properties of the polymers used. This results in long test periods.

Modern test systems therefore require contactless laser scanning of the actual diameter of the stent-tube system. The internal pressure of the system is changed periodically and the response calculated from the outer diameter is used to close a PID-loop.

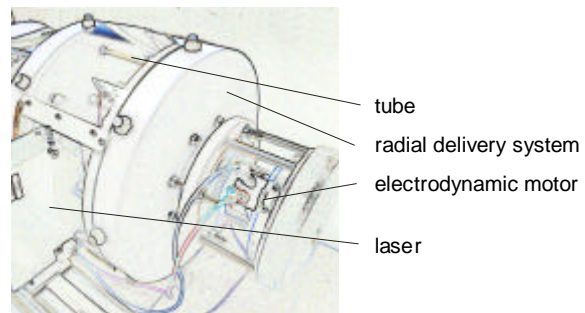
In general, a frequency of about 85 Hz can be achieved resulting in a test period of about 8 weeks. The equipment used by EndoLab enables simultaneous testing of up to 16 stents.

It has to be noted that in general, the stent fatigue test can be regarded as the last pre-clinical test to be performed. Due to the fact that a relatively long test period is required, radial force tests as well as Finite-Element studies should be performed before starting an 400 million cycle in-vitro fatigue test.

Please contact our staff for further information.



Test setup for the in-vitro fatigue test of stents.



### Test parameter:

complexity:	high
test medium:	Ringer's solution @ 37°C
number of spec.:	8
cycles:	400 Mio.
test frequency:	up to 100 Hz
change in diameter:	0.1-10% (depends on stent type)
additional evaluation:	SEM
FDA-approval:	yes

### Links:

[www.enduratec.com](http://www.enduratec.com)  
[www.fda.gov](http://www.fda.gov)  
[www.medmarket.com](http://www.medmarket.com)  
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