Standard testing for balloon expandable devices

Standard tests in medical devices represent a consensus on testing procedures that foster innovation while protecting public health. Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, is facilitated by the appropriate use of relevant medical device standards.
Standards developed by organizations like ISO and ASTM outline the essential principles of safety and performance of medical devices.

While setting up their cardiovascular device development and regulatory submission programs, medical device companies encounter the following challenges:

- High costs for the testing of multiple device prototypes before manufacturing
- Collection of scientific evidence about the safety and performance of the device to provide to the regulatory bodies

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What is Standard test suite for balloon expandable devices?

Standard test suite for balloon expandable devices is a suite comprehensive of various in silico reproduction of standard tests to assess the performance of balloon-expandable stents or heart valve substitutes.

Standard test suite for balloon expandable devices is based on finite element models replicating the mechanical systems used to assess device mechanical behavior and performance, as well as durability under pulsatile conditions.

Standard test suite for balloon expandable devices enables simulations of different standard tests in various types of balloon-expandable stents and heart valves, such as coronary or peripheral stents as well as transcatheter aortic valve and transcatheter mitral valve.

The tool can be used to test different prototype designs before manufacturing, or to test the final device design for regulatory submission, as a report following FDA guidelines is provided to the user.

The suite allows to replicate the following standard tests:

1. Crush test in Flat Plate Compression

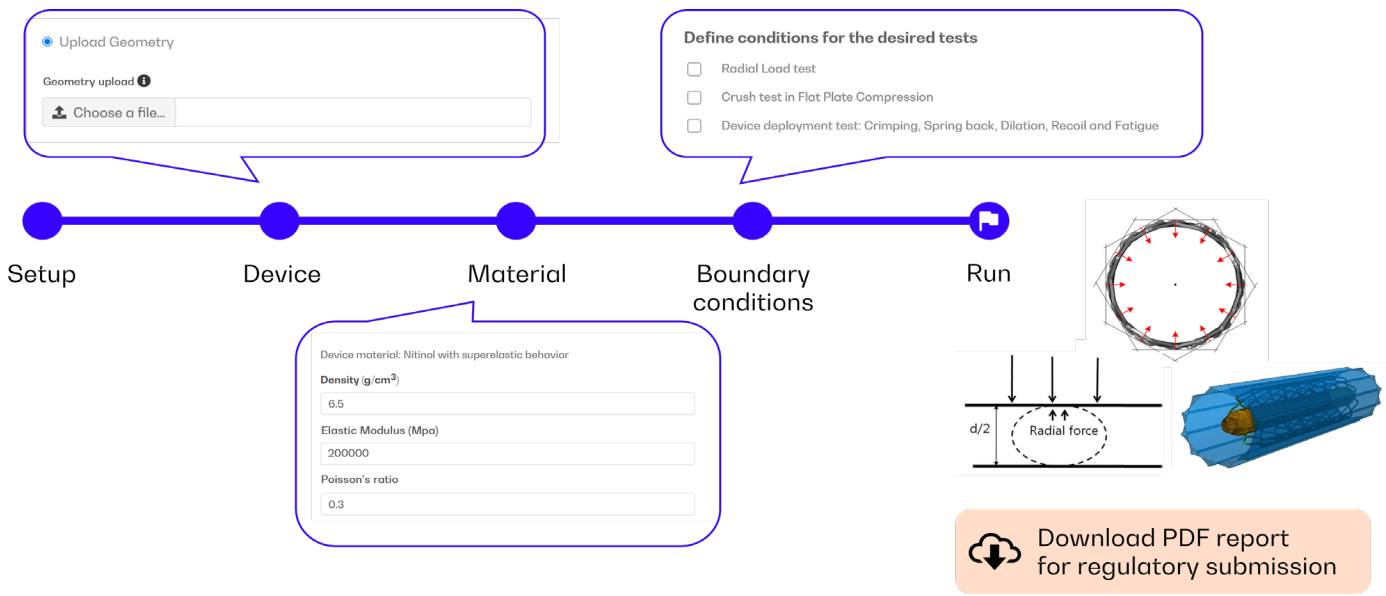
To simulate the force that the device exerts when compressed by two flat plates at 50% of the device diameter.

2. Radial Load Test

To simulate the load/deformation characteristics of the stent while a circumferentially uniform radial load is applied.

3. Device Development

To reproduce deployment steps (including Crimping, Spring back, Dilation, Recoil & Fatigue) and simulate force/deformation behavior of the device during each deployment step, maximum force/deformation and final diameter/length, and Fatigue life S-N curve.



Advantages

Securely test a proprietary stent or valve design before prototyping

Run simulations under conditions predefined following standard test methods

Inspect predicted quantities of interest like stresses and strains within the device geometry

Customize material parameters or use literature params

Generate a report for regulatory submission based on FDA guidelines

How it works

Standard test suite for balloon expandable devices enables to setup and run computational simulations in a user-friendly way by using a step-by-step integrated workflow that can be applied to any balloon-expandable stent or valve uploaded by the user:

- Set the simulation name
- Upload the device geometry in the admissible format
- Insert material properties or use the values from the library
- Insert details related to boundary conditions for each test

After running the simulation, results will be displayed as:

- Graphs and tables with relevant quantities of interest such as forces, stresses, and deformations in function of the diameter, max stress and strain, etc.
- Color maps of stresses and strain in the device

Simulation details, settings and results can be reported and exported in .pdf format following FDA guidelines (1).

In silico methods can innovate medical device research and development

Today, the costs and duration of the development and regulatory assessment of new medicines and medical devices are becoming a burden to innovation in healthcare.

Regulatory agencies have been encouraging the use of in silico methods in research and development for years (9), since the use of these methods can significantly reduce costs and greatly accelerate the go-to-market of new products while maintaining or improving the level of safety.

However, specialize expertise and dedicated computing infrastructures require a continuous investment from companies, hence representing a barrier to a rapid uptake of computational solutions.

To help solve these challenges, InSilicoTrials Technologies has developed a game-changing-solution. Our experts:

Select computational models from research centers of excellence around the world
Integrate them in our cloud-based platform
Make them available through user-friendly online products

This solution enables companies to leverage cutting-edge in silico methods at low costs without specific computational expertise, IT infrastructure and solvers investments requirements. On our cloud-based platform, users can select the online computational product of their choice in pay-per-use, or ask us to build the digital product they need.

Why working with InSilicoTrials

SaaS

Buy tokens and use the online products of your choice among those available on the platform

VIRTUAL PATIENTS

Design and accelerate your clinical trials with the virtual patient populations you need

ON DEMAND & CUSTOM

Ask us for the models and simulations you need, or ask us to evaluate where modeling and simulation can support you

TECHNOLOGY-ENABLED SERVICES

Ask us for support on technology integration, in silico trials planning, execution and reporting, in line with regulatory requirements

Reference standards:

- *ISO 25539- 2: Cardiovascular implants - Endovascular devices*
- *ISO 7198: Cardiovascular implants - Tubular vascular prostheses*
- *ASTM F3067-14 (2021) Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents.*
- *ASTM F2514: Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading*
- *ASTM F2477: Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents*

References:

1. Reporting of Computational Modeling Studies in Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff, 2016.