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AMENDMENT 1
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Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter

AMENDEMENT 1

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

AMENDMENT 1

Clause 1, Scope

Replace the second paragraph with the following:

This document is applicable to both newly developed and modified transcatheter heart valve substitutes and to the delivery system, accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted.

6.3.2.3

Replace the entire subclause with the following text.

The intended performance of the transcatheter heart valve substitute shall include, but not be limited to the following:

a) the ability to be consistently, accurately and safely loaded onto the delivery system;

b) the ability to be consistently, accurately and safely deployed;

c) the ability to be safely retrieved and/or repositioned (if applicable);

d) the ability to maintain structural and functional integrity throughout the anticipated lifetime of the device;

e) the ability to conform or interact with anatomical structures within the implant site (e.g. in the aortic position, there is potential for interaction with the coronary ostia, the anterior mitral leaflet and the conduction system; in the mitral position, there is potential for interaction with the aortic root, LA, LAA, LVOT and the subvalvular apparatus);

f) the ability to conform or interact with previously implanted device (e.g. surgical valve, annuloplasty ring, transcatheter valve, valve docking device), if applicable;

g) the ability to allow forward flow with an acceptably small mean pressure difference in all anticipated configurations;

h) the ability to prevent retrograde flow with acceptably small regurgitation, including paravalvular leakage;

i) the ability to resist migration and embolization;

j) the ability to avoid haemolysis;

k) the ability to resist thrombus formation;

l) biocompatibility;

m) the ability to maintain its functionality and sterility for a reasonable shelf life prior to implantation;

n) reproducibility of function.

7.2.4, fifth paragraph

Add the following text to the end of the paragraph:

The values in Table 1 and Table 2 are applicable to new or modified heart valve substitutes which have not been clinically proven.

C.2.2.1

Replace this subclause with the following:

Each pressure measurement (e.g. ventricular pressure, aortic pressure) should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz and a measurement accuracy of at least ±0,26 kPa (±2 mmHg). The flow meter should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz.

C.2.4.2

Replace the entire subclause with the following text.

C.2.4.2 This test fixture is not expected to be used for periodic hydrodynamic performance testing conducted during AWT or with steady flow testing.

Annex C, Table C.4

Replace the entire table with the following:

Beat rate cycles/min	**Systolic duration** %	**Cardiac output** l/min	**Differential pressure across closed valve**[a]
45	30	5	Hypotensive, normotensive, severe hypertensive
70	35	5	Hypotensive, normotensive, severe hypertensive
120	50	5	Hypotensive, normotensive, severe hypertensive
[a] Refers to the mean differential pressure across the closed valve.			

C.2.7

Replace the list item g) with the following:

g) regurgitant volume, including the closing volume and leakage volume (see ISO 5840-1:2021, Figure 2), expressed in millilitres and as a percentage of forward flow volume; and the corresponding differential pressure across closed valve (i.e. mean back pressure).

Clause G.5

Replace the first paragraph with the following: