

Input from external expert and manufacturer on the **2nd draft assessment “Bioresorbable Stents in cardiovascular indications (coronary artery disease)”**

(Project ID: OTCA16)



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Content

MANUFACTURER	3
EXTERNAL EXPERT	5

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c "linguistic": grammar, wording, spelling or comprehensibility

January 2019



MANUFACTURER

Comments were received from:

Name	
BIOTRONIK	Factual accuracy check

Comment from	Page number	Line or section number	Comment and suggestion for rewording	Character of comment • 'major' ^a = 1 • 'minor' ^b = 2 • 'linguistic' ^c = 3	Author's reply
BIOTRONIK	35	567	The Fantom dissolves not within approximately 1 year, but within 4 years. Claim support: TCT 2018 – On-going Activities with a Radiopaque Tyrosine-Carbonate-Based Polymeric BRS: FANTOM; Slide 5 & Homepage(27.12.2018):https://www.revamedical.com/for-physicians/fantom-encore/ - 24 month OCT of Fantom II Trial & Tyrocore Technical Data (pdf in Mail)	1	Thank you for this correction. Corrected
BIOTRONIK	35	553-570	The key-differentiation of Fantom is highly biased – Fantom is the only product on this page, which is allowed to presents it's unique features	1	Thank you for your advice. We have now revised the B0001 section, in order to ensure a more balanced description of the products.
BIOTRONIK	35	563-567	The key-differentiation is in some extent not accurate. – "Single step inflation", "good expansion rate" (0,6mm over-dilatation for Magmaris) and "no special storage or handling requirements" are also true for Magmaris.	1	Section revised
BIOTRONIK	35	568-570	Unique features and therefore unique characteristics of Magmaris are: - The only metal based Scaffold - Electropolished struts for better laminar blood flow - Reduced Thrombogenicity compared to Polymeric Scaffolds - Accelerated Endothelialisation compared to Polymeric Scaffolds Accelerated Endothelialisation compared to Polymeric Scaffolds (Joner M, Ruppelt P, Zumstein P, Haude M, Waksman R et al Preclinical Evaluation of Degradation Kinetics and Elemental Mapping of First and Second Generation Bioresorbable Magnesium Scaffolds, EuroIntervention 2017;13:440-449 published online March 2017; The effects	1	Section revised

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c "linguistic": grammar, wording, spelling or comprehensibility

January 2019



Comment from	Page number	Line or section number	Comment and suggestion for rewording	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3	Author's reply
			of nanostructured hydroxyapatite coating on the biodegradation and cytocompatibility of magnesium implants Maria Emil Iskandar, ¹ Arash Aslani, ² Huinan Liu ^{1,3} ¹ Department of Bioengineering, University of California at Riverside, Riverside, California ² Spire Biomedical Inc., One Patriots Park, Bedford, Massachusetts ³ Materials Science and Engineering, University of California at Riverside, Riverside, California; Published online 28 January 2013 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/jbm.a.34530		
BIOTRONIK	37	592	Magmaris does not "require" invasive imaging	2	Corrected
	38	564	"...wether BVS or metallic..." – Magmaris is a BRS and metallic. In the future the wording "permanent" should be favoured over "metallic stents". ". BVS as abbreviation is incorrect – BRS is the correct category name	1	Here and in all other places the term "permanent" was added to describe conventional metal stents. Thank you for this advice, we changed to abbreviation for the scaffold category from BVS to BRS.
BIOTRONIK	e.g. 58 e.g. 45	614ff 563 ff	On a regular basis general statements about BVS are made and accordingly general questions are answered based on data, which exclusively are based on Absorb-data. – Throughout the paper the differentiation of the data is described well, leading to the statement, that there is a lack of data for every Scaffold except Absorb. But also throughout the paper there could be clear statements, that the outcomes of Absorb cannot be transferred to other Scaffold-Technologies, especially the metallic ones. <u>It is specifically stated in the Guidelines the following that has not been stated in the report: "The resorption process of the stent platforms takes from several months to 2 years, depending on polymer composition. To date, bioresorbable stents have been shown to dissolve completely over time, to restore the vasomotion of treated segments, and to result in positive remodelling with late lumen enlargement. In small series of patients with relatively simple lesions, early results are promising and appear to be similar to new-generation DES.685-687"</u>	1	We have now included an additional statement in the discussion section that emphasizes the lack of transferability of Absorb data to other devices. The statement you cite, comes from the 2014 ESC guideline on myocardial revascularisation, which is already expired and superseded by the current 2018 ESC guideline on myocardial revascularisation. This current guidelines states: "...Therefore, the Task Force endorses the recommendation of the recent ESC/European Association for

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c"linguistic": grammar, wording, spelling or comprehensibility

January 2019



Comment from	Page number	Line or section number	Comment and suggestion for rewording	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3	Author's reply
					<p>Percutaneous Cardiovascular Interventions (EAPCI) document on bioresorbable scaffolds that any BRS should not be used outside well-controlled clinical studies." This statement is now included in the discussion section of the report.</p>

EXTERNAL EXPERT

Comments were received from:

Name
Priv.Doz.Dr. Schuchlenz Herwig

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c "linguistic": grammar, wording, spelling or comprehensibility

EUnetHTA JA3 WP4 - Other technologies, OTCA16

Comments by external experts on the 2nd draft rapid assessment on “Bioresorbable stents for the treatment of cardiovascular indications”



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Comments should be submitted not later than 12:00, 07/01/2019

SCHUCHLENZ

Comment from <i>Insert your name, title and affiliation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/section number	Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i>	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	Author's reply
Summary					EXCELLENT
Description and technical characteristics of the technology					Correct
Health problem and current use					Well taken

Please add extra rows as needed.

¹ a “major”: the comment points to a highly relevant aspect and a thorough answer is expected from the author

b “minor”: the comment does not necessarily have to be answered in a detailed manner

c“linguistic“: grammar, wording, spelling that affect comprehensibility of the document

EUnetHTA JA3 WP4 - Other technologies, OTCA16

Comments by external experts on the 2nd draft rapid assessment on “Bioresorbable stents for the treatment of cardiovascular indications”



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Comments should be submitted not later than 12:00, 07/01/2019

SCHUCHLENZ

Comment from <i>Insert your name, title and affiliation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/section number	Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i>	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	Author's reply
Clinical effectiveness					
					correct
Safety					
					correct
Appendix					
					perfect

Please add extra rows as needed.

¹ a “major”: the comment points to a highly relevant aspect and a thorough answer is expected from the author

b “minor”: the comment does not necessarily have to be answered in a detailed manner

c“linguistic”: grammar, wording, spelling that affect comprehensibility of the document

EUnetHTA JA3 WP4 - Other technologies, OTCA16

Comments by external experts on the 2nd draft rapid assessment on “Bioresorbable stents for the treatment of cardiovascular indications”

Comments should be submitted not later than 12:00, 07/01/2019

SCHUCHLENZ



This “review” and its conclusion is consistent, clear and comprehensible.

All issues (scope, methods, description and technical characteristics, health problem and current use, effectiveness and safety) are correctly described.

I have nothing to criticise, to add or to change.

Please add extra rows as needed.

¹ a “major”: the comment points to a highly relevant aspect and a thorough answer is expected from the author

b “minor”: the comment does not necessarily have to be answered in a detailed manner

c “linguistic”: grammar, wording, spelling that affect comprehensibility of the document