

[REVA MEDICAL LOGO]

TECHNICAL FILE SUMMARY REPORT

Regulation (EU) 2017/745 Annex II and III

TF Document:	TF-001 Module 2 (M2) – Device Information
Revision:	A
Application Type:	CE Marking — Class III Drug-Device Combination
Target Market:	European Union

MEDICAL DEVICES

***FANTOM® SIROLIMUS-ELUTING BIORESORBABLE CORONARY
SCAFFOLD***

***FANTOM® ENCORE SIROLIMUS-ELUTING BIORESORBABLE
CORONARY SCAFFOLD***

***MOTIV® SIROLIMUS-ELUTING BIORESORBABLE VASCULAR
SCAFFOLD***

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2. Product Description, Intended Use and Classification

2.1 Product Description

The FANTOM® Sirolimus-Eluting Bioresorbable Coronary Scaffold System, the FANTOM® ENCORE Sirolimus-Eluting Bioresorbable Coronary Scaffold System, and the MOTIV® Sirolimus-Eluting Bioresorbable Vascular Scaffold System (collectively, the "R400 Family") are bioresorbable scaffold systems designed to treat coronary artery disease and peripheral vascular disease. The scaffold is fabricated from Tyrocore™, a proprietary iodinated tyrosine-based polycarbonate copolymer that is fully bioresorbable. Sirolimus, an antiproliferative drug, is coated on the scaffold to inhibit neointimal hyperplasia.

Unlike metallic drug-eluting stents, the R400 Family scaffold provides temporary mechanical support during the critical healing phase following percutaneous coronary or vascular intervention (PCI/PVI), then gradually degrades and resorbs over approximately 36 months, leaving no permanent metallic implant in the vessel. The bioresorbable nature of the device is intended to restore vasomotion and allow vessel remodeling following complete resorption.

The device consists of two primary components:

1. **Scaffold** — A laser-cut tubular structure made from Tyrocore™ polymer, coated with a Sirolimus/Tyrocore drug formulation. The scaffold is crimped onto the balloon catheter of the delivery system.
2. **Delivery System** — A balloon catheter system used to deliver and deploy the scaffold at the target lesion site via standard percutaneous transluminal techniques. The delivery system consists of an inner catheter with a semi-compliant balloon, an outer catheter, a hypotube, and a hub assembly.

The scaffold and delivery system are supplied as a single, sterile, single-use assembly packaged in a sealed pouch with an outer box. The device is supplied pre-mounted on the delivery system and ready for use without further preparation, except for standard preparation steps described in the Instructions for Use (IFU).

Note: The Tyrocore™ polymer is iodinated, which provides inherent fluoroscopic visibility without the need for separate radiopaque markers. This is a key differentiating characteristic of the R400 Family compared to other bioresorbable scaffold platforms.

2.1.1 List of Variants (Scaffold Configurations)

The R400 Family is available in multiple scaffold sizes (diameter × length combinations) to accommodate the range of target vessel and lesion dimensions encountered in clinical use. The available scaffold configurations for each product line are documented in the supporting technical documents referenced below.

Each scaffold configuration is defined by:

- Nominal scaffold diameter (mm)
- Nominal scaffold length (mm)
- Corresponding drug dose (µg Sirolimus)

- Part number and labeling designation

Table 2.1.1-1 — Supporting Documents: Scaffold Configurations

Document Title	Document ID	Location
Scaffold Configurations and Part Numbers	A-001	Part A folder
Device Dimensions and Specifications	A-002	Part A folder

2.1.2 Device Technical Information

The scaffold is characterized by the following key technical parameters:

Parameter	Value / Description
Scaffold Material	Tyrocore™ (iodinated tyrosine-based polycarbonate copolymer)
Drug Substance	Sirolimus (Rapamycin, CAS 53123-88-9)
Drug Coating Matrix	Sirolimus / Tyrocore polymer blend
Drug Dose	Varies by scaffold size (see Table 3.2.P.1.2-3 in Part H)
Sterilization Method	Electron beam (E-beam) irradiation
Shelf Life	36 months from date of manufacture
Use Condition	Single-use only — do not resterilize or reuse
Delivery System	Rapid exchange (Rx) balloon catheter, over-the-wire (OTW) compatible
Guidewire Compatibility	0.014" (0.36 mm) guidewire
Guide Catheter Compatibility	6 Fr minimum guide catheter inner diameter
Resorption Timeline	Approximately 36 months in vivo

2.1.3 Manufacturer, Manufacturing Site, and Authorized Representative

Manufacturer: REVA Medical, LLC
5751 Copley Drive
San Diego, CA 92111
United States

Manufacturing activities are conducted at the San Diego facility, which is the primary design, development, and manufacturing site for the R400 Family. The site operates under a Quality Management System certified to ISO 13485:2016 (see Part J for QMS certificate details).

Authorized Representative (EU): [AR Name and full address to be inserted prior to submission]

Note: Contact details for the EU Authorized Representative will be confirmed and inserted into this section at the time of final regulatory submission. The AR is registered with the relevant competent authority as required by Regulation (EU) 2017/745 Article 11.

2.2 Intended Purpose, Indications, and Contraindications

2.2.1 Intended Purpose

The R400 Family of devices is intended to improve luminal diameter in patients with symptomatic ischemic heart disease due to de novo native coronary artery lesions (FANTOM® and FANTOM® ENCORE) or peripheral vascular lesions (MOTIV®). The scaffold provides temporary mechanical support to the vessel wall while the artery heals, and then gradually resorbs over approximately 3 years, leaving no permanent implant in the vessel.

The primary mechanism of action is mechanical: the scaffold is expanded within the target vessel to restore and maintain vessel patency. The Sirolimus drug coating provides a secondary pharmacological action by inhibiting neointimal hyperplasia at the treatment site. Per Regulation (EU) 2017/745 Article 1(8), the medicinal substance (Sirolimus) is ancillary to the principal device function.

The intended users of the device are interventional cardiologists or vascular surgeons trained in percutaneous coronary or peripheral vascular intervention techniques. The device is intended for use in a hospital catheterization laboratory or equivalent interventional suite setting.

2.2.2 Indications

The R400 Family devices are indicated for use in patients with the following conditions:

FANTOM® and FANTOM® ENCORE (Coronary Indications):

- Symptomatic coronary artery disease due to de novo lesions in native coronary arteries
- Reference vessel diameter (RVD): 2.5 mm to 3.75 mm
- Lesion length: ≤ 24 mm
- Patients who are candidates for percutaneous coronary intervention (PCI) with stenting

MOTIV® (Peripheral Vascular Indications):

- Symptomatic peripheral artery disease due to de novo or restenotic obstructive lesions in native peripheral vessels
- Reference vessel diameter and lesion length as specified in the MOTIV IFU (see Part D folder)
- Patients who are candidates for percutaneous vascular intervention

2.2.3 Contra-Indications

The R400 Family devices are contraindicated in patients with the following conditions:

- Known hypersensitivity or allergy to Sirolimus (Rapamycin), Tyrocore™ polymer, or structurally related compounds
- Known hypersensitivity to contrast media that cannot be adequately premedicated
- Patients in whom antiplatelet therapy and/or anticoagulation therapy is contraindicated, or in whom compliance with dual antiplatelet therapy (DAPT) cannot be ensured for the required duration
- Lesions involving a bifurcation requiring planned side branch stenting that would jeopardize the main vessel or side branch
- Severely calcified lesions that cannot be adequately pre-dilated
- Chronic total occlusions (CTOs)

- Patients with a life expectancy of less than 12 months
- Patients who are pregnant or breastfeeding
- Left main coronary artery disease (FANTOM/FANTOM ENCORE)
- In-stent restenosis

2.2.4 Warnings and Precautions

WARNING: Read all instructions carefully. Failure to properly follow the Instructions for Use (IFU) could result in serious adverse outcomes for the patient.

General Warnings:

- **Dual Antiplatelet Therapy (DAPT):** DAPT (e.g., aspirin plus a P2Y12 inhibitor such as clopidogrel, ticagrelor, or prasugrel) must be administered as directed in the Instructions for Use. Premature discontinuation of DAPT may increase the risk of scaffold thrombosis, which can result in myocardial infarction or death.
- **Fluoroscopic Visibility:** The Tyrocore™ scaffold is radiolucent. Iodine incorporated into the Tyrocore polymer provides inherent fluoroscopic visibility. However, the operator must confirm scaffold position under fluoroscopy before and after deployment. Radiopaque markers on the delivery system balloon indicate the scaffold position.
- **Package Integrity:** Do not use the device if the packaging is opened, damaged, or if the sterility barrier is compromised. Inspect the package before use.
- **Single Use Only:** This device is intended for single use only. Do not resterilize. Resterilization may result in device malfunction, patient injury, or inadequate sterilization.
- **Resorption and Imaging:** After complete scaffold resorption, the device will no longer be visible under fluoroscopy or CT angiography. Bioresorbable scaffold resorption timelines may vary by patient. Operators should maintain records of implant dates and sizes.

Pre-Procedural Precautions:

- Assess the patient's allergy history before implantation, particularly with respect to Sirolimus and polymer components.
- Confirm that the patient is able to comply with the required DAPT regimen for the minimum duration specified in the IFU.
- Confirm that the patient does not have any condition that would contraindicate implantation (see Section 2.2.3).
- Perform adequate lesion preparation (pre-dilation) before scaffold implantation. Inadequate lesion preparation may result in scaffold underexpansion, malapposition, or inadequate deployment.

Intra-Procedural Precautions:

- Use standard anticoagulation therapy during the procedure per institutional protocol and the IFU.
- Confirm scaffold position under fluoroscopy using the delivery system balloon markers before deployment.
- Inflate the balloon slowly and to the recommended nominal pressure as specified in the IFU.

- Post-dilation using a non-compliant balloon is recommended to ensure optimal scaffold apposition and expansion. Post-dilation must be performed within the scaffold boundaries to avoid scaffold edge damage.
- Do not exceed the rated burst pressure of the delivery system balloon. Exceeding rated burst pressure may result in balloon rupture, embolism, or vessel injury.
- Avoid crossing a deployed scaffold with another device if not clinically necessary; if crossing is required, use careful technique to avoid scaffold disruption.

Post-Procedural Precautions:

- Instruct the patient to comply with DAPT for the minimum duration specified in the IFU and not to discontinue therapy without first consulting their physician.
- Advise the patient to carry implant information (product name, lot number, date of implant, vessel treated) for future medical consultations.
- Monitor the patient for signs of scaffold thrombosis, particularly in the acute and subacute periods (first 30 days post-implant).

2.2.9 Medicinal Substances

Sirolimus (also known as Rapamycin; CAS No. 53123-88-9) is incorporated as a drug coating on the scaffold. Sirolimus is classified as an immunosuppressant and antiproliferative agent (ATC Code: L04AA10).

Sirolimus acts by binding to the intracellular protein FKBP12 (FK506-binding protein 12). The resulting Sirolimus-FKBP12 complex inhibits the mammalian target of rapamycin (mTOR), a key regulatory kinase involved in cell cycle progression. By blocking mTOR, Sirolimus inhibits smooth muscle cell (SMC) proliferation and migration, thereby reducing neointimal hyperplasia and in-stent/in-scaffold restenosis following scaffold implantation.

Drug Classification and Regulatory Status:

- Sirolimus is a well-characterized medicinal substance with a long history of clinical use as an oral immunosuppressant (Rapamune®, Wyeth/Pfizer) for prevention of organ rejection in renal transplant patients.
- When used as a coating on the R400 Family scaffold, the Sirolimus dose is significantly lower than systemic therapeutic doses and is released locally at the treatment site.
- The medicinal substance consultation under Regulation (EU) 2017/745 Article 52(9) has been initiated with the relevant Competent Authority. Refer to Part J documentation for details of the consultation process and outcomes.

Drug-Device Combination Classification:

As the R400 Family incorporates Sirolimus as a drug coating that acts ancillary to the principal action of the device (mechanical support and vessel patency restoration), the R400 Family is classified as a drug-device combination product per MDR Article 1(8) and Annex IX Rule 14. The device achieves its principal intended action by physical means; the pharmacological action of Sirolimus is ancillary to and supportive of the device's primary mechanical function.

Table 2.2.9-1 — Supporting Documents: Medicinal Substance

Document Title	Document ID	Location
Sirolimus Drug Substance Technical File	H-001	Part H folder
Drug Elution Study Report	ST-DRUG-001	Part H folder
Biocompatibility Assessment — Sirolimus Coating	ST-BIO-002	Part F folder

2.3 Classification

2.3.1 Rationale for Qualification of Product as a Medical Device

The R400 Family qualifies as a medical device under Regulation (EU) 2017/745 Article 2(1), as it is a device intended for human beings for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease (specifically, coronary artery disease and peripheral vascular disease). The R400 Family achieves its principal intended action within or on the human body by physical means (mechanical scaffold support for vessel patency restoration) rather than by pharmacological, immunological, or metabolic means.

As the device incorporates Sirolimus as a medicinal substance that acts in a manner ancillary to that of the device, it is classified as a drug-device combination product pursuant to MDR Article 1(8) and Annex VIII, Rule 14. The applicable regulatory framework is Regulation (EU) 2017/745 (MDR) as the integral drug-device combination.

2.3.2 Description of Classification

Classification: Class III (implantable drug-device combination)

Applicable Classification Rules:

- **Rule 8** (MDR Annex VIII): All implantable devices, and long-term surgically invasive devices are in Class IIb, unless they are intended to be placed in the teeth (Class IIa) or in direct contact with the heart, the central circulatory system, or the central nervous system (Class III). The R400 Family is intended to be placed in the coronary arteries and peripheral vessels in direct contact with the central circulatory system → **Class III**.
- **Rule 14** (MDR Annex VIII): Devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, and that has an action ancillary to that of the devices, are classified as Class III. Sirolimus is a medicinal product (Rapamune® marketing authorization); the drug action is ancillary to the device → **Class III**.

Conformity Assessment:

- Annex II (Technical Documentation)
- Annex III (Post-Market Surveillance)

2.4 Conformity Route

The conformity assessment route for the R400 Family is pursuant to Article 52(4) of Regulation (EU) 2017/745, which requires a conformity assessment involving a Notified Body for Class III devices. The applicable routes are:

- Full Quality Assurance System (Annex IX) — covering the manufacturer's quality management system and the device technical documentation; or
- Technical Documentation assessment (Annex II) with Post-Market Surveillance per Annex III, in conjunction with a Type Examination procedure (Annex X) where applicable.

For the R400 Family, the selected conformity assessment route is **Annex IX (Full Quality Assurance System) + Annex II (Technical Documentation Assessment)**.

Medicinal Substance Consultation:

As required by Regulation (EU) 2017/745 Article 52(9), the Notified Body assessment for the R400 Family includes mandatory consultation with the relevant Competent Authority (or the European Medicines Agency, EMA) on the medicinal substance (Sirolimus) component. The Notified Body is required to seek a scientific opinion from the relevant authority on the quality and safety of the drug substance, including the benefit/risk profile of the ancillary medicinal substance. This consultation process is documented in Part J.

UDI Compliance:

The R400 Family complies with the UDI requirements of Regulation (EU) 2017/745 Article 27 and Annex VI. UDI-DI and UDI-PI information is registered in the European database on medical devices (EUDAMED) as required.

Table 2.4-1 — Supporting Documents: Conformity Assessment

Document Title	Document ID	Location
CE Marking Application	J-001	Part J folder
Notified Body Assessment Report	J-002	Part J folder
Quality Management System Certificate (ISO 13485)	J-003	Part J folder