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Summary of Safety and Effectiveness for IMPRA Carboflo™ ePTFE Vascular Graft

SUBMITTER

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DATE SUMMARY WAS PREPARED

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NAME OF THE DEVICE

IMPRA Carboflo™ ePTFE Vascular Graft

IDENTIFICATION OF PREDICATE DEVICE

IMPRA ePTFE Vascular Graft

DESCRIPTION OF THE DEVICE

IMPRA Carboflo™ ePTFE Vascular Grafts are made primarily of expanded polytetrafluoroethylene (ePTFE) using the same manufacturing procedures that are used to manufacture IMPRA ePTFE Vascular Grafts, the devices to which substantial equivalence is claimed. The region of the graft wall adjacent to the lumen, approximately 20-25% of the total wall thickness, is uniformly impregnated with Carbon particles along the entire length of the graft. The carbon impregnated region is formed integral to the outer region of the wall by mixing the PTFE resin mixed with carbon particles, with the non-carbon containing PTFE resin during a singular extrusion process, which results in a monolithic graft wall. The carbon used in the device is USP grade activated charcoal. All other components of the Carboflo graft, namely PTFE, lubricant used as a manufacturing aid, blue pigment incorporated in the orientation lines, and the external support PTFE beading are the same as those used in the manufacture of the predicate devices. These grafts are supplied in the same product configurations as the predicate device, and are packaged, labeled, and sterilized in the same manner as the predicate devices.

Extensive bench testing and microscopic analysis has shown that the carbon

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particles are an integral part of the wall and cannot be separated. The amount of carbon incorporated in each Carboflo vascular graft is less than 1% of the total weight of the graft.

INTENDED USE

IMPRA Carboflo™ ePTFE Vascular Grafts are intended for use as vascular prostheses.

COMPARISON OF THE DEVICE CHARACTERISTICS TO THE PREDICATE

Physical properties of the Carboflo vascular grafts were compared to the values for Standard IMPRA ePTFE vascular grafts, using methods recommended by the AAMI Vascular Graft Standard or the FDA Guidance Document on Vascular Prostheses. Testing of a variety of product types shows that the addition of carbon particles into the graft wall did not affect the physical properties of the Carboflo grafts. Both the new device and predicate device undergo the same testing and evaluation procedures. The acceptance criteria for both the new device and predicate devices are the same.

NON-CLINICAL TESTING

Carbon containing surfaces in medical devices, e.g. Heart valves, have been shown to impart anti-thrombogenic properties¹. Short-term pre-clinical studies have been conducted with IMPRA Carboflo™ ePTFE Vascular Grafts to determine the performance of carbon containing blood contact surface. Animal studies comparing the Carboflo grafts with Standard IMPRA ePTFE grafts have shown that the inside surfaces of the Carboflo grafts have a significantly higher Thrombus Free Surface Area after 3 months². Patencies of both Carboflo and Standard grafts were similar. Short-term animal studies in dogs and rabbits have shown that the Carboflo inside surfaces have reduced platelet accumulation when compared to Standard ePTFE vascular grafts, suggesting that the addition of carbon particles reduces the thrombogenicity of the surface³.

Additional bench testing performed to determine the response of the Carboflo ePTFE graft compared to the Standard ePTFE in repeated puncture test and the

¹ References on file

² Data on file

³ References on file

particulate flow test showed them to be equivalent.

CLINICAL INFORMATION

A multi-center, prospective, randomized clinical trial comparing IMPRA Carboflo™ ePTFE Vascular Grafts to commercially available ePTFE Vascular Grafts, was performed in France between 1990-1994. The purpose of the investigation was to compare the patencies of both IMPRA Carboflo ePTFE Vascular Grafts and Standard ePTFE Vascular Grafts. A total of 81 patients received Carboflo grafts and 79 received Standard ePTFE grafts. All grafts were implanted to treat lower extremity vascular disease. Of the 160 grafts, only 5 grafts (3 Carboflo, 2 Standard) were considered to be Above-Knee, and the remaining grafts were all Below-Knee.

73% of the distal anastomoses were direct graft to vessel, with the following types comprising the other anastomoses: venous patch (16%), distal arterio-venous fistula (5.8%), or interpositional vein cuff graft (5.2%). All implanted grafts were followed for at least 24 months, or until failure, lost to follow-up, or death of patient. Adverse events were recorded and documented on Case Report Forms (CRF).

Analysis

PRIMARY PATENCY was defined as the time between implant date and date of follow-up when the graft was patent, prior to the first intervention to correct complications. Interventions included immediate re-operations to correct any complication post implantation. SECONDARY PATENCY was defined as the time between implant date and date on which the graft is no longer patent or useful, after a series of interventions. Conventional life-tables were then constructed to determine the Cumulative Primary and Secondary Patencies. At the end of the 2 yr follow-up, patencies were as follows:

Cumulative Primary Patency for Carboflo grafts was 36.8 % compared to 27.7% for Standard grafts at the end of 24 months.

Cumulative Secondary Patency for Carboflo grafts was 42.7% compared to 32.3% for Standard grafts.

These results are not statistically significantly different at $p=0.05$.

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DEVICE SAFETY was demonstrated by determining adverse events for both Carboflo and Standard grafts. Complications were counted as they were encountered and added up at the end of the study period for each patient. The results are tabulated below:

COMPLICATIONS: CARBOFLO VS. STANDARD

Adverse event	Device Type	
	Standard	Carboflo
No. At Start	79	81
No. LFU @2yrs *	7	17
No. Patent @2yrs	17	16
No. Immed. Redos	6	12
No. Failed @2yrs	52	43
Thrombosis	34	26
False aneurysm	1	1
Infection	5	4
Other adverse events	2	3
Amputation	26	28
Deaths	16	13

* LFU = Lost to follow-up

It is important to note that no new type of complications were identified with Carboflo grafts.

RISK FACTORS in patients with Carboflo and Standard ePTFE Vascular Grafts were similar ($p > 0.05$), except for Smoking. There were a higher number of patients who were smokers, in the Carboflo group ($p < 0.05$). The risk factors for the patients in this study were then compared to the risk factors for patients in USA who had treatment for peripheral vascular disease (information was summarized from published literature). Risk factors were comparable for both groups ($p > 0.05$), except for Smoking. There were a higher number of patients who were smokers, in the US ($p < 0.05$).

CONCLUSION

IMPRA ePTFE Carboflo Vascular Grafts are substantially equivalent to the currently marketed IMPRA ePTFE Vascular Grafts.