

# The INCRAFT® AAA Stent Graft System: PEVAR Utilizing the New Ultra-Low Profile in Infrarenal AAAs

Prof. Do and Dr. Makaloski discuss how a device with an ultra-low profile offers advantages to patients and the practice.



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*Financial disclosures: He has disclosed he is a paid consultant to Cordis.*



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*Minimally invasive treatment of abdominal aortic aneurysms (AAAs) was first introduced by Volodos and colleagues in the 1980s and then became popularized by Parodi in the early 1990s. Until recently, most stent grafts with rather large delivery system profiles required bilateral open surgical cutdown of the common femoral artery (CFA). Newer delivery systems with lower profiles, such as the INCRAFT® AAA Stent Graft System (Cordis Corporation), enable safe and effective percutaneous treatment of patients with AAAs on a much larger scale. Prof. Do and Dr. Makaloski discuss their firsthand experience with the INCRAFT® System and present a case that demonstrates use of the device in percutaneous endovascular aneurysm repair (PEVAR).*

## Why did you decide to first try the INCRAFT® AAA Stent Graft System? How have you adopted it in your practice?

**Prof. Do:** I started with the EVAR program 20 years ago. I was the interventional angiologist who convinced the vascular surgeon on our team to treat the first endovascular case at that time—successful implantation of the Stentor stent graft (MinTec, Inc.)\* in a patient with an infrarenal AAA. Since that time, I am always looking for new technology, which was my reason for using the INCRAFT® Stent Graft System. We have adopted it very well into our practice.

## Why is low profile important to you?

**Prof. Do:** Low-profile devices enable treatment of patients with challenging access vessels; these patients may otherwise be excluded from an EVAR program.

## In your experience, how does the low profile of the INCRAFT® System compare to other devices?

**Prof. Do:** The INCRAFT® System performs as well or even better than other devices with a low profile. The ultra-low profile, the lowest outer diameter (OD) sheath for both the main body and contralateral limb (14 F and 12 F, respectively,<sup>†,‡</sup>) compared to other devices, improves flexibility, which in turn favors advancement of the stent graft through very tortuous access vessels.

## What are the benefits of low profile in patients with small access vessels and in those with regular anatomy?

**Prof. Do:** As stated previously, patients with small access vessels may not be candidates for EVAR if not for a device with an ultra-low profile. Patients with regular anatomy

\*The third-party trademarks used herein are trademarks of their respective owners.

<sup>†</sup>For the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15 F (outer diameter of 16 F).

<sup>‡</sup>For the iliac limb prosthesis with a 24-mm diameter, the outer diameter is 13 F.

For EMEA healthcare professionals only. Important information: Prior to use, refer to the Instructions for Use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings, and precautions. As part of the Cordis policy of continuous product development, we reserve the right to change product specifications without prior notification.

The use of the INCRAFT® AAA Stent-Graft System requires that physicians be specially trained in endovascular abdominal aortic aneurysm repair techniques, including experience with high-resolution fluoroscopy and radiation safety. Cordis Corporation will provide training specific to the INCRAFT® AAA Stent-Graft System.

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get all of the benefits of a low-profile device: percutaneous implantation with local anesthesia and early discharge.

**Does the low-profile feature of the INCRAFT® System provide specific benefits to any other patient groups?**

**Prof. Do:** In our experience, a reduction in interven-

tion time, blood loss, wound complications, and secondary interventions can be expected, even in patients with small access arteries. There is also a reduced need for closure devices. As a result, there is shorter hospitalization for inpatient treatment and outpatient treatment is a more feasible option; both options result in cost savings. ■

## CASE PRESENTATION: PEVAR IN AN INFRARENAL AAA WITH A LONG PROXIMAL NECK

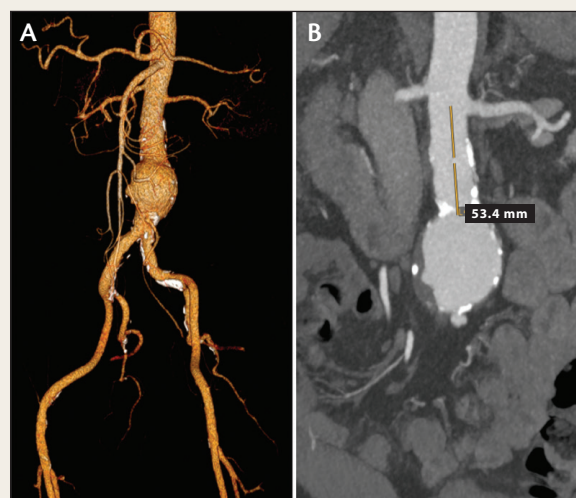
A 68-year-old man with an asymptomatic abdominal aortic aneurysm (AAA) was referred to our center for evaluation for EVAR. He was a former heavy smoker, but otherwise without a history of hypertension, hyperlipidemia, diabetes mellitus, and coronary artery disease. The preoperative CT scan confirmed the ultrasound findings of an infrarenal AAA of 5.5 cm in diameter with a long proximal neck (Figure 1). The patient was offered either open surgery or EVAR, and the decision was to proceed with PEVAR.

### PERCUTANEOUS ENDOVASCULAR REPAIR

PEVAR took place in the hybrid operating room. Under local anesthesia, the preclosure technique was performed on both common femoral arteries (CFAs) using Perclose ProGlide devices (Abbott Vascular).<sup>\*</sup> The anterior wall of the right CFA was first punctured at a 45° angle and at the appropriate site based on the preoperative CT findings. A stiff 0.035-inch Radifocus M stiff type guidewire (Terumo Interventional Systems)<sup>\*</sup> was engaged. After predilatation of the subcutaneous tissue and vessel wall using the dilator of an 8-F sheath, the two ProGlide systems were deployed at 30° medially, lateral from the centerline (Figure 2). The two sutures with pretied knots of each device were secured with a covered clamp, and an 8-F sheath was inserted over the guidewire. Knowing the very low profile of the contralateral limb of the INCRAFT® Stent Graft (Cordis Corporation), only one ProGlide device was placed into the left CFA.

The Radifocus guidewire on the right side was then exchanged for a stiffer 0.035-inch guidewire (E-wire, JOTEC).<sup>\*</sup> Next, the 8-F sheath was removed, and the delivery system of the INCRAFT® AAA Stent Graft System (14-F OD<sup>†</sup>) with the main body inside was lined up with the contralateral gate and advanced smoothly up to the level of the renal arteries. At this step, an initial angiogram using a graduated pigtail catheter from the left side was done, showing the position of the device and the lower location of the left renal artery as well as the two

normal common iliac arteries (Figure 3). After adjusting the INCRAFT® Stent Graft just below the take-off of the left renal artery, the main body (26 mm in diameter and 94 mm in length) was deployed. The AAA was then successfully excluded after percutaneous placement of the contralateral and then ipsilateral limb. An iliac limb 13 mm in diameter and 120 mm in length was used for



**Figure 1.** Preoperative CT scan showing the infrarenal AAA (A) with a rather long proximal neck (B).



**Figure 2.** Preclosure of the access sites using ProGlide devices.

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<sup>†</sup>For the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15 F (outer diameter of 16 F).



**Figure 3.** Initial angiogram using a graduated pigtail catheter showing the position of the ultra-low profile delivery system within the abdominal aorta with the still undeployed INCRAFT® main body. Note the lower take-off of the left renal artery (A) and the normal common iliac arteries (B).

the contralateral left side. An iliac limb 16 mm in diameter and 120 mm in length was placed into the right side common iliac artery (both delivery systems 12-F OD<sup>†</sup>). The proximal and distal seal zones, as well as the stent graft component junctions, were subsequently ballooned using a Reliant stent graft balloon catheter (Medtronic, Inc.).\* The final angiogram demonstrated an excellent result of PEVAR and good perfusion of the hypogastric arteries (Figure 4).

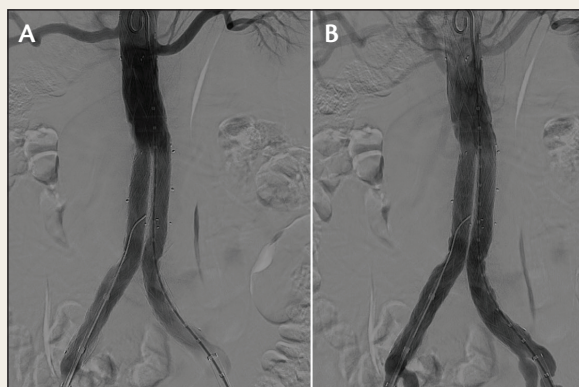
At the end of the PEVAR procedure, the access sites in both groins were sealed one after the other by withdrawing the delivery system, then advancing and tying the knots using the knot pusher of the ProGlide system. Immediate hemostasis was obtained so that the guidewires could be removed, and no compression bandage was needed. The whole procedure took 55 minutes, and just 57 mL of contrast media was administered.

#### MEDICAL THERAPY AND FOLLOW-UP

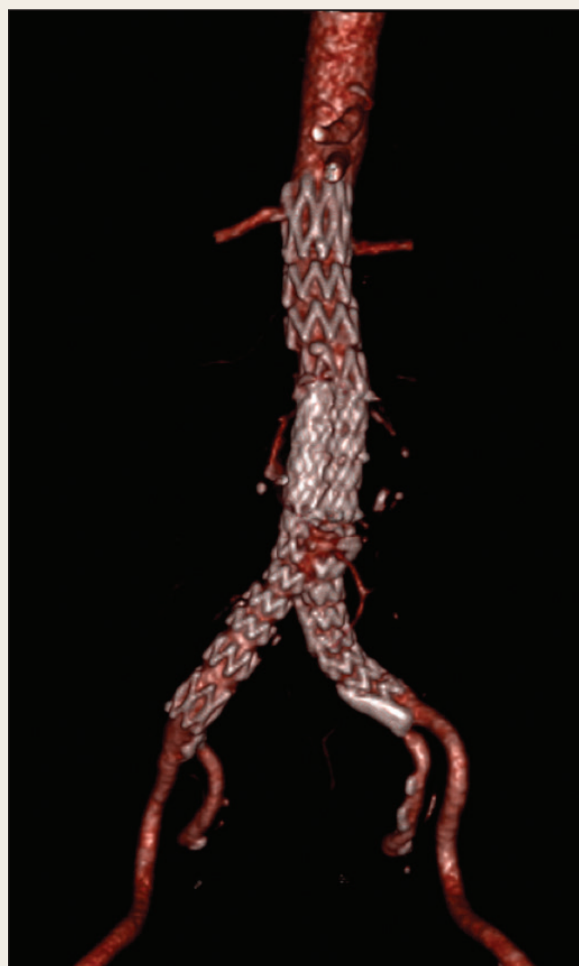
The patient was discharged with antiplatelet monotherapy (acetylsalicylic acid, 100 mg/day). A controlled CT angiogram performed at 1 month post-intervention confirmed the good initial result after PEVAR with complete exclusion of the aneurysm and no endoleak (Figure 5).

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<sup>†</sup>For the iliac limb prosthesis with a 24-mm diameter, the outer diameter is 13 F.



**Figure 4.** Final angiogram showing the complete exclusion of the AAA using the ultra-low-profile INCRAFT® AAA Stent Graft System (A, B).



**Figure 5.** Follow-up CT scan confirmed the good result of PEVAR.