



The Society for Cardiac Angiography & Interventions

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Instructions for Use: Instructions for Whom?

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I used to joke with fellows in the cath lab who eagerly collected the packaged *Instructions For Use* from interventional devices, “if you have to read the directions, you probably should not be using the device”.

It seems that the details for use of interventional devices is something we know in painful detail long before we have the opportunity to read *Instructions For Use*. The instructions are not packaged sterile, thus it is not easy to use them when we encounter a device with a nuance that we are unfamiliar with.

If the *Instructions For Use* are not generally useful to the practicing interventional cardiologist, what are they for? Or better, who are they for? The *Instructions For Use* (IFU) are developed as part of the FDA approval process for devices (see www.FDA.gov). A great deal of thought and work go into preparing an IFU for submission to the FDA. Tremendous detail regarding the wording of the IFU is a matter of concern during the approval process. The labeling must be justified by clinical data provided during the approval process.

The intention of the IFU should be to provide useful information for the user. However, many elements of the IFU have unintended consequences. The IFU provides a list of elements that take on a life of their own, and sometimes seem to be written in stone. The language in an IFU does not usually change as clinical practice

changes. A wonderful example is the lack of labeling (until fairly recently) for the use of aspirin in treating acute myocardial infarction.

Numerous statements in *Instructions For Use* do not relate to real practice. I have reviewed the IFU from a variety of interventional devices recently and found the following statements:

- Dilatation catheter testing prior to use: “When all connections are completed test the connections under 75 psi/5 atm/bar of pressure for possible fluid leaks. . .test the dilatation catheter by inflating the balloon to the rated burst pressure for 5 seconds. . .” Have you ever test inflated a PTCA balloon (to the rated burst on the back-table!) prior to use?
- “Prior to angioplasty carefully examine all equipment to be used during the procedure including the dilatation catheter to verify proper function.” How can inspection verify function?

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DOI 10.1002/ccd.10470

Published online in Wiley InterScience (www.interscience.wiley.com).

- Regarding a coronary balloon dilatation catheter, "Treatment of moderately or heavily calcified lesions is considered to be moderate risk with an expected success rate of 60%–85% and increases in the risk of acute closure. . ." This recommendation in the IFU does not consider that by intravascular ultrasound almost 80% of lesions are calcified, and that we have certainly better than 85% overall success rates with current PCI practice.
- For a guide catheter, "Set up a continuous heparinized saline flush through the side arm of a hemostatic valve attached to the guiding catheter hub. It is recommended that a continuous heparinized saline flush be maintained between the guiding catheter and any intraluminal device passed through it." How often do you run a continuous pressurized flush through a guide catheter?
- Regarding a guidewire, "Free movement of the guidewire within the interventional device is an important feature of a steerable guidewire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guidewire movement." How does one test the guidewire prior to use?
- Regarding balloon and stent delivery systems, "Do not exceed the rated burst pressure as indicated on the product label." The rated burst pressure is 16 atmospheres. Have you ever exceeded 16 atmospheres with a stent delivery balloon?
- For the rotablator atherectomy system, "Adjust the operating speed, 1.25 to 2 mm burs, 180,000 r.p.m., 2.15 mm and larger burs, 160,000 r.p.m." A number of important trials have demonstrated the importance of lower speed rotational atherectomy. In this case, the instructions for use have not kept pace with changing practices[1,2].

Some of these IFU statements seem similar to the warnings on coffee cups at fast food restaurants: "Warning: contents may be hot!" Again, the question must be asked: who are these warnings for?

We routinely use devices for "off label" purposes. Off label use of devices comprises a large part of angioplasty practice. In the early stent era, one study estimated that as many as 80% of stent procedures were "off label" [3]. The adaptation of angioplasty equipment to off label uses has always been an important part of the practice of angioplasty, the management of complications, and improvements in technique in the field [4–6]. Some of the departures from labeling are minor, such as the use of guide catheters without pressurized flush systems, while others are more substantial, such as the use of biliary stents in the carotids, or recent anecdotes describing placement of ASD closure devices in the left atrial appendage.

How much do we as practitioners know about the instructions for device use? No more than we know about some of the labeling for intended use for pharmaceutical agents. Few of us can recite which ACE inhibitor drugs are approved for hypertension versus heart failure, or which calcium blockers are labeled for angina versus hypertension.

Practice defines use. The FDA mandates surveillance and reporting of adverse device-related events. The web reporting for unanticipated procedure device-related failures or events may be more valuable than any package insert. Visit www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM to see the reports to the Center for Devices and Radiological Health of device related adverse events.

Incorporating summaries of these reports as a mechanism of feedback to update the IFU based on reported events would be a vast improvement over the existing package labeling system.

Our off label use is a result of changes in practice. More importantly, our development of new techniques and new applications for interventional cardiology is dependent on extending the use of existing products beyond their labeling. Our colleagues in cardiovascular surgery do not acquire "new labeling" for surgical techniques, such as off-pump bypass. These represent departures from established practice that are as great as most of the off label use that we practice in the interventional laboratory on a day-to-day basis.

It is clear that new procedures and the development of new techniques require organized trials, registries and randomized studies, driven by institutional review board approved protocols. At the same time, many creative uses of angioplasty equipment develop "on the fly" outside of the context of investigation and are important for advances in interventional cardiology.

The case reports of Catheterization and Cardiovascular Intervention are full of examples of the creative, innovative and off label use of interventional equipment [7–11]. Even the conventional use of PCI devices routinely evolves beyond the IFU labeling. Our ability to adapt our tools to difficult or challenging circumstances is part of what makes the fieldwork so effectively for our patients. We as interventionalists may ourselves in essence be writing the "instructions for use" each day, as we put these devices to use in creative new ways for the benefit of our patients.

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