

WHY ARE IFUS STILL BEING PRINTED?



Efforts to transition from paper to electronic instructions for use.

BY EMILY SCHELEIN, MD

In the OR several years ago, my circulating nurse watched me switch to cortical removal, the signal for him to open the preselected IOL.

Over the whirs and dings of the phaco machine, I heard the crinkle of plastic wrap, the opening of cardboard, and the thunk of a 70-page instructions for use (IFU) pamphlet landing in the waste bin. He pulled open the peel pack and delivered the lens to my assistant.

An IFU pamphlet provides guidance on the safe and proper use of surgical devices and products. Most surgeons associate IFU with IOL packaging, but these pamphlets accompany most of the items used in cataract surgery, including the IOL and its cartridge, OVDs, saline bottles, and phaco sleeves and tips. The IFU pamphlet for IOLs typically weighs 64 g, whereas the actual IOL weighs less than 1 g. The carbon footprint of cataract surgery is great (Figure).¹

This article discusses why printed IFU pamphlets continue to be

packaged with ophthalmic surgical products and efforts to transition to an electronic format.

THE REASONS FOR PRINTED IFU PAMPHLETS

Why are paper IFU in more than 10 different languages packaged with scores of products used during ophthalmic surgery? The simple answer is that regulatory agencies require that IFU be printed for some products, and manufacturers and industry must comply. The regulations vary across countries and products. Some agencies, such as the European Union Medical Device Regulation, permit electronic IFU (e-IFU) for certain products but not others. The distinction is onerous for industry, particularly global companies serving multiple different markets.

In 2023, EyeSustain developed a survey with the Medical Device Manufacturers Association in the United States and found that 95% of companies considered e-IFU to be an acceptable

alternative to paper IFU. They were confident that e-IFU would reduce paperwork (84% of companies) and production costs (80% of companies). Only 20%, however, used e-IFU for all products. Among the reasons cited were varying and inconsistent IFU requirements among different countries (100% of companies).²

INCENTIVES FOR INDUSTRY

Manufacturers may be incentivized to reduce waste to boost profits and efficiency. One global IOL manufacturer reduced packaging weight by 53% simply by removing paper IFU where allowed.³ Decreasing packaging weight should reduce shipping costs and may increase shipping efficiency. Additional advantages of e-IFU for industry are how quickly the information can be updated and a reduced need to dispose of and repackage affected products.

It is worth noting that physicians and other health care professionals support reducing waste. In a 2020 survey by



Figure. Dr. Schehlein handles large amounts of waste from the OR.

David F. Chang, MD, and Cassandra L. Thiel, PhD, 76% of surgeons and 72% of nurses agreed that “device and supply manufacturers should consider the environment/carbon footprint in their product design.”⁴

PATIENT SAFETY

The overarching goal of the control that regulatory agencies and bodies exert over the activities of health care organizations and individual physicians is to protect patients’ health and safety. A transition from printed to e-IFU, however, does not pose a threat to patient safety and may actually enhance it.

The small print in paper IFU pamphlets can be difficult to read, especially for presbyopic members of the surgery team in a dimly lit OR. Printed IFU also cannot be accessed without breaking the sterile seal on the package and, as noted earlier, cannot be immediately updated. With e-IFU, surgeons can access the most current information online, easily search for relevant information, and increase

“A TRANSITION TO E-IFU COULD

REDUCE PAPER PRODUCTION BY 84%,

PRESERVING 50,000 REAMS OF COPY

PAPER OR 2,000 TREES EACH YEAR.”

screen brightness and adjust the font size of the guidance as needed.

This all assumes that a surgeon needs to access the IFU. Ophthalmologists, however, generally have a working knowledge of the IFU of the equipment and products they use repeatedly.

ENVIRONMENTAL BENEFITS OF E-IFU

A transition to e-IFU could reduce paper production by 84%, preserving 50,000 reams of copy paper or 2,000 trees each year.⁵ Earlier this year, the EyeSustain Task Force on e-IFU published a position statement in the *Journal of Cataract & Refractive Surgery* with the support of the AAO, ASCRS, and ESCRS.² EyeSustain is also working closely with industry partners to advocate for a transition to e-IFU. Additionally, the organization is collaborating with ophthalmologists and their local organizations to communicate the message to regulators.

CONCLUSION

On my most recent surgery day, I heard the whirrs and dings of the phaco machine, the crinkle of plastic, and the opening of cardboard. What was missing from the ambient noise was the thunk of a printed IFU pamphlet. Instead, a single piece of paper with a QR code floated into the waste bin. The transition to e-IFU has begun, but there is more work to do. ■

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