



Reducing Ophthalmic Surgical Waste through Electronic Instructions For Use Multisociety Policy Statement

Background

Regulatory agencies, such as the European Union (EU) Medical Device Regulation (MDR) and the United States (US) Food and Drug Administration (FDA), require manufacturers to provide detailed instructions for use (IFU) to guide proper and safe use of surgical devices and products. The IFU describe how to use the product, and may include information about applications, component parts, indications and contraindications, precautions, warnings, study results, and adverse events. In ophthalmic surgery, IFU accompany most devices and supplies used, such as dropper bottles of saline, ophthalmic devices and irrigating solution. Although some IFU may be printed on the package exterior, most are separately supplied as a printed booklet or folded handout within the product package. As an alternative to paper IFU, electronic instructions for use (e-IFU) can be accessed through websites linked through QR codes on the package. Both MDR and FDA regulations permit e-IFU, although for MDR, this is limited to certain products. To understand the potential benefits and disadvantages of e-IFU for all ophthalmic surgical products, it is helpful to consider the case example of IOLs.

e-IFU for IOLs

Only a few companies have implemented e-IFU for IOLs in the US and EU. The content of each IOL IFU is repeated in multiple languages and includes information on the IOL power calculation (such as the A constant), insertion instructions, warnings/precautions, expected postoperative results, and patient registration information. Because of the extensive information provided in multiple languages, the IFU print size is small, making it more difficult to read than newsprint, even in the bright light of an operating room. Printed paper IFU booklets also contribute significantly to the overall weight and size of the IOL package.

In a 2013 analysis of carbon emissions from cataract surgery in the NHS, Morris et al noted that the IOL packaging (plastic and paper) weighed 64 grams and included a 70-page IFU booklet translated into 11 languages. By comparison, the actual IOL weighed

less than 1 gram.¹ A 2017 analysis performed at the Aravind Eye Care System found that each cataract surgery produced only 250 grams of waste because of the routine reuse of most surgical and pharmaceutical supplies. The IFU and IOL packaging accounted for 25% of this waste.² Eliminating the excess weight of IOL packaging might reduce costs for waste treatment and product shipment.

The ramifications of implementing e-IFU for IOLs can also be considered from the standpoint of four different parties and stakeholders. These considerations can be generalized to ophthalmic surgery products.

1. Surgical Facility Considerations

Reliable internet connectivity is an important consideration for e-IFU. In most countries, wireless internet or cellular data is widely available and global internet access is rapidly expanding. In the unlikely event that a surgeon urgently needed to refer to the IFU in the operating room, e-IFU would expedite searching for the required information via the 'find' option, as opposed to reading the multiple pages and small print of a paper IFU pamphlet. Viewing e-IFU on a computer, tablet, or mobile device would allow the user to enlarge the font and adjust brightness. With a QR code linking to the e-IFU, any mobile device could display the information without the need for a desktop or laptop computer in the OR. As a backup to e-IFU, such as when internet or LTE access is unreliable, facilities should print and file one copy from a downloadable PDF on the company's website or request a printed copy from the company.

2. Surgeon Considerations

For cataract surgery, the IOL model and power are selected preoperatively. Because printed IFU are only accessible after the sterile IOL package is opened, digital IFU would be much easier for surgeons to review in the clinic when the IOL model and parameters are selected. From a practical standpoint, surgeons rarely need to reference the IFU and the fact that we repetitively use the same IOL models makes inclusion of paper IFU booklets within every IOL box exceedingly wasteful.

3. Manufacturer Considerations

One manufacturer was able to reduce their IOL packing weight by 53% by removing the paper IFU where this is allowed.³ Decreasing packaging size and weight should reduce shipping costs, making this an economical as well as an ecological choice. Manufacturers can update e-IFU much faster than paper IFU and updated e-IFU would immediately become available for units that are already in the manufacturer's or the surgical facility's inventory.

4. Regulatory Agency Considerations

A major obstacle to e-IFU adoption is that several countries still require printed IFU (Table 1). Many are low to middle-income countries, but this list also includes several

larger markets as well. For companies that sell IOLs in these global markets, it may be impractical and expensive to have two different packaging lines - one that includes a paper IFU in the package, and another that does not. We believe that requiring paper IFU is outdated and environmentally detrimental. There is no evidence that e-IFU pose any danger to patient care. On the contrary, safety information can be updated much faster and more effectively with e-IFU. This is particularly important for IOLs, given the common practice where IOLs are stored under consignment in surgical facilities. Some infrequently used IOL powers may sit on OR shelves for long periods of time, allowing the enclosed paper IFU to become outdated.

In the United States, the Federal Food, Drug and Cosmetic Act (FFDCA) ensures that IFU for devices used in health care settings “...*may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.*”⁴ In Europe, the MDR provides a set of regulations that all companies in the EU market must abide by for production and distribution of medical devices.⁵ Currently, e-IFU for implants such as IOLs are accepted by the MDR across EU member states. However, e-IFU are not accepted by MDR for other products used in cataract surgery, such as instruments and phacoemulsification tubing and machines, because they are not implants or permanently installed systems. MedTech Europe, a trade association for medical technology and devices, published a position paper calling for the use of e-IFU for all medical devices.⁶ We encourage MDR to resolve this inconsistent logic by permitting e-IFU for all ophthalmic surgical products.

Conclusion

Paper IFU contribute significantly to unnecessary waste and adverse environmental impact of ophthalmic surgery. Compared to an e-IFU, disadvantages of a printed IFU include smaller print, inability to immediately update, and difficulty accessing the information in clinic. Because of the extremely high volume of ophthalmic devices used in surgery, implementing e-IFU is a straightforward way for manufacturers to reduce unnecessary waste and carbon emissions. We recommend that the ophthalmic surgical manufacturing industry move exclusively to e-IFU, initially prioritizing those products routinely used. We request that every global government and regulatory agency facilitate these efforts.

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References

1. Morris DS, Wright T, Somner JE a, Connor a. The carbon footprint of cataract surgery. *Eye (Lond)*. 2013;(January):1-7. doi:10.1038/eye.2013.9
2. Thiel CL, Schehlein E, Ravilla T, et al. Cataract surgery and environmental sustainability: Waste and lifecycle assessment of phacoemulsification at a private healthcare facility. *J Cataract Refract Surg*. 2017;43(11):1391-1398. doi:10.1016/j.jcrs.2017.08.017
3. Alcon. *Alcon Corporate Social Responsibility Report*. Geneva, Switzerland; 2023.
4. Congress 107th. *Medical Device User Fee and Modernization Act of 2002 (MDUFMA)*.; 2002. <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-and-modernization-act-2002-mdufma-pl-107-250>.
5. Commission E. Factsheet for manufacturers of medical devices. https://health.ec.europa.eu/system/files/2020-09/md_manufacturers_factsheet_en_0.pdf. Published 2020. Accessed August 5, 2023.
6. Europe M. *Electronic Instructions for Use for All Professional Use Medical Devices: MedTech Europe Calls for Scope Expansion of EU 2021/2226*. <https://www.medtecheurope.org/resource-library/electronic-instructions-for-use-for-all-professional-use-medical-devices-medtech-europe-calls-for-scope-expansion-of-eu-2021-2226-position-paper/>.

Table 1: Current State of e-IFU by Country

(Source: Personal communication with industry representatives)

e-IFU accepted (with restrictions)	e-IFU not accepted	e-IFU acceptance unclear
Angola, Anguilla, Antigua and Barbuda, Argentina, Aruba, Australia, Austria, Bahamas, Bangladesh, Barbados, Belgium, Belize, Bolivia, Brazil, Bulgaria, Canada, Cayman Islands, Chile, Columbia, Costa Rica, Croatia, Curacao, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, El Salvador, Eritrea, Estonia, Ethiopia, Finland, France, Germany, Greece, Grenada, Guatemala, Guyana, Honduras, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Latvia, Liberia, Lichtenstein, Lithuania, Luxembourg, Maldives, Malta, Mauritius, Nepal, Netherlands, New Zealand, Nicaragua, Norway, Poland, Portugal, Romania, San Marino, Saudi Arabia, Singapore, Slovakia, Slovenia, South Korea, Spain, St. Lucia, St. Maarten, St. Vincent and the Grenadines, Suriname, Sweden, Switzerland, Tanzania, Thailand, Trinidad and Tobago, Turkey, Turks and Caicos, Uganda, United Kingdom, United States, Venezuela, Zambia, Zimbabwe	Afghanistan, Algeria, Albania, Armenia, Azerbaijan, Bahrain, Belarus, Benin, Bhutan, Brunei, Bosnia, Cambodia, Cameroon, Central Africa, Chad, China, Comoros, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Iran, Iraq, Jordan, Kazakhstan, Kosovo, Kuwait, Lebanon, Libya, Macedonia, Malaysia, Mali, Mexico, Moldova, Montenegro, Morocco, Niger, Oman, Pakistan, Peru, Qatar, Russia, Serbia, Sri Lanka, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Vietnam	Bosnia and Herzegovina, Botswana, Burundi, Dominican Republic, Ghana, Guinea, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Mongolia, Namibia, Panama, Paraguay, Philippines, Republic of Macedonia, South Africa, Taiwan, Yemen