









# The Unmet Need for Multiuse Phacoemulsification Machine Products Multisociety Position Paper

Collaboration between ophthalmologists and industry has produced extraordinary advances in phacoemulsification technology since Kelman's invention was commercialized more than 5 decades ago. Thanks to these advances, cataract surgery with intraocular lens implantation is one of the most successful and common surgical procedures in medicine, with global volumes approaching 30 million cases per year. Rising surgical volume, largely associated with aging populations, raises concerns about the sustainability of this sight-restoring surgery. In addition to concerns regarding cost and access to care, cataract surgery's environmental impact from carbon emissions and waste generation is also unsustainable. Disposing of phacoemulsification supplies after each procedure increases cost, turnover time, emissions, and plastic waste, without evidence that single-use supplies improve patient outcomes or safety over multiuse supplies. Our organizations believe that ophthalmology stakeholders must encourage industry development, efficient regulatory body review, and broad adoption of safe multiuse supplies, such as phacoemulsification tubing, cassettes, tips and sleeves, and when feasible, irrigation solution containers.

# **Background**

Worldwide, most phacoemulsification machines, including all but one in the United States (U.S.), employ single-use phacoemulsification tubing and cassettes. Only a few manufacturers offer multiple-use phacoemulsification tubing and cassettes. Some manufacturers only offer single-use phacoemulsification tips and sleeves. Single-use supplies may produce significant per case revenue for the manufacturer, but also a large amount of plastic and packaging trash. Because of high cataract surgical volumes, the cumulative carbon footprint associated with the raw material extraction, manufacture, packaging, shipping, and disposal of these products is significant.<sup>3,4</sup>

It has been estimated that the healthcare sector accounts for 4.4% of total global greenhouse gas (GHG) emissions, and nearly 10% of GHG emissions in the U.S.<sup>5,6</sup> More than 70% of this carbon footprint is attributable to the manufacture, use, and disposal of supplies.<sup>5</sup> Operating rooms (OR) account for a major share of the GHG and waste from the healthcare sector.<sup>7</sup> *The Lancet* Climate Change Commission called climate change the biggest global health threat of the 21<sup>st</sup> century.<sup>8</sup> Excess morbidity and mortality due to heat, poor air quality, water and food insecurity, and infectious disease are disproportionately borne by the poorest countries and communities.<sup>5,8</sup>

In addition to carbon emissions, the harmful health impact of non-degradable microplastics and nanoplastics that pollute our environment is increasingly recognized. 4-11 Worldwide, around 30% of healthcare waste generated is plastic. The U.S. healthcare system generates more than 1.7 million tons of plastic waste annually, which is more than 10 times the weight of the Great Pacific Garbage Patch. 12

Most plastic waste from healthcare is not recycled due to contamination risks and instead ends up in landfills, incinerators, or natural environments. The plastic in intravenous bags and tubing is often softened with a carcinogen called Di(2-ethylhexyl) phthalate (DEHP). In addition, "forever chemicals" known as per- and polyfluoroalkyl substances (PFAS) have been used in the manufacture of surgical gowns, gloves, drapes, and tubing. Because of potential adverse health effects there is mounting pressure for manufacturers to phase out DEHP and PFAS from medical products.<sup>13,14</sup>

Estimates that the healthcare sector might undermine public health through its contribution to waste and climate change are both alarming and paradoxical. As one of the highest volume procedures in medicine, cataract surgery is a major contributor to healthcare-derived waste and ophthalmology has an obligation to lead efforts to mitigate this harm. Central to this opportunity to decrease waste is the often-overlooked fact that cataract surgery does not generate contaminated fluids and tissue requiring complicated disposal. Therefore, we believe the current practice of disposing of phacoemulsification machine supplies after every case is unnecessarily wasteful. We encourage research and development of ophthalmic surgical supplies that are validated for multiple uses.

# Ophthalmic surgeons want multiuse phaco supplies

North American, European, and Asian Pacific cataract surgeons were surveyed through their ophthalmic societies regarding attitudes about OR waste and sustainability. More than 1200 cataract surgeons responded to the initial survey conducted by the multisociety Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force and sent to members of the American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (AAO), the Outpatient Ophthalmic Surgery Society (OOSS), and the Canadian Ophthalmological Society (COS). <sup>15</sup> Another 450 surgeons responded to the European Society of Cataract and Refractive Surgeons (ESCRS)-sponsored survey and nearly 2200 surgeons to the Asia-Pacific Academy of Ophthalmology (APAO)-sponsored survey. <sup>16,17</sup> The same questionnaire and methodology was used in all three surveys to allow direct comparison. Most ophthalmologists felt that OR waste from cataract surgery is excessive (92%) and that we should reduce surgical waste and its environmental impact (96%). Overwhelmingly, cataract surgeons wanted manufacturers to offer more reusable options and allow surgeons more discretion to reuse surgical supplies in their product's instructions for use (IFU) (Table 1). Most also wanted more discretion from regulatory agencies to reuse cataract surgical supplies.

(OICS, ESCRS, and APAO member survey results)						
OICS n = 1101 ESCRS n = 336 APAO n = 2169	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	
Device and supply manufacturers should consider environment/carbon footprint in their product design.	76% / 85% / 65%	16% / 10% /25%	5% / 3% / 8%	1% / 0% / 1%	1% / 1% / 1%	
Manufacturers should offer more reusable	81% / 74% / 65%	13% / 18% / 27%	5% / 5% / 6%	1% / 1% / 1%	0% / 1% / 1%	

Device and supply manufacturers should allow surgeons more discretion in their IFU (e.g. suggest single use but allow reuse).	75% / 60% / 66%	18% / 29% / 26%	5% / 5% / 6%	2% / 4% / 1%	1% / 1% /1%
Regulatory bodies should allow surgeons more discretion in reusing supplies, drugs, and devices.	81% / 64% / 65%	14% / 25% / 25%	3% / 6% /7%	1% / 4% / 2%	0% / 1% / 1%

APAO = Asia-Pacific Academy of Ophthalmology; ESCRS = European Society of Cataract and Refractive Surgeons; IFU = instructions for use; OICS = Ophthalmic Instrument Cleaning and Sterilization Task Force (North America)

These surveys specifically addressed surgeons' willingness to reuse phacoemulsification machine supplies (Table 2). <sup>15-17</sup> Most ophthalmologists felt that phacoemulsification tubing, cassettes, tips, and irrigating solution containers could be safely reused. More than 90% were already reusing or willing to consider reusing phacoemulsification and irrigation/aspiration (IA) tips. At least 75% of surgeons from all 3 regions were willing to reuse phacoemulsification/IA tubing, which means that an approved multiuse product would be commercially well received. However, there were significant regional differences in the number of surgeons currently reusing phacoemulsification/IA tubing ranging from 7% in North America to 41% in Asia Pacific. This likely reflected local availability of reusable phacoemulsification tubing/cassettes or local regulations on ability to reuse single-use phacoemulsification machine supplies off-label.

Table 2: Willingness to reuse phaco supplies on multiple patients  (OICS, ESCRS, and APAO member survey results)					
OICS n = 1070 ESCRS n = 332 APAO n = 1929	Currently use as multiuse	Willing to consider multiuse	Unwilling to use as multiuse	Unsure	
Phaco tips	38% / 48% / 68%	54% / 42% / 25%	5% / 8% / 6%	3% / 2% / 1%	
IA tips	41% / 48% / 73%	49% / 40% / 20%	6% / 9% / 6%	4% / 3% / 1%	
Phaco and IA tubing	7% / 21%/ 41%	69% / 55% / 40%	17% / 17% / 16%	7% / 8% / 3%	
Irrigating solution/bottle*	8% / 26% / 50%	70% /47% / 30%	15% / 21% /18%	6% / 7% / 2%	

APAO = Asia-Pacific Academy of Ophthalmology; ESCRS = European Society of Cataract and Refractive Surgeons; OICS = Ophthalmic Instrument Cleaning and Sterilization Task Force (North America)

### IFU: single use versus multiuse

The United States Food and Drug Administration (FDA) and the European Union (EU) Medical Device Regulation (MDR) require phacoemulsification machine manufacturers to validate the safety and efficacy of reusing a product before it can be labeled reusable in the manufacturer's IFU. Recommendations for using and processing a reusable product are included in the IFU. Unless the manufacturer validates a specific number of reuses in their regulatory submission, the product will be labelled "single use". <sup>18</sup> For the single-use label, neither the FDA nor MDR require evidence that reuse is dangerous, and the actual

<sup>\*</sup> use open bottles for >1 patient

risk of reuse may not have been studied. The manufacturer might be warning surgeons about known problems with reuse, or they may simply not have tested or chosen to undertake the time and expense to validate the safety of reuse of that product with regulatory authorities. Manufacturers might also prefer a single-use label to reduce product liability, to increase product sales, or to reduce regulatory hurdles to commercial approval. 15-17

Despite disincentives for manufacturers to validate reuse safety and the ambiguity of the single-use designation in IFUs, some regulatory agencies and hospitals have interpreted this to be a mandatory requirement. Regulatory enforcement during facility audits of this unproven assumption that reuse is dangerous effectively removes ophthalmologists' ability to practice off-label within their local practice setting. This produces the current regulatory stalemate in many countries contributing to needless waste. Surgeon surveys found worldwide consensus as to these causes (Table 3). 15-17

Table 3: Surgeon rating of factors driving cataract surgical waste/trash generation  (OICS, ESCRS, and APAO member survey results)					
OICS	High impact	Moderate impact	Little or no impact		
Hospital/facility policies limit surgeon discretion for reusing supplies	74% / 58% / 59%	21% / 36% / 34%	5% / 6% / 7%		
Regulatory agencies limit surgeon discretion for reusin supplies	82% / 65% / 66%	15% / 28% / 29%	3% / 7% / 5%		
Manufacturers mandate single use IFU to limit liability	70% / 67% / 71%	26% / 27% / 25%	4% / 6% / 4%		
Manufacturers drive the market towards more profitable single use products	77% / 74% / 72%	20% / 24% / 24%	3% / 1% / 4%		

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Titanium phacoemulsification tips exemplify the arbitrary way that single-use designation is applied to phaco products. There is little variation in the composition and design of phacoemulsification tips produced by a variety of manufacturers, yet some are labeled single use while others can be reused. 18-20 Some manufacturers offer the same phacoemulsification tip as either a single-use or reusable product by changing the model number. Independent studies at the Moran Eye Center found no morphologic or ultrastructural damage to single-use phacoemulsification tips exposed to multiple autoclave sterilization cycles or to multiple simulated uses in a porcine cataract surgery model. 19,20 Based on these studies, the multisociety 2018 OICS guidelines for the cleaning and sterilization of intraocular surgical instruments stated that cataract surgeons should be allowed discretion to reuse phacoemulsification tips off-label based on their clinical observations and judgment. 21

# Off-label reuse of phacoemulsification tubing and cassettes

Off-label use of drugs and devices is common clinical practice and is based on medical judgment and evidence. To reduce cost and waste, surgeons in many countries reuse single-use phacoemulsification

tubing/cassettes on multiple patients, often for the entire OR day. Estimates of the prevalence of this practice were lacking until the recent APAO survey in which 41% of respondents said that they were currently reusing phacoemulsification tubing/cassettes (Table 2).<sup>17</sup>

Published data on off-label phacoemulsification cassette/tubing reuse is available from the Aravind Eye Care System (AECS) in southern India, which performs approximately 450,000 cataract surgeries a year in its network of 15 surgical facilities.<sup>22-24</sup> AECS maximizes productivity and efficiency by standardizing cataract surgical protocols for all surgeons and facilities, including using the same phacoemulsification machines, instruments, supplies, perioperative drugs, and processing procedures.

AECS's protocol for phacoemulsification is to leave the same cassette in place for multiple consecutive surgeries throughout the OR day. <sup>23,24</sup> A single phacoemulsification handpiece and tubing set are also reused continuously without reprocessing or autoclaving throughout the day. A hole is cut into the aspiration fluid collection bag allowing it to drain into a larger waste receptacle. Only the phacoemulsification tip and sleeve are exchanged following each case because of direct contact with the eye. The same irrigating solution bag is used for multiple cases and is only changed when nearly empty. The cassette and tubing set are discarded at the end of the surgical day, after having been used for 20 to 25 cases. Several different phacoemulsification machines are used at AECS, but the most common model is widely sold in the U.S. and Europe. <sup>24</sup>

Using this protocol, AECS in 2019 reported their endophthalmitis rate to be 0.01% for 335,000 consecutive phacoemulsification cases. More recent data from AECS shows an endophthalmitis rate of 0.01% in 1,133,959 consecutive phacoemulsification procedures performed during the 9 year period between 2016 and 2024. All cases were performed with this off-label protocol of reusing a single-use phacoemulsification tubing/cassette continuously all day. This is lower than the 0.06% endophthalmitis rate reported from the AAO Intelligent Research in Sight (IRIS) Registry during an overlapping 10-year period (2013-2023) in 9.7 million consecutive cataract surgeries. One important distinction is that AECS uses intracameral moxifloxacin in all cataract surgeries, whereas this would not have been true of many IRIS Registry surgical facilities during the study period. However, because of universal regulations requiring U.S. facilities to follow the manufacturer's IFU, virtually all IRIS Registry procedures would have been performed with single-use phacoemulsification tubing/cassettes and irrigation bottles or bags. A recent review of registry publications in ophthalmology highlighted the value of these retrospective studies, such as from the AECS and IRIS registries, in analyzing rare events such as POE.

AECS investigators published a microbiology study in which they cultured the tubing and phacoemulsification handpieces that were continuously reused without resterilization on multiple eyes throughout the OR day.<sup>23</sup> They reported no growth in 370 cultures. They also cultured residual irrigation fluid from bags that had been continuously used on several patients until nearly empty; they again found no positive cultures among the 185 taken. Reusing irrigation bags and the same phacoemulsification cassette and tubing set all day without reprocessing or sterilizing was not associated with positive bacterial cultures or a higher endophthalmitis rate compared with published rates from facilities that adhered to the single-use IFU for their phacoemulsification supplies.<sup>22-25</sup> This is consistent with phacoemulsification being a clean procedure that does not aerosolize microbes or soil the surgical field and instruments with contaminated body fluids and tissue. The low risk of microbial cross-contamination from phacoemulsification was also supported by in vitro and clinical studies undertaken during the COVID-19 pandemic.<sup>27-33</sup> Considering surgeon survey data and these clinical and microbiological studies, we found no evidence that reuse of single-use phacoemulsification tubing/cassettes increases the rate of endophthalmitis or other adverse events.

## Phacoemulsification machines with approved multiuse tubing/cassettes

Several phacoemulsification machine manufacturers in the EU currently provide an IFU-validated option of multiuse phacoemulsification tubing and cassettes (Table 4). In the U.S., multiple phacoemulsification machines offered the option of reusable, autoclavable tubing in the past. However, at present only J&J Vision sells a machine (Compact Intuitive) with the option of autoclavable multiuse phacoemulsification cassettes and tubing.<sup>34</sup> This reusable option is approved for up to 20 cases. After each case, the tubing/cassette apparatus is removed, flushed, air dried, and autoclaved using a short, unwrapped sterilizer cycle, after which it can be immediately reused. Terminal sterilization with a full wrapped cycle is performed prior to overnight storage.

A life-cycle analysis (LCA) was performed for single-use and multiuse phacoemulsification tubing/cassette options offered for the Compact Intuitive machine.<sup>34</sup> The carbon footprint of 1000 single-use cassettes with packaging was 725 kg CO2eq, equivalent to driving a car 2840 km (1764 miles). This would generate 239 kg (527 lbs) of waste, 85% of which is plastic. Because the weight and materials of the autoclavable and single-use supplies are nearly identical, the emissions and plastic/packaging waste would be reduced 20-fold with the reusable tubing/cassette approach.

In the EU and other countries, several phacoemulsification platforms offer the option of a "day" cassette that is used for multiple consecutive patients without being removed, cleaned, or autoclaved between cases (Table 4). In addition to reducing plastic waste, these systems reduce OR turnover time and consumption of irrigation fluid needed to reprime the phacoemulsification cassette. Compared with autoclavable multiuse products, additional staff time is not needed to process and resterilize the day cassette. Machines with the option of a day cassette approved for multiple consecutive cases in 1 day include the Rayner Sophi machine (10 cases), Oertli CataRhex 3 (6 cases), and Zeiss/DORC EVA NEXUS (20 cases). The maximum number of cases is not specified with 2 other day cassette options (Geuder Megatron S4 HPS and Ruck Qube Pro). Instead, these platforms limit the consecutive number of hours that the day cassette can be used (6 hours for the Geuder machine, and 16 hours for the Ruck machine). With most of these day cassette options the infusion fluid container and infusion tubing remain connected to the indwelling phaco cassette without needing to be changed until the container is nearly empty. At the conclusion of 1 case, only the I/A tubing connecting the phacoemulsification handpiece to the cassette is discarded and replaced. Comparing the Sophi day cassette with the use of 10 disposable tubing/cassettes with the J&J Signature machine, the Sophi system reduced plastic waste by 75% and cost by 17% for every 10 operations. 35 The authors estimated 307 kg less plastic would be discarded per 1000 cataract surgeries using this system.

All day cassette options in Table 4 are available in the EU, but the largest phacoemulsification manufacturers that account of the majority of global market share do not offer this option. Although none are currently available in the U.S., several manufacturers plan to seek FDA approval of their day cassette option. These manufacturers confirmed an excellent safety record with these approved multiuse or day cassette products (personal communication). Because they reduce both waste and supply costs per case, we encourage ophthalmologists and facilities to consider multiuse and day cassettes if they are an available option.

Table 4: Phacoemulsification machines with approved multi-use tubing/cassette options in US or EU \*

Manufacturer/Model	Autoclavable tubing/cassette?	Day cassette?	# countries w/multiuse option	Available in US (FDA)?	Available in EU (CE)?
J&J Compact Intuitive	20 cases	NA	18	yes	no
Oertli CataRhex 3/Faros	6 cases	6 cases	21	no	yes
Rayner Sophi	NA	10 cases	60+	no	yes
Zeiss/DORC EVA NEXUS	NA	20 cases	50+	no	yes
Geuder Megatron S4 HPS	NA	max 6 hours	65	no	yes
Ruck Qube Pro	NA	max 16 hours	45	no	yes

<sup>\*</sup>This table may not include phaco machines with multiuse options that are not available in EU

# Addressing an unmet need

Based on reported clinical experience, safety, and outcomes with reusable phacoemulsification tubing/cassettes, there is a compelling need for all phacoemulsification machine manufacturers to offer this option. This need has been consistently highlighted in global surveys of cataract surgeons. <sup>15-17</sup> In terms of research and innovation, there would be advantages to a day phacoemulsification cassette that can be left in the machine for the entire day's caseload. In addition to improving OR efficiency, this would significantly reduce the per case costs of manufacturing the product, the facility shelf space to store the product, and the significant carbon emissions and non-recyclable plastic waste from this very high-volume procedure. Implementing innovations such as these worldwide would make cataract surgery more financially and environmentally sustainable without compromising patient safety. It is helpful to consider the impact of moving to multiuse phacoemulsification tubing/cassettes from the perspective of different stakeholders.

### Manufacturers

We are encouraged by discussions with phacoemulsification machine manufacturers that these design goals are achievable from an engineering perspective. Reusable phacoemulsification tubing/cassettes would reduce raw material, manufacturing, packaging, and shipping costs compared to producing single-use products for the equivalent number of cases. This could also reduce the risk of supply chain shortages and ordering or shipping delays.

In a few major markets, such as the U.S., phacoemulsification tubing/cassettes are discarded after every case because approved day cassettes are not available. As mentioned, one machine platform with negligible market share currently offers the option of an approved autoclavable tubing/cassette pack in the U.S. Their example might illustrate how a manufacturer could maintain reasonable margins in the U.S. market, while lowering the facility's costs for these products.<sup>34</sup>

## **Surgical facilities**

Passing some of the manufacturing savings to the purchasing facility would lower their supply costs per case. Reduced shipments and inventory of tubing/cassette packs would free up storage space and staff time spent tracking, unpacking, and handling supply deliveries. A day cassette would improve OR efficiency and turnover time by eliminating the need to exchange a new cassette and irrigation container after each case, decreasing the cassette priming time, and reducing nursing time spent unwrapping and later disposing of single-use phacoemulsification cassettes.<sup>35</sup> It would also reduce the waste of discarding an irrigation fluid bag and tubing for every case and avoid the need to reprocess an autoclavable

tubing/cassette between cases. Some facilities might still prefer the option of single-use products due to local issues, but multinational surveys suggest a strong uptake of multiuse options. <sup>15-17</sup>

# Patient safety and regulatory oversight

Reusing single-use phacoemulsification tubing/cassettes is already practiced off-label in many countries without any documented evidence of increased complications.<sup>17</sup> What exits the eye via the closed phacoemulsification fluidic system is sterile aqueous, lens material, ophthalmic viscosurgical device, irrigation fluid, and sterile solutions such as lidocaine. In addition to the clinical experience of these facilities, the safety of reuse is supported by published studies that did not show any increase in potential microbial cross-contamination or infection rate from reusing a leading manufacturer's phacoemulsification tubing/cassettes off-label.<sup>22-24</sup>

Formal regulatory validation of multiuse protocols through agencies such as the FDA or MDR would markedly increase confidence in safety and surgical performance. Because every phacoemulsification machine manufacturer already offers single-use tubing/cassette packs, this can remain an option for those ophthalmologists who maintain this preference. Considering surgeon survey data calling for reusable options, published evidence from facilities already reusing phacoemulsification tubing/cassettes, and the public health mandate to reduce needless waste from cataract surgery, we urge regulatory agencies to facilitate and expedite the approval process for multiuse phacoemulsification tubing/cassettes and other products such as tips and sleeves.

## **Environmental impact and public health**

Based on high surgical volumes of cataract surgery, decreasing unnecessary phacoemulsification machine supply waste would significantly reduce the carbon footprint of cataract surgery and the generation of plastic and packaging waste.<sup>2-4</sup> The plastic in irrigation bags and phacoemulsification tubing/cassettes is non-recyclable and ends up in landfill or incinerators. Compared with single-use cassettes, reusing a day cassette for 20 cases would reduce cassette and associated packaging waste by a factor of 20.<sup>34</sup> LCA studies project that the reduction of carbon emissions and waste associated with manufacturing, packaging, shipping, and disposing of single-use phacoemulsification machine products would be enormous on a global scale.<sup>34,35</sup>

### Conclusion

The global volume of cataract surgery – already approaching 30 million cases annually – is projected to climb much higher as the world population increases and ages. Ophthalmology has an obligation to safeguard the sustainability of its essential services. Unnecessary resource consumption and waste incur significant financial and environmental costs. Current mandates and manufacturer IFUs for single use of phacoemulsification machine supplies contribute to unnecessary waste. These practices have evolved from liability concerns over hypothetical risks. Single use of phacoemulsification supplies became the industry default in many countries partly because of stringent regulations requiring manufacturers to pursue costly studies to prove the safety of reuse. <sup>18</sup> Despite this barrier, there are several approved multiuse options commercially available outside the US.

Non-degradable microplastic waste, chemicals used to soften medical device plastics, and carbon emissions from the manufacture, use, and disposal of surgical supplies pose threats to the environment and to public health.<sup>2-14</sup> Considering the low risk of bacterial cross-contamination from cataract surgery, ophthalmologists and surgical facilities can significantly reduce carbon emissions and non-recyclable

plastic waste by adopting multiuse phacoemulsification machine supplies. <sup>18,23,34,35</sup> Such strategies can potentially reduce supply expenditure without financially penalizing manufacturers. Surgeons in many countries are routinely reusing single-use phacoemulsification cassettes off-label and there is supporting evidence that this can be done safely. <sup>17,23,24</sup>

### **Recommendations:**

- The entire phacoemulsification machine industry should prioritize innovation and development of safe multiuse cassettes, tubing and other phacoemulsification machine supplies.
- Because the U.S. is one of the largest global markets without commercially available
  phacoemulsification day cassette options, we urge the FDA, along with all global regulatory
  agencies, to develop a process to affirm the safety of reuse of phacoemulsification cassettes
  and other supplies, and to facilitate and expedite review of multiuse products when submitted
  by industry for regulatory approval.
- Surgeons and their surgical facilities should strongly consider adopting waste and costreducing multiuse phacoemulsification supply options when they are available.

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This position paper has been endorsed by ASCRS, ESCRS, APACRS, LATAMSCRS, and EyeSustain. The latter is a coalition of more than 50 global eye societies committed to advancing sustainability through education, innovation, research, and advocacy.

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