Surgical Design

has transformed the

FUTURE OF PHACO and it's DISPOSABLE

The first **DISPOSABLE Handpiece** that performs **BOTH Phaco** and **I/A**

Surgical Design's new disposable handpiece combining phaco and I/A in one instrument is the most important innovation since the original Anton Banko and Charles Kelman phacoemulsification invention in 1967.

– E. MIKE RAPHTIS, MD

The design features of the disposable combined phaco and I/A handpiece are light years ahead of any competition.

– TOBIAS NEUHANN, MD

Surgical Design

Contents

Executive Summary

The Opportunity

Over the last several years, Surgical Design has focused on developing and patenting new low-cost disposable ultrasonic handpieces that combine phacoemulsification and I/A functionalities into one handpiece, and have significant advantages over today's reusable handpieces. This technology has the potential to completely transform cataract surgery worldwide.

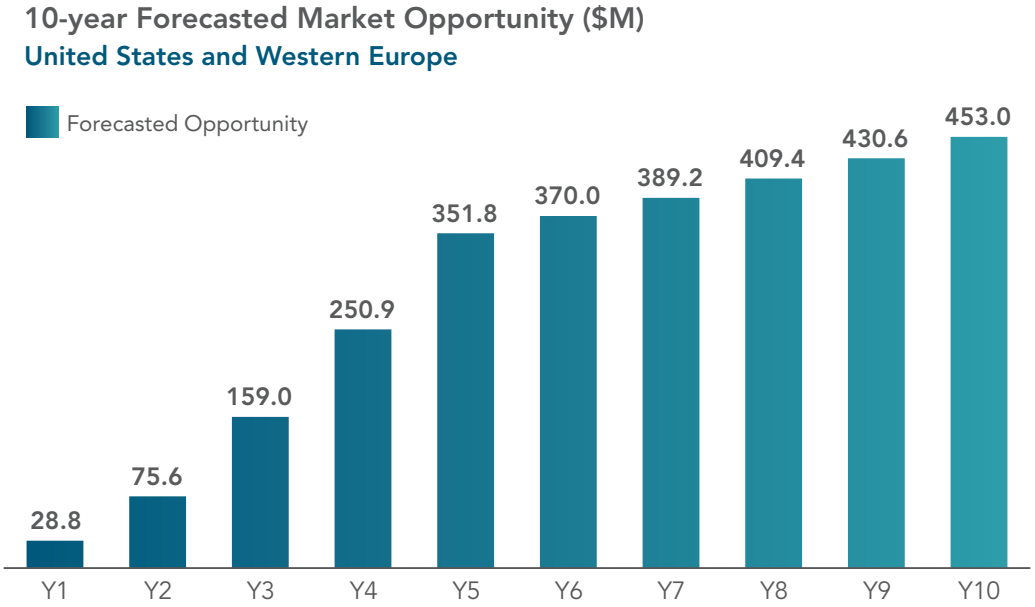
We will describe these advantages in this presentation, supported by a cataract surgeon survey conducted by **Market Scope**. The financial benefit of converting the market from reusable to disposable handpieces is substantial as we will demonstrate in this presentation.

We have successfully tested prototypes of the handpieces and are now actively seeking to license our patents and patent applications to a leading ophthalmic company that will bring these significant innovations to the world market.

Source: 2022 Market Scope Global Cataract Equipment Report

Disposable Phaco Handpiece Global Market Potential Overview

- **ULTRASONIC PHACO (USP) GLOBAL MARKET:** $1.33B in 2022 growing to $1.76B by 2027, a CAGR of 6%.
- **USP PROCEDURES:** 19.5 million procedures in 2022, growing to 27.2 million by 2027.
- **ULTRASONIC HANDPIECES:** Today reusable USP handpieces are used in every USP cataract procedure. The installed base approximates 250,000 handpieces globally.
- **REUSABLE ULTRASONIC HANDPIECE DISADVANTAGES:** Cost of disassembly, cleaning, sterilization and inventory management. Performance denigrates with time. (Refer to survey for other disadvantages.)
- **USP PACKS:** Contain nearly all the surgical devices needed for USP **except** the ultrasonic handpiece. (15.6 million USP packs sold in 2022 with revenue of $660M.)
- **SURGICAL DESIGN USP HANDPIECE:** Also combines a disposable irrigation/aspiration handpiece which typically costs $25 for a disposable version.
- **TEN YEAR FORECASTED MARKET OPPORTUNITY ($M):** Is based on the results of the Market Scope Survey indicating that USA phaco surgeons would use the new handpiece an average of 72.7% and Western Europe surgeons would use the handpiece an average of 76.7% , at an estimated cost of USD 35 for the handpiece.



The Future of Cataract Surgery

Introduction

A positive patient outcome and cost effectiveness have been the driving forces for all the innovation of phacoemulsification surgical systems from the very beginning.

The future of cataract surgery is best described by **Dr. Richard L. Lindstrom** as quoted below from the editorial "Future of cataract surgery seems promising" printed in the *Ocular Surgery News*, Feb. 10, 2021 Issue. Emphasis added.

"Cataract surgery is a modern-day miracle. Since 1995, more than 500 million cataract procedures have been performed worldwide, and about 130 million living people are benefiting from this miracle procedure today. At present, approximately 4 million cataract procedures are performed every year in the U.S. and nearly 28 million worldwide. **About 60,000 cataract procedures are performed every day globally.**

"The aging of our population and increased life expectancy project a compound annual growth rate of 3% to 4% per year for cataract surgery in the next 30+ years. That means that in 24 years or less, we will be performing 8 million cataract surgeries a year in the U.S. and more than 60 million in the world. If the 8 to 11 cataract procedures a year per 1,000 population done in the advanced countries is the correct number, and resources allow it, **volume could approach 100 million procedures a year by 2050.**

"The vast majority of cataract will be removed in an ASC or **office-based surgery suite** using a cataract workstation that integrates phacoemulsification, phaco aspiration and FLACS.

"The past and future of ophthalmology are closely tied to cataract surgery, and my vision of the future for this field is bright indeed."

The Next Steps

Engineering advances will continue and result in even safer surgical procedures.

Surgical Design has tested and patented significant improvements to the current phacoemulsification technology, including the following:

PHACO AND I/A HANDPIECE. The combination of phaco and I/A functions in one work tip allows alternating between removal of cataract and cortical material with a single instrument. In essence, we have combined the functions of three separate instruments: the phaco handpiece, the I/A handpiece, and the ultrasonic I/A handpiece.

DISPOSABLE. Patented design features that result in a significantly lower cost will enable the phaco-I/A handpiece to be sold as disposable – a first in the cataract surgery market. The elimination of meticulous cleaning, sterilization and administrative costs will result in the perfect surgical platform for OFFICE BASED SURGERY.

SIGNIFICANT INCREASE IN ULTRASOUND EFFICIENCY. Eliminating the thread between the work tip and connecting body, and replacing the hollow phaco tube with a blade, results in a substantial increase in ultrasound efficiency.

AUTOMATED CONTROL OF ULTRASOUND, VACUUM, AND FLOW. The surgeon's skills are enhanced by automated control of all major fluid and ultrasound parameters.

ELIMINATION OF POST-OCCLUSION SURGES. We have eliminated a major complication of cataract surgery. With our handpiece design, it is impossible to grab the posterior capsule because of a suction surge after the release of the occlusion.

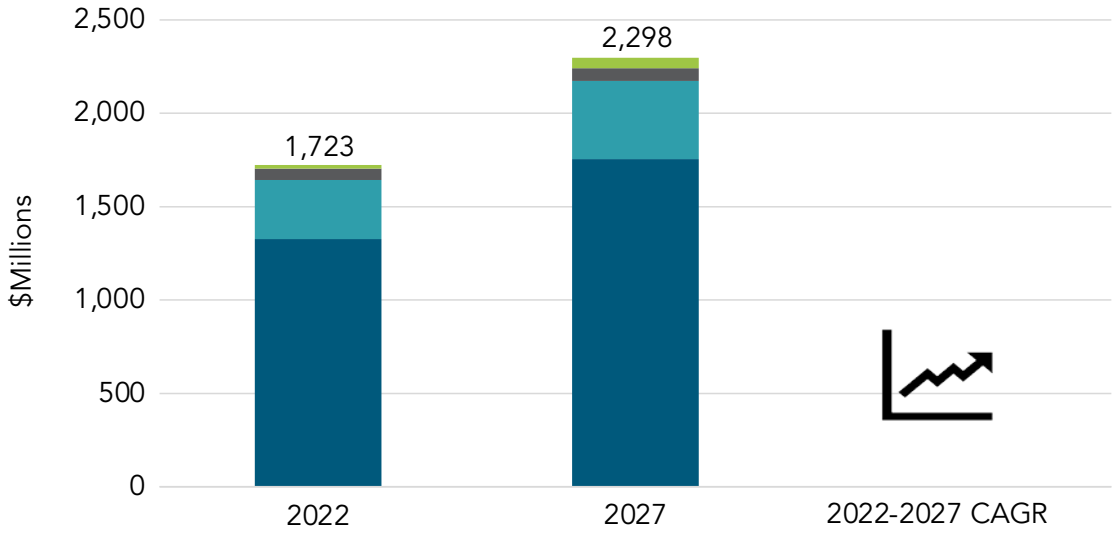
REDUCTION OF COSTS AND WASTE IN MAINTAINING A STERILE SURGICAL FIELD. By rethinking how to maintain a sterile field during surgery, Surgical Design has applied for a patent that eliminates the need for most sterile robes and drapes, as well as masks and caps – another ideal benefit for OFFICE BASED SURGERY and the operating room in an ASC.

2022 Market Scope

Global Cataract Equipment Report

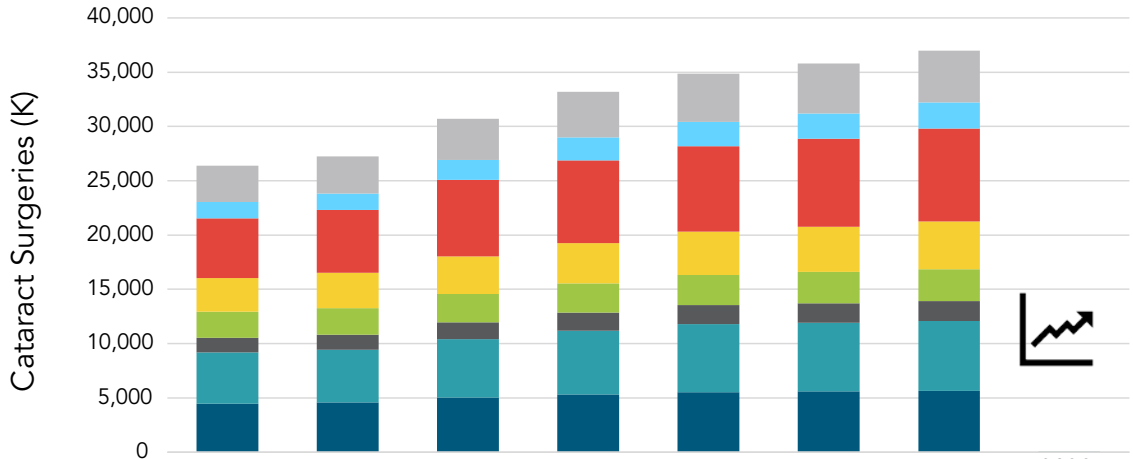
The Global Cataract Equipment Market

- **USP MARKET:** $1.33B in 2022, $1.76B by 2027
- **ANNUAL GROWTH:** Nearly 6% Annual Projected



	2022	2027	2022-2027 CAGR
ACCD	20	56	23.3%
Nd:YAG	60	67	2.2%
FLACS	317	419	5.7%
Phaco Systems, Packs	1,326	1,755	5.8%

Cataract Surgery is the Main USP Products Driver



	2021	2022	2023	2024	2025	2026	2027	2022 - 2027 CAGR
Rest of World	3,351	3,420	3,792	4,160	4,428	4,598	4,773	6.9%
Latin America	1,487	1,529	1,803	2,127	2,233	2,324	2,418	9.6%
India	5,517	5,793	7,068	7,612	7,863	8,099	8,545	8.1%
China	3,095	3,250	3,477	3,721	3,981	4,180	4,389	6.2%
Other Wealthy Nations	2,417	2,446	2,578	2,691	2,791	2,864	2,939	3.7%
Japan	1,328	1,395	1,548	1,672	1,756	1,791	1,827	5.5%
Western Europe	4,746	4,829	5,403	5,868	6,255	6,348	6,443	5.9%
United States	4,455	4,589	5,025	5,327	5,540	5,595	5,651	4.3%

Source: 2022 Market Scope Global Cataract Equipment Report

Cataract/RLE Surgeries Performed by Ultrasonic Phaco Machine

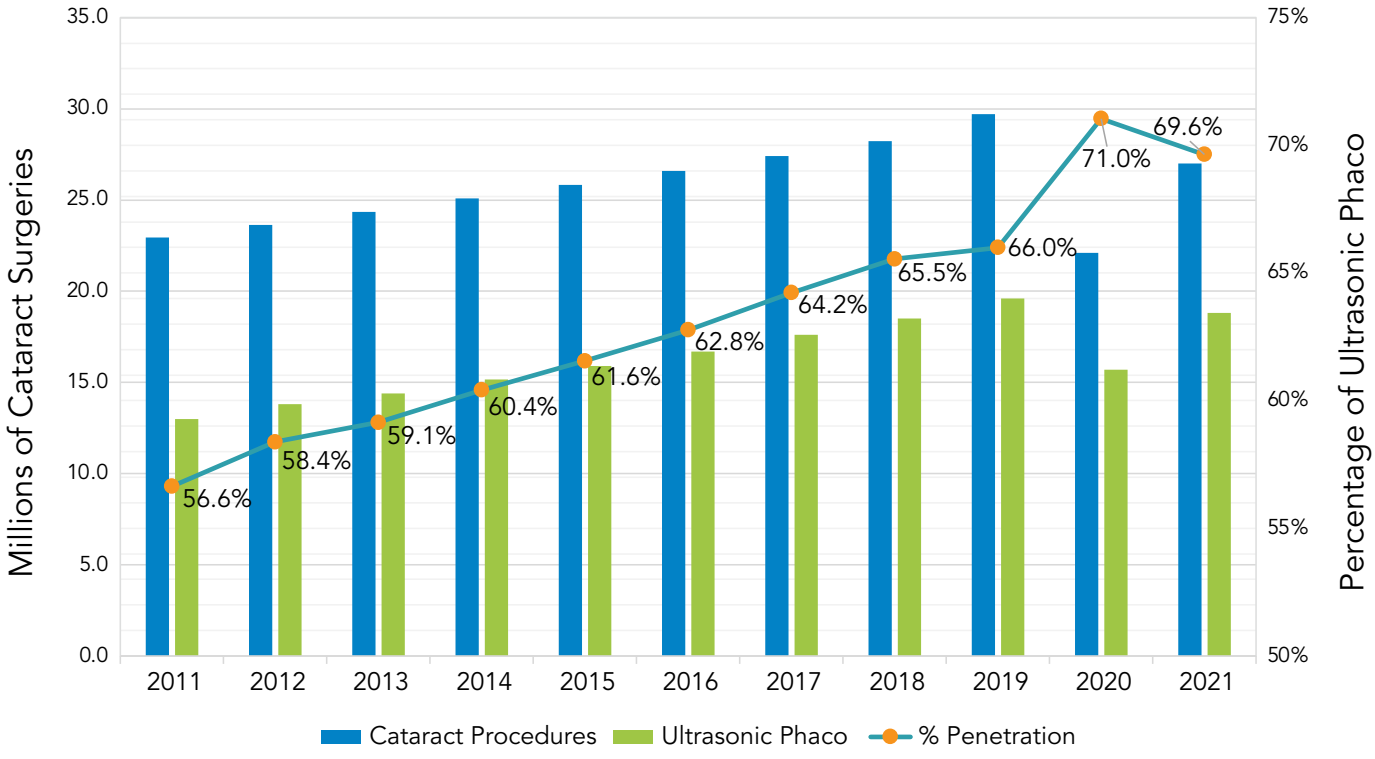
- **TARGET MARKET** – 70% of cataract surgery today is performed with USP or USP/FLACS
- **2022 MARKET SIZE** – In 2022 the number of cataract procedures with USP is 19.5M
- **2027 MARKET SIZE** – 27.2 million USP procedures

Region	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States	4,577	4,715	5,158	5,466	5,685	5,746	5,808	4.3%
Western Europe	4,928	5,017	5,599	6,072	6,467	6,567	6,668	5.9%
Japan	1,359	1,428	1,586	1,713	1,800	1,836	1,873	5.6%
Other Wealthy Nations	2,504	2,535	2,671	2,787	2,891	2,968	3,047	3.7%
China	3,130	3,287	3,518	3,765	4,029	4,232	4,445	6.2%
India	5,581	5,860	7,143	7,692	7,947	8,186	8,636	8.1%
Latin America	1,535	1,579	1,856	2,184	2,293	2,386	2,483	9.5%
Rest of World	3,381	3,452	3,826	4,196	4,466	4,637	4,813	6.9%
Worldwide	26,995	27,874	31,357	33,875	35,578	36,559	37,774	6.3%
USP Procedures	17,914	18,600	20,987	22,935	24,273	25,012	25,889	6.8%
FLACS + USP	874	914	974	1,043	1,121	1,205	1,304	7.4%
ECCE & Other	8,207	8,360	9,396	9,897	10,184	10,342	10,581	4.8%

Source: 2022 Market Scope Global Cataract Equipment Report

Historical Growth in Phaco Cataract Surgery Penetration

2022 USP PENETRATION – The global penetration of ultrasonic phaco is now nearly 70% of cataract procedures, up from 56.4% a decade ago



Source: 2022 Market Scope Global Cataract Equipment Report

The Phaco Machine Market is Growing

- **2022** – Just over 7,000 USP machines sold, with revenue of $342 million
- **2027** – Nearly 9,000 machines and $425M
- **MACHINES** – Are an important driver but nearly 2.7 times the revenue comes from consumables (phaco packs, tips, US handpieces, IA handpieces, tips, sleeves, etc.)
- **LARGE PHACO INSTALLED BASE** – Consumables sales are determined mainly by a company's installed USP machine base

Phaco Machine All Levels	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Units	1,136	1,217	1,267	1,314	1,365	1,416	1,469	**3.8%**
ASP $	58,745	59,258	59,555	59,933	60,229	60,598	60,966	**0.6%**
Dollars ($M)	66.7	72.1	75.5	78.8	82.2	85.8	89.6	**4.4%**
Western Europe								
Units	1,302	1,344	1,393	1,441	1,491	1,539	1,589	**3.4%**
ASP $	49,495	50,124	50,341	50,694	50,999	51,315	51,544	**0.6%**
Dollars ($M)	64.4	67.4	70.1	73.0	76.0	79.0	81.9	**4.0%**
Worldwide Total								
Units	6,795	7,117	7,407	7,692	7,993	8,313	8,650	**4.0%**
ASP $	47,616	48,061	48,269	48,513	48,758	48,961	49,160	**0.5%**
Dollars ($M)	323.6	342.0	357.5	373.2	389.7	407.0	425.2	**4.5%**

Source: 2022 Market Scope Global Cataract Equipment Report

USP Machine Packs are the largest Rev. Generator

- **DISPOSABLE PACKS** – Represent the largest revenue category – $660M in 2022, growing to $913M by 2027
- **SURGICAL DESIGN TARGET MARKET** – This category is the target market and should be the focus of market penetration forecasting

Disposable Packs	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Units	4,456,649	4,599,576	5,046,389	5,362,884	5,582,901	5,642,782	5,703,445	**4.4%**
ASP $	44	44	44	44	45	45	45	**0.5%**
Dollars ($M)	194.9	202.1	222.9	238.1	249.1	253.1	257.1	**4.9%**
Western Europe								
Units	4,704,944	4,795,472	5,355,370	5,810,961	6,193,945	6,294,161	6,396,270	**5.9%**
ASP $	41	42	42	42	42	42	43	**0.5%**
Dollars ($M)	194.6	199.2	223.5	243.6	261.1	266.6	272.4	**6.5%**
Worldwide Total								
Units	15,018,731	15,560,537	17,359,711	18,854,234	19,996,850	20,588,326	21,225,258	**6.4%**
ASP $	42	42	43	43	43	43	43	**0.3%**
Dollars ($M)	633.9	660.2	737.9	803.4	855.3	883.2	912.5	**6.7%**

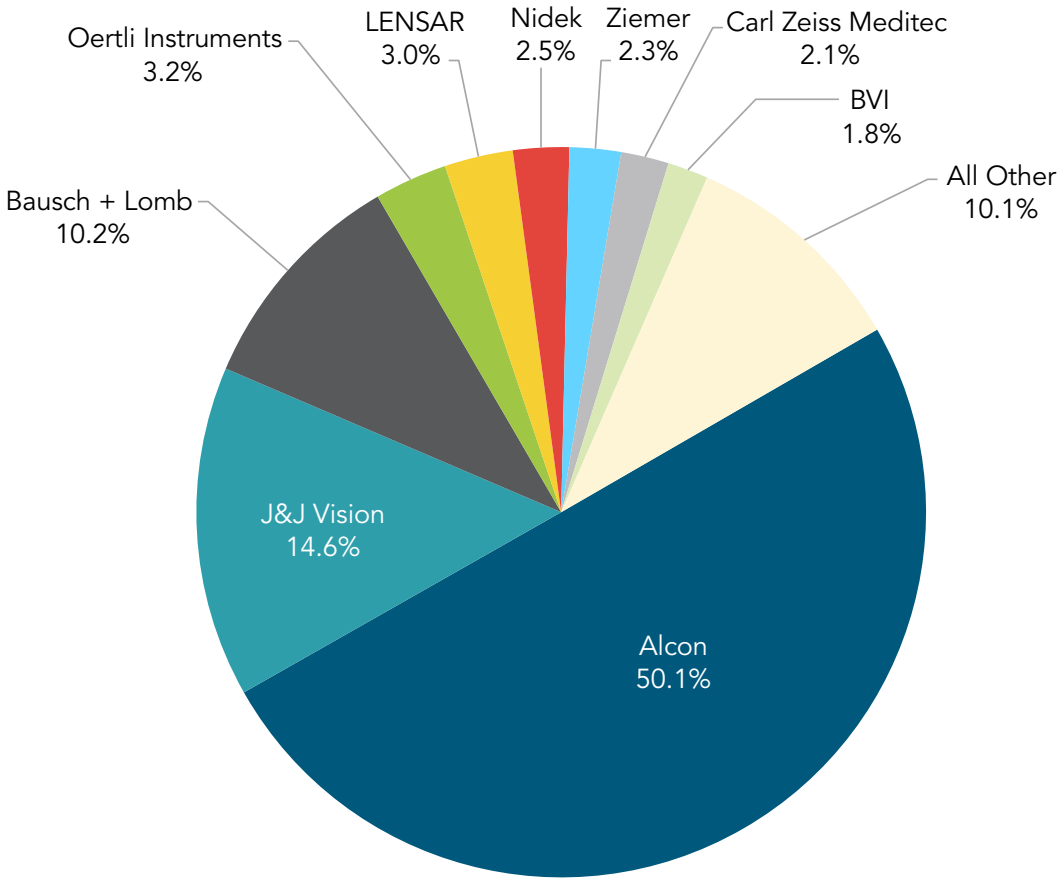
Source: 2022 Market Scope Global Cataract Equipment Report

Individual USP Accessories that are usually not part of Machine Packs

Region	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Ultrasonic Handpieces	20.9	21.3	21.8	22.3	22.8	23.3	23.9	**2.4%**
Ultrasonic Tips	19.6	20.4	21.2	22.2	22.8	23.4	24.0	**3.3%**
USP I/A Reusable	6.8	6.9	7.1	7.3	7.4	7.6	7.8	**2.4%**
USP I/A Disposable	26.5	28.3	30.4	32.7	34.1	34.9	35.8	**4.8%**
Total (M)	**73.7**	**76.9**	**80.5**	**84.5**	**87.1**	**89.2**	**91.4**	**3.5%**
Western Europe								
Ultrasonic Handpieces	19.5	20.1	20.7	21.3	21.9	22.5	23.1	**2.9%**
Ultrasonic Tips	17.3	18.1	19.0	20.0	20.5	21.1	21.7	**3.7%**
USP I/A Reusable	6.0	6.2	6.3	6.5	6.7	6.9	7.1	**2.8%**
USP I/A Disposable	16.7	18.0	19.5	21.1	21.7	22.3	22.9	**4.9%**
Total (M)	**59.5**	**62.4**	**65.5**	**68.9**	**70.8**	**72.7**	**74.7**	**3.7%**
World Total								
Ultrasonic Handpieces	73.1	76.5	80.2	84.1	87.8	91.7	95.3	**4.5%**
Ultrasonic Tips	62.8	66.4	70.4	74.6	77.6	80.2	83.0	**4.6%**
USP I/A Reusable	23.1	24.0	25.0	26.0	27.0	28.0	29.0	**3.9%**
USP I/A Disposable	53.1	57.3	62.0	67.1	69.7	71.7	73.8	**5.2%**
Total (M)	**212.0**	**224.2**	**237.6**	**251.8**	**262.1**	**271.6**	**281.2**	**4.6%**

Source: 2022 Market Scope Global Cataract Equipment Report

Leading Market Competitors by 2022 Global Revenue Share



Source: 2022 Market Scope Global Cataract Equipment Report

Company Installed USP Machine Base Drive Consumables Business

USP INSTALLED BASE – A large installed base is key to large consumable revenues

Phaco Installed Base	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Installed Base	10,652	10,804	10,991	11,206	11,450	11,722	12,018	**4.0%**
USP Sales	1,136	1,217	1,267	1,314	1,365	1,416	1,469	**3.4%**
Surgeries per USP	418	425	457	475	484	477	470	**0.9%**
Western Europe								
Installed Base	10,947	11,195	11,468	11,762	12,077	12,408	12,755	**3.8%**
USP Sales	1,302	1,344	1,393	1,441	1,491	1,539	1,589	**3.1%**
Surgeries per USP	434	431	471	499	518	512	505	**1.9%**
World Total								
Installed Base	49,173	51,186	53,468	55,743	58,099	60,547	63,072	**4.1%**
USP Sales	6,795	7,117	7,407	7,692	7,993	8,313	8,650	**4.3%**
Surgeries per USP	382	381	411	430	437	433	431	**3.8%**

Source: 2022 Market Scope Global Cataract Equipment Report

Forecast for Ultrasonic Replacement Handpieces

Ultrasonic Handpieces	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Units	7,456.0	7,563.0	7,694.0	7,844.0	8,015.0	8,205.0	8,413.0	**2.2%**
ASP $	2,799.4	2,813.4	2,827.5	2,841.7	2,841.7	2,841.7	2,841.7	**0.2%**
Dollars ($M)	20.9	21.3	21.8	22.3	22.8	23.3	23.9	**2.4%**
Western Europe								
Units	7,115	7,277	7,454	7,648	7,850	8,066	8,292	**2.6%**
ASP $	2,747	2,760	2,774	2,788	2,788	2,788	2,788	**0.2%**
Dollars ($M)	19.5	20.1	20.7	21.3	21.9	22.5	23.1	**2.9%**
Worldwide Total								
Units	26,650	27,783	29,033	30,329	31,701	33,135	34,479	**4.4%**
ASP $	2,741	2,752	2,762	2,771	2,770	2,766	2,764	**0.1%**
Dollars ($M)	73.1	76.5	80.2	84.1	87.8	91.7	95.3	**4.5%**

Source: 2022 Market Scope Global Cataract Equipment Report

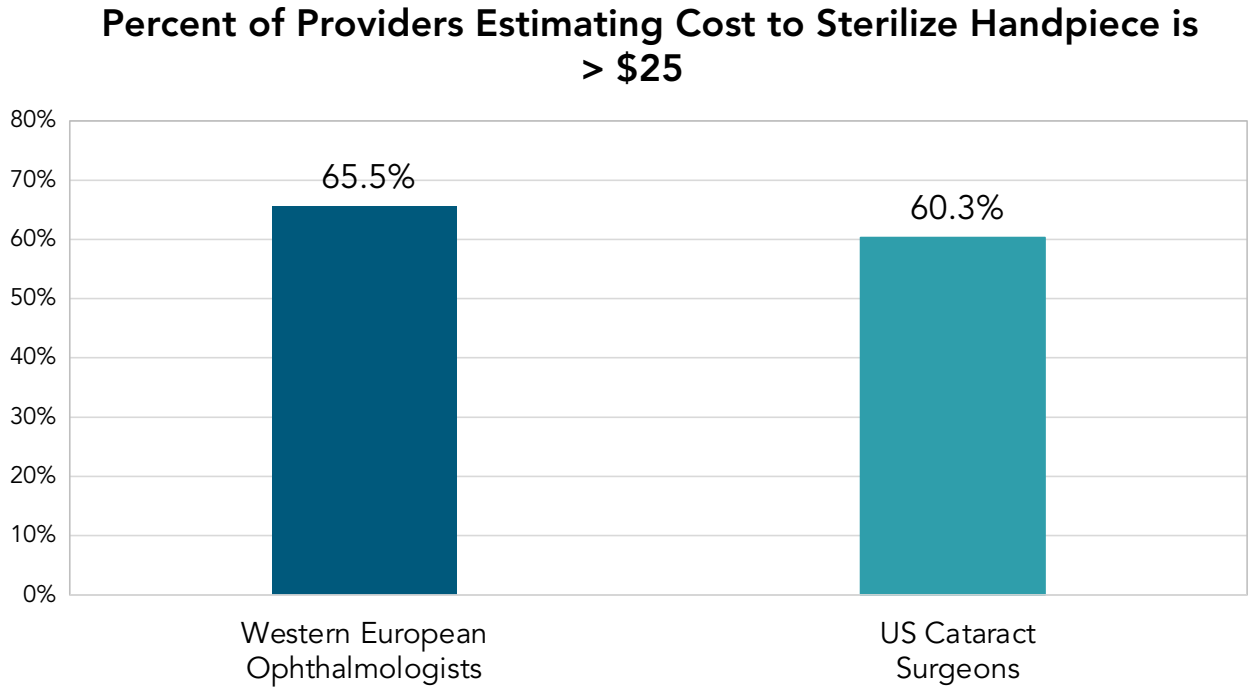
Forecast for Reusable I/A Handpieces

USP I/A Reusable	2021	2022	2023	2024	2025	2026	2027	2022-2027 CAGR
United States								
Units	18,108	18,367	18,685	19,050	19,465	19,927	20,431	**2.2%**
ASP $	375	377	379	381	381	381	381	**0.2%**
Dollars ($M)	6.8	6.9	7.1	7.3	7.4	7.6	7.8	**2.4%**
Western Europe								
Units	16,424	16,796	17,205	17,646	18,121	18,616	19,137	**2.6%**
ASP $	364	366	368	370	370	370	370	**0.2%**
Dollars ($M)	6.0	6.2	6.3	6.5	6.7	6.9	7.1	**2.8%**
Worldwide Total								
Units	61,790	63,932	66,314	68,742	71,276	73,923	76,660	**3.7%**
ASP $	373	375	377	379	379	379	379	**0.2%**
Dollars ($M)	23.1	24.0	25.0	26.0	27.0	28.0	29.0	**3.9%**

Source: 2022 Market Scope Global Cataract Equipment Report

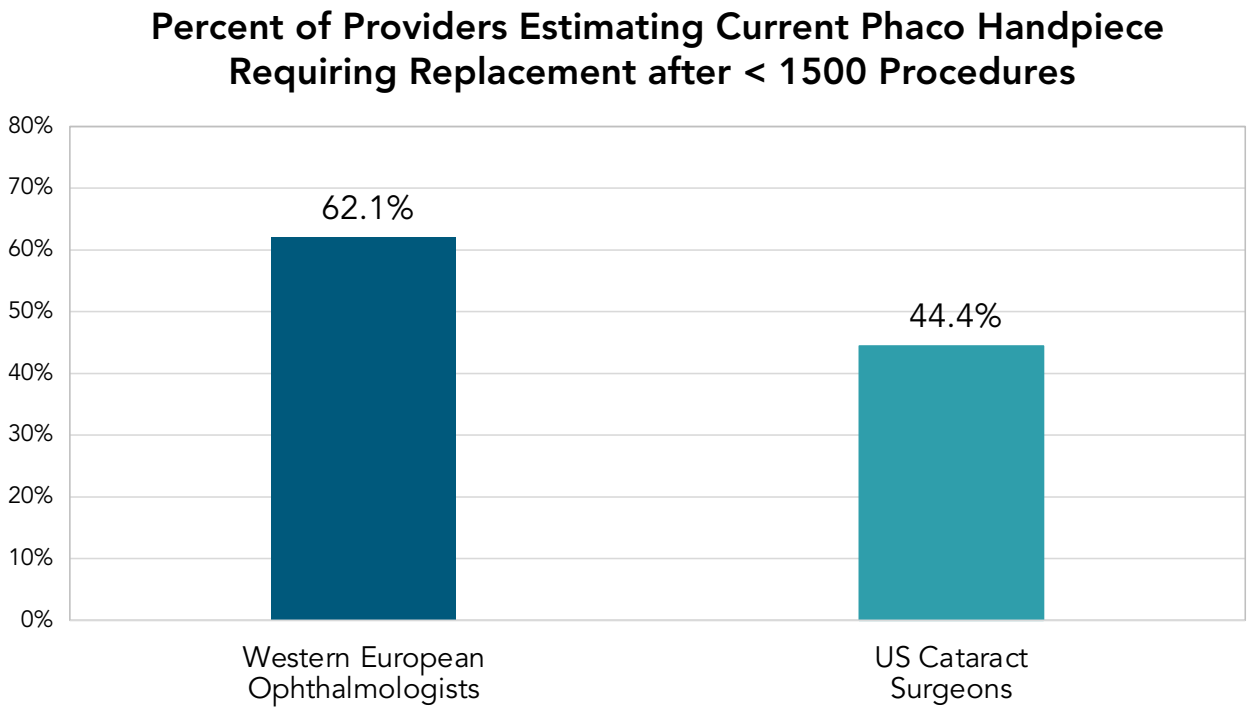
Phaco Handpiece Sterilization

What would be your best estimate of the cost to re-sterilize an ultrasonic handpiece after each surgery (taking into account time, labor, thorough cleaning, autoclave supplies, maintenance, axillary supplies, sterilization indicators, etc.)?



Phaco Handpiece Replacement

On average, for how many procedures does an ultrasonic handpiece last before it requires replacement or refurbishment?

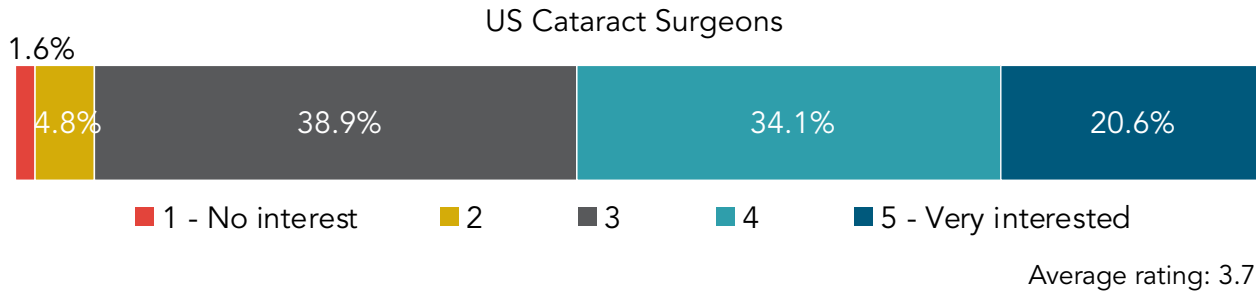


Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

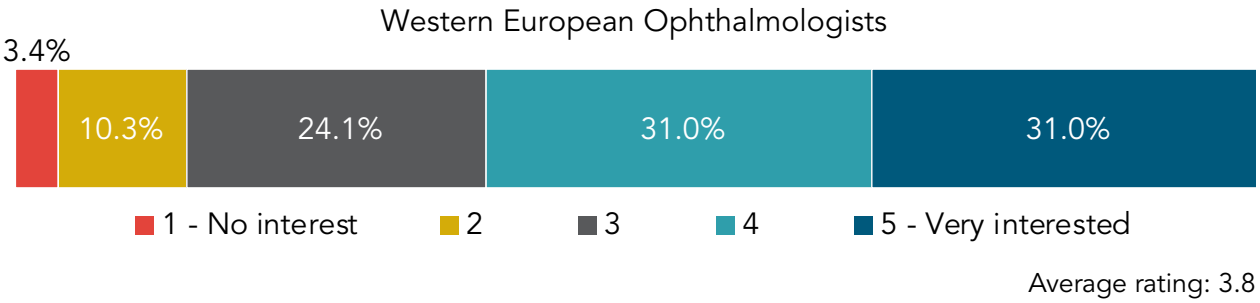
Provider Interest in New Phaco Handpiece

How interested are you in a more maneuverable, smaller, and much lighter ultrasonic handpiece?

(Please rate on a scale of 1 to 5, with 1 being not at all interested and 5 very interested.)



Average rating: 3.7



Average rating: 3.8

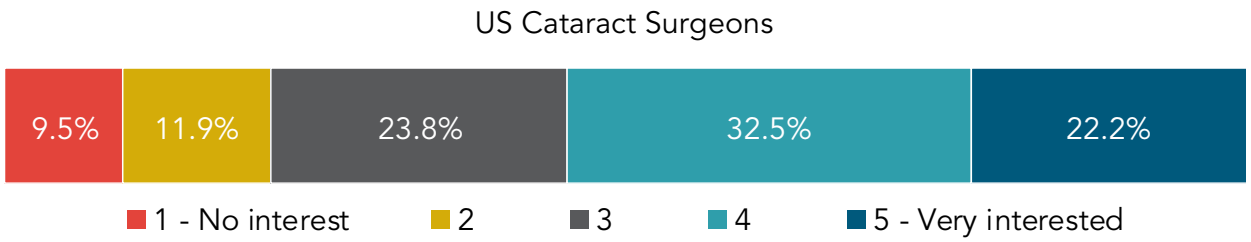
Both US and Western European Ophthalmologists expressed strong interest in a phaco handpiece what was smaller, lighter and more maneuverable.

Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

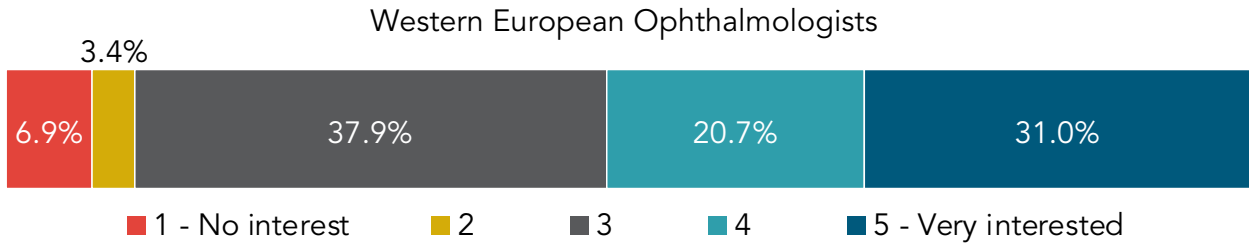
Provider Interest in New $25 Disposable Phaco Handpiece

If a $25 per use disposable handpiece was available that performed at least as effectively as your current reusable ultrasonic handpiece(s), but you would have 100% assurance of sterility, how interested would you be?

(Please rate on a scale of 1 to 5, with 1 being not at all interested and 5 very interested.)



Average rating: 3.5



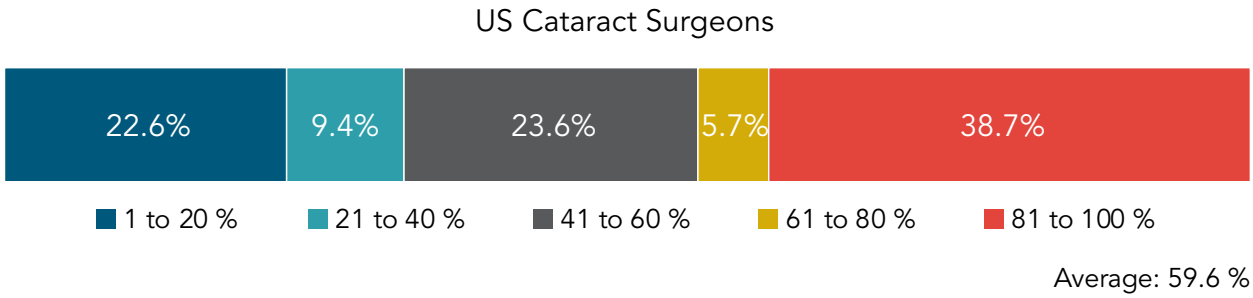
Average rating: 3.7

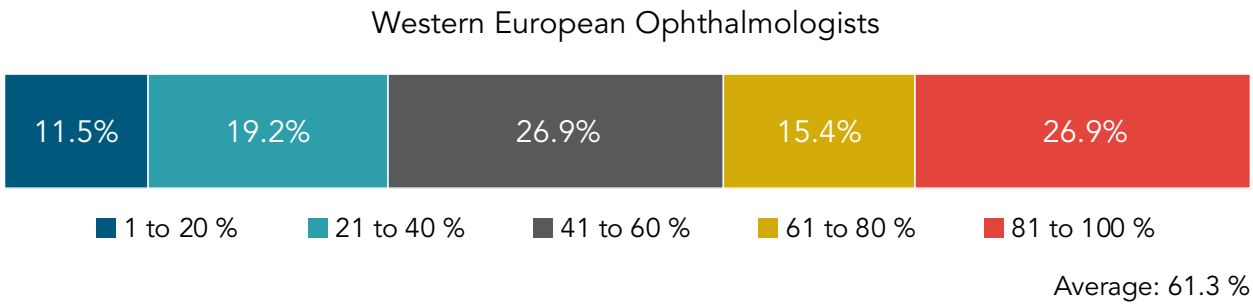
Interest remained high with both US and Western European Ophthalmologists in a phaco handpiece that was disposable, costs $25, and performed as well as current platforms.

Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

Provider Expected Use of New $25 Phaco Disposable Handpiece

When this product is available, in what percentage of cases would you use this disposable handpiece?

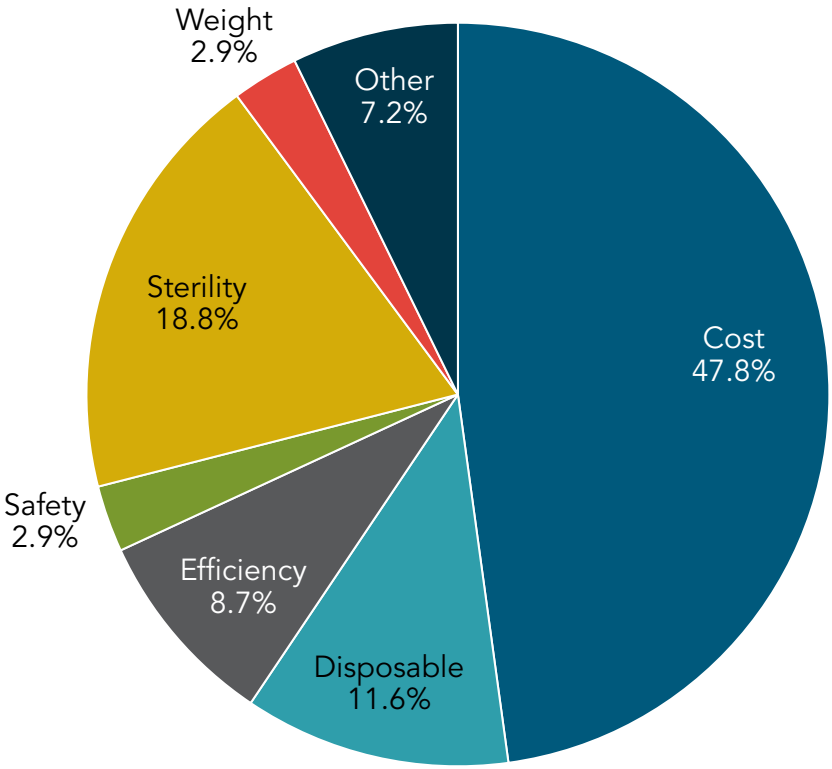




Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

US Provider Interest in New $25 Disposable Phaco Handpiece

What specifically are you interested in? (Summary of free text fields)

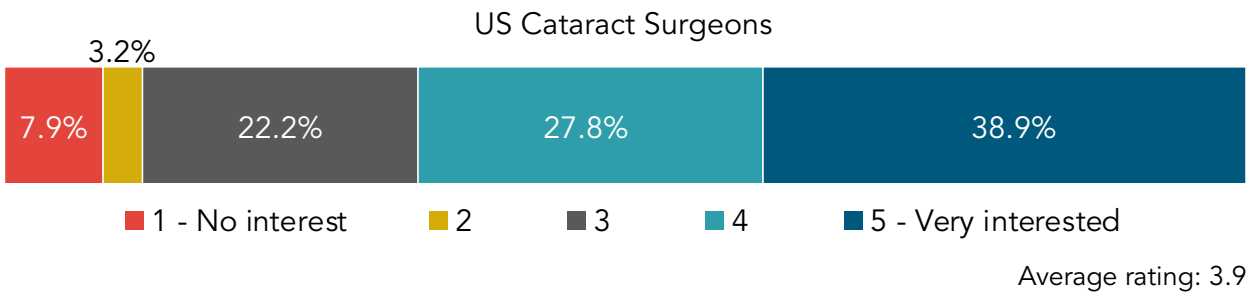


Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

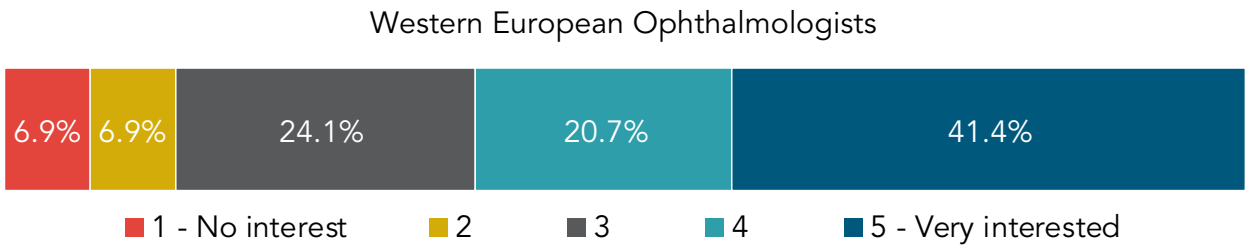
Provider Interest Level in New Phaco Disposable Handpiece with Irrigation and Aspiration

If this disposable ultrasonic handpiece also performed irrigation/aspiration, and ultrasonic irrigation/aspiration, so that you wouldn't need to buy a separate disposable I/A handpiece, how would this impact your interest in this technology?

(Please rate on a scale of 1 to 5, with 1 being not at all interested and 5 very interested.)



Average rating: 3.9

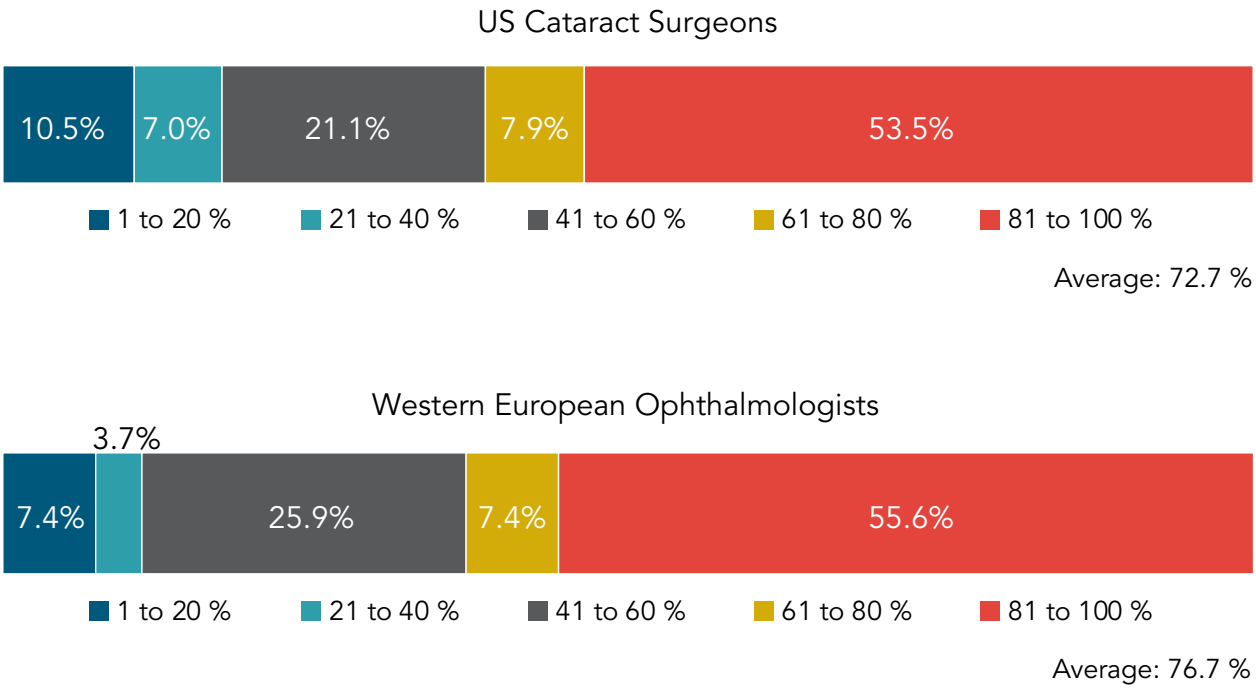


Average rating: 3.8

Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

Provider Expected Use of New Phaco Disposable Handpiece with Irrigation and Aspiration

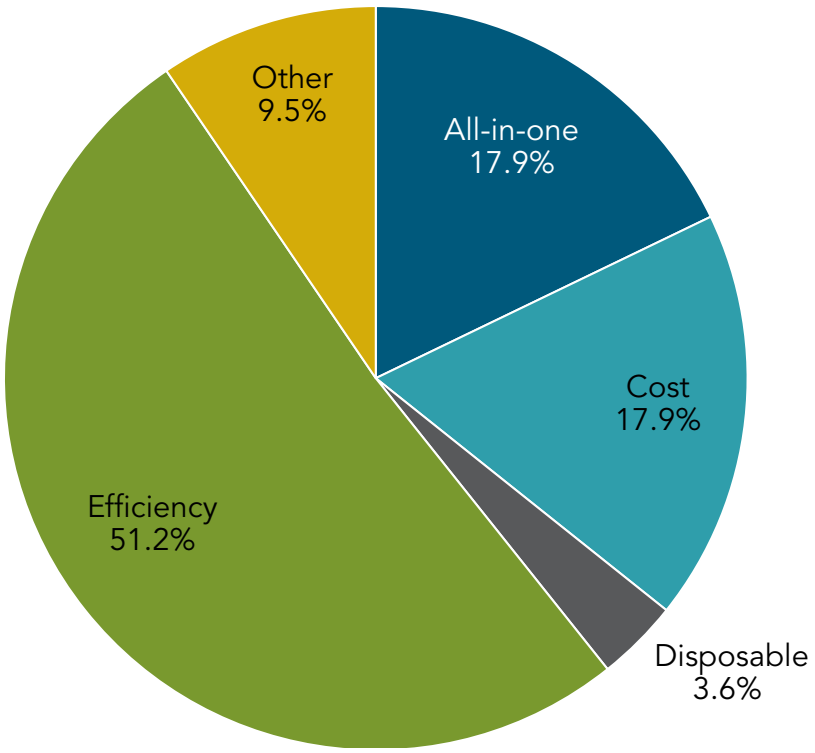
When this version of the phaco handpiece is available, that includes an irrigation/aspiration function, in what percentage of cases would you use this disposable handpiece?



Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

US Provider Interest in New $25 Disposable Phaco Handpiece with Irrigation and Aspiration

What specifically are you interested in? (Summary of free text fields)

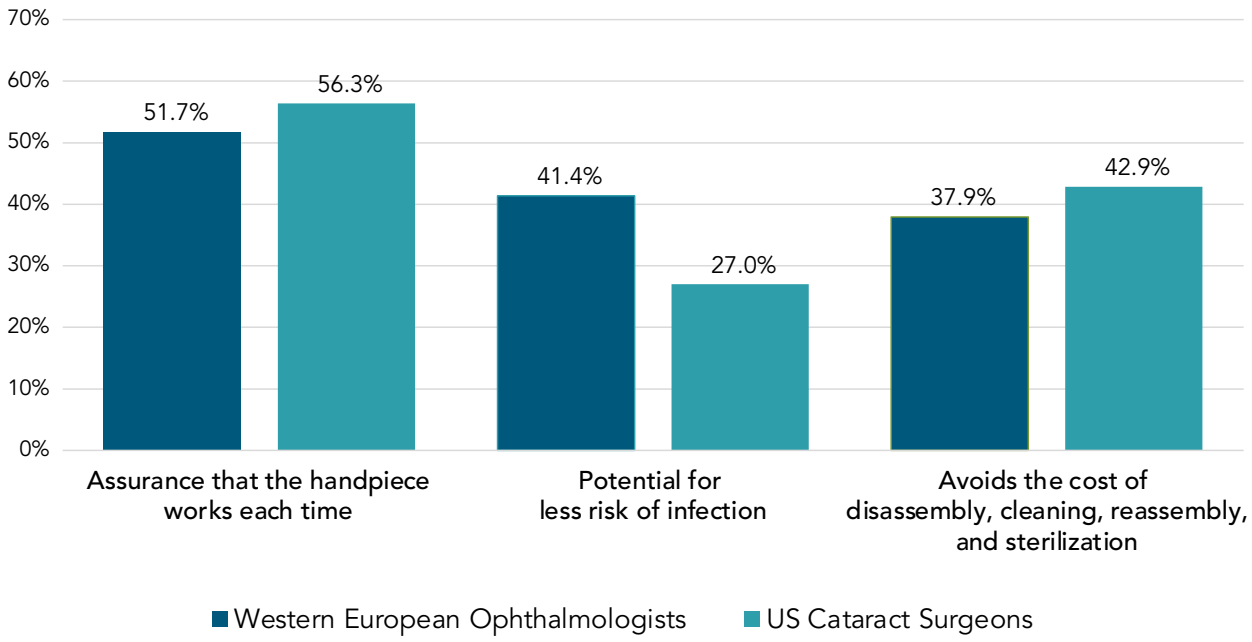


Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

Provider Ranking of New Phaco Handpiece Benefits

Which of the following would be most important to you if choosing to use a disposable phaco handpiece?

(Please rank in descending order of importance, with most important potential advantage on top.)



Note: US cataract surgeons also ranked "decreased cost per handpiece" very favorably.

Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

Surgeon Comments on the Disposable Combined Phaco & I/A Handpiece

"Great idea as long as cost is reasonable, keeping in mind declining reimbursement."

"If they can be recycled so as to avoid more garbage added to the environment, then I'm 100% in."

"This sounds very appealing from a safety and efficacy standpoint."

"This would be perfect for our transition to office-based surgery which we are planning on for 2023."

"Seems like a great idea!"

"I love the combined phaco/I/A handpiece."

"Emphasize the convenience and efficiency."

"Sounds like a winner if economical."

"Sounds like a great idea. Can't wait to try it!"

"Sell to company that makes phaco."

Market Scope Custom Survey of US Cataract Surgeons & Western European Ophthalmologists

Surgical Design

Patent Overview

Surgical Design Portfolio

Surgical Design's patent portfolio includes a total of 24 patents and patent applications, both U.S. and foreign, related to our new ultrasonic phaco-I/A handpieces and advanced flow control systems. To the right is a breakdown of the status of these patents/patent applications.

Total No. of Patents/Patent Applications (U.S. and Foreign)	24
Patents Issued	16
European Patents	1
Patent Applications (U.S.)	2
Patent Applications (Foreign)	5
US Patent Claims Pending	54
US Patent Claims Allowed	297

Benefits

The viability of our designs has already been proven in a surgical setting. Three different prototypes were tested on animal eyes by **Dr. Mike E. Raphtis** at Michigan Eye Institute (formerly Balian Eye Center) 432 W University Drive, Rochester, Michigan 48307 on the dates to the right.

3/25/2017	Dual lumen
8/26/2017	Dual lumen

4/28/2018	Blade tip
9/15/2018	Hybrid tip

Dr. Tobias Neuhann at the Eye Clinic at Marienplatz, in Munich, Germany, tested the hand pieces on animal eyes on these dates:

5/16/2019	Blade tip

5/16/2019	Hybrid tip

As these surgeries have demonstrated, our new handpiece designs can offer truly remarkable benefits for both patients and surgeons:

TWO-IN-ONE. Combines phaco and I/A functions in a work tip that allows alternating between removal of cataract and cortical material with a single instrument. In essence, we have combined the functions of three separate instruments: the phaco handpiece, the I/A handpiece, and the ultrasonic I/A handpiece. This simplifies the surgical technique, reduces operating time, and allows instant alternation between I/A and phaco.

ELIMINATES POST-OCCLUSION SURGES. We have eliminated a major complication of cataract surgery. With our handpiece designs, it is impossible to grab the posterior capsule because of a suction surge after the release of the occlusion.

SIGNIFICANT COST SAVINGS. Removing the irrigation and aspiration tubes from the interior of the handpiece opens the door for the next generation of handpieces that are smaller, lighter, and more ergonomically shaped than anything currently available in the marketplace.

DISPOSABLE. In addition to the cost savings, eliminating the inner tubes of the handpiece and other patented design features will enable the phaco-I/A handpiece to be sold as disposable: **a first in the cataract surgery market.**

SMALL INCISION CAPABILITY. Instead of using a hollow tube to remove the cataract, using a phaco knife with semi-circular tubes on either side allows a higher level of performance to be achieved with a smaller incision.

SIGNIFICANT INCREASE IN ULTRASOUND EFFICIENCY. Eliminating the thread between the work tip and connecting body and replacing the hollow phaco tube with a blade results in a substantial increase in ultrasound efficiency and the amplitude of the vibrating work tip.

AUTOMATED CONTROL OF ULTRASOUND, VACUUM, AND FLOW. The surgeon's skills are enhanced by automated control of all major fluid and ultrasound parameters.

NO LEARNING CURVES. The prototype handpieces we developed use the same phaco and I/A surgical procedures that surgeons are already familiar with.

Surgical Design

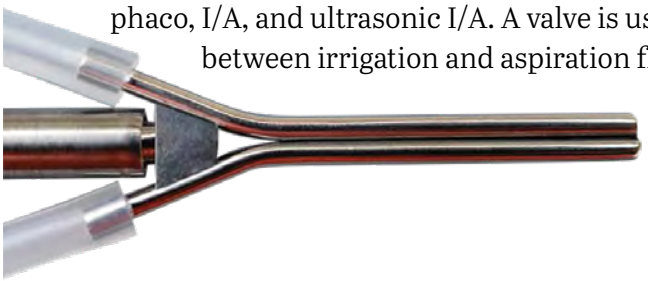
Patent Synopses

Patents Issued

1 Surgical Handpiece with Dual Lumen Work Tip

US 8,641,658 17 claims

This patent describes a work tip with 2 attached tubes, one for I/A and one for phaco. Both tubes vibrate ultrasonically. The result is a combined handpiece with three instruments in one: phaco, I/A, and ultrasonic I/A. A valve is used to switch between irrigation and aspiration fluids.



2 Surgical Handpiece with Dual Lumen Work Tip for Use with Infusion Cannula

US 10,166,317 28 claims

Broader claims for the two-in-one handpiece, without the switching valve. Claims include a cannula to protect the cornea. The claims include a cannula with separate irrigation.

3 Surgical Handpiece with Rotatable Dual Lumen Work Tip

US 10,179,068 23 claims

This patent describes a rotatable mechanism on the handpiece to switch irrigation and aspiration functions, instead of using a valve. A dual lumen version of an I/A handpiece is also described.

4 Surgical Handpiece with Disposable Concentric Lumen Work Tip

US 10,207,045 15 Claims

This patent describes a standard phaco handpiece that has a titanium work tip with a silicone sleeve. There are no tubings going through the handpiece, and the entire work tip and the tubings are disposable (see Fig. 5).

A sterile sheet to cover the housing is also described (see Fig. 4 in US 10,207,045). **This eliminates the need to autoclave the housing and power cord.**

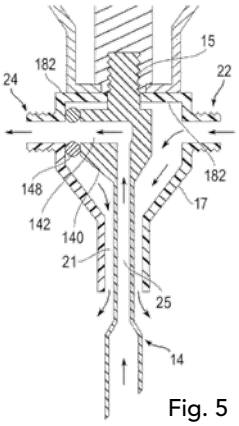


Fig. 5

5 Dual Lumen Surgical Work Tip for Placing Chemicals to Dissolve Cataracts

US 10,350,110 15 Claims

The work tip described in this patent has two vibrating tubes – one can be used for irrigation, and the other for aspiration. The irrigation tube can also be used to insert compounds to dissolve cataracts.

6 Surgical Handpiece with Dual Lumen Work Tip for Use with Infusion Cannula

US 10,500,319 7 claims

The work tip described in this patent describes a cannula that will prevent any wound burns at the incision site.

7 Ocular Work Tip Sleeve Adapter

US 11,116,890 12 Claims

This patent describes a sleeve design that can convert a phaco tip to an I/A tip. See Fig. 5

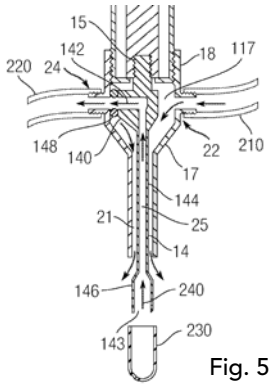


Fig. 5

8 Ocular Surgical Work Tip Adapter

US 11,419,971 9 Claims

Various adapters that can convert a phaco tip to an I/A tip are described in this patent.

9 Surgical Handpiece with Ultrasonic Knife

US 10,758,410 14 Claims

In this patent, a blade replaces the traditional hollow needle phaco tip. The blade is inserted inside a disposable evacuation tube that can be mounted as a sleeve around the blade. See Fig. 4

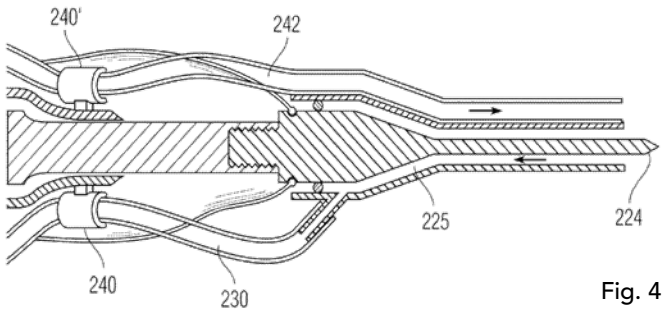


Fig. 4

10 Surgical Handpiece with Ultrasonic Knife

PCT/US2018/055183 16 claims pending

11 Dual Lumen Surgical Handpiece with Ultrasonic Knife

US 10,709,603 22 Claims

Expanding on the concept of replacing the traditional titanium hollow needle phaco tip, with a blade, this patent describes how inexpensive plastic tubes for irrigation and aspiration can be placed next to the blade. See Fig. 5A

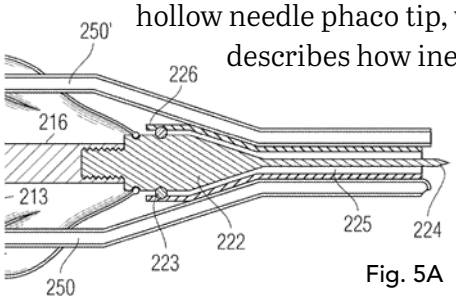


Fig. 5A

12 Dual Lumen Surgical Handpiece with Ultrasonic Knife

European Patent Number: EP 3694452 21 Claims

13 Automatic Ultrasonic Phacoemulsification Control

US 10,940,039 21 Claims

The automatic ultrasound feature was introduced on the Surgical Design Ocusystem in 1980. Ultrasound was only activated when the tip was occluded by lens material, this dramatically reduced the ultrasound energy going into the eye. This patent describes how various modalities of ultrasound and flow can be automatically regulated by algorithms that analyze pressure changes, in addition to activating ultrasound based on the vacuum limit. See Fig. 5

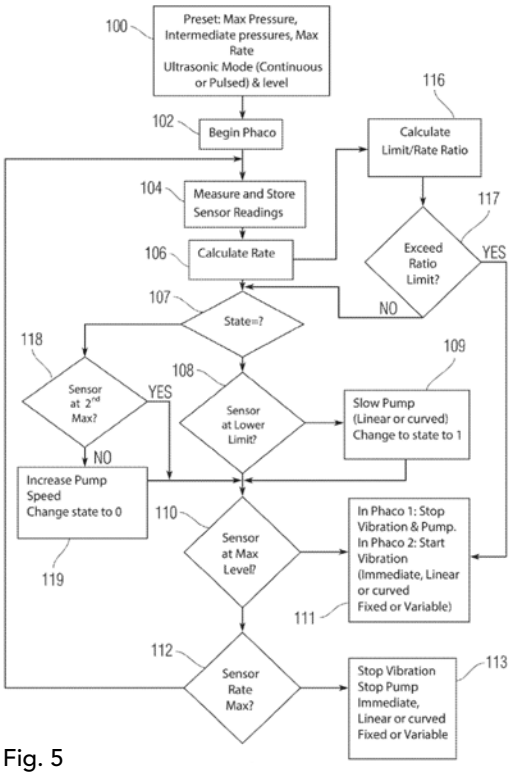


Fig. 5

14 Automatic Ultrasonic Phacoemulsification Control

PCT/US2018/055205 49 claims pending

15 Single Piece Connecting Member and Work Tip for Surgical Handpiece

US 11,207,094 B2 3 Claims

This patent eliminates the threaded connection between the work tip and connecting body in an ultrasonic transducer. This results in a substantial increase in ultrasound efficiency and the amplitude of the vibrating work tip, as well as significant manufacturing cost savings, and is one of the critical design features that enables the development of a disposable phaco-I/A handpiece.

16 Single Piece Connecting Member and Work Tip for Surgical Handpiece

PCT/US2018/061940 5 claims pending

17 Phaco Cone Work Tip for a Surgical Handpiece

US 11,207,212 21 claims

A further refinement of the blade design includes placing a ring around the blade at the end of the ultrasonic Phaco work tip. This ring will exactly mimic the ultrasonic cutting of the traditional hollow needle phaco tip. The ring can have a funnel shape (see Fig. 13 and photos below) that mirrors the performance of a **Phaco Cobra** tip. This work tip can also perform I/A and ultrasonic I/A.

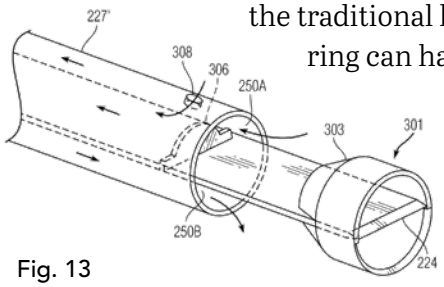
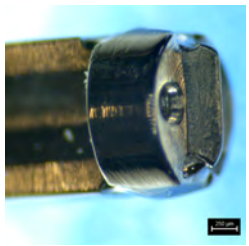
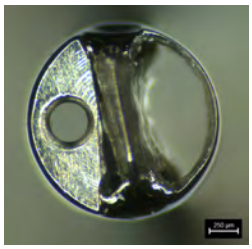


Fig. 13





18 Phaco Cone Work Tip for a Surgical Handpiece

PCT/US2019/024910 26 claims pending

19 Low-Cost Disposable Ultrasonic Surgical Handpiece

US 11,039,955 30 claims

A disposable combined phaco handpiece and I/A handpiece are described. This design reduces manufacturing costs so greatly that the entire handpiece can be disposable. This patented design is the only practical solution to the lowest cost disposable phaco handpiece for OFFICE BASED CATARACT SURGERY. Alternatively, the ceramic crystals, connecting body, and work tip can be unplugged from a receptacle located internally within the housing and discarded, allowing the housing and power cord to be reused. In this configuration, a sterile sheet is attached to the connecting body.

The patent also describes several methods for enabling transverse motion of the work tip, in order to increase the cutting efficiency. See Fig. 7

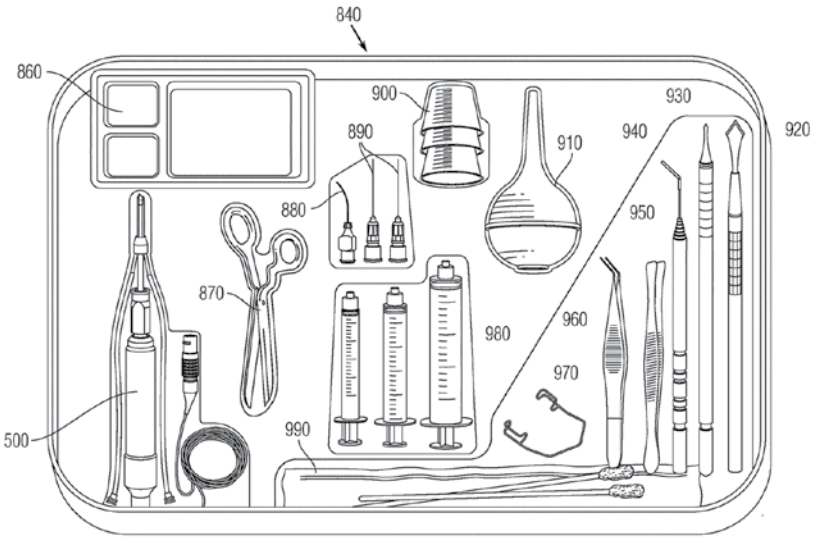
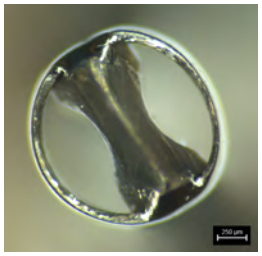


Fig. 7



20 Low-Cost Disposable Ultrasonic Surgical Handpiece

PCT/US2019/03574 30 claims pending

21 Low-Cost Disposable Ultrasonic Surgical Handpiece

US 11,369,513 26 claims

A disposable phaco handpiece and phaco-I/A handpiece are described. This design reduces manufacturing costs so greatly that the entire handpiece can be disposable. This design includes a **standard titanium phaco aspiration tip** and is also very practical solution to a low-cost disposable phaco handpiece for OFFICE BASED CATARACT SURGERY.

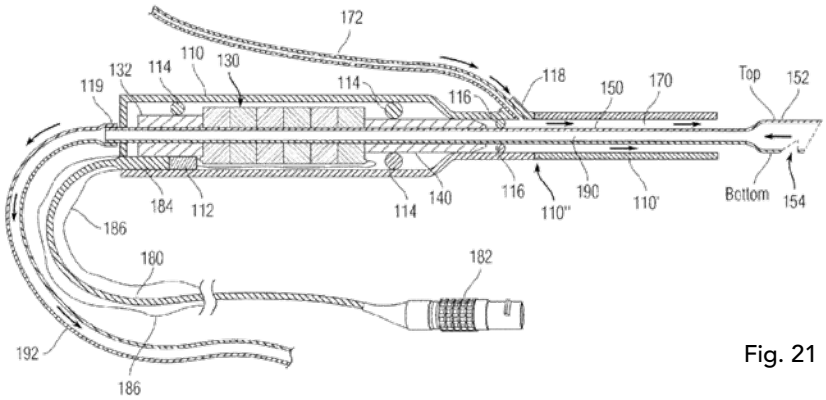


Fig. 21

22 Surgical Handpiece with Post-Occlusion Surge Elimination

Publication No. US 2019/0209374 A1 35 claims pending

This application describes grooves in the blade and connecting body to accommodate different shapes of inexpensive irrigation and aspiration tubes (see Figs. 32A, 32B, 33A, and 33B in Application No. 16/240,513). The tubes can be slid back and forth to switch between I/A and phaco functions.

This design also eliminates a major complication of cataract surgery: post-occlusion surges, in which tissue is grabbed.

23 Surgical Handpiece with a Bottom Fluid Tube Convertible from Irrigation to Aspiration

US 11,504,271 34 claims granted

This patent describes several designs that the surgeon can use to easily convert a phaco handpiece into an I/A handpiece and also use ultrasound I/A for capsule polishing.

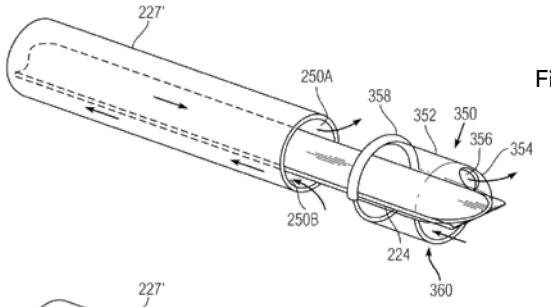


Fig. 21A

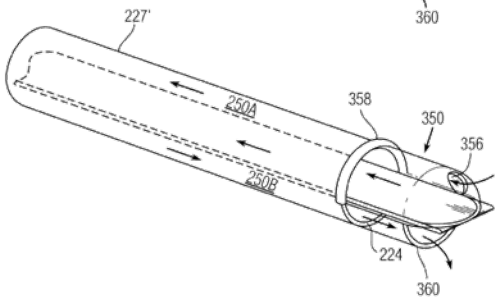


Fig. 21B

24 Surgical Sterile Field

Patent Application Number 17,984,780

The invention relates to a microsurgical sterile field for cataract surgery that is compact, portable, disposable and cost-effective.

This sterile enclosure is ideal for Office Based Cataract Surgery.

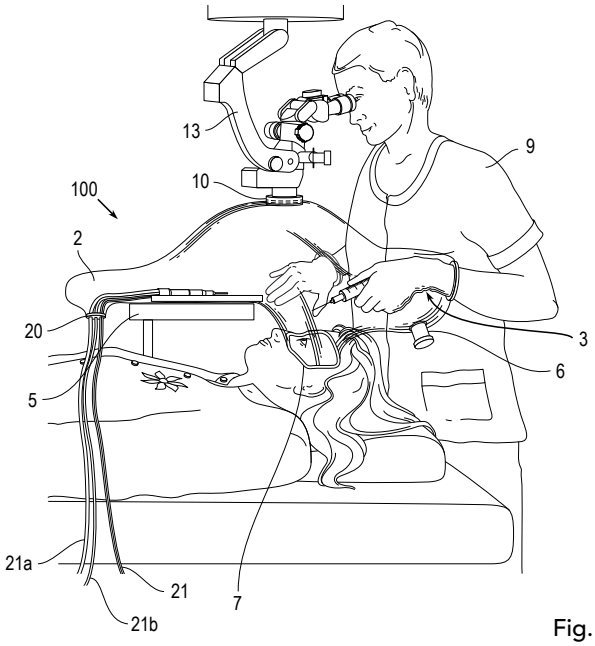
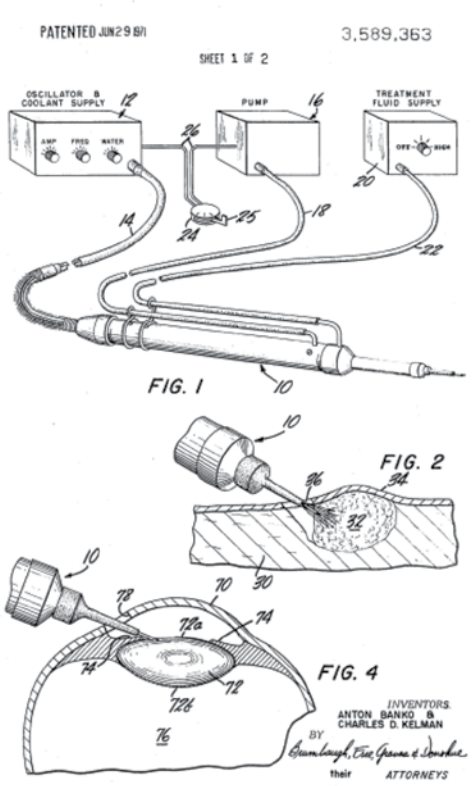


Fig. 1

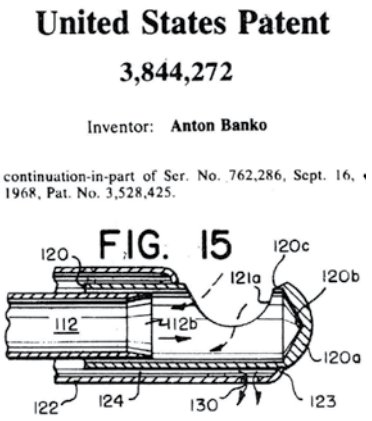
Surgical Design

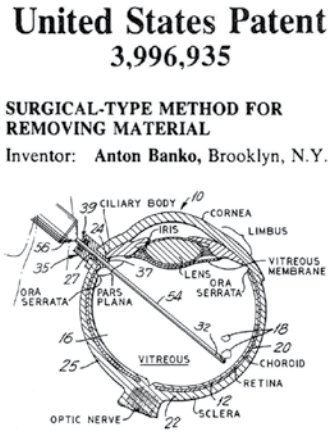
History of Innovation

Modern cataract surgery began when **Dr. Charles Kelman** worked with **Anton Banko** at **Cavitron Ultrasonics** in New York, the result was a large, heavy, water-cooled handpiece that proved cataracts can be removed through a small incision.

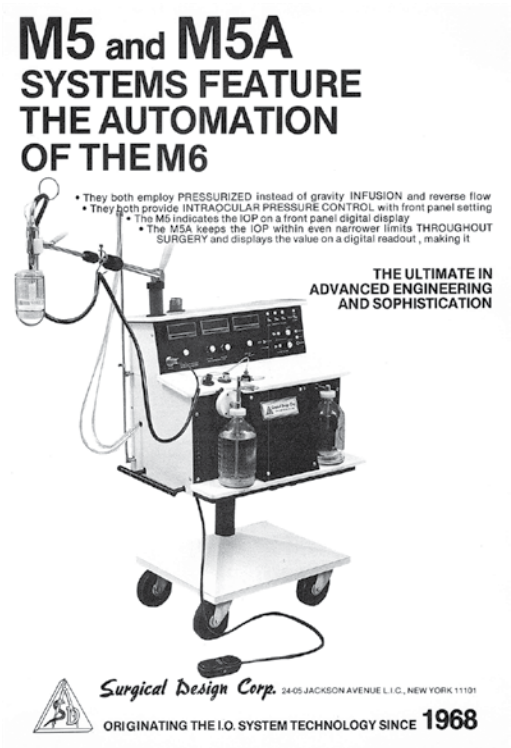


Inspired by Dr. Kelman, Anton Banko founded **Surgical Design** in 1968 and was the first to develop and patent every type of **vitrectomy instrument** (guillotine and rotary) including a patent on the actual vitrectomy surgical procedure.





Anton then developed the world's first completely automated intraocular surgical system with automated flow control and pressurized infusion.



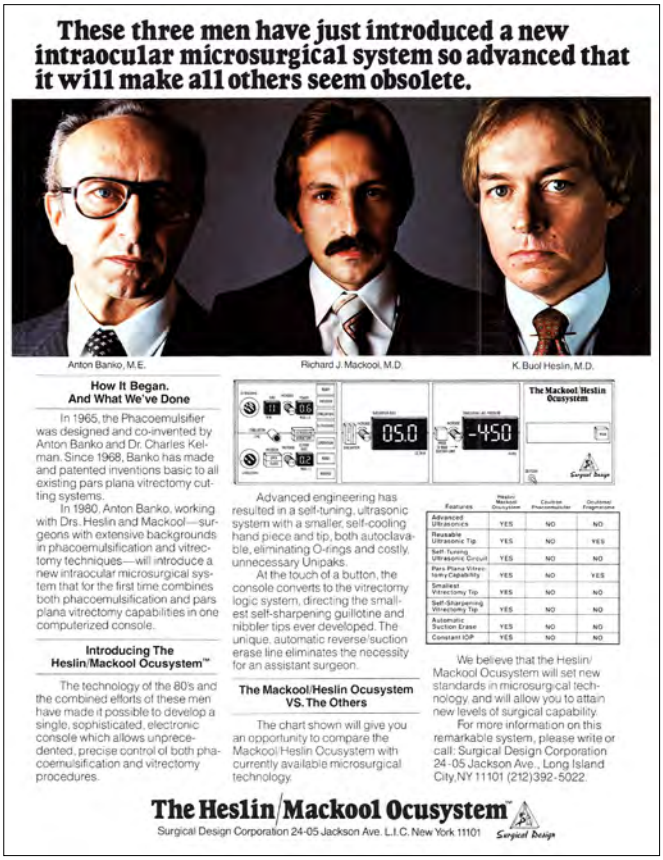
OPHTHALMOLOGY | Vol.88, No. 5 | May 1981

Closed Vitrectomy and the Intraocular Implant

RICHARD J. MACKOOL, MD

Closed vitrectomy instrumentation that permits simultaneous cutting, aspiration, and replacement of the vitreous was first developed in 1968 by Banko,[1] but was not reported in the opthalmic literature until 1971 by Machemer.[2–4]

Surgical Design, in 1980, introduced the world's most advanced phacoemulsification surgical system with vitrectomy capabilities.



Surgical Design created a continuous stream of innovation that included:

CATARACT | January 1985

Routine phacoemulsification through a one-millimeter non-sutured incision

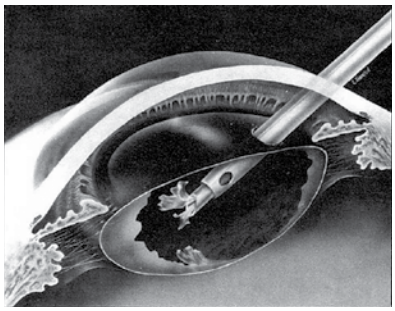
Steven P. Shearing, M.D., Richard L. Relyea, M.D., Augusto Loaiza, M.D., and Robert L. Shearing, B.A.
Las Vegas, Nevada

Demonstration of Accommodation in an injectable silicone fluid lens

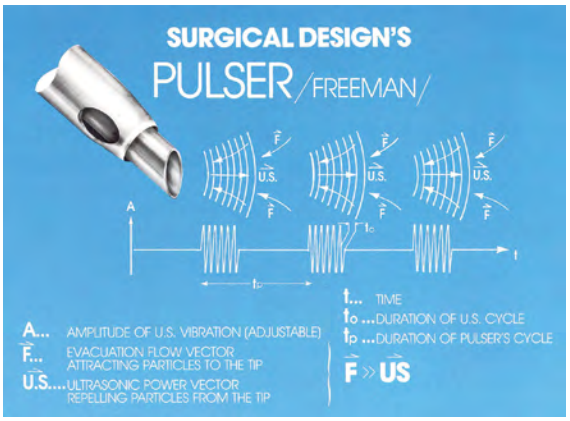
OPHTHALMOLOGY | May 1987

Accommodation of an Endocapsular Silicone Lens (Phaco-Ersatz) in the Nonhuman Primate

EDUARD HAEFLIGER, MD, Et al.



The world's first pulsed phaco



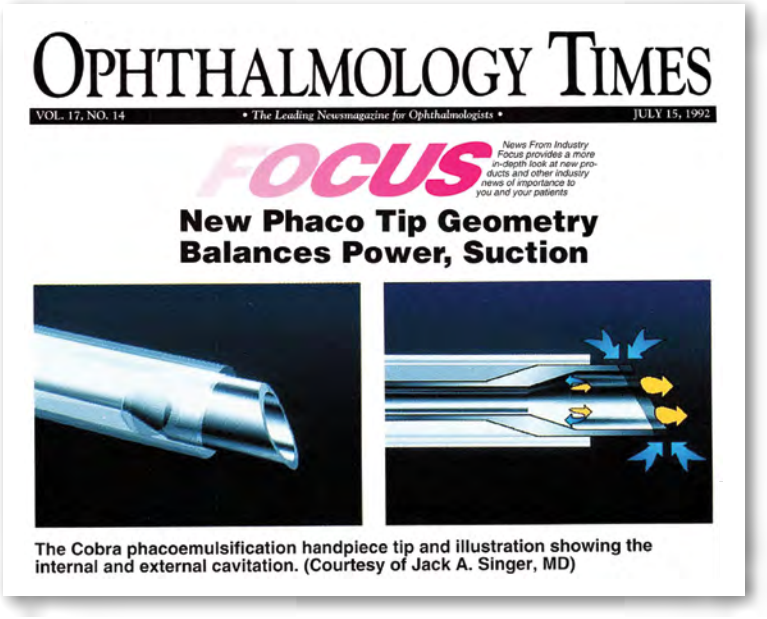
OPHTHALMOLOGY TIMES | August 15, 1986

Pulsar Cuts Phaco Time, Boosts Efficiency in Cataract Removal

LOS ANGELES—A pulsing device can increase both the efficiency and safety of cataract removal by phacoemulsification, reported Jerre M. Freeman, MD, during a presentation here at the American Society of Cataract and Refractive Surgery's Symposium on Cataract, IOL, and Refractive Surgery.

Surgical Design developed the Cobra Phaco Tip (wide opening and narrow evacuation tube) which is still the industry gold standard for Phaco tips.

OPHTHALMOLOGY TIMES | July 15, 1992



OPHTHALMOLOGY TIMES

VOL. 17, NO. 14 • The Leading Newsmagazine for Ophthalmologists • JULY 15, 1992

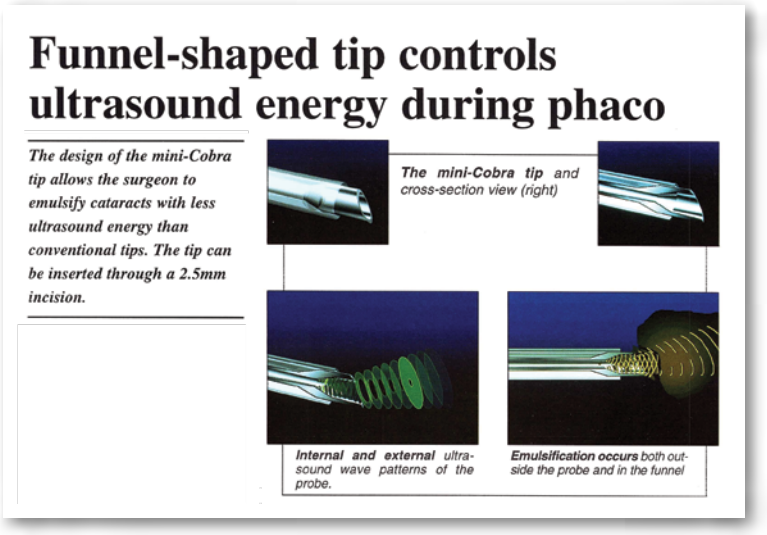
FOCUS

News From Industry
Focus provides a more in-depth look at new products and other industry news of importance to you and your patients

New Phaco Tip Geometry Balances Power, Suction

The Cobra phacoemulsification handpiece tip and illustration showing the internal and external cavitation. (Courtesy of Jack A. Singer, MD)

OCULAR SURGERY NEWS | July 1, 1992



Funnel-shaped tip controls ultrasound energy during phaco

The design of the mini-Cobra tip allows the surgeon to emulsify cataracts with less ultrasound energy than conventional tips. The tip can be inserted through a 2.5mm incision.

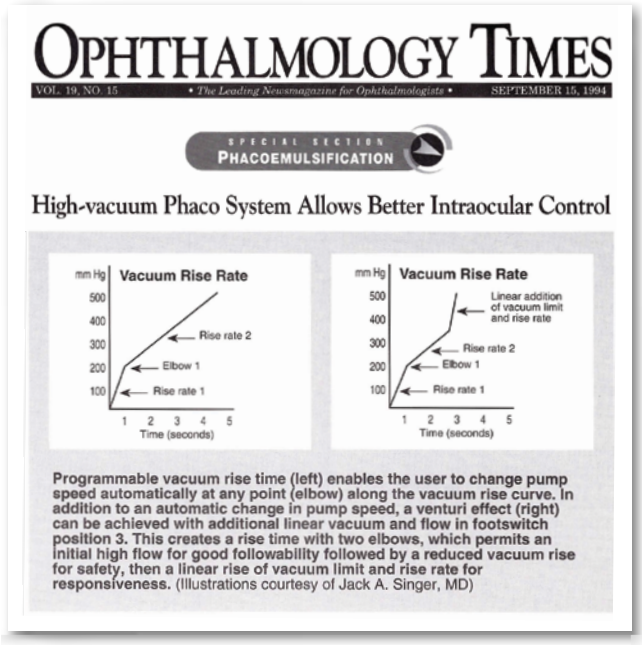
The mini-Cobra tip *and cross-section view (right)*

Internal and external *ultrasound wave patterns of the probe.*

Emulsification occurs *both outside the probe and in the funnel*

Surgical Design then introduced high vacuum settings for safer cataract surgery.

OPHTHALMOLOGY TIMES | September 15, 1994



OPHTHALMOLOGY TIMES

VOL. 19, NO. 15 • *The Leading Newsmagazine for Ophthalmologists* • SEPTEMBER 15, 1994

SPECIAL SECTION
PHACOEMULSIFICATION

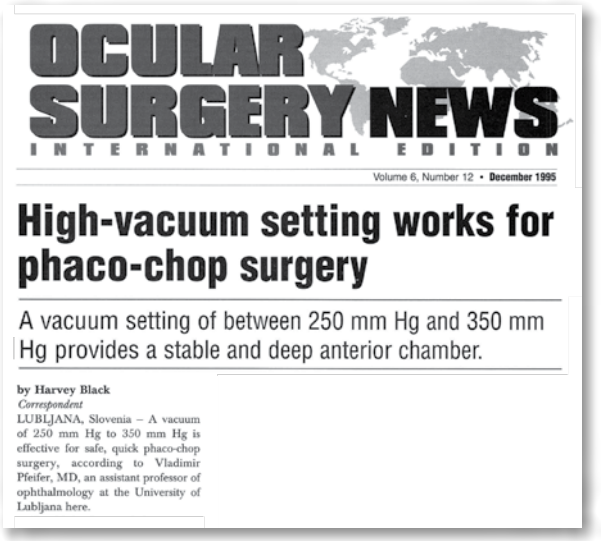
High-vacuum Phaco System Allows Better Intraocular Control

mm Hg Vacuum Rise Rate
500
400
300
200
100
Rise rate 2
Elbow 1
Rise rate 1
1 2 3 4 5
Time (seconds)

mm Hg Vacuum Rise Rate
500
400
300
200
100
Linear addition of vacuum limit and rise rate
Rise rate 2
Elbow 1
Rise rate 1
1 2 3 4 5
Time (seconds)

Programmable vacuum rise time (left) enables the user to change pump speed automatically at any point (elbow) along the vacuum rise curve. In addition to an automatic change in pump speed, a venturi effect (right) can be achieved with additional linear vacuum and flow in footswitch position 3. This creates a rise time with two elbows, which permits an initial high flow for good followability followed by a reduced vacuum rise for safety, then a linear rise of vacuum limit and rise rate for responsiveness. (Illustrations courtesy of Jack A. Singer, MD)

OCULAR SURGERY NEWS | December 1995



OCULAR SURGERY NEWS
INTERNATIONAL EDITION

Volume 6, Number 12 • **December 1995**

High-vacuum setting works for phaco-chop surgery

A vacuum setting of between 250 mm Hg and 350 mm Hg provides a stable and deep anterior chamber.

by Harvey Black
Correspondent

LUBLJANA, Slovenia – A vacuum of 250 mm Hg to 350 mm Hg is effective for safe, quick phaco-chop surgery, according to Vladimir Pfeifer, MD, an assistant professor of ophthalmology at the University of Lubljana here.

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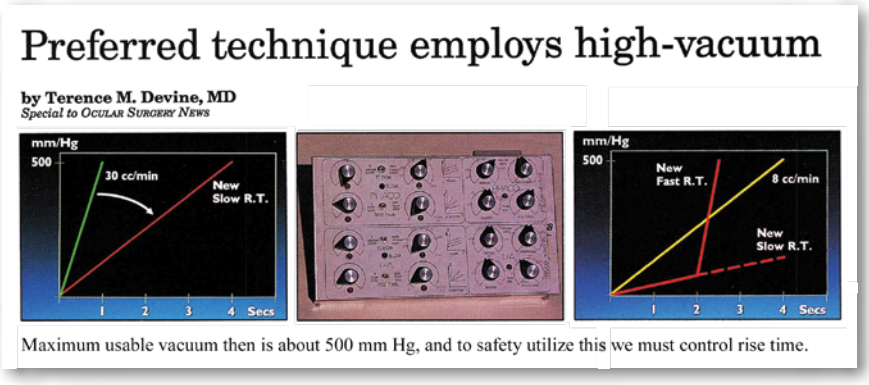

Preferred technique employs high-vacuum

by Terence M. Devine, MD
Special to Ocular Surgery News

mm/Hg
500
30 cc/min
New Slow R.T.
1 2 3 4 Secs

mm/Hg
500
New Fast R.T.
8 cc/min
New Slow R.T.
1 2 3 4 Secs

Maximum usable vacuum then is about 500 mm Hg, and to safety utilize this we must control rise time.

Surgical Design's innovations led to high volume surgeons using the Ocusystem worldwide.

James P. Gills, M.D.
Tarpon Springs, FL

Dr. Gills, the world's most experienced cataract surgeon, began using the Ocusystem®ART in April 1994. He quickly surpassed his own record, performing more than 3800 cases before vitreous loss.

How much better can he get?

Dr. Gills' new personal best is 4,000 consecutive cases and counting!

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OCULAR SURGERY NEWS
The leading medical newspaper for ophthalmologists Vol. 14, No. 8 April 15, 1996

Ocusystem

To the Editor:

Ocusystem has been easy to adapt to and has the following advantages:

• The smaller handpiece can be introduced through a 2.3-mm incision and has the capability of a vacuum level of 500 mm Hg. This enables quick and efficient emulsification of even the hardest nuclei. The system functions well at high-vacuum levels, which allows me to operate on some patients older than 50 years without ultrasound. (These patients are 10 years older than those I previously operated on with no ultrasound and a lower vacuum level.) The ability to use low vacuum for softer nuclei and high vacuum for the harder cataracts has diminished both operative and ultrasonic time.

• The 2.3-mm incision increases the stability of the wound – reducing possible leaks that could lead to infections – and markedly decreases postop astigmatism.

James P. Gills, MD
Tarpon Springs, Fla.

"The *Cobra Phaco Tip* concentrates ultrasonic energy inside the mouth of the phaco tip, creating a safer and more efficient phacoemulsification of all cataract types, with greatly reduced power levels." **Thomas Neuhann, MD**

"The *Cobra Seal Phaco Infusion Sleeve* is ideally suited for clear corneal micro incisions. It completely conforms to the wound, while internal spiral silicon ribs safely isolate and protect the cornea from the ultrasonic energy." **Harry B. Grabow, MD**

"The *Cobra Innovation* offers a wide range of *clear corneal micro incision sizes* to suit any surgical requirement. I currently use a 2.3mm micro incision to capitalize on the newest foldable IOL technology." **James P. Gills, MD**

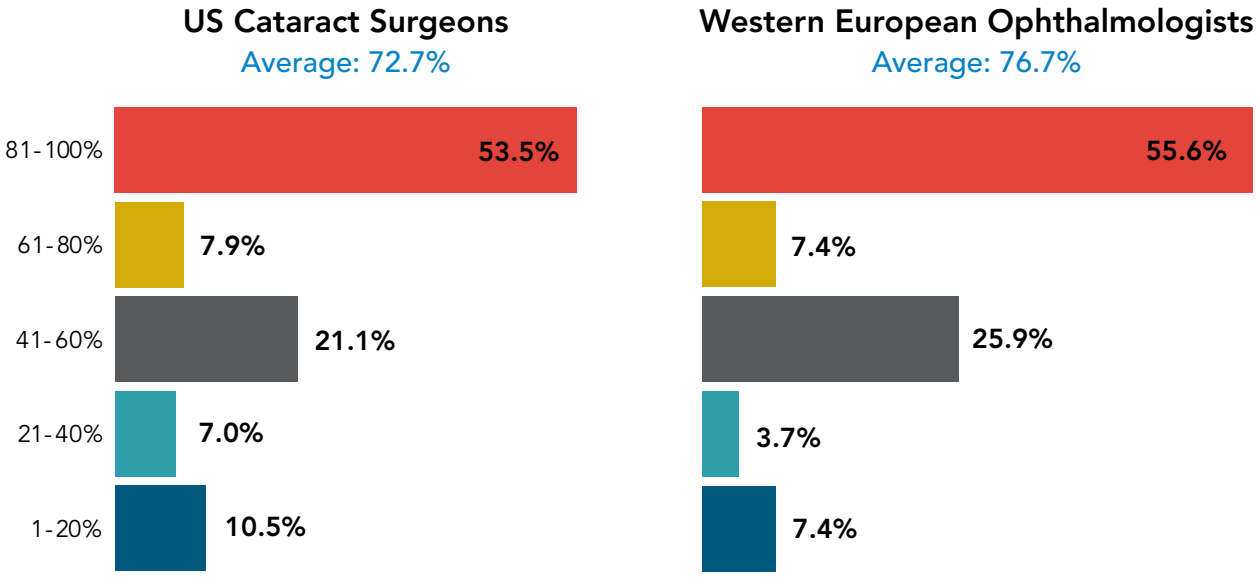
"The *Ocusystem's advanced fluidics* provide absolute chamber stability at vacuums as high as 500 mmHg. Adjustable Rise Time (ART) then allows the surgeon to program the vacuum response that best suits their personal technique, resulting in enhanced intra-ocular control and safety." **Terence M. Devine, MD**

Surgical Design's innovative Cobra technology and low operational cost are why more cataract surgeons are switching to the Ocusystem, which has been *Setting the Standard in Phaco Innovation Since 1968.*

Conclusion

Surgeon Expected Use of New Phaco Disposable Handpiece with Irrigation and Aspiration

When this version of the phaco handpiece is available, that includes an irrigation/aspiration function, in what percentage of cases would you use this disposable handpiece?



US surgeons expect to use the handpiece 72.7% of the time, while Western European Ophthalmologists planned usage in 76.7% of their cases.

These results reinforce our vision for the production of a low-cost, disposable handpiece that can provide more accessible cataract surgery globally.

Source: 2022 Market Scope Global Cataract Equipment Report

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