WORKSHOP:

LE NUOVE TECNOLOGIE PER LA CHIRURGIA OFTALMICA. ASPETTI INNOVATIVI E DI SICUREZZA PER IL PAZIENTE

Forlì, 12 Aprile 2019 – Hotel Globus City, Sala Congressi America

MICROSCOPI PER CHIRURGIA OFTALMICA E SISTEMI DI GUIDA PER LENTI TORICHE

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Microscope definition by User Manual

Il microscopio operatorio è uno strumento ottico destinato a rendere meglio visibili gli oggetti tramite ingrandimento e illuminazione.

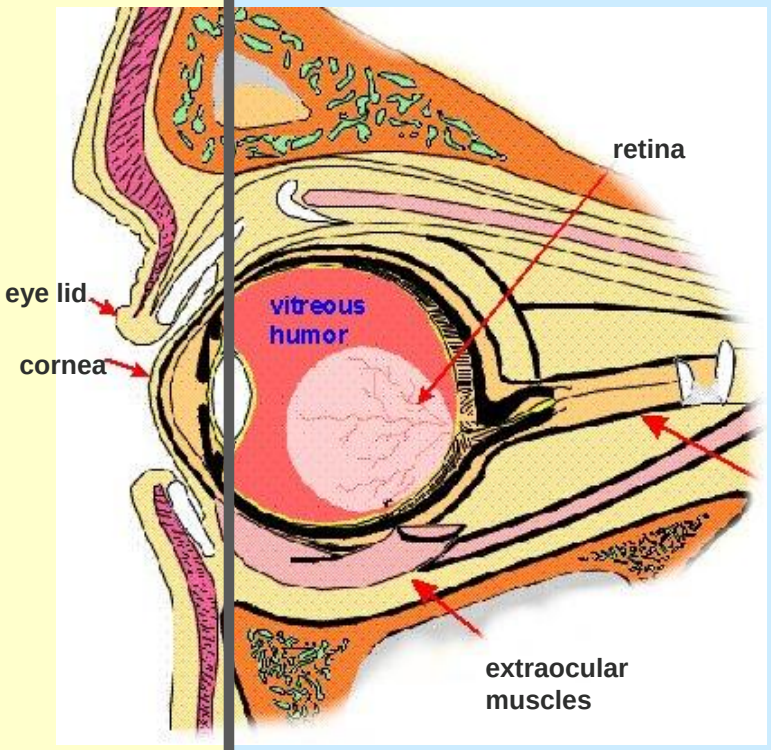
Può essere utilizzato per l'osservazione e la documentazione e per il trattamento medico in ambito umano e veterinario.

Field of Application
Ophthalmology Subdisciplines & Specialties

Anterior segment surgery

Posterior segment surgery

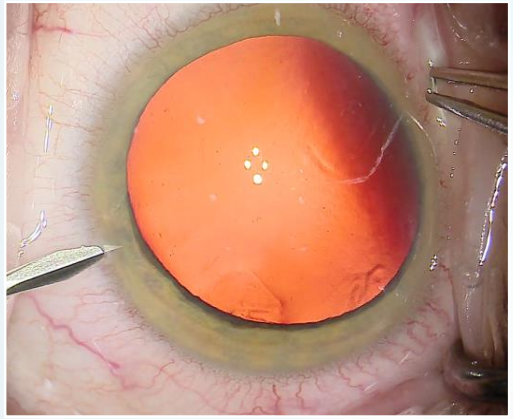
Oculoplastic,
Corneal
&
Lens Implant



Retinal / Vitreal

Field of Application
Ophthalmology Subdisciplines & Specialties

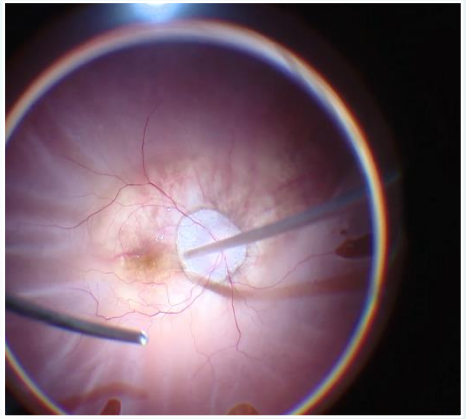
Anterior Segment



Main Applications

- Cataract Surgery
- Corneal Surgery
- Glaucoma Surgery

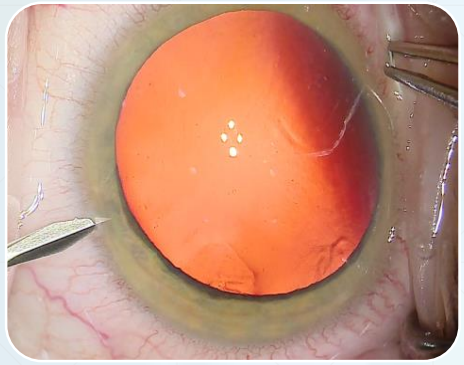
Posterior Segment



Main Applications

- Vitreous Surgery
- Retinal Surgery

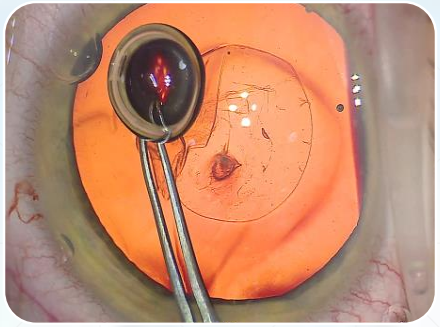
Steps of Cataract Surgery



1. CCI – Clear Corneal Incisions

2.Parazenthesis

1 or 2 additional openings for instruments



3.Capsularhexis in the Anterior Capsule

4. **Phaco-Emulsification** & cataract removal

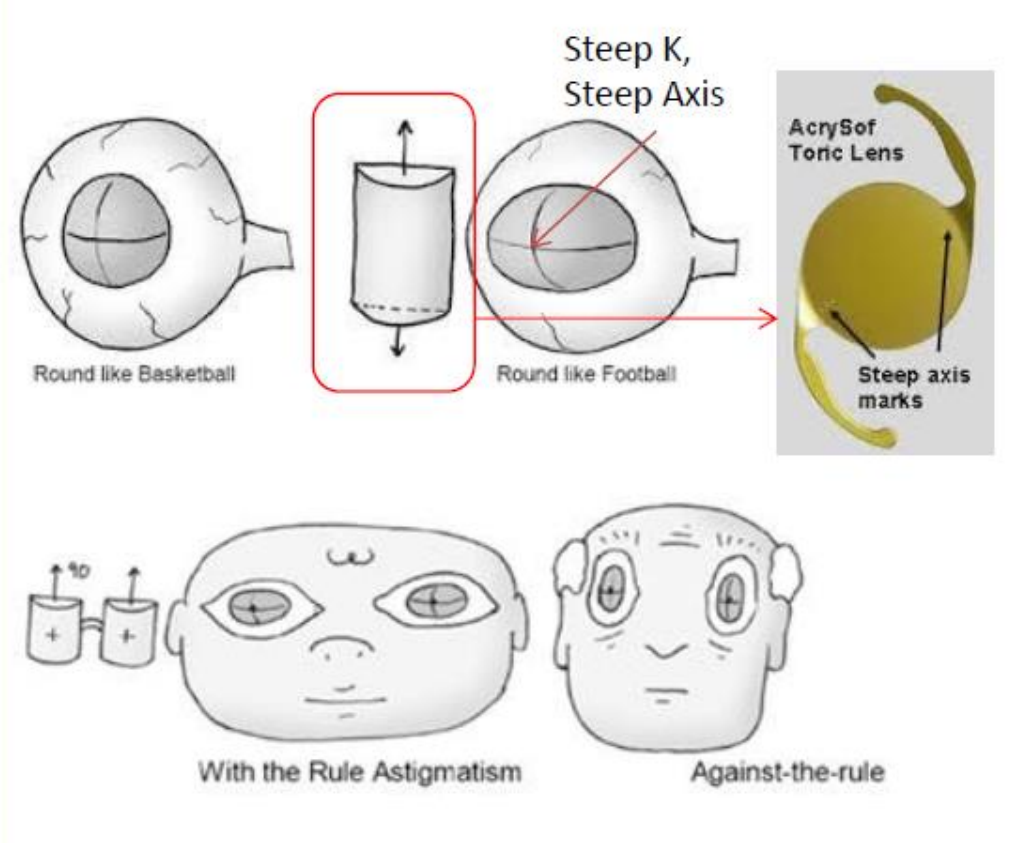
5. IOL Insertion, using a lens injector.

Monofocal IOL

Multifocal IOL

Toric IOL

Astigmatism Correction Thanks to Toric Lenses

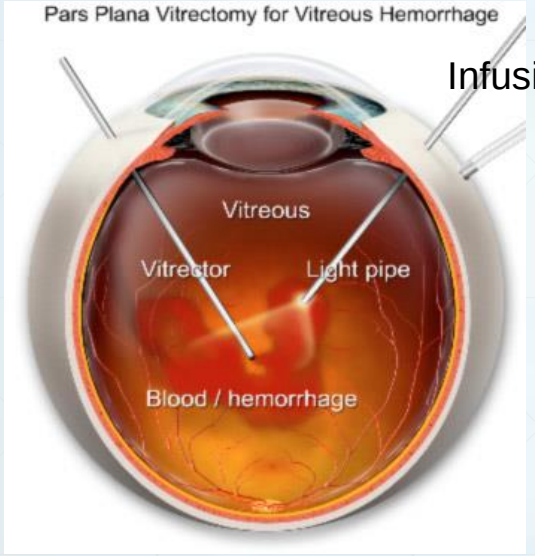


L’astigmatismo è un disturbo della vista (ametropia) che comporta una minore nitidezza visiva a causa di una deformazione della superficie dell’occhio o di un’alterazione delle strutture interne del bulbo oculare. Di conseguenza le immagini risultano poco definite (i contorni non appaiono nitidi) ed è necessario correggere il difetto.

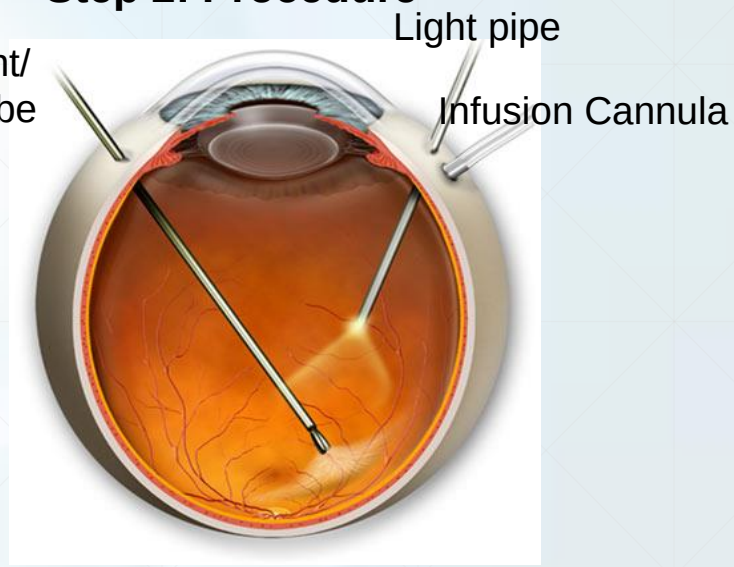
Posterior / VR surgery in essence – 2 steps

- VR surgery is conducted normally with light pipe – under dim light condition.
- Highly skilled surgery influenced strongly by surgeon`s technique/training.

Step1: Vitrectomy



Step 2: Procedure



Basics Microscopy Content

- Overview Microscopy
- Elements of Microscopes
- Terms for Microscopes

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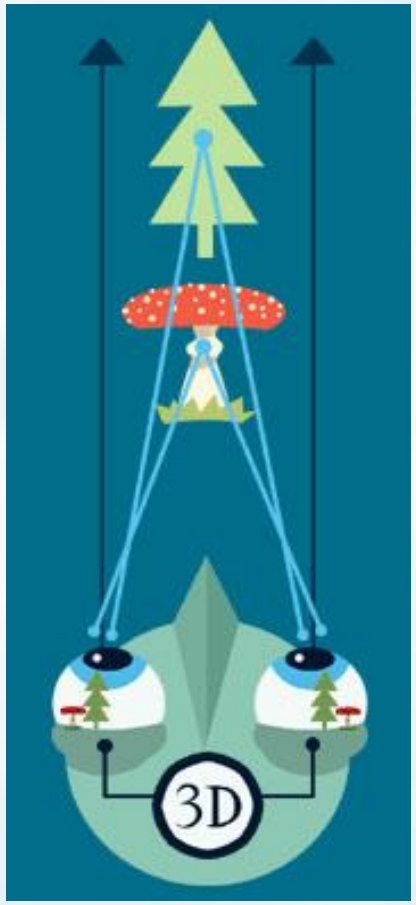
- **Overview Microscopy**
- Elements of Microscopes
- Terms for Microscopes

Stereomicroscopy concepts

Binocular vision



Is the use of both eyes to produce a single image in the brain from two separate images on the retina. The superposition of both images in one produces a vision property called stereoscopic, the vision depth by parallax, impossible to get by only one eye.

Stereomicroscopy concepts

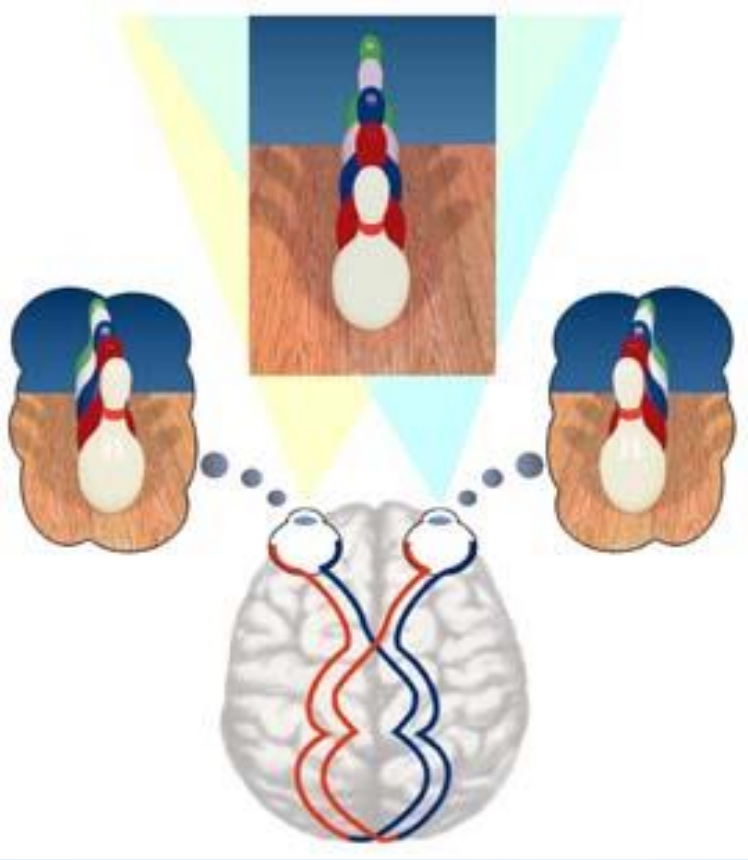
Binocular vision

LEFT

RIGHT

Stereomicroscopy concepts

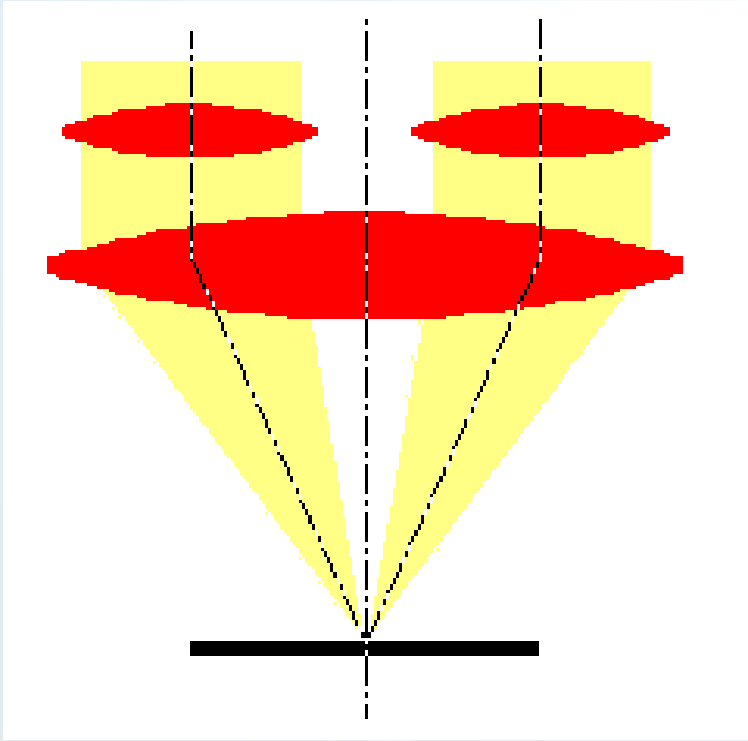
- **Stereoscopic Vision**



The 3 dimensions perception is due to the fact that the images created in both retinaes are not exactly the sames.

Stereomicroscopy concepts

- **Common Main Objective (C.M.O.) Stereomicroscope**



- 3D image
- Big field depth
- Long working distance
- Big image brightness
- It works without forcing visual system

Basics Microscopy Content

- Overview Microscopy
- **Terms for Microscopes**
- Elements of Microscopes

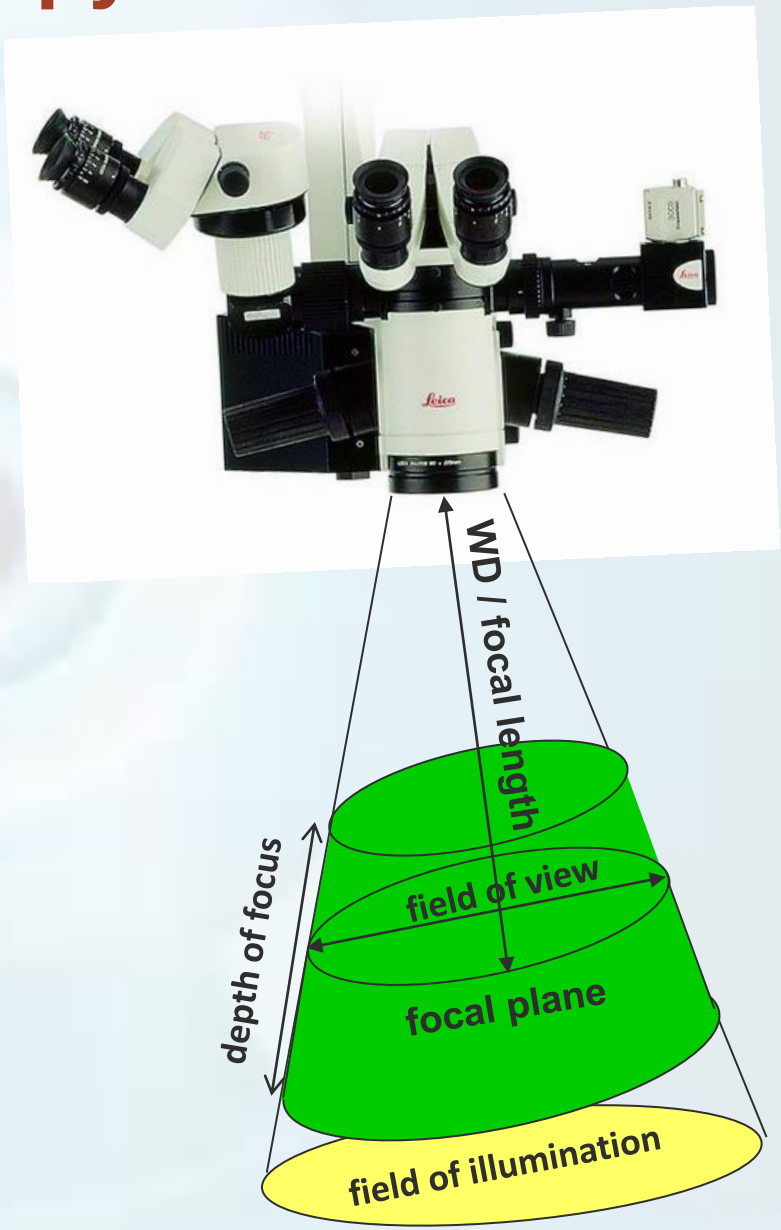
Parameters

- Focal Length / Working Distance (f / WD)
- Magnification (Γ)
- Depth of Field
- Spacial Resolution
- Stereo Base

Basics Microscopy in Focus

Zoom and focus define an area which appears sharp (green). Outside the object begins to be un-sharp.

Longer focal length and low magnification (zoom) lead into a large depth of focus.



Basics Microscopy Magnification

The magnification is the ratio of actual size of the object under observation to the size of the image as projected onto the retina of the eye (or onto a piece of film in the case of a camera).

The total magnification is the product of the magnifications of the eyepiece and objective and the magnification changer:

$$M_{total} = (P * M_{eye} * 10mm) / F_{ob}$$

F_{ob}	focal length of objective [mm]
M_{eye}	magnification of eyepiece
P	zoom/ magnification changer
M_{total}	total magnification

Basics Microscopy Depth of Focus/Field

These terms relate to that area in front of, and behind, the point of perfect optical focus, where sharp focus is maintained.

The depth-of-field depends on many factors, the most influential of which are:

1. **Quality of the optical design.**
2. **Size of the objective lens aperture relative to the focal length of the optic.**
3. **Magnification of the optic the higher the magnification, the more shallow the marginal area of sharp focus and vice-versa.**

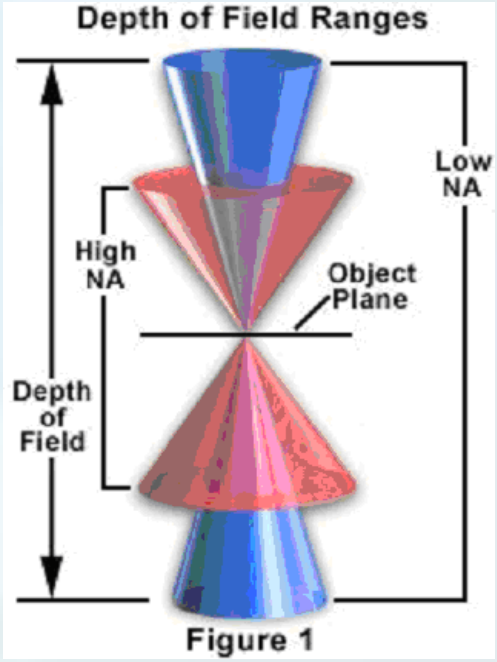
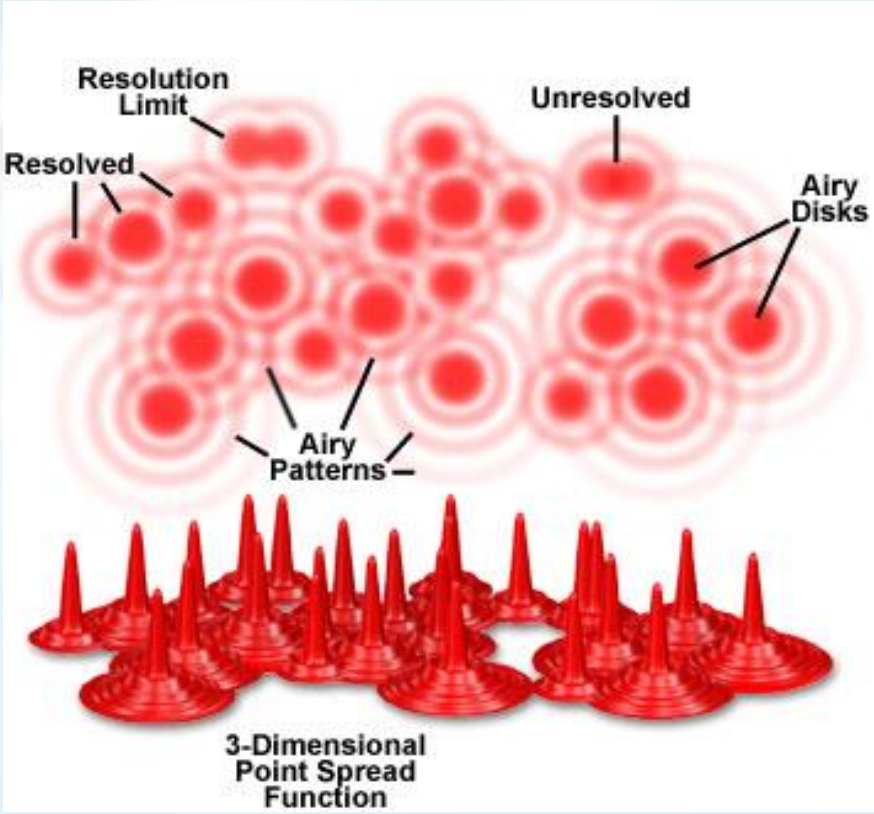


Figure 1

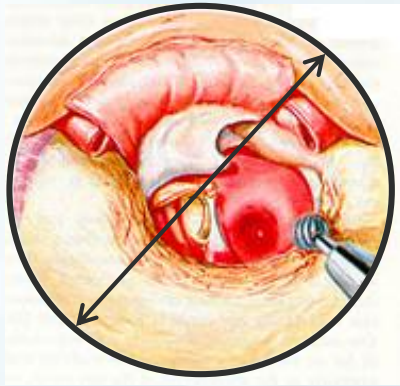
Basics Microscopy Resolution

The resolving power of a stereomicroscope is a measure of its ability to distinguish fine detail, i.e. to separate two closely-spaced points.



Basics Microscopy Field of View

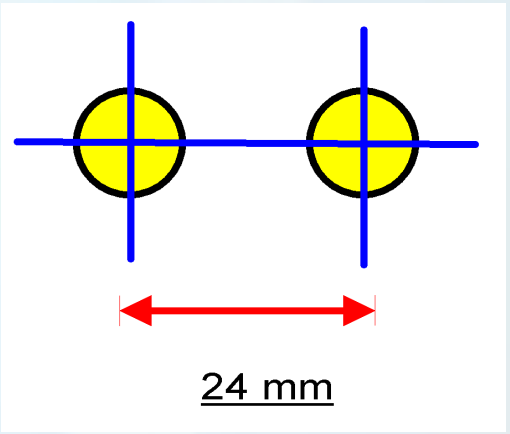
The field of view is the circular area of the specimen which can be seen through the microscope. It is influenced by objective and eyepiece characteristics and decreases with increasing magnification.



Basics Microscopy Stereo Base

The stereo base means the distance from the left observing beam path to the right observing beam path.

- A **large** stereo view gives a ideal 3D vision and a real 3D picture.
- A **small** stereo view allows looking into deep cavities.
- **24mm** is the optimal stereo basis for highest stereopsis without vignetting in narrow cavities.



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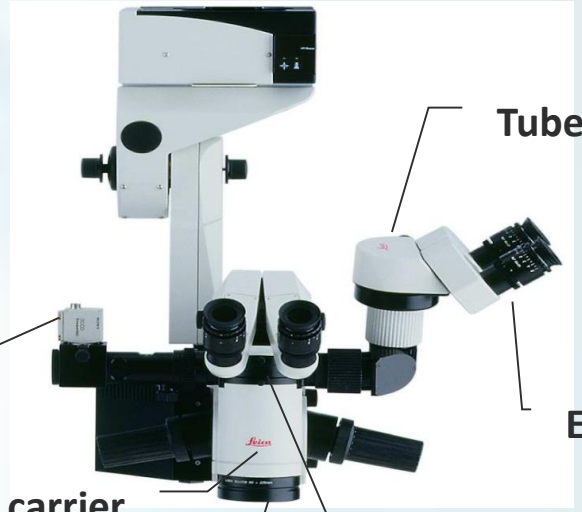
Basics Microscopy Complete System

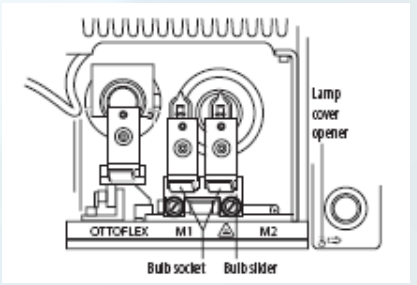
Basics Microscopy
Microscope



Control unit

Lamp changer

Illumination



Basics Microscopy Optic Carrier

This part holds main objective lens, tube, and include zoom lenses.

Components of a Surgical Operating Microscope

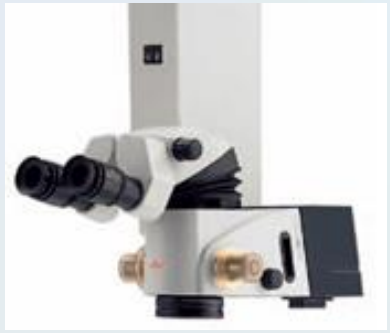
Stand

The stand is probably the one element where the gap between the surgeon's wishes and what is technically feasible is most readily perceptible. It should be stable, but provide a wide reach, so that it can be placed as far from the operating area as possible. And the stand should permit unlimited free movement, yet take up a minimum of space in the operating theatre. It is clearly impossible to meet all these requirements equally well, but several features make it possible to come very close to the ideal.

Basics Microscopy Tubes

The tube is the connection between optics carrier and eyepiece.

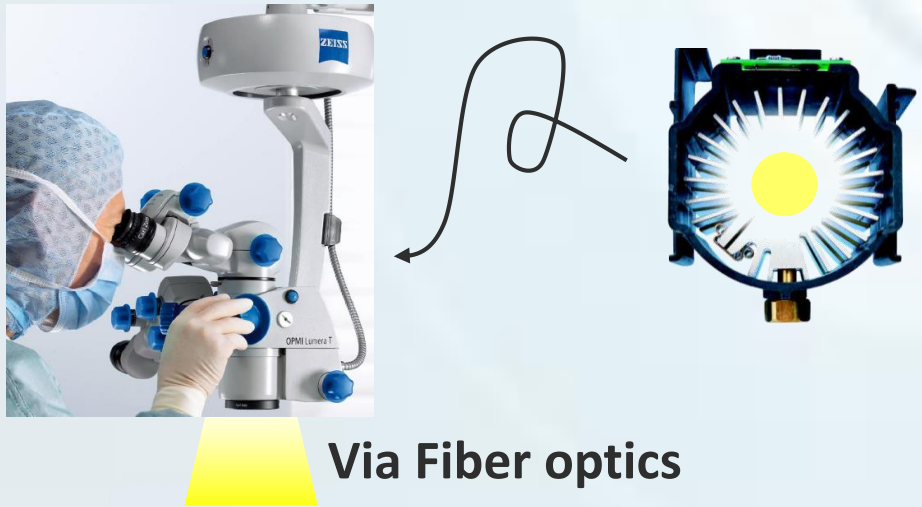
A range of different designs of binocular tubes is available to meet the needs of a wide variety of procedures.



Basics Microscopy Illumination

Coaxial illumination:

The light is re-routed to a point very near the viewing axis of the microscope and is projected down through the same objective lens for viewing.



Via Fiber optics

In optics carrier

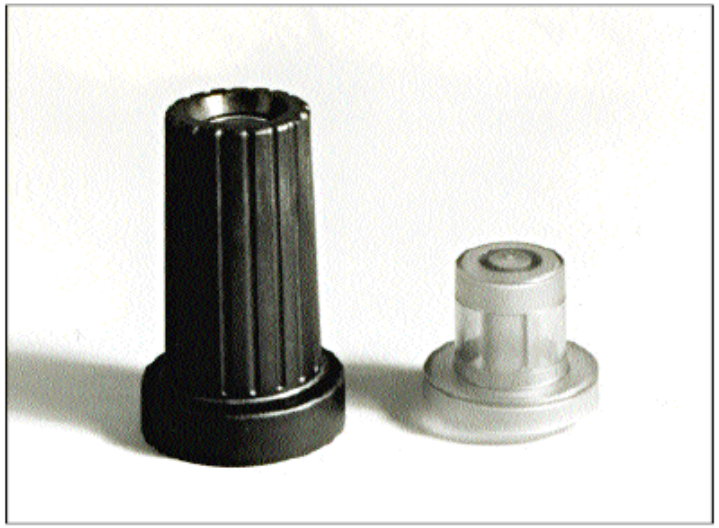
Basics Microscopy Control

Handle

Footswitch

Sterile controls

The controls can be steam-sterilized. Snap-lock fittings make them quick and easy to fit and hold them firmly attached. They are large enough and provide a firm grip to ensure that even when used blind there is no contamination from non-sterile parts of the microscope. In addition to sterile covers, there is also a range of sterilizable positioning handles, cover glasses for microscope objectives, lens caps, etc., for use as necessary.



Retinal viewing system
Key points summary

Automatic activation with swing-in

VR mode/
Light-off/Inversion/
XY-movement

Slim but durable

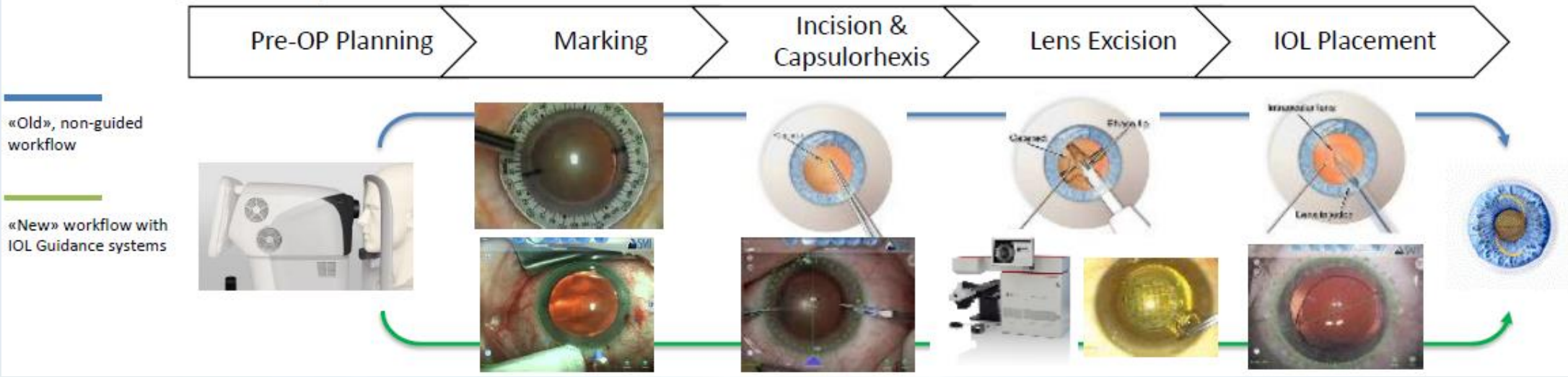
Minimized intervention with surgeon's hands.

Excellent resistance to sterilization.

Wide range of high-quality lens selection

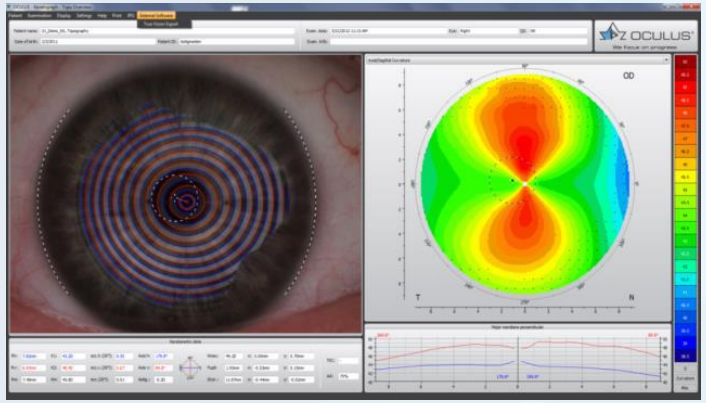
reusable & disposable

Cataract workflow for (toric / premium) IOL and pain points



Cataract workflow for (toric / premium) IOL and pain points

Step 1: Data transfer



- Topography of patient measured pre op
- Automated data transfer by USB stick / Lan

Step 2: Registration

Automated pattern recognition of the limbus and scleral blood vessel structure performed by **surgeon** using foot-pedal

Step 3: Display template

- CCI / LRI / Rhexis / toric axis / topography templates to be injected into the DIC800 / displayed on screen with low latency due to 3D ready PC performance
- Full control by surgeon using foot-pedal
- Smart algorithm for real-time optimization of plan

Patient Safety

Surgical Microscope

meets all the provisions of the Directive 93/42/EEC and amendments which apply to it
allen Anforderungen der Richtlinie 93/42/EWG mit Änderungen entspricht
remplit toutes les exigences de la 93/42/CEE avec modifications qui le concernait
adempie a tutte le esigenze della direttiva 93/42/CEE con modifiche che lo riguardano
reúna todos los requisitos de la norma 93/42/CEE con modificación que le afecta

Classification: (MDD 93/42/EEC, annex IX, rule 1 and 12) **Class I**
Klassifizierung: (Richtlinie 93/42/EWG, Anhang IX, Regel 1 und 12)
Classification: (MDD 93/42/EEC, annexe IX, règle 1 et 12)
Classificazione: (MDD 93/42/EEC, allegato IX, regola 1 e 12)
Classificatión: (MDD 93/42/EEC, anexo IX, regla 1 y 12)

Applied harmonized standards:	**EN 60601-1:2005/AMD1:2012**
Angewandte harmonisierte Normen:	**EN 60601-1-2:2014**
Normes harmonisées appliquées:	**EN 60601-1-6:2010**
Norme armonizzate applicate:	**EN 62366:2008**
Norma armonización da:	**EN ISO 14971:2012**
	EN 980:2008

Patient Safety

La IEC 60601 è una serie di standard tecnici che garantiscono la sicurezza e le prestazioni essenziali delle apparecchiature elettromedicali.
La IEC 60601-1:2005 si occupa dei requisiti sulla sicurezza di base e sulle prestazioni essenziali riferite ad apparecchiature elettromedicali, e serve a garantire che nessun singolo guasto elettrico, meccanico o funzionale comporti un rischio inaccettabile per pazienti e operatori.

La norma CEI EN 61000-4-5:2016-10 dal titolo "Compatibilità elettromagnetica (EMC) Parte 4-5: Tecniche di prova e di misura – Prova di immunità ad impulso" si riferisce ai requisiti di immunità, ai metodi di prova e alla gamma dei livelli di prova raccomandati per le apparecchiature nei riguardi di impulsi unidirezionali causati da **sovratensioni derivanti da transitori di commutazioni oppure da fulmini**.

Lo standard EN 60601-1 si applica a tutti gli apparecchi e i sistemi elettromedicali. Un apparecchio elettromedicale viene definito nello standard come apparecchio elettrico dotato di una PARTE APPLICATA, che trasferisce energia verso il o dal PAZIENTE o che rileva tale trasferimento di energia verso il o dal PAZIENTE, e che è:

- Dotato di non più di una connessione a una particolare RETE DI ALIMENTAZIONE
- Progettato dal suo PRODUTTORE per essere usato: per la diagnosi, il trattamento o il monitoraggio del PAZIENTE o per la compensazione o attenuazione di malattie, lesioni o invalidità.

Service and maintenance

• Mentre i freni sono operativi, coprire lo strumento con un telo antipolvere.
• Quando non vengono utilizzati tenere gli accessori in un luogo privo di polvere.
• Spolverare con un soffietto di gomma e un pennello morbido.
• Pulire gli oculari e gli obiettivi con panni per la pulizia delle ottiche e alcol puro.
• Proteggere il microscopio operatorio da umidita, vapori, acidi, alcali, e sostanze corrosive.
Non conservare sostanze chimiche nelle vicinanze degli strumenti.
• Proteggere il microscopio operatorio da un uso improprio.
Installare altre prese per dispositivi o svitare i sistemi ottici e i componenti meccanici solo se indicato esplicitamente nel presente manuale.
• Proteggere il microscopio operatorio da olio e grasso. Non lubrificare mai le superfici scorrevoli ne le parti meccaniche.
• Rimuovere lo sporco più intenso con un panno monouso umido.
• Per la disinfezione del microscopio operatorio, usare preparati del gruppo dei disinfettanti per superfici sulla seguente base:
• aldeidi,
• alcoli,
• legami quaternari di ammonio.

Impatto economico

- Acquisto normalmente effettuato in conto capitale
- Il microscopio non prevede l’uso di consumabili
- Bene con durata intorno ai 10 anni
- Impatto economico per acquisto è tra 80.000 e fino a circa 350.000 Euro se integrato con nuove tecnologie OCT, 3D e sistemi di impianto per lenti toriche
- Costo manutenzione annua pari a circa 7% del valore del bene

Diffusione tecnologia a livello nazionale

- Tecnologia diffusa in tutte le sale operatorie pubbliche e private dove si effettua chirurgia oculistica di segmento anteriore e posteriore
- Nei blocchi operatori con più sale dedicate all’oculistica normalmente una sala è dedicata alla chirurgia della cataratta e una seconda sala alla chirurgia vitreoretinica
- Il prezzo dei modelli entry level e la facilità di spostamento e utilizzo hanno fatto sì che la tecnologia prendesse piede anche a livello ambulatoriale e non solo ospedaliero

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