

LENTICOLI *READY FOR USE* PER DSAEK

-UPDATE-

Alessandro Ruzza

20 Febbraio 2014

XVIII CONGRESSO NAZIONALE S.I.TRA.C.

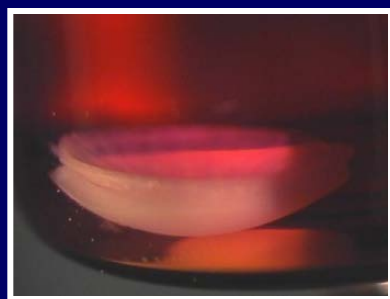
Simposio SIBO

SCOPO

CORNEE
PRE-TAGLIATE



LENTICOLI
POSTERIORI



CONSERVAZIONE



Ruzza et al. Banking of Donor Tissues for DSAEK.
Cornea Jrl. 2013 - 32(1):70-75

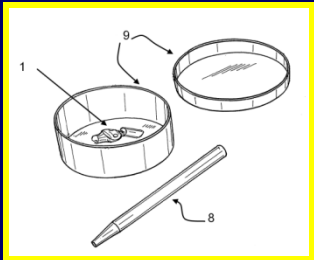
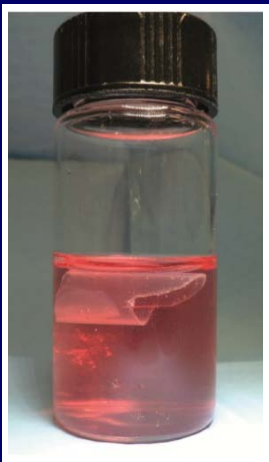
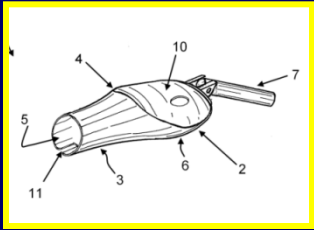
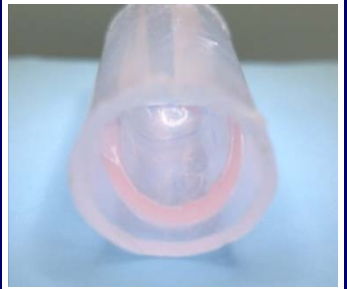
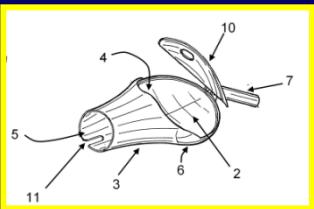
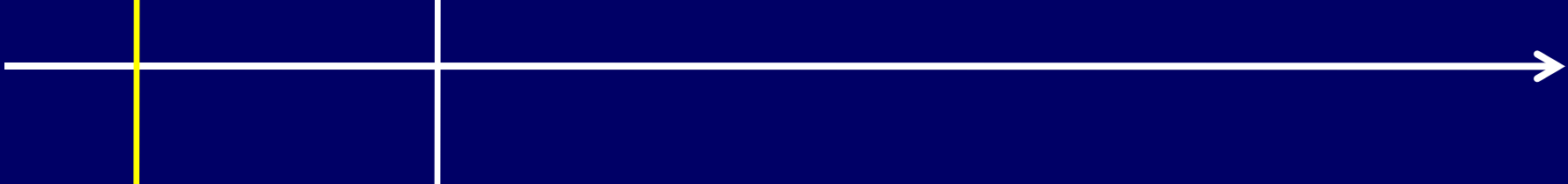
TRASPORTO



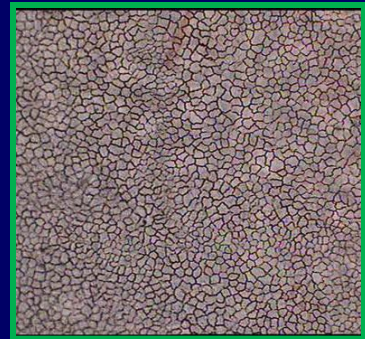
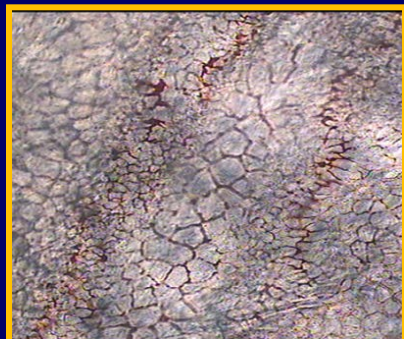
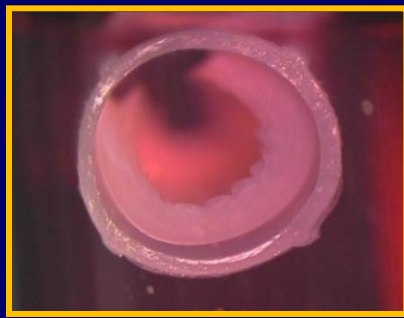
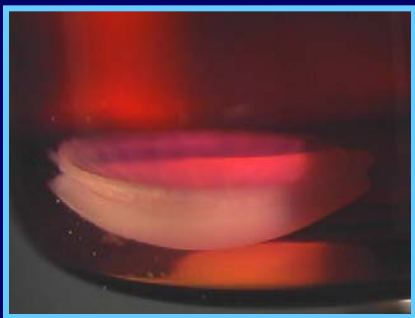
SVILUPPO DEL DISPOSITIVO

IDEA

MODEL



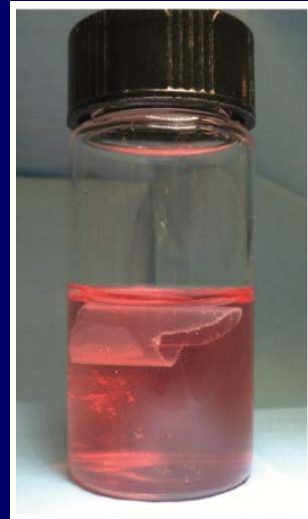
MODELLO



100x – Sucrose, Trypan blue

100x – Sucrose, Alizatina/Trypan Blue

100x – Saccarosio, Alizatina/Trypan Blue



MODIFIED TIP with different diameter

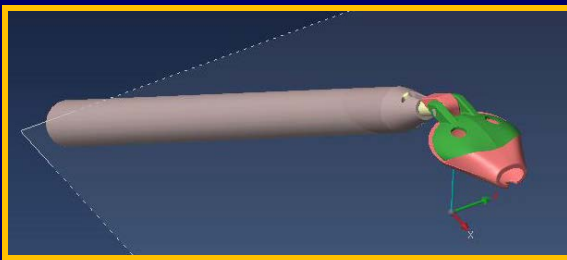
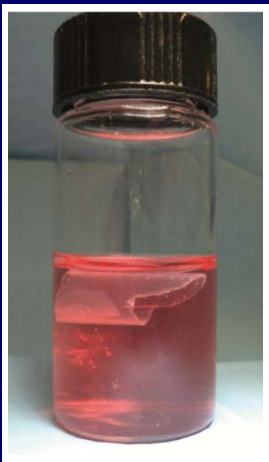
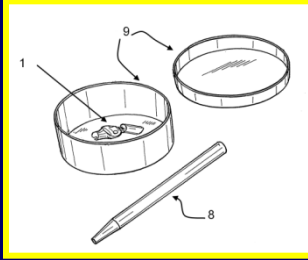
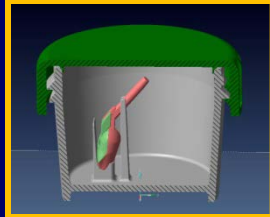
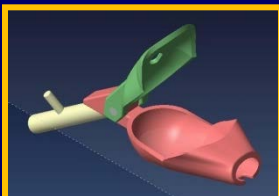
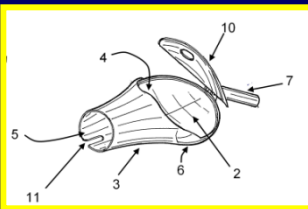
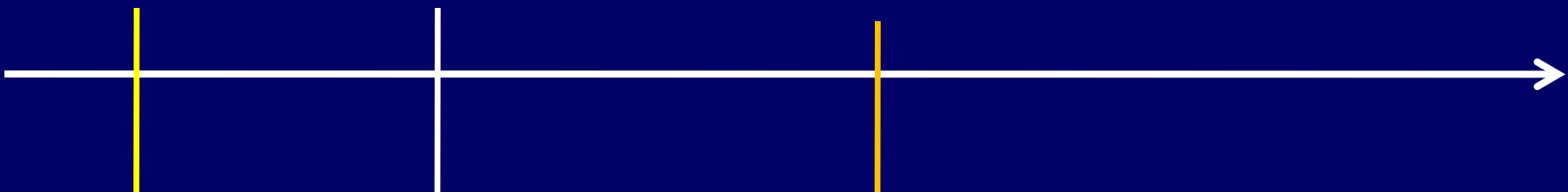
	Free Lenticules	5 mm	5 mm	7 mm
	7 days (n=17)	3 days (n=5)	7 days (n=5)	7 days (n=10)
cell loss (cell/mm ²)	253±177	420±297	620±335	240±97
cell loss (%)	10,7±6,6	23±11	23±11	10,3±4
p	0,08	0,04	0,03	0,3

SVILUPPO DEL DISPOSITIVO

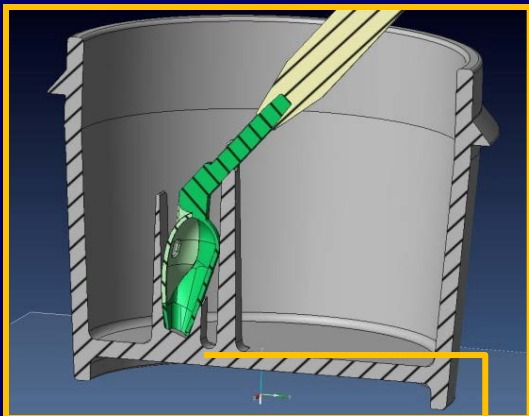
IDEA

MODEL

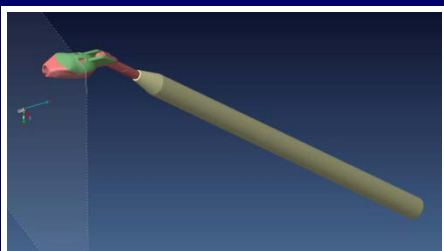
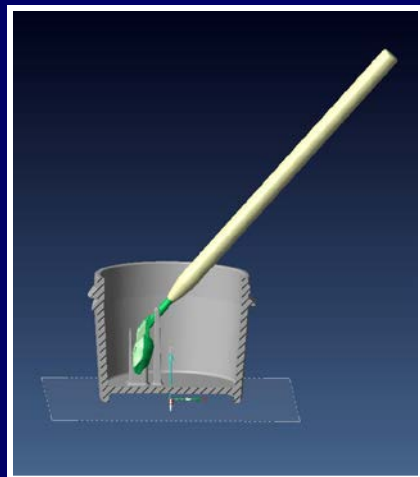
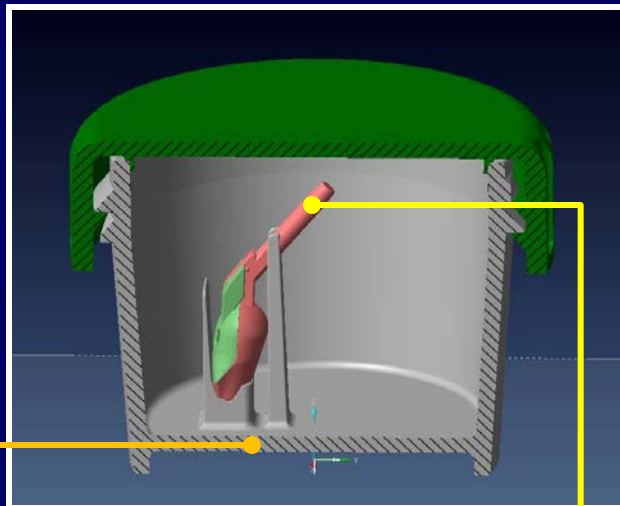
DESIGN



LAYOUT

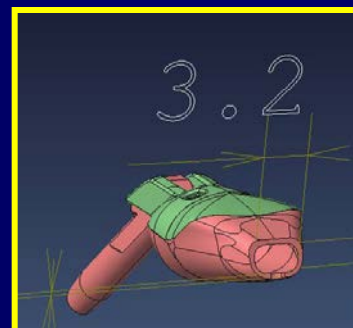
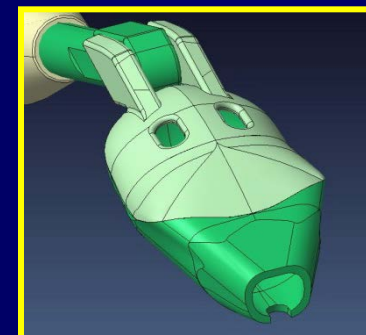
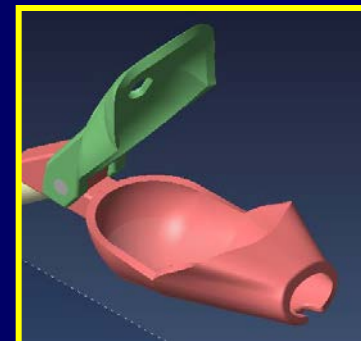


CONTAINER

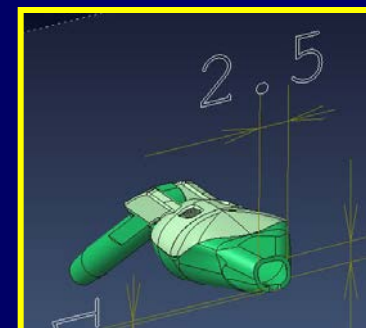


HANDLE

INSERTER / GLIDE



PL Thickness > 120 μ m



PL Thickness \leq 120 μ m

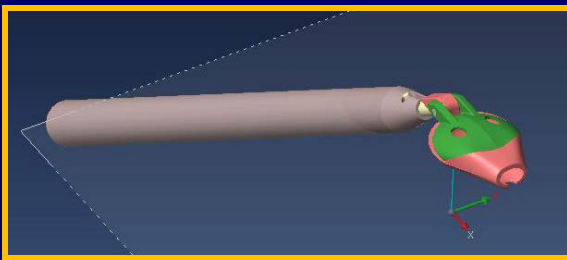
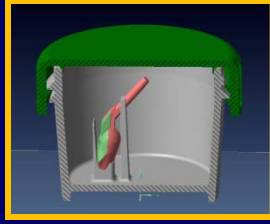
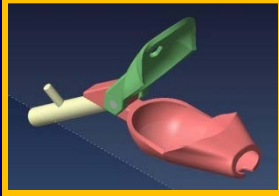
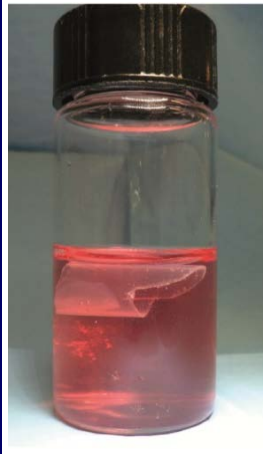
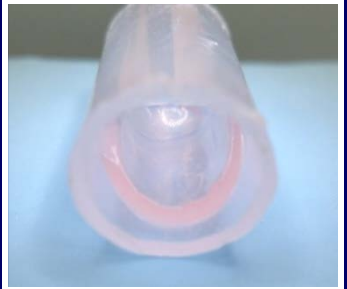
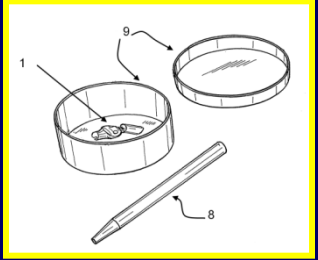
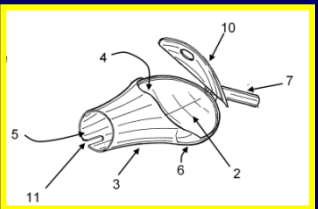
SVILUPPO DEL DISPOSITIVO

IDEA

MODEL

DESIGN

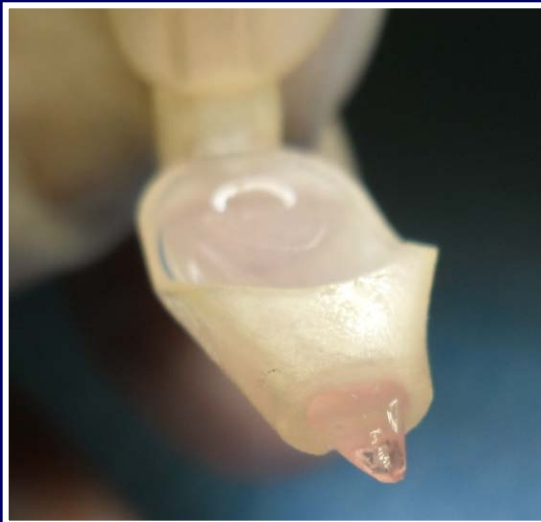
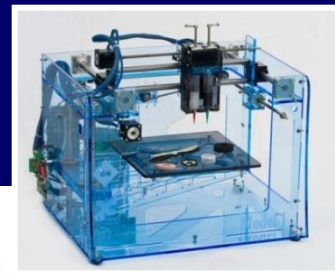
PROTOTYPE



TEST DI VALIDAZIONE

PROTOTIPIZZAZIONE 3D

- Funzionalità
- Materiale
 - *Class: USP-VI*
 - Testato *in vivo*
 - *Medical device*
- *Test in vitro*
 - Analisi dell'endoteliale



TEST DI VALIDAZIONE

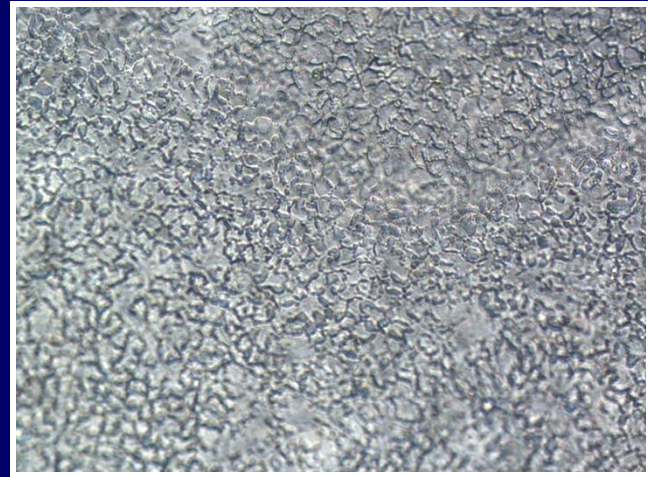
PRE-CUT (n=17)			PRE-LOADED for 7 days in MEM+Dextran		
Density (cell/mm ²)	Mortality (%)	Thickness (μ m)	Density (cell/mm ²)	Mortality (%)	cellloss (cell/mm ²)
2153 \pm 407	0,01 \pm 0.05	130 \pm 45	2064 \pm 379	0,03 \pm 0,12	88 \pm 99

P=0,52

4%



100x – Sucrose and Trypan blue

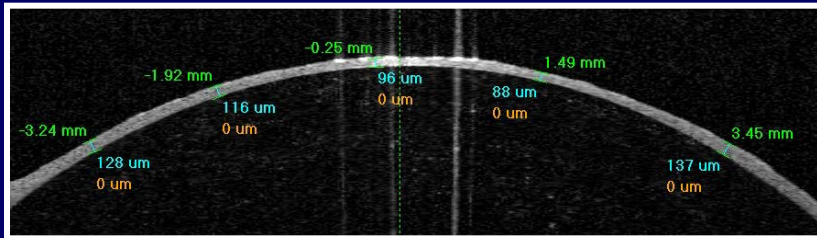


100x – Sucrose and Trypan blue

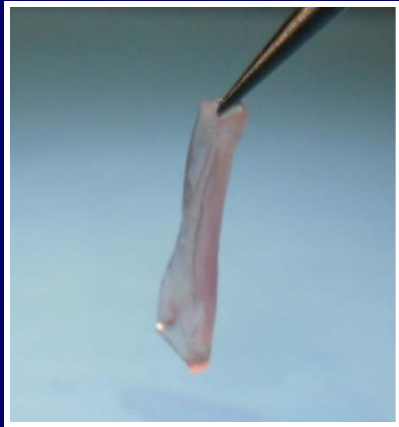
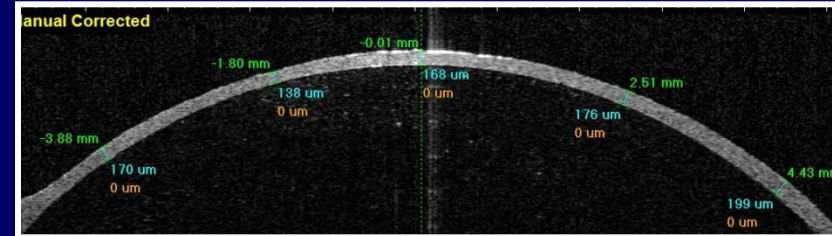
SUPPORTO STROMALE

SPESSORE

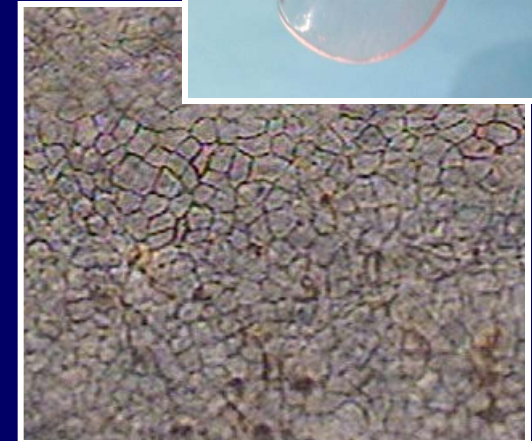
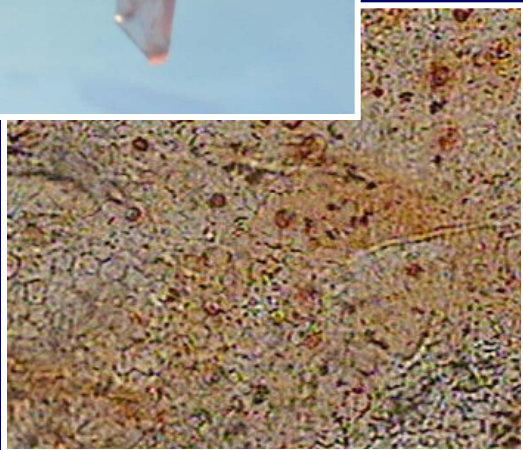
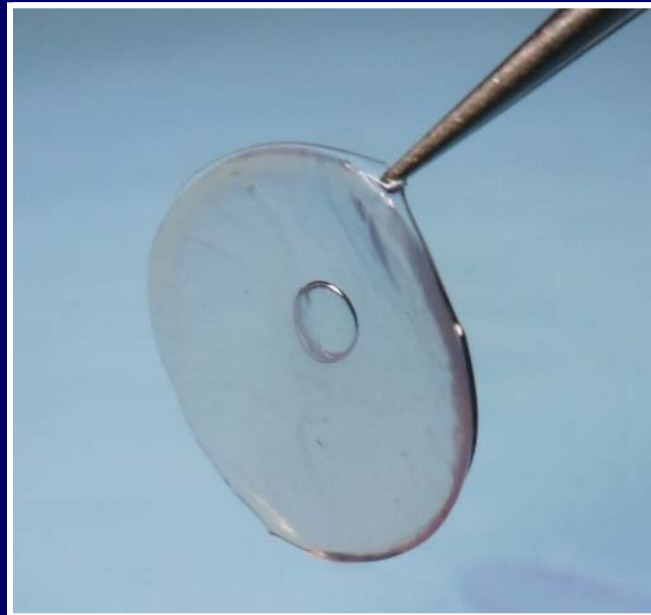
100 μm



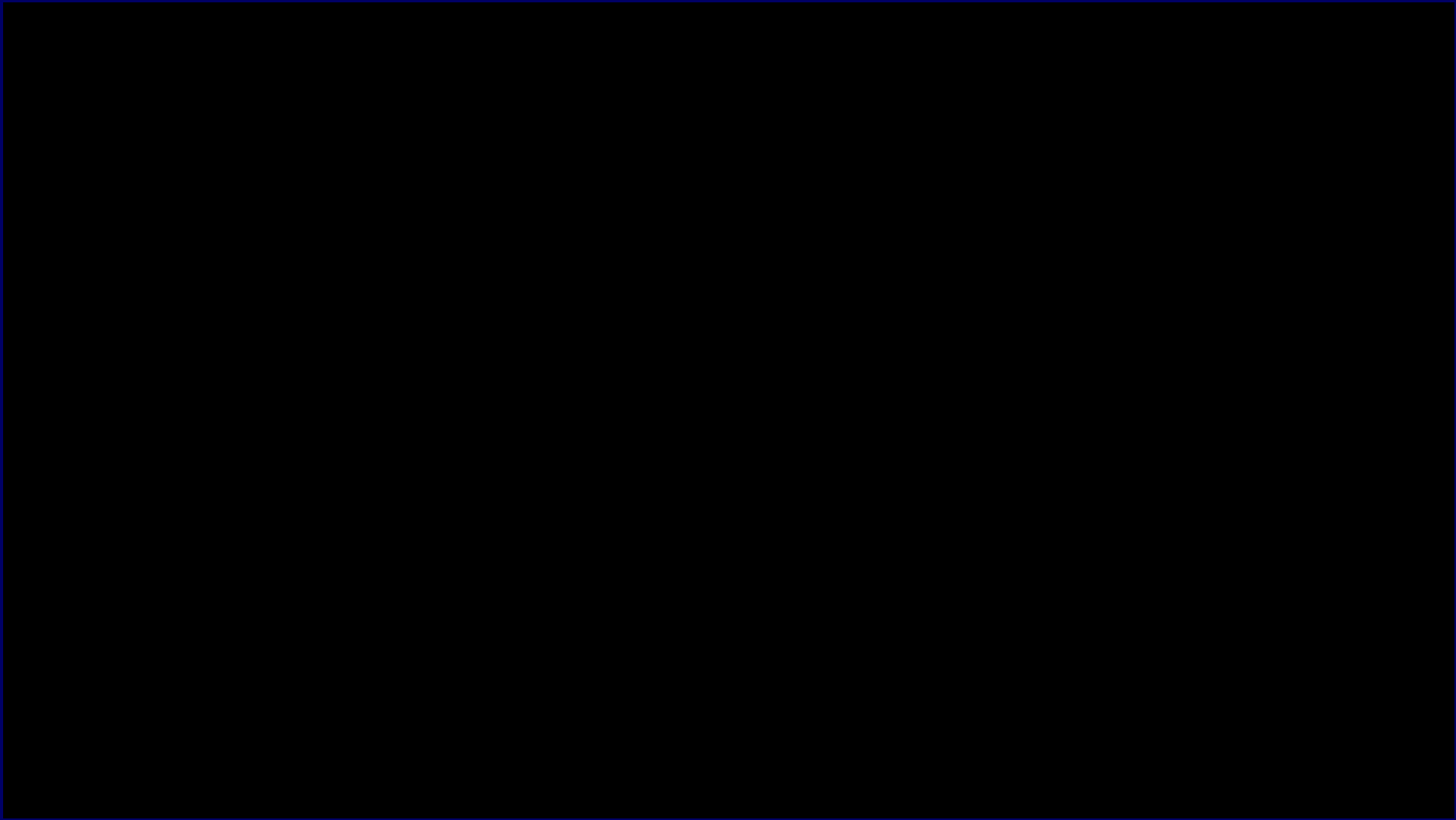
150 μm



Supporto: Lente a contatto



PREPARAZIONE IN BANCA DEGLI OCCHI



CONCLUSIONI

SMART STORAGE GLIDE

- Brevetto USA e Europeo
- 23 lenticoli pre-caricati utilizzati per DSAEK
- PRODUZIONE
 - Preparazione degli stampi
 - Selezione di plastiche certificate
 - Test di validazione finale