AUDIO 3D RESINS

HIGH PERFORMANCE POLYMERS

» PRODUCT CATALOGUE «
2023

DETAX
HIGHEND MEDICAL MATERIALS

MDR CERTIFIED 2020

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3D PREMIUM RESINS

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In-Ear-Monitoring
Earmoulds
Hearing Protection
ITE Shells

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In-Ear-Monitoring
Earmoulds
Hearing Protection
ITE Shells

MEDICALPRINT® SHELL

ITE Shells
In-Ear-Monitoring
Foil-Earmoulds
Hearing Protection (active)

LUXAPRINT® MOULD

In-Ear-Monitoring
Earmoulds
Hearing Protection
ITE Shells

LUXAPRINT® SHELL

ITE Shells
In-Ear-Monitoring
Foil-Earmoulds
Hearing Protection (active)

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PRODUCT OVERVIEW

ACCESSORIES

luxaprint® shellac

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ITE Shells
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luxaprint® shellac color

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ITE Shells
In-Ear-Monitoring
Earmould
Hearing Protection


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In-Ear-Monitoring
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CASTINGS/Casting Mould


Cast Separator PU

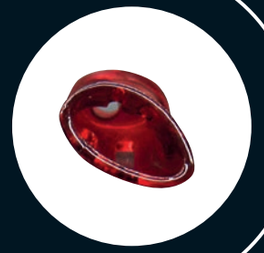
Separating agent for
CASTINGS/Casting Mould


APPLICATIONS

ITE SHELLS
luxaprint® shell
luxaprint® mould
medicalprint® shell
medicalprint® mould
medicalprint® nobreak

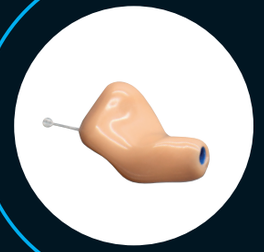

EARMOULD
luxaprint® mould
luxaprint® flex
medicalprint® mould
medicalprint® nobreak

HEARING PROTECTION
luxaprint® mould
luxaprint® flex
medicalprint® mould
medicalprint® nobreak

FOIL-EARMOULD
luxaprint® shell
luxaprint® mould
medicalprint® shell
medicalprint® mould
medicalprint® nobreak

HEARING PROTECTION (ACTIVE)
luxaprint® shell
luxaprint® mould
medicalprint® shell
medicalprint® mould
medicalprint® nobreak



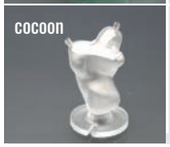

IN-EAR-MONITORING
luxaprint® shell
luxaprint® mould
medicalprint® shell
medicalprint® mould
medicalprint® nobreak

SWIM PLUG
luxaprint® cast 2.0
luxaprint® flex


CASTINGS/ CASTING MOULD
luxaprint® cast 2.0
luxaprint® cocoon

MATRIX

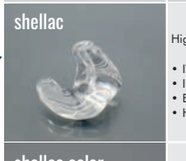
LUXAPRINT®

Material type	Application	Colour	Colour intensity low high	Product features	Medical devices Class MDR
mould 	• In-Ear-Monitoring • Earmoulds • Hearing Protection • ITE Shells	blue, clear, light beige, intensive blue, rose, rose-orange, red	transparent	• low viscosity • highest precision • maximum initial hardness • very high surface hardness • biocompatible	IIa
shell 	• ITE Shells • In-Ear-Monitoring • Foil-Earmoulds • Hearing Protection (active)	beige, intensive blue, intensive red, black,white	transparent opaque	• low sedimentation tendency • highest precision • maximum initial hardness • very high surface hardness • optimal depth curing • biocompatible	IIa
flex 	• In-Ear-Monitoring, • Hearing Protection • Earmoulds • Swim Plugs	clear	transparent	• high impact resistance with memory effect • fast elastic recovery • 90 Shore A at 23 °C • 70 Shore A at 37 °C • biocompatible	IIa
cast 2.0 	• Casting Mould for silicone earmoulds / polyurethane	green-transparent	transparent	• easy to remove • very low viscosity	TEC resin
cocoon 	• Special Casting Mould for silicone earmoulds	clear-transparent	transparent	• easy to remove < 2 sec • flexible and stable in form • filling level control • usage without separator	TEC resin

MEDICALPRINT®

Material type	Application	Colour	Colour intensity low high	Product features	Medical devices Class MDR
mould 	• Earmoulds • Hearing Protection • In-Ear-Monitoring • ITE Shells	brilliant-clear, rose, rose-orange	transparent	• low viscosity • high impact resistance • high initial transparency • maximal precision • biocompatible	IIa
shell 	• ITE Shells • Foil-Earmoulds • Hearing Protection (active) • In-Ear-Monitoring	beige, blue-opaque, red-opaque, black, skin, white	opaque	• low sedimentation tendency • high impact resistance • break resistance • maximal precision • optimal depth curing • biocompatible	IIa
nobreak 	• Earmoulds • Hearing Protection • In-Ear-Monitoring • ITE Shells	beige, clear, rosé	transparent	• highest breaking strength • max. impact resistance • high initial transparency • easy processing	in process

LUXAPRINT® LACQUERS

Material type	Application	Colour	Colour intensity low high	Product features	Medical devices Class MDR
shellac 	High gloss sealing: • ITE Shells • In-Ear-Monitoring • Earmoulds • Hearing Protection	transparent	transparent	• easy to clean surface • „blue ray" yellowing protection • high surface hardness • strong adhesion • very low viscosity • biocompatible	IIa
shellac color 	Coloured sealing: • ITE Shells • In-Ear-Monitoring • Earmoulds • Hearing Protection	blue, brown, yellow, green, orange, red, black, violet	transparent	• colours freely mixable • long-term colour stable • extended colour stability • scratch proof • very low viscosity • strong adhesion • biocompatible	IIa
flex coat 	Soft surface sealing for hard & soft Earmoulds: • In-Ear-Monitoring, • Hearing Protection • Earmoulds • Swim Plugs	transparent	transparent	• permanently soft • strong bonding • „blue ray" yellowing protection • low viscosity • perfect for dipping • biocompatible	IIa

LUXAPRINT®

- Bisphenol A-free, MMA free
- highest initial hardness
- minimal initial discolouration
- highest surface hardness
- drying process

MEDICALPRINT®

- MMA free
- high initial hardness
- no initial discolouration
- highest impact resistance
- no drying process

MDR certified · Medical Product Class I · Medical Product Class IIa · Technical Product · Eco-Bag 3/5 kg

36 Months Shelf life · Premiumquality · THF-MA free · Bisphenol A free · MMA free

THF-MA-free does not contain any tetrahydrofurfuryl methacrylate [Reproductive Toxicity, Cat. 1B] **BPA-free** does not contain any raw material based on bisphenol A [Reproductive Toxicity, Cat. 1B] **MMA-free** does not contain any methyl methacrylate **MDR** Medical Device Regulation EU

LUXAPRINT® MOULD

IN-EAR-MONITORING
EARMOULDS
HEARING PROTECTION
ITE SHELLS

Light-curing formulation for 3D printing of hard earmoulds & hearing protection.

Colours: blue, clear, light beige, intensive blue, rose, rose-orange, red
Wavelength: 385 nm
Medical Device Class IIa

- High initial hardness
- Max construction precision
- Optimum depth curing
- Low material consumption

BPA FREE
MMA FREE

MDR · 36 MONTHS · CE 0483 · eco · PREMIUM FORMULA

Property	Standard	Unit measurement	Result
Flexural strength	DIN EN ISO 178[1)]	MPa	> 75
Flexural modulus	DIN EN ISO 178[1)]	MPa	> 1750
Tensile strength	DIN EN ISO 527-1[2)]	MPa	> 47
Elongation	DIN EN ISO 527-1[2)]	-	> 9 %
Hardness	-	Shore D	> 84
Biocompatibility	DIN EN ISO 10993-1[3)]	-	complies

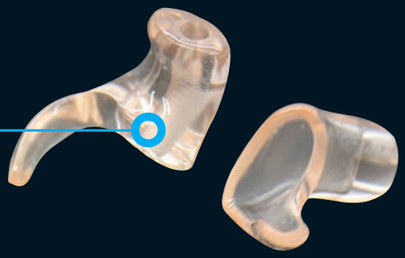
[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2)] Plastics: Determination of tensile properties (in accordance with the norm at room temperature)
[3)] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

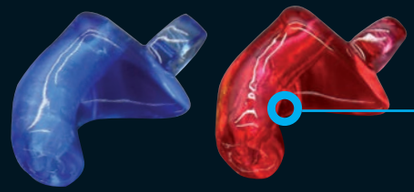
light beige*			1.000 g	03973	
blue	500 g	03716	1.000 g	03610	
clear	500 g	03717	1.000 g	03608	5 kg 03325
intensive blue			1.000 g	03728	5 kg 03324
rose	500 g	03718	1.000 g	03609	5 kg 03323
rose-orange*	500 g	03718	1.000 g	03946	
red	500 g	03715	1.000 g	03611	

* upon request

Wide range of classic colours of supreme transparency, especially for hearing protection and hearing aid earmoulds.

Maximum production process reliability thanks to high green part/initial hardness and strength.





Very high mechanical flexural and tensile strength without brittleness.

LUXAPRINT® SHELL

ITE SHELLS
IN-EAR-MONITORING
FOIL-EARMOULDS
HEARING PROTECTION (ACTIVE)

Light-curing formulation for 3D printing of hard ITE Shells.

Colours: beige, intensive blue, intensive red, black, white
Wavelength: 385 nm
Medical Device Class IIa

- Low viscosity
- High initial hardness
- Max construction precision
- Very high surface hardness

BPA FREE
MMA FREE

MDR · 36 MONTHS · CE 0483 · PREMIUM FORMULA

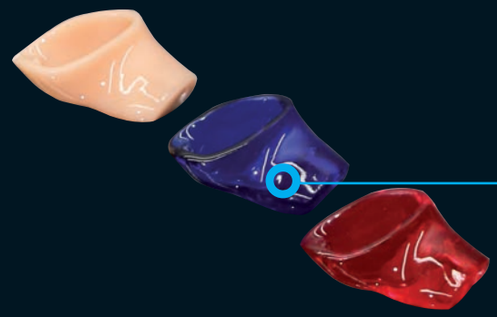
Property	Standard	Unit measurement	Result
Flexural strength	DIN EN ISO 178[1)]	MPa	> 70
Flexural modulus	DIN EN ISO 178[1)]	MPa	> 1800
Tensile strength	DIN EN ISO 527-1[2)]	MPa	> 47
Elongation	DIN EN ISO 527-1[2)]	-	> 9 %
Hardness	-	Shore D	> 82
Biocompatibility	DIN EN ISO 10993-1[3)]	-	complies

[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2)] Plastics: Determination of tensile properties (in accordance with the norm at room temperature)
[3)] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

beige	500 g	03538	1.000 g	03513
intensive blue	500 g	03720	1.000 g	03591
intensive red			1.000 g	03601
black	500 g	03844	1.000 g	03843
white	500 g	03842	1.000 g	03841

Classic or modern: The color palette offers the right colour for every application. Especially suitable for high-end monitoring.

Very high mechanical flexural and fracture strength without brittleness, even in thin-walled ITE shells.



Targeted colour setting for very high opacity with simultaneous optimum curing.

LUXAPRINT® FLEX

SWIM PLUGS
HEARING PROTECTION
EARMOULDS
IN-EAR-MONITORING

luxaprint® flex: Light-curing formulation for 3D printing of soft, massive earmoulds.
luxaprint® flex coat: UV curing one component lacquer for sealing of 3D printed hard and soft earmoulds.

Colour: clear
Wavelength: 385 nm
Medical Device Class IIa

- Permanently soft
- Memory effect
- High impact resistance
- Fast elastic recovery

BPA FREE
THF-MA FREE
MMA FREE

MDR
36 MONTHS
CE 0483
PREMIUM FORMULA

Property	Standard	Unit measurement	Result	
Tensile strength	DIN EN ISO 527-1[1]	MPa	> 8	> 8
Elongation	DIN EN ISO 527-1[1]	-	> 60 %	> 60 %
Tear strength	DIN ISO 34-1[2]	N/mm	> 35 without luxaprint® flex coat	> 45 with luxaprint® flex coat
Hardness	-	Shore A	> 90 at room temperature	> 70 at body temperature
Biocompatibility	DIN EN ISO 10993-1[3]	-	complies	

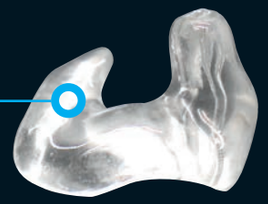
[1] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2] Rubber, vulcanized or thermoplastic: Determination of tear strength (in accordance with the norm at room temperature)
[3] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

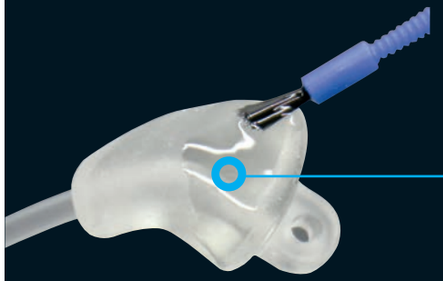
04246	luxaprint® flex	500 g
04245	luxaprint® flex	1.000 g
04247	luxaprint® flex coat*	100 ml

* not MMA-free

Thanks to the memory effect, the earmould returns to its original shape after deformation, retaining the dimensions.

Earmoulds printed with luxaprint® flex guarantee a natural feel: rigid at room temperature, flexible and supple at body temperature.





The permanently soft sealing with luxaprint® flex coat improves tear resistance and impact strength and protects the flexible earmold from dirt and cerumen adhesion.

LUXAPRINT® CAST 2.0

CASTINGS/CASTING MOULD

Light-curing formulation for 3D printing of hard cast forms, manufacturing of silicone earmoulds or polyurethane earmoulds.

Colour: green-transparent
Wavelength: 385 nm
Technical Product

- Easy to break
- Predefined brittleness
- Low viscosity
- „easy peel off“ with Cast Separator 2.0

MMA FREE

36 MONTHS | TEC | eco | PREMIUM FORMULA

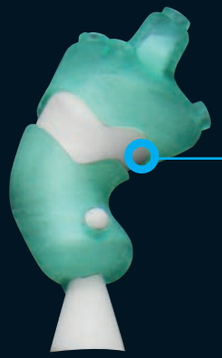
Property	Standard	Unit measurement	Result
Flexural strength	DIN EN ISO 178[1)]	MPa	> 75
Flexural modulus	DIN EN ISO 178[1)]	MPa	> 2300
Hardness	-	Shore D	> 85

[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)

03918	green-transparent	1.000 g
03327	green-transparent	5 kg

Highest process reliability and production precision with minimum wall thickness.

The high stability of the material enables production of very thin-walled cast forms. The transparency enables visual control of the filling process.



Effortless break-up of the cast form due to defined brittleness and easy peel-off when using the cast separator, especially for more complicated structures.

LUXAPRINT® COCOON

CASTINGS/CASTING MOULD

Light-curing formulation for 3D printing of soft elastic, transparent cast forms, manufacturing of silicone earmoulds.

Colour: clear-transparent
Wavelength: 385 nm
Technical Product

- Flexible and stable in form
- Easy to remove
- No sticking to the form
- Common VPS silicones

BPA FREE
THF-MA FREE
MMA FREE

36 MONTHS
TEC
eco
PREMIUM FORMULA

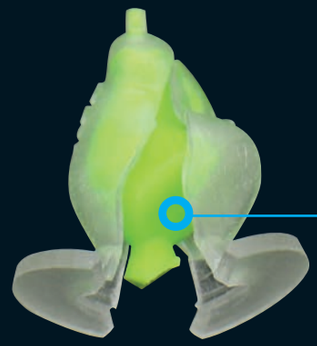
Property	Standard	Unit measurement	Result
Tensile strength	DIN EN ISO 527-1[1)]	MPa	> 7
Tear strength	DIN ISO 34-1[2)]	N/mm	> 30
Hardness	-	Shore A	> 90

[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2)] Rubber, vulcanized or thermoplastic: Determination of tear strength (in accordance with the norm at room temperature)

03031	clear-transparent	1.000 g
03326	clear-transparent	5 kg

Fast peel-off – quick removal of the blank: No adhesion of silicone to the cast form; no additional separator necessary.

The transparent cast form made of luxaprint® cocoon allows visual control of the filling process; air pockets are avoided.



Due to the predetermined tear line and the flexible material properties, the earmould can be demolded without tools. This prevents formation of sharp-edged fragments that could damage the silicone earmould. The nominal tear line can be easily created directly in the design software (3shape, Cyfex).

MEDICALPRINT® MOULD

IN-EAR-MONITORING
EARMOULDS
HEARING PROTECTION
ITE SHELLS

Light-curing formulation for 3D printing of earmoulds, In-Ear-Monitoring & ITE shells.

Colours: brilliant-clear, rose, rose-orange
Wavelength: 385 nm
Medical Device Class IIa

- High initial transparency
- High impact resistance
- Max. construction precision
- No drying process required

THF-MA FREE
MMA FREE

MDR · 36 MONTHS · CE 0483 · eco

Property	Standard	Unit measurement	Result
Flexural strength	DIN EN ISO 178[1)]	MPa	> 75
Flexural modulus	DIN EN ISO 178[1)]	MPa	> 1900
Tensile strength	DIN EN ISO 527-1[2)]	MPa	> 50
Elongation	DIN EN ISO 527-1[2)]	-	> 4 %
Hardness	-	Shore D	> 80
Biocompatibility	DIN EN ISO 10993-1[3)]	-	complies

[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2)] Plastics: Determination of tensile properties (in accordance with the norm at room temperature)
[3)] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

brilliant-clear 2.0	1.000 g	04224	5 kg	03316
rose 2.0	1.000 g	02449	5 kg	03314
rose-orange 2.0*	1.000 g	02904	5 kg	03304

* upon request

Brilliant transparency directly after printing. Long-term colour stability, without yellowing effects due to post exposure.

The high impact strength and good mechanical flexural and fracture strengths ensure long service life of the earmoulds.

Particularly suitable for delicate foil earmolds and RIC earmoulds, with long supports.

MEDICALPRINT® SHELL

ITE SHELLS
IN-EAR-MONITORING
FOIL-EARMOULDS
HEARING PROTECTION (ACTIVE)

Light-curing formulation for 3D printing of hearing aid shells, In-Ear-Monitoring, foil earmoulds..

Colours: beige, blue-opaque, red-opaque, black, skin, white
Wavelength: 385 nm
Medical Device Class IIa

- Very high construction precision
- High impact resistance
- Reduced sedimentation tendency
- No drying process required

THF-MA FREE
MMA FREE

MDR
36 MONTHS
CE 0483

Property	Standard	Unit measurement	Result
Flexural strength	DIN EN ISO 178[1]	MPa	> 75
Flexural modulus	DIN EN ISO 178[1]	MPa	> 1900
Tensile strength	DIN EN ISO 527-1[2]	MPa	> 50
Elongation	DIN EN ISO 527-1[2]	-	> 4 %
Hardness	-	Shore D	> 80
Biocompatibility	DIN EN ISO 10993-1[3]	-	complies

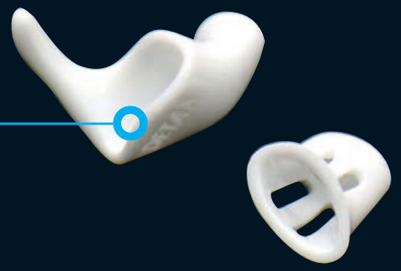
[1] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)
[2] Plastics: Determination of tensile properties (in accordance with the norm at room temperature)
[3] Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

03016	beige 2.0	1.000 g
04164	blue-opaque*	1.000 g
04165	red-opaque*	1.000 g
03043	black*	1.000 g
02192	skin 2.0	1.000 g
04073	white*	1.000 g

* not THF-MA free

Wide range of classic and modern colours, long-term stability, particularly for thin-walled earmolds.

Very high production precision and surface hardness, outstanding mechanical flexural and breaking strength.



The intense colours are particularly suitable for hearing protection earmoulds and can be optimally used in the area of in-ear monitoring for visual side marking.

MEDICALPRINT® NOBREAK

IN-EAR-MONITORING
EARMOULDS
HEARING PROTECTION
ITE SHELLS

Light-curing formulation for 3D printing of earmoulds, In-Ear-Monitoring & ITE shells.

Colours: beige, clear, rose
Wavelength: 385 nm

- Highest breaking strength
- Max. impact resistance
- High initial transparency
- Easy processing

THF-MA FREE

TPO FREE

Property	Standard	Unit measurement	Result
Tensile strength	DIN EN ISO 527-1[1)]	MPa	> 45*
Elongation	DIN EN ISO 527-1[1)]	-	> 7 %*
Hardness	-	Shore D	> 70*

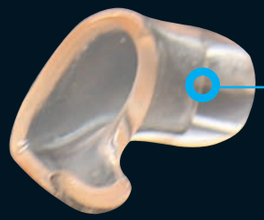
[1)] Plastics: Determination of flexural properties (in accordance with the norm at room temperature)

04429	medicalprint® nobreak	1.000 g
04430	medicalprint® nobreak	5 kg

* Q1/2023

Classic color selection for the fabrication of ITE shells and earmolds.

No cracks, breaks or chipping due to extremely high impact resistance.



Maximum space efficiency thanks to extremely thin-walled shells and foil earmolds.

LUXAPRINT® shellac

HIGH GLOSS SEALING:

ITE SHELLS
IN-EAR-MONITORING
EARMOULD
HEARING PROTECTION

Light curing lacquer for permanent surface sealing of 3D printed earmoulds made of (meth)acrylat.

Colour: transparent
Medical Device Class IIa

- Easy to clean surface
- High surface hardness
- Strong bonding
- Very low viscosity
- „blue ray“- yellowing protection

THF-MA FREE

MDR · CE 0483 · PREMIUM FORMULA

Brilliant finish without mechanical repolishing.

Easy to process (dip/brush). Creates a homogeneous, scratch-resistant and easy-to-clean surface (easy clean) and reduces cerumen adhesion.

Can be used in combination with luxaprint® shellac color for mixing individual colours or for marking lettering.

04006	transparent	50 ml
03594	transparent	100 ml
03595	transparent	300 ml

LUXAPRINT® shellac color

COLOURED SEALING:

ITE SHELLS
IN-EAR-MONITORING
EARMOULD
HEARING PROTECTION

Light curing lacquer for permanent coloured sealing of 3D printed earmoulds made of (meth)acrylat.

Colours: blue, brown, yellow, green, orange, red, black, violet
Medical Device Class IIa

- Colours freely mixable
- Long-term colour stable
- Extended colour stability
- Scratch-proof
- Very low viscosity

THF-MA FREE

MDR · CE 0483 · PREMIUM FORMULA

blue	50 ml	03701	100 ml	03683
brown	50 ml	03995	100 ml	03994
yellow	50 ml	03702	100 ml	03684
green	50 ml	03705	100 ml	03678
orange	50 ml	03703	100 ml	03685
red	50 ml	03700	100 ml	03682
black	50 ml	03857	100 ml	03856
violet	50 ml	03704	100 ml	03686

FREELY MIXABLE

Transparent earmoulds can be simultaneously sealed with a high-gloss finish and permanently colour-coated. The surface is protected and has long-term colour stability.

Skin tones unlimited: All colours are individually mixable. As a result, any desired skin tone can be achieved. There are no limits to the colour wishes.

Easy to process (dip/brush). Creates a homogeneous, scratch-resistant, easy-to-clean surface and reduces cerumen adhesion.

LUXAPRINT® softseal Primer

BONDING OF
(METH-)ACRYLATES AND SILICONES (SOFTTIP)

Primer for perfect binding of (Meth-)acrylates (luxaprint®, medicalprint®) and silicones (detax softwear® 2.0, earflex®).

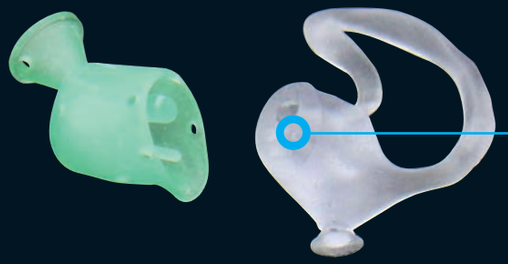
Colour: transparent
Medical Device Class IIa

- Especially for combination earmoulds (hard / soft)
- Excellent and permanent bonding
- Firm fit, even during chewing movements
- Easy handling

BPA FREE
THF-MA FREE

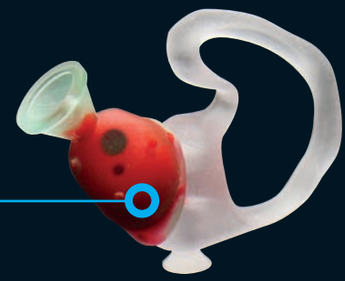
MDR CE 0483 PREMIUM FORMULA

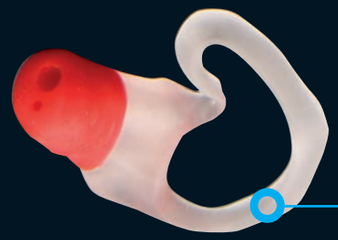
04161	Bottle with brush	15 ml



Reliable adhesive composite of (meth)acrylate and silicone. Easy surface conditioning by means of integrated brush.

The cast form printed with luxaprint® cast 2.0 brings the silicone into the desired shape for the soft-tip application.





Combination earmoulds (hard/soft) improve fit and wearing comfort. The soft-tip application adapts harmoniously to the chewing movements, among others.

Cast Separator 2.0

SEPARATING AGENT FOR CASTINGS/CASTING MOULD

Separating agent for an effective isolation of 3D printed cast forms against VPS or A-silicone.

Colour: transparent
Technical Product

BPA FREE · THF-MA FREE · MMA FREE

03636	Cast Separator 2.0	500 ml

Cast Separator PU

SEPARATING AGENT FOR CASTINGS/CASTING MOULD

Separating agent for an effective isolation of 3D printed cast forms against thermoplastic polyurethane.

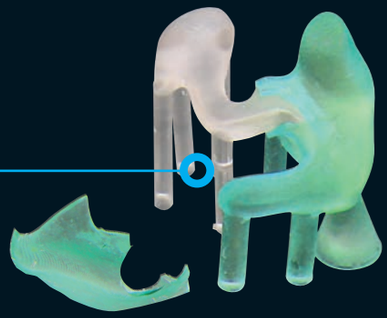
Colour: transparent
Technical Product

BPA FREE · THF-MA FREE · MMA FREE

04142	Cast Separator PU	500 ml

Provides a durable and safe insulating layer for the additively manufactured cast forms.

Effortless and easy demolding of the silicone and PU blank.



The ready-to-use immersion solution enables quick and easy application.

PROCESS VALIDATION

3D PRINTERS

Qualification

- ☑ Done
- ☐ In process

	ASIGA MAX Max / Mini	ASIGA Pico2	ASIGA PRO2	ASIGA PRO 4K	MICROLAY Versus	Miicraft Prime / Hyper Series	Miicraft Ultra Series	Miicraft Profession / Advance Series	Rapid shape 20 / 30 Series	Rapid shape 40 Series	Rapid shape 90 Series	W2P
LUXAPRINT®												
luxaprint® mould In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
luxaprint® shell ITE Shells In-Ear-Monitoring Foil-Earmoulds Hearing Protection (active)	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
luxaprint® flex Swim Plugs Hearing Protection Earmoulds In-Ear-Monitoring	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
luxaprint® cast 2.0 CASTINGS / Casting Mould	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
luxaprint® cocoon CASTINGS / Special Casting Mould	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
MEDICALPRINT®												
medicalprint® mould In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
medicalprint® shell ITE Shells In-Ear-Monitoring Foil-Earmoulds Hearing Protection (active)	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑	☑
medicalprint® nobreak In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

edition: 05.10.22

CERTIFIED
ISO 13485:2016

VALIDATED
Printing Process

BIOCOMPATIBLE
ISO 10993

CERTIFIED VALIDATED RELIABLE

Only the combination of high-performance resins with scientifically based expert knowledge from all areas of the digital workflow leads to cumulated expertise, to truly innovative products, and thus to an unlimited choice of materials. DETAX 3D materials are validated for all standard DLP printers. Our validation portfolio is continuously being expanded with new materials and qualified printers. To this end, our experts check and document complete process sequences in accordance with the relevant standards and regulatory requirements. This ensures permanently reproducible results and constant product quality.

Digital Workflow requires profound material competence and a close cooperation with the technology partners in order to perfectly match individual elements of the process chain. For transparency and process reliability, all instructions for use comprise an overview of validated printers, certified finishing equipment (post-exposure, cleaning, etc.) and detailed flowcharts of the manufacturing process.

Our expert team will support you with useful tips.

PROCESS VALIDATION

CURING DEVICES

Qualification

- ☑ Done
- ☐ In process
- ● On request

	NK Optik Otoflash G171 N2	Rapid Shape RS Cure	Dentalfarm Photopol	Meccatronic-core BB Cure	Scheu Imprimo Cure	Phrozen Phrozen Cure	Sprint Ray Pro Cure	Formlabs Form Cure	Dreve PCU LED N2
LUXAPRINT®									
luxaprint® mould In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☑	☐	☐	●	●	☐	●	●	●
rose-orange, clear, rose, light beige	☑	☑	☐	☐	●	☐	●	●	●
red, blue, int.-blue									
luxaprint® shell ITE Shells In-Ear-Monitoring Foil-Earmoulds Hearing Protection (active)	☑	☑	☑	●	●	☐	●	●	●
beige, white	☑	☑	☑	●	●	☐	●	●	●
black, int.-blue, int.-red									
luxaprint® flex Swim Plugs Hearing Protection Earmoulds In-Ear-Monitoring	☑	☑	☑	☐	☐	☐	●	●	●
clear									
luxaprint® cast 2.0 CASTINGS / Casting Mould	☑	☑	☑	☑	☑	☑	☑	☑	☑
green-transparent									
luxaprint® cocoon CASTINGS / Special Casting Mould	☑	☑	☑	☑	☑	☑	☑	☑	☑
transparent									
MEDICALPRINT®									
medicalprint® mould In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☑	☑	☑	☐	☐	☐	●	☐	●
brilliant-clear 2.0, rose 2.0, rose-orange 2.0,	☑	☑	●	●	●	●	●	●	●
clear, rose									
medicalprint® shell ITE Shells In-Ear-Monitoring Foil-Earmoulds Hearing Protection (active)	☑	☑	☑	☐	☐	☐	●	☐	●
beige 2.0, skin 2.0	☑	☑	☑	☐	☐	☐	●	☐	●
black, blue-opaque, red-opaque									
white	☑	●	☑	●	●	●	●	●	●
medicalprint® nobreak In-Ear-Monitoring Earmoulds Hearing Protection ITE Shells	☐	☐	☐	●	●	●	●	●	●

edition: 06.10.22

GOOD TO KNOW ...

BOTTLE ROLLER

By using a bottle roller, optimum mixing of the material is achieved, thus preventing possible segregation. The Eco Bags can be homogenized with an appropriate attachment.

CLEANING

Best cleaning results of the production jobs are achieved when the pre- and post-cleaning are carried out in separate tanks in the ultrasonic unit. After cleaning with isopropanol, it is recommended to clean the bores/openings with compressed air.

POST-CURING UNIT

The post-curing units recommended in the instructions for use ensure optimum through-hardening and surface curing, thus a biocompatible end product, and ensure high color brilliance and transparency, without discoloration.

DETAX EXPERTS@

3D WORKFLOW

SCANNING

Digitization of the patient's initial situation is the basis for the digital manufacturing process. It is done by scanning the ear directly, or the impression. From the data thus generated, a three-dimensional surface structure is generated – in most cases in the form of an STL file –, which is then transferred to a design software.

SLICING

After completion of the design (CAD), the slicing software prepares the objects for printing. The slicing process creates the individual layers to be exposed. The software serves as an intermediary between the 3D model and the 3D printer.

PRINTING

For a precise print job, the setting parameters of the corresponding material in the printer are necessary. These data are used not only to control the exposure process for the material, but also to determine the corresponding movement mechanics of the printers. Coordination of these processes is the prerequisite for successful DLP/LCD printing of challenging structures.

CLEANING

After printing, the non-polymerized material on the surface must be removed so as to leave no residue before the final post-exposure. Drain the print job off in the printer, then carry out a 2-stage secondary cleaning with isopropanol in an ultrasonic device. Cleaning can also be carried out in suitable separate devices.

CURING

The properties of the final product depend, among other things, on the finishing process. Correct post-exposure is very important for biocompatibility. To ensure that the printed structures are fully cured, post-exposure in devices with LED lamps or xenon flashlight in an inert gas atmosphere is recommended.

FINISHING

Finally, the surface is finished as required, e.g. mechanically polished. Perfect fit, optimal product properties and reliable reproduction are the results of a validated and certified process.

CERTIFICATION

DETAX MDR CERTIFIED 2020

All luxaprint® and medicalprint® Class IIa printing resins have been MDR-certified since October 2020. Thus, DETAX 3D materials are among the first in the industry with MDR certification.

PREMIUM SHELF LIFE 36 MONTHS

All DETAX 3D Premium printing materials have a shelf life of 36 months and can be used during this period without any loss of quality in the printing process.


mdc

EU Quality Management System Certificate


EC Certificate

mdc medical device certification GmbH

DETAX GmbH & Co. KG
Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

Quality System

Annex II – excluding Section 4 of the Council Directive 93/42/EEC


Certificate

mdc medical device certification GmbH

DETAX GmbH & Co. KG
Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

Quality Management System

EN ISO 13485


CERTIFICATE

DETAX GmbH & Co. KG

ISO 13485 : 2016

MDSAP


Annex to certificate
Certificate registration No.: 352715 MDSAP16
Certificate unique ID: 170770120
Effective date: 2020-09-15

DETAX GmbH & Co. KG


Annex to certificate
Certificate registration No.: 352715 MDSAP16
Certificate unique ID: 170770120
Effective date: 2020-09-15

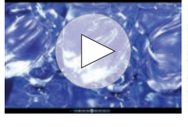
DETAX GmbH & Co. KG

#HELLO ECOBAG

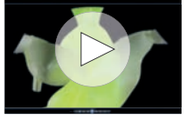
In addition to the 1-kg standard bottles, many luxaprint® and medicalprint® materials will in future be offered in practical 3- or 5-kg Eco Bags. The bags are perfect for frequent users and are handy to use: The 2 handles (top and bottom) make it easy to fill the printer tray. Highly pigmented materials can be homogenized with a roller mixer (with appropriate attachment). The empty bag can be rolled up to a tiny ball, thus taking up much less waste volume and significantly reducing plastic waste.

PRODUCTCLIPS „HOW TO“

luxaprint® mould



luxaprint® cocoon



luxaprint® shell

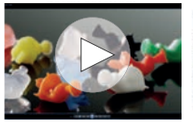
cast separator

luxaprint® cast

luxaprint® shellac color

luxaprint® flex

detax softwear®



DETAX
HIGHEND MEDICAL MATERIALS

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