Workshop: "Silicone and its applications in the medical field"
MIRANDOLA , Hotel La Cantina, Via Statale 179, Medolla
4th june 2024, 11h00 & 15h00

SILICONE'S CONTRIBUTION AND PROCESSES FOR MEDICAL FIELD

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Laboratory and R&D manager

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EXSTO GROUP

SUMMARY

1. The history of silicone
2. Silicone production
3. How silicone takes shape ?
4. Silicone transformation processes
5. Physico-chemical properties of silicones versus applicable regulations

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Key dates for raw materials

1823 - 1854

Jöns Jakob Berzelius
Henri Sainte-Claire Deville

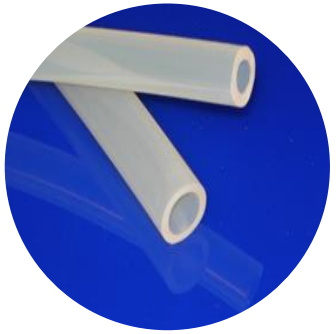
Isolate the element silicon from sand in metal form

1930-1940

Frederic Stanley Kipping
James Franklin Hyde

Creating silicone from silicon

Key dates for raw materials



1946

1st implantation into human body

1950

Boric acid + PDMS
=
Silly PUTTY

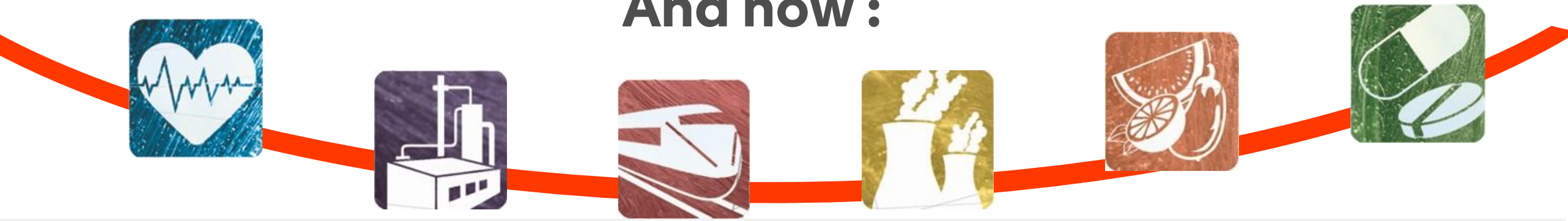
1960

First
Pressure Sensitive
Adhesive (PSA)

1969

Neil Armstrong
had silicone soles!

And now :



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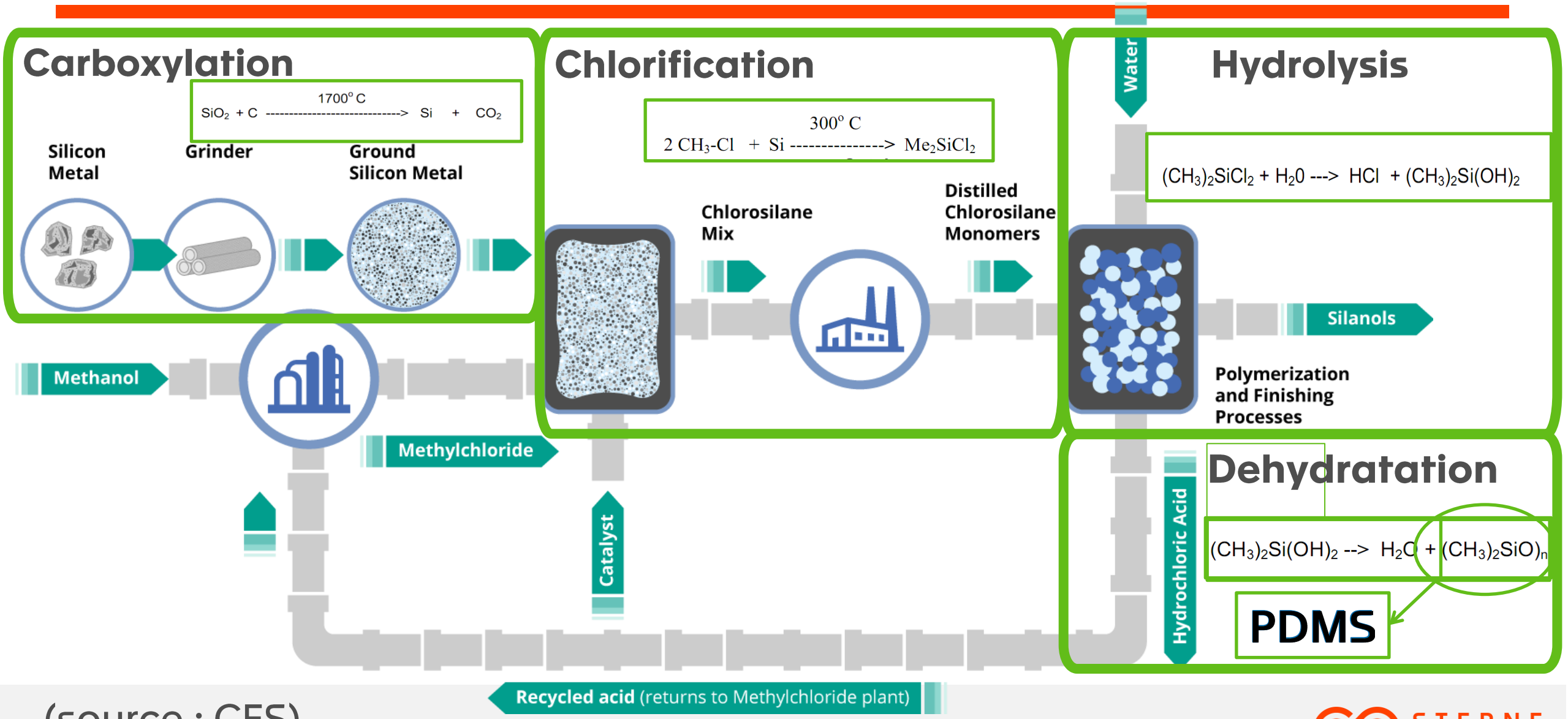
Silicone manufacturing stages



(source : CES)

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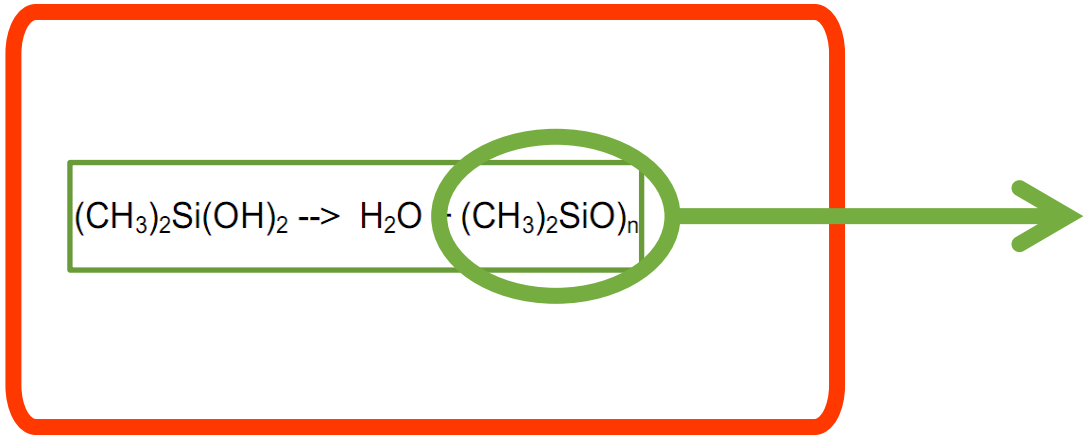
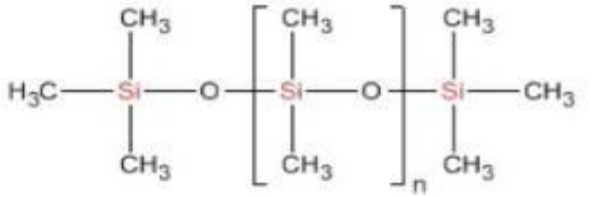
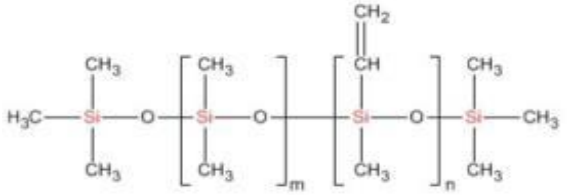
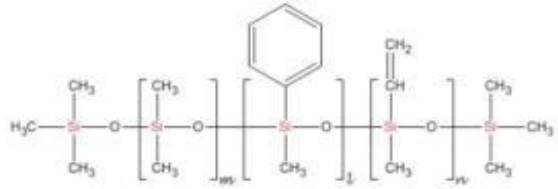
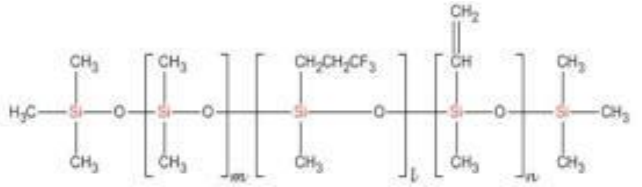
SILICONE ELASTOMERS: FUNCTIONAL GROUPS



Classification	Lewis representation
MQ (PDMS)	
VMQ	
PVMQ	
FVMQ	

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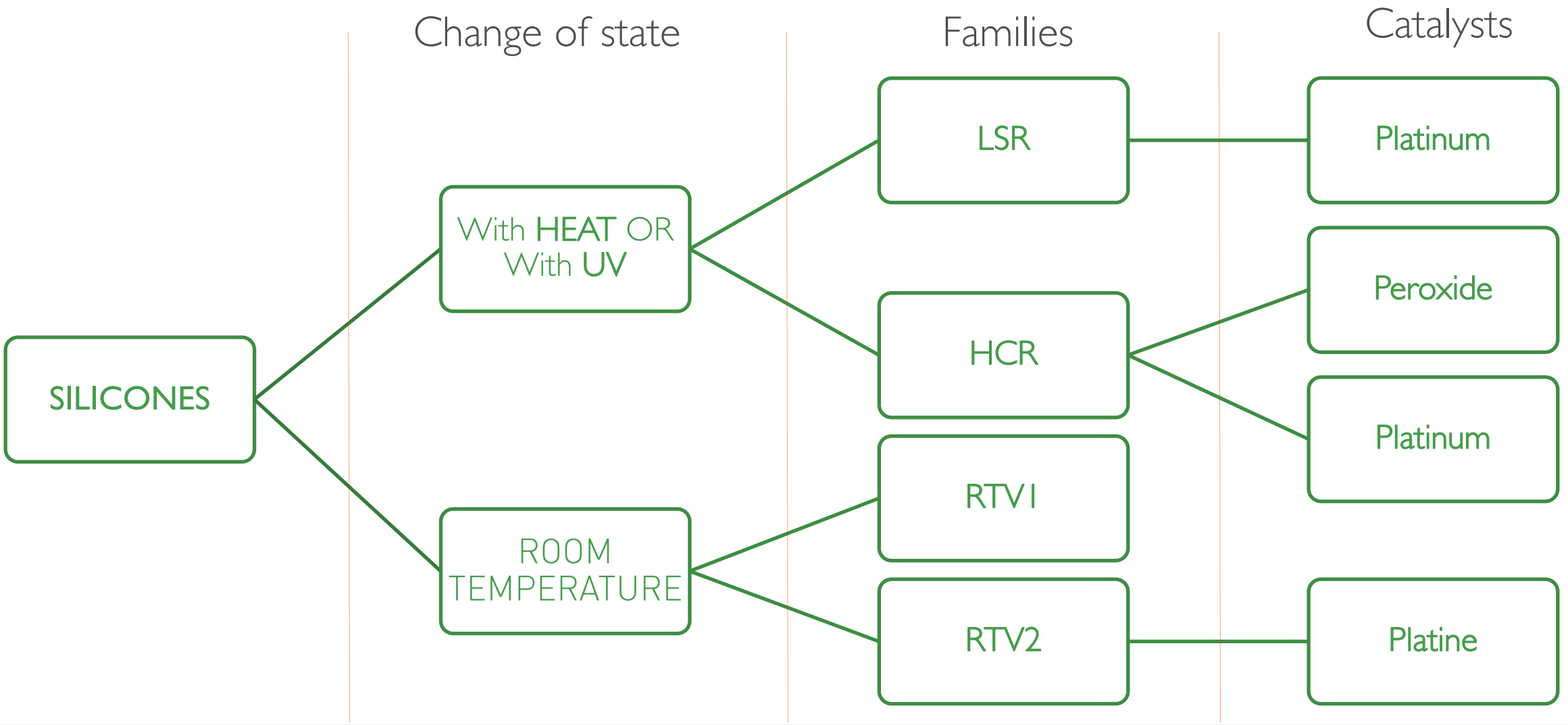
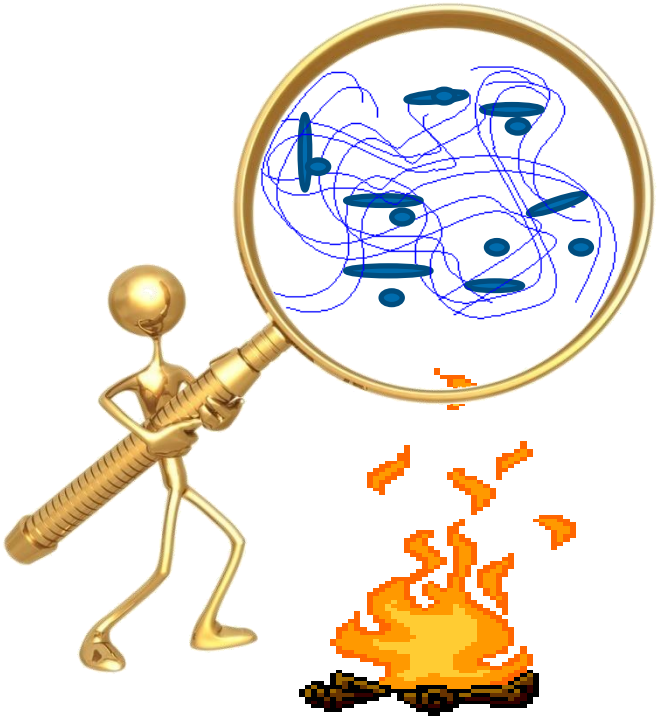
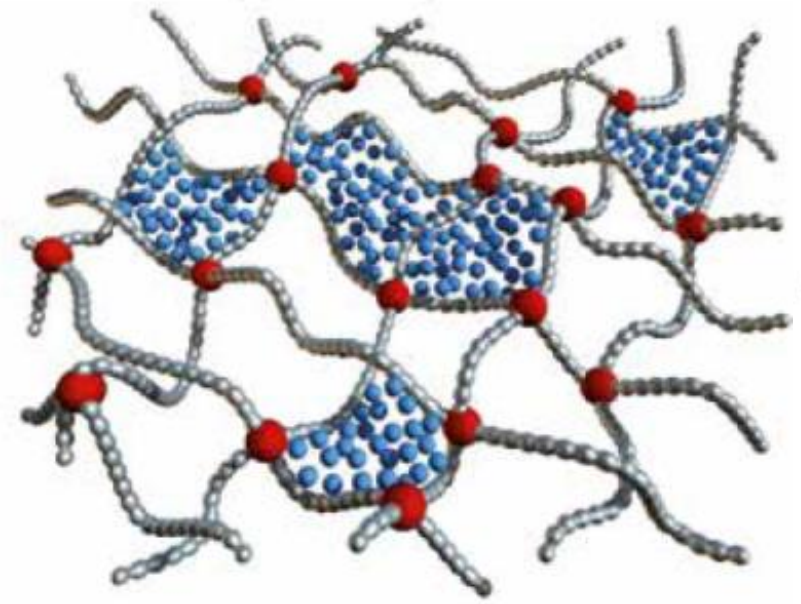
SILICONE GLOSSARIES



Definition of cross-linking





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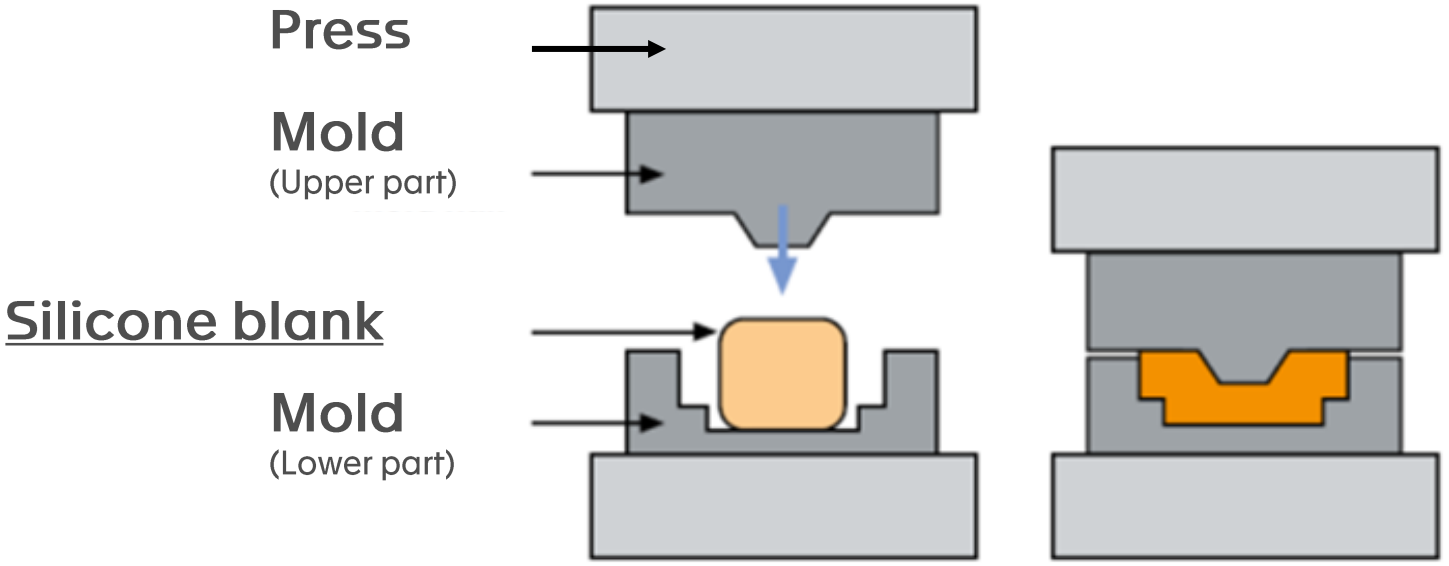
TYPE OF MOLDING : COMPRESSION



Temperature 120 < T°C < 180°C depends on the type of silicone

Curing time Depends on thickness

Current applications Low production runs, big parts or overmodling

Materials : **Deposited in the mold by the operator**
Peroxide (specific) or platinum catalyst

MOLDING CYCLE : COMPRESSION

0. Deburring previous part

1. Weighing the blank

2. Shaping the blank

3. Placing the blank in the mould

4. Closing the mould and pressurising

5. Cross-linking

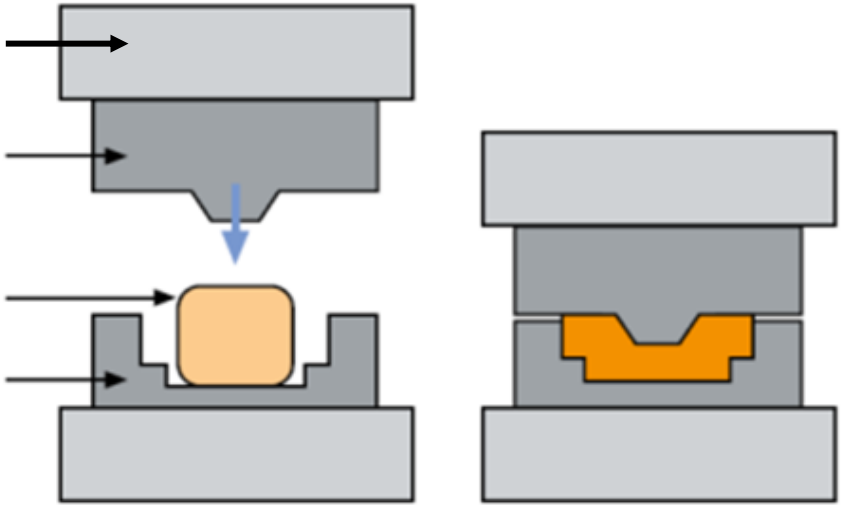
6. Demoulding

Press

Mold
(Upper part)

Silicone blank

Mold
(Lower part)



TYPE OF MOLDING : LSR Injection molding

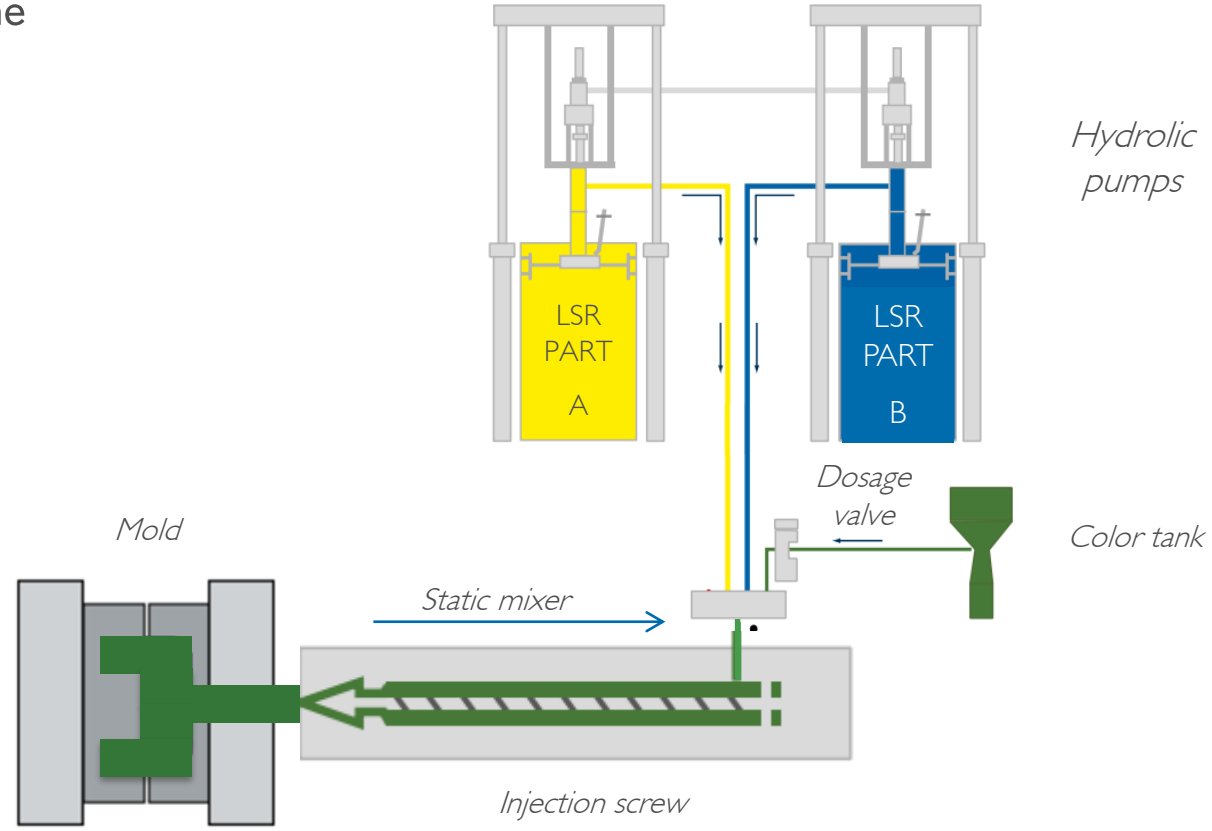
Temperature 120 < T°C < 180°C depends on the type of silicone

Curing time Depends on thickness

Materials : **LSR injected by the machine**
Platinum catalyst
No risk of material contamination

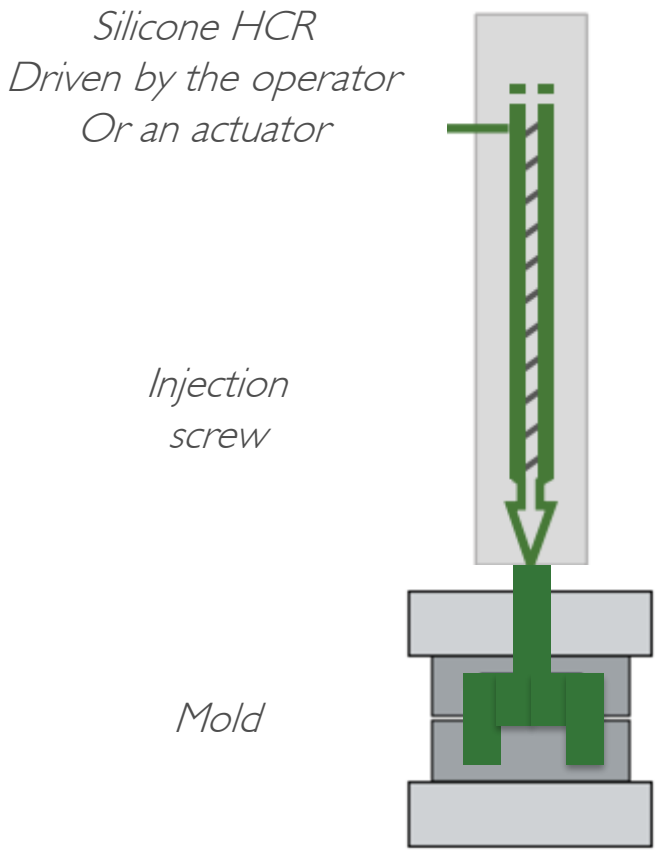
Current application : Medium and large production runs

Thin parts
Overmoulding

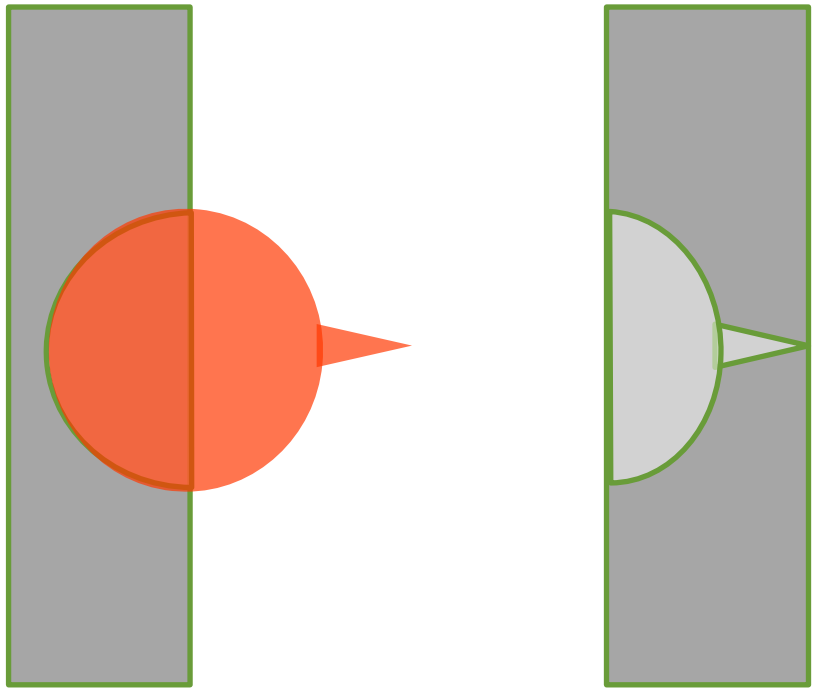


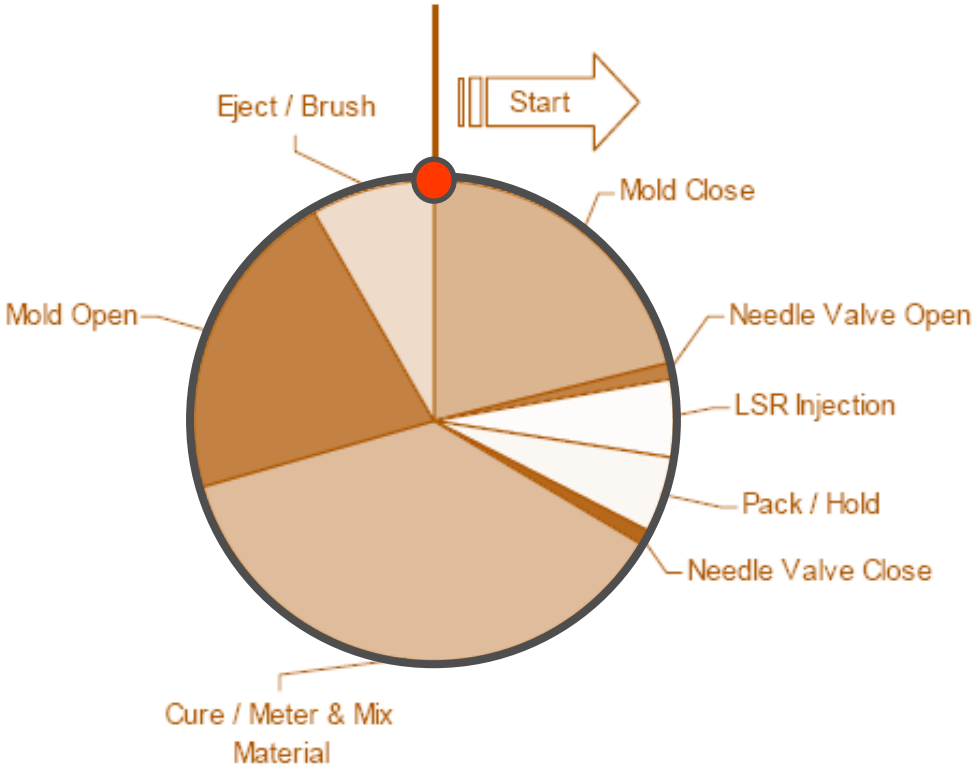
TYPE OF MOLDING : HCR Injection molding

Temperature	115°C < T°C < 190°C dépends de la matière
Curing time	Depends on thickness
Current application : production runs	Medium and large Thin parts Overmoulding
Materials : **actuator**	**HCR injected by the machine or an** Platinum or peroxide catalyst

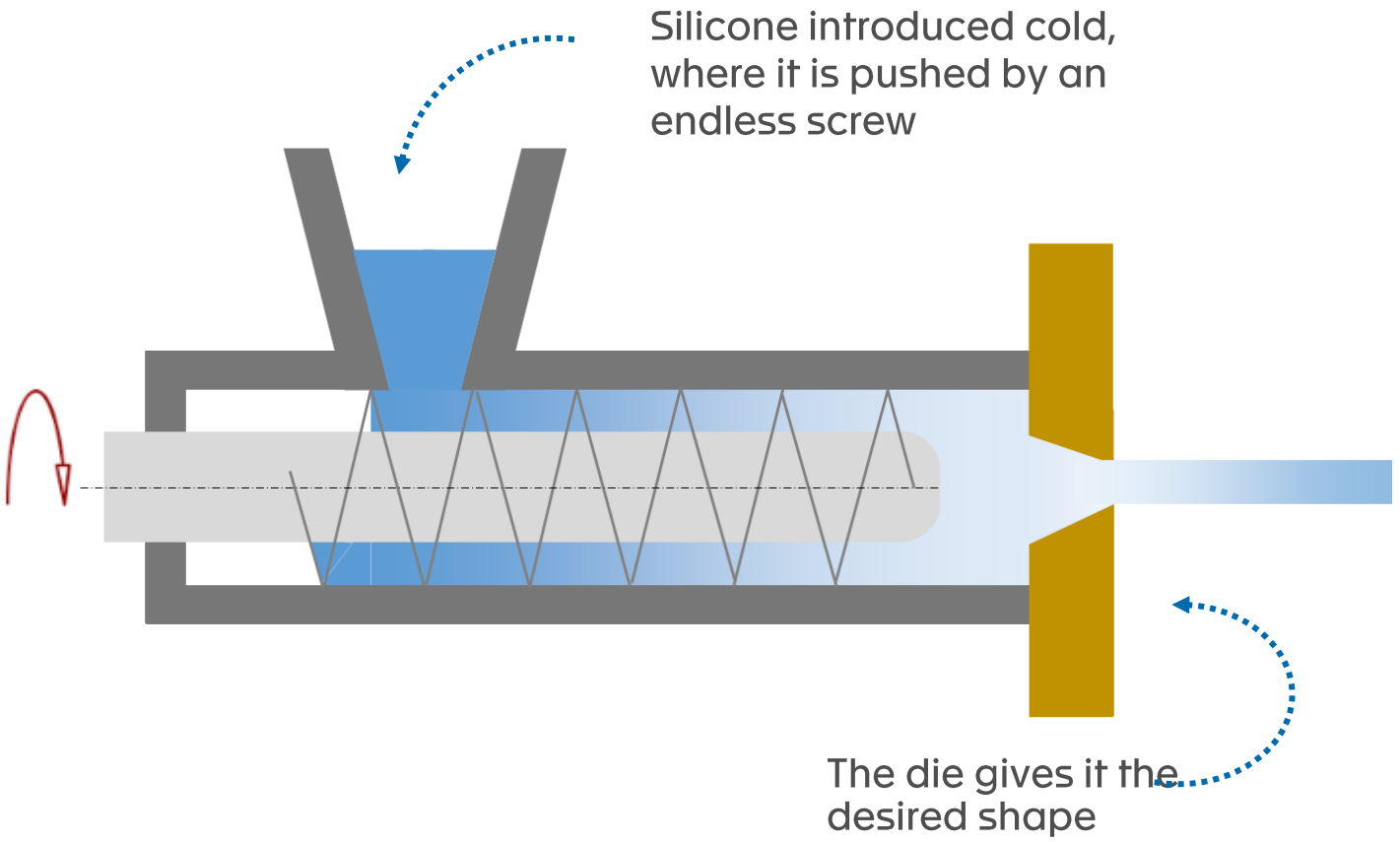


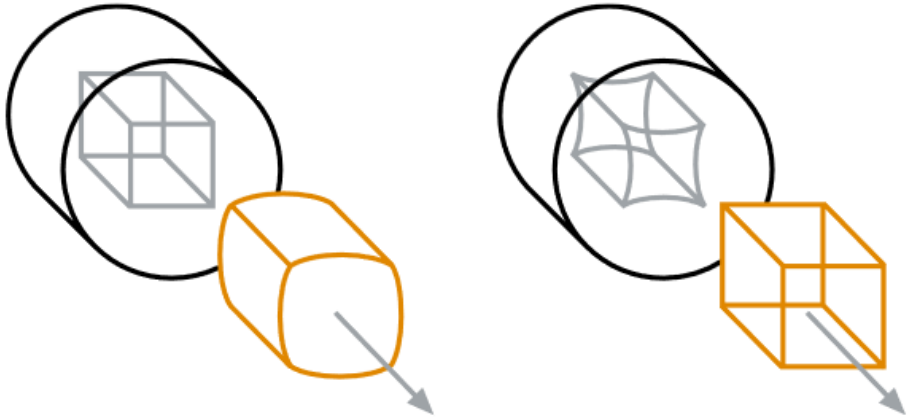
MOLDING CYCLE : INJECTION MOLDING



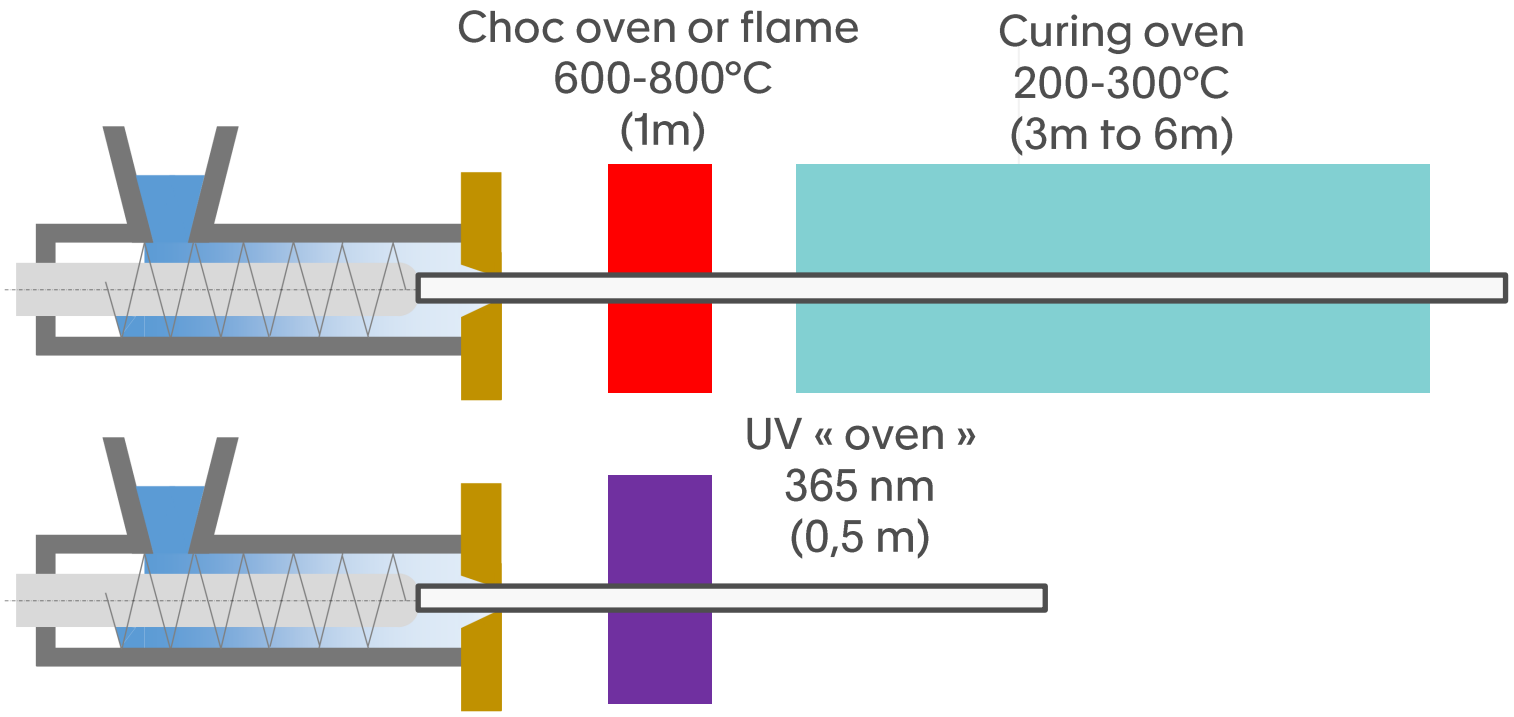


EXTRUSION 1/2





EXTRUSION 2/2



Curing :

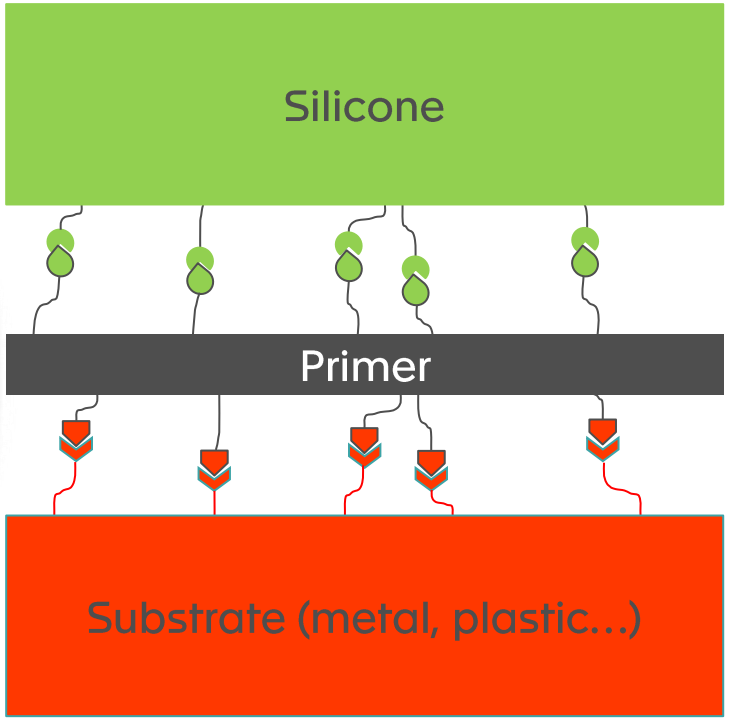
Between 200 and 800°C or 365 nm Hot air, radiant, hot bath or UV oven.

Time varies according to profile and material

Material :
HCR,
peroxide ou platinum

Applications courantes :
- Tubes
- Profiles (solid or hollow)
- Ropes

OVERMOULDING : SURFACE PREPARATION



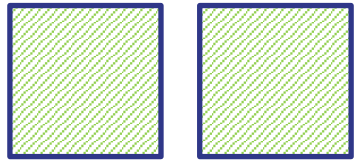
Tools required :
Specific wipe/stem
Iso-alcohol as a degreaser

Common applications
Before overmoulding on any type of material
(Silicone, metal, plastic, etc.)

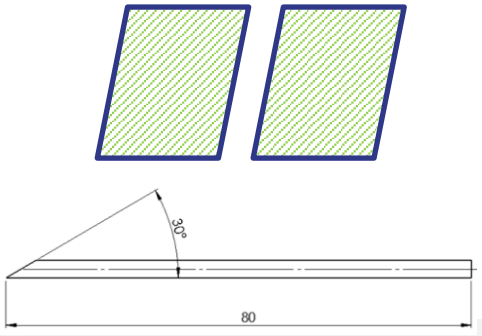
CUTTING

CUTTING

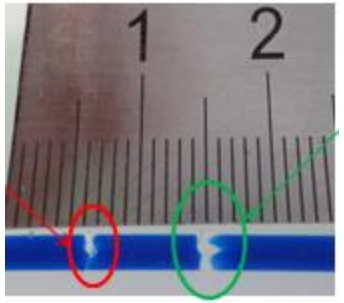
Straight



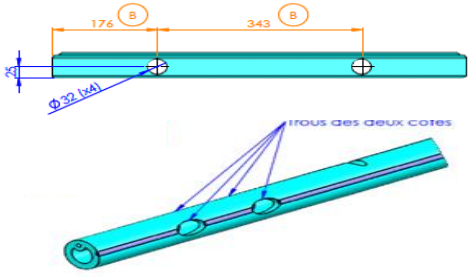
Angled



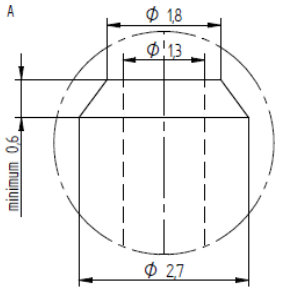
Notching



Drilling



Chamfering



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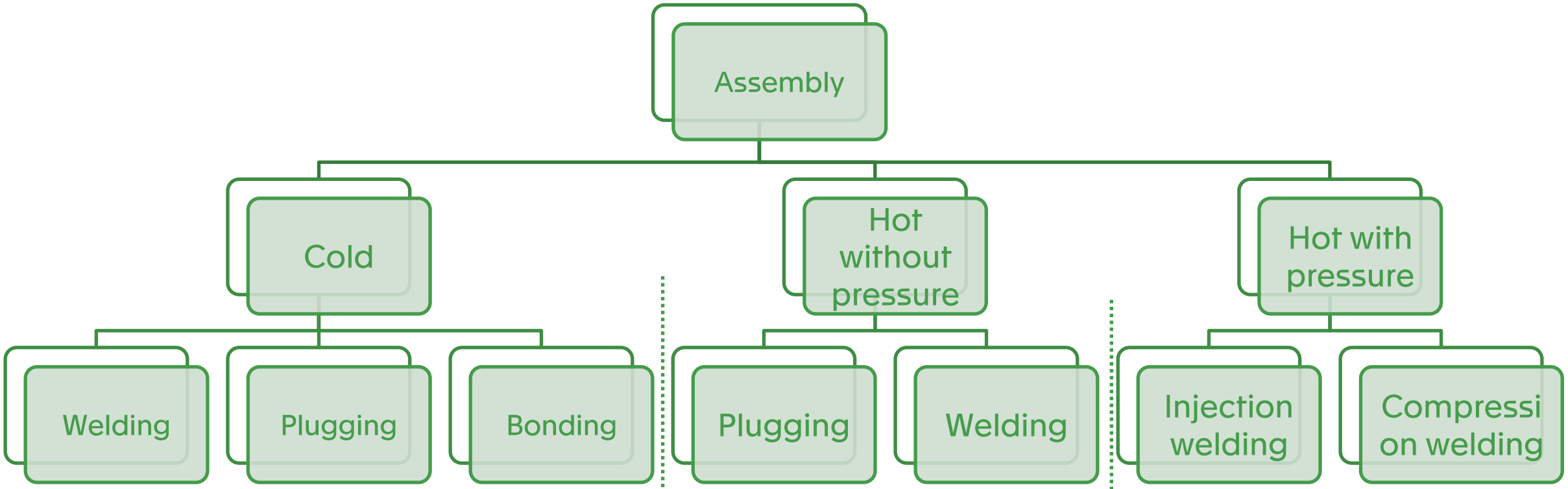
ASSEMBLY : THE HEART OF MAKING



With or without tools
RTV without temperature
Drying time could be long

Without tools
HCR
With heat

With tools/mold and a press
HCR/LSR
with temperature + pression

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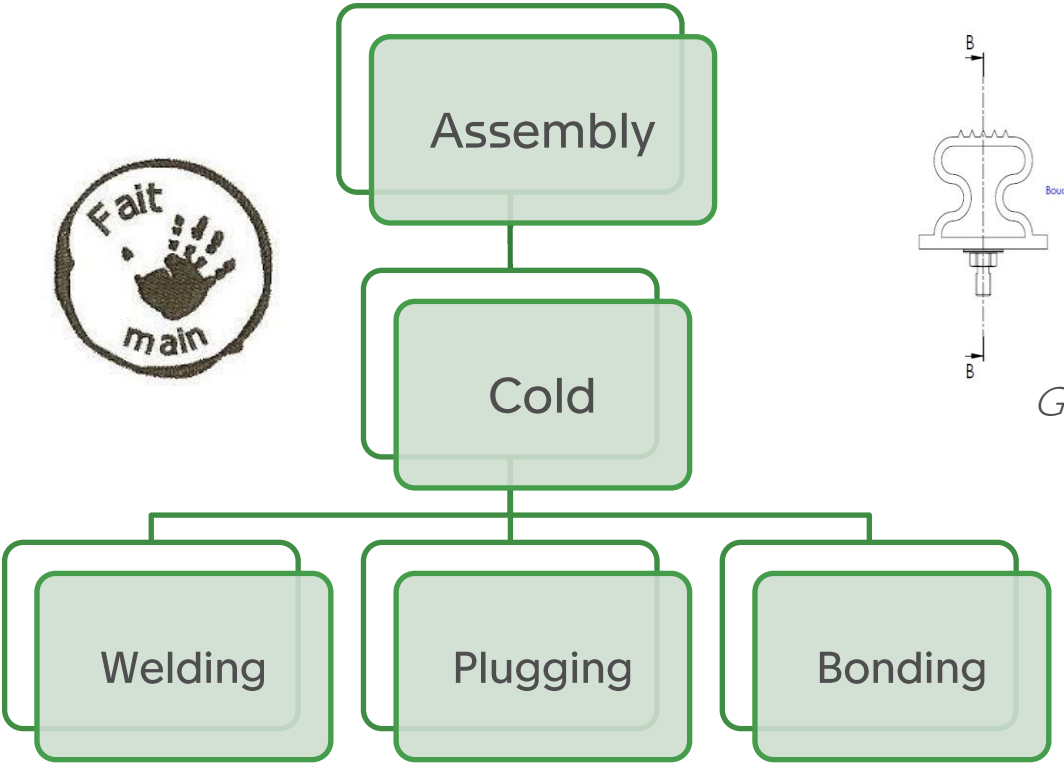
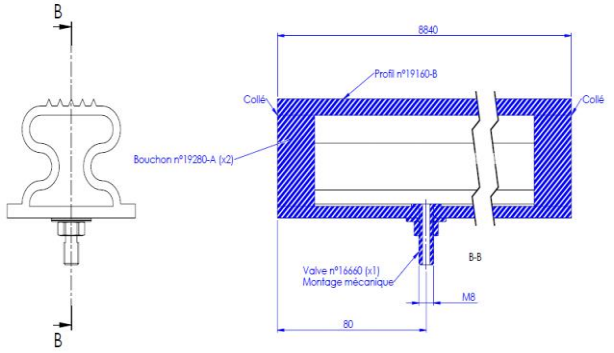
COLD ASSEMBLY





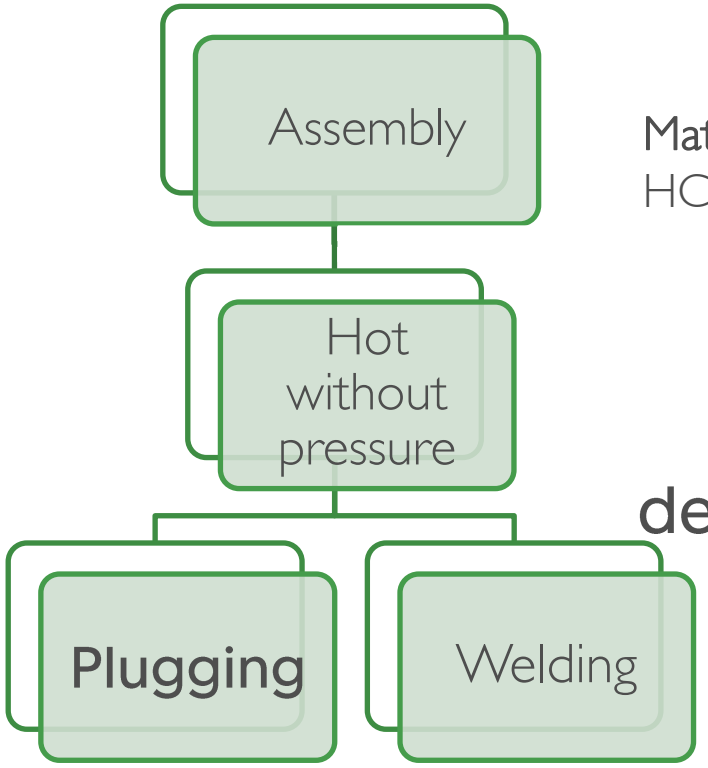
Gluing caps and valves

Adding textiles to medical parts

Material

RTV

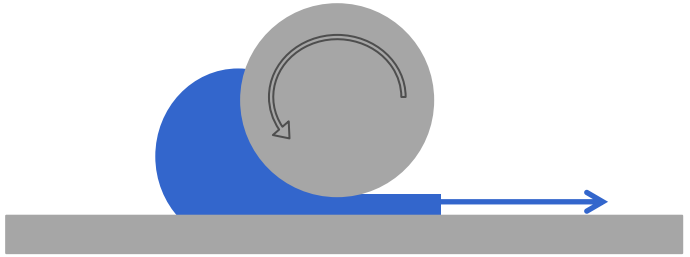
HEAT ASSEMBLY WITHOUT PRESSURE

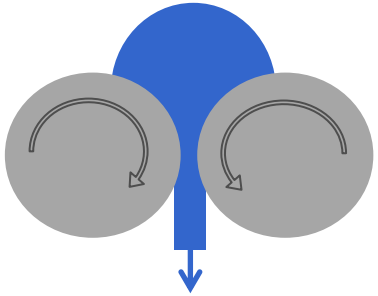


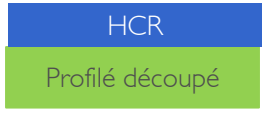
Material
HCR

deposeplugging

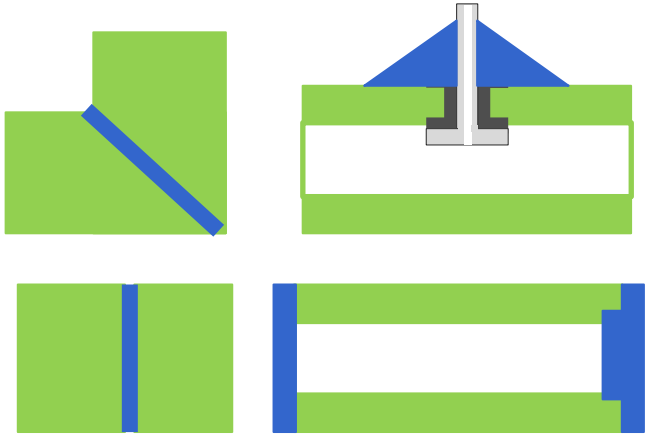
Phase 1: Calibration of the HCR







Phase 2 : Laying of HCR, shaping and curing



Temperature	115 < T°C < 180°C
Common applications	Frame, cone, inflatable seals, plugging HCR laying into other materials

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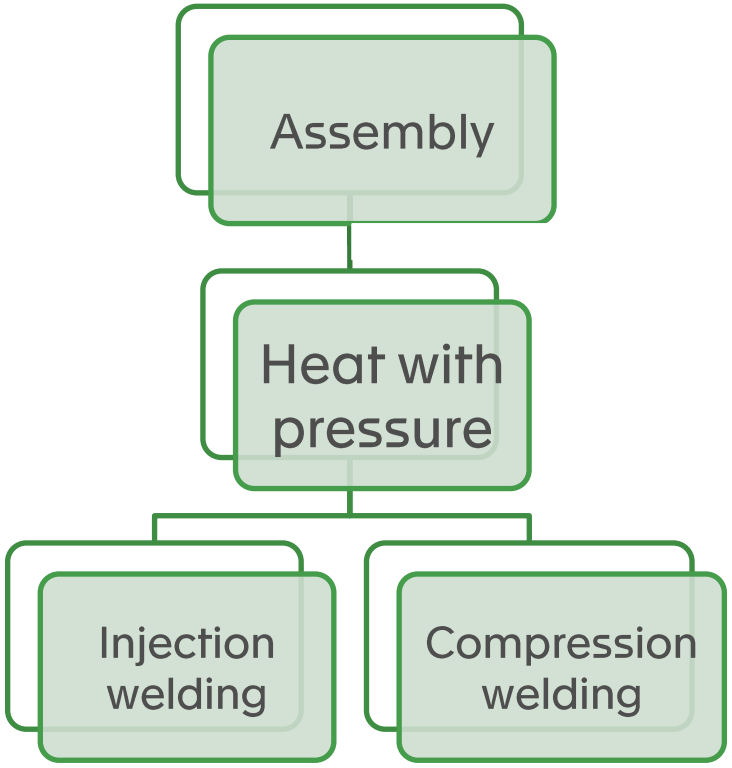
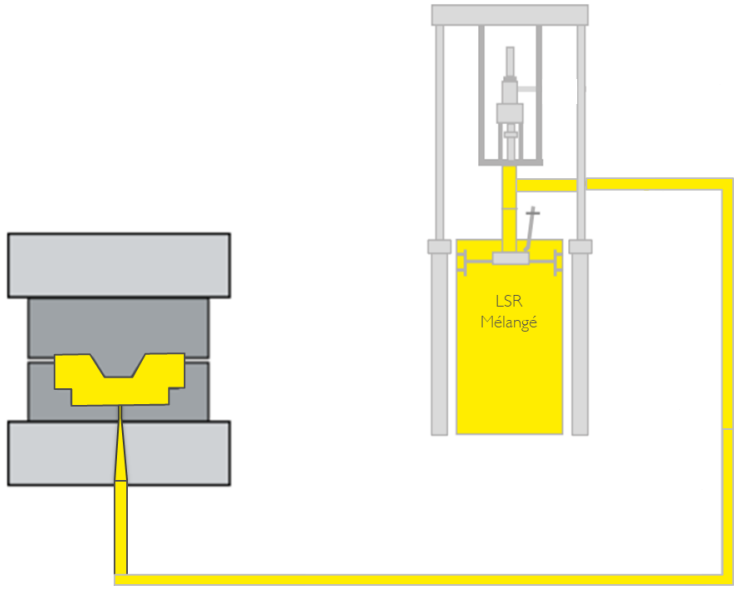
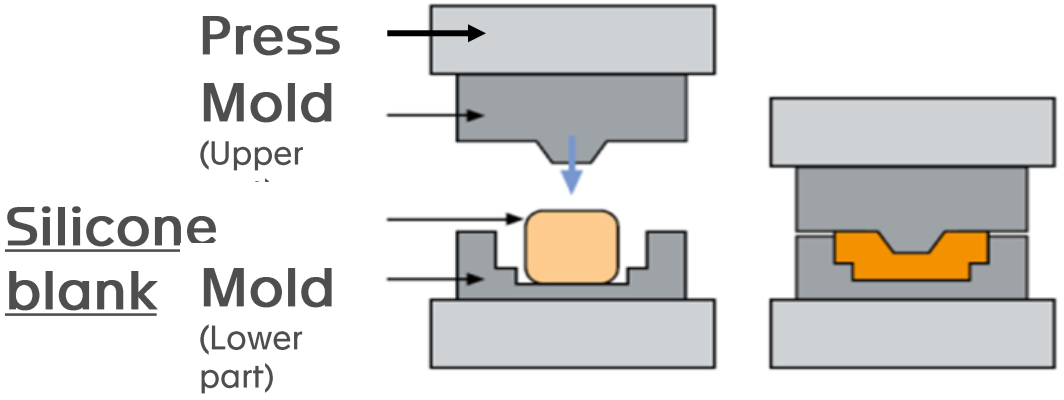
HEAT ASSEMBLY WITH PRESSURE



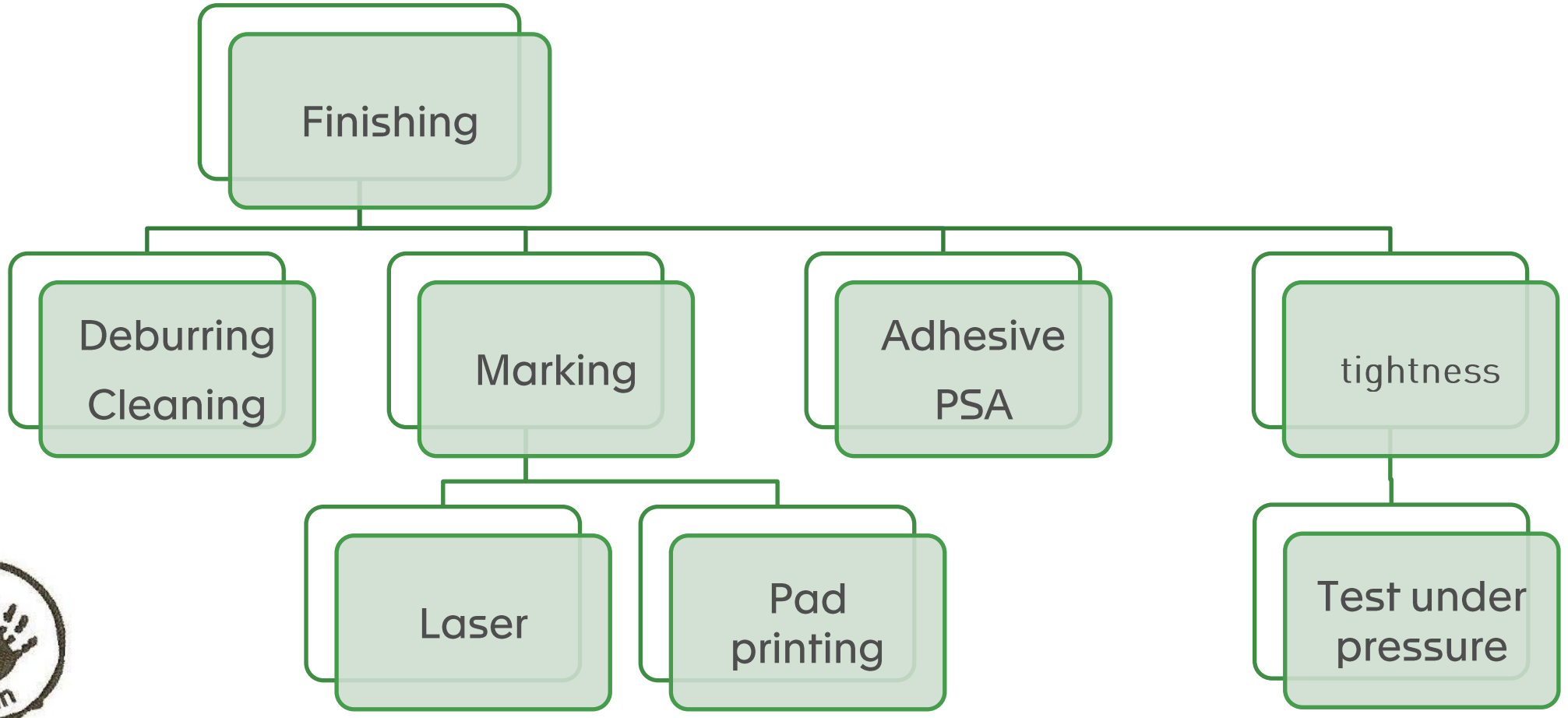
Material

HCR or LSR





FINISHING: THE LAST STAGE, THE FIRST THING THE CUSTOMER SEES



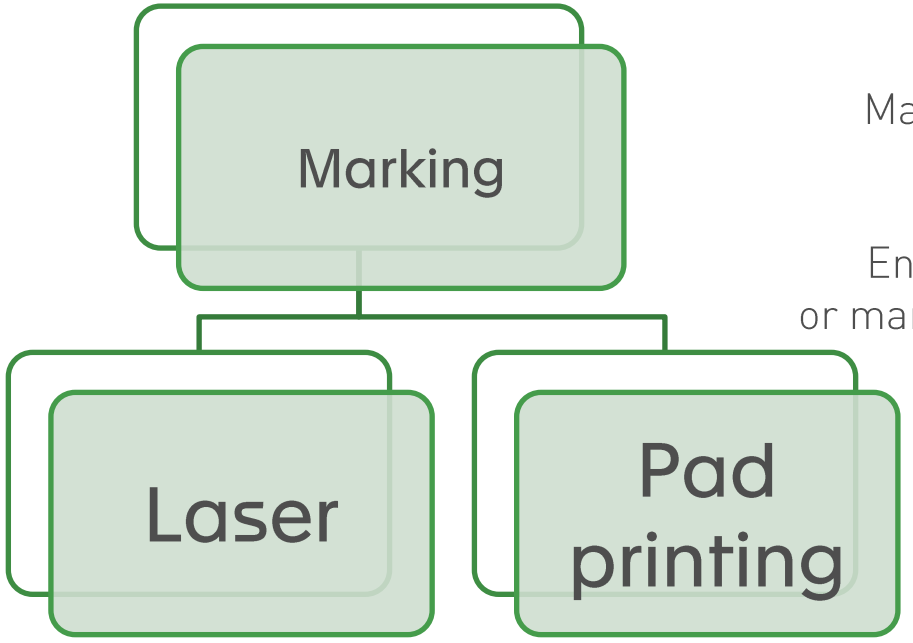
FINISHING

- Finition
- Deburring
- Cleaning

Principle of the step :

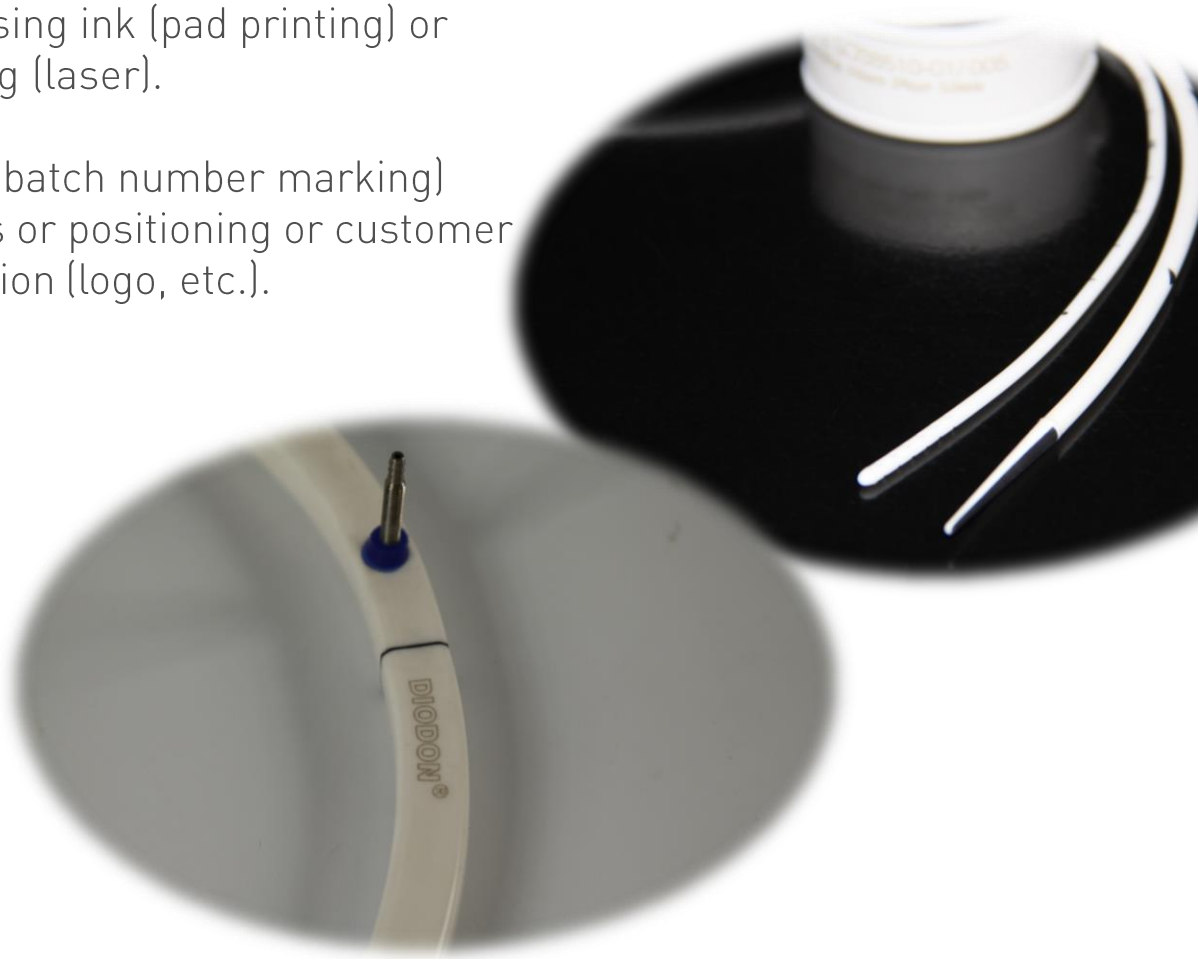
Remove excess of material generated by the assembly or molding stage and clean the fine particles.

FINISHING



Principle of the step :
Marking on silicone using ink (pad printing) or burning (laser).

Ensuring traceability (batch number marking) or marking of dimensions or positioning or customer personalisation (logo, etc.).



Tools required :
Tampo machine or laser
Safety glasses

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FINISHING

tightness

Test under pressure

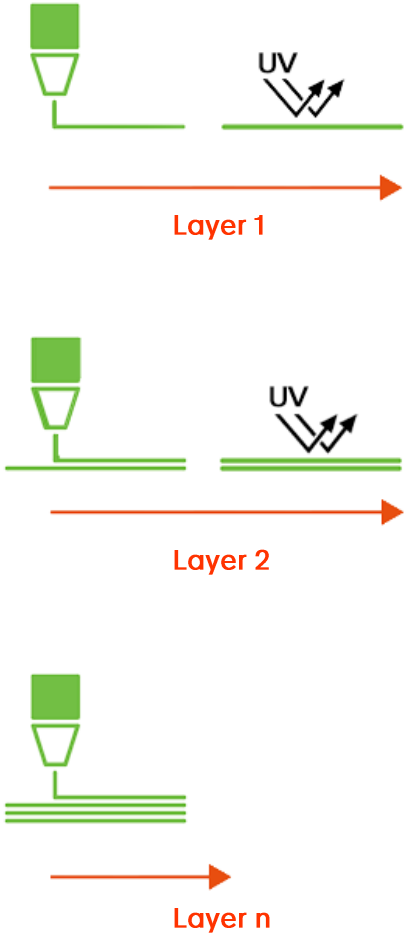
Principle of the step :
Check the conformity and tightness of the inflatable seals

Tools required :
No. 385 test bench or syringe
Inflatable gasket
Container of water or alcohol

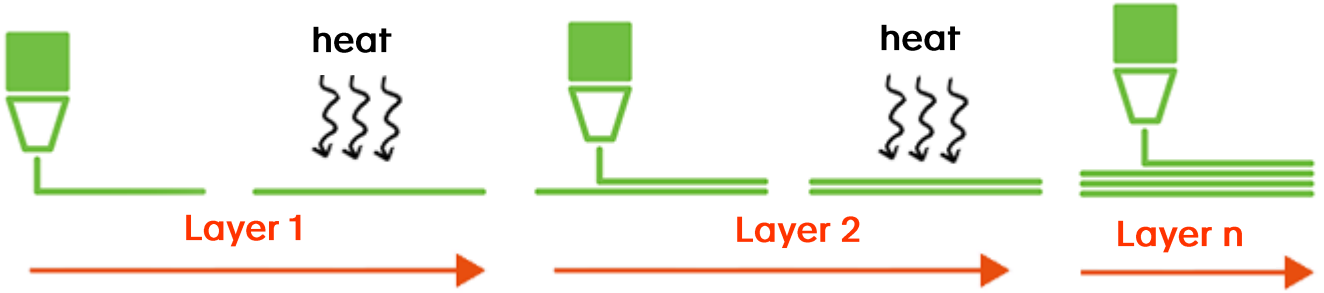
3D PRINTING : SIO-SHAPING 1601 UV CURING

- No heat — UV curing
- Mechanical properties Similar to injection
- Two-component printing — Possible
- Printing on component — possible
- Hardness — 30 to 60 shA
- Dimensions mm — 200x200x150

Example of a product validated using 3D printing and then molded.



3D PRINTING SIO-SHAPING 2201® HEAT-CURED SILICONE



•Heat	True LSR
•Two-component printing	
•Printing on component	possible
•Hardness	10 to 80 shA
•Dimensions	500x500x500 mm

3D PRINTING SIO-SHAPING 2401® : SHORT-LIVED MOLD
PROTOTYPING QUALITY AS CLOSE AS POSSIBLE TO THE FINAL PRODUCT

Mold conception → Molding part → Curing → Demolding → Post treatment

· Printing hardness	10 to 80 shA
· Colouring	All colors
· Heat curing	
· Over-molding possible	
· Number of pieces	1 to 10 pcs

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Few exemples

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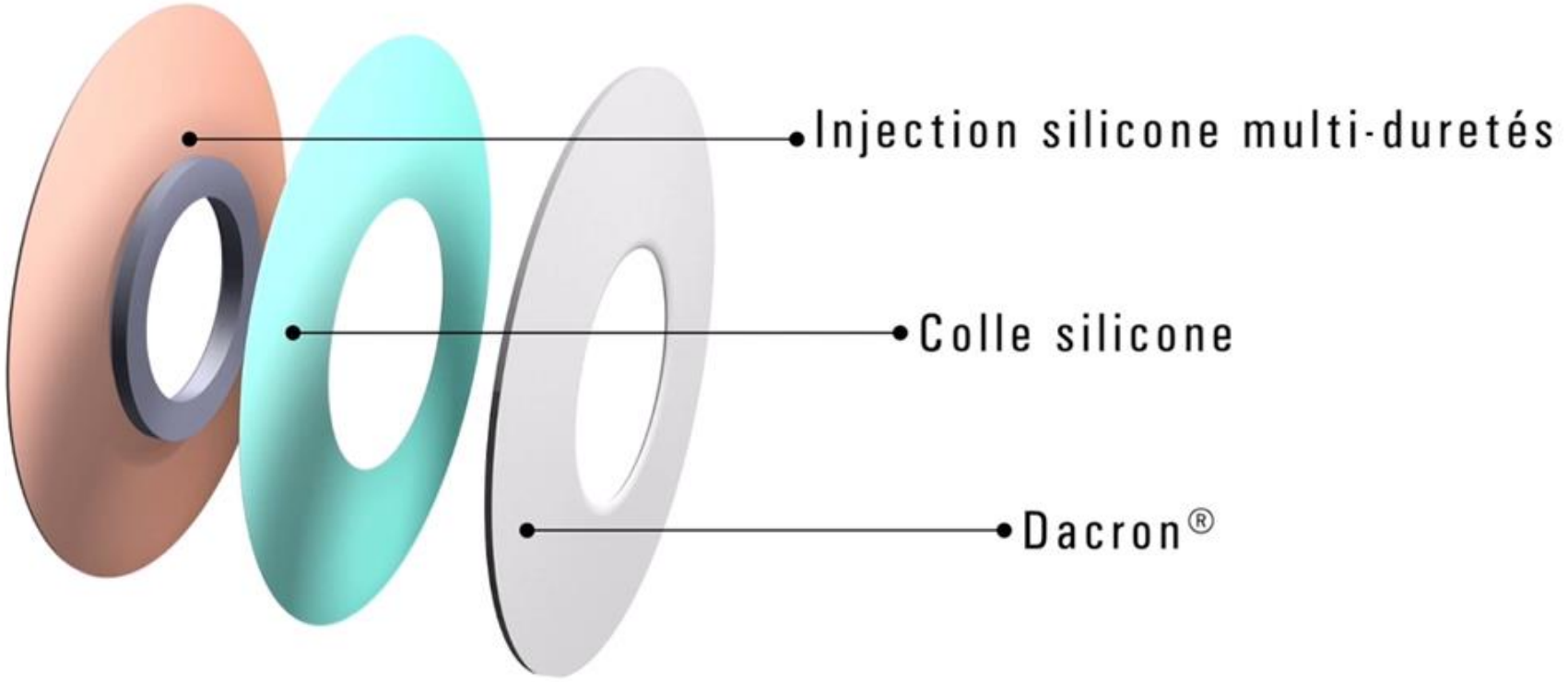
Gastric tube

Co-extrusion
Molding
Making

Tampographie

Artificial heart

Overmolding several silicone Making



Perineal probe | LSR injection molding

Fizimed

silicone
qualité médicale

SUMMARY

1. The history of silicone
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Physico-chemical properties and their impact on biocompatibility

Properties	Averages values
Density	1,05 – 1,30
Hardness (ShA)	3 – 85
Tensile strength (Mpa)	5 – 12
Elongation (%)	100 – 1100
Tear strength ($KN.m^{-1}$)	5 – 55
Compression set (%)	5 – 30
Resiliency (%)	20 – 70%

Molecular characteristics	Physico-chemical properties	Consequences for biocompatibility
Flexibility and mobility of the siloxane chain Very open structure Regular arrangement of methyl side-chains Substitution of non-polar methyl groups Very slight molecular interaction	Very low surface tension - γ_{liquid} = 20,4 mN/m (20° C) - $\gamma_{c\ wetting}$ = 24 mN/m Flow properties Wetting and film-forming properties Lubricant, antifoaming, anti-adhesive, water-repellent properties Very low vitreous transition - T_g = 146 K polydimethylsiloxane Rubber-like behaviour Ready intra-intermolecular reaction Very high permeability to gases Stable physical properties over a wide temperature range Excellent dielectric properties	Decreased molecular and cellular adhesion Permeability to steam Decreased tissue stress with soft, elastic materials
Homolytic stability of Si—O Stability of Si—C Absorption of methyls < 300 nm	Thermal and oxidative stability Transparency Stability to light	Stable in biological media Readily sterilisable

Physico-chemical properties and their impact on biocompatibility

Some typical properties of silicone

Hypoallergenic
Strong,
durable
flexible from -110°C to 200°C
Sterilisable
Realistic skin feel
Biodurability
Phthalate-free
Latex-free

Can answer to several chapters of ISO 10993

Medical device categorization			Endpoints of biological evaluation															
Nature of body contact		Contact duration A-limited (≤24h) B-prolonged (>24h to 30d) C-long term (>30d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation	Material mediated pyrogenicity	Acute systemic toxicity	Subacute toxicity	Subchronic toxicity	Chronic toxicity	Implantation	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive/ developmental toxicity	Degradation
Category	Contact																	
Surface medical device	Intact skin	A	X	E	E	E												
		B	X	E	E	E												
		C	X	E	E	E												
	Mucosal membrane	A	X	E	E	E												
		B	X	E	E	E		E	E			E						
		C	X	E	E	E		E	E	E	E	E		E				
	Breached or compromised surface	A	X	E	E	E	E	E										
		B	X	E	E	E	E	E	E			E						
		C	X	E	E	E	E	E	E	E	E	E		E	E			
Externally communicating	Blood path, indirect	A	X	E	E	E	E	E					E					
		B	X	E	E	E	E	E	E				E					
		C	X	E	E	E	E	E	E	E	E	E	E	E	E			
	Tissue/ bone/ detin	A	X	E	E	E	E	E										
		B	X	E	E	E	E	E	E			E		E				
		C	X	E	E	E	E	E	E	E	E	E		E	E			
	Circulating blood	A	X	E	E	E	E	E					E	E				
		B	X	E	E	E	E	E	E			E	E	E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E			
Implant	Tissue/ bone	A	X	E	E	E	E	E										
		B	X	E	E	E	E	E	E			E		E				
		C	X	E	E	E	E	E	E	E	E	E		E	E			
	Blood	A	X	E	E	E	E	E				E	E	E				
		B	X	E	E	E	E	E	E			E	E	E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E			

Physico-chemical properties and their impact on biocompatibility

Some typical properties of silicone

Hypoallergenic
Strong,
durable
flexible from -110°C to 200°C
Sterilisable
Realistic skin feel
Biodurability
Phthalate-free
Latex-free

Can be USP, FDA 21 CFR 177.2600,
European Pharmacopoeia 3.1.9 and many more

Test	Extracts	USP Class					
		I	II	III	IV	V	VI
Systemic injection test – injection in test model 1	Sodium chloride (intravenous)	X	X	X	X	X	X
	Alcohol saline (intravenous)		X	X	X	X	X
	Polyethylene glycol (intraperitoneal)			X		X	X
	Vegetable oil (intraperitoneal)			X	X	X	X
Intracutaneous test – injection in test model 2	Sodium chloride (intravenous)	X	X	X	X	X	X
	Alcohol saline (intravenous)		X	X	X	X	X
	Polyethylene glycol (intraperitoneal)					X	X
	Vegetable oil (intraperitoneal)				X	X	X
Implantation test – strips implanted in test model 2	None				X		X

Workshop: "Silicone and its applications in the medical field"
MIRANDOLA , Hotel La Cantina, Via Statale 179, Medolla
4th june 2024

SILICONE'S CONTRIBUTION AND PROCESSES FOR MEDICAL FIELD

THANK YOU FOR YOUR ATTENTION.
DO YOU HAVE ANY QUESTIONS?

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STERNE
EXSTO GROUP