

#### **Step Toward Tomorrow**



Silicone Prosthesis - Semi Custom Made Manual

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- What is Semi Custom Made
- Order Procedure
- <u>iPhone scanning on Plaster Cast</u>
- Trial Modification
- Final Product
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# Semi-Custom Made (SCM)

- What is SCM?
  - Semi Custom Made is NOT Fully Custom Made
  - Semi Custom Made main concept is changing measurements of our standard size silicone products according to residual limb measurements so as to provide a comfort fit to the patient.
  - Semi Custom Made is based on existing sizes mold to modify the measurements ONLY.
    - we can only modify the size around 1-2 sizes up and down.
    - That means we may be able to modify size M to size ML or size L
    - we are not able to modify the sizes from XS to XL, or vice versa.



Nail shape and skin pattern CANNOT be modified.

- When the patient select sizes:
  - 1. First, choose several similar sizes
  - Second, choose the nail shape and skin patterns closest to the sound hand among these sizes

# Semi-Custom Made (SCM)

When does the patient need SCM?



When the silicone product need to fit onto the residual limb.

- Suitable for partial finger, partial hand, partial foot, lose of partial arm muscle, and lose of partial calf muscle
- Which Models are highly recommended for SCM?
  - Finger prosthesis Model 200 series
  - Model 103 partial hand glove
  - Model 102L cosmetic glove fit to the wrist amputation patient
  - Partial footcover Model HDSF series
  - Model SL arm sleeve
  - Model BKSL below knee sleeve
- Which Models are NOT available for SCM?
  - Model 100 / 100L
  - Model CH

#### Order Procedure

1. Collect information

2. Trial prosthesis

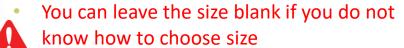
3. Modification

4. Final prosthesis

- Fill up the hand order form
  - We have S1, S2, S3 order form, choose the appropriate order form
  - The top of the order form show the related model
  - You MUST fill in:
    - Patient name or reference no.
    - Gender
    - Side
    - Selected color, see below YouTube to learn color choosing

https://www.youtube.com/watch?v=q495hf\_0 4B0&t=6s

- Any upgrade options
- Remark





#### Regal Prosthesis Ltd.

Semi-Custom Made (SCM) Order Form Model 103 Partial Hand V2.0.2022 P9.2/5

Patient name	Age	Sex	Occupation
Patient contact number / E-mail			
Side and Level of amputation			

Note 1: If the residual limb still swelling, the prosthesis may not fit the residual limb after the swelling is gone.

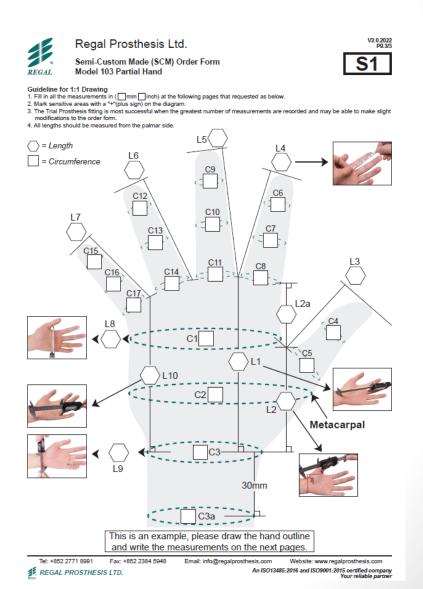
Note 2: Avoid wearing the prosthesis while there are unhealed cuts or sores on the residual limb, and the prosthesis
should only be worn after the cuts or sores are completely healed.

Note 3: If the residual limb is sensitive, please modify the cast to relieve the sensitive area.

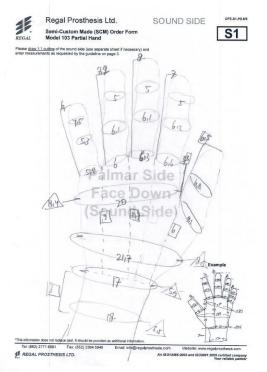
Model 103 Partial Hand Regal Catalogue 2015 V3.1 page 2015 V3.1 page					
5 Models Partial Hand 49			49	103	
cati	Gender, Size	please refer to catalogue 2015 v.3.1 page 54 -10.	3		
S B B	Models				
S	Color - Single use color sample from Regal				
	SCM	Semi-Custom Made	7	SCM	SCM
8		Dual Coloring (e.g. D3 - P2)	14	D/P	
± 4	Color	Custom Coloring (color sample is required)	1-	cc	
Options: Aesthetics and Surface Enhancement		X Series		Х	
tion ance		- Hair Dimension (2D, 3D)	16	2D / 3D	
용발표	Nails, Hairs	- Hair Color (Brown-Black, Brown, Black)	1	BB/BR/BL	
att.		Acrylic Nails 17		ACRN	
¥	Smooth Coating	Smooth Coating	19	SC	
ଞ୍ଚଳ g Custom Filling		- Foam, Silicone, Foam and Silicone	21	F/S/F+S	
Options: Structural Changes	Fingers Construction	Wired Fingers / Hinged Fingers	23	W/HF	
Zipper Plastic Zipper (Default) / No Zipper (NZ) 25				NZ	
Any special trimming requirement?  (If yes, please ensure to mark the trim line.)					
Is residual finger(s) bendable ? (If yes, please specify which finger(s):					
Is the thenar movable ?					
Cut out the prosthesis finger(s) to enhance mobility.  (Please write down the prosthesis finger(s) to be cut out:  YES / NO					
Return the cast with Final Prosthesis?  (Please be informed that we already adopted the 3D scanning technique to keep the data of plaster cast / wax cast, thus the plaster cast / wax cast from customers will be disposed during the fabrication process)					

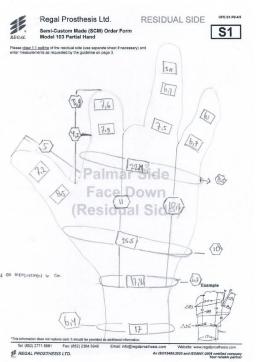
emark:		

- Take measurements
  - You can watch our YouTube to learn how to take measurements
     <a href="https://www.youtube.com/watch?v">https://www.youtube.com/watch?v</a>
     =kSDUxD PEYg&t=18s
  - DO NOT put the measurements
     onto the diagram, the diagram is
     only for telling you what
     measurements we need



- First draw the sketch on the blank page, both sound and residual sides
- Mark the measurements onto the sketch. (Please follow the measurements requirement in the diagram, DO NOT miss any measurements)
  - Use the sketch example in lower right corner as reference

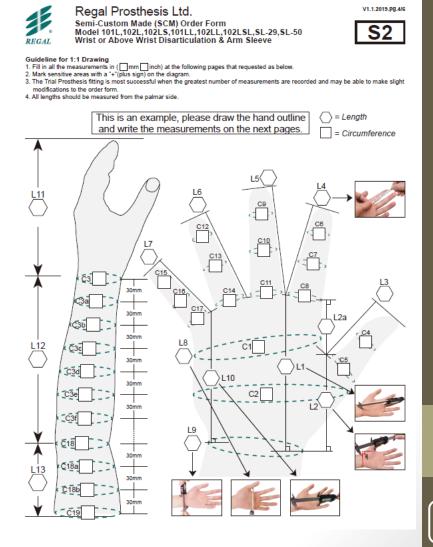




- When you take measurements for model 102L (for wrist amputation patient)
  - First, take measurements on the sound hand
  - Then take measurements on the residual forearm circumference:



- If the patient has socket, give us the socket circumference, 30mm apart
- If the patient wear the glove without socket, give us the residual forearm circumference, 30mm apart
- If the patient has not yet fabricated socket, give us the sound hand forearm circumference, 30mm apart
- Give us residual forearm circumference at least up to 80mm-90mm above wrist



- The more the photos, the better we judge the patients
- At least one dorsal side, both residual and sound sides
- Put the sound and residual hand side by side









- Put residual and sound side wrist to wrist
- If you order Model 102L for wrist amputation patient, please also take photo on patient both hands at relax stage.

For above wrist amputation, we DO NOT recommend direct wearing the glove. The patient should wear socket and order Model 102LS







- Take cast
  - At least take cast on residual side
  - Make up the positive cast
  - Mark the wrist position, if the cast does not have obvious wrist line.
  - Mark the sensitive area
  - Cast the hand at least 80mm-90mm above wrist
  - For Model 102LS / 102LSL which are fit to the sockets, you can skip casting. We only need measurements taking.

 After cast completion, please check the cast measurements against your order form measurements.

- Make sure both measurements do not exceed 4% difference
- Otherwise, modify the cast to eliminate the difference



Remeasure plaster cast and verify with ordering form



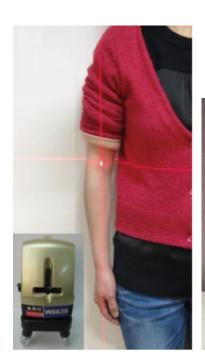
Modify cast down to size on ordering form Picture shows a discrepancy between cast and chart

 When your patient is wrist amputation, but not using socket, the residual limb directly wear the Model 102L glove

 You will need to mark the alignment line on the cast, so that we will know how to position the hand arch.



Use laser to determine the alignment at the sound hand arch, put the same line in residual limb, then transfer the alignment to the cast





- Fill up the foot order form
  - We have S4, S5, S6 order form, choose the appropriate order form
  - The top of the order form show the related model
  - You MUST fill in:
    - Patient name or reference no.
    - Gender
    - Side
    - Selected color, see below YouTube to learn color choosing

https://www.youtube.com/watch?v=q495hf\_04B0&t=6s



Any upgrade options

- Remark
- You can leave the size blank if you do not know how to choose size



#### Regal Prosthesis Ltd.

Semi-Custom Made (SCM) Order Form Model HDSF, HDSF-ER, HDSFHT, HDSFHT-ER Partial Foot



Patient name	Age	Sex	Weight
Patient contact number / E-mail		Occupation _	
Side and Level of amputation			

Note 1: If the residual limb still swelling, the prosthesis may not fit the residual limb after the swelling is gone. Note 2: Avoid wearing the prosthesis while there are unhealed cuts or sores on the residual limb, and the pro-

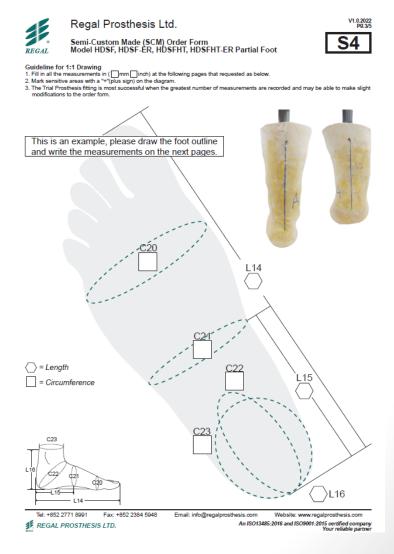
Note 2: Avoid wearing the prosthesis while there are unhealed cuts or sores on the residual limb, and the prosthesis should only be worn after the cuts or sores are completely healed.

Note 3: If the residual limb is sensitive, please modify the cast to relieve the sensitive are

	Model HDSF, HDSF-ER, Catalogue 2015 Order Code 1.1 PosFHT, HDSFHT-ER Partial Foot V.1.1 page					
_	Models	Standard Model	104-105	HDSF, HDSFHT		
, Lig	Models	Footplate Model	104-105	HDSF-ER, HDSFHT-ER	1	
ilica	Size	please refer to catalogue 2015 v.3.1 page 110	-137			
Basic Specification	Side	Left / Right	L/R			
•	Color - Single	use color sample from Regal				
	SCM	SCM	SCM			
	Color	Dual Coloring (e.g. D3 - P2)	14	D/P		
투발	Color	Custom Coloring (color sample is required)	14	cc		
d St		X Series		х		
tion ance	- Hair Dimension (2D, 3D) 16		2D / 3D			
오음트	Nails, Hairs	- Hair Color (Brown-Black, Brown, Black)		BB / BR / BL		
Options: Aesthetics and Surface Enhancement	Acrylic Nails 17			ACRN		
₹	Smooth Coating Smooth Coating 19 SC					
Options: Structural Changes	Custom Filling	- Foam, Silicone, Foam and Silicone	21	F/S/F+S		
Struc	Zipper	Plastic Zipper (Default) / No Zipper (NZ)	25	NZ		
Fabricate the foot cover's length 10mm shorter than the sound side to help putting into the shoe easily.						
Any special trimming requirement? (If yes, please ensure to mark the trim line.)						
Cut out the prosthesis toe(s) to enhance mobility. (Please write down the prosthesis toe(s) to be cut out:						
Return the cast with Final Prosthesis?  (Please be informed that we already adopted the 3D scanning technique to keep the data of plaster cast / wax cast, thus the plaster cast / wax cast from customers will be disposed during the fabrication process)						

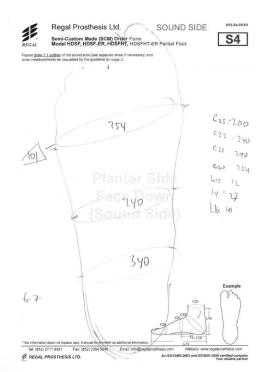
regalnmethesis com	Website: www.regalprosthesis.co
ā	@regalprosthesis.com An ISO134

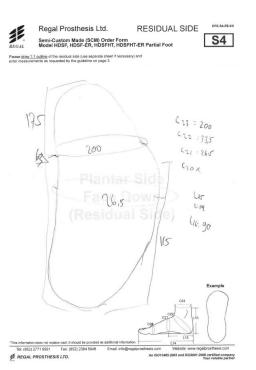
- Take measurements
  - You can watch our YouTube to learn how to take measurements <a href="https://www.youtube.com/watch?v">https://www.youtube.com/watch?v</a>
     =kSDUxD PEYg&t=18s
  - DO NOT put the measurements onto the diagram, the diagram is only for telling you what measurements we need



- First draw the sketch on the blank page, both sound and residual sides

  Mark the measurements onto the sketch. (Please follow the
  measurements requirement in the diagram, DO NOT miss any
  measurements)
  - Use the sketch example in lower right corner as reference





- Take photos on sound and residual sides
  - Also take the photo with patient standing up (if possible)
  - If the plantar has sensitive area, need to take photo as well.







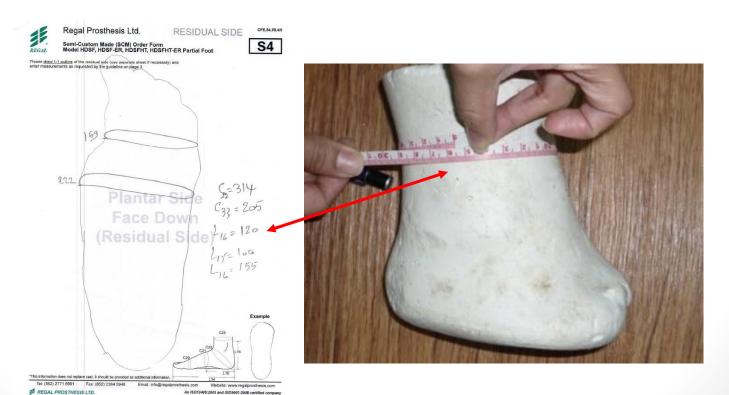
- Take cast
  - At least take residual side
  - Make up positive cast
  - At least mark the medial, posterior alignment line, otherwise, we do know how the patient actual stand.
  - Mark the sensitive area
  - Cast the foot at least 70mm above ankle
  - If the patient need to wear insole, or silicone sock with the footcover, please cast the residual foot with the insole or silicone sock as well.

 After cast completion, please check the cast measurements against your order form measurements.



Make sure both measurements do not exceed 4% difference.

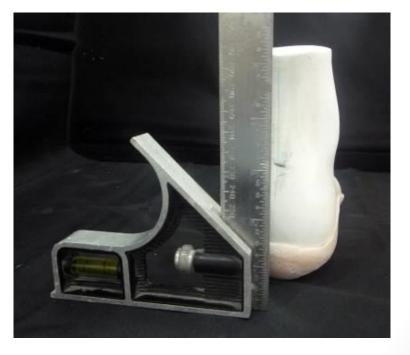
Otherwise, modify the cast to eliminate the difference.



1

Remember the foot cast MUST mark at least Medial and Posterior alignment line





#### iPhone Scanning on the Plaster Cast

You have an option of NOT sending us plaster cast, instead, you can scan the plaster cast by iPhone with Regal kits, then you send us the stl file to save time and courier cost.



Watch this video for instruction:

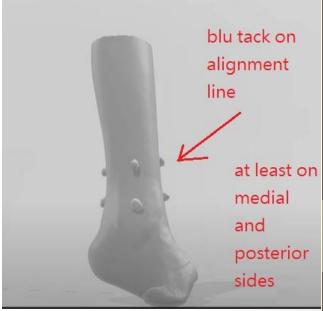
https://www.youtube.com/watch?v=Mpf5UeCq49Y

## iPhone Scanning on the Plaster Cast

- Pay attention when you scan the cast:
  - For partial hand, wrist or above wrist amputation, if the cast has no obvious palmar side or wrist, please Blu Tack the palmar side and the wrist line
  - Please blu tack on the alignment line on hand or foot cast

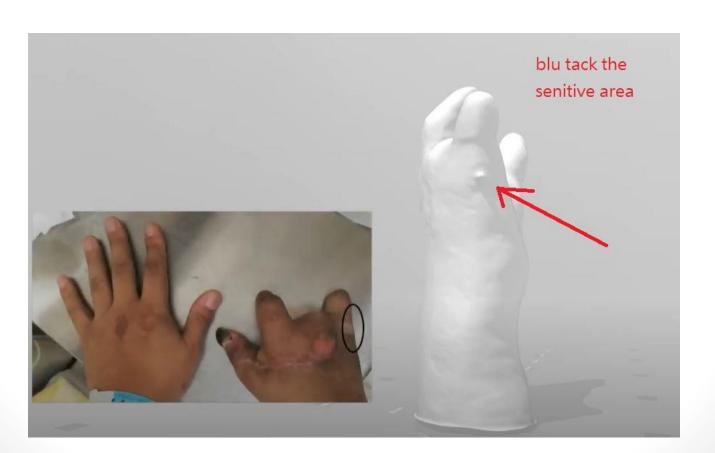






## iPhone Scanning on the Plaster Cast

- Please blu tack on the sensitive area
- Otherwise, we cannot capture this information when you send us stl file.



#### **Customer Confirmation Email for Trial Prosthesis**

 After Regal Customer Service gather your order form, photos and cast, they will reply an email to you for order detail.



Please read the email line by line. It has a lot of important details.

- If you agree, please confirm to the customer service, otherwise, please raise your questions until you agree all the terms.
- The fabrication lead time for Trial is 21 working days.

Patient Name:		Internal ref. #:
Your PO / Ref. #:	SCM-042	C21083001
Order Date:	30/08/2021	E001

#### Our reply:

- We shall fabricate the T1\_Trial Prosthesis (SCM-202-203S-F-R-M-A2) YES 2 separate fingers
- Please be reminded that due to mold design, the nail shape and handprint on the trial prosthesis cannot be changed, for the nail and handprint, please refer to page 86 of our catalogue 2015. OK
- Make the residual area according to the order form measurement. YES
- 4. Make the amputated area according to the order form measurement. YES
- However, there are missing the circumference of C6 and C9 for the sound side. We need them for reference. Please provide. C9=42 мм., C6=43 мм.
- We shall treat the finger length as the distance between the fingertip and the finger root from the palmar side. YES
- Final Prosthesis: Standard Foam Filling YES
- Quantity for Final prosthesis: 1pc YES

#### Please confirm the above before we begin fabrication.

#### eadtime:

Upon receiving your confirmation for this SCM order, counted from the next working day:

- Trial prosthesis shall be ready within 21 working days. YES
- 2. Final prosthesis shall be ready within 14 working days.
- 3. With Express Delivery Service (EDS), SCM prosthesis shall be ready within 8 working days.

Should you have any questions, please feel free to ask.

#### Note:

- 1. Each extra trial prosthesis after T2 will be charged. Please refer to the quotation for the extra charge.
- We already adopted the 3D scanning (STL) technique to keep the data of plaster cast/wax cast, thus if customer does not request returning the plaster cast/wax cast, the plaster cast/wax cast will be disposed during the fabrication process.

#### **Trial Prosthesis**

- Once you confirm all the terms, Regal will start fabrication of the Trial prosthesis.
- The lead time for the Trial will be 21 working days
- Please pay attention of the Trial:
  - Trial is NOT a Final product. It is only for checking purpose.
  - Trial has no color shading, it only has base color.
  - Trial has no nail color, no reddish.
  - Trial has no upgrade features
  - Trial has no carbon footplate even if you order footcover with carbon footplate
  - If you want to add upgrade features to the Trial, there will be extra cost.
  - Trial has no warranty
  - Trial need to be returned upon Regal's request

#### Trial Prosthesis Modification

- Once you receive the Trial, you need to give us comment on the followings:
  - Base color
  - Fitting
  - Inner filling comfort
- Prepare the TMOD form to put down your comment



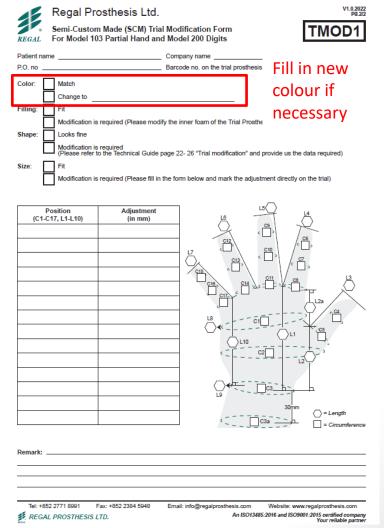
We have TMOD1, TMOD2, TMOD3, TMOD4, choose the appropriate form for related model

45	Regal Pro	osthesis Ltd.	V1.0.2022 P9.2/2
REGAL		n Made (SCM) Trial 3 Partial Hand and	
atient nan	ne		Company name
.O. no			Barcode no. on the trial prosthesis
color:	Match Change to		
hape:	Modification is Looks fine Modification is	required	the inner foam of the Trial Prosthesis and send the trial back to us)
ize:	Fit		age 22- 26 "Trial modification" and provide us the data required)  ne form below and mark the adjustment directly on the trial)
	Position (-17, L1-L10)	Adjustment (in mm)	C12
Remark: _			
-	2 2771 8991 F L PROSTHESIS L	Fax: +852 2384 5948 TD.	Email: info@regalprosthesis.com Website: www.regalprosthesis.com An ISO13485:2016 and ISO9001:2015 certified company Your reliable partner

#### Trial Prosthesis Modification

- Trial prosthesis is made in base color, does not included Nail color or other shading;
- Check whether the chosen color matches to the patient's skin tone;
- You can still change color in the Trial stage.
- Usually customer only request color change in 1 or 2 shade. (for example, color 1 change to 1-2, or 2)
- If you want to change color more than 2 shade, we will suggest to make up another Trial. (bear in mind that we

will charge extra when you request 3<sup>rd</sup> Trial)



- Next, you need to comment on the inner filling, which includes:
  - A comfortable fit
  - Good suspension
  - A right amount of suspension
- The inner filling of Trial is always foam material, even though the patient may order custom silicone or custom foam + silicone filling, the Trial is still at foam filling because we need to keep inner filling adjustable.

- Finally, please check the inner filling, make sure the filling conform to the distal end of the stump.
- If the inner filling is too much, please use the hand-held grinder to grind the filling bit by bit, until the patient feel comfortable, then
   you need to return the Trial with the modified inner feeling to us.





 If the inner filling is too less, please use the Regal silicone putty (or any local putty) to fill up the gap, ask the patient to wear the Trial again until the patient feel comfortable, then return the Trial and the inner filling with putty to us.



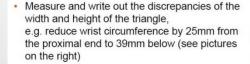


If you need to reduce the proximal opening, follow the below example, mark on the Trial and send photo to us. (no need to return Trial)















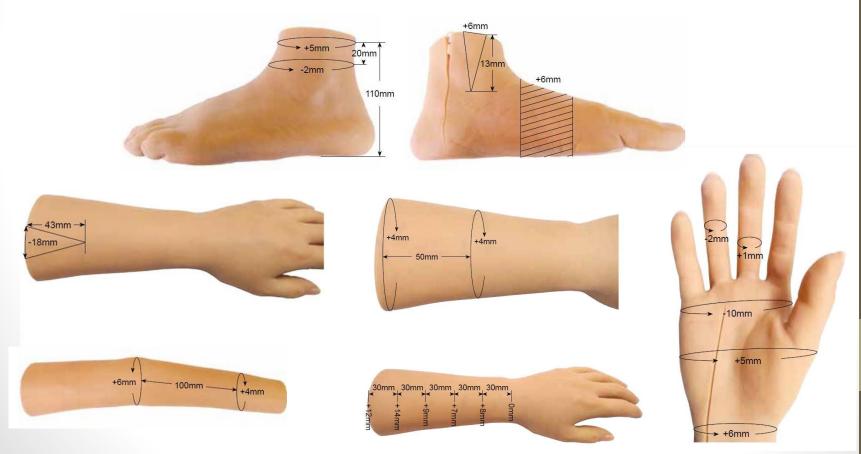






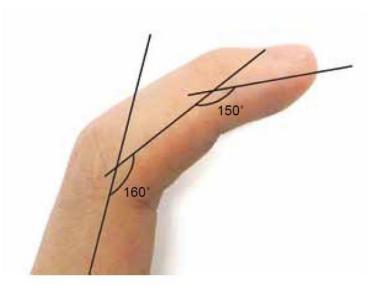


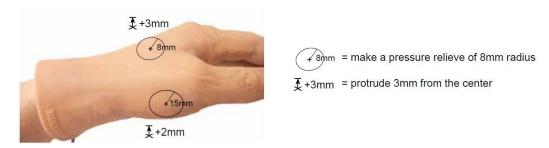
 You can also mark on the Trial to show us how to modify the fitting, and send us the photo (no need to send back Trial on this kind of comment)





You can mark how many degree on the finger bending. (no need to return Trial)

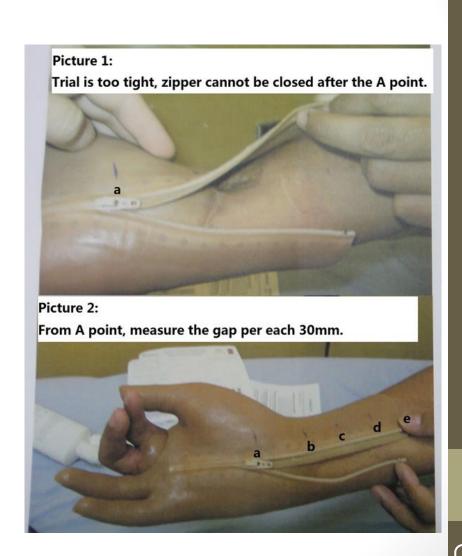




If the opening is not big enough, please mark the bigger opening by indicate the increased measurements, then send us photo. (no need to return Trial)



- For zip glove, if the proximal opening and whole forearm circumference is too small, patient cannot close the zip, please mark on the Trial how many mm need to increase on the forearm circumference,
   30mm apart
- Then send us photo. (for this kind of comment, no need to return Trial)



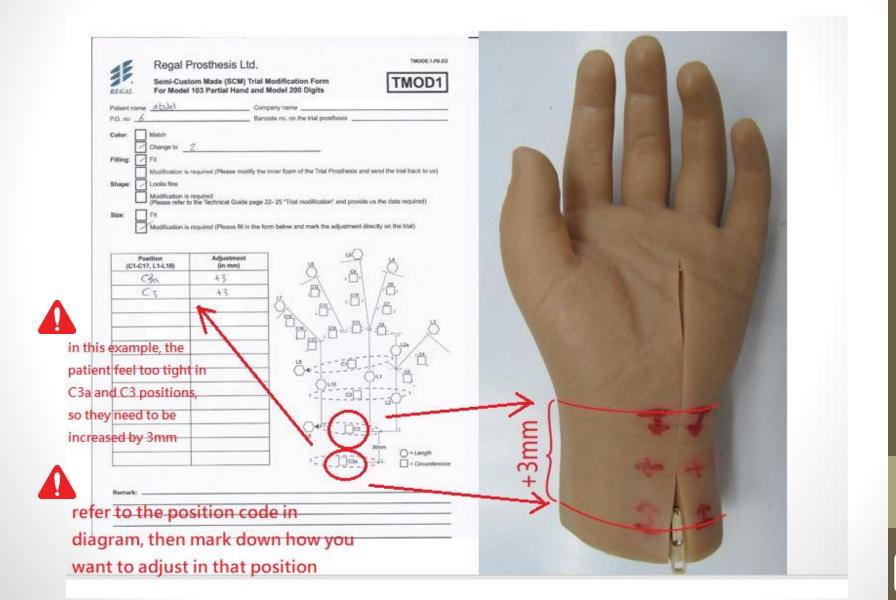
#### Trial Prosthesis Modification

 Finally, please fill up the TMOD form, tell us what you want to change.



NEVER give us new measurements! ONLY give us the adjustment based on Trial.

### **Trial Prosthesis Modification**



#### **Customer Confirmation Email: Final Prosthesis**

- After Regal Customer Service gather your TMOD form, returned Trial (if any) and photos, they will reply an email to you for Final order detail.
- Please read the email line by line. It has a lot of important details.
  - If you agree, please confirm to the customer service, otherwise, please raise your questions until you agree all the terms.
  - The Fabrication lead time for Final will be 14 working days.

	Patient Name:		Internal ref. #
	Your PO / Ref. #:	1688833	C21012501
	Order Date:	02/03/2021	ME026
Our	reply:		
1.	We shall fabricate the Final Prosthesis (SCM-203-M-R-M3-D6-PA3)		
2.	The color, measurement and inner filling shale are same as T1.		
3.	Final Prosthesis: Custom Silicone Filling.		
4.	Others same as T1, nail color and knuckle reddish shall be added according to our standard.		
5.	Quantity for Final prosthesis: 1pc		
Plea	se confirm the above	before we begin fabrication.	
Lead	ltime:		
9/02		nation for this SCM order,	
		ready within 21 working days.	
	Final prosthesis shall be ready within 14 working days.		
3.	With Express Delivery S	ervice (EDS), SCM prosthesis shall be ready within 8 worl	king days.
Shou	uld you have any questi	ons, please feel free to ask.	
Note	e:		
1. Ea	ch extra trial prosthesi	s after T2 will be charged. Please refer to the quotation fo	or the extra charge.

2. We already adopted the 3D scanning (STL) technique to keep the data of plaster cast/wax cast, thus if

customer does not request returning the plaster cast/wax cast, the plaster cast/wax cast will be

disposed during the fabrication process.

#### **Final Prosthesis**

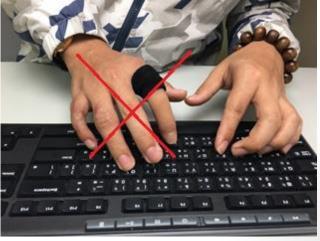
- Always be very serious in Trial fitting and give us comprehensive comment during Trial stage. Once we complete the Final according to the Trial comment, NO MORE change is allow in the Final product.
- If the patient need further change on the Final, we will treat this as a new order with new charge.
- When you hand over the Final to the patient, please explain the warranty and maintenance details to the patient.
  - You can download our limited warranty conditions from our web site. <a href="https://regalprosthesis.com/web/download">https://regalprosthesis.com/web/download</a>
  - For maintenance information, please read the "Instruction for Use" booklet that come with the Final product.

- Our silicone prosthesis is ONLY for cosmetic purpose, never use the product for any functional activity. Otherwise, the warranty will be void.
  - Please see the YouTube video for good maintenance practice <a href="https://www.youtube.com/watch?v=-L9Ii02EoT0">https://www.youtube.com/watch?v=-L9Ii02EoT0</a>

- Finger Prosthesis
  - Be aware of the vacuum effect when wearing the finger prosthesis, never force to pull the finger prosthesis out from the residual limb.
  - Do not ignore small split when it happens in the opening.
  - Please send back to Regal or local workshop, cut out the split and grind the edge. Otherwise, the split will grow and break the whole prosthesis.
  - If patient use it in functional activities, warranty will be void (eg. Typing keyboard)
  - If the patient want the finger prosthesis to be long lasting, please consider to order silicone filling when the patient place order. (standard is foam filling)







- Wired Finger and Hinged Finger
  - Never hard press on the fingers
  - Never use fingers to carry object
  - Never use the fingers to hold any object





- Silicone glove with zip
- Zip is fully integrated with the silicone, not replaceable.
- If the zip is broken and cannot be repaired, the patient need to place order for a new prosthesis
- Always unzip all the way when donning and doffing
- Otherwise, the split will be easily happen along the opening.
- If the split happens, DO NOT ignore the split.
- Please send back to Regal or local workshop, cut out the split and grind the edge.
   Otherwise, the split will grow and break the whole prosthesis.
- Use toothbrush to clean up and remove the dirt everyday during washing the glove.





- HDSF footcover
- Zip is fully integrated with the silicone, not replaceable.
- If the zip is broken and cannot be repaired, the patient need to place order for a new prosthesis
- Always unzip all the way when donning and doffing
- Otherwise, the split will be easily happen along the opening.
- If the split happens, DO NOT ignore the split.
- Please send back to Regal or local workshop, cut out the split and grind the edge.
   Otherwise, the split will grow and break the whole prosthesis.
- Use toothbrush to clean up and remove the dirt everyday during washing the glove.



# Before and After SCM









# Before and After SCIII











## Before and After Sam







## Before and After Sam











## Before and After Sall





