

# TRANS TIBIAL

Product Standards

# PURPOSE

## Hanger Fabrication Product Standards

The Hanger Fabrication Product Standards are a collaborative effort to deliver Best in Class O&P devices to our patients.

The goals of the product standards are to:

- 1) **ALIGN** expectations between clinicians and technicians
- 2) **CONTROL** input and output variations and
- 3) **REFERENCE** best in class blueprints and orthomerty sheets to fabricate products that translate into maximizing clinical outcomes for Hanger patients
- 4) **SUPPORT** future system integration (MRP)
- 5) **REINFORCE** clinical research outcome reliability through controlling design variation

**Endorsements:** Mary-Kate Ennis, MBA, CO | Aaron Flores, PhD  
Phil Stevens, MEd, CPO, FAAOP | John Rheinstein, CPO | Kevin Carroll, CP  
Tim Fair, CPO | Dan Strzempka, CP | Damien Borrás

**Acknowledgment:** We would like to extend our appreciation to the many clinicians and technicians across Hanger who collaborated on the Hanger Product Standards development.

# CONTENTS

Click on page # line  
to jump to that page

## OVERVIEW

- 5 Anatomy and terminology
- 6 Lower limb anatomy
- 7 Amputation levels

## FUNDAMENTALS

- 9 Pressure tolerances/sensitivities
- 10 3D printed check socket
- 11 Socket motions
- 12 Bench alignment
- 13 Initial alignment
- 14 Alignment variations
- 15 Pylon alignment
- 16 Laminations | Epoxy resin, 6-carbon braid
- 17 Laminations | Non-epoxy resin, 12-carbon braid
- 18 Color swatch reference (Ottobock)
- 19 Color swatch reference (PRS)

## DESIGNS

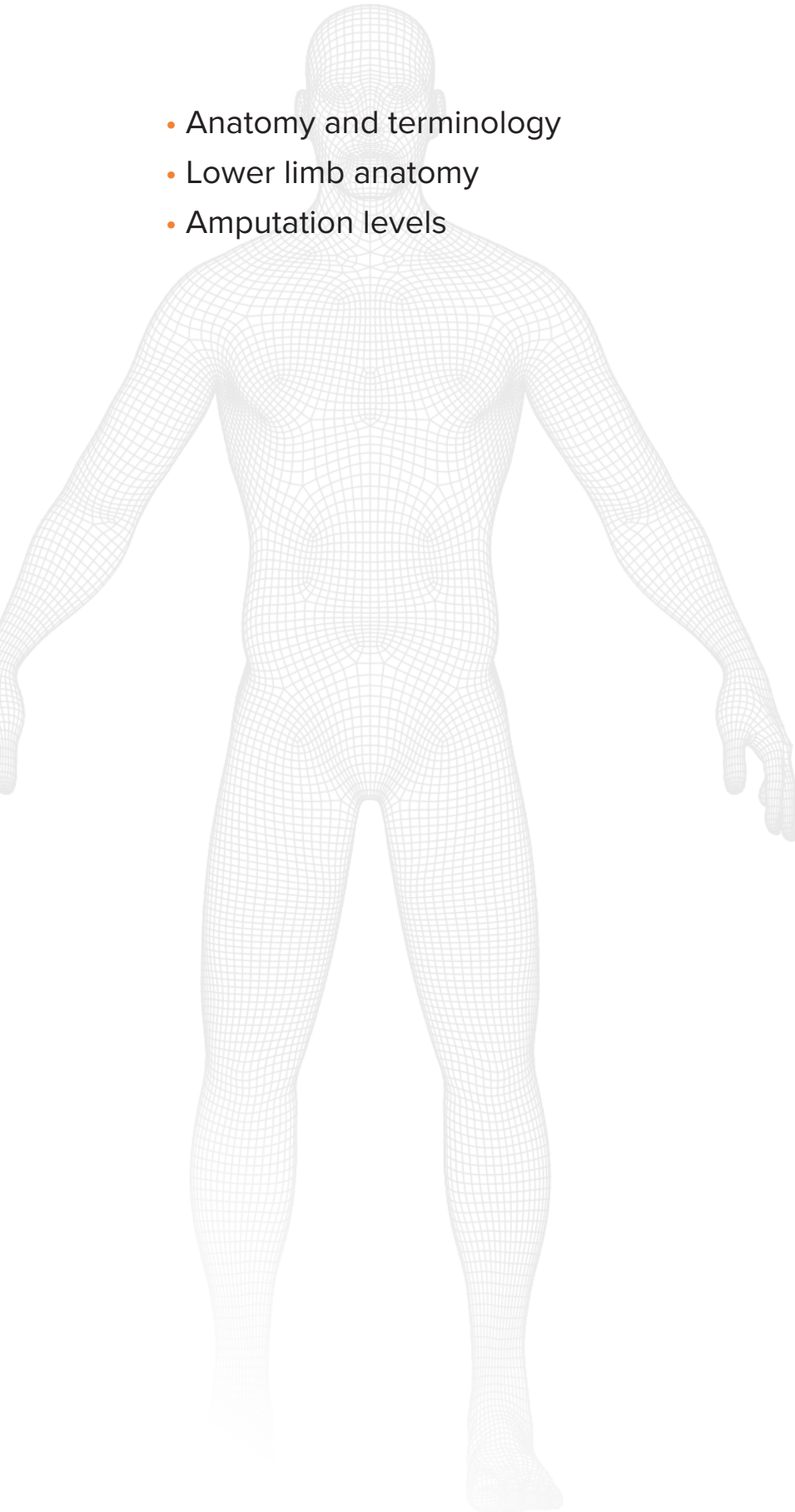
- 21 Check socket
- 22 Total surface bearing (TSB)
- 23 TSB variations
- 24 Patella tendon bearing (PTB) CDC-CAD modification protocols
- 25 Patella tendon bearing trimlines
- 26 Flexible inner liners
- 27 PTB-SC/PTB-SCSP
- 28 Glossary

## APPENDIX

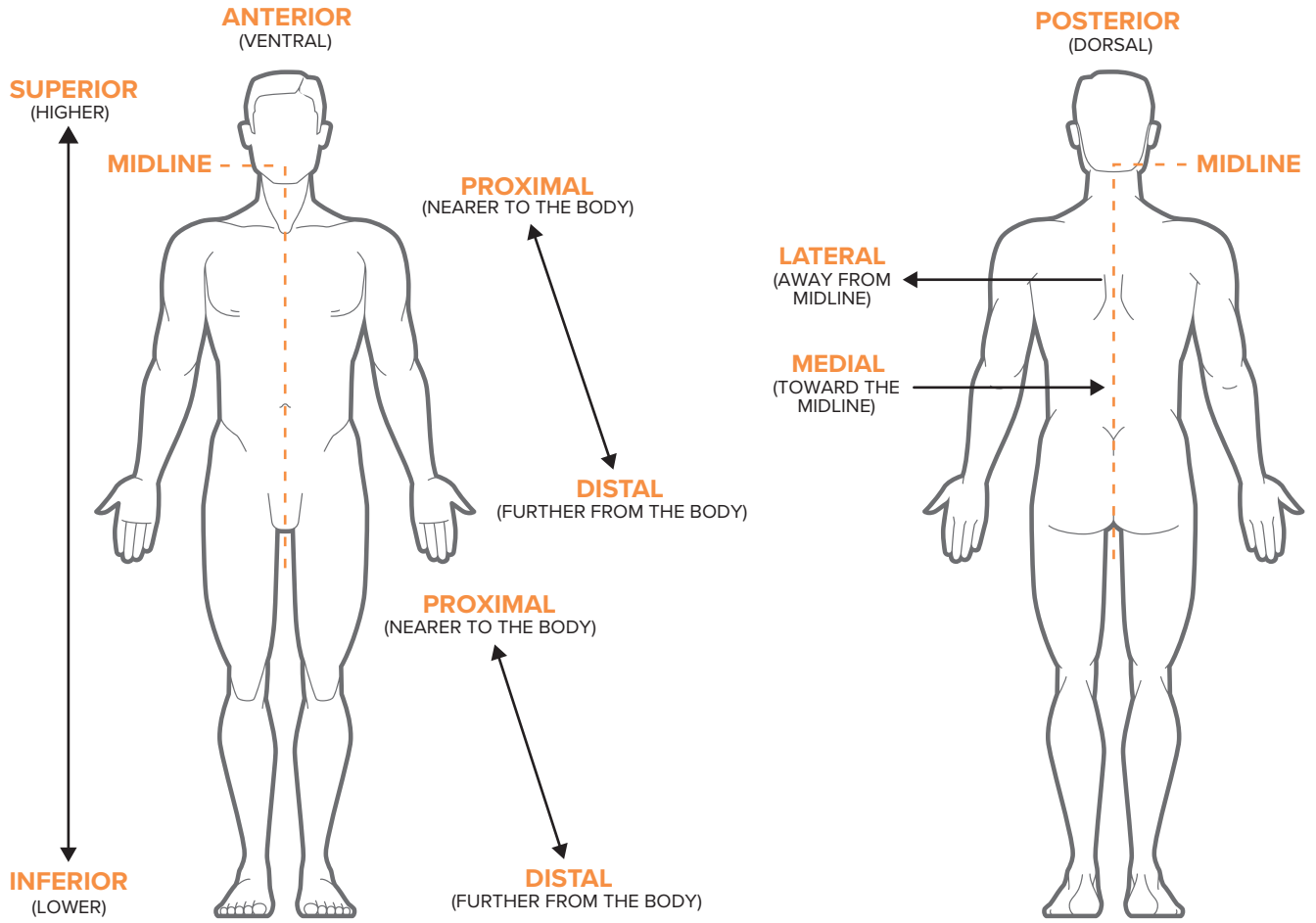
- 30 Sock ply adjustments
- 31 Cosmetic fabric in lamination guidelines

# OVERVIEW

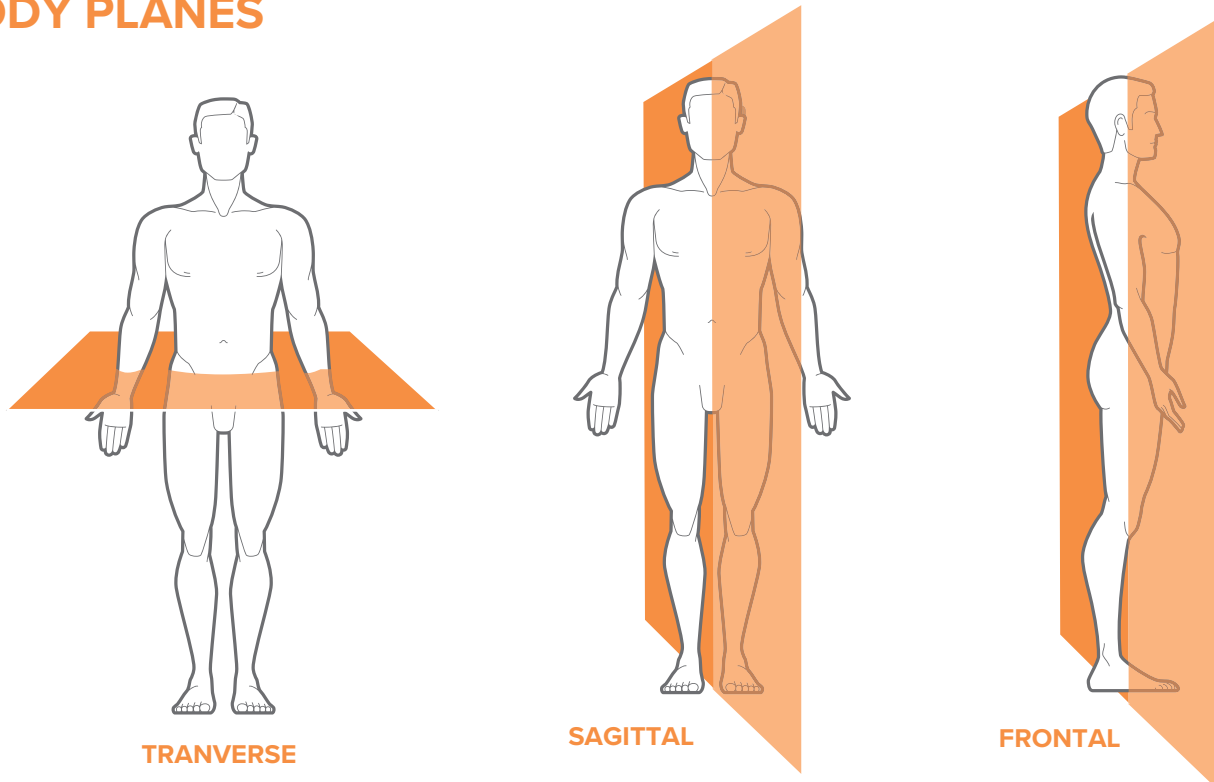
- Anatomy and terminology
- Lower limb anatomy
- Amputation levels

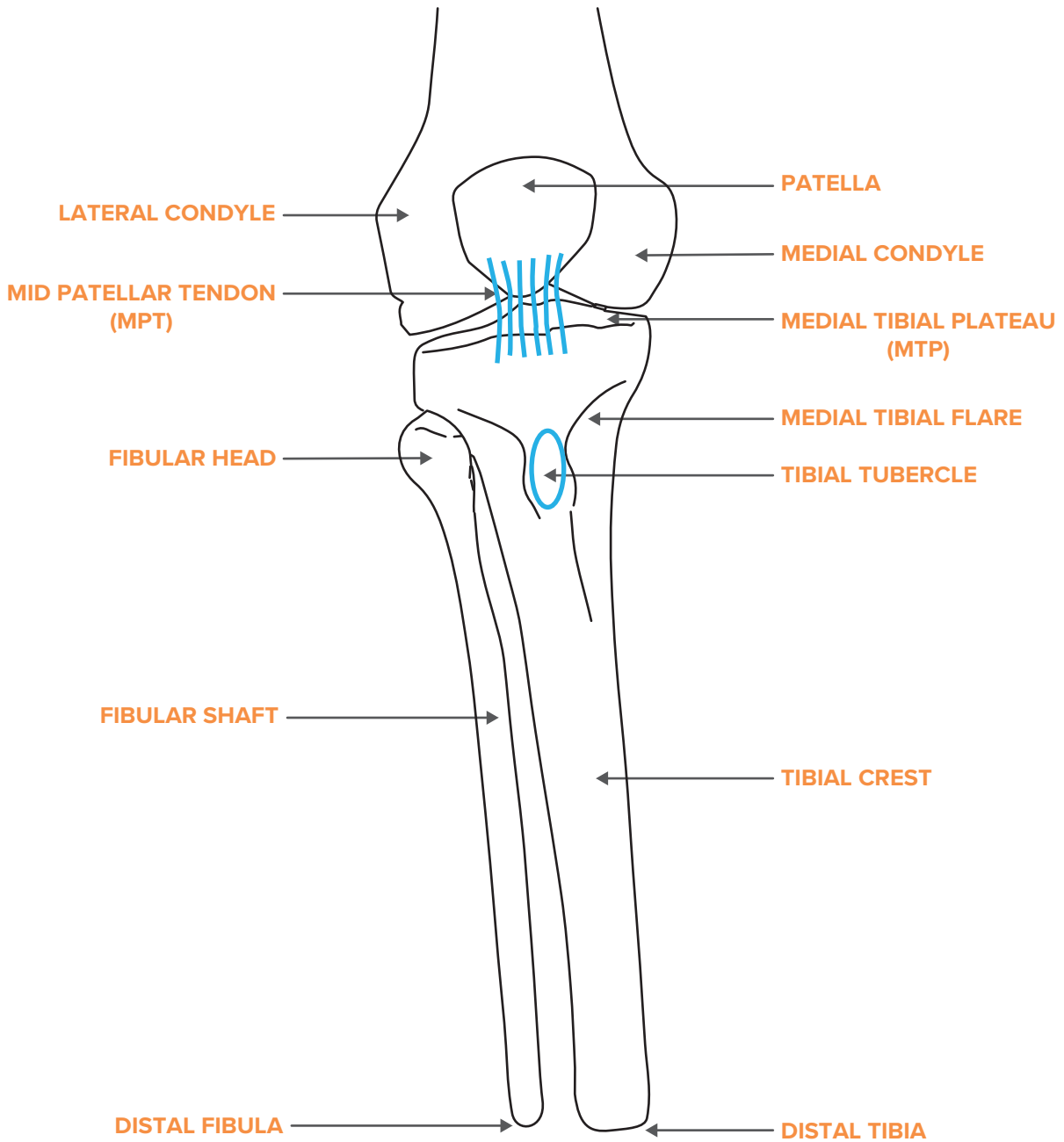


# ANATOMY AND TERMINOLOGY

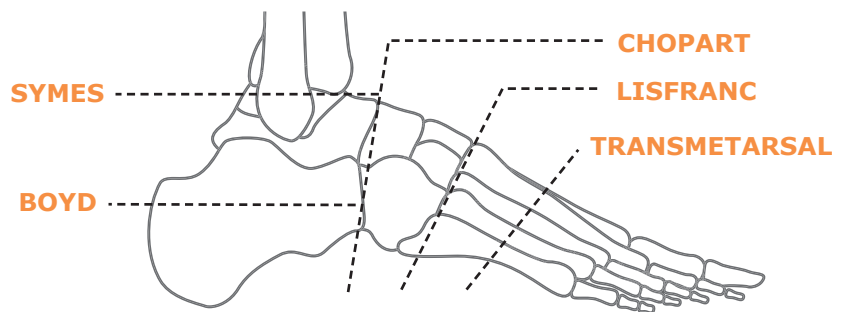
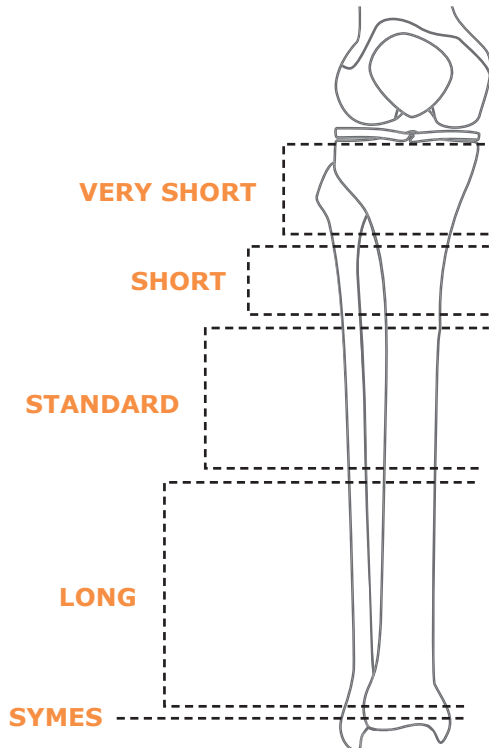
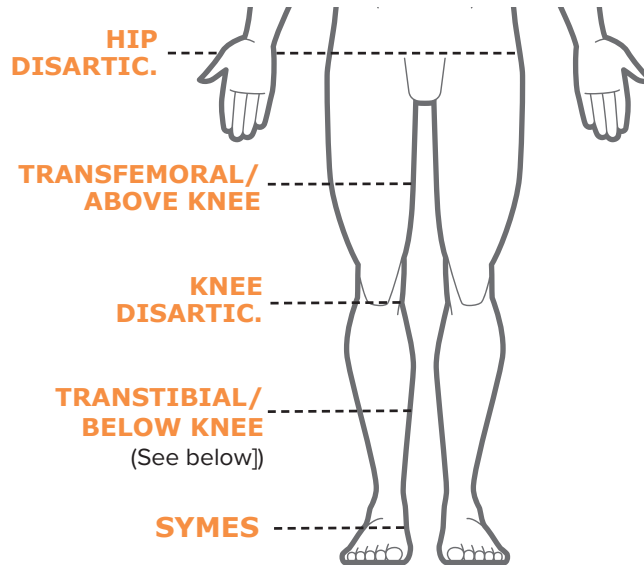


## BODY PLANES



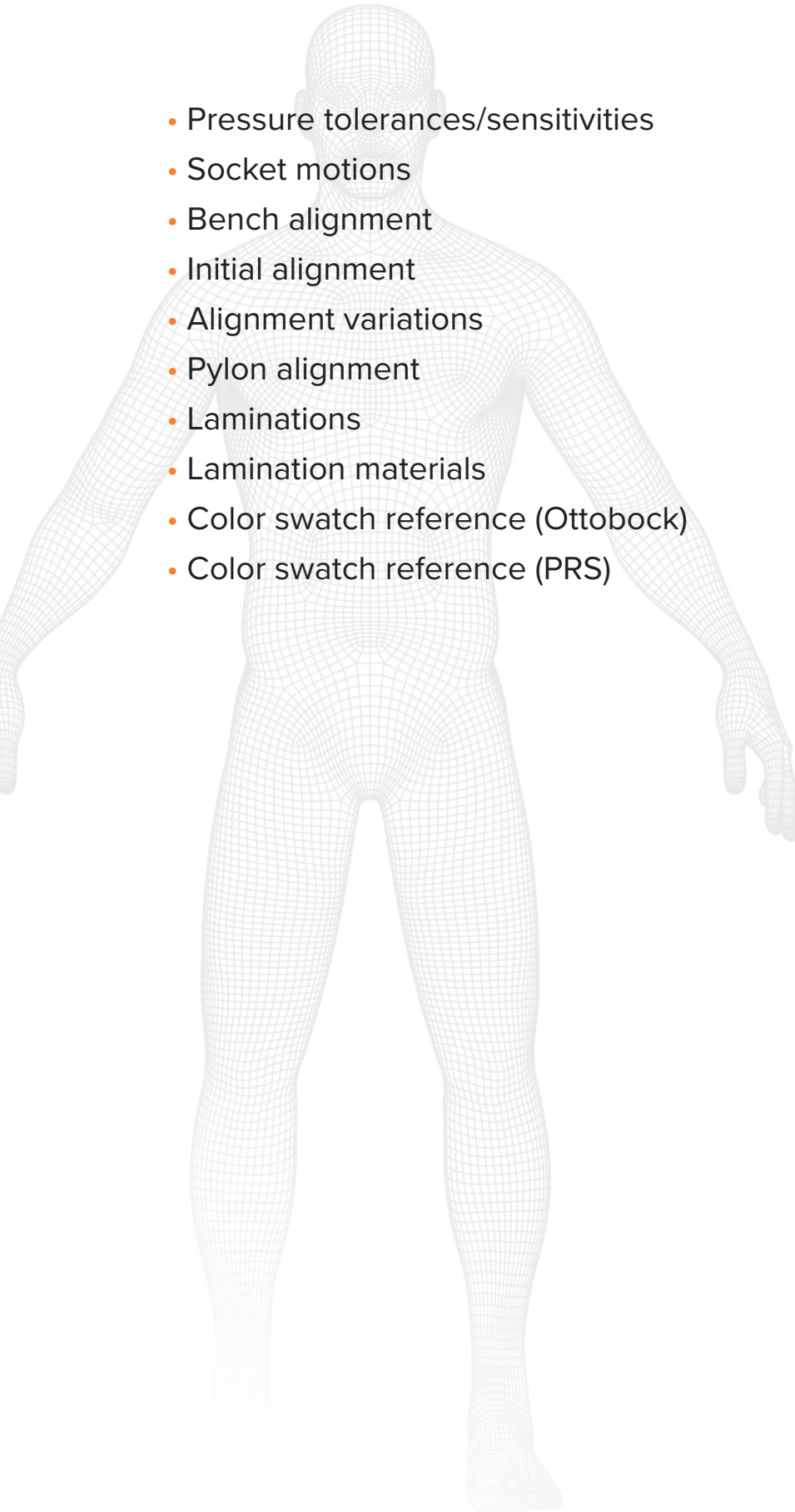


# AMPUTATION LEVELS

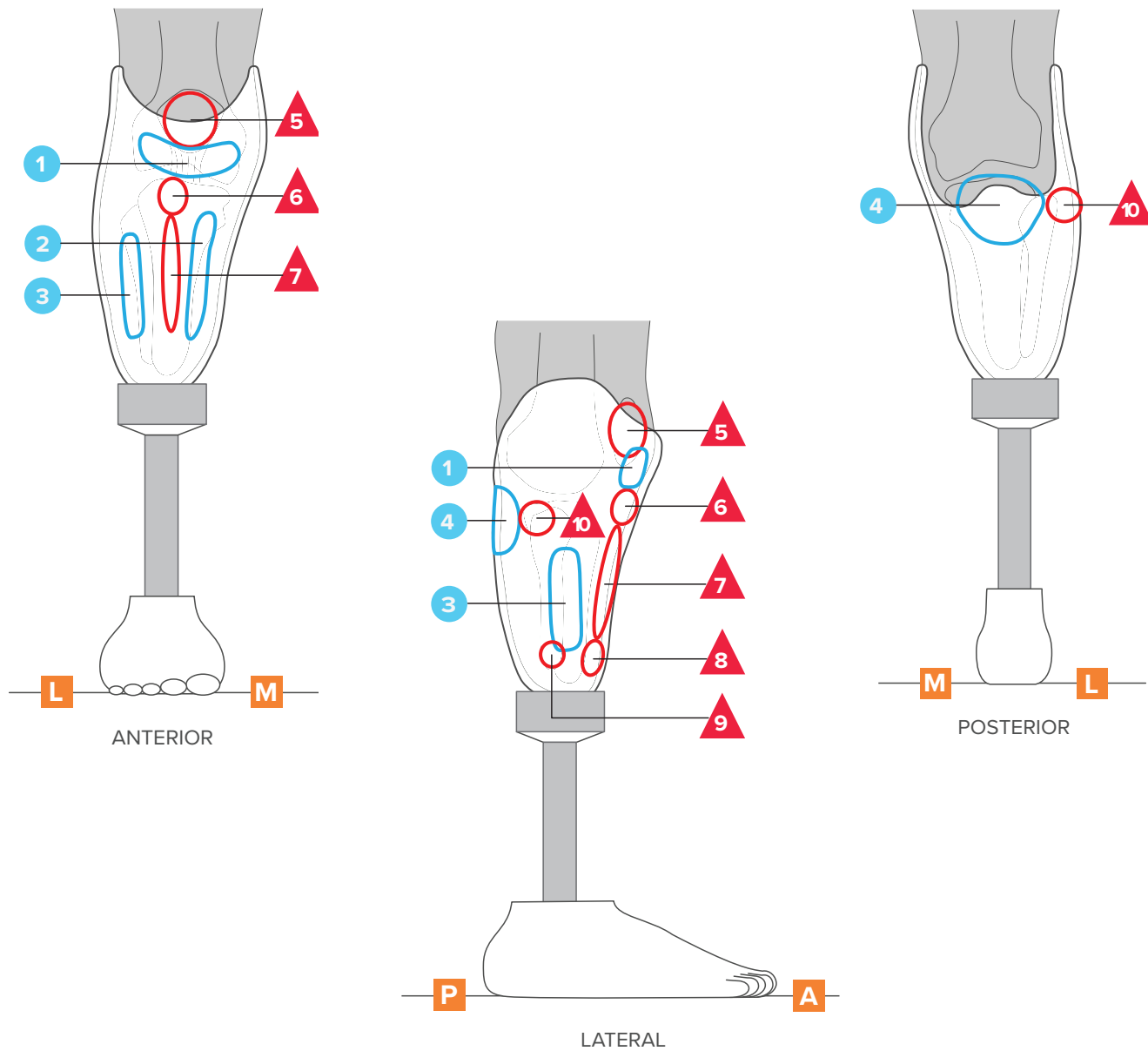




# FUNDAMENTALS

- Pressure tolerances/sensitivities
- Socket motions
- Bench alignment
- Initial alignment
- Alignment variations
- Pylon alignment
- Laminations
- Lamination materials
- Color swatch reference (Ottobock)
- Color swatch reference (PRS)



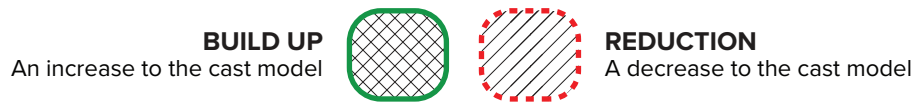
# PRESSURE TOLERANCES/SENSITIVITIES



 TOLERANT	 SENSITIVE
1. Patella Tendon "Bar" 2. Medial Tibial Flare 3. Inner Osseous 4. Gastrocnemius	5. Patella 6. Tibial Tubercle 7. Tibial Crest 8. Distal Tibia 9. Distal Fibula 10. Fibula Head

# 3D PRINTED CHECK SOCKET

TRIMLINE, BUILD UPS, REDUCTIONS



(Blend will vary according to patient's anatomy)

## TRIMLINE

2 mm Ant/Lat/Med Internal Flare

4 mm Posterior Flare

4 mm Post/Lat/Med External Flare for Shuttle Lock Suspension Only

### Patella Tendon Bar

Modified TSB: 3 mm  
Modified PTB: 5 mm

### Fib Head

Modified TSB: 0 mm  
Modified PTB: 3 mm

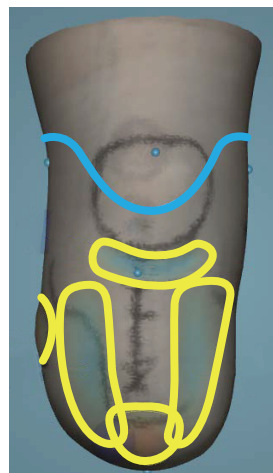
KC Cir. Reduction to Match ML & PML

### Pretibial Push

Modified TSB: 3 mm  
Modified PTB: 5 mm

### Diatal Tibia

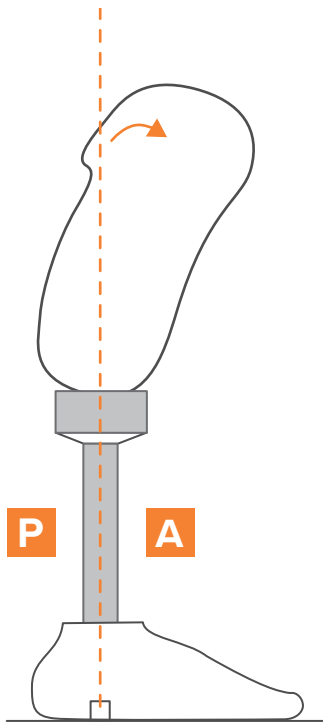
Modified TSB: 0 mm  
Modified PTB: 3 mm



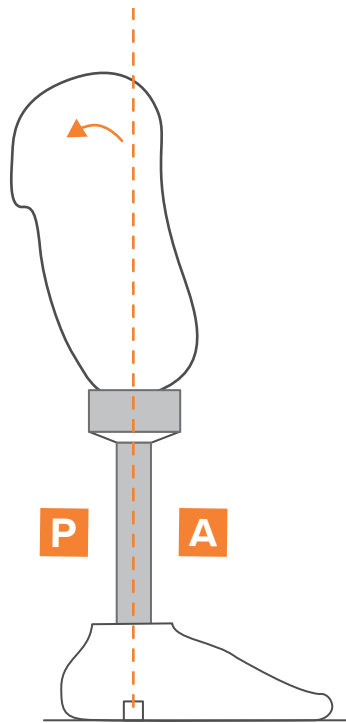
Online Ordering Visual Example

# SOCKET MOTIONS

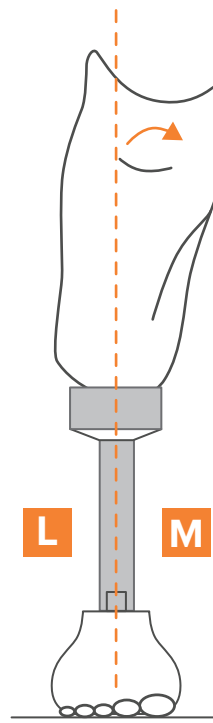
Socket motions are relative to the socket, not the foot.



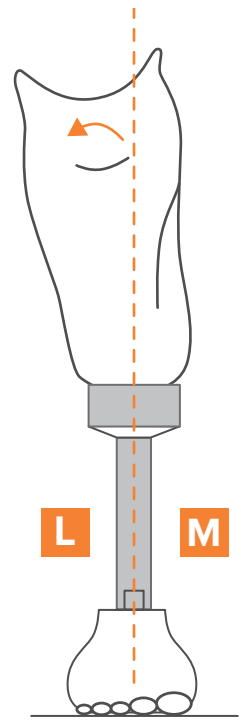
FLEXION



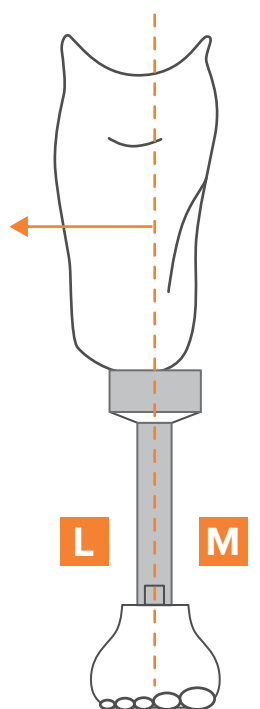
EXTENSION



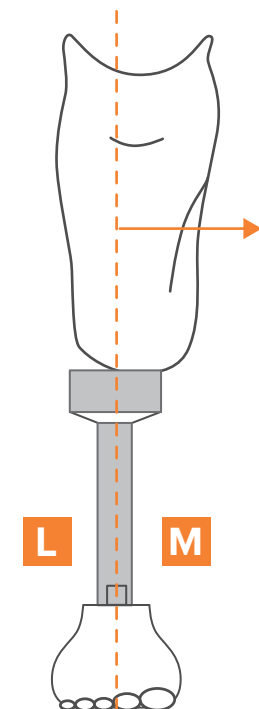
ABDUCTION



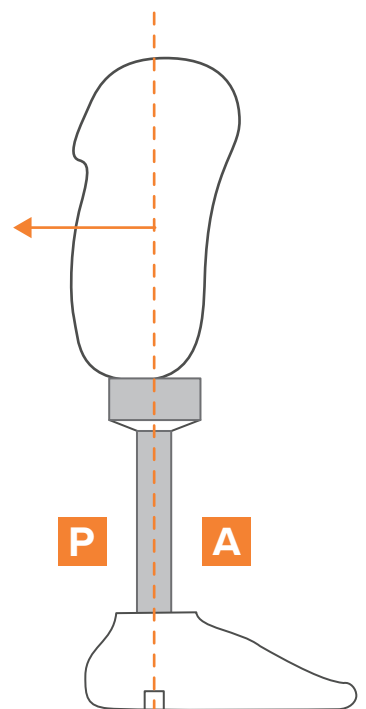
ADDUCTION



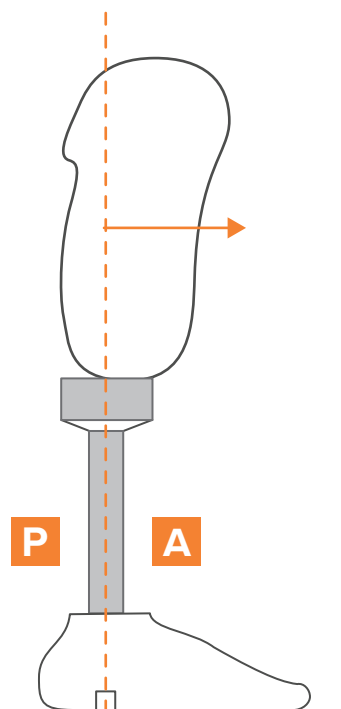
LATERAL SLIDE  
/FOOT INSET



MEDIAL SLIDE  
/FOOT OUTSET



POSTERIOR SLIDE

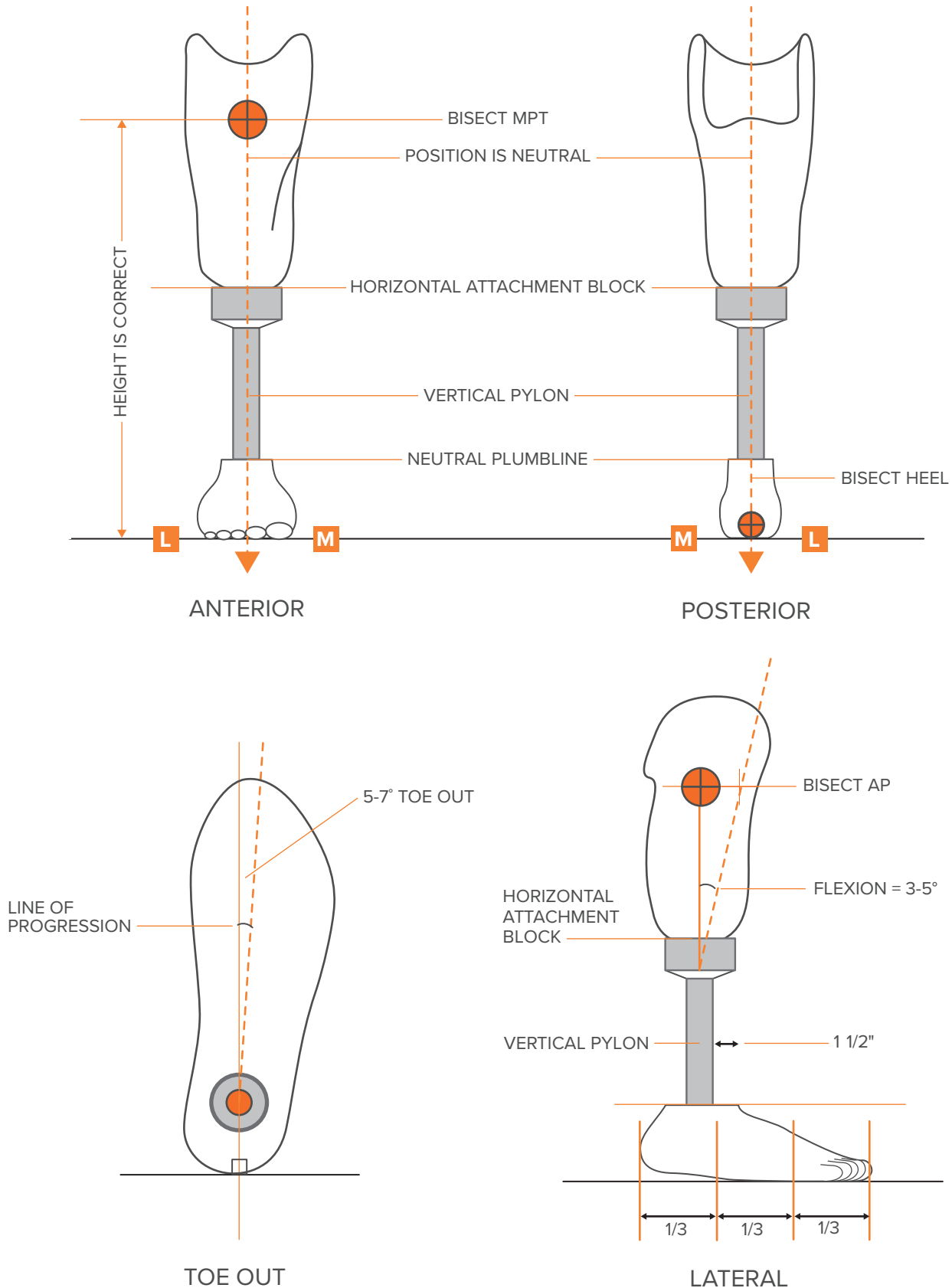


ANTERIOR SLIDE

# BENCH ALIGNMENT

## STANDARD\*

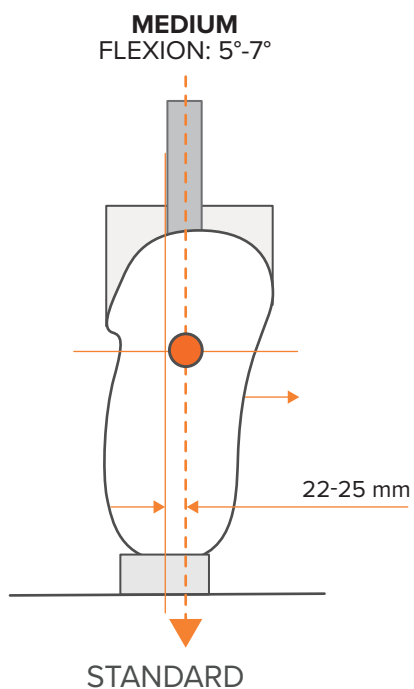
Bench alignment detailed below will apply if not otherwise indicated by the requester.



\*or per Clinician instructions

## MEDIAL OR LATERAL VIEW

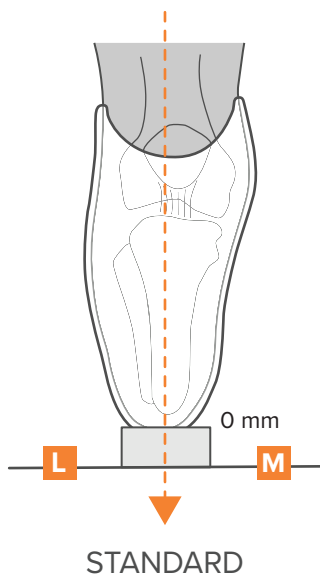
### DISTAL ATTACHMENT ANTERO-POSTERIOR PLACEMENT



## ANTERIOR VIEW

### DISTAL ATTACHMENT MEDIO-LATERAL PLACEMENT

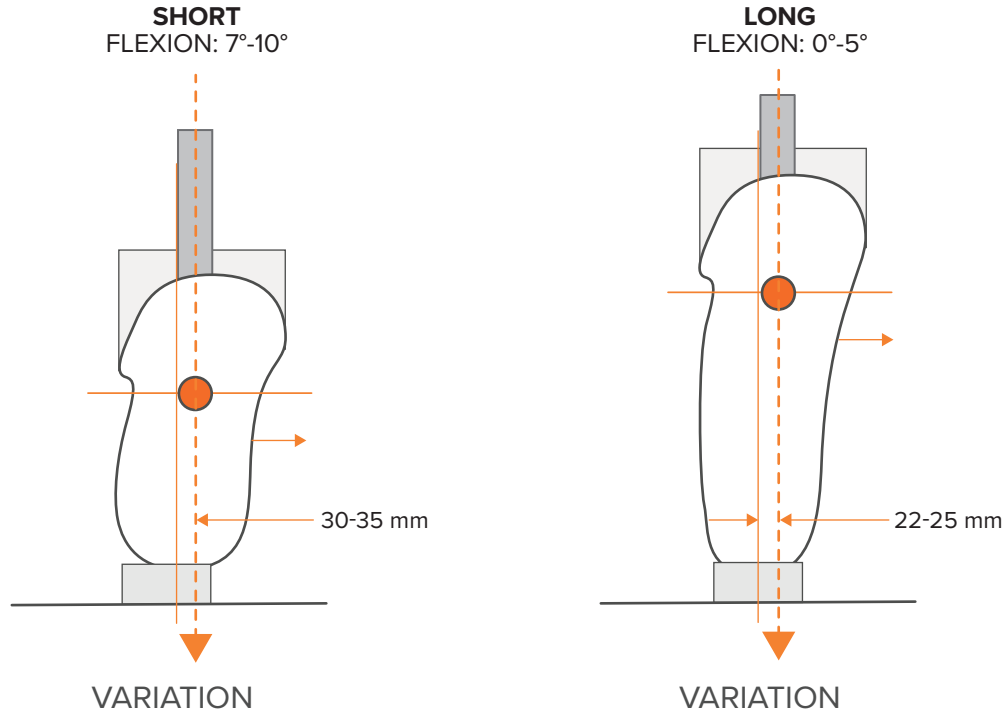
**MEDIUM**  
FROM 1/3 TO 2/3 OF THE  
ANATOMICAL LENGTH;  
NORMAL POSITION: NEUTRAL



# ALIGNMENT VARIATIONS

## MEDIAL OR LATERAL VIEW

### DISTAL ATTACHMENT ANTERO-POSTERIOR PLACEMENT

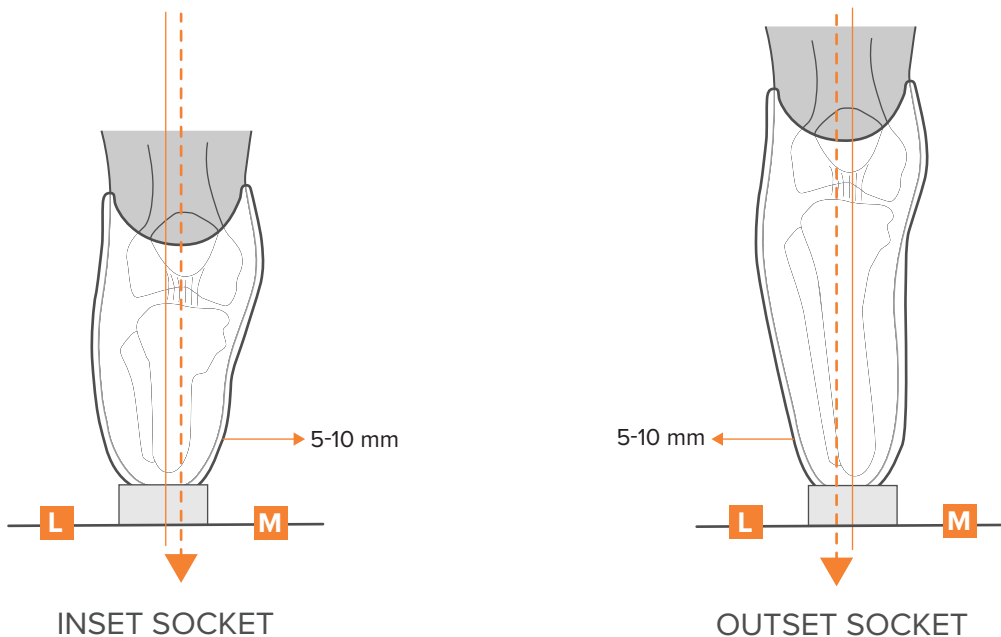


## ANTERIOR VIEW

### DISTAL ATTACHMENT MEDIO-LATERAL PLACEMENT

**SHORT**  
LESS THAN 1/3 OF THE ANATOMICAL LENGTH;  
NORMAL POSITION: ABDUCTION = VALGUM

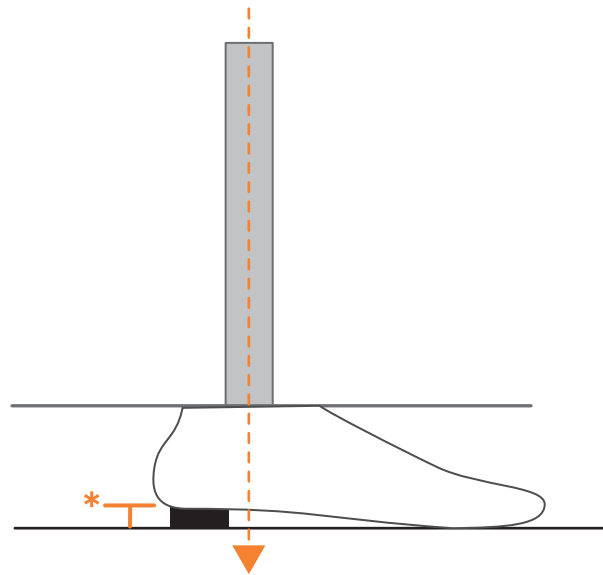
**LONG**  
MORE THAN 2/3 OF THE ANATOMICAL LENGTH;  
NORMAL POSITION: ADDUCTION = VARUM



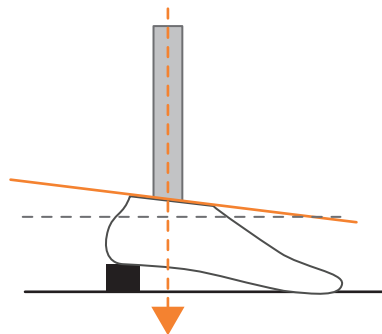
# PYLON ALIGNMENT

## HEEL HEIGHT IMPACT

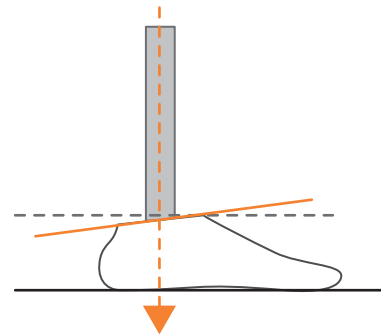
**NEUTRAL** = PYLON PERPENDICULAR TO FLOOR  
– RELATIVE TO FOOT HEEL HEIGHT\*



HIGH HEEL = PLANTAR FLEXION



LOW HEEL = DORSI FLEXION



# LAMINATIONS

FOR EPOXY RESINS AND 6K CARBON BRAID

## UNDER 220 lbs

### Single Shot

Carbon Finish	
Layup Material	Quantity
Carbon Fiber Braid	1
Nyglass	4
Carbon Fiber Braid	1
Pigmented/Custom Fabric Finish	
FlexaStretch	1
NSP	1
Nyglass	2
NSP	1
FlexaStretch	1
FlexaStretch and Custom Fabric	2

### Two Stage

Carbon Finish	
Layup Material	Quantity
First Stage	
Carbon Fiber Braid	1
Flex-a-stretch	2
Carbon Fiber Braid	Cap
Second Stage	
Carbon Fiber Braid	1
Nyglass	2
Carbon Fiber Braid	1
Pigmented/Custom Fabric Finish	
First Stage	
FlexaStretch	1
NSP	1
NSP	Cap
FlexaStretch	1
Second Stage	
NSP	Cap
Nyglass	2
NSP	1
FlexaStretch and Custom Fabric	2

## 220 to 300 lbs

### Single Shot

Carbon Finish	
Layup Material	Quantity
Carbon Fiber Braid	1
Carbon Fiber Braid	Cap
Nyglass	2
Carbon Fiber Braid	1
Nyglass	2
Carbon Fiber Braid	1
Pigmented/Custom Fabric Finish	
FlexaStretch	1
NSP	1
Nyglass	4
NSP	1
FlexaStretch	1
FlexaStretch and Custom Fabric	2

### Two Stage

Carbon Finish	
Layup Material	Quantity
First Stage	
Carbon Fiber Braid	1
FlexaStretch	2
Carbon Fiber Braid	Cap
Second Stage	
Carbon Fiber Braid	1
Nyglass	4
Carbon Fiber Braid	1
Pigmented/Custom Fabric Finish	
First Stage	
FlexaStretch	1
NSP	1
NSP	Cap
FlexaStretch	1
Second Stage	
NSP	Cap
Nyglass	4
NSP	1
FlexaStretch and Custom Fabric	2

# LAMINATIONS

## FOR NON-EPOXY RESINS AND 12K CARBON BRAID

Carbon Finished Sockets (1-stage slight black pigment)		
Variation 1 (V1)	Variation 2 (V2)	Variation 3 (V3)
2 Nyglass	1 Carbon Braid	1 Carbon Braid
Carbon Tape Reinforcement over Distal End and AP/ML	2 Nyglass	2 Nyglass
2 Nyglass	1 Carbon Braid	1 Carbon Braid
		2 Nyglass
		1 Carbon Braid
Pigment Finished Sockets (1-stage)		
Variation 1 (V1)	Variation 2 (V2)	Variation 3 (V3)
2 Nylon	2 Nylon	2 Nylon
Carbon Tape Reinforcement over Distal End and AP/ML	1 Carbon Braid	1 Carbon Braid
1 Carbon Braid	1 1/2 Carbon Braid	2 Nyglass
		1 Carbon Braid
2 Nylon	2 Nylon	2 Nylon
2 FlexaStretch	2 FlexaStretch	2 FlexaStretch
2-Stage Carbon Laminations (slight black pigment)		
Variation 1 (V1)	Variation 2 (V2)	Variation 3 (V3)
1 Carbon Braid	1 Carbon Braid	1 Carbon Braid
2 Nyglass	2 Nyglass	2 Nyglass
Laminate First and Transfer	Laminate First and Transfer	Laminate First and Transfer
2 Nyglass	2 Nyglass	4 Nyglass
1 Carbon Braid	1 1/2 Carbon Braid	2 Carbon Braid
2-Stage Pigment/Fabric Finished Sockets		
Variation 1 (V1)	Variation 2 (V2)	Variation 3 (V3)
2 Nylon	2 Nylon	2 Nylon
2 Nyglass	2 Nyglass	2 Nyglass
Carbon Tape Reinforcement over Distal End and AP/ML	1 Carbon Braid	1 Carbon Braid
Laminate First and Transfer	Laminate First and Transfer	Laminate First and Transfer
1 Carbon Braid	1 1/2 Carbon Braid	2 Carbon Braid
2 Nylon	2 Nylon	2 Nylon
2 FlexaStretch	2 FlexaStretch	2 FlexaStretch

# COLOR SWATCH REFERENCE

OTTOBOCK

**646M3** – Color Swatch Set (cosmetic gloves)



**NOTE:** For demonstration purpose only. Please refer to actual lamination color swatch sample. Variation in color may occur.

# COLOR SWATCH REFERENCE

PROSTHETIC RESEARCH SPECIALISTS

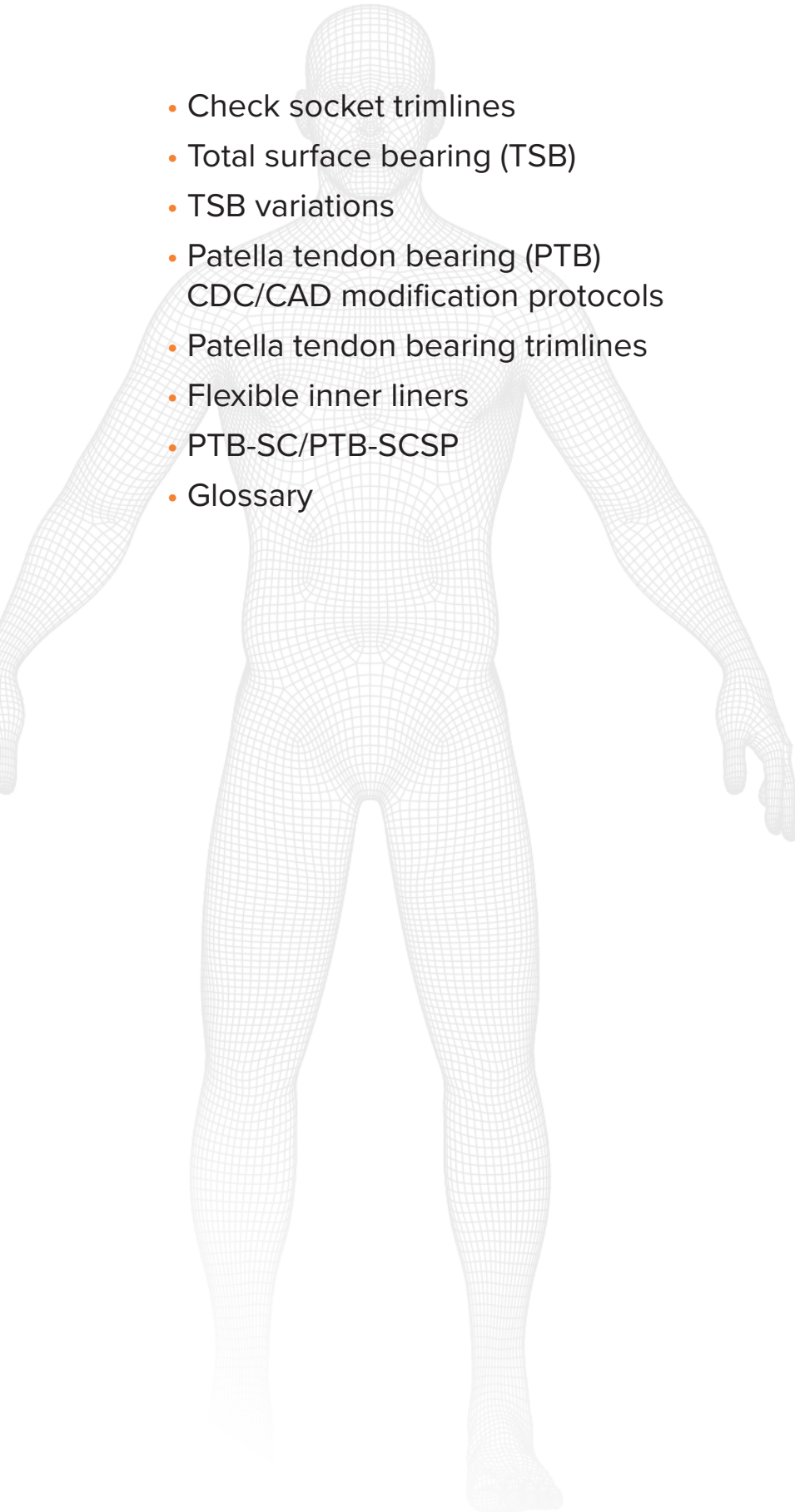
## Flesh Color System Pigment Color Approximations



**NOTE:** For demonstration purpose only. Please refer to actual lamination color swatch sample. Variation in color may occur.

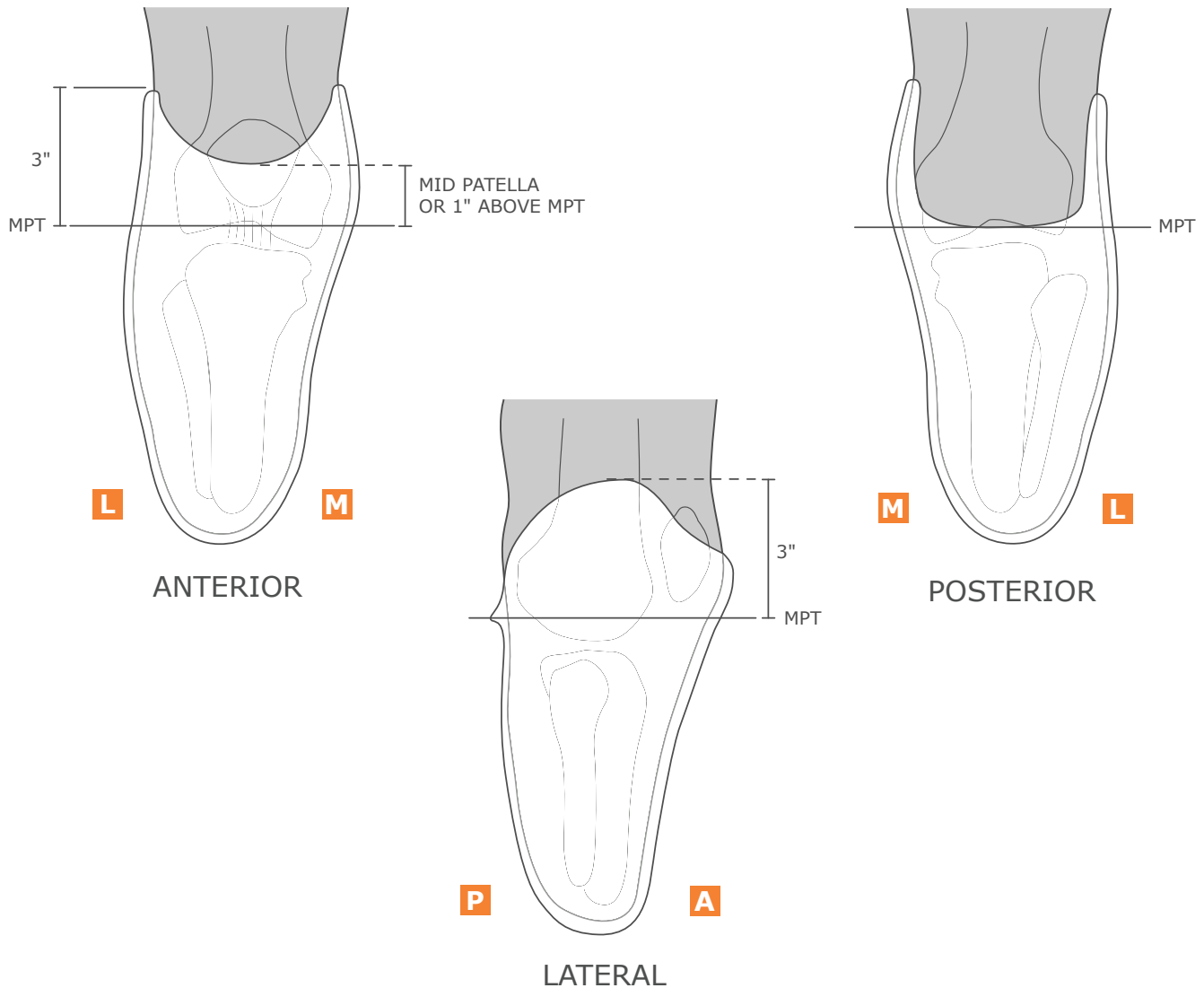
# DESIGNS

- Check socket trimlines
- Total surface bearing (TSB)
- TSB variations
- Patella tendon bearing (PTB)  
CDC/CAD modification protocols
- Patella tendon bearing trimlines
- Flexible inner liners
- PTB-SC/PTB-SCSP
- Glossary



# CHECK SOCKET

## TRIMLINES

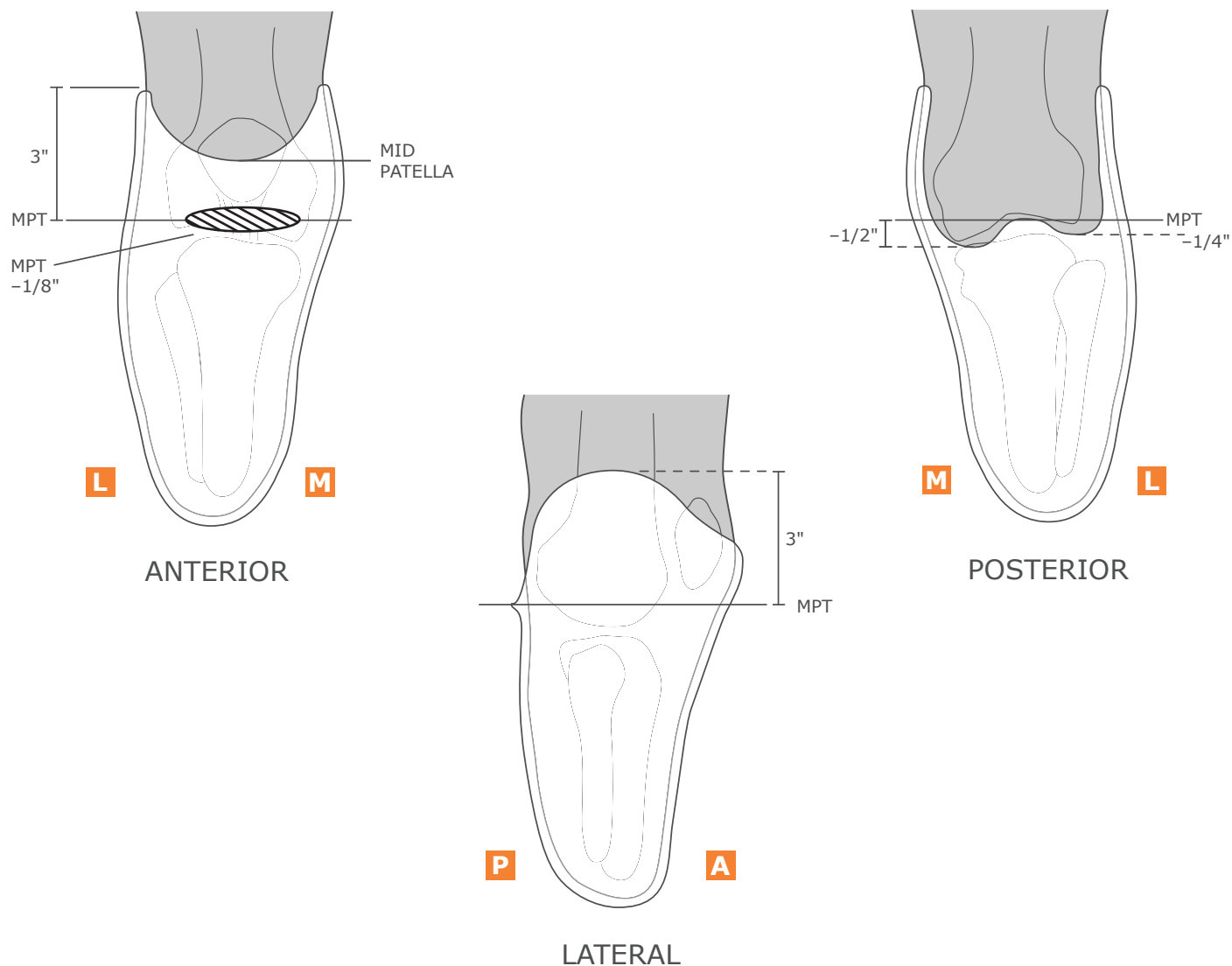


### BLISTER FORMING SIZE SELECTION TABLE

					PETG		
Cast length	Use plastic square size	Less than key cast diameter use 3/8" thickness	Key cast diameter	Greater than key cast diameter use 1/2" thickness	3/8"	1/2"	1/4"
≤ 12"	12"x12"		6 3/4		304-381	304-121	304-141
≤ 14"	14"x14"		8				
≤ 16"	16"x16"		9 1/2		3751616PT	5001616PT	304-146
≤ 18"	18"x18"		10 3/4		3751818PT	304-127	304-147
≤ 20"	20"x20"		12		304-380	304-120	304-140
≤ 24"	24"x24"		14 3/4		VIV382424	VIV122424	

# TOTAL SURFACE BEARING (TSB)

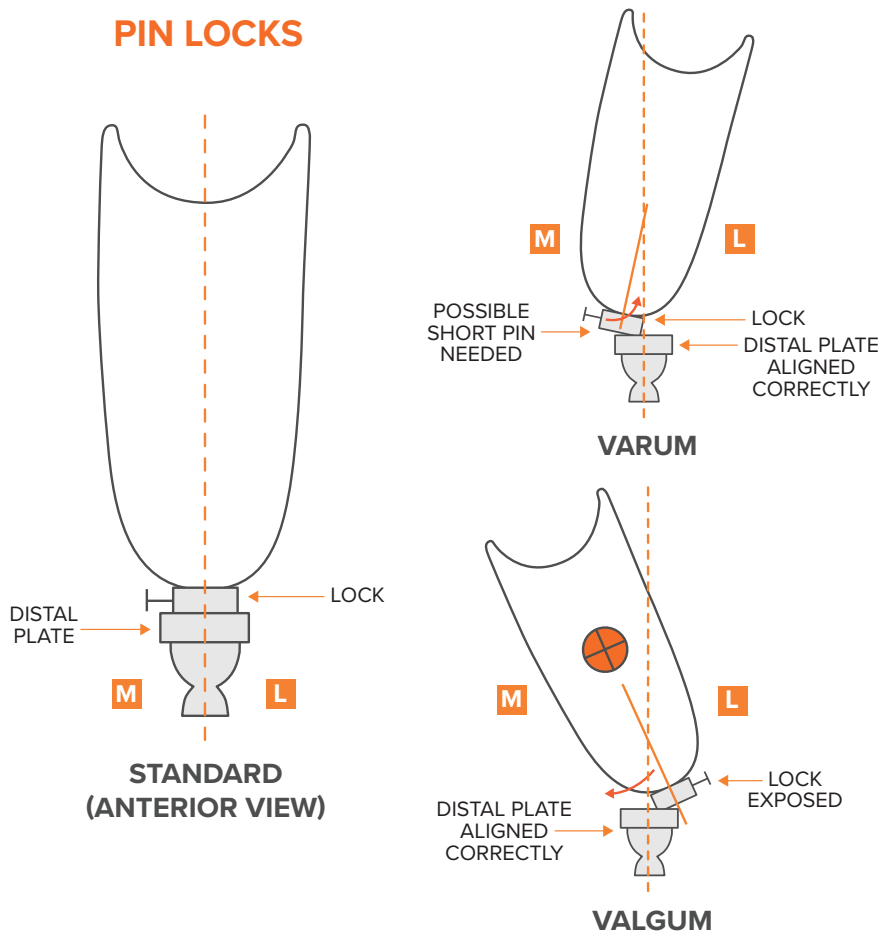
REDUCTION



CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES	VARIATIONS
<ul style="list-style-type: none"> <li>□ MPT to distal end</li> <li>△ ML apex of condyles</li> <li>△ PML</li> <li>△ AP at level of MPT</li> </ul>	<ul style="list-style-type: none"> <li>• Medial/Lateral = 2 1/2" above MPT</li> <li>• Anterior = 1/2" prox to MPT or distal 1/2 of patella</li> <li>• Posterior = apex at -1/2" proximal to MPT level</li> <li>• Medial hamstring relief = -1/2" distal to MPT level</li> <li>• Lateral hamstring relief = -1/4" distal to MPT level</li> </ul> <div style="background-color: #f4a460; padding: 2px; text-align: center; font-weight: bold; margin: 5px 0;">STANDARD MODIFICATIONS</div> <ul style="list-style-type: none"> <li>• Goal: 0-1 ply fit</li> <li>• 5% global reduction</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Note:</b> modifications will vary with patient tissue type, input types (scan vs. cast) and input measurements (with or without a liner)</li> </ul> <p>Design guidelines:</p> <ul style="list-style-type: none"> <li>3 mm liner = 7 ply reduction</li> <li>6 mm liner = 9 ply reduction</li> <li>9 mm liner = 12 ply reduction</li> </ul> <ul style="list-style-type: none"> <li>• <b>Posterior Shelf Modification</b> – Added upon request only</li> </ul>

# TSB VARIATIONS

## PIN LOCKS



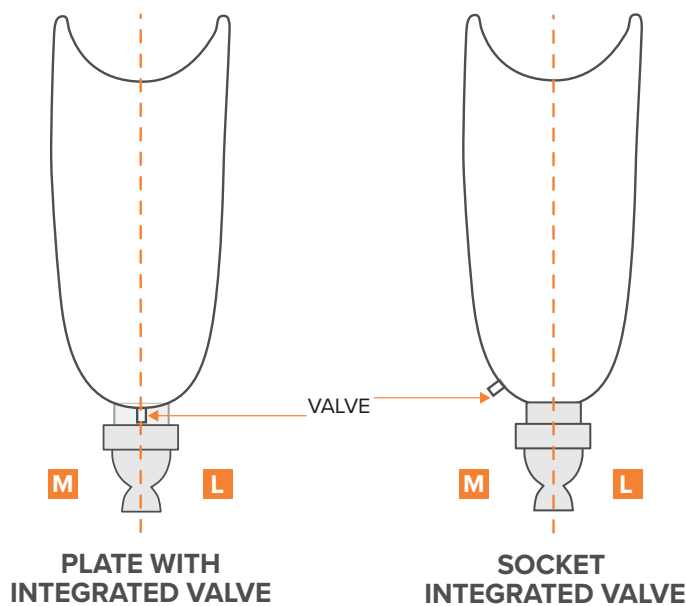
### STANDARD

- Pin lock
- Align along lateral and anterior long axis of limb
- Release button medial

### OPTIONS

- Fillauer
- Ossur
- Coyote
- Clutch and ratchet
- Per clinician request

## SUCTION



### STANDARD

- External valve located distal medial quadrant

### OPTIONS

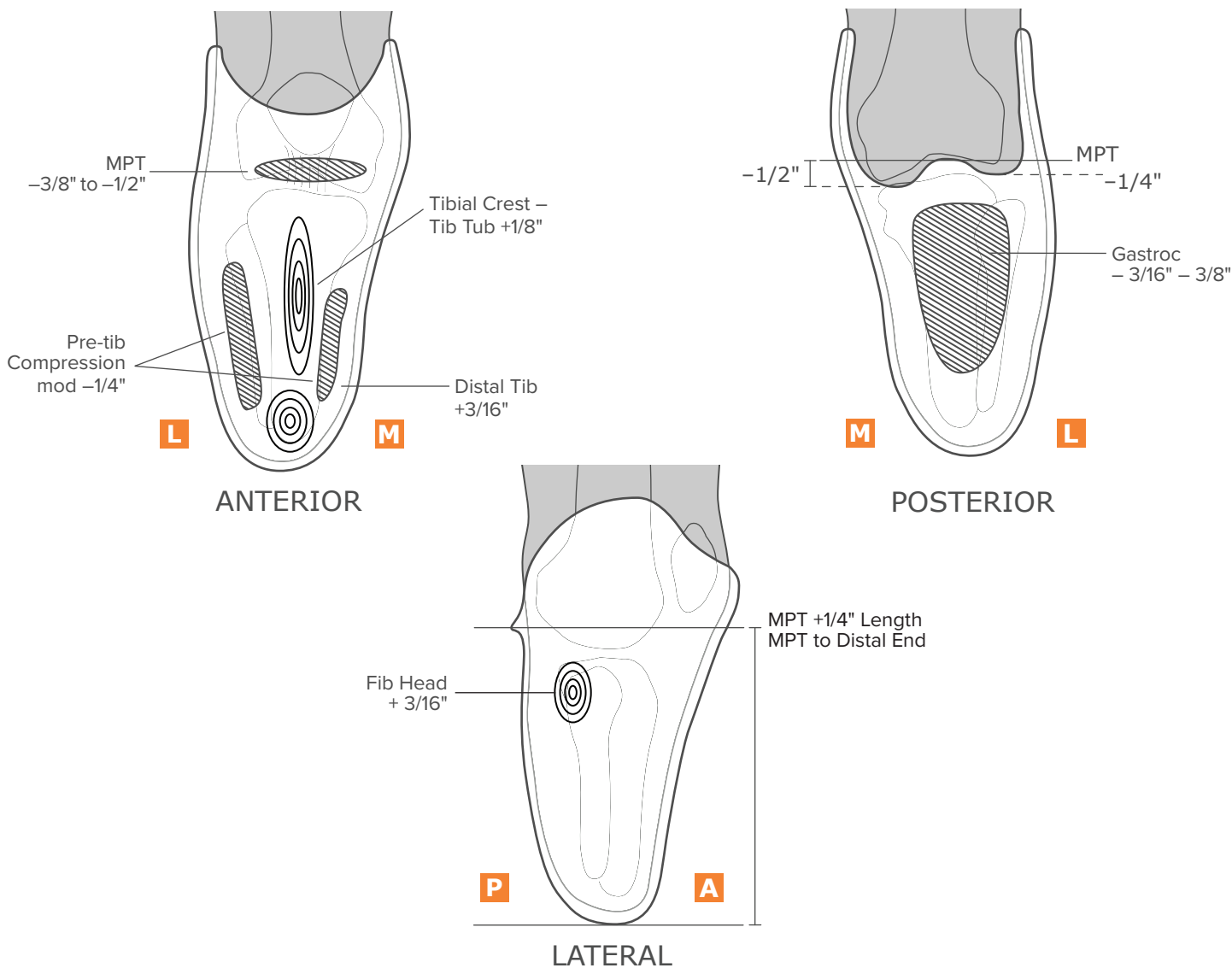
- Ossur flat valve plate
- Lyn valve
- Flexible inner liner
- Per clinician request

# PATELLA TENDON BEARING (PTB)

## CDC-CAD MODIFICATION PROTOCOLS

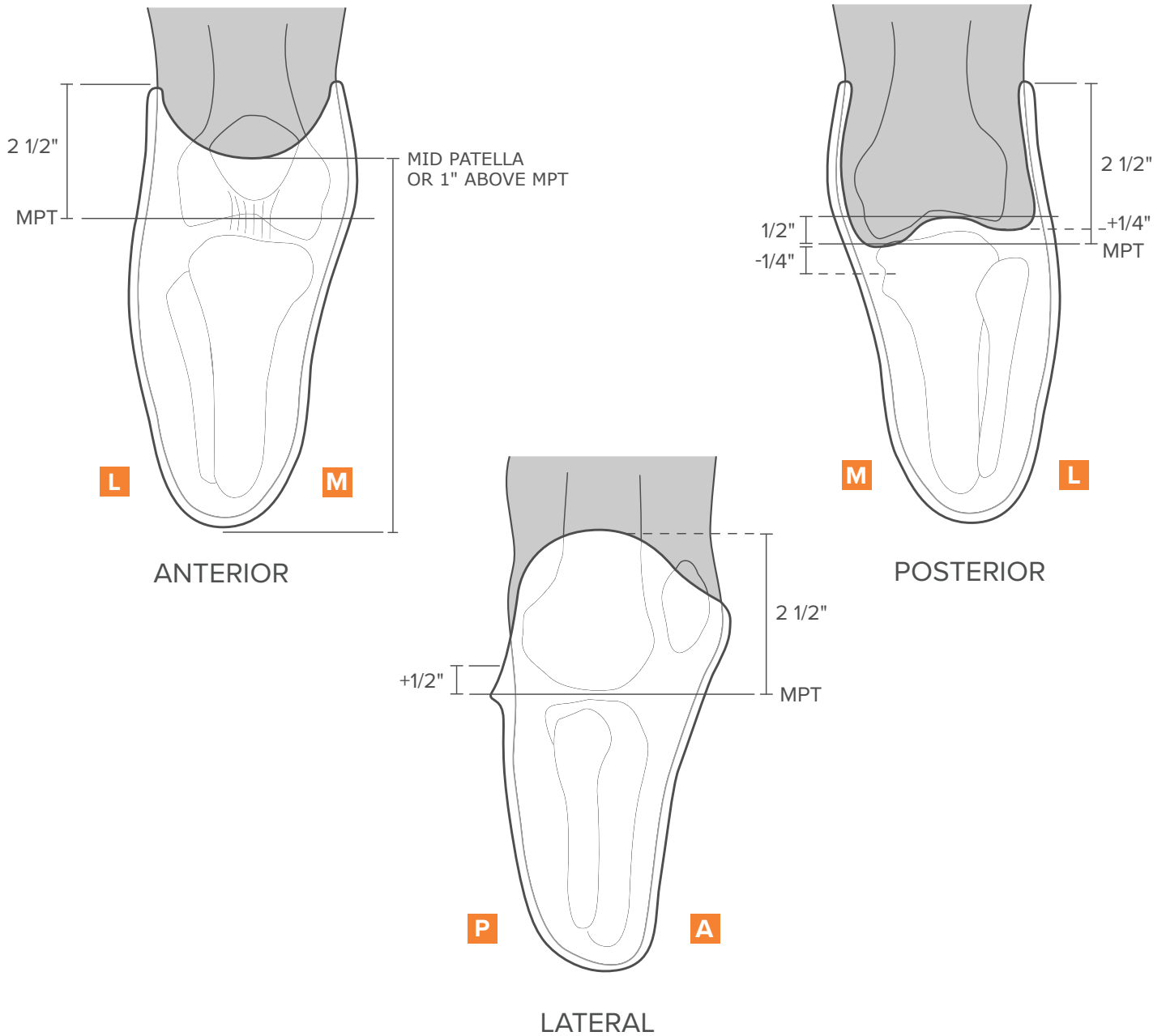
☉ BUILD UP    ▨ REDUCTION

(Blend will vary according to patient's anatomy)



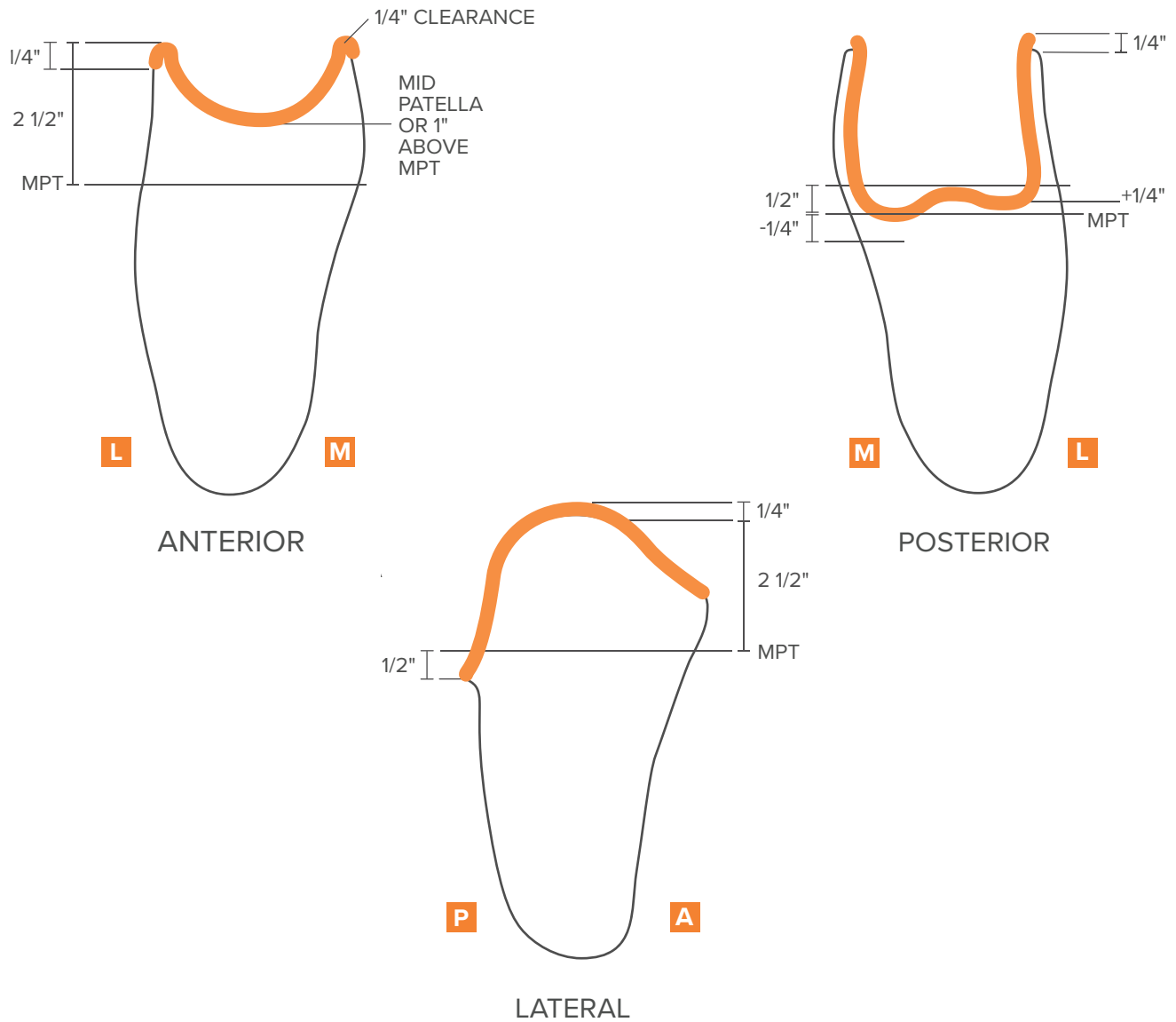
<b>CTQ MEASUREMENTS + OTHER</b> CTQ = Critical to Quality	<b>STANDARD MODIFICATIONS</b>	<b>VARIATIONS</b>
<p><b>- Tissue Type and Liner – REQUIRED</b></p> <p>☐ MPT to distal end</p> <p>△ MPT</p> <p>○ Every 2" (5 cm) increment distally</p>	<p><b>CTQ Other – (Reduction Value Calculation)</b></p> <ul style="list-style-type: none"> <li>• Reductions are applied only upon clinician request</li> <li>• CDC Reduction Protocols-Tissue Type, Liner Scanned/Mx Over                             <ul style="list-style-type: none"> <li>- Scan of Cast – Volumetric Reduction Calculated based on liner &amp; tissue type (0-6%)</li> <li>- Direct Patient Scan-Over Liner – Ply Reduction Calculated based on liner &amp; tissue type (6-12ply)</li> </ul> </li> <li>- Indicate "Skin" for skin fit</li> </ul>	<p><b>Posterior Shelf</b></p> <p>– Added upon request only</p>
<p><b>CTQ LANDMARKS</b></p> <p>CTQ = Critical to Quality</p>		
<ul style="list-style-type: none"> <li>• MPT – Mid-Patella Tendon</li> <li>• Fibular Head</li> <li>• Distal Tib</li> </ul> <p><i>Include instructions with any additional info on scan/cast</i></p>		

# PATELLA TENDON BEARING TRIMLINES



CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES
<ul style="list-style-type: none"> <li>□ MPT to distal end</li> <li>△ ML apex of condyles</li> <li>△ PML</li> <li>△ AP at level of MPT</li> </ul>	Anterior • Midpoint of patella Lateral • 2 1/2" proximal to MPT Posterior • Medial hamstring relief -1/2" distal to MPT • Lateral hamstring relief -1/4" distal to MPT

# FLEXIBLE INNER LINERS



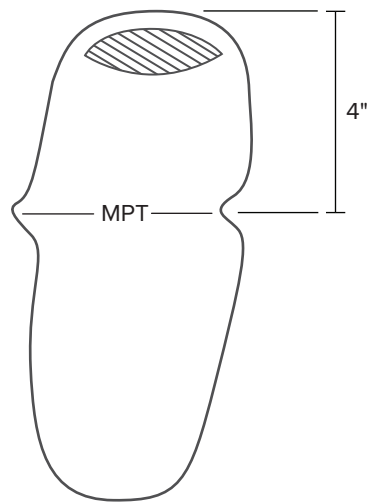
STANDARD MATERIAL /TRIMLINES	VARIATIONS
<ul style="list-style-type: none"><li>• Flexible inner liner standards are pulled from ProFlex</li><li>• 1/4" clearance above frame</li><li>• Symmetrical to frame</li></ul>	<ul style="list-style-type: none"><li>• Per clinician</li><li>• Pelite</li><li>• Northvane</li><li>• Polyethelene</li></ul>

# PTB-SC/PTB-SCSP

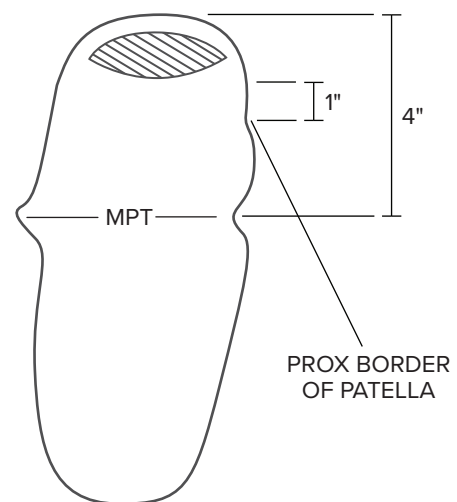
## SUPRACONDYLAR/SUPRACONDYLAR SUPRAPATELLAR

 REDUCTION

### PTB-SC



### PTB-SCSP



CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES	VARIATIONS
<ul style="list-style-type: none"> <li>• Proximal m/l measurement for supra condylar (Critical)</li> <li>• AP at MPT</li> <li>• ML at apex of condyles</li> </ul>	<ul style="list-style-type: none"> <li>• Supracondylar material is made from Pelite</li> <li>• Deepest wedge is always on medial side</li> <li>• Trim line over patella will be 1" above proximal border of patella</li> <li>• Medial/lateral trim lines will be 65 mm above MPT, same as PTB-SC</li> </ul>	<p>Laminated removable wedge is available upon work order request</p>

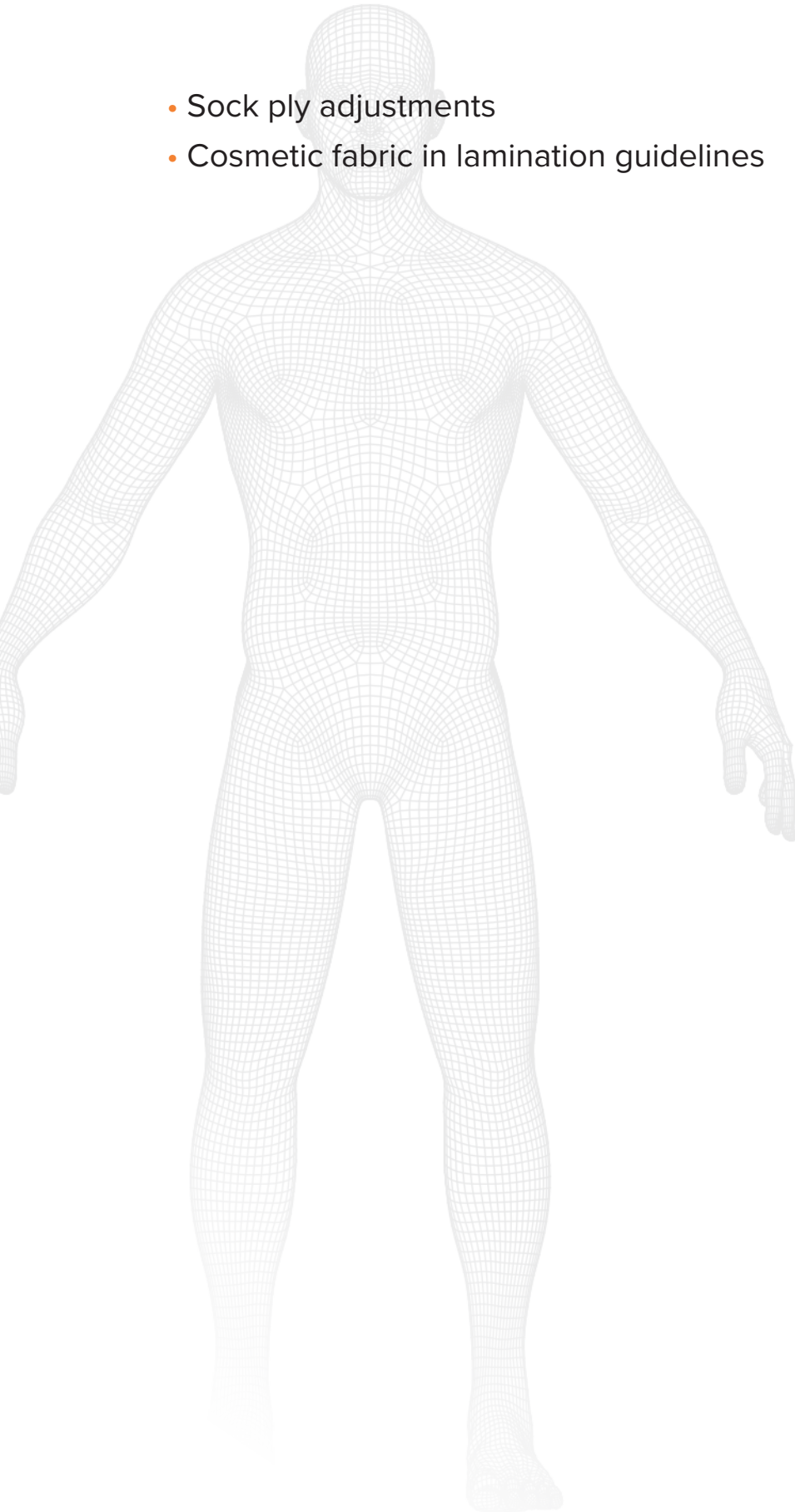
# GLOSSARY

## BELOW THE KNEE TERMINOLOGY

PROSTHETIC TERMS		NOTES
<b>Flexion</b>	Tilting of the proximal socket forward over the foot	
<b>Extension</b>	Tilting of the proximal socket back over the heel	
<b>Proximal</b>	Situated nearer toward the center of the body or point of origin	
<b>Distal</b>	Situated away from the center of the body, farthest from body	
<b>Anterior</b>	Situated near the front of the body	
<b>Posterior</b>	Situated near the back of the body	
<b>Abduction</b>	Distal end of socket situated away from the midline of body	
<b>Adduction</b>	Distal end of socket situated towards the midline of body	
<b>Lateral</b>	Side of the body farthest from the midline of the body	
<b>Medial</b>	Nearer to the middle of the body	
<b>Slide</b>	Liner translation with no angular change	
<b>Rotation</b>	To pivot on a point in a clockwise or counterclockwise rotation	
<b>Build Up</b>	To add plaster to a cast to make relief for a boney or problem area	
<b>Reduction</b>	To take away plaster on a cast to tighten in that area for firm contact, shave down	
<b>LE</b>	Lower extremity	
<b>UE</b>	Upper extremity	
<b>AK</b>	Above-knee amputation	
<b>BK</b>	Below-knee amputation	
<b>PH</b>	Partial hand amputation	
<b>TH</b>	Transhumeral amputation	
<b>ED</b>	Elbow disarticulation	
<b>KD</b>	Knee disarticulation (thru the joint of the knee)	
<b>HD</b>	Hip disarticulation (thru the hip joint)	
<b>PF</b>	Partial-foot amputation	
<b>Symes</b>	Amputation through the ankle	
<b>Chopart</b>	Amputation through the tarsels and midfoot	
<b>Lisfranc</b>	Amputation through the tarsels and metatarsals	
<b>Transmet</b>	Amputation generally through the middle of the long metatarsal bones	
<b>Varus/Varum</b>	Socket leaning towards the outside or lateral side	
<b>Valgus/Valgum</b>	Socket leaning towards the inside or midline of body	

# APPENDIX

- Sock ply adjustments
- Cosmetic fabric in lamination guidelines



# SOCK PLY ADJUSTMENTS

Requests for changes to a prosthetic model are frequently given in terms of “sock ply.” Here are some guidelines to assist you in better understanding this process and determining how to communicate desired changes.

## What is single ply?

There is no consensus surrounding what a single sock ply equates to. A series of research articles appearing in *Prosthetics and Orthotics International* suggest that the thickness of a single sock ply varies significantly by manufacturer and with the age of the sock. Additionally, the cumulative thickness of multiple single ply socks does not equate to thickness of their higher ply counterpart. (i.e. three “1 ply” socks do not equal one “3 ply” sock). This leads to challenges in addressing requests for changes in terms of sock ply, especially requests for large adjustments.

## How does HFN make ply adjustments to check sockets?

Large ply adjustments are often done using a CAD system by scanning the check socket or mold. The digital model is reduced using 1.3mm of circumference equal to 1 ply. Depending on the fabrication site, smaller ply adjustments may be carried out by hand on the plaster model.

## What other methods exist for reducing by sock ply?

There are numerous methods developed over the years by prosthetists to estimate how much to reduce a plaster mold. Here is a summary of some of the responses when posed with this question:

- 1 ply equals 1/8" in circumference
- Reduce .75% as a single ply reduction
- 2 mm off each perimeter per ply for a typical TT, 3 mm for a TF
- As a general rule, I use .8-.9 mm per ply
- 3-5 mm (depending on limb or tissue type) reduction equals a one ply sock reduction
- Place socks into the check socket. Line with latex balloon and pull vacuum. Then pour with plaster. (Some say simply to spray glue or even just hold sock in place)
- Place socks on mold and measure circumference change compared to no sock and reduce model by that amount
- 5 ply equals 1/4" reduction. 3 ply equals 1/8"

## Bottom Line

HFN strives to be as consistent and accurate as possible when dealing with ply changes. However, there is a certain amount of imprecision inherent in this process. Requests for changes greater than 5 ply cannot be guaranteed.

## Sources:

Sanders JE, Cagle JC, Harrison DS, Karchin A. Amputee socks: how does sock ply relate to sock thickness?. *Prosthet Orthot Int.* 2012;36(1):77-86. doi:10.1177/0309364611431290

Cagle JC, Yu AJ, Ciol MA, Sanders JE. Amputee socks: thickness of multiple socks. *Prosthet Orthot Int.* 2014 Oct;38(5):405-12. doi: 10.1177/0309364613506915. Epub 2013 Nov 15. PMID: 24240023; PMCID: PMC4440227.

Cagle JC, D'Silva KJ, Hafner BJ, Harrison DS, Sanders JE. Amputee socks: Sock thickness changes with normal use. *Prosthet Orthot Int.* 2016 Jun;40(3):329-35. doi: 10.1177/0309364614568412. Epub 2015 Mar 2. PMID: 25733408; PMCID: PMC4558393.

## COSMETIC FABRIC IN LAMINATIONS GUIDELINES

HFN frequently receives requests for a laminated cosmetic finish using patient supplied fabric. In order to guide patient expectations and decision making, here are some things to consider:

**Darkening:** Fabric almost always end up darker in the final product than what it started out like. Think of what happens when fabric gets wet with water.

**Amount of Fabric:** It's a good idea to provide enough fabric to do the job twice just in case problems arise.

**Placement:** Often patients will have a particular way an image should be placed on their socket. If this is the case, this needs to be clearly communicated. Sketching an outline of the location on the check socket helps the technicians know what is expected. Additionally, be realistic about what can and cannot fit onto the socket. Sometimes images are cut off because they are too big for the surface of the socket. Also help your patients be aware how wrapping a flat image on a round surface may distort the image.

**Type of Fabric:** Vinyl and screen printing can be tricky as resin is often unable to saturate these areas. Anything that feels rubbery or has patches on top of the fabric may present a problem. Additionally, fabric with a little elasticity is much easier to work with than completely rigid fabric.

**Aging:** Be aware that as a lamination ages, the colors can age as well. UV light can cause fading. White colors often yellow with time. Guiding patient expectations and color choices can help.

**Where to get fabric:** Fred's Legs is a good start, but it does help to order well in advance, though. A fabric store is a great place to look as well. There are also several sites online that will print a custom image on a fabric of your choice for a reasonable price (Spoonflower and Contrado are two examples. Fred's Legs will print a custom sleeve as well).

**If you're unsure how the chosen fabric will work, have a backup plan. You can always default to a carbon or skin tone finish. When in doubt, contact one of the HFN sites to speak with a technician about the chosen fabric and what to expect.**