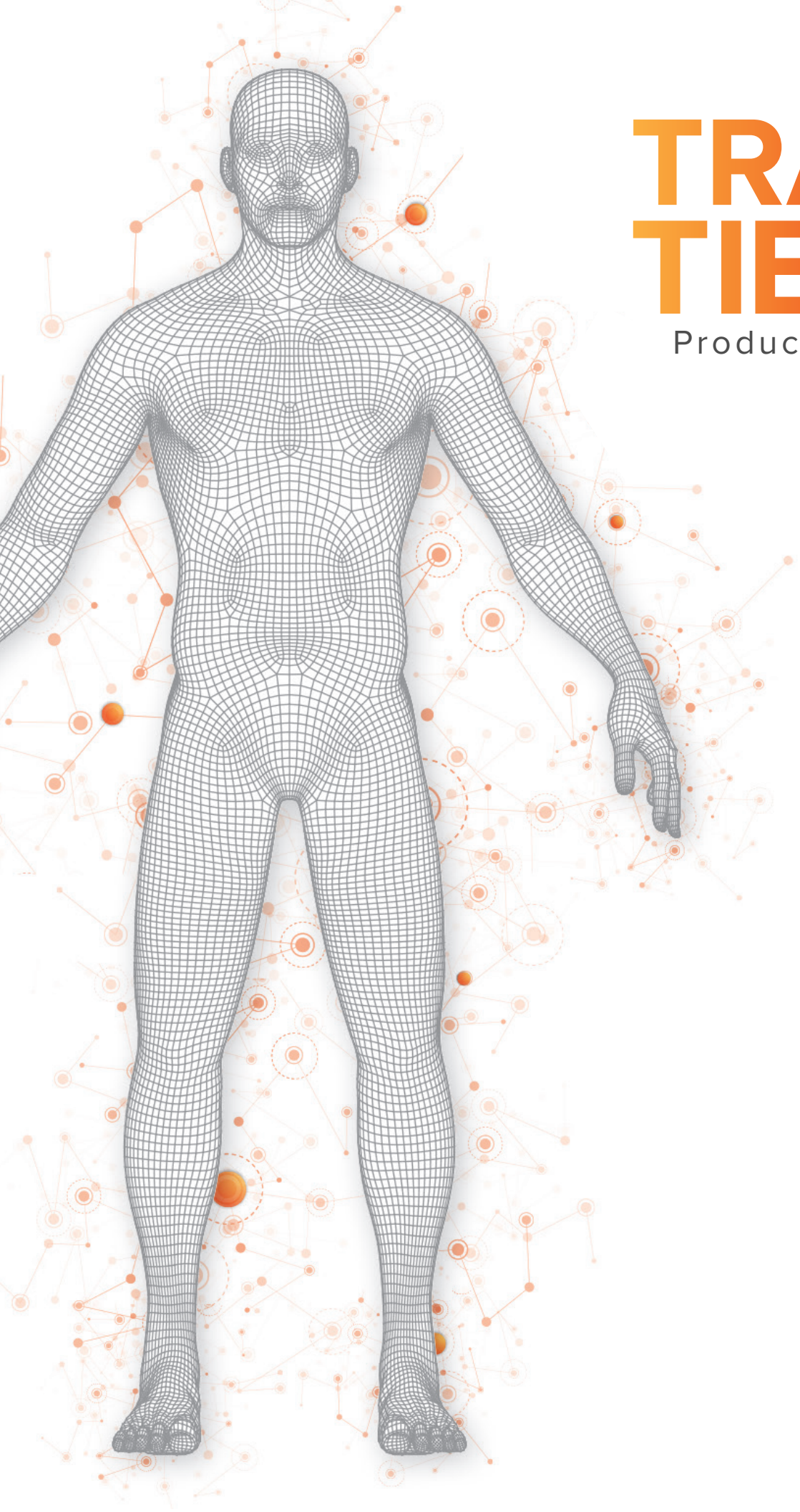


TRANS TIBIAL

Product Standards

HFN

PURPOSE

Hanger Clinic Product Standards

The Hanger Clinic Product Standards are a collaborative effort between Hanger Clinic and the Hanger Fabrication Network 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 Borras

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

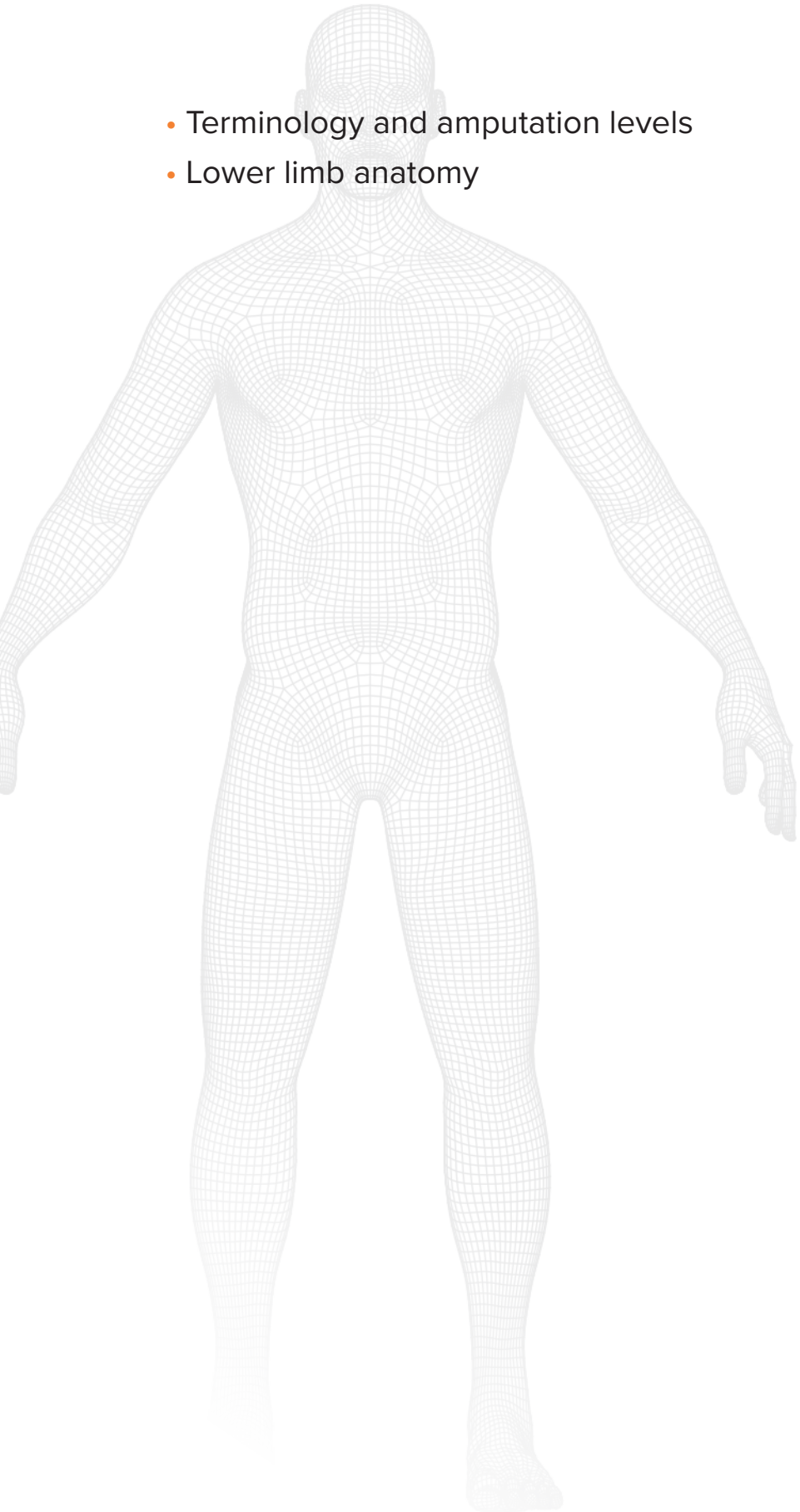
HFN

CONTENTS

HFN

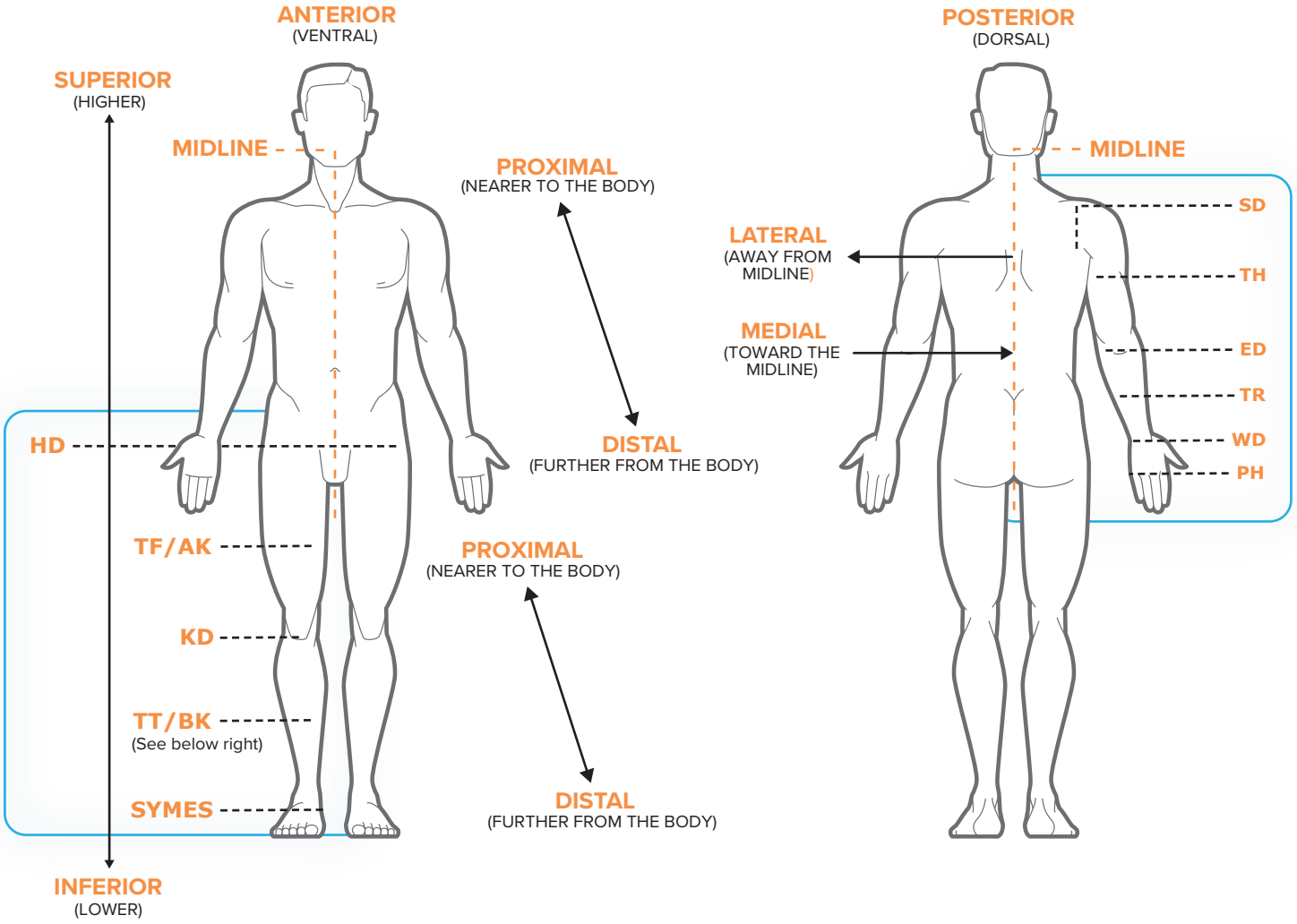
OVERVIEW

- Terminology and amputation levels
- Lower limb anatomy

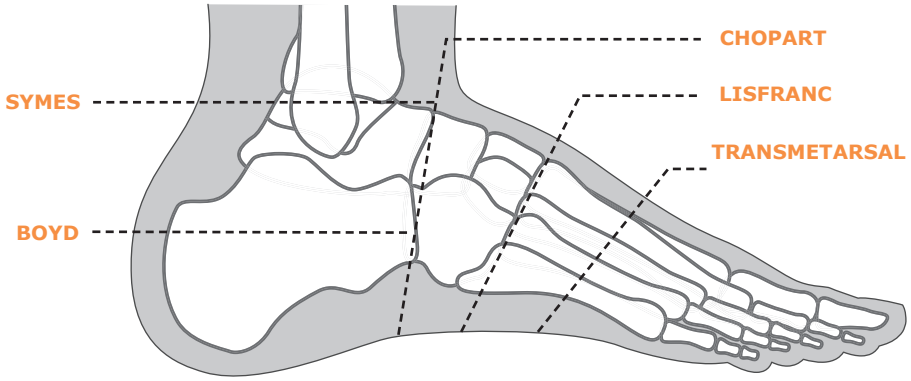


HFN

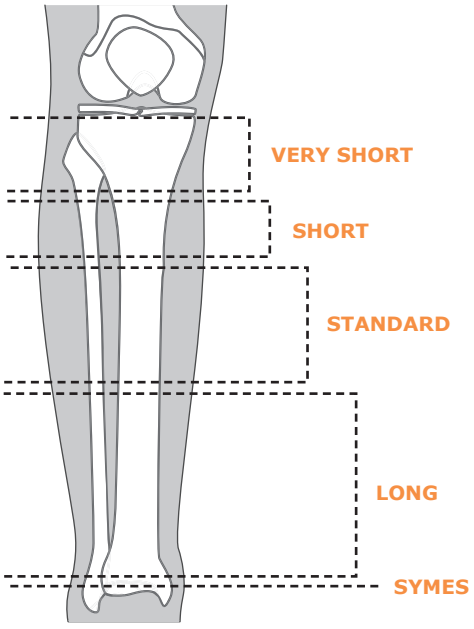
TERMINOLOGY AND AMPUTATION LEVELS



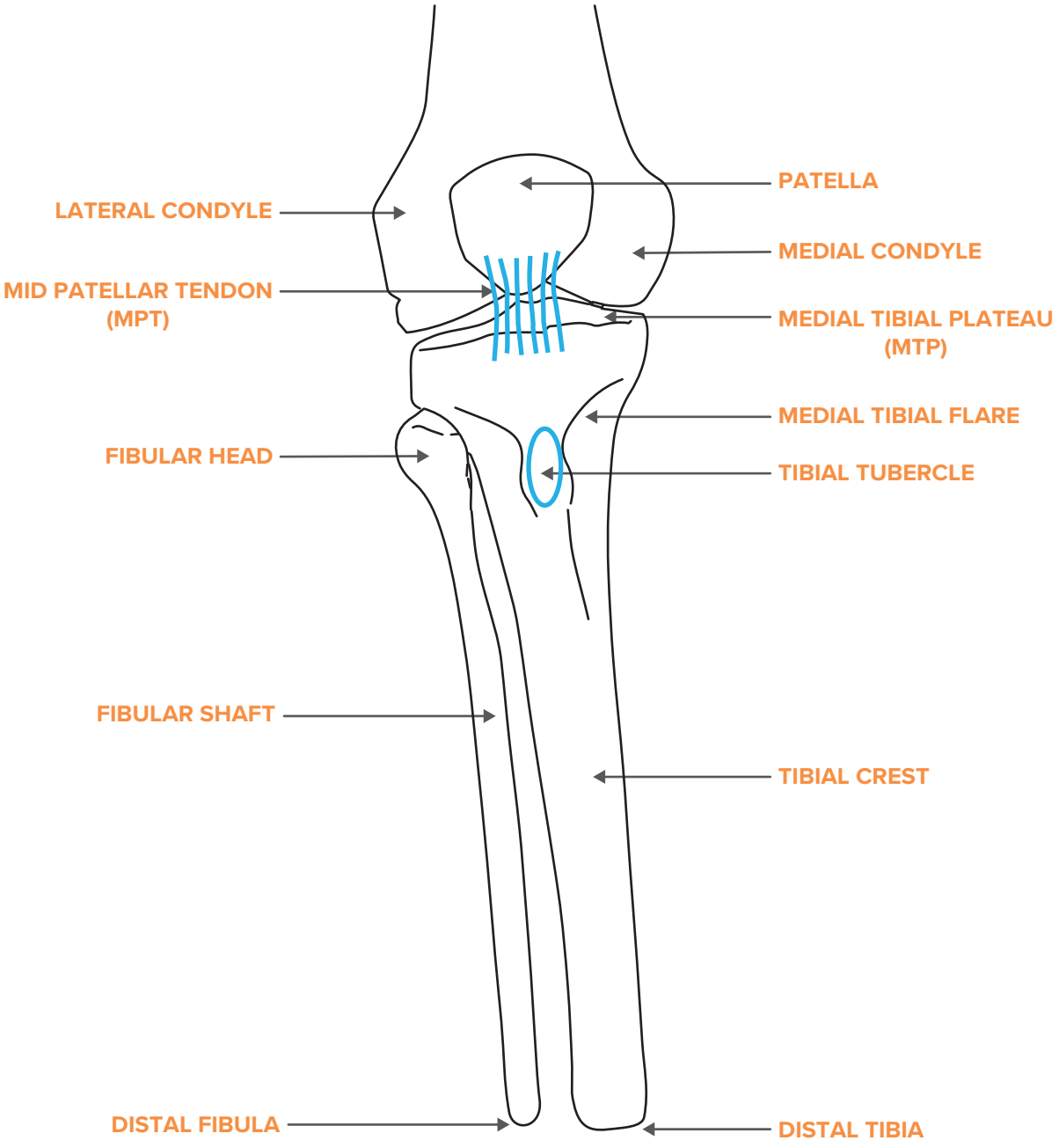
FOOT AMPUTATION LEVELS



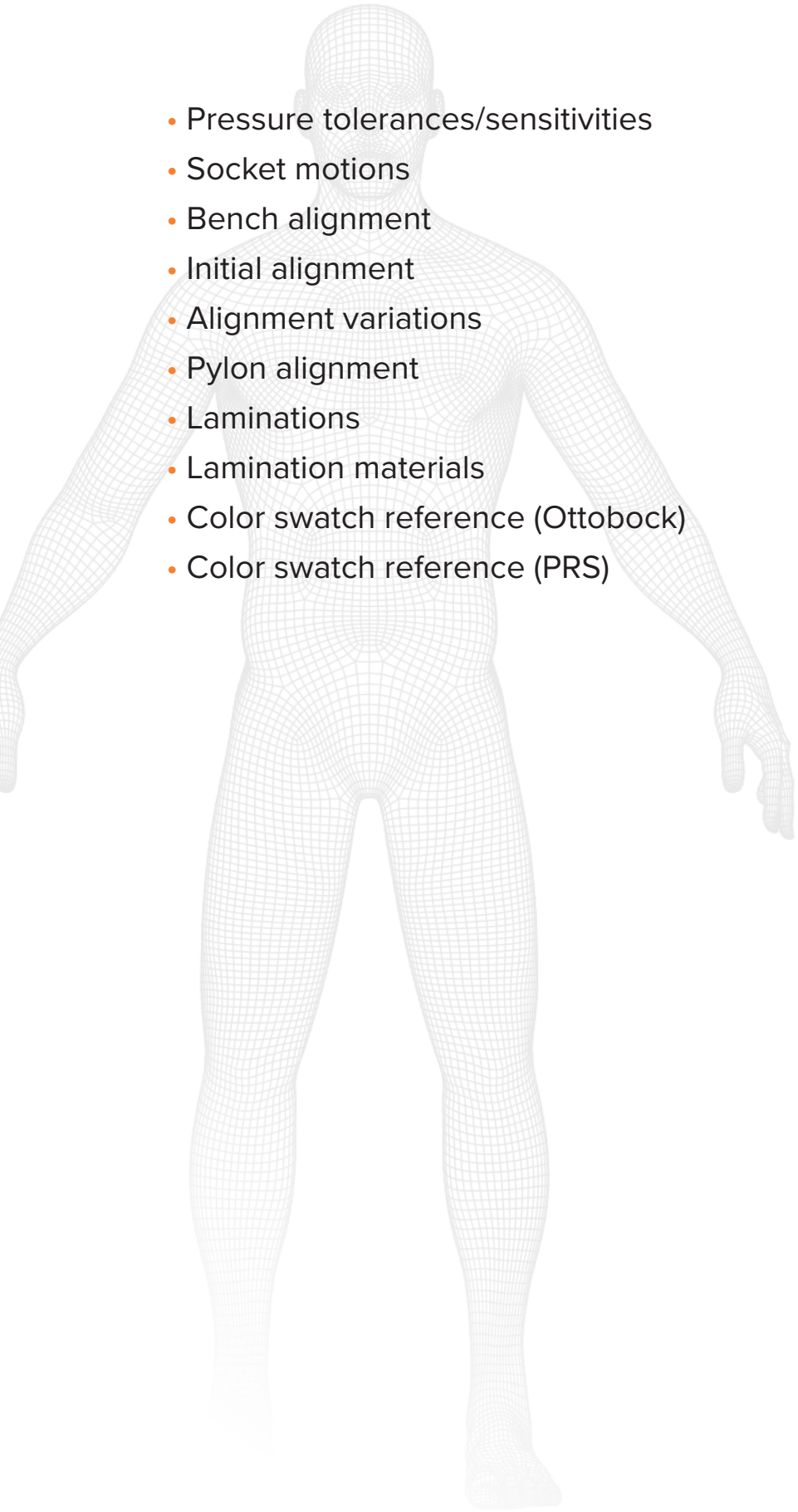
TRANSTIBIAL LEVELS (TT/BK)



LOWER LIMB ANATOMY



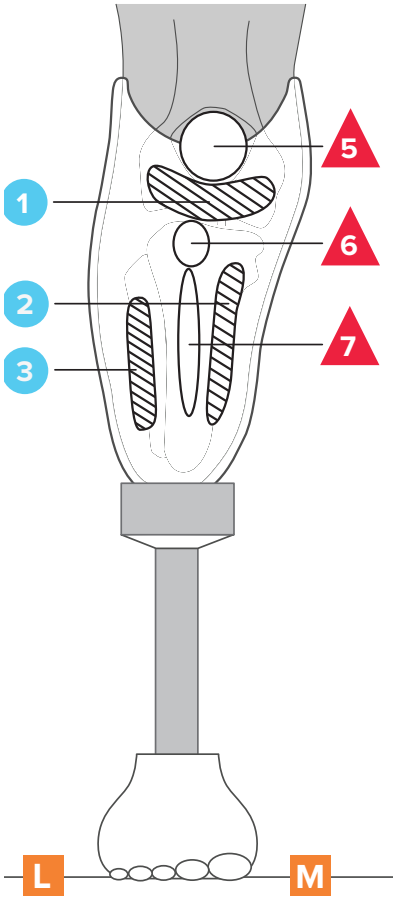
FUNDAMENTALS



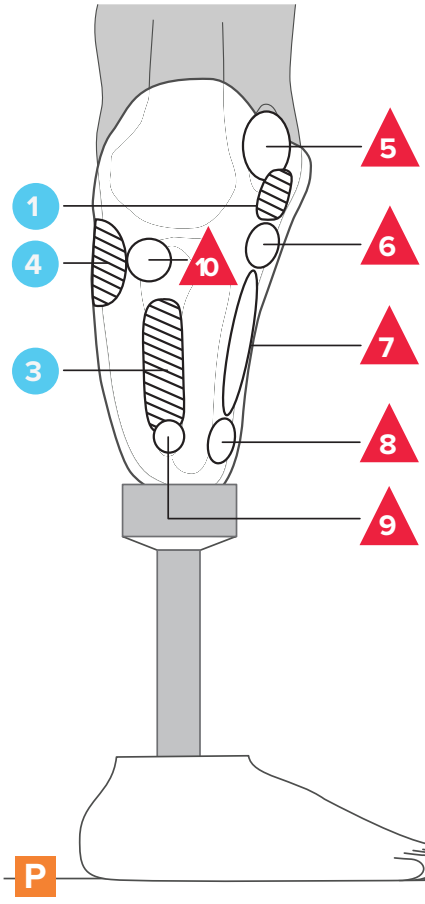
- Pressure tolerances/sensitivities
- Socket motions
- Bench alignment
- Initial alignment
- Alignment variations
- Pylon alignment
- Laminations
- Lamination materials
- Color swatch reference (Ottobock)
- Color swatch reference (PRS)

HFN

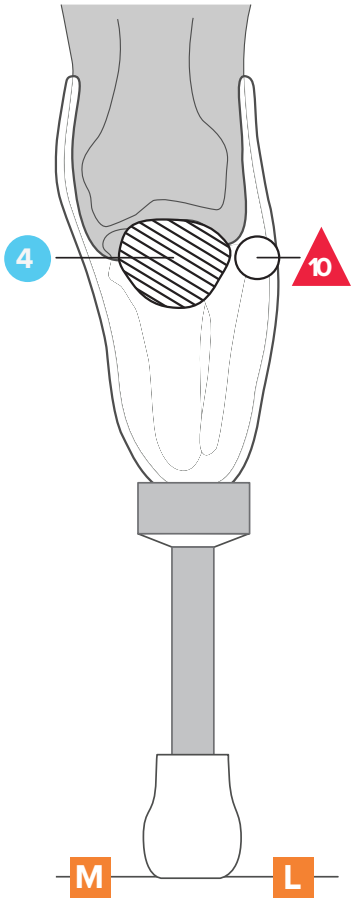
PRESSURE TOLERANCES/SENSITIVITIES



ANTERIOR



LATERAL

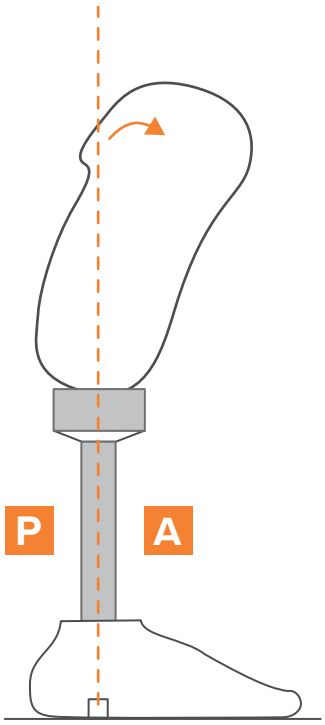


POSTERIOR

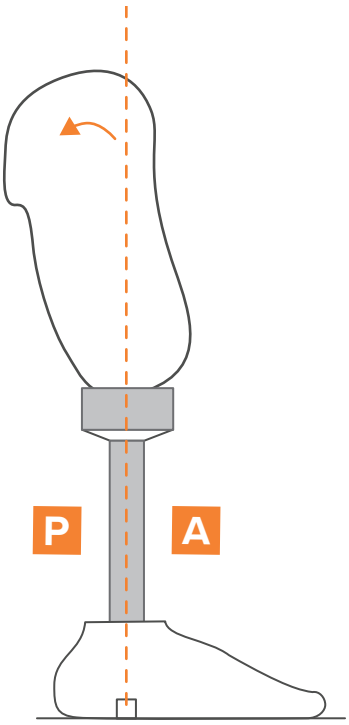
TOLERANT	SENSITIVE
1. Patella Tendon 2. Medial Tibial Flare 3. Lateral Fibular Shaft 4. Gastroenemius	5. Patella 6. Tibial Tuberale 7. Tibial Crest 8. Distal Tibia 9. Distal Fibula 10. Fibula Head

SOCKET MOTIONS

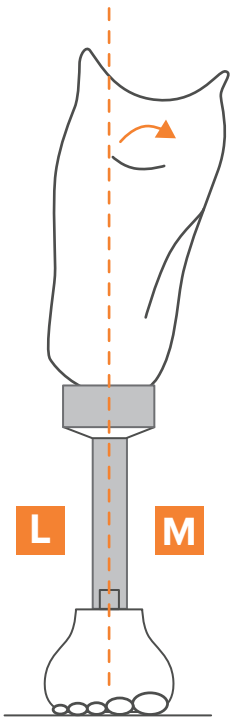
Socket motions are relative to the socket, not the foot.



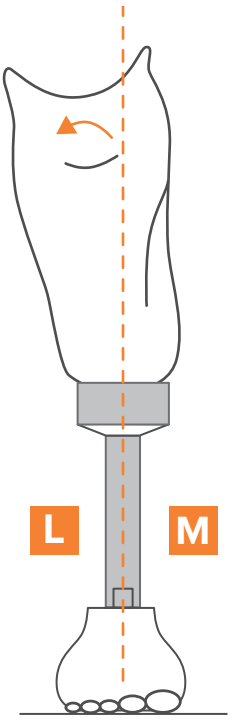
FLEXION



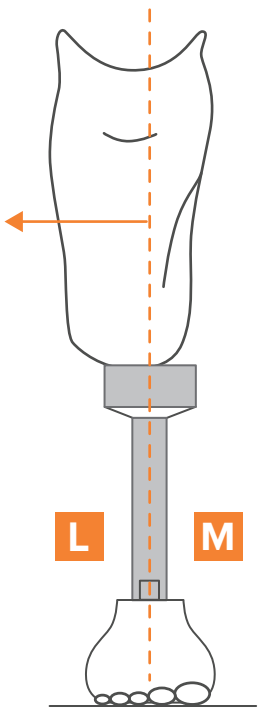
EXTENSION



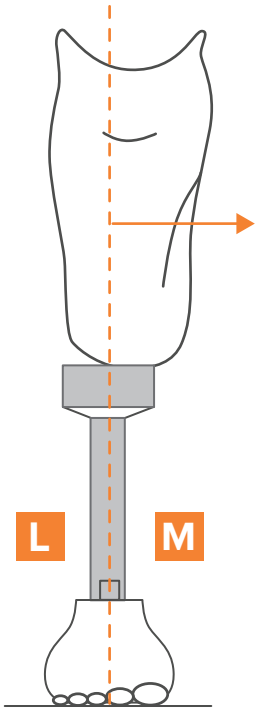
ABDUCTION



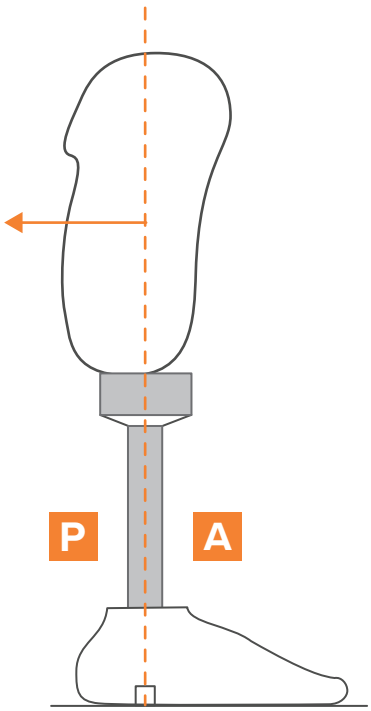
ADDUCTION



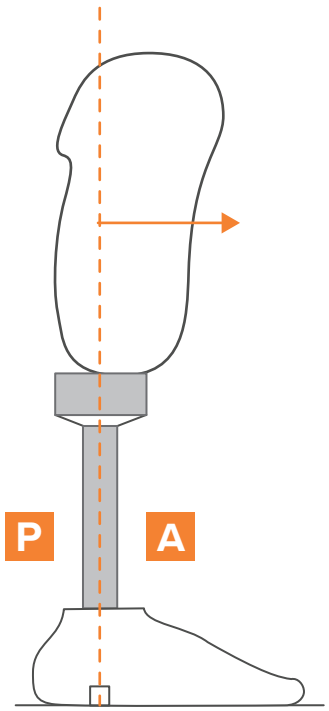
LATERAL SLIDE
/FOOT INSET



MEDIAL SLIDE
/FOOT OUTSET



POSTERIOR SLIDE

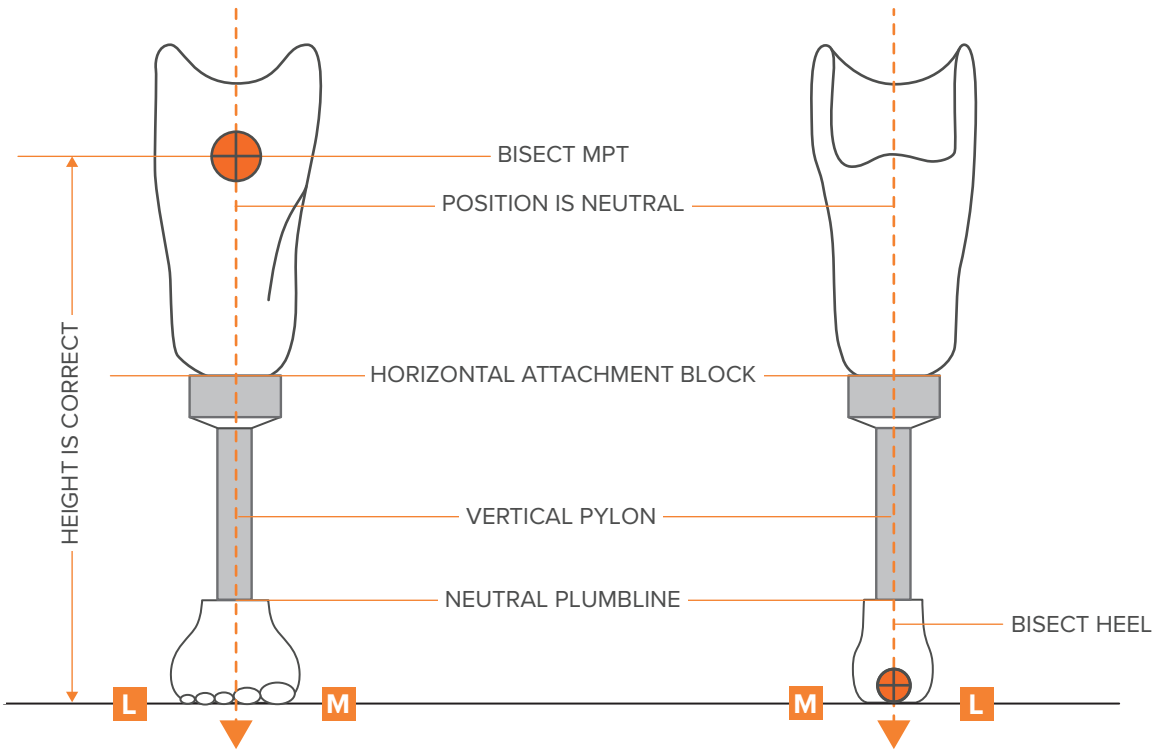


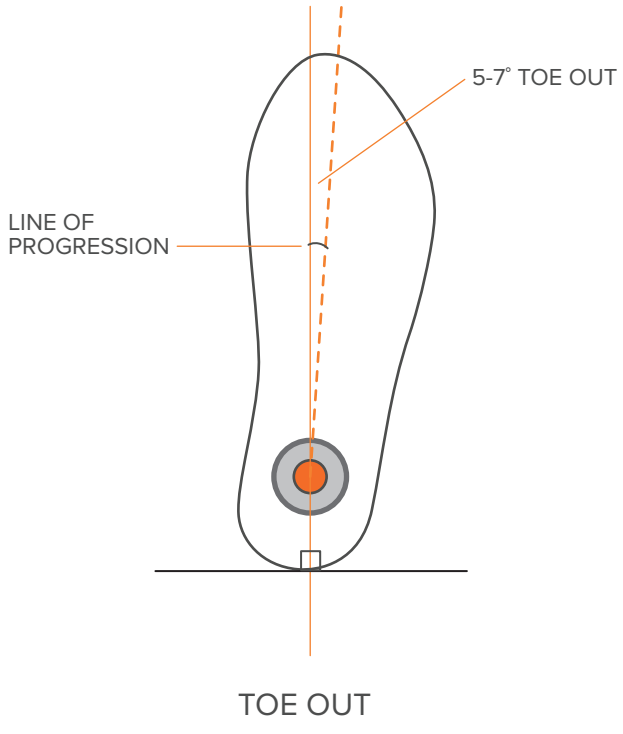
ANTERIOR SLIDE

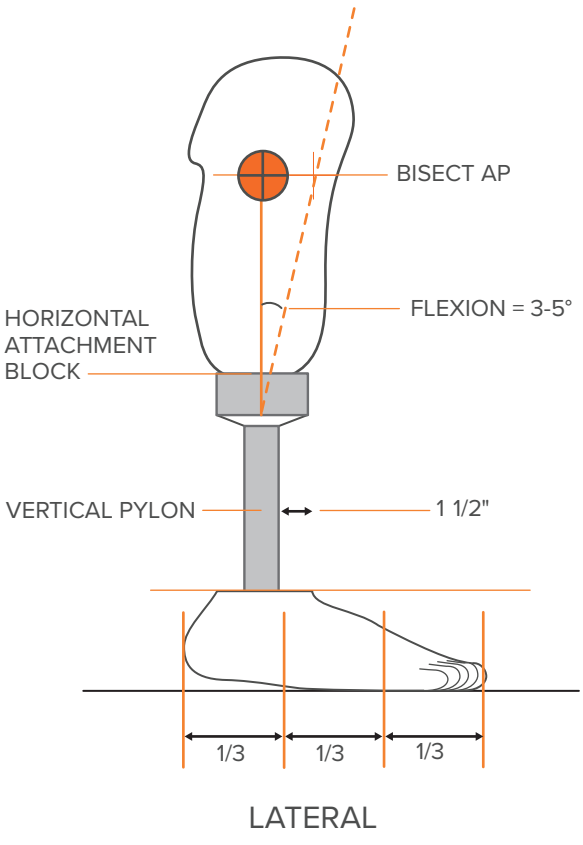
BENCH ALIGNMENT

STANDARD*

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





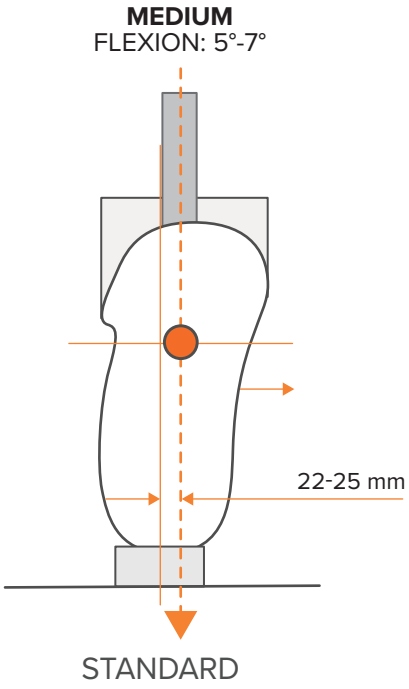


*or per Clinician instructions

INITIAL ALIGNMENT

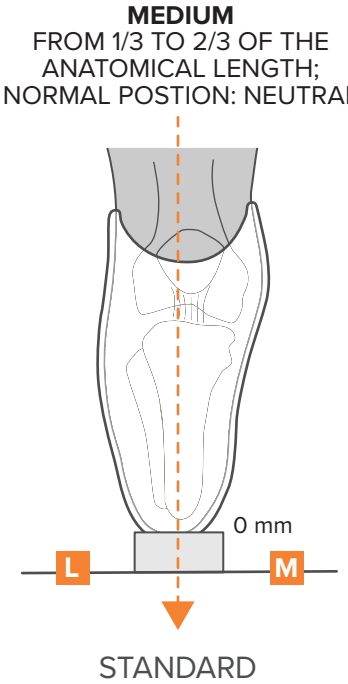
MEDIAL OR LATERAL VIEW

DISTAL ATTACHMENT ANTERO-POSTERIOR PLACEMENT



ANTERIOR VIEW

DISTAL ATTACHMENT MEDIO-LATERAL PLACEMENT

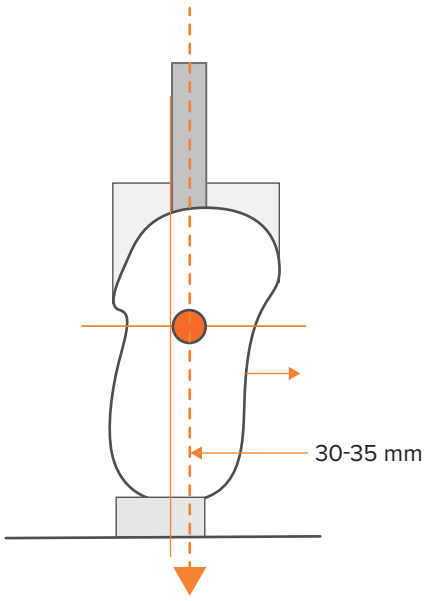


ALIGNMENT VARIATIONS

MEDIAL OR LATERAL VIEW

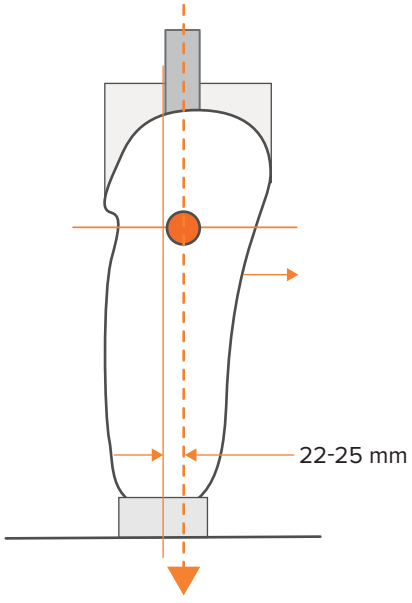
DISTAL ATTACHMENT ANTERO-POSTERIOR PLACEMENT

SHORT
FLEXION: 7°-10°



VARIATION

LONG
FLEXION: 0°-5°

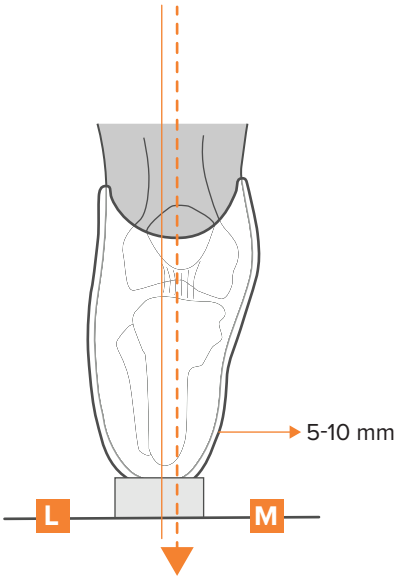


VARIATION

ANTERIOR VIEW

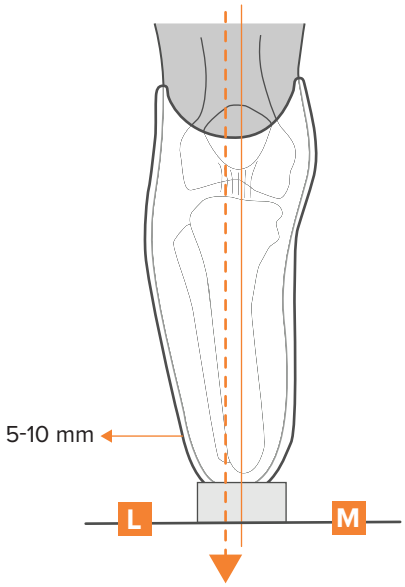
DISTAL ATTACHMENT MEDIO-LATERAL PLACEMENT

SHORT
LESS THAN 1/3 OF THEANATOMICAL LENGTH;
NORMAL POSTION: ABDUCTION = VALGUM



INSET SOCKET

LONG
MORE THAN 2/3 OF THEANATOMICAL LENGTH;
NORMAL POSTION: ADDUCTION = VARUM

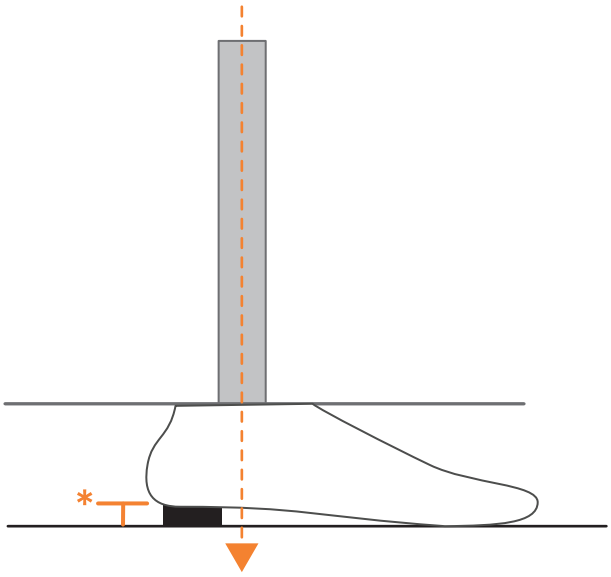


OUTSET SOCKET

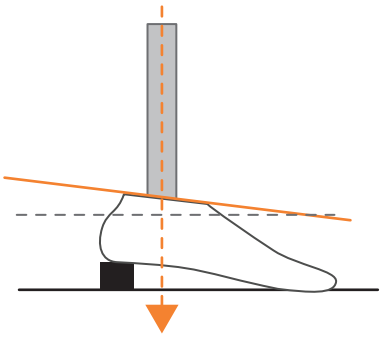
PYLON ALIGNMENT

HEEL HEIGHT IMPACT

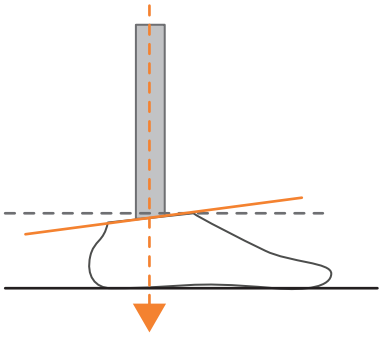
NEUTRAL = PYLON PERPENDICULAR TO FLOOR
– **RELATIVE TO FOOT HEEL HEIGHT***



HIGH HEEL = PLANTAR FLEXION



LOW HEEL = DORSI FLEXION



LAMINATIONS

CARBON/PIGMENT 1-STAGE/2-STAGE

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 Flex Stretch	2 Flex Stretch	2 Flex Stretch

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 Flex Stretch	2 Flex Stretch	2 Flex Stretch

LAMINATION MATERIALS

HFN STANDARD

CARBON SLEEVE BRAIDS (most common 5-6")
5" x 75' (V57M5 25YD)
6" x 75' (V57T6 25YD)
8" x 75' (V57H8 25YD)
RESIN PROSTHETICS
ORTHOLAM DURALAM EAR 1 Matrix Resin
ORGANIC PEROXIDE (160 gm)
RESIN HHPAFO & PROSTHETICS WITH FABRIC
RESTECH Side A Resin 1 Gal (#RES3A-1)
RESTECH Side B Hardener 1 Gal (#RES3B-1)
REINFORCEMENT TAPES
FABTECH SYSTEMS 12k Plain Weave Fringe Edge (CT6-5FR) 6" x 50' Roll
KINETIC RESEARCH Carbon Graphite 3/4" x 10' (CG007510)
MUTUAL INDUSTRIES 3" x 10 (MI-1016)
PACELINE Carbon Tape 2" x 10 yds (MI10162)
NYGLASS/NYLONS/FILLERS
PACELINE Flexastretch Nylon LG 1/2 Kilo (0010100)
PACELINE Nyglass 15 CM 1 Kilo (0011300)
BEST VALUE SPS Felt

COLOR SWATCH REFERENCE

OTTOBOCK

646M3 – Color Swatch Set (cosmetic gloves)

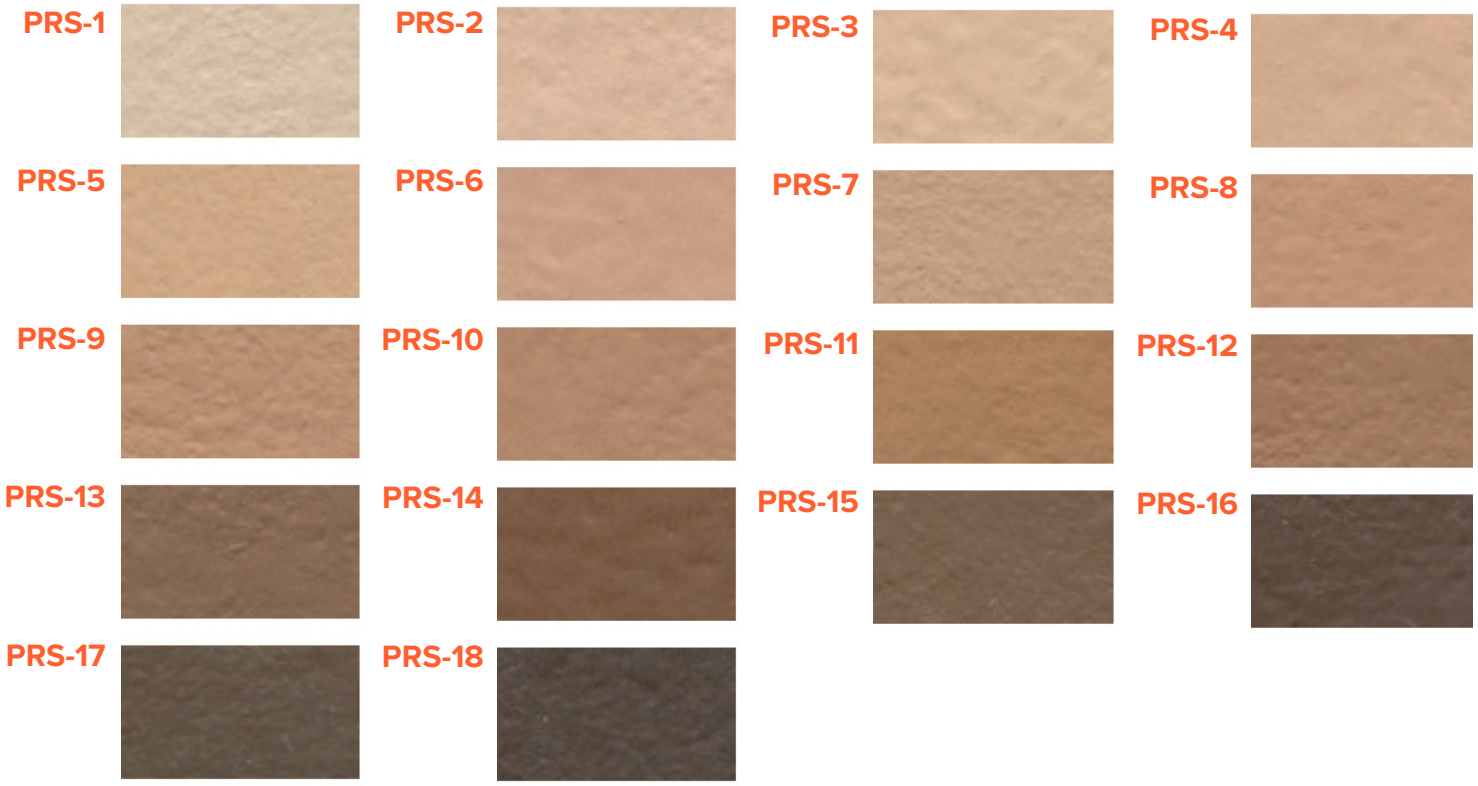
NOTE: For demonstration purpose only. Please refer to actual lamination color swatch sample. Variation in color may occur.

COLOR SWATCH REFERENCE

PROSTHETIC RESEARCH SPECIALISTS

Flesh Color System

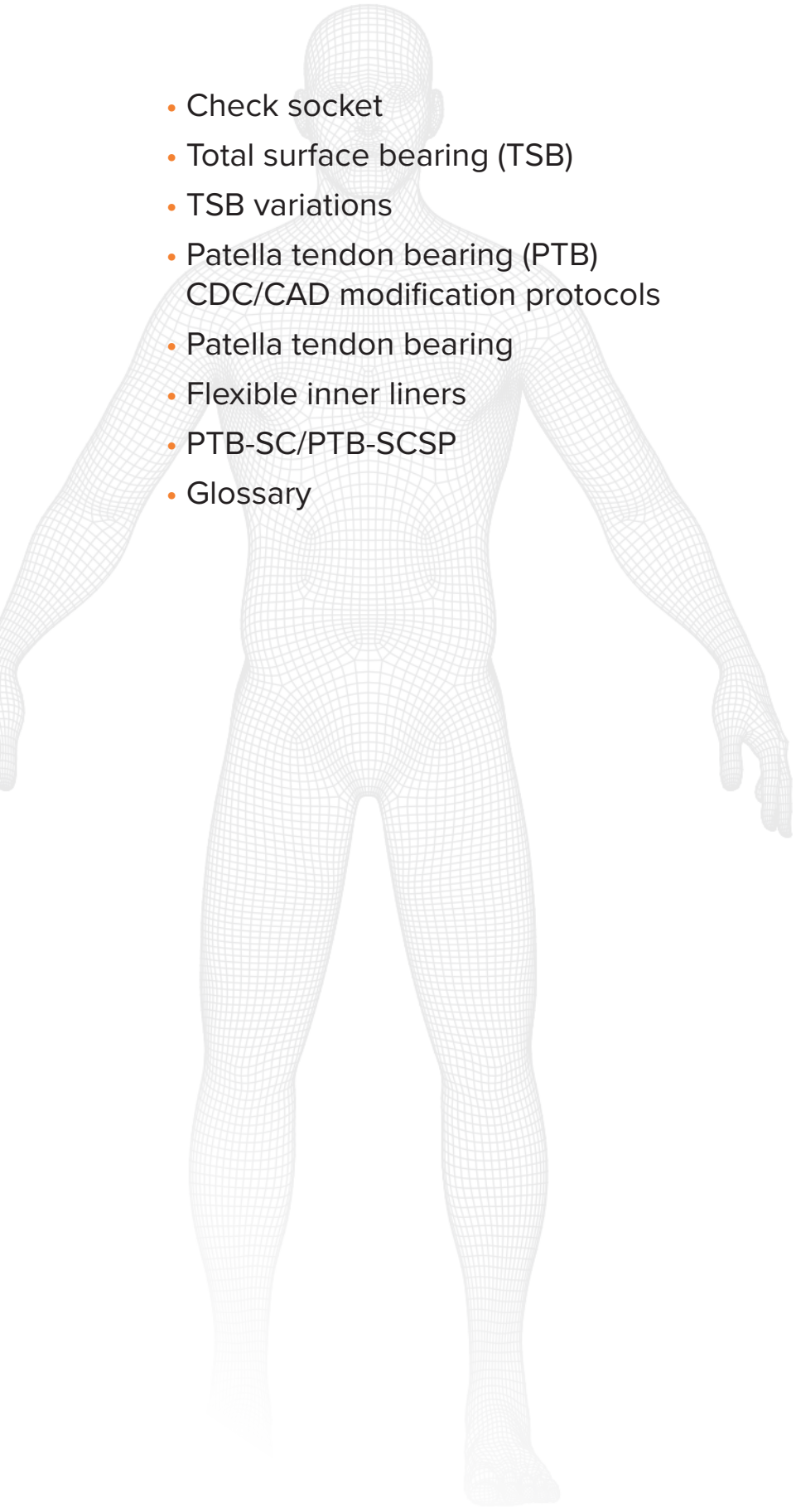
Pigment Color Approximations



If you do not have current swatches, you can order them **HERE** at no charge.

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

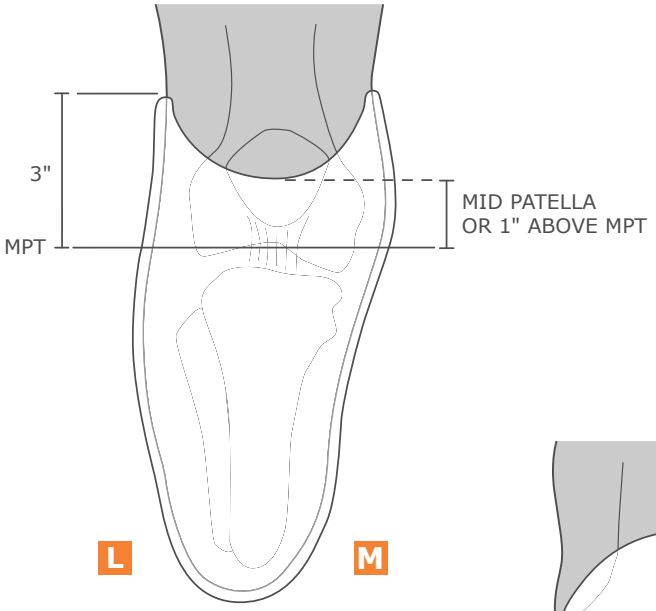
DESIGNS



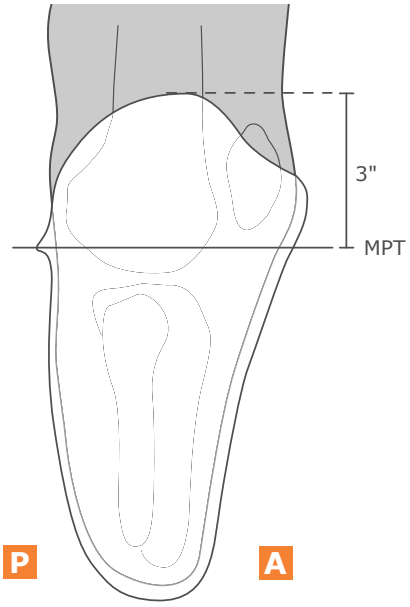
- Check socket
- Total surface bearing (TSB)
- TSB variations
- Patella tendon bearing (PTB)
  CDC/CAD modification protocols
- Patella tendon bearing
- Flexible inner liners
- PTB-SC/PTB-SCSP
- Glossary

HFN

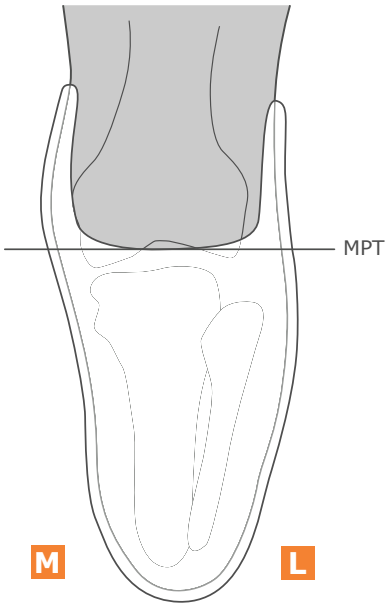
CHECK SOCKET
TRIMLINES



ANTERIOR



LATERAL



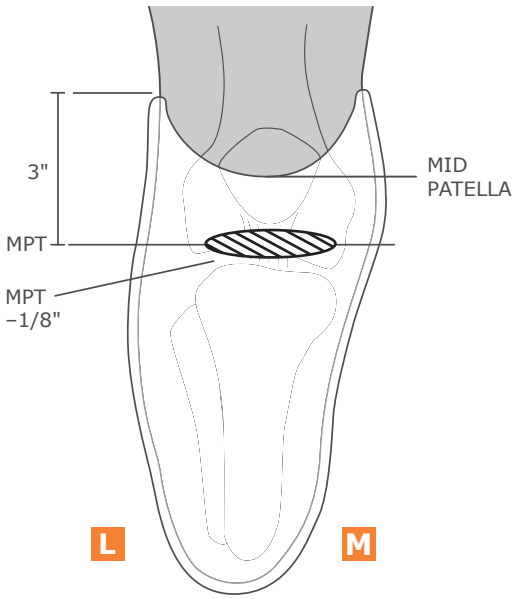
POSTERIOR

BLISTER FORMING SIZE SELECTION TABLE

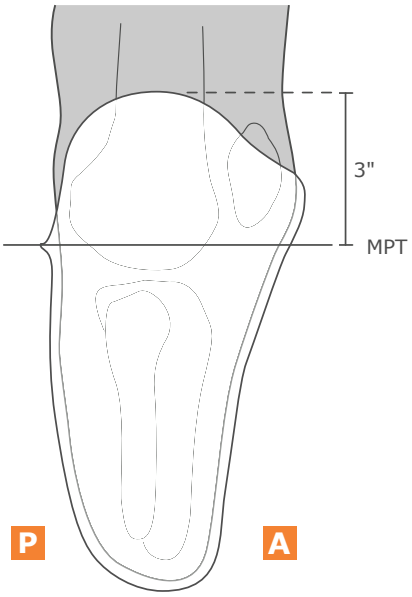
					PETG		
Cast length	**Use plastic square size**	**Less than key cast diameter use 3/8" thickness**	**Key cast diameter**	**Greater than key cast diameter use 1/2" thickness**	**3/8"**	**1/2"**	**1/4"**
≤ 12"	12"x12"		6 3/4		304-381	304-121	304-141
≤ 14"	14"x14"		8				
≤ 16"	16"x16"		9 1/2		3751616PT	5001616PT	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)

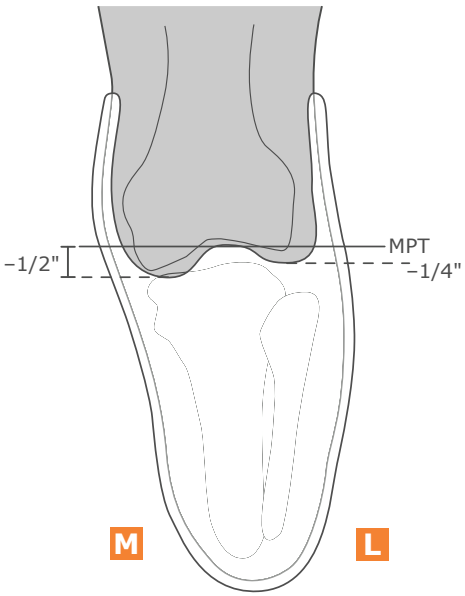
REDUCTION



ANTERIOR



LATERAL

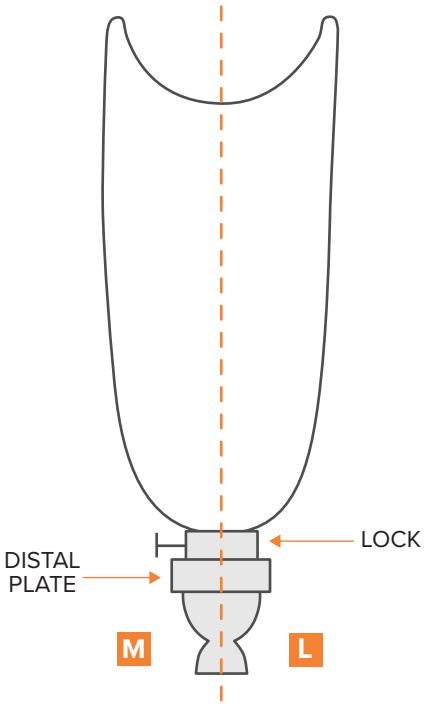


POSTERIOR

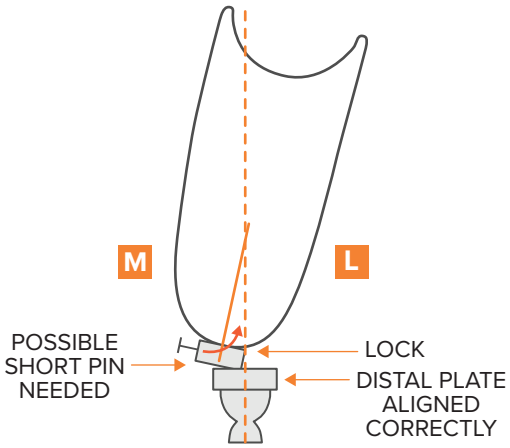
CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES	VARIATIONS
☐ MPT to distal end △ ML apex of condyles △ PML △ AP at level of MPT	• Medial/Lateral = 2 1/2" above MPT • Anterior = 1/2" prox to MPT or distal 1/2 of patella • Posterior = apex at -1/2" proximal to MPT level • Medial hamstring relief = -1/2" distal to MPT level • Lateral hamstring relief = -1/4" distal to MPT level **STANDARD MODIFICATIONS** • Goal: 0-1 ply fit • 5% global reduction	• **Note:** modifications will vary with patient tissue type, input types (scan vs. cast) and input measurements (with or without a liner) Design guidelines: 3 mm liner = 7 ply reduction 6 mm liner = 9 ply reduction 9 mm liner = 12 ply reduction • **Posterior Shelf Modification** – Added upon request only

TSB VARIATIONS

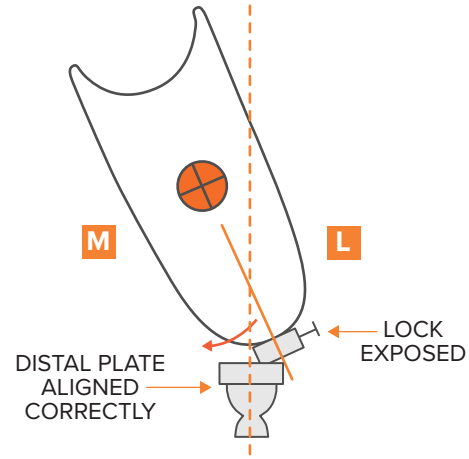
PIN LOCKS



STANDARD (ANTERIOR VIEW)



VARUM



VALGUM

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

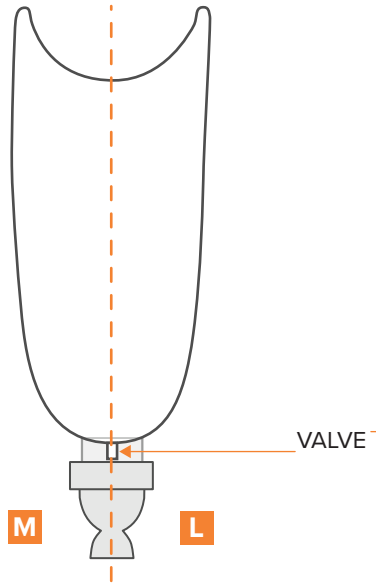
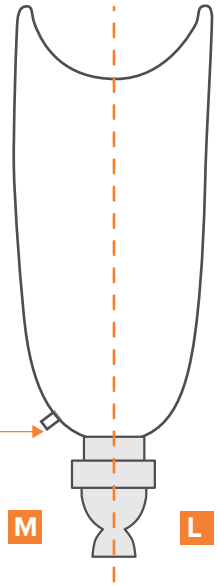


PLATE WITH INTEGRATED VALVE



SOCKET INTEGRATED VALVE

STANDARD

- External valve located distal medial quadrant

OPTIONS

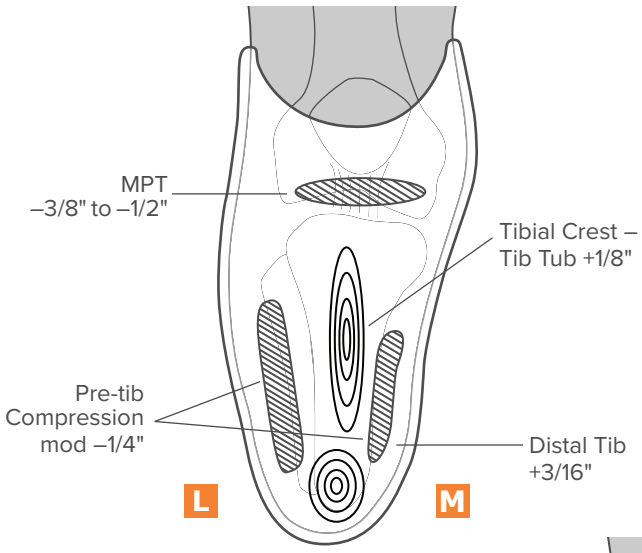
- Ossur flat valve plate
- Lyn valve
- Flexible inner liner
- Per clinician request

PATELLA TENDON BEARING (PTB)

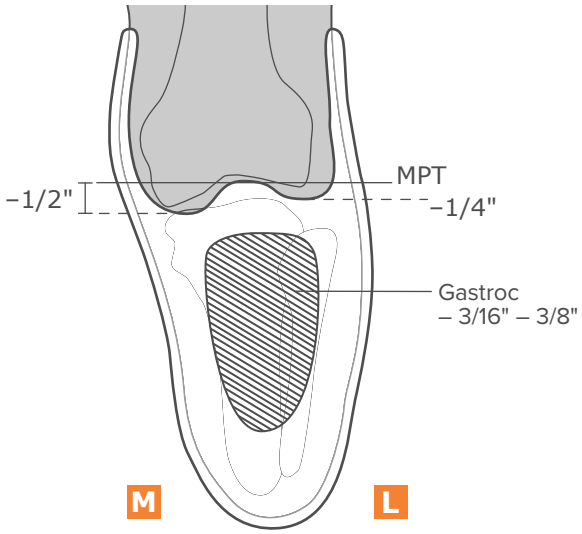
CDC-CAD MODIFICATION PROTOCOLS

BUILD UP REDUCTION

(Blend will vary according to patient's anatomy)



ANTERIOR



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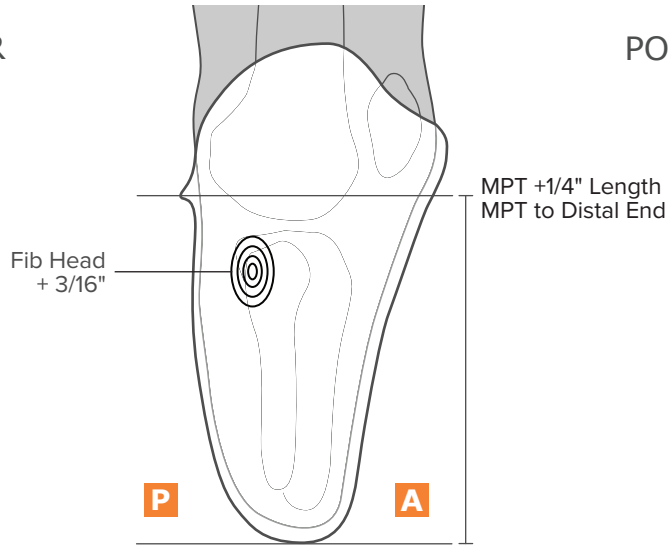
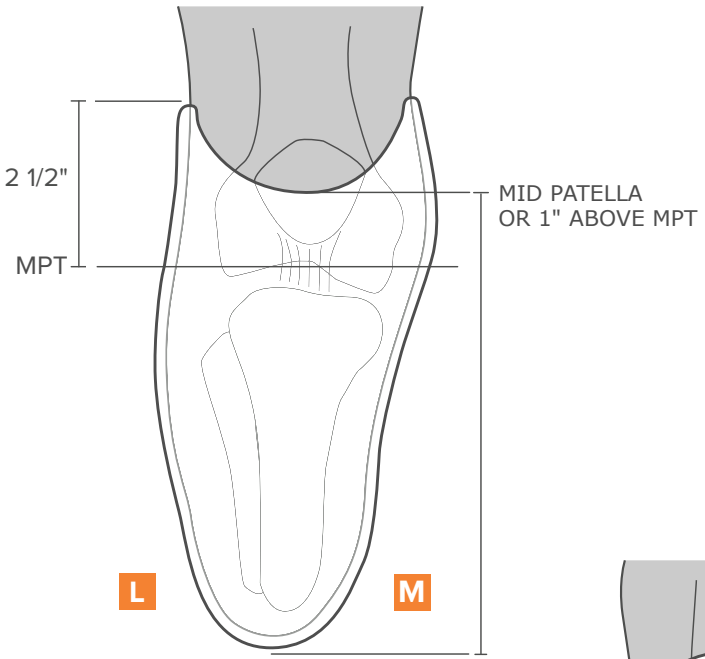


LATERAL

CTQ MEASUREMENTS + OTHER CTQ = Critical to Quality	STANDARD MODIFICATIONS	VARIATIONS
– Tissue Type and Liner – REQUIRED □ MPT to distal end △ MPT ○ Every 2" (5 cm) increment distally	**CTQ Other** – (Reduction Value Calculation) • Reductions are applied only upon clinician request • CDC Reduction Protocols-Tissue Type, Liner Scanned/Mx Over - Scan of Cast – Volumetric Reduction Calculated based on liner & tissue type (0-6%) - Direct Patient Scan-Over Liner – Ply Reduction Calculated based on liner & tissue type (6-12ply) - Indicate "Skin" for skin fit	**Posterior Shelf** – Added upon request only
CTQ LANDMARKS CTQ = Critical to Quality		
• MPT – Mid-Patella Tendon • Fibular Head • Distal Tib *Include instructions with any additional info on scan/cast*		

PATELLA TENDON BEARING TRIMLINES



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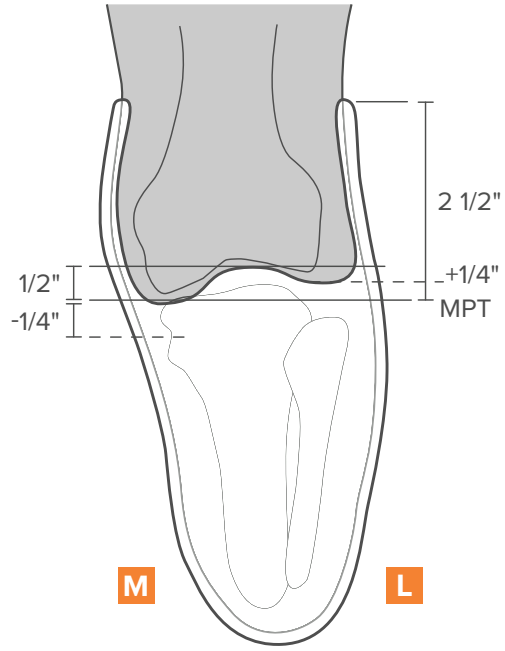

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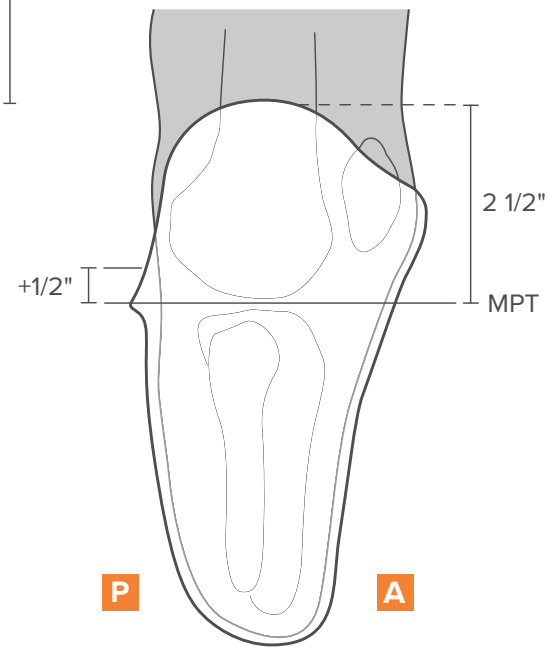
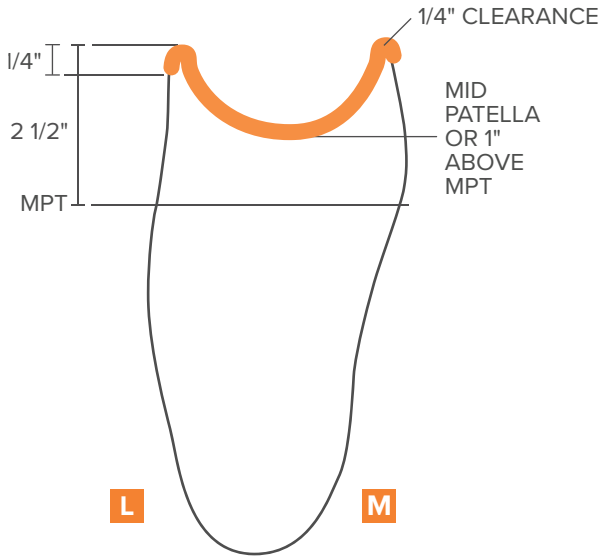


LATERAL

CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES
☐ MPT to distal end △ ML apex of condyles △ PML △ AP at level of MPT	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



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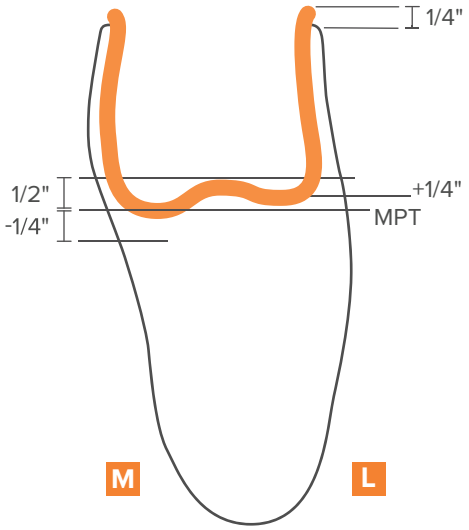

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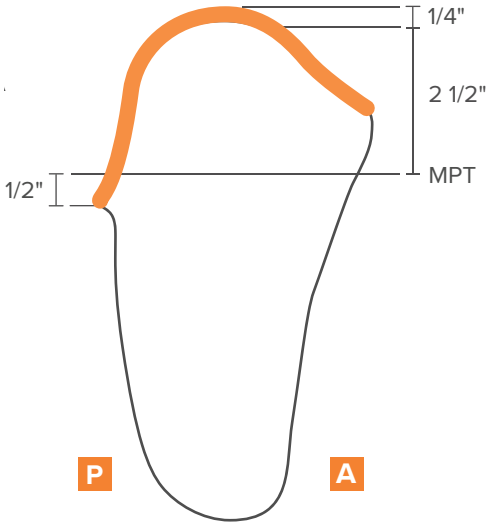


LATERAL

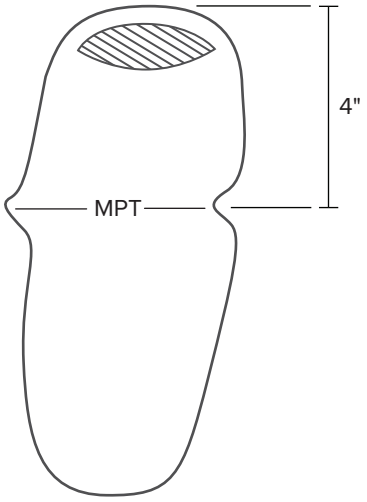
STANDARD MATERIAL /TRIMLINES	VARIATIONS
• Flexible inner liner standards are pulled from ProFlex • 1/4" clearance above frame • Symmetrical to frame	• Per clinician • Pelite • Northvane • Polyethelene

PTB-SC/PTB-SCSP

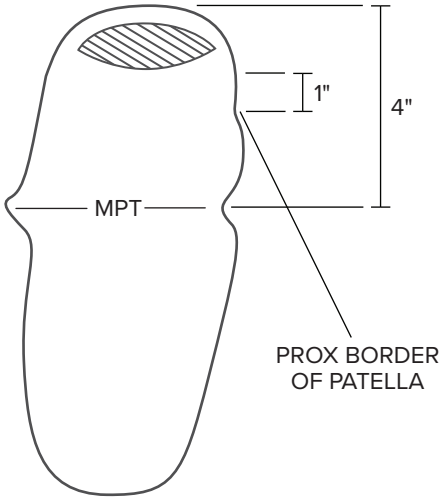
SUPRACONDYLAR/SUPRACONDYLAR SUPRAPATELLAR

REDUCTION

PTB-SC



PTB-SCSP



CTQ MEASUREMENTS CTQ = Critical to Quality	STANDARD MATERIAL /TRIMLINES	VARIATIONS
• Proximal m/1 measurement for supra condylar (Critical) • AP at MPT • ML at apex of condyles	• Supracondylar material is made from Pelite • Deepest wedge is always on medial side • Trim line over patella will be 1" above proximal border of patella • Medial/lateral trim lines will be 65 mm above MPT, same as PTB-SC	Laminated removable wedge is available upon work order request

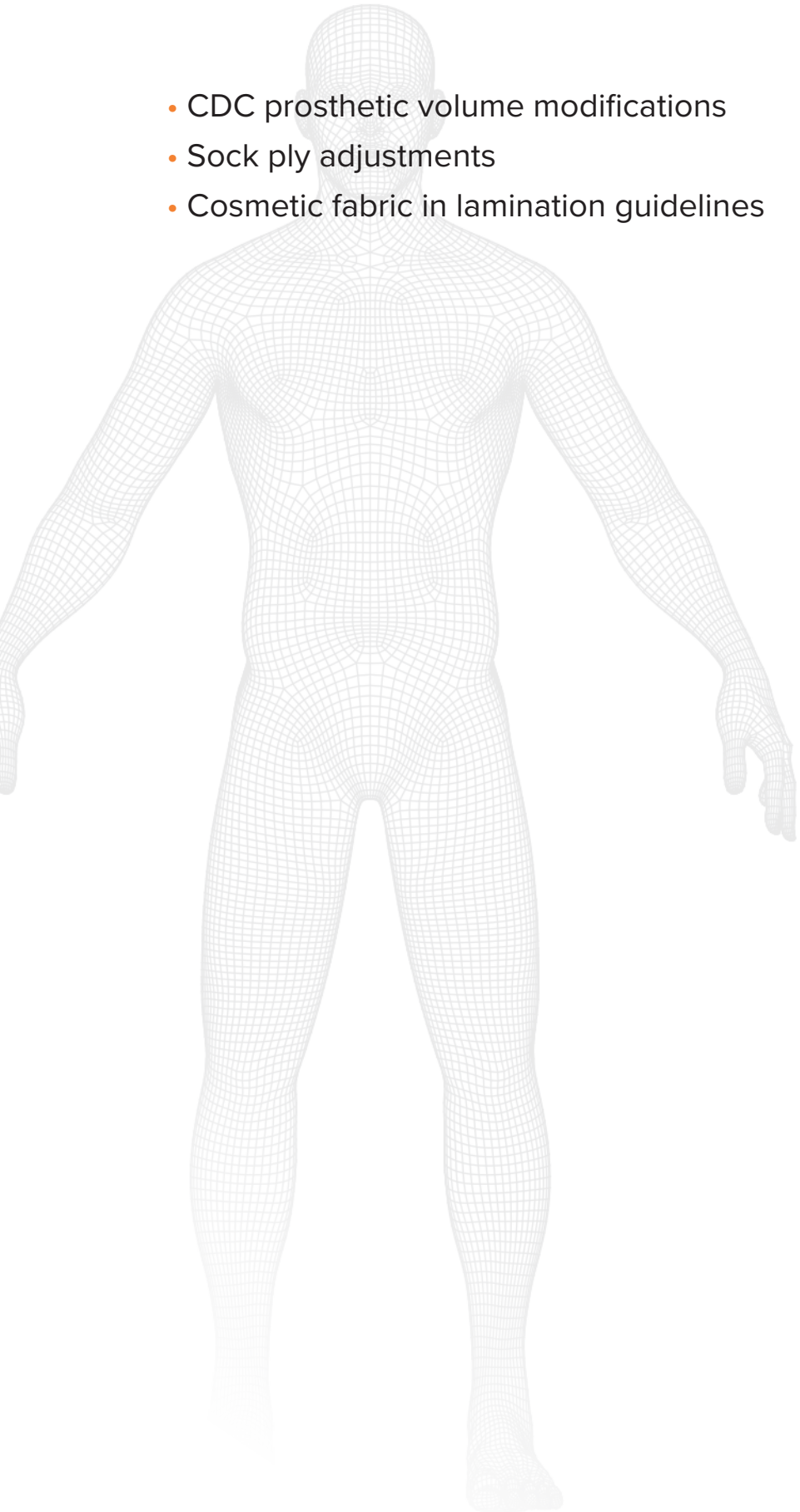
GLOSSARY

BELOW THE KNEE TERMINOLOGY

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

APPENDIX

- CDC prosthetic volume modifications
- Sock ply adjustments
- Cosmetic fabric in lamination guidelines



HFN

CDC PROSTHETIC VOLUME MODIFICATIONS

There are two options when submitting a prosthetic order for CDC modification:
1) Percent Reduction, or **2) CDC Protocol**

Percent Reduction:

If percent reduction is selected, the scan is first brought to hand measurements. It will then be ***reduced by volume*** according to the percentage selected. If there's a large discrepancy between hand measurement and scan measurement, the clinician is contacted.

THE PROBLEM – Volume vs Circumference

Clinicians are accustomed to thinking in *circumferential percent reductions*. However, a 4% circumferential reduction equates to a 7.84% *volume reduction*. Conversely, a 4% *volume reduction* is equal to about a 2% *circumferential reduction*. If 4% is selected in hopes of a standard 4% circumferential reduction, the socket will be too loose. See chart below.

Volume Reduction	1%	2%	3%	4%	5%	6%	7%	8%
Equivalent Circ. Reduction	0.5%	1.0%	1.5%	2.0%	2.5%	3.0%	3.6%	4.1%

CDC Reduction:

The CDC uses an algorithm based on liner, tissue density, and hand measurements to reduce a model. Resulting reductions range from 1% to 4.5% circumferentially depending on the given inputs. For example, a firm limb in a 3 mm liner would be reduced closer to 1% while a soft limb with a 6 mm liner would be reduced closer to 4.5%.

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 by 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.