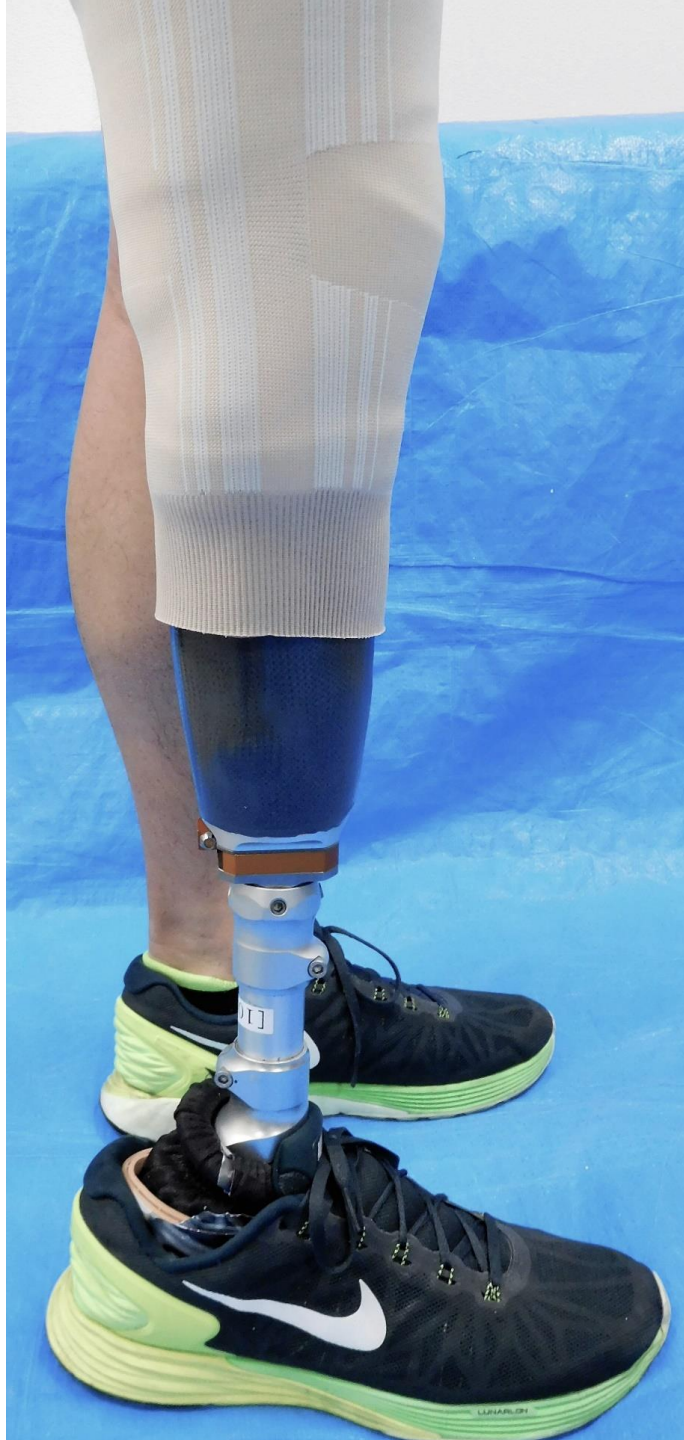


Introduction

- Overview of Direct Socket including material and tool updates
- Process updates and improvements
- New basalt braids and resin
- Liner selection and suspension options
 - Locking liner suspension
 - Seal-In suspension
 - Unity elevated vacuum
- Icecast bladder update
- Direct Socket manufacturing



Direct Socket

Enables you to fabricate a complete prosthesis in one visit (under 2 hours)

- Saves time for clients living long distances from facility
- Ideal for remote clinics
- Hospital and Interim use



Accurate anatomical fitting using Icecast provides consistent and repeatable results between clinicians

Direct Socket

- ***Standardised, efficient and consistent results***
- Directly laminate a TSB socket on a TT residual limb
- Wide range of suspension and interface options
- Utilises new Icecast pressure cast
- Efficient and clean
 - 14 min working time
 - 60 min cure time
- Max user weight 166kg



Renaming and Improvements

- Previous MSS product has been available since 2006
- Changes have been made to improve safety and ease of use
 - Renamed: Modular Socket System (MSS) to **Direct Socket (DS)**

Changes:

- Improvements to reduce chances of resin leaks
- 400ml resin cartridges- no need to switch between cartridges
- Black resin available
- New Basalt braids

Updates to:

- Tools
- Materials



Updates to tools and materials have improved process for direct lamination, providing consistent results

Product Improvements - Summary

- **Distal Connector** on fibre braids (aluminium puck) changed for improved resin flow and prevention of resin leakage
- **Process improvements and standardisation:**
 - Tape ring change
 - New O-Rings provided with Tape ring
 - Changes to distal attachment pin
 - Standardised injection tube with crimp rings to prevent resin backflow
- **Resin offering:**
 - Resin now available in both 200 and 400ml cartridges
 - Available both in **black** and neutral colour
- **Basalt** added to braid offering
- New standardised set of **Relief pads**
- Resin injection tool for 400ml cartridges

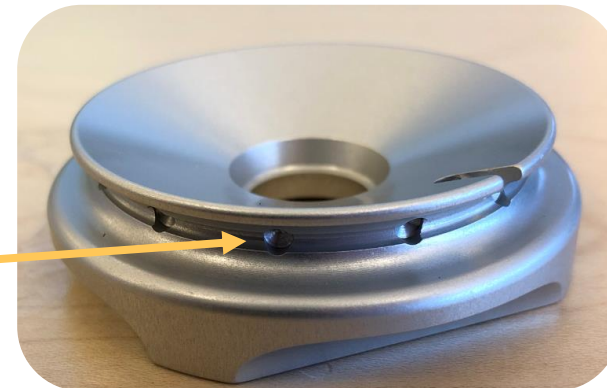


Distal Connector Improvements

- Injection hole:
 - Enlarged from 1mm to 1.5mm for better resin flow and prevention of leakage
 - Depth accommodates injection grommet length decreasing likelihood of cracking causing leakage
- New groove cut- easier flow of resin
- The conical top of the aluminum puck has been enlarged, to prevent the steel ring to slip off
- A small resin flow channel added in bottom of the steel ring groove for improved rotational strength



Enlarged injection hole and groove for easier flow of resin



Process Improvements

Injection valve and tube

- Groove for injection valve has been adjusted for a correct depth, decreasing the likelihood of cracked valve causing resin leakage
- Injection tube has been standardised (both for 200 and 400 ml)

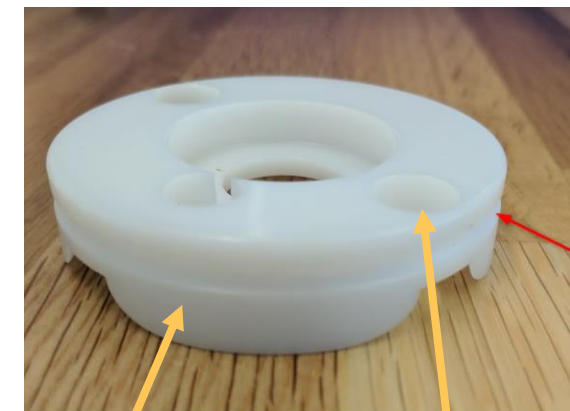
Tape ring

- Added two screwholes to fasten the puck during injection
- Added groove for O-ring
- Tape ring together with two screws and 2 O-rings sold as a Tape Ring Kit



Injection tube standardised

Groove for injection valve



Groove for O-ring

Screwholes to fasten the puck during injection

Process Improvements

Distal attachment pin

- Longer to have better indication of the correct tightening of the distal connector
- The pin end changed to make it easier to release with pliers



Distal attachment pin



Crimp rings on injection tube

- Crimp rings to seal the tube in both direction before it is cut
- To minimise the risk of resin leakage after injection, both from the injection tool and the injection valve when handling during the curing process
- Note:
 - Can use new resin kit on old braids
 - **Can not** use old resin kit on new braids



Crimp rings

Material Update: New Basalt braid

- Basalt fibre benefits:
 - No skin irritation, no ventilation requirements
 - Smoother finish than glass fibres
 - Better function with Seal-In suspension
 - 5 inch braid option only



Direct Socket from Basalt



- The WHO distinguishes ‘breathable’ fibres with a diameter $<3.5\mu\text{m}$ from ‘non breathable’ fibres with a diameter $>3.5\mu\text{m}$
- Basalt fibres have diameter of $10\text{-}22\mu\text{m}$ and are continuous
- French Agency for Environmental and work Health Safety defines basalt as inert, non-toxic, non-carcinogenic

Updated Materials

Standardised Relief Pads

- Relief pads to make small reliefs in socket
- Made from EVA material
- Standard in shapes and sizes, labeled with identifiers



Trim line tape

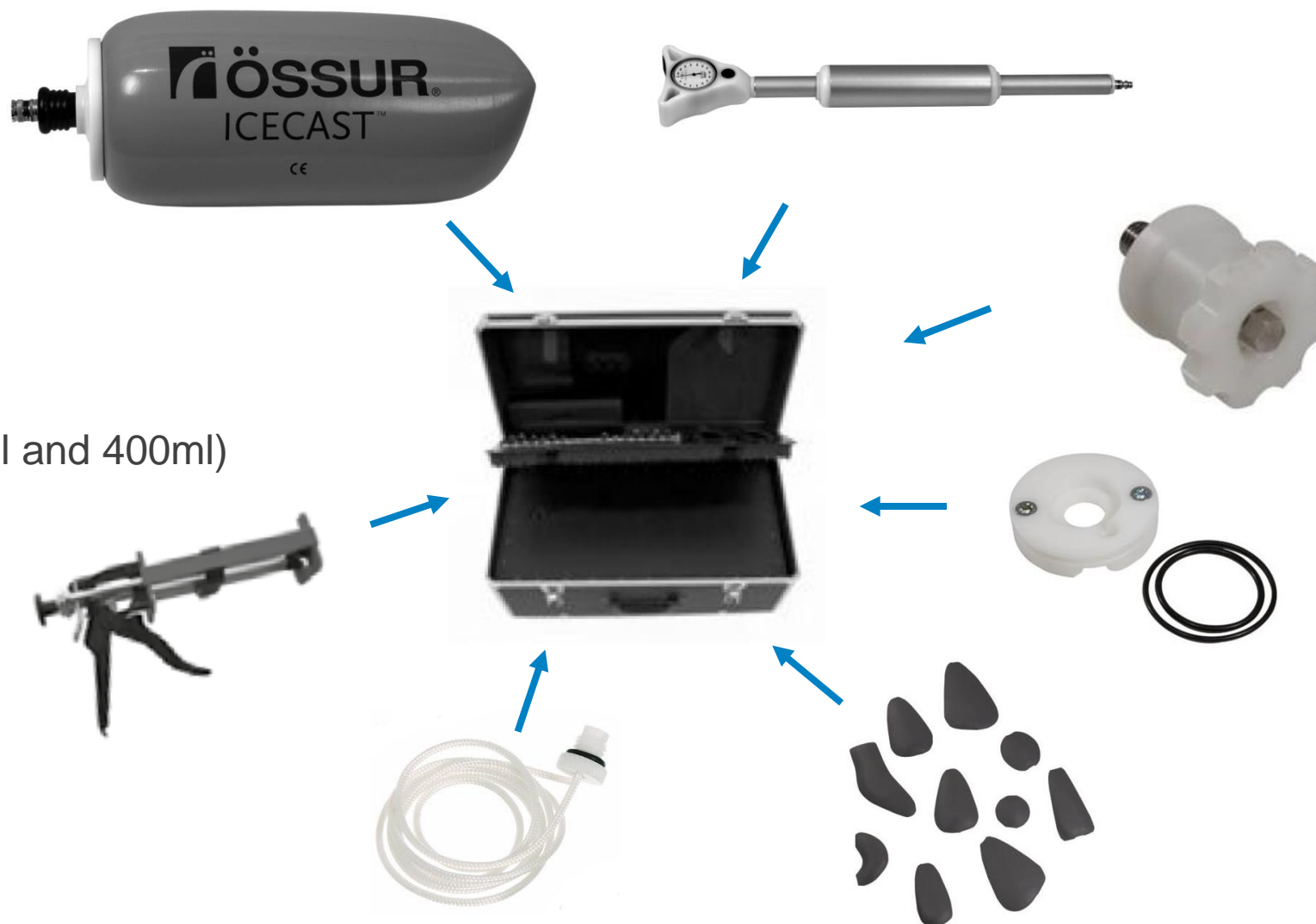
- Protection for socket edges
- Neutral and black
- Comes with resin cartridge kit



Direct Socket: Toolkit

Direct Socket toolkit:

- Icecast bladder
- Icecast pump
- Distal attachment tool
- Tape ring kit
- Lanyard cord
- Relief pads EVA
- Resin injection tools (200ml and 400ml)



Direct Socket: Material kit

- Direct Socket TT – Material kits

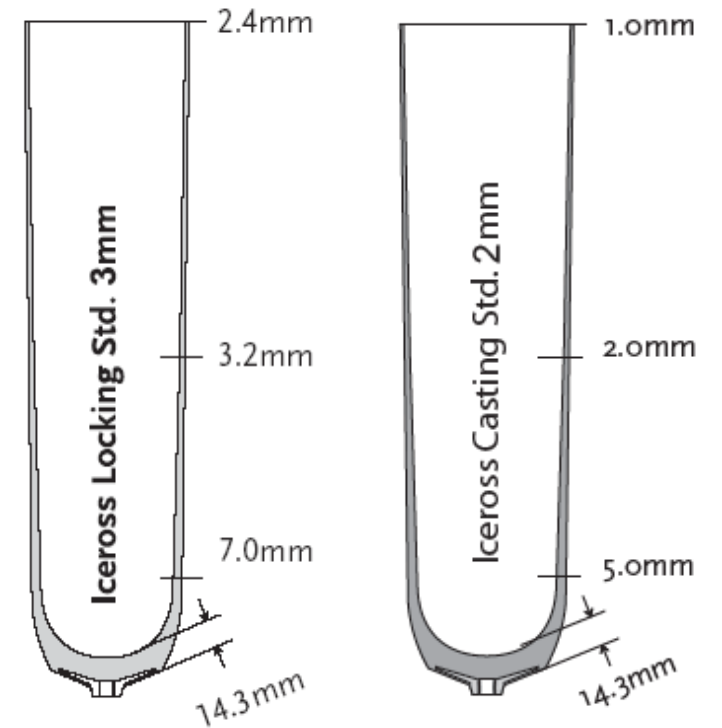
- Glass fibre braids with 5 or 7 inch distal connector and black and neutral resin
- Carbon fibre braids with 5 or 7 inch distal connector and black resin
- **Basalt fibre braids with 5 inch distal connector and black resin**



Iceross Direct Socket Casting Liners



- Specifically developed for direct lamination
- Laminate over 2mm tapered liner
- 2mm tapered profile
- Full length matrix (TF cover)
- High durometer silicone
- Limits longitudinal stretch however allows circumferential stretch
- Better socket shape for differing tissue densities



Sizes:
18, 20, 22, 23.5, 25, 26.5, 28, 30, 32, 34

Direct Socket: Liner Options

- Direct laminate over 2mm DS casting liner and fit with 3mm liners:



Synergy



Comfort



Dermo



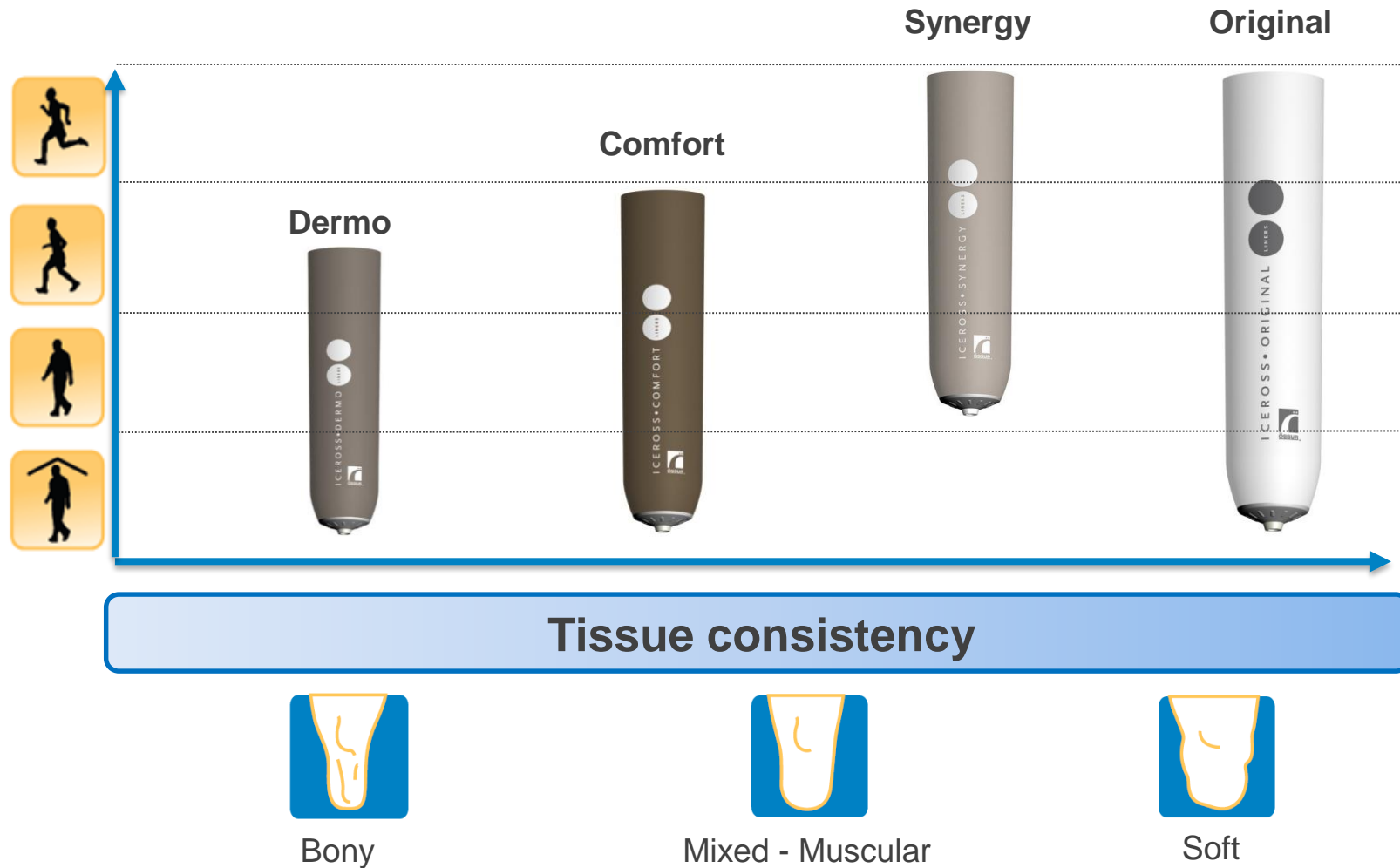
Cushion Liner and Knee Sleeve



Seal-In Liner range and Seal Rings



Iceross- Transtibial locking range



Transtibial liners: Seal-In Options



Seal-In X



Seal-In V



Seal-In X5 TT



Dermo Seal-in

Seal-Ring Options- *No Donning spray required*

Seal-In X-Classic

- Improved version of previous Seal-In X TT Seal with Easy Glide coating and more stable stretching properties
- The classic day-to-day seal ring



Seal-In X TF

- Standard or
- Conical -



Seal-In X

- 3mm or 6mm -



Seal-In X-Grip

- An adapted movable version of the Seal-In X5 seal
- For good rotational control



Seal-In X-Volume

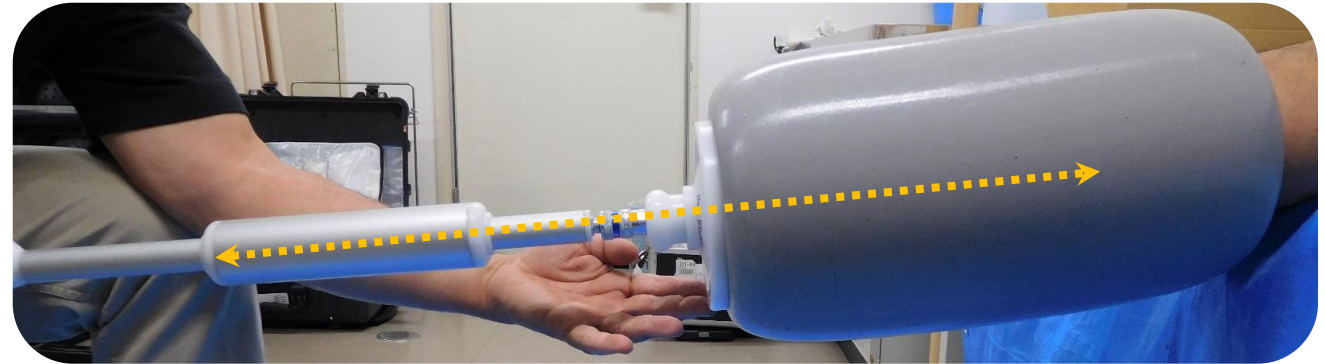
- An adapted movable version of Dermo Seal-In and Seal-In TF (HSM)
- Accommodates more volume reduction than the other two options



Available seal sizes
20,22,24,26,28,30,32,35,38,41,44,47,51,55,
60,65

Direct Socket: Icecast

- Single chamber pressure casting system
- Designed to distribute pressure to stabilise soft tissue and pre-shape the residual limb during casting
- Reinforcing matrix makes chamber durable and controls elongation
- Improved reliability
- Used to apply pressure whilst resin is curing

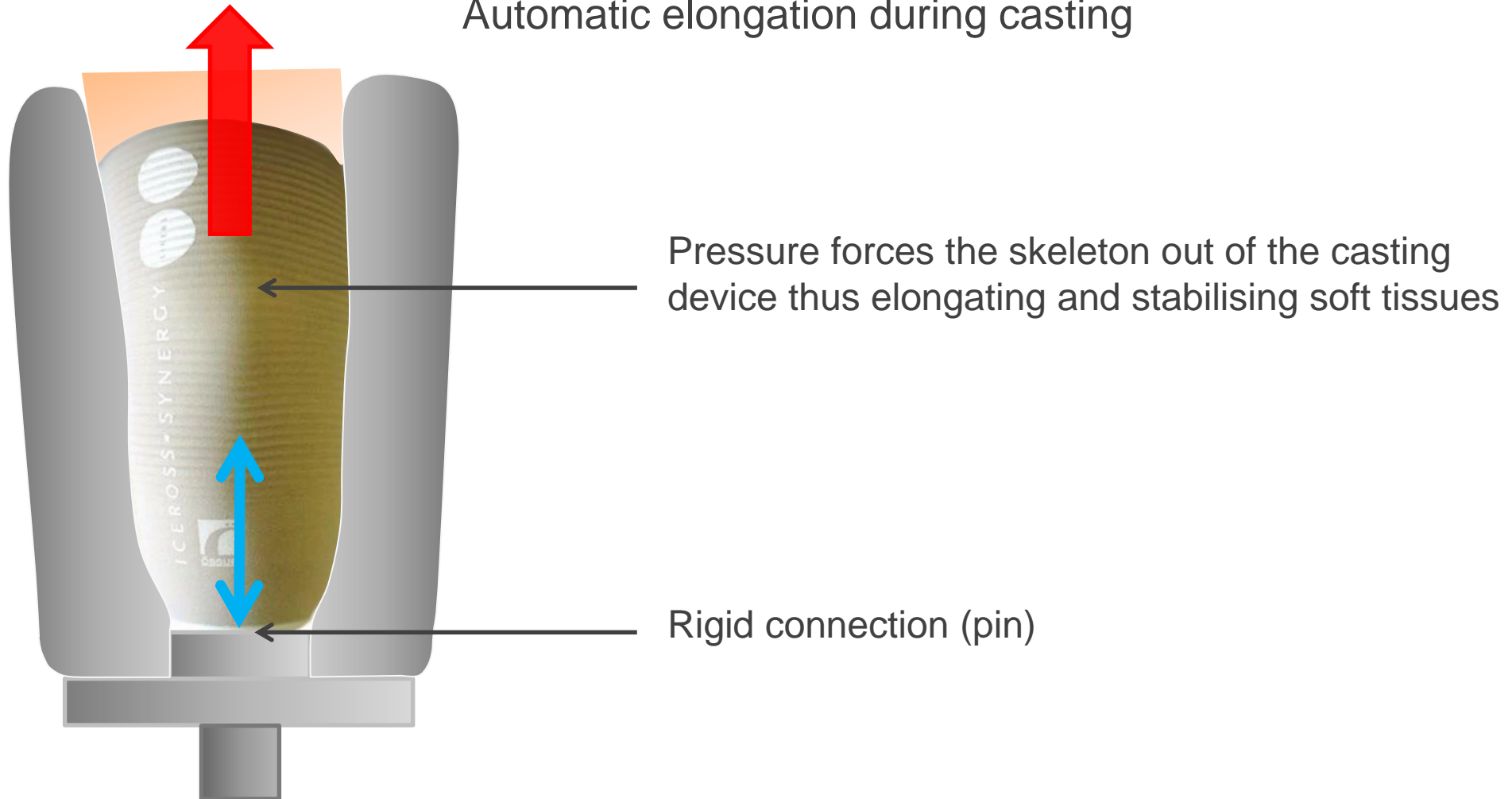


		FLESHY	MUSCULAR	BONY
ACTIVITY	LOW	50	60	70
	MEDIUM	70	80	90
	HIGH	90	100	110

All values in mmHg

Direct Socket: Icecast

Automatic elongation during casting



Direct Socket: Icecast Pressure Assessment



- Leave casting bladder on for 3 mins to ensure that the casting pressure is comfortable for the user
- Maintain support of the bladder (hold/prop onto chair)
- Disconnect the pump from the casting bladder
- If required, trial different pressures as per table



Push release high pressure coupling

Equipment



5mm Allen Key
for tape ring kit

Pliers and Scissors
to crimp and cut the
injection tube

Direct Socket: Relief Pads

Following residual limb assessment, the following relief pads may be required over bony prominences

- Anterior distal tibia
- Fibula head
- Distal Fibula
- Position under casting liner
- May hold in place with stocking or cling film



Direct Socket: Inner Silicone Insulation sheet

- To determine silicone sheet length
- Fold liner to a minimum of 5cm to proximal patella
- Measure proximal liner to distal pin (will shorten with circumferential stretch)
- Cut clean edge for silicone sheet length



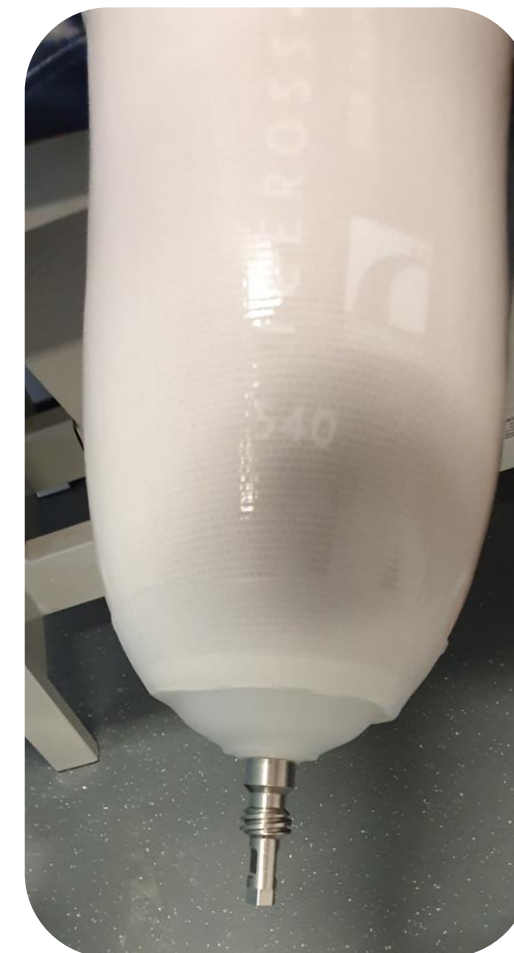
Direct Socket: Inner Silicone Insulation Sheet

- Pull up insulation sheet
- Fabric on the inside

SILICONE FACING THE OUTSIDE

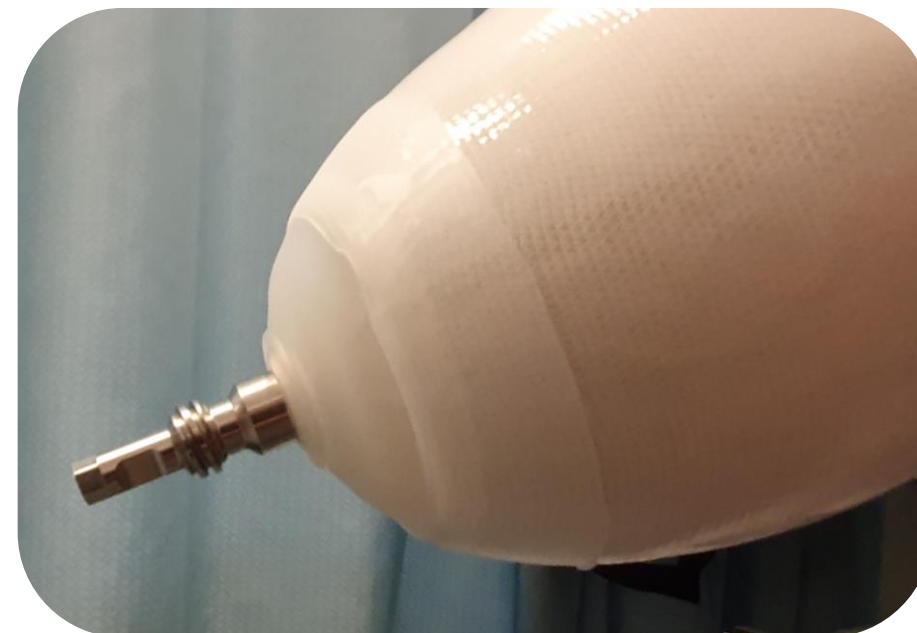


- Finish around distal umbrella



Direct Socket: Distal Insulation Cap

- Fit insulation cap in correct orientation
- Relief in the silicone cap fits the shape of the liners Delrin end
- Ensure centred on pin
- Smooth wrinkles in the cap



Direct Socket: Trim Line

Establishing trim lines leads to a timely outcome

- Identify patella
- Mark mid patella tendon
- Mark 5cm up from mid patella tendon for M-L proximal trimline
 - (approximate guide depending on user)



Direct Socket: Braid with Distal Adapter



For fibreglass braid length:

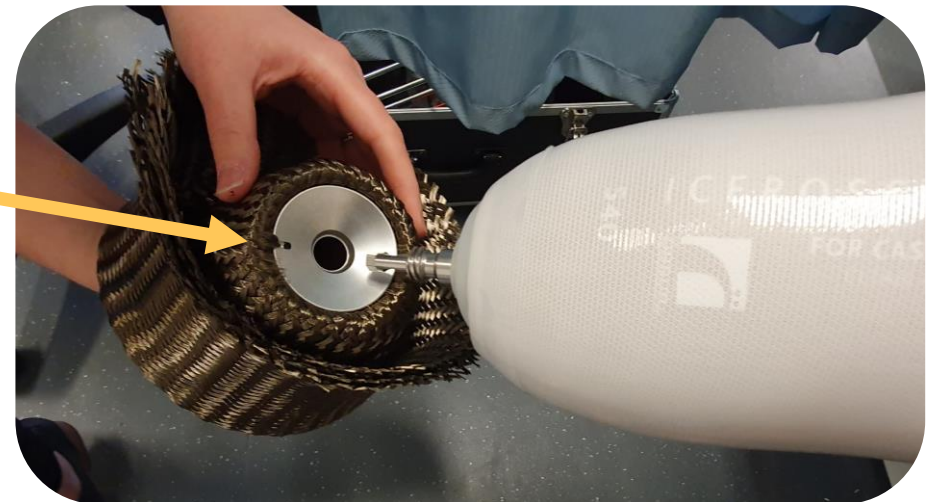
- Lay braid on residual limb
- Align the braids distal adapter with residual limb end
- Mark proximal braid 5cm longer than trim line (braid shortens as stretches circumferentially)
- Trim with scissors

Direct Socket: Braid with Distal Adapter

1. Identify hole for resin injection
2. Invert braid & orient the adapter with the **lamination channel anterior**
3. Position adapter firmly against silicone cap ensuring no wrinkles
4. Roll on fibre layer one at a time

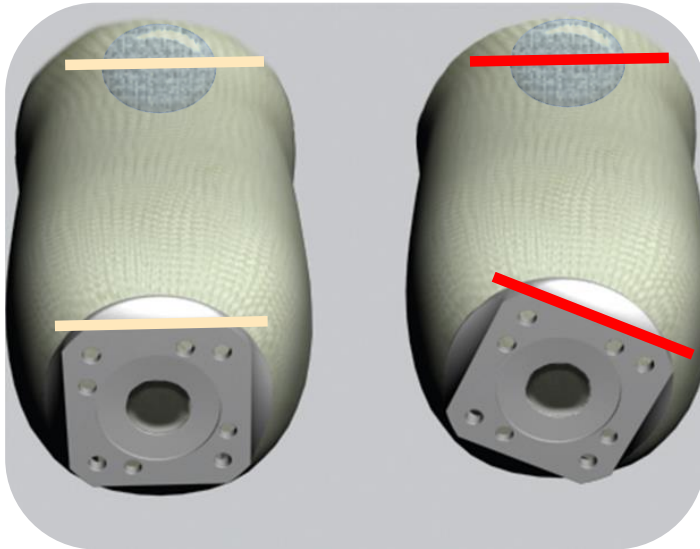
Ensure the proximal fibres:

- Extend beyond the trim line
- Finish before silicon sheet end



Direct Socket: 4-hole Adapter Orientation

Position the anterior face of the 4-hole adapter 90° to line of progression

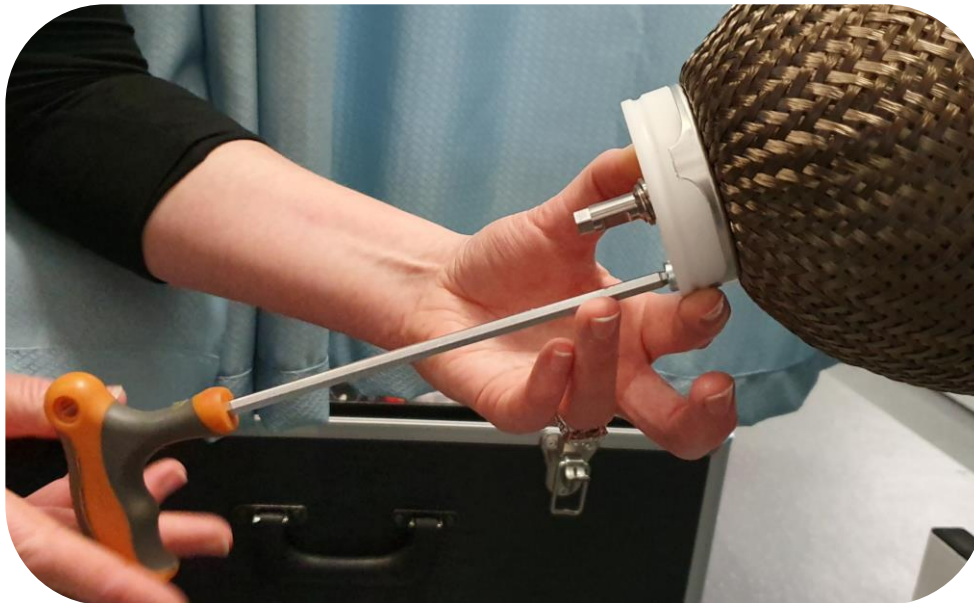


Screw in the lamination grommet fully

Direct Socket: Distal Attachment

Distal attachment tool updates:

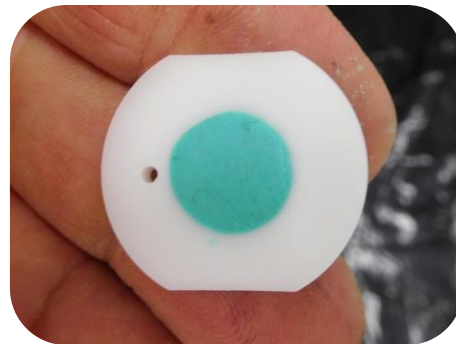
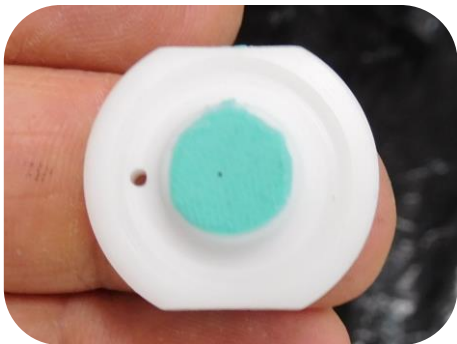
- Attach puck using the x2 screw holes to fasten during injection
- Fasten distal attachment tool securely (no need to loosen off when injecting resin)



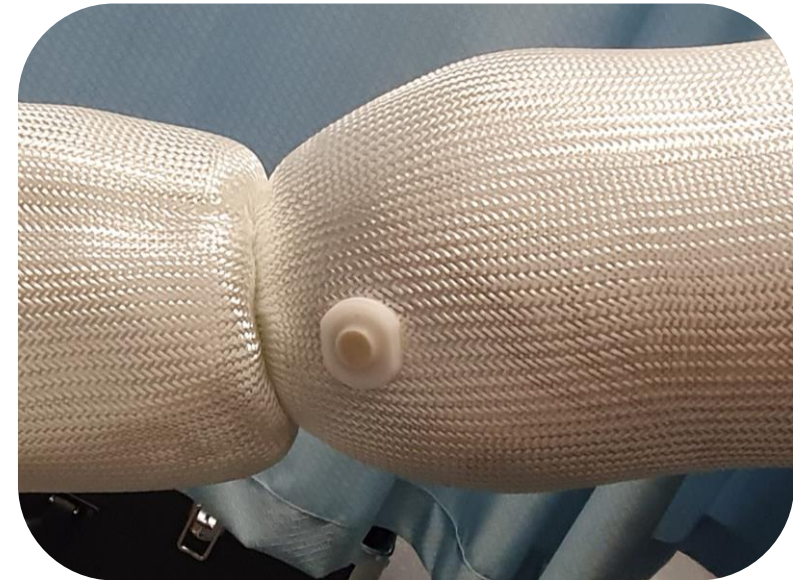
Direct Socket: Valve Options

The addition of the 551 or UTT socket housing will allow the use of both passive and elevated vacuum for either:

- Seal In liners
- Cushion liners with knee sleeve



Fill housing with putty

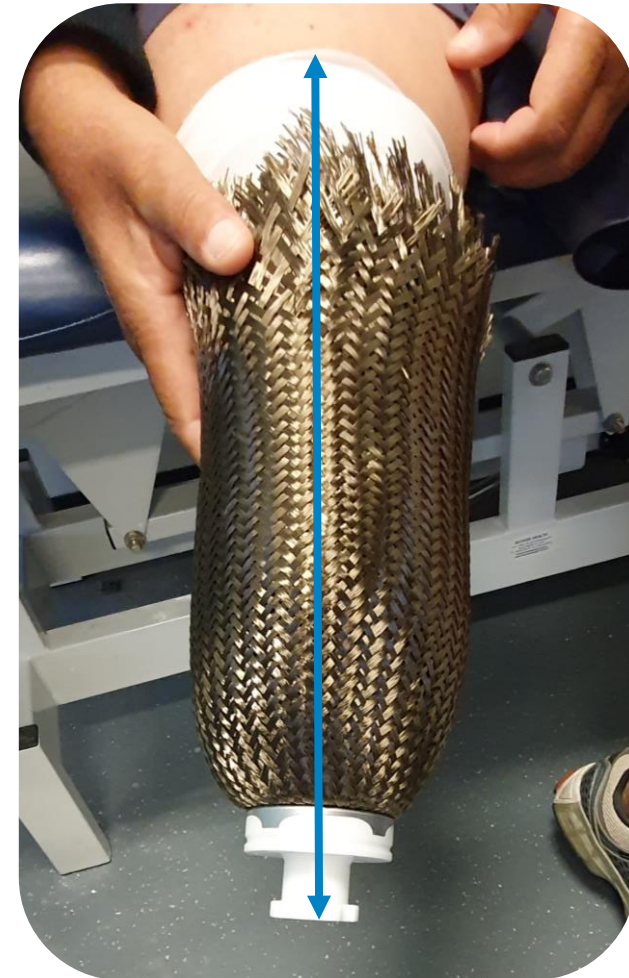


Between second and third layers

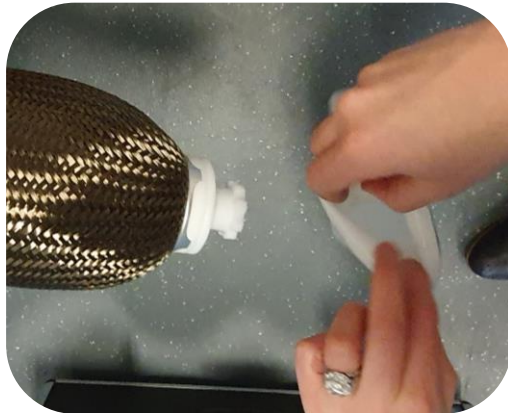
Direct Socket: Outer Silicone Insulation Sheet

For outer silicone sheet length:

- Measure from proximal tip of inner silicone sheet to distal attachment tool
- Add 4cm
- Silicone sheet shortens as it stretches circumferentially



Direct Socket: Outer Silicone Insulation Sheet



- Invert 3cm of the distal edge of the silicone sheet
- Roll the sheet onto the limb so that the
 - SILICONE SIDE FACES THE FIBRE
 - Fabric outside
- This technique is similar to donning the silicone liner



Direct Socket: Outer Silicone Insulation Sheet

Air wick



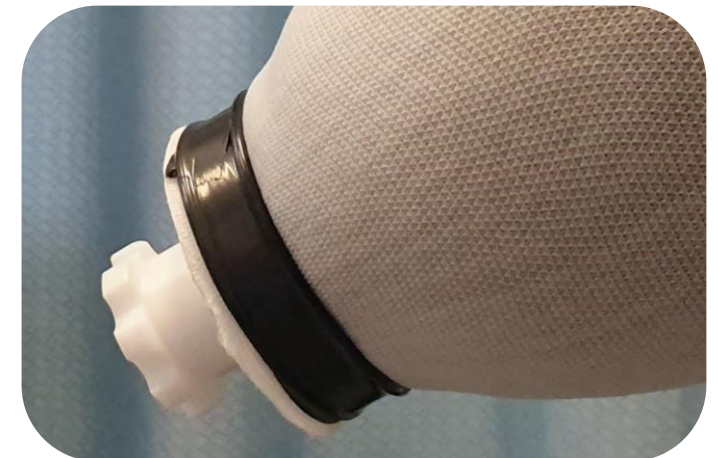
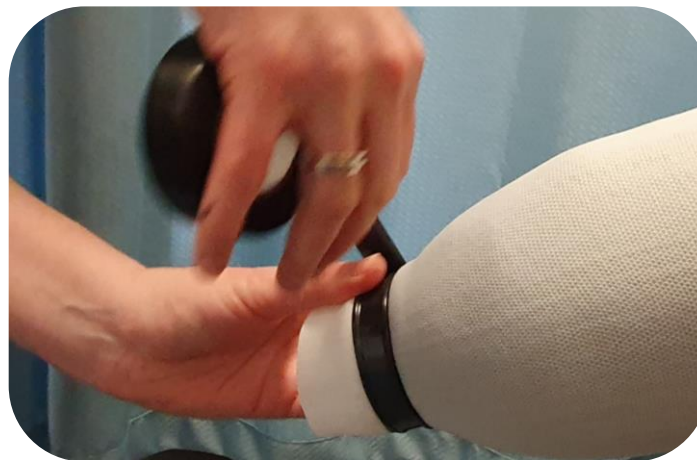
Roll on the silicone sheet to cover the length of the fibre

- At least 2cm **proximal** overlap of inner and outer sheets to create seal
- Silicone sheet overhangs distally
- Ensure even contact distally over the adapter
- Work out folds and wrinkles

Seal the silicone insulation sheet to the taping ring



1. Position both O-rings onto puck onto grooves
2. Firmly apply tape between O-rings for additional security (avoid taping over braid)
3. Trim excess distal silicone sheet



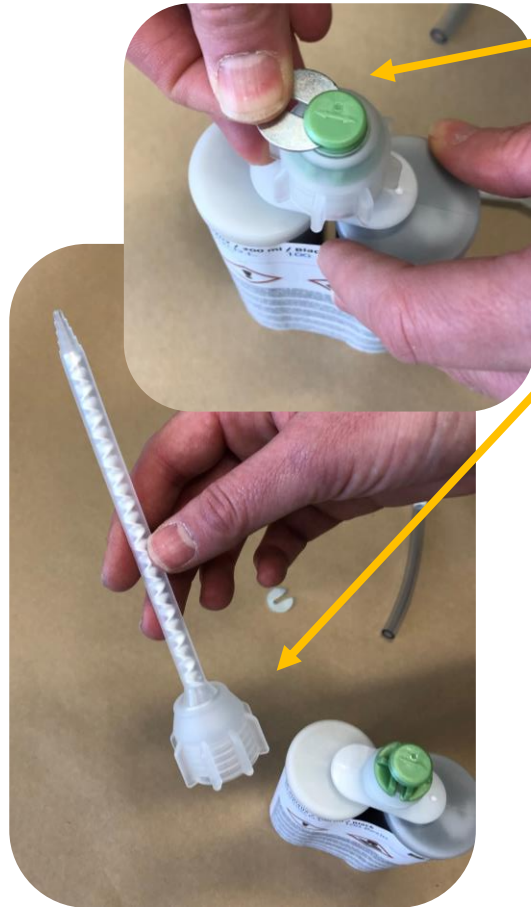
Direct Socket: Technical Note

Mark proximal resin indicators:

- Proximal to Patella
- M-L trimlines 1cm proximal patella
- Gives a guide to ensure enough resin coverage



Direct Socket



- Remove the metal cap on the resin cartridge
- Remove the screw cap from the resin cartridge
- Position screw cap onto mixing tube
- Insert mixing tube into crimp cut feeder tube at least 1cm



Mixing tube

Crimp cut feeder tube

Direct Socket: Resin process



- Remove green resin plug with pliers
- Screw on mixing tube



- Insert prepared resin cartridge into injection tool
- Ensure tabs are positioned outside



- Maintain injection tool in an upright position at all times

Direct Socket: Resin Process

**4 minute
working time**



- Maintain injection tool in an upright position
- Slide feeder tube onto entire grommet
- Then invert injection tool, removing air bubbles
- Gradually inject resin steadily
- Use hands to evenly distribute the majority of the resin
- Use lanyard to string resin up to trimlines



Direct Socket: Resin Process

Technical tips

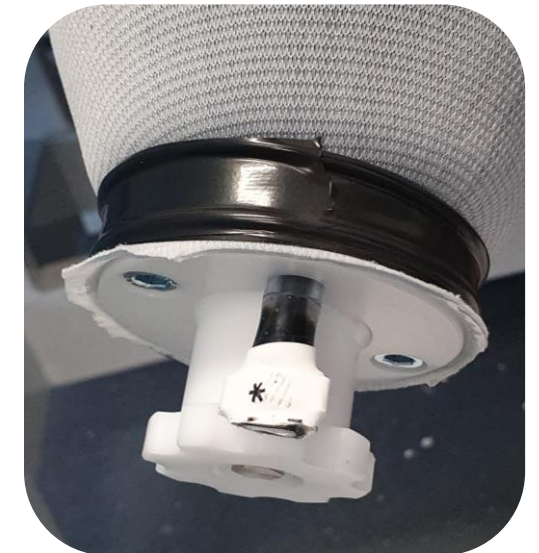
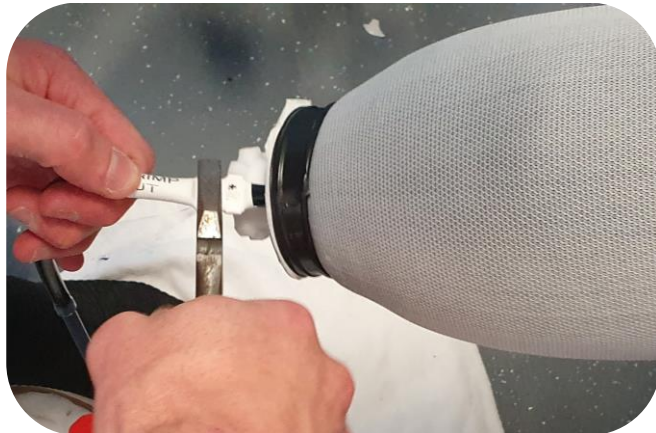
- Maintain inverted injection tool
- Use hands to distribute resin towards trim lines
- String resin evenly to trim lines once finished with resin
- Avoid resin proximal to patella and posterior thigh
- Larger limbs require all resin



Direct Socket: *Resin Process*

When amount of resin is complete:

- Crimp rings to seal the tube in both direction before it is cut
- This minimises the risk of resin leakage after injection, both from the injection tool and the injection valve when handling during the curing process



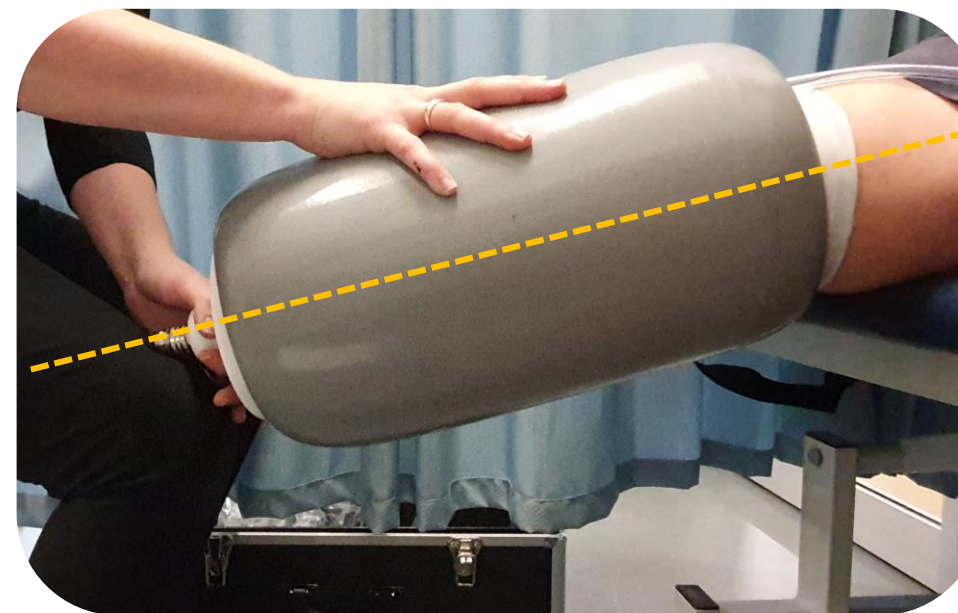
Direct Socket: Icecast Application



- Evenly engage Icecast
- Deflate to assist donning
- Roll on fully in correct alignment
- Pump to selected pressure from pressure assessment chart

		FLESHY	MUSCULAR	BONY
ACTIVITY	LOW	50	60	70
	MEDIUM	70	80	90
	HIGH	90	100	110

All values in mmHg



Direct Socket: Icecast Application



- Disconnect the pump after setting the pressure
- Support limb and bladder

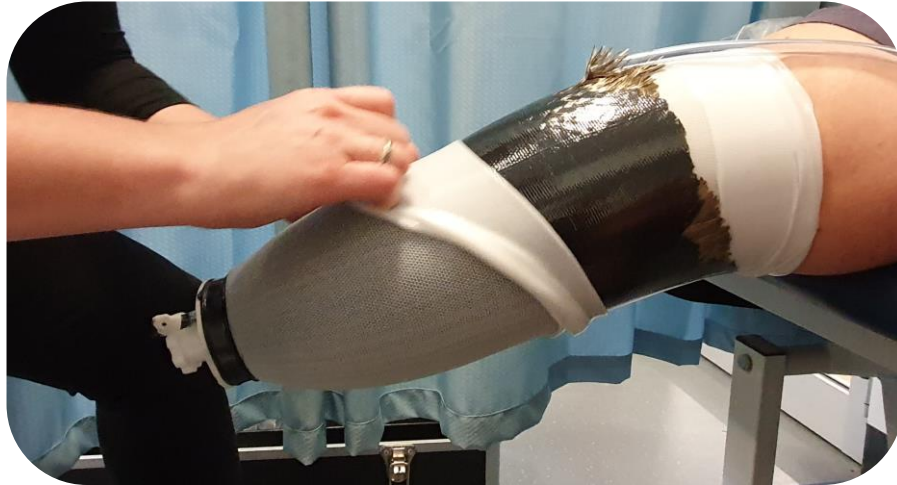
10 Minutes

- Allow 10 minutes for setting of the resin under pressure

14 minutes total

- 0 - 4 minutes laminating
- 4 - 14 minutes pressure cast

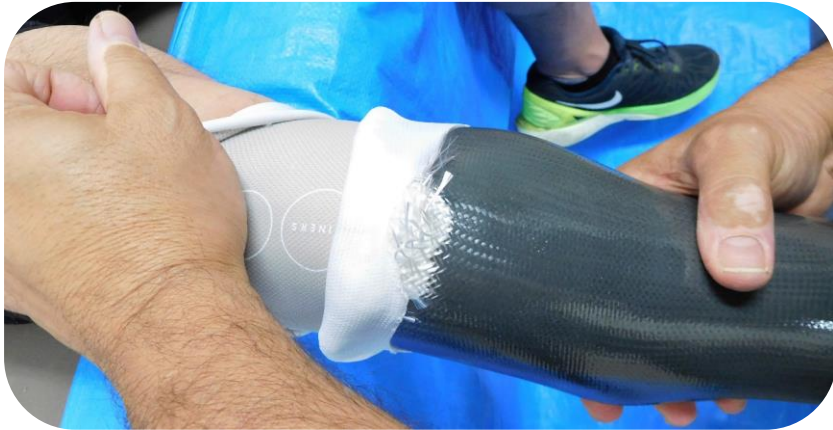
Direct Socket: Socket Removal



- Roll down outside silicone
- Remove distal attachment tool
- Lamination ring removal (optional)



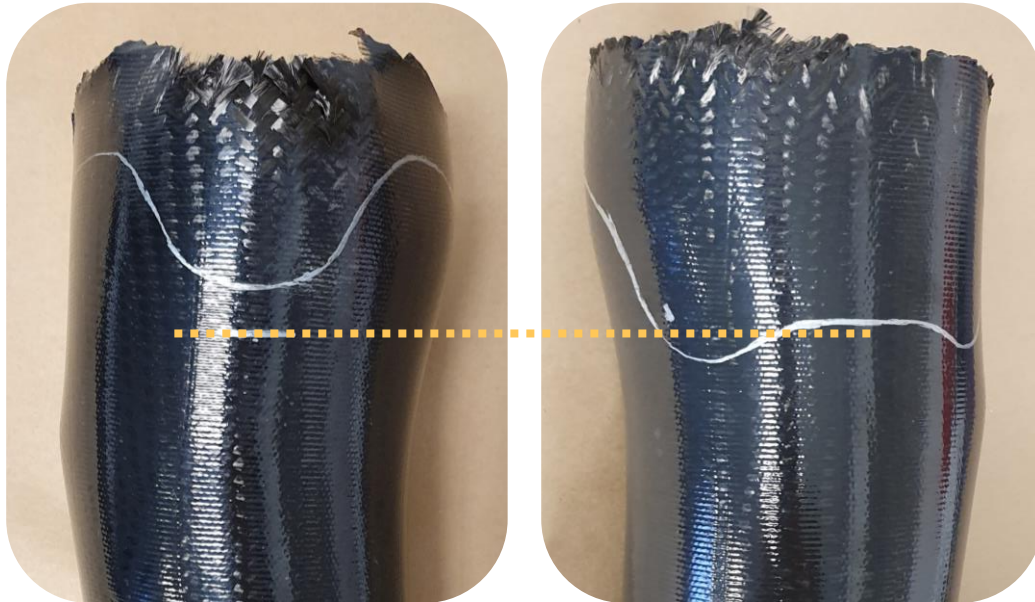
Direct Socket: Socket Removal



- Fold inner silicone sheet over socket
- Hold onto Casting Liner and pull residual limb out of the socket
- Remove both inner silicone and distal cap
- Observe marks - Silver markers transfer well



Direct Socket: Trim Lines



- Transfer trim lines from inside of socket to outside
- Posterior wall
 - Opening is centred around ML midline (check rotation)
 - Transfer MPT mark to posterior wall
 - Mid point of posterior wall at MPT height
 - Medial relief 1.5cm lower
 - Lateral relief 1 cm lower

Direct Socket: Trim Lines



- Cut through any excess fibre with scissors to the hard socket
- Cut trim lines with jigsaw or oscillating saw
- Fine sand trim line with upto 600 grit wet sand paper
- Sanding can also be completed with files if in remote location
- Allow 60 minutes for resin curing prior fitting



Height Adjustable Pylons



- Quick and easy height and rotation adjustability
- No cutting required
- Designed and tested for definitive use for K2- K4 activity level
- Weight limit 100kg



Long



Standard



Junior

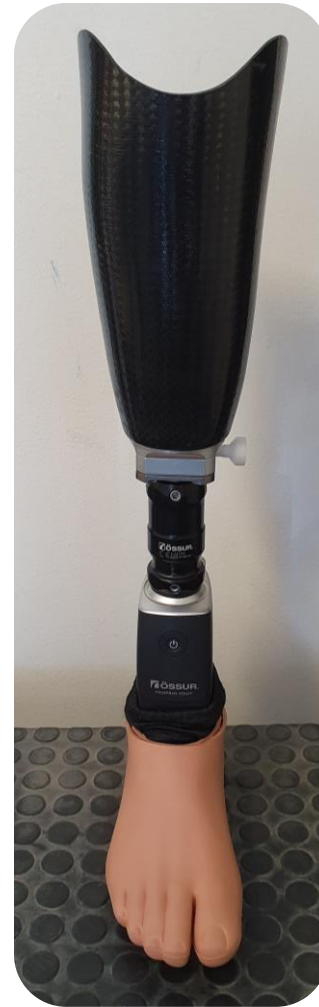
ORDERING INFORMATION

Model	Diameter	Extension Range	Patient Weight Limit	Part Numbers
Long	32mm	9.4cm - 12.8cm	100 kg	A-542360
Standard	35mm	7.7cm - 9.5cm	100 kg	A-542350
Junior	28mm	7.6cm - 10.2cm	45 kg	AJ-542350

Direct Socket: Icelock 200 and 600 Series

- Icelock 214

- Clutch lock
- Assemble with a 4-hole adapter
- Position release arm medially (unless alternative orientation preferred)



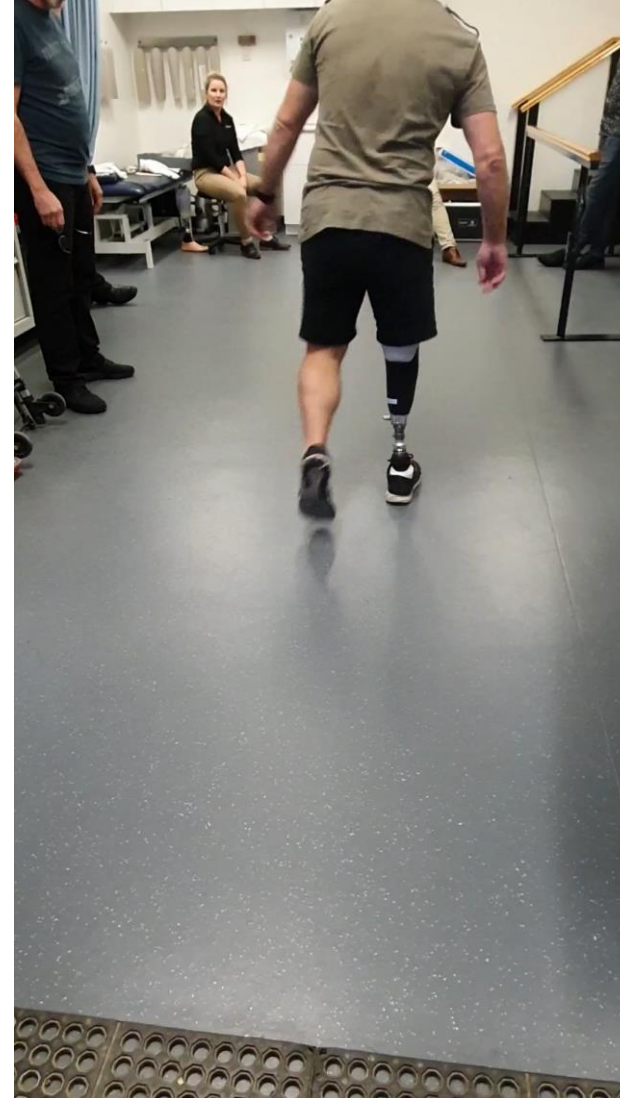
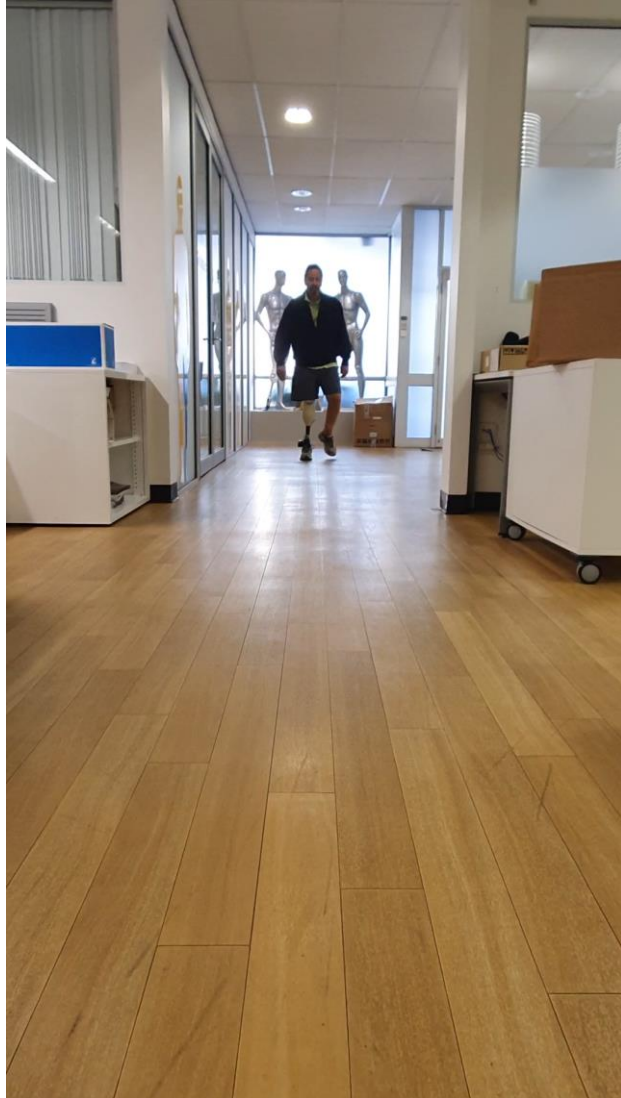
- Icelock 600 series:

- Ratchet 621
- Lanyard 631
- Smooth pin 651

Low profile series of modular locks



Direct Socket: Icelock 600 and 200 Series



Direct Socket: Interface and Suspension Options

- Cushion liner and knee sleeve:

- Synergy Cushion
- Comfort Cushion
- Dermo Cushion

- Iceross Sleeve

- Genu Sleeve



- Valve Options:

- Pin Valve (Pure expulsion)
- 551 valve
- 544 valve options for Unity and Passive



- Seal-In Liner Options:

- Seal-In X (Seal rings)
- Seal-In V
- Seal-In X5

- Unity and passive options:

- 544 unity/expulsion plate
- 551 valve
- Unity UTT0001 valve



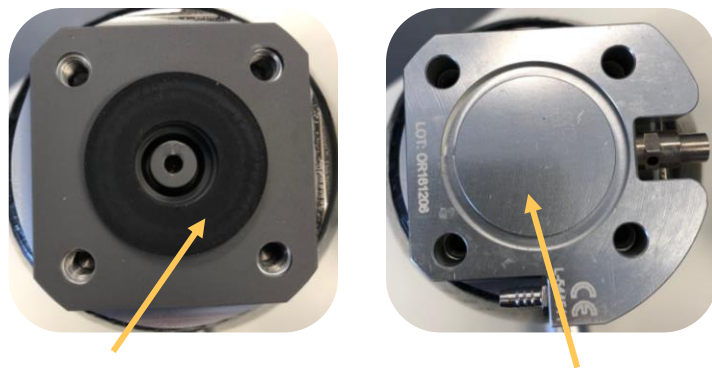
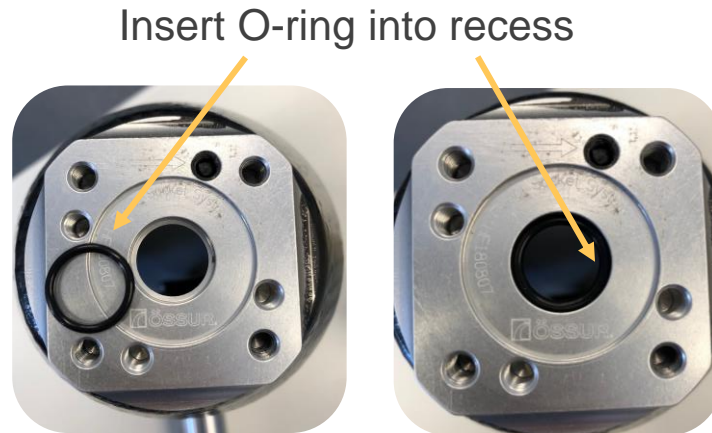
Advantages of the Unity™ system

- **Very firm suspension** providing excellent security and improved **proprioception**
- Elevated vacuum tends to assist in maintaining more **constant limb volume**, thereby decreasing the need to add additional socks
- Elevated vacuum **assists with wound healing** by improving circulation through the residual limb
- **Sleeveless:** Increased knee flexion range with greater comfort and user acceptance
- **Light weight and discreet:** 130g added weight and housed within foot cover
- **Simple and efficient:** Quick and easy to elevate and release vacuum levels
- **Independent pump:** Does not depend on shock mechanisms and can be added to a wide range of performance Flex-Foot and Pro-Flex systems to meet every mobility need.

Direct Socket: 544 Unity Valve

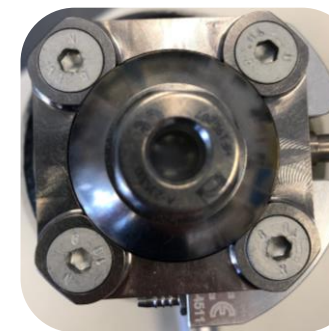
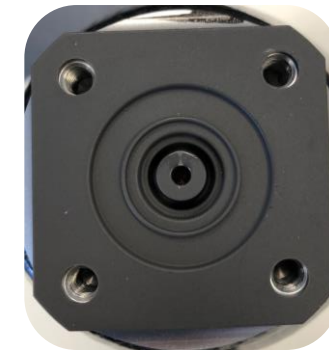


Direct Socket Adapter:
L-544050



Position O-ring and Unity plate

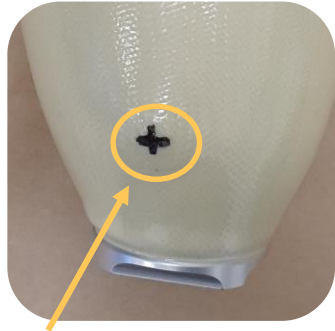
Push Direct socket adapter in to create a seal



Attach 4 hole adapter



Direct Socket Assembly: Unity Valve



Valve seat



Grind to expose edge



Drill bit: 8.5mm



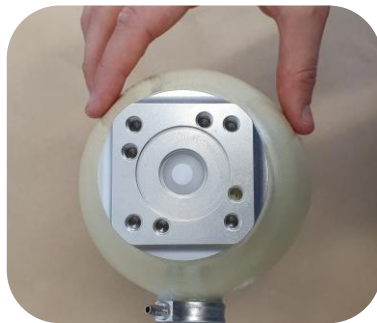
M10x1.5 tap



Trim valve



Bottom Seal for Direct socket M-400206



Tighten using tool to create seal



Use O-ring L-693112 to seal (cut to size)

Insert filter



Direct Socket: Unity Application



Unity options can fit with the following liners:

- Seal-In X
- Seal-In V
- Cushion liner and knee sleeve



Create solid suspension upto -22inHg



Direct Socket: Icelock 544 Series



L-544050

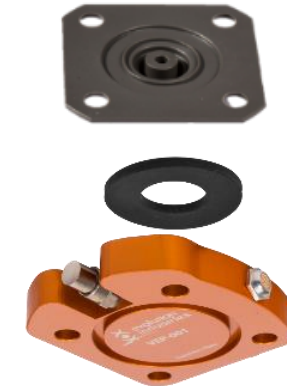
Icelock 544 DS Adapter

+

L-544511

Icelock 544 Unity Plate

Button release expulsion plate for elevated vacuum



L-544050

Icelock 544 DS Adapter

+

L-544521

Icelock 544 Expulsion Plate

Button release expulsion plate for passive vacuum

Direct Socket: Summary

- Standardised, efficient and consistent results
- Enables you to fabricate a complete prosthesis in one visit (under 2 hours)
- Accurate anatomical fitting using Icecast provides consistent and repeatable results between clinicians
- Can utilise a wide range of suspension and interface options

Technical details:

- New catalogue has all Direct socket product codes
- Resin has a shelf life of 1 year
- Environmental Conditions:
 - Operating Temperature: 0°C to 40°C
 - Operating Humidity: ambient relative humidity 10% to 95%
 - Recommended resin storage temperature 15°C to 25°C
 - Shipping and storage temperature: 15°C to 40°C
 - Shipping and storage humidity: ambient relative humidity 10% to 90%



Q&A

Contact Sarah Mulroy-Lang: smulroy-lang@ossur.com

Össur Academy webinars: <https://www.ossur.com.au/about-ossur/ossur-academy/prosthetic-webinars>