

ORTHOCARE
TECHNICAL BRACING
CATALOGUE
2025 - 2026



EDITO

Dear Customers,

We are pleased to share with you our new catalog featuring all our advanced solutions.

In the past year, we have demonstrated our resilience in delivering our solutions despite a fragile geopolitical and economic context. From yarn to delivery, our integrated business model enabled us to limit the impact of these factors.

More than ever, Thuasne® is committed to be by your side as a strong partner, to provide innovative and concrete solutions to improve the mobility and the quality of life of patients. We are currently conducting over 30 clinical, biomechanical and medical-economic studies to evaluate the medical benefits of our solutions.

In 2024, you discovered the new design of our lumbar belts, the result of the exclusive know-how and expertise of our R&D, marketing, design and industrial teams. Innovation was also at the center of our actions with the development of an exoskeleton.

In 2025, our aim is to continue providing a range of solutions, services and training to better support you in your day-to-day activities. This year will be marked by the launch of Action Reliever® in sleeve and wraparound versions as well as our universal sized posterior AFO, SpryStep® One and Thuasne® Academy.

All these projects are a promise of our commitment to you.

We thank you for your trust and wish you a wonderful and successful year.

Thuasne® today is...



2,400 employees around the globe



Improved mobility for over **100,000 patients*** with SpryStep®



35 years experience in functional and OA knee bracing



50% of turnover registered outside of france



17

industrial sites in Europe North America and Africa



30 to 40

new product references every year



A commercial presence in

110 countries



23.000

B2B customers



One Thuasne® brace sold every

6 seconds

somewhere in the world



A turnover of **281 M€** in 2023



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Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or $clearance\ requirements\ for\ sale\ in\ such\ country\ or\ region.\ All\ the\ medical\ devices\ mentioned\ on\ this\ document\ are\ CE\ marked\ according$ to the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices, unless specifically identified as "NOT CE MARKED" and the Regulation 2017/745 on medical devices are the Regulation 2017/745 on medical devices and the Regulation 2017/745 on medical devices are the Regulation 2017/745 on medical devic

 $Some of the products featured in this document are also UKCA-marked according to S.I 2002/618 \, regulation on medical devices.$ Medical devices mentioned in this document are CE class I.

 $Please\ contact\ Thuasne^a\ should\ you\ need\ any\ additional\ information\ on\ devices\ classification.\ Please\ carefully\ read\ the\ instructions$ for use, indications and contraindications of the products. The main medical indications for the products are available on the product pages or are summarised in decision trees or in tables throughout the catalogue. The full list of medical indications,



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MEASUREMENTS INDEX





– KNEE —



Measure the calf circumference X cm/in below the knee



Measure the thigh circumference X cm/in above the knee and the calf circumference Y cm/in below the knee



Measure the calf circumference X cm/in below the fibular head



Measure the width of the knee



Measure the knee circumference in the middle of the patella, knee in slight flexion



Measure the thigh circumference at the highest point or X cm/in above the knee



Measure the thigh circumference

SPINE-



Measure the waist circumference

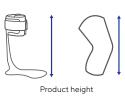


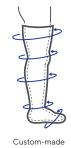
Measure the height between the pubic symphisis and the sternum

NECK-



Measure the neck circumference





L≠R silable is 2 made

Available in 2 models: right and left



Voice of CPO symbol: in the AFO section, our clinicians give their recommendation and highlight the features of some of our products



Tips

About this catalogue

ORTHOCARE TECHNICAL BRACING

Welcome to the new Orthocare technical bracing catalogue, dedicated to the devices that require clinical expertise in terms of fitting and adjustment.

This catalogue is designed for experts like you and offers an overview of the Thuasne® solutions. From AFOs and KAFOs designed to address lower limb neuromuscular deficits, to knee bracing for osteoarthritis, there is an array of options when it comes to treating your most complex patients.

The Thuasne® value chain







Create



Manufacture



Control



Supply



Deliver

Introduction to our solutions

Historical craftsmanship from Thuasne®

We are committed to offering patients and healthcare professionals products designed and manufactured in-house using technology mastered by the Group and based on decades of experience.

Maximising the potential in each patient

Thuasne® Orthocare technical bracing solutions combine cutting edge processes with quality materials to provide a variety of options for prescribers and positive outcomes for patients.

Our values put patients first:

- Providing care, by supporting the patient with individualised solutions, crafted to their unique lifestyles and conditions;
- Increasing autonomy, so patients can manage their own health and wellbeing;
- Promoting freedom, by increasing a patient's capacity for choice, mobility, and a better quality of life.

Many products featured in this catalogue have a specific "Custom-Made" designation identifying devices that are custom fabricated based on a model of the patient limb and a thorough clinical assessment.



Core technologies

The Thuasne® Group employs a vast array of manufacturing technologies to design orthotic solutions. These core technologies can be found across our ranges and are a cornerstone of Thuasne®'s success.

TEXTILE

Textile expertise for the benefit of patients

The origins of Thuasne® can be found in textile and it has been a focus since the company was founded, in 1847. Using both knitting and weaving technologies within its solutions, Thuasne® is on the cutting edge of the textile industry when it comes to medical device manufacturing.

Thuasne®'s spinal bracing solutions (LombaStab range) use weaving technology that provides compression to increase intra-abdominal pressure while helping to relieve pain and discomfort $^{(0)}$. This same weaving is also breathable, featuring a unique double-sided design that encourages the evaporation of moisture for a cool, comfortable fit(2).

The knitting technology used on upper and lower extremity bracing provides multiple features within a single knit structure: medical grade compression⁽³⁾, anti-migration technology⁽⁴⁾, anatomical shape, lower compression areas for comfort⁽⁵⁾, contribute to efficacy, comfort and compliance.







COMPOSITES

Innovation in orthotics through the science of composite materials

Thuasne® is committed to maximising the potential of each patient through innovative design and cuttingedge technology. Using the unique mechanical properties of a proprietary blend of composite materials, Thuasne®'s devices help improve mobility with every step. Inspired by the strength and flexibility of materials used in the automotive and aeronautics industries, Thuasne®'s off-the-shelf (OTS) and custom braces offer elegant⁽⁶⁾ and reliable solutions to the most complex biomechanical deficits.

Thuasne®'s success in composite science and orthotics is based on three tenets of design:



1 - The use of material diversity for enhanced features and benefits



2 - The geometry, size and length of fibres



3 - The ratio of fibre to matrix



The back braces effect relies on 2 parameters: abdominal pressure and rigid stays located around the spine. This creates a 3 points system which reduces the lordosis.

RET Evaluation - IN2103 project - Comfort evaluation of moisture (while wearing the device), July 2021; oc 1806 report on material characterisation.

ASQUAL certification.

Use of anti-slip yarn made with silicone.

Panel knitting with adapted and/or specific design shapes. Compression is tested internally.

Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem.

KNEE AND SPINAL TECHNOLOGY

Knee bracing technology

Thuasne®'s functional knee braces are designed for better fit and function(1). Featuring Thuasne®'s Motion hinge technology, the TM5 is a biomechanically correct knee joint that mimics the roll and glide motion of the knee(1)(2).

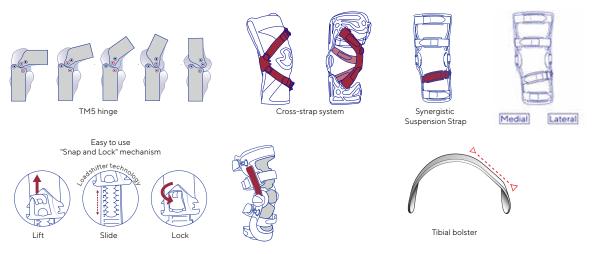
The tibial bolster addresses rotary instability by contouring the brace to fit the flatter medial side of the tibia. The combination of the TM5 hinge and anterior tibial bolster helps protect the knee against the two leading causes of ACL injuries: anterior tibial drawer and internal tibial rotation⁽²⁾.

The Synergistic Suspension Strap maintains intimacy of fit and brace positioning thanks to its non-elastic materials and angled placement at the top of the calf muscle. The Compression and Suspension (C/S) package provides an additional suspension element for patients who lack calf muscle shape⁽²⁾.

Osteoarthritis (OA) braces feature two offloading technologies⁽²⁾:

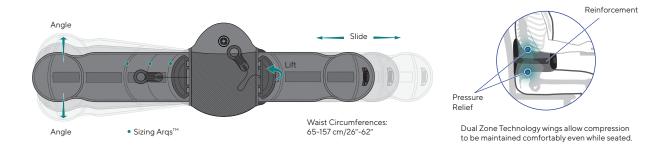
- Loadshifter technology (rigid double uprights knee braces): the upper shell varus or valgus angle can be adjusted to create a corrective force specific to the patient's needs.
- Cross-strap system (on single upright knee braces): inelastic straps intersect on the unaffected side of the leg to create a dynamic 3-point lever arm while the leg is in extension.

The Rebel Reliever® (see page 64), featuring Loadshifter technology, averaged a 36% reduction of force through the knee (peak KAM)⁽³⁾ leading to decreased pain and improved function⁽²⁾⁽⁴⁾.



Technical features for Back braces

Acquired by the Thuasne® Group in 2016, the Sleeq® Universal family of LSO's and TLSO's revolutionised back bracing with its simple adjustment technology designed for various patient body sizes and types. With adjustable dual wings, crescent self-fastening connectors, corset style compressive cinching and the ability to customise panel heights and support, the Sleeq® range is a truly universal solution for a variety of indications and patient needs.



⁽⁹⁾ A2S biomechanical study « Biomechanical study of the stride during use of different braces » 2020, including the Rebel® Standard, a rigid ligament brace with the TM5 hinge and conducted on a panel of 18 people.

Internal CE marking data.

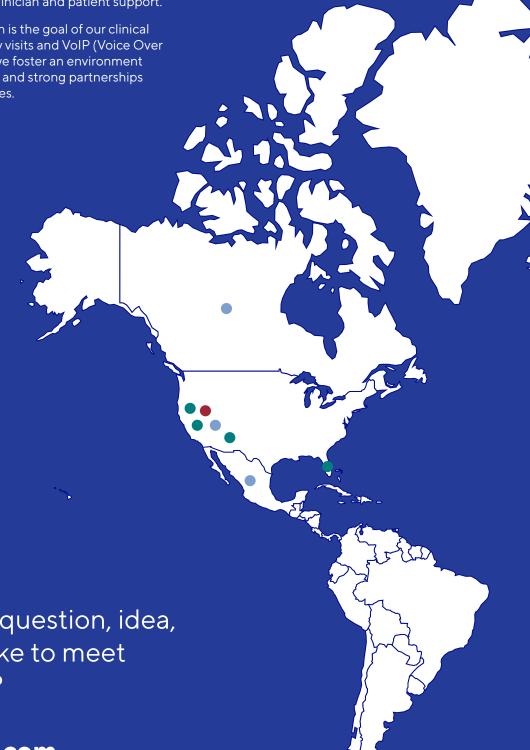
Lamberg, Eric M., Robert Streb, Marc Werner, Ian Kremenic, and James Penna. 2016b. "The 2-and 8-Week Effects of Decompressive Brace Use in People with Medial Compartment Knee Osteoarthritis." Prosthetics and Orthotics International 40 ⁽⁶⁾, 447-453.

^{**}Thournie, Philippe, Marc Marty, Bernard Avouac, Adeline Pallez, Arnaud Vaumousse, Linh Pham Thi Pipet, André Monroche, et al. 2018. "Effect of Unloading Brace Treatment on Pain and Function in Patients with Symptomatic Knee Osteoarthritis: The ROTOR Randomized Clinical Trial." Scientific Reports 8 9: 10519.

CPO TEAM

The Thuasne® Group is invested in clinical excellence when it comes to advanced orthotics and a team of experts is on-hand to assist from design to patient application. Based in the United States of America and Europe, our team of Certified Prosthetist/Orthotists (CPOs) support all aspects of the device lifecycle, including: concept, development, marketing, sales education and training, and clinician and patient support.

Success through collaboration is the goal of our clinical support team. Through facility visits and VoIP (Voice Over Internet Protocol) meetings we foster an environment where strong communication and strong partnerships lead to better clinical outcomes.



Technical Experts

Clinical Experts

Design

Do you have a question, idea, or would you like to meet with our team?

Contact us at: cpo@thuasne.com







LOWER LIMB ORTHOSES

Available from paediatric to adult sizes, the SpryStep® AFO range is customisable, versatile and built to last.

From off-the-shelf (OTS, prefabricated AFO) to custom products, our main objective is to get better patient outcomes.



Weight reduction

Improve clinical results particularly for weight sensitive patient populations.⁽¹⁾



High Strength

The highest standard material from aerospace, navy, and high-end sports. (2)



Energy return

Stiffness where orthotic control is needed and flexibility in other sections for fine-tuned biomechanics.



Optimised Trim Lines

Minimalistic trim lines using material only where force systems dictate.



Durability

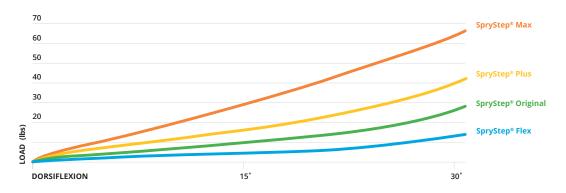
Structure and components tested to 2,000,000 cycles⁽³⁾.







STIFFNESS COMPARISON: RESISTIVE LOAD INTO DORSIFLEXION



Proven Durability(3)

For a diverse range of clinical indications and patient needs, you can rely on the performance, quality and durability of our growing range of composite AFOs. The SpryStep® Flex, SpryStep® One, SpryStep® Original, SpryStep® Plus and SpryStep® Max were independently tested by mechanical engineers using a surrogate leg and a loaded cyclic testing device, achieving two million cycles with no structural deficits.

AFO Prefabricated ankle-foot orthoses

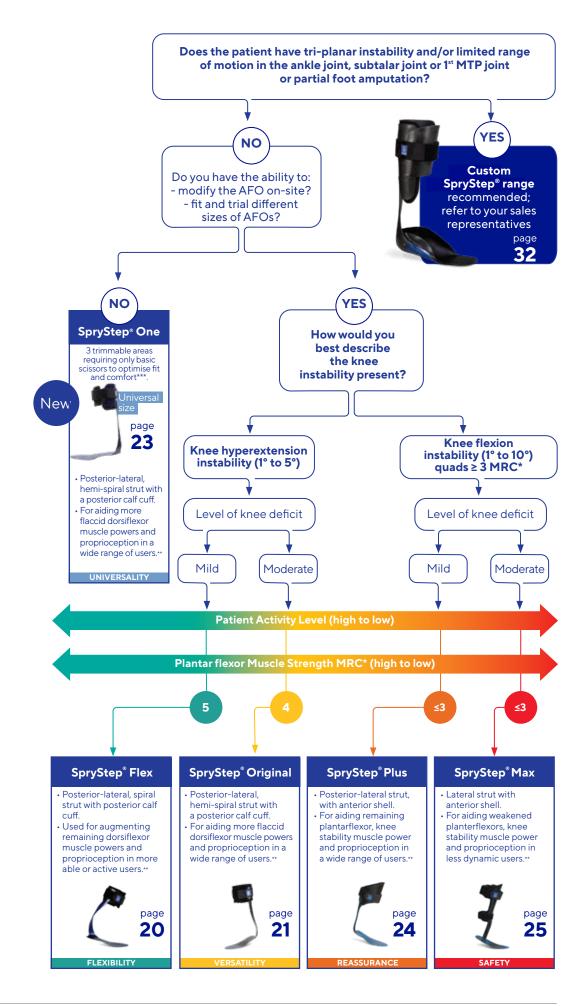
SpryStep® AFO prescription guide

The SpryStep® AFO range is designed for patients who have foot and ankle deficits.

Defined by elegance⁽¹⁾, Thuasne⁽²⁾'s SpryStep⁽²⁾ range of AFOs is transforming the way people move. Using a proprietary blend of composite materials, the SpryStep⁽²⁾ AFOs come in a variety of solutions that are improving mobility and quality of life for patients.



Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem.



^{*}Medical Research Council (MRC) scale for muscle strength.

** CE internal marking data + Aruin AS, and all. "Ankle-Foot Orthoses: Proprioceptive Inputs and Balance Implications".

J Prosthet Orthot. 2010;22(4 Suppl):3-37. doi: 10.1097/jpo.0b013e3181f25071. PMID: 25774078; PMCID: PMC4357018.

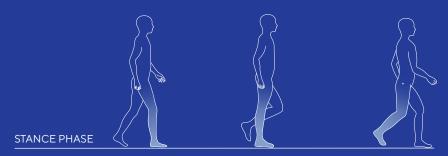
*** Trimming allows to adapt the brace to the anatomy of the patient and to position it well in order to avoids anatomical areas.

SpryStep® range

This Ankle-Foot Orthoses range is composed of posterior and anterior composite fibre shell models for adults and paediatrics.

Each product provides varying control of the lower limb, biomechanical correction and energy return dependent on the product prescribed and the patient's clinical deficit.

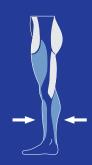
The composite properties will impact both the swing phase and stance phase of the gait cycle in the sagittal plane, providing a greater ability for multi segment control of the whole lower limb.





Posterior	Anterior
Main function is to provide external force to control the ankle	Primary function is to provide reaction force to assist in controlling knee flexion
Main muscle weakness: anterior tibial muscles	Main muscle weakness: posterior calf muscles
Most impact in early stance	Most impact in late stance

phase



phase

SpryStep® Flex SpryStep® Pediatric SpryStep® One SpryStep® Original



EFFICACY

Energy return provided by a specific brace structure and the combination of high-quality composite materials.

Balance restoration with a specific 3-point force system geometry which enhances foot and ankle motion and knee stabilisation.

Improvement of gait thanks to strut stiffness and graduated footplate flexibility.



DURABILITY

Durable device that uses a well-balanced combination of composite materials in a brace structure that maximises their properties.

Resistant: 2 million cycles without any compromise of the structural integrity⁽¹⁾ (2 million cycles, equivalent to about 2 years of use).

4 million cycles resistance for SpryStep® One⁽¹⁾.



USER FRIENDLY

Comfort: textile inner padding with smooth surface.

Pre-assembled product

Easy adjustment, fitting and care: low-profile device to improve compliance

- Anatomically shaped design;
- Low materials thickness;
- Washable fabric part.

Individual adaptation thanks to trimmable/customisable areas:

- Adjustment of calf size (on the Pediatric and One versions only).
- Trimmable footplate to fit the tip of the foot in length and width.

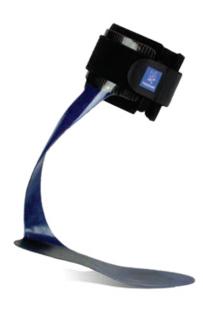
ANTERIOR SHELL AFO



LEVEL OF RIGIDITY

SpryStep® Plus

SpryStep® Max



SpryStep® Flex Posterior dynamic ankle-foot orthosis

U01712

MAIN INDICATIONS

· Lower limb muscle weakness of neurological, traumatic or muscular origin.

PATIENT PROFILE

- Patients with mild weakness of the lower limb (weakness of the anterior tibial muscle).
- Patients with dynamic activities (fast walking, running, unstable surface...).

MAIN FEATURES

- Dynamism: posterior lateral 180° spiral strut offers a great flexibility while allowing an adapted energy return for patients having an intense physical activity⁽¹⁾.
- $\hbox{\bf Gait\ optimisation:}\ material\ selection\ and\ macro-geometry\ designed\ to\ support\ patient\ mobility {}^{(1)}.$
- Strength and lightness: composite structure, lightweight⁽¹⁾ and resistant⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽¹⁾.
- Adaptability: trimmable insole for a better anatomical adjustment.
- Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





		_	>
	Shoe size	Hei	ght
XS	33 - 37	30 cm	11 ¾ "
S	36 - 39	32 cm	12 % "
М	38 - 42	34 cm	13 % "
L	41 - 44	36 cm	14 1/8"
VI	44 - 47	29 cm	15"

SPARE PARTS FOR SPRYSTEP® FLEX

Pads & Strap Kit (right or left)

UU01703



The SpryStep® Flex is suited for those active patients who suffer from foot drop, and who want to maintain an active lifestyle. The unique design of the strut and the composite materials allow the user to have virtually unimpeded plantarflexion and dorsiflexion whilst still remaining safe in swing phase⁽¹⁾.

Fitting video





SpryStep® Original

Posterior dynamic ankle-foot orthosis

U01703

MAIN INDICATIONS

• Lower limb muscle weakness of neurological, traumatic or muscular origin.

PATIENT PROFILE

- Patients with mild to moderate weakness of the lower limb (weakness of the anterior tibial muscle).
- · Patients with moderate activity (walking on a flat surface).

MAIN FEATURES

- $\bullet \ \, \text{\bf Dynamism:} \ posterior \ lateral\ position\ of\ the\ strut\ to\ optimise\ the\ compliance\ and\ the\ energy\ return$ during physical activity(1).
- $\bullet \ \ \textbf{Gait optimisation}: material \ selection \ and \ macro-geometry \ designed \ to \ support \ patient \ mobility ^{(1)}.$
- Strength and lightness: composite structure, lightweight⁽¹⁾ and resistant⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽¹⁾.
- Adaptability: trimmable insole for a better anatomical⁽¹⁾ adjustment.
- Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





		<u></u>	>!
	Shoe size	Hei	ght
XS	33 - 37	30 cm	11 ¾ "
S	36 - 39	32 cm	12 % "
M	38 - 42	34 cm	13 % "
L	41 - 44	36 cm	14 1/8"
XL	44 - 47	38 cm	15"

SPARE PARTS FOR SPRYSTEP® ORIGINAL

Pads & Strap Kit (right or left)

UU01703



The SpryStep® Original is much stiffer in its design and material selection and gives a great level of support and confidence to the user in both stance and swing phases, as well as the highest level of the energy return of all of SpryStep® off-the-shelf AFOs⁽¹⁾.

Fitting video





SpryStep® Pediatric

Posterior dynamic ankle-foot orthosis

U01752

MAIN INDICATIONS

Biomechanical deficits of neurological, traumatic or muscular origin.

- · Footdrop.
- Mild knee hyperextension.
- Mild ankle and foot tri-planar instability.
- · Hypotonia.
- Hypertonia.
- · Delayed standing.

PATIENT PROFILE

Children presenting gait deficit(s) or a physical impairment which affect the lower limb and predominantly the ankle and the foot with associated mid/moderate involvement at the knee.

MAIN FEATURES

- $\bullet \ \, \text{\bf Dynamism:} \ posterior \ lateral \ position \ of the strut \ to \ optimise \ compliance \ and \ energy \ return \ during$ physical activity(1).
- Gait optimisation: material selection and macro-geometry designed to support patient mobility⁽¹⁾.
- Strength and lightness: composite structure, lightweight $^{(1)}$ and resistant $^{(2)}$, designed with a specific material combination and a precise manufacturing process(1).
- Adaptability: 3 trimmable areas to optimise fit and comfort; footplate (toe and medial side of footplate) and calf cuff can easily be adjusted.
- · Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





		Foot length		
	Shoe size	cm	in	
XS	17 - 22	9.5 - 14.5	3 1/2 - 5 3/4	
S	22 - 26	11 - 16	4 1/4 - 6 1/4	
M	26 - 28	12.5 - 17.5	5 - 7	
L	28 - 31	14 - 19	5 1/2 - 7 1/2	
XL	31 - 33	15.5 - 20.5	6 - 8	

SPARE PARTS FOR SPRYSTEP® PEDIATRIC

Pad & Strap Kit from XS/S/M to L/XL size (bilateral):

UU01752

Legal manufacturer: Thuasne® Deutschland GmbH.

® Internal CE marking data.

© Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.



SpryStep® One

Posterior dynamic ankle-foot orthosis (AFO) - universal size

U01741

MAIN INDICATIONS

• Lower limb muscle weakness of neurological, traumatic or muscular origin.

PATIENT PROFILE

- Patients with mild to moderate weakness of the lower limb (weakness of the anteriortibial muscle).
- Patients with moderate activity (walking on a flat surface).

MAIN FEATURES

- Adaptability: universal size model with 3 trimmable areas to optimize fit and comfort⁽¹⁾: footplate (toe, heel and medial side of footplate) and calf cuff can easily be adjusted with scissors.
- Dynamism: posterior lateral position of the strut to optimise the compliance and the energy return during physical activity⁽²⁾
- Gait optimisation: material selection and macro-geometry designed to support patient mobility⁽²⁾.
- Strength⁽³⁾ and lightness: composite structure, lightweight⁽²⁾ and resistant⁽³⁾, designed with a specific material combination and a precise manufacturing process(2).

7 - 7,5 cm / 2¾ - 3"

• Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





		cm/³¼" size		Foot	ength	Product) t height
EUR	ď	JS	UK	cm	in	cm	in
36 - 45	6 - 11	5 - 12.5	3.5 - 10	23 - 29	91/8 - 113/8	38	15

SPARE PARTS

Pads & Strap Kit (right or left):

UU01741

Fitting videos available online

Legal manufacturer: Thuasne® Deutschland GmbH. $^{\circ}$ Trimming allows to adapt the brace to the anatomy of the patients and to position it correctly in order to take into consideration the anatomical areas. $^{\circ}$ Internal CE marking data. $^{\circ}$ Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System. $^{\circ}$ THUASNE $^{\circ}$ / 23



SpryStep® Plus

Anterior shell dynamic ankle-foot orthosis

U01724

For isolated quadriceps

or gastroc weakness. For quadriceps and gastroc weakness, please escalate to

KAFO (see page 40)

MAIN INDICATIONS

• Lower limb muscle weakness of neurological, traumatic or muscular origin.

PATIENT PROFILE

- Patients with mild to moderate weakness of the lower limb (weakness of the anterior tibial muscle and gastrocnemius muscle).
- Patients who are moderately active.

MAIN FEATURES

- Knee support: anterior carbon structure that supports and guides the knee towards extension, helps weakened plantar flexors for propulsion and maintains the knee during stance phase.
- Stability: the diversity of the materials used provides the patient with a good balance between flexibility and rigidity to improve walking and allow the tibia to tilt during the stance phase $^{\circ}$.
- Strength and lightness: composite structure, lightweight⁽¹⁾ and resistant⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽¹⁾.
- Energy return: posterior lateral position of the strut to optimise compliance and energy return during
- Anatomical adjustment: trimmable insole for an optimal comfort.
- · Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





	Shoe size	Foot length		2		He	gight
		cm	in	cm	in	cm	in
XS	33 - 37	21.5 - 24.5	8 1/2 - 9 5/8	29 - 37	11 1/2 - 14 1/2	33	13
S	36 - 39	23 - 26	9 1/8 - 10 1/4	32.5 - 40	12 ¾ - 15 ¾	36	14 1/2
M	38 - 42	24.5 - 27.5	9 % - 10 %	35.5 - 43	13 1/2 - 17 1/2	39.5	15 1/2
L	41 - 44	26 - 29	10 1/4 - 11 3/8	38.5 - 46.5	15 ¾ - 18 ¾	42.5	16 ¾
XL	44 - 47	29 - 30.5	11 3/8 - 12	42 - 49.5	16 1/2 - 19 1/2	45.5	18

SPARE PARTS FOR SPRYSTEP® PLUS

Pad & Strap Kit from XS, S/M to L/XL size (right or left):

UU01724



The SpryStep® Plus provides knee stability in stance phase for the active user, while still allowing enough dynamic movement to help deal with (take on) slopes and steps easier and help reach a more normal gait pattern⁽¹⁾.

Fitting video



⁽¹⁾ Internal CE marking data.

[©] Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.



SpryStep® Max

Anterior shell dynamic ankle-foot orthosis

U01734

MAIN INDICATIONS

• Lower limb muscle weakness of neurological, traumatic or muscular origin.

PATIENT PROFILE

- Patients with mild to moderate weakness of the lower limb (weakness of the anterior tibial muscle).
- Those who have a lower activity level only.

MAIN FEATURES

- Knee support: anterior carbon structure that supports and guides the knee towards extension, helps weakened plantar flexors for propulsion and maintains the knee during stance phase.
- Stability: the rigidity of the structure, combined with the flexibility of the sole, offers a great stability while allowing the gait cycle.
- Strength and lightness: composite structure, lightweight⁽¹⁾ and resistant⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽¹⁾.
- Practicality: lateral position of the strut, anterior to the malleolus allows an easy insertion into the shoe.
- Anatomical adjustment: trimmable insole for an improved comfort.
- Available in right or left model.

MODES OF ACTION







Biomechanical correction



Energy return





	Shoe size	Foot length		Hei	ght
		cm	in	cm	in
XS	31 - 34	19.5 - 21.5	7 ¾ - 8 ½	33.5	13 1/4
S	34 - 37	21 - 23	8 1/4 - 9	37	14 1/2
M	37 - 40	23 - 25.5	9 - 10	39.5	15 1/2
L	40 - 43	25.5 - 27.5	10 - 10 ¾	42	16 1/2
XL	43 - 46	27.5 - 29	10 ¾ - 11 ½	42	16 1/2

SPARE PARTS FOR SPRYSTEP® MAX

Pad & Strap Kit from XS to XL size (right or left):

UU01734



The SpryStep® Max offers improved stability in stance phase with a more rigid material selection, which enhances support and confidence for the low activity user, such as those with a step-to gait pattern $^{(i)}$.

Fitting video



Legal manufacturer: Thuasne® Deutschland GmbH.

Internal CE marking data

⁽²⁾ Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.

SpryStep® Footplate Semi-rigid composite materials footplate

U312046 (Adult) U312047 (Paediatric)



- · Idiopathic toe walking.
- $\bullet \ \ Metatars ophalange aljoint\ osteoarthrit is\ (for efoot).$
- · Midfoot osteoarthritis.
- Grade I lesions of the plantar plate of the first metatarsal joint (Turf-toe).
- Morton's neuroma*.
- ${}^* For this indication it is recommended to use the SpryStep {}^{ \circ } Footplate in combination with soft insole.$

• MAIN FEATURES

- \bullet Efficacy: energy return provided by the combination of composite materials. Support thanks to the footplate stiffness. $^{(!)}$
- $\bullet \ \ \textbf{Adaptability} : \textbf{trimmable edge, to fit the patient's foot shape}. \ \textbf{Adult and paediatric versions}. \ \textbf{Foot length}$ from 16 cm to 33 cm.
- Comfort: anatomically shaped design. Low material thickness.
- Available in right or left model.

MODES OF ACTION



Energy return

	ADULTVERSION						
	7-7.5 cm / 2 ² / ₄ -3 ³ 2 cm / 3 ⁴ Shoe size				Foot length		
		IS	UK	EU	mm	in	
S	♂ 6 - 8½	Ç 5 - 10	3.5 - 5.5	36 - 39	217- 264	01/ 101/	
 M	7 - 10		5.5 - 8	39 - 42		8½ - 10½	
		8 - 12			240 - 280	94/9 - 11	
L	9 - 12	11 - 15	8 - 101/2	42 - 45	256 - 295	10 - 11%	
XL	11 - 14	15 - 18	10½ - 13	45 - 48	270 - 317	10% - 12½	
XXL	13 - 16	-	13 - 151/2	48 - 51	282 - 332	11 - 13	
3XL*	15 -18	-	-	51 - 54	318 - 342	121/2 - 131/2	
	PAEDIATRIC VERSION						
	US		UK	EU	mm	in	
4XS	8 - 10		7-9	24 - 27	156 - 182	61/8 - 71/8	
3XS	10 - 12		9 - 11.5	27 - 30	163 - 200	6% - 7%	
XXS	12 - 2		11.5 - 1	30 - 33	180 - 224	7 - 81/8	
XS	2 - 4		1 - 3.5	33 - 36	186 - 240	73/8 - 91/2	









Product selection and fitting guidance

Choosing the correct SpryStep® and fitting the patient's shoe can be simplified by following this guide. The following information will help you to pick the correct size and give some pointers on shoe fit and alignment to optimise function.

SELECTING THE CORRECT SPRYSTEP® AFO

Please refer to the decision tree on page 17 which will guide you to the ideal SpryStep® for your patient, remember to focus on knee control requirement, plantar flexor power and activity level.

CHOOSING THE CORRECT SPRYSTEP® SIZE

 Measure the foot length from heel to the end of the longest toe.



 Measure the height from the base of the heel to the fibular head and subtract 2 cm/3/4".



What should be prioritised: height or footplate length?

Height needs to be prioritised because:

- The efficacy of the product will be maximised with a higher device as it provides a longer functional leverage.
- The higher device will also ensure more space for the heel and ensure there is no impingement issues.



The footplate can be trimmed for length and width, both at the forefoot and at the medial heel (see page 30 for guidance).

If you are in-between 2 sizes choose the larger one.

FITTING GUIDANCE FOR THE SPRYSTEP® AFO

Please refer to our step-by-step fitting video before fitting a patient with a SpryStep® AFO. If the shoe has a removable inlay, place the SpryStep® underneath it; otherwise, a sock must be worn.



- · Loosen the shoelaces and the front tongue.
- Place the Sprystep® in the shoe.
- Place the original inlay back into the shoe on top of the AFO footplate.
- If the patient needs some additional foot support, a corrective inlay can be used on top of the SpryStep® footplate in place of the original inlay.

SHOE SELECTION

Shoe selection is critical! The shoe is just as important as the AFO: it contributes to the force pattern. Spend time with the patient to ensure they know what to use to get the best outcome.

SHOE SELECTION FOR SPRYSTEP®

Ideally shoe will have:

- Moderate shoe pitch 11 13 mm/≈ ½" in (mid heel height minus height at joint (metatarsal level));
- · Dense sole unit material;
- Heel counter 70-75 mm/ 2 ¾ -3" (strong heel counters);



- Fastening laces (preferred because good closure) but a selffastening system can work as well;
- Straight sole unit (avoid narrow heels as they decrease the stability of the foot).



Do not hesitate to do the "2-finger test".

Put two fingers inside the posterior lateral region of each shoe with the patient wearing it. If the fingers can fit, it means the shoe will accommodate the AFO, if the shoe is too narrow for two fingers it may mean it is not compatible with the device.

Troubleshooting and fitting guidance

SHOE DISTORTION

The SpryStep® strut can distort the side of the shoes.

- Once the SpryStep® is inserted in the shoe, the sole should be parallel to the ground and the top of the strut perpendicular to the ground.
- If the SpryStep® doesn't fit properly inside the shoe, it is recommended to grind the medial side of the footplate (see instructions on page 30).
- The strut cannot be modified. Do not grind anywhere near the strut.
- SpryStep® cannot be modified with heat (it's a thermoset resin).

POOR SHOE FIT

How to modify the SpryStep®?

The SpryStep® AFO can be trimmed for foot length using scissors. The SpryStep® AFO can also be trimmed on the medial heel border with a router to accommodate shoes that have a narrower fit in the heel portion (see page 30 for trimming instructions).

STRUT IMPINGEMENT:

Identify the root cause:

- Clinical cause: varus ankle? Pes cavus? If the tri-planar control cannot be adequately met by an OTS SpryStep® and a corrective insole on top of the footplate in supportive shoes, it would suggest that a SpryStep® Vector is indicated (see page 33).
- Sizing cause: see CHOOSING THE CORRECT SPRYSTEP® SIZE. Too small, a SpryStep® can cause impingement issues, better to size up and trim as per instructions.



Do not add padding: it adds thickness, potentially increasing pressure.
Overly padded heel counters should be avoided with a SpyStep® as they will hinder proper shoe fit.

ALIGNMENT:

Bench alignment should be done to replicate a vertical shank alignment at mid-stance which will lead to 7 degrees of tibial inclination.

- Ensure correct sagittal plane alignment by using a shoe with a 11-13 mm/ \approx ½" in heel-sole differential or by using a smaller pitch and an extrinsic post.
- Mild to moderate tri-planar control can be facilitated with the use of a functional/corrective insole on top the footplate.



Heel or foot pistoning in the shoe? Check pitch shoes with any less than 11 mm/½" pitch will require the use of an extrinsic heel post.



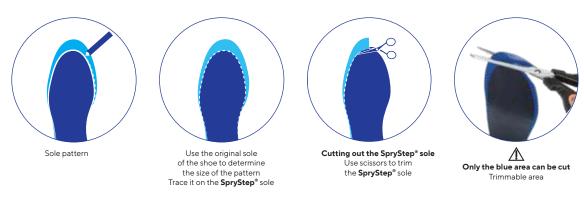


Trimming guidance/instructions

Our SpryStep® off-the-shelf prefabricated range can be adapted for patient foot length and forefoot width. The light blue zone in the footplate of the SpryStep® is trimmable and can be adapted using scissors or by grinding with a router and smoothing with a buffing cone.

Only the light blue zone of our SpryStep® off-the-shelf can be trimmed by scissors; in the adult models, the trimmable zone is in the footplate.

In the SpryStep® Pediatric, the trimmable zone is the footplate and the calf cuff; see images below and see sizing chart on page 22 for maximum trimming amounts.

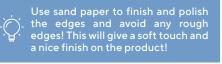




ADVANCED ADAPTATION:

The medial heel width of the footplate can be reduced but this modification requires a router or grinder. Use the insoles as a template if useful and grind away any excess width. Small reductions and rechecking in the shoe is the best method to avoid overtrimming. Once the width reduction is deemed acceptable, please smooth with a buffing cone. A maximum of 10 mm/½" in can be removed.







Tips & tricks

The tips and tricks listed below are provided to help you with the fitting of the SpryStep® AFO range of products and provide advice and guidance to the patient.

STRAPS FITTING (FIRST TIME)

- We recommend fastening the calf strap once, then releasing it, then fastening it again. This procedure will apply sufficient tension and ensure the strap holds in place.
- When the calf strap is fastened on the patient, you should be able to put a finger between the strap and the leg to avoid constrictions. Be mindful that the strap is not too loose.
- Straps can be marked or stitched to indicate the adequate tension to ensure consistency of donning for the parent and child.

FIRST WEAR

- We recommend gently breaking in a new AFO: our advice is to wear the AFO for an hour of activity on day one. Then 2 hours for the second day and then 3 hours for the third. Continue in this fashion until you/the patient/the parents are sure that the brace is safe and comfortable to wear all day long.
- After ensuring the AFO is not causing any discomfort or skin irritation, it is suitable for regular wear/prescribed wear

SKIN INSPECTION

- We advise that the patient (or the patient's parents for the Pediatric version) inspect the skin after every use of the SpryStep®.
- Red marks can appear and are not detrimental if they disappear within 45 minutes. If not, and especially if over bony prominences, advise the patient to consult a healthcare practitioner.

SOCK WEAR

- Socks (cotton or bamboo) are recommended to be used while wearing the SpryStep® products. Ensure that the socks stay in place and do not roll down or twist, negatively affecting the fit of the AFO against the patient's anatomy. We don't recommend the use of ribbed socks as they can cause high pressure areas.

RIGID FOOTPLATE

- The SpryStep® needs to sit as deep as possible in the shoe, under the insole or inlay if possible.
- We recommend the patient's original inlay (of the shoe) be placed on top of the sole of the SpryStep® for more comfort while wearing, but only if the fit of the shoe is NOT compromised.
- If there is no original inlay, then a simple, soft and thin insole can be added. It is important that this insole does not make the fit too tight.

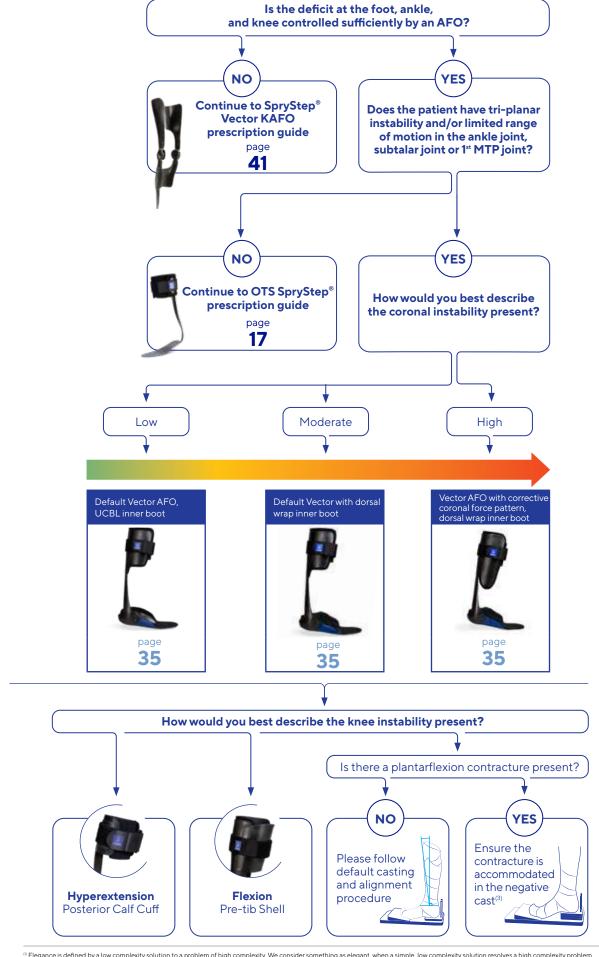
AFO Custom ankle-foot orthoses

SpryStep® Vector AFO prescription guide

From the elegant⁽¹⁾ yet durable⁽²⁾ range of SpryStep[®] AFOs, to custom knee braces and specialty KAFOs, Thuasne[®] Group offers effective custom solutions for the most complex patients.



Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem. Council Cycle-testing performed by an independent lab under ISO10328 servo pneumatic test system. This standard is typically used to test prosthetic feet.



Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem.
 Cycle-testing performed by an independent lab under ISO10328 servo pneumatic test system. This standard is typically used to test prosthetic feet.
 Accommodative wedging to be applied by clinician during dynamic fitting.



SpryStep® Flex Available Options: Molded Inner Boot, Pre-Tib Shell



SpryStep® Original Available options: Molded Inner Boot, Pre-Tib Shell



SpryStep® custom range

Custom dynamic ankle-foot orthosis

SpryStep® Flex custom	U33201
SpryStep® Original custom	U33101
SpryStep® Plus custom	U33301

SpryStep® custom is a wide range of elegant(1), durable(2) custom AFOs. All three models offer biomechanical and fitting advantages to better serve patient's expectations. Each model can have a molded inner boot (if selected when ordering).





For quadriceps and gastroc weakness, please choose KAFO (see page 40)

PATIENT PROFILE

- $\bullet \ \, \text{Patients who managed well with the biomechanical stiffness of the OTS SpryStep} \, \text{device but require}$ custom because of:
- Patient's morphology.
- Patients who have a fixed contracture of the ankle.
- Patients with a fixed forefoot equinus.
- Patients who require more control of the STJ and MTJs.

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- Strength and lightness: composite structure, lightweight⁽¹⁾ and durable⁽²⁾, designed with a specific material combination and a precise manufacturing process(3)
- Minimalistic composite structure: avoids bony prominences limiting fitting error.
- Absence of ankle joint: minimising distal weight and shoe bulk.
- Dynamism: posterior lateral position of the strut to optimise compliance and energy return during physical activity(3)
- Gait optimisation: material selection and shelf configuration designed to support patient mobility⁽³⁾.
- · Adaptability: trimmable areas to adapt the fit.
- Available with different options: refer to the order form.

MODES OF ACTION



Stabilisation



Biomechanical correction



Energy return







The custom SpryStep® offers the user with a customised fit but with the same biomechanical characteristicis of the off-the-shelf SpryStep® AFO range.

PLEASE REFER TO THE CASTING AND SCANNING PART OF THE CATALOGUE PAGE 80 FOR MORE INFORMATION

Legal manufacturer: Thuasne® Deutschland GmbH.

© Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem.

© Cycle-testing performed by an independent lab under ISO10328 servo pneumatic test system. This standard is typically used to test prosthetic feet.

⁽³⁾ Internal CE marking data.



Posterior Shell

Pre-Tibial Shell



Posterior Shell & Coronal Correction

SpryStep® Vector

Custom posterior dynamic ankle-foot orthosis

SpryStep® Vector is an elegant(1), durable(2) custom composite AFO. All four models feature our signature posterior lateral spiral strut that offers biomechanical and fitting advantages.

Each model also includes a molded inner boot (as standard).

- Patients with complex biomechanical deficits such as tri-planar instability.
- Patients with limited range of motion in the ankle, STJ or 1st MPJ whether this be contracture or tonal.
- Patients with spasticity of 2 or above on Modified Ashworth Scale.
- Patients with specific hobbies where activities levels would be outside of normal levels, e.g. running, golfing, weight lifting.

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- Digital workflow: premanufacture report communicates the outcomes of the modelling process and identifies areas of attention for fitting.
- Strength and lightness: composite structure, lightweight⁽³⁾ and durable⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽³⁾.
- Customised strut stiffnesses: depending on the patient's presentation.
- · Customised foot and ankle control: with inner boot trimline options.
- Minimalistic composite structure: avoids bony prominences limiting fitting error.
- · Absence of ankle joint: minimising distal weight and shoe bulk.
- Dynamism: posterior lateral position of the strut to optimise compliance and energy return during
- $\bullet \ \, \textbf{Gait optimisation} : \textbf{material selection and shell configuration designed to support patient mobility} {}^{(3)}. \\$
- · Adaptability: trimmable areas to adapt the fit.
- Available with different options: refer to the order form.

MODES OF ACTION



Stabilisation



Biomechanical correction



Energy return









The SpryStep® Vector AFO is the pinnacle of the SpryStep® composite AFO family, suitable for patients with complex biomechanical needs, and complex functional demands whilst still maintaining our low weight, high strength and energy returning formula! energy returning formula!

PLEASE REFER TO THE CASTING AND SCANNING PART OF THE CATALOGUE PAGE 80 FOR MORE INFORMATION

Pre-Tibial Shell & Coronal Correction

Legal manufacturer: Thuasne® Deutschland GmbH.

© Elegance is defined by a low complexity solution to a problem of high complexity. We consider something as elegant, when a simple, low complexity solution resolves a high complexity problem.

© Cycle-testing has been performed under ISO 10328 Servo-Pneumatic Test System.

© Internal CE marking data.



SpryStep® Custom Specialty Bracing

Contact Information Clinician Fitter/Assistant/Tech Other: Name: Email: Phone:	Ordering Clinician □ CP □ Other: Name: Email: Phone:		
Billing & Shipping Billing Account#: Shipping Account#:			
Shipping Preference Ground Next Day A	AM		
Patient Information By filling this order form and placing an order for this device, I hereby certify that I am authorized to dispense this medical device in virtue of any national law governing the fitting and adjustment of orthopedic medical devices Please do not provide any personal information (name etc) regarding the patient, but only provide health information necessary to the fabrication of this medical device Fit Date: Patient ID: Age Male Female Weight Male Height In. Cm. Leg: Left Right Diagnosis:	Perpendicular measurement from the casting platform to the Fibula head Height Measurement		
Shoe Size: Appropriately scaled tracing of shoe insole provided with order form Not sending shoe or tracing (toe segment will be made longer and wider, requiring trimming during fitting) PLEASE PROVIDE MEASUREMENTS Shoe Height Measurement (Shoe sole thickness at heel and forefoot) Heel in. □ cm. Forefoot in. □ cm.	Activity Level (Check one) Limited ambulator: sits to stands and transfers Household ambulator: level surfaces with walking aids Limited community ambulator: level surfaces with walking aids Active community ambulator: mild inclines and declines with or without walking aids Independent ambulator: varied cadence, uneven surfaces and no walking aids Active ambulator: walking, running, some athletic activity Observational Gait Analysis (Check all that apply)		
Please Follow Step-By-Step Cast Protocol Instructions Range Of Motion a. Knee ROM: ° extension to ° flexion b. Ankle ROM, with knee extended Dorsi-Flexion ° Plantar-Flexion ° c. Plantarflexion contracture	□ Footslap □ Crouch in stance □ Footdrop □ Knee hyperextension □ Excessive dorsiflexion in stance □ in terminal stance Biomechanical objectives (Check all that apply) □ Control dorsiflexion weakness □ Control ankle varus instability □ Control plantar flexion weakness □ Resist knee hyperextension in stance □ Control ankle valgus instability □ Resist knee flexion in stance Other: □ Crouch in stance		
c. Plantarflexion contracture Yes o No 90°			

Brace Options

- ☐ SpryStep® Flex
- ☐ SpryStep®
- ☐ SpryStep® Plus







${\bf Optional\ pre-tib\ Shell\ } ({\it SpryStep}^{\circledcirc}\ \&\ {\it SpryStep}^{\circledcirc}\ Flex\ only)$

- ☐ Yes
- □ No

Footplate Options





- ☐ Contoured footplate (no molded inner boot)
- ☐ Molded arch footplate with molded inner boot (must select one below)

Molded Inner Boot Options (if ordered)





- ☐ Molded Inner Boot (Low)
- ☐ Molded Inner Boot (Dorsal wrap)
- ☐ Leave inner boot unattached

Strap Option



- ☐ Include ankle strap
- ☐ Leave ankle strap unattached

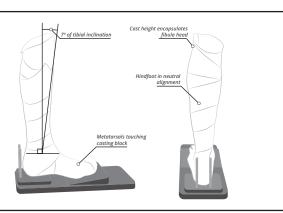
Co	m	m	6	n	t	s	•
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AFO Cast Parameters

Accurate representation of heel height must be captured in the negative cast (use of Thuasne USA casting platform)

Markings on the cast

- Fibula head
- · Tibial tubercle
- · Tibial crest
- Medial & lateral malleolus
- · Navicular bone
- 1st metatarsal head
- 5th metatarsal head
- Base of 5th metatarsal
- · If applicable deformity, tissue or any other area of concern



Production Description Product

1 Todact #	i roduction bescription
35700	SpryStep Original, Contoured Footplate
35700-PT	SpryStep Original, Contoured Footplate, Pre-tibial shell
35700-MIB	SpryStep Original, Molded inner boot
35700-PTMIB	SpryStep Original, Molded inner boot, Pre-tibial shell
37810	SpryStep Flex, Contoured Footplate
37810-PT	SpryStep Flex, Contoured Footplate, Pre-tibial shell
37810-MIB	SpryStep Flex, Molded inner boot
37810-PTMIB	SpryStep Flex, Molded inner boot, Pre-tibial shell
37820	SpryStep Plus, Contoured Footplate
37820-MIB	SpryStep Plus, Molded inner boot



Received Date Thuasne USA's shipping department use only

Custom Spiral AFO (SpryStep® Vector)

Specialty Bracing

Contact Information Clinician Fitter/Assistant/Tech Other: Name: Email: Phone: Billing & Shipping PO#: Shipping Account#: Shipping Account#:	Shipping Address: State: Zip:
Shipping Preference ☐ Ground ☐ Next Day A (If no preference is indicated, this order will	AM Next Day PM 2-Day AM 2-Day PM II be shipped 2 Day PM) Note: We do not ship products directly to patients.
To The Clinician Thuasne USA will determine the stiffness category of the Vector AFO based on the Orthotist's objective measures and patient goals. Detailed completion of all requested information is required for our CPOs to select the AFO stiffness. Patient Information By filling this order form and placing an order for this device, I hereby certify that I am authorized to dispense this medical device in virtue of any national law governing the fitting and adjustment of orthopedic medical devices Please do not provide any personal information (name etc) regarding the patient, but only provide health information necessary to the fabrication of this medical device Fit Date: Patient ID: Age Male	Range Of Motion a. Knee ROM: ° extension to ° flexion b. Ankle ROM, with knee extended Dorsi-Flexion ° Plantar-Flexion ° c. Plantarflexion contracture Yes ° No Perpendicular measurement from the casting platform to the Fibula head Height Measurement
PLEASE PROVIDE MEASUREMENTS Shoe Height Measurement (Shoe sole thickness at heel and forefoot) Heel in. cm. Forefoot in. cm. Please Follow Step-By-Step Cast Protocol Instructions	□ Partial Foot or Transmet Amputation (Vector is not appropriate for Lisfranc, Chopart or Symes) Activity Level (Check one) □ Limited ambulator: sits to stands and transfers □ Household ambulator: level surfaces with walking aids □ Limited community ambulator: level surfaces with walking aids □ Active community ambulator: mild inclines and declines with or without walking aids □ Independent ambulator: varied cadence, uneven surfaces and no walking aids □ Active ambulator: walking, running, some athletic activity

Manual Muscle Tests (MMT) **Ordering Options** Quadriceps strength The base structure of all models includes a spiral strut, posterior Hamstring strength shell and molded inner boot. Right Right With Pre-Tibial Shell **Posterior Shell** П ☐ Right ☐ Right **Dorsiflexion strength** Plantar-flexor strength ☐ Left ☐ Left (37600-P) (37600-P) (37600-PT) (37600-PT) Right Number of Single Limb Heel Raises П With Coronal With Pre-Tibial Shell Right Left Extension & Coronal Extension ☐ Valgus Resist ☐ Valgus Resist ☐ Varus Resist ☐ Varus Resist Observational Gait Analysis (Check all that apply) ☐ Left ☐ Right ☐ Left ☐ Right ☐ Footslap ☐ Knee hyperextension (37600-V) (37600-V) (37600-PTV) (37600-PTV) ☐ Footdrop in stance ☐ Excessive dorsiflexion ☐ Crouch in stance **Molded Inner Boot Options** in terminal stance Desired Level of Control (Check one) ☐ **Flexible:** guides the lower limb during swing with minimal restriction to tibial advancement in stance ☐ **Moderate:** supports the foot and ankle in swing with mild resistance and spring to tibial advancement. ☐ Low Profile ☐ Dorsal Wrap ☐ **Firm:** strong foot and ankle control with resistance to tibial advancement forcing a ground reaction response in stance. ☐ Leave inner boot unattached ☐ **Rigid:** strong foot and ankle control with rigid resistance to **Strap Option** tibial advancement in stance blocking movement and influencing proximal segments. Biomechanical objectives (Check all that apply) ☐ Include ankle strap ☐ Control dorsiflexion weakness ☐ Leave ankle strap unattached ☐ Control plantar flexion weakness ☐ Control ankle valgus instability ☐ Control ankle varus instability ☐ Resist knee hyperextension in stance ☐ Resist knee flexion in stance Comments/Special Instructions: ___ Other_

KAFO Knee ankle-foot orthosis

SpryStep® Vector KAFO range is a series of custom KAFO designs using the most technologically advanced composite materials and manufacturing available to modern engineering.

Evidence based advantages: the SpryStep® KAFO range uses multisegmented differences in stiffness to support the lower limb, while allowing forward progression.

Modern composite materials offer the potential to reduce the weight of a device by a minimum of 27%⁽¹⁾ to 30%⁽²⁾ and up to 60% over traditional manufacturing techniques.

- Decrease energy cost of walking(3)
- Increase maximum walking distance⁽⁴⁾
- Increased step length and walking speed(5)
- Lower oxygen cost of gait⁽¹⁾
- Compliance increase(2)

This can improve patient outcomes.

SpryStep® Vector KAFO prescription guide

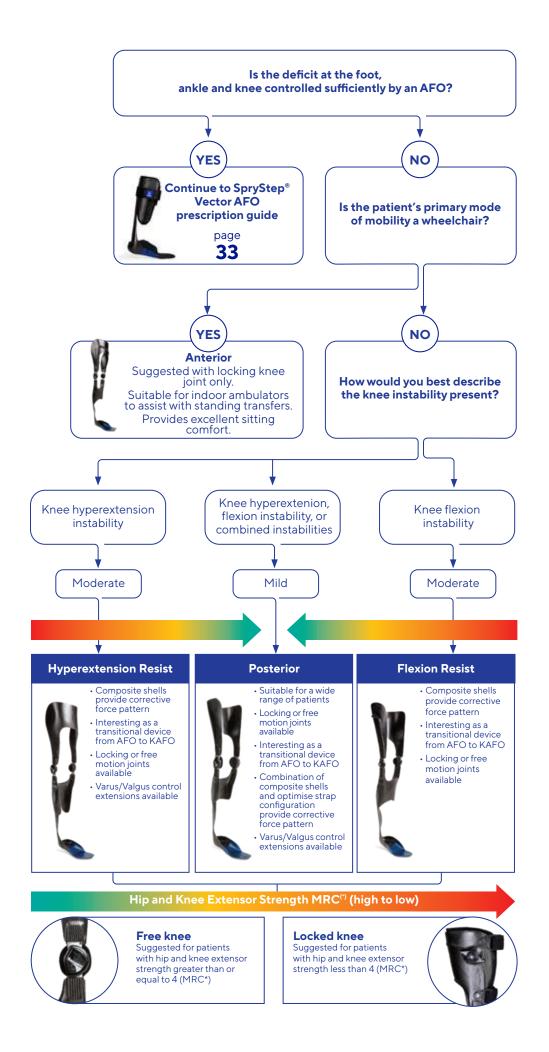
The SpryStep® Vector KAFO range is designed for patients who have foot, ankle and knee deficits.

As different options are possible, the following guide will help you determine which product configuration will better answer the patient's needs.

Our KAFOs incorporate our composites know-how as well as our expertise on knee joints and offer solutions for better outcomes.



Hachisuka, K. et al. 2007 'Oxygen consumption, oxygen cost and physiological cost index in polio survivors: A comparison of walking without orthosis, with an ordinary or a carbon fibre reinforced plastic knee ankle-foot orthosis', Journal of Rehabilitation Medicine, 39th, pp. 646 650. doi: 10.2340/16501977 0105.
Heim M, Yaacobi E, Azaria M. A pilot study to determine the efficiency of lightweight carbon fibre orthoses in the management of patients suffering from post poliomyelitis syndrome. Clin Rehabil 1997; 11: 302 305.
Brehm, M. A et al. 2007 'Effect of carbon composite knee ankle-foot orthoses on walking efficiency and gait in former polio patients', Journal of Rehabilitation Medicine, 39th, pp. 651 657.
Steinfeldk F, Seifert W, Gunther KP. Modern carbon Fibre orthoses in the management of polio patients a critical evaluation of the functional aspects. Z Orthop lhre Grenzgeb 2003; 141:357 361.
Hachisuka, K. et al. (no date) 'Clinical application of carbon fibre reinforced plastic leg orthosis for polio survivors and its advantages'.





SpryStep® Vector KAFO Custom dynamic knee ankle-foot orthosis (KAFO)

U3300

 $Durable^{(2)}, versatile\ and\ lightweight^{(1)}, the\ SpryStep^{\otimes}\ Vector\ KAFO\ combines\ the\ power\ of\ modern$ composite manufacturing with the performance of the trusted SpryStep® AFO range, with trusted Thuasne® hinges.

Featuring four shell configurations, a variety of joint options and two molded inner boot styles, the SpryStep® Vector KAFO is the comprehensive solution giving patients the confidence they need to return to a normalised life.

PATIENT PROFILE

- Patients with varying neurological lower limb deficits e.g. CVA, MS, TBI, CMT, spinal cord injury, polio.
- Patients whose biomechanical control cannot be optimised by an AFO alone.
- $\bullet \ \ \text{Patients whose neurological deficit requires locking of the knee} \ \text{and control of the foot and ankle}$ (locking optional).
- · Patients with potential for recovery via rehabilitation.

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- Digital workflow: premanufacture report communicates the outcomes of the modelling process and identifies areas of attention for fitting.
- Strength and lightness: composite structure, lightweight $^{(\!0\!)}$ and durable $^{(\!2\!)}$, designed with a specific material combination and a precise manufacturing process(1).
- Minimalistic composite structure: avoids bony prominences limiting fitting error.
- · Absence of ankle joint: minimising distal weight and shoe bulk.
- Dynamism: posterior lateral position of the strut to optimise compliance and energy return during
- $\bullet \ \ \textbf{Gait optimisation}: material \ selection \ and \ shell \ configuration \ designed \ to \ support \ patient \ mobility \ ^{(1)}.$
- · Adaptability: trimmable areas to adapt the fit.
- · Available with different options: refer to the order form.

MODES OF ACTION



Stabilisation



Biomechanical



Energy return







The SpryStep® posterior/posterior KAFO configuration is the default design of the KAFO range. Combining a good cast with optimal strap positioning, makes it the most versatile and forgiving device with a track record of success⁽¹⁾ for a wide variety of conditions.

PLEASE REFER TO THE CASTING AND SCANNING PART OF THE CATALOGUE PAGE 80 FOR MORE INFORMATION



Molded inner boot comes as standard to ensure optimal tri-planar control



Optional coronal correction for increased control

Legal manufacturer. Thuasne® Deutschland GmbH.

Internal CE marking data.

Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.

Brace configurations - 4 possible options









Anterior

Posterior

Hyperextension Resist

Flexion Resist

Apply force patterns effectively with the brace configuration that is appropriate for the patient's deficit.

JOINT OPTIONS



5 Bar Knee Component

Option 1: Free Motion Option 2:

Locking with manual triggers

Option 3:

Locking with integrated cable and Twist Release



Single Pivot Knee Component

Option 1: Locking with manual triggers

Option 2:

Locking with integrated cable and Twist Release



Twist Release Mechanism

Acts as a simple release lever that can also be use to provide free motion to a locked joint



Extension Assist

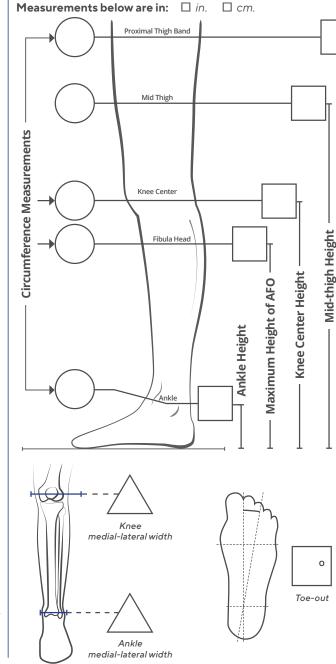
Extension assist bands available on all joint configurations



SpryStep® Vector KAFO Specialty Bracing

Contact Information		Ordering Clinician					
☐ Clinician ☐ Fitter/Assistan Name:	t/Tech	□ CPO □ CO □ CP □ Other: Name:					
Email:							
Liliali.	- Filotie.	Liliali. Filolie.					
Billing & Shipping	PO#:						
Billing Account#:		Shipping Address:					
Shipping Account#:		City: State: Zip:					
11 3	☐ Ground ☐ Next Day A	AM Next Day PM 2-Day AM 2-Day PM The shipped 2 Day PM) Note: We do not ship products directly to patients.					
Patient Information		Range Of Motion					
By filling this order form and placing an orde authorized to dispense this medical device i fitting and adjustment of orthopedic medical	n virtue of any national law governing the	a. Hip ROM: ° extension to ° flexion					
Please do not provide any personal informatio provide health information necessary to the		b. Knee ROM:° extension to° flexion					
Fit Date: Pa	tient ID:	c. Ankle ROM, with knee extended					
Age	☐ Female	Dorsi-Flexion°					
Weight \(\Bar{\text{Lbs.}} \Bar{\text{Kg. H}}	Height ☐ in. ☐ cm.	Plantar-Flexion°					
Leg: □ Left □ Right		Plantar-Flexion° d. Plantarflexion contracture					
Diagnosis:		☐ Yes° ☐ No 90°					
Surgeries (type/date):		e. Knee flexion contracture					
Is the patient currently using any	assistive device?	☐ Yes° ☐ No					
☐ Brace/KAFO ☐ Crutch ☐ Cane ☐ Walket		Activity Level (Check one) Limited ambulator; sits to stands and transfers					
Shoe Size:		☐ Household ambulator: level surfaces with walking aids					
 □ Appropriately scaled tracing of order form □ Not sending shoe or tracing (twider, requiring trimming during fitting) 	oe segment will be made longer and	 ☐ Limited community ambulator: level surfaces with walking aids ☐ Active community ambulator: mild inclines and declines with or without walking aids ☐ Independent ambulator: varied cadence, uneven surfaces and 					
		no walking aids ☐ Active ambulator: walking, running, some athletic activity					
PLEASE PROVIDE N Shoe Height Measurement (Shoe so							
Shoe Height Heasurement (3110e st	Sie thiekiless at heeraliu lorelootj	Biomechanical objectives ☐ Resist Knee Hyperextension in Stance					
Heel 🗆 in. 🗆 cm.	Toro	Resist Knee Flexion in Stance					
Forefoot 🗆 in. 🗆 cm.		☐ Knee Valgus Control					
		☐ Knee Varus Control ☐ Posterior/Anterior Knee Drawer Control					
Cast Info		☐ Control Dorsiflexion Weakness					
Cast Adjustments Required (corona	al and sagittal plane)	☐ Control Plantar Flexion weakness☐ Control Ankle Valgus Instability					
		☐ Control Ankle Varus Instability					

Brace Configuration Shell Configuration Posterior Hyperextension Flexion Resist Anterior Resist □ 3 **Coronal Plane Extension** ☐ Valgus Resist ☐ Varus Resist **Molded Inner Boot** ☐ Low ☐ Dorsal wrap ☐ Leave inner boot unattached **Strap Options** ☐ Include ankle strap ☐ Leave ankle strap unattached **Knee Joint Options**



☐ 5-bar Free **37700**

5 bar Locking **37700-L**

Suggested L-Codes*

Single Pivot Locking 37700-L

☐ Install Extension Assist Bands/Posts

(Twist Release with free motion)

Juggesteu L-	Codes
L2036	KAFO Base Code
L2387	Polycentric hinges (5 Bar Hinge)
L2390	Posterior offset hinges (Single Pivot Hinge)
L2415	Built in release mechanism (if locking joints are used)
L2810	Condyle pads

Suggested L-Codes*

Measurements

Suggested L-	uggested L-Codes				
L2820	Below knee padding				
L2830	Above knee padding				
L2280	Molded inner boot				
L2755	Carbon graphite construction				
L2275	Varus or valgus correction				

^{*} Thuasne USA's suggested uses of Medicare billing codes are developed based on nationally accepted industry standards and billing practices, they do not ensure a specific device will be reimbursed. It is the responsibility of the provider to abide by lawful Medicare billing practices and Thuasne USA is not liable for the denial of reimbursements when it comes to the use of suggested billing codes

Maximum Height of KAFO





SpryStep® Neuro Knee Custom locking knee brace

U3370299999999

Durable, versatile and lightweight⁽ⁱ⁾, the SpryStep[®] Neuro Knee combines the power of modern composite manufacturing and the trusted Thuasne[®] hinge technology. SpryStep[®] Neuro Knee features four shell configurations, two locking joint options, two possible frame designs and the ability to select Thuasne $^{\circ}$'s C/S package, to ensure that the optimal support and durability is afforded to the user.

INDICATIONS

- These indications are biomechanical deficits of neurological, traumatic, muscular or degenerative origin.

 Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral
- · Joint instability/laxity (including for knee osteoarthritis).
- · Post-operative immobilisation or/and rehabilitation.
- · Post traumatic immobilisation.
- Weakness of the knee flexor muscles ≤ 3.
- · Knee instability during stance phase.
- · Quadriceps weakness.
- · Knee hyperextension.

PATIENT PROFILE

- · Patients with select neurological lower limb deficits.
- Patients with good control of distal muscles of foot and ankle, presenting quadriceps weakness requiring locking.
- Patients with good control of distal muscles of the foot and ankle but requiring more optimised control of knee hyperextension.

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- Digital workflow: premanufacture report communicates the outcomes of the modelling process and identifies areas of attention for fitting.
- $\bullet \ \, \textbf{Strength, lightness and intimate fit:} composite structure, lightweight \ ^{(1)} and durable \ ^{(2)}, designed with a \ ^{(3)}$ specific material combination and a precise manufacturing process⁽¹⁾
- Frame design: available both in Full Shell and Uband style.
- Locking mechanism: twist release or manual triggers.
- Suspension on the leg: synergistic suspension strap.
- · Comfort: interior padding and condylar pads in foam.
- Available with different options: refer to the order form.

MODE OF ACTION



Stabilisation





SpryStep® Neuro Knee

U3370

Contact Information ☐ Clinician ☐ Fitter/Assistant/Tech ☐ Other: Name:					
Email: Phone:					
Billing & Shipping Billing Account#: Shipping Account#:					
Shipping Preference Ground Next Day A (If no preference is indicated, this order will	AM Next Day PM 2-Day AM 2-Day PM be shipped 2 Day PM) Note: We do not ship products directly to patients.				
Patient Information Fit Date: Patient ID: Age	□ Cable with twist release Joints Accessory □ Install Extension assist Bands/Posts □ Extension Stop Kit (5 Bar Free only) □ Flexion Stop for 5 Bar Free and 5 Bar Locking (Factory installed only) □ 15° □ 30° □ 45° □ 60° □ 75° □ 90° Brace Rigidity/ Stiffness For larger and heavier framed patients- increased rigidity / stiffness is				
Measurement Data These measurements are required to check the accuracy of the patient model submitted, a patient model must be provided for fabrication (scan).	recommended □ Level 1 (default) □ Level 2 (medium) □ Level 3 (high) Femoral shell length □ 7 in 175mm (default) □ -1 in 150mm □ +1 in 200mm				
Proximal circumference 7 in / 175mm above mid-patella Medial-Lateral Knee Width (not circumference) at knee center Distal circumference 7 in / 175mm below mid-patella	Femoral shell configuration Anterior Posterior Tibial shell length 7 in 175mm (default) -1 in 150mm +1 in 200mm *Custom length requests require pre-fabrication consultation, additional charges will be applied.				
Brace Configuration NB by default: riveted anchor tabs + d-rings + 1/4" padding + condylar pads + 2 additional thicker condylar pads + synergistic suspension strap Knee Joint Options	Tibial shell configuration ☐ Anterior ☐ Posterior				
□ Single Pivot Locking U3370 (Twist Release with free motion) □ Single Pivot Locking U3370 (Manual Triggers) □ 5-bar Free U3370 □ 5 bar Locking U3370 (Twist Release with Free motion) □ 5 Bar Locking U3370 (Manual Triggers)	Options Please select only one of the following selections Full Shell*				
☐ Optional Extension assist bands/posts* ☐ Set hinges to LOCK at cast position ☐ OR ☐ Set hinge at:	□ Neoprene Undersleeve 18 in (46cm)* □ CS wrap* □ Anti-migration silicon infused strap pads* Comments:				
□ 0° □ 5° □ 10° □ 15° □ Other <u></u> °					

*Indicates additional charges apply

By filling this order form and placing an order for this device, I hereby certify that I am authorized to dispense this medical device in virtue of any national law governing the fitting and adjustment of orthopedic medical devices.

Please do not provide any personal information (name etc) regarding the patient, but only provide health information necessary to the fabrication of this medical device.

Distributed by Thuasne USA

4615 Shepard Street, Bakersfield, CA 93313 Tele: 800.432.3466 • Fax: 844.261.5628



Knee OA



Affects 30% of people aged 60 or over⁽¹⁾



Each year, 86 million people develop knee OA(1)



Women

are more affected than men(1)



Obesity is strongly associated with **developing knee OA**⁽¹⁾, due to excess stress on the joint

Previous knee injuries can increase the risk of developing knee OA later in life⁽²⁾

Knee ligament injury (sprains):



Most common knee injury (43%)(3)





Incidence 1 per 1,000 per year approximately(3)

In over **1/3** of cases during a sport activity⁽³⁾

Men are more affected than women⁽³⁾

Knee injuries are most common among adolescents and young adults(3)

OA = Osteoarthritis.

Gui A, Li H, Wang D, Zhong J, Chen Y, Lu H. Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population based studies. EClinicalMedicine . 2020;29 30:100587.

Published 2020 Nov 26. doi:10.1016/j.eclinm.2020.100587.

IRSST. Literature Review of Risk Factors, Evaluation Instruments, and Care and Service Interventions for Knee Osteoarthritis.

Part ET. Gage et al. «Epidemiology of 6.6 Million Knee Injuries Presenting to United States Emergency Departments From 1999 Though 2008» Academic Emergency Medicine 2012; 19:378 385

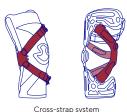
Literature Review of Risk Factors, Evaluation Instruments, and Care and Service Interventions for Knee Osteoarthritis.

Thuasne® OA Braces - Main technical features

AN OFFLOADING PRINCIPLE - 3-point pressure system



DYNAMIC OFFLOADING - for Action Reliever® and UniReliever®



Non elastic straps creating a dynamic 3-point pressure system: maximum straps' tension in extension and so most effective on heel strike(1).

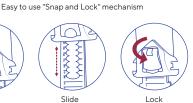
LOADSHIFTERS - for Rebel Reliever®





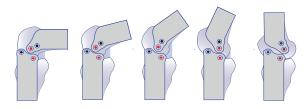






Mechanical offloading of the affected compartment⁽²⁾ provided by a significant varus and valgus correction of the thigh shell. Averaged 36% reduction of force through the knee⁽³⁾ leading to less pain, better function and clinical benefit⁽¹⁾.

TM5 HINGE - for Rebel Reliever® and UniReliever®



Ligament protection, prevents instabilities(1)(4). Roll-back and glide movement similar to natural movement of the knee⁽⁴⁾. No pistonning, no migration⁽⁴⁾.

KNIT STRUCTURE - for Action Reliever®



Anatomically-shaped elastic knit providing compression which contributes to enhanced **proprioception** and helps reduce **oedema**(1).

Internal CE marking data.

Thoumie, Philippe, Marc Marty, Bernard Avouac, Adeline Pallez, Arnaud Vaumousse, Linh Pham Thi Pipet, André Monroche, et al. 2018. "Effect of Unloading Brace Treatment on Pain and Function in Patients with Symptomatic Knee Osteoarthrists: The ROTOR Randomized Clinical Trial." Scientific Reports 8 % 10519.

Lamberg, Eric M, Robert Streb, Marc Werner, Ian Kremenic, and James Penna. 2016b. "The 2 and 8 Week Effects of Decompressive Brace Use in People with Medial Compartment Knee Osteoarthritis." Prosthetics and Orthotics International 40 % 447 453.

⁴⁹ A2S biomechanical study "Biomechanical study of the stride during use of different braces" 2020, including the Rebel® Standard, a rigid ligament brace with the TM5 hinge and conducted on a panel of 18 people

Clinical studies

Three products of our range of knee braces have been clinically tested and have demonstrated a real **benefit on knee pain for patients with knee OA** $^{()}$. This pain reduction combined with improved functions restore mobility and allow patients to move again.

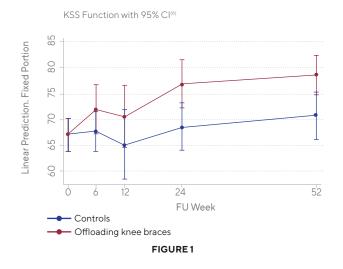
This creates a virtuous circle: better cartilage nutrition, less wear and tear, less inflammation and reduction of compensatory posture and movements. All of this leads to an enhanced quality of life.

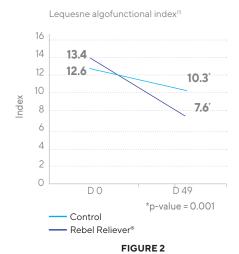
The following pages are showing the clinical study results.

THE EFFECTS OF OFFLOADING KNEE BRACES ON FUNCTION AND QUALITY OF LIFE

With decreased pain comes increased function and quality of life(1)(2)(3)(4).

An offloading knee brace improves activity of daily living (3)(5)(6), sports (5) and recreation (5), with an increased activity level⁽⁶⁾. Hjartarson⁽⁵⁾ (figure 1) showed that the improvements in KSS score are not evident at the 6 weeks follow-up, but are improved in comparison to place bo during 1-year use of an offloading knee brace, suggesting that long-term follow-up is needed and that it may take time for the patients to adjust to the brace in the clinical setting and full results should not be expected immediately.





Thournie⁽¹⁾ showed that more than 80% of patients feel a definite and considerable improvement of their condition with Rebel Reliever® (figure 2).

These improvements can be explained by biomechanical effects of offloading knee braces: increased walking speed⁽⁴⁾⁽⁸⁾ (p<0.001) and distance⁽⁵⁾ (p=0.0001), increase in step length⁽⁸⁾, increase in knee muscle strength⁽⁴⁾ (p<0.05), or increased gait symmetry⁽⁸⁾. This leads to a better balance confidence⁽⁴⁾ (p<0.01), and an increased independence (5)(7).

Conclusion

Offloading knee braces should be considered a reasonable alternative, as part of a multimodal approach, to more invasive options, such as Total Knee Arthroplasty⁽⁷⁾.

Thournie Philippe, et al. "Effect of Unloading Brace Treatment on Pain and Function in Patients with Symptomatic Knee Osteoarthritis: The ROTOR Randomized Clinical Trial." Scientific Reports 8 (1): 10519

⁽a) Nathanael L. Feehan, et al. "The Effectiveness of Off-Loading Knee Orthoses in the Reduction of Pain in Medial Compartment Knee Osteoarthritis: A Systematic Review." Journal of Prosthetists and Orthotics 2012: 24(1): 39-49

and Orthotics, 2012; 24(1): 39-49.

Dylan A. Mistry, et al. "An Update on Unloading Knee Braces in the Treatment of Unicompartment Knee Osteoarthritis from the Last 10 Years: A Literature Review". The Surgery Journal 2018;4:e110-e118.

Lamberg, et al. 2016a. "Improvements in Function and Strength with Decompressive Bracing of the Osteoarthritic Knee." JPO: Journal of Prosthetics and Orthotics 28 (4): 173-179.

My Benning, et al. "Superiority of a knee relief orthosis in the treatment of knee osteoarthritis: A prospective randomized controlled trial." ORTHOPÄDIE TECHNOLOGY 08/17, Page 24.

Hjartarson HF, et al. "The clinical effect of an unloader brace on patients with osteoarthritis of the knee, a randomized placebo-controlled trial with one year follow up." BMC Musculoskelet

Disorders. 2018 Sep 22;19(1):341.

Roger V. Ostrander, et al. "Efficacy of Unloader Bracing in Reducing Symptoms of Knee Osteoarthritis." The American Journal of Orthopedics, 2016;45(5):306-311

Wolf Petersen, et al. "Biomechanical effect of unloader braces for medial osteoarthritis of the knee: a systematic review". Archives of Orthopaedic and Trauma Surgery (2016) 136:649-659.

Clinical studies

THE EFFECTS OF OFFLOADING KNEE BRACES ON PAIN



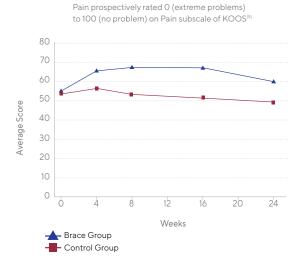
3 metanalysis made by Feehan⁽¹⁾, Petersen⁽²⁾ and Mistry⁽³⁾ conclude that offloading knee braces are an effective way to relieve pain in the osteoarthritic knee. Pain relief was documented help in 98.6% of patients for medial compartment OA.

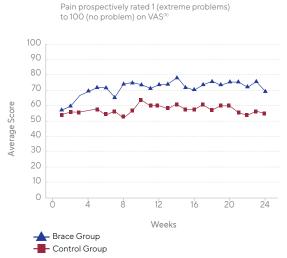


According to Hjartarson⁽⁴⁾, with a single upright offloading brace, pain can be improved in comparison to placebo during 1-year of use (study on 149 OA patients).



The 2 clinical outcome tools (KOOS and weekly diary VAS) used in the study of Roger⁽⁵⁾ showed significant improvement in pain (p<0.001 and p=0.021) in patients wearing offloading rigid braces compared with the control group (study on 50 OA patients).





In the same way, offloading rigid braces were found by Giori⁽⁶⁾ to be successful in a majority of patients 3 years after brace using, with patients reporting some benefit, primarily with pain (study on 49 OA patients).

Nathanael L. Feehan, et al. "The Effectiveness of OFFLOADING Knee Orthoses in the Reduction of Pain in Medial Compartment Knee Osteoarthritis: A Systematic Review." Journal of Prosthetists and Orthotics, 2012; 24%: 39-49.

Wolf Petersen, et al. "Biomechanical effect of unloader braces for medial osteoarthritis of the knee: a systematic review". Archives of Orthopaedic and Trauma Surgery (2016) 136:649-659.

Hjartarson HF, et al. "The Clinical effect of an unloader brace on patients with osteoarthritis of the knee, a randomized placebo-controlled trial with one year follow-up." BMC Musculoskelet Disorders. 2018 Sep 22;19%:341.

Dylan A. Mistry, et al. "An Update on Unloading Knee Braces in the Treatment of Unicompartment Knee Osteoarthritis from the Last 10 Years: A Literature Review". The Surgery Journal 2018;4:e110-e118.

^{2013;4:}e110-e118.

Roger V. Ostrander, et al. "Efficacy of Unloader Bracing in Reducing Symptoms of Knee Osteoarthritis." The American Journal of Orthopedics. 2016;45^(a):306-311.

Nicholas J. Giori "Load-shifting brace treatment for osteoarthritis of the knee: A minimum 2 ½ -year follow-up study." Journal of Rehabilitation Research & Development, volume 41, Number 2, Pages 187-194. March/April 2004.

Thourine Philippe, et al. "Effect of Unloading Brace Treatment on Pain and Function in Patients with Symptomatic Knee Osteoarthritis: The ROTOR Randomized Clinical Trial." Scientific Reports 8 (1): 10519.

Lamberg, et al. 2016a. "Improvements in Function and Strength with Decompressive Bracing of the Osteoarthritic Knee." JPO: Journal of Prosthetics and Orthotics 28 (4): 173-179.

[&]quot;Lamberg, et al. 2010a. Improvements in Function and Strength with Decompressive Bracing of the Osteoarthritic Knee. JPC. Journal of Prostnetics and Orthotics 2e (4): 1/3-174.

M. Benning et al. 2012 "Prospective study with control group to demonstrate the medical benefits and the usability of the frame orthosis is Rebel Reliever » by Townsend Design, Bakersfield, CA
Product Type 23.04.04.2". Internal study not published.

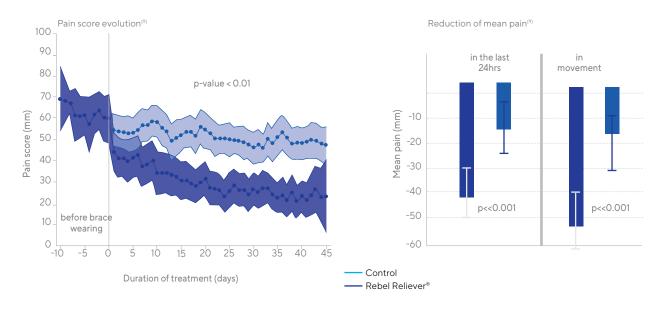
M. Benning, et al. "Superiority of a knee relief orthosis in the treatment of knee osteoarthritis: A prospective randomized controlled trial." ORTHOPÄDIE TECHNOLOGY 08/17, Page 24.

Dan K Ramsey, et al. "A mechanical hypothesis for the effectiveness of knee bracing for medial compartment knee osteoarthritis". Journal of Bone and Joint Surgery Am. 2007 November, 89(11):
2398-2407.

Kanto Nagai, et al. "Unloader knee brace increases medial compartment joint space during gait in knee osteoarthritis patients." Knee Surgery, Sports Traumatology, Arthroscopy (2019) 27:2354-2360



Thoumie⁽⁷⁾ showed that the **Rebel Reliever**[®] knee brace significantly **reduces pain immediately and for a sustainable time** (p<0.01), and also **reduces pain when in movement** (p<<0.001). Lamberg⁽⁸⁾ corroborated these findings, showing that after 6 months of **Rebel Reliever**[®] use there were **improvements with regard to pain reduction** (42% of KOOS pain score improvement p<0.01) (study on 19 patients). Similarly, Benning⁽⁹⁾ confirmed the **reduction of symptoms** and **extension of pain-free walking distance** with the **Rebel Reliever**[®] (study on 16 patients).





Wearing a soft offloading knee brace had a significantly superior effect on pain (pain-free walking distance increased p=0.0001, decreased of pain on loading p<0.0001) compared with standard treatment for Benning⁽¹⁰⁾ (study on 32 patients).



Ramsey⁽¹¹⁾ suggested that **pain relief** may result from **diminished muscle co-contraction** with **knee braces**, which may **result in decreased joint compression**. Indeed, in OA patients, joint laxity and instability is compensated by increased co-contraction (stiffer knee).

The subjects of the Nagai⁽¹²⁾ study felt **reduced pain** when wearing an **offloading brace**. He showed that **the brace** induced a small (0.3 mm/0.011" on average) but significant **increase** (around 10%) in medial compartment dynamic joint space during gait while no significant differences was found in vertical ground reaction force, suggesting that this increase was not due to decreased external limb load. This increase was **consistent from heel strike to terminal stance**.

Conclusion

Offloading knee braces are a cost-effective means⁽¹⁾⁽³⁾ of treating OA and could help delay the need for surgery⁽³⁾.



A brochure that summarizes clinical and biomechanical studies is available by scanning.

Clinical studies

Controlled, randomised study to assess the efficacy of UniReliever® offloading brace in the management of knee osteoarthritis – UNIBRACE study

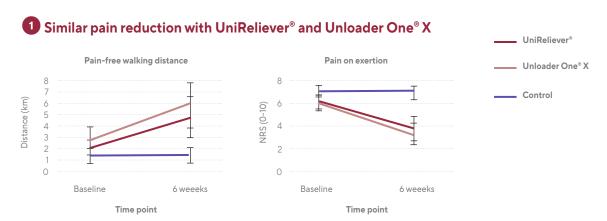
Benning M. et al. 2024 – 24th Congress of the European Society for Physical and Rehabilitation Medicine (ESPRM).

METHODS



60 patients diagnosed with medial knee osteoarthritis were randomly divided into three groups of twenty. Over a six-week period, one group received treatment with the UniReliever®, another with the Unloader One® X, while the third group served as a control group without any knee brace intervention.

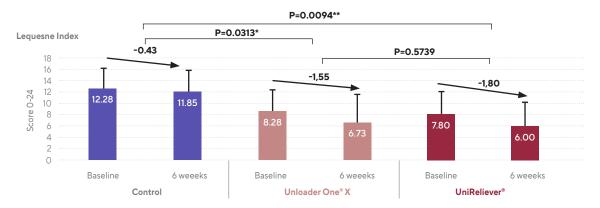
RESULTS



Pain-free walking distance more than doubled for patients wearing UniReliever® (+2.6 km) and Unloader One® X (+2.6 km) in contrast to the control group(+0.1 km) (p<0.0001).

Pain on exertion significantly decreased for patients wearing UniReliever $^{\circ}$ (p<0.0001) and Unloader One $^{\circ}$ X (p<0.0001) as compared to the control group. No significant difference was observed between both orthoses (p=0.3443).

2 An improvement in patient's condition for UniReliever® & Unloader One® X



The decrease in mean algofunctional Lequesne index was significantly higher in the UniReliever® (p=0.0094) and Unloader One® X (p=0.0313) groups as compared to the control group. This result corresponds to a **higher improvement in functional capacity with both orthoses**, without a significant difference between both orthoses (p=0.5739).

Most patients in the knee brace groups reported **moderate or greater improvement of their general condition** (Patient's Global Impression of Change: UniReliever®: 80%; Unloader One® X: 85%), **and improved range of knee motion** (UniReliever®: 85%; Unloader One® X: 80%), while the controls did not report any improvement.

3 A better compliance with UniReliever® vs Unloader One® X



The mean number of hours the brace was worn during the day was higher for UniReliever®, with 4.4 hours a day vs 3.1 hours a day for Unloader One® X.

The compliance with UniReliever® was higher than with Unloader One X®.

4 A good satisfaction with both knee braces

Patients were generally satisfied with both knee braces in terms of the ease-of-use, fit, aesthetics, and comfort. 95% of patients planned to continue using the brace. But some skin complaints (N=4) were reported by patients wearing Unloader One® X in contrast to UniReliever® (N=0).

Of the patients who initially took analgesics, most reduced or stopped this medication in the two knee brace groups (57.1% for UniReliever® and 72.7% for Unloader One® X groups), but only 11.1% in the control group. Through the study, 70% of patients reported never taken analgesics in the UniReliever® group vs 35% and 55% in the Unloader One® X and control groups respectively.

CONČLUSION

This study supports the **effectiveness and safety of the UniReliever**® offloading knee brace for treating medial knee osteoarthritis.

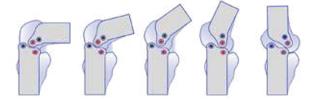
Wearing UniReliever® improved pain and functional capacity with the same efficiency as Unloader One® X.

Patients reported a **better compliance and no skin issue with UniReliever®** as compared to Unloader One®X.

Thuasne® Ligament Braces - Main technical features

TM5 HINGE

Ligament protection, prevent tibial instabilities(1)(2). Roll-back and glide movement similar to natural movement of the knee⁽²⁾. No pistonning, no migration(2).

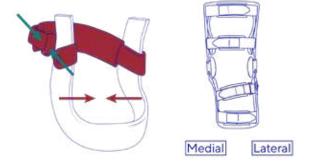


SYNERGISTIC SUSPENSION STRAP

Enhanced comfort⁽¹⁾ as the brace stays in place on the leg.

Anterior-posterior (AP) + medio-lateral (ML) tightening (front/back and left/right).

Asymmetrical attachment on the narrowest part of the leg.

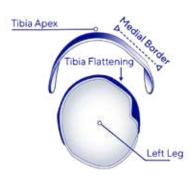


TIBIAL BOLSTER

Prevents rotation⁽¹⁾ and protects the ligaments⁽¹⁾.

Musculo-skeletal lock using the flat medial border of the tibia.





CLINICAL AND BIOMECHANICAL STUDIES

Ligament knee braces help increase joint stability after ACL traumatism and can favor a safe return to sport. Soft and rigid knee braces both have advantages. Soft braces provide a proprioceptive effect enhancing neurocontrol of the knee, rigid braces provide a better stabilisation during more demanding activities.



A brochure that summarises clinical and biomechanical studies is available by scanning.

In Internal CE marking data.

A 2S biomechanical study « Biomechanical study of the stride during use of different braces » 2020, including the Rebel® Standard, a rigid ligament brace with the TM5 hinge and conducted on a panel of 18 people.

Effect of different Knee Braces in ACL-Deficient Patients.

Focke A. et al. 2020 Front. Bioeng. Biotechnol. 8:964.



17 subjects with ACL deficient knee were treated in alternation with a **soft and a rigid ligament brace** for a period of at least 4 weeks.

VALGUS

Both braces significantly reduced the maximum valgus angle during walking \longrightarrow stabilisation of the knee joint.

FLEXION

Patients generally walked with a more flexed knee in braced conditions, whereby mainly the rigid brace showed significant and larger differences.

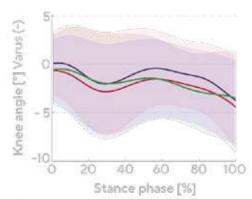
EXTERNAL ROTATION ANGLE

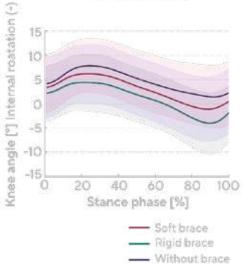
Significantly smaller for the rigid brace for walking, and significantly smaller for both braces during cutting.

ROM

With **both braces** a significant increase. **Significantly larger** with the **rigid brace** (**soft brace** $<1^\circ$; **rigid brace** $\approx 1-2^\circ$).

KNEE KINEMATICS DURING STANCE PHASE





Conclusion

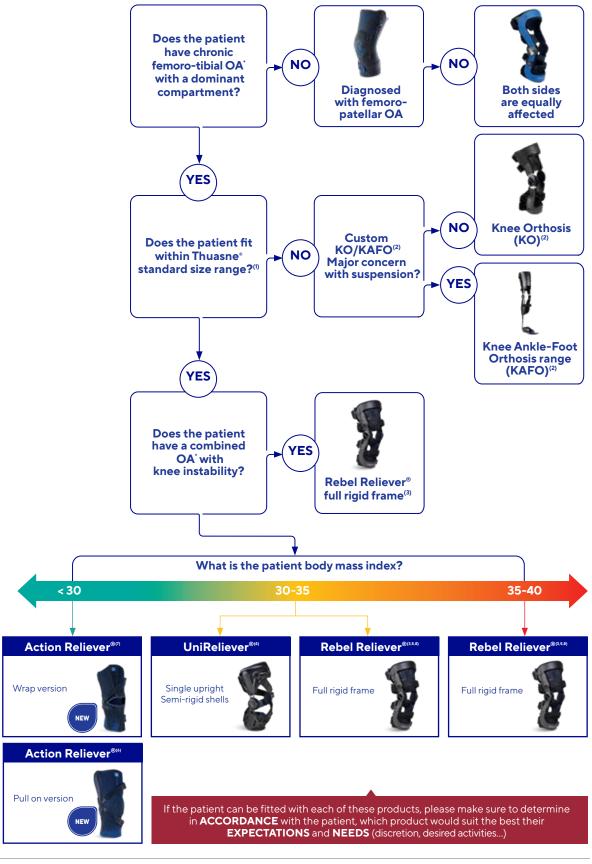
Evidence for the functional effectiveness of brace when applied to ACL-deficient patients.

Both rigid and soft **braces** are able to **limit valgus and provide additional stability** when patients return to sports.

Both rigid and soft braces had similar effects on joint angles in the frontal and transverse plane.

Rigid brace showed a **stronger reduction of the external rotation** in walking condition but have a significant **extension deficit.**

Therefore, for moderate intensity movement tasks, the **soft brace seems to be able to stabilise** ACL with a lesser impact on physiological gait compared to **rigid brace**.



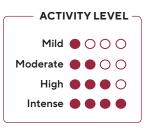
^{*}OA = Osteoarthritis.

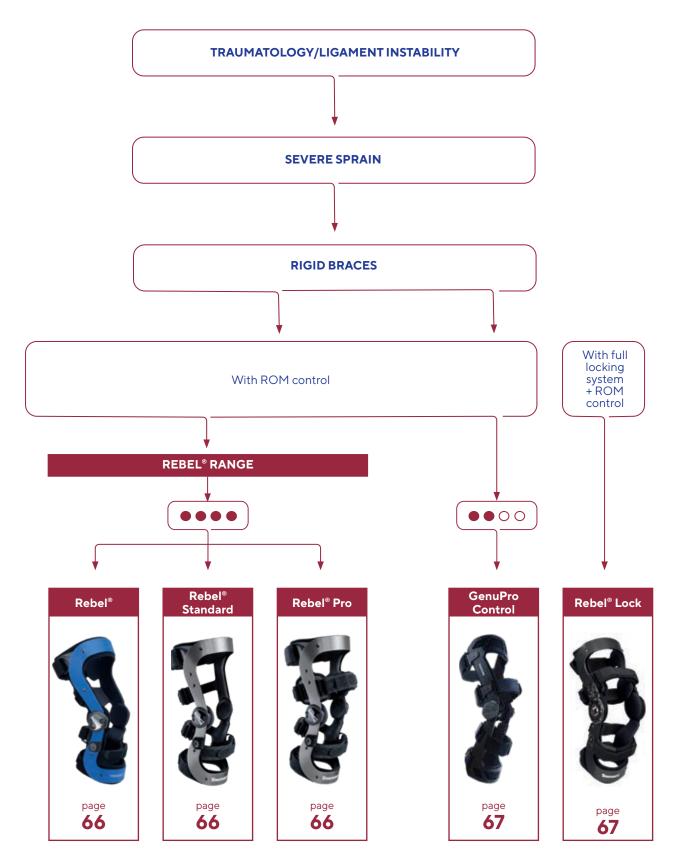
⁽¹⁾ Max thigh circumference = 71 cm/28". (2) KO: Knee Orthosis / KAFO: Knee-Ankle-Foot orthosis.

⁽²⁾ KC: Knee Orthosis / KAFC: Knee-Ankle-Foot orthosis.
(3) Full rigid metallic frame with double upright.
(4) Semi-rigid shells with a metallic upright.
(5) Lamberg, Eric M., Robert Streb, Marc Werner, Ian Kremenic, and James Penna. 2016b. "The 2-and 8-Week Effects of Decompressive Brace Use in People with Medial Compartment Knee Osteoarthritis." Prosthetics and Orthotics International 40 (4): 447-453. + Full rigid metallic frame with double upright.
(6) Soft close knitted product without shells (mild stabilisation in case of weight), Need to be pulled on the leg.
(7) Open product with quick buckles that can be put on the leg without stepping through or pulling on.
(8) Thoumie Philippe, et al. 2018 "Effect of Unloading Brace Treatment on Pain and Function in Patients with Symptomatic Knee Osteoarthritis: The ROTOR Randomized Clinical Trial." Scientific Reports 8 (1):10519. Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. All the medical devices mentioned on this document are CE marked according to the Regulation 2017/745 on medical devices. Medical devices mentioned in this document are CE class I. Please contact Thuasnes" should you need any additional information on devices classification. Please carefully read the instructions for use, indications and contraindications of the products. The full list of medical indications, are available in the instructions for use.

Last revision date: 11/2024, Ref: 2410390. Thuasne SAS - SIREN/RCS Nanterre 542 091186 - capital 1950 000 euros - 120, rue Marius Aufan 92300 Levallois-Perret (France)

Which ligament knee brace?







Action Reliever® Soft offloading knee brace



Sleeve: 234902 Wrap: 234903

MAIN INDICATIONS

- Symptomatic unicompartmental femoro-tibial osteoarthritis (mild to moderate).
- $\bullet \ \, \text{Knee offloading for post-traumatic, post-operative or degenerative conditions.}$
- Knee pain and/or swelling management.

PATIENT PROFILE

- Patient with femoro-tibial osteoarthritis (mild to moderate).
- Patient with low to moderate activity level.
- Patient looking for a low-profile, discreet knee brace.

MAIN FEATURES

- Efficient dynamic offloading $^{(1)}$: Effective 4 straps system $oldsymbol{0}$ allows proven $^{(1)}$ offloading of affected compartment and dynamic 3-point 2 correction leading meaning targeted offload.
- Patella support: anatomical oval-shaped insert (in sleeve version only).
- Compression and proprioceptive effect: due to compressive elastic knit.
- Lateral support: 1 rigid upright and 1 flexible stay.
- Comfort: anatomically-shaped extensible knit and no strapping crossing at popliteal crease. 3
- Hold: silicone-coated threads at top edge of brace.
- Ease of application: magnetic buckles 4 (sleeve version) and quick buckles 5 and full opening (wrap version)⁽²⁾.
- · Available in 2 models:
- left leg medial offloading / right leg lateral offloading
- right leg medial offloading / left leg lateral offloading

MODES OF ACTION







Compression



Proprioceptive effect













		Sleeve	version		Wrap version					
	Thigh circumference (15 cm above the knee)		Calf circumference (12 cm below the knee)		Thigh circumference (15 cm above the knee)		Calf circumference (12 cm below the kne			
	cm	in	cm	in	cm	in	cm	in		
XXS	35 - 37	13 ¾ - 14 ½	29.5 - 32	11 ½ - 12 ½	35 - 40	13 ¾ - 15 ¾	29.5 - 33	11 ½ - 13		
XS	37 - 41	14 ½ - 16	32 - 34.5	12 ½ - 13 ½	37 - 44	14 ½ - 17 ¼	32 - 36.5	12 ½ - 14 ¼		
S	41 - 45	16 - 17 ¾	34.5 - 37	13 ½ - 14 ½	41 - 48	16 ¼ - 19	35.5 - 40	14 - 15 ¾		
М	45 - 50	17 ¾ - 19 ¾	37 - 39.5	14 1/2 - 15 1/2	46 - 54	18 - 21 1/4	39 - 43.5	15 1/4 - 17 1/4		
L	50 - 55	19 ¾ - 21 ¾	39.5 - 42	15 ½ - 16 ½	51 - 59	20 - 23 1/4	42.5 - 47	16 ¾ - 18 ½		
XL	55 - 61	21 ¾ - 24	42 - 44.5	16 ½ - 17 ½	57 - 66	22 ½ - 26	46 - 50.5	18 - 20		
XXL	61 - 67	24 - 26 1/4	44.5 - 47	17 1/2 - 18 1/2	63 - 72	24 ¾ - 28 ¼	49.5 - 54	19 1/2 - 21 1/4		



Fitting videos available on line





UniReliever®

Offloading single-upright knee brace

U30901





MAIN INDICATIONS

- Symptomatic unicompartimental femoro-tibial osteoarthritis (moderate to severe).
- $\bullet \ \, \text{Knee offloading for post-traumatic, post-operative or degenerative conditions}.$
- · Joint instability/laxity.
- · Alternative to osteotomy or leg misalignment surgery.

PATIENT PROFILE

- Mainly senior adult with knee OA.
- · Patients with dexterity issues.
- · Patients with atypical body shape.

MAIN FEATURES

- Efficient knee offloading⁽²⁾: adjustable 3-point leverage system 1 with inelastic straps 2 and self-dosing adjustment 3
- TM5+ hinge 4 that reproduces the natural movement of the knee⁽¹⁾.
- Motion control: adjustment of extension (from 0° to 30°) and flexion (from 0° to 110° in option).
- Comfort: 2 semi-rigid shells allowing an intimate fit to the patient's unique anatomy.
- Suspension: inner silicon paddings (shells and straps).
- Ease of application: self-dosing adjustment and color-coded clip buckles.
- · Available in 2 models:
- left leg medial offloading / right leg lateral offloading
- right leg medial offloading / left leg lateral offloading

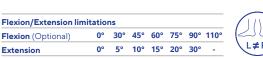
MODES OF ACTION

















SPARE PARTS FOR UNIRELIEVER®

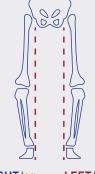
13 - 30'

Universal size 33 - 76 cm

- The kits include: straps, BOA® Fit System, strap padding, buckles and shell padding.
- · Left Medial / Right Lateral Kit: UU3090010001
- · Right Medial / Left Lateral Kit: UU3090010002

Which brace do I need to choose? Always choose the brace for the affected side





LEFT Medial/ Right Lateral model

Action Reliever® Sleeve version : 234902xxxx851 Wrap version : 234903xxxx851

UniReliever® **U30901**29900351

RIGHT leg **LEFT** leg **VARUS**

Medial (internal) OA

Left Medial/ **RIGHT Lateral** model

Action Reliever® Sleeve version : 234902xxxx851 Wrap version: 234903xxxx851

UniReliever® U3090129900351



Right Medial/ **LEFT Lateral** model

Action Reliever® Sleeve version: 234902xxxx852 Wrap version: 234903xxxx852

UniReliever⁶ **U30901**29900352

VALGUS Lateral (external) OA



Legal manufacturer, influsaire Deutschland omburn," Biomechanical study of the stride during use of different braces" 2020 on similar Rebell[®] device.

Michael Benning, Ralf-Dieter Hilgers, Stephanie Villet, Prasanna Shrestha and Nils Lynen. Efficacy and safety of a new offloading brace in the management of A randomized controlled UNIBRACE Study. 24th European congress of Physical and Rehabilitation Medicine - ESPRM. Ljubljana, Slovenia. 23-27 April 2024.





Rebel Reliever®

Rigid offloading knee brace

U03309

MAIN INDICATIONS

- Symptomatic unicompartimental femoro-tibial osteoarthritis (moderate to severe).
- $\bullet \ \, \text{Knee offloading for post-traumatic, post-operative or degenerative conditions}.$
- · Joint instability/laxity.
- · Alternative to osteotomy or leg misalignment surgery.
- · Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).

PATIENT PROFILE

• Patient with femoro-tibial osteoarthritis (moderate to severe) and medium to high activity.

MAIN FEATURES

- 1 Knee offloading(1); adjustable 3-point leverage system (Loadshifter technology) up to 9° in varus or valgus.
- · Clinically proven efficacy(2).
- 2 Ligament stabilisation: rigid frame with TM5+ hinge that reproduces the natural movement of the knee⁽³⁾.
- Motion control: adjustment of extension (from 0° to 40°) and flexion (from 0° to 90°) with a tool-less system.
- $\bullet \hspace{0.1in} \textbf{Suspension}^{(0)}: synergistic \hspace{0.1in} suspension \hspace{0.1in} strap, \hspace{0.1in} tibial \hspace{0.1in} bolster \hspace{0.1in} to \hspace{0.1in} avoid \hspace{0.1in} rotation, \hspace{0.1in} C/S \hspace{0.1in} (Compression/Suspension)$ package to enhance support by preventing slipping.
- ${\bf Comfort}:$ interior padding and condylar pads in foam.
- 4 Ease of application: buckles and tool-less offloading setting (Snap Lock).
- Available in: right or left leg model

MODES OF ACTION





Offloading

Motion control













SPARE PARTS FOR REBEL RELIEVER®

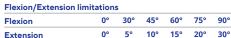
- Padding kit from XS to XXL (pads with strap pads, right or left): UU072
- Condylar pads (universal size and side): $\hbox{UU}020001001$
- Straps kit from XS/SM, MD/LG to XL/2XL, bilateral): UU033
- Buckles kit (x4 units): UU033009001

		15 cm		l	ENTION Knee width	15 cm		
		cm	in	cm	in	cm	in	
ES	XS	31 - 39	12 1/2 - 15 1/2	7.5 - 9	3 - 3 1/2	28 - 32	11 - 12 1/2	
SIZES	S	39 - 47	15 1/2 - 18 1/2	9 - 10	3 1/2 - 4	31 - 35	12 ¼ - 13 ¼	
	M	47 - 53	18 ½ - 21	10 - 11.5	4 - 4 1/2	34 - 38	13 1/4 - 15	
Α̈́	L	53 - 60	21 - 23 1/2	11.5 - 12.5	4 ½ - 5	37 - 40	14 1/4 - 15 3/4	
TANDARD	XL	60 - 64	23 ½ - 25	12.5 - 14	5 - 5 1/2	38 - 43	15 - 17	
1	VVI	64 71	25 20	14 - 15 5	E 16 - 6	12 . 10	17 10	



		Ž	15 cm	ATTENTION Knee width		15 cm 6"		
		cm	in	cm	in	cm	in	
	S/XS	39 - 47	15 ½ - 18 ½	9 - 10	3 ½ - 4	28 - 32	11 - 12 1/2	
	S/M	39 - 47	15 ½ - 18 ½	10 - 11.5	4 - 4 1/2	34 - 38	13 ¼ - 15	
ဂ္ဂ	M/S	47 - 53	18 ½ - 21	10 - 11.5	4 - 4 1/2	31 - 35	12 ¼ - 13 ¼	
SIZES	M/L	47 - 53	18 ½ - 21	11.5 - 12.5	4 1/2 - 5	37 - 40	14 ¼ - 15 ¾	
٠ ص	L/M	53 - 60	21 - 23 ½	11.5 - 12.5	4 1/2 - 5	34 - 38	13 ¼ - 15	
FITTED	L/XL	53 - 60	21 - 23 1/2	12.5 - 14	5 - 5 1/2	38 - 43	15 - 17	
证	XL/L	60 - 64	23 ½ - 25	12.5 - 14	5 - 5 1/2	37 - 40	14 ¼ - 15 ¾	
	XL/XXL	60 - 64	23 ½ - 25	14 - 15.5	5 ½ - 6	43 - 48	17 - 19	
	XXL/XL	64 - 71	25 - 28	14 - 15.5	5 ½ - 6	38 - 43	15 - 17	









40°

Legal manufacturer: Thuasne® France

Internal CE marking data.

Effect of unloading brace treatment on pain and function in patients with symptomatic knee osteoarthritis: The ROTOR randomized clinical trial. Thournie P. et al, Scientific Report (2018) 8:10519, Improvements in Function and Strength with Decompressive Bracing of the Osteoarthritic Knee. E. Lamberget al. Journal of Prosthetics and Orthotics. 28(4):173-179, Oct 2016.

^[9] Internal CE marking data / A2S biomechanical study "Biomechanical study of the stride during use of different braces" 2020 on similar Rebel® device.



Rebel® range

Hinged rigid ligament knee brace

MAIN INDICATIONS

- Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
- Post-operative immobilisation and/or rehabilitation.
- · Post-traumatic immobilisation.
- Joint instability/laxity (including for knee osteoarthritis).

MAIN FEATURES

- Ligament stabilisation: prevention of abnormal translation and rotation movements of the tibia (aluminum rigid frame, anterior tibial bolster shell and TM5+ hinge that reproduces the natural movement of the knee⁽¹⁾).
- $\bullet \ \ \textbf{Suspension on the leg:} \ \ \text{synergistic suspension strap, tibial bolster to avoid rotation.}$
- Motion control: adjustment of extension (from 0° to 30°) and flexion in option (from 0° to 110°).
- · Comfort: interior padding and condylar pads in foam.
- · Available in right or left model.

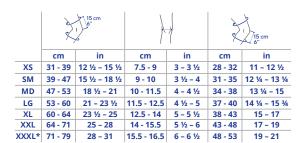
MODES OF ACTION





Stabilisation

Motion control



Flexion/Extension	limitations

Flexion (Optional)	0°	30°	45°	60°	75°	90°	110°
Extension	0°	5°	10°	15°	20°	30°	-









Rebel®

Hinged rigid ligament knee brace

U03401

MAIN FEATURES

- Medium stiffness aluminium
- · One colour available: atlantic blue.
- Optional accessory: flexion stop kit (ref UU005001001).





Rebel® Standard

Hinged rigid ligament knee brace U03002

MAIN FEATURES

• Medium stiffness aluminium.

U03102

• Optional accessory: flexion stop kit (ref UU005001001).









Rebel® Pro

Hinged rigid ligament knee brace

MAIN FEATURES

- · High stiffness aluminium.
- · C/S (Compression/Suspension) package to enhance support by preventing slipping.
- *Available in XXXL.
- · Optional accessory: flexion stop kit (ref UU005001001).



Rebel® Lock

Hinged, rigid ligament knee brace with locking mechanism

MAIN INDICATIONS

- Severe joint instability/laxity (including for knee osteoarthritis).
- Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
- · Post-operative immobilisation and/or rehabilitation.
- Post-traumatic immobilisation.

MAIN FEATURES

- Ligament stabilisation: rigid frame with a 4 point stabilisation system and TM5+ hinge that reproduces the natural movement
- Locking mechanism: drop locks for an extension lock (O and 5°) and a flexion lock (30° 60° and 90°) with simple pressure.
- · Suspension on the leg: suspension strap, tibia bolster to avoid rotation, C/S (Compression/Suspension) package to enhance support by preventing slipping.

XS

SM

MD

cm

53 - 60

- Comfort: interior padding and condylar pads in foam.
- · Available in right or left leg model.

MODES OF ACTION





Stabilisation



31 - 39 | 12 ½ - 15 ½

39 - 47 | 15 ½ - 18 ½



cm

28 - 32

in

3-31/2

3 1/2 - 4

cm

7.5 - 9

9 - 10

47 - 53 | 18 ½ - 21 | 10 - 11.5 | 4 - 4 ½ | 34 - 38 | 13 ¼ - 15

GenuPro Control

Knee orthosis for bracing and stabilisation

T391001

11 - 12 1/2

31 - 35 | 12 1/4 - 13 1/4



MAIN INDICATIONS

- · Post-operative immobilisation and/or rehabilitation.
- · Joint instability/laxity (including for knee osteoarthritis).
- · Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
- Post-traumatic immobilisation.

MAIN FEATURES

- · Ligament stabilisation: prevention of abnormal translation and rotation movements of the tibia (aluminum rigid frame, anterior tibial bolster shell and TM5+ hinge that reproduces the natural movement of the knee⁽¹⁾).
- Suspension on the leg: synergistic suspension strap, tibia bolster to avoid rotation, C/S (Compression/Suspension) package to enhance support by preventing slipping.
- Motion control: adjustment of extension (from 0° to 40°) and flexion (from 0° to 90°) with a tool-less system.
- Comfort: interior padding and condylar pads in foam, split tibial padding for pressure relief.
- Ease of application: quick release buckles with a low profile.
- · Available in right or left leg model.

MODES OF ACTION







Immobilisation

Stabilisation

Proprioceptive effect

	15 cm		ATTENTION Knee width		15 cm		
	cm	in	cm	in	cm	in	
S	39 - 47	15 ½ - 18 ½	9 - 10	3 ½ - 4	31 - 35	12 ¼ - 13 ¼	
М	47 - 53	18 ½ - 21	10 - 11.5	4 - 4 1/2	34 - 38	13 ¼ - 15	
L	53 - 60	21 - 23 1/2	11.5 - 12.5	4 1/2 - 5	37 - 40	14 1/4 - 15 3/4	
XL	60 - 64	23 ½ - 25	12.5 - 14	5 - 5 1/2	38 - 43	15 - 17	
XXL	64 - 71	25 - 28	14 - 15.5	5 ½ - 6	43 - 48	17 - 19	





Flexion/Extension	limitations

Flexion	0°	30°	45°	60°	75°	90°	-
Extension	0°	5°	10°	15°	20°	30°	40°



SPARE PARTS FOR GENUPRO CONTROL

- Padding Kit S-XXL (pads with strap pads, right or left): T391013
- Condylar pads (universal size and side): T391011
- Hinge caps Kit (1 inner and 1 outer): T391015
- Kit strap (S-XXL, bilateral): T391012
- Extension/Flexion stops Kit: T391014





SpryStep® OA knee

Custom osteoarthritis knee brace

U3360399999999

MAIN INDICATIONS

 $These \ indications \ are \ biomechanical \ deficits \ of \ neurological, \ traumatic, \ muscular \ or \ degenerative \ origin.$

- · Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
- · Joint instability/laxity (including for knee osteoarthritis).
- Symptomatic unicompartmental femoro-tibial osteoarthritis (moderate to severe).
- Knee offloading for post-traumatic, post-operative or degenerative conditions.
- · Alternative to osteotomy or leg misalignment surgery.

PATIENT PROFILE

• Patient who requires stability of the knee joint and offloading of the medial or lateral compartment of $the \ knee\ joint\ due\ to\ OA,\ or\ specific\ unicompartmental\ conditions\ who\ may\ not\ fit\ an\ off-the-shelf$ brace because of their anatomy, or potentially who present a fixed varus or valgus degree.

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- Digital workflow: premanufacture report communicates the outcomes of the modelling process and identifies areas of attention for fitting.
- Strength, lightness and intimate fit: composite structure, lightweight⁽¹⁾ and durable⁽²⁾, designed with a specific material combination and a precise manufacturing process⁽¹⁾
- $\bullet \ \, \textbf{Knee offloading} \ ^{\text{(1)}} : \text{adjustable 3-point leverage system (Loadshifter technology) up to 9} \ \text{in varus or } \ \, \text{(Loadshifter technology)} \ \text{(Loadshifter tech$ valgus. Correction can also be directly built into the frame.
- · Ligament stabilisation: rigid frame with TM5+ hinge that reproduces the natural movement of the knee(1)(3
- Motion control: adjustment of extension (from 0° to 30°) and flexion in option (from 0° to 110°).
- Suspension on the leg⁽¹⁾: synergistic suspension strap, C/S (Compression/Suspension) package in
- Frame design: available both in Full Shell and Uband style.
- · Comfort: interior padding and condylar pads in foam.
- Available with different options: refer to the order form.

MODES OF ACTION







Motion control



Legal manufacturer. Thuasne® Deutschland GmbH.

Internal CE marking data.

Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.

AZS biomechanical study « Biomechanical study of the stride during use of different braces » 2020, including the Rebel® Standard, a rigid ligament brace with the TM5 hinge and conducted on a panel of 18 people.



SpryStep® OA Knee

Contact Information Clinician Fitter/Assistant/Tech Other: Name: Email: Phone: Billing & Shipping PO#: Shipping Account#: Shipping Account#: Shipping Preference Ground Next Day Account Information Information (If no preference is indicated, this order with Information Information Information Information Information Name: Phone: Phone: Po#: Shipping Account#:	Shipping Address: State: Zip:
Patient Information Fit Date: Patient ID: Age	Brace Rigidity/ Stiffness For larger and heavier framed patients- increased rigidity / stiffness is recommended Level 1 (default) Level 2 (medium) Level 3 (high) Femoral shell length 7 in 175mm (default) -1 in 150mm +1 in 200mm Femoral shell configuration
Compartment: Unload Medial Unload Lateral Measurement Data These measurements are required to check the accuracy of the patient model submitted, a patient model must be provided for fabrication (scan). Proximal circumference 7 in / 175mm above mid-patella Medial-Lateral Knee Width (not circumference) at knee center Distal circumference 7 in / 175mm below mid-patella	□ Anterior □ Posterior Tibial shell length □ 7 in 175mm (default) □ -1 in 150mm □ +1 in 200mm (Loadshifter not available for this length) *Custom length requests require pre-fabrication consultation, additional charges will be applied. Tibial shell configuration □ Anterior □ Posterior Options Please select only one of the following selections □ Full Shell* □ C/S Package (not available with FullShell) □ Combined legtonility Strop (PCL)
Brace Configuration NB by default: riveted anchor tabs + d-rings + 1/4" padding + condylar pads + 2 additional thicker condylar pads + synergistic suspension strap Hinge (Extension stop kit inclued with hinges) TM5 Aluminum with Loadshifter TM5 Aluminum without Loadshifter, Correction built into the frame: °	□ Combined Instability Strap(PCL) not available with Full Shell Accessories □ Spooner Patella Stabilizing Attachment* □ Brace cover (pull-on style)* □ Cotton Undersleeve 18 in (46cm)* □ Neoprene Undersleeve 18 in (46cm)* □ CS wrap* □ Anti-migration silicon infused strap pads* Comments:

*Indicates additional charges apply

OF-067 REV. B

By filling this order form and placing an order for this device, I hereby certify that I am authorized to dispense this medical device in virtue of any national law governing the fitting and adjustment of orthopedic medical devices.

Distributed by Thuasne USA





SpryStep® Ligament KO

Custom functional knee brace

U335039999999

MAIN INDICATIONS

 $These\ indications\ are\ biomechanical\ deficits\ of\ neurological, traumatic, muscular\ or\ degenerative\ origin.$

- Conservative treatment of knee ligament injuries and/or ruptures (cruciate and/or lateral ligaments).
- · Joint instability/laxity (including for knee osteoarthritis).

PATIENT PROFILE

 $\bullet \ \ \text{Patients who require custom brace because of their anatomy and potential high-level activities}.$

MAIN FEATURES

- Made to patient: custom fabricated from a model of the patient leg.
- $\hbox{\bf Digital workflow:} premanufacture \ report \ communicates \ the \ outcomes \ of \ the \ modelling \ process \ and$ identifies areas of attention for fitting.
- $\bullet \ \, \textbf{Strength, lightness and intimate fit: } composite structure, lightweight \textbf{(!)} and durable \textbf{(2)}, designed with a lightweight \textbf{(!)} and durable \textbf{(2)}, designed with a lightweight \textbf{(!)} and durable \textbf{(2)}, designed with a lightweight \textbf{(!)} and durable \textbf{(!)}. \\$ specific material combination and a precise manufacturing process⁽¹⁾
- · Ligament stabilisation: prevention of abnormal translation and rotation movements of the tibia (composite rigid frame and TM5+ hinge that reproduces the natural movement of the knee⁽¹⁾).
- Suspension on the leg: synergistic suspension strap.
- Frame design: available both in Full Shell and Uband style.
- Motion control: adjustment of extension (from 0° to 30°) and flexion in option (from 0° to 110°).
- Comfort: interior padding and condylar pads in foam.
- Available with different options: refer to the order form.

MODES OF ACTION











Legal manufacturer: Thuasne® Deutschland GmbH.

Internal CE marking data / A25 biomechanical study « Biomechanical study of the stride during use of different braces » 2020, including the Rebel® Standard, a rigid ligament brace with the TM5 hinge and conducted on a panel of 18 people.

Cycle-testing independently performed under ISO 10328 Servo-Pneumatic Test System.



SpryStep® Ligament Knee

U3350

Billing & Shipping Billing Account#: Shipping Account#: Shipping Preference	City: State: Zip:
Patient Information Fit Date: Patient ID: Age	Femoral shell length ☐ 7 in 175mm (default) ☐ -1 in 150mm ☐ +1 in 200mm Femoral shell configuration ☐ Anterior ☐ Posterior Tibial shell length ☐ 7 in 175mm (default) ☐ -1 in 150mm ☐ +1 in 200mm
Measurement Data These measurements are required to check the accuracy of the patient model submitted, a patient model must be provided for fabrication (scan). — Proximal circumference 7 in / 175mm above mid-patella — Medial-Lateral Knee Width (not circumference) at knee center — Distal circumference 7 in / 175mm below mid-patella Brace Configuration NB by default: riveted anchor tabs + d-rings + 1/4" padding + condylar pads + 2 additional thicker condylar pads + synergistic suspension strap Hinge (Extension stop kit inclued with hinges)	*Custom length requests require pre-fabrication consultation, additional charges will be applied. Tibial shell configuration Anterior Posterior Options Please select only one of the following selections Full Shell* C/S Package (not available with FullShell) Combined Instability Strap(PCL) not available with Full Shell Accessories Spooner Patella Stabilizing Attachment* Brace cover (pull-on style)* Cotton Undersleeve 18 in (46cm)* CS wrap* X-treme Guard* Anti-migration silicon infused strap pads* Comments:

*Indicates additional charges apply

OF-066 REV. B

Received Date Thuasne USA's shipping department use only

SPINAL BRACING

and degenerative conditions

Thuasne®'s technical spinal solutions address a variety of traumatic & degenerative conditions, with distinct structures (LSO, TLSO) and level of stabilisation.



Osteoporosis and vertebral fractures:



Across Europe⁽¹⁾ in 2019,

32 million

individuals aged 50+ are estimated to have osteoporosis⁽²⁾:

- Equivalent to 5.6% of the total European population aged 50+.
- Approximately 25.5 million women (22.1% of women aged 50+) and **6.5 million men** (6.6% of men aged 50+).



Worldwide,

will experience osteoporosis fractures, as will 1 in 5 men aged over 50.(3)

Vertebral fractures due to osteoporosis are common - with one occurring every 22 seconds worldwide in men and women aged over 50.⁽⁴⁾

Vertebral fractures can lead to back pain, loss of height, deformity, immobility, increased number of bed days, and even reduced pulmonary function. Their impact on quality of life can be profound as a result of loss of self-esteem, distorted body image and depression. Vertebral fractures also significantly impact activities of daily living. (5)

Spine trauma:

The thoracolumbar junction (T10-L2) is subject to significant biomechanical

Hence, fractures of the thoracolumbar region are the most common injuries of the vertebral column.(6)

of these are unstable and can result in significant disability, deformity and neurological deficit. (7)

Among the thoracolumbar injuries

50-60% affected the transitional zone (T11-L2) 25-40% affected the thoracic spine 10-14% involved the lower lumbar spine and sacrum⁽⁸⁾

European Union, plus Switzerland & UK.

** Kanis J.A., et al., SCOPE 2021: a New Scorecard for Osteoporosis in Europe, Arch Osteoporos, 2021, 16**82.

** Kanis J.A., et al., Long-term risk of osteoporotic fracture in Malmo. Osteoporosint, 2000. 11**9: p. 669-74. / Melton, L.J., 3rd, et al., Bone density and fracture risk in men. J Bone Miner Res, 1998. 13(12): p. 1915-23. / Melton, L.J., 3rd, et al., Perspective. How many women have osteoporosis? J Bone Miner Res, 1992. 7**; p. 1005-10 / Curtis, E.M., et al., Epidemiology of fractures in the United Kingdom IP88-2012: Variation with age, sex, geography, ethnicity and socioeconomic status. Bone, 2016. 87; p. 19-26.

**Johnell, O. and J.A. Kanis, An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosint, 2006. 17(12): p. 1726-33.

**Johnell, O. and J.A. Kanis, An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosint, 2006. 17(12): p. 1726-33.

**Johnell, O. and J.A. Kanis, An estimate of the worldwide prevalence and disability associated with osteoporosint, 2006. 17(12): p. 1726-33.

**Johnell, O. and J.A. Kanis, An estimate of the worldwide prevalence and disability associated with osteoporosint, 2006. 17(12): p. 1726-33.

Lips, P., et al., Quality of Life of the European Foundation for Osteoporosis. Osteoporosis. 1999. 10: p. 150-60. / Nevitt, M.C., et al., The association for Osteoporosis (QUALEFFO). Working Party for Quality of Life of the European Foundation for Osteoporosis. 1999. 10**: p. 150-60. / Nevitt, M.C., et al., The association of apolipoprotein E epsilon4 with bone mineral density, bone turnover and the risk of fractures in older people. Osteoporosisth, 2002. 13**, 170-9. [odl., D.T.). F. ond. Ds. The non skeletal consequences of osteoporotic fractures. Psychologic and social outcomes. Rheum Dis Clin North Am, 2001. 27**, p. 255-62. / Lyles, K.W., Osteoporosis and depression: shedding more light upon a complex relationship. J Am GeriatrSoc, 20

⁹ S Rajasekaran, Rishi MugeshKanna, and AjoyPrasad Shetty, Management of thoracolumbar spine trauma: An overview, Indian J Orthop. 2015 Jan-Feb; 49%: 72-82. doi: 10.4103/0019-5413.143914 Gertzbein SD. Scoliosis Research Society. Multicenter spine fracture study. Spine (Phila Pa 1976) 1992;17:528-40.

Main technical features on Thuasne® Spinal braces

LOMBASTAB RANGE



Easy and precise tightening(1): wire lacing system with easy-grip handles.



Adapts to the anatomy: 4 conformable dorsal stays and independent back plates for the Immo and Dorso version.



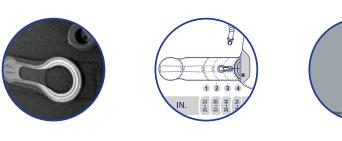
Ease of application: symmetrical hand loops to ensure lumbar support is properly centred on the spine.



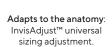
Comfort: specific Lombastab elastic fabric with breathable Coolmax⁽²⁾ lining.

Easy care: machine-washable at 30°C.

SLEEQ® RANGE

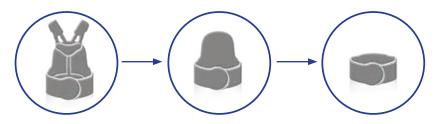


Easy and precise tightening(3): lacing system with easygrip handles.





accurate fitting.



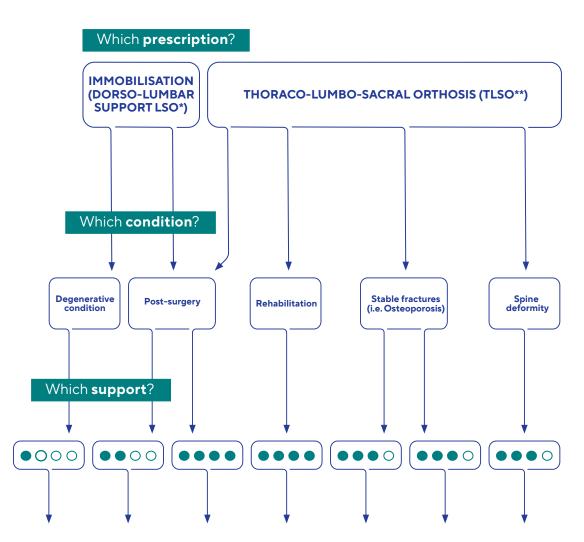
Step down system:

modular design easily accommodates progressive patient therapies.

Study conducted in-house on the « Quick lacing system » on a panel of 13 people, July 2019.
 https://coolmax.com/en/
 Study conducted in-house on the lacing system of Sleeq®, on a panel of 17 people, February 2023.

Which spinal brace for which condition?



























LombaStab High Dorso-lumbar support with easy and precise tightening (1)

085501 (35 cm) 085601 (40 cm)

MAIN INDICATIONS

- · Spinal stenosis.
- $\bullet \ {\sf Spondylolysis/spondyloarthrosis}.$
- · Stable vertebral fracture (osteoporotic).
- · Osteochondrosis/Scheuermann's disease.
- · Spondylolistesis.

MAIN FEATURES

• Adapts to the anatomy: 4 conformable dorsal stays and independent back plates.

cm 60 - 80 23 ¾ - 31 ½ 75 - 95 29 1/2 - 37 1/4 3 90 - 110 35 % - 43 ½ 4 105 - 125 41 % - 49 1/4 5 120 - 140 47 1/4 - 55 1/8









Stabilisation

Postural education Proprioceptive effect

LombaStab Immo

Dorso-lumbar support with corset easy and precise tightening⁽¹⁾

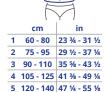
085901

MAIN INDICATIONS

- Post-operative immobilisation.
- · Lumbar-spinal stenosis.
- · Spondylolysis.
- · MODIC type 1 discopathy.

MAIN FEATURES

• Step-down design: thermoformable and removable corset with removable 3D mesh cover.











MODES OF ACTION



Stabilisation

Postural education Proprioceptive effect

LombaStab Dorso

TLSO with easy and precise tightening(1)

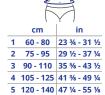
084701



- · Stable vertebral fracture (traumatic and osteoporotic).
- Scheuermann's disease
- · Static disorders (kyphosis, lordosis).

MAIN FEATURES

· Adapts to the anatomy: conformable and height-adjustable back straightener (from 36 cm to 61 cm) adapts to patient size.





- · Hyperextension: achieved by back frame, sternal support and shoulder straps.
- Comfort: S-shaped and padded shoulder straps prevent armpit friction.

MODES OF ACTION







Stabilisation

Postural education Proprioceptive effect









Legal manufacturer: Thuasne® Deutschland GmbH



Legal manufacturer: Thuasne® Deutschland GmbH.



Legal manufacturer: e-life International Co., Ltd., 7F., No.I, Baosheng Rd., Yonghe Dist., New Taipei City 234, Taiwan (R.O.C.) EC REP: MDSS GmbH Schiffgraben 41. 30175 Hannover, Germany

Sleeq® Flex

TLSO for active relief and correction of spine in sagittal plane

• Stable vertebral fracture (traumatic and osteoporotic).

MAIN FEATURES

- Immobilisation: semi-rigid structure provides support.
- Comfort: ventilated self-moulding support panels.
- Ease of use: lacing system with easy-grip handles.
- Universal size: easily adjustable to fit waist sizes 65 145 cm (26"-57").
- Adjustable design: additional extension panel accommodates waist sizes 145 165 cm (57" 65").

Sleeq® Max Post-op/post-Injury TLSO

U5040

T54660

MAIN INDICATIONS

- Post-operative rehabilitation with sagittal/coronal/transverse plane motion restriction.
- · Stable vertebral fracture (traumatic and osteoporotic).

MAIN FEATURES

- Strong immobilisation: rigid tri-planar control with full circumference shell design, reinforced panels and steel components.
- · Customisable: anterior panels can be trimmed or heat moulded for anatomic fit and adjustable sternal bar.
- Adjustable design: steps down to LSO to evolve with patient's condition. Additional extension panel accommodates waist sizes 145 - 165 cm (57" - 65").
- Comfort: ventilated components and anatomically moulded back panel.
- $\bullet \ \, \textbf{Ease of use} : \textbf{lacing system with easy-grip handles and practical straps with snap \& release buckles}.$
- Universal size: easily adjustable to fit waist sizes 65 145 cm (26"-57").

Dorso Rigid 35

Hyperextension TLSO brace

089003

) 1 (

MAIN INDICATIONS

- · Postoperative immobilisation after spinal surgery.
- · Post-traumatic anterior body fractures (T6-L2).
- Dorsolumbar / thoracolumbar osteoarthritis.
- Conservative treatment of stable spinal fractures (T6-L2).
- · Osteoporotic or metastatic-related compression fractures of T6-L2.

	cm	in	cm	in	
S	60 - 75	24 - 29	39 - 46	15 - 18	
M	75 - 90	29 - 35	42 - 49	16 - 19	
L	90 - 105	35 - 41	45 - 52	18 - 20	
XL	105 - 115	41 - 45	49 - 56	19 - 22	

) (

MAIN FEATURES

- · Stabilising and immobilising action:
- three pressure point design to promote spinal extension and restrict forward flexion and rotation.
- Adjustable: telescoping lightweight frame, adjustable sternal plate, articulated pelvic band.
- $\bullet \ \, \textbf{Comfort} : \textbf{padded sternal pad and lateral uprights}. \ \, \textbf{Posterior panel can be positioned horizontally or} \\$ vertically on the patient.
- Water-resistant: can be used in water-based physiotherapy sessions, rust-proof.

MODES OF ACTION







Immobilisation

Stabilisation

Water-resistant







Osteoporosis/spine deformity orthosis

T548803

MAIN INDICATIONS

- · Osteoporosis.
- Scheuermann's disease.
- Static disorders (kyphosis, lordosis).

MAIN FEATURES

- Adjustable: adapts easily to patient's size and shape, additional straps can be trimmed.
- Posture correction: height-adjustable back straightener, can be adapted to the patient's lordosis.
- $\bullet \ \, \textbf{Ease of application} : \textbf{ergonomic hand loops, simple strapping system}.$
- · Universal size.



HipLocEvo

Hip joint orthosis

T540502

MAIN INDICATIONS

- Instability of the hip joint.
- Stabilisation of the hip joint after total endoprothetic replacement with loose muscle control and a tendency to luxation.
- Stabilisation of the hip joint after repositioning a luxated hip joint following endoprothetic replacement.

MAIN FEATURES

- $\bullet \ \ \textbf{Prevention of dislocations}; without impeding day-to-day \ movements.$
- Hip alignment: thanks to integrated splint at the pelvis and knee.
- $\bullet \ \ \textbf{Motion control} : possibility of limiting flexion and extension movements.$
- Available in right of left version.
- · Universal size.

31 - 48 cm 12 ¼ - 19"

Cervical collar for immobilisation

MAIN INDICATIONS

- Traumatic conditions: sprain, post-operative immobilisation.
- $\bullet \ \ \text{Degenerative conditions: cervical arthritis.}$

- Reinforced support: rigid structure combines anterior shell with chin rest and sternal pad, and posterior shell with high occipital and dorsal supports.
- · Comfort: removable and washable foam padding.
- Anterior opening: facilitates access to trachea.
- Precise fit: height-adjustable from 9 to 16 cm.

MODES OF ACTION





Immobilisation

Stabilisation



Ortel T-Neck

Ortel T-Neck Plus

Ortel T-Neck

Cervical collar for reinforced immobilisation

T49100

Ortel T-Neck Plus

Cervical collar for reinforced immobilisation with occipital support

T49105

MAIN INDICATIONS T-NECK

- · Cervical spine radicular pain.
- · Severe whiplash injury.
- Moderate to severe cervical syndrome.
- Stable, non-displaced vertebral fractures (without neurological symptoms).

MAIN INDICATIONS (T-NECK PLUS)

- · Pre-op, post-op, post-traumatic use.
- · Inflammatory conditions.
- Degenerative conditions.
- · Severe instabilities of the cervical spine.
- Stable, non-displaced vertebral fractures (without neurological symptoms).

MAIN FEATURES

- Immobilisation: rigid frame and reinforced two-part structure comprising chin, sternal, occipital and dorsal supports.
- Comfort: lightweight structure with foam pads.
- Precise fit: 5-step height adjustable chin rest.
- X-ray and MRI compatibility: both products are metal-free^(1,2).
- Anterior opening: facilitates access to trachea.
- Ease of application: simple, one-hand height adjustment.
- · Universal size.

MODES OF ACTION





Immobilisation

Stabilisation



Legal manufacturer: Thuasne® Deutschland GmbH.

Test conducted on the Ortel T-Neck to ensure the X-Ray transparency and compatibility, July 2020.

Cycle testing has been performed for the validation of the plastic springs and bolts, February 2021.

CASTING & SCANNING

Why do we need the scan of a cast?

Ensuring proper alignment is key to a successful orthotic outcome.

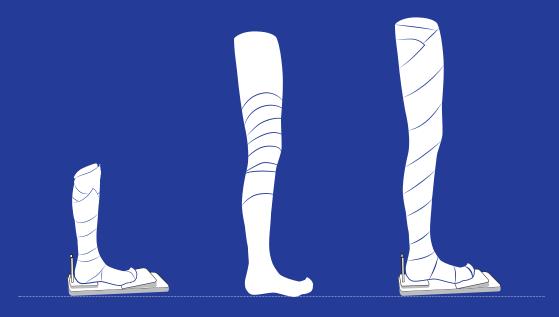
Therefore, we require a shape capture through a cast that takes into account the footwear profile (heel height, toe ramp position etc.) as well as the intended brace alignment.

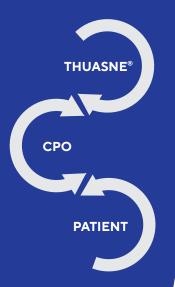
Our default alignment is:

Foot and ankle positioned as for the intended footwear;

The tibial crest 7° inclined to the vertical;

The midline of the thigh vertical.





Shape capture (cast + scan)

Making custom products is a collaborative effort to satisfy the patient and improve their daily life.

To create a unique solution for each patient, we need information and shape which will be used to manufacture each product.



The two main inputs we require are the following:

Order form

- Give the biomechanical goals and the context of the brace.
- Measurements are important to validate scan accuracy and certain landmarks (knee M-L, knee center height) → can be a reason for fit warranty withdrawal.
- A printed version is available in this catalogue for each custom product.



Shape capture

- Gives the shape and anatomical references for the job.
- The goal is to replicate the intended brace alignment.
- Once the shape is obtained you can either scan the negative cast (if the cast is no more than 3 ply of fiberglass at any level) or scan the positive cast (recommended for thick casts or plaster of paris casts).
- Direct scans of the leg are accepted for knee orthoses.
- Thuasne® facilities ONLY accept scans of casts casts can no longer be shipped.
- Various formats possible (ideally .stl).

A COMPLETED ORDER FORM IS FUNDAMENTAL TO UNDERSTAND YOUR GOALS AND THE CLINICAL PRESENTATION OF THE PATIENT

Patient Inform	nation			
By filling this order for authorized to dispens fitting and adjustment	e this medical dev	ice in virtue of any		
Please do not provide a provide health inform				
Fit Date:		Patient ID:		
Age	☐ Male	☐ Femal	e	
Weight	□ Lbs. □ Kg	g. Height	🗆 in.	□ cm.
Leg: □ L	eft 🗆 Righ	it		
Diagnosis:				
Shoe Size:				
☐ Appropriate	y scaled tracin	g of shoe insol	e provided v	with
order form Not sending	shoe or tracin		II be made long	ger and

П in П ст

efoot____ 🗆 in. 🗆 cm

Initials

Please do not provide any patient personal information. **NO PATIENT NAME**

Diagnosis

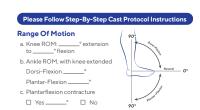
Can influence the design in some instances.

Insole

Tracing of shoe insole helps to make a foot section as precise as possible. **No tracing = trimming may be required at fitting.**

Shop

Heel & forefoot height are crucial; they will contribute to *determining the alignment*.



 \leq

ROM + cast information

Will determine if we can reach the default Thuasne® alignment:

- Foot and ankle positioned as for the intended footwear;
- Tibial crest 7° inclined to the vertical;
- · Midline of the thigh vertical.

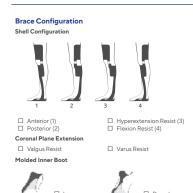
If not, the brace may require extrinsic posting during fitting.

Activity Level (Check one) Limited ambulator: sits to stands and transfers Household ambulator: level surfaces with walking aids Limited community ambulator: level surfaces with walking aids Limited community ambulator: level surfaces with walking aids Independent ambulator: walking aids Independent ambulator: walking aids Active ambulator: walking, running, some athletic activity Observational Gait Analysis (Check all that apply) Footslap Coruto in stance Excessive dorsiflexion in terminal stance Biomechanical objectives (Check all that apply) Control dorsiflexion weakness Control plantar flexion weakness Control anide valgus instability Resist knee hyperextension in stance Control anide valgus instability Resist knee hyperextension in stance Control anide valgus instability Resist knee hyperextension in stance

Activity level and biomechanical objectives are two

fundamental sections to understand what you and the patient are expecting to achieve with the device.

For example, a high activity goal may influence the recommended shell configuration of the device.



Shell configuration

Posterior is the default. If you do not know what to prescribe, start with a Posterior and find a reason not to use it. Our design team can help on this design aspect and provide advice on which shell configuration would be the most suitable and durable.

Coronal plane extension

Extends from the calf cuff.

Molded inner boot

Plastic inner boot gives room, attached to the composites frame, can be removed for on the spot tuning by the clinician (this part can be heat molded).

Knee Joint Options



☐ Leave inner boot unattached

☐ Single Pivot Locking 37700-(Manual Triggers)
☐ Single Pivot Locking* 37700-



□ 5-bar Free 37700
□ 5 Bar Locking 37700-L
(Manual Triggers)
□ 5 bar Locking* 37700-L

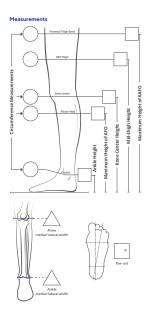
☐ Install Extension Assist Bands/Posts

Knee joint

The choice is limited to two options (for KAFO only), **single pivot** and **5-bar**:

- 5-bar is usually the default.
- 5-bar can be totally free or locking with free motion (manual triggers are not recommended).

Extension assist can be added. It consists of removable elastic bands, and the resistance can easily be increased or decreased.



Measurements have two purposes:

1. Confirm the scan accuracy

- Circumferences can help confirm if anything is "off" with the scan \rightarrow consistently bigger/smaller.
- 2. Define critical measurements that are difficult to assess on scan
 - Especially when there is a lot of soft tissue.
 - Knee center height and knee M-L are the two most critical measurements. Fit warranty may be withdrawn if those two measurements are not provided.

TO HELP YOU WITH CASTING, WE PROPOSE THE FOLLOWING TOOLS:



Casting platform

UU10101001001

Allows to replicate the shoe pitch in the cast.
Heel blocks must match the pitch of the shoe.
Toe ramp must be positioned at the base of the metatarsal heads.



Shoe caliper

UU10201001001

Allows to measure heel height & forefoot height.

Heel height - Forefoot height = Block height



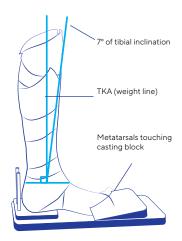
Caliper

0117092827

Allows to measure knee width.

The following guidelines are provided to help you obtain the most suitable shape capture. If any questions, feel free to contact our CPO team at the following address: cpo@thuasne.com

AFO CASTING GUIDELINES





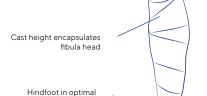
Fiberglass (recommended brands are C-Form from ST&G, Delta Conformable BSN, Delta Lite BSN and Össur Techform).

2. Recommended technique

- · Fiberglass casting.
- Use of a casting platform.

3. Position

- · Sitting on a chair.
- Using casting platform to replicate heel height and toe ramp (or another system allowing to replicate heel height and toe ramp).
- · Metatarsal touching the casting platform.
- Optimal sagittal alignment: correlates with heel height of the shoe (+/- 5° of the functional alignment).
- Optimal coronal alignment: to represent biomechanical goals (+/- 3° of functional alignment).
- Tibial inclination of 7°.



alignment

4. Cast length

· Mid-calf and captures all toes.

5. Cut strip

• Anterior on the dorsum of the foot to transition laterally.

6. Markings on the cast

- Fibula head, metatarsal heads, base of 5th metatarsal, navicular, medial and lateral malleoli, tibial crest, tibial tubercle.
- If applicable mark: deformity, scar tissue, and any other area of concern.
- Reference hash-marks on top of cutting strip.
- · Add patient's initials and clinic on cast.

7. Rigidity/Thickness

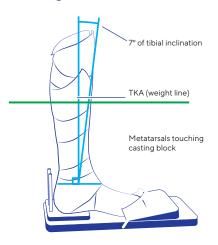
A minimum of 3 layers of fiberglass throughout the cast from proximal to distal end

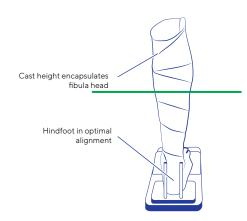


KAFO CASTING GUIDELINES

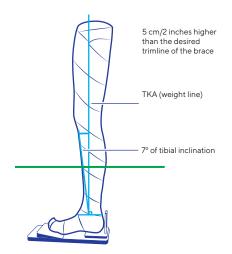
Two stage one piece casting

Stage 1 - Ankle Foot Section





Stage 2 - Knee Section



1. Medium

Fiberglass (recommended brands are C-Form from ST&G, Delta Conformable BSN, Delta Lite BSN and Össur Techform).

2. Recommended materials

- · 2 stages fiberglass casting.
- Use of a casting platform.
- Plastic wrap if needed (see below).

3. Position and technique

Stage 1- ankle foot section

- · Sitting on a chair.
- Using casting platform to replicate heel height and toe ramp (or another system allowing to replicate heel height and toe ramp).
- Metatarsals touching the casting platform.

Optimal sagittal alignment: correlates with heel height of the shoe (+/- 5° of the functional alignment).

Optimal coronal alignment: to represent biomechanical goals (+/- 3° of functional alignment).

- · Tibial inclination of 7°.
- Wrap from mid calf to toe ends.

Stage 2- above knee

- · Non-weightbearing.
- Sitting on the edge of a chair, or lying back on bed (patient will need to be moved carefully after stage 1).
- Wrap two layers round the upper edge of the finished ankle foot section and wrap up to higher than intended top height of KAFO.
- Terminal extension.
- Coronal and sagittal alignment must be within +/- 5° of the intended brace position* (*except in case of contracture).
- If there is a lot of soft tissue use plastic wrap to stabilise limb volume.

4. Cast length

Stage 1: mid-calf and captures all toes.

Stage 2: 2"/5 cm taller than the desired length of the brace (proximally).

5. Cut strip

Anterior on the dorsum of the foot to transition laterally.

6. Markings on the cast

AFO section - Outside of the cast

- Fibula head, metatarsal heads, base of 5th metatarsal, navicular, medial and lateral malleoli, tibial crest, tibial tubercle.
- If applicable mark: deformity, scar tissue, and any other area of concern.
- Reference hash-marks on top of cutting strip.
- · Add patient's initials and clinic on cast.

KAFO section - outside of cast

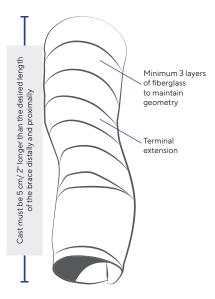
- · Fibula head, patella, medial & lateral condyle.
- $\boldsymbol{\cdot}$ If applicable mark: deformity, scar tissue, and any other area of concern.

7. Rigidity/Thickness

A minimum of 3 layers of fiberglass throughout the cast from proximal to distal end.



KO CASTING GUIDELINES



1. Medium

Fiberglass (any brand).

2. Recommended technique

Traditional technique.

3. Position

- · Non-weightbearing.
- ${\boldsymbol{\cdot}}$ Sitting on the edge of a chair.
- · Terminal extension.
- Foot in dorsiflexion: should naturally give a proper toe out.

4. Cast length

Cast must be 5 cm/2" longer than the desired length of the brace.

5. Cut strip

Posterior.

6. Markings on the cast

- Fibula head, patella, medial & lateral condyle (+ if applicable: deformity, scar tissue, and any other area of concern).
- $\boldsymbol{\cdot}$ Reference hash-marks on top of cutting strip.
- Add patient's initials and clinic on cast.

7. Rigidity/Thickness

A minimum of 3 layers of fiberglass throughout the cast from proximal to distal end.

Ordering/information

ORDERING (OFF-THE-SHELF AND CUSTOM PRODUCTS)

Our customer service teams are available to assist you when placing your orders or for any questions related to lead, delivery, payment time. Depending on the products you want (please refer to the product page and icon "order in" with the country of origin). Do not hesitate to reach out the entity from which you ordered the product.

For questions on products or if you need technical assistance for casting, scanning or any other inquiry, do not hesitate to reach out our CPO team: cpo@thuasne.com

For any product's returns or exchanges, please refer to the entity from which you ordered the product.

FOR SPRYSTEP® AFO-KAFO-KO RANGE - OFF-THE-SHELF AND CUSTOM

In case of failure with a SpryStep® AFO-KAFO-KO, please refer to the entity which sold you the device. A dedicated questionnaire will be provided. It will have to be returned fully completed, with or without additional picture(s) or video(s). An analysis will be conducted internally by our CPO team in order to understand the root cause of the failure and give you a recommendation if needed.

For custom products

Our custom devices are all made in Bakersfield, California, USA.



WARRANTY COMMERCIAL AGREEMENT AND WARRANTY LIMITATIONS

(Applicable for the following products only: SpryStep® Original – SpryStep® Flex – SpryStep® Plus – SpryStep® Max – SpryStep® Pediatric – SpryStep® One – SpryStep® custom – SpryStep® Vector – SpryStep® KAFO Vector – SpryStep® KO – UniReliever® – Rebel Reliever® – Rebel® Standard – Rebel® Lite – Rebel® Pro – Rebel® Lock – GenuPro Control)

Thuasne® offers a free, limited commercial warranty to the user, in the territory where the device was purchased, against defects in manufacturing and workmanship for a period of:

- · six months for the textile components;
- one year for the rigid components (two years only for the SpryStep® One).

The limited warranty is effective from the date of purchase of the product by the end-user.

The limited commercial warranty does not apply to any defects in manufacturing and workmanship in case of:

- any damage occurred by a usage outside the normal and intended use of the product as mentioned in the instructions for use,
- damages occurred as part of attempts to modify the product.

Any claim for this commercial warranty must be sent by the user to the entity where the product was purchased, which will forward this claim to the corresponding Thuasne® entity.

Any warranty claim will first be reviewed by Thuasne® to determine if the conditions of the limited warranty are fulfilled and do not fall into one of the cases of exclusion of the commercial warranty.

To benefit from the warranty, the buyer must mandatorily provide an original and dated proof of purchase of the product.

If the conditions of the limited warranty are fulfilled and the claim is made by the user or its legal representative (parents, guardian...) within the warranty delays indicated above, the buyer will get a new substitution product.

It is expressly agreed that this commercial warranty is in addition to the legal warranties binding the entity which sold the product to the user, in accordance with the applicable local legislation in the country of purchaseof the product.

For all off-the-shelf products listed in this catalogue and purchased by the consumer in a member state of European Union, the legal European warranty applies.

Outside the European Union, please refer to the applicable local legislation. For more information, please contact your local entity from which you ordered the product.

WINGS FOR YOUR HEALTH

Thuasne Export Department

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We reserve the right to modify our products as shown and described in this catalogue, without previous notice. Non-contractual photographs.

Please check the availability of products from your dealer.

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