

Orthopedic Braces

SLEEQ® Spinal Therapy System



SLEEQ® Spinal Bracing System manufactured by Quinn Medical is the world's most advanced spinal compression LSO (Lumbar Sacral Orthosis) brace on the market that truly enables a universal fit for a vast majority of patients in a single model. With one model, it dramatically reduces the hassle and cost of unwanted inventory, while its elegant, easy-to-use, and patient-friendly design offers best-in-class comfort and support for the lumbo-sacral region of the spine. Also available, the new SLEEQ® Flex, a flexible sagittal (anterior-posterior) control TLSO (Thoracic Lumbar Sacral Orthosis) brace. Both are non-pharmaceutical solutions for the relief of low back pain. PDAC approved for Medicare reimbursement.

SLEEQ's state-of-the-art tightening system makes it easy to achieve optimal compression for the most effective pain relief on the majority of patient profiles. Advanced eco-friendly materials promote air flow and breathability to keep patients cool and dry. The low-profile support system automatically conforms (cold molds) to a patient's anatomy for a custom fit, providing optimum comfort and support for pain management and promotes patient compliance.



Universal Fit • Elegant Design • Unparalleled Value

Proven Pain Relief › Lumbar braces significantly improve patient's functional status, pain level while reducing pharmacologic consumption

Universal Fit › You will always have the right size on hand even if your patients lose or gain weight, which also means you will dramatically reduce inventory costs (26" - 62"+ Waist).

Easy-To-Use › SLEEQ® is so simple to adjust and provides effortless comfort, control and support.

Metal-Free › Metal-free construction means it's medical imaging friendly.

Custom Fit › SLEEQ's AeroFlex™ support panels are designed with high density polyethylene that "cold-molds" to each patient's individual anatomy for a custom fit.

Breathable › SLEEQ's AeroFlex™ support panels promote airflow complementing SLEEQ's Q-Lex™ OrthoSport material to keep patients cool and clean.

Eco-Friendly › Repreve® certified recycled fibers in every SLEEQ® LSO and SLEEQ® TLSO brace.

Lightweight and Low-Profile › SLEEQ's elegant design is up to 50% lighter and thinner than most other leading compression braces on the market and provides for superior comfort and compliance. Can be worn discreetly under clothing, while ambulatory, seated or supine.

Made in the USA › Unlike other leading compression LSO braces, SLEEQ® is designed and manufactured right here in the United States!

(((SLEEQ)))
spinal • therapy • system



How Does the SLEEQ® Mechanical Compression LSO Work?

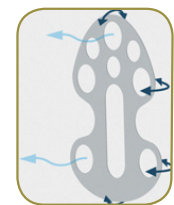
By pulling the ergonomically friendly pull tabs, the bearing assisted tightening mechanism compresses the lower back and abdominal areas while the AeroFlex™ support panels “cold mold” to form fit to the patient.

Benefits:

- Hydrostatic compression is easily achieved by the patient.
- No sharp edges - hands rejoice as they effortlessly engage low-profile, ergonomically friendly pull tabs
- Conforming support panel material promote airflow and ventilation to keep patients cool and clean
- Conforming support panels function to splint the anatomy adding mechanical stabilization as well as providing an important kinesthetic reminder for a patient to limit potentially injurious gross motion.
- Flexible and comfortable.
- Metal-free construction means it's medical imaging friendly



Low Profile Design for discreet wear under clothing.



SLEEQ's AeroFlex™ support panels promote airflow.

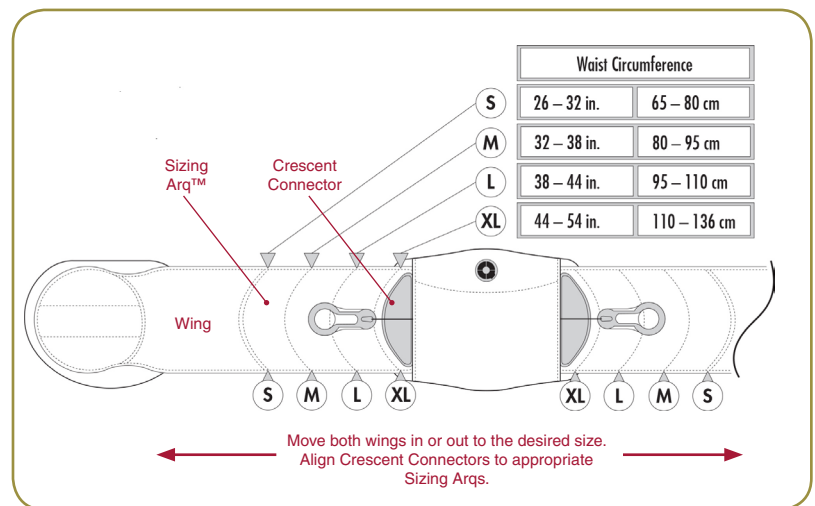
Universal Fit

Infinite Sizing with One Brace

Each SLEEQ® model adjusts to fit the vast majority of patients. Measurement is closely related to waist circumference. Four **Sizing Arqs™** (S, M, L, XL) provide landmarks for waist circumference and proper alignment. These act only as guides as there is infinite adjustability and customization options within the **Sizing Arq™** range.

Benefits:

- You will always have the right size on hand even if your patients lose or gain weight
- Nearly infinite girth adjustment & alignment is a breeze
- Fits a waist range of 26"– 54" waist with one model
- **SLEEQ® EXT extension panel** lengthens any SLEEQ® Spinal System brace to accommodate a waist circumference range of 54" - 62"
- No tools required and no cutting
- You will dramatically reduce inventory costs (only need one size on hand as opposed to inventorying several sizes to fit your patient base)



SLEEQ® Extension Panel



Contraindications:

- Pregnancy
- Pulmonary compromise or associated disease that may be altered by increased abdominal pressure, including diaphragmatic hernias or deep vein thrombosis.

SLEEQ® Spinal Therapy System Product Line:

SLEEQ® AP



Item #: BBL0627

PDAC
APPROVED

SLEEQ® AP is a low-profile sagittal (anterior-posterior) control compression brace:

- Ideal for a smaller framed patient and low lumbar issues
- Built with semi-rigid panels that function to splint the anatomy adding mechanical stabilization as well as providing an important kinesthetic reminder for a patient to limit potentially injurious gross motion.
- Covers L1-L5 of the spine (Lumbar Vertebrae)
- Sizes up to 26" - 54" (SLEEQ® EXT extension panel lengthens brace to accommodate a waist circumference range of 54" - 62")
- PDAC approved for Off-the-Shelf (OTS) under L0642 and Custom Fitted under L0627

SLEEQ® AP+



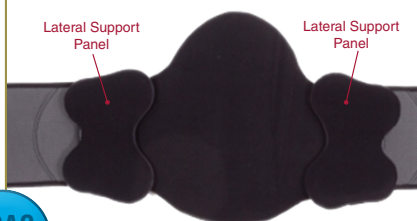
Item #: BBL0631

PDAC
APPROVED

SLEEQ® AP+ is an enhanced-profile sagittal (anterior-posterior) control compression brace:

- Ideal for taller profile patient (5 ft - 6 ft) and for low thoracic/lumbar issues
- Built with semi-rigid panels that function to splint the anatomy adding mechanical stabilization as well as providing an important kinesthetic reminder for a patient to limit potentially injurious gross motion.
- 14" back panel extends higher
- Covers T9-S1 of the spine (half of the Thoracic Vertebrae, all of Lumbar Vertebrae and Sacrum)
- Sizes up to 26" - 54" (SLEEQ® EXT extension panel lengthens brace to accommodate a waist circumference range of 54" - 62")
- PDAC approved for Off-the-Shelf (OTS) under L0648 and Custom Fitted under L0631

SLEEQ® APL



Item #: BBL0637

PDAC
APPROVED

SLEEQ® APL is **SLEEQ® AP+** with the addition of two rigid side panels that increase lateral support for patients requiring additional stabilization as part of their treatment.

- Ideal for taller profile patient (5 ft - 6 ft) and for low thoracic/lumbar issues
- 14" back panel extends higher
- Includes two rigid lateral support panels that function to splint the anatomy adding mechanical stabilization as well as providing an important kinesthetic reminder for a patient to limit potentially injurious gross motion.
- Covers T9-S1 of the spine (half of the Thoracic Vertebrae, all of Lumbar Vertebrae and Sacrum)
- Sizes up to 26" - 54" (SLEEQ® EXT extension panel lengthens brace to accommodate a waist circumference range of 54" - 62")
- PDAC approved for Off-the-Shelf (OTS) under L0650 and Custom Fitted under L0637

SLEEQ® FLEX



Item #: BBTLSO

PDAC
APPROVED

SLEEQ® FLEX offers all the benefits of LSO products in a TLSO design that maximizes patient comfort, control and compliance.

- Ideal for taller profile patient (5 ft - 6 ft) and for low thoracic/lumbar issues
- 18.5" back panel
- Telescoping posterior thoracic extension makes donning and doffing a cinch with well padded and breathable shoulder control straps that remind patients to extend their thoracic spine by using their own muscles.
- Lightweight and low profile
- Covers T3-S1 of the spine (Scapular Spine T3 through Sacrococcygeal Junction)
- Sizes up to 26" - 54" (SLEEQ® EXT extension panel lengthens brace to accommodate a waist circumference range of 54" - 62")
- PDAC approved under L0456

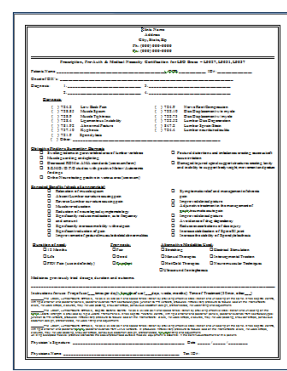


SLEEQ® EXT extension panel lengthens any SLEEQ® Spinal System brace to accommodate a waist circumference range of 54" - 62".

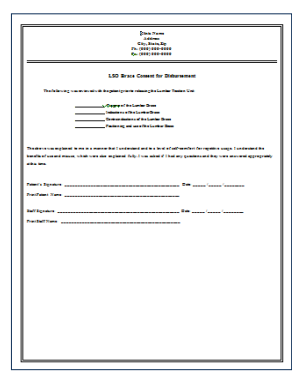
Marketing Tool-Kit:

Roscoe Medical offers a number of tools to assist you in building your referral base:

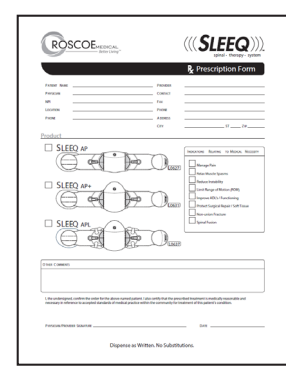
- Customizable “**Letter of Medical Necessity**” for the physician to complete.
- Roscoe “**Prescription Sheet**”
- Customizable “**Delivery Acceptance**” Letter
- **Point-of-Purchase Mannequin Display** that holds 25 patient brochures
- **25 Patient Brochures** with an area on the back which allows for you to label with your personal HME/Provider information (standard Avery 5160 Address Label)



Letter of Medical Necessity



Delivery Acceptance



Prescription Sheet

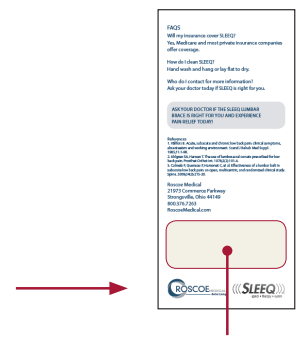
SLEEQ-KIT:



Mannequin Display



Patient Brochure



BACK of Brochure
Add your own label with your HME/Provider Information (Avery Address Label 5160)

Item #	Description	Dimensions	Weight	Qty
BBL0627	SLEEQ® AP (All-in-one LSO back brace)	14" x 12" x 4"	3 lb	each
BBL0631	SLEEQ® AP+ (All-in-one enhanced profile LSO back brace)	14" x 12" x 4"	3 lb	each
BBL0637	SLEEQ® APL (All-in-one enhanced profile LSO back brace with Lateral Supports)	14" x 12" x 4"	3 lb	each
BBTLSO	SLEEQ® FLEX (All-in-one enhanced profile TLSO back brace)	20" x 14" x 6"	4 lb	each
BBLSOEXT	SLEEQ® Extension Panel (to accommodate a waist circumference range of 54" - 62")	11" x 7" small mailer	1 lb	each
SLEEQ-KIT	SLEEQ® Marketing Tool-Kit (Mannequin Display + 25 Patient Brochures)	n/a	n/a	each

Coding and Reimbursement

SLEEQ® is PDAC approved & reimbursed by Medicare and all private & worker's comp insurances. Medicare (in LCD) reasons that justify prescribing back braces are as follows:

- To reduce pain by restricting mobility of the trunk (T1-S1)
- To facilitate healing following an injury to the spine or related soft tissues
- To facilitate healing following a surgical procedure on the spine or related soft tissue
- To otherwise support weak spinal muscles and/or a deformed spine

PDAC Code	Medicare Floor	Medicare Ceiling
L0457 (OTS)	\$346.36	\$461.82
L0642 (OTS)	\$378.34	\$416.18
L0648 (OTS)	\$944.87	\$ 1039.33
L0650 (OTS)	\$988.78	\$1290.74
L0627 (Custom Fitted)	\$346.36	\$461.82
L0631 (Custom Fitted)	\$865.02	\$1,153.37
L0637 (Custom Fitted)	\$988.78	\$1,318.37
L0456 (Custom Fitted)	\$837.85	\$1,117.14

Local Coverage Determination (LCD) for Spinal Orthoses: TLSO and LSO (L11470)

Contractor Information		
Contractor Name HNIC, Corp. Back to Top	Contractor Number 16003	Contractor Type DME MAC
LCD Information		
Document Information LCD ID Number L11470	Primary Geographic Jurisdiction Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey - Entire State Pennsylvania Rhode Island Vermont	
LCD Title Spinal Orthoses: TLSO and LSO	Contractor's Determination Number TLSO	AMA CPT/ADA CDT Copyright Statement CPT codes, descriptions and other data only are copyright 2010 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology (CDT) (including procedure codes, nomenclature, descriptions and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.
	Overweight Region Region 1	DME Region LCD Covers Jurisdiction A
	Original Determination Effective Date For services performed on or after 10/01/1993	Original Determination Ending Date
	Revision Effective Date For services performed on or after 01/01/2010	Revision Ending Date
CMS National Coverage Policy None		
Indications and Limitations of Coverage and/or Medical Necessity For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category; 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.		

Off-the-Shelf vs. Custom Fitted:

Off-the Shelf (OTS) codes were established for competitive bidding purposes when such products are furnished to a patient and only require minimal self-adjustment.² Custom Fitted codes require that the item has been **trimmed, bent, molded, assembled, or otherwise customized to fit a patient by an individual with expertise.**¹ The difference between furnishing an item OTS or Custom Fitted are provided for under CMS regulations at 42 CFR 414.402 that define the term "minimal self-adjustment" to mean an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.²

Products like SLEEQ® that require customization are eligible to be billed under the "Custom Fitted" code when fitted by an individual with expertise or specialized training. PDAC stated that products like SLEEQ® are also eligible to be billed under the new corresponding OTS codes when they are furnished with minimal self-adjustment. A PDAC verification letter for the new OTS code is not required for products like SLEEQ® that are already verified under the corresponding Custom Fitted codes. PDAC stated that the CMS published Crosswalk is sufficient for these purposes.³ Codes affecting SLEEQ® are shown above.

Quinn Medical Product Training and Fitting Certification

Quinn Medical offers a curriculum created by an ABC certified orthotist to ensure you receive specialized training in the proper measurement, customization, application, and patient education when furnishing the SLEEQ® Spinal Therapy System.



Billing information and Citations provided by Quinn Medical:

¹ Medicare Pricing, Data Analysis and Coding (PDAC), Noridian Healthcare Solutions. <http://www.dmpdac.com>

² Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Learning Network® (MLN) Matters Number: MM8531, December 13, 2013, Effective: January 1, 2014.

³ Quinn Medical phone conversation with PDAC representative (Casey) on February 19, 2014 at 11:21 AM PST. PDAC Contact Center: 877.735.1326

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