

Title	Rosidal® 1C Pilot PMCF study A monocentric, prospective, randomized controlled trial in healthy volunteers									
Project code/number	2023-05									
Version and date	1.0 – 15.05.2024									
Name of sponsor/SRN	Lohmann & Rauscher GmbH & Co. KG Irlicher Straße 55, 56567 Neuwied, Germany									
Participating Centers and Countries	PI Prof. Dr. Valentina Dini Department of Clinical and Experimental Medicine, University of Pisa - UOC Dermatologia Universitaria - Santa Chiara Hospital – AOUP, Via Roma n. 67, 56126 Pisa Italy Phone: + 39 50 992660 e-mail: valentina.dini@unipi.it https://www.medmcs.unipi.it									
Rationale	Rosidal 1 C is a new compression bandage after CE certification. The pilot study aims to evaluate sub bandage pressures reached with this new L&R One Component Compression Bandage Rosidal 1 C in human beings in comparison to Urgo K1. Particularly, the maintenance of a therapeutically relevant compression pressure over the course of 7 days shall be studied. Additionally wearing comfort and skin protection will be evaluated.									
Investigational device	Rosidal 1C compression bandage Ref number(s) <table><tr><td>162154</td><td>8 cm x 6 m / 1piece</td></tr><tr><td>162155</td><td>8 cm x 6 m / 6 pieces</td></tr><tr><td>162156</td><td>10 cm x 6 m / 1 piece</td></tr><tr><td>162157</td><td>10 cm x 6 m / 6 pieces</td></tr></table>		162154	8 cm x 6 m / 1piece	162155	8 cm x 6 m / 6 pieces	162156	10 cm x 6 m / 1 piece	162157	10 cm x 6 m / 6 pieces
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	Manufacturer: Lohmann & Rauscher International GmbH & Co. KG Westerwaldstraße 4, 56579 Rengsdorf Germany
Basic UDI-DI	4021447-0002-JQ
Development Stage	CE-marked
Investigational device description	Rosidal 1 C is a new compression bandage system combining a skin protection, padding and compression in one single bandage. It is a textile elastic bandage with a short stretch for compression of the extremities and additional inherent padding properties. This way it can serve as a one component device. When applied the bandage develops a low resting pressure and a high working pressure, by which compression of the deep venous system (upon movement by the patient) is assured. The all-in-one short-stretch bandage is used for the treatment of phlebological indications and can be used quickly and easily. Rosidal® 1C is available in two versions (8 cm, 10 cm) and in different pack sizes. The product is made of 48% polyamide, 41 % cotton, 7% polyester and 4% elastane.
Intended Purpose	Rosidal 1C is intended for compression, retention of dressings, support and relief and for immobilization of limbs.
Indications	Rosidal 1C is to be used in phlebological diseases like varicosis, venous insufficiency, thrombophlebitis, phlebothrombosis, post-thrombotic syndrome, stage I to III b chronic venous insufficiency according to Widmer, venous and mixed ulcers, oedema (phleboedema, post-traumatic, post-operative, during pregnancy), after sclerotherapy and venous surgery as well as in contusions, sprains, tendon injuries and joint dislocations.
Intended patient population or subjects	In this pilot study the investigational device will be examined with apparently healthy adult volunteers. Applicable with an ankle brachial pressure index (ABPI) above 0.8 and below 1.3

Intended users	Healthcare professionals and lay persons who are initially instructed by healthcare professionals.
Intended environment	In- and outside settings of healthcare institutions
Contraindications	Advanced peripheral arterial occlusive diseases, congestive heart failure, septic phlebitis, phlegmasia cerulea dolens, sensation disorders of the skin, known allergies and/or hypersensitivity to any of the product components. ABPI < 0.8 and > 1.3
Name of Comparator	Urgo K1 A single-layer, multi-component compression system made of polyamide, elastane and polyester yarns bonded together using 3D weaving technology. Manufacturer: URGO GmbH Justus-von-Liebig-Straße 16 D-66280 Sulzbach, Germany
Study design	
Study objectives	Primary objectives: To evaluate sub bandage pressures over the course of 7 days (day and night) Secondary objectives: To assess the sub-bandage resting pressure up to day 7, the wearing comfort and tolerance and skin protection. To collect and assess any adverse events that may occur compared to the comparator device Urgo K1.
Endpoints	Primary endpoint: The percentage of subjects with static stiffness index $SSI \geq 10$ mm Hg (SSI = sub-bandage pressure difference between active standing and lying) Secondary Endpoints: Sub-bandage resting pressure ≥ 20 mm Hg up to day 7 Percentage of subjects with resting pressure ≥ 40 mm Hg up to day 7

	Tolerance: Rating and percentage of respondents on sensation of heat, sweating, burning, itching, tickling, pain, tactile sensation. Tolerance: 4-level scale: none (1)-slight (2)-moderate (3)-severe (4): $\geq 60\%$ slight ($< 40\%$ moderate or severe) at day 7 Comfort: Rating and percentage of respondents on immobility of the ankle joint, slippage and/or loosening of bandage, comfort when sleeping, sitting and walking, wearing normal shoes - Comfort: 6-level scale: The wearing comfort.. during day/during night is rated in six-level scale from excellent (1), very good (2), good (3), acceptable (4), poor (5), and insufficient (6) ($> 60\%$ acceptable at day 7) Slippage of bandage in cm since start of application is max 5 cm after 72 h Getting feedback on soft padding effect and aesthetics of the bandage. Frequency and severity of skin changes; Number and severity of device related adverse events - compared to comparator device.
Inclusion criteria	- Apparently healthy volunteers ≥ 18 years - Healthy intact skin with no clinical signs of chronic venous insufficiency and no signs of any dermatological condition such as eczema or psoriasis as assessed by investigating physician - Ankle circumference 18 to 25 cm (2 cm above ankle)
Exclusion criteria	- Known sensitivity to the study products (Rosidal 1C or Urgo K1) or any of their components - ABPI < 0.8 or > 1.3 - Venous echo-Doppler with recognizable abnormalities - History of - malignant ulcer - clinically infected wound

	○ peripheral arterial occlusive diseases, ○ cardiac insufficiency or cardiac disease such as congestive heart failure, coronary artery disease, myocardial infarction, coronary artery bypass graft ○ cerebrovascular disease ○ liver or renal disease ○ septic phlebitis, ○ phlegmasia coerulea dolens, ○ sensation disorders of the skin ○ eczema, psoriasis ● Pregnancy or breast feeding ● Use of diuretics, antihypertension or drugs that influence the capillary infiltration ● Comorbidities that could affect compression therapy, particularly diseases causing oedema ● Participation in an interventional clinical trial within the last 3 months and during participation in this study ● Patient is analphabet ● Reliable severe malnutrition ● BMI > 30 kg/m² ● CEAP ≥2 (chronic venous insufficiency) ● Diabetes Mellitus ● Ankle circumference < 18 or > 32 cm	
Cohort size	● 25 healthy volunteers	
Overall study duration	Study duration:	4.5 to 5 months
	Distributed among:	
	Study set up phase: (familiarization with investigational device and measuring method of sub-bandage pressure)	2 weeks
	Proband recruitment::	2 months
	Data validation, database lock, statistical analysis, study report:	2 months
Methodology	The investigational device will be randomly applied to one of the subjects' lower limbs, the comparator device on the other limb. Randomization is done computerized and independently from investigation site (closed	

	envelop method). Subjects will wear bandages throughout day and night for 7 days. A pressure transducer is being used to measure the sub bandage pressure. The transducer will be placed on the anatomical position B1 on the medial aspect of the lower leg at the transition of the gastrocnemius muscle into the Achilles' tendon (proximal to the inner ankle) prior to the application of the bandages. The transducer remain in this position throughout the study at both legs. The sub bandage pressure at rest and working will be measured and registered immediately after bandage application at day 0, and then at days 1, 3, and 7. In addition slippage of bandage will be measured. Subjects will be asked for wearing comfort and quality of life at day 0,1 and the last visit. Skin will be assessed for any changes or distinctive features at day 0 and last visit. Adverse events will be recorded.
Statistical methods	Statistical analysis will be performed using descriptive statistical methods. Descriptive statistics will be presented as frequency and percentages for categorical variables and as frequency, mean, and standard deviation, median with first and third quartile, and minimal and maximal value for continuous variables. Results for assessment of primary endpoint (percentage of subjects successfully reaching endpoint of SSI ≥ 10 at day 7) will be presented along with respective one-sided confidence intervals for percentage. The number of missing values will be reported in respective tables. In exploratory analyses, to compare results of the continuous endpoints between subgroups, in case of two groups Student's t-test or non-parametric Mann-Whitney U test, in case of more than two groups ANOVA or Kruskal-Wallis test will be applied. Categorical endpoints results will be compared between subgroups using Pearson chi-square test of Fisher exact test. For the analysis of changes of parameters in time paired tests (Student's or Wilcoxon for continuous data and McNemar for categorical data) will be used.
Sample size calculation	The study design is explorative. No study hypothesis are defined. The primary endpoint is a metric endpoints (sub-bandage pressure in mm Hg). The difference of

	the sub-bandage pressure by the investigational and by the comparator device is estimated to be small and a the relative effect size was assumed (0.1 – 0.3). For a 80% power the sample size was estimated to be n =40 and 20 per arm (n= 20 investigational device, n = 20 comparator (control) device). Assuming a drop-out rate between 25% a sample size of 25 subjects is recommended.
Insurance	As the product is marketed and the study will be performed according to the IFU without additional measures, no additional insurance – beside the product insurance of the company - is necessary.
Name and address of responsible/leading ethics committee	Bioethics Committee University of Pisa
Name and address of responsible authority	Not applicable