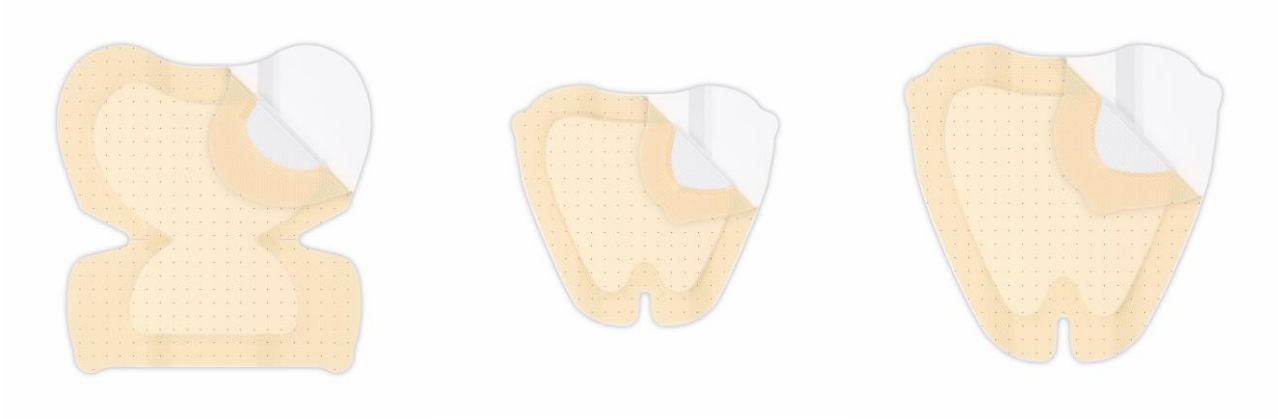
Askina® DresSil Active Sacrum & Heel

Product Data Sheet



Administrative information	
Legal Manufacturer	Winner Medical Co. Ltd. Winner Industrial Park,No 660 Bulong Road, Longhua District, 518109 Shenzhen, China
Importer	B. Braun Avitum AG, Schwarzenberger Weg 73-79, 34212 Melsungen, Germany
Product management	Wound Management
Last Update	30/05/2025

Description, composition and properties of the device	
Trade Name	Askina® DresSil Active Sacrum & Askina® DresSil Active Heel
Reference	WIN5592205; WIN5491605; WIN5492105
Medical Class	Class IIb (MDR)
Description of the device	Askina® DresSil Active Sacrum & Heel are silicone foam dressings with border, that improve absorption and retention by the combination of a foam and superabsorbent layer. They absorb exudate through silicone perforations from the wound and provides a moist wound healing environment to promote wound healing. The silicone wound contact layer reduces pain and trauma during dressing changes and enhances patient's comfort. The waterproof outer layer protects the wound from dirt and bacteria.
Composition of the device	Polyurethane film backing Super absorbent fibers Non-woven fabric Polyurethane foam Silicone net Release film

Key drivers & Indications	
Key drivers	Good absorption and retention Maintains a moist wound environment Minimizes pain during dressing changes Easy application and removal Breathable Does not adhere to the wound bed
Intended Purpose	Askina® DresSil Active Sacrum & Heel are wound dressings that absorb wound exudate and provide a moist wound healing environment to promote wound healing. Askina® DresSil Active Sacrum & Heel can also prevent pressure ulcer.
Indications	Askina® DresSil Active Sacrum & Heel are designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. It can also be used on dry/necrotic wounds in combination with gels. The dressing can reduce post operative blistering and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.
Precautions of use	Askina® DresSil Active Sacrum & Heel are contraindicated in: • Check the wound for signs of infection before use, if infection occurs, see a health care professional. • Do not use on the patients with a known hypersensitivity to the product itself or to its components. • Do not use on third degree burns. Warnings: • Do not reuse. Reuse will cause cross-contamination. • Do not use if package is damaged or open. • Do not use together with oxidizing agents such as hypochlorite solutions or hydrogen peroxide. • Due to the gentle adhesive used, do not use this dressing to secure other medical devices to the patient. • If reddening or sensitization occurs discontinue use and see a healthcare professional.
IFU: Yes/No	Yes
Reusable/single use device	Single use device

Sterilization process	
Sterile: Yes/No	Yes
Sterilization method	Ethylene Oxide (EO)

Conservation and storage conditions	
Storage conditions	The product should be stored in dry conditions. Keep the product away from direct sunlight and keep dry.
Transport conditions	The product should be transported in dry conditions. Keep the product away from direct sunlight and keep dry.
Shelf life	3 years

Safety in use	
Technical: MRI, X-ray detectable	N/A
Biocompatibility	Biocompatibility studies showed the device has no indication of eliciting the following responses: Cytotoxicity Irritation or sensitization Systemic Toxicity Local effects after implantation

Standards List	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 15223-2: 2010	Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
EN ISO 10993-1: 2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11: 2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-6: 2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-11: 2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 11135: 2014/ A1: 2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release
ISO 10993-7: 2008/Amd 1: 2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants

Packaging & references

Reference	Description	Size	Box Quantity
WIN5592205	Askina® DresSil Active Heel	23,5 x 24,5 cm	5
WIN5491605	Askina® DresSil Active Sacrum	18 x 20 cm	5
WIN5492105	Askina® DresSil Active Sacrum	23 x 23 cm	5

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