

**White paper on user observation* of the 'Leyla'
postoperative bra from the Amoena Recovery Care
product line**

*conducted in the period May-July 2019 under specialist medical supervision

We are seeing an increasing tendency in the number of interventions on the female breast. In addition to tumour surgery, oncoplastic and reconstructive surgery, the number of aesthetic procedures is also growing continuously.

Regardless of the type and extent of the operation, appropriate compression, immobilisation, support and relief of the operated breast are necessary for optimal wound healing and stabilisation of the surgical result.

This can be achieved with a specially designed postoperative recovery care bra that meets these requirements with maximum safety and proven ease of use.

At the same time, the product should also meet the comfort requirements of patients and thus play an important role in a positive healing process.

This white paper examines the results of an observational study of the Amoena Recovery Care product range conducted under specialist supervision in 2019 with regard to 'compression of chest belts and/or compression bandages by adjustment' as well as the 'verifiable securing in the post-treatment period'.

Our product was developed to achieve the best possible stabilisation of the operated breast tissue and at the same time the highest possible wearing comfort for the patient.



Fig.

The 'Leyla' postoperative bra enables precise fitting thanks to seamless technology and visual sizing, and our prewash and disinfection process means it is prepared for direct clinical use.

Positive effects of postoperative use of recovery care

Breast cancer is by far the most common cancer among women in Germany and generally in countries of the industrialised world. ¹

Depending on the injury to tissue, three phases of wound healing can be distinguished medically

- **Exudation** (inflammation phase)
- **Proliferation** (granulation phase)
- **Regeneration** (reparative phase)

At all stages of wound healing, recovery care products have a positive effect, helping to achieve undisturbed and therefore better healing.

In the **exudation phase**, postoperative oedema and haematomas can be reduced, lymph drainage promoted and the tissue held in position from the outside, both when standing and lying down. The physiological processes of wound healing can thus run optimally, the postoperative pain during movement can be reduced and the necessary wound rest can be ensured due to the high wearing comfort.

During the **proliferation phase**, the immobilisation of the healing tissue supports the formation of fragile cell structures and thus creates the best conditions for the regeneration phase.

In the **regeneration phase**, recovery care products support the remodelling of the healing tissue and thus make a decisive contribution to the functional and aesthetic result of the breast surgery.

This positive support of the wound healing process not only improves patient comfort but also shortens regeneration time. ²

Higher wearing comfort with consistent support after breast operations

With the 'Leyla' postoperative bra, part of the seamless product family of the Amoena Recovery Care range, the focus is on relief, appropriate anatomically adapted compression and stabilisation of the breast without impairing blood circulation and at the same time maximum patient comfort in the healing phase. Our goal in developing 'Leyla' was to offer a user-friendly bra for patients, doctors, clinical professionals and medical supply stores alike. Precise fit and fitting characteristics through seamless technology, double sizes and universal cup shapes as well as simple visual size determination make it easier for users to determine the optimum bra. 'Leyla' is pre-washed for disinfection, packed in a peel bag in a protective atmosphere as a germ and bacteria barrier, and meets the hygiene standards for use in the operating theatre. It can thus be removed from the packaging immediately after the operation in the operating theatre and applied to the patient.

An optimal fit is achieved by the seamless circular knitting technique bustier styling, which adapts well to the chest. This prevents the bra from slipping when the patient is lying down or moving. The wide, adjustable straps avoid pressure points in the shoulder area. The hook-secured zipper on the front of the bra enables both the patient and the nurse to easily and effortlessly open the bra when changing bandages and putting it on and taking it off. The soft, breathable fabric with woven-in compression zones at anatomically and physiologically important points on the lateral thorax and back support the lymph drainage channels.

Easy determination of the correct bra size

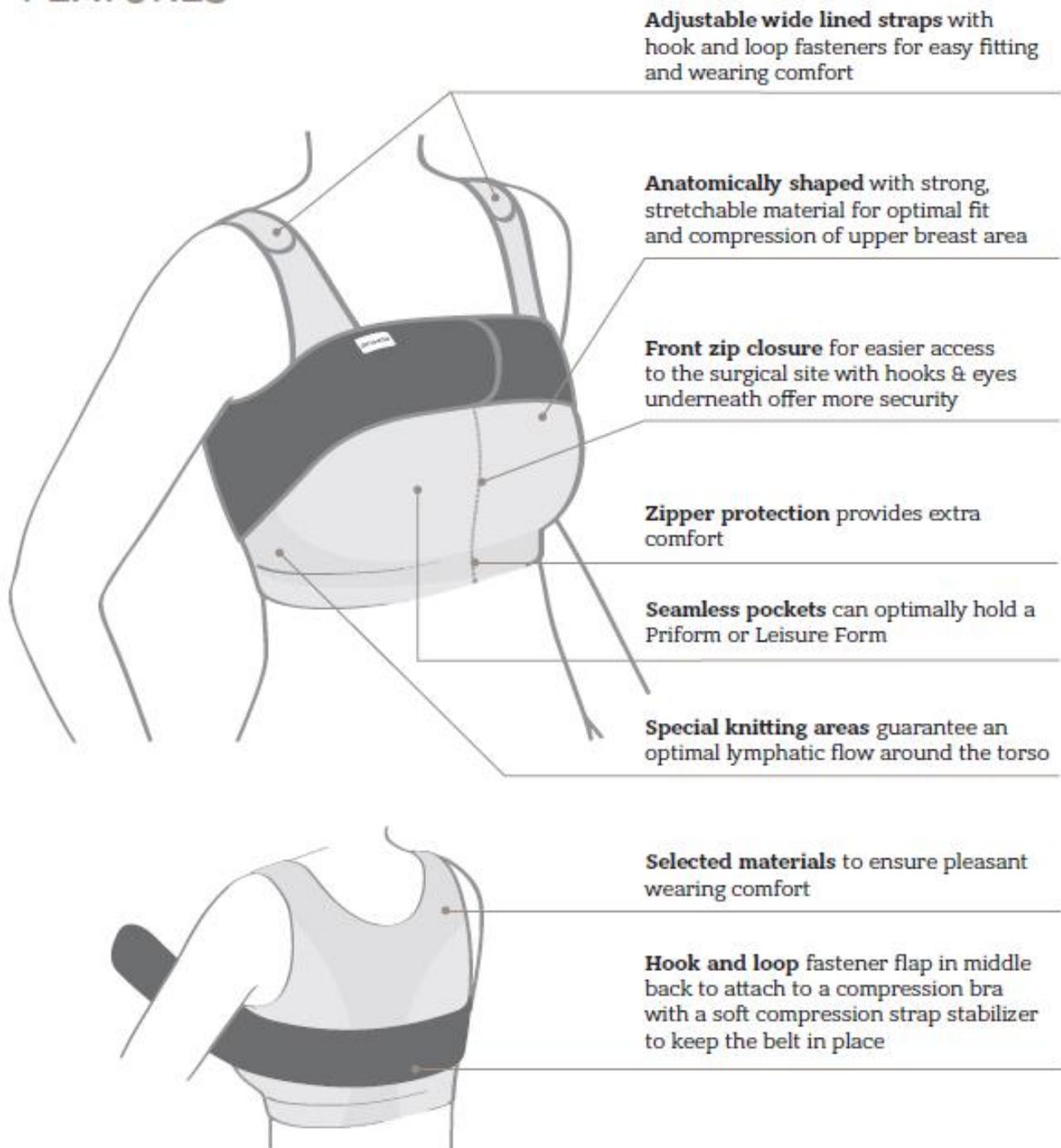
Thanks to visual sizing, it is quick and easy to determine the correct fit of the postoperative bra for the patient. With maximum inhalation, the patient's underbust measurement is taken. This is then matched to a colour and symbol, which clearly assigns it to the appropriate bra size. This information is located on both the primary and secondary packaging. The seamless technology enables universal cup sizes and adapts individually to breast size and shape.

Characteristics and clinical benefits

We have developed 'Leyla' with the aim of achieving the best possible surgical result while at the same time ensuring easy handling and the greatest possible patient comfort.

Seamless technology and visual sizing enable accurate fitting and 'Leyla' is also prepared for direct clinical use thanks pre-washing and disinfection process.

FEATURES



User Study

Parameters

Test method:	Recording the subjective sensation using the above-mentioned product with the help of a structured questionnaire in a suitable patient group.
Patient collective:	Test subjects after breast conserving tumour surgery, oncoplastic surgery, mastectomy, breast reconstruction with own tissue and implants, aesthetic breast augmentation and breast reduction.
Exclusion criteria:	Ongoing radiotherapy (primary exclusion criterion) Unstable, open wound conditions (primary exclusion criterion)
Test duration:	30 consecutive days (daily wearing time 24 hours)

The application test included the following steps:

- Determination of suitable test subjects and establishment of contact on the basis of the defined patient collective and the primary exclusion criteria.
- After approval for participation, a suitable bra size from the product range to be tested was selected in a fitting process by the attending physician for the respective test person.
- Each test subject received a test bra with instructions for their own use for 30 days at home.
- A questionnaire was sent to the respondents to answer after the end of the test period without prior knowledge of the questions.
- A second questionnaire was sent to the attending physician to answer after completion of the test without prior knowledge of the questions.
- The respondents were responsible for wearing the bra themselves.

The patient questionnaire contained 20 statements, which were filled in by the test subjects after the end of the test period by marking given answer options. The questionnaire for physicians contained 16 statements, which were filled in by the physicians after the end of the test period independently by ticking given answer possibilities. The statements serve to determine the degree of fulfilment of requirements 1 and 2 of the test bra.

Statements used:

1. Compression of chest belts and/or compression bandages by means of adjustment.
2. Proven assurance of the surgical result in the necessary follow-up treatment.

Key findings

All participating doctors used this test bra for women who had undergone various breast operations.

Visual sizing and fit

100% of the physicians were convinced by the visual sizing, both regarding the accuracy of the method and its easy handling. The fit was also 100% convincing.

Prewashing, disinfection and preparation in a clean environment (for direct clinical use)

This criterion was evaluated 100% by the participating physicians as very true.

Immobilisation and stabilisation of the breast

In each case 100% of the doctors and patients confirmed the assumptions as very true with regard to the immobilisation and stabilisation of the breast by the 'Leyla' bra, especially when lying down. The patient's freedom of movement during the wearing period is not restricted and no pressure is exerted on the breast tissue by the compression bra.

Handling

More than 90% of all study participants (patients and physicians) rated the handling of the postoperative bra with regard to tightening and closing, as well as the opening and pulling out and the slip resistance of the straps, as very good.

Skin compatibility and wearing comfort

95% of all testers did not feel constricted by wearing 'Leyla' and rated the wearing comfort as pleasant and the skin compatibility as good. The material feels pleasant on the body and back. No additional perspiration could be detected.

The skin compatibility also convinced 95% of the participating physicians.

Inference

After breast operations, regardless of type and extent, postoperative care is necessary. In addition to the sterile dressing of the wounds, the breast must be stabilized, redressed and relieved without impairing tissue circulation and the patient's well-being. This is only possible to a limited extent with circular dressing techniques, as these slip quickly, negatively affect the patient's freedom of movement and can lead to unwanted pressure points. The user test showed that ‚Leyla‘, a bra specially designed for postoperative treatment, meets all medical requirements in every respect.

An optimal fit is achieved by the seamless circular knitting technique in bustier styling and the bra adapts well to the chest. This prevents the bra from slipping while the patient is lying down or moving. The wide, adjustable straps can also be used to counteract the development of pressure points in the shoulder area. In the first six weeks after the operation, simple, effortless opening is required by the patient and the practitioner for dressing changes as well as for dressing and undressing. This requirement is met by ‚Leyla‘ thanks to the hook-secured zipper on the front of the bra. The soft, breathable fabrics with woven-in compression zones at anatomically and physiologically important zones on the lateral thorax and back also support the lymph drainage channels.

The bra applied immediately after the breast surgery fulfilled all medical requirements regarding immobilization, stabilization and redressing for optimal wound healing with maximum comfort for the patients for the entire duration of the postoperative treatment, i.e. until wound healing is completed after the sixth postoperative week.

The results of the clinical observational study confirm a high level of acceptance and patient satisfaction on the one hand and a medical benefit on the other.

Source:

¹ www.krebsinformationsdienst.de/tumorarten/brustkrebs/was-ist-brustkrebs.php

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