Instructions for Use
80458-9 — 2022-01
EN

bess|rhino Thermo-Splint

Thermoplastic Nasal Splints



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63050394884440075 —25.01.2022 09:54

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1 About these Instructions for Use

1.1 Symbols Glossary

Symbol	Description
	Caution: Consult Instructions for Use
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Use-by date
	Do not re-use
	MR safe
	Medical device
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Quantity per packaging unit
	Manufacturer
	Distributor
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).

Table 1: Symbols Glossary

1.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

NOTICE

Product damage or other damage may occur in case of non-compliance.

1.3 Additional Information

Download link for these Instructions for Use:[1)]	https://www.besspro.eu/ifu/80458

[1)] Updated on an ongoing basis.

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use. Otherwise there are risks to the health of your patient.

ATTENTION: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

3 Product Codes / REF

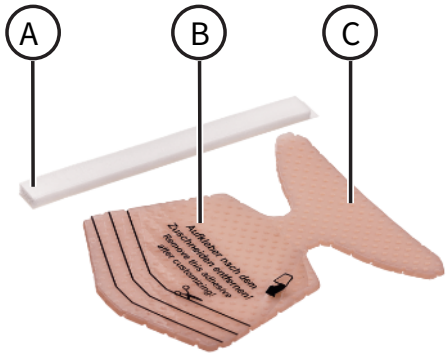
[▸General information, page 4]

4 Scope of Delivery

- 10 x nasal splint and one padded strip

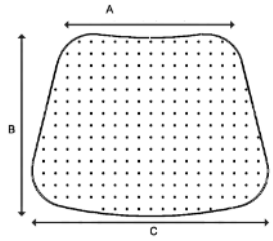
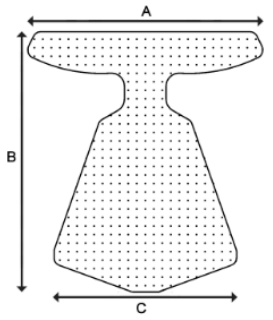
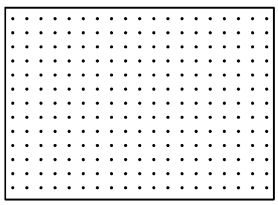
5 Product Description

5.1 General information



A	Padding
B	Nasal splint
C	Forehead flange (depending on specifications)

- Both sides can be used
- Preshaped / trimmable (depending on specifications)

	BM 12 1301	A: 32 mm B: 39 mm C: 52 mm
	BM 12 1302	A: 34 mm B: 43 mm C: 62 mm
	BM 12 1304	A: 70 mm B: 80 mm C: 60 mm
	BM 12 1305	A: 70 mm B: 95 mm C: 70 mm
	BM 12 1303	50 x 70 mm
	BM 12 1306	70 x 100 mm

5.2 Structure and Operation

The product consists of a nasal splint made of thermoplastic material and a double-faced adhesive pad. The splint is fixed to the bandaged nasal bridge with the help of the pad and thus stabilizes the nasal bridge externally.

5.3 Materials

- Plastic

Not made with natural rubber (latex).
No products made with natural rubber (latex) are used in the production process.

5.4 Other Devices to be Used in Combination with the Device

Apart from the equipment and materials required for placement, the product bess|rhino Thermo-Splint is not intended to be used in conjunction with any other products.

6 Intended Use

6.1 Intended Purpose

External splint to stabilise the nasal bridge.

6.2 Indications

- Rhinoplasty
- Trauma

6.3 Contraindications

There are no known contraindications.

6.4 Patient Target Group

The product is suitable for use in the following patient groups:

- Infants and young children
- Children and youth
- Adults
- Patients of all genders

6.5 Intended User

The intended user is a physician with experience in treating similar cases with this product or with comparable products or a physician with the following speciality:

- ENT (otorhinolaryngology)
- Oral and maxillofacial surgery

6.6 Expected Lifetime

Expected lifetime: 29 days
Maximum application duration: 29 days

6.7 Intended place of use

- Operating theatre
- Treatment room
- Examination room
- Examination room

It is the responsibility of the user to decide on a case-by-case basis which precautions must be taken for any complications that may arise.

7 Expected Clinical Benefit

Improved wound healing.

8 Possible Complications and Side Effects

There are no known complications or side effects.

9 Combining with Other Procedures

The product is MRI safe.

10 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in unopened original packaging.

11 Processing

NOTICE

- Single use product: Do not process (e.g., clean, disinfect) or reuse.
  This is the only way to ensure product functionality. Due to the mechanical properties of the product, processing may lead to material degradation.

12 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product are damaged or expired.
  This is the only way to ensure product functionality.

12.1 Required Equipment and Materials

- Tape with a highly textured surface

- Water bath, 70 °C

12.2 Placement

ATTENTION: Ensure that in situ the product does not come in contact with the skin.

1. Tape the nose in layers. [▸Tape (Ill. left), with nasal splint (Ill. right), page 6]
2. Remove the protective film from the padding. Apply the padding from the root to the tip of the nose onto the tape.
3. If needed, trim the nasal splint with appropriate scissors.
4. Soak the nasal splint in a water bath (approx. 70 °C) until the nasal splint becomes transparent (approx. 60-90 seconds).
5. Take the nasal splint out of the water bath using tweezers. Dab off excess water.
6. Shape the nasal splint manually.
7. Place the nasal splint on the tape bandage and attach it by gently pressing with your fingers. The nasal splint will adhere directly to the tape.

The material will harden quickly when cooling down.



Illustration 1: Tape (Ill. left), with nasal splint (Ill. right)

12.3 Remove

1. Carefully remove the nasal splint together with the tape manually or using a dull bayonetted rongeur. Ensure that in doing so you do not pull up the skin.

13 Instructing the Patient

Does not apply.

14 Aftercare

At the discretion of the treating physician.

15 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

16 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.

Due to biological and individual differences, no product is 100% effective under all circumstances.

Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.

The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.

If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.
Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.
All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.
Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.
No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.
The General Terms and Conditions of the manufacturer, which can be accessed at http://www.bess.eu/agb apply in all remaining instances.