



Technical data sheet (TDS)

# Silicone Bland-Rosé

## REF: F-01930



REDACTADO POR:		REVISADO POR:		APROVADO POR:
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## 1. DEVICE DESCRIPTION

Poli-condensation soft silicone.

## 2. INTENDED PURPOSE

Specially designed for use in podiatry, it is indicated for the manufacture of palliative orthoses, specially in geriatrics and diabetic feet, reducing pain immediately. Protect painful areas of the feet from friction and pressure.

## 3. PATIENT TARGET GROUP

Anyone requiring protection for pain-prone areas of the foot, moisturising, regenerating and/or softening hard parts of the skin

## 4. INTENDED USERS

Intended for use in professional healthcare facilities by medically trained users.

## 5. MODE OF ACTION

As it can be molded in different shapes and sizes, it adapts to the shape of the foot. Once applied, when walking or exerting pressure, the orthosis is in constant contact with the footwear or area of high friction, preventing the skin from rubbing, moisturizing the skin, regenerating it and softening the hard parts.

## 6. INSTRUCTIONS FOR USE

1. Clean and dry the desired application foot area.
2. Remove the product from the packaging.
3. Before taking the needed amount, homogenize all the content of the jar.
4. Mix with the catalyst until reaching a uniform paste (30-60 seconds). Mix in a maximum proportion of 1 drop of catalyst to 1 gram of product. In the case of paste catalyst, use approximately one lineal centimetre of catalyst for every 5 grams of silicone. The mix needs approximately 5 minutes to solidify.
5. Mold it onto the foot.

## 7. END OF LIFE DISPOSAL

Replace when:

- « Shows visible wear.
- « Its loss of integrity causes it to stop providing complete coverage in the area that can suffer pressure damage.

At the end of its life cycle, dispose it with non-hazardous waste.

## 8. WARNINGS AND PRECAUTIONS

Do not use in direct contact with the skin in case of open or oozing wounds.

For external use only.

Single patient use.

Do not use more than 16 hours per day.

Inspect the skin at regular intervals.

Discontinue use and seek healthcare professional advice if:

- « Loss of skin integrity occurs i.e., breakdown.
- « Deep tissue injury is suspected or confirmed.

- « Any skin irritation is present.
- « Heat rash or reddening of the skin occurs.

Keep out of reach of children.

Diabetics and those with poor blood circulation should seek professional medical advice

## 9. DEVICE COMPOSITION

### 9.1. Raw Material

- Mixed of Polydimethylsiloxane and Silica.
- Silicone Elastomers, Medicinal White Oils, Silicone Oils and Silicone Pigment Paste.



### 9.2. Biocompatibility tests

Testing has been conducted in accordance with "ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process".

The specific biocompatibility test conducted are the following:

1. Cytotoxicity.
2. Intracutaneous.
3. Skin sensitization.

### 9.3. Physical and chemical characteristics

Colour:	Pink
Aspect:	Solid
Solubility:	No solubility in water

## 10. DEVICE VARIANTS, DIMENSIONS AND PACKAGING.

References	Weight (gr)	Quantities	Packaging
F-01930-00	500	1	Plastic jar
F-01930-01	500	1	Plastic jar
F-01930-01PP	500	1	Plastic jar
F-01930-02	500	1	Plastic jar
F-01930-10	100	1	Plastic jar
F-01930-20	200	1	Plastic jar
F-01930-21	200	1	Plastic jar
F-01930-30	100	1	Plastic jar
F-01930-32	200	1	Plastic jar
F-01930-50	50	1	Plastic jar
F-01930-52	50	1	Plastic jar
F-01930-60	50	1	Plastic jar

### 10.1. Packaging Material Specifications

	PapPet: Paper +Plastic (PP)
Label	

**Silicona masilla blanda** indicada para la elaboración de ortesis paliativas, uso en pie diabético y geriatría. Es hidratante y suaviza las partes duras. Si nota adhesividad en el amasado, se recomienda humedecer las manos con agua fría. Endurece con catalizador. Puede mezclarse con las demás siliconas Fresco de poli-condensación para obtener distintas durezas. Orteses lavables y reutilizables.

**Soft putty silicone** indicated for the preparation of palliative orthoses, use in diabetic foot and geriatrics. It has moisturising properties and softens the hard parts. If it feels sticky during the kneading, it is recommended to wet the hands with cold water. Hardens with catalyst. It can be mixed with the other Fresco polycondensation silicones to obtain different hardnesses. Washable and reusable orthoses.

**Massa de silicone suave** indicada para a confecção de orteses paliativas, para utilização em pé diabético e em geriatría. É hidratante e suaviza as partes duras. Se notar adesão à massa, recomenda-se humedecer as mãos em água fria. Endurece com catalizador. Pode misturar-se com outras siliconas de poli-condensação da Fresco para obter diferentes tipos de dureza. Orteses laváveis e reutilizáveis.

**BLAND-ROSÉ**  
Since 1988

**Fresco**

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**MD** Medical Device  
**CE** CE Mark  
**MADE IN SPAIN**  
**Medical Manufacturer Licence 7521-PS**  
**MANAGEMENT SYSTEM CERTIFIED ISO 9001 | ISO 13485**

Referencia   Code	F-01930
Color   Colour	Rosa intenso   Pink
Dureza Shore A   Hardness Shore A	Blanda   Soft 2-4
Cantidad   Quantity	500 gr

**Silicone morbido** in pasta per la realizzazione di ortesi palliative per piede diabetico e per l'uso in geriatría. Con proprietà idratanti ed emollienti per le parti più dure. Se la pasta risulta appiccicosa, si consiglia di inumidire le mani con acqua fredda. Indurisce con l'uso di un catalizzatore. È possibile effettuare miscole con gli altri tipi di siliconi per poli-condensazione Fresco, per ottenere durezze diverse. Ortesis lavabili e riutilizzabili.

**Silicone mastic souple** indiquée pour l'élaboration d'orthèses palliatives pour un usage en cas de pied diabétique et en geriatría. Elle est hydratante et adoucit les parties dures. En cas d'adhérence de la pâte, il est recommandé d'humidifier les mains à l'eau froide. Elle durcit avec un catalyseur. Elle peut être mélangée aux autres silicones Fresco polycondensation pour obtenir différentes duretés. Ortheses lavables et réutilisables.

**Weiche Silikonmasse** für die Herstellung palliativer Orthesen zur Verwendung bei diabetischem Fuß und in der Geriatrie. Feuchtigkeitspendend und hartenerweichend. Wenn die Masse bei der Bearbeitung an den Händen kleben bleibt, empfiehlt es sich, die Hände mit kaltem Wasser zu befeuchten. Härtet mit Katalysator aus. Kann für den Erhalt unterschiedlicher Härtegrade mit anderen polykondensierenden Fresco-Silikonem gemischt werden. Waschbare und wiederverwendbare Orthesen.

All materials are 100% recyclable

**10.2. SYMBOL**



Medical device



CE Mark



Manufacturer



Single patient – Multiple use



Read the instructions



Keep away from sunlight



Do not use if package is damaged



Keep dry

**10.3. BATCH CODE**



**YYXXXX**  
6 digits

**YY**  
Year of production

**XXXX**  
Automatic and contiguous, system generated.

**10.4. EXPIRY DATE**



**AAAA-MM**    AAAA    MM  
6 dígitos    Año    Mes

5 años des de la fecha de manufactura

**11. PAO (PERIOD AFTER OPENING)**

Do not apply. There is no caducity or changes on the product composition due to open the packaging.

**12. STORAGE**

Temperature ambient. Do not stock it on higher temperatures than 40°C, its final shape can vary. Keep container dry. Preserve in a cool, well-ventilated place. Avoid direct sunlight exposure.

### 13. TRANSPORTATION

Temperature: Room temperature.

Pressure: Atmospheric

### 14. HANDLING

The products are in direct contact with the skin on its normal use, nonspecific cares should be taken neither is needed to wear gloves for its manipulation.

Risks of electrostatic accumulation: not applicable.

Do not use damage products.

### 15. CONTROL OF INDIVIDUAL PROTECTION

Not specific cares should be taken on normal use.

### 16. EMERGENCY AND FIRST AID PROCEDURES

#### **Eye contact**

Is a solid product.

#### **Skin contact**

The product is used on direct contact with the skin.

#### **Inhalation**

Is a solid product. No risk of inhalation.

#### **Ingestion**

Medical oils used are non-toxic, but in case of ingestion we recommend to get medical advice.

#### **Supplemental health information**

None identified.

#### **Anti-inflammable measures**

Not flammable but will burn. Combustion products may include carbon monoxide and carbon dioxide.

#### **Extinguishing media**

Foam, water spray or fog. Dry chemical powder, carbon dioxide, sand or earth may be used for small fires only. Do not use direct water jet on burning material.

#### **Fire and explosion hazards**

None Identified.

### 17. MEASURES TO FOLLOW IN CASE OF A FORTUITE ACCIDENT

Fresco International 2005, S.A. must be notified of any serious incident that has occurred in relation to the products declared in this document, using the information provided in the cover of this document.

### 18. IMPORTANT INFORMATION

The information provided should be regarded as a description of the relevant requirements of the safety of the product, it does not constitute a guarantee and does not replace the work or opinion of the Medical Professional.

Fresco International 2005, S.A., does not accept responsibility for misuse of the manufactured products, or if used for a different activity, the conditions of its use are not under Fresco Internationals 2005, S.A. control.

## 19. DOCUMENT VERSION CONTROL

<b>Version</b>	<b>Description of changes made to the doc.</b>	<b>Effective from</b>
00	Document Development	25/09/2011
01	MDR (EU) 2017/745 adaptation	03/02/2023
02	Updating the drafter of the document and reviewers. Adding new product variants. Update of instructions for use.	11/01/2023
03	Update to new format by languages. Elimination of contraindications.	15/04/2024