



Silicone FRESCO

REF: F-01923



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2024-02	2024-02	2024-02	2024-02	2024-02

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INDEX

1.	DEVICE DESCRIPTION	10
2.	INTENDED PURPOSE	10
3.	PATIENT TARGET GROUP	10
4.	INTENDED USERS	10
5.	MODE OF ACTION	10
6.	INSTRUCTIONS FOR USE	10
7.	END OF LIFE DISPOSAL	10
8.	WARNINGS AND PRECAUTIONS	10
9.	DEVICE COMPOSITION	11
9.1	Raw Material	11
9.2	Biocompatibility tests	11
9.3	Physical and chemical characteristics	11
10.	DEVICE VARIANTS, DIMENSIONS AND PACKAGING	11
10.1	PACKAGING MATERIAL SPECIFICATIONS	11
10.2	SYMBOLS	12
10.3	BATCH NUMBER	12
10.4	EXPIRY DATE	12
11.	PAO (PERIOD AFTER OPENING)	12
12.	STORAGE	12
13.	TRANSPORTATION	12
14.	HANDLING	13
15.	CONTROL OF INDIVIDUAL PROTECTION	13
16.	EMERGENCY AND FIRST AID PROCEDURES	13
17.	MEASURES TO FOLLOW IN CASE OF A FORTUITE ACCIDENT	13
18.	IMPORTANT INFORMATION	13
19.	DOCUMENT VERSION CONTROL	14

1. DEVICE DESCRIPTION

Poly-condensation medium hardness silicone.

2. INTENDED PURPOSE

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

3. PATIENT TARGET GROUP

Anyone requiring protection for pain-prone areas of the foot, moisturizing, 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 foot desired for application.
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:

- « Looks outworn.
- « Its loss of integrity causes it to stop providing complete coverage in the desired area.

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

8. WARNINGS AND PRECAUTIONS

Only for use in intact skin, do not use on open or weeping wounds.

For external use only.

Single patient use.

Do not use more than 16 hours per day.

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

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.

9. DEVICE COMPOSITION

9.1 Raw Material

Polydimethylsiloxane with functional groups and auxiliary agents for reticulation by addition.



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

Color: Pink
 Aspect: Solid
 Solubility: Not soluble in water

10. DEVICE VARIANTS, DIMENSIONS AND PACKAGING.

References	Weight (gr)	Quantities	Packaging
F-01923-00	500	1	Plastic jar
F-01923-01	500	1	Plastic jar
F-01923-02	500	1	Plastic jar
F-01923-03	500	1	Plastic jar
F-01923-04	1000	1	Plastic jar
F-01923-05	1000	1	Plastic jar
F-01923-10	100	1	Plastic jar
F-01923-11	100	1	Plastic jar
F-01923-20	200	1	Plastic jar
F-01923-21	200	1	Plastic jar
F-01923-50	50	1	Plastic jar
F-01923-51	50	1	Plastic jar

10.1 PACKAGING MATERIAL SPECIFICATIONS

	PapPet: Paper +Plastic (PP)
Label	

SILICONA FRESCO
SILICONA MEDIA | MEDIUM SILICONE

Fresco

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MADE IN SPAIN

Referencia Code	F-01923-00
Color	Rosa
Colour	Pink
Dureza Shore A	Media 14-16
Hardness Shore A	Medium 14-16
Cantidad Quantity	500 gr

■ Silicóna semi-morbida in pasta, concepto específicamente per l'ús en podologia. Indicat per la realització de orteses palliatives i correctives. El·le durirà amb un catalitzador líquid o en pasta. Pot ésser barrejat amb altres silicones de policondensació produïts da Fresco, per obtenir diferents dureses. Ortesis lavables i reutilitzables.

■ Silicone semi-souple spécialement conçu pour un usage en podologie. Indiqué pour l'élaboration d'orthèses palliatives et correctives. Elle durcit avec un catalyseur liquide ou en pâte. Elle peut être mélangée à d'autres silicones polycondensation de la marque Fresco pour obtenir différentes duretés. Ortheses lavables et réutilisables.

■ Hávvelike Silicon speciál for die Verwendung der Podologie. Zu Herstellung von palliativen und korrigierenden Orthesen. Härten Katalysator Flüssigkeit oder Paste. Sie kann mit anderen Polykondensationsprodukten der Marke Fresco gemischt werden. Waschen und wiederverwenden.

SILICONA MEDIA | MEDIUM SILICONE SILICONA MEDIA | MEDIUM SILICONE SILICONA MEDIA | MEDIUM SILICONE SILICONA MEDIA | MEDIUM SILICONE

All materials are 100% recyclable

10.2 SYMBOLS



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 NUMBER



YYXXXX
6 digits

YY

Year of production

XXXX

Automatic and contiguous, system generated.

10.4 EXPIRY DATE



YYYY-MM
6 digits

YYYY
Year

MM
Month

11. PAO (PERIOD AFTER OPENING)

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

12. STORAGE

Room temperature. 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 damaged 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 not 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 International's 2005, S.A. control.

19. DOCUMENT VERSION CONTROL

Version	Description of changes made to the doc.	Effective from
00	Document Development	08/02/2024