



Silicone 1400

REF: F-01921



WRITTEN BY:		CHECKED BY:		APPROVED BY:
Álvaro Monteis	Paula Deu	Yanina Trombino	Guillermo Segura	Aitor Fresco
QA assistant	RA technician	QA/RA Director	Sales director	General manager
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MANUFACTURER'S DETAILS



Fresco International 2005, S.A.
 Calle Torre de Cellers, 5, 08150, Paret del Vallès, Barcelona, España.
 (+34) 93 573 94 00
 info@fresco.es
 www.fresco.es

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1. DEVICE DESCRIPTION

Poly-condensation hard 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 auxiliar 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: Gray
 Aspect: Solid
 Solubility: Not soluble in water
 Hardness (Shore A): 28-32

10. DEVICE VARIANTS, DIMENSIONS AND PACKAGING.

References	Weight (gr)	Quantities	Packaging
F-01921-01	500	1	Bote plástico
F-01921-03	500	1	Bote plástico
F-01921-04	500	1	Bote plástico
F-01921-05	500	1	Bote plástico
F-01921-20	200	1	Bote plástico
F-01921-51	50	1	Bote plástico
F-01921-B1	500	1	Bote plástico
F-01921-B2	1000	1	Bote plástico
F-01921-B3	200	1	Bote plástico
F-01921-B5	50	1	Bote plástico

10.1 PACKAGING MATERIAL SPECIFICATIONS

	PapPet: Paper +Plastic (PP)
Label	

<p>ES Silicona maciza, dura y elástica. Indicada para la elaboración de ortesis correctivas o de sustitución. Si nota adhesividad en el amasado, se recomienda humedecer las manos con agua fría. Endurece con catalizador. No debe mezclarse con otros tipos de siliconas Fresco de poli-condensación para obtener distintas durezas. Ortosis lavables y reutilizables.</p>	<p>EN Hard and elastic putty silicone. Indicated for the preparation of corrective or replacement orthoses. If it feels sticky during the kneading, it is recommended to wet the hands with cold water. Hardens with catalyst. Do not mix with other Fresco polycondensation silicones to obtain different hardnesses. Washable and reusable orthoses.</p>	<p>PT Massa de silicone, dura e elástica. Indicada para a confecção de ortótes corretivas, ou de substituição. Se notar aderência à massa, recomenda-se humedecer as mãos em água fria. Endurece com catalizador. Não misturar com outros tipos de silicone de policondensação da Fresco para obter diferentes tipos de dureza. Ortótes laváveis e reutilizáveis.</p>	<p>SILICONA 1400</p> <p>SILICONA DURA HARD SILICONE</p> <p>Fresco</p> <p>Medical Manufacturer Licence 7521-IPB</p> <p>FRESCO INTERNATIONAL 2005, S.A. Torre de Cristal 5, Valldu (Pob. de Sant Joan), Barcelona (Spain) (+34) 932 314 812 info@fresco.es www.fresco.es</p> <p>MADE IN SPAIN</p>	<p>Referencia Code: F-01921-20</p> <p>Color: Gris</p> <p>Dureza Shore A: Dura 28-32</p> <p>Hardness Shore A: Haro 28-32</p> <p>Cantidad Quantity: 200 gr</p>	<p>IT Silicone in pasta, duro ed elastico. Indicato per la realizzazione di ortesi correttive o sostitutive. Se la pasta risulta appiccicosa, si consiglia di inumidire le mani con acqua fredda. Indurisce con l'uso di un catalizzatore. E' possibile effettuare miscele con gli altri tipi di siliconi per policondensazione Fresco, per ottenere durezze diverse (Ortosi lavabili e riutilizzabili).</p> <p>FR Silicone macisz, dure et elastique. Indique pour la realisation d'ortheses correctives ou de substitution. En cas de resultats appiccicosos, si conseille d'humidifier les mains a l'eau froide. Indurisse avec un catalyseur. Elle peut etre melangee aux autres silicones Fresco polycondensation pour obtenir differentes duretes. Orthoses lavables et reutilisables.</p> <p>DE Harte und elastische Silikonmasse. Zerstärkungsvorgeschrieben Orthese od als Ersatzteil. Wenn die Masse bei d Bearbeitung an den Händen kleben bleibt, empfiehlt sich, die Hände mit kaltem Wasser zu befeuchten. Harzt mit Katalysator zu. Kann für den Einsatz unverschmutzt mit anderen Polykondensations-Fresco-Silicone gemischt werden. Waschtisch- und wiederverwendbare Orthosen.</p>
SILICONA DURA HARD SILICONE	SILICONA DURA HARD SILICONE	SILICONA DURA HARD SILICONE	SILICONA DURA HARD SILICONE	SILICONA DURA HARD SILICONE	SILICONA DURA HARD 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 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 no toxically, 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

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