



# Silicone Duo 10

## REF: F-01924



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## 1. DEVICE DESCRIPTION

Bi-compound 1+1 malaxable soft 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 moulded 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, moisturising 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. Take the same amount of both components (A+B) and mix until reaching a uniform colour (for 30-60 seconds). The mix needs approximately 5 minutes to solidify.
4. Mold it onto the foot.

Hardness Shore A10 us reached after 24h.

## 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 and white  
 Aspect: Solid  
 Solubility: Not soluble in water

## 10. DEVICE VARIANTS, DIMENSIONS AND PACKAGING.

References	Weight	Quantities	Packaging
F-01924-00	250g+250g	1	Plastic jar
F-01924-00C-10	250g+250g	10	Plastic jar in cardboard box
F-01924-01G	1Kg+1Kg	1	Bulk
F-01924-02B	100g+100g	1	Clam shell
F-01924-04	250g+250g	1	Blank plastic jar
F-01924-04B	100g+100g	1	Blank clam shell
F-01924-04C-10	250g+250g	10	Blank plastic jar in cardboard box
F-01924-50	50g+50g	1	Sample

### 10.1 PACKAGING MATERIAL SPECIFICATIONS

PapPet: Paper +Plastic (PP)

Plastic jar label

<p><b>DUO 10 - A</b> SILICONA MEDIA   MEDIUM SILICONE</p>	<p><b>A CATALIZADOR HARDENER</b></p> <table border="1" style="font-size: small;"> <tr><td>Referencia   Code</td><td>F-01924-00</td></tr> <tr><td>Color</td><td>Bianco</td></tr> <tr><td>Colour</td><td>White</td></tr> <tr><td>Durezza Shore A</td><td>Media 10-12</td></tr> <tr><td>Hardness Shore A</td><td>Medium 10-12</td></tr> <tr><td>Cantidad   Quantity</td><td>200 gr</td></tr> </table> <p><b>Fresco</b> FRESCO INTERNATIONAL 2005, S.A. Calle Terra de Casters 1, C/SGO Pinedo del Valle - Barcelona (España) 902 552 214 (Ext)   info@fresco.es www.fresco.es MADE IN SPAIN</p>	Referencia   Code	F-01924-00	Color	Bianco	Colour	White	Durezza Shore A	Media 10-12	Hardness Shore A	Medium 10-12	Cantidad   Quantity	200 gr	<p><b>Silicone medio bi-componente (poliaddizione)</b> especialmente diseñada para la elaboración de ortesis paliativas sencillas y correctivas leves. Molto facile da usare per produrre ortesi e sufficiente mescolare la stessa quantità di entrambi i componenti (A e B). La miscela si indurisce rapidamente. Risultato morbido ed elastico. Le ortesi sono lavabili e riutilizzabili. *Non vendibili separatamente.</p> <p><b>Silicone moyenne bi-composant (poly-addition)</b> spécialement conçue pour l'élaboration d'orthèses palliatives simples et légèrement correctives. Très facile à utiliser - pour réaliser l'orthèse, il suffit de mélanger la même quantité des deux composants (A et B). Le mélange durcit rapidement. Résultat souple et élastique. Les orthèses sont lavables et réutilisables. *Ne sont pas vendues séparément.</p> <p><b>Mittelhartes Zwei-Komponenten-Silikon (Polyaddition)</b> speziell entwickelt für die Herstellung einfacher palliativer und leicht korrigierender Orthesen. Sehr einfache Anwendung: Zur Herstellung der Orthese müssen lediglich beide Komponenten (A und B) zu gleichen Teilen gemischt werden. Die Mischung härtet rasch aus. Das Ergebnis ist weich und elastisch. Die Orthesen sind waschbar und wiederverwendbar. *Können nicht getrennt verkauft werden.</p>
Referencia   Code	F-01924-00													
Color	Bianco													
Colour	White													
Durezza Shore A	Media 10-12													
Hardness Shore A	Medium 10-12													
Cantidad   Quantity	200 gr													
<p><b>DUO 10 - B</b> SILICONA MEDIA   MEDIUM SILICONE</p>	<p><b>B BASE   BASE</b></p> <table border="1" style="font-size: small;"> <tr><td>Referencia   Code</td><td>F-01924-00</td></tr> <tr><td>Color</td><td>Rojito</td></tr> <tr><td>Colour</td><td>Red</td></tr> <tr><td>Durezza Shore A</td><td>Media 10-12</td></tr> <tr><td>Hardness Shore A</td><td>Medium 10-12</td></tr> <tr><td>Cantidad   Quantity</td><td>200 gr</td></tr> </table> <p><b>Fresco</b> FRESCO INTERNATIONAL 2005, S.A. Calle Terra de Casters 1, C/SGO Pinedo del Valle - Barcelona (España) 902 552 214 (Ext)   info@fresco.es www.fresco.es MADE IN SPAIN</p>	Referencia   Code	F-01924-00	Color	Rojito	Colour	Red	Durezza Shore A	Media 10-12	Hardness Shore A	Medium 10-12	Cantidad   Quantity	200 gr	<p><b>Silicona media bi-componente (poli-addición)</b> especialmente diseñada para la elaboración de ortesis paliativas sencillas y correctivas leves. Muy fácil de usar para realizar la ortesis sólo es necesario mezclar la misma cantidad de ambos componentes (A y B). La mezcla endurece rápidamente. Resultado blando y elástico. Las ortesis son lavables y reutilizables. *No se venden por separado.</p> <p><b>Medium bi-component (poly-addition) silicone</b> especially designed for the preparation of simple palliative and mild corrective orthoses. Very easy to use: to make the orthosis just mix the same amount of both components (A and B). The mixture hardens quickly. Soft and elastic end result. Washable and reusable orthoses. *Not sold separately.</p> <p><b>Silicono médio bicomponente (poliaddição)</b> especialmente criado para a confecção de orteses paliativas simples e corretivas leves. Muito fácil de usar: para realizar a ortese é apenas necessário misturar a mesma quantidade de ambos componentes (A e B). A mistura endurece rapidamente. Resultado suave e elástico. As orteses são laváveis e reutilizáveis. *Não se vendem em separado.</p>
Referencia   Code	F-01924-00													
Color	Rojito													
Colour	Red													
Durezza Shore A	Media 10-12													
Hardness Shore A	Medium 10-12													
Cantidad   Quantity	200 gr													

Clam Shell label



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 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

<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. Index update. Distribution by language.	08/01/2024
03	Amendment for error correction	23/12/2024