Technical data sheet (TDS)

Silicone Duo 10

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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

Polydimethilsiloxane 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:	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 carboard 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 carboard box
F-01924-50	50g+50g	1	Sample

10.1 PACKAGING MATERIAL SPECIFICATIONS

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PapPet: Paper +Plastic (PP)

Plastic jar label

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

LOT	**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	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