

Maxflex™ coping sheet Instruction

Preface:

This instruction is applicable to the dental coping sheet produced by Maxflex™, which is used for orthodontic appliance, orthodontic auxiliary appliance, bleaching tray, bruxism dental guard, fluoride trays, etc.

Maxflex™ is a strong thermoplastic elastomer material, which is specially developed for the application of retainer and orthodontic devices. After product optimization, it can achieve the balance of various theoretical properties including tear resistance, impact strength, stress retention, durability, stain resistance and optical transparency.

Maxflex™ has the safety implantable compatibility, durability, and ease of processing required for modern orthodontic procedures.

The main component of this product is medical grade thermoplastic polyurethane (TPU) material, which is not only with excellent biocompatibility but also with obvious elastic effect because of the special soft segment and hard segment phase separation structure in the molecular structure. This kind of effect makes the Maxflex™ dental coping sheet used in tooth and jaw correction quite different and excellent from the general polymer plastic. Please read this instruction carefully before using Maxflex™ dental coping sheet.

Application fields:

Orthodontic appliance, orthodontic auxiliary appliance, bleaching tray, bruxism dental guard or fluoride trays, etc.

Product features:

◇ **Stress retention**

Stress retention is the ability of materials to resist deformation. This product uses special high-performance polyurethane materials for medical use, which combines the high strength, ductility, low stress relaxation and toughness of materials.

✧ Transparency

Maxflex™ dental coping sheet material has excellent transparency and color stability; it can't be easily seen in the mouth.

✧ Easy Fabrication

Maxflex™ dental coping sheet can be formed by vacuum or pressure forming machine. You can fabricate the dental appliance in a very short time and be sure that it can fit every patient's dental model perfectly.

Product Specification:

Maxflex™ group, which has a first-class materials development and process manufacturing team. Also, we have various precision injection and extrusion manufacturing facilities. As an industry solution provider for orthodontic and oral care devices, the new orthodontic materials are produced and operate in the 10K class cleanroom and meet the requirements of ISO 13485:2016 quality management system, which can meet the needs of clinical changes in different stages.

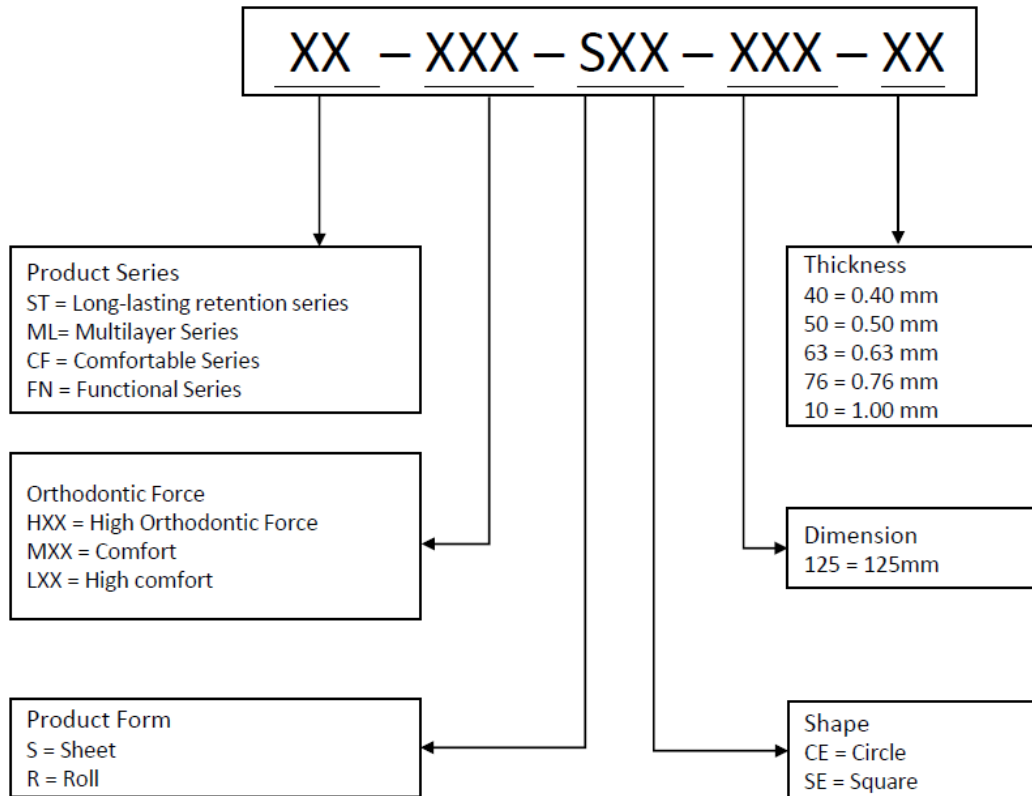
4 different series are provided for you to choose: CF (Economic and Comfortable series), ST (Long-lasting retention series), ML (Multilayer Compound Series), FN (Special Functional Series).

Each series can be used flexibly according to different orthodontic periods and different types of patients. ST series has the best orthodontic force, is suitable for mid-term orthodontic and long displacement needs. CF series is comfort-oriented, in CF series is divided into three products, CFL is "high comfort" ; CFM is "comfort" and CFH is "high orthodontic force" .

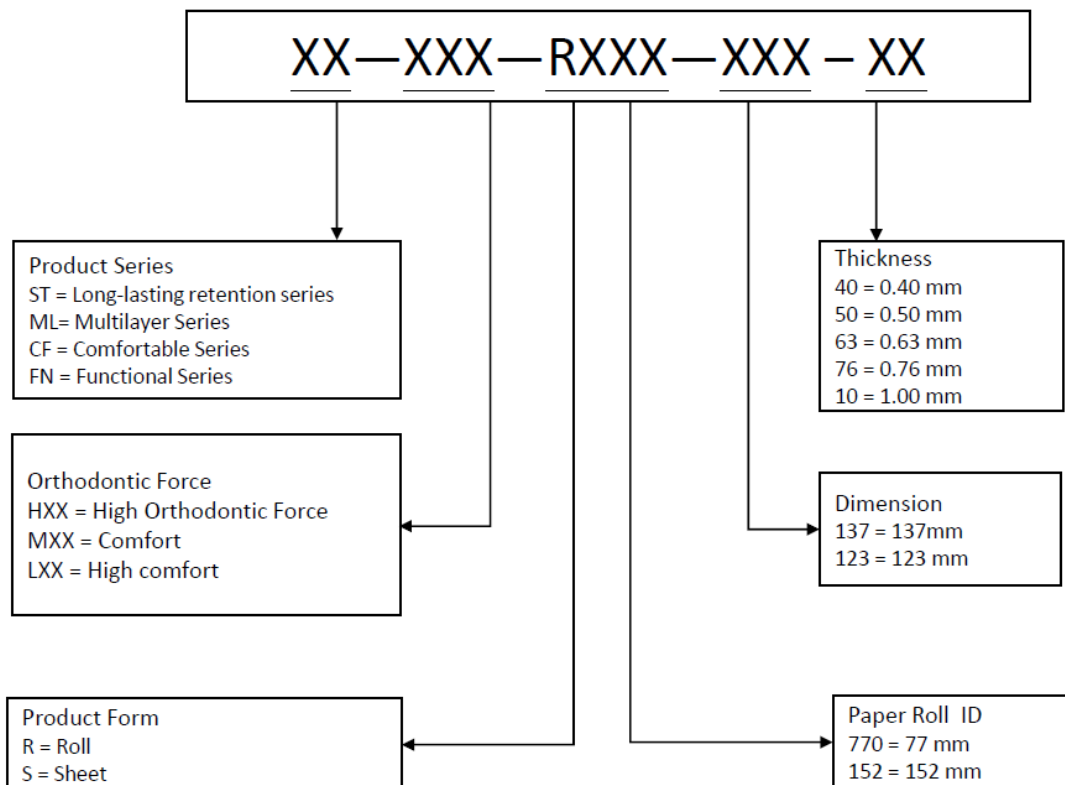
ML series is a multilayer dental coping sheets, developed for different needs. It has a balanced and excellent biomechanical property.

FN series is an innovative product, includes drug-carrying and anti-bruxism. It can provide the best solution for dental health.

Dental coping sheet: Guide for Dental Coping Sheet



Dental coping sheet (roll): Guide for Dental Coping Roll



Attention:



Contraindications: Patients with a history of allergic reaction to plastics should avoid this material.



Caution: if the dental coping sheet is heated overtime during thermoforming, it may cause plastic to sag and with a risk of skin burns to technicians. Please wear appropriate protective equipment.

Instructions:

(A) Model preparation

- (1) The model should be fully cured and dry.
- (2) The model should be trimmed to be about 20-25mm.
- (3) Assemble and place any special molding machine accessories with positive or negative pressure.
- (4) It is recommended to apply medical release agent on the model (to prevent the appliance from sticking to the model).
- (5) Positive pressure thermoforming machine:
 - (5-1) Turn on the thermoforming machine and enter the reference code and set the appropriate heating temperature and time (Please refer to the table of thermoforming parameters).
 - (5-2) Use 3.5-4.5 bar for thermoforming (a more complicated sheet usually requires a higher pressure).
 - (5-3) Place the model on the forming platform and adjust to the appropriate position.
- (6) Negative pressure thermoforming machine:(vacuum thermoforming machine)
 - (6-1) Turn on the thermoforming machine and enter the reference code and adjust the appropriate heating temperature and time (Please refer to the table of thermoforming parameters)
 - (6-2) Adjust the appropriate vacuum degree for thermoforming (a more complicated sheet usually requires a higher vacuum degree)
 - (6-3) Place the model on the forming platform and adjust the appropriate position.
- (7) Open the foil bag and place the Maxflex™ dental coping sheet on the thermoforming frame (open the foil bag and use the Maxflex™

dental coping sheet within 15 minutes).

(8) Swing the heating element (usually is Tungsten wire heating hood) over the Maxflex™ dental coping sheet to start heating until the sheet sags about 12 to 20 mm.

(9) Move the heating element away from the Maxflex™ dental coping sheet.

(10) Use positive compressed air pressure or negative vacuum suction to form the dental coping sheet onto the model and allow the part to cool before handling.

(11) Trim and finish the appliance.

(12) Clean the Maxflex™ appliance with a mild detergent that complies with medical specifications. (please clean it under 40 °C)

(B) Trimming instructions

(1) Use a trimming wheel or a twist drill to cut Maxflex™ appliance off the model.

(2) operate the trimming wheel or twist drill (recommended diameter is about 1mm) at around 20,000-30,000 rpm and cut as close to the finished outline of the appliance as possible. (At least 3mm of the gingiva is suggested.)

(3) Use an edge polisher to polish the edges of Maxflex™ appliance.

(4) Finally, clean the Maxflex™ appliance with a mild detergent that complies with medical specifications. (please clean it under 40°C)









Table of thermoforming parameters

| Thickness | Product code | Temperature (°C) | Heating time (s econd) | Pressure (positive pressure/bar) |
|-----------|-------------------|------------------|------------------------|----------------------------------|
| 0.76 mm | ST-0-SCE-125-76 | 220 | 20-30 | 4.0 – 4.5 |
| 0.63 mm | ST-0-SCE-125-63 | 220 | 20-30 | 3.5 – 4.0 |
| 0.40 mm | ST-0-SCE-125-40 | 220 | 20-30 | 3.5 – 4.0 |
| 0.76 mm | CF-H01-SCE-125-76 | 220 | 20-30 | 4.0 – 4.5 |
| 0.63 mm | CF-H01-SCE-125-63 | 220 | 20-30 | 3.5 – 4.0 |
| 0.40 mm | CF-H01-SCE-125-40 | 220 | 20-30 | 3.5 – 4.0 |
| 0.76 mm | CF-M01-SCE-125-76 | 220 | 20-30 | 4.0 – 4.5 |
| 0.63 mm | CF-M01-SCE-125-63 | 220 | 20-30 | 3.5 – 4.0 |
| 0.40 mm | CF-M01-SCE-125-40 | 220 | 20-30 | 3.5 – 4.0 |
| 0.76 mm | CF-L01-SCE-125-76 | 220 | 20-30 | 4.0 – 4.5 |
| 0.63 mm | CF-L01-SCE-125-63 | 220 | 20-30 | 3.5 – 4.0 |
| 0.40 mm | CF-L01-SCE-125-40 | 220 | 20-30 | 3.5 – 4.0 |

Notes:

- (a) These are recommended thermoforming parameters for Maxflex™ dental coping sheet materials.
- (b) The heating time varies between different machines.
- (c) If Maxflex™ sheet doesn't form well to the model, the heating time can be add by 3-5 seconds at a time until the appliance is well formed.
- (d) If the sheet sags to form wrinkles or abnormal deformation, reduce the heating time until no wrinkles or abnormal deformation occurs.
- (e) The Maxflex™ dental coping sheet should be used within 15 minutes after opening the foil bag. If there are bubbles in the process of plastic heating and sagging, it means that the sheet has absorbed water. Please replace it with a new dental coping sheet.
- (f) Since there can be many variations in Maxflex™' s design, learning to make perfect appliances with this material may require some additional guidance and technical communication. We encourage you to visit www.maxflexaligner.com for Maxflex™' s technical application.

Symbols used on labeling

| | |
|---|------------------------------|
|  | CONSULT INSTRUCTIONS FOR USE |
|  | DATE OF MANUFACTURE |
|  | CAUTION |
|  | KEEP AWAY FROM RAIN |
|  | KEEP AWAY FROM SUNLIGHT |
|  | TEMPERATURE LIMITATION |

Maxflex

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