

The Smartest Polyurethane Material





# 1. DESCRIPTION:

Taglus PU-Flex is a high-performance aligner/retainer material made of polyurethane that offers exceptional flexibility, strength, and durability which provides stronger orthodontic force. It has masking layer on both sides, preventing dust particles/moisture and scratches before use. The material has been tested and approved for its biological safety.

### 2. INTENDED PURPOSE:

The Taglus Pu-Flex Thermoforming Foils can be used as an aligner/retainer after thermoforming on a 3D printed model designed and planned by registered orthodontist or registered dental lab technician.

#### 3. NOTE BEFORE USING:

- Heating times may vary with current fluctuations or time.
- If the Foils do not adapt well to the model, add or reduce 5 seconds to heating time until the result is ideal.
- If Foils form folds, the thermoformed aligner/retainer is not clear or shows bubble formation on the thermoformed model then recalibrate your heating element or reduce the heating time until the result is ideal.

# 4. WORKING INSTRUCTIONS:

- Take 3D Printed Model required to be thermoformed. Do not remove the masking of the sheet before thermoforming.
- Place a sheet of aligner/retainer material in the pressure chamber of the thermoforming machine and enter the correct code or adjust the heating & cooling time for the Taglus sheet (see chart below- times are general guidelines only as each individual machine acts slightly different).
- Pressure should be set above 4.2 Bars and temperature is at machine default.
- Observe the sheet as it heats & as per the timer move the heating element away from the Foils.
- Then close the Pressure chamber on the model for thermoforming. After completing the cooling time open the machine & see the adaptation of the sheet with a model.

⚠ USE THE SHEETS WITHIN 15 MINUTES AFTER OPENING THE PACKET.

	0.018" (0.45mm)	0.030" (0.762mm)	0.040" (1.020mm)
BioSTAR MiniSTAR/ MiniSTAR S	Code 112	Code 142	Code 162
Dreve Drufomat Scan	Heating - 1:15 Cooling - 1:20	Heating - 1:30 Cooling - 1:30	Heating - 1:45 Cooling - 1:40

- Vedia Solutions strongly recommends using pressure thermoforming units such as the Biostar and Ministar when forming appliances with Taglus. More information on how to form Taglus appliances can be found in the Resources section of www.taglus.com
- MiniSTAR / MiniSTAR S / BioSTAR are trademarks of Scheu Dental Technology and Drufomat Scan is the trademark of Dreve Dentamid.

# 5. STORAGE CONDITIONS:

- Keep the foils in the original packaging without removing the protective lamination foil during storage.
- Storage should be in a cool and dry environment at room temperature.
- Place unused sheets back in the resealable zip-lock pack along with desiccant/silica packs.

# 6. TRIMMING INSTRUCTIONS:

- First cut the excess plastic surrounding the appliance and cut the Taglus appliance off the model with scissors using a trimming wheel or a twist drill. Operate the trimming wheel or twist drill at around 35,000 rpm and cut as close to the finished outline of the appliance as possible. Remove the appliance from the foil, and trim off extra parts with crown and bridge scissors or rotary burs.
- Polish the edges of the Taglus appliance with an edge polisher at around 10,000 RPM and then before delivering rinse the Taglus appliance with cool water and mild soap.

#### 7. CONTRAINDICATIONS:

■ This product is contraindicated for patients with a history of allergic reactions to plastic.

#### 8. CLEANING:

Products from the TAGLUS range are the best choice for daily cleaning and care.
 Detergents or products on the base of alcohol or plants as well as hot water or steam jets should not be used.

#### 9. CAUTION:

- This product is for use by a Medical Professional, according to the instructions of use.
  Visually inspect and carefully check the product and packaging before use for damage during transportation and handling.
- Do not expose to extreme temperature and humidity.
- In case of any serious incident that has occurred in relation to the device please contact us at info@taglus.com and/or the competent authority of the Member State in which the user and/or patient is established.

# 10. SYMBOLS USED ON LABELLING:

2	Single Use		NON STEPALE	Non-Sterlie
MD	Medical Device		<u>~</u>	Date of Manufacture
$\square$	Expiry Date		*	Keep Away from Sunlight
$\triangle$	Caution		43	Recycle
LOT	Batch / Lot Number		<b>***</b>	Keep Dry
[]i	Consult Instruction for	Use	<u>u</u>	Manufacturer
	Do not use if package is damage	S	·c	Upper & Lower Limit of Temperature
(M)	Non-Pyrogenic		CE	CE Mark



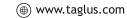


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