INSTRUCTIONS FOR USE

POSITIONING TOOL

1. Product Family & Part Numbers

Product Family	Product Part Numbers	Measurement Range
Positioning Tool 	916.2063-10 (Sold in 10 pack)	3.5mm – 5.0mm
	916.2064-10 (Sold in 10 pack)	5.5mm – 7.0mm

**XXXXX = Multiple part numbers in product family*

2. Intended Use

The Positioning Tool is design as a single-use instrument. It consists of two instruments representing 8 height reference dimensions to be used on appropriate teeth with any .021" & .022" bracket type.

The Positioning Tool is designed to improve consistent and predictable bracket placement for clinician. Use it to guide bracket placement heights from the incisal edge.

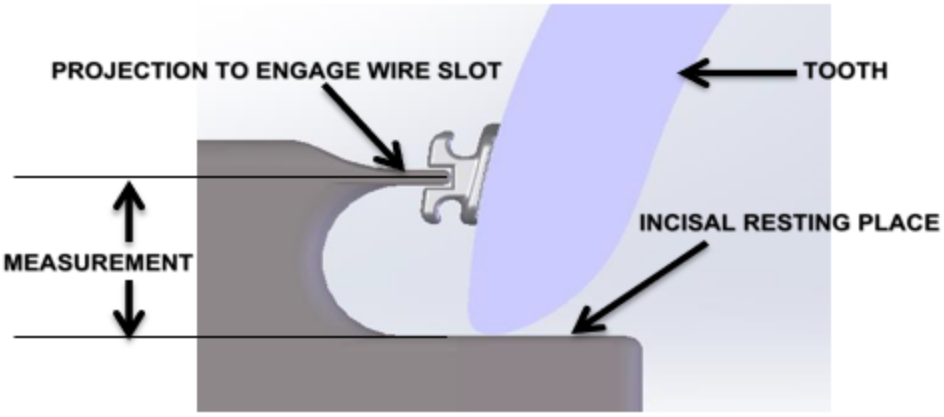
Devices are supplied:

- Non-sterile
- Designed for single-use
- For use by dentists and orthodontists only.

3. Indications for use

The Positioning Tool is made up of an incisal resting place and projection that engages the .021" or .022" slot of any bracket type, see Figure1.

Figure 1



4. Contraindications

- Patient's inability or unwillingness to cooperate/or follow the treatment plan.
- Known allergies to any of the components or materials in the system (see Table1).

5. Materials

All part numbers referenced on sec. 1 are manufactured using materials per Table 1

Table 1

Trademark	Material Code	Material Description
Sabic IP's THERMOCOMP™	DF002H - GY09953	Poly (bisphenol-A-carbonate) glass fiber filled.

6. Warnings and Precautionary Measures

℞ ONLY	Federal law restricts this device to the sale by or on the order of a licensed orthodontist.
NON STERILE	The Positioning Tool is provided non-sterile and designed to be used only by a professional or on the order of an orthodontist or dentist.
②	The Positioning Tool is single use-only, intended for one use or for use on a single patient during single procedure. There is a risk of cross-contamination between patients if re-used.
Do not use on patients with known allergies to any of the materials in the system (see Section 5).	

Immediately remove Orthodontic Appliance(s) in the event of an allergic reaction.
Follow all regional and national standards regarding the use of orthodontic appliances.
Do not use any products which are damaged, or do not comply with the labeling specifications.
Handle used and contaminated instruments with protective gloves in accordance with local policies and procedures.
If, in relation to the use of this product, a death or serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.

7. Patient Information

- Not Applicable

8. General Information for the Dentist/Orthodontist

- As part of developing a treatment plan, and before appliance placement, assess the need for interdisciplinary coordination with other professionals, such as speech pathologists, otolaryngologists, physicians, dentists and/or orthodontists.
- Follow the manufacturer's instructions for any orthodontic bonding agents, instruments or other materials used in the orthodontic treatment.
- Orthodontic training in standard procedures will determine appropriate instruments for use during appliance placement and removal.
- Oral hygiene is of particular importance for immunocompromised patients. Closely monitor oral hygiene on immunocompromised patients.
- Assess whether further orthodontic treatment is advisable in the presence of root resorption.

9. Disposal (if applicable)

- Disposal of all orthodontic appliances must follow regional and national regulations.

10. Storage and Handling for medical devices (if applicable)

- The device should be stored in a dry environment under ambient conditions.

11. Name and address of labeler

World Class Technology
1300 NE Alpha Dr.
McMinnville. OR 97128
USA

12. Name, address and number of Notified Body

CE 0197

TUV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nurnberg, Germany
+49 221 808-1371
Notified Body No.: 0197

13. Name, address, and number of Authorized Representative

EC REP

MDI Europa
Langenhagener STR.71 30855
Langenhagen, Germany
+49-511-3908-9530
SRN: DE-AR-000006218

14. Explanation of Symbols

The following are per ISO 15223-1 (*References as indicated*).

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
Ref. 5.1.1	**Manufacturer**: Indicates the medical device manufacturer.
EC REP Ref. 5.1.2	**Authorized Representative:** Indicates the Authorized representative in the European Community.
LOT Ref. 5.1.5	**Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF Ref. 5.1.6	**Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
NON STERILE Ref. 5.2.7	**Non-sterile:** Indicates a medical device that has not been subjected to a sterilization process.
Single Use Ref. 5.4.2	**Do not re-use/single patient use:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

The following are per ISO 15223-1 (*References as indicated*).

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
 Ref. 5.4.3	**Consult instructions for use:** Indicates the need for the user to consult the instructions for use.
 Ref. 5.7.7 MDR 2017/745 Annex 1 23.2(q)	**Medical Device:** Indicates that the device is a medical device.

Symbols Not Derived from Standards	
CE MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	**European conformity:** European conformity (CE) mark with Notified Body identification number.