

TITLE: DFU, GCB00, TECNIS 1PC IOL, PRIMARY

NOTE: THE CHANGES THAT ARE MADE TO THE DFU ENGLISH PANEL CONTENT SHOULD ALSO BE APPLIED TO THE SECONDARY Z311060S LANGUAGE PANELS. DFU# Z311060P AND Z311060S NEED TO BE KEPT IN SYNC.

ISSUED

SPECIFICATIONS:

1. DIMENSIONS:

- a. Horizontal: 38-1/2" ± 1/32"
- b. Vertical: 19" ± 1/32"
- c. Flat: 19" x 38-1/2" (Tolerance: ± 1/32")
- d. Folded: 3-7/8" x 5-1/2" (Tolerance: ± 1/8")
 - i. Accordion fold 7 panels to 5-1/2" x 19"
 - ii. Right Angle fold to 5-1/2" x 11-5/8"
 - iii. Lap fold in thirds to 5-1/2" x 3-7/8"

2. STOCK: 27-30 lb. Offset or 16 lb. Bond, Smooth Opaque Finish
(Thickness range: 0.0020" – 0.0025")

3. STYLE: One sheet, printed both sides, seven panels per side, English and barcode facing out.

4. COLOR OF COPY: Black permanent pigmented ink on white paper.

5. See attached for artwork layout.

6. Manufacturer specific information (i.e. Manufacture Part Number) if on the label would need to be verified and confirmed by the Manufacturing site.

7. POINTS OF USE: JJSV Añasco, Puerto Rico

8. DATA SHEET LANGUAGES:

English (EN), Graphs, Dutch (NL), German (DE), French (FR), Spanish (ES), Norwegian (NO), Italian (IT), Danish (DA), Finnish (FI), Estonian (ET), Brazilian Portuguese (PT) (BR), Portuguese (PT), Swedish (SV), Latvian (LV)

CHANGE SUMMARY

REVISION	DESCRIPTION OF CHANGE
	See History
03	Update to statement for recommended hydration time. Update to BSS hydration method to align with OVD hydration method.
04	Update DFU to include FDA comments and add Australian Sponsor's information.
05	Resize line weights of tables/figures to enhance print quality.

