

	LABEL SPECIFICATION	DOCUMENT NO: Z311278
		REVISION: 02
TITLE: DFU, TECNIS® SYMPHONY ACRYLIC 1-PIECE IOL, MODELS ZXR00 / ZXT (INT) (ZXR00, ZXT100 - ZXT600)		

NOTE:

The same changes that are made to this DFU should also be made to DFU Z311211 and Z311278S. Revision level of Z311211, Z311278, and Z311278S needs to be kept in sync for reason of document control.

SPECIFICATION:

ISSUED

- 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")
 - Accordion fold 7 panels to 5-1/2" x 19"
 - Right Angle fold to 5-1/2" x 11-5/8"
 - Lap fold in thirds to 5-1/2" x 3-7/8"

Two sheets folded separately.
- 2. STOCK:** 27-30 lb. Offset or 16 lb. Bond, Smooth Opaque Finish. (thickness range: 0.0020" – 0.0025")
- 3. STYLE:** Two sheets, printed both sides, seven panels per side
 - a. Sheet 1 of 2: English faces out
 - b. Sheet 2 of 2: Estonian faces out.

Folded sheet 2 will be placed inside of folded sheet 1 by manual assembly by the vendor.
- 4. COLOR OF COPY:** Black permanent pigmented ink on white paper.
- 5.** Printing to be clear and legible with no ink smears.
- 6.** Insert to be clean. No visible damage, loose or attached particles (fibers) are permitted.
- 7.** Vendor to package product following guidelines according to AMOS #3110.
- 8.** See attached for artwork layout.
- 9.** Manufacturer specific information (i.e. Manufacture Part number) if on the label would need to be verified and confirmed by the Manufacturing site.
- 10. POINT OF USE:** JJSV Groningen, The Netherlands
- 11. DATA SHEET LAYOUT:**

Sheet 1	Front	English (EN)	Graphs	Dutch (NL)	German (DE)	French (FR)	Spanish (ES)	Italian (IT)
	Back	Norwegian (NO)	Danish (DA)	Finnish (FI)	Greek (EL)	Portuguese (PT)	Swedish (SV)	Czech (CS)

Sheet 2	Front	Estonian (ET)	Hungarian (HU)	Latvian (LV)	Lithuanian (LT)	Polish (PL)	Slovak (SK)	Slovenian (SL)
	Back	Russian (RU)	Bulgarian (BG)	Turkish (TR)	Romanian (RO)	Croatian (HR)	Arabic (AR)	Serbian (SR)

CHANGE SUMMARY

REVISION	DESCRIPTION OF CHANGE
01	Initial release for J&J branding project.
02	Update CE Mark to MDD 93/42/EEC standards. Update label specification page to clarify all changes must coordinate with Z311211 and Z311278S. Revision level of Z311211, Z311278, and Z311278S must keep in sync. Remove minor changes indicated in "NOTE." Template update to SOP501027-T020 Rev. 05.

