

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
**ECOFIT® ACETABULAR CUP
SYSTEM**

PRODUCT GROUP: PRIMARY ARTHROPLASTY

RISK CLASS: III

LOCATION: HIP

REV.0

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ECOFIT® ACETABULAR CUP SYSTEM

ECOFIT® CUP - DESIGN DESCRIPTION

The EcoFit® Cup is a hemi-spherical, 2-piece modular metal shell / polyethylene- or ceramic- insert acetabular cup. The metal shells are manufactured from wrought TiAl₆V₄ alloy acc. to ISO 5832-3 in 12 outer diameter sizes from 46 mm – 68 mm.



FIG. 1: EcoFit® NH CUP



FIG. 2: EcoFit® CUP

The metal shell is available in two (2) versions: one with a cluster of three (3) 6.6 mm diameter peripheral holes for placement of 6.5 mm diameter flat head adjunctive bone screws for adjunctive fixation as needed and a version with no peripheral screw holes (designated as the “NH” version with “NH” representing “No Holes”). Both versions have a 10 mm diameter threaded apex hole for attachment of the cup shell insertion instrument. A threaded 10 mm diameter apex hole plug is provided to eliminate the apex hole after insertion of the shell and 6.5 mm diameter bone screw hole plugs are available to fill any screw holes that are not used for bone screws in the shell that has peripheral screw holes). The optional 6.5 mm diameter bone screws for adjunctive fixation are provided in lengths from 15 mm to 55 mm in 5 mm increments. The metal shells, apex hole plug, bone screw hole plugs, and bone screws hole plugs are manufactured from TiAl₆V₄ alloy acc. to ISO 5832-3.



FIG. 3: SCREW HOLE

The EcoFit® acetabular cups are intended for uncemented press fit application.

ECOFIT® CUP - SIZES

OUTER DIAMETERS	INNER DIAMETER
46 mm, 48 mm	39 mm
50 mm, 52 mm, 54 mm	44 mm
56 mm, 58 mm	48 mm
60 mm, 62 mm, 64 mm, 66 mm, 68 mm	52 mm

TABLE 1: EcoFit® CUP SIZES WITH INNER AND OUTER DIAMETER

ECOFIT® CUP - COATINGS

The EcoFit® cups are available with either a plasma sprayed coating of commercially pure titanium (cpTi) or a double layered coating of commercially pure titanium (cpTi) and hydroxyapatite (HA) which is applied to the back of the metal shell. It provides a press fit cementless fixation surface.

The cpTi plasma sprayed coating is manufactured from commercially pure titanium (cpTi) meeting the specifications of ISO 5832-2, while the Hydroxyapatite coating is according to ISO 13779.

COATING SPECIFICATIONS

CHARACTERISTICS	VALUE		
	EcoFit® HA & EcoFit® NH HA		EcoFit® & EcoFit® NH
	cpTi	HA	cpTi
COATING THICKNESS	250 ± 50 µm	90 ± 30 µm	300 ± 50 µm
POROSITY	30 ± 10 %	≤ 30%	30 ± 10 %
AVERAGE ROUGHNESS Ra	50 ± 15 µm	/	50 ± 15 µm
AVERAGE ROUGHNESS Rt	/	50 ± 20 µm	/
TENSILE STRENGTH	> 22 MPa	≥ 15 MPa	> 22 MPa
SHEAR STRENGTH	> 20 MPa	≥ 20 MPa	> 20 MPa

TABLE 2: COATING SPECIFICATIONS

POLYETHYLENE (PE) INSERTS

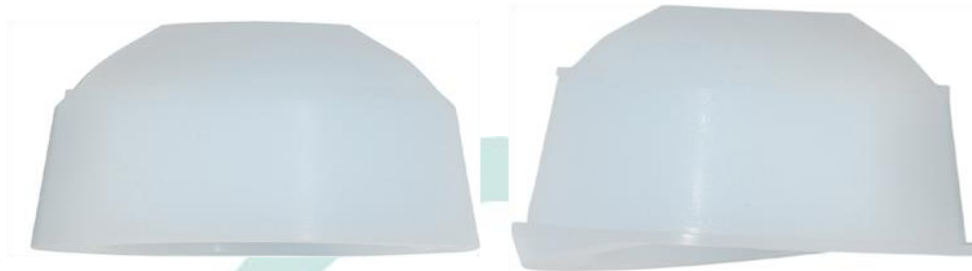


FIG. 4: PE INSERT 0° (LEFT), 10° (RIGHT)

The PE inserts are available in a standard profile configuration (0°, no lateral overhang) and a 10° lateral lip version to provide greater coverage of the femoral head to help prevent dislocation in cases at greater risk of dislocation, such as hip dysplasia.

The PE inserts are coupled to the metal shell by two (2) mechanisms: 1) a taper fit between the insert and the metal shell provided by a conical taper shape of the exterior surface of the insert that matches the conical taper geometry and inner diameter size of the interior of the metal shell and 2) a snap fit mechanism of four (4) lugs on the inferior aspect of the PE insert that snap into a circumferential groove at the bottom of the metal shell.

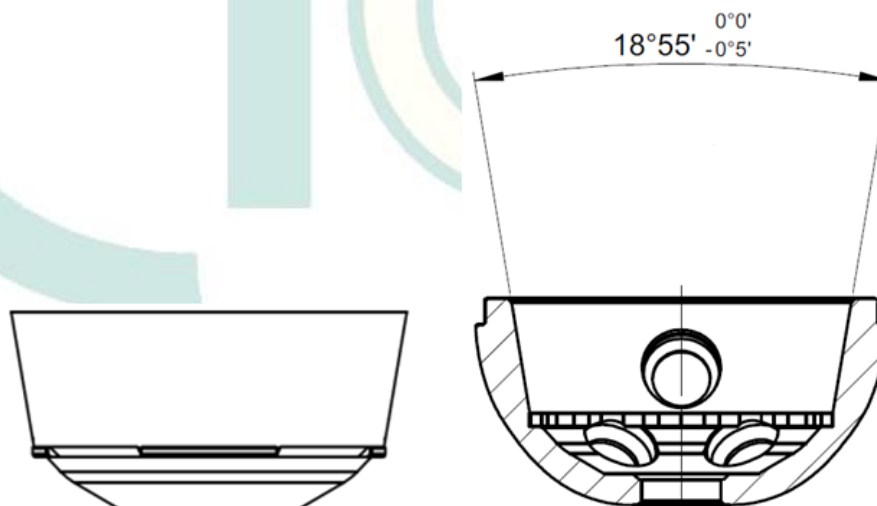


FIG. 5: SHELL – LINER CONICAL TAPER FIXATION (LINER LEFT; SHELL RIGHT)

PE INSERTS – COMPATIBILITY

The PE inserts mate with metal shells having an inner diameter (ID) corresponding to the outer diameter (OD) of the insert (i.e., PE inserts with an outer diameter of 39 mm mates with any shell having an inner diameter size of 39 mm). The compatible PE inserts and metal shells are listed in the following table.

	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD
	46 – 48 mm	50 – 54 mm	56 – 58 mm	60 – 68 mm
0° / 10° INSERT SIZE ID/OD	28 mm / 39 mm	28 mm / 44 mm	28 mm / 48 mm	28 mm / 52 mm
0° / 10° INSERT SIZE ID/OD	32 mm / 39 mm	32 mm / 44 mm	32 mm / 48 mm	32 mm / 52 mm
0° / 10° INSERT SIZE ID/OD	n/a	36 mm / 44 mm	36 mm / 48 mm	36 mm / 52 mm

TABLE 3: PE INSERTS - COMPATIBILITY

BIOLOX® DELTA INSERTS



FIG. 6: BIOLOX® DELTA INSERT

The BioloX® delta inserts are coupled to the metal shell by a taper fit between the insert and the metal shell provided by a conical taper shape of the exterior surface of the insert that matches the conical taper geometry and inner diameter size of the interior of the metal shell.

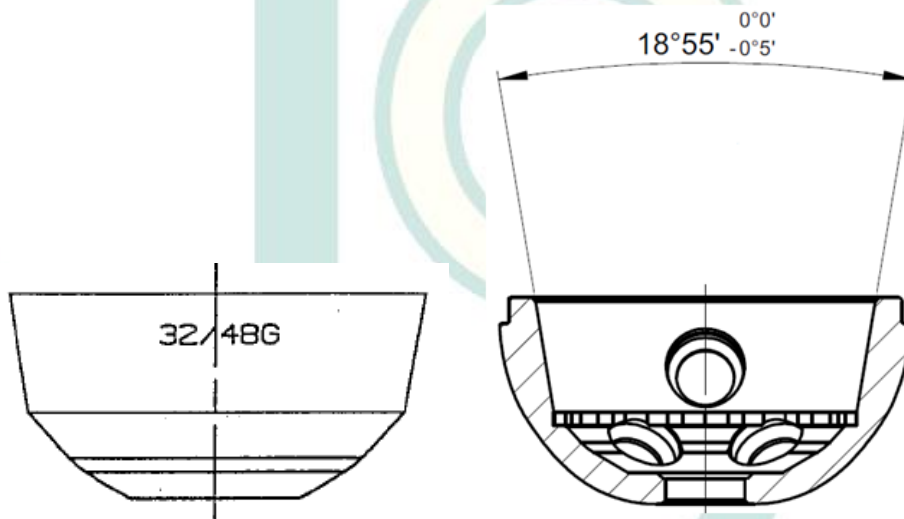


FIG. 7: SHELL – LINER CONICAL TAPER FIXATION (LINER LEFT; SHELL RIGHT)

BIOLOX® DELTA INSERTS – COMPATIBILITY

The BioloX® delta inserts mate with metal shells having an inner diameter (ID) corresponding to the outer diameter (OD) of the BioloX® delta liner (i.e., BioloX® delta insert with an outer diameter of 39 mm mates with any shell having an inner diameter size of 39 mm). The compatible BioloX® delta inserts and metal shells are listed in the following table.

	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD	METAL SHELL SIZE - OD
	46 – 48 mm	50 – 54 mm	56 – 58 mm	60 – 68 mm
BIOLOX® DELTA INSERT SIZE ID/OD	32 mm / 39 mm	32 mm / 44 mm	32 mm / 48 mm	32 mm / 52 mm
	n/a	36 mm / 44 mm	36 mm / 48 mm	36 mm / 52 mm
	n/a	n/a	40 mm / 48 mm (*)	40 mm / 52 mm (*)

TABLE 4: BIOLOX® DELTA INSERTS – COMPATIBILITY; (*) only available on request