

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION
ECOFIT® EPORE® CUPS

PRODUCT GROUP: PRIMARY ARTHROPLASTY

RISK CLASS: III

LOCATION: HIP

REV.0

DATE: 02.11.2015

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ECOFIT® CUP EPORE® SYSTEM

EcoFit® Cup EPORE® - DESIGN DESCRIPTION

The EcoFit® Cup EPORE® is a hemi-spherical, 2-piece modular metal shell / polyethylene insert liner acetabular cup. The metal shells are manufactured from wrought TiAl₆V₄ alloy acc. to ISO 5832-3 in 14 outer diameter sizes from 42 mm – 72 mm through an EBM® Electron Beam Melting process. By using the EBM® process the manufacturing of complex porous structures can be achieved which resembles cancellous bony structures to enhance osseointegration. EPORE® is such a porous structure that is designed to match the natural cancellous bone structure. Specification of this structure is given below.



FIG. 3: EcoFit® CUP EPORE®



FIG. 2: EcoFit® NH CUP EPORE®



FIG. 1: EcoFit® CUP EPORE® MULTI-HOLE



The metal shell is available in three (3) 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, one with a cluster of seven (7) peripheral holes (designated as Multi-Hole) and one version with no peripheral screw holes (designated as the “NH” version with “NH” representing “No Holes”). All versions feature 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. 4: SCREW HOLE

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

ECOFIT® CUP EPORE® - SIZES

| OUTER DIAMETERS | INNER DIAMETER |
|---|----------------|
| 42 mm, 44 mm | 35 mm |
| 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, 70 mm, 72 mm | 52 mm |

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

EcoFit® Cup EPORE® - SPECIFICATIONS

The EcoFit® Cups incorporate the highly porous EPORE® structure. The EPORE® structure has a high porosity and a low modulus of elasticity so it can enhance biological in-growth. The structure is characterized by rods of 330-390 µm thickness which are arrayed in a way that resembles cancellous bone structures.

EPORE® SPECIFICATIONS

| PARAMETER | VALUE |
|-----------------------|------------------------|
| MANUFACTURING PROCESS | Additive Manufacturing |
| POROSITY | 61% ± 8% |
| SPECIFIC E-MODULE | 3.1 GPa ± 0.6 GPa |
| ROD DIAMETER | 360 µm ± 50 µm |

TABLE 2: EPORE® SPECIFICATIONS

EcoFit® Cup EPORE® - COATINGS

The EcoFit® Cups EPORE® are available with a TCP (Tricalcium Phosphate) coating which is applied to the back of the metal shell.

COATING SPECIFICATIONS

| CHARACTERISTICS | VALUE |
|-------------------|----------|
| COATING THICKNESS | 20±10 µm |

| CHARACTERISTICS | VALUE |
|---------------------------|----------------------------|
| TENSILE STRENGTH | ≥ 15 MPa |
| PHASE COMPOSITION | >70 % Brushite <30 % HA |
| CaP – RATIO | 1.1 ± 0.1 |
| HEAVY METAL CONCENTRATION | acc. to ASTM F 1609-03 |

TABLE 3: COATING SPECIFICATIONS

POLYETHYLENE (PE) INSERTS



FIG. 5: 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.

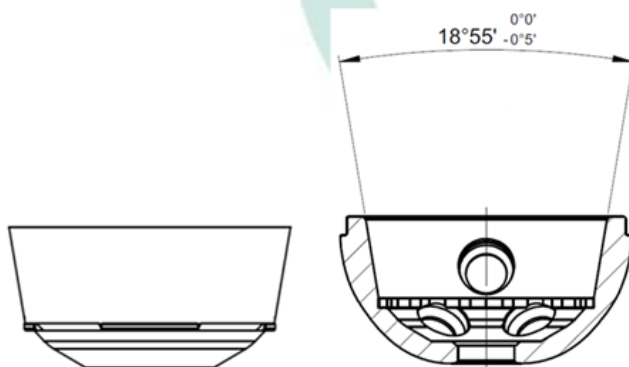


FIG. 1: SHELL – LINER CONICAL TAPER FIXATION (LINER LEFT; SHELL RIGHT)

PE INSERTS – MATERIALS

The polyethylene insert liners are available in three different materials:

1. UHMWPE acc. to ISO 5834-2
2. Crosslinked UHMWPE (Gamma Radiation with 75kGy)
3. Crosslinked UHMWPE doped with 1000 ppm Vitamin E (Gamma Radiation with 75kGy)

PE INSERTS – SIZES

The insert liners are available in five (5) outer diameters matching the five (5) inner diameters of the metal shells discussed above; the outer diameter is measured at the top edge of the insert. The sizes of the insert liners are provided in the following table.

| INNER DIAMETER | OUTER DIAMETER |
|---|--------------------------|
| PE insert 0° / 10° | |
| 28 mm | 39, 44, 48 and 52 mm |
| 32 mm | 39, 44, 48 and 52 mm |
| 36 mm | 48 and 52 mm |
| implacross® PE insert 0° / 10° (Crosslinked PE) | |
| 28 mm | 35, 39, 44, 48 and 52 mm |
| 32 mm | 39, 44, 48 and 52 mm |
| 36 mm | 44, 48 and 52 mm |
| implacross® E PE insert 0° / 10° (Crosslinked PE enriched with Vitamin E) | |
| 32 mm | 39, 44, 48, and 52 mm |
| 36 mm | 44, 48 and 52 mm |

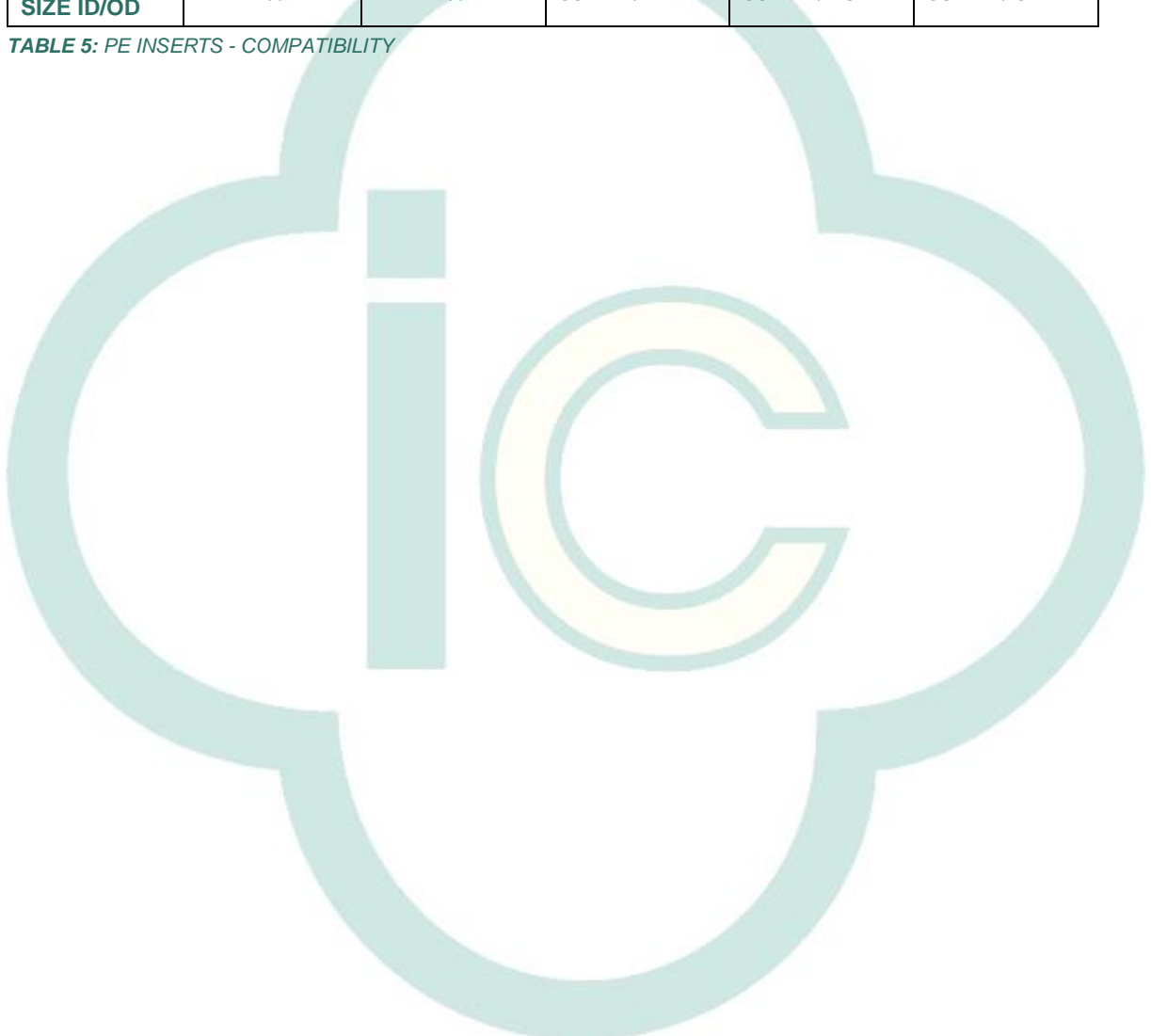
TABLE 4: PE-CUP INSERT SIZES

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 | | | | |
|--------------------------------------|-----------------------|---------------|---------------|---------------|---------------|
| | 42 – 44 mm | 46 – 48 mm | 50 – 54 mm | 56 – 58 mm | 60 – 72 mm |
| 0° / 10° LINER SIZE ID/OD | 28 mm / 35 mm | 28 mm / 39 mm | 28 mm / 44 mm | 28 mm / 48 mm | 28 mm / 52 mm |
| 0° / 10° LINER SIZE ID/OD | n/a | 32 mm / 39 mm | 32 mm / 44 mm | 32 mm / 48 mm | 32 mm / 52 mm |
| 0° / 10° LINER SIZE ID/OD | n/a | n/a | 36 mm / 44 mm | 36 mm / 48 mm | 36 mm / 52 mm |

TABLE 5: PE INSERTS - COMPATIBILITY



BILOX® DELTA INSERTS



FIG. 6: BILOX® DELTA INSERT

BILOX® DELTA INSERTS – MATERIAL

The BioloX® delta inserts are made of a composite ceramic based on a high-purity alumina matrix with zirconia reinforcement acc. to ISO 6474-2.

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.

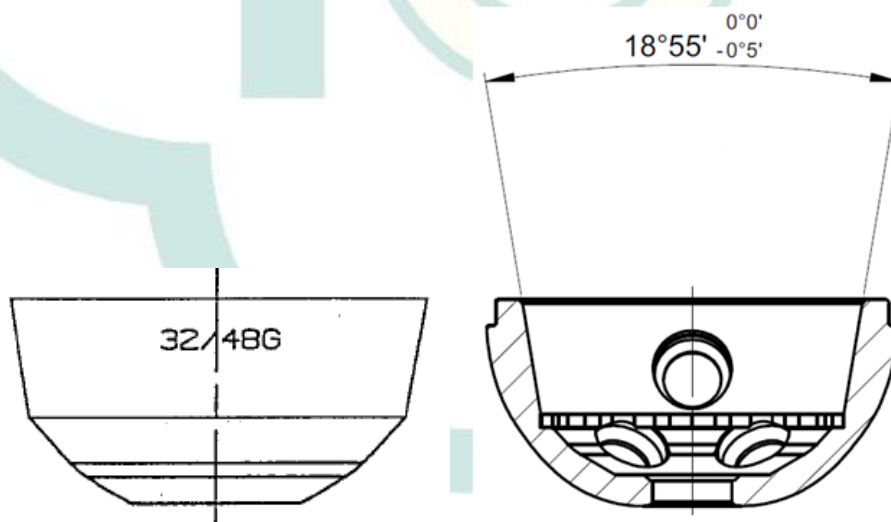


FIG. 7: SHELL – LINER CONICAL TAPER FIXATION (LINER LEFT; SHELL RIGHT)

BIOLOX® DELTA INSERTS – SIZES

The insert liners are available in five (5) outer diameters matching the five (5) inner diameters of the metal shells discussed above; the outer diameter is measured at the top edge of the insert. The sizes of the insert liners are provided in the following table.

| INNER DIAMETER | OUTER DIAMETER |
|----------------|----------------------|
| 28 mm | 35 mm |
| 32 mm | 39, 44, 48 and 52 mm |
| 36 mm | 44, 48 and 52 mm |
| 40 mm | 48 and 52 mm |

TABLE 6: BIOLOX® DELTA INSERT SIZES

BIOLOX® DELTA INSERTS – COMPATIBILITY

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

| | METAL SHELL SIZE - OD | | | | |
|---------------------------------------|-----------------------|---------------|---------------|---------------|---------------|
| | 42 – 44 mm | 46 – 48 mm | 50 – 54 mm | 56 – 58 mm | 60 – 72 mm |
| BIOLOX® DELTA LINER SIZE ID/OD | 28 mm /35 mm | 28 mm / 39 mm | n/a | n/a | n/a |
| | n/a | 32 mm / 39 mm | 32 mm / 44 mm | 32 mm / 48 mm | 32 mm / 52 mm |
| | n/a | n/a | 36 mm / 44 mm | 36 mm / 48 mm | 36 mm / 52 mm |
| | n/a | n/a | n/a | 40 mm / 48 mm | 40 mm / 52 mm |

TABLE 7: BIOLOX® DELTA INSERTS - COMPATIBILITY