

Device Schedule:

Intended Purpose as per the Instructions for Use:

The BIOLOX delta and Option Ceramic Femoral Head is used in conjunction with compatible acetabular and femoral stem components in total hip arthroplasty.

Risk Classification: Class III implantable

Type: (Codes as per (EU) 2017/2185): MDN 1102

Device Name	Model	Basic UDI-DI
BioloX delta head 12/14, 28 x -3.5	00-8775-028-01	889024AHDZF
BioloX delta head 12/14, 28 x 0	00-8775-028-02	889024AHDZF
BioloX delta head 12/14, 28 x +3.5	00-8775-028-03	889024AHDZF
BioloX delta head 12/14, 32 x -3.5	00-8775-032-01	889024AHDZF
BioloX delta head 12/14, 32 x 0	00-8775-032-02	889024AHDZF
BioloX delta head 12/14, 32 x +3.5	00-8775-032-03	889024AHDZF
BioloX delta head 12/14, 32 x +7	00-8775-032-04	889024AHDZF
BioloX delta head 12/14, 36 x -3.5	00-8775-036-01	889024AHDZF
BioloX delta head 12/14, 36 x 0	00-8775-036-02	889024AHDZF
BioloX delta head 12/14, 36 x +3.5	00-8775-036-03	889024AHDZF
BioloX delta head 12/14, 36 x +7	00-8775-036-04	889024AHDZF
BioloX delta head 12/14, 40 x -3.5	00-8775-040-01	889024AHDZF
BioloX delta head 12/14, 40 x 0	00-8775-040-02	889024AHDZF
BioloX delta head 12/14, 40 x +3.5	00-8775-040-03	889024AHDZF
BioloX delta head 12/14, 40 x +7	00-8775-040-04	889024AHDZF

Device Name	Model	Basic UDI-DI
Biolog OPTION Hd/Adpt, 12/14, 28 x -3.0	00-8777-028-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 28 x 0	00-8777-028-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 28 x +3.5	00-8777-028-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 28 x +7	00-8777-028-04	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 32 x -3.0	00-8777-032-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 32 x 0	00-8777-032-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 32 x +3.5	00-8777-032-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 32 x +7	00-8777-032-04	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 36 x -3.0	00-8777-036-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 36 x 0	00-8777-036-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 36 x +3.5	00-8777-036-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 36 x +7	00-8777-036-04	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 40 x -3.0	00-8777-040-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 40 x 0	00-8777-040-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 40 x +3.5	00-8777-040-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 40 x +7	00-8777-040-04	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 44 x -3.0	00-8777-044-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 44 x 0	00-8777-044-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 44 x +3.5	00-8777-044-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 44 x +7	00-8777-044-04	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 48 x -3.0	00-8777-048-01	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 48 x 0	00-8777-048-02	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 48 x +3.5	00-8777-048-03	889024AHEZH
Biolog OPTION Hd/Adpt, 12/14, 48 x +7	00-8777-048-04	889024AHEZH
Biolog OPTION Hd/Adpt, 8/10, 28 x -3.0	00-8778-028-01	889024AHFZK
Biolog OPTION Hd/Adpt, 8/10, 28 x 0	00-8778-028-02	889024AHFZK
Biolog OPTION Hd/Adpt, 8/10, 28 x +4.0	00-8778-028-03	889024AHFZK

Device Name	Model	Basic UDI-DI
BioloX OPTION Hd/Adpt, 8/10, 32 x -3.0	00-8778-032-01	889024AHFZK
BioloX OPTION Hd/Adpt, 8/10, 32 x 0	00-8778-032-02	889024AHFZK
BioloX OPTION Hd/Adpt, 8/10, 32 x +4.0	00-8778-032-03	889024AHFZK
BioloX OPTION Hd/Adpt, 8/10, 36 x -3.0	00-8778-036-01	889024AHFZK
BioloX OPTION Hd/Adpt, 8/10, 36 x 0	00-8778-036-02	889024AHFZK
BioloX OPTION Hd/Adpt, 8/10, 36 x +4.0	00-8778-036-03	889024AHFZK