Patient Leaflet
Hip Replacement Product Range

1. Device Identification

1.a. Name of Device

The device may include the following:

1. Hip Stem, Cemented
2. Hip Stem, Press-Fit
3. Modular Neck
4. Modular Sleeve
5. Head, BIOLOX® Delta Ceramic
6. Acetabular Shell, Press-Fit
7. Acetabular Shell, Cemented
8. Acetabular Cup, Press-Fit
9. Liner, Cross-Linked Polyethylene 0° Neutral
10. Liner, Cross-Linked Polyethylene 15° Hooded
11. Liner, Cross-Linked Polyethylene
12. Insert TiNbN, CoCr, Delta Ceramic
13. Screw

1.b. Model of Device

The model of the device is tabled below:

Product Reference	Description
0107101	Hydra Cementless Stem Size 9
0107102	Hydra Cementless Stem Size 10
0107103	Hydra Cementless Stem Size 11
0107104	Hydra Cementless Stem Size 12
0107105	Hydra Cementless Stem Size 13
0107106	Hydra Cementless Stem Size 14
0107107	Hydra Cementless Stem Size 15
0107108	Hydra Cementless Stem Size 16
0107109	Hydra Cementless Stem Size 17
0107110	Hydra Cementless Stem Size 18
0107900	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 8
0107901	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 9
0107902	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 10
0107903	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 11
0107904	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 12
0107905	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 13
0107906	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 14
0107907	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 15
0107908	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 16
0107909	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 17
0107910	Hydra-Fix Cementless Stem Neck 12/14 Standard Size 18
0108000	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 8
0108001	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 9
0108002	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 10
0108003	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 11
0108004	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 12
0108005	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 13
0108006	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 14
0108007	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 15
0108008	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 16
0108009	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 17
0108010	Hydra-Fix Cementless Stem Neck 12/14 Offset Size 18
0460110	Modula Neck 12/14 S.F. Size 0X
0460210	Modula Neck 12/14 S.F. Size 0A
0460220	Modula Neck 12/14 S.F. Size 0Y
0460310	Modula Neck 12/14 S.F. Size 0B
0460320	Modula Neck 12/14 S.F. Size 0C
0460330	Modula Neck 12/14 S.F. Size 0Z
0469110	Modula Neck 12/14 S.F. Size 9X
0469120	Modula Neck 12/14 S.F. Size 9Aa
0469130	Modula Neck 12/14 S.F. Size 9Bb
0469210	Modula Neck 12/14 S.F. Size 9 A
0469220	Modula Neck 12/14 S.F. Size 9Y
0469230	Modula Neck 12/14 S.F. Size 9Cc
0469310	Modula Neck 12/14 S.F. Size 9B
0469320	Modula Neck 12/14 S.F. Size 9C
0469330	Modula Neck 12/14 S.F. Size 9Z
0513001	Modular Sleeve 12/14 For Revision Head Short
0513002	Modular Sleeve 12/14 For Revision Head Medium
0513003	Modular Sleeve 12/14 For Revision Head Long
0513004	Modular Sleeve 12/14 For Revision Head Extra Long
0513320	Modular Delta Alumina Ceramic Revision Head Diam 32
0513360	Modular Delta Alumina Ceramic Revision Head Diam 36
0513400	Modular Delta Alumina Ceramic Revision Head Diam 40
0513440	Modular Delta Alumina Ceramic Revision Head Diam 44
0513480	Modular Delta Alumina Ceramic Revision Head Diam 48
0514281	Delta Alumina Ceramic Head 12/14 Diam 28 Short
0514282	Delta Alumina Ceramic Head 12/14 Diam 28 Medium
0514283	Delta Alumina Ceramic Head 12/14 Diam 28 Long
0514321	Delta Alumina Ceramic Head 12/14 Diam 32 Short
0514322	Delta Alumina Ceramic Head 12/14 Diam 32 Medium
0514323	Delta Alumina Ceramic Head 12/14 Diam 32 Long
0514324	Delta Alumina Ceramic Head 12/14 Diam 32 Extra-Long
0514361	Delta Alumina Ceramic Head 12/14 Diam 36 Short
0514362	Delta Alumina Ceramic Head 12/14 Diam 36 Medium
0514363	Delta Alumina Ceramic Head 12/14 Diam 36 Long
0514364	Delta Alumina Ceramic Head 12/14 Diam 36 Extra-Long
0514402	Delta Alumina Ceramic Head 12/14 Diam 40 Medium
0514403	Delta Alumina Ceramic Head 12/14 Diam 40 Long
0514404	Delta Alumina Ceramic Head 12/14 Diam 40 Extra-Long
0514441	Delta Alumina Ceramic Head 12/14 Diam 44 Short
0514442	Delta Alumina Ceramic Head 12/14 Diam 44 Medium
0514443	Delta Alumina Ceramic Head 12/14 Diam 44 Long
0520281	Co-Cr-Mo Femoral Head Cone 12/14 Diam 28 Short
0520282	Co-Cr-Mo Femoral Head Cone 12/14 Diam 28 Medium
0520283	Co-Cr-Mo Femoral Head Cone 12/14 Diam 28 Long
0524221	Co-Cr-Mo Femoral Head Cone 12/14 Diam 22 Short
0524222	Co-Cr-Mo Femoral Head Cone 12/14 Diam 22 Medium
0524223	Co-Cr-Mo Femoral Head Cone 12/14 Diam 22 Long
0601020	Titanium Acetabular Screw Diam. 6,5 Mm L. 20 Mm
0601025	Titanium Acetabular Screw Diam. 6,5 Mm L. 25 Mm
0601030	Titanium Acetabular Screw Diam. 6,5 Mm L. 30 Mm
0601035	Titanium Acetabular Screw Diam. 6,5 Mm L. 35 Mm
0601040	Titanium Acetabular Screw Diam. 6,5 Mm L. 40 Mm
0601045	Titanium Acetabular Screw Diam. 6,5 Mm L. 45 Mm
0601050	Titanium Acetabular Screw Diam. 6,5 Mm L. 50 Mm
0753142	Fixa Ti-Por Cup Size 42 Group A
0753144	Fixa Ti-Por Cup Size 44 Group A
0753146	Fixa Ti-Por Cup Size 46 Group A
0753148	Fixa Ti-Por Cup Size 48 Group A
0753350	Fixa Ti-Por Cup Size 50 Group B
0753352	Fixa Ti-Por Cup Size 52 Group B
0753454	Fixa Ti-Por Cup Size 54 Group C
0753456	Fixa Ti-Por Cup Size 56 Group C
0753558	Fixa Ti-Por Cup Size 58 Group D
0753560	Fixa Ti-Por Cup Size 60 Group D
0753562	Fixa Ti-Por Cup Size 62 Group D
0753564	Fixa Ti-Por Cup Size 64 Group D
0758142	Agilis Ti-Por Cup Size 42 For 32 Mm Head
0758144	Agilis Ti-Por Cup Size 44 For 32 Mm Head
0758246	Agilis Ti-Por Cup Size 46 For 36 Mm Head
0758248	Agilis Ti-Por Cup Size 48 For 36 Mm Head
0758350	Agilis Ti-Por Cup Size 50 For 40 Mm Head
0758352	Agilis Ti-Por Cup Size 52 For 40 Mm Head
0758454	Agilis Ti-Por Cup Size 54 For 44 Mm Head
0758456	Agilis Ti-Por Cup Size 56 For 44 Mm Head
0758558	Agilis Ti-Por Cup Size 58 For 48 Mm Head
0758560	Agilis Ti-Por Cup Size 60 For 48 Mm Head
0758562	Agilis Ti-Por Cup Size 62 For 48 Mm Head
0758564	Agilis Ti-Por Cup Size 64 For 48 Mm Head
0758566	Agilis Ti-Por Cup Size 66 For 48 Mm Head
0772142	Fixa Duplex Dual Mobility Cemented Cup Size 42
0772144	Fixa Duplex Dual Mobility Cemented Cup Size 44
0772146	Fixa Duplex Dual Mobility Cemented Cup Size 46
0772248	Fixa Duplex Dual Mobility Cemented Cup Size 48
0772250	Fixa Duplex Dual Mobility Cemented Cup Size 50
0772252	Fixa Duplex Dual Mobility Cemented Cup Size 52
0772254	Fixa Duplex Dual Mobility Cemented Cup Size 54
0772256	Fixa Duplex Dual Mobility Cemented Cup Size 56
0772258	Fixa Duplex Dual Mobility Cemented Cup Size 58
0772260	Fixa Duplex Dual Mobility Cemented Cup Size 60
0772262	Fixa Duplex Dual Mobility Cemented Cup Size 62
0771142	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 42
0771144	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 44
0771146	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 46
0771248	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 48
0771250	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 50
0771252	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 52
0771254	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 54
0771256	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 56
0771258	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 58
0771260	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 60
0771262	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 62
0771264	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 64
0771266	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 66
0771268	Fixa Duplex Dual Mobility Cementless Cup Co-Por + Ha Size 68
0813201	Delta Ceramic Insert Diam. 32 Gr. A - Gr. 1
0813603	Delta Ceramic Insert Diam. 36 Gr. B - Gr. 3
0813604	Delta Ceramic Insert Diam. 36 Gr.C - Gr. 4
0813605	Delta Ceramic Insert Diam. 36 Gr. D - Gr. 5
0814004	Delta Ceramic Insert Diam. 40 Gr. C - Gr. 4
0814005	Delta Ceramic Insert Diam. 40 Gr. D - Gr. 5
0833221	Cross-Linked Pe Insert Flat Diam. 32 Gr. A
0833224	Cross-Linked Pe Insert Flat Diam. 32 Gr. C
0833623	Cross-Linked Pe Insert Flat Diam. 36 Gr. B
0833624	Cross-Linked Pe Insert Flat Diam. 36 Gr. C
0833625	Cross-Linked Pe Insert Flat Diam. 36 Gr. D
0842821	Cross-Linked Pe Insert 15° Offset Diam. 28 Gr. A
0843221	Cross-Linked Pe Insert 15° Offset Diam. 32 Gr. A
0843223	Cross-Linked Pe Insert 15° Offset Diam. 32 Gr. B
0843224	Cross-Linked Pe Insert 15° Offset Diam. 32 Gr. C
0843225	Cross-Linked Pe Insert 15° Offset Diam. 32 Gr. D
0843623	Cross-Linked Pe Insert 15° Offset Diam. 36 Gr. B
0943624	Cross-Linked Pe Insert 15° Offset Diam. 36 Gr. C
0943625	Cross-Linked Pe Insert 15° Offset Diam. 36 Gr. D
0871201	Bis Dual Mobility X-Link Pe Component Diam. 22 Gr. 1 A
0871203	Bis Dual Mobility X-Link Pe Component Diam. 22 Gr. 3 B
0871204	Bis Dual Mobility X-Link Pe Component Diam. 28 Gr. 4 C
0871205	Bis Dual Mobility X-Link Pe Component Diam. 28 Gr. 5 D
0871301	Bis Dual Mobility Co-Cr Anti-Allergic Tinbn Coated Component Diam. 22 Gr. 1 A
0871303	Bis Dual Mobility Co-Cr Anti-Allergic Tinbn Coated Component Diam. 22 Gr. 3 B
0871304	Bis Dual Mobility Co-Cr Anti-Allergic Tinbn Coated Component Diam. 28 Gr. 4 C
0871305	Bis Dual Mobility Co-Cr Anti-Allergic Tinbn Coated Component Diam. 28 Gr. 5 D
0895001	Bis Dual Mobility Co-Cr Component Diam. 22 Gr. 1 A
0895003	Bis Dual Mobility Co-Cr Component Diam. 22 Gr. 3 B
0895004	Bis Dual Mobility Co-Cr Component Diam. 28 Gr. 4 C
0895005	Bis Dual Mobility Co-Cr Component Diam. 28 Gr. 5 D
0872142	Fixa Duplex Cross-Linked Pe Insert Size 42 For 22 Mm Head
0872144	Fixa Duplex Cross-Linked Pe Insert Size 44 For 22 Mm Head
0872146	Fixa Duplex Cross-Linked Pe Insert Size 46 For 22 Mm Head
0872248	Fixa Duplex Cross-Linked Pe Insert Size 48 For 28 Mm Head
0872250	Fixa Duplex Cross-Linked Pe Insert Size 50 For 28 Mm Head
0872252	Fixa Duplex Cross-Linked Pe Insert Size 52 For 28 Mm Head
0872254	Fixa Duplex Cross-Linked Pe Insert Size 54 For 28 Mm Head
0872256	Fixa Duplex Cross-Linked Pe Insert Size 56 For 28 Mm Head
0872258	Fixa Duplex Cross-Linked Pe Insert Size 58 For 28 Mm Head
0872260	Fixa Duplex Cross-Linked Pe Insert Size 60 For 28 Mm Head
0872262	Fixa Duplex Cross-Linked Pe Insert Size 62 For 28 Mm Head

2. Intended Purpose and Patient

2.a. Intended Purpose of the Device

ADLER ORTHO implants are intended for use in total hip arthroplasty.

2.b. Patient Whom the Device is Intended to be Used

Treatment selection for the patient is the surgeon's responsibility. When a surgeon has selected total hip arthroplasty as the preferred treatment for the patient, the devices are indicated for:

- Primary and secondary arthrosis (degeneration of hip joint)
- Rheumatoid and degenerative arthritis
- Deformities, such as dysplasia (abnormal alignment of hip joint)
- Fractures and necrosis (death) of bone
- Revisions, where other devices or treatments have failed
- Metastatic diseases (cancer)

Total hip arthroplasty is contraindicated in the following conditions:

- infection, septicaemia, and osteomyelitis constitute cases of absolute contraindication;
- serious metabolic, cardiovascular, respiratory or neurological pathologies;
- serious osteoporosis;
- rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- obesity;
- skeletally immature patients;
- female patients of childbearing age, for whom a negative pregnancy test is not obtained;
- high patient activity which could lead to overloading of the implant.

3. Special Operating Instructions

Not applicable. There is no such information for the patient. The instructions for use of the device are only applicable to the surgeon.

4. Intended Performance and Side Effects

4.a. Intended Performance of the Device

Provide increased patient mobility and reduce where there is evidence of sufficient sound bone to seat and support the components.

4.b. Potential Undesirable Side Effects

GENERAL

- Loosening, displacement, or migration of the implant
- Component dislocation or disassembly
- Change in position of the implant
- Implant breakage
- Fatigue fracture of the implant
- Wear of the polyethylene component
- Incomplete cement mantle
- Infection
- Peripheral neuropathies
- Subclinical nerve damage as a result of surgical trauma
- Tissue reactions, osteolysis

INTRAOPERATIVE OR EARLY POSTOPERATIVE

- Acetabular or femoral perforation/fracture
- Trochanteric facture
- Damage to blood vessels
- Temporary or permanent nerve damage
- Lengthening or shortening of the affected extremity
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, and myocardial infarction
- Haematoma
- Delayed wound healing
- Infection.

LATE POSTOPERATIVE

- Trochanteric avulsion as a result of excessive muscular tensions, weight bearing or inadvertent intraoperative weakening
- Femoral fracture by trauma or excessive loading
- Bone resorption which may lead to loosening of the implant
- Instability as a result of subluxation or dislocation
- Comprised ambulation (patient limping)

5. Residual Risks

- Weight and physical activity can still have an impact on the implant lifetime an allergic reaction to the implant material is possible, although extremely rare.
- Implantation of a foreign material inside the body can cause a cellular reaction.

6. Warnings and Precautions

6.a. Warnings

Adler Ortho Australia does not recommend magnetic resonance imaging (MRI) for any patients implanted with metallic hip components without prior consultation with an expert radiologist. The safety of the devices in the MR environment has not been tested and scanning of patients who have the device may result in patient injuries. The device should be considered MRI not tested.

6.b. Precautions

In the event of having an MRI or equivalent intervention, the patient needs to inform qualified health professionals prior to having this examination

7. Postoperative

7.a. Examination

Post-operative follow-up and examination should be scheduled on a regular basis by the health professional

7.b Symptoms or signs that could indicate the device is malfunctioning

- Pain
- Discomfort
- Inflammation
- Infection
- Persisting haematoma
- Joint dislocation
- Subluxation
- Abnormal joint noise
- Lengthening or shortening of the affected extremity

7.c. Precautions that should be taken if the performance of the device changes or the patient experiences any of the symptoms mentioned in section 7.b.

Inform the health professional without delay then follow their instruction. In the meantime, reduce physical activity and limit weight bearing of the affected extremity.

7.d. Expected device lifetime

Approx. 95% survivorship at 10 years.

7.e. Factors that could shorten device lifetime

- Increased patient weight may shorten device lifetime
- Physical activity may shorten device lifetime

7.f. Precautions to be taken at or near the end of the expected device lifetime

No specific precautions should be taken at or near the end of the expected device lifetime as long as:

- No symptoms or sign that could indicate that the device is malfunctioning are observed (See section 7.b.)
- Radiographic examination (if recommended) by a specialist health professional is performed and shows no sign of undesirable effects

7.g. Other circumstances

If in doubt regarding the operation of the device, the patient should contact their health professional.

8. Materials and Residues

8.a. Materials

1. Hip Stem, Press-Fit: Titanium Alloy with HA Coating
2. Modular Neck: Titanium Alloy
3. Modular Sleeve: Titanium Alloy
4. Head, BIOLOX® Delta ZTA Ceramic: Zirconia Toughened Alumina
5. Head, CoCrMo: Cobalt-Chrome-Molybdenum
6. Acetabular Shell, Press-Fit: Titanium Alloy
7. Acetabular Shell, Cemented: Stainless Steel
8. Acetabular Shell, Press-Fit: Cobalt-Chrome-Molybdenum
9. Acetabular Cup, Press-Fit: Titanium Alloy with Porous Titanium Coating + Zirconia Toughened Alumina (Liner)
10. Liner, Cross-Linked Polyethylene 0° Neutral: Polyethylene
11. Liner, Cross-Linked Polyethylene 15° Hooded: Polyethylene
12. Liner, BIOLOX® Delta ZTA Ceramic: Zirconia Toughened Alumina
13. Insert, Cross-Linked Polyethylene: Polyethylene
14. Insert, TiNbN: Titanium Niobium Nitride
15. Insert, CoCr: Cobalt-Chrome-Molybdenum
16. Screw: Titanium Alloy

8.b. Manufacturing Residuals

There is no known patient risk associated with potential residual manufacturing residues

9. Therapeutic Goods Administration

9.a. Incident Reporting

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the appropriate regulatory body.

9.b. Address

Therapeutic Goods Administration website:
https://www.tga.gov.au/

Name & address of manufacturer:
Adler Ortho SpA
Via dell'Innovazione 9, 20032 Cormano – (MI), Italy

Adler Ortho Australia contact details:
http://www.adlerortho.com.au/contact-us