INSTRUCTIONS FOR USE

AVANTAGE RELOAD ACETABULUM
AVANTAGE CEMENTED ACETABULUM
AVANTAGE 3P ACETABULUM
AVANTAGE REVISION ACETABULUM
AVANTAGE 3P Ti+HA ACETABULUM

1. Product name and description

This box contains a medical device from the AVANTAGE ACETABULUM range intended to replace the natural bone acetabulum during total hip arthroplasty.
This range is made up of the following components:
- AVANTAGE RELOAD Cup P0460Pxx
- AVANTAGE CEMENTED Cup P04630xx
- AVANTAGE 3P Cup P04610xx
- AVANTAGE REVISION Cup P0464Hxx
- AVANTAGE 3P Ti+HA Cup P0461PXX
- AVANTAGE Insert P05600xx / P05610xx
- AVANTAGE E1 Insert P0560Exx / P0561Exx
- AVANTAGE Pin P0461070

2. Materials used for the implant

Name	Material	Standards
AVANTAGE RELOAD Cup AVANTAGE 3P Ti+HA Cup	Stainless steel	ISO 5832-9: 07
	Hydroxyapatite Ceramic	ASTM F1185-03
	Rough pure titanium	ASTM 1580-07
AVANTAGE CEMENTED Cup	Stainless steel	ISO 5832-9: 07
AVANTAGE 3P Cup AVANTAGE REVISION Cup	Stainless steel	ISO 5832-9: 07
	Hydroxyapatite Ceramic	ASTM F1185-03
AVANTAGE Insert	ARCOM UHMWP	ASTM F648-10
AVANTAGE E1 Insert	E1 HXLPE (highly cross-linked polyethylene enhanced with vitamin E)	ASTM F648-10
AVANTAGE Pin	Stainless steel	ISO 5832-9: 07

3. Choice of implants

The use of radiographic templates during preoperative planning and instrumentation specific to the surgical technique will aid in the choice of the most appropriate sizes for the patient's morphology.

4. Indications

AVANTAGE range acetabula can be used for the following indications of total hip arthroplasty:
• Primitive or secondary coxarthrosis;
• Inflammation of the hip; rheumatoid arthritis, etc.;
• Sequelae from previous hip operations, osteotomies, etc.;
• Congenital hip dysplasia;

• Femoral neck fracture;
• Femoral head necrosis.
• Revision of the bearing with a RECAP/MAGNUM cup or an AVANTAGE cup (see below).

Revision of the bearing – AVANTAGE cup;
Only AVANTAGE E1 P0560Exx and P0561Eyy (xx=44 to 66, *yy=50 to 66*) inserts may be used for a revision of the bearing (revision of the head and insert) when an AVANTAGE cup has already been fitted.

Revision of the bearing – RECAP/MAGNUM cup:
The AVANTAGE E1 P0560Ezz and P0561Ezz (zz=44 to 66) inserts may be used for revisions of the bearing when a RECAP/MAGNUM cup has already been fitted following the failure of the metal/metal association.
Note : AVANTAGE E1 inserts – sizes 44/46/48 Ø 28 mm - are only intended to be used with a RECAP/MAGNUM cup that has already been fitted and not for an AVANTAGE cup revision.

AVANTAGE range acetabula are double mobility and are therefore particularly recommended for patients presenting the following profiles:
• Patients of any age with a high risk of dislocation.
• Pathology exposing a patient to a risk of dislocation:
    - Neck fracture;
    - Tumor surgery;
    - Neuromuscular disorder (Parkinson's, buttock muscle paralysis, etc.).
• Hip prosthesis revision especially for recurring dislocations.

AVANTAGE REVISION range cup can be used for the following indications of total hip arthroplasty revision:
• Aseptic loosening.
• Septic loosening in connection with a replacement in one or two steps depending on the surgeon's therapeutic choice for treating the infection.
• Acetabular bone defect with or without damage to the bony ring and/or destruction of the area (Paprosky Classification: 2B – 2C – 3A).
• Periprosthetic fracture of the coxo-femoral joint.
• Unexplained persistent pain.
• Recurring dislocation.

The choice between the different versions of AVANTAGE ACETABULUM depends on the acetabulum bone defect which gives the following grades using the Paprosky classification:

AVANTAGE ACETABULUM	**Paprosky Classification**
AVANTAGE RELOAD Cup + AVANTAGE or AVANTAGE E1 Insert	1 – 2A
AVANTAGE 3P Cup and 3P Ti+HA + AVANTAGE or AVANTAGE E1 Insert + AVANTAGE Pins	1 – 2A – 2C
CEMENTED AVANTAGE Cup + AVANTAGE or AVANTAGE E1 Insert	1 – 2A
AVANTAGE REVISION + AVANTAGE or AVANTAGE E1 insert	2B – 2C – 3A

5. Expected performance
• Restoration of joint function and pain reduction

• Osteo-integration for hydroxyapatite-coated medical devices.

6. Contraindications

• Local or systemic infections.
• Severe muscular, neurological or vascular deficiencies of the extremity involved.
• Bone destruction or poor bone quality that is likely to affect implant stability (Paget's disease, osteoporosis).
• Any concomitant disease that is likely to affect implant function.
• Allergy to any of the components of the implant.
• Patients incapable of following surgeon's recommendations.
• Patients weighing over 110 kg for the AVANTAGE cup / AVANTAGE insert association.
• Patients weighing over 100 kg for the RECAP/MAGNUM cup/ AVANTAGE E1 insert association.
• The AVANTAGE Insert and AVANTAGE E1 Insert are not cleared for use with the Magnum Tri-Spike Acetabular Cup.

7. Factors likely to compromise implant success and device performance

• Significant deformations, congenital dislocation.
• Local bone tumors.
• Ligament instability or serious and untreatable muscle contractures.
• Patient history of infections or repeated falls.
• Substance dependence.
• Poor positioning of insert in cup.
• Trauma possibly causing an implant to break.
• Poor orientation of acetabulum.

8. Adverse reactions

• Wearing of the acetabular components' polyethylene joint surfaces has been observed following total hip replacement. Higher wear rates may be caused by particles of cement, metal or other debris that may lead to abrasion of joint surfaces. Significant wear may shorten the prosthesis' useful life and lead to premature replacement of the prosthesis' worn components.
For insert revisions (the cup remaining in place), an inspection of the cup (no deep scratches, etc.) and thorough cleaning are required to remove all debris (bone, metal, tissue, cement, etc.) which could lead to excessive and/or premature wearing of the insert. The surgeon will evaluate whether the cup is showing signs of wear requiring its complete removal or the replacement of the insert alone.
For insert revisions, it is recommended that the prosthetic femoral head should be revised to prevent any excessive and/or premature wearing of the components.
• In all cases of joint replacement, asymptomatic localized progressive bone resorption (osteolysis) may be noted around prosthetic components as a result of foreign body reactions triggered by particles. These particles are generated by the interaction between the various components, as well as between the components and bone, mainly through mechanisms of wear, adhesion and fatigue. Other particles may also be produced by the wearing of another body. Osteolysis may lead to successive complications requiring the removal and replacement of prosthetic components.
• Although rare, cases of metal intolerance following joint replacement have been observed. Implantation of foreign material in tissues may result in histological reactions involving the formation of macrophages and fibroblasts.

• Dislocation or subluxation of prosthetic components due to improper positioning and/or migration of components can occur. Muscle and fibrous tissue laxity can also contribute to these conditions.
An unsuitable choice, incorrect positioning, poor alignment or incorrect fixation of the cup may result in excessive stresses on the insert, which can reduce the life expectancy of the prosthesis.
• Prosthetic components can come loose or migrate following trauma.
• When used in association with the RECAP/MAGNUM cup in patients weighing over 100 kg, a blocking of the mobility of the insert in the cup (large joint) may occur.

9. Shelf life and sterility

Implants are supplied sterile and packaged individually in double wrapping. Sterilization is carried out by exposure to a minimum dose of 25 kGy of gamma irradiation.
The expiration date is printed on the label. Do not use implants after the expiration date.

SINGLE USE - DO NOT RESTERILIZE IMPLANTS

The performance of the device cannot be guaranteed if implants are reused after a re-sterilisation process (as plastic parts can become distorted or change structurally during the sterilisation process, and surfaces can become damaged; moreover, the efficacy of the decontamination method and integrity of the coating cannot be guaranteed).

10. Specific instructions for use

• Packaging must not show signs that could indicate a defect in the sterility and/or integrity of the medical device.
• Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient. Furthermore, reusing an implant, could cause patient contamination
• When handling implants in the operating room, all necessary precautions must be taken to avoid damaging the implants (scratches, etc.).
• The implantation must be performed by an orthopedic surgeon experienced in lower limb surgery, according to the manufacturer's recommended surgical technique.
• For bearing revisions, following the removal of the prosthetic head, check for the absence of damage to the neck and/or cone of the femoral stem opposite.
• Do not use inserts made from ArCom Polyethylene (P05610xx and P05600xx) for bearing revisions already in place.
• Use the instrumentation designed by the manufacturer for inserting this implant.
• Do not use components of this prosthetic system with components from another manufacturer other than the one indicate in § 11
• Comply with size relationships between various related prosthetic parts.
• The surgeon must consider the design and size of the related stem to prevent a cam effect.
• Never allow antibiotics or acid local antiseptics to come into contact with the hydroxyapatite coating.
• Do not cement a hydroxyapatite-coated cup.
• The possible effects of a magnetic resonance imaging environment on this device have not been determined. This product has not been subjected to heating or migration tests in a magnetic resonance imaging environment.

• Dirty implants should be treated as biological waste.
• Comply with size relationships between various related prosthetic parts: insert and cup sizes must be identical.

11. Compatible medical devices

• Specific instrumentation:

Instrumentation name	**Reference**
AVANTAGE UPGRADE INSTRUMENT KIT	110026613
AVANTAGE instrumentation	A0900046
Additional AVANTAGE Revision instrumentation	A0900067
MINI-INVASIVE instrumentation for acetabulum	A0900164
MINI-INVASIVE instrumentation for AVANTAGE acetabulum	A0900165
Instrumentation for removing heads and stems	31-601496

• Femoral stems from the Biomet range: AURA/ARPEGE, AURA RR, AURA II, ART, DB-10, EXCEPTION, UP-TION, PERTROCH+, MAINSTREAM MÜLLER, GTS. TAPERLOC, BIMETRIC, STANMORE, F40, PPF, MALLORY HEAD, CONELOCK, Oxford Revision, Reach.
• RECAP/MAGNUM acetabula: 1578xx / 1579xx / 1308xxxx in association with an AVANTAGE E1 insert.
• Biomet Femoral heads, 22.2 and 28mm diameter, made of stainless steel, alumina ceramic or cobalt chromium with a 12/14 taper and aluminia ceramics (Biolox Delta) or cobalt-chromium with a Type 1 taper
• A CEMENTED AVANTAGE cup can be used with an AVANTAGE acetabular reinforcement cross in cases of revision of the acetabular part of a total hip prosthesis:

AVANTAGE acetabular reinforcement cross
P0464xxx / P0465xxx

• AVANTAGE screws:
AVANTAGE Ø 4.5mm screws should be used with AVANTAGE 3P & REVISION cups and 3P Ti+HA cups:

Name	**Reference**
AVANTAGE Ø 4.5mm screws	P06060xx

• Radiographic templates:
AVANTAGE RELOAD Acetabulum templates: ref. CA057
AVANTAGE 3P Acetabulum templates: ref. CA056
AVANTAGE CEMENTED Acetabulum templates: ref. CA080 and ref. CA086.
AVANTAGE REVISION template : ref. CA079.
AVANTAGE 3P Ti+HA Acetabulum templates :

Preoperative template designation	**Reference**
AVANTAGE 3P Plasma Ti HA cup template 100%	XRAY000356
AVANTAGE 3P Plasma Ti HA cup template 110%	XRAY000357
AVANTAGE 3P Plasma Ti HA cup template 115%	XRAY000358
AVANTAGE 3P Plasma Ti HA cup template 120%	XRAY000359

• PMMA-type surgical bone cement used with AVANTAGE CEMENTED cups.
• REGENEREX cages:
The AVANTAGE CEMENTED cup can be used with a REGENEREX cage when revising the acetabular component of a total hip prosthesis.
The table below shows the corresponding size in the REGENEREX range for each size of AVANTAGE cemented cup:

REGENEREX CAGE		**AVANTAGE CEMENTED CUP**	
Size	**Reference**	**Size**	**Reference**
T60	Pt-1250-60	T44	P0463044
T62	Pt-1252-62	T46	P0463046
T64	Pt-1254-64	T48	P0463048
T66	Pt-1256-66	T50	P0463050
T68	Pt-1258-68	T52	P0463052
T70	Pt-1260-70	T54	P0463054
T72	Pt-1262-72	T56	P0463056
T74	Pt-1264-74	T58	P0463058
T76	Pt-1266-76	T60	P0463060

12. Storage
Products should be stored in their original packaging.

13. Additional instructions for the surgeon
The surgeon should be aware that the anatomic, chemical and physical characteristics of living tissue limit the possibilities in the form and choice of material. Consequently, it should be noted that, like bone that no longer carries out its functions, prosthetics have their limits.
The proper implantation of the hip prosthesis is essential for successful arthroplasty and long-lasting results. This is why the detailed recommendations for surgical technique must be followed.

14. Patient information
Patients should be informed that hip arthroplasty is a major operation, and their hopes should not be raised too high. Patients should be warned not to overwork their prosthesis by performing unreasonable activities that could cause shocks, and to monitor their weight.

Warning, see instruction leaflet
Do not reuse
Batch code
REF Catalog reference
Use by
Sterilised by irradiation