Summary of Safety and Clinical Performance

1. General Information

1.1. Device trade name

Verso Shoulder System
Product family: Implantable device, Joint replacement
Product type: Shoulder replacement

1.2. Device classification

On 5 April 2017, new Regulations on medical devices that replace the existing Directives were adopted and entered into force on 25 May 2017.
According to ANNEX VIII of the REGULATION (EU) 2017/745, rule 8, the Verso Shoulder System is classified as class III.

1.3. Manufacturer name and address

Name:	**Innovative Design Orthopedics Limited (IDO)**
Address:	6 Brewery Court, High Street Theale, Reading, Berkshire RG7 5AJ, UK.
Phone:	+44 033 0202 0840
Fax:	+44 033 0202 0841
Email:	sales@idorth.com

1.4. Authorized Representative name and address

Name:	**MedNet EC-REP GmbH**
Address:	Borkstrasse 10, 48163 Muenster, Germany
Phone:	+49 2513226661
Fax:	+49 2513226622
Email:	ecrep@medneteurope.com

1.5. Basic UDI-DI

IDO Verso Implants System's Basic UDI-DI	506040645IDO1245VM

1.6. SRN

IDO Verso Implants System's SRN	GB-MF-000026411

1.7. Certificates

Certificate CE 598317 was first issued to IDO Ltd on 25 Sep 2013
Certificate CE 598321 was first issued to IDO Ltd on 11 Oct 2013
Certificate ISO 13458 was first issued to IDO Ltd on 25 Sep 2013

1.8. Notified Body

Name:	**BSI Netherlands**
Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam
Phone:	+31 (0)20 346 07 80
Fax:	+31 (0)20 346 07 81
Email	info.nl@bsigroup.com

2. Intended use of the device

2.1. Intended purpose

The device is intended for use in total shoulder replacement in a reverse configuration.
The humeral heads are intended for use as a salvage hemi-arthroplasty option.

2.2. Indications and intended patient group

The Verso shoulder joint replacement system is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled function.

- A replacement of shoulder joints in primary reverse arthroplasty.
- A replacement of other shoulder joint devices in case of revisions, if sufficient bone stock remains (In revisions of resurfacing implants, if sufficient bone stock remains - the short metaphyseal humeral component can be used) .
- A replacement of other shoulder joint devices in case of revisions if the remaining bone stock is insufficient or in case of revisions of a previous stemmed implant - the Diaphyseal stemmed Verso should be used.

2.3. Contraindications

Absolute contraindications

- Infection, sepsis and osteomyelitis

Relative contraindications:

- Osteoporosis;
- Metabolic disorders;
- Vascular insufficiency, muscular atrophy or neuromuscular disease;
- Uncooperative patient or patient unwilling or unable to follow instructions;
- Incompetent or deficient soft tissue surrounding the bone;
- Obesity;
- Foreign body sensitivity;
- Osteomalacia;
- Distant foci of infections which may spread to the implant site;
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

Contraindications for the Humeral Head component:

- The Humeral Head component is not recommended for use with the Verso shells and should only be used in conjunction with humeral stems.

3. Device description

3.1. Device description

Product category: Implantable device

Product family: Joint replacement

Product type: Shoulder replacement

Many patients suffer from shoulder disorders that are characterized by rotator cuff dysfunction and glenohumeral joint arthrosis, and may demonstrate findings, such as pain, inability to raise their arm (pseudo-paralysis), and proximal migration of the humeral head. In order to regain functional improvement, reverse total shoulder replacements (rTSAs) have recently been utilized. Unlike the traditional replacement systems that emulate the standard "ball-and-socket" anatomy of the shoulder, in this reverse design, the "ball" component is placed on the glenoid, while the "socket" component is fixed in the proximal humerus. This altered anatomy is intended to provide a greater lever arm for the deltoid muscle, allowing the patients to regain active shoulder elevation. Hence, in addition to relief of pain, these patients are able to regain an average active shoulder elevation and perform various activities of daily living.

Verso shoulder system is a congruent and hence fixed center prosthesis based on the idea of a reverse total shoulder replacement: a hemispherical cobalt chrome component is fixed to the glenoid, and a congruent stemmed or stemless humeral component fixed within the proximal humerus. The prosthesis will offset the deltoid to correct the medialization associated with RCA, and so increase the deltoid moment arm. This will increase the range of motion of the shoulder joint and will also cosmetically improve the appearance of the wasted shoulder.

The system consists of a humeral component fitted with an Ultra High Molecular Weight Polyethylene (UHMWPE) liner which articulates with the glenoid component, a glenoid hemispherical head attached on a glenoid baseplate.

The glenoid head exists in two diameters (36 mm and 41 mm) and the glenoid baseplate in one size. The head is manufactured from Co-Cr-Mo alloy and is highly polished on the articulating surface. It is fitted to the baseplate with a Morse taper. The baseplate is made of Ti-6Al-4V titanium alloy and has a hydroxyapatite coated screw thread for primary cementless fixation. In addition, the baseplate has six holes, which can be used for supplementary fixation with screws.

There are two types of humeral components：

a. Humeral shells. The humeral shells have three fins that extend from the underside of the cup to enable primary bone fixation and provide a secure cementless metaphyseal fit without requiring a stem. The shells come in four sizes: small, medium ,large, and extra-large. Shells are manufactured from Co-Cr-Mo alloy and all surfaces in contact with bone are coated with porous titanium, which in turn is coated with hydroxyapatite. The design is bone conserving, requiring minimal bone resection. The UHMWPE humeral liner fits into the humeral shell.

b. Humeral stems. The humeral stems have a proximal cup with fins and an intramedullary stem extending from the underside for additional primary fixation. The stems are manufactured from industry standard Co-Cr-Mo alloy. The upper third of the stem is coated with porous titanium, which in turn is coated with hydroxyapatite, while the lower two-thirds of the stem is polished. It is designed for cementless press-fit application, however, bone cement may be used with the distal stem, if necessary.

Stems also come in four sizes: small, medium, large, and extra-large. The UHMWPE humeral liner fits into the proximal end of the stem. As an option, stems can be used for hemiarthroplasty when fitted with the modular humeral head option instead of the liner.

3.2. Previous generation

The Verso shoulder system was manufactured and disturbed by Biomet UK Ltd since 2005: Certificate CE 542151 was issued to Biomet UK Ltd on 14 August 2009.

By contract effective on 17 August 2012, Biomet transferred and assigned the intellectual property associated with the Verso Shoulder System including the worldwide commercialization rights to the company that licenses the rights to Innovative Design Orthopaedics.

3.3. Material in contact with patient tissues

Part	Material	Materials Standards
Glenoid Baseplate	Titanium Alloy Surface Coatings: Hydroxyapatite (HA)	ISO 5832-3 ISO 13779
Baseplate Screws	Titanium Alloy	ISO 5832-3
Glenoid Heads	CoCrMo Alloy	ISO 5832-12
Humeral Heads	CoCrMo Alloy/ Titanium Alloy/ UHMWPE	ISO 5832-12 ISO 5832-3 ISO 5834
Humeral Shells	CoCrMo Alloy Surface Coatings: Titanium & Hydroxyapatite (HA)	ISO 5832-12 ASTM F1580 ISO 13779
Humeral liners	UHMWPE	ISO 5834
Locking Ring	Titanium Alloy	ISO 5832-3
Stemmed Humeral Shells	CoCrMo Alloy Surface Coatings: Titanium & Hydroxyapatite (HA)	ISO 5832-12 ASTM F1580 ISO 13779

3.4. Information about medicinal substances in the device

The Verso Shoulder System components do not incorporate any medicinal products or human blood derivate, they do not utilize non-viable, material of animal origin.

3.5. Description of accessories

A dedicated instruments set was designed to aid in the accurate implantation of the prosthetic components. The set is divided into two trays: Glenoid tray and Humeral tray.

4. Risks and warnings

4.1. Residual risks and undesirable effects

Implants design is based on commonly used longstanding technology and well-known scientific knowledge. This enables to achieve clinical safety and efficacy of the device. All the potential risks identified were reduced as far as possible by using all the means we could think of. The efficacy of the risk's mitigation is strengthened by the lack of any harmful severe adverse events associated with the use of VERSO during the 15 years of use.

4.2. Warnings and precautions

WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. The use of reverse shoulder prosthesis in patients with a deficient rotator cuff could increase the risk of component loosening due to non- anatomic loading conditions. Mal alignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate pre-closure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissues have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

Humeral Shell / Stemmed humeral shell, Glenoid Head and Baseplate components should be used only when there is good quality bone.

Disassociations of modular components have been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular components to avoid crevice corrosion and improper seating. All additional locking screws must be adequately tightened.

Care is to be taken to assure complete support of all parts of the device embedded in bone to prevent stress concentrations that may lead to failure of the procedure. Complete pre-closure cleaning and removal of metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight bearing have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made

aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits.

WARNING: Should it be necessary to remove the definitive humeral liner at any stage the Verso head removal wedge or a thin osteotome should be fitted carefully between the liner and the rim of the Verso shell and the liner should be loosened circumferentially and removed. This procedure may damage the locking ring, so prior to inserting a new liner a new universal locking ring should be fitted into the circumferential recess in the proximal part of the humeral shell / stemmed humeral shell.

PRECAUTIONS

Patient selection factors to be considered include:
Need to obtain pain relief and improve function,
Ability and willingness of the patient to follow instructions, including control of weight and activity levels, A good nutritional state of the patient and The patient must have reached full skeletal maturity, and The patient must have a functional deltoid muscle.

Specialized instruments are designed for IDO joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose.

IDO recommends that all instruments be regularly inspected for wear and disfigurement.

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.

4.3. Summary of any field safety corrective action, (FSCA including FSN) if applicable

NA

4.4. Other relevant aspects of safety

NA

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data

Clinical evaluation is based on PMS and PMCF data for the VERSO systems as well as on published data of clinically equivalent shoulder systems.
PMS activities are defined in the PMS plan. The plan outlines the personnel responsible for gathering and analyzing each type of PMS data. A detailed PMS report is provided once a year with discussion and conclusion following each input.

The evaluation provides sufficient evidence for the following:

- The presented studies and market experience demonstrate that the Verso Shoulder prosthesis can be safely implanted in humans with a very high overall success rate.
- The presented studies and market experience demonstrate compliance of the device in question with the essential requirements regarding safety and performance, under normal conditions of use.
- The device performs as intended by the manufacturer.

- The device does not pose any excessive safety concerns.
- The risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

5.2. An overall summary of the clinical performance and safety

Results showed higher safety of Verso rTSA device in comparison with predicate devices, as demonstrated by lower rates of complications, adverse events and revisions.
In addition, results indicate similar effectiveness assessments between Verso rTSA device and predicate device for CS activity score, and active external rotation score. Although the Verso rTSA device showed lower delta improvement for pain, the post-operative pain score for the Verso implant was higher than the predicate device. Better effectiveness was found for mobility, strength, active elevation and internal rotation. Moreover, higher rates of revisions of other previous implants were reported in Verso rTSA in comparison with the predicate devices. Hence, by achieving similar or larger final improvement from worse starting point, results of Verso rTSA are even more promising.
Finally, improvement in adjusted CS score was found to be larger in Verso rTSA device compared with predicate devices, yielding higher effect size between pre and post operation. Therefore, Verso rTSA showed similar or better improvements across all main measures for safety and effectiveness.

5.3. Ongoing or planned post-market clinical follow-up

Performance of the VERSO is continuously evaluated using:

A. Data collected in Reading Shoulder Unit. The following performance parameters are extracted from the data:
   - Age and sex distribution of VERSO implanted patients
   - Prosthesis type (stem, shell or salvage hemi)
   - Number of operations per year
   - Number of revisions
   - Average pain and range of motion scores at the following time points: before operation, immediately post op, 3 weeks postop, 6 weeks postop, 1 year postop, each consequent year following.
   - Average Constant score and adjusted Constant score at the following time points: before operation, immediately post op, 3 weeks postop, 6 weeks postop, 1 year postop, each consequent year following.
   - Average Constant score pre and post operation, grouped by diagnosis.

B. Questionnaires filled by customers are analyzed to assess performance information.
C. NJR yearly reports are analyzed in order to compare performance with equivalent devices.
D. Scientific literature search results analyzed as additional source of information for performance outcomes of VERSO and other reverse shoulder prosthesis.

6. Possible alternatives

During the last years, total joint market has seen a dramatic increase; one of the brightest spots in the orthopedics industry is the market for shoulder replacements.
The increase is based to a large extent on scientific advances and clinical improvements in implantology. The extension of indications has broadened the opportunities to rehabilitate patients that were formerly considered to possess restricted indications to place implants. Growth in the shoulder replacement market is being driven by the increasing use of reverse shoulder replacements, which now comprise over 50% of the shoulder replacement market.
Additionally, patient desires (high aesthetic demands, fast prosthetic rehabilitation) were placed more in focus, resulting in new approaches in shoulder joint prosthesis. As a result, the scientific and clinical

community has reached high standards and at the same time has founded the basis for new opportunities in implantology.
Shoulder replacement is a surgical procedure in which all or part of the glenohumeral joint is replaced by a prosthetic implant. Such joint replacement surgery generally is conducted to relieve arthritis pain or fix severe physical joint damage. In 1985 Paul Grammont designed the Delta reverse total shoulder prosthesis. The main goal of the reverse prosthesis is to provide a fixed center of rotation allowing the deltoid to rotate the humerus, even with a deficient rotator cuff, providing concavity compression.
Over the years, some changes were introduced, but the original techniques are still well respected. The technique is composed of the following actions: Incision, Humeral preparation by resection of the humeral head, humeral shell implant, glenoid base plate Insertion, Implant insertion, closure and post-operative management. Once fitted, the system provides the foundation for long-term effective shoulder functionality.

7. Reference to harmonized standards and CS applied

Standard	Revision	Description	Level of Compliance
MDD 93/42/EEC amended by MDD 2007/47/EC	2007	Directive for Medical Devices	Fully comply
Regulation (EU) 2017/745	2017	Regulation of Medical Devices	Transition process
EN ISO 13485	2016	Medical devices - Quality management systems	Fully comply
EN ISO 10993	2018	Biological evaluation of medical devices	Fully comply
EN ISO 11137	2006	Sterilization of health care products Radiation	Fully comply
EN ISO 14630	2012	Non-active surgical implants - General requirements	Fully comply
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices	Fully comply
EN ISO 62366-1	2015	Medical devices- Application of usability engineering to medical devices	Fully comply

8. Suggested training for users

New users should be initially trained by Clinical specialist, to provide users with information for safely use of the IDO Verso system.