

mirai®

MODULAR SHOULDER SYSTEM



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“The Future”

mirai®

MODULAR SHOULDER SYSTEM

1 SYSTEM: ALWAYS 2 POSSIBILITIES

2 Configurations

- Anatomic
- Reverse

2 Humeral fixations

- Stemmed
- Stemless

2 Glenoid fixations

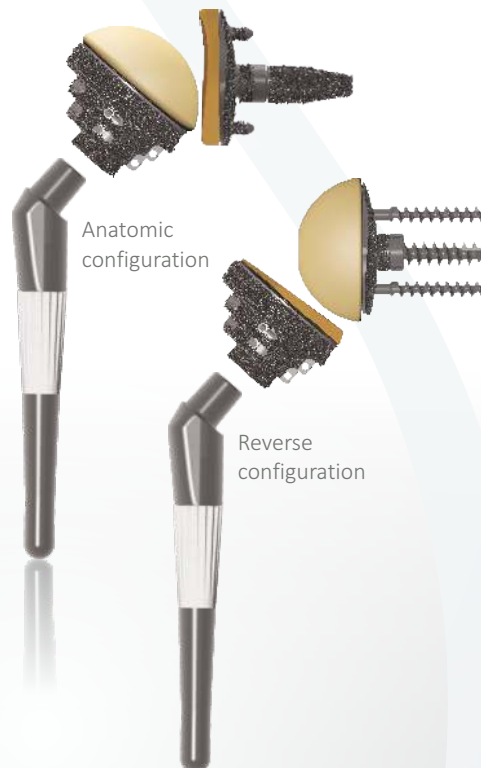
- Press-fit Central Peg
- Compression Central Screw

2 Fixation options

- Cementless
- Cemented

2 Materials

- Ti6Al4V
- VITAL-E®



2 Technologies :

TRASER®

TRABECULAR LASER
MELTED TITANIUM

BILOY®

TiNbN COATING

HUMERAL CORE CAGE TRASER®

The Mirai® Shoulder System was conceived and developed by exploiting the modularity on both the glenoid and humeral compartments, in order to offer solutions for a wide range of typical indications in shoulder arthroplasty surgery. The humeral core cage and the glenoid baseplate form the heart of the system.

The humeral core cage design offers a high osseointegration potential thanks to the TRASER® trabecular structure.

Multiple options of holes distributed on the surface of the component also allow the possibility of re-fixation of the subscapularis tendon.

The presence of these holes at the same time promotes the osseointegration of the bone grafting deposited inside the core cage with the surrounding humeral bone tissue.

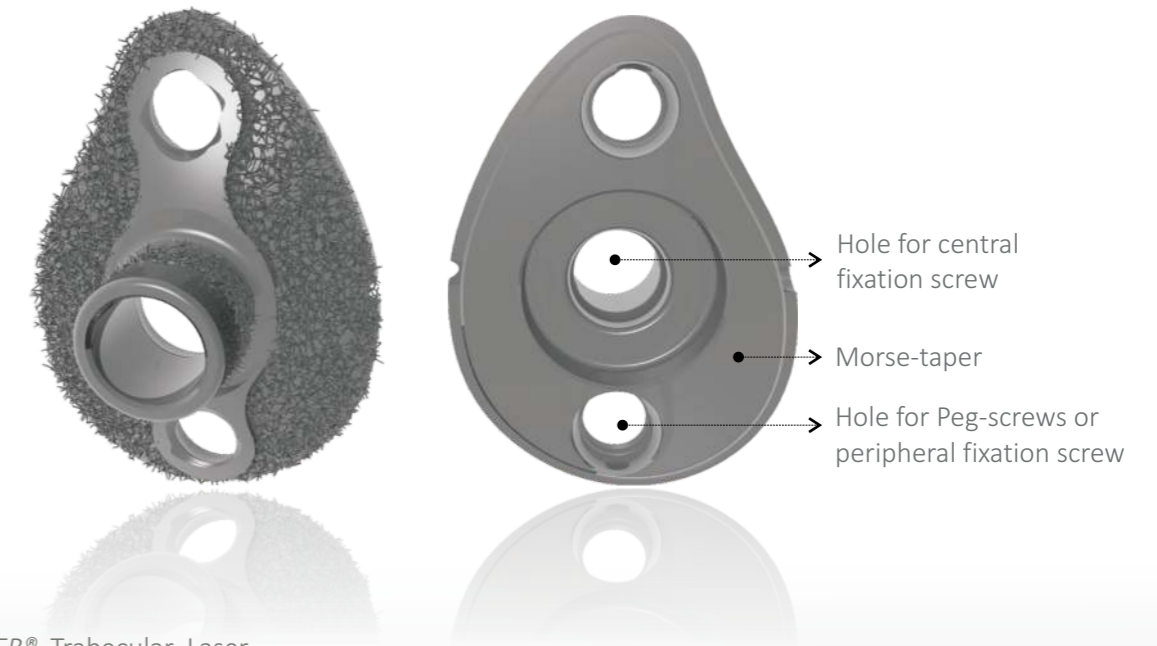


Made using TRASER® Trabecular Laser Melted Titanium additive manufacturing technology.

- Morse-taper connection with Metaphyseal Humeral Component
- Eccentric conformation
- 5 sizes: XS/S/M/L/XL

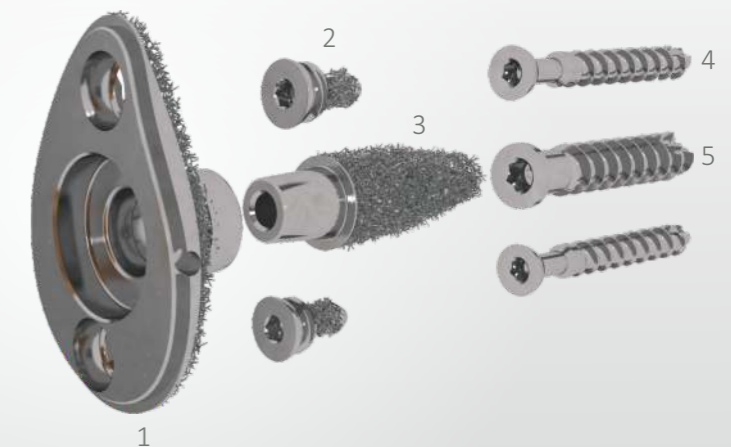
SIZE	XS	S	M	L	XL
∅	32mm	34mm	36mm	38mm	40mm
H	19mm	20mm	22mm	23mm	25mm

GLENOID BASEPLATE TRASER®



Made using TRASER® Trabecular Laser Melted Titanium additive manufacturing technology.

1. Glenoid Base-Plate available in 5 sizes: XS / S / M / L / XL
2. Peg-Screws supplied separately
3. Glenoid Baseplate press-fit central Peg L. 18/25/30 mm
4. Base-Plate peripheral fixation screws
∅4.5 x L. 20/25/30/35/40/45/50 mm
∅3.5 x L. 20/25/30/35/40/45/50 mm
5. Base-Plate central fixation screw
∅6.5 x L. 30/35/40/45/50 mm

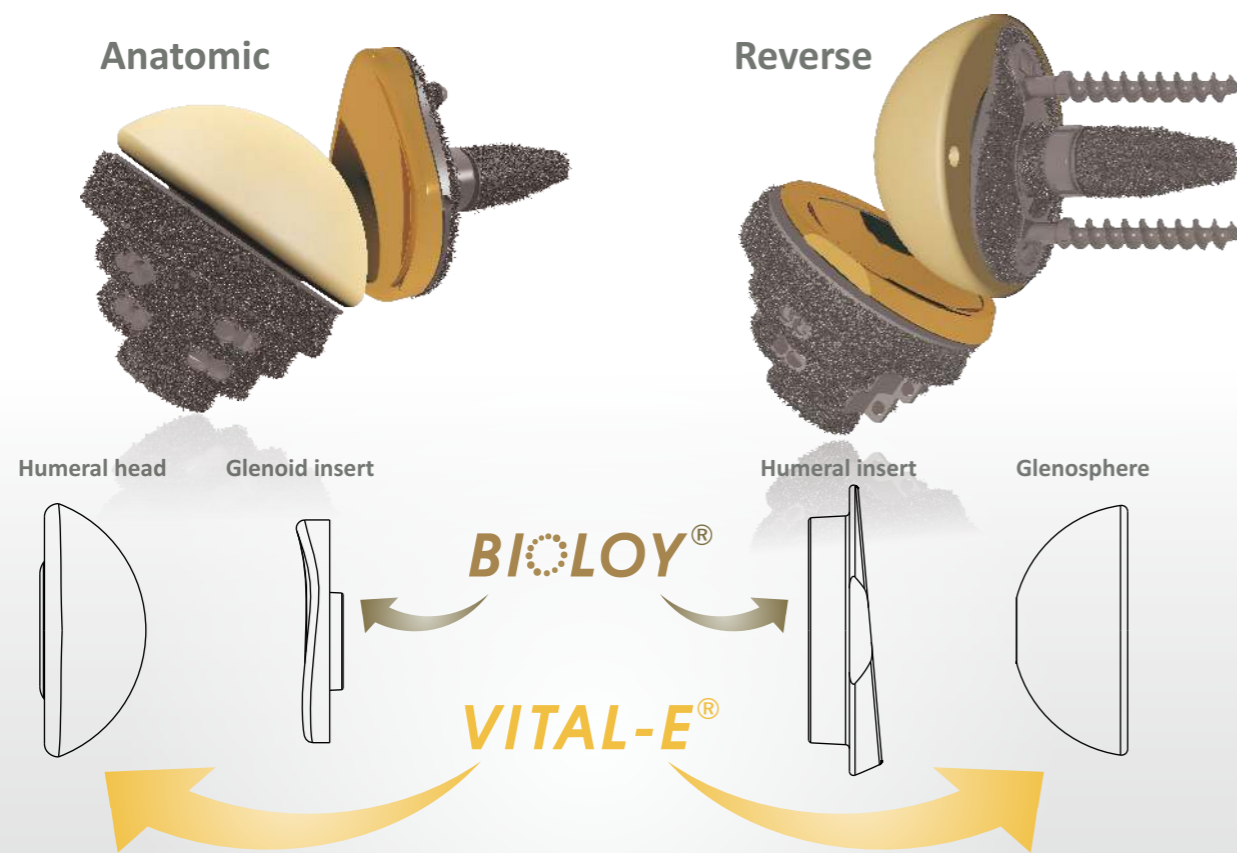


MATERIALS and TECHNOLOGIES

The Mirai® system involves the inversion of the materials of the joint components: in the anatomical configuration to prevent any complications related to polyethylene on the glenoid side; in the reverse configuration to reduce the wear of the polyethylene.

The inversion of the materials of the joint components in the anatomical and inverse configuration involves:

- Anatomical humeral head and Glenosphere in VITAL-E®-UHMWPE (GUR 1020) added with 0.1% of Vitamin E, EtO sterilized.
- Glenoid insert and humeral insert in Ti6Al4V alloy (ISO 5832/3) BIOLOY® PVD coated (TiNbN).



Unlike a conventional polyethylene glenoid insert, a metal insert can be made with a lower thickness, thus reducing the risk of shoulder over-stuffing.

The elimination of CrCo and stainless steel alloys from joint materials in favor of UHMWPE and Ti6Al4V alloy allows to obtain prosthetic components with a significantly reduced weight.

The absence of these alloys also avoids the release of chromium, cobalt and nickel ions making the Mirai® system totally hypoallergenic

TRABECULAR LASER MELTED TITANIUM

The TRASER® components are obtained through the SLM (Selective Laser Melting) additive manufacturing process, starting from Ti6Al4V titanium alloy powder.

TRASER® technology allows the creation of structures with peculiar characteristics in terms of porosity and trabeculation.

The components are created in a single process, with no discontinuity or application of surface coatings.

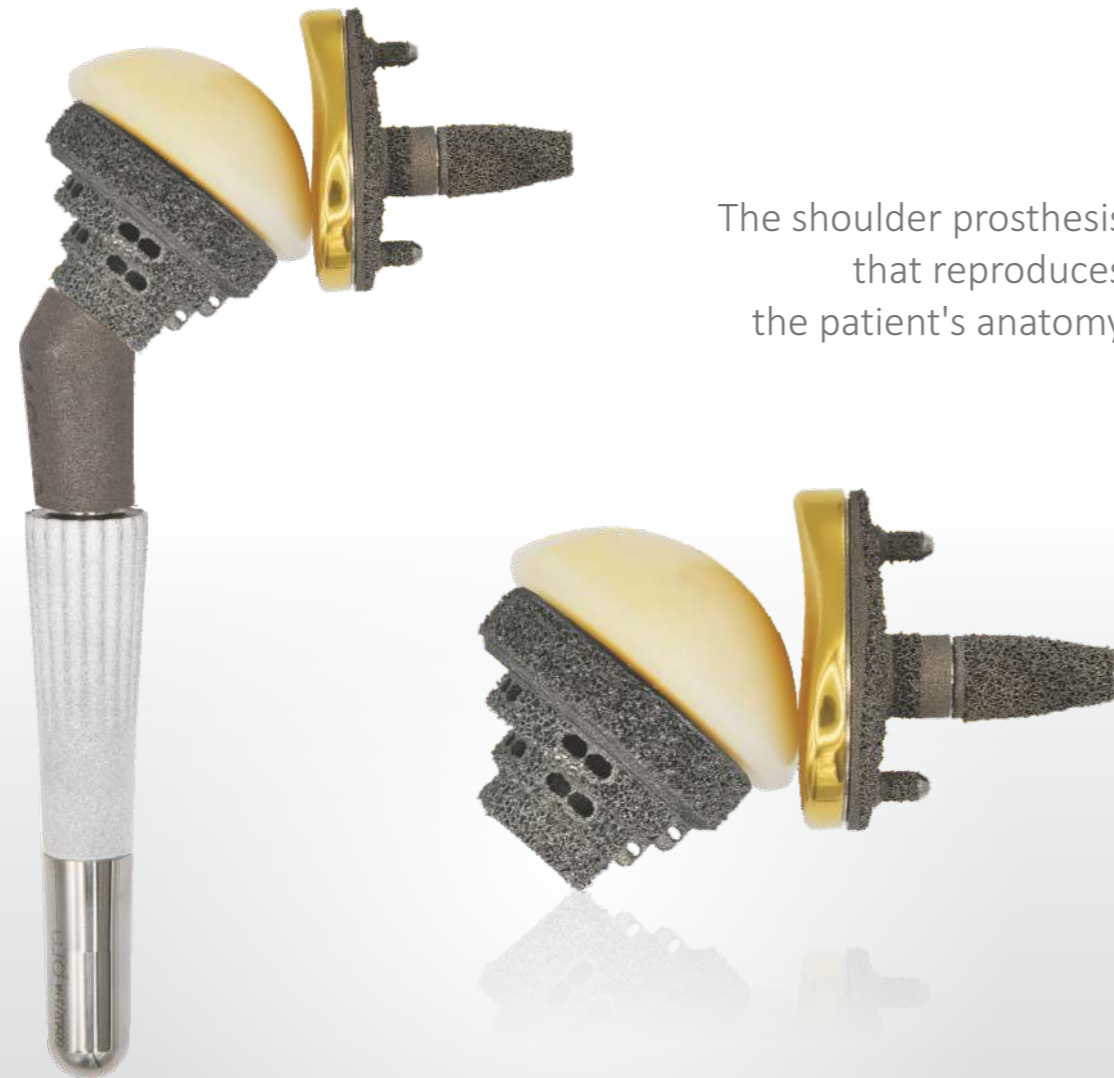
The TRASER® structure allows for significant bone regrowth within the pores and rapid osseointegration of the component for optimal secondary stability.

A high coefficient of friction with the bone allows a significant initial stability of the implant through press-fit insertion.



ANATOMICAL CONFIGURATION

In the anatomical configuration, the Mirai® prosthesis aims to reproduce the characteristics of the glenohumeral joint: the humeral head in fact has an ellipsoidal geometry that is articulated on a double radius anatomical glenoid insert.



The shoulder prosthesis that reproduces the patient's anatomy

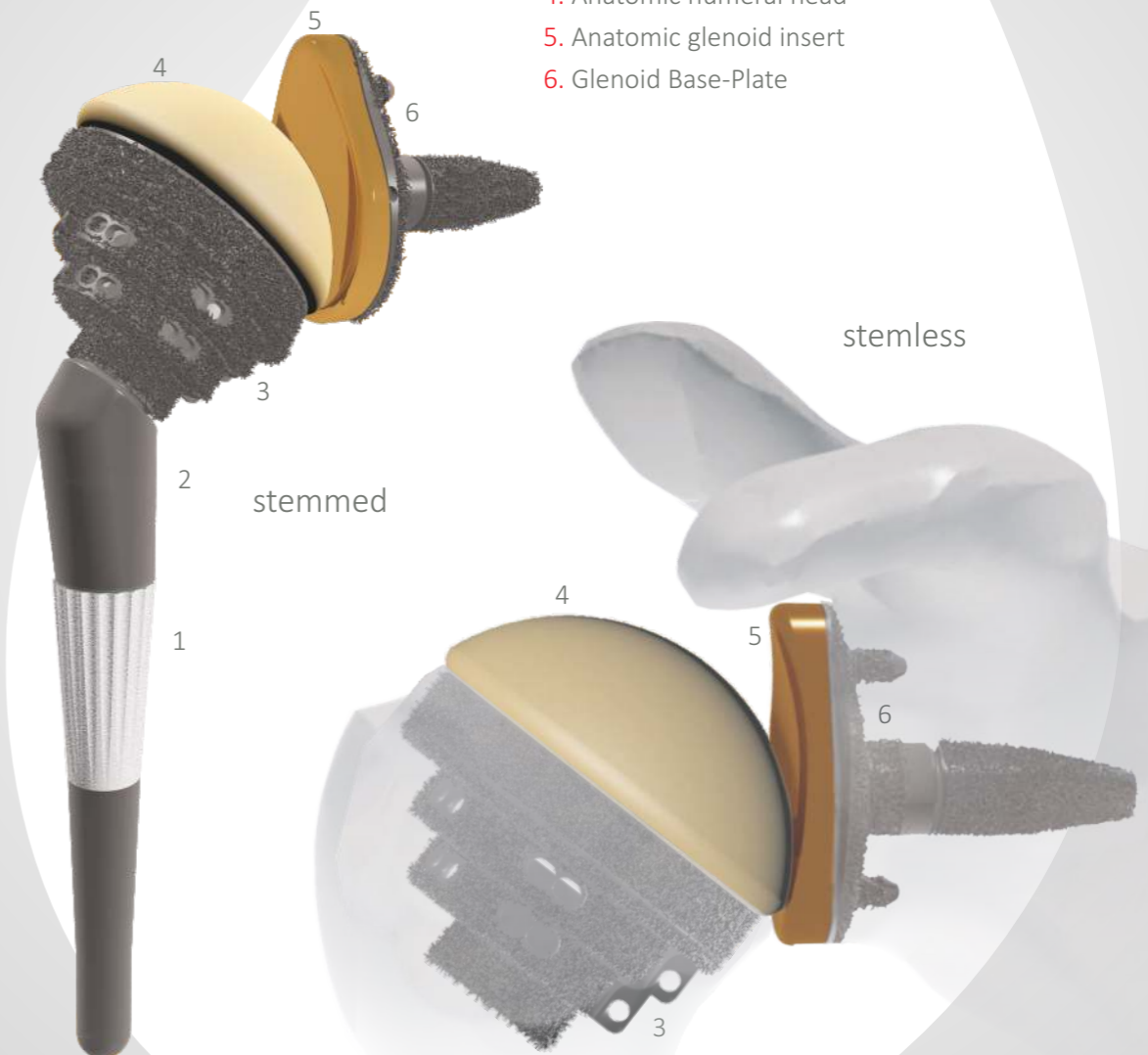
Mirai® is a modular convertible system:

- from Stemless to Stemmed
- from Anatomical to Reverse

mirai®
MODULAR SHOULDER SYSTEM



1. Humeral stem
2. Metaphyseal component
3. Humeral Core cage
4. Anatomic humeral head
5. Anatomic glenoid insert
6. Glenoid Base-Plate



ANATOMIC HUMERAL HEAD

VITAL-E®

Humeral Head Adapter
3 offset: 0mm / +2mm / +4mm

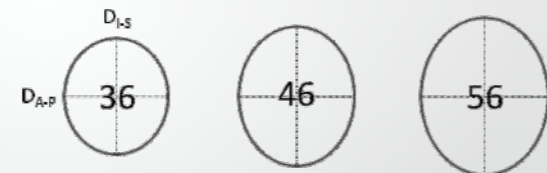
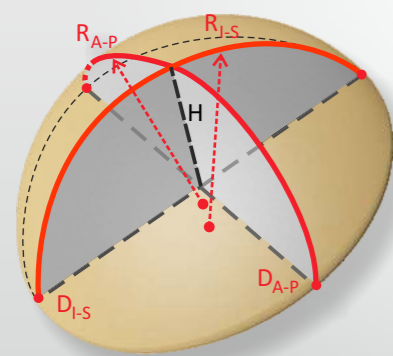


Metal sleeve for morse-taper connection



Non spherical humeral head with ellipsoidal geometry

- Base with elliptical section with major axis and minor axis
- Articular surface with 2 curvature profiles described by 2 different average radii
- VITAL-E® and UHMWPE version
- 3 offset (0 mm / +2 mm / +4 mm) using the Humeral Head Adapter
- 11 sizes: 36 / 38 / 40 / 42 / 44 / 46 / 48 / 50 / 52 / 54 / 56 mm



$$\frac{D_{A-P}}{D_{I-S}} = 0.968 \quad 0.950 \quad 0.935$$

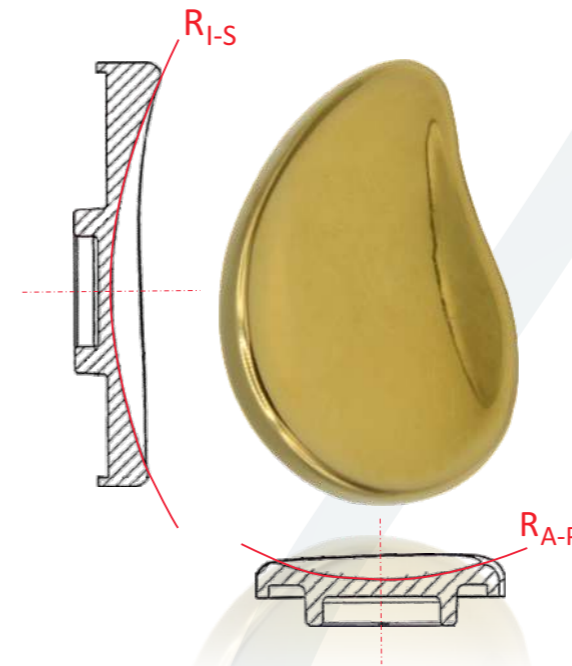


More circular ellipse base

More elongated ellipse base

ANATOMIC GLENOID INSERT

BIOLOY®



Dual radius articular surface:

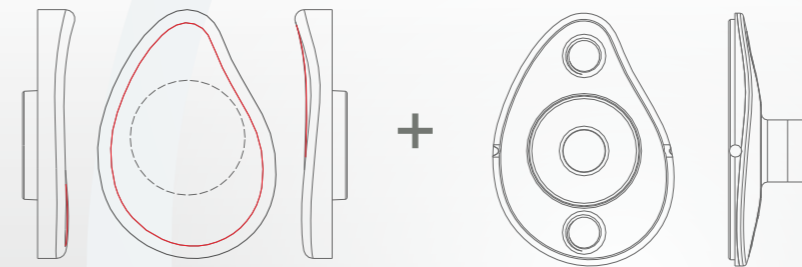
- Antero-Posterior radius (transversal plane)
- Infero-superior radius (coronal plane)

SIZE	XS	S	M	L	XL
D _{A-P}	21mm	26mm	29mm	31mm	32.5mm
D _{S-I}	31mm	36mm	41mm	46mm	49mm

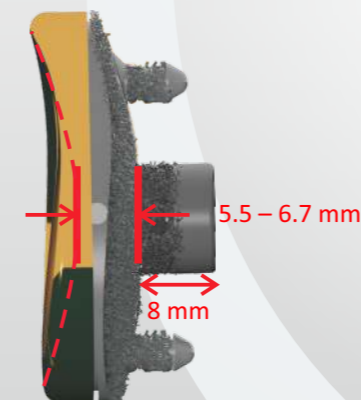
D_{A-P} and D_{S-I} dimensions of Glenoid Base-Plate for each size are the same of the Anatomic Glenoid Insert dimensions.

Anatomic Glenoid Insert

Glenoid Base-Plate



same anatomical design
same shape
same dimensions
Same sizes
XS / S / M / L / XL
RIGHT side and LEFT side



Minimal head lateralization and scapular bone sparing

The thickness of the Glenoid Insert + Glenoid Base-Plate at the central hole ranges from 5.5 mm (size XS) to 6.7 mm (size XL).

By reaming 2 mm of cartilage, the glenoid component lateralizes the joint line from a minimum of 3.5 mm (size XS) to a maximum of 4.7 mm (size XL).

The length of the cylindrical portion of the Glenoid Baseplate is 8 mm.

REVERSE CONFIGURATION

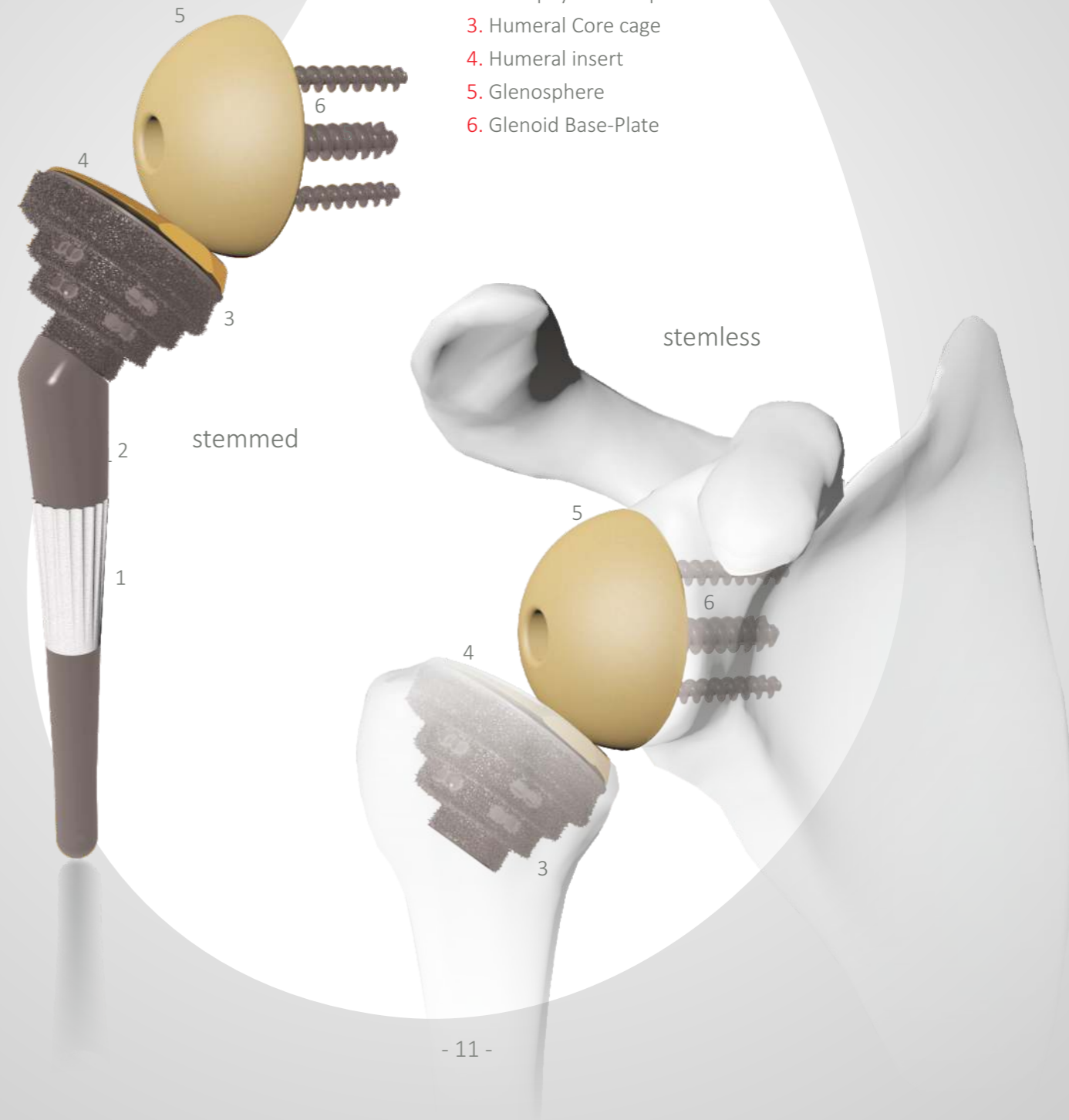
Mirai® allows conversion to a reverse implant with a single modular system without replacing the osseointegrated components



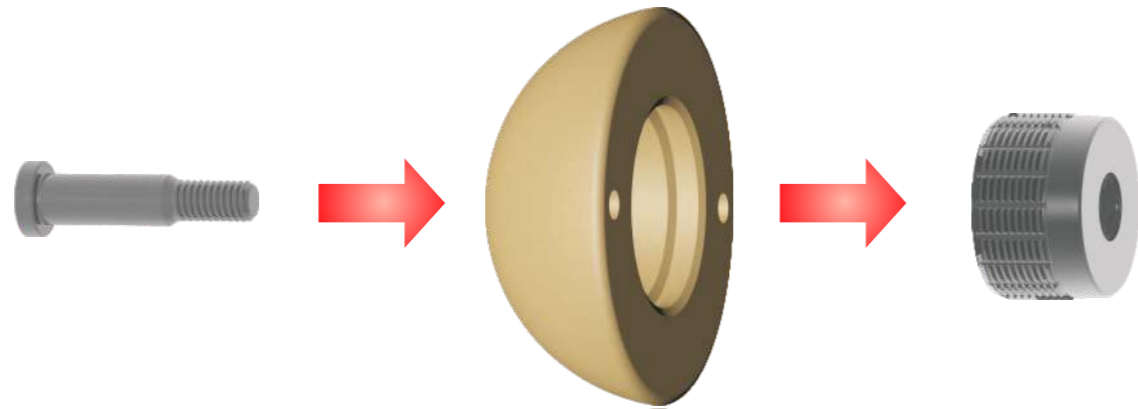
- Mirai® is a modular convertible system:
- from Stemless to Stemmed
 - from Anatomical to Reverse



1. Humeral Stem
2. Metaphyseal component
3. Humeral Core cage
4. Humeral insert
5. Glenosphere
6. Glenoid Base-Plate



GLENOSPHERE VITAL-E®



Safety Screw

- 2 sizes:
- **S** in combination with Central Fixation Screw
 - **L** in combination with Central Peg

Spherical concentric Glenosphere

- 2 versions: standard and corrective
 Ø 36 / 40 / 44 / 48 mm
 Materials: VITAL-E® and UHMWPE

Adapter

- 3 sizes:
- XS
 - S
 - M-L-XL

HUMERAL INSERT BIOLOY®

Spacer

1 size (9 mm) to be used only in reverse configuration, in combination with the humeral Core Cage to increase the thickness of the Humeral Insert.



Humeral Insert

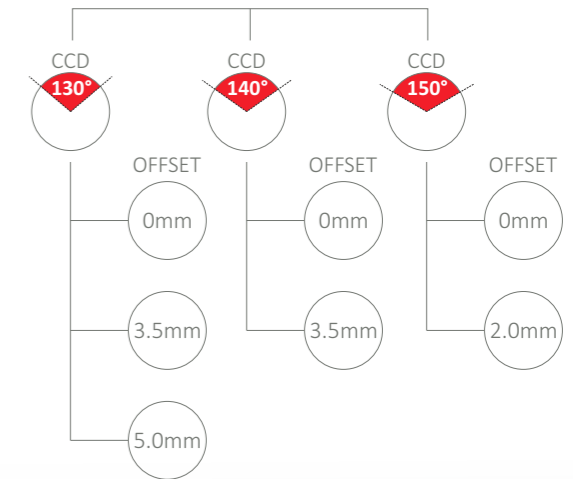
- Spherical bearing surface
- 4 CCD angles and 4 thicknesses:
 (0° + 0 mm)
 (3° + 3 mm)
 (6° + 6 mm)
 (10° + 10 mm)
- Ø 36 / 40 / 44 / 48 mm
- Ti6Al4V (ISO 5832/3)
 BIOLOY® coated

CONVERSION INTO STEMMED IMPLANT with a single modular system



Humeral Core Cage

The Humeral Core Cage can be rotated to restore the eccentricity of the humeral head



Metaphyseal Humeral Component

Possibility to restore the humeral head center thanks to a component with 3 different CCD angles and 3 different offsets.

Humeral Stem

- Cementless Press-fit with HA coating
 17 sizes: Ø10 - 26 mm
 Length: 75 mm
- Cemented
 13 sizes: Ø10 - 22 mm
 Length: 75 mm
- Cementless Revision with HA coating
 12 sizes: Ø10 - 18 mm
 Length: 150 mm / 180 mm
- Cemented revision
 6 sizes: Ø13 / 15 mm
 Length: 150 mm / 180 mm / 210 mm



TRAUMA CONFIGURATION

TRAUMA CORE

a new solution for the reconstruction procedure of the meta-epiphyseal humeral region with a single component.

available in two CCD angles (140° and 150°) and two Humeral Core sizes (S and M).

In case a different CCD angle and/or Core size should be necessary to achieve an anatomic reconstruction of the shoulder, the modular solution (by assembling Metaphysis and Humeral Core) is indicated.

The Trauma Core can be used as an alternative to the modular solution with the same indication:

- Meta-epiphyseal fracture of the humerus
- Anatomical or Reverse Total Prosthesis in the treatment of glenohumeral osteoarthritis.

CTA HUMERAL HEAD

A further solution for prosthetic treatment in the presence of severe cuff tear injuries.

The CTA Humeral Head (available in 4 sizes: 40, 44, 48, 52 mm) offers a further solution to treat shoulders with severe cuff tear lesions / cuff tear arthropathy.

Leaving the glenoid compartment unaltered, the use of the CTA Humeral Head is particularly indicated in all those cases where it is not possible to provide for its reconstruction.



The CTA Humeral Head is indicated in case of:

- cuff injuries in elderly patients with severe pain and limited functional needs
- cuff injuries / cuff tear arthropathy in elderly patients with impossibility to reconstruct the glenoid and implantation of total reverse prosthesis
- plurifragmental humeral head fracture in cuff tear arthropathy and/or non reconstructable cuff lesion in case of impossibility to implant a total reverse prosthesis
- revision surgeries

REVISION CONFIGURATION

SOLUTION FOR REVISION CASES

To deal with primary cases with complex glenoid defects (such as B2 / B3 according to Walch's classification) or revision cases with significant bone loss on the glenoid side, trial glenoid wedges are provided together with the instruments allowing to define the geometry of the bone- graft needed to correct the glenoid version.

Long, cemented and cementless humeral stems are available up to 180mm in length to reconstruct metadiaphyseal humeral fractures and / or address revision cases.

1. Cemented humeral revision stem
2. Cementless press-fit humeral revision stem
3. Trauma core
4. Humeral insert spacer
5. Humeral insert
6. Glenosphere
7. Baseplate
8. Glenoid wedges



3Dmirai® PLANNING



3DMirai® Planning is a platform designed to simplify pre-operative planning with 3D technology and improve the accuracy of implant placement.

The system offers a planning proposal to the surgeon who has the possibility to modify it at any time and subsequently to validate it.

Patient Specific Guides (PSI) are supplied for accurate positioning of the glenoid prosthetic components as planned.

- **Web-based and user-friendly software**
- **Based on CT images**
- **Accurate and with visualization of the implant-bone contact areas on the glenoid side**
- **Visualization of implant components superimposed on CT images**
- **PSI (Patient Specific Instruments)**

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