

# EXCLUSIVE DISTRIBUTOR IN BRAZIL

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Preservation in motion

# Affinis Inverse Metaglene (Locking Cap System)

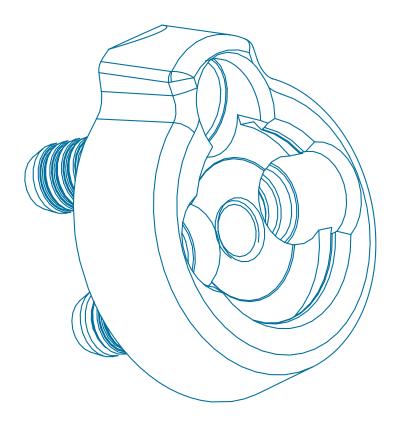
# EVOLUTIONARY

# EVOLUTION VERSUS REVOLUTION

Strong anchoring in the bone with a stable bone-implant connection forms the basis of a durable glenoid component in inverse shoulder arthroplasty. Due to the delicate structure of the glenoid, the joint socket must be prepared with as little bone loss as possible in order to preserve valuable subchondral bone stock.

To reduce the rate of infection, a design with a small number of individual components and few cavities is necessary, since their cleaning, sterilisation and assembly is time-consuming and difficult. According to Molé et al.<sup>1</sup>, an infection rate four times as high as with anatomical shoulder prosthesis procedures was observed in the case of the Grammont concept with its large number of individual components and cavities. The connection of multiple individual components additionally entails a higher risk of connections becoming loose.

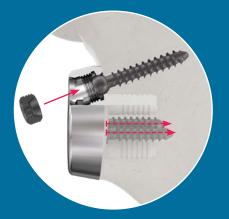
The Affinis Inverse is based on knowledge from inverse shoulder arthroplasty and takes proven clinical experience into account. What works should not be radically changed. Instead, innovative solutions for clinical challenges should be found. The Affinis Inverse Metaglene (Locking Cap System) was developed under this premise and thus corresponds to the «evolutionary» concept of the Affinis Inverse shoulder system.



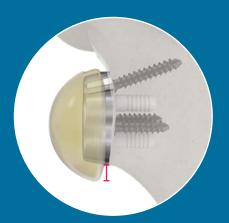
# ADVANTAGES METAGLENE



The metaglene made of titanium is not only free of nickel but also allows uncemented anchoring of the implant, thanks to its surface. The double coating of titanium plasma spray and an absorbable calcium phosphate compound, which accelerates osseointegration through its osteoconductive effect, contributes to good primary and lasting secondary stability.

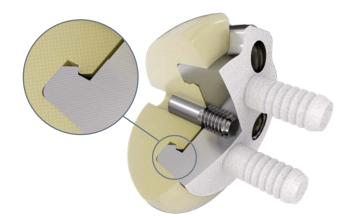


Even higher primary stability is provided by the compression screws that press the implant against the bone. In addition, once turned in, in the superior – in the case of the Metaglene CP also in the inferior – position the screw is eventually screwed together with the base plate using a locking cap, creating a fixed-angle connection. This provides additional stability.



An increased impingement-free range of motion is achieved through a systematic glenosphere overhang. The by-design eccentricity of the metaglene, together with the alignment on the inferior edge of the glenoid, reduces the risk of notching.

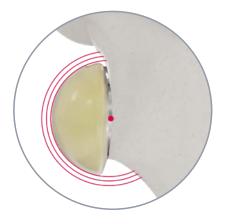
## ADVANTAGES METAGLENE



A snap-in mechanism ensures a stable connection between the metaglene and glenosphere. The snap-in attachment of the glenosphere is secured by means of a fixation screw, in order to prevent loosening of the connection between the components. A compact design with only two parts (metaglene and glenosphere) was deliberately chosen. By reducing the number of cavities and individual parts, the risk of infection is intended to be minimised. The rate of infection was reduced from 4.0 % with earlier systems<sup>2</sup> to 0.7 % with the Affinis Inverse<sup>3</sup>.



The convex backside of the metaglene allows anatomical glenoid preparation. Only a thin layer of bone should be reamed off, and as much of the valuable subchondral bone stock as possible be preserved.



In the development of the Affinis Inverse Metaglene, care was taken to avoid lateralising the centre of rotation of the glenoid components, and instead to place it directly on the bone-implant level. Stresses in the joint and shear forces which act on the bone-implant connection and which can lead to loosening are reduced as a result. This has a positive effect on the long-term preservation of the prosthesis.

# OVERVIEW – AFFINIS INVERSE METAGLENE

### Overview of the variants of the Affinis Inverse Metaglene (Locking Cap System)

The two-peg Metaglene DP (Double Peg) serves as the base plate for the glenosphere and is recommended as the standard solution for primary restorations.

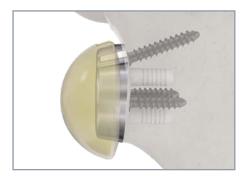
The Metaglene CP (central peg) also serves as a base plate for the glenosphere and is recommended for larger defects, deformities or in revision cases.

## METAGLENE DP (DOUBLE PEG)

Inlay-screw notching was eliminated by optimisation of the metaglene to a two-peg design without an inferior screw. For stable anchoring, the Metaglene DP has, in addition to the two press-fit pegs, a sophisticated screw design. The screws are used everywhere as compression screws.

Thanks to the two-peg design, the two anterior/posterior screws can be placed more centrally and also in a converging orientation, thus enabling deep anchoring in the anterior as well as in the posterior bone stock.

In addition, once turned in, the superior screw of the Metaglene DP is eventually screwed together with the base plate using a locking cap, creating a fixed-angle connection. All three screws are given a certain amount of freedom during placement so as to allow optimal anchoring in the cortical bone.









# Standard primary solution



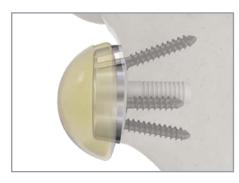
Metaglene DP (Double Peg)

Larger defects / Deformities / Revision cases



Metaglene CP (Central Peg)

# METAGLENE CP (CENTRAL PEG)





For more options in the treatment of larger defects or deformities, or in revision cases, the Metaglene CP with its somewhat stronger central press-fit peg, which is available in four lengths, is ideal. Where bone augmentation must be performed, the Metaglene CP is likewise a suitable solution

For stable anchoring, the Metaglene CP has the same screw design as the Metaglene DP has, in addition to the central peg. In the Metaglene CP, too, all four screws are used as compression screws, and they are likewise given a certain amount of freedom during placement in order to permit optimal anchoring in the cortical bone.

Moreover, in the superior as well as in the inferior position, they are eventually screwed together using a locking cap after insertion, creating a fixed-angle connection.



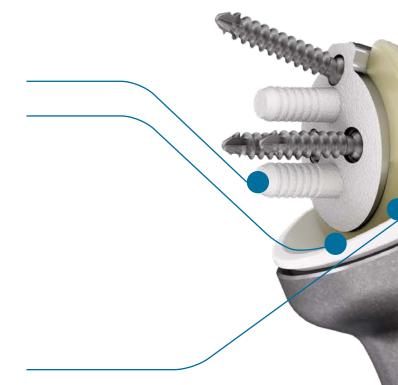


# Affinis Inverse

# AFFINIS INVERSE SHOULDER PROSTHESIS

### Evolutionary

The inlay-screw-notching was eliminated by the metaglene optimization to a two-peg design without inferior screw. An increased impingement-free range of motion is achieved by a systematic glenosphere overhang and chamfered inlays – with an effective humeral stem inclination of 147 degrees<sup>4</sup>.



#### Inverse

With an inversion of the materials in the tribological pairing, polyethylene abrasion at the scapular neck and the surrounding structures is eliminated <sup>5</sup>. This results in a reduced risk of polyethylene induced diseases <sup>6</sup>.

### Proven

Proven primary procedure with more than 10 years of clinical experience and strong clinical evidence <sup>7</sup>.

### Progressive

In case of possible hypersensitivity to metal ions, Affinis Inverse provides a standard solution for allergy patients. The unique vitamys-ceramic tribological pairing highlights the principle for low wear<sup>8–11</sup> and durable prostheses.

### Clever

A straightforward set concept and a clever instrumentation simplify the workflow during implantation. Furthermore, all surgical steps are instrument guided, thereby reproducible results can be achieved.

# Evolutionary, inverse & proven Affinis Inverse

## REFERENCES

- <sup>1</sup> Mole D, Favard L. [Excentered scapulohumeral osteoarthritis]. Rev Chir Orthop Reparatrice Appar Mot. 2007;93(6 Suppl):37-94.
- <sup>2</sup> Wall B, Nove-Josserand L, O'Connor D P, Edwards T B, Walch G. Reverse total shoulder arthroplasty: a review of results according to etiology. J Bone Joint Surg Am. 2007;89(7):1476-85.
- <sup>3</sup> National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR). Summary Report SP Humeral Affinis Inverse (Reverse Total) 25-08-20. Data valid to 25 December 2020.
- <sup>4</sup> de Wilde L F, Poncet D, Middernacht B, Ekelund A. Prosthetic overhang is the most effective way to prevent scapular conflict in a reverse total shoulder prosthesis. Acta Orthop. 2010;81(6):719-26.
- <sup>5</sup> Kohut G, Dallmann F, Irlenbusch U. Wear-induced loss of mass in reversed total shoulder arthroplasty with conventional and inverted bearing materials. J Biomech. 2012;45(3):469-73.
- <sup>6</sup> Alexander J J, Bell S N, Coghlan J, Lerf R, Dallmann F. The effect of vitamin E-enhanced cross-linked polyethylene on wear in shoulder arthroplasty-a wear simulator study. J Shoulder Elbow Surg. 2019; 28(9):1771-8.
- <sup>7</sup> ODEP Rating: http://www.odep.org.uk/products.aspx, last access 15.07.2020.
- <sup>8</sup> Lerf R, Wuttke V, Reimelt I, Dallmann F, Delfosse D. Tribological Behaviour of the «Reverse» Inverse Shoulder Prosthesis. 7<sup>th</sup> International UHMWPE Meeting. Philadelphia 2015.
- <sup>9</sup> Boileau P, Moineau G, Morin-Salvo N, Avidor C, Godeneche A, Levigne C, Baba M, Walch G. Metal-backed glenoid implant with polyethylene insert is not a viable long-term therapeutic option. J Shoulder Elbow Surg. 2015;24(10):1534-43.
- <sup>10</sup> Harris W H. Wear and periprosthetic osteolysis: the problem. Clin Orthop Relat Res. 2001(393):66-70.
- <sup>11</sup> Huang C H, Lu Y C, Chang T K, Hsiao I L, Su Y C, Yeh S T, Fang H W, Huang C H. In vivo biological response to highly cross-linked and vitamin e-doped polyethylene--a particle-Induced osteolysis animal study. J Biomed Mater Res B Appl Biomater. 2016;104(3):561-7.

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