

Affinis® Fracture

Proven concept with new features

- Bioactive coating for active on growth of the tuberosities
- Continuously variable adjustment of height and rotation
- Simple, precise instrumentation
- Anatomical shaping: exact, stable fixation of the tuberosities, volume of the metaphysial part replaces the zone of comminuted fracture
- Lateral refixation hole for anatomical reintegration of the tuberosities close to the head
- Primary cementing of the stem (no trial prosthesis required)
- Polished medial and lateral hole for secure and frictionless threading of thread or cable
- Compatible with optional eccentric heads

- Bioactive coating
- Proven spike surface structure ensures firm anchorage of the tubercles

Bionit® ceramic head

- Biologically inert
- Lightweight

- 10 mm continuously variable height adjustment
- Retroversion can be set as desired
- Simple adjustment enables optimum ligamentous balance

Primary stem cementing provides several advantages

- No need for elaborate stabilisation of a trial prosthesis
- Simple instrument set
- No transferring of the settings for the trial prosthesis to the definitive prosthesis
- More exact adjustment possible
- Saves time

Additional lateral refixation hole, and anatomical shaping for re-attachment of the tuberosities close to the head

Affinis® Fracture

The principle: Anatomical-biological healing

Important factors in biological support for anatomical healing

- Bioactive coating
- Anatomical design
- Maximum primary stability
- Reduced impairment of blood circulation

Anatomical positioning of the tuberosities

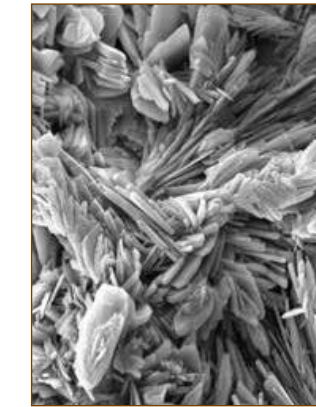
Bioactive calcium phosphate coating (CaP) on the proven «spike» structure improves adhesion and osteointegration

Conservative yet stable refixation

- 2 holding/positioning sutures (red/green)
- 2 fixation/compression sutures (blue/grey)

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One step further



The anatomical shaping and the spike structure have now also been adopted for other fracture endoprostheses.

With the Affinis Fracture, we are now taking the next innovative step. The focus is on improving the problem of the high number of vanishing tuberosities, which has remained unsolved to date.

Besides the stable refixation and the prosthesis design, a leading role is also played here above all by the bioactive coating of the central component. Through the porous surface structure, blood cells are attracted, which support bone growth. The calcium phosphate is converted into endogenous bone in a very short space of time (approx. 6 weeks), which leads to greatly improved adhesion of the tuberosities.

Bioactive coating concept

Macro environment

- Roughness (Ra): min. 120 µm
- Pore size: 100–350 µm
- Pore proportion: 20–40 %
- Layer thickness: 300–500 µm

Coating

- Ca/P ratio: 1.0–1.2
- Layer thickness: max. 20 µm
- Fine crystalline structure
- Coating of the entire pore surface

High degree of primary stability of the implant-bone anchorage

High degree of secondary stability through osteointegration

Gradual absorption in approx. 6 weeks

Bioactive calcium phosphate coating (CaP)

Properties

- Fine crystalline structure with large free surface area
- Needle-shaped and plate-shaped crystals, standing perpendicular, ensure rapid, reliable osteointegration
- Complete, controlled absorption leads to replacement by new, endogenous bone
- Low layer thickness, 20 µm maximum

Benefits

- Large free surface area with a high capillary action on the blood
- Stimulation of the body's own osteosynthesis
- Activates the surrounding bone to grow onto the implant
- Rapid substitution by new bone directly on the implant surface within 6–10 weeks post-operative
- No detachment of particles and layers
- Implant can be subjected to loads early

Affinis® Fracture

Simple instrument set, with just 14 instruments



Materials

Shoulder head

Bionit®, high-purity fine crystalline Al₂O₃ ceramic conforming to ISO 6474-2

Central component

Ti6, TiAl6V4 alloy conforming to ISO 5832-3 CaP-coating

Stem

Ti6, TiAl6V4 alloy conforming to ISO 5832-3

System

Item no.	Description
60.25.0042	Affinis Fracture head 42
60.25.0045	Affinis Fracture head 45
60.25.0048	Affinis Fracture head 48
60.21.0000	Affinis Fracture central part 1
60.21.0001	Affinis Fracture central part 2
60.21.0006	Affinis Fracture stem 6/125
60.21.0009	Affinis Fracture stem 9/125
60.21.0012	Affinis Fracture stem 12/125
60.21.0209	Affinis Fracture stem 9/200
60.21.0212	Affinis Fracture stem 12/200

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