ON REGISTER

FX V135®

CementlessPrimary
Anatomical & Reverse Configurations

Anatomical

135/145°
Reverse

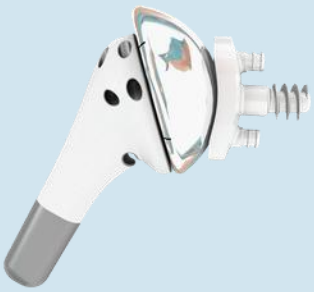
135° Reverse

ATTiS MEDICAL

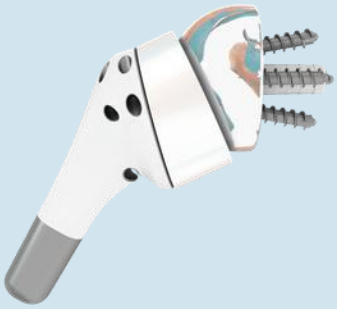
FX Shoulder Solutions

DEVICE DESCRIPTION

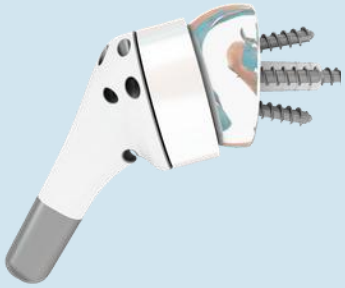
The FX V135® Shoulder Prosthesis is a shoulder replacement system that can be used in either anatomic or reverse shoulder configuration. The Humeral Stem of the FX V135® Shoulder Prosthesis is manufactured from Ti-6Al-4V ELI alloy conforming to ISO 5832-3 and is available in diameters of 10-20mm in the diaphysis dependent upon the epiphyseal sizes Ø32, Ø36, or Ø40mm. All have an overall length of 70mm, functional length 57.5mm. The distal end of the humeral stem is quadrangular and bead blasted. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP-Ti) and Hydroxyapatite (HA) coating. The FX V135® Humeral Stems have suture holes proximally (anterior and posterior) and a recess in the proximal medial stem to facilitate the use of sutures, if needed. The FX V135® Humeral Stem incorporates a female taper for attachment of compatible components. The new FX V135® Humeral Head is available in two versions, one that is thinner -2mm and one that is thicker +2mm and are manufactured from CoCrMo alloy conforming to ISO 5832-12. The new FX V135® Humeral Cup 135/145° is available in three sizes, Ø32, Ø36 and Ø40mm. Each size is available in two versions, standard and stability. Each version is availablein three heights: +3mm, +6mm, +9mm; and is compatible with all sizes of FX V135® Humeral Stems. A 24mm male taper allows attachment of the FX V135® Humeral Cup 135°/145° to the FX V135® Humeral Stem. The new FX V135® Humeral Cup 135°/145° is pre-assembled, one-piece component manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO5834-2 and Ti-6Al-4V ELI alloy conforming to ISO 5832-3. The new Humeral Cup 135°/145° may be used with the new Humeral Spacer +9mm to increase the cup offset to +12mm, +15mm, +18mm.



Anatomical



135/145°
Reverse



135° Reverse

ATTiS MEDICAL

DEVICE DESCRIPTION

HUMERAL STEMS

The Humeral Stem of the FX V135® Shoulder Prosthesis is manufactured from Ti-6Al-4V ELI alloy conforming to ISO 5832-3 and is available in diameters of 10-20mm in the diaphysis dependent upon the epiphyseal Ø32, Ø36, or Ø40mm. All have an overall length of 70mm, functional length 57.5mm. The distal end of the humeral stem is quandrangular and bead blasted.

The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP-Ti) and Hydroxyapatite (HA) coating. The FX V135® Humeral Stems have suture holes proximally (anterior and posterior) and a recess in the proximal medial stem to facilitate the use of sutures also, if needed.

FX V135®
HUMERAL STEM

CEMENTLESS			
EPYPHYSIS	Ø32M	Ø36M	Ø40M
DIAPHYSIS	Ø10MM Ø12MM Ø14MM Ø16MM	Ø12MM Ø14MM Ø16MM Ø18MM	Ø14MM Ø16MM Ø18MM Ø20MM
COMBINATION	Ø32/10 Ø32/12 Ø32/14 Ø32/16	Ø36/12 Ø36/14 Ø36/16 Ø36/18	Ø40/14 Ø40/16 Ø40/18 Ø40/20

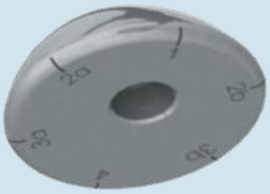
DEVICE DESCRIPTION

HUMERAL HEADS

The new FX V135® Humeral Head is available in three versions, standard head height, one that is thinner (-2mm)1, and one that is thicker (+2mm). They are manufactured from CoCrMo alloy conforming to ISO 5832-12.

An eccentric taper adapter can be dialed in 360° of rotation and impacted into the desired position connecting the humeral stem to the humeral head through this morse taper. Allows for dual eccentricity between the taper and the humeral head for a maximum offset of 7.5mm combined.

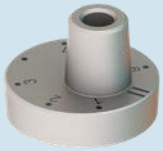
CoCr
CONCENTRIC HEADS



CoCr
ECCENTRIC HEADS

CONCENTRIC HEAD

39x131 / 39x14 / 39x16
41x13 / 41x15 / 41x17
43x14 / 43x16 / 43x18
46x15 / 46x17 / 46x19
48x16 / 48x18 / 48x20
50x17 / 50x19 / 50x21



ECCENTRIC TAPER ADAPTER

ECCENTRIC HEAD

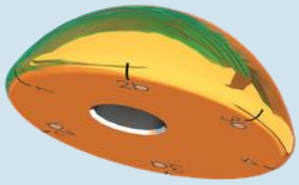
39x132 / 39x15 / 39x17
41x14 / 41x16 / 41x18
43x15 / 43x17 / 43x19
46x16 / 46x18 / 46x20
48x17 / 48x19 / 48x21
50x18 / 50x20 / 50x22
52x21 - Hemi Only**
54x21 - Hemi Only**

[1]Ø39 Centered Thin Option is -1MM NOT -2MM
[2]Ø39 Eccentric Thin Option = 1MM Eccentricity

TIN (TITANIUM NITRIDE) COATED HUMERAL HEADS**

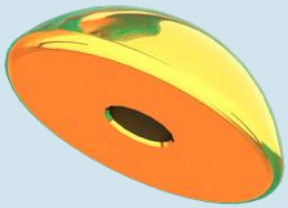
NEXTGENERATION COATINGTECHNOLOGY

FIRST-TO-MARKET TiN HUMERAL HEADS AND GLENOSPHERES IN THE U.S. MARKET AS AN ALTERNATE BEARING FOR TOTAL SHOULDER ARTHROPLASTY • **HARD, THIN SMOOTH COATING • APPROXIMATELY 2300Hv • WORST CASE LOAD & ENVIRONMENT • EXCELLENT WEAR RESISTANCE*** • SINGLE LAYER • BIOCOMPATIBLE TiN COATING OVER CoCr*** • SURFACE ROUGHNESS • PARTICLE ANALYSIS • 1-6 MICRONS THICK**



TiN* COATED
CONCENTRIC HEADS

CAUTION



TiN* COATED
ECCENTRIC HEADS

ATTiS MEDICAL

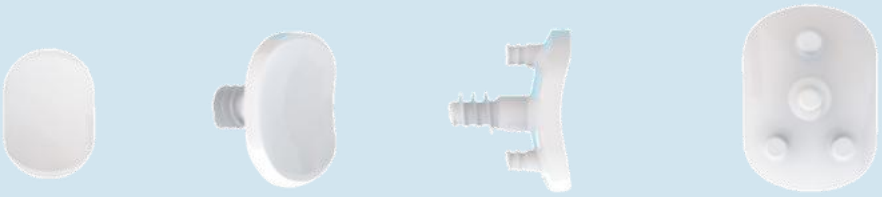
DEVICE DESCRIPTION

2-PEG GLENOID

The 2-peg cemented glenoid component is available in sizes extra small, small, medium and large. They feature two pegs for cemented fixation to the glenoid bone. It is manufactured from ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. Each peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

3-4 PEG GLENOID

The 3-4 peg cemented glenoid component is available in sizes extra small, small, medium and large. Sizes extra small and small have three fixation pegs. Sizes medium and large have four fixation pegs. It is manufactured from ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. The central peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.



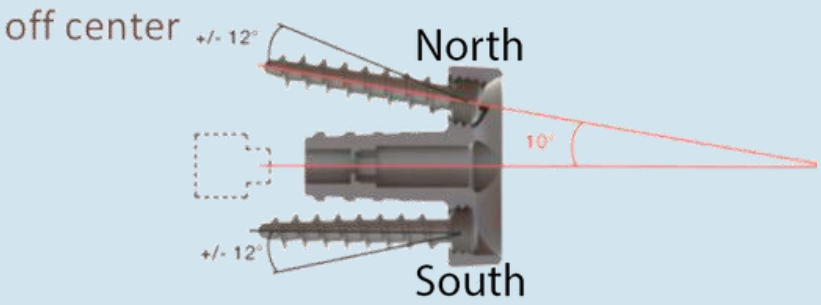
ATTiS MEDICAL

DEVICE DESCRIPTION

BASEPLATE (24mm)

The Ti6Al4V ELI 24mm size and cannulation allows for optimal placement in the inferior glenoid. 17mm post that tapers from 7.5mm proximally to 6.5mm distally with the option for an additional +6mm and +10mm extension posts. Preoriented 10° superiorly at the 12 o'clock position with 12° of variability off center.

A glenoid baseplate with a central screw is also available with central screw sizes from 8mm-20mm.

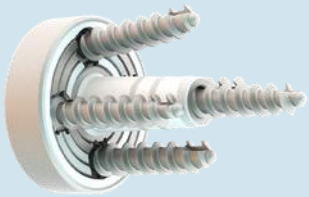


Baseplate with Central Post

Baseplate with Central Screw

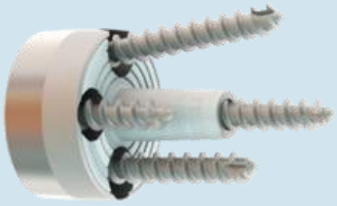
LATERALIZED OPTIONS

Ø24mm Baseplate Extension Post or Central Screw Option +3mm or +6mm Lateralization Options



HALF-WEDGE AUGMENTED GLENOID BASEPLATES

Ø24mm Baseplate Central Screw Option Only 7.5° Half-Wedge 15° Half-Wedge Standard or +3mm or +6mm Lateralization Options



Lateralized Baseplate with Central Screw

Augmented and Lateralized Baseplate with Central Screw

ATTiS MEDICAL

DEVICE DESCRIPTION

GLENOSPHERES

The Humelock Reversed® Glenosphere is available in Ø32, Ø36 and Ø40mm diameter in centered and eccentric styles. The eccentric glenospheres are designed to be offset from the center of the glenoid baseplate. All glenospheres are slightly lateralized of 3.5mm corresponding to 10° of tilt. The curvature of the glenosphere extends 10° beyond the equator of a hemisphere. This additional articular surface lateralizes the center of rotation to help reduce the potential for scapular notching by the humeral cup.

DIAMETERS

32mm, 36mm, 40mm

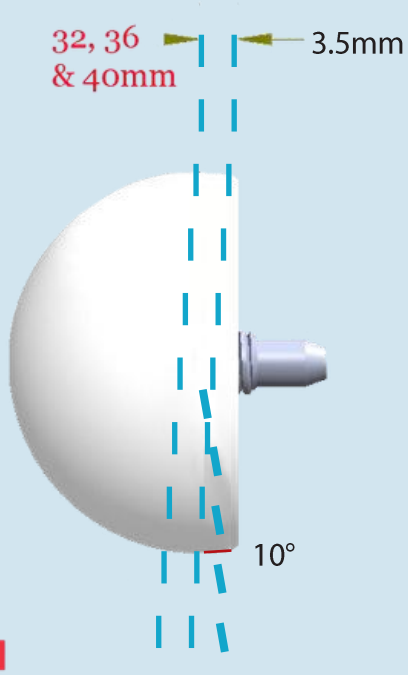
SIZES AND STYLES

Centered or Eccentric Size 32
= 1mm of Eccentricty Size 36
= 3mm of Eccentricty Size 40
= 1mm of Eccentricty
Lateralization = 3.5mm

TiN (TITANIUM NITRIDE) ECCENTRIC AND CENTERED GLENOSPHERE
Ø32/36/40MM

TIN COATED GLENOSPHERES*

NEXTGENERATION COATINGTECHNOLOGY FIRST-TO-MARKET TiN HUMERAL HEADS AND GLENOSPHERES IN THE U.S. MARKET AS AN ALTERNATE BEARING FOR TOTAL SHOULDER ARTHROPLASTY **• HARD, THIN SMOOTH COATING • APPROXIMATELY 2300Hv • WORST CASE LOAD & ENVIRONMENT • EXCELLENT WEAR RESISTANCE*** **• SINGLE LAYER • BIOCOMPATIBLE TiN COATING OVER CoCr*** **• SURFACE ROUGHNESS • PARTICLE ANALYSIS • 1-6 MICRONS THICK**



ATTiS MEDICAL

DEVICE DESCRIPTION

HUMERAL CUP - 135°

The FX V135® symmetrical (standard reverse) humeral cup is available in three sizes, Ø32, Ø36 and Ø40mm. Each size is available in two versions, standard and stability. Each version is available in three heights: +3mm, +6mm, +9mm; and is compatible with all sizes of FX V135® humeral stems. A 24mm male taper allows attachment of the symmetrical humeral cup to the FX V135® humeral stem.

STANDARD REVERSE HUMERAL CUP

+9MM Humeral Spacer

Figure A

135°/145° HUMERAL CUP OPTION

An asymmetric humeral cup allows for a 145° option perioperatively. The new FX V135® humeral cup 135/145° is net shape molded manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO5834-2 and Ti-6Al-4V ELI alloy conforming to ISO 5832-3. It is available in the same size options as listed above for the standard reverse humeral cup. The new humeral cup 135/145° may be used with the new asymmetric humeral spacer +9mm (part number 203-0007) to increase the cup offset to +12mm, +15mm, +18mm. (Figure B)

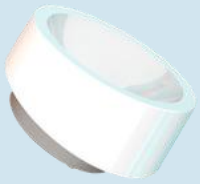


Figure B
135/145°
Humeral Cup Option

+9MM
Asymmetric Humeral
Spacer for 135°/145°
Humeral Cup

STABILITY CUP- OPTION

In extreme cases of instability, the stability variant of the humeral cup can provide added constraint by capturing more of the glenosphere with a deeper dish of the humeral cup without adding to the joint space. The stability variant may also reduce the potential range of motion that can be achieved. (Figure C)

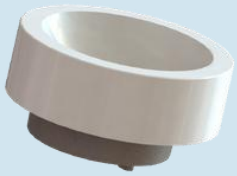


Figure C
STABILITY
HUMERAL CUP

HUMERAL STABILITY CUP			
	135/145° STANDARD CUP	STANDARD CUP	STABILITY CUP
DEPTH OF SPHERE	8MM	8MM	9MM