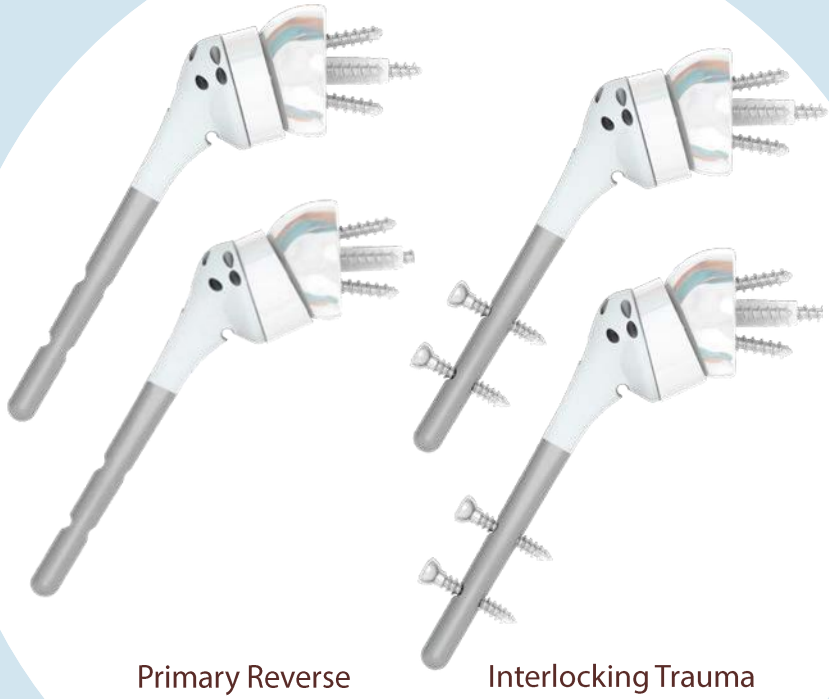
ON REGISTER

FX V135®
HUMELOCK
Cementless



Primary Reverse
135° & 145° Options

Interlocking Trauma
Reverse 135° & 145°
Options

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FX Shoulder Solutions

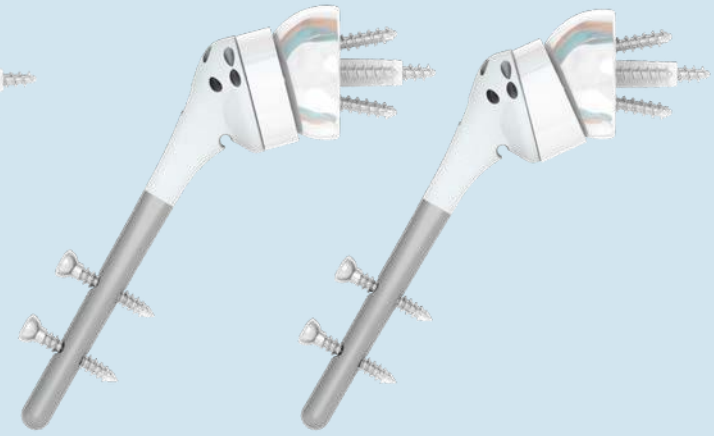
DEVICE DESCRIPTION

The FX V135® Humelock is a total shoulder prosthesis designed for use in patients with non-functional rotator cuffs. The articulation of this design is inverted so that the ball of the articulation is on the glenoid side and the mating humeral cup fits into the humeral stem. The components of the system include a glenoid baseplate, standard (non-locking) and locking bone screws, humeral cups, cementless stems, and an optional humeral spacer (+9mm). 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 glenoid baseplate is a 24mm round base with a central, cannulated post and four peripheral polyaxially (12°) oriented screw holes. The outer edges of the baseplate are tapered to lock with the glenosphere component. The 4.5mm standard (non-locking) and locking screws come in lengths from 15-40mm (5mm increments) which are used to secure the baseplate. The screw holes have 12° of polyaxial orientation with the superior hole preoriented of 10° allowing for up to 22° of angulation to reach the coracoid. There are optional post extensions available to extend the central post of the baseplate from 17mm to provide additional anchoring in cases with poor bone quality or to lateralize the baseplate. The post extensions are available in +6mm and +10mm lengths. When used, the post extensions screw into the baseplate post. There are baseplate options with a central screw with central screw lengths from 8mm-20mm (in 2mm increments). Both the extension post and central screw baseplates have lateralized options. The lateralization of +0mm, +3mm, or +6mm are available 7.5° or 15° half-wedge augmented baseplates are available in the central screw option with lateralization options of +0mm, +3mm, +6mm.

A 24mm male taper allows attachment of the FX V135® humeral cup to the FX V135® humeral stem. The new FX V135® humeral cup is a pre-assembled, net-shape molded component manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO5834-2 and Ti-6Al-4V ELI alloy conforming to ISO 5832-3. There are two humeral cup options in the reverse configuration: a 135° symmetrical humeral cup or a 145° asymmetrical humeral cup. There are three poly thickness options available: +3mm, +6mm, or +9mm. The new humeral cups may also be used with a humeral spacer (+9mm) to increase the cup offset to +12mm, +15mm, +18mm.

Primary Reverse
135° & 145° Options



Interlocking Trauma Reverse
135° & 145° Options

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DEVICE DESCRIPTION

HUMERAL STEMS

Inlay design at 135° with proximal plasma-sprayed hydroxyapatite coating (HA) on Ti6Al4V ELI (conforming to ISO 5832-3). Metaphyseal press fit, bi-cortical distal interlocking. 120mm humeral stem with options for 135° or 145° reverse configurations through the humeral cup selection.

CEMENTLESS			
EPIPHYSIS	Ø32M	Ø36M	Ø40M
DIAPHYSIS	M Ø08 Ø10 Ø12	M Ø10 Ø12 Ø14	M Ø12 Ø14 Ø16
COMBINATION	Ø32/08 Ø32/10 Ø32/12	Ø36/10 Ø36/12 Ø36/14	Ø40/12 Ø40/14 Ø40/16

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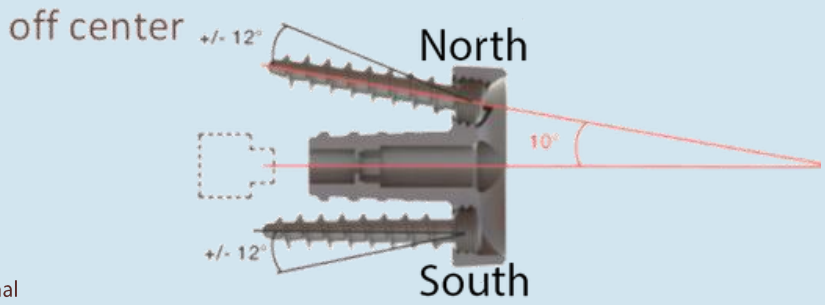
DEVICE DESCRIPTION



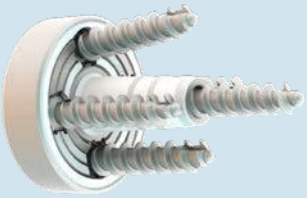
BASEPLATE (24mm)

The Ti6Al4V ELI 24mm size and cannulation allow 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 (2mm increments).

BASEPLATE WITH CENTRAL POST

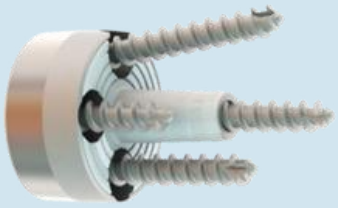
BASEPLATE WITH CENTRAL SCREW



LATERALIZED OPTIONS

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

LATERALIZED BASEPLATE WITH CENTRAL SCREW



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

AUGMENTED AND LATERALIZED BASEPLATE WITH CENTRAL SCREW

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DEVICE DESCRIPTION

GLENOSPHERES

The Humelock Reversed® Glenosphere is available in 32mm, 36mm, and 40mm diameter sizes 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

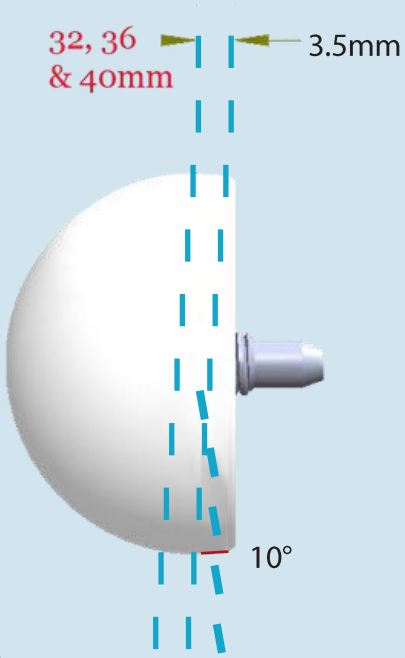
Centered or Eccentric Size 32
= 1mm of Eccentricty Size 36
= 3mm of Eccentricty Size 40
= 1mm of Eccentricty
Lateralization = 3.5mm

TIN 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**

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



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DEVICE DESCRIPTION

HUMERAL CUP - 135° SYMMETRIC OPTION

The FX V135® 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 taper allows attachment of the humeral cup to the humeral stem. The FX V135® humeral cups are pre-assembled, net-shape molded components manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO5834-2 and Ti-6Al-4V ELI alloy conforming to ISO 5832-3. The FX V135® humeral cups are available in symmetrical (135°) or asymmetrical (145°) configurations and the surgeon may trial both options intraoperatively--even at the last minute.

135° SYMMETRIC HUMERAL CUP

SYMMETRIC +9MM HUMERAL SPACER

Figure A

HUMERAL CUP - 135°/145° ASYMMETRIC SPACER (+9MM OPTION)

The new asymmetric 135°/145° humeral cup should be used with the asymmetric humeral spacer +9mm (Figure B) to increase the cup offset to +12mm, +15mm, +18mm. (Figure B)

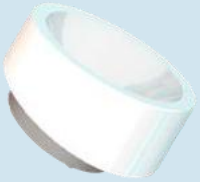

Figure B
135/145° ASYMMETRIC HUMERAL CUP OPTION

Figure B
ASYMMETRIC +9MM HUMERAL SPACER

STABILITY CUP-OPTION

In extreme cases of instability, the stability variant of the humeral cups 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

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