

Arthrex Virtual Implant Positioning™  
(VIP) System Glenoid Targeter with  
3D Model or 5D Calibrator  
**DFU-0289 Rev. 0**

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Glenoid Targeter with 3D Model or 5D Calibrator



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### Directions for Use

The Arthrex VIP System consists of patient specific instruments (the Glenoid 3D Model or Glenoid 5D Calibrator, and Glenoid Targeter) intended for use to facilitate accurate preoperative planning and intraoperative placement of the glenoid guide pin used in preparing the glenoid for implantation of the glenoid implant in Total Shoulder Arthroplasty (TSA). Based on patient CT scan data submitted by the surgeon, Arthrex uses 3D preoperative planning software, OrthoVis, to create a glenoid implant placement surgical plan for that specific patient. The Arthrex VIP System instructions for use guidelines, the Arthrex OrthoVis Preoperative Plan instructions for use guidelines, and the Arthrex VIP System surgical technique can be found at [www.arthrexvip.com/labeling](http://www.arthrexvip.com/labeling).



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# Arthrex Virtual Implant Positioning (VIP) System – Glenoid Targeter with 3D Model or 5D Calibrator

## 1. DESCRIPTION

The Arthrex VIP System consists of patient specific instruments (the Glenoid 3D Model or Glenoid 5D Calibrator, and Glenoid Targeter) intended for use to facilitate accurate preoperative planning and intraoperative placement of the glenoid guide pin used in preparing the glenoid for implantation of the glenoid implant in Total Shoulder Arthroplasty (TSA) or Reverse Total Shoulder Arthroplasty (RTSA). Based on patient CT scan data submitted by the surgeon, Arthrex uses 3D preoperative planning software, to create a glenoid implant placement surgical plan for that specific patient. The software allows bones (e.g., scapula, humerus) to be extracted from patient CT data and to be virtually implanted with an Arthrex shoulder prosthesis component. Arthrex OrthoVis creates digital models of the patient's bony anatomy of which an Arthrex technician plans a glenoid implant trajectory within an established protocol. After approval of the plan by the surgeon, a patient-specific Glenoid 3D Model may be manufactured, packaged, and sent to the surgeon along with patient-specific instructions (PDF Plan) for use with the 3D Model and Glenoid Targeter instruments. The Glenoid 3D Model is cleaned and sterilized according to the validated cleaning and sterilization instructions. Intraoperatively, the Glenoid 3D Model, with an inserted guide pin, is used to set the adjustable Glenoid Targeter instrument to reflect the planned pin/implant trajectory. The Glenoid Targeter is then used to transfer the planned glenoid guide pin trajectory to the patient for placement of the final guide pin used for preparation of the glenoid for implantation.

Alternatively, following the surgeon's approval of the plan, the Targeter legs and Glenoid 5D Ruler Heights can be determined via the Arthrex OrthoVis software and subsequently used with the Glenoid 5D Calibrator instrument to capture the implant trajectory without needing the Glenoid 3D Model.

### 1.1. OrthoVis Software and Preoperative Plan

The Arthrex OrthoVis software is in-house software that allows Arthrex employees to import patient CT scans, which are then rendered in a 3D model for virtual implantation of the glenoid component. Once the desired location of the glenoid component is planned, the trajectory and location of the guide pin used to direct the preparation of the glenoid to achieve this implant location/trajectory is embedded in the model. The guide pin will determine glenoid preparation. After the location of the glenoid component is determined, the trajectory and location of the guide pin are embedded in the 3D model. The software then produces a preoperative plan based on the virtual implantation and resultant information regarding pin trajectory; the preoperative plan is a pdf document containing pictures, text, measurements, and pictures of the 3D bony anatomy that are useful for planning the upcoming TSA/RTSA for the patient. The plan is sent to the surgeon for approval (and revision, if necessary) via the Arthrex VIP Web Portal. The surgeon-approved OrthoVis preoperative plan is then used to create a digital patient-specific Glenoid 3D Model with the embedded guide pin trajectory information. The Glenoid 5D Calibrator (reusable instrument) may be used instead of the Glenoid 3D Model to set the legs of the Glenoid Targeter Instrument. If a Glenoid 5D Calibrator is ordered, the surgeon-approved OrthoVis preoperative plan will contain the 5D Ruler heights needed to set the Glenoid Targeter instrument.

### 1.2. Glenoid 3D Model

The Glenoid 3D Model is a patient-specific instrument that is created from a photopolymer that is selectively photopolymerized using Digital Light Projection (DLP) laser technology to build a layer-by-layer exact replica of the bone extracted from the patient CT scan using the OrthoVis software. The Glenoid 3D Model is labeled with the order number, patient's ID number (MRN), patient's first initial and last name, and the surgeon's last name. It is shipped non-sterile to the surgeon/hospital/distributor for subsequent cleaning and sterilization on-site at the hospital. A non-sterile packaged 3D Model mounting stand is provided along with the other reusable metal components of the Arthrex VIP system. The 3D Model Mount is designed so that when the Glenoid 3D Model is placed on the mount, the guide pin trajectory is shown in the plane of the scapula for that patient.

### 1.3. Glenoid 5D Calibrator

The Glenoid 5D Calibrator is an anodized aluminum setting stand that has 5 equally-spaced stainless steel rulers that may be adjusted in height that correspond to the Glenoid Targeter leg slots. The 5D Calibrator allows the different (A through E) rulers to be raised to designated heights 0 through 65 (0.5mm increments) and then locked individually in place using brass thumb screws. The 5D Calibrator allows the user to receive a patient-specific plan from Arthrex that includes the recommended Targeter legs (10 mm through 25 mm), the corresponding Targeter leg slot (A through E), and the corresponding 5D Calibrator Ruler Heights for the planned legs. Pictures of the virtual setting of the Targeter device are able to be sent to or downloaded by the user to visually determine where the Targeter instrument is to be set

on the patient. With the Glenoid Targeter is loaded with the recommended legs in the recommended slots and the 5D Calibrator rulers set for each corresponding slot to the recommended height, the user may set the Targeter on the 5D Calibrator and lock, all at once, the Targeter legs at the height at which they rest on the 5D Calibrator, using the collet/wing cap. The Glenoid 5D Calibrator option allows the user to electronically obtain a patient-specific plan and utilize the Glenoid Targeter to transfer the planned guide pin trajectory to the patient, using all reusable instruments.

#### **1.4. Glenoid Targeter**

The Glenoid Targeter device consists of a main body manufactured from medical-grade stainless steel that is used with three (3) to five (5) stainless steel legs of various offset lengths. The barrel of the Glenoid Targeter (main body) contains five equally spaced T-slots with a hole running concentric down the barrel to accept the guide pin. The proximal end of the barrel is threaded and screws onto the Targeter handle. The distal end of the handle is a collet with a screw-on winged, metal cap. The Targeter legs slide into the barrel slots; tightening of the cap tightens the collet, locking the metal legs in position (over the knurled portion of the legs). A disassembly slot/tool is included in the Arthrex VIP instrument tray to assist in disassembly/loosening of the Targeter barrel and handle.

### **2. INTENDED USE / INDICATIONS FOR USE**

The Arthrex VIP System is a patient-specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Arthrex Glenoid Targeter is indicated for use with the Arthrex Univers II and Arthrex Univers Apex, Keeled or Pegged Glenoid components, the Vault Lock Glenoid Component, as well as the Univers Revers Baseplate components.

The indications for use of the Arthrex shoulder systems with which the Arthrex VIP System is intended to be used are the same as those described in the labeling for these shoulder systems.

### **3. CONTRAINDICATIONS**

1. The Arthrex VIP System is not to be used with any shoulder replacement system or component other than the total shoulder systems and components identified in the Indications for Use of the Arthrex VIP.
2. The contraindications for the total shoulder systems with which the Arthrex VIP System is indicated for use remain the same as those described in each implant system's labeling.
3. The Arthrex VIP System should not be used if the legs of the Glenoid Targeter instrument are not stable or move when Glenoid Targeter collet is tightened and used for guide pin placement, and the failure should be reported to Arthrex.
4. If the seating of the Glenoid Targeter instrument on the patient cannot be exactly matched with the seating of the Targeter on the Glenoid 3D Model or the 5D Calibrator instructions, the surgeon must choose to either address the issue so that the Targeter instrument seating is matched between the patient and the Glenoid 3D Model or 5D Calibrator instructions, or alternatively, refrain from using the Arthrex VIP System.
5. The Arthrex VIP System is not indicated for use in hemi-shoulder arthroplasty.

#### **Contraindications for Arthrex VIP with Glenoid 3D Model**

1. The Arthrex VIP System should not be used with the Glenoid 3D Model if the patient's glenoid does not appear to the surgeon to be accurately represented in shape and size of the Glenoid 3D Model and the surgeon cannot or does not elect to make changes to the patient's anatomy to accurately correspond to the Glenoid 3D Model.
2. If the location or trajectory of the guide pin in the Glenoid 3D Model does not match the intended/planned location or trajectory of the guide pin, do not use the Arthrex VIP System.

### **4. WARNINGS**

1. Do not use if Glenoid Targeter slots, legs, or collet are damaged or broken. Contact Arthrex for a replacement.
2. Do not use after the expiration date.
3. The warnings for the total shoulder systems with which the Arthrex VIP System is indicated for use remain the same as those described in each of these system's labeling
4. If the surgeon determines that the implant position is not appropriate after placing the pin guide or preparing the glenoid for the component, the surgeon should re-position the guide pin and / or implant. To achieve this, the surgeon should use the standard Arthrex glenoid instrumentation provided to achieve the position desired, as would be done if similar conditions were encountered if the procedure were completed using the standard pin placement instruments and technique.

#### **Glenoid 3D Model**

1. Do not use Glenoid 3D Model if damaged or broken.

### **Glenoid 5D Calibrator**

1. If the recommended Targeter leg length for an overhanging leg is insufficient to overhang the edge of the glenoid, use one leg length longer at the same recommended leg slot and the 5D Calibrator ruler height. Otherwise, do not deviate from the recommended Targeter leg lengths, slots, or 5D Calibrator ruler heights if a patient-specific Glenoid 3D Model is not also present.
2. Do not use the 5D Calibrator if damaged or broken or if the 5D Calibrator rulers cannot be locked into place without sliding. Contact Arthrex for a replacement.
3. The 5D Calibrator Instructions expire 6 months from the date of the CT scan used for the patient-specific preoperative plan.

### **5. PRECAUTIONS**

1. The Glenoid 3D Model, Glenoid 5D Calibrator, and Glenoid Targeter devices should only be used by physicians who have received appropriate training.
2. The Glenoid 3D Model, Glenoid 5D Calibrator, and Glenoid Targeter devices should only be used at hospitals where total shoulder arthroplasty surgery is accessible.
3. The Glenoid 3D Model, Glenoid 5D Calibrator, and Glenoid Targeter devices should only be used when the surgical exposure allows sufficient access to the glenoid, so that the Arthrex VIP System can be used according to these Directions for Use.
4. The Glenoid 3D Model, Glenoid 5D Calibrator, and Glenoid Targeter devices should be used with no fewer than 3 Targeter legs and at least 2 Targeter legs should hang over the glenoid rim.
5. Do not use the 2.8 mm guide pin that is placed in the Glenoid 3D Model to adjust the Glenoid Targeter in the patient; it is recommended that a separate, sterile 2.8 mm pin be used for placement in the patient's glenoid.
6. Following glenoid guide pin placement, standard surgical instruments should be used for the remainder of the procedure, according to the manufacturer's instructions and surgical techniques.
7. **Glenoid 3D Model (Optional) Provided non-sterile for single-patient use only.** Do not reuse, reprocess, or resterilize. Note the "Use by" (expiration) date on the product label. The 3D Model should be safely disposed of in accordance with hospital policy after use.
8. Reusable Arthrex VIP components (Glenoid Targeter, Glenoid Targeter legs, 3D Model Mount, Glenoid 5D Calibrator) should be visually inspected for damage (breakage, bending, corrosion, marking no longer readable, etc.) prior to each re-use. Do not reuse if damaged/broken. Contact Arthrex for a replacement.
9. The precautions for the total shoulder systems with which the Arthrex VIP is indicated for use remain the same as those described in each of these system's labeling.

### **6. PATIENT COUNSELING AND PATIENT INFORMATION**

Physicians should consider the following in counseling patients about this product:

1. Discuss the risks of using the Arthrex VIP System for total/reverse shoulder arthroplasty.
2. Discuss the risk/benefit issues for this particular patient.

### **7. CLEANING AND STERILIZATION**

Devices must be adequately cleaned and sterilized prior to use or re-use. All devices are to be cleaned and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile devices. An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the devices.

#### **7.1. Point-of-Use Preparation, Containment, and Transportation**

It is recommended that instruments are reprocessed within a maximum of 1 hour of use. At point of use, soiled instruments must be removed from trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Soaking in enzyme solutions facilitates cleaning, especially in devices with complex features and hard-to-reach areas (lumens, etc.). These enzyme solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on devices. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. Devices should be contained and transported in a closed, puncture-proof device to ensure safety.

**Do not** clean soiled instruments while in cases or trays. Instrument cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use.

#### **7.2. Detergent Selection**

Consider the following points during selection of the cleaning detergent:

1. Suitability of the cleaning agent for ultrasonic cleaning (no foam development).
2. Compatibility of the cleaning agent with the instruments. Arthrex recommends the use of neutral pH or

enzymatic cleaning agents. Enzol®, Steris® Prolystica 2X Enzymatic Cleaner, and Steris® Prolystica 2X Neutral Detergent were used during the validation of these instructions.

3. Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either manual or automated cleaning. Please use only freshly prepared solutions as well as only purified water at least for final rinse, and a soft, low-linting cloth and/or filtered medical grade air for drying, respectively.

**7.3. Preliminary Cleaning for Glenoid 5D Calibrator Components, Glenoid Targeter, Targeter legs, and 3D Model Mount (metal components)**

1. Devices that require disassembly are to be disassembled prior to cleaning.
2. Remove excess soil from devices, especially in areas such as joints and crevices, by cleaning the surfaces with a sponge or brush under cold running water or with a non-shedding disposable wipe for a minimum of 1 minute.
3. Rinse the devices at least 2 minutes under running utility water (temperature < 35 °C/95 °F). Special attention should be given to lumens, joint, crevices, and other hard-to-reach areas.
4. After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning **or** Automated Cleaning.

**7.4. Manual Cleaning of Glenoid 5D Calibrator Components, Glenoid Targeter, Targeter legs, and 3D Model Mount (metal components)**

1. After Preliminary Cleaning is complete, immerse the devices in cleaning solution inside an ultrasonic bath. While immersed in solution, brush the devices for 1 minute using a soft-bristled brush. Special attention should be given to lumens, joints, crevices, and other hard-to-reach areas. Lumens should be brushed with appropriate diameter and length bristle sizes for the particular lumen.
2. After brushing, turn on ultrasonic power and soak and sonicate for 10 minutes at a minimum of 40±5 kHz. Ensure devices are in the open position and that lumens have complete contact with cleaning solution during soaking.
3. Remove the devices from the cleaning solution and rinse at least 2 minutes with purified (critical, e.g. reverse osmosis (RO) or deionized (DI)) water. Thoroughly and aggressively rinse lumens, joints, crevices, and other hard-to-reach areas.
4. Dry devices thoroughly utilizing filtered medical grade air or a soft, clean, and low-linting cloth.
5. Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.

**7.5. Automated Cleaning of Glenoid 5D Calibrator Components, Glenoid Targeter, Targeter legs, and 3D Model Mount (metal components)**

1. After preliminary cleaning is complete, immerse the devices in cleaning solution inside an ultrasonic bath. While immersed in solution, brush the devices for 1 minute using a soft-bristled brush. Special attention should be given to lumens, joints, crevices, and other hard-to-reach areas. Lumens should be brushed with appropriate diameter and length bristle sizes for the particular lumen.
2. After brushing, turn on ultrasonic power and soak and sonicate for 10 minutes at a minimum of 40±5 kHz. Ensure devices are in the open position and that lumens have complete contact with cleaning solution during soaking.
3. Remove the devices from solution and load the devices in the automated washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations/holes positioned to drain).
4. Run an automated wash cycle with fundamentally approved efficiency of the automated washer (for example, CE marking according to EN ISO 15883 or FDA approval/clearance/registration). The following minimum recommended wash cycle parameters were utilized during the validation of these instructions.

Phase	Recirculation Time (Minutes)	Temperature	Detergent
Enzymatic Wash	04:00	Follow detergent manufacturer's recommendation	Enzymatic Detergent
Detergent Wash	02:00	Follow detergent manufacturer's recommendation	Neutral Detergent
Rinse	02:00	Warm purified water	N/A

Dry	15:00	80°C (176°F) minimum	N/A
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5. Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.

**7.6. Manual Cleaning of Glenoid 3D Model prior to Sterilization**

1. Rinse the 3D Model under cold running tap water for minimum of 1 minute. (Note: the 3D Model will be marked where the recommended Targeter legs would sit. Do not attempt to remove these markings.)
2. Immerse the 3D Model in cleaning solution and allow to soak for a minimum of 2 minutes.
3. Brush the 3D Model using a soft bristled brush and lumen brush.
4. Flush hard to reach areas using a syringe with a minimum of 50 mL (1.7 oz.) and repeat three times.
5. Thoroughly rinse the 3D Model with purified (critical, e.g. RO/DI) water for a minimum of 1 minute to remove detergent residuals.
6. Dry devices thoroughly utilizing filtered medical grade air or a soft, clean, and low-linting cloth.
7. Allow the 3D Model to air dry for a minimum of 40 minutes.

**7.7. Automated Cleaning of Glenoid 3D Model prior to Sterilization**

1. Load the 3D Model into the automated washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, cannulations/holes positioned to drain).
2. Run an automated wash cycle with fundamentally approved efficiency of the automated washer (for example, CE marking according to EN ISO 15883 or FDA approval/clearance/registration). The following minimum wash cycle parameters are recommended.

PHASE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT
Pre-wash 1	02:00	Cold tap water	N/A
Wash 1	10:00	Follow detergent manufacturer's recommendation	Neutral Detergent
Rinse 1	02:00	Warm critical water	N/A
Drying	30:00	80°C (176°F) minimum	N/A

3. Remove the 3D Model from the washer.

**7.8. Sterile Packaging**

Sterilization is to be performed following cleaning and sterile packaging prior to use.

1. Single devices should be packed as to ensure that the pack is large enough to contain the device without stressing the seals. Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).
2. Where appropriate, cleaned and inspected devices should be placed into trays/cases as provided.
3. Prior to sterilizing the Arthrex VIP instruments and tray, ensure that all the Arthrex VIP components have been cleaned according to the above instructions and are disassembled and in their corresponding labeled locations in the instrument tray.
4. If the Glenoid 3D Model or 5D Calibrator is being used, ensure that each has been cleaned according to the above instructions. It is placed in its labeled location in the Arthrex VIP instrument tray.
5. The recommended Targeter leg lengths from the Patient-Specific Targeter Instructions should be selected from among the legs in the bottom tray and placed into the corresponding labeled bracket (A, B, C, D, or E) in the smaller inner tray.
6. The total weight of trays/cases should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may

apply). Trays/cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

- DO NOT STACK trays during sterilization. Stacking of trays may adversely affect sterilization and drying effectiveness.

### 7.9. Sterilization of Arthrex VIP System

The recommended sterilization method and cycle parameters in these instructions have been validated in compliance with federal and international guidance/standards. In accordance with ISO 17665, the “overkill” approach for moist heat (steam) was used for sterilization validation, and demonstrates a sterility assurance level (SAL) of 10<sup>-6</sup>.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer’s instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS			
Cycle Type	Exposure Temperature	Exposure Time	Minimum Drying Time
Prevacuum Cycle	132°C (270°F)	4 Minutes	30 Minutes

### 8. PACKAGING AND LABELING

- Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact Customer Service if the package has been opened or altered.
- All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at [www.arthrex.com/symbolsglossary](http://www.arthrex.com/symbolsglossary).

### 9. MATERIAL SPECIFICATIONS

#### Glenoid 3D Model (Optional)

- E-Denstone

#### Glenoid 3D Model Mounting Stand

- Aluminum, anodized

#### Glenoid 5D Calibrator

- Rulers: Stainless steel
- Thumb screws: Brass
- Calibrator core: Anodized aluminum
- Pillar: Stainless steel

#### Glenoid Targeter

- Barrel, Handle, Cap: Stainless steel

#### Glenoid Targeter Legs (metal components)

- Stainless steel

### 10. STORAGE CONDITIONS

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions. It is the responsibility of the end-user to ensure devices, once sterilized, are stored in such a way as to maintain the sterility of the device until use. Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes. Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, shows any evidence of tampering, or has been exposed to moisture, the device or set

must be cleaned, repackaged, and sterilized.

## 11. INFORMATION

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

## 12. INSTRUCTIONS

### 12.1. Inspection Prior to Use

1. Do not use the Glenoid 3D Model after the "Use by" date.
2. Maintain aseptic surgical techniques throughout use of the Arthrex VIP devices once Arthrex VIP system is removed from the sterile wrap.
3. Inspect the Arthrex VIP devices for damage prior to each use/re-use (e.g., broken/bent Targeter leg tips, corrosion, or laser marking has rubbed off and is no longer readable). If damage is present, DO NOT USE as damage may interfere with the function of the device. Please contact Arthrex for a replacement.
4. Prior to use of the Glenoid 3D Model, inspect for damage. If upon inspection the 3D Model is broken or damaged, DO NOT USE.

### 12.2. Materials Required

1. Two (2) sterile 2.8 mm diameter guide pins if 3D Model is to be used.
2. One (1) sterile 2.8 mm diameter guide pin if Glenoid 5D Calibrator is to be used.
3. Standard manual glenoid instrumentation for the Arthrex shoulder replacement system being used.

### 12.3. Using the Arthrex VIP Devices

1. Follow the surgical technique for the Arthrex VIP System.
2. For the portions of the shoulder replacement procedure that are not accomplished with the Arthrex VIP devices, follow the Arthrex surgical technique of the shoulder system being implanted.

## 13. MAGNETIC RESONANCE IMAGING (MRI)

There are inherent risks associated with the use of metallic implants and instruments in the MR environment, including component migration, heat induction and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to the component geometry and material, as well as the MR power, duration and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of these occurrences are unknown.

The Glenoid Targeter device is manufactured from stainless steel and is **not compatible for use in the MR environment**. The Glenoid 5D Calibrator device is manufactured from stainless steel and aluminum and is **not compatible for use in the MR environment**. The Glenoid 3D Model has not been evaluated for safety and compatibility in the MR environment. The Glenoid 3D Model has not been tested for heating or migration in the MR environment. Since the 3D Model has not been tested, Arthrex cannot make a recommendation for the use or presence of this device during MRIs with these implants, neither for safety considerations nor imaging accuracy.

CAUTION: Federal law (USA) restricts this device to sale on or by the order of a physician.