

Comprehensive[®] Nano Stemless Shoulder

Surgical Technique – United States Version



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Patient in beach chair position

Figure 1



Thumb Test

Figure 2

Preoperative Considerations

- Utilize preoperative templating (X-ray templates) to ensure the humeral neck is of sufficient diameter to implant the smallest Nano humeral component.

Patient Positioning

- Place patient in a beach chair position on the edge of the operating table (Figure 1).
- Extend involved shoulder over the edge of the table so the arm can be brought into full extension and adduction.
 - Armrest is optional.
 - The upper part of the operating table has to be open on the homolateral side to allow shoulder extension (shoulder table).

Intraoperative Considerations

Bone Test

- To achieve a good outcome, the patient must have adequate bone stock to support the fixation of the implant (Figure 2).
- Poor metaphyseal bone quality assessment is not possible until the humeral head has been resected. As a result, you should always be prepared with a back-up system.

Surgical Technique Summary



Attach the humeral cut guide and place central pin



Resect the humeral head at the anatomic neck



Size the humeral component



Ream the humerus parallel to the resected surface



Broach the humerus



Remove broach handle leaving the broach trial



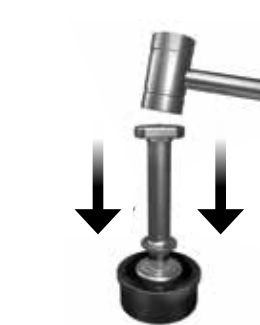
Humeral head sizing and offset



Remove the trial Broach



Implant the final Nano Humeral Component



Assemble humeral head to taper adapter



Insert the humeral head onto the final Nano Humeral component

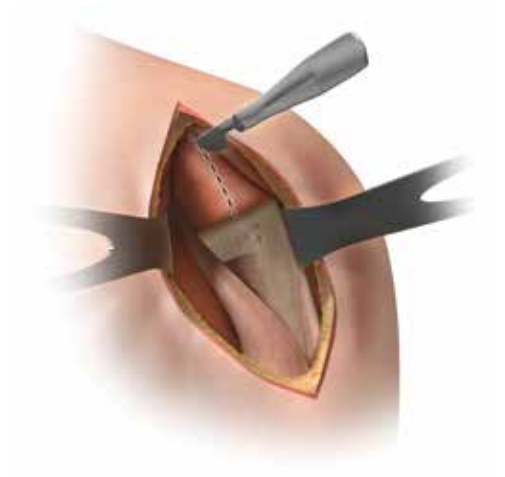


Revision: Remove the Nano Humeral Component.



Delto-pectoral approach

Figure 3

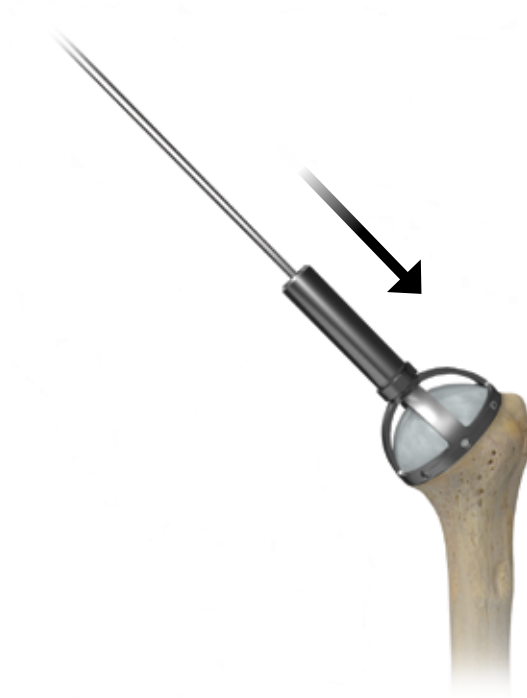


Humeral Head exposure

Figure 4

Initial Incision

- Utilize an extended deltopectoral anterior incision with an optional biceps tenodesis beginning immediately above the coracoid process and extending distally and laterally, following the deltopectoral groove along the anterior border of the deltoid (Figure 3).
- Laterally retract the deltoid muscle, avoiding release of the deltoid from the clavicle. The deltoid may be partially released from its distal insertion by subperiosteal dissection.
- If needed, make a partial relaxing incision through the proximal coracoid tendon and medially retract the conjoined tendon.
- Additional exposure can be aided via a partial release of the upper 1/3 of the pectoralis major tendon at the distal aspect of the incision.
- Identify anterior structures and externally rotate the humerus.
- Make a longitudinal incision through the tendinous portion of the subscapularis muscle and capsule, just medial to the lesser tuberosity (Figure 4).
- In cases of severe contracture, subscapularis lengthening may be required (a lesser tuberosity osteotomy can be utilized based on surgeon preference).



Attach humeral cut guide and place central pin

Figure 5

Humeral Head Technique

Humeral Head Resection

- Tag the subscapularis tendon with non-absorbent sutures.
- Externally rotate and extend the humerus to expose the humeral head, while protecting the axillary nerve.
- Mobilize the subscapularis tendon to restore excursion by releasing the upper border including the coracohumeral ligament, the anterior capsule from the glenoid rim and inferior subscapularis.
- It is not recommended to perform releases anterior to the subscapularis so as to avoid inadvertent denervation.
- Remove osteophytes and assess the version of the head and the neck shaft angle.
- Position the appropriate sized cutting guide over the head to reproduce the patient's anatomy (Figure 5).



A Comprehensive Nano Resection Guide
31-406994/95/96/97/98/99



B Comprehensive Nano Resection Guide Handle
31-406993



C Comprehensive Nano Pin 3.2mm (disposable)
110045821



Resect the Humeral Head at
the anatomic neck

Figure 6

- Insert the pin through the center of the humeral head guide.
- Cut at the anatomic neck using an oscillating saw parallel to the underside of the guide (Figure 6).
- ⓘ **Note:** It is recommended to drive the pin till just above the anatomic neck/point where the resection guide ends. This will ensure that the resection can be done without having to move around the pin, and have a flat resected surface to use the pin once again to lock the center of the humerus.
- Remove the pin and the humeral cut guide. Complete the cut if necessary.
- ⓘ **Note:** According to surgeon preference, an extramedullary guide is also available and may be used to resect the humerus.
- ⓘ **Note:** If the guide is not used, perform an osteotomy along anatomic neck after removal of all osteophytes anteriorly and inferiorly.
- ⓘ **Note:** Aim saw toward junction of posterior articular cartilage and bare area. Avoid injury to the insertions of the supraspinatus and infraspinatus/teres minor.
- ⓘ **Note:** After completing humeral head resection, inspect resected surface for cysts. If there are single cysts greater than 1 cm or multiple cysts at implantation site, abandon stemless implantation and utilize a stemmed prosthesis.



A Comprehensive Nano
Resection Guide
31-406994/95/96/97/98/99



B Comprehensive Nano
Resection Guide Handle
31-406993



C Comprehensive Nano
Pin 3.2mm (disposable)
110045821

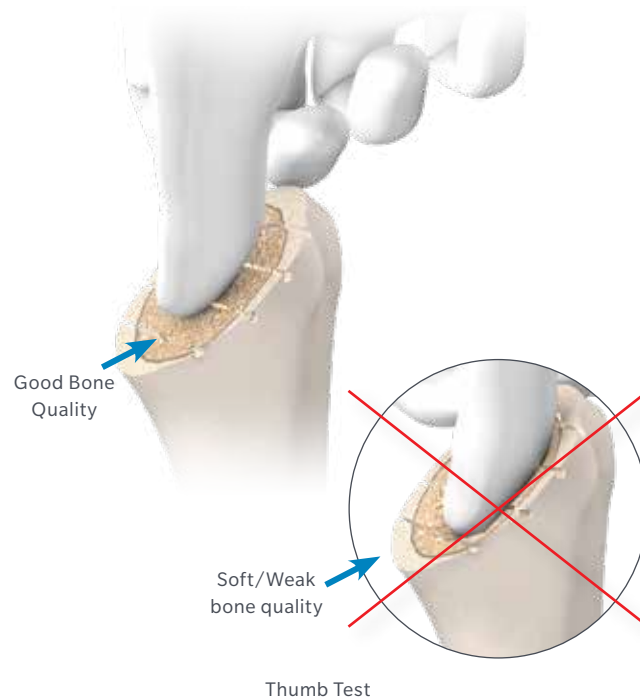


Figure 7

Perform first bone test:

- To achieve a good outcome, the patient must have adequate bone stock to support the fixation of the implant.
- Press thumb on resected humeral surface to assess bone quality (Figure 7).
- If you can depress thumb into humerus without much resistance then primary stability of the implant may be insufficient. In this case a stemmed prosthesis will provide better fixation.
- Poor metaphyseal bone quality assessment is not possible until the humeral head has been resected. As a result, you should always be prepared with a back-up system.



Figure 8



Figure 9

Size the humeral component

Humeral Sizing

- Choose the size of the Nano Humeral Component by laying a Humeral Sizer onto the head resection (Figure 8).
- ⓘ **Note:** The most appropriate size is the one which gives maximum coverage of cancellous bone without involving the cortical bone.
- ⓘ **Note:** At minimum, 1mm of cortical bone should be seen around the circumference of the template.
- Insert the 3.2 mm Steinmann Pin into the center of the Humeral Sizer and to the lateral cortex of the humerus (Figure 9) if it backs off during resection.
- ⓘ **Note:** Avoid deep penetration of the lateral humeral cortex with the pin to avoid potential injury to the axillary nerve, as it courses around the lateral side of the humerus.
- Remove the Humeral Sizer, leaving the pin in place.



C Comprehensive Nano Pin 3.2mm (disposable)
110045821

D Comprehensive Nano Sizer Handle
31-406917

E Comprehensive Nano Humeral Sizer
31-406930/32/34/36/38/40





Calcar planing the resected humerus

Figure 10

Perform second bone quality test:

- If the 3.2 mm Steinmann Pin is unstable in the humerus, then this may indicate that the bone is soft/weak. A stemmed prosthesis is recommended for soft/weak bone.

Calcar Planer

- If desired, use the Calcar Planer to refine the resected surface.
- Attach the Planer Blade that most closely matches the diameter of the resected surface to the barrel of the calcar planer.
- Place the Planer over the Steinmann Pin. Begin rotation of the calcar planer before contacting the resected surface.
- Apply slight pressure and plane the resected surface (Figure 10).



**Comprehensive Nano
Calcar Planer**
31-406991





Ream the humerus parallel to the resected surface

Figure 11

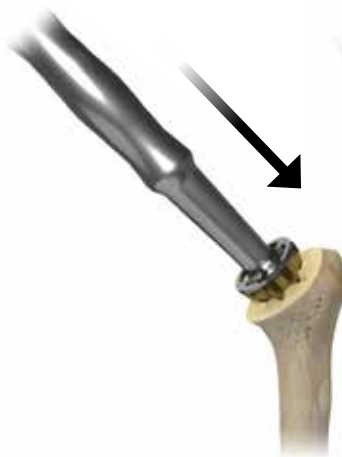


Figure 12a



Broach the humerus

Figure 12b

Humeral Reaming

- Select a Reamer that is the same size as the Humeral Sizer used previously. Pass the Reamer over the pin until the stop bottoms out on the head resection (Figure 11).

Note: The Reamer should be moving when it comes in contact with bone.

- If the Reamer should reach the lateral cortex before bottoming out, stop and repeat reaming with the next smaller reamer, or until lateral cortex is not contacted with reamer.

Note: Take care to not lean or lever on the reamer as this can change the plane of reaming.

Humeral Broaching

- Select a Broach that is the same size as the Humeral Sizer used previously and attach it to the Inserter. Advance the broach into the humerus in several successive motions ensuring that proper version and inclination are achieved (Figure 12a).

Note: Do not forcibly impact the broach.

- The broach is fully seated when the collar on the inserter handle rests on the resected surface of the humerus (Figure 12b).



F Comprehensive Nano Humeral Reamer
31-406941/42/43/44/45/46



G Comprehensive Nano Humeral Broach
31-406950\52\54\56\58\60



J Comprehensive Nano Inserter
31-406929





Figure 13a

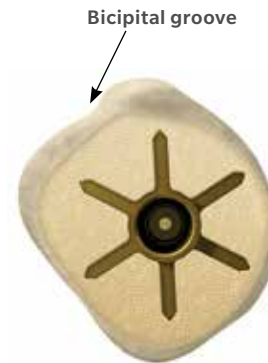


Figure 13b

⊖ **Note:** If the initial broach is sized incorrectly, repeat steps for reaming and broaching with a larger size. It is not recommended to size smaller. Remove the Inserter, leaving the broach in place (Figure 13a).

⊖ **Note:** The Broach should be inserted into the humerus so the wings are not in line with the bicipital groove (Figure 13b).

Perform third bone quality test:

- If the broach is unstable after impaction, this indicates the bone is weak/soft and a stemmed prosthesis is recommended.

⊖ **Note:** The Versa-Dial® Head Trial can be trialed off the Nano Humeral Broach or the final Nano Humeral Component to determine the appropriate Humeral Head height and offset for the patient.

- Use the Comprehensive Nano Humeral Protector to place over the Broach to protect the humerus if one decides to go to placement of the glenoid.

⊖ **Note:** Failure to correctly align Nano Humeral component and Humeral Head to resection surface may lead to complications that include rotator cuff damage. It is recommended to use intraoperative fluoroscopy to confirm varus/valgus alignment and stem positioning.



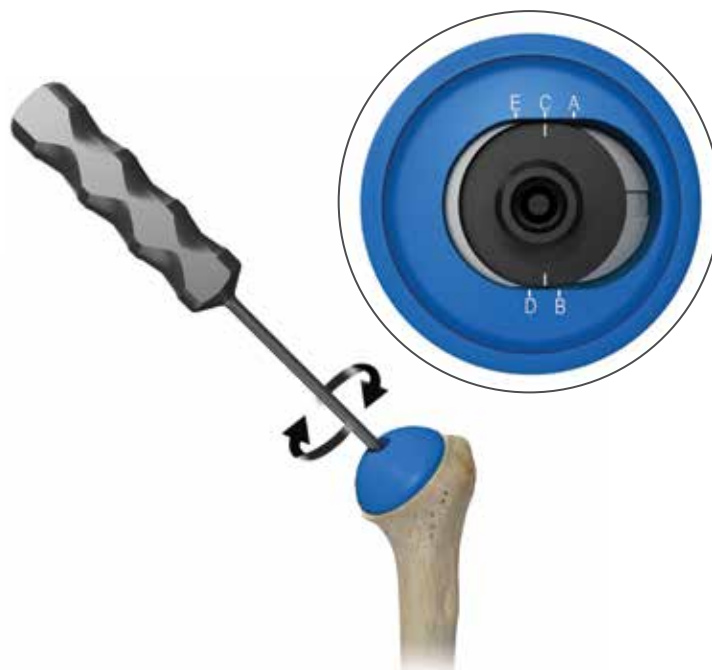
1 Comprehensive Nano Humeral Protector
31-406968/72/76/80/84/88





Maximize coverage of humeral resection

Figure 14



Determine the ideal humeral head offset required for optimal coverage of resection

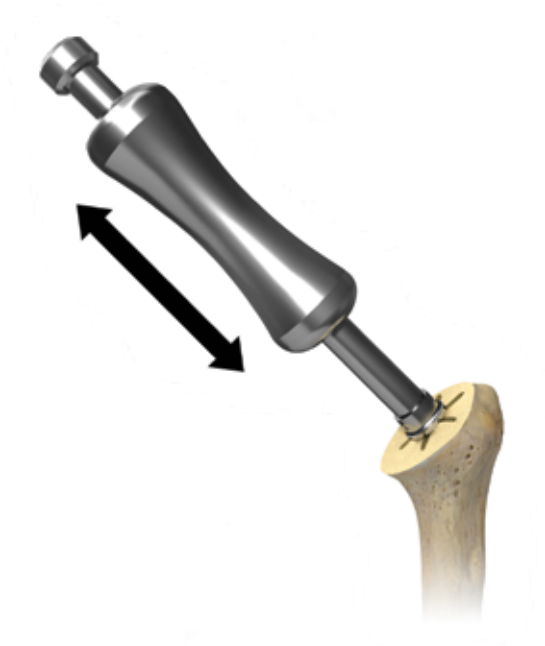
Figure 15

Humeral Head Selection

- Using the resected humeral head for comparison, select an appropriately sized head trial and assemble to a standard trial taper adaptor.
- Determine the amount of desired offset by maximizing the coverage of the Versa-Dial provisional over the resected surface of the humerus (Figure 14).
- After maximum coverage of the resected surface is achieved, tighten the taper adaptor trial in the head trial with a hex driver (Figure 15).
- Reduce the joint and perform a trial range of motion.

Head Offset

- Remove the Versa-Dial trial assembly from the humeral component.
 - Determine the amount of offset needed by referencing the indications on the underside of the trial head and trial adaptor (Figure 15).
- ⓘ **Note:** It is recommended to impact the Versa-Dial provisional head flush with the humeral osteotomy prior to performing a trial range of motion.



Remove the trial Broach

Figure 16



Implant the final Nano Humeral Component

Figure 17

Nano Humeral Component Insertion

- Remove the Pin. Attach the Slap Hammer to the broach/trial and remove it from the humerus (Figure 16).
 - Select a Nano Humeral Component that matches the final broach/trial used. Assemble the Comprehensive Nano Humeral Component onto the Inserter.
 - Insert the Nano Humeral Component into the proximal humerus ensuring proper version and inclination are achieved (Figure 17). The collar of the inserter should be flush with the resection.
- ⓘ **Note:** This typically will result in an implant that is flush with the cut surface of the osteotomy in anatomic version and inclination.
- ⓘ **Note:** Tilting of the device superior/inferior will modify inclination. Tilting the device anterior/posterior will alter version.



J Comprehensive Nano
Magnetic Inserter
31-406929



K Comprehensive Nano
Slap Hammer
31-406921





Assemble the humeral head implant with desired offset

Figure 18a



Figure 18b

Head Assembly

- Place the Versa-Dial head into the Impactor Tray. Ensuring the components are clean and dry, insert the Versa-Dial Taper Adaptor into the Head (Figure 18a).
- Rotate the taper adaptor until the trial offset is replicated. For example, if trialing indicated halfway between the B and C hashmarks, the implant taper adaptor is aligned so its hashmark is halfway between the B and C on the head.
- Engage the Morse taper with two strikes, using the Taper Impactor Tool and mallet (Figure 18b). The taper/head assembly is now securely fastened.



Insert the humeral head onto the final Nano Humeral component

Figure 20



Figure 21

Head Insertion

- Clean and dry the reverse Morse taper. Gently place the Versa-Dial head onto the humeral component and rotate to achieve maximum coverage of the resected surface (Figure 20).
- Impact the Comprehensive Versa-Dial Head onto the Comprehensive Nano Humeral Component to complete humeral head implantation by using at least two blows with an appropriately sized surgical mallet and the Head Impactor tool.

ⓘ **Note:** It is recommended to impact the Versa-Dial Humeral Head flush with the osteotomy.



R Comprehensive
Nano Slap Hammer
31-406921



L Comprehensive
Nano Extractor
31-406920



Revision

Humeral Component Extraction

- Place the Versa-Dial Head Removal Tool between the under surface of the Versa-Dial Humeral Head and the Nano Humeral Component.
- Firmly tap the end of the Tool to loosen the Humeral Head.
- Place the Extractor on the inserter handle.
- Position the Extractor with the blades surrounding the Humeral Component (Figure 21). The taper portion of the Nano component has hash marks that better help identify the wings of the Nano implant to help align the Extractor. Tap the extractor with a mallet until it is completely seated into the Nano component.
- Remove the Extractor. Thread the Slap Hammer to the Comprehensive Nano Humeral Component and extract by slapping out with the slap hammer.



Glenoid Options

The glenoid can be prepared either with the Nano Humeral Broach in place or with the Nano Humeral Component in place. This is surgeon preference and whichever option is chosen it is important to use the Comprehensive Nano Humeral Protector to place over the broach or the final humeral component to protect the humerus.

For more information, please refer to the Zimmer Biomet Product Compatibility website: <http://www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html#shoulder>.

Closure

Irrigate the wound and repair or reattach the subscapularis. The subscapularis can be repaired per surgeon preference using multiple non-absorbable sutures. Approximate the delto-pectoral interval with simple absorbable sutures. Subcutaneous closure should be achieved with interrupted absorbable sutures and skin closure with staples or sutures in a routine manner.

Postoperative Care

Evaluate the limits of external rotation at the time of the subscapularis tendon repair to determine the maximum amount of external rotation during the rehabilitation period. Immobilize the patient in a sling and swathe for 24 hours; use the sling intermittently for up to three weeks to protect the subscapularis repair. Encourage early active motion of the hand and elbow. Begin gentle passive range of motion two days postoperatively. Initiate active assisted elevation three to four days after surgery, based on surgeon preference. Begin strengthening exercises two to three months postoperatively. Continue therapy for many months, with improvement in range of motion and function expected for up to one year.

Clinical Results

The Comprehensive Nano IDE Clinical Study was designed as a prospective, randomized, blinded, multi-center study. The performance of the Comprehensive Nano Humeral Component was analyzed for 116 subjects who reached the two-year follow-up time point or were removed from the study at that point, and compared to 123 subjects who received the Comprehensive Mini Stem. Success was analyzed based on three independent co-primary endpoints. Of the 112 Nano subjects who completed two-year follow-up, 14 were outside the protocol defined visit window (1 to 95 days). Of the 121 Mini Stem subjects who completed two-year follow-up, 16 were outside the protocol defined visit window (1 to 178 days). They include the following:

Study Endpoints

- ASES mean scores in each group at two years;
- % of subjects in each group without unanticipated device-related adverse events, fracture, perforation of the bone or joint dislocation, fracture, perforation or dissociation of the device, or revision or removal of any component, and
- Radiographic success at two years defined by:
 - Subsidence of the humeral component < 5mm, and
 - Migration of the humeral component < 5mm, and
 - No progressive lucency around the humeral component > 2mm in two or more contiguous zones, and
 - Migration of the glenoid component < 5mm, and
 - No progressive lucency > 2mm around the entire glenoid component

Endpoint a: ASES Comparison

The mean ASES score was calculated for subjects in both groups at two years. The mean ASES score for the Nano group was 92.5 at two years, and the mean ASES score for the Mini Stem group was 92.2 at two years. The difference between the two groups was calculated (0.27), and using a 95% Confidence

Interval, the Nano was shown to be non-inferior at the two year time point ($p = <0.0001$, 95% CI lower bound = -2.81). (Table 1)

Variable	Visit Time	Comparing Test P Value	Mini Stem mean±std	Nano mean±std
ASES Score	PREOP	0.5576	25.8 ± 9.6	25.1 ± 10.7
	6 WEEK	0.5285	60.1 ± 18.3	61.5 ± 17.4
	3 MONTH	0.8917	80.2 ± 16.4	80.5 ± 15.3
	1 YEAR	0.2999	91.2 ± 12.8	92.8 ± 12.2
	2 YEAR	0.8858	92.2 ± 13.5	92.5 ± 14.9

Table 1

When compared to the Minimal Clinically Important Difference (MCID) of 20.9 points defined by Tashjian et al, three subjects in the Mini Stem group and two subjects in the Nano group did not meet¹ this ASES improvement at two years¹. The following table summarized this data:

ASES Score MCID Improvement at 2 Years

Group	ASES Improvement > 20.9?	N	%	Fisher Exact Test P Value
Control	No	3	2.48%	1.000000
	Yes	118	97.52%	.
Investigational	No	2	1.79%	.
	Yes	110	98.21%	.

Table 2

Endpoint b: Revision/Removal/Unanticipated Adverse Device Effect

Nine subjects in the Nano group (1 humeral fracture, 2 revisions, 1 glenoid perforation, 1 dislocation and 4 glenoid fractures) and 9 subjects in the Mini Stem group (3 humeral fractures, 4 revisions, and 2 dislocations) failed this criteria.

The outcomes success rate for subjects in the Comprehensive Nano group was 92.2% (107 of 116). The outcomes success rate for subjects in the Comprehensive Mini Stem group was 92.7% (114 of 123). The difference (-0.0044) was well within the 95% non-inferiority confidence interval ($p = 0.0063$, 95% CI lower bound = -0.0674). Based on endpoint b, the Comprehensive Nano was shown to be non-inferior to the Comprehensive Mini Stem.

Endpoint c: Radiographic Success

Radiographic Success is defined as subsidence of the humeral component less than 5mm, migration of the humeral component less than 5mm, no progressive lucency around the humeral component greater than 2mm in two or more contiguous zones, migration of the glenoid component less than 5mm, and no progressive lucency greater than 2mm around the entire glenoid component.

All subjects in both groups successfully passed the radiographic endpoint criteria.

Device-Related Adverse Events Reported during Comprehensive nano IDE Clinical Study

The table below provides a summary of all events reported during this study for subjects who received a study device that were classified by the principal investigator as definitely related, probably related, or possibly related to the device. All adverse events not considered related to the device are excluded from the table. (Table 3)

Two revisions of the Comprehensive Shoulder System with Nano Humeral Component were reported during this study. The first patient was revised due to inadequate range of motion, shoulder pain, and a suspected infection. The second patient was revised following suspected infection. In both cases, infection of the operative shoulder was later confirmed. Neither revision was classified by the investigator as related to the study devices.

Four revisions of the Comprehensive Mini Stem were reported through the course of the study, one of which was classified as possibly related to the device. One subject was revised following a fall and a deep shoulder infection, and this event was classified as possibly related to the study device by the investigator. One subject was revised following unusual shoulder pain, suspected rotator cuff tear, and suspected infection which was confirmed post-operatively (not device related). One subject was revised following pain, immobility, and limited function stemming from a suspected complete

Adverse Event Description	Number of Occurrences, Nano group	Occurrence Rate, Nano group (n = 116)	Number of Occurrences, Mini Stem group	Occurrence Rate, Mini Stem group (n = 123)
Dislocation	2	2/116 (1.7%)	1	1/123 (0.8%)
Hematoma	0	0	1	1/123 (0.8%)
Humeral Fracture or Perforation	0	0	1	1/123 (0.8%)
Implant or Part Failure or Fracture	0	0	1	1/123 (0.8%)
Inadequate Range of Motion	1	1/116 (0.9%)	3	3/123 (2.4%)
Infection	1	1/116 (0.9%)	0	0
Unusual Shoulder Pain	3	3/116 (2.6%)	5	5/123 (4.1%)
Other Shoulder-Related Complication				
• Dropped Glenoid During Surgery	1	1/116 (0.9%)	0	0
• Glenoid Radiolucency	4	4/116 (3.4%)	2	2/123 (1.6%)
• Glenoid Perforation during Implantation	1	1/116 (0.9%)	0	0
• Humeral Radiolucency	3	3/116 (2.6%)	3	3/123 (2.4%)
• Increased Soreness, Clicking, Weakness, Catching	1	1/116 (0.9%)	0	0
• Locking Sensation	0	0	1	1/123 (0.8%)
• Osteopenia	1	1/116 (0.9%)	1	1/123 (0.8%)
• Popping/Cracking in Shoulder	2	2/116 (1.7%)	0	0
• Revision: Infection	0	0	1	1/123 (0.8%)
• Shoulder Migration	0	0	1	1/123 (0.8%)
• Shoulder Stiffness	1	1/116 (0.9%)	0	0"
Total Number of Subjects who Experienced a Device- Related Adverse Event	20	20/116 (17.2%)	20	20/123 (16.3%)

Table 3

subscapularis tear that was confirmed intra-operatively (not device related). The last subject was revised following a potential subscapularis tear with dislocation/subluxation, where the subscapularis tear was confirmed intra-operative (not device related).

Serious Device-Related Adverse Events Reported during Comprehensive Nano IDE Clinical Study

There were no serious device-related adverse events reported during the Comprehensive Nano IDE Clinical Study.

INDICATIONS

1. Primary total shoulder arthroplasty.
2. Non-inflammatory degenerative joint disease including osteoarthritis

Comprehensive Nano Stemless Shoulder humeral components have a porous coated surface coating and are indicated for uncemented biological fixation applications.

The Comprehensive Modular Hybrid Glenoid is intended to be implanted with bone cement. The porous titanium peg may be inserted **without** bone cement.

CONTRAINDICATIONS

Absolute contraindications include infection, sepsis, and osteomyelitis. Relative contraindications include:

1. Diagnosis of avascular necrosis or post-traumatic arthritis of the humeral head.
2. Presence of single cyst > 1 cm or multiple cysts at implantation site.
3. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions.
4. Osteoporosis
5. Metabolic disorders which may impair bone formation.
6. Osteomalacia
7. Distant foci of infections which may spread to the implant site.
8. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
9. Cuff tear arthropathy
10. Malunion or non-union of the tuberosities of the proximal humerus.
11. Rheumatoid arthritis
12. Bone cancer that affects the shoulder.
13. Patient who presents with symptoms of chronic steroid use as defined as use of oral steroids for a chronic condition for 12 months prior to and including the date of surgery.
14. Severe shoulder instability
15. Subcapularis incompetence
16. Severe destruction or deformity of proximal humerus that precludes placement of device.

Reference

1. Tashjian RZ, Hung M, Keener JD, Bowen RC, McAllister J, Chen W, Ebersole G, Granger EK, Chamberlain AM. Determining the minimal clinically important difference for the American Shoulder and Elbow Surgeons score, Simple Shoulder Test, and visual analog scale (VAS) measuring pain after shoulder arthroplasty. *J Shoulder Elbow Surg.* 2017 Jan;26(1):144-148.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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