



OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT
FACILITIES DEVELOPMENT DIVISION

APPLICATION FOR OSHPD PREAPPROVAL OF MANUFACTURER'S CERTIFICATION (OPM)

OFFICE USE ONLY
APPLICATION #: OPM-0358-13

OSHPD Preapproval of Manufacturer's Certification (OPM)

Type: [X] New [] Renewal [] Update to Pre-CBC 2013 OPA Number:

Manufacturer Information

Manufacturer: Hologic

Manufacturer's Technical Representative: Robert Percy

Mailing Address: 36 apple Ridge Rd., Danbury, CT 06810

Telephone: 203-207-4565 Email: robert.percy@hologic.com

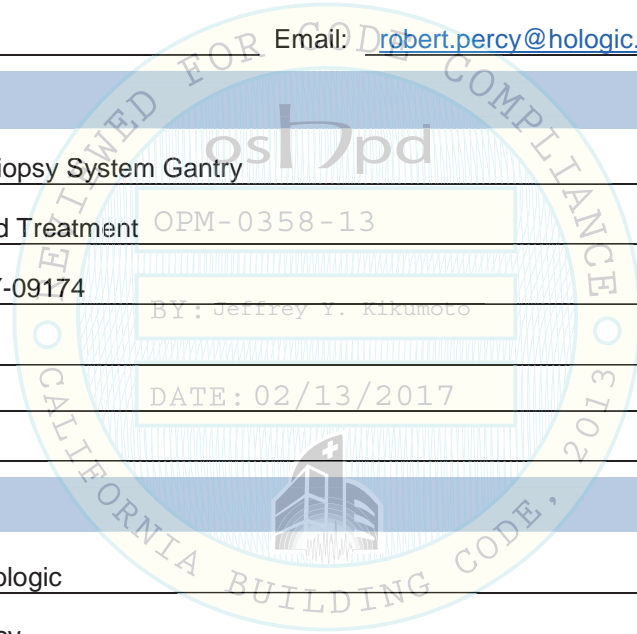
Product Information

Product Name: Affirm Prone Biopsy System Gantry

Product Type: Intervention and Treatment OPM-0358-13

Product Model Number: ASY-09174

General Description:



Applicant Information

Applicant Company Name: Hologic

Contact Person: Robert Percy

Mailing Address: 36 apple Ridge Rd., Danbury, CT 06810

Telephone: 203-207-4565 Email: robert.percy@hologic.com

I hereby agree to reimburse the Office of Statewide Health Planning and Development review fees in accordance with the California Administrative Code, 2016.

Signature of Applicant: [Signature] Date: 5-22-16
Title: Mechanical Engineer Company Name: Hologic

"Access to Safe, Quality Healthcare Environments that Meet California's Diverse and Dynamic Needs"





**OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT
FACILITIES DEVELOPMENT DIVISION**

Registered Design Professional Preparing Engineering Recommendations

Company Name: Don Lee Engineering

Name: Donald E. Lee California License Number: SE 2311

Mailing Address: 21008 Sylvanwood Ave., Lakewood, Ca 90715

Telephone: 526-860-7896 Email: donleese@aol.com

OSHPD Special Seismic Certification Preapproval (OSP)

- Special Seismic Certification is preapproved under OSP-
(Separate application for OSP is required)
- Special Seismic Certification is not preapproved

Certification Method(s)

- Testing in accordance with: ICC-ES AC156 FM 1950-15
- Other* (Please Specify): _____

*Use of criteria other than those adopted by the California Building Standards Code, 2016 (CBSC 2016) for component supports and attachments are not permitted. For distribution system, interior partition wall, and suspended ceiling seismic bracings, test criteria other than those adopted in the CBSC 2016 may be used when approved by OSHPD prior to testing.

- Analysis
- Experience Data
- Combination of Testing, Analysis, and/or Experience Data (Please Specify): _____

List of Attachments Supporting the Manufacturer's Certification

- Test Report Drawings Calculations Manufacturer's Catalog
- Other(s) (Please Specify): _____

OFFICE USE ONLY – OSHPD APPROVAL VALID FOR CBC 2016 & ALL PRE-2016 CODE BASED PROJECTS

Signature:  Date: 02-13-2017

Print Name: Jeffrey Kikumoto

Title: SSE

Condition of Approval (if applicable): _____

"Access to Safe, Quality Healthcare Environments that Meet California's Diverse and Dynamic Needs"



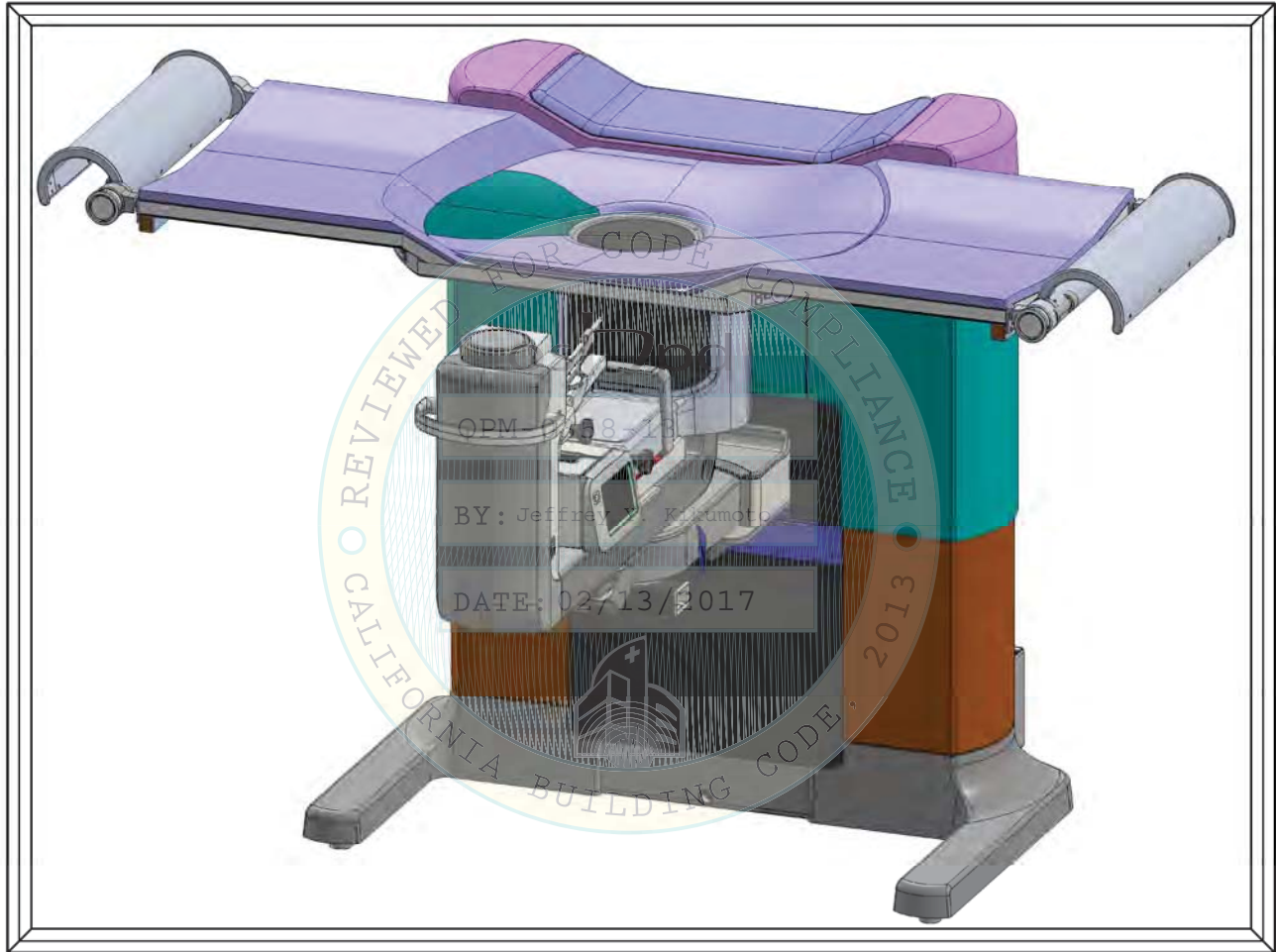
Don Lee Engineering

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Donald E. Lee Structural Engineer #2311

OPM-0358-13

Hologic Affirm Prone Biopsy System Attachment Forces & Details



Prepared by
Don Lee S. E. #2311

Signed 2-7-2017



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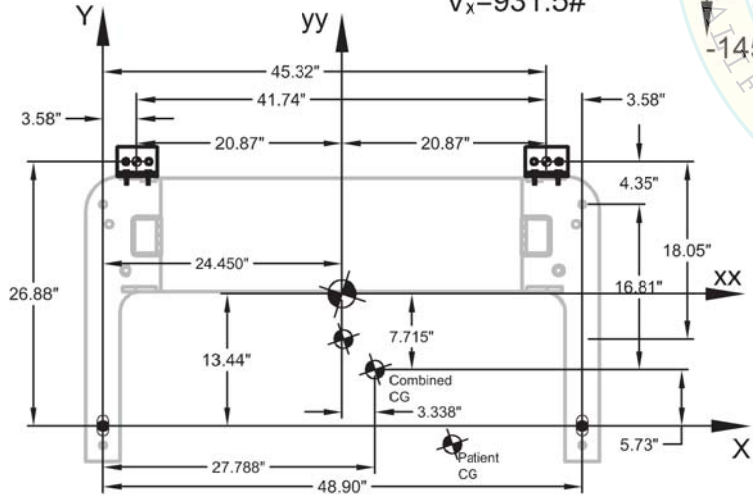
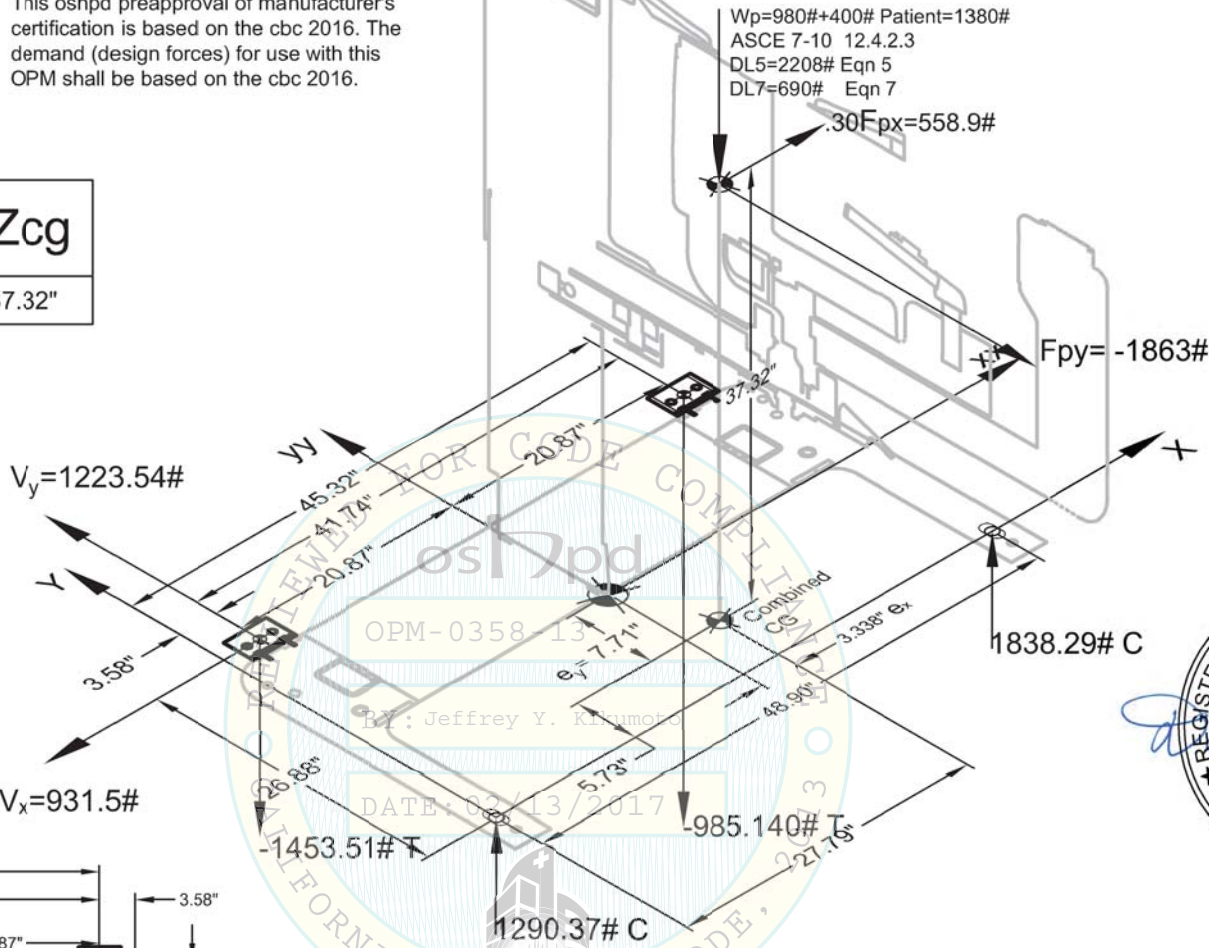
Coordinates

| Location | X | Y | Zcg |
|----------|--------|--------|--------|
| ① | 0" | 0" | |
| ② | 48.90" | 0" | |
| ③ | 3.58" | 26.88" | |
| ④ | 45.32" | 26.88" | |
| (cg) | 27.79" | 5.73" | 37.32" |

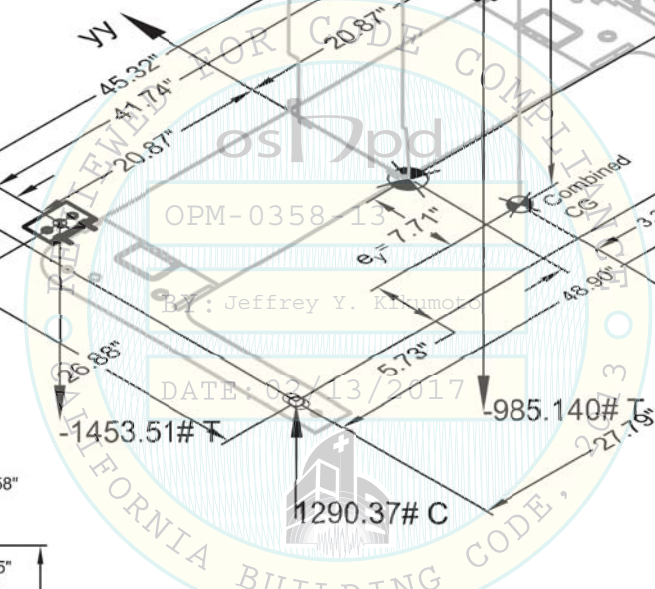
This oshpd preapproval of manufacturer's certification is based on the cbc 2016. The demand (design forces) for use with this OPM shall be based on the cbc 2016.

Bolt Pattern Properties

| | |
|----------|-------------------------|
| I_{xx} | 722.73 In ⁴ |
| I_{yy} | 2066.92 In ⁴ |



Wp=980#+400# Patient=1380#
 ASCE 7-10 12.4.2.3
 DL5=2208# Eqn 5
 DL7=690# Eqn 7



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 OPM-0358-13

1. This pre-approval covers only the supports & attachments of the unit to the structure based on the relation of the Cg and bolt pattern shown at the left.
2. The details in this pre-approval may be used at any location in the state of California where S_{DS} is ≤ 2.00
3. The forces shown using Strength Design were obtained from ASCE 7-10 Using Eqn's. 13.3-1,2,3 and Load Combinations 5 & 7 from Section 12.4.3.2 with these parameters: $W_p=1380$ Lbs. $S_{DS}=2.00$ $I_p=1.5$ $z=0$ $h=1.0$ $Z/h=0$ At Grade ASCE 7-10 Table 13.6-1: Other Mechanical or Electrical Equipment, $a_p=1.0$ $R_p=1.5$ $\Omega_0=1.5$
4. This pre-approval encompasses all of the weights and Cg locations up to those shown.

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| | |
|-------------------------|----|
| Project HL-2-2015 | SO |
| Date January 9, 2017 | |
| Scale None | |

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Affirm Prone Biopsy System Gantry

EXPANSION BOLTS

Version 12-18-2014

1. CONCRETE ANCHORS SHALL BE:

HILTI KB-TZ-ESR1917, Reissued May 2015

2. INSPECTION AND TESTING OF EXPANSION BOLTS SHALL COMPLY WITH 2016 CBC Section 1910A.5.1 USING THE TORQUE WRENCH METHOD AND IN ACCORDANCE WITH THE PROCEDURES BELOW.

3. TORQUE WRENCHES SHALL BE FLAT OR ROUND BEAM TYPE CALIBRATED BY AN APPROVED LABORATORY IN ACCORDANCE WITH ACCEPTED PROCEDURES.

4. THE BOLTS SHALL BE INSTALLED AS DESCRIBED IN THE APPLICABLE ICC-ESR REPORT.

5. TESTING OF THE POST-INSTALLED ANCHORS SHALL BE DONE IN THE PRESENCE OF THE SPECIAL INSPECTOR AND A REPORT OF THE TEST RESULTS SHALL BE SUBMITTED TO THE ENFORCEMENT AGENCY.

6. THE HOLES SHALL NOT BE DRILLED UNTIL THE BOLTS TO BE USED ARE ON SITE.

7. INSPECTOR SHALL MEASURE THE LENGTH OF THE BOLTS AND ENSURE THAT THEY ARE THE PROPER PART NUMBER AND LENGTH SHOWN IN DETAIL 3/S2.

8. CONTINUOUSLY INSPECT THE DRILLING OF THE HOLES AND MEASURE THE ACTUAL DEPTH.

9. IF THE HOLE DEPTH EXCEEDS THAT SHOWN IN DETAIL 3/S2, CARE SHALL BE TAKEN WHEN DRIVING THE BOLTS INTO THE HOLES SO THAT THE EXTENSION OF THE BOLT ABOVE THE SURFACE IS AS SHOWN IN DETAIL 3/S2.

10. INITIAL INSTALLATION: TIGHTEN ALL ANCHORS ON EACH UNIT TO THE SPECIFIED TORQUE AND HOLD IT FOR 2 MINUTES. THE NUT SHALL NOT CONTINUE TO TURN. THE REQUIRED TORQUE SHALL BE REACHED WITHIN THE NUMBER OF TURNS AND/OR STICK OUT SHOWN IN DETAIL 3/S2.

11. FINAL TEST A MINIMUM 24 HOURS AFTER INITIAL INSTALLATION. THE NUTS SHALL REACH THE REQUIRED TORQUE WITHIN 1/2 TURN.

12. BOLT HOLES MAY NOT BE REUSED. MINIMUM DISTANCE BETWEEN NEW BOLT AND ABANDONED HOLE SHALL BE 1-1/2". OLD HOLE SHALL BE FILLED WITH NON-SHRINK GROUT.

The Structural Engineer of Record Shall:

Version 7-7-14

1. Verify the equipment is anchored to a normal weight concrete slab at grade (Minimum T=6" f'c=2500 Psi), located such that adequate bolt strength and foundation size are provided. The anchors shall meet the requirements of the applicable ICC-ESR.

2. Verify that the anchors are an adequate distance from any slab edge, opening or control joint. (see Detail 2/S2).

3. Verify that all new or existing anchors are an adequate distance from the anchors shown in this pre-approval. SEOR shall verify that there is no adverse interaction where other anchors are within 18" from this unit's anchors.

4. Verify that the installation is in conformance with the 2016 CBC, that the site specific values of S_{DS} & z/h do not exceed the values shown on Sheet S0, and with the details shown in this pre-approval. Verify that the actual equipment's weight, CG location, anchor locations, anchor details, and the material and gage of the unit where attachments are made agree with the information shown on the pre-approval documents. Provide any support structure required to support the weights and forces shown in addition to all other required loads.

General notes:

Version 7-7-14

THIS OSHPD PREAPPROVAL OF MANUFACTURER'S CERTIFICATION IS BASED ON THE CBC 2016. THE DEMAND (DESIGN FORCES) FOR USE WITH THIS OPM SHALL BE BASED ON THE CBC 2016.

ALL CONSTRUCTION SHALL COMPLY WITH THE CBC 2016 & ITS REFERENCED STANDARDS.

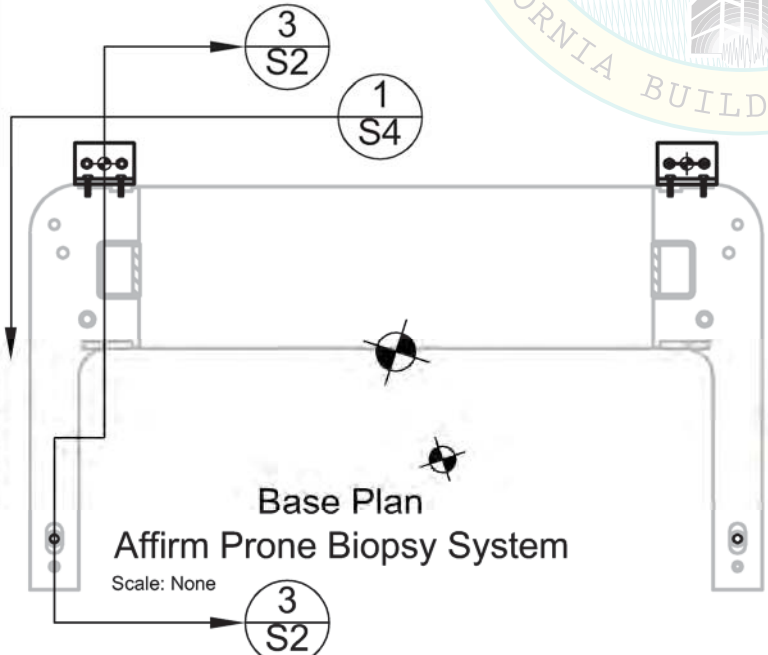
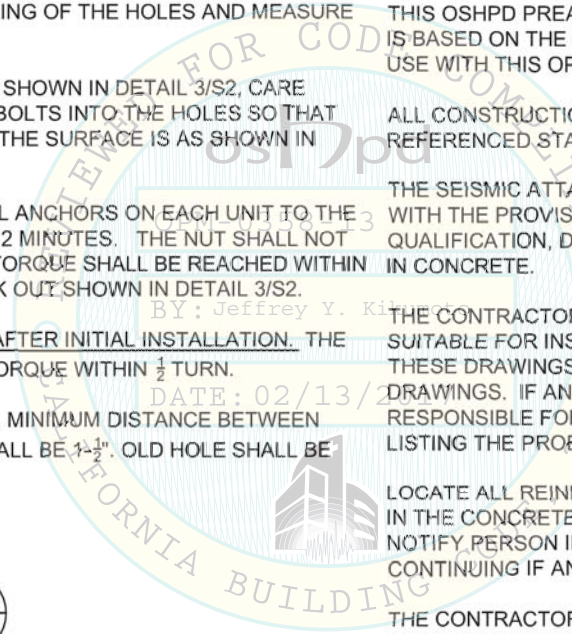
THE SEISMIC ATTACHMENTS SHOWN ON THESE PLANS COMPLY WITH THE PROVISIONS OF 2016 CBC 1910A.5 FOR THE QUALIFICATION, DESIGN AND USE OF POST-INSTALLED ANCHORS IN CONCRETE.

THE CONTRACTOR SHALL VERIFY THAT THE SITE CONDITIONS ARE SUITABLE FOR INSTALLATION OF THE EQUIPMENT AS SHOWN ON THESE DRAWINGS AND ANY OTHER APPLICABLE PROJECT DRAWINGS. IF ANY PROBLEMS ARE FOUND, THE PERSON RESPONSIBLE FOR THE PROJECT SHALL BE NOTIFIED IN WRITING LISTING THE PROBLEMS.

LOCATE ALL REINFORCEMENT, CONDUIT, PIPES OR OTHER ITEMS IN THE CONCRETE SLAB PRIOR TO DRILLING THE BOLT HOLES. NOTIFY PERSON IN CHARGE OF THE PROJECT BEFORE CONTINUING IF ANY INTERFERENCE IS FOUND.

THE CONTRACTOR IS RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE CONSTRUCTION SAFETY PROCEDURES.

WHEN THE TEST LAB IS CALLED TO THE SITE, A REPORT MUST BE FILED STATING THE REASON FOR THE CALL AND THE DISPOSITION OF THE CALL.



Affirm Prone Biopsy System Gantry



Signed 2-7-2017

OPM-0358-13

| | |
|---|-----------|
| Don Lee Engineering | |
| 21008 Sylvanwood Ave. Lakewood, Ca 90715 562-860-7896 | |
| Project HL-2015-2 | S1 |
| Date January 9, 2017 | |
| Scale None | |

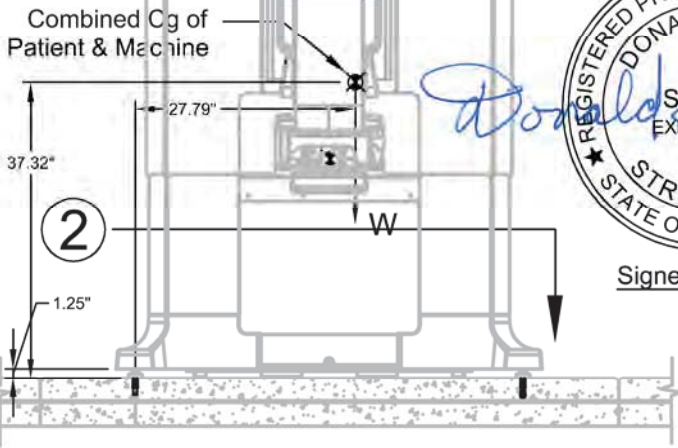
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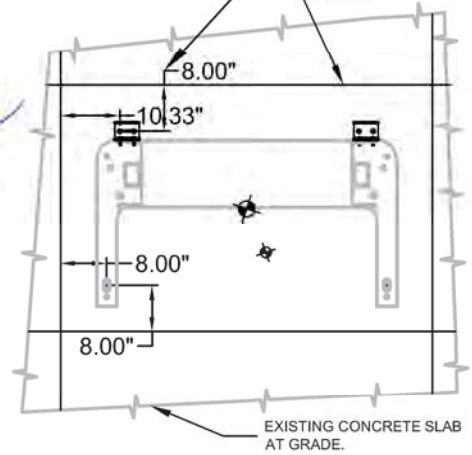
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These are minimum joint distances and **DO NOT** represent the size of slab required for an adequate foundation.

BOLT PATTERN SHALL NOT BE LOCATED CLOSER THAN SHOWN TO EXISTING SLAB EDGES, CONTROL OR CONSTRUCTION JOINTS



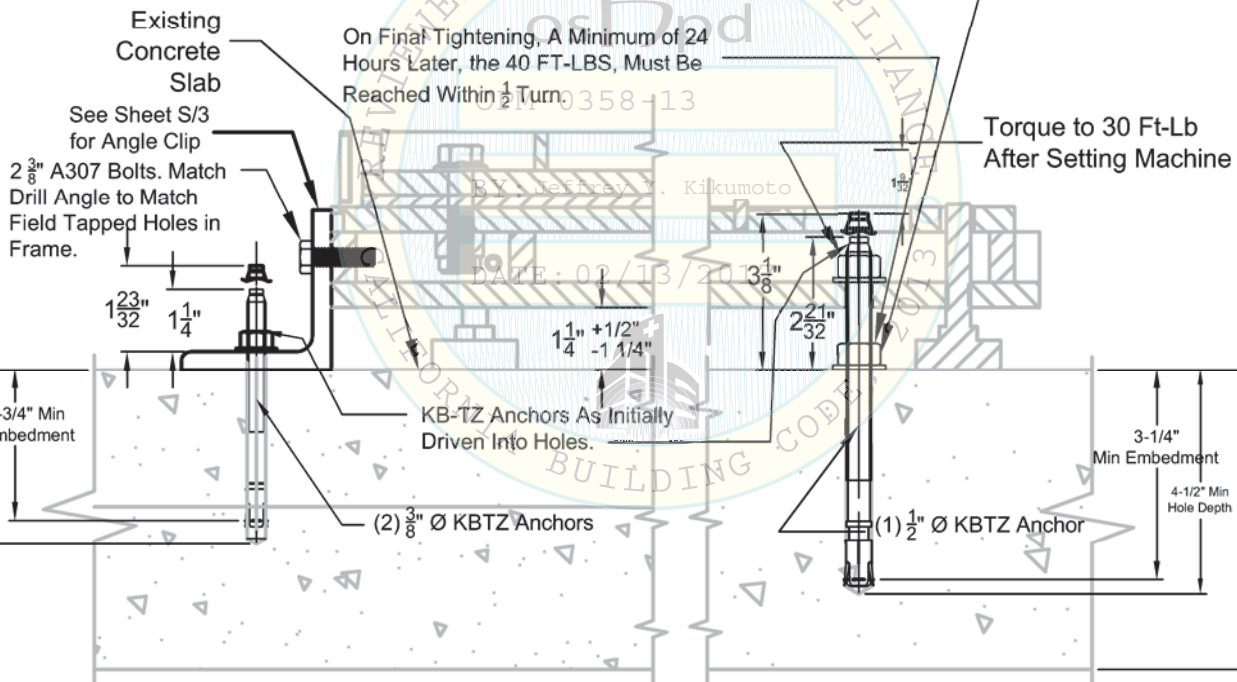
Signed 2-7-2017



1 Front Elevation Affirm Prone Biopsy System Gantry
Scale: None

2 Affirm Prone Biopsy System Installed on Existing Concrete Slab. (6" Thick, $f_c=2500$ psi) Minimum
Scale $\frac{3}{8}"=1'-0"$

On Initial Tightening the Bolt shall not Move Upward more than 6 Turns, or the Extension Shown, Before it Reaches a Torque of ($\frac{1}{2}$ " 40 ft-lb.) ($\frac{3}{8}"$ 25 ft-lb.) the required torque Shall be Held for 2 Minutes.



3 / **S2** Expansion Bolt Installation Details
Scale: None

OPM-0358-13

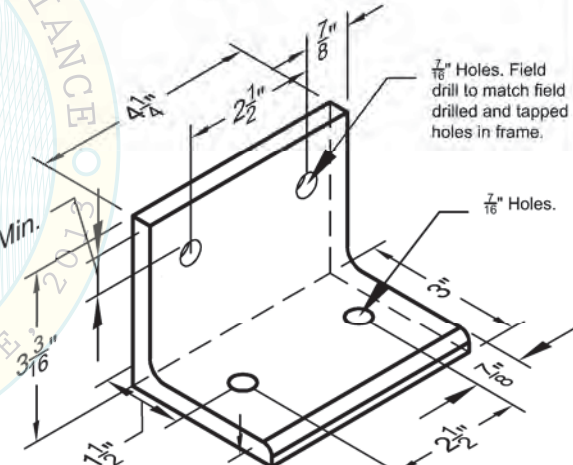
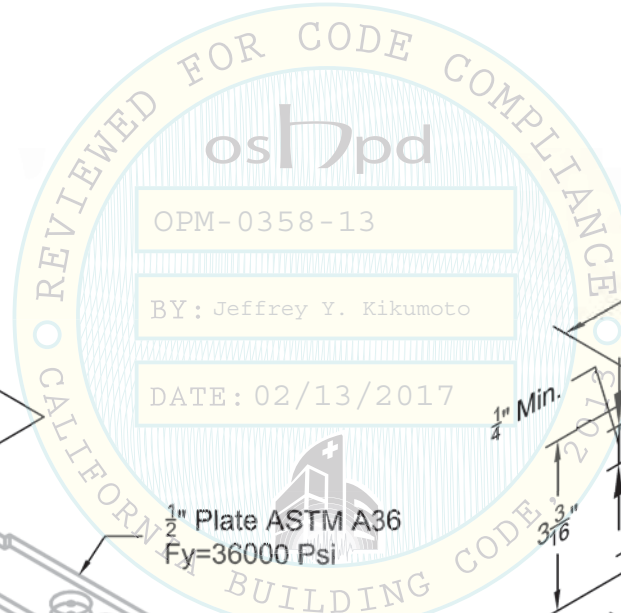
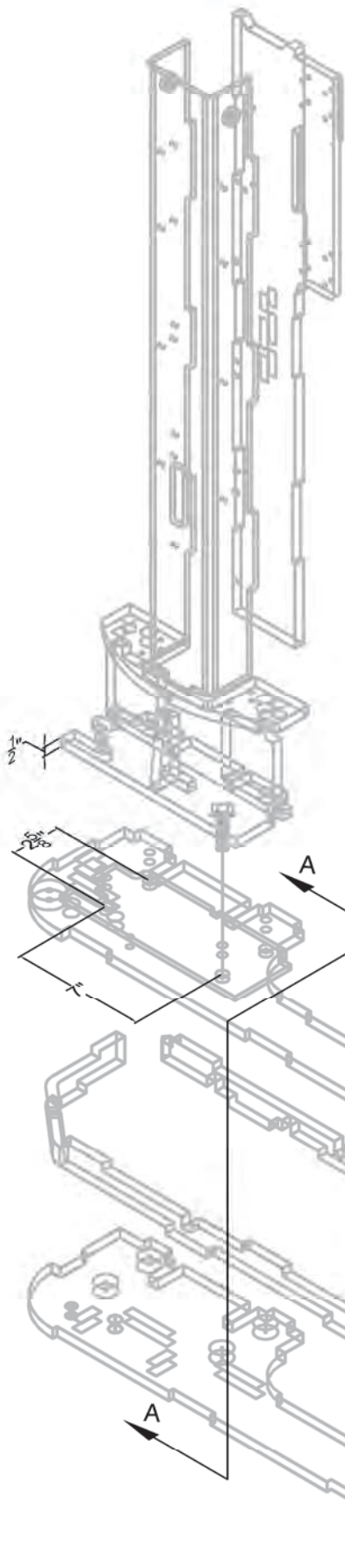
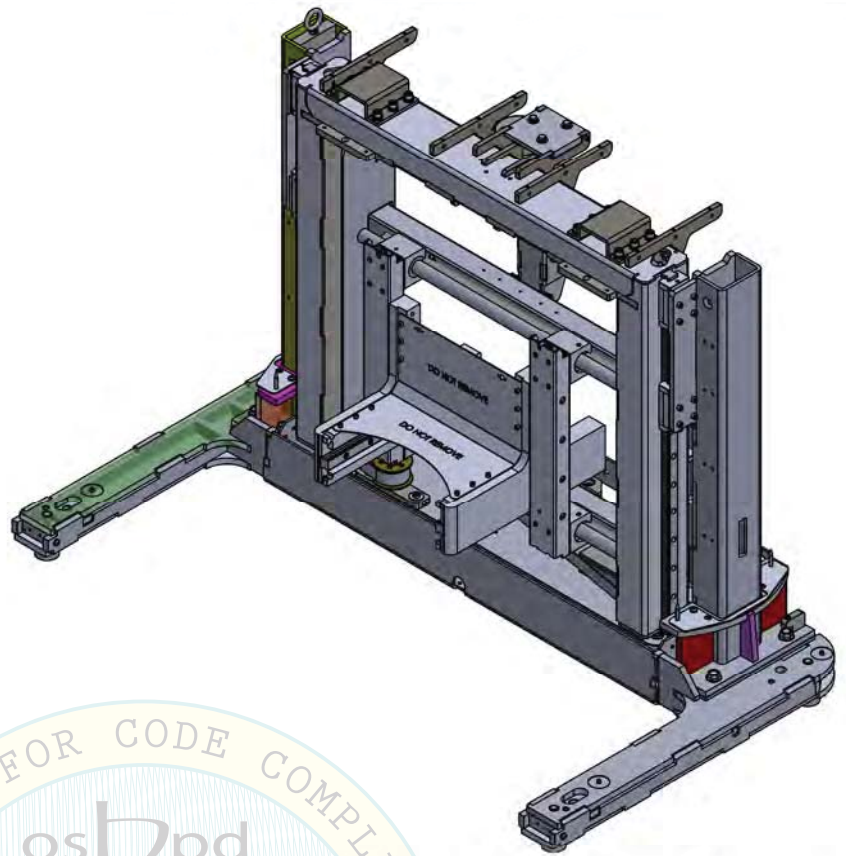
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Project
HL-2015-2
Date
January 9, 2017
Scale
None

S2

Affirm Prone Biopsy System Gantry



1/2" Plate ASTM A36
Fy=36000 Psi

Angle Clip ASTM A36 Fy= 36Ksi

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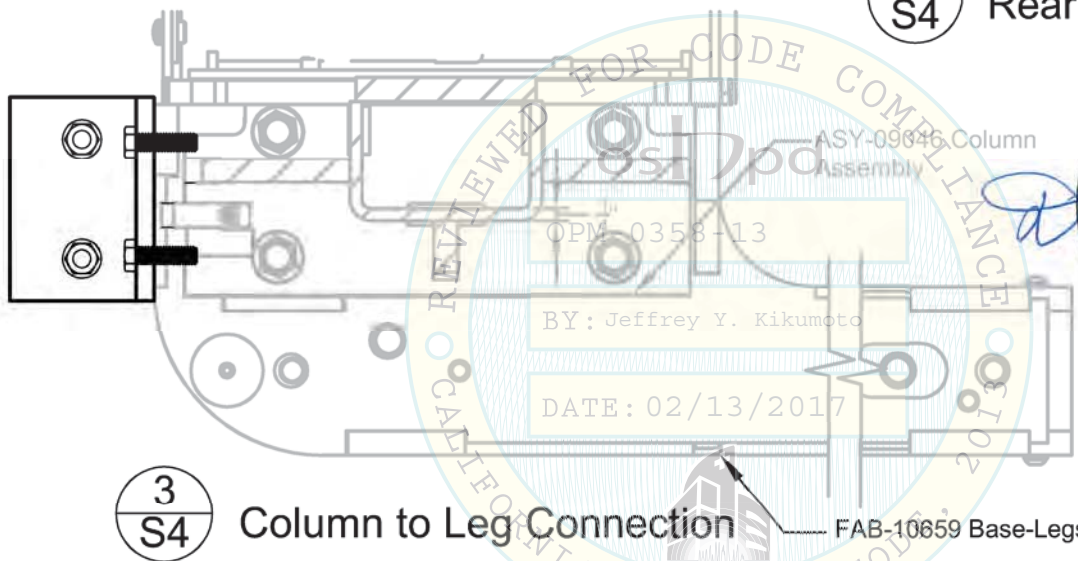
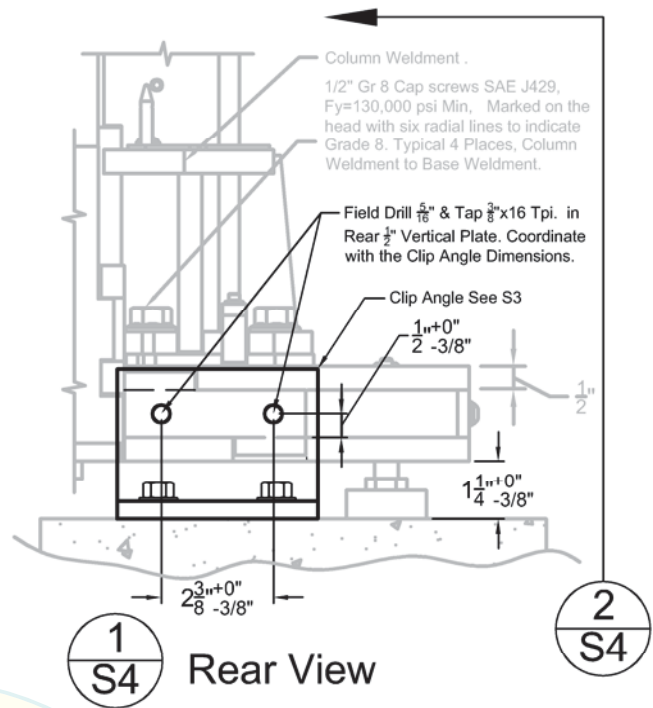


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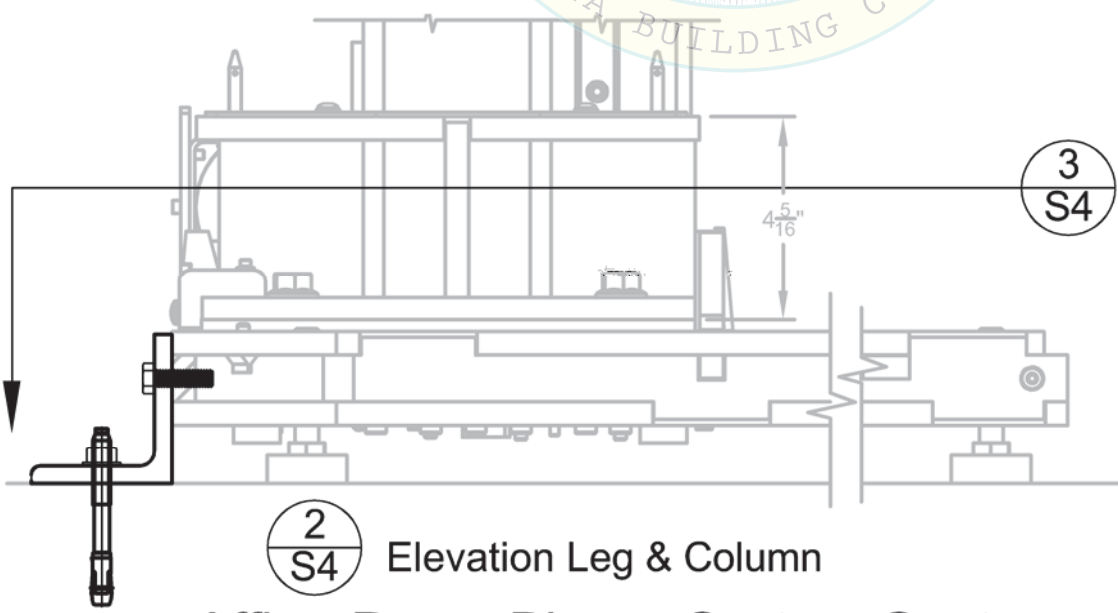
Section A-A

Affirm Prone Biopsy System Gantry

| | |
|---|-----------|
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| Project HL-2015-2 | S3 |
| Date January 9, 2017 | |
| Scale None | |



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| Project HL-2015-2 | S4 |
| Date January 9, 2017 | |
| Scale None | |

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