

Process instruction

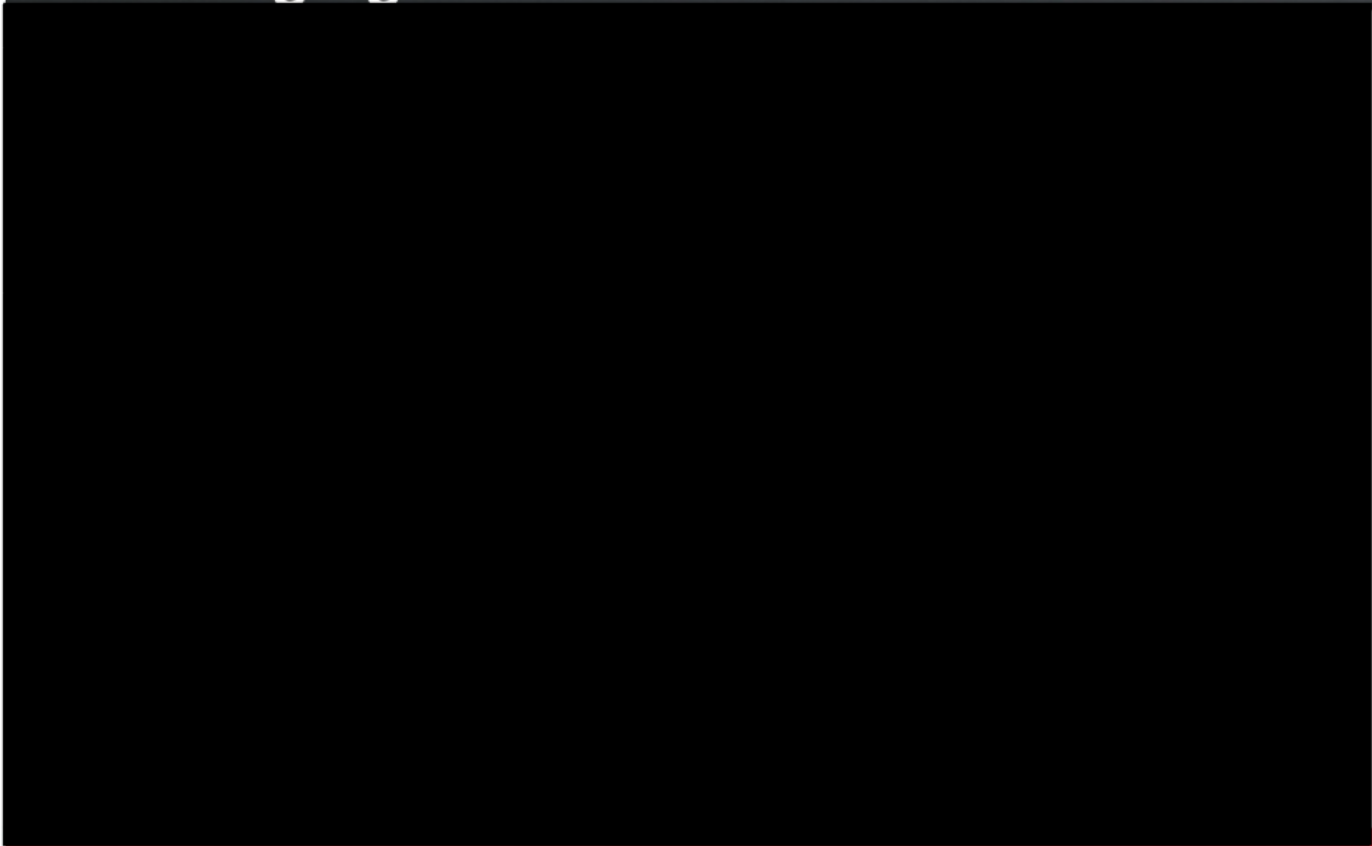
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SAPIEN 3 – Process Flow and Final Packaging



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Review of feasibility DV test

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Test Results



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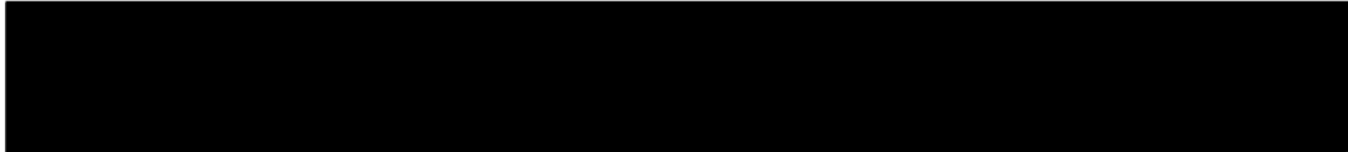
Frame structural performance - Oval

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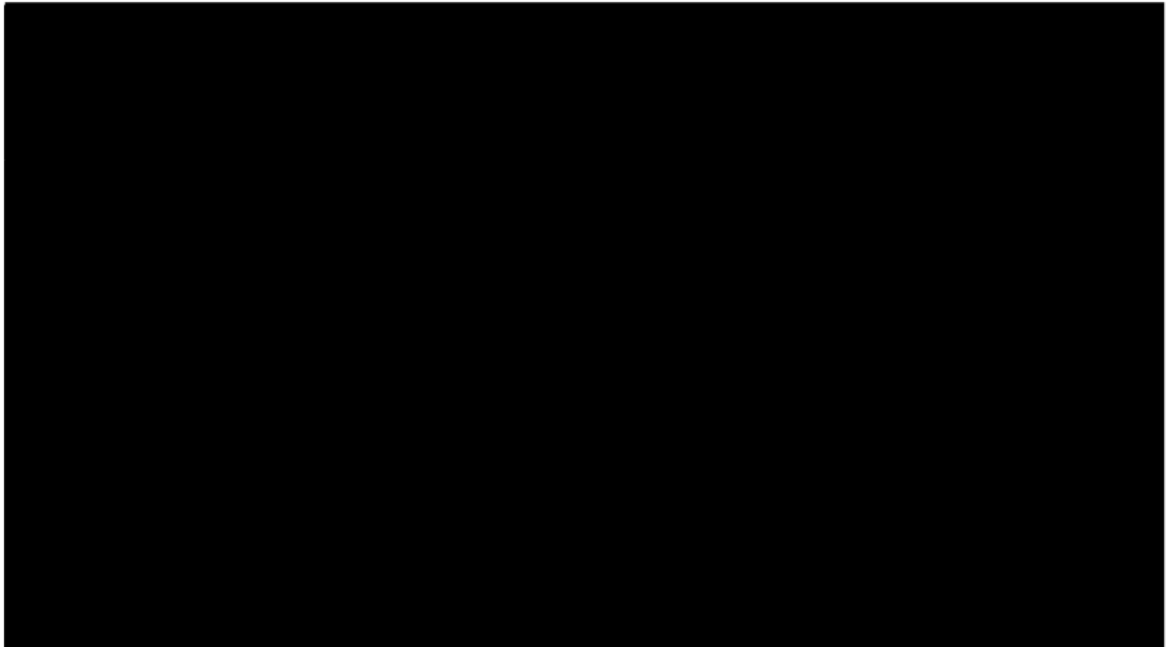
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Frame structural performance – Over Expansion



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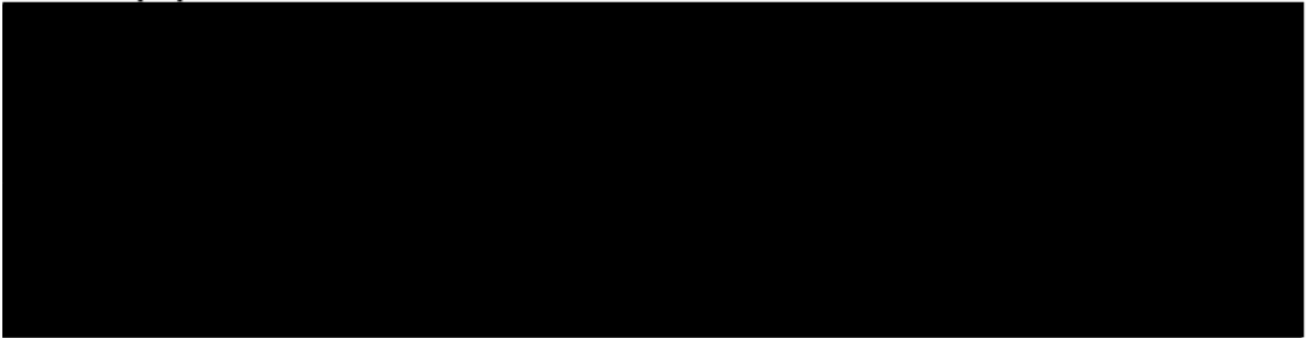
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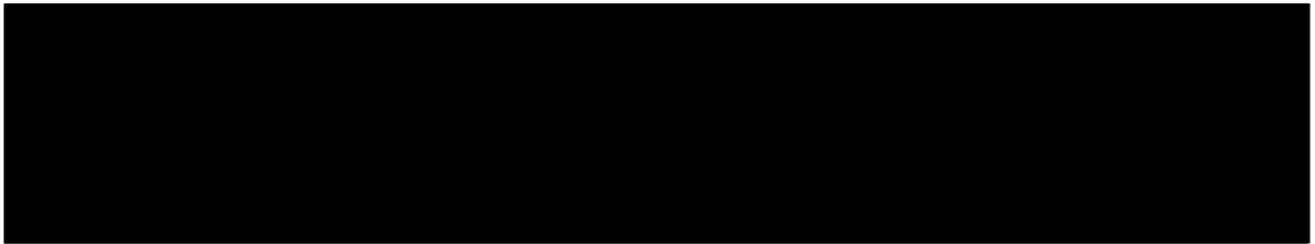


Crimp profile evaluations - Latest Iterations

Crimp profile:

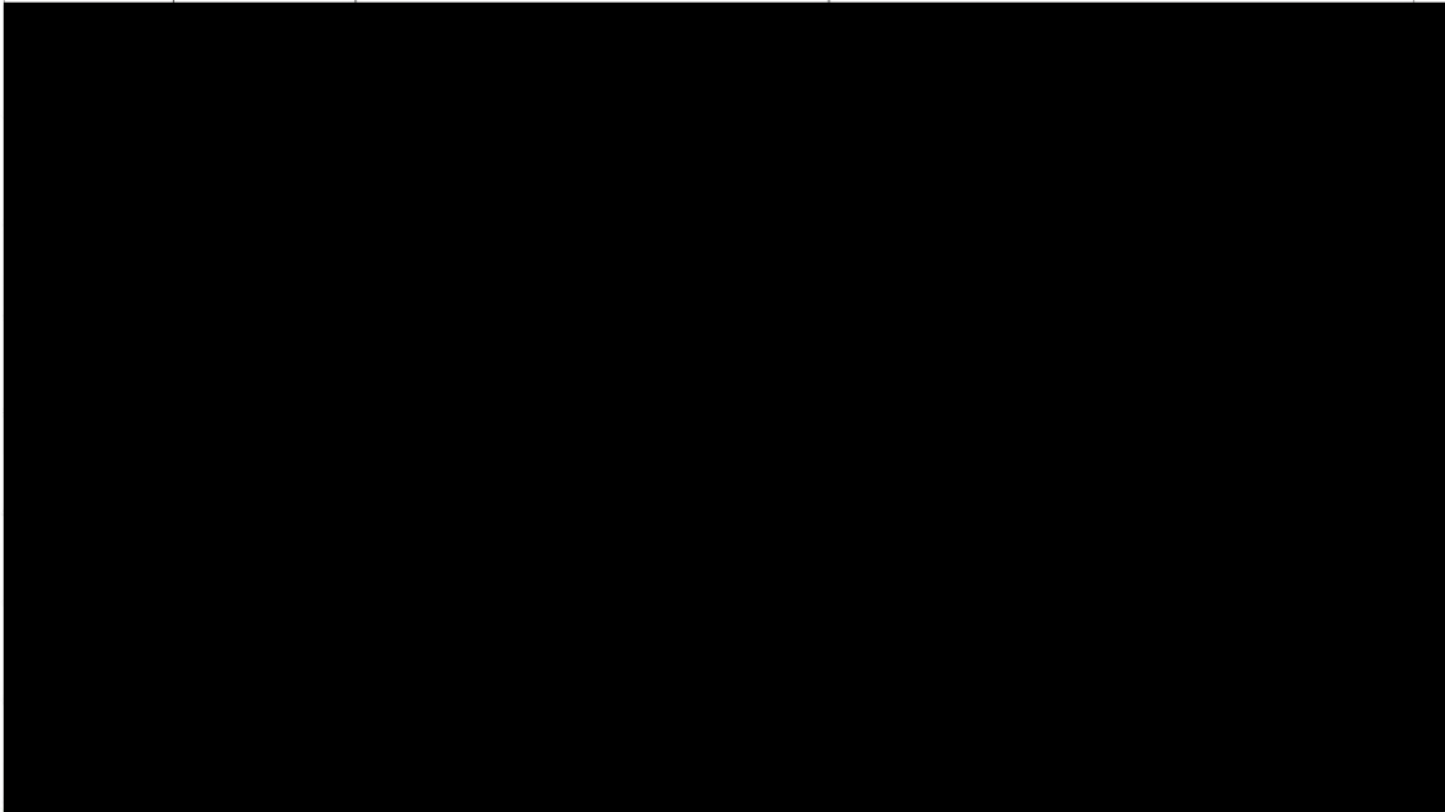


More features:



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Crimp profile evaluations - Latest Iterations



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Crimp profile evaluations - Current status

- Possible improvements:

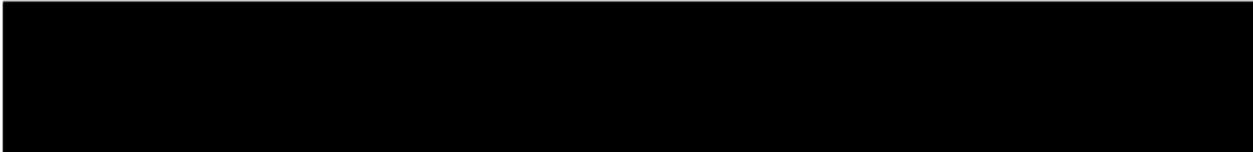
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Final prototype manufacturing plan

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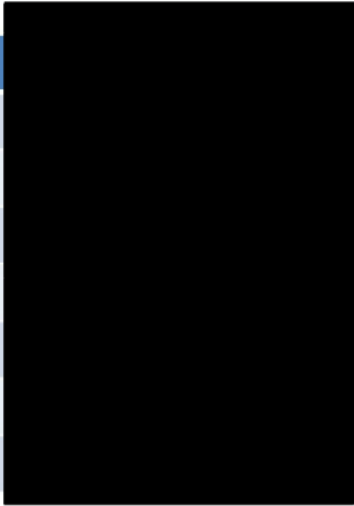
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S3 Valve Build plan for 2010 - 2011

Valve Size	
23	
26	
29	
20	
Total	



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In Vitro Plan

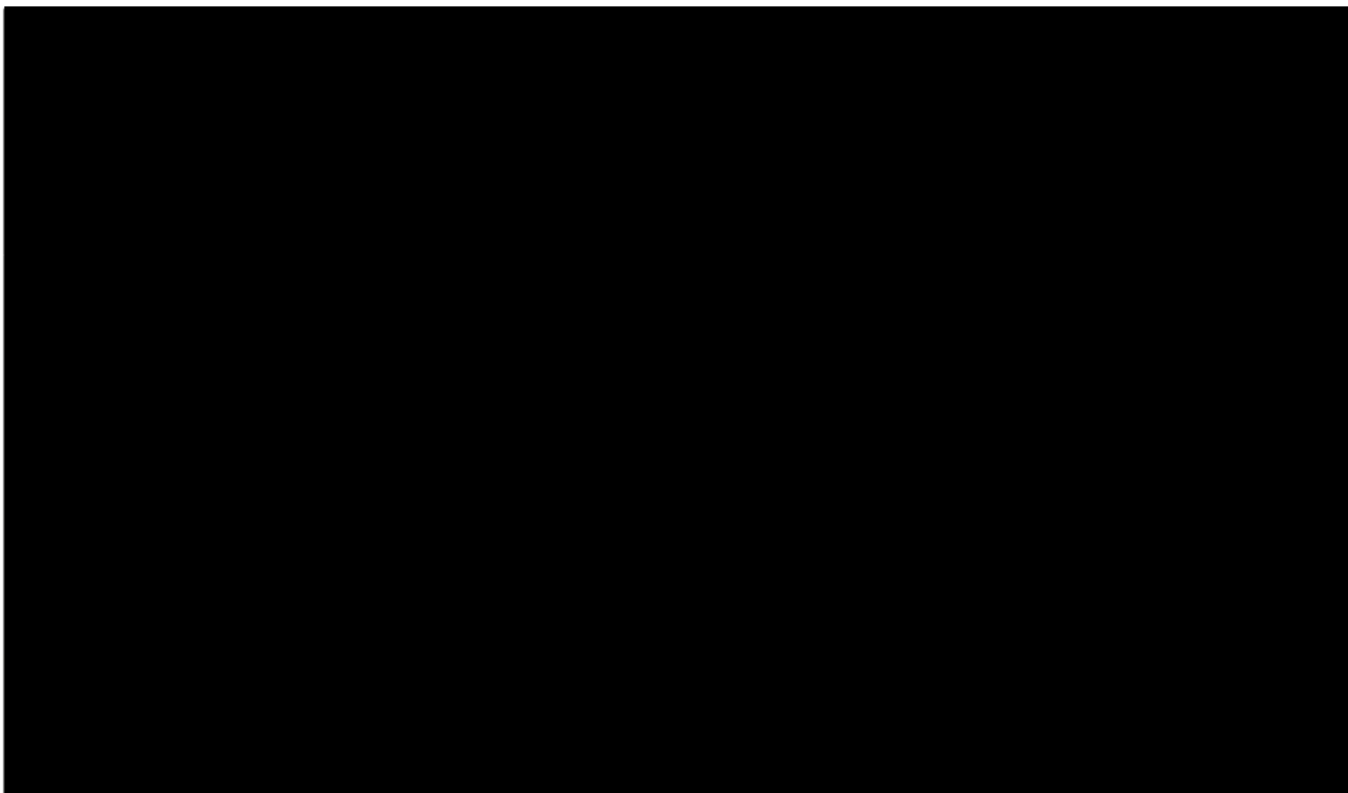
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Verification & Validation Main Tasks



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Animal Study GLP Study- Plan



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Labeling and Packaging

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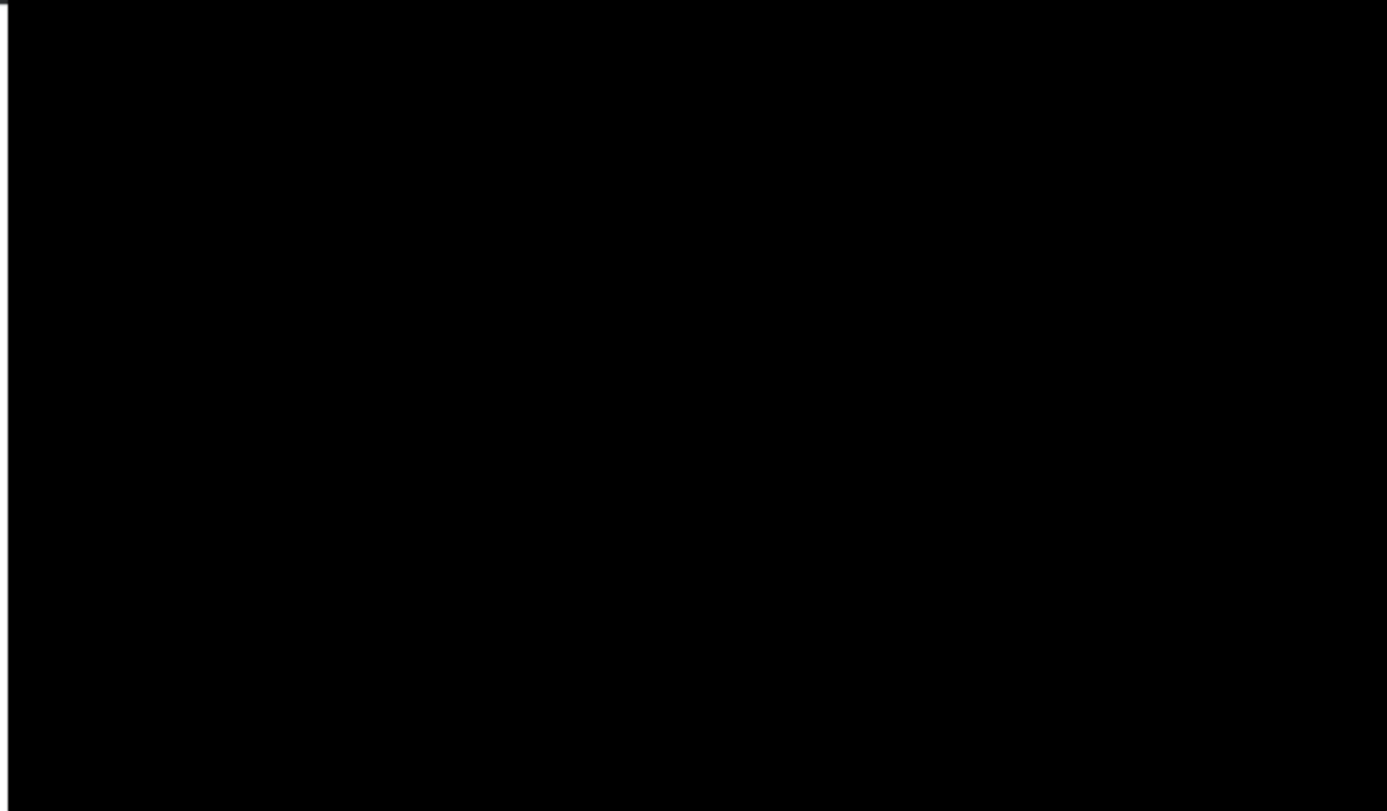
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SAPIEN 3 – Model 9500TFX

Final Packaging Configuration



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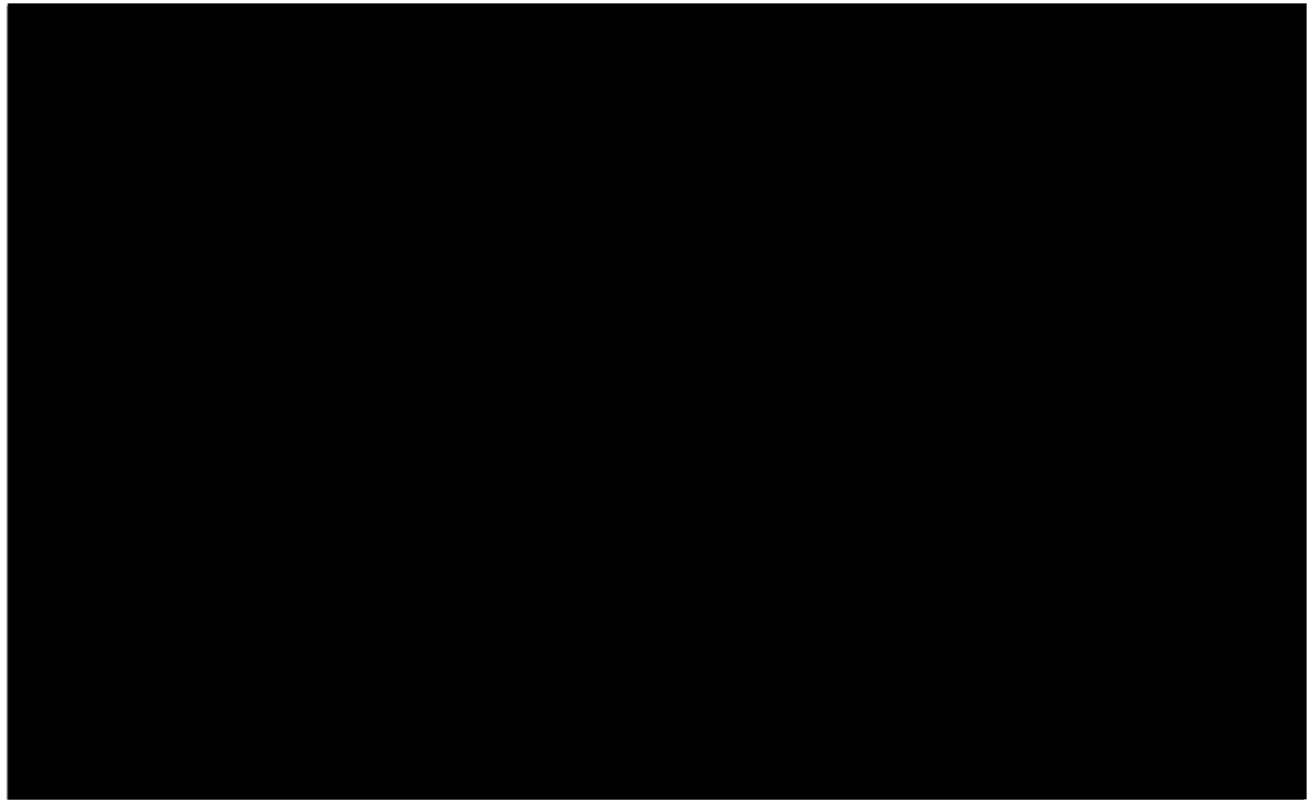
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SAPIEN 3 - Model 9500TFX

Final Packaging



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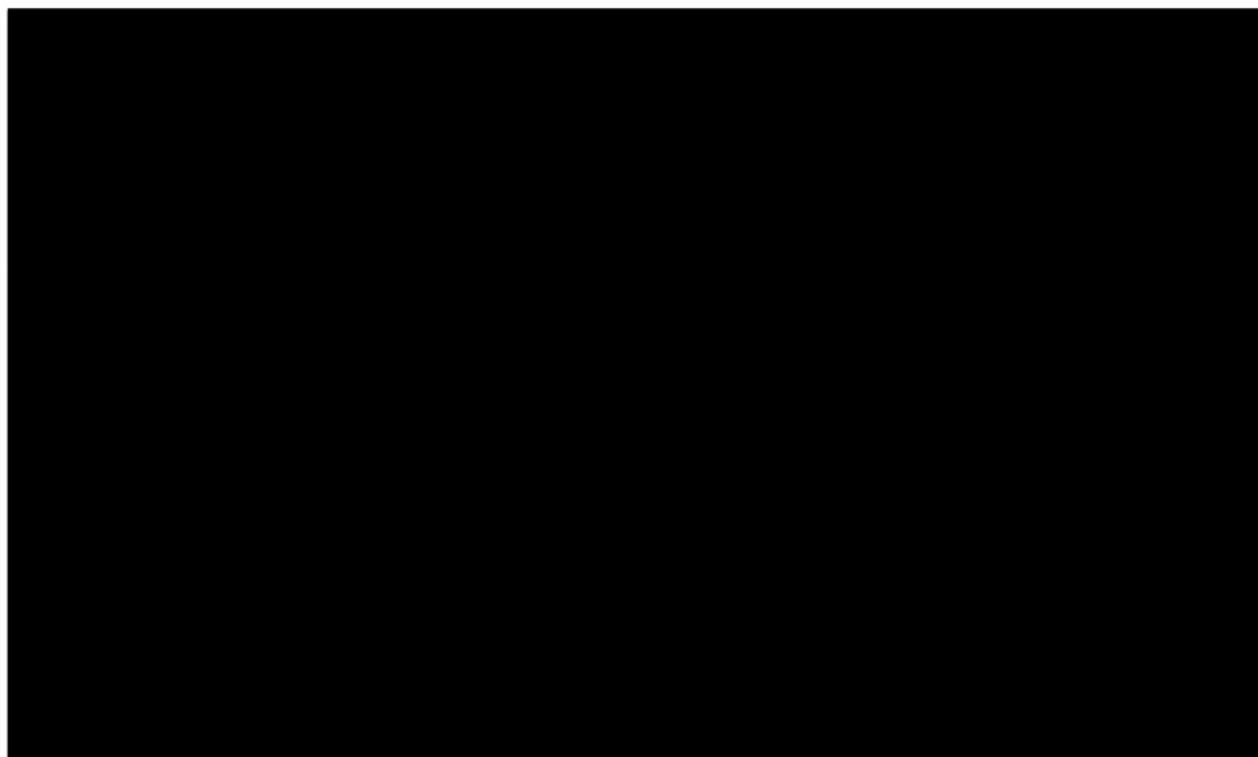
Regulatory and clinical plan

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Regulatory Strategy - Assumptions

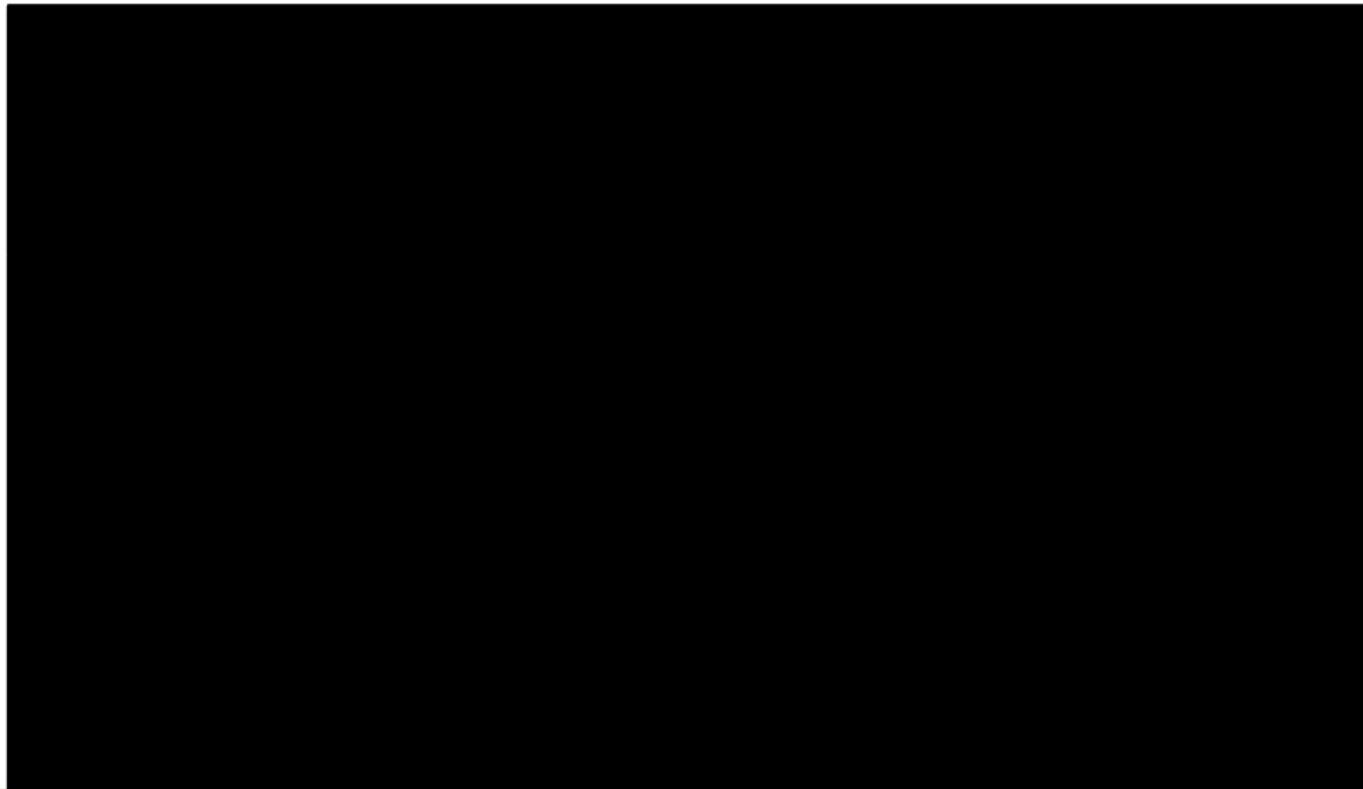


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Regulatory Strategy - Overview



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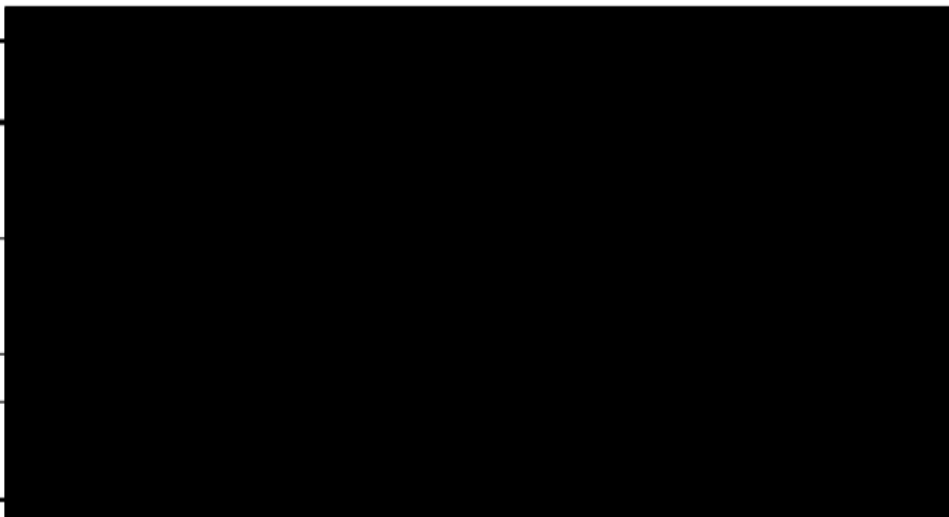
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Regulatory Review Periods

Submission
IDE
PMA Supplement
Canada
Dossier Change Notification



* Based on historical product registration approval timeframes

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Risk management plan

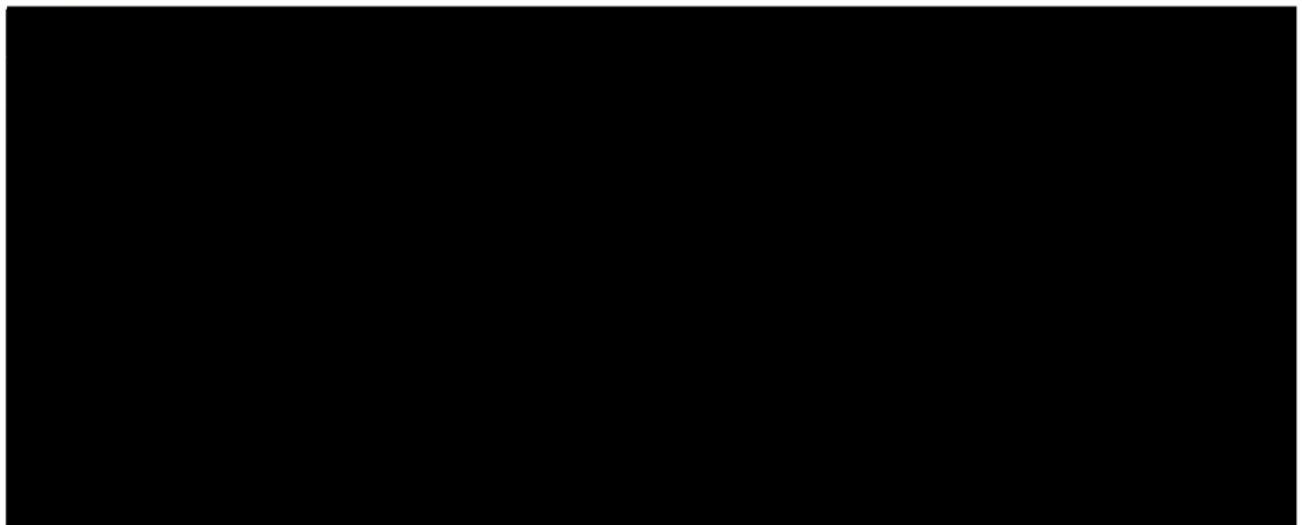
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Risk management plan

- ❖ RMP HVOO7
- ❖ The Risk Management Plan covers only the valve design control stage.



Major project and technical risks

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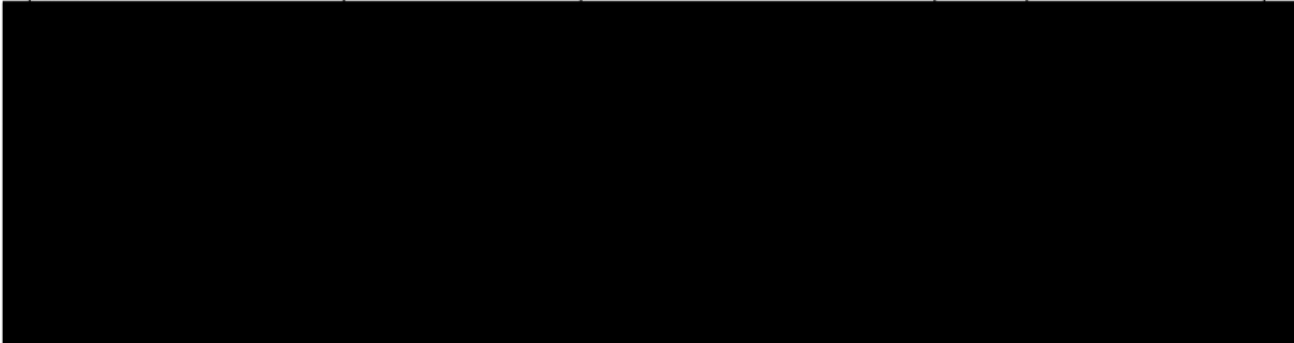
Main Design FMEA Risks

Potential Failure mode	Potential Cause	Design Control	Risk	Comments



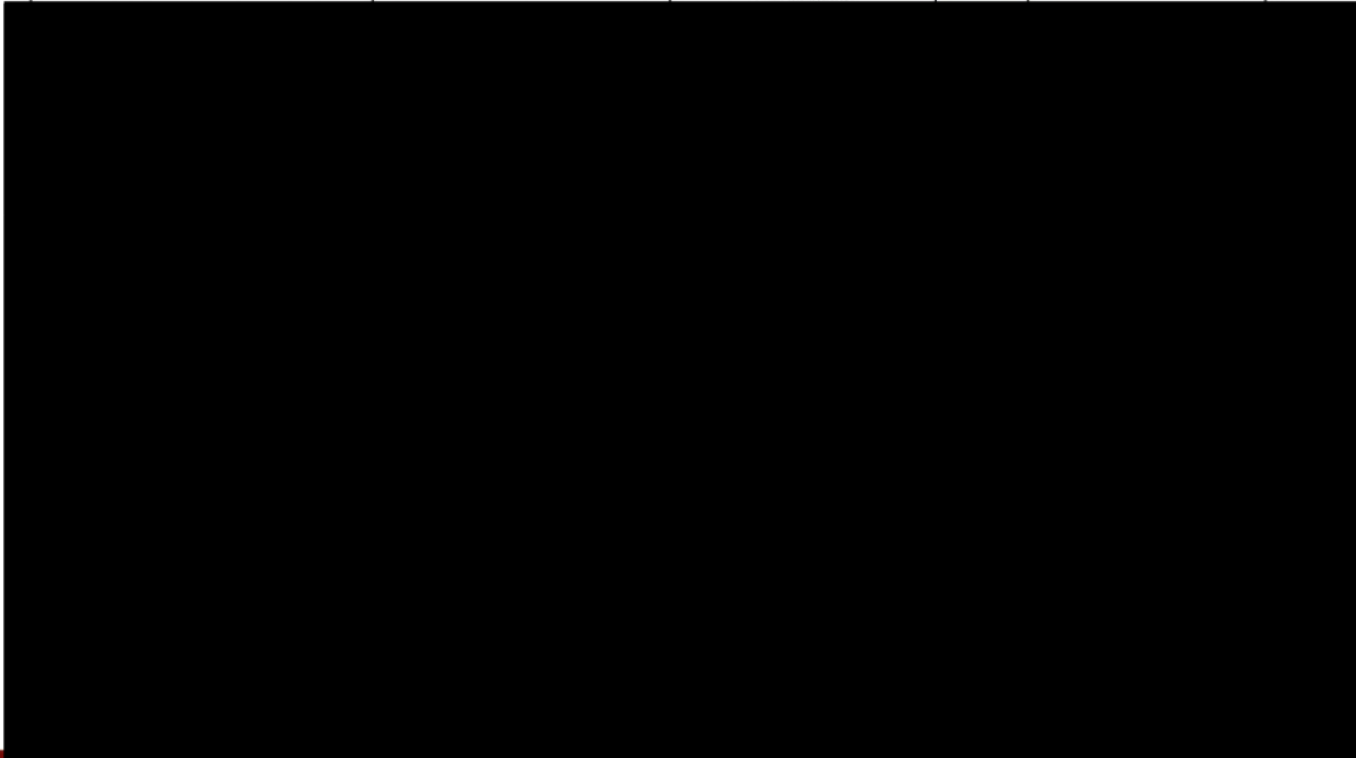
Main System Risks

Potential Failure mode	Potential Cause	System/Process Control	Risk	Comments
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Main Project Risks

Potential Failure mode	Potential Cause	System/Process Control	Risk	Comments
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Documentation checklist

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Document Checklist for CDR:

In compliance to SOP [REDACTED]

[REDACTED]

Documents Pending signature

[REDACTED]

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Budget

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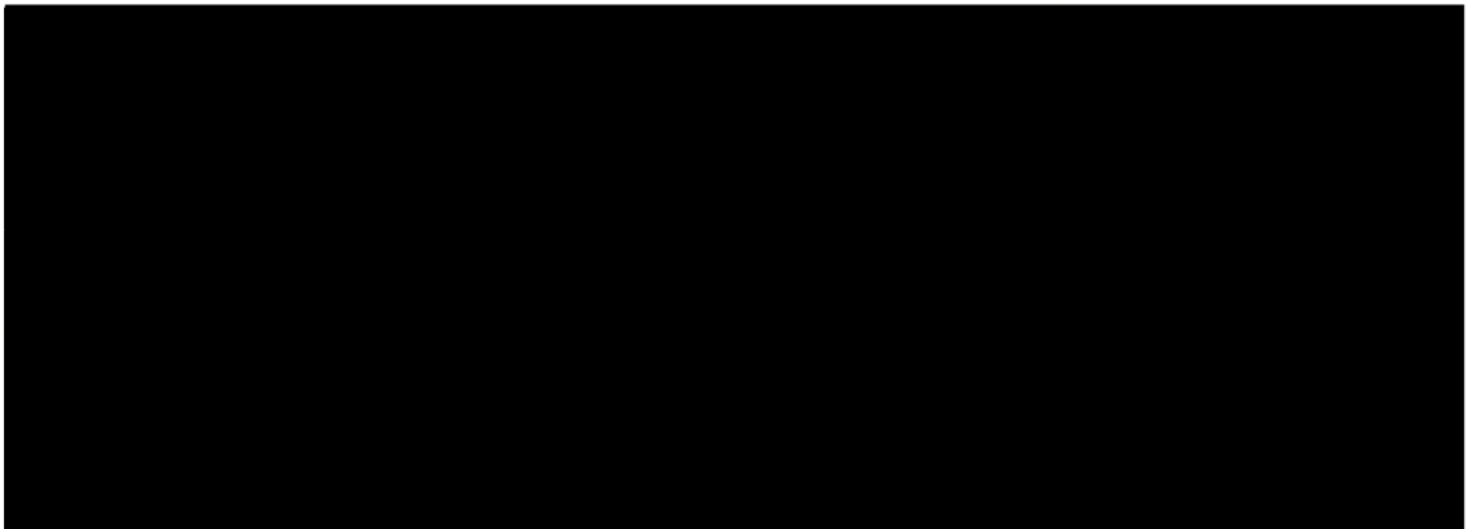
Manufacturing & Raw Material Supply

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THV3 26mm Frames Manufacturing Material Flow

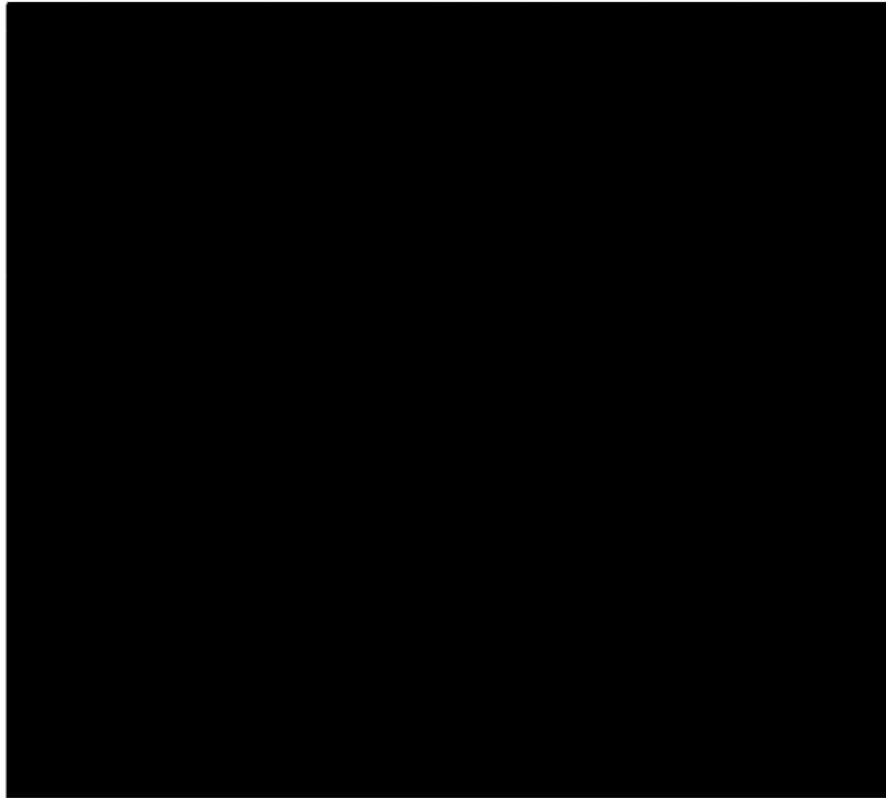


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Detailed Frame Manufacturing Current Flow Chart



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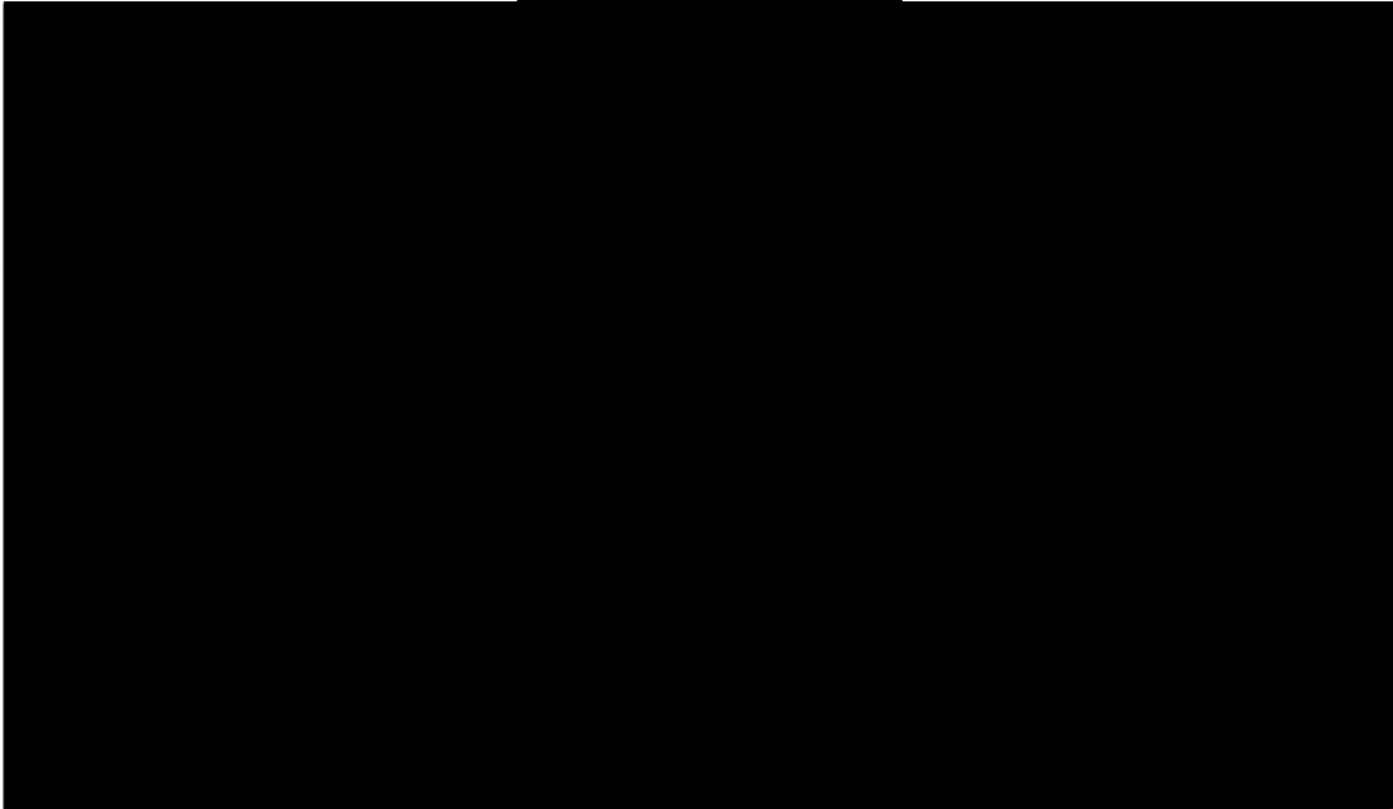
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Helping patients is our life's work, and *life is now*



Animal Trial –



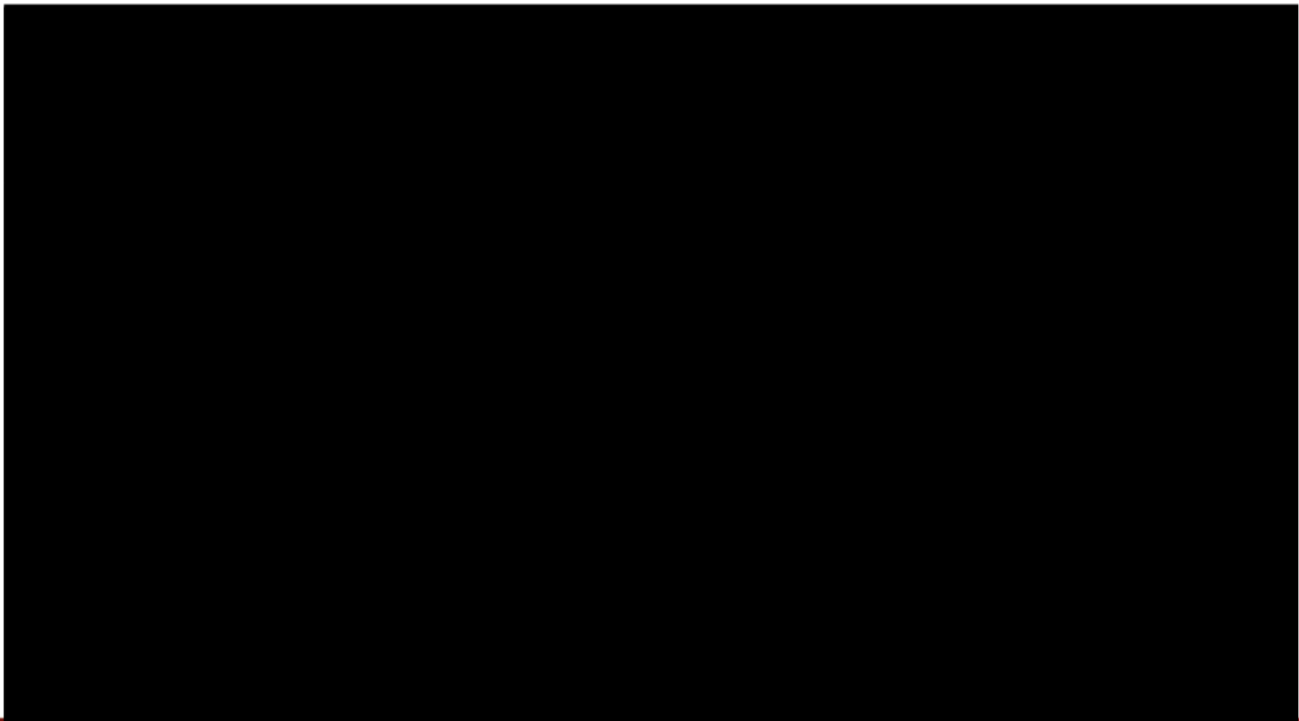
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Animal Trial –



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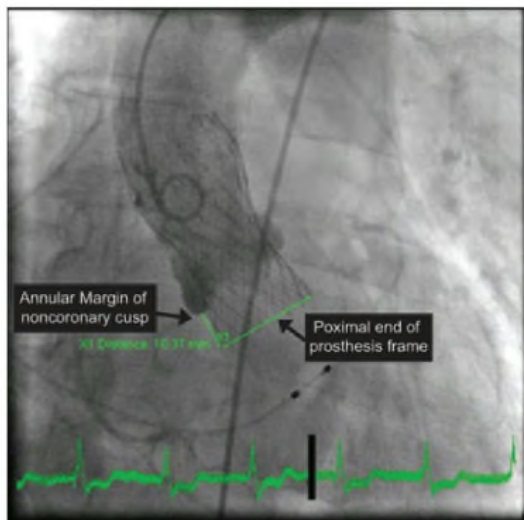
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Incidence and Predictors of Permanent Pacemaker Requirement after Transcatheter Aortic Valve Implantation with a Self-Expanding Bioprosthesis

NUNO DIAS FERREIRA, M.D., DANIEL CAEIRO, M.D., LUÍS ADÃO, M.D., MARCO OLIVEIRA, M.D., HELENA GONÇALVES, M.D., JOSÉ RIBEIRO, M.D., MADALENA TEIXEIRA, M.D., ANÍBAL ALBUQUERQUE, M.D., JOÃO PRIMO, M.D., PEDRO BRAGA, M.D., LINO SIMÕES, M.D., and VASCO GAMA RIBEIRO, M.D.

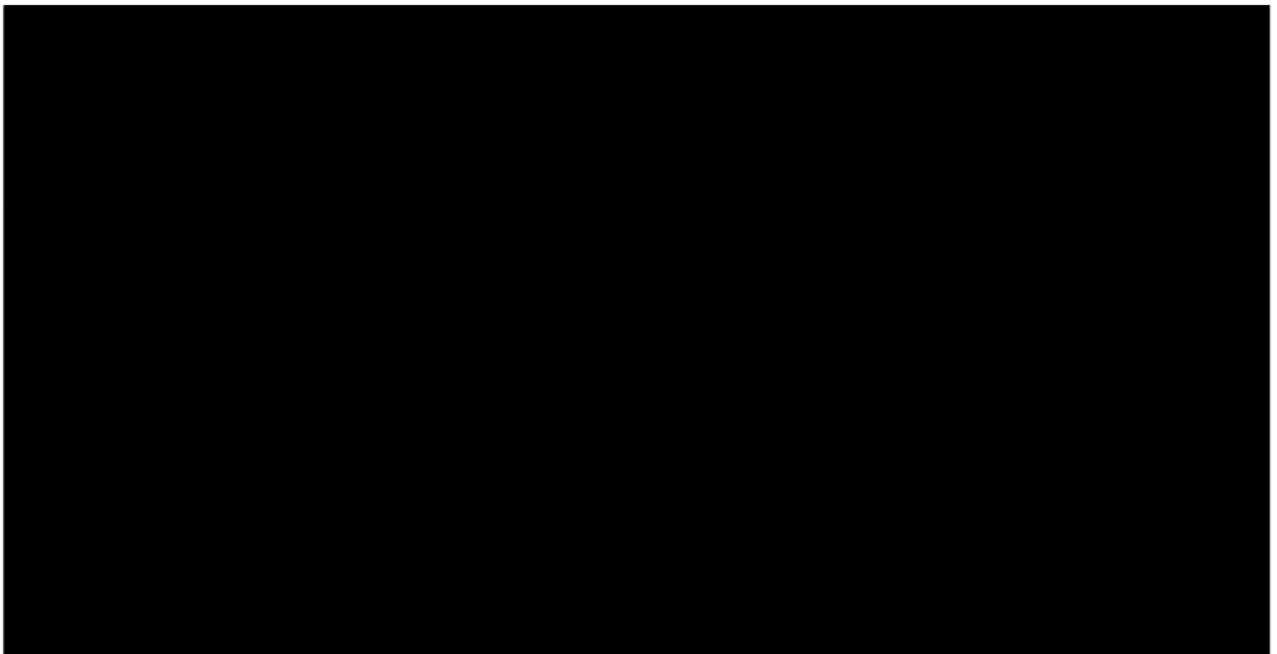
From the Department of Cardiology, Centro Hospitalar de Vila Nova de Gaia/Espinho, Vila Nova de Gaia, Portugal



Requirement for PPM was significantly correlated with prosthesis depth in the LVOT ($P = 0.001$; $r = 0.590$). Mean distance from the annular margin of the noncoronary cusp to the ventricular end of the prosthesis was significantly greater in patients with PPM requirement than patients without PPM requirement (12.9 ± 2.5 mm vs 8.6 ± 2.9 , respectively). At a cutoff point of 10.1 mm, the likelihood of PPM implantation could be predicted with 87.5% sensitivity and 74% specificity and a receiver operator characteristic curve area of 0.86 ± 0.07 ($P = 0.003$).

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SAPIEN 3 Valve development team



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Back-Up Slides (Son)

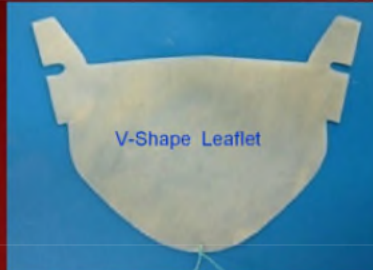
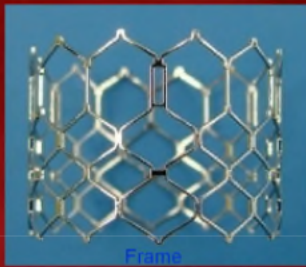
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SAPIEN 3

Third Generation Transcatheter Heart Valve



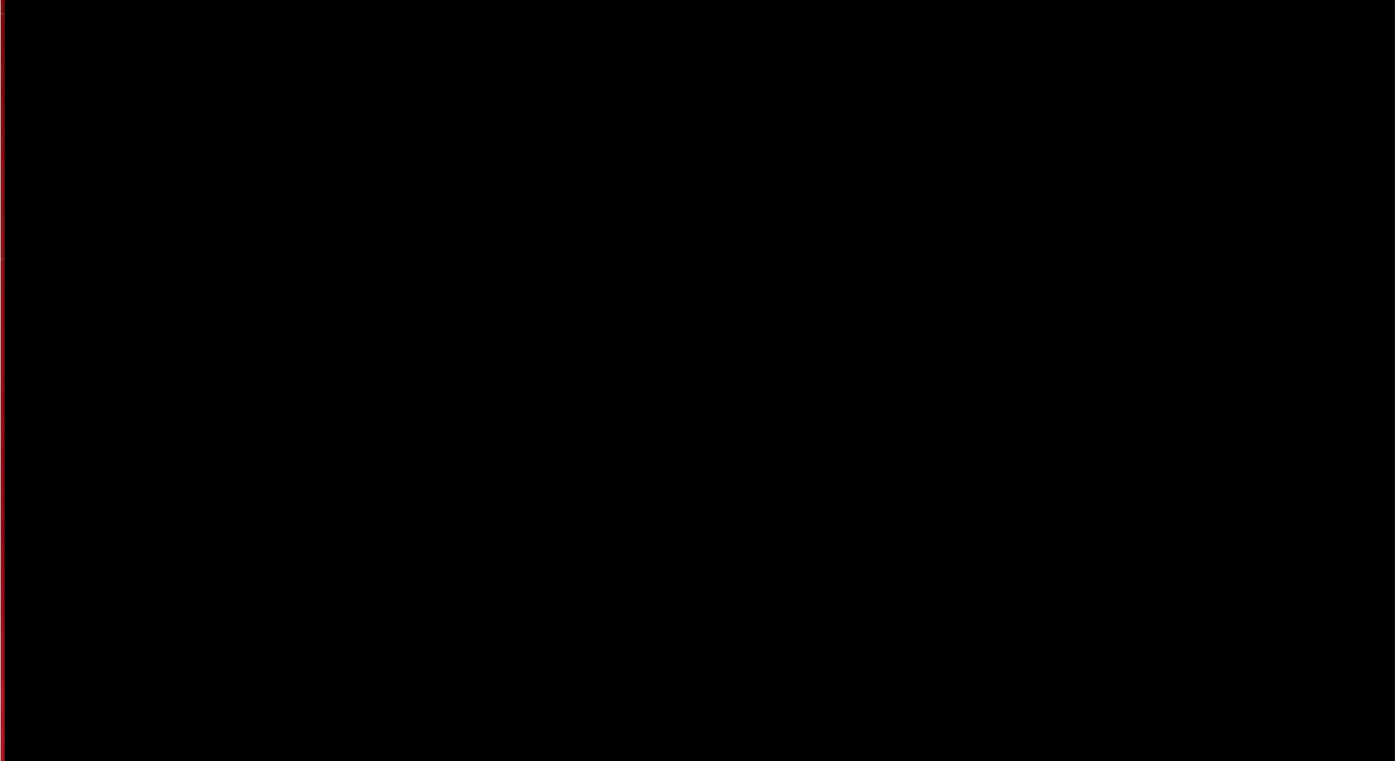
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Sapien 3
Suture Counts and Time per operational sequence
Without Tooling and at Present Development

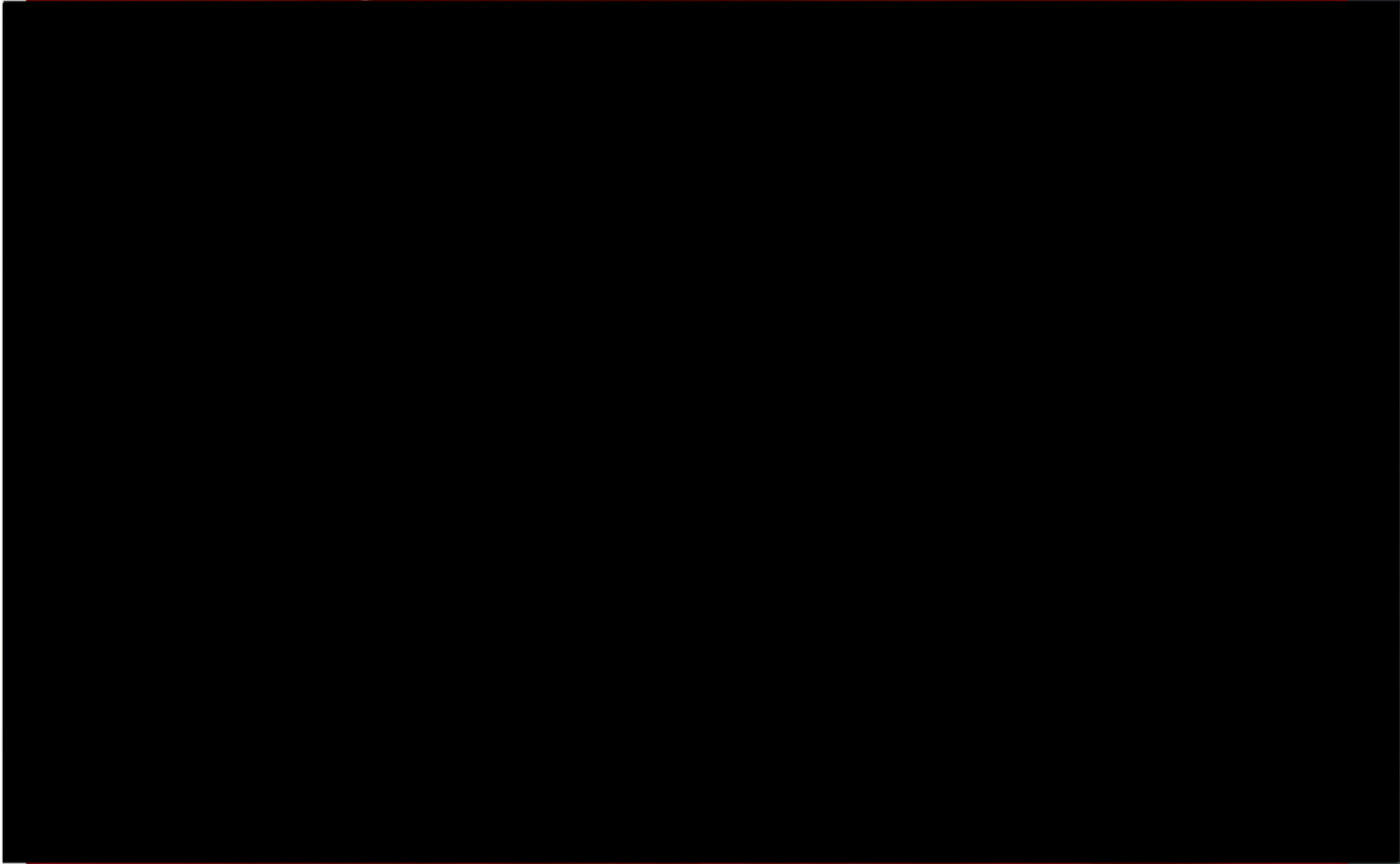


EDWARDS TRANSCATHETER HEART VALVE PROGRAM

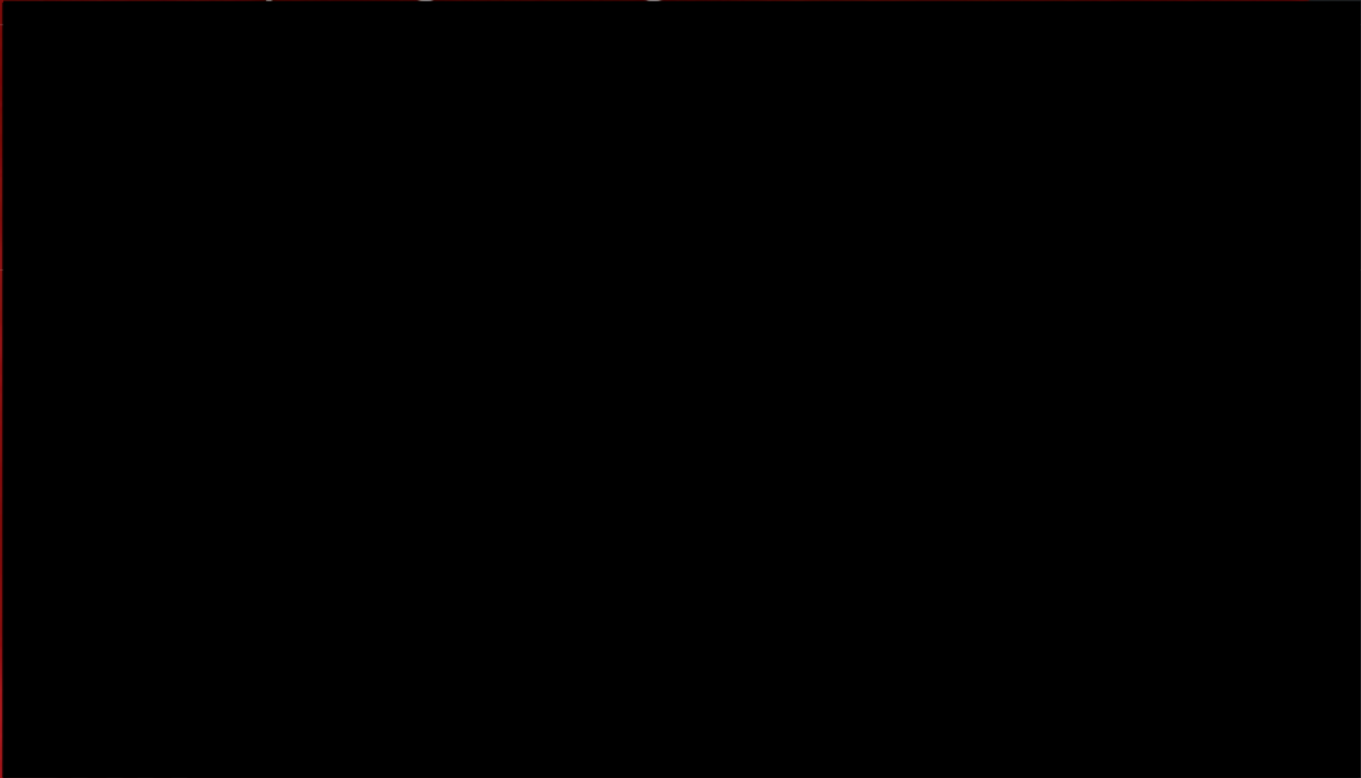
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Sapien 3
Suture Counts and Time per operational sequence
Without Tooling and at Present Development



Sapien 3
Suture Counts and Time per operational sequence
With Scale-up Tooling and Sewing Skill

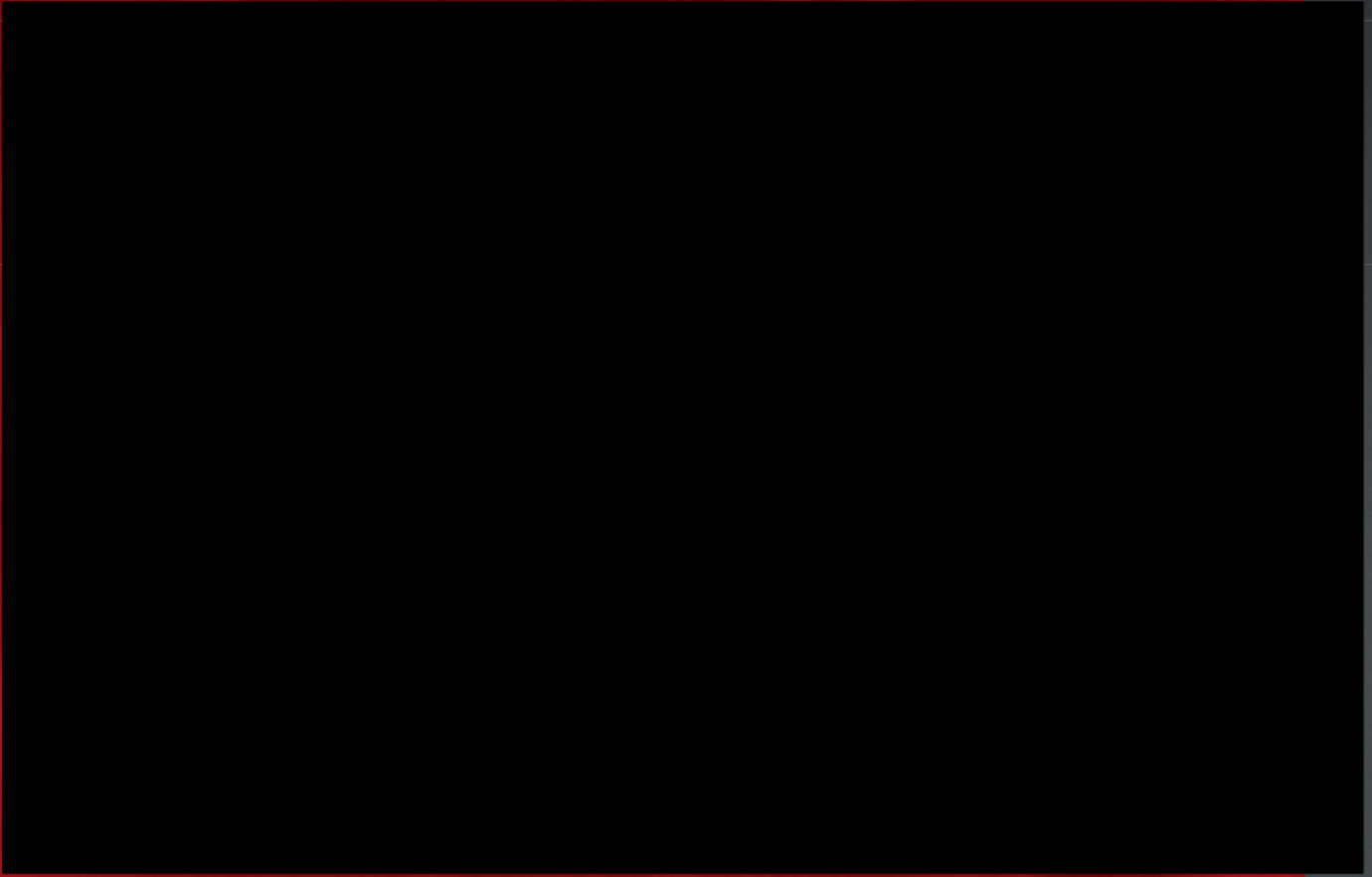


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Sapien 3
Suture Counts and Time per operational sequence
With Scale-up Tooling and Sewing Skill

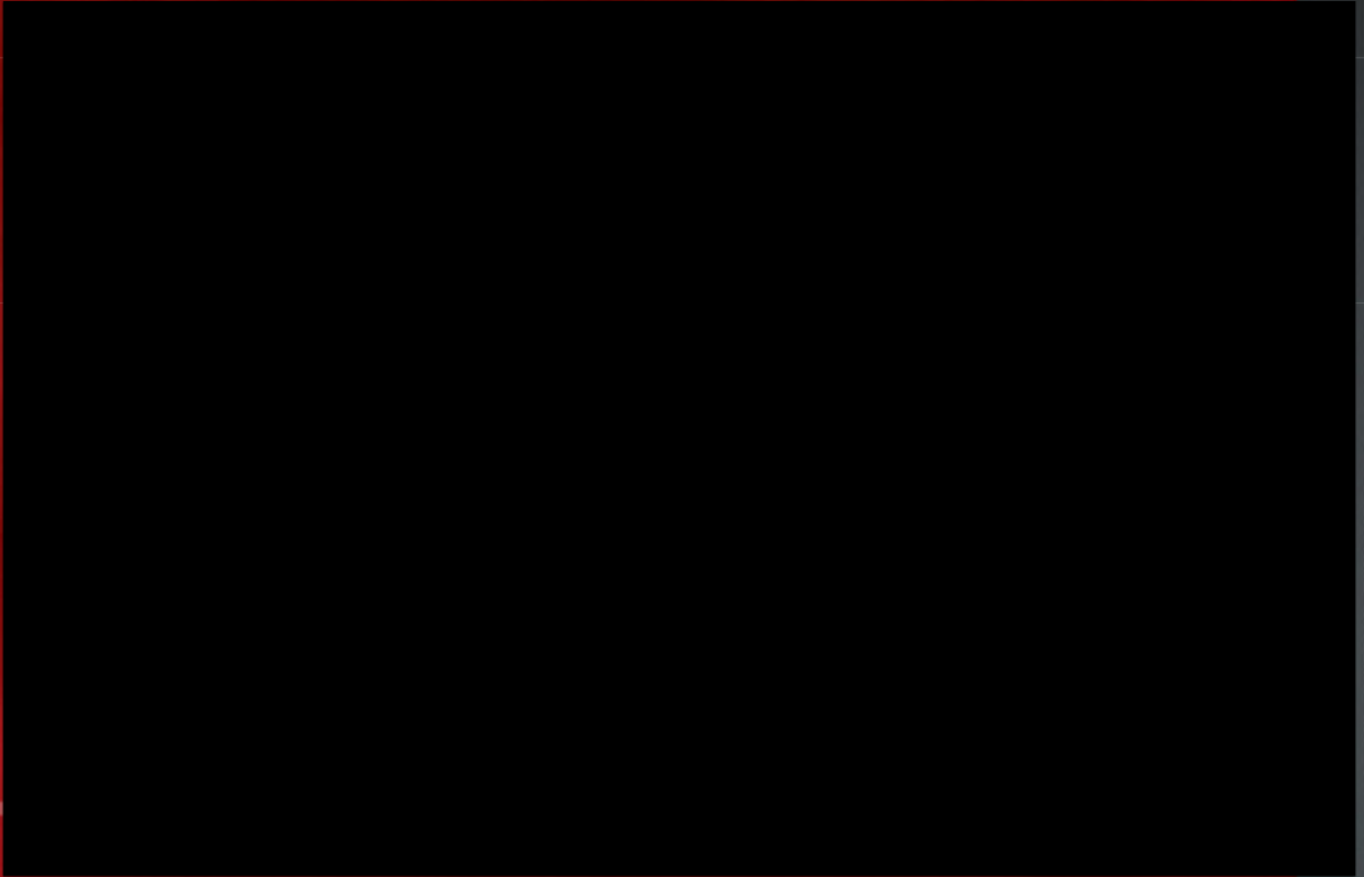


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SAPIEN and SAPIEN XT

Suture Counts and Cost Reference



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