Improving Medical Devices using Optical Metrology

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Agenda

- Novo Nordisk – who are we?
- Device R&D in Novo Nordisk
- Challenges within deformation and strain analysis
- Case study: Code Cap for 3ml Penfill® drug cartridge
- Program for mechanical testing of plastics

Novo Nordisk A/S – a pharma company

- A world leader since 1923
  - in diabetes care
  - in insulin
  - in injection devices

Device R&D:

310/32,500 employees

- Also leading positions in:
  - Haemostasis Management
  - Growth Hormone Therapy
  - Hormone Replacement Therapy (HRT)

Device R&D in Novo Nordisk

- Device history

Insulin Novo Syringe

NovoPen® first pen device

NovoLet® the world's first disposable insulin device

FlexPen® new disposable pen designed for easy use

NovoPen Echo® Improved durable pen for children (memory function)

FlexTouch® Platform device approved for use with modern insulin

1925 1985 1989 2001 2010 2011

Only diabetes devices shown

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Idea with ARAMIS in Device R&D

- Displacement and strain evaluation/visualisation for
  - Mechanical characterisation of plastics
    - Material performance input to design engineers
    - Material modelling input for CAE
  - Component tests
  - Assembly simulation tests
  - Product verification tests
  - Production optimisation

- 12 MP 3D ARAMIS system acquired primo 2012

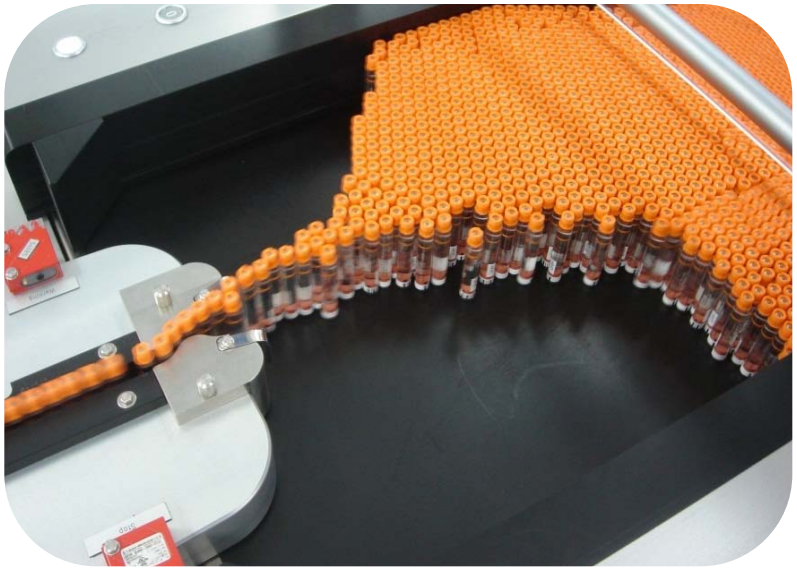
Case study: NovoTwist® Code Cap for Penfill®

- NovoTwist® needle interface – combines standard thread and 'bayonet-type' interface
  - Developed for prefilled devices

- After successful launch: "*Please develop a NovoTwist® Code Cap for 3ml Penfill® as well…*"
  - Intense design and process optimisation required!

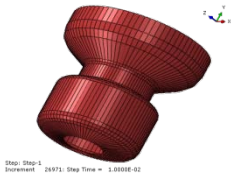
NovoTwist® Code Cap

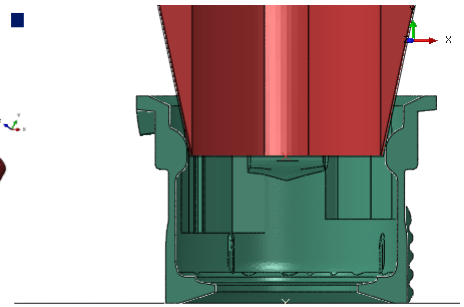
- Interface between 3ml Penfill® and needle
  - Injection moulded PP
  - Ring snap to cartridge

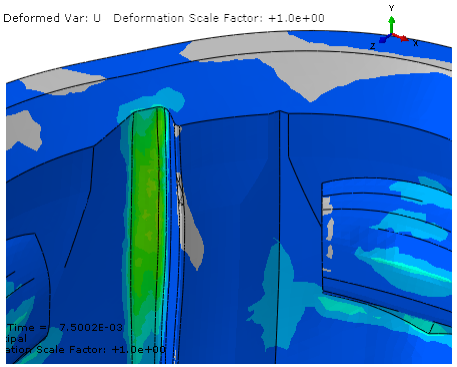


- High volume production
  - Many million per year
- Challenging design
  - Thin walled: 0.7-0.8 mm
  - Flow restrictors: 0.2 mm(!)
  - Challenging worst-case assembly strain due to segmented ring snap to glass cartridge

What then? The short version…







- First design iteration
- CAE model of assembly
- Ductility test method
- CAE model of test method
- CAE on design iterations
- New candidate design
- Prototype moulding of new design
- Ductility test of new design
- Production implementation of new design
- Assembly verification of new design

High spend!

FEA by Linda Nilsson, Novo Nordisk A/S

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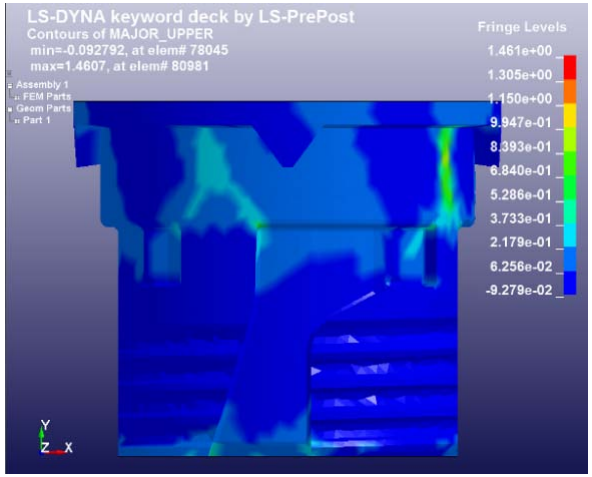
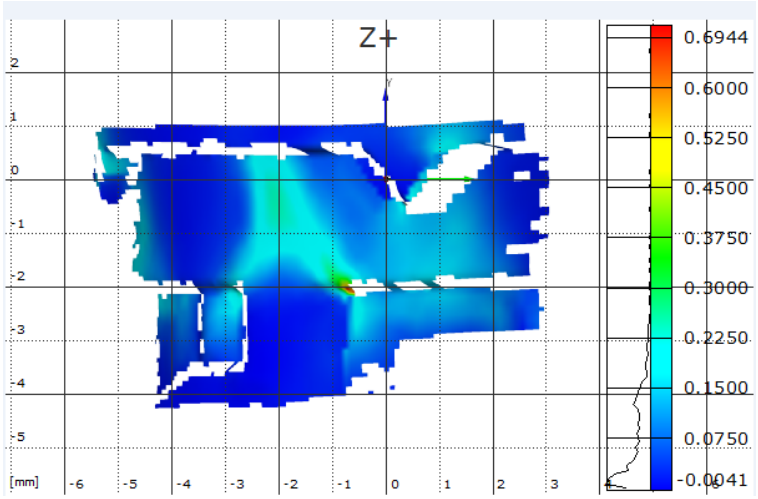
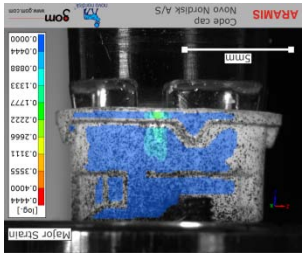
Potential with ARAMIS on ductility test

- **Direct strain evaluation on Code Cap in test**
  - **Better fit of material model to capture post yield behaviour**







- **Potential for higher certainty in CAE prediction!**

ARAMIS measurement by Theo Möller, GOM

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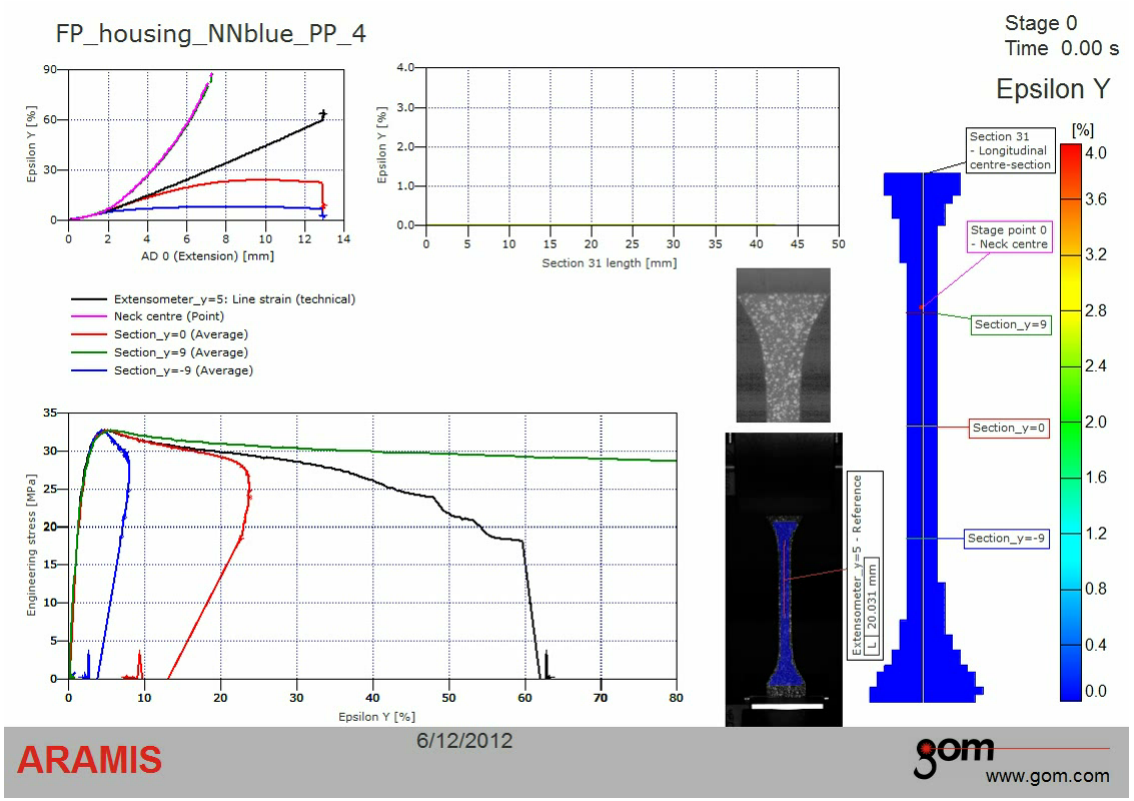
Mechanical characterisation of plastics

- **90-100 uniaxial tests per material**
  - **5 loading scenarios, 3 temp's, 3-5 strain rates**



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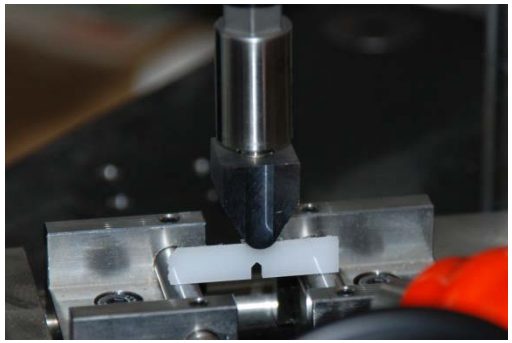
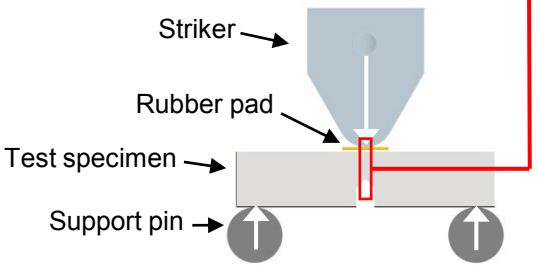
Impact test on POM – moulded-in notch

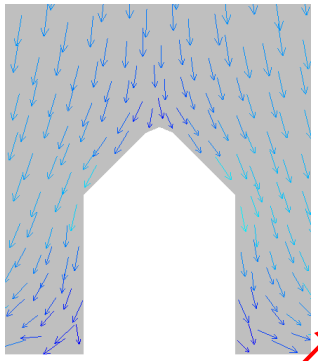
Unfilled POM, 1 m/s

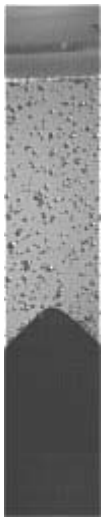


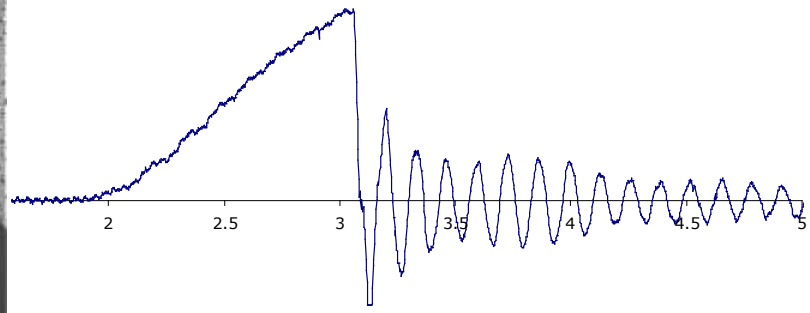


Material in notch root loaded:

Transverse to mould flow



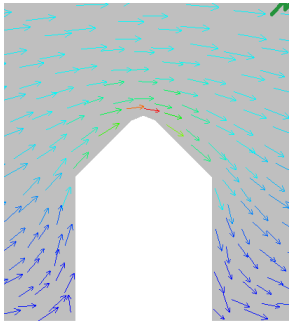


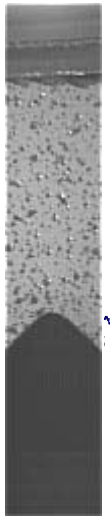


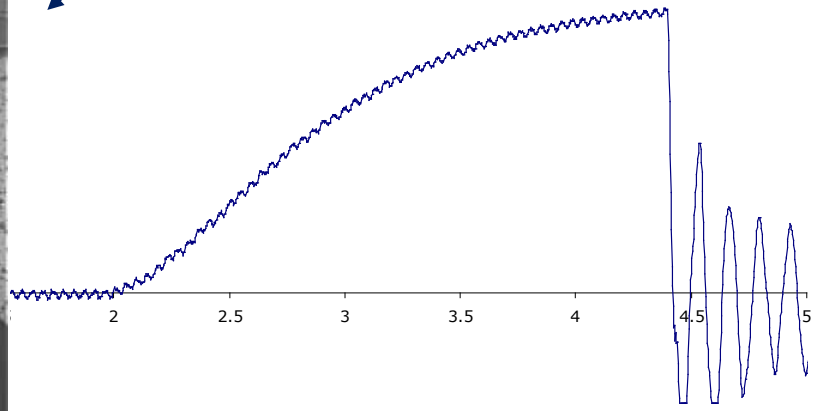
Click to start!

Time [ms]

Parallel to mould flow







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Thank you for your attention!

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QUESTIONS..?