



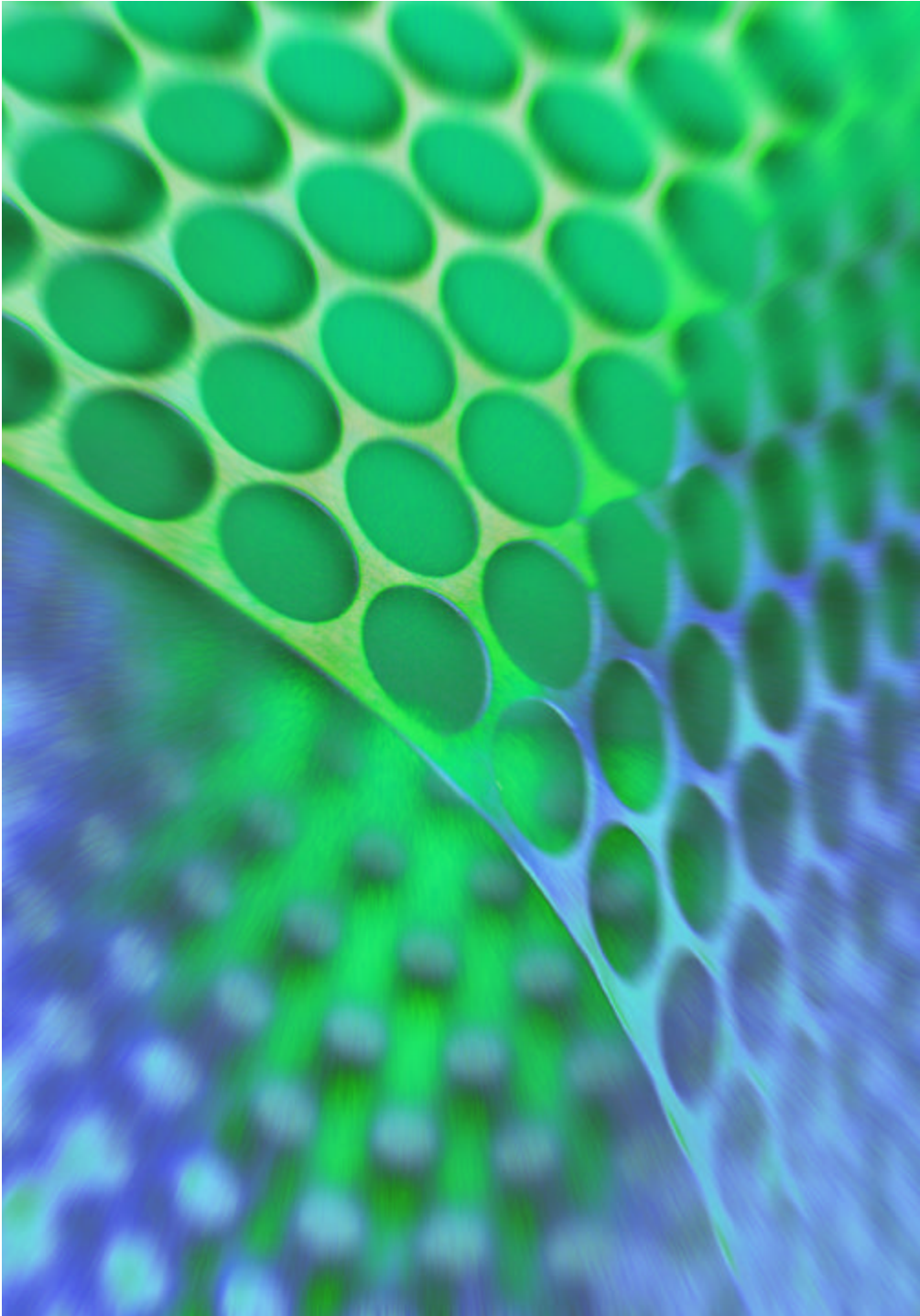
Hole Committee Update

For Presentation to:
The IoPP Medical Device
Packaging Committee
October 22, 2003



Agenda

Holes



Work

- **Review of the literature of “penetration thresholds”**
- **Why?**
- **Investigation into making holes**
- **Investigation into measuring holes**
- **Thanks**

Review of the Literature Investigating Penetration Thresholds

Floros (1994)	10 μm
Howard and Duberstein (1980)	0.2 μm
Lampi (1980)	11 μm
Keller et al. (1994)	10 μm
Keller et al. (1994)	<10 μm
Axelsson et al. (1990)	80 μm
Gilchrist et al. (1989)	22 μm
Chen et al. (1991)	10 μm
Chen et al. (1991)	5 μm
Harper (1994)	10 μm
Rose et al. (1994)	7 μm

Why?

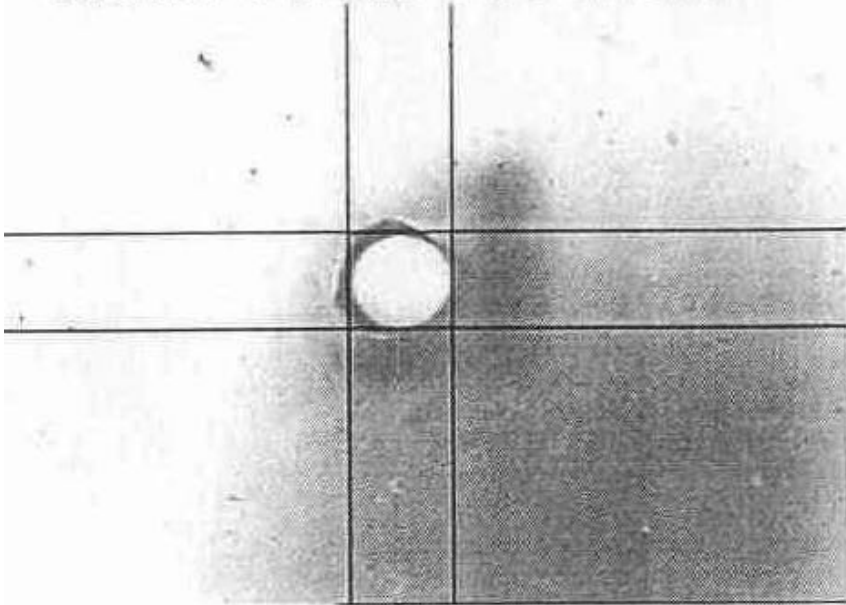
- Microbes
- Test methods
- Pressure differentials
- Package geometries
- Etc., Etc.
- Holes

Consider a tray that has a thickness of 21 mils

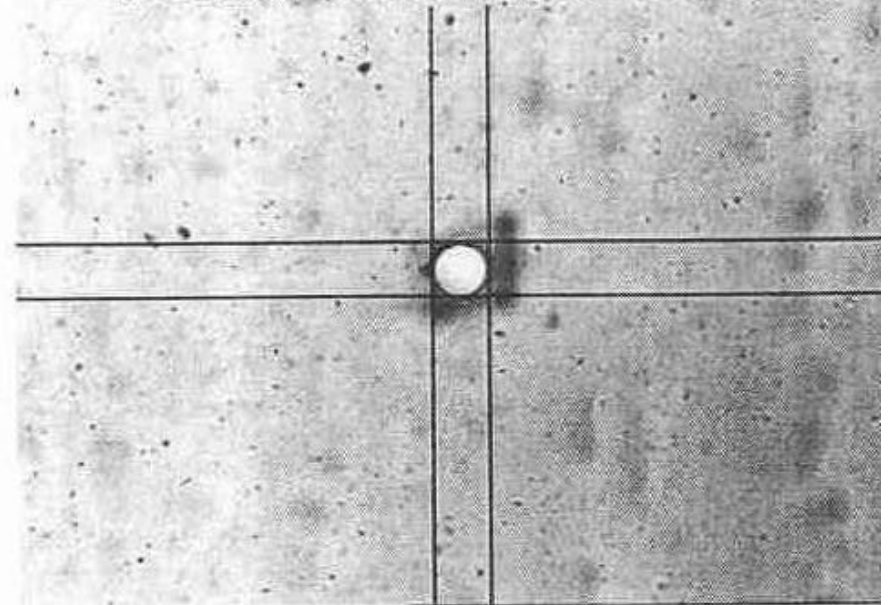
- 21 mils \longrightarrow 0.021 inches
- 0.0005334 meters \longrightarrow 533.4 μm
- Consider a 50 μm hole, the thickness is more than 10 times the hole diameter
- Consider a 5 μm hole, the thickness is more than 100 times the hole diameter
- Torturous path, “aspect ratio”, volume or flow rate may be a better way to consider these defects

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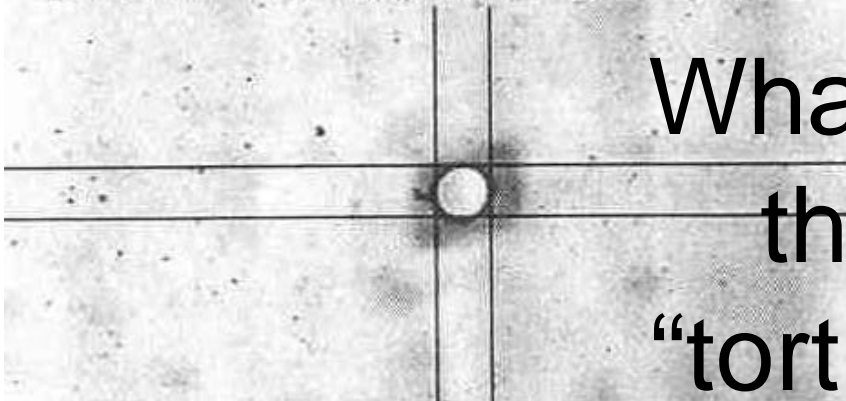
X=0.0491 Y=0.0496 M S/U SF1=0010



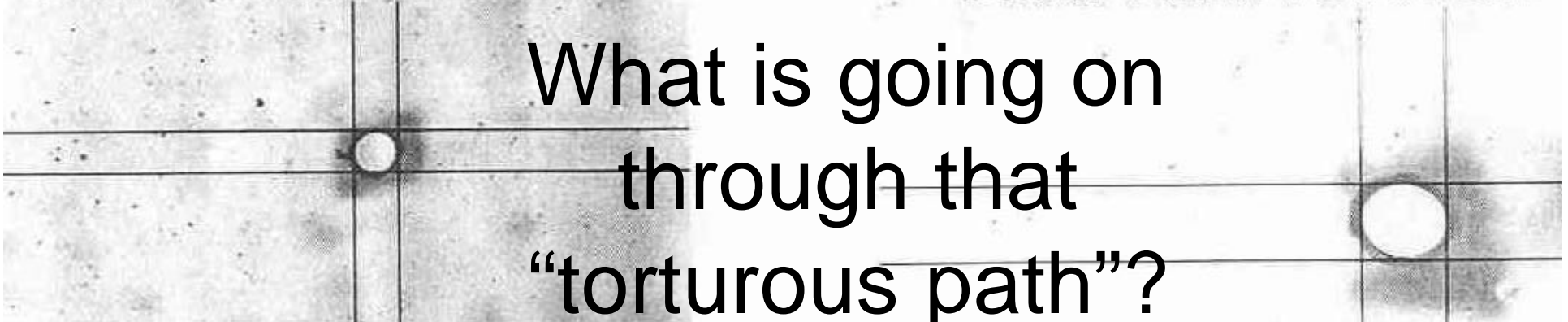
X=0.0526 Y=0.0541 M S/U SF0=0005



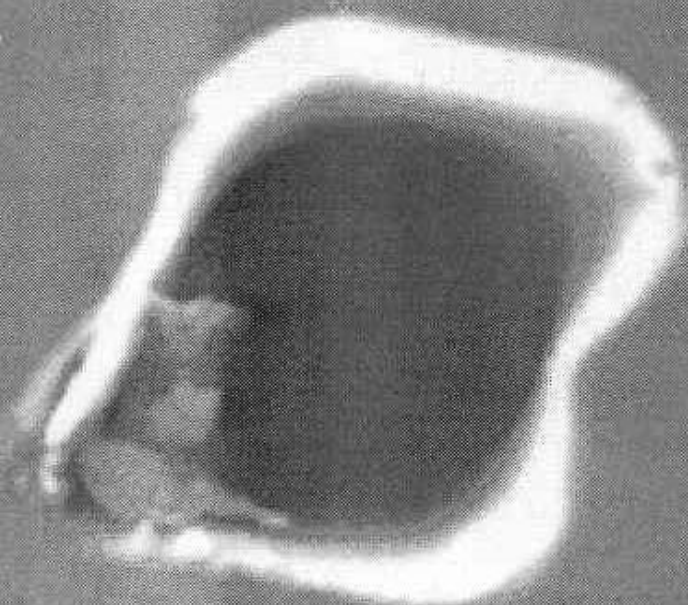
X=0.0517 Y=0.0526 M S/U SF0=0005



X=0.0485 Y=0.0481 M S/U SF1=0010



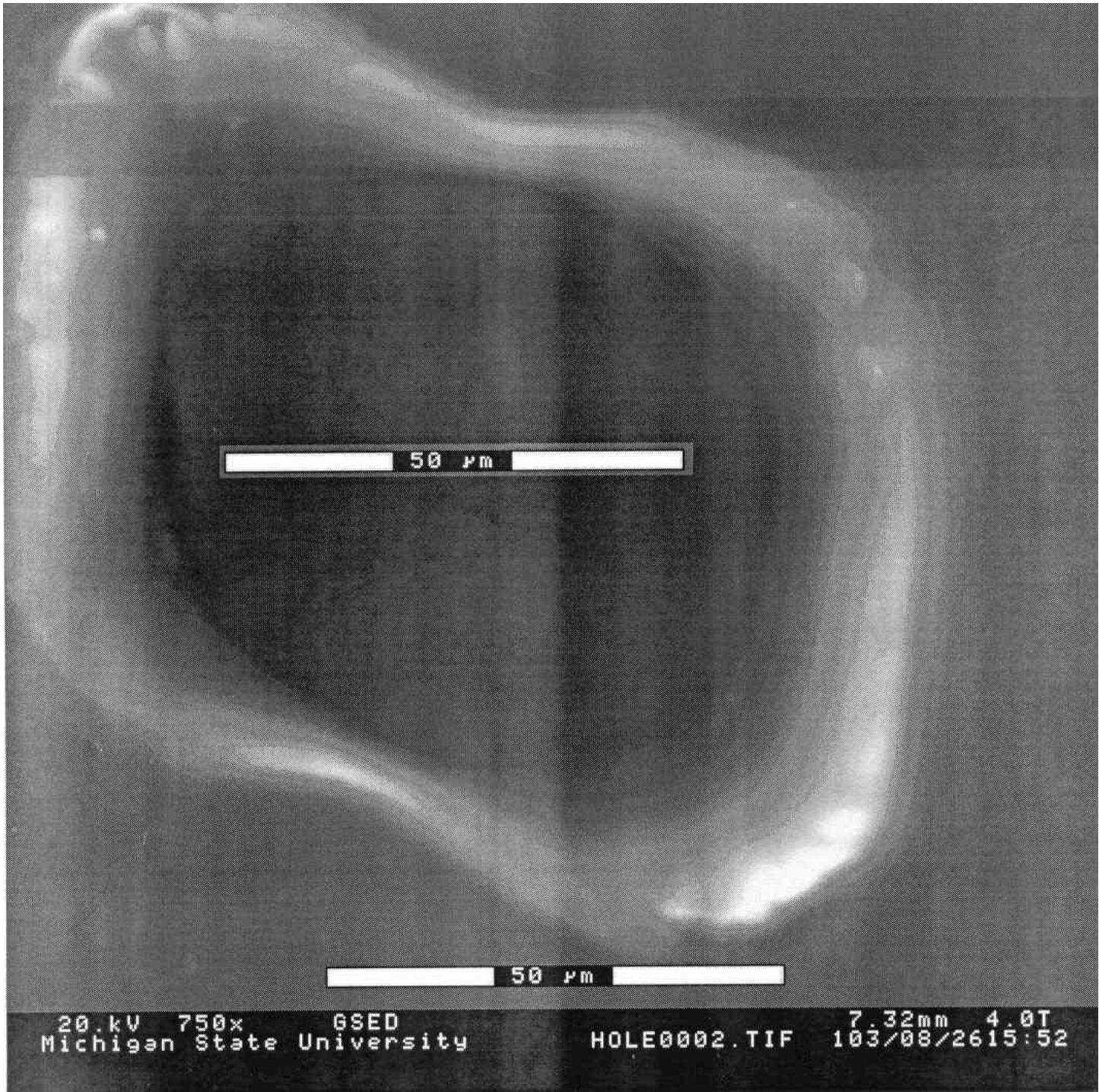
What is going on
through that
“torturous path”?



150 μ m

20.kV 265x GSED
Michigan State University

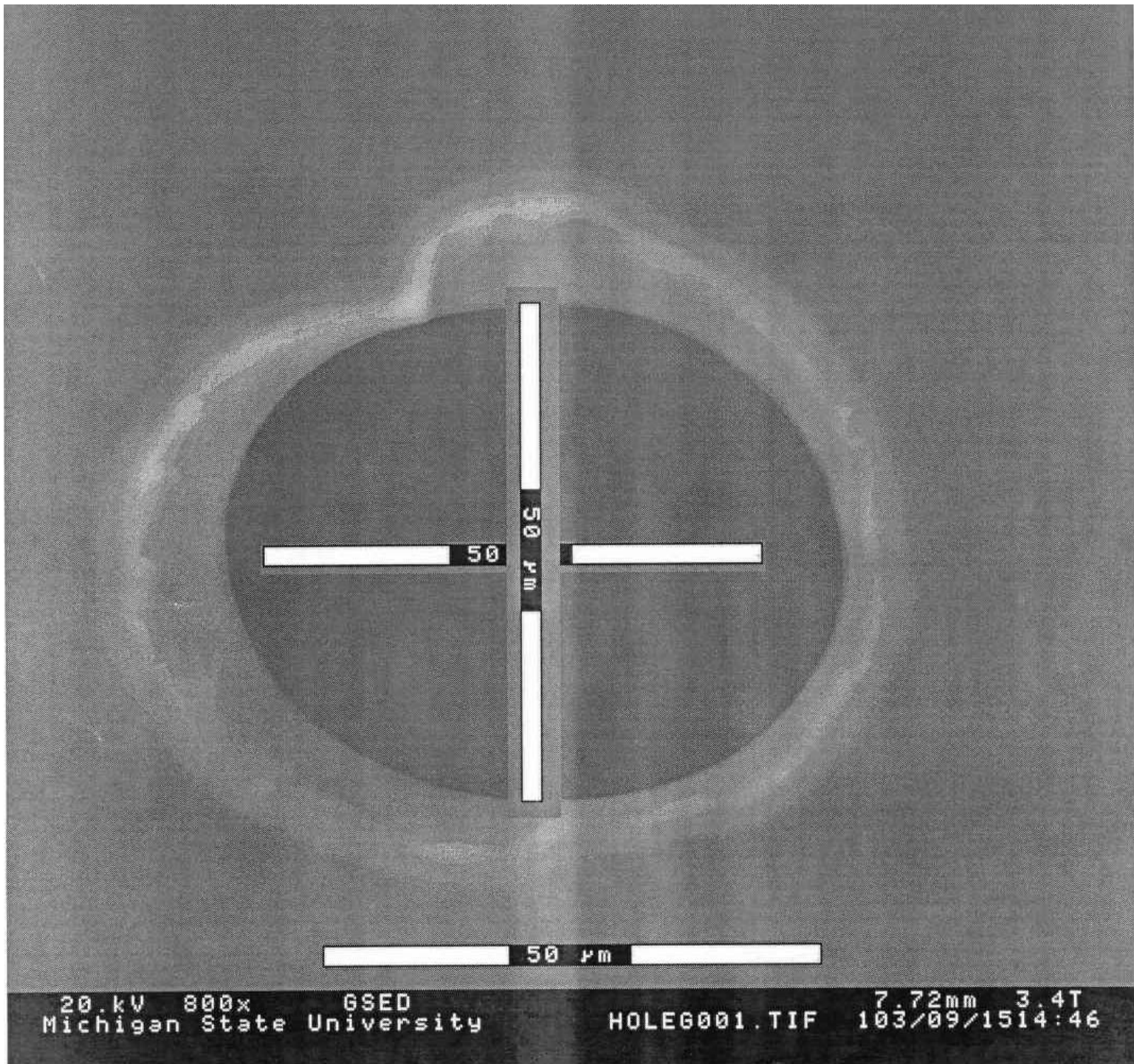
HOLEF000.TIF 7.93mm 3.6T
103/09/1115:38



20.kV 750x GSED
Michigan State University

HOLE0002.TIF

7.32mm 4.0T
103/08/2615:52



20.kV 800x GSED
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HOLE001.TIF

7.72mm 3.4T
103/09/1514:46

What is happening?

- **Difference in microscope?**
- **Hour-glass shape?**
 - **What does this do for microbial penetration?**
- **Tunneling Microscopy?**
- **Different specification?**
- **Different hole production?**

Thank You

- CFPPR
- Medtronic
 - Mocon
 - PTI
 - Perfecseal
- Rexam Medical
 - Sencorp

