

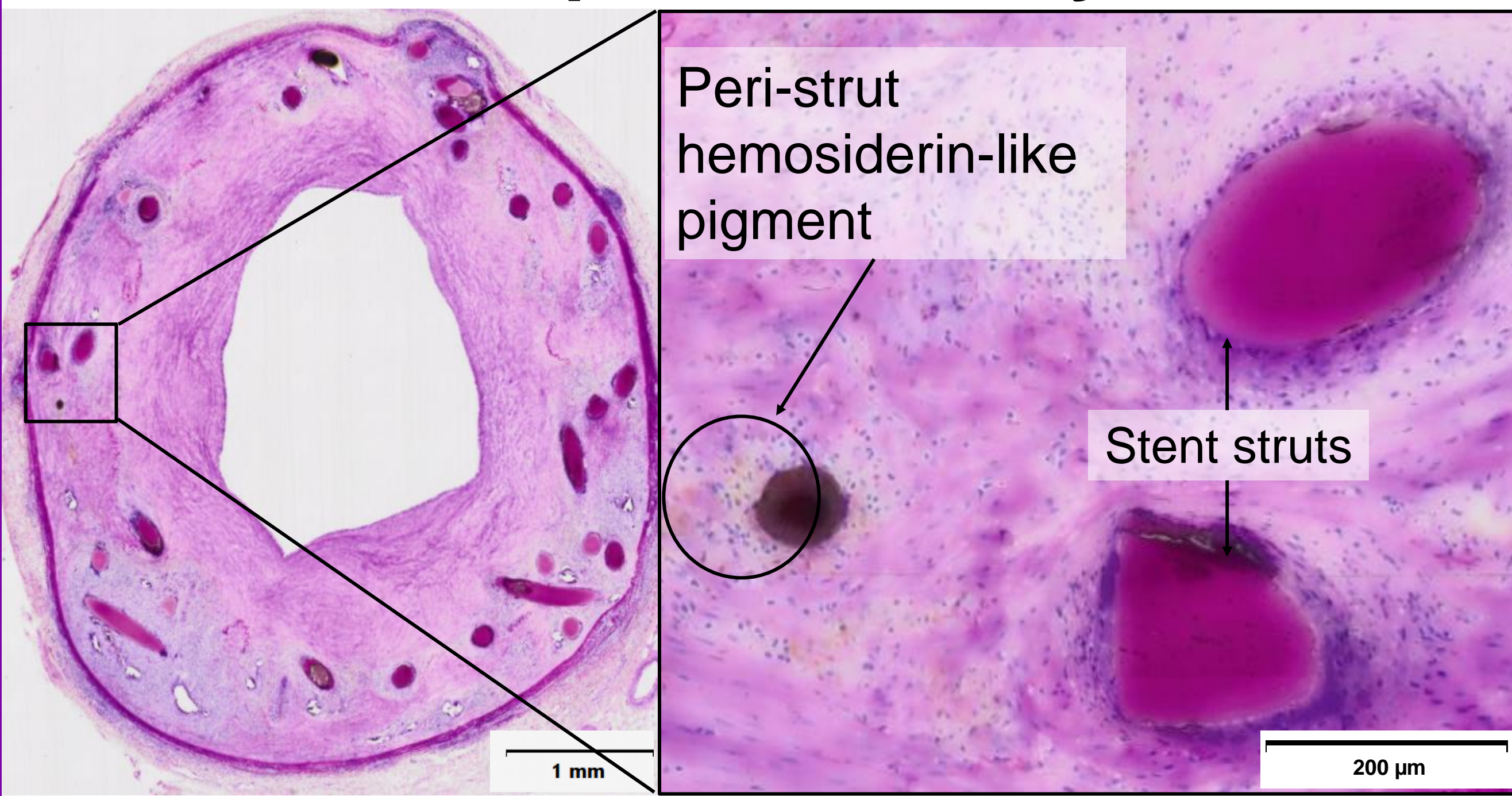
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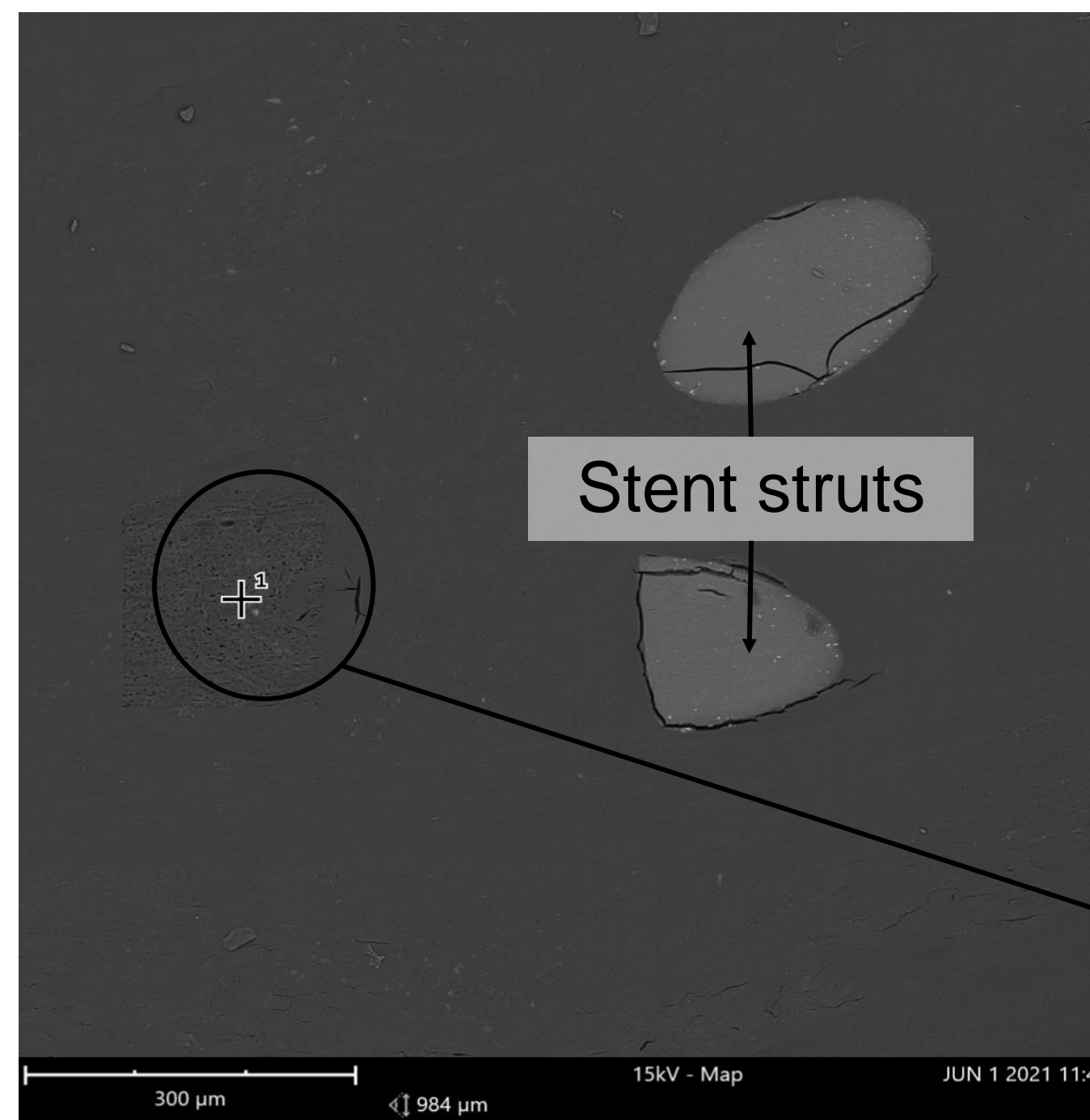
Background

Medical devices have become indispensable for health care, increasing the demand for novel methodologies, technologies, and biomaterials. These new therapeutic applications and materials are often associated with novel, unexpected or unpublished histological findings with challenging interpretation.

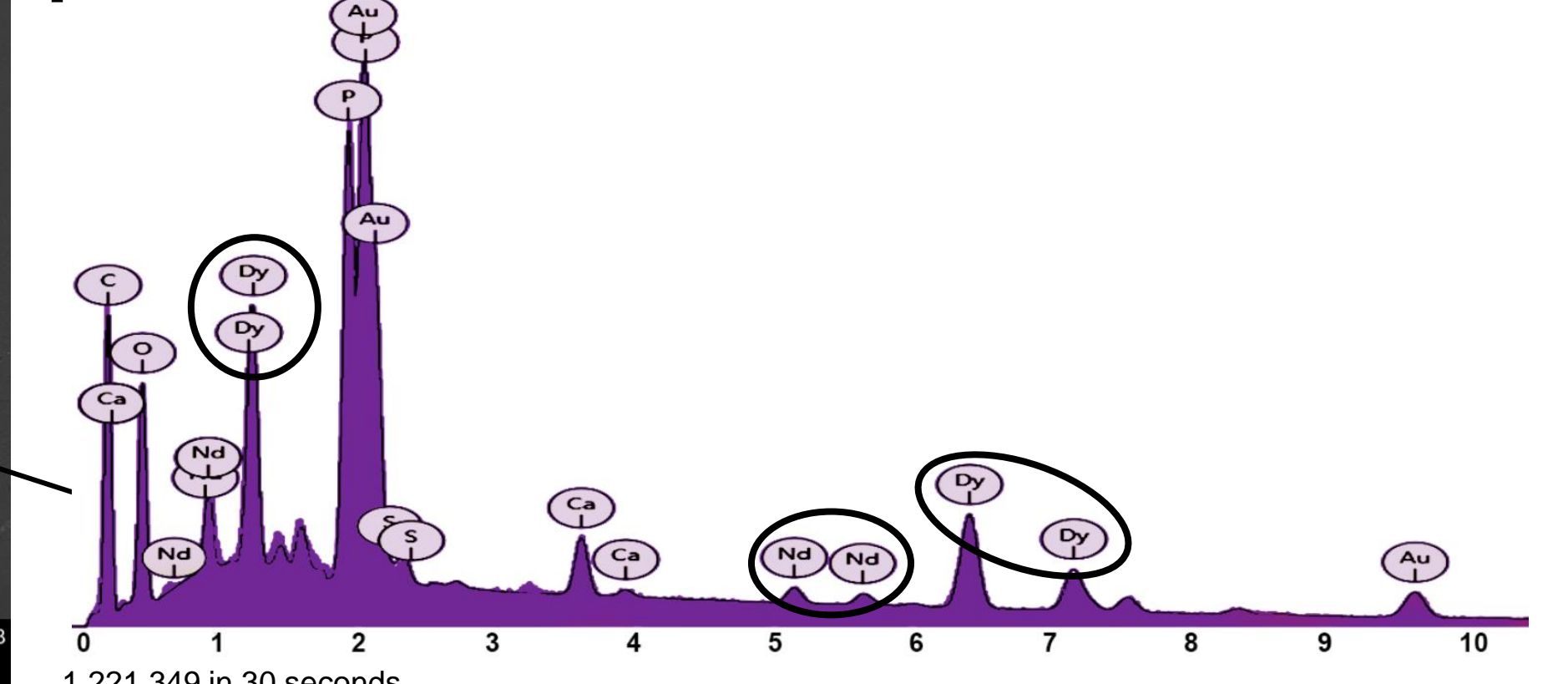
Case 1: Stent porcine artery model



Methyl methacrylate (MMA) resin embedding, Paragon (basic fuchsin and toluidine blue)



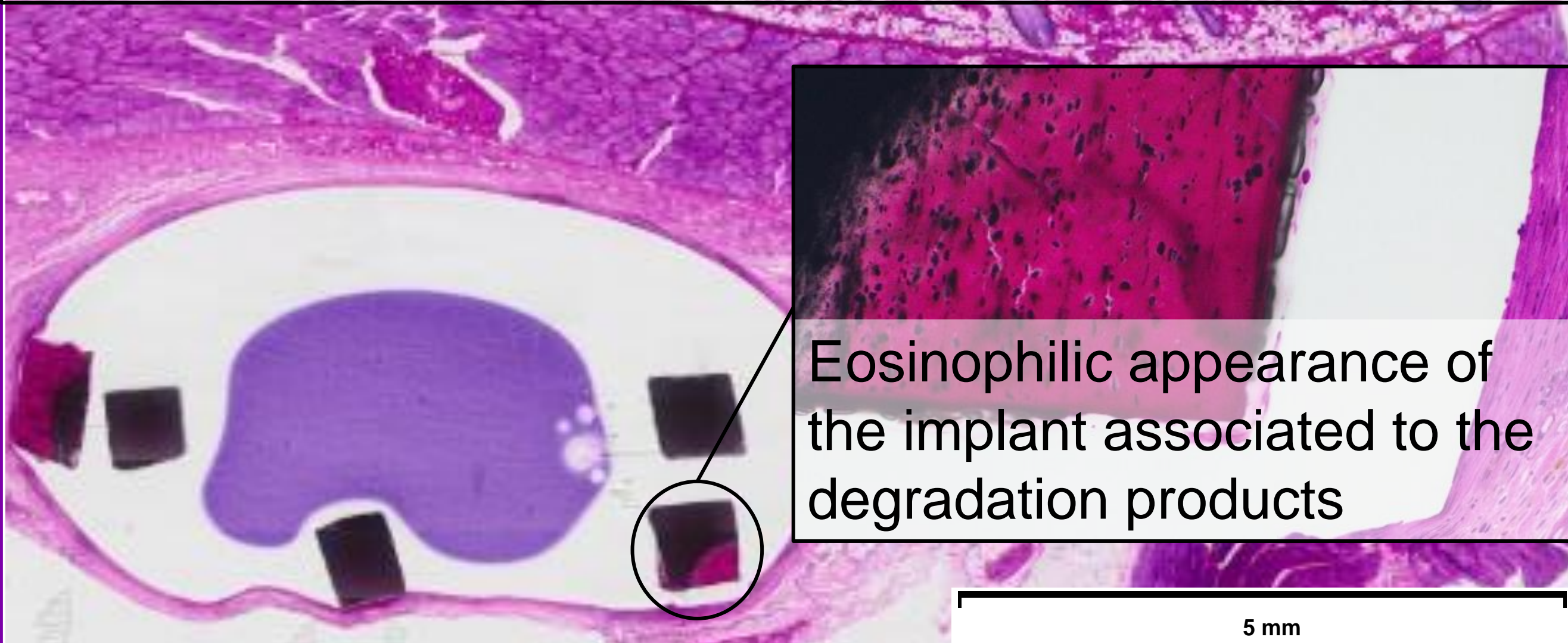
Presence of the stent alloy components: Rare Earth Elements **Dy** (Dysprosium) and **Nd** (Neodymium). Confirms that the pigmentation is the **stent degradation products**.



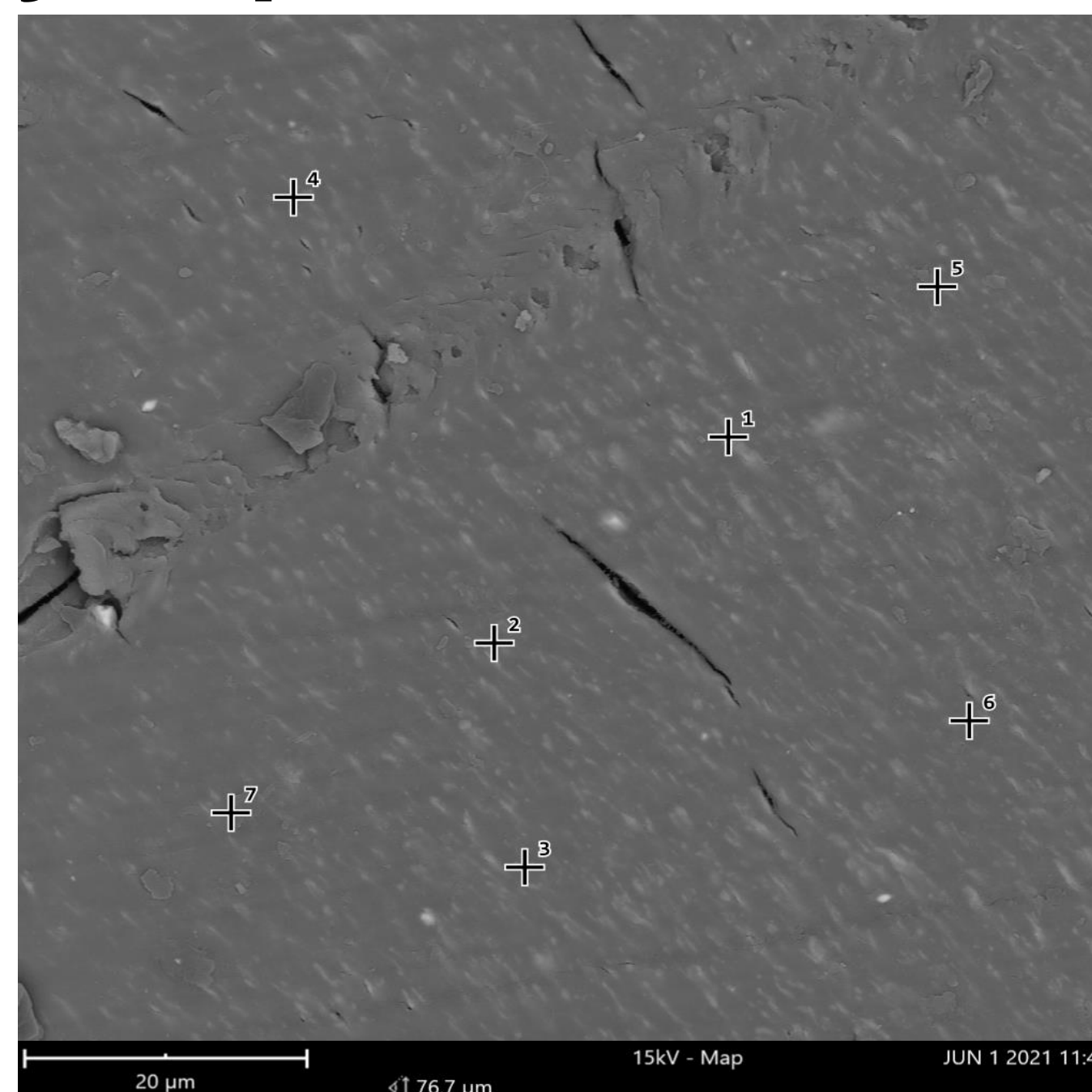
Energy-dispersive X-ray spectroscopy (EDX)

Case 2: Subcutaneous Magnesium alloy implantation model in rabbit

Hydrogen gas-void associated to the hydrolysis of magnesium¹: $Mg + 2H_2O \rightarrow Mg^{+2} + 2OH^- + H_2$



Methyl methacrylate (MMA) resin embedding, Paragon (basic fuchsin and toluidine blue)



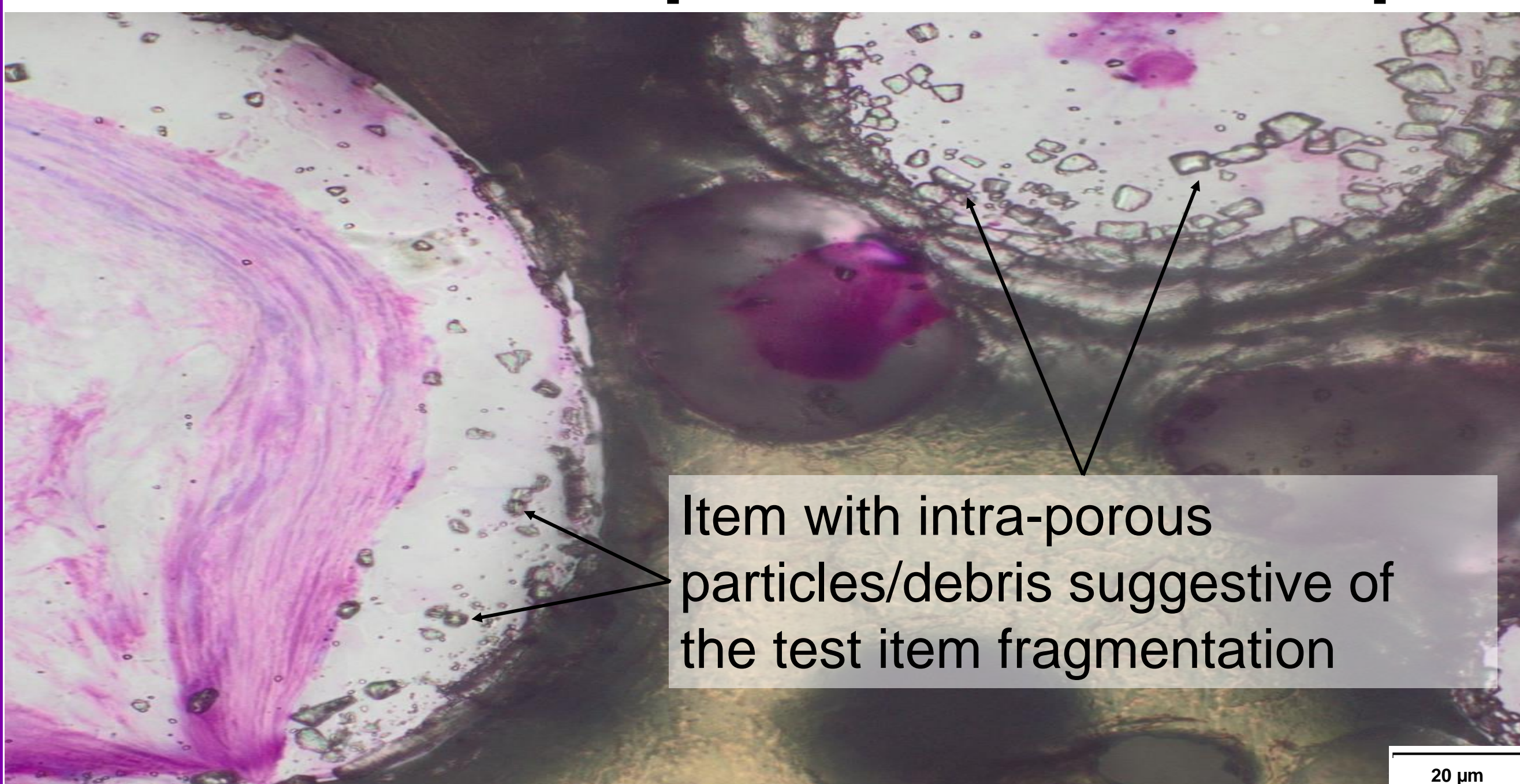
EDX points measurements on the degraded struts:

Element Number	Element Symbol	Element Name	Atomic Concentration (%)	Weight Concentration (%)
8	O	Oxygen	23.66	6.32
20	Ca	Calcium	22.40	14.99
15	P	Phosphorus	15.09	7.80

- High concentration of Ca, P and O.
- Precipitation of Ca^{2+} and PO_4^{3-} due to the local alkalization related to the Mg degradation^{1,2}.

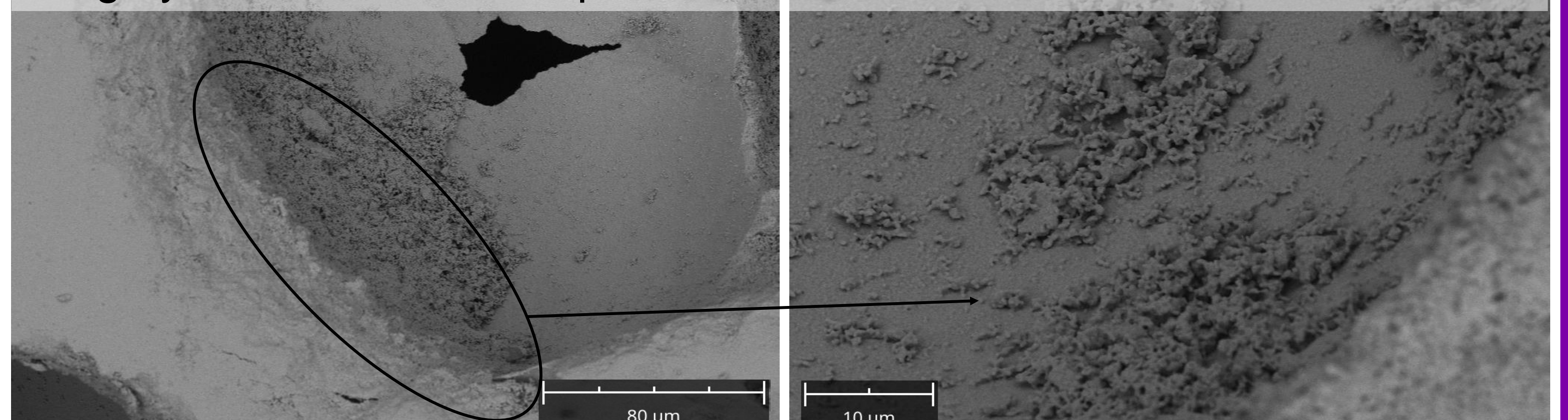
Energy-dispersive X-ray spectroscopy (EDX)

Case 3: Bone implantation in sheep



Methyl methacrylate (MMA) resin embedding, Paragon (basic fuchsin and toluidine blue)

Scanning Electron Microscopy (SEM) revealed the irregular surface of the porous structures in a non-implanted item. The item ultrastructural evaluation confirmed that these particles are artefactual, assuring the integrity of the item after implantation.



Scanning Electron Microscope (SEM)

Conclusion

- Need for careful interpretation of medical device studies
- Special technologies such as EDX and SEM are useful to ensure an accurate assessment of medical device studies safety and efficacy