OXFORD LASERS

Positive Controls for CCIT

Laser-Drilled Defects Down to 2 µm

Precisely calibrated holes are drilled directly into your glass, polymer or foil containers to create a certified, fully traceable positive-control package

REGISTERED scientist.com SUPPLIER

www.oxfordlasers.com/ccit

Vials

Calibrated micro-holes laser drilled into all types of vials

Glass

Calibrated leaks down to 2 µm

Materials: Glass type I, II, III

Size: up to ~100 mL

Thickness: up to ~2 mm

Location: Standard (body) or customised

Filled or empty

Polymer

Calibrated leaks down to 5 µm

Option: pinhole discs down to 2 µm

Materials: Plastics and speciality polymers **including COC/COP for cryogenic storage**

Size: up to 100 mL

Thickness: up to ~1.5 mm

Location: Standard (body) or customised

Filled or empty

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Ampoules

We laser drill calibrated micro-holes directly into your packaging

Glass

Calibrated leaks down to 2 µm

Materials: Glass type I, II, III

Size: up to 20 mL

Thickness: up to ~2 mm

Location: Standard (body) or customised

Filled or empty

Polymer

Calibrated leaks down to 5 µm

Option: pinhole discs down to 2 µm

Materials: Flexible plastics

Size: up to 30 mL

Thickness: up to ~1.5 mm

Location: Standard (body) or customised

Filled or empty

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Syringes

Calibrated micro-holes laser drilled into all types of syringes

Glass

Calibrated leaks down to 2 µm

Materials: Glass type I, II, III

Size: up to 10 mL

Thickness: up to ~1.5 mm

Location: Standard (body) or customised

Filled or empty

Polymer

Calibrated leaks down to 5 µm

Materials: Plastics and speciality polymers **including COC/COP for cryogenic storage**

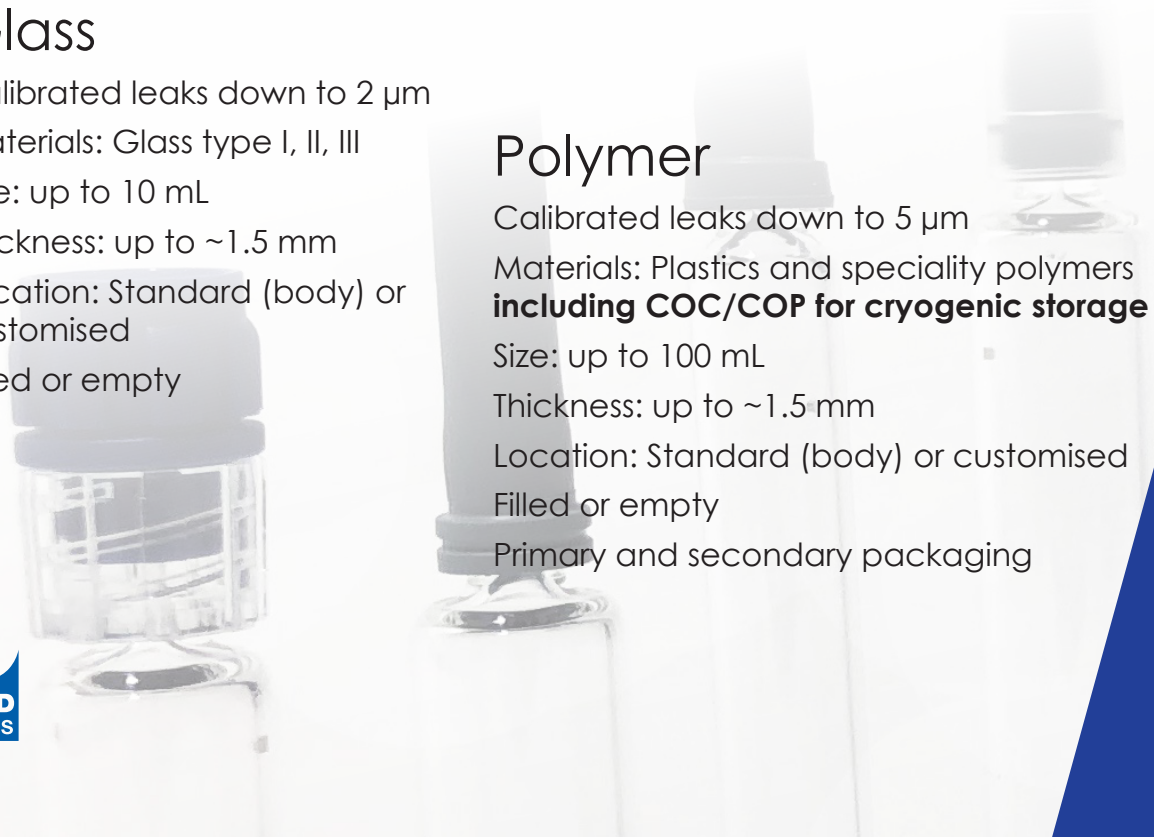
Size: up to 100 mL

Thickness: up to ~1.5 mm

Location: Standard (body) or customised

Filled or empty

Primary and secondary packaging



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Autoinjectors

We laser drill calibrated micro-holes directly into your autoinjector syringes and cartridges

Pre-filled Syringes (PFS)

Calibrated leaks down to 2 µm (glass cartridge only); down to 5 µm (fully assembled device)

Materials: Borosilicate Type 1 glass syringe, polymer window

Size: up to 5 mL syringes

Thickness: up to ~1.5 mm (glass)

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IV Bags - Flexible Plastics

Calibrated micro-holes laser drilled into flexible plastics including IV bags, sachets and pouches

Calibrated leaks down to 5 µm

Option: pinhole discs down to 2 µm

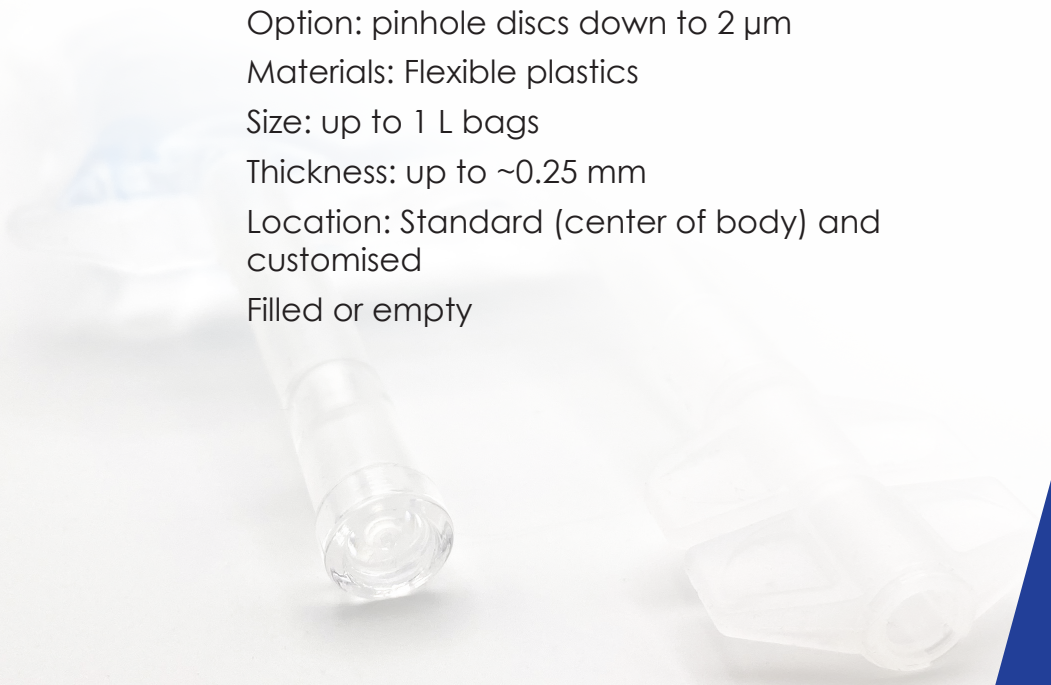
Materials: Flexible plastics

Size: up to 1 L bags

Thickness: up to ~0.25 mm

Location: Standard (center of body) and customised

Filled or empty



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Blister Packs

We laser drill calibrated micro-holes directly into your metal and polymer blister packs

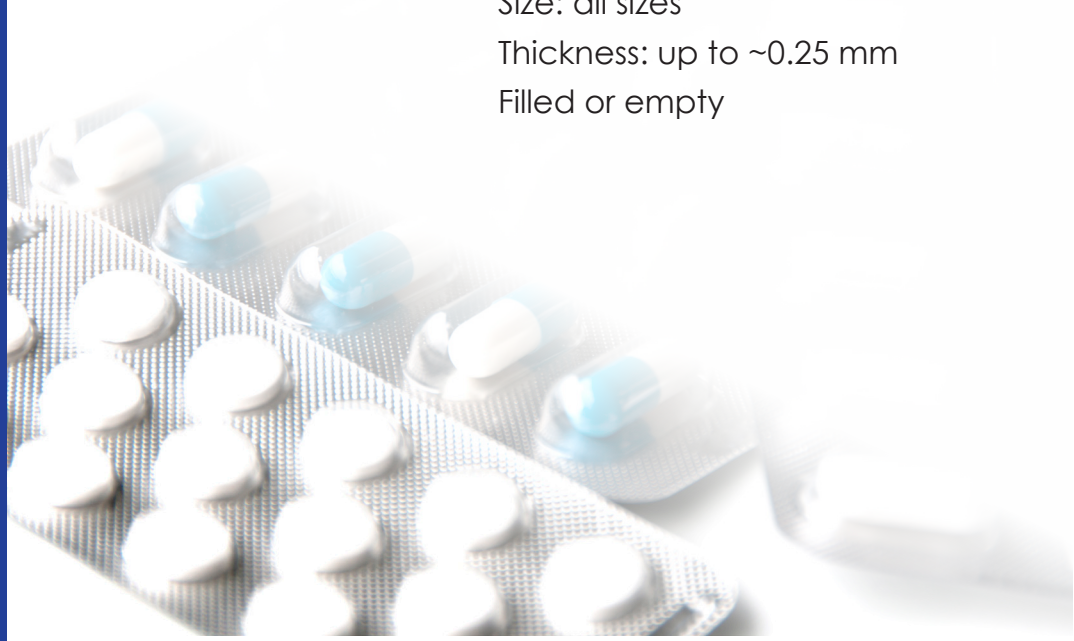
Calibrated leaks down to 5 µm

Materials: composite polymer and metal foils

Size: all sizes

Thickness: up to ~0.25 mm

Filled or empty



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Pinhole Discs

Calibrated micro-holes in stainless steel discs that you apply via a self-adhesive mount to your packaging when direct laser drilling into packaging is not practical. Commonly used for testing flexible packaging such as IV bags, blister packs, sachets and pouches.

- Manufactured from 50 µm thick, 316 stainless steel with 3 mm outer diameter
- Standard sizes 5, 10, 15, 20, 25, 30, 40, 50, 75, 100 µm holes available off the shelf
- Custom hole sizes (including 2 µm holes), outer diameters and thicknesses available upon request
- Certificate of conformity supplied free of charge for every hole size
- Blank discs available for process validation in line with GMP compliance

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Certificates of Conformity

CERTIFICATE OF CONFORMITY

Unit 8 | Moorbrook Park | Didcot | Oxfordshire | OX11 7HP | UK
Tel: +44 (0)1235 814433 | www.oxfordlasers.com

CUSTOMER INFORMATION

Name:	*** Customer Company Name ***
Purchase Order:	*** Customer PO Number ***

PART INFORMATION

Part Description:	Eg/ "2R glass vial to ISO 8362-1:2018"
Part ID:	*** Customer Part ID ***
Nominal Defect Diameter:	20 µm
Serial ID:	001
Comments:	Eg/ "Hole located in the centre of the body of the vial"

FLOW MEASUREMENT INFORMATION

Flow Effective Diameter:	19.6 µm
Diameter Uncertainty:	± 1 µm
Gas Type:	Air
Inlet Pressure:	1.004 bar
Outlet Pressure:	0.094 bar
Temperature:	20.8 °C
Measured Flow Rate:	3.3 ml/min
Flow Rate Uncertainty:	± 0.1 ml/min

CERTIFICATE INFORMATION

Certification ID:	Customer-Part-ID-20240101-020-001
Issue Date:	1st January 2024
Expiry Date:	1st January 2025
Technician:	A. Laser Technician
Signed:	*A. L. Technician*

These single-use parts are certified with 12 months' validity subject to storage within appropriate environmental conditions (eg/ temperature, cleanliness, vibration), handling per laboratory Best Practises and removal from their sealed packaging immediately prior to test.

All measurements presented on this certificate were performed on calibrated test equipment traceable to national standards.

We provide individual or batch certificates of conformity (CoC) for all our laser-drilled products. Validated via:

- Optical microscopy, or
- Flow effective diameter (FED) measurement
- Valid for one year

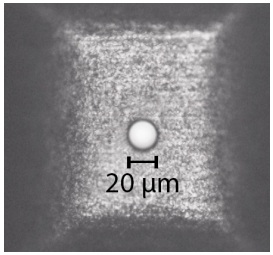
We provide you with a robust audit trail giving you full traceability, aligned with USP 1207, EU Annex 1 Best Practice guidelines and supporting FDA CGMP regulations.

Precise & Consistent

Not all laser-drilled holes are the same. Different laser-drilling methodologies can produce highly variable holes, shapes and profiles.

It is crucial to understand how these differences may affect your results across different CCI testing methodologies (e.g. blue dye ingress, vacuum/pressure decay, mass extraction, headspace analysis, HVLD, etc.), different testing equipment and operating conditions. Consistency is essential in achieving predictable, repeatable results.

Oxford Lasers creates precise and consistent micro-holes every time. For more than a decade, Oxford Lasers has used ultrafast lasers and developed a best practice micromachining technique which replicates the theoretical mathematical model defining the relationship between hole size and flow rate in USP 1207 as closely as possible to create dependable CCIT positive controls.



View down a laser-drilled square counerbore with a perfectly round hole in centre, with no stress cracking or carbonised debris.

Gases:

$$Flow = .01749 \times \frac{P_1}{29.7} \times \sqrt{\frac{29}{M.W.Gas}} \times Factor\#3 \times \sqrt{\frac{528}{Temp°R}} \times d_1^2$$

$$d_{1=} \sqrt{\frac{Flow}{0.1749 \times \frac{P_1}{29.7} \times \sqrt{\frac{29}{M.W.Gas}} \times Factor\#3 \times \sqrt{\frac{528}{Temp°R}}}}$$

USP 1207 theoretical mathematical model deriving relationship between hole size and flow rate.

What is a Positive Control?

A positive control is a testing sample that is created to generate an intended result. Positive controls are used in experiments to verify that the testing procedure is working as expected.

In CCI testing, a sample is created with defects (leaks) at a defined leak rate on purpose. It is then placed within the testing system to confirm the system is working correctly and therefore the equipment and the batch can be validated.

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Request a Quote - Order Now

Scan the QR code and request a quote or visit www.oxfordlasers.com/ccit-quote or email enquiries@oxfordlasers.com

We support CCIT quality programmes and ship across the globe.

Contact us

United Kingdom
Oxford Lasers Ltd
8 Moorbrook Park
Didcot, Oxfordshire
OX11 7HP, United Kingdom
+44 (0) 1235 810088

USA
Oxford Lasers Inc.
2 Shaker Rd., Unit A101
Shirley, MA 01464, USA
+1 800 222 3632 (Toll free)
+1 978 425 0755

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