

LUMEA BxChip™

COST SAVING SOLUTION | DECREASED WORKLOADS |
REDUCED FRAGMENTATION

Needle Core Biopsy Processing - The Conventional Methodology

Needle core biopsies are used to understand the features of a tumour and determine the most effective treatment, whilst minimising patient discomfort and reducing the need for more invasive surgery. Organs which may be subject to needle core biopsy include prostate, breast, kidney, spleen, liver, lung and bone marrow. Needle core biopsies are taken from the body using a biopsy gun. Following the removal procedure, the tiny delicate samples are placed in formalin and sent to the laboratory for processing and analysis.

Within the histology laboratory these friable samples typically require special treatment to preserve their structure and integrity. Most patients will have multiple biopsies taken at once, resulting in a large workload for the laboratory, the use of large quantities of consumables and expensive labour costs.

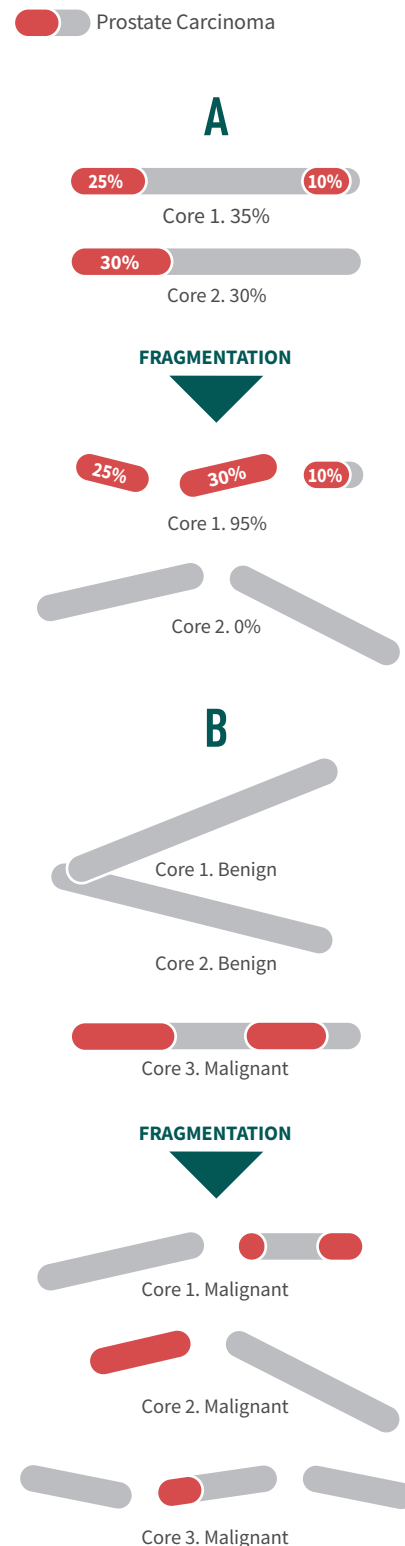
As well as the extensive consumables cost and labour required to process needle core biopsies, the delicate nature of the sample also means there is potential for biopsies to be damaged or lost during manual handling or processing. Cores containing cancer have a high gland to stromal ratio which makes them more likely to break into smaller fragments. This can cause problems with tissue loss and compromise diagnostic accuracy.

The smaller pieces of tissue broken from the already tiny cores are more likely to be lost during processing and, if retained, become more difficult to manipulate. When fragmentation occurs whilst multiple cores are processed together it may become difficult to ascertain which cores originally contained cancerous cells if the pieces of tissue become mixed (Murugan et al, 2019). As shown in Figure 1, this could lead to assuming there is a concentration of cancer in one core which is actually spread across several, or vice versa.

Conventional processing methods do not typically allow for the sample to be correctly oriented which can be a further useful source of diagnostic information. The opportunities for misdiagnosis, and consequently inefficient treatment, when the quality of diagnostic information is compromised increase. The importance of preserving tissue core quality by preventing fragmentation, and processing tissue in the correct orientation has many benefits for Pathologists, and consequently patients. Diagnosis will be easier, treatment plans will be more accurate and the chance of recall for incomplete samples is minimised. To assist laboratories with their aim of achieving greater laboratory efficiency and diagnostic accuracy, CellPath Ltd are pleased to offer the LUMEA BxChip™.



Figure 1. Misdiagnosis can occur when cores fragment during processing (Murugan et al, 2019)

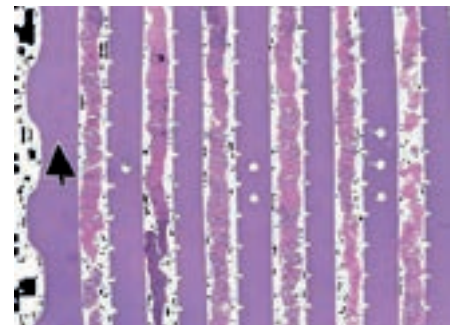


Processing 6 cores simultaneously allows for significant cost savings on consumables.

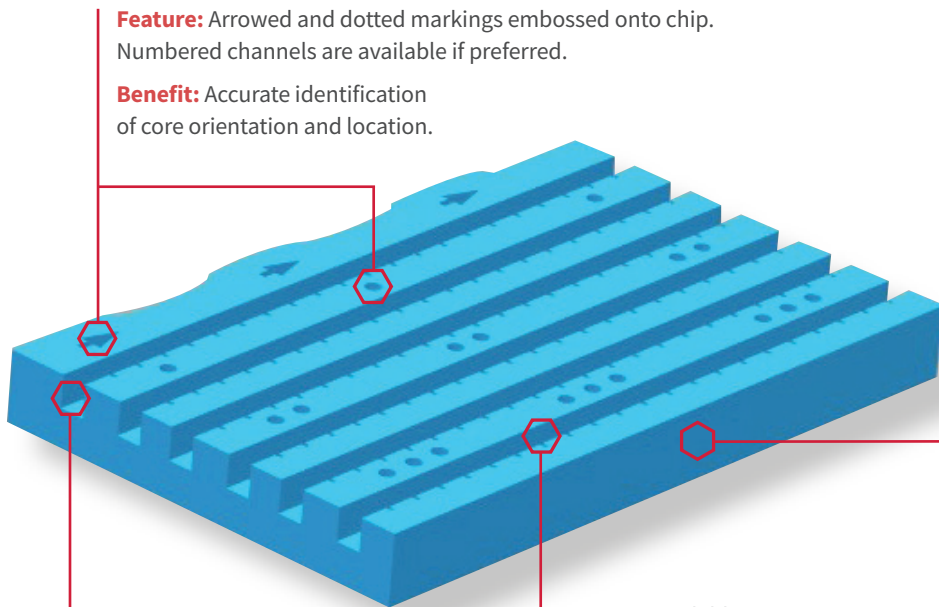


The BxChip™ Key Features and Benefits

The BxChip™ depicted below is the EBS-BxC 001, 6 core, dotted design. Various other chip designs are available as described.



Using the BxChip™, more tissue can be seen under the microscope.



Feature: Arrowed and dotted markings embossed onto chip. Numbered channels are available if preferred.

Benefit: Accurate identification of core orientation and location.

Feature: Matrix made from biomimetic material.

Benefit: Can be safely sectioned on the microtome without damaging the blade or specimen.

Feature: The single packaged BxChip™ is coloured blue.

Benefit: Provides high contrast against pale specimens.

Feature: BxChip™ incorporates linear channels.

Benefit: Holds samples safely and securely, aiding diagnosis by minimising fragmentation.

Feature: Available in a range of gauge sizes.

Benefit: BxChip™ can accommodate an 18 gauge needle biopsy - the most common gauge for prostate biopsies (Wan *et al*; 2015), as well as 12, 14 and 16 gauge needle core biopsies for other tissues.



Case Study - University Hospital of North Durham

The University Hospital of North Durham in North East England serves a local population of more than 250,000 people. They were the first users of the BxChip™ in the United Kingdom. The implementation of the chip was led by Dr Mitul Sharma, Consultant Pathologist, and Andrew Munro, Deputy Laboratory Manager.

What inspired you to use the BxChip™?

We were definitely looking for an alternative method to what we were using. We were handling samples too many times and increasing our risk of picking up the wrong cassette which meant patient samples could be transposed. That's what led us to try the chip.

What sort of savings have you noticed since using the BxChip™?

We worked out that we save £1,400 on consumables per annum. Even though the chips appear costly, we're now using less consumables such as slides. However, the time saved by the BMS and the Pathologist is probably the biggest saving.

Do you think the chip has reduced fragmentation at all?

I would say yes. When the prostate cores were placed in our previous 5-well cassette, they had more room to move around and break or separate, but when they go into the channels of the chip, the sponge goes on top of them, resulting in less movement for them to break up. Generally, they are now consistently in one piece.

Have you faced any challenges during the implementation of the BxChip™?

There's a bit of a learning curve for the microtomists and the pathologists. Our lab has quite a mix of both experienced and inexperienced staff. The more experienced microtomists were happy with knowing how far to cut into these chips whereas some of the less experienced staff took a bit longer to be confident that they were going far enough

into the chip getting the balance right between a full face section, but not too deep. For the pathologists, I think the main concern was that they weren't always confident that we'd gone deep enough in. We're currently trialling staining cores and chips with carbol fuchsin to counteract this issue.

Taking your advice on board, is the BxChip™ something you would recommend to others?

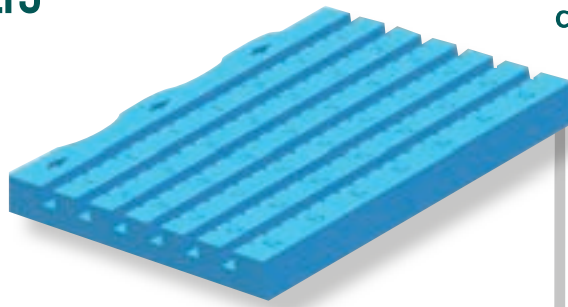
Yes, I would. Some hospitals embed one core per block leaving them with 10 or 12 blocks which must create a nightmare...with more than 30 slides per prostate case - compared with the 4 that we currently produce. If they can get to that level of reducing their slide use that would be an even bigger bonus.

Benefiting the Patient Whilst Reducing Laboratory Costs - Evidence

In a recent publication in the American Journal of Clinical Pathology, researchers from the University of Minnesota, Minneapolis, compared a standard protocol for processing six prostate biopsies with a new protocol using the BxChip™ and found significant savings could be made.

SUMMARY OF RESULTS

- 1 Using the BxChip™ is cheaper than conventional processing
- 2 Less time is needed at all stages of biopsy processing when the BxChip™ is used
- 3 Patients benefit from greater average intact core length after processing



Reducing the cost of processing

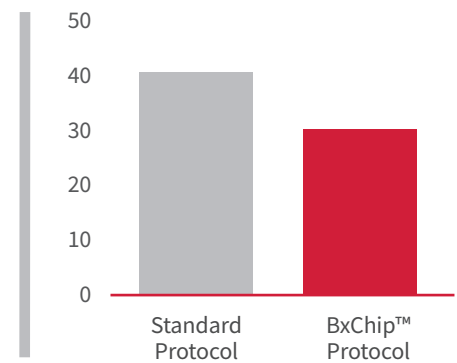
Cost analysis consistently shows BxChip™ users save money due to the reduced quantities of consumables they need and reduced labour costs. A recent study conducted by a team at the University of Minneapolis compared using the BxChip™ to process 6 cores simultaneously with a standard protocol in which each core was embedded individually. Murugan et al (2019) found that users could save over 26% of the costs associated with biopsy processing by choosing the chip over a standard protocol.

Reducing time required

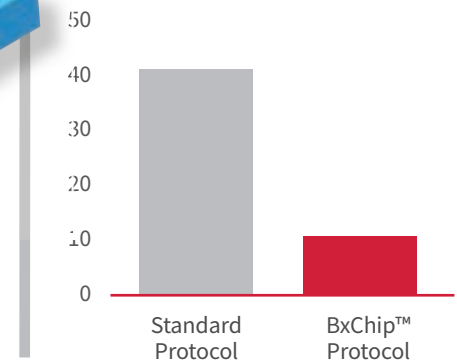
The team also found that significant time savings could be made throughout all stages of protocol when the BxChip™ was used, instead of a standard method. For example, embedding time reduced from 6.25 to 1.06 minutes and sectioning time reduced from 23.02 to 6.23 minutes. Time could even be saved by pathologists with the slide reading stage reduced from 7.72 to 5.00 minutes. The BxChip™ is much easier to manipulate than individual biopsies and their excellent specimen security means biopsies do not fall out during the minimal handling required.

Increasing core length

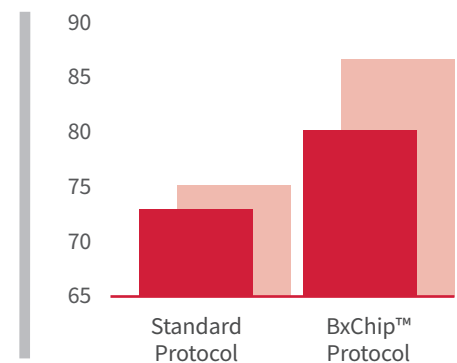
Murugan et al (2019) found that using the BxChip™ meant non-linear fragmentation was eliminated and linear fragmentation was greatly reduced. With this method, processed biopsies also have a longer intact core length than when a standard protocol is used. Results also showed that both benign and malignant cores were significantly longer, though there was no difference in the incidence of cancer detected. Longer intact cores contain the most diagnostic information meaning patients benefit from the use of the BxChip™.



Cost per core



Time per core



Intact core length

- Intact core length - malignant
- Intact core length - benign

BxChip™ Product Options

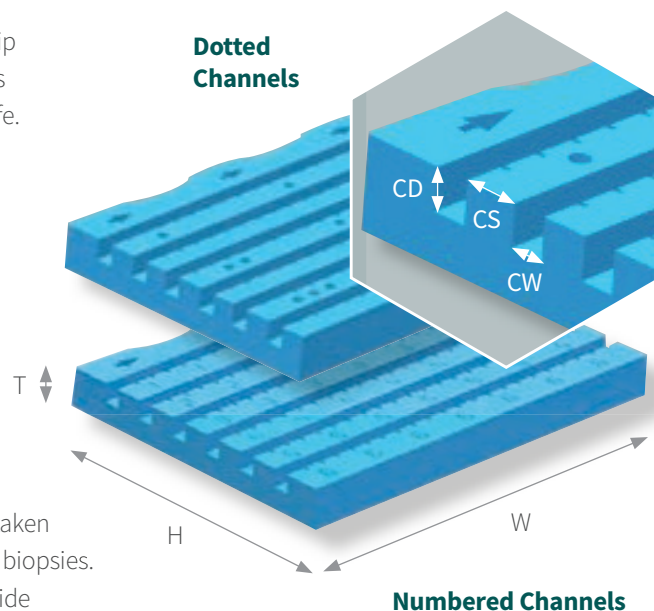
Fixative - The BxChip™ is supplied sterile, in either a small volume of low concentration formalin or sterile saline to prevent contamination of the chip prior to opening. Typically, laboratories work with formalin-based products whereas theatres work with sterile saline. All chips have a 12 month shelf life.

Core Biopsy Gauge - To accommodate the various needs of different practitioners and the requirements of different biopsy types there are a range of needle gauges which can be accommodated by the BxChip™, including 12, 14, 16 and 18 gauge.

Channel Identification Method - Each channel in the chip can be easily identified by use of either dotted or numbered markers (see diagram right). This ensures traceability of each core is maintained throughout, and also aids in orientation.

Pack Size - Single packs contain one chip. Double or triple packs can be used for undertaking prostate fusion biopsies, where samples are taken from either hemisphere of the prostate as well as additional targeted core biopsies. Double packed chips come in a box of 5 sealed packets with two chips inside each packet (blue and green) and are provided with 10 cassettes – 1 per chip. Triple packed chips are provided in 3 boxes – 2 boxes each contain 5 packs of 2 chips (blue and green) and 1 box contains 10 packs of the third chip (aqua), 30 cassettes are provided with these.

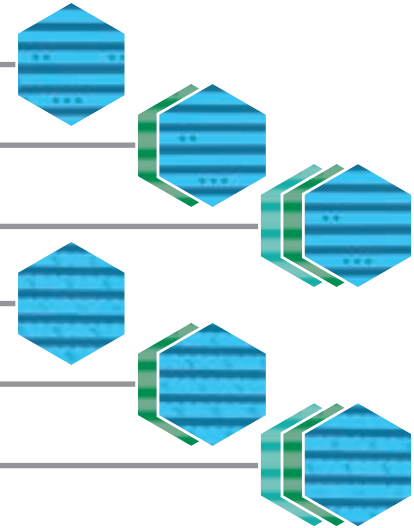
Colour - Chips are available in blue which provides excellent contrast for pale specimens. If a twin or triple pack is purchased, the chips will each be a different colour – twin containing blue and green, and triple containing blue, green and aqua.



Legend			
Chips	Chips Per Pack	T	Thickness
Packs	Packs Per Box	CD	Channel Depth
W	Width	CW	Channel Width
H	Height	Units	Millimetres
CS	Channel Separator		

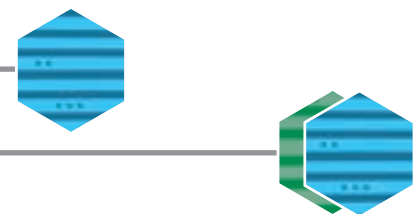
Gauge 18

Item Code	Chips	Packs	W	H	CS	T	CD	CW	Packed In
EBS-BxC 001	1	10	22	14	1.3	2.2	0.95	0.8	Formalin
EBS-BxC 001s	1	10	22	14	1.3	2.2	0.95	0.8	Saline
EBS-BxC 002	2	5	22	14	1.3	2.2	0.95	0.8	Formalin
EBS-BxC 002s	2	5	22	14	1.3	2.2	0.95	0.8	Saline
EBS-BxC 003	3	10	22	14	1.3	2.2	0.95	0.8	Formalin
EBS-BxC 003s	3	10	22	14	1.3	2.2	0.95	0.8	Saline
EBS-BxC 005	1	10	22	15.8	1.6	2.2	0.95	0.8	Formalin
EBS-BxC 005s	1	10	22	15.8	1.6	2.2	0.95	0.8	Saline
EBS-BxC 005.2	2	5	22	15.8	1.6	2.2	0.95	0.8	Formalin
EBS-BxC 005.2s	2	5	22	15.8	1.6	2.2	0.95	0.8	Saline
EBS-BxC 005.3	3	10	22	15.8	1.6	2.2	0.95	0.8	Formalin
EBS-BxC 005.3s	3	10	22	15.8	1.6	2.2	0.95	0.8	Saline



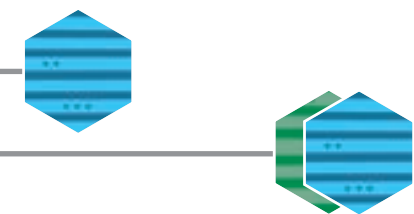
Gauge 16

Item Code	Chips	Packs	W	H	CS	T	CD	CW	Packed In
EBS-BxC 300	1	10	22	17.7	1.2	2.2	1.29	1.2	Formalin
EBS-BxC 300s	1	10	22	17.7	1.2	2.2	1.29	1.2	Saline
EBS-BxC 302	2	5	22	17.7	1.2	2.2	1.29	1.2	Formalin
EBS-BxC 302s	2	5	22	17.7	1.2	2.2	1.29	1.2	Saline



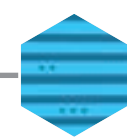
Gauge 14

Item Code	Chips	Packs	W	H	CS	T	CD	CW	Packed In
EBS-BxC 100	1	10	22	19.4	1.2	2.7	1.6	1.6	Formalin
EBS-BxC 100s	1	10	22	19.4	1.2	2.7	1.6	1.6	Saline
EBS-BxC 102	2	5	22	19.4	1.2	2.7	1.6	1.6	Formalin
EBS-BxC 102s	2	5	22	19.4	1.2	2.7	1.6	1.6	Saline



Gauge 12

Item Code	Chips	Packs	W	H	CS	T	CD	CW	Packed In
EBS-BxC 200	1	10	22	21.6	1.2	3	2.16	2.16	Formalin
EBS-BxC 200s	1	10	22	21.6	1.2	3	2.16	2.16	Saline



Double pack contains:
 1 x Blue chip
 1 x Green chip

Triple pack contains:
 1 x Blue chip
 1 x Green chip
 1 x Aqua chip

References and Further Reading

Cancer Research UK. (2019). What is Prostate Cancer? [Online] Available at: <https://about-cancer.cancerresearchuk.org/about-cancer/prostate-cancer/about> [Accessed 8 August 2019].

Fairgreaves, S. (2019). Needle core biopsies: ease and efficiency of processing with LUMEA BxChip. *Pathology in Practice*, 20(6), 55-57.

Fairgreaves, S. (2019). Shining a Light on Small Biopsy Handling. [Blog] Fixation on Histology. Available at: <https://www.fixationonhistology.com/post/small-biopsy-handling> [Accessed 16.03.20]

Farcas, C.P., Spînu, A.D., Petrescu, A., Dumitrescu, M., Vasilescu, F., Musat, S., Dinu, M., Mischianu, D. (2014). High throughput processing and analysis of prostate core biopsies for research applications, *Romanian Journal of Urology*, 13(3), p.9.

Murugan, P., Shukla, D., Morocho, J., Smith, D., Sciacca, D., Pickard, M., Wahlsten, M., Gunderson, A., Konety, B., Khalifa, M.A., Warlick, C. (2019). Prostate Biopsy Processing An Innovative Model for Reducing Cost, Decreasing Test Time, and Improving Diagnostic Material, *American Journal of Clinical Pathology*, 152(6), pp.757-765.

Radavoi, D., Petrescu, A., Berdan, A., Manea, N., Tanase, F., Braticevici, B., Musat, S., Jinga, V. The use of multiplex biopsies as a cost-effective method in the diagnostic of prostate cancer- EAU 2014, 29th Annual European Association Of Urology Congress, 11-15 April 2014, Stockholm, Sweden.

Shukla, D., Morocho, J., Smith, D., Sciacca, D., Pickard, M., Wahlsten, M., Gunderson, A., Thompson, A., Warlick, C., Murugan, P. Prostate Biopsy Processing: An Innovative Model for Reducing Cost, Test Time and Improving Diagnostic Material, 107th Annual Meeting of the United States and Canadian Academy of Pathology, 17-23 March 2018, Vancouver, BC, Canada.

Wan, B., Li, C., Wang, J., Zhao, W., Fu, Q., Zhang, K. (2015). Diagnostic yield and complications using a 20 gauge prostate biopsy needle versus a standard 18 gauge needle: a randomized controlled study. *Urology Journal*, 12(5), pp.2329-2333.

Based in the UK, CellPath Ltd is a manufacturer and distributor of pathology consumables, instruments & services.

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