



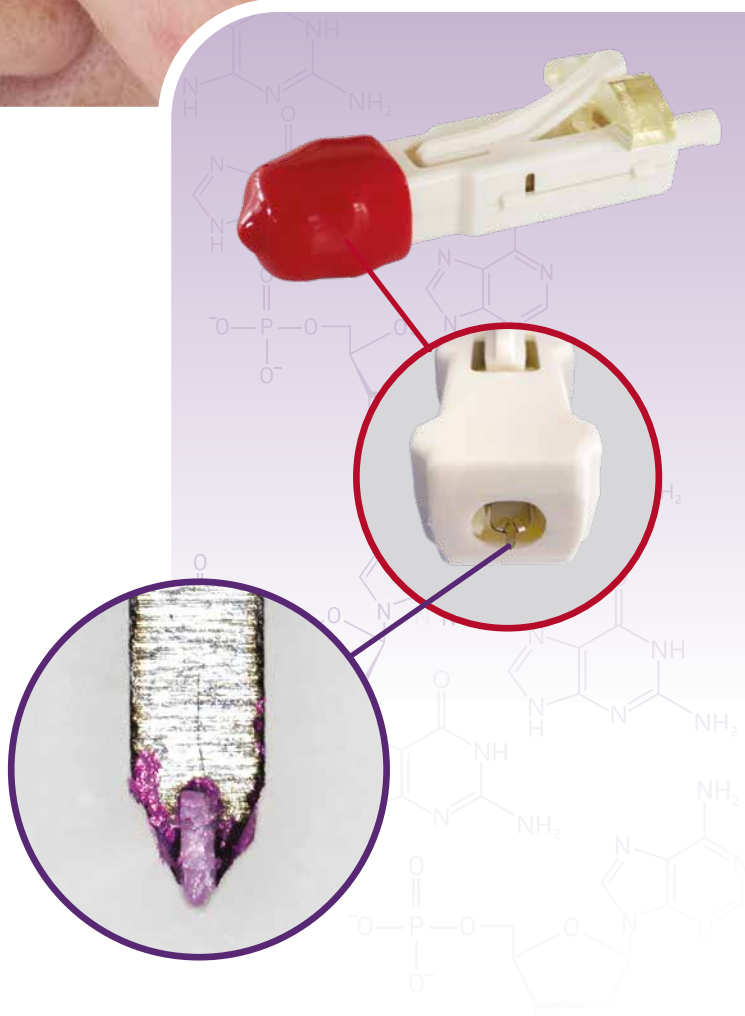
A Skin Microsampling Solution

Harpera[™] Microbiopsy[™] Punch (IUO)

What is Microbiopsy™?

The patented Microbiopsy™ technology is at the heart of the Harpera™ Microbiopsy™ Punch, featuring a Microbiopsy collector crafted from high-precision laser-cut stainless steel.

The Microbiopsy collector is designed for virtually pain-free skin sampling, collecting thousands of skin cells in a single punch. The handle allows safe and easy manipulation during the sampling procedure and the retrieval of the Microbiopsy specimen.



Key Features

- **Microbiopsy collector**
Crafted from precision laser-cut stainless steel
- **Ergonomic handle**
Lightweight, for effortless handling
- **Sterile**
Gamma irradiation sterilization process
- **Safety cap and insert**
For enhanced protection during handling and disposal
- **Tyvek sterile pouch**
Individually wrapped
- **Packaging convenience**
In dispensing box of 20 units

Benefits of Microbiopsy

Minimally invasive

The Microbiopsy punch design offers a virtually painless, suture-free experience, ideal for collecting specimens in sensitive areas, such as the face.

Ease of use

Designed with a controlled punch for easy sampling and safe handling before and after the procedure. The Harpera facilitates specimen collection in the clinic or out in the field.

Precision sampling

Collects specimens within and at vicinity of targeted site. Suitable for all topical sampling procedures.

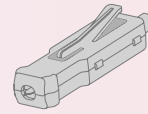
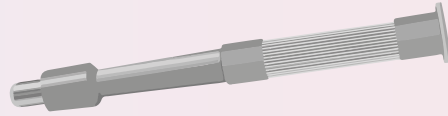
Versatility

Offering an advanced method for collecting specimens in various environments. Suitable for a range of clinical and research dermatology applications.










Facilitate rapid, suture-free, virtually painless skin biopsy procedures

Comparison of Traditional Biopsy vs. Microbiopsy Punch



Traditional Biopsy Punch

Harpera Microbiopsy Punch

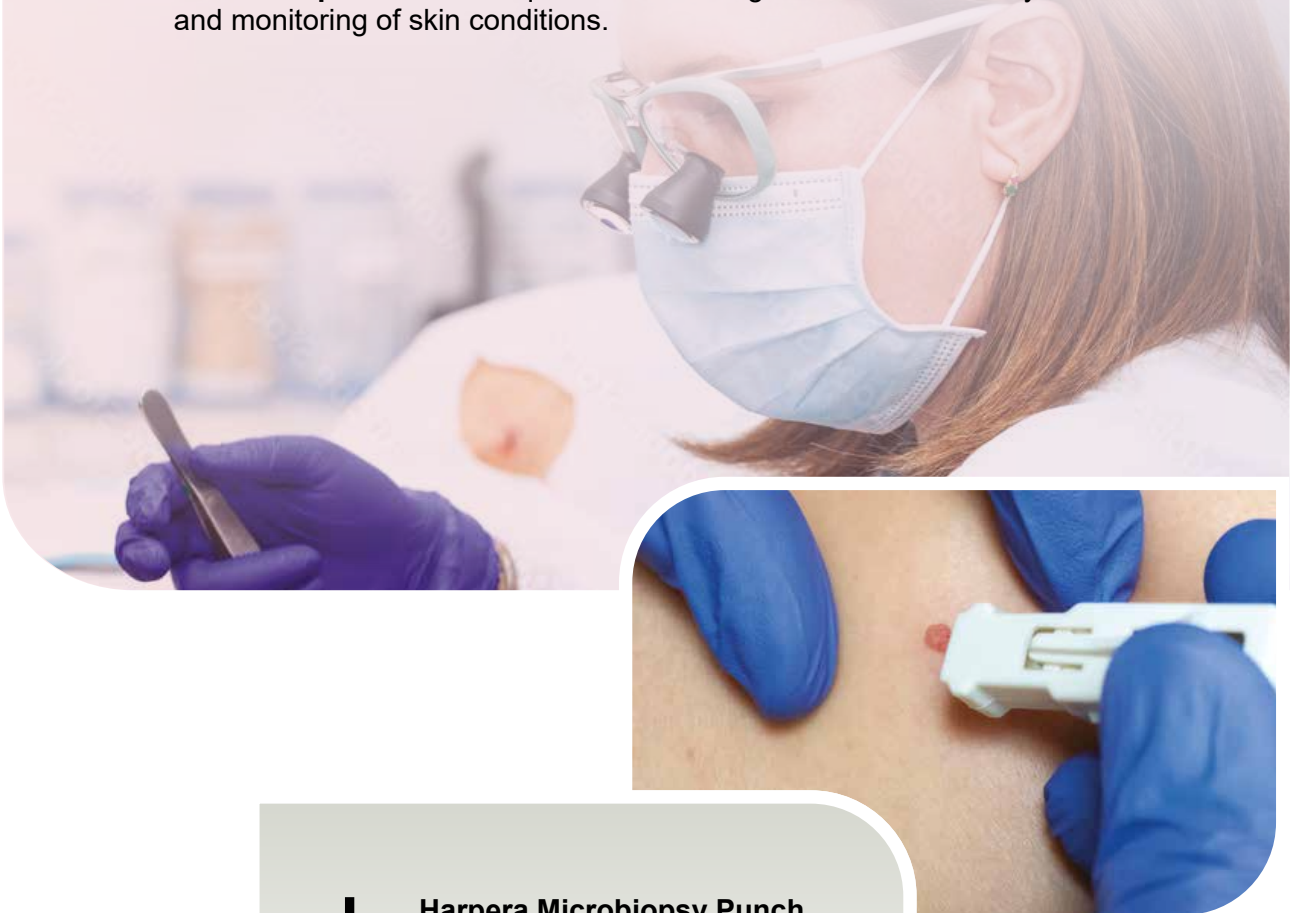
 Invasiveness	Requires cutting a ø3-6 mm piece of skin tissue	Collects a micro specimen, with a small puncture (0.1 x 0.5 mm)
 Procedure time	Takes about 15-30 minutes	Takes few seconds
 Pain level	Typically requires local anesthesia	Does not require anesthesia
 Wound care	Requires stitches and/or wound dressing	No stitches, minimal wound No scar
 Recovery	Recovery time can be several days to weeks, depending on the biopsy site	Faster healing, typically within a few days
 Cost	Physician and nurses required to perform procedure 30 USD of materials 80 USD for whole procedure ¹	Any healthcare provider (i.e. nurse) can perform procedure 20 USD in materials Est. 30 USD for whole procedure
 Frequency	Not suited for multiple biopsies in narrow time window	Suited for frequent sampling at one site and/or over time

¹ Matsumoto, M., *et al.* (2018). "Estimating the cost of skin cancer detection by dermatology providers in a large health care system." *J Am Acad Dermatol* 78(4): 701-709 e701.

Unleash the Potential of Skin Microbiopsy

For dermatologists and other researchers who struggle to consistently and accurately evaluate skin conditions in a minimally invasive manner, the Harpera Microbiopsy Punch has the potential to provide a virtually painless way to routinely & precisely collect skin specimens for targeted biomarker analysis and other studies.

- **Facilitate Recruitment to Clinical Studies:** Rapid collection with minimally invasive device. Minimal discomfort, even on cosmetic and sensitive areas.
- **Economical:** Eliminate complex processes associated with skin biopsy such as anesthesia during sample collection, and wound suturing post-procedure.
- **Fit-for-Purpose:** Meets requirements for targeted biomarker analyses and monitoring of skin conditions.



FACT

Harpera Microbiopsy Punch provides a highly efficient and minimally invasive skin biopsy solution particularly suited for modern molecular analytical techniques.

Microbiopsy. Poised to revolutionize dermatological research.



Skin cancer

Jain, M., *et al.* (2022). "Minimally invasive microbiopsy for genetic profiling of melanocytic lesions: A case series." [*J Am Acad Dermatol* 87\(4\): 903-904.](#)

Sobarun, P., *et al.* (2017). "Microbiopsy Biomarker Profiling in a Superficial Melanoma Resembling a Pigmented Basal Cell Carcinoma." [*JAMA Dermatol* 153\(4\): 334-336.](#)

Dermatology Research Centre, School of Medicine The University of Queensland (March 2016), "Natural history and properties of naevi in advanced melanoma patients receiving treatment", [CTRN 12616000272493 \(ANZCTR\)](#)

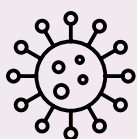
Tan, J.-M., *et al.* (2015). "BRAFWild-Type Melanoma in Situ Arising In a BRAFV600E Mutant Dysplastic Nevus." [*JAMA Dermatology* 151\(4\).](#)



Skin disorders

Preis, S., *et al.* (2022). "Munich atopy prediction study (MAPS): protocol for a prospective birth cohort addressing clinical and molecular risk factors for atopic dermatitis in early childhood." [*BMJ Open* 12\(9\): e059256.](#)

Yamada, M., *et al.* (2020). "Microbiopsy-based minimally invasive skin sampling for molecular analysis is acceptable to Epidermolysis Bullosa Simplex patients where conventional diagnostic biopsy was refused." [*Skin Res Technol.*](#)



Infectious skin disease

Van Henten, S., *et al.* (2024). "Evaluation of Less Invasive Sampling Tools for the Diagnosis of Cutaneous Leishmaniasis." [*Open Forum Infect Dis* 11\(4\): ofae113.](#)

Carter, E., *et al.* (2023). "A feasibility study of controlled human infection with intradermal Bacillus Calmette-Guerin (BCG) injection: Pilot BCG controlled human infection model." [*Wellcome Open Res* 8: 424.](#)

Liverpool School of Tropical Medicine (2023). "Using BCG Vaccine to Understand Tuberculosis Infection", [NCT05820594 \(ClinicalTrials.gov\)](#)

Cloots, K., *et al.* (2021). "Assessing L. donovani Skin Parasite Load: A Proof of Concept Study of a Microbiopsy Device in an Indian Setting." [*Front Cell Infect Microbiol* 11: 645121.](#)

Owen, S. I., *et al.* (2021). "Evaluation of qPCR on blood and skin microbiopsies, peripheral blood buffy coat smear, and urine antigen ELISA for diagnosis and test of cure for visceral leishmaniasis in HIV- coinfected patients in India: a prospective cohort study." [*BMJ Open* 11\(4\): e042519.](#)

Churiso, G., *et al.* (2020). "Minimally Invasive Microbiopsies as an Improved Sampling Method for the Diagnosis of Cutaneous Leishmaniasis." [*Open Forum Infect Dis* 7\(9\): ofaa364.](#)

Kirstein, O. D., *et al.* (2017). "Minimally invasive microbiopsies: a novel sampling method for identifying asymptomatic, potentially infectious carriers of Leishmania donovani." [*Int J Parasitol* 47\(10-11\): 609- 616.](#)



General dermatology

Primiero, C. A., *et al.* (2024). "Skin 2.0: How Cutaneous Digital Twins Could Reshape Dermatology." [*J Invest Dermatol.*](#)

Haderl E (2021). Innovations in translational research in dermatology: minimally invasive methods for biosample acquisition. [*Dermatol Online J.* 2021 Oct 15;27\(10\).](#)

Michele Fimiani, P. R., Elisa Cinotti (2020). Technology in Practical Dermatology, [Springer Cham.](#)

Lei, B. U. W., *et al.* (2019). "Absorbent Microbiopsy Sampling and RNA Extraction for Minimally Invasive, Simultaneous Blood and Skin Analysis." [*JoVE*\(144\): e58614.](#)

Lin, L. L., *et al.* (2013). "Microbiopsy engineered for minimally invasive and suture-free sub-millimetre skin sampling." [*F1000Res* 2: 120.](#)

Want more?

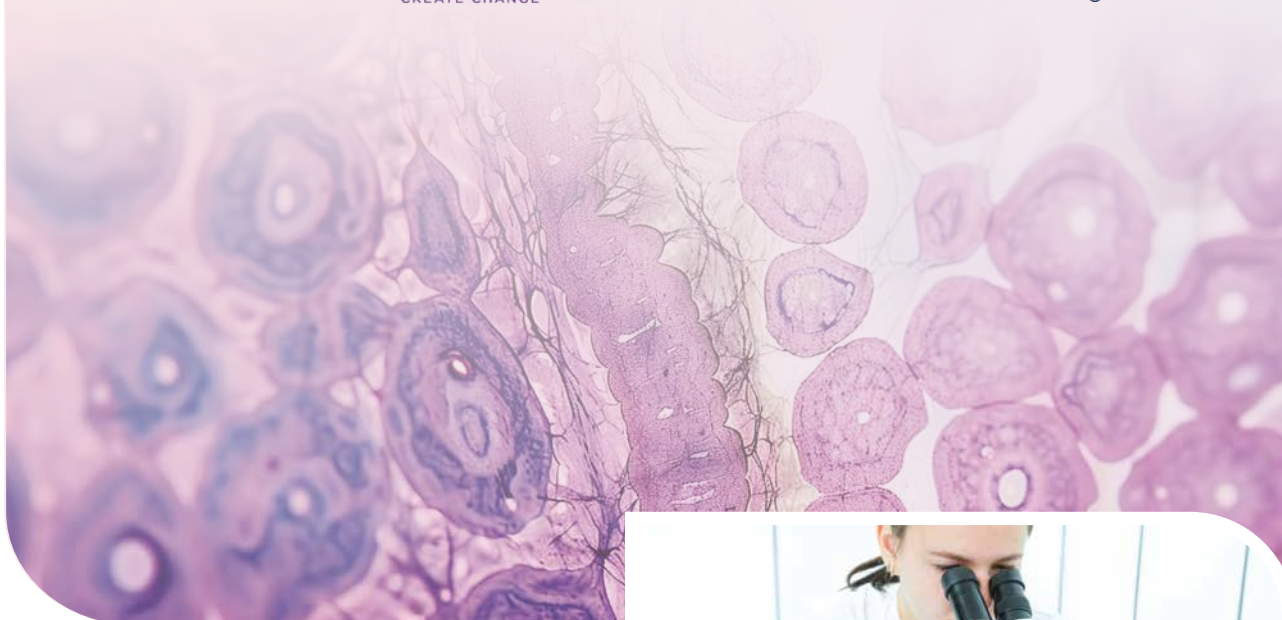
Access the full list of journal articles at:

www.neoteryx.com/harpera-micro-skin-biopsy

Are you conducting human research studies or clinical trials?

The aim of making Harpera devices available to the clinical research community is to continue assessing this microsampling device's utility for dermatological applications and to understand the benefits of Microbiopsy technology use through controlled and diverse clinical investigations. Harpera Microbiopsy Punch (IUO) offers staff and participants the ease and satisfaction of a non-surgical skin biopsy method.

Trajan partners with researchers at top organizations on studies applying Harpera.



**Visit the Harpera
resource page**

Harpera Microbiopsy Punch (IUO)



Intended Use

The Harpera Microbiopsy Punch for investigational use only (IUO) is intended to enable the collection of a specimen from the cutaneous skin surface by a healthcare professional for clinical studies.

Product Description

The Harpera device is a single-use manual microbiopsy punch, a hand-held disposable device intended to achieve a controlled skin puncture in order to obtain a specimen. The punch is supplied individually packaged and has been subjected to gamma irradiation.

Compliance Certification

The Harpera Microbiopsy Punch is manufactured according to ISO 13485:2016 and is supplied for investigational use only (IUO).

Technical Data

Product Features	
Specimen type	Cellular material from the cutaneous skin surface
Format	Harpera Microbiopsy Punch alone, in a Tyvek pouch
Sterilization process	Gamma irradiation at 25 kGy
Number of specimens collected	1
Maximum penetration depth	1.2 mm
Shelf life	12 months
Materials and Colors	
Device	Nylon 6 (white) with red safety cap and yellow safety insert
Microbiopsy collector	304 Stainless Steel
Dimensions	
Microbiopsy collector	L 10 mm x W 5 mm x H 0.15 mm
Device	L 65 mm x W 17 mm x H 18 mm
Unit (device in Tyvek pouch)	L 130 mm x W 185 mm x H 18 mm
Units/box	20 units in a dispensing box, L 166 mm x W 194 mm x H 103 mm

Visit us at www.neoteryx.com or contact your regional Trajan representative for assistance and further information.

The Harpera™ Microbiopsy™ Punch is intended to enable the collection of a specimen from the cutaneous skin surface by a healthcare professional for clinical studies and is currently supplied globally as an investigational use only (IUO) product. The performance characteristics of this device have not been fully validated. Subject to Trajan's Terms & Conditions, which may be viewed at www.neoteryx.com/site-terms-of-use-neoteryx. Neoteryx® is a registered trademark owned by Trajan Scientific Australia Pty Ltd. Harpera™ and Microbiopsy™ are trademarks owned by Trajan Scientific Australia Pty Ltd.

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Trajan is a global developer and manufacturer of analytical and life sciences products and devices founded to enrich personal health through scientific tools and solutions. We aim to support science that benefits people. Trajan's products and solutions are used in the analysis of biological, food, and environmental samples. Trajan has a portfolio and pipeline of new technologies which support the move towards decentralized personalized data-based healthcare. Trajan has manufacturing and operational sites in multiple locations across the US, Australia, Europe and Asia.