



A Skin Microsampling Solution

Harpera[™] Microbiopsy Tool (IUO)

Harpera™ — The Minimally Invasive Microbiopsy Alternative to Traditional Biopsy in your Clinical Studies



Trajan Scientific and Medical has developed a novel microbiopsy tool – the Harpera™ - that enables the collection of skin specimens using a minimally invasive method. The Harpera tool is currently in development and available as an Investigational Use Only (IUO) product and its design is intended to offer a minimally invasive, suture-free, and virtually painless option for scarless skin microbiopsy.

The small size and portability of the Harpera tool make it a user-friendly departure from conventional skin biopsy. Initial clinical performance studies indicate that no anesthesia or post-biopsy suturing is required during or after the Harpera microbiopsy procedure.

Photo enlargement of the unfolded stainless steel microbiopsy collector containing skin cells (with augmented specimen color).

The Harpera tool in development may offer potential benefits for clinical study applications, based on the clinical experience reported from our research collaborators:

- No body site preparation (anesthesia)
- Rapid skin specimen collection
- Portability and simplicity
- Small puncture site (0.5 x 0.15 mm)
- Topical sampling
- Minimal penetration (≤ 1.2 mm depth)
- No body site post-sampling treatment
- Local erythema resolved within 24 hours
- Suited for multiple sampling on one site*
- Suited for frequent sampling over time*
- Enables sampling in sensitive areas
- Sampling from a variety of cohorts

**Using multiple single-use Harpera tools.*



Biopsies taken with the Harpera tool have been used in different testing methodologies but the tool appears to be particularly suited for modern molecular techniques.

Are you conducting human research studies or clinical trials?

The aim of making Harpera available to the clinical research community is to continue the assessment of this microsampling tool's utility for dermatological applications and to understand any limitations of the tool's use through controlled and diverse clinical investigations. Your research or clinical staff may also appreciate the ease of use of the Harpera tool (IUO) in clinical research.

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



Have you seen our Harpera microbiopsy case studies in the literature?

The following publications highlight clinical studies evaluating the performance of the Harpera microbiopsy tool (IUO) to collect specimens from various skin abnormalities:

Skin Cancer

1. Banan, P., et al. (2013). "Effects of ex vivo skin microbiopsy on histopathologic diagnosis in melanocytic skin lesions." [JAMA Dermatol 149\(9\): 1107-1109.](#)
2. Prow, T. W., et al. (2013). "The opportunity for microbiopsies for skin cancer." [Future Oncol 9\(9\): 1241- 1243](#)
3. McClenahan, P., et al. (2014). "BRAFV600E mutation status of involuting and stable nevi in dabrafenib therapy with or without trametinib." [JAMA Dermatol 150\(10\): 1079-1082](#)
4. Tan, J.-M., et al. (2015). "BRAFWild-Type Melanoma in Situ Arising In a BRAFV600E Mutant Dysplastic Nevus." [JAMA Dermatology 151\(4\).](#)
5. Dermatology Research Centre, School of Medicine The University of Queensland (March 2016),
["Natural history and properties of naevi in advanced melanoma patients receiving treatment", ACTRN 12616000272493 \(ANZCTR\)](#)
6. Sobarun, P., et al. (2017). "Microbiopsy Biomarker Profiling in a Superficial Melanoma Resembling a Pigmented Basal Cell Carcinoma." [JAMA Dermatol 153\(4\): 334-336.](#)
7. 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.](#)

Skin Disorders

8. 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.](#)

Inflammatory Skin Disease

9. 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.](#)

Infectious Skin Disease

10. Tom, L. N., et al. (2016). "Skin microbiopsy for HPV DNA detection in cutaneous warts." [J Eur Acad Dermatol Venereol 30\(12\): e216-e217.](#)
11. 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.](#)

12. 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.](#)
13. 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.](#)
14. Cutaneous Leishmaniasis diagnostics: microbiopsy device for minimally invasive sampling - [YouTube](#)
15. 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- coinfectd patients in India: a prospective cohort study." [BMJ Open 11\(4\): e042519.](#)
16. Liverpool School of Tropical Medicine (April 2023). ["Using BCG Vaccine to Understand Tuberculosis Infection", NCT05820594 \(ClinicalTrials.gov\)](#)
17. 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.](#)

General Dermatology

18. Lin, L. L. and T. W. Prow (2017). "Novel microdevices for controlled blood and skin extraction, NHMRC." [Impact 2017\(6\): 58-60.](#)
19. Michele Fimiani, P. R., Elisa Cinotti (2020). Technology in Practical Dermatology, [Springer Cham.](#)
20. Hadelier E, Mosca M, Hong J, Brownstone N, Liao W, Bhutani T. Innovations in translational research in dermatology: minimally invasive methods for biosample acquisition. [Dermatol Online J. 2021 Oct 15;27\(10\).](#)

Method Development

21. Lin, L. L., et al. (2013). "Microbiopsy engineered for minimally invasive and suture-free sub-millimetre skin sampling." [F1000Res 2: 120.](#)
22. Lei, B. U. W., et al. (2019). "Absorbent Microbiopsy Sampling and RNA Extraction for Minimally Invasive, Simultaneous Blood and Skin Analysis." [JoVE\(144\): e58614.](#)

Cosmeceutical Applications

23. Yamada, M., et al. (2020). "A minimally invasive clinical model to test sunscreen toxicity based on oxidative stress levels using microbiopsy and confocal microscopy - A Proof of concept study." [Int J Cosmet Sci.](#)



Harpera Microbiopsy Tool (IUO)



Intended Use

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

Compliance Certification

The Harpera microbiopsy tool is currently in development under ISO 13485:2016 and is supplied for investigational use only (IUO).



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

Disclaimer

The Harpera tool is a skin microsampling solution in development with a microbiopsy technology that enables minimally invasive collection of skin cells for convenient, scar-free biopsy procedures. The Harpera skin microbiopsy tool is currently supplied globally as an investigational use only (IUO) product available for use in clinical studies. The Harpera has not been validated for use with any diagnostic testing. No safety or effectiveness claims have been currently validated.

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About Trajan Scientific and Medical

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.



Science that benefits people

Trajan is actively engaged in developing and delivering solutions that have a positive impact on human wellbeing. Our vision focuses on enriching personal health through scientific tools and solutions.
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