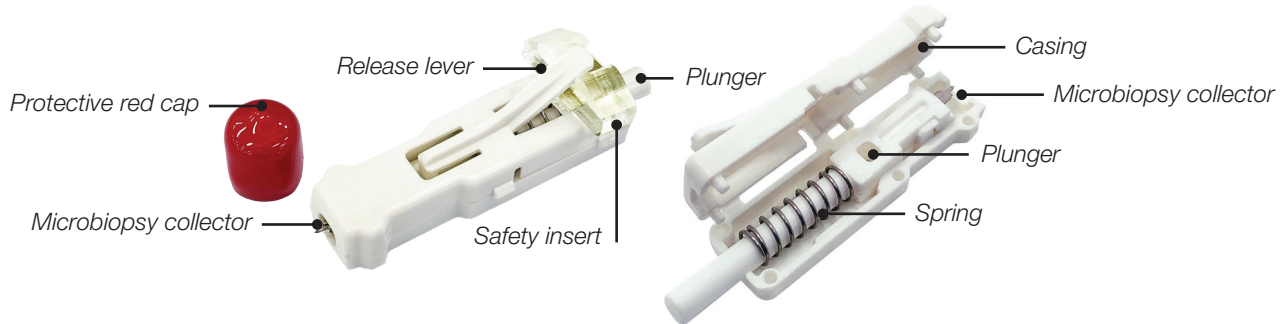


# Harpera™ Microbiopsy Tool

Investigational Use Only (IUO)

The Harpera™ skin microsampling tool integrates a patented microbiopsy technology and is designed to enable minimally invasive specimen collection from the cutaneous skin surface with minimal discomfort, even on cosmetic or sensitive sampling sites.



<b>Intended Use</b>	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.
<b>Product Description</b>	The Harpera microbiopsy tool is a single-use manual microbiopsy punch, a hand-held disposable tool intended to achieve a controlled skin puncture in order to obtain a specimen. The tool is supplied individually packaged and has been subjected to gamma irradiation.
<b>Compliance Certification</b>	The Harpera microbiopsy tool is manufactured in accordance to ISO 9001 and is supplied for investigational use only (IUO).

Technical Data	
<b>Product Features</b>	
Specimen type	Cellular material from the cutaneous skin surface
Format	Harpera tool alone, in a Tyvek pouch
Sterilization process	Gamma irradiation at 25 kGy
Number of specimens collected	1
Maximum penetration depth	1.2 mm
Substrate (microbiopsy collector)	304 Stainless Steel
Substrate dimensions	5 mm x 10 mm x 0.15 mm
Shelf life	Under evaluation
<b>Materials and Colors</b>	
Product color	Nylon 6 (white) with red protective cap
<b>Packaging</b>	
Unit/pack	20 units/pack
Tool dimensions	L 65 mm x W 17 mm x H 18 mm
Unit dimensions	L 102 mm x W 127 mm x H 20 mm
Pack dimensions	W 23 cm x H 30.5 cm

The Harpera™ skin microbiopsy tool is currently supplied globally as an investigational use only (IUO) product available for use in clinical studies.

# Harpera<sup>™</sup>

## Potential Benefits of Skin Microbiopsy



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

- **Facilitate Recruitment to Clinical Studies:** Rapid collection with minimally invasive tool. 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, decentralized clinical studies, requiring monitoring of skin conditions.

Specimen Collection	Traditional Biopsy	Harpera Microbiopsy
Body site preparation (anesthesia)	Required	Not required
Minimally invasive	No	Yes
Rapid sample collection	No	Yes
Portability	Limited	Yes
For any healthcare provider	Surgeon or dermatology specialist	Yes
Body site post-sampling treatment	Required	Not required
Short healing period	No	Yes
Suited for topical sampling	Limited	Yes
Suited for additional sampling on one site	No	Yes*
Suited for frequent sampling over time	No	Yes*
Suited for sensitive areas (i.e., lesion, face)	No	Yes

\*Using multiple single-use Harpera tools.

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