PRODUCT DATA SHEET



BIOHOLE™ SCAB REMOVER

SINGLE-USE DEVICE INTENDED TO REMOVE THE SCAB AT THE BUTTONHOLE ENTRY SITE

NIPRO

BIOHOLE SCAB REMOVER

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- **Used with the buttonhole technique**
- **Comes with cover tube to protect the scab remover's point**
- **Textured grip to enable easy hold and manipulation**
- **Individual packaging**
- **Non-toxic, non-pyrogenic**
- **Gamma ray sterilization**

CE 0123

Class I Sterile

In conformity with MDD 93/42/EEC

PRODUCT COMPLIANCE

- Terminology, symbols, and information are designed according to EN 980 and EN 1041
- All products are labeled according to MDD Annex I Section 13, EN 1041, EN 980, and EN 868
- Outer box displays barcodes relative to EAN 13 and EAN 128
- Labels contain 27 languages and have been designed according to the recommendations of the European Medical Device Directive
- Complies with the following regulations:
  - ISO 9001 (Quality Management System)
  - ISO 10993 (Biocompatibility)
  - ISO 11607 (European Standard for Packing Materials of Sterilized Medical Devices)
  - ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes)
  - ISO 14155 (Clinical Investigation of Medical Devices for Human Subjects)
  - ISO 14644-1 (Controlled Environment)
  - ISO 14971 (Risk Management)

MANUFACTURING LOCATION

Nipro Corporation, THAILAND

STERILIZATION AND SHELF LIFE

Sterilization	Single-use only	Indicator sticker	Shelf life
Gamma ray STERILE R		Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a yellow sticker that turns red when sterilized.	5 years

MATERIALS USED



Scab remover
Material: Acylic based multipolymer cyrolite (MED2)

Cover tube
Material: Polyvinylchloride (PVC)

DEHP-free
BPA-free
Latex-free

REFERENCE CODE

SCAB-REMOVER-GT | Individual scab remover Gamma

PACKAGING DETAILS

- Inner box contains 50 units
- Outer box contains 10 inner boxes (500 units total)
- 36 outer boxes per Euro pallet

Measurements

Scab remover	Individual unit	Inner box	Outer box
Material	coated paper	coated cardboard	corrugated cardboard
Depth (mm)	107	260	532
Width (mm)	58,88	125	272
Height (mm)	N.A.	102	292

Languages on packaging

On individual unit, inner box, outerbox.

English (EN), French (FR), Dutch (NL), German (DE), Spanish (ES), Italian (IT), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), Russian (RU), Polish (PL), Romanian (RO), Bulgarian (BG), Finnish (FI), Czech (CS), Hungarian (HU), Croatian (HR), Lithuanian (LT), Latvian (LV), Slovenian (SL), Slovakian (SK), Estonian (ET), Turkish (TR), Serbian (SR), and Ukrainian (UK).

"Caution" included

In inner box

EN, FR, NL, IT, ES, PT, DE

Transport conditions

22°C to 40°C

Storage conditions

22°C to 40°C

Label details

	Individual unit	Inner box	Outer box
Product name	✓	✓	✓
Quantity (pieces)	—	✓	✓
REF	✓	—	—
LOT	✓	✓	—
	✓	✓	✓
STERILE	✓	✓	—
CE	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
EC REP	✓	✓	✓
	—	✓	✓
	—	—	✓
	—	—	✓

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