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e-mail: info@rustech.ru, www.rustech.ru

«УТВЕРЖДАЮ»

ООО «МК РУСТЕК»
Генеральный директор
Письменюк А.В.

«10» мая 2024 г.

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

Ланцеты (скарификаторы) автоматические стерильные одноразовые RusTech®, модель
SteriHeel Plus

1) Ланцеты (скарifikаторы) автоматические стерильные одноразовые RusTech®, модель SteriHeel Plus, в варианте исполнения Micro-Premie



PEEL TO OPEN

SteriHeelTM Plus



HEEL INCISION SAFETY LANCET

Single use, Latex free.
STERILE unless damaged or opened.
Refer to instructions prior to use.

CE 0123



Do not use if package
is damaged



Caution

STERILE R

Sterilized using
irradiation



Do not re-use

SteriLance Medical (Suzhou) Inc.

No.168 PuTuoShan Road, New District, 215153
Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Made in China

Patents Pending

STERILANCETM

Innovation for Safety

Micro-Premie Incision Depth: 0.65 mm
Incision Length: 1.4 mm
LOT: SM0576 MFG. : 2023-10-10 EXP. : 2028-10-09



STERILANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Micro-Preemie **50** Lancets

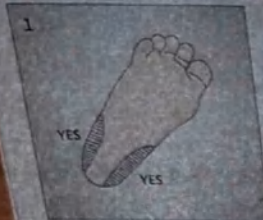
Sterile Single-Use Latex Free
for Newborn Blood Sampling
Integrated Safety Tab Design
Comfort Grip
Safety Engineered
Intuitive Use



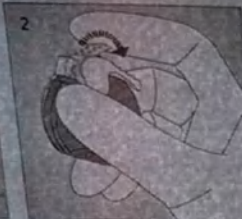
Incision Depth: 0.65 mm
Incision Length: 1.40 mm

Reorder No. : 30-106514

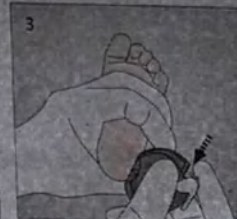
Instructions for Use :



Select a site identified in the shaded areas above. Clean the incision site of the heel with an antiseptic swab and allow skin to air dry.



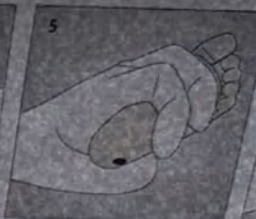
Release trigger lock mechanism by pushing down the screw button.



Place the blade slot surface of the device flush against heel site. Ensure that both ends of the device in contact with the skin, and depress the trigger.



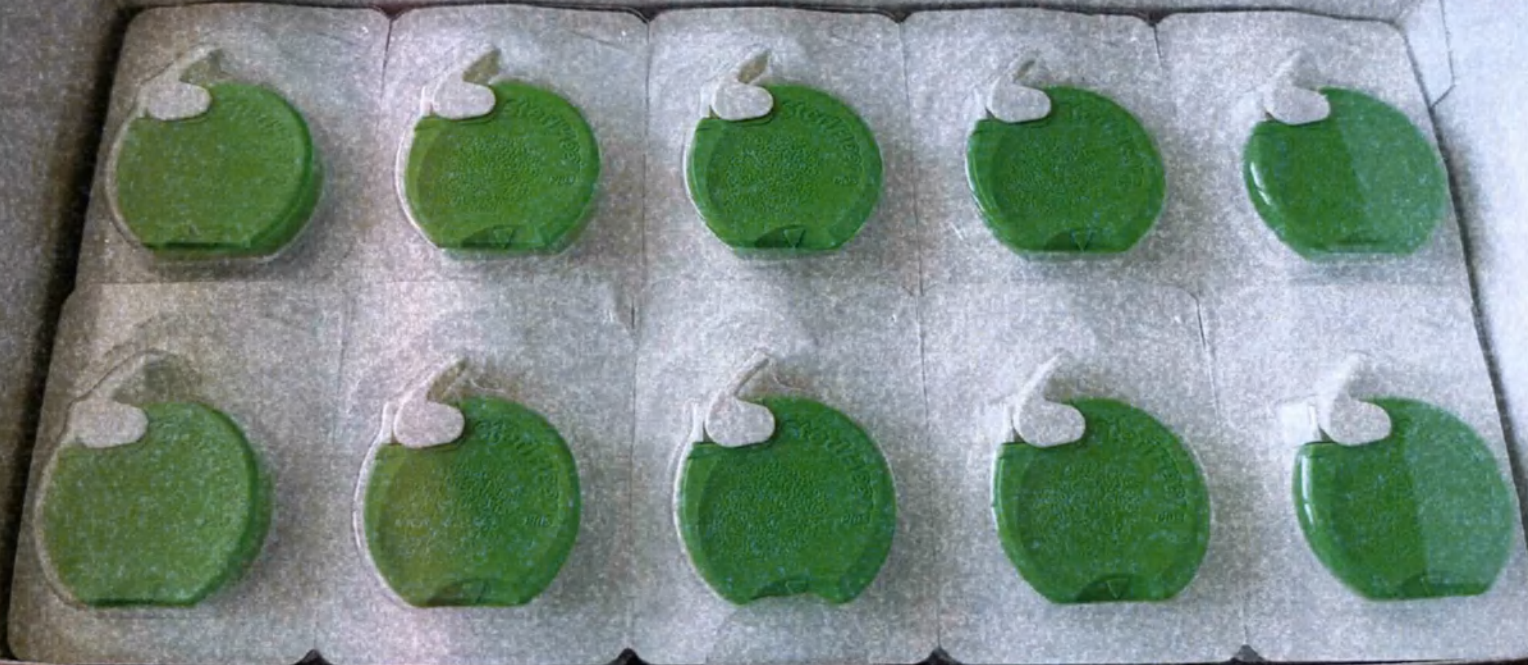
After triggering, immediately remove the device from infant's heel and discard it into a suitable sharps container.



First drop of blood should be wiped away gently with a dry sterile swab. Apply gentle pressure with the thumb and ease intermittently as drops of blood form.



Following blood collection, gently press a dry sterile swab to the incision site until bleeding has ceased.



STERI/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Incision Depth: 0.65 mm

Incision Length: 1.40 mm

50 Lancets

Sterile / Single-Use / Latex Free / for Newborn Blood Sampling / Integrated Safety Tab
Design / Comfort Grip / Safety Engineered / Intuitive Use

REF/Reorder No: 30-106514



LOT SM0576

2023-10-10

2028-10-09

Symbolic interpretation:

STERILE

Sterilized using
irradiation



Do not re-use

LOT

Batch code



Use-by date



Date of manufacture

MD

Medical device



Consult instructions
for use



Manufacturer

EC REP

European Authorized
Representative



Do not use if package
is damaged



Caution

Not made with Natural rubber

CE 0123

Notified Body

Made in China

STERILANCE™

Intended use : It is used for blood sampling from heels of infants during blood tests.

Warning :

1. Do not repeat blood sampling at the same incision site.
2. Do not use in infants with edema, infection or inflammation at the incision site.
3. Do not use in infants with skin diseases or skin lesions at the incision site.

Contraindications : Unknown.

Cautions :

1. Do not use if the individual packaging has been previously damaged
2. Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3. The safety lancet is for disposable use and do not reuse.
4. Discard the used lancet into a suitable sharps container.

 Manufacturer
Sterilance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District, 215153 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA



European Authorized Representative
Emergo Europe B.V.
Westervoortse dijk 60, 6827 AT Arnhem,
The Netherlands

Revised date: June 19, 2023 (Version 03)

STERILANCE™

Specification:

Product Selection:	Reorder No.	30-106514	30-108575	30-101075	30-101428	30-102030
	Description	Micro-Premie	Premie	Newborn	Newborn Plus	Toddler
	Incision Depth	0.65mm	0.85mm	1.0mm	1.4mm	2.0mm
	Incision Length	1.40mm	1.75mm	2.5mm	3.8mm	3.0mm

2) Ланцеты (скарifikаторы) автоматические стерильные одноразовые RusTech®, модель SteriHeel Plus, в варианте исполнения Preemie



PEEL TO OPEN

SteriHeel™ Plus



HEEL INCISION SAFETY LANCET

Single use. Latex free.
STERILE unless damaged or opened.
Refer to instructions prior to use.



Do not use if package is damaged

Caution

Sterilized using irradiation

Do not re-use

SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District, 215153
Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Made in China Patents Pending

STERILANCE™

Innovation for Safety

Incision Depth: 0.85 mm
Incision Length: 1.75 mm
Preemie
LOT: SMD574 MFG: 2023-10-10 EXP: 2028-10-09

STERI/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Preemie

50 Lancets

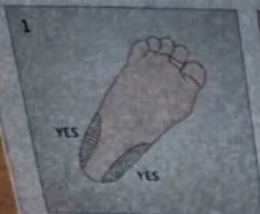
Sterile Single-Use Latex Free
for Newborn Blood Sampling
Integrated Safety Tab Design
Comfort Grip
Safety Engineered
Intuitive Use



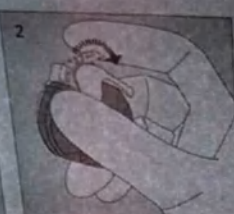
Incision Depth: 0.85 mm
Incision Length: 1.75 mm

Reorder No. : 30-108575

Instructions for Use :



1 Select a site identified in the shaded areas above. Clean the incision site of the heel with an antiseptic swab and allow skin to air dry.



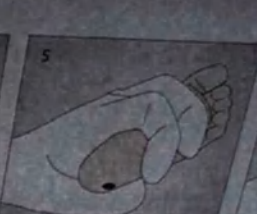
2 Release trigger lock mechanism by pushing down the screw button.



3 Place the blade slot surface of the device flush against heel site. Ensure that both ends of the device in contact with the skin, and depress the trigger.



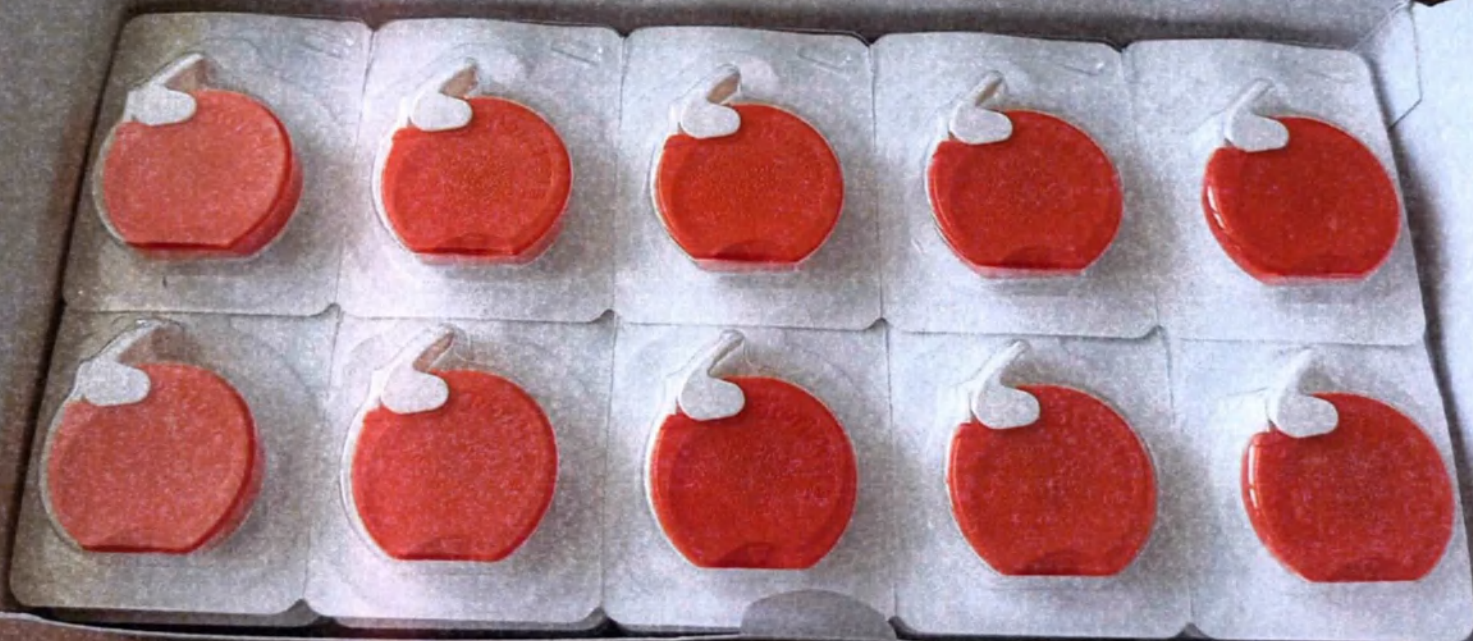
4 After triggering, immediately remove the device from infant's heel and discard it into a suitable sharps container.



5 First drop of blood should be wiped away gently with a dry sterile swab. Apply gentle pressure with the thumb and ease intermittently as drops of blood form.



6 Following blood collection, gently press a dry sterile swab to the incision site until bleeding has ceased.



STER/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Incision Depth: 0.85 mm

Incision Length: 1.75 mm

50 Lancets

Sterile / Single-Use / Latex Free / for Newborn Blood Sampling / Integrated Safety Tab
Design / Comfort Grip / Safety Engineered / Intuitive Use

REF/Reorder No: 30-108575



LOT SM0574

2023-10-10

2028-10-09

Symbolic interpretation

STERILE

sterile
package



No open flame

LOT

Batch code



Use-by date



Date of manufacture

MD

Medical device



Consult instructions
for use



Manufacturer



European Conformity
Registration

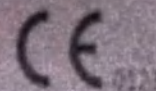


Do not use if package
is damaged



Caution

Product name and description



0123

Serial No.

Made in China

STER/LANCE™

Intended use : It is used for blood sampling form heels of infants during blood tests.

Warning :

1. Do not repeat blood sampling at the same incision site.
2. Do not use in infants with edema, infection or inflammation at the incision site.
3. Do not use in infants with skin diseases or skin lesions at the incision site.

Contraindications : Unknown.

Cautions :

1. Do not use if the individual packaging has been previously damaged
2. Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3. The safety lancet is for disposable use and do not reuse.
4. Discard the used lancet into a suitable sharps container.

Manufacturer

SteriLance Medical (Suzhou) Inc .
No.168 PuTuoShan Road, New District, 215153 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA



European Authorized Representative
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem,
The Netherlands

Revised date: June 19, 2023 (Version 03)

3) Ланцеты (скарификаторы) автоматические стерильные одноразовые RusTech®, модель SteriHeel Plus, в варианте исполнения Newborn





STERI/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Newborn **50** Lancets

Sterile Single-Use Latex Free
for Newborn Blood Sampling
Integrated Safety Tab Design
Comfort Grip
Safety Engineered
Intuitive Use



Incision Depth: 1.0 mm
Incision Length: 2.5 mm

Reorder No.: 30-101025

Instructions for Use :



Soak a soft, clean cloth in the disinfectant solution. Clean the bottom of the foot with the solution. Wash and dry the foot.



Remove the patch from the foot by pulling down the screen.



Place the blade side surface of the device flush against heel of the foot. Ensure that both ends of the device are in contact with the skin, and depress the trigger.



After triggering, immediately remove the device from contact with the foot and discard it into a suitable sharps container.



Any drop of blood should be wiped away gently with a dry, sterile cloth. Apply gentle pressure with the thumb and index finger to the site of the blood flow.



Following blood collection, gently press a dry, sterile cloth to the incision site until bleeding has stopped.



STER/LANCE

SteriHeelTM Plus

Heel Incision Safety Lancet

Incision Depth: 1.0 mm

Incision Length: 2.5 mm

50 Lancets

Sterile / Single-Use / Latex Free / for Newborn Blood Sampling / Integrated Safety Tab
Design / Comfort Grip / Safety Engineered / Intuitive Use

REF/Reorder No: 30-101025



LOT SM0577

 2023-10-10

 2028-10-09

Symbolic interpretation

STERILE A

Sterile along
the whole



Do not use

LOT

Lot code



Use-by date



Date of manufacture

MD

Medical device



Consult instructions
for use



Not for use



Device not for use
in the field



Do not use if damaged
or expired



Caution

Product made in the People's Republic of China

CE 0123

Medical device

Made in China

STERILANCE™

Intended use : It is used for blood sampling form heels of infants during blood tests.

Warning :

1. Do not repeat blood sampling at the same incision site.
2. Do not use in infants with edema, infection or inflammation at the incision site.
3. Do not use in infants with skin diseases or skin lesions at the incision site.

Contraindications : Unknown.

Cautions :

1. Do not use if the individual packaging has been previously damaged
2. Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3. The safety lancet is for disposable use and do not reuse.
4. Discard the used lancet into a suitable sharps container.

Manufacturer

 SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District, 215153 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA



European Authorized Representative
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem,
The Netherlands

Revised date: June 19, 2023 (Version 03)

4) Ланцеты (скарификаторы) автоматические стерильные одноразовые RusTech®, модель SteriHeel Plus, в варианте исполнения Newborn Plus

4) Ланцеты (скарifikаторы) автоматические стерильные одноразовые RusTech®, модель SteriHeel Plus, в варианте исполнения Newborn Plus



PEEL TO OPEN

SteriHeelTM Plus



HEEL INCISION SAFETY LANCET

Single use, Latex free.

STERILE unless damaged or opened.

Refer to instructions prior to use.

CE 0123



Do not use if package
is damaged



Caution

STERILE R

Sterilized using
irradiation



Do not re-use

SteriLance Medical (Suzhou) Inc.



No.168 PuTuoShan Road, New District, 215153
Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Made in China

Patents Pending

STERILANCETM

Innovation for Safety

Incision Depth: 1.14 mm
Newborn Plus Incision Length: 2.8 mm
LOT: SM0578 MFG: 2023-10-10 EXP: 2028-10-09

Instructions for Use :



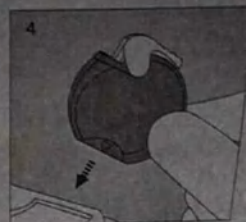
1 Select a site identified in the shaded areas above. Clean the incision site of the heel with an antiseptic swab and allow skin to air dry.



2 Release trigger lock mechanism by pushing down the screw button.



3 Place the blade slot surface of the device flush against heel site. Ensure that both ends of the device in contact with the skin, and depress the trigger.



4 After triggering, immediately remove the device from infant's heel and discard it into a suitable sharps container.



5 First drop of blood should be wiped away gently with a dry sterile swab. Apply gentle pressure with the thumb and ease intermittently as drops of blood form.



6 Following blood collection, gently press a dry sterile swab to the incision site until bleeding has ceased.



STERI/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Newborn Plus 50 Lancets

Sterile Single-Use Latex Free
for Newborn Blood Sampling
Integrated Safety Tab Design
Comfort Grip
Safety Engineered
Intuitive Use



Incision Depth: 1.14 mm
Incision Length: 2.8 mm

Reorder No. : 30-101428

STER/LANCE™

SteriHeel™ Plus

Heel Incision Safety Lancet

Incision Depth: 1.14 mm

Incision Length: 2.8 mm

50 Lancets

Sterile / Single-Use / Latex Free / for Newborn Blood Sampling / Integrated Safety Tab
Design / Comfort Grip / Safety Engineered / Intuitive Use

REF/Reorder No: 30-101428



LOT SM0578

2023-10-10

2028-10-09

Symbolic interpretation:

STERILE R
Sterilized using
irradiation

Do not re-use

LOT
Batch code

Use-by date

Date of manufacture

MD
Medical device

Consult instructions
for use

Manufacturer

EC REP
European Authorized
Representative

Do not use if package
is damaged

Caution

Not made with Natural rubber

CE 0123
Notified Body

Made in China

STER/LANCE™

Intended use : It is used for blood sampling form heels of infants during blood tests.

Warning :

1. Do not repeat blood sampling at the same incision site.
2. Do not use in infants with edema, infection or inflammation at the incision site.
3. Do not use in infants with skin diseases or skin lesions at the incision site.

Contraindications : Unknown.

Cautions :

1. Do not use if the individual packaging has been previously damaged
2. Check the use-by date on the packaging, and do not use the lancet beyond the use-by date.
3. The safety lancet is for disposable use and do not reuse.
4. Discard the used lancet into a suitable sharps container.

 **Manufacturer**
SteriLance Medical (Suzhou) Inc .
No.168 PuTuoShan Road, New District, 215153 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA



European Authorized Representative
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem,
The Netherlands

Revised date: June 19, 2023 (Version 03)

Инструкция по применению
**Ланцеты (скарификаторы) автоматические
стерильные одноразовые RusTech®, модель SteriHeel
Plus**

ПРОШИТО, ПРОНУМЕРОВАНО

И СКРЕПЛЕНО ПЕЧАТЬЮ

32 (тридцать два) ЛИСТОВ

Генеральный директор

Лисменюк А.

