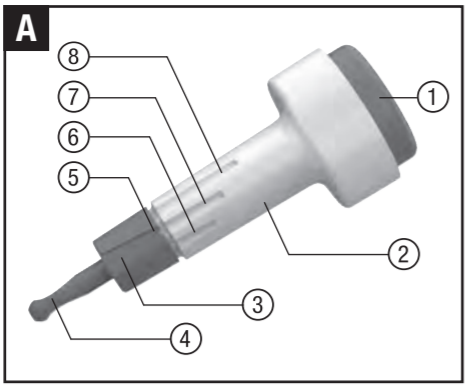


**Sterile, single-use lancng device**

**Sterile Einmalstechhilfe**

**Autopiqueur stérile à usage unique**

REF 03603539, 05217610



**Instructions for Use**

Read these instructions for use before you obtain blood with the lancng device.

**Intended Use**

The lancng device is intended for obtaining capillary blood.

**Indication**

The lancng device is indicated for obtaining capillary blood for the detection of diagnostic parameters.

**Intended User**

Intended users are non-professional users 10 years and older and healthcare professionals.

**Target Group**

Healthcare professionals can use the lancng device for adults, adolescents, children, and neonates.

**Contraindications**

Healthcare professionals as user  
Obtain capillary blood from the fingertip of children 1 year and older, adolescents, and adults.

Blood must be obtained from the heel of children younger than 1 year and from neonates. Do not use the lancng device on the heel of children younger than 3 years.

**Non-professional users**

Blood must be obtained from the fingertip. Non-professional users must not obtain blood from children younger than 3 years.

**Clinical Benefits**

Depending on the amount of blood volume required, 5 depth settings can be selected. The specially beveled needle cuts the thin, natural diameter, and the lancng device also obtans blood virtually pain free.

**Limitations**

There are no limitations.

**General Safety Information**

The instructions for use contain warnings and precautions. A WARNING indicates a foreseeable serious hazard. A PRECAUTION describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

**Risk of infection**

This product contains small parts that can be swallowed. Keep the small parts away from small children and people who might swallow them. If the lancng device was dropped or exposed to other mechanical stress, check it for damages. If you spot damages such as cracks, do not use the lancng device.

If the lancng device is used on broken, for example, with a fingernail or skin infection, they can be unsuitable for infection.

The lancng device is intended for single use in clinical and non-clinical settings.

**Device Description**

See illustration **1**  
 ① Release button  
 ② Housing  
 ③ Penetration depth adjuster  
 ④ Sterility cap of the needle  
 ⑤ Penetration depth indicator  
 ⑥ Low penetration depth (approx. 1.3 mm)  
 ⑦ Medium penetration depth (approx. 1.8 mm, pre-set)  
 ⑧ High penetration depth (approx. 2.3 mm). Do not use at the heel of children younger than 1 year and neonates.

The lancng device is a sterile product, which has been sterilized using irradiation.

**Preparing to Obtain Blood**

**PRECAUTION**  
 Risk of infection  
 A puncture site that was not cleaned can lead to infection. Before obtaining blood clean the puncture site.

**Non-professional users**  
 Only for children 3 years and older, adolescents, and adults  
 Obtain capillary blood from the sides of the fingertips (see black areas in illustration **2**). The sides of the fingertips are the least sensitive to pain compared to other areas of the finger. Any finger can be used for the puncture.

► Wash the patient's hands with warm water and soap, rise their hands thoroughly and let them dry completely. This ensures that the puncture site is clean and it increases the blood flow. Dry the hands thoroughly.

**Healthcare professionals as user**  
 Children 1 year and older, adolescents, and adults  
 Obtain capillary blood from the sides of the fingertips (see black areas in illustration **2**). The sides of the fingertips are the least sensitive to pain compared to other areas of the finger. Any finger can be used for the puncture.

► Wash the patient's hands with warm water and soap, rise their hands thoroughly and let them dry completely. This ensures that the puncture site is clean and it increases the blood flow. Dry the hands thoroughly.

**Children younger than 1 year and neonates**  
**WARNING**  
 Risk of injury  
 The lancng device is used on the fingertip of children younger than 1 year and of neonates. It can injure the finger.

**REF** 03603539, 05217610

**Istruzioni per l'uso**

Leggere queste istruzioni per l'uso prima di eseguire il prelievo di sangue con il pungidito.

**Usò previsto**

Il pungidito è destinato al prelievo di sangue capillare.

**Indicazioni**

Il pungidito è indicato per il prelievo di sangue capillare ai fini della determinazione dei parametri diagnostici.

**Utilizzatori previsti**

Il pungidito è previsto come gli utilizzatori previsti di età pari o superiore a 10 anni e i professionisti sanitari.

**Gruppo di destinatari**

**Utilizzatori professionali**  
 I professionisti sanitari possono usare il pungidito su adulti, adolescenti, bambini e neonati.

**Utilizzatori profani**  
 Gli adulti possono usare il pungidito su se stessi o su altre persone di età pari o superiore a 10 anni. Per i bambini è adatto (da 3 a 17 anni), un caregiver autorizzato deve prelevare il campione di sangue capillare. Prima di utilizzare il pungidito per la prima volta su bambini e adolescenti, consultare il proprio professionista sanitario.

**Contraindicazioni**

**Utilizzatori professionali**  
 Il sangue deve essere prelevato dai polpastrelli di bambini di età pari o superiore a 1 anno, adolescenti e adulti.

Il sangue deve essere prelevato dal tallone di bambini di età inferiore a 1 anno e neonati. È necessario usare la profondità di puntura minima e media (vedere la tabella di riferimento all'uso del dispositivo).

**Utilizzatori profani**

Il sangue deve essere prelevato dai polpastrelli. Gli utilizzatori profani non devono prelevare il sangue dai bambini di età inferiore ai 3 anni.

**Benefici clinici**

Se il marcatore di capacità sterile o è danneggiato, l'ago potrebbe non essere sterile e causare un'infezione.

Controllare visivamente il pungidito. Non utilizzare il pungidito se il capoccchio anteriore presenta deformazioni, crepe o risulta danneggiato in altro modo. Non utilizzare il pungidito se manca il cappuccio sterile o se qualsiasi parte dell'ago è esposta. Eliminare il pungidito.

Un pungidito usato più volte per eseguire il prelievo di sangue.

**Limitazioni**  
 Non esistono limitazioni.

**Informazioni generali sulla sicurezza**

Un'AVVERTENZA indica un pericolo grave e prevedibile. Una PRECAUZIONE descrive una misura da adottare al fine di utilizzare il prodotto in maniera sicura ed efficace o per evitare di danneggiare il prodotto.

**AVVERTENZA**  
 Rischio di soffocamento  
 Il prodotto contiene parti di piccole dimensioni che possono essere ingerite.

Conservare le parti di piccole dimensioni fuori dalla portata dei bambini e di persone che potrebbero ingerirle.

Il pungidito è caduto o è stato sottoposto a stress meccanici, verificare che non presenti danni. In presenza di danni come ad es. crepe, non utilizzare il pungidito.

In presenza di infezioni su aree dette dita o dita nude, ad esempio infezione di un'unghia o della cute, tali aree potrebbero non essere idonee per il prelievo di sangue.

Il pungidito è monouso ed è destinato all'uso in ambito clinico e non sanitario.

**Descrizione del dispositivo**

Vedere la figura **1**  
 ① Palanetto di rilascio  
 ② Alloggiamento  
 ③ Regolatore della profondità di puntura  
 ④ Cappuccio sterile dell'ago  
 ⑤ Indicatore della profondità di puntura  
 ⑥ Profondità minima di puntura (circa 1,3 mm)  
 ⑦ Profondità media di puntura (circa 1,8 mm, preimpostata)  
 ⑧ Profondità massima di puntura (circa 2,3 mm) Non usare sul tallone di bambini di età inferiore a 1 anno e di neonati.

**Preparazione al prelievo di sangue**

**PRECAUTIONE**  
 Rischio di infezione  
 Se il punto di prelievo non viene pulito prima del prelievo, potrebbe subentrare un'infezione.

Prima di eseguire il prelievo di sangue, pulire il punto di prelievo.

**Utilizzatori profani**

**Solo per bambini di età pari o superiore a 3 anni, adolescenti e adulti**  
 Prelevare il sangue capillare dalle parti laterali dei polpastrelli (vedere le aree marcate in nero nella figura **2**). Le parti laterali dei polpastrelli sono meno sensibili al dolore rispetto ad altre aree della dita. La puntura può essere eseguita su un dito qualsiasi.

► Lavare le mani con acqua calda e sapone e risciacquare bene. In tal modo si garantisce la necessaria pulizia del punto di prelievo e si evita l'infezione sanguigna.

► Asciugare bene le mani.

**Utilizzatori professionali**

**Bambini di età pari o superiore a 1 anno, adolescenti e adulti**  
 Prelevare il sangue capillare dalle parti laterali dei polpastrelli (vedere le aree marcate in nero nella figura **2**). Le parti laterali dei polpastrelli sono meno sensibili al dolore rispetto ad altre aree delle dita. La puntura può essere eseguita su un dito qualsiasi.

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**Segnalazione di incidenti gravi**

Utilizzare l'identificatore terzi parti dell'Unione Europea e nei Paesi in cui si applica un identico regolamento (non presente separatamente) il produttore e l'autorità nazionale competente un incidente grave avvenuto durante l'utilizzo o in seguito all'utilizzo del dispositivo.

Only use the lancng device at the heel of children younger than 1 year and of neonates.

**PRECAUTION**

Risk of infection  
 If the high penetration depth is used, the calcaneus (heel bone) of children younger than 1 year and of neonates can be injured.

Only use the low or medium penetration depth.  
 The capillary blood must be obtained from the heel. Obtaining blood must be obtained from the lateral side of the heel (see black areas in illustration **2**). The puncture must occur vertically to the sole (see arrows in the enlargement). While obtaining blood, the child should be held with its foot vertically facing the floor. The heel, which has already been punctured, must not be punctured a second time.

► To improve blood flow at the heel before obtaining blood, you can massage the heel, as recommended, by wrapping it in a warm, moist cloth at a maximum 42 °C.

► Wash the heel with warm water and soap, rise it thoroughly and let it dry completely. Disinfect the heel with an alcohol wipe. Afterwards, let the heel dry completely.

**Obtaining Blood**

**WARNING**  
 Risk of infection  
 If the sterility cap is damaged or missing, the needle can be unsterile and lead to infection.

Visually inspect the lancng device. If the sterility cap is deformed, damaged or missing, do not use the lancng device. If the sterility cap is missing or any part of the needle is exposed, do not use the lancng device. Discard the lancng device.

► Wash the heel with warm water and soap, rise it thoroughly and let it dry completely. Disinfect the heel with an alcohol wipe. Afterwards, let the heel dry completely.

**Obtaining Blood**  
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