

## Multiple Skin Test System FOR PUNCTURE SKIN TESTING

**ComforTen®** is a ten-test skin test device designed to apply allergenic extract using the puncture test technique.

**ComforTen®** is designed for use by allergy practitioners who are trained in the application and interpretation of the puncture technique and who are trained in the recognition and treatment of adverse allergic reactions should they occur. **ComforTen®** Multiple Skin Test System consists of three components:

The **ComforTen®** skin test device (Figure 1), the **HollisterStier Skin Test** reservoirs (Figure 2), and the **ComforTen®** 60-hole covered tray (Figure 3) that holds the reservoirs. A 30-hole tray is also available.

### PRODUCT DESCRIPTION

The **ComforTen®** device has a molded plastic handle containing ten stainless steel lancet tips that slightly protrude from the legs of the device (Figure 4). The **ComforTen®** device is to be used once and discarded in an approved sharps container.

The sterile test devices are packaged three per blister pack container, 27 blister packs (81 devices) per case. The stackable, covered trays hold up to 30 or 60 reservoirs and accommodates 3 or 6 **ComforTen®** skin test devices. They are designed for testing and storage flexibility. Both trays are provided as single units and include optional-use spacers (Figure 5) for

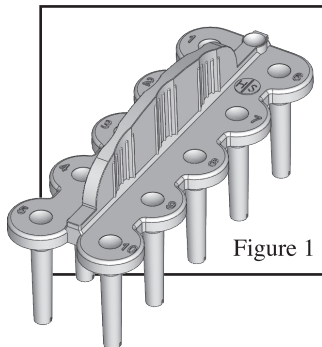


Figure 1

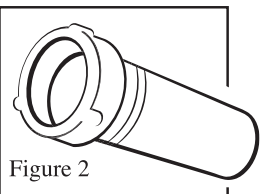


Figure 2

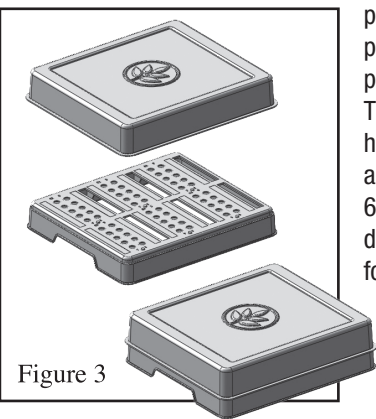


Figure 3

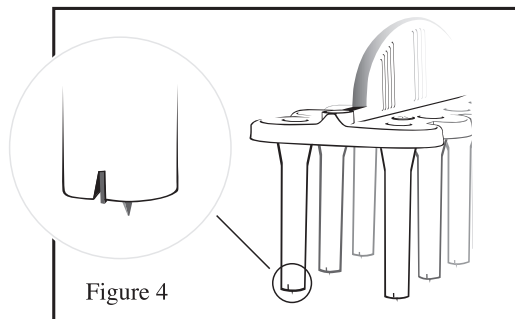


Figure 4

increasing the number of tests between filling the reservoirs. The reservoirs are supplied in sterile pouches of 30. The **ComforTen®** device covers the reservoir, helping protect the allergenic extract from foreign material and evaporation.

### SET-UP INSTRUCTIONS

Remove the **ComforTen®** covered tray from the box. Each **ComforTen®** covered tray is supplied with blank self-adhesive labels and spacers (Figure 5). Each label strip has five designated areas corresponding to the reservoirs. Note the name of each allergenic extract in the area provided. Remove the label backing and place on the tray inline with the corresponding reservoirs.

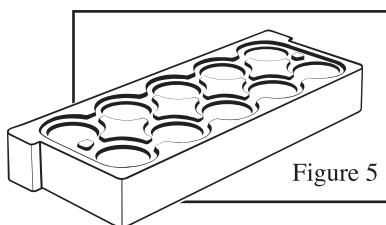


Figure 5

HollisterStier Skin Test Reservoirs are provided in a sterile pouch of 30. Peel back the paper label as indicated on the pouch of the reservoirs. Firmly place a reservoir into each hole

in the **ComforTen®** tray. If using the optional spacers, fill the appropriate reservoir with approximately 20 drops (not more than 0.8 mL) using the dropper from the HollisterStier Allergy 5mL scratch test extract vial (Figure 6b). Place the spacers on top of the reservoirs as noted in Figure 6a. If the spacers are not used, fill the appropriate reservoir with approximately

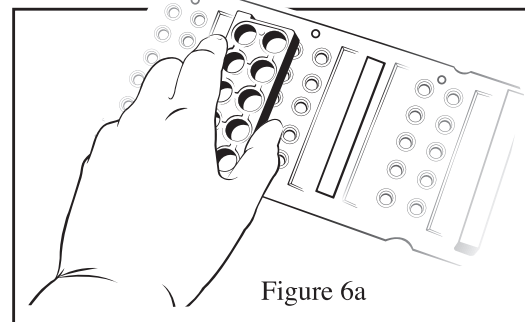


Figure 6a

12 drops (not more than 0.5 mL) using the dropper from the HollisterStier Allergy 5mL scratch test extract vial (Figure 6c). Store the unused spacers in the slots provided on the tray. Once the tray is prepared, remove a **ComforTen®** device from the blister pack by peeling off the label as indicated on the package. Pick up the device by the handle using caution not to touch any part of the legs or the lancet tips. Place the tips in the prefilled reservoirs. Important: To assure that test extracts are applied to the proper test sites, several directional indicators are built into

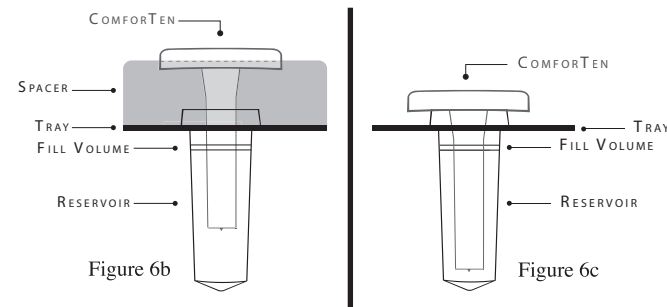


Figure 6b

Figure 6c

the device and tray (Figure 7). When placing the device into the tray always ensure that the indent on the device located between legs 1 and 6, are aligned with the spot on the tray and that the notch in the opposite end of the device is furthestmost away. When removing the device to apply to the patient's skin, place

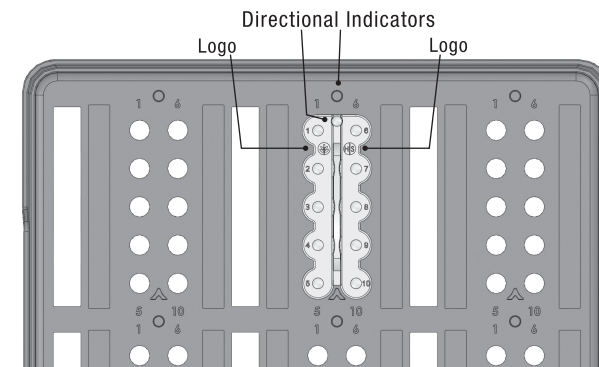


Figure 7

the test device handle with the directional indicators plus the numbers 1 and 6 facing upward and toward the patient's head. The 30-hole and 60-hole trays hold 3 or 6 **ComforTen®** devices respectively. With the **ComforTen®** device in the tray, the reservoirs are covered to prevent foreign matter from entering the extract. Once the tray is loaded, it can be used immediately or covered and stored at 2°–8°C until needed.

### SKIN TEST PROCEDURE

Prior to skin testing, clean the test area with alcohol and allow to dry. (Refer to "Allergenic Extracts for Scratch, Prick or

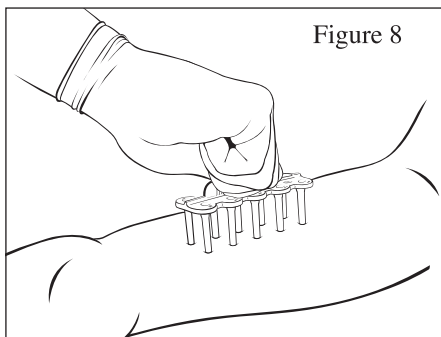


Figure 8

## STORAGE

Once a patient's test session has been completed, place new **ComforTen**® devices in the extract filled tray, cover and store at 2°-8° C until the next test session.

## READING SKIN TEST REACTIONS

Measure wheal and erythema responses for histamine positive control at 10 minutes and allergens at 15 and 30 minutes. For optimal response, use a positive control with a 6mg/mL histamine base. Immediate reactions to histamine typically peak at 8 minutes while allergens peak at 15 minutes.<sup>1</sup> HollisterStier Allergy recommends recording wheal and erythema measurements to improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response. Reactions from the **ComforTen**® device may be graded as follows:

European Prick Test Grading System		
Grade	Wheal (mm)	Erythema
Negative	<3	Not Measured
Positive	>3	Not Measured
Graduated System		
Grade	Wheal (mm)	Erythema (mm)
0+	<3	<15
2+	<6	<15
3+	7-9	16-30
4+	>9	>30

A positive skin reaction to any allergenic extract must be interpreted in light of the patient's history of symptoms, time of the year, and known allergen exposures.

The skin tests are in no way a substitute for a careful allergic history. Rather, they serve as additional information to aid in identifying causative allergens in patients with allergic disorders.

## DISPOSAL

**ComforTen**® devices are designed to be used once and discarded (in accordance with all local, state and federal regulations). These devices cannot be cleaned sufficiently to prevent cross contamination from repeated use or to protect subsequent patients from possible transfer of serum hepatitis or other bloodborne pathogens.

HollisterStier Skin Test Reservoirs in the **ComforTen**® tray should be replaced periodically. For best results, discard and replace the reservoirs as they are emptied and fill with fresh allergenic extract. If a used **ComforTen**® device is inadvertently placed in the reservoirs, the affected reservoirs should be discarded and new reservoirs prepared prior to the next test session.

## REFERENCES

1.Oppenheimer J, Nelson HS. Skin testing *Ann Allergy Asthma Immunol.* 2006; 96(Suppl 1):S6–S12.

## HOW SUPPLIED

Item#	Description
8000000021	<b>ComforTen</b> ® Multiple Skin Test Device (sterile), Case of 27 blister packs (81 devices). Manufactured in England.
8406ZA	<b>ComforTen</b> ® Covered 30-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8407ZA	<b>ComforTen</b> ® Covered 60-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8924ZA	<b>HollisterStier Skin Test Reservoirs</b> (sterile), 30 per pouch. Manufactured in the U.S.A. (Available in U.S.A. only)
8000000011	<b>HollisterStier Allergy Skin Test Reservoirs</b> 4-pack Box (120 Reservoirs) Manufactured in the U.S.A. (Available in Canada only)

Puncture Testing” and “Positive Skin Test Control – Histamine” package inserts for more detailed testing instructions.) Remove a **ComforTen**® skin test device slowly from a prepared tray by lifting it vertically, being careful not to touch the tips on the reservoirs or spacer. With the **ComforTen**® perpendicular to the skin, press down on the skin with medium pressure (Figure 8).

While maintaining this pressure, slightly tilt the device once to the right, and then to the left while ensuring that all 10 lancets remain in contact with the skin. Remove by lifting vertically and discard the **ComforTen**®. Small circles about 4mm in diameter created by the device's depth-control guards should remain at the test site indicating the correct amount of pressure was applied (Figure 9). The actual duration and visibility of the circles will vary between patients according to

the thickness, fragility, or pigmentation of their skin. The amount of pressure needed to produce a satisfactory test site requires that all of the ten depth-control guards (Figure 9) come in full contact with the skin. When used as described above, the **ComforTen**® device will produce ten uniform skin tests all at the proper depth without inducing bleeding.

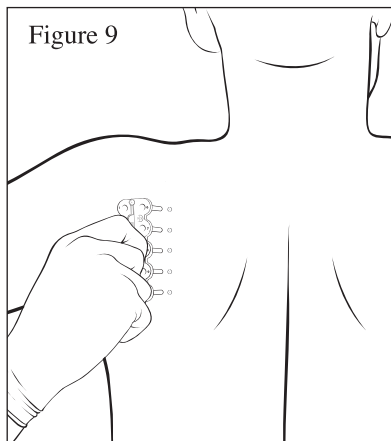


Figure 9

The spacers are used to increase the number of tests between refilling the reservoirs. Once the allergenic extract volume in the reservoirs has dropped to approximately half with a device in place, remove the spacer and continue using the extracts until reservoirs are nearly empty and need to be refilled. To maintain tray cleanliness, the spacers can be washed with soap and rinsed with warm water, then dried thoroughly.



**HollisterStier**  
Allergy

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